Improving Chronic Care

Developing and testing disease-management interventions applied in COPD care

Karin Lemmens

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Verbetering van chronische zorg

Het ontwikkelen en testen van disease management interventies in de COPD zorg

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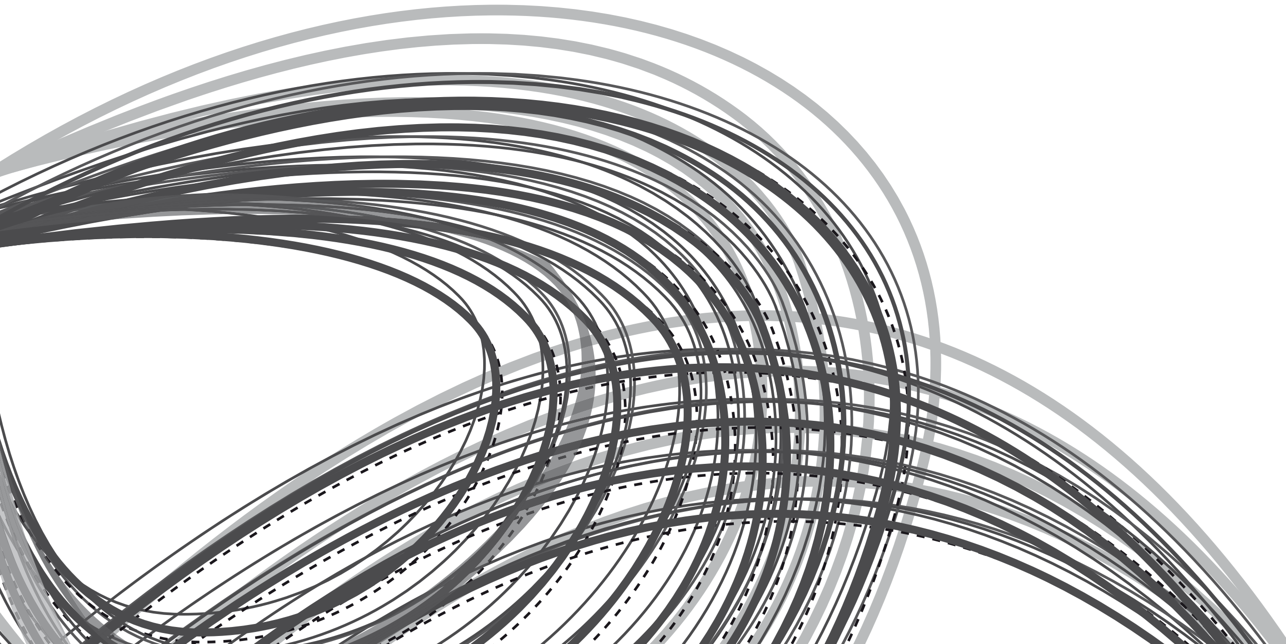
Chapter 1

General Introduction



Introduction

The rapid increase in the prevalence of chronic illness has altered medical care irrevocably. In 2007, 45% of Dutch adults reported at least one chronic condition, among which hypertension, heart disease, diabetes, chronic obstructive pulmonary disease (COPD), and depression.[1] Despite clinical differences, essentially all chronic conditions present similar challenges to patients and their families. They all have to deal with symptoms, disability, emotional impacts, complex medication regimens, difficult lifestyle adjustments, and must ensure helpful medical care.[2] It follows that all chronic conditions place comparable demands on healthcare systems.[3] Unfortunately, much of Western medicine is steeped in antiquated practice systems unfit to care for growing numbers of patients with ongoing health problems and increasingly complex treatment regimens.[4] In response, integrative approaches towards care based on the concept of disease management have been introduced.[5] These are innovative programmes run by pro-active caregivers from many different disciplines. They basically stimulate self-management and lifestyle improvements such as more physical activity, better nutrition, and fulfilling social engagement. Moreover, organisational structures of medical practice are altered from a system designed for acute care to a chronic care system; in other words: a paradigm shift from a reactive system focussing on acute treatment by solo professionals to a proactive approach by a multidisciplinary team – giving room to timely detection, systematic monitoring, and active patient involvement. These programmes aim at reducing fragmentation of care and at achieving better outcomes for chronic patients at acceptable costs. Although a good deal of evidence on the effectiveness of disease management is available, many questions still remain. Interpretation of programmes is hampered by differences in content, external context of care providers, implementation problems, and availability of resources.[6] Furthermore, evaluation of a complex multi-component interventions is a challenge because developing, identifying, documenting, and reproducing the intervention is not easy.[7] Evaluation studies hardly ever systematically address *how* disease management affects processes and outcomes of care.

The research described in this thesis has two main purposes:

First, to determine the core elements of disease management and to *understand* how they operate and interact, so that disease-management programmes can be effectively captured in one single conceptual framework.

Second, to assess the extent to which disease-management programmes applied to COPD patients are effective in improving processes and outcomes of care.

Disease Management

Disease-management programmes have emerged to level off the rising trend in chronic diseases, by postponing or even preventing complications and co-morbidities and most of all by enhancing chronic patients' quality of life.[8] In the Netherlands, most initiatives so far do not embrace the total concept of disease management; they rather consist of separate disease-management components.[9] Typical attributes of disease management, such as evidence-based care and multidisciplinary care teams, have long been used to identify and treat patients, albeit inconsistently.[10] Yet, key to disease management is integrated implementation of multiple interventions.[11] In this thesis, three types of interventions have been found key components for success of this approach: patient-related, professional-directed, and organisational interventions (see Chapter 2). It is all-important to understand how these operate and interact, as these are the mechanisms that actually make disease management work.[12 13]

Thus, disease management is a complex intervention that contains several interacting components.[7] This multidimensional approach implies a major change in the way health care is delivered. A disease-oriented, horizontal approach to patient care is expected to allow much better coordination of care than the traditional, fragmented, vertical approach with its strict separation between different care settings.[14] Moreover, it places a different set of demands on patients and professionals. Effective chronic illness care is characterised by productive interactions between prepared professionals who engage with an activated, informed patient.[15] Professionals must have the necessary expertise, information, time, and resources. Patients should also have the information and confidence to make best use of their involvement with the professional team.[2] There is a wealth of literature emphasising the importance of organising care around patients' needs and preferences, of involving patients in their care, and of multidisciplinary care cooperation.[2 16 17] In addition, systematic reviews pooling evidence from different chronic diseases[15-17] or one single chronic condition (e.g. heart failure [18 19], depression [20 21], diabetes [5 22], and COPD [23 24]) suggest that disease-management programmes are to some extent effective. But evidence on the effectiveness of multiple interventions in the chronic care continuum is scattered and an overview on the state of the art in COPD care is lacking. So far, there is no review that evaluates the effects of combinations of patient-related, professional-directed and/ or organisational interventions in COPD care.

Chronic Obstructive Pulmonary Disease

COPD represents an enormous burden on patients, healthcare services and society, by its impact on quality of life, health resource utilisation, and mortality.[25-27] Listed as the fifth leading cause of death in the world, its prevalence and mortality rates are expected to go up in the coming decades.[28] The growing burden of COPD is partly due to the ageing of the population and partly to the continued use of tobacco, which is the most important risk factor for this disease.[29] Although the increasing prevalence worldwide would suggest otherwise, COPD is still an under diagnosed disease. Herein, the general public, patients and health care professionals alike play a role.[29] As COPD is a slowly progressive disease, patients generally fail to present their symptoms in an early stage – as they do not want to stop smoking or seem to adapt to the functional limitations – and both professionals and the general public at large seem to lack of awareness of the disease.

COPD is a complex disease. It can not be cured, but its burden can be reduced and its progression be stopped. But no single intervention can reduce the disease burden. It is, therefore, important to ensure that it is managed as effectively as possible.[29] As outlined above, a multifaceted approach will help to optimise COPD management. This approach typically requires the integration of several different disciplines, a variety of treatment modalities, and a commitment of the professional to the continued support of the patient as the illness progresses.[30] In addition to education, health advice, and pharmacotherapy, COPD patients may require specific counselling about smoking cessation or instruction in physical exercise. It is necessary to change beliefs, behaviours and practices of professionals and patients.[14] All in all, disease management appears a suitable response to the current challenges to conventional COPD.

PICASSO for COPD – A Disease-Management Programme

Partners in Care Solutions (PICASSO) for COPD is a Dutch nationwide disease-management programme. PICASSO focuses on care optimisation and combines knowledge, experience and resources to support new and existing COPD projects. Furthermore, it stimulates interaction between these projects. Care professionals, patients as well as healthcare organisations will have to adjust their behaviour to realise optimal COPD care. To that aim PICASSO has developed an integral programme consisting of four main activities: 1) defining the outcome indicators, 2) increasing the scientific evidence on COPD care interventions, 3) supporting the implementation of regional COPD disease-management programmes, and 4) stimulating and facilitating changes in COPD care.[31]

This thesis focuses on the evaluation of the implementation of regional COPD disease-management programmes within PICASSO; which offers a unique bottom-up approach for inducing and sustaining organisational change. Essential components of the disease-management programme are identified through a bottleneck analysis with regional stakeholders (such as general practitioners, pulmonologists and patient platforms). This bottom-up approach contrasts with most disease-management models that focus on top-down efforts of organisations to direct and secure the adoption and diffusion of organisational change.[32] Indeed, the use of bottlenecks experienced in professional practice as points of departure enables a focus on locally supported interventions and involves professionals to flexibly configure practices in ways that meet specific local situations and requirements.[32] Since many decisions to adapt clinical practice are individual professional decisions it is hypothesised that this approach will help further implementation of the programme in real-life settings. Furthermore, programmes are supported by strategic planning and change management support. Sharing knowledge between programmes is facilitated by various communication instruments, such as conferences, site visits and a periodic bulletin.

Evaluation of Complex Interventions

Evaluation of complex interventions is challenging to researchers. For one thing, incomplete definition of the intervention is likely to present problems.[7] Moreover, evaluation studies hardly ever systematically address how disease management affects processes and outcomes of care. In this thesis a theory-based evaluation of disease management is performed. This mode of action contrasts with that in other studies on other complex interventions that are often defined pragmatically and lack any clear theoretical basis.[33] Best practice in evaluating complex interventions is to develop interventions systematically, using the best available evidence and appropriate theory, then to test them through well-chosen steps, starting with pilot studies, and moving on to an exploratory and then a definitive evaluation.[34] However, the complexity of disease-management interventions makes rigorous evaluation and determining their practical feasibility quite problematic. Hence, a trade-off between the importance of the intervention and the value of the evidence that can be gathered given these constraints was carefully considered. In this light, a phased approach to evaluate disease-management programmes was performed in this thesis. A systematic review and meta-analysis were performed to explore relevant theory and to identify the evidence that the intervention might have the desired effect. Current bottlenecks in practice were assessed following a structured approach. Next, the programme theory was developed to define the presenting problem and the target population for whom the programme is designed, and to unravel the changes that are expected and the way in which change is to be achieved.[35 36] The evaluation model derived from the programme theory incorporates variables that reflect theoretical concepts and implementation issues. Then, the theoretically expected associations were tested in cross-sectional and longitudinal studies. Process, intermediate as well as final outcome indicators were selected on theoretical grounds. Finally, in a non-randomised comparison the effects of the implementation of three regional COPD disease-management programmes were evaluated by capturing them in one single conceptual framework. This opened the way to uncover associations between existing bottlenecks, implementation of selected interventions, and outcomes of care. This design was chosen as it allowed to gain better insight in the problems pointed out by the professionals, the implemented interventions, and the evaluation[33], supported by a theoretical base.

Research Questions and Outline of the Thesis

This thesis is divided into two sections consistent with the two main research purposes: 1) to determine the core elements of disease management and to understand how they operate and interact and 2) to effectively evaluate disease-management programmes, particularly for patients with chronic obstructive pulmonary disease. The focus of Part one is theoretical exploration of the concept of disease management and provision of an update of the published evidence regarding the (cost) effectiveness of these programmes. Chapter two focuses on the programme theory, inquiring how a comprehensive, integrated model for disease management enables evaluation of chronic care. Evaluating complex interventions can pose a considerable challenge due to lack of understanding of components of an intervention and their interrelationships; what is needed is a rationale of the likely process of change by drawing on existing evidence and theory. Thus, an evaluation model based on social learning theories is presented linking disease-management components with the underlying mechanisms by which they influence outcomes, and proposing direct and indirect relationships among them. The model can also serve to guide development of proper indicators to evaluate programmes and to enable comparisons among programmes.

The results of systematic reviews are described in chapters three and four. An important step in developing an evaluation method for complex interventions is to identify what is already known about similar interventions and about methods applied. Given the comprehensive and complex nature of disease-management interventions it is assumed that this evidence will be heterogeneous. The aim of chapter three is to understand the effectiveness of multiple disease-management interventions in improving care and cost effectiveness for patients with asthma or COPD. In chapter four it is illustrated how potentially cost effective programmes can be identified, based on literature review. Furthermore, for decision-making purposes the likelihood of short and long term cost effectiveness of particular programmes was estimated.

1. How does a comprehensive, integrated model for disease management enable evaluation of chronic care?
2. What is the effectiveness of multiple disease-management interventions in improving care and cost-effectiveness for patients with asthma or COPD?
3. Are COPD disease-management programmes potentially cost effective?

Part two comprises four empirical chapters in which the associations between disease-management programme elements and the effects of their implementation are studied. In chapter five it was tested whether theoretically expected associations between determinants and outcomes of patient-related interventions indeed could be found. In the evaluation model is it assumed that the effected outcomes stem from cognitive and behavioural changes. The results of this exploratory study on the associations of patient-related characteristics, intermediate outcomes and functional and clinical outcomes are presented. Chapter six goes into detail on the effects of the implementation of disease-management programmes on professionals. It explores the extent to which primary care professionals are able to change their processes for delivering care to COPD patients and which professional and organisational factors are associated with the degree of process implementation. As the previous two chapters tested separate parts of the evaluation model, chapter seven tests the full evaluation model on a COPD disease-management programme. The effects of the implementation of this programme on process, intermediate and final outcomes of care in a single setting are described. A multisite comparison of three regional COPD disease-management programmes, combining patient-related, professional-directed and organisational interventions, is reported in chapter eight. This is an example of bottom-up implementation of disease-management programmes explicating the associations between existing bottlenecks, implementation of selected interventions and outcomes of care.

4. Are theoretically expected associations between determinants and outcomes of patient-related interventions existent?
5. To what extent are primary care professionals able to change their processes for delivering care to COPD patients and which professional and organisational factors are associated with the degree of process implementation?
6. What are the effects of the implementation of this programme on process, intermediate and final outcome indicators as derived from the evaluation model?
7. What is the impact of bottom-up implementation of three regional COPD disease-management programmes and how are existing bottlenecks, implementation of selected interventions and outcomes of care associated?

A summary and reflection on the main findings and methodological issues are presented in chapter nine. In this chapter recommendations for future research and practice implications are addressed as well.

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Chapter 2

A Model to Evaluate Quality and Effectiveness of Disease Management

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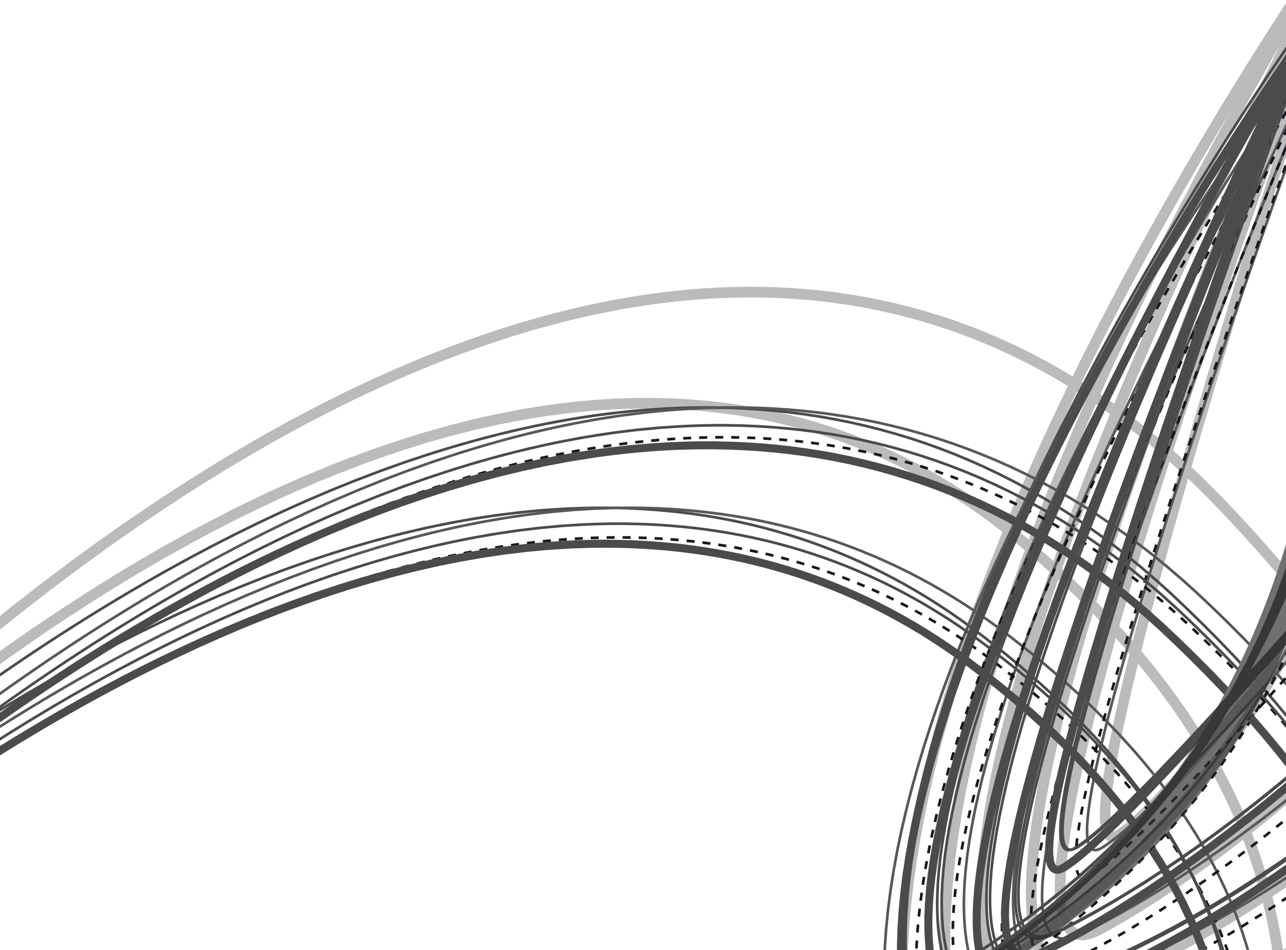

Abstract

Disease management has emerged as a new strategy to enhance quality of care for patients suffering from chronic conditions, and to control health care costs. So far, however, the effects of this strategy remain unclear. Although current models define the concept of disease management, they do not provide a systematic development or an explanatory theory of how disease management affects the outcomes of care. The objective of this chapter is to present a framework for valid evaluation of disease-management initiatives.

The evaluation model is built on two pillars of disease management: patient-related and professional-directed interventions. Effectiveness of these interventions is thought to be affected by the organisational design of the health care system. Disease management requires a multifaceted approach; hence disease-management programme evaluations should focus on the effects of multiple interventions, namely patient-related, professional-directed and organisational interventions. The framework has been built upon the conceptualisation of these disease-management interventions. Analysis of the underlying mechanisms of these interventions revealed that learning and behavioural theories support the core assumptions of disease management. The evaluation model can be used to identify the components of disease-management programmes and the mechanisms behind them, making valid comparison feasible. Next to that, this model links the programme interventions to indicators that can be used to evaluate the disease-management programme. Consistent use of this framework will enable comparisons among disease-management programmes and outcomes in evaluation research.

Introduction

Health care systems throughout the world increasingly place primary emphasis on chronic conditions. And yet, traditional health care delivery systems have not fully evolved to meet the needs of patients and populations with chronic diseases: care is fragmented, duplicated and directed at acute disease.[1] Recognition of this shortcoming has nevertheless led to new strategies for care delivery[2], including the concept of disease management. Over the past two decades these strategies emerged from the overlapping approaches of integrated care (United States) and shared care (Western Europe). In the Netherlands, for example, shared care was a precursor to disease management, which was introduced here in 1997.[3] Disease management appears to be a broad concept, however, and has been operationalised in very different ways.[4-7] It is this heterogeneity that makes it hard to determine possible effects on quality and effectiveness of chronic care. For it not only hinders our understanding of what disease management actually *is* but also hinders uniform evaluation of programmes and, consequently, comparison of study results.[8 9] This chapter focuses on the programme theory of disease-management evaluation, asking the question: "How does a comprehensive, integrated model for disease management enable evaluation of chronic care?"

A consistent definition is indispensable to determine the pillars of disease management. The Disease Management Association of America (DMAA) was the first to state a clear definition.[10] This definition, however, overexposes self-management, seeing that the DMAA's primary aim is providing direct care to the patient. We therefore slightly adapted it to the purpose of this chapter: "a system of coordinated health care interventions and communications for populations with chronic health conditions". Disease management has three key features. One, it supports the professional/patient relationship and plan of care. Two, it uses evidence-based practice guidelines and patient empowerment strategies to prevent exacerbations and complications. And third, it continuously evaluates clinical, humanistic and economic outcomes so as to improve overall health.[10] It would seem to follow that disease management involves the implementation and integration of various components to form a system of collaborative management that may accomplish better chronic care. It is therefore essential to define these pillars or core components and to understand how they operate and interact, since these are the mechanisms that actually make disease management work.

The relevant literature proposes several components of disease management.[4 5 10-13] The categorisation of components and the delineation of specific interventions will help to provide a framework to develop and evaluate disease-management programmes.[2] Such a framework could also help to define specific indicators for evaluation, dependent on the components of a disease-management programme.[8] What this article therefore adds to the existing body of knowledge is a deeper understanding of the underlying mechanisms of disease management and a framework to guide development of proper indicators to evaluate disease-management programmes.

Pillars of disease management

There are two basic types of disease-management programmes: those based on primary care and integrated within organisation of physician practice (like the Chronic Care Model (CCM)), and commercial vendors to which employers and health plans may outsource their disease-management functions (carve-out).[14-16] By and large, these models share the same objectives, yet they largely differ in the processes applied to achieve the objectives. A major difference lies in integration of the provided services with patients' other medical care.[16] Carve-out programmes are not integrated with primary care; they rather are for-profit ventures, and are marketed primarily as a cost-containment strategy.[15] In contrast, primary care based programmes like the CCM attempt to enhance communication with patients while trying to change the organisation of physician practice.[17] And even though the DMAA, the voice of commercial (carve-out) programmes, defines disease management as supporting the practitioner/patient relationship, this is not represented in its programmes. Therefore, the DMAA and CCM programmes do not really differ in the components defined but rather in the way these components are organised.[18] The CCM's focus on redesigning practices has the potential to improve care broadly.[17] The CCM[19-22] thus provides the basis for the definitions of disease-management components. The CCM incorporates self-management interventions, decision support, delivery system design, and clinical information systems, as well as relationships of the health care delivery system with the larger health care organisation and community. The interventions proposed should result in a well-prepared, pro-active practice team that interacts with an informed, activated patient. This interaction, in its turn, should improve outcomes.

From a review of disease-management components we identified two key elements: patient-related and professional-directed interventions. These are strong pillars, seeing that effective control of most chronic diseases requires appropriate medical therapy *as well as* competent self-management.[23-25] These interventions are directed at equipping both the patient *and* the professional in managing the disease. Patient-related and professional-directed interventions are not possible, however, unless supported by the delivery system; they occur within the broader context of the social, political, and physical environment.[26] The interventions should therefore be supported by a third element; the organisational design of the health care system at different levels: delivery system design, health care organisation and community. It can be concluded that the concept of disease management supports the use of multiple interventions.

Development of the evaluation model

The programme theory defines the presenting problem and the target population for whom the programme is designed (input), specifies the causal processes underlying the programme effects (process), and identifies its expected outcomes (outcome) as well as factors that affect treatment processes.[27 28] The evaluation model, as derived from the programme theory, incorporates variables that reflect theoretical concepts and implementation issues addressed in disease-management evaluation. In the following sections we will conceptualise the disease-management processes to indicate the mechanisms responsible for producing favourable, intended outcomes. In the programme theory, outcomes that are responsive to the evaluated processes of care are selected. These outcomes – clinical outcomes, quality of life, resource utilization, and patient satisfaction – reflect the primary goals of disease management, to promote, maintain and enhance a patient's health state.

Patient-related interventions

Patients with chronic conditions make decisions and engage in behaviours that affect their health. It would seem crucial, therefore, to involve them in their own care processes.[12 13] Patients that are empowered and effective in self-management are better prepared to positively influence disease control and health outcomes.[29 30] The continuum of self-management programmes ranges from the provision of written material only to more intensive programmes such as the Chronic Disease Self-Management Programme (CDSMP) designed to enhance self-efficacy.[31] Still, the question remains what mechanisms will make patient-related interventions really work.

Various meta-analyses, review articles, randomised trials, and observational studies provide substantial evidence that programmes providing counselling, education, information and feedback to patients with common chronic conditions are associated with improved outcomes.[11 23 32-37] In their meta-analysis of several disease-management components within various chronic diseases, Weingarten and colleagues[38] found that programmes using patient strategies produced slight but significant improvement in disease control. On the other hand, not all self-management education programmes for all diseases are effective and possible publication bias is also evident.[37 39-41] There is still much to be learned about the specifics of self-management programmes in chronic care. Nevertheless, some empirical evidence is available. For one, knowledge and skills are necessary but not sufficient conditions to bring about change in behaviour.[42 43] And then, education should have more bearing upon behaviour and health outcomes.[44] Actively involving patients and integrating competencies in everyday life appear to be more effective, however, than didactic education.[37 44 45] Moreover, collaborative decision making and goal setting appear to be crucial: self-management improves when a patient's opinions and values are taken note of.[46 47] And finally, self-efficacy, the confidence that one can behave in a certain way to reach a desired goal, is associated with collaborative decision making.[48 49]

Relating these empirical findings to the theories on behavioural change can guide the programme theory. Linden and colleagues[50] provided an overview of behavioural change models that intend to change patient self-management, much of which build on the Behavioural Model developed by Andersen.[51] Most of these models, however, are concerned only with predicting health habits, but do not tell how to change health behaviour. Social learning theory offers both predictors and principles of behavioural change.[52 53] Social cognitive learning theory emphasises the interactions between patients' cognitions, on the one hand, and their behaviour on the other, through processes such as self-efficacy and outcome expectancies.[53 54] Belief in self-efficacy as a means to exercise control is a common pathway through which psychosocial influences affect health functioning. Knowledge of health risks and benefits creates the precondition for change. Those who are unaware of how lifestyle habits affect health, have little reason to change. Stronger self-efficacy is bound to positively influence health behaviour and eventually health status, as borne out by the findings of many relevant studies.[52 55] As a result, the effects of a self-management programme on health status and health care utilization are hypothesised to result from behavioural change, which in turn is caused by enhanced self-efficacy, knowledge and skills.[43 53 55-59]

Professional-directed interventions

Effective chronic disease management demands that professionals have a rich knowledge base.[4 60] One of the knowledge elements is a set of clinical guidelines. These are systematically developed statements to assist practitioner decisions on appropriate health care for specific clinical circumstances.[61] However, guidelines alone do not suffice. Continuing medical education, audit and feedback, reminders and critical pathways also represent a major thrust of these efforts.[62]

In the past decade several meta-analyses have looked into the effects of guidelines[63-66] and other professional-directed interventions, such as education and feedback.[67-70] Improvement in health care outcomes was no more than modest, however, mainly as a result of implementation problems. The interventions that produced modest improvements tended to be multifaceted, with actively involved professionals.[64 71-73] Results suggest that effective strategies include educational outreach and reminders. However, conclusions about what works are still tentative.[74]

A number of techniques have been used to modify the behaviour of practicing physicians. However, the relative effectiveness of each technique is largely dependent on the particular strategy employed in the implementation. As a result there is a need to understand the underlying mechanisms strengthening physicians' behaviour. Individual professionals need to be informed, motivated and trained to incorporate the latest evidence into their daily work. A review identified factors associated with physician barriers to change[75]; all factors appeared to be associated with knowledge, attitude (behavioural intention) and behaviour.[76 77] Before professional-directed interventions can affect patient outcomes, they must first affect physicians' knowledge, then behavioural intention and finally behaviour.[75] Although behaviour can be modified without knowledge and intention being affected, behavioural change based on influencing knowledge and intentions is probably more sustainable than indirect manipulation of behaviour alone.[75] As explained below, several theories also suggest similar constructs.

A variety of forces influence normative patterns of practice behaviour for the practicing physician. Therefore, researchers have been unable to formulate a unifying theory of physician behavioural change, applicable and successfully proven among physicians in practice.[78] However, social and behavioural science theories can further our understanding of the interplay of factors contributing to improve physician performance. Grol[65] developed a general framework that integrates theoretical approaches and applications for changing clinical practice of physicians. Similarly, a number of researchers[64 79 80] have provided overviews of behavioural, social and educational theories underlying different approaches to implementing professional-directed interventions. We must conclude, however, that no single theory stands out as the most effective one; various theories may be valid and effective.[65] In spite of this, a principal rationale underlying professional-directed interventions has been identified, based on various learning theories (adult learning, behavioural learning and social learning theory). It appears to combine intrinsic motivation, rational information seeking and decision making, controlling performance by external stimuli, and social influence of significant peers or role models. For example, reminders are approaches that seek to control physicians' performance by external stimuli. They stem from behavioural and learning theory.[81] These theories suggest that professional-directed interventions will be effective in modifying physician behaviour by governing professional behavioural intention, a process which in its turn is influenced by knowledge and skills. Despite adequate knowledge and behavioural intention, organisational and contextual factors can affect physician's ability to execute recommended care. [65 82 83] The functioning of collaborative teams or broader organisational structures could therefore offer important explanatory mechanisms for quality improvement.[84]

The current empirical and theoretical knowledge leads to the following hypotheses. The common goal of professional-directed interventions is to increase knowledge and expertise necessary to care for patients. If professionals are better educated and are supported in decision-making, knowledge and expertise will improve. The necessary expertise, information, time and resources will affect behavioural intention (attitude), which leads to professional behavioural change. Eventually this should lead to improved health effects.[85-91]

The interaction between the patient and the professional

In the previous sections on patient-related and professional-directed interventions we hypothesised that these interventions lead to positive health effects. The hypothesis, however, concerned effects coming from single interventions. The current literature on disease management supports the assumption that combining these interventions should have more effect on health outcome and resource utilisation.[43 59 92] Glasgow and colleagues[44] emphasise that notwithstanding helpful recommendations, advice, and counselling from health care professionals, patients themselves must decide which self-care actions to put into practice. Collaborative management is put in place when these two perspectives are combined, leading to shared goals, a sustained working relationship, and mutual understanding of roles and responsibilities.[93] When informed patients take an active role in managing their health and professionals feel prepared and supported with time and resources, their interaction is likely to be much more productive.[94]

In the light of the empirical evidence about behavioural principles Von Korff[59] identified four critical elements that enhance collaborative management: 1) a collaborate definition of problems; 2) targeting, goal setting and planning; 3) creation of a continuum of self-management training and support services; and 4) active, sustained follow-up. Health care providers *and* patients have a better chance of seeing improvements in adherence and outcomes if they focus on a specific problem, establish realistic goals and develop an action plan for attaining those goals.[11 95-97] This supports the essence of the defined pillars of disease management; high-quality chronic illness care is characterised by productive interactions between professionals *and* patients.[25] Enhancing communication between patient and professional is likely to result in more coordinated care. The evidence supporting sustained follow-up shows that patients benefit from knowing that they will have ongoing planned contact with healthcare providers in the absence of a medical crisis.[34 98] Professionals, on the other hand, benefit from obtaining information on their patients' medical and functional status.

Health care organisation

Effective chronic disease management will often require changes in the delivery system.[99] Patients with chronic conditions in particular will benefit most from coherence in care delivery and cooperation between care professionals.[100] Theories of integrated care stress the radical or gradual redesign of the steps in providing care; focusing on improved organising and managing the care of specific categories of patients to more readily meet their needs.[83] Effective chronic care programmes often include organising new collaborations of care providers, allocating tasks differently, transferring information more effectively, scheduling appointments and contacts more efficiently, case management, and using new types of health professionals.[7 101 102] These concepts of organisational (re)design act as coordinating mechanisms[103], which in turn can be described by the organisational design[104] and relational coordination frameworks.[105] These coordinating mechanisms are all pitched under the umbrella of organisation of health care in Wagner's model.[103 106] For example, delivery system re-design could reflect *organisational design* when telemedicine for rural patients is implemented or *relational coordination* when nurse educator is included in a planned COPD visit. Delivery system support and clinical information systems are described as separate components in the CCM.[25] In the programme theory presented here, these are both considered organisational interventions supportive of the patient-professional interaction.

A clear description of the programme organisation and articulation of the underlying assumptions reveal many aspects that determine how effectively the programme performs its various functions. Next to that, the organisational context of these interventions should be clearly described, since certain interventions are effective only in specific settings.[65 107] There is a growing evidence base of rigorous evaluations of organisational strategies. But the evidence underlying some strategies is limited, and the effects cannot be predicted with great certainty.[84 108] However, a recent meta-regression analysis by Shojania and colleagues[109] showed that team changes and case management produced more robust improvements in diabetes care. Evidence also supports benefits of case management for depression.[110] Health care is also placed in a larger community context, and this should be taken into account when examining the organisational context. For example, a particular community's health care systems and socio-demographics have been found to influence health outcomes.

Programme implementation

The implementation of quality improvement interventions such as disease management often appears to be a difficult affair. To understand why some interventions are successful whereas others fail to change practice, it is necessary to gain insight into the "black box", i.e. the sequence of events through which targets contact the intervention.[111] The programme must be organised such that the services intended to produce the desired outcome can and actually will be provided.[112] The framework of assumptions and expectations about how to reach the target population is called the implementation plan. This plan lies at the basis of evaluation of the implementation process. Process evaluation checks whether the planned improvement activities have indeed been executed uniformly and whether the target population has actually been exposed to these activities as planned.[111] Too often, however, interventions are evaluated without prior data regarding basic processes expected to mediate the target improvements.[111] This practice is like conducting a drug trial lacking information on whether the patients actually took the medication.[74] Implementation error is to blame if the intervention in its ultimate form differs considerably from the original plan.[113]

Disease management evaluation framework

The evaluation framework presented here is directed at the most aspects of the disease-management programme as described above, and also provides some indication of the level of intended performance (Figure 2.1). The model provides a heuristic for understanding how interventions within the context of disease management affect outcomes of care. Two mechanisms are taken to be responsible for the effects of disease management on the final outcomes of care: (1) the patient's learning and behavioural change mechanism; and (2) the professional support and professional behavioural change mechanism. Social learning theories clarify these mechanisms. The patient-professional partnership paradigm implies that while professionals are experts about diseases, patients are experts about their own lives.[11] Learning is essential for being an expert; it gives professionals more knowledge and expertise and it allows patients to identify their problems and cope with their conditions. As we have seen, knowledge, skills and expertise form the first step in patient-related and professional-directed interventions. For patients, the provision of knowledge should lead to enhanced self-efficacy, which in its turn influences health behaviour and eventually health status. For professionals, access to decision support should affect professional behavioural intention, which in its turn influences professional behaviour and eventually leads to improved health outcomes. Education alone, however, was found to have limited influence on physician behaviour[114]; disease-management programmes should therefore incorporate more rigorous educational strategies. Approaches of learning that actively involve participants and focus on behavioural change seem most suitable for both professionals and patients. The model also shows that organisational support may facilitate learning; moreover it can act as a catalyst to behavioural

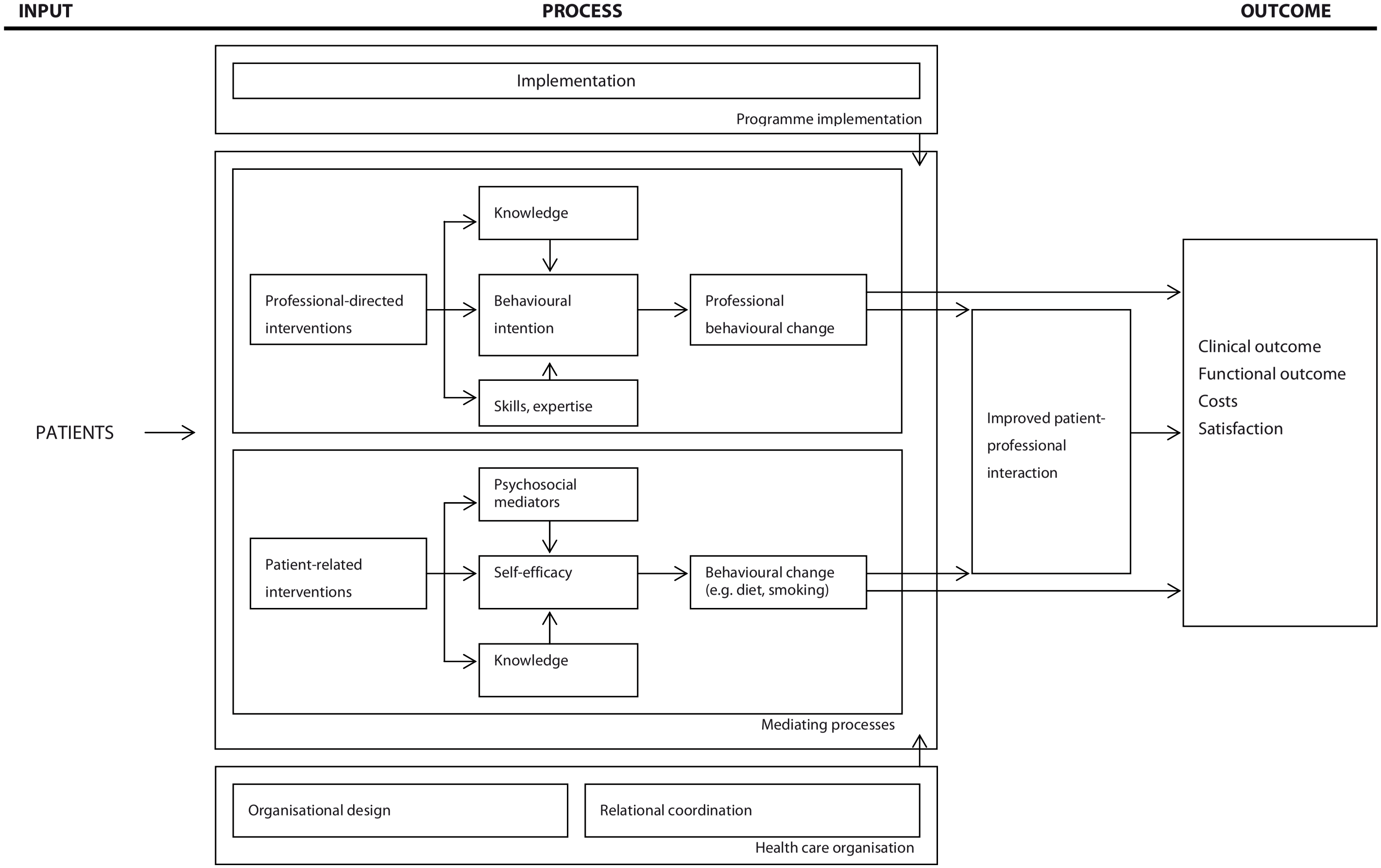

Figure 2.1 Evaluation model for disease-management programmes

change, for example in the case of a system that generates regular feedback for clinical teams on guideline compliance from registry data. The organisational interventions should thus be clearly described.

As we have seen, organisational structure and process variables are also crucial in comparing disease-management programmes. The evaluation framework provides the starting point for the definition of structure, process as well as outcome indicators.[115] Structure indicators can be based on health care organisation. Process indicators evaluate whether the implementation plan has indeed been executed accordingly.[111] This information should be integrated with findings of the outcome evaluation. Consequently, the model suggests how to measure the various elements of the organisation of chronic disease management and how to resolve traditional controversies surrounding the evaluation of disease management. A detailed example is given in box 1.

Discussion and conclusion

Disease management is assumed to be a systematic and comprehensive approach to improve the management of chronic health care. Regrettably, the supportive evidence-base is not yet very powerful. As mentioned earlier, there is a need for a sound analytic method of evaluating the outcomes of disease management.[116] The evaluation model introduced here provides a good starting point. It puts the interaction between the patient and the professional first, and thus the interventions directed at these two key players. It follows that evaluation should focus on the combined effects of these interventions. In addition, the programme theory shows that organisational support is indispensable. This theoretical model supports the premise that the use of supplementary interventions strengthens the effects of disease management.

We feel that the current models on disease management, such as the Chronic Care Model (CCM), do not clarify the underlying mechanisms of the components of disease management. They rather focus on the definition and components of disease management and their empirical evidence. The evaluation model provided in this article indeed elucidates these mechanisms: on the one hand the patient's learning and behavioural change mechanism, on the other hand the professional support and professional behavioural change mechanism. Having identified these mechanisms, which are nested in social learning theories, facilitated the construction of an evaluation framework. A valid set of indicators for the disease-management programme can be determined by linking indicators to the elements of this framework.

The evaluation model can be used to characterise a wide range of disease-management programmes. Placing a programme in the model can disentangle its components, thus allowing to compare different programmes on comparable indicators. Consistent use of this framework will therefore enable valid comparisons of efficiency and outcomes of disease-management programmes. Next to that, our framework corresponds to the three defined domains of care coordina-

Box 1 Example: Evaluating a disease-management programme on COPD

In a Dutch nationwide disease-management programme on chronic obstructive pulmonary disease (COPD), regional projects to improve care were supported by a multifaceted and multidisciplinary approach.

Input: The programme targets COPD patients diagnosed according to the guidelines. Patient characteristics such as age, sex, smoking habit, lung function and dyspnoea were gathered to address the question which patients, presenting with which characteristics, would benefit from the COPD programme.

Process: The approach comprised three facets: One, a *patient-related intervention* designed to promote increased understanding of the condition and teach specific prevention or treatment strategies (self-management) at every contact. Information booklets were also provided. Secondly, a *professional-directed intervention* designed to educate professionals on the guidelines and project. Continuing medical education meetings requiring active involvement were organised for GPs and practice assistants. Third, an *organisational intervention* in the shape of case management supported the two other interventions. A multidisciplinary team developed a system for coordinating diagnostic procedures, treatment, and ongoing patient management (arrangement for referrals and follow-up). The team consisted of a general practitioner, physician-assistant and a pulmonologist, whose tasks and responsibilities were described in a protocol based on the guidelines. The physician-assistant independently carried out diagnostic and therapeutic activities, and taught patients on self-management.

Implementation: To check actual exposure to the disease-management programme, process indicators, linked to the specific interventions, were defined: adherence to evidence based guidelines (an adherence score on four main guideline aspects) (professional), percentage of patients receiving information and instruction (patient), and percentages of planned routine visits and referral behaviour (organisational).

Mediating processes: The processes represent the series of changes for both patients and professionals occurring after receiving the interventions within the organisational setting. Therefore, intermediate outcomes were also defined. In the case of patients, these intermediate outcomes should reflect behavioural change as a result of enhanced self-efficacy, knowledge and skills, seeing that this is essential to achieve the intended effect of the COPD disease-management programme. To this aim, subjective and objective increase of knowledge on COPD, self-efficacy and self-care behaviour (medication and lifestyle) were measured. Likewise, intermediate outcomes were established for professional behaviour, behavioural intention, knowledge and skills.

*Health care organisation**:*** Information on specific characteristics of the programme organisation and organisational context, such as, available resources and regional structure was collected.

Outcome: The ultimate outcome of the disease-management programme is improved quality of life. Next to that, positive effects were expected on health status, patient satisfaction, severity of dyspnoea, and direct costs.

tion programmes: baseline assessment of the specific patient care situation (input), coordination mechanisms (process), and outcomes of care (outcomes).[103]

This multifaceted perspective on disease management helps to frame the consequences of chronic disease (e.g. COPD) in a theoretically fruitful model that may have important research and policy implications. An important research implication lies in the field of methodology. For example, as disease management is typically integrated with the organisational context, a randomised controlled trial (RCT) design will not always be applicable. The methodology therefore must be determined by the degree of control over the delivery of the intervention (real world feasibility) and the most rigorous research design possible. Quasi-experimental research designs or mixed methods are often more suitable. A major policy implication is the call for a consistent definition and framework for disease management. In this era plagued by ever-tightening health care resources, it is of utmost important to identify interventions that are of added value to quality and efficiency of care.

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Chapter 3

A Systematic Review of Integrated Use of Disease-Management Interventions in Asthma and COPD

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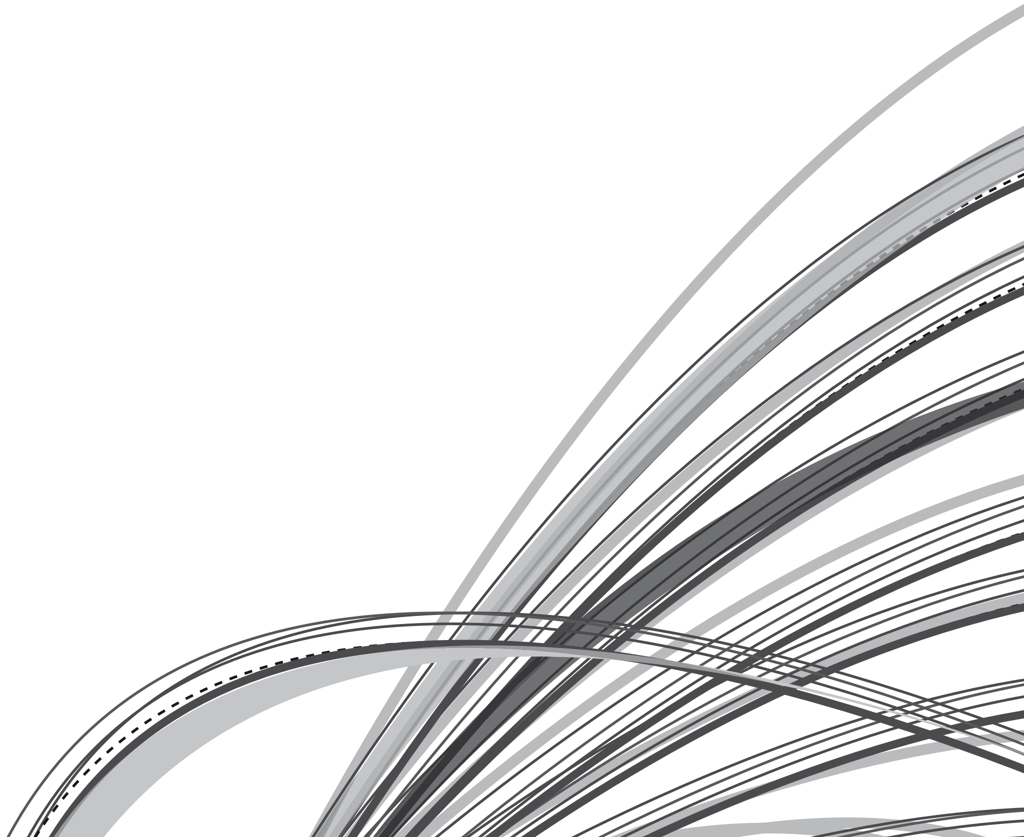


Abstract

Background: The effectiveness of multiple interventions in asthma and chronic obstructive pulmonary disease (COPD) is unclear.

Objective: To examine the effectiveness of multiple interventions as compared to single interventions or usual care on health outcomes and health care utilisation within the context of integrated disease management in asthma and COPD.

Methods: MEDLINE and the Cochrane Library (1995 to May 2008) were searched for controlled trials. Two reviewers independently extracted data and assessed study quality. Meta-analyses were performed on quality of life and health care utilisation data. Furthermore, the effects of multiple interventions versus single interventions and usual care were assessed qualitatively.

Results: Of the 36 studies included, seventeen targeted double interventions (patient-related and organisational interventions); nineteen studies performed triple interventions (patient-related, professional-directed and organisational interventions). They were heterogeneous in terms of (combinations of) interventions, outcomes measured, study design and setting. Pooled data showed that studied disease-management programmes significantly improved quality of life on several domains. Patients within triple intervention programmes had less chance of at least one hospital admission compared with usual care. No significant effects were found in number of emergency department visits. Qualitative analyses revealed positive trends on process improvements and satisfaction. Inconclusive results were reported on symptoms; no effects were found in lung function.

Conclusion: In spite of the heterogeneity of disease-management studies in asthma and COPD care, this review showed promising improvements in quality of life and reductions in hospitalisations, especially for triple intervention programmes.

Background

Chronic conditions account for more than 50% of the global disease burden, and this figure is projected to rise.[1] Among the most common chronic diseases worldwide are asthma and chronic obstructive pulmonary diseases (COPD). These respiratory diseases represent an enormous burden on individuals, families and societies, by their impact on quality of life and health resource utilisation, as well as mortality.[2 3] Yet, health care systems are often not organised to provide effective and efficient care for chronic health problems.[4] The causes of chronic conditions are complex and responses to patients' needs therefore should be multifaceted and multi-institutional.[5] Disease management has been introduced as the answer to these demands.[6-8]

Disease management is a concept by which care delivery is better coordinated through the integration of several components across the entire delivery system and the application of tools specifically designed for the population in question, e.g. guidelines, education, information systems.[9] The Disease Management Association of America (DMAA)[10] defined disease management as: "a system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant". There are high expectations for disease management; it is expected to improve quality and efficacy of care for patients with chronic diseases. Disease management supports the use of multiple interventions, defined as combinations of at least two of three types of intervention: patient-related, professional-directed and organisational interventions, according to Cochrane Effective Practice and Organisation of Care (EPOC).[11 12] Key to disease management is therefore to involve the implementation and integration of combined interventions.[13] But evidence on the effectiveness of combined interventions in the care continuum is scattered and an overview on the state of the art in asthma and COPD is lacking. The question addressed in this chapter is: "what is the effect of the use of multiple interventions within the context of integrated disease management in asthma and COPD".

Current literature contains evidence implying improvements in health care as a result of multiple interventions. Grol[14] concludes that multifaceted strategies – combining different approaches and targeting different barriers to improvement – are in general more effective than individual approaches. He assumes this will probably hold for disease management too. The chronic care model (CCM)[15 16] also emphasises a multifaceted approach, supposedly leading to healthier patients, more satisfied professionals and lower costs.[6 17] Several systematic reviews across a number of chronic diseases (e.g. diabetes, heart failure) confirm positive effects on quality of care.[18-22] But, many studies have focused on the effects of interventions solely directed either at the patient[23-26] or the professional. [27-32] So far, these interventions have only been partly successful. Weingarten and colleagues[33] conclude from a meta-analysis that most disease-management programmes directed at either professionals or patients are associated with improvements in care. However, this analysis solely covered single interventions within disease-management programmes; the effectiveness of the combined interventions was left out of consideration. A systematic review on the effectiveness of the CCM in COPD patients focussed on interventions including one or more components, but did not look at combinations of interventions. Studies with two or more components had lower health care use compared with controls. Although previous reviews cover a wide range of interventions, little is known about the effectiveness of combined disease-management components in asthma and COPD care. This review aims to understand the effectiveness of multiple disease-management interventions in improving care and cost-effectiveness for patients with asthma or COPD.

Methods

Identification of studies

We included studies that evaluated the effectiveness of disease-management programmes consisting of multiple interventions targeted at patients aged ≥ 16 years with a principal diagnosis of asthma or COPD. Studies were included if they met the following methodological criteria: experimental, randomised controlled trials (RCTs) and controlled clinical trails (CCTs), or quasi-experimental, controlled before and after studies (CBAs) or time series designs (ITS). The control group needed to have been provided usual care or single intervention. Studies were included if they reported any objective measure of outcomes reflecting the primary goals of disease management, i.e. to promote, maintain and enhance the health of patients. Studies therefore needed to provide details on clinical outcomes, quality of life, health care utilisation, and/ or patient satisfaction.[10]

According to EPOC[11], an intervention was classified as 'patient' when targeting patient behaviour, such as patient education, or self-management interventions; 'professional' when aiming at professional practice behaviour, for example professional education, audit and feedback; 'organisational' when interfering in the structure or organisation of care, for instance revision of professional roles, or arrangements for follow-up (Table 3.1). Since the focus of the study was on *multiple* interventions within the context of *disease management*, studies on the effects of single interventions versus usual

Table 3.1 Observed EPOC Definitions of Interventions in Asthma and COPD Care

Patient Education: Interventions designed to promote increased understanding of a target condition or to teach specific prevention or treatment strategies, or specific in-person patient education (e.g., individual or group sessions with diabetes nurse educator; distribution of printed or electronic educational materials). Interventions with patient education were included only if they also included at least 1 other strategy related to clinician or organizational change.	**Expansion or revision of professional roles:** Changes to the structure or organisation of the primary health care team: • Adding a team member or "shared care," e.g., routine visits with personnel other than the primary physician (including physician or nurse specialists in COPD care, pharmacists). • Expansion or revision of professional roles (e.g., nurse or pharmacist plays more active role in patient monitoring).
Professional Education: Interventions designed to promote increased understanding of principles guiding clinical care or awareness of specific recommendations for a target condition or patient population (e.g. educational meetings, active distribution of educational materials, and educational outreach visits).	**Case Management:** Any system for coordinating diagnosis, treatment, or ongoing patient management (e.g., arrangement for referrals, follow-up of test results) by a person or multidisciplinary team in collaboration with or supplementary to the primary care clinician.

care were excluded. Moreover, pulmonary rehabilitation programmes were defined as single intervention, since they already are a part of the organisational structure of care, and therefore excluded.

Literature search

Searches of MEDLINE (1995–May 2008) and the Cochrane Library (1995–May 2008) were undertaken. Studies published before 1995 were not considered for inclusion, as it was not until 1995 before disease management appeared frequently in the medical literature.[13] The following key words (Medical Subject Headings) were entered: disease management, disease state management, delivery of integrated health care, comprehensive health care, patient care planning, primary health care, patient care team, critical pathways, case management, continuity of patient care, practice guidelines, guidelines, clinical protocols, patient education, self care, reminder systems, health education, health promotion, community health planning, ambulatory care, feedback, reminder or monitoring[33] in combination with asthma and COPD specific terms. These all aimed to identify studies evaluating the effectiveness of multiple interventions.

Methods of the review

Potentially relevant studies retrieved from the electronic searches were independently screened for eligibility (KL and AN). Next, three reviewers (KL, AN and RH) independently reviewed the selected studies and extracted data with the use of a standardised abstraction form. Data were collected which described the interventions, methods, sample size, population characteristics, setting, and measures of programme effects on processes and outcomes of care from unmasked articles that met the inclusion criteria. Where possible, data were tabulated in terms of means ± SD for patient outcomes and proportions for process measures; other data were presented as reported in the original sources. Any discrepancies between reviewers were resolved by discussion.

Study quality was assessed with the Health Technology Assessment-Disease Management (HTA-DM) instrument developed by Steuten et al.[34] The scope of this instrument comprises quasi-experimental and experimental studies as well as controlled, uncontrolled and observational studies.[34] The instrument includes four components, namely, study population, description of the intervention, measurement of outcomes, and data-analysis/ presentation of data. Methodological quality is scored between 0 to 100 points with scores <50 points indicating inferior quality and ≥ 70 points indicating good quality.[35] Studies of inferior quality were excluded from this review. The HTA-DM is a reliable instrument for methodological quality assessment of HTA of disease management.[34]

Data analysis

Given the likely heterogeneity of the studies, we performed a qualitative assessment of the effects of studies, based upon the combination of interventions, study quality and population differences. Potential differences were analysed by preparing tables to examine the size of observed effects relative to these variables. When possible, meta-analyses were performed, using RevMan 4.2.[36]

Data were pooled for the Asthma Quality of Life Questionnaire (AQLQ) in pharmacist disease-management programmes, and the St. George's Respiratory Questionnaire (SGRQ), emergency department visits and hospital admissions in COPD disease-management programmes. Outcomes were analysed as continuous variables using standard statistical techniques (weighted mean difference (WMD)) and with dichotomous outcomes pooled odds ratios (OR) were calculated. Both combined with a fixed effect model and 95% confidence intervals were calculated as appropriate. Statistical variation between study findings was explored using the I^2 statistical measurement.[37]

Results

Description of studies

Figure 3.1 shows the flow of papers through the review. Overall, 2.414 references published from January 1995 to May 2008 were identified; 680 were accepted for further screening. After reading titles and abstracts 409 papers were excluded, leaving 271 articles for a full-text review. Screening of the Cochrane Library and references resulted in another 49 potentially relevant articles. Of all 320 articles, 271 (85%) did not meet the inclusion criteria. Another nine studies were excluded due to inferior methodological quality.[38-46] Eventually, 36 studies[47-86] (40 papers) were identified as multiple intervention studies on asthma and/ or COPD; 18 of which focused on COPD, 16 on asthma, and two on both diseases. Fourteen studies had 'good' methodological quality (≥70 points) [51-53 58 60 63 70 73 77 79 82 84-86]; 22 scored between 50 and 69 points and were therefore considered of 'moderate' quality.[47-49 54-56 61 62 64 65 67-69 71 72 74-76 78 80 81 83]

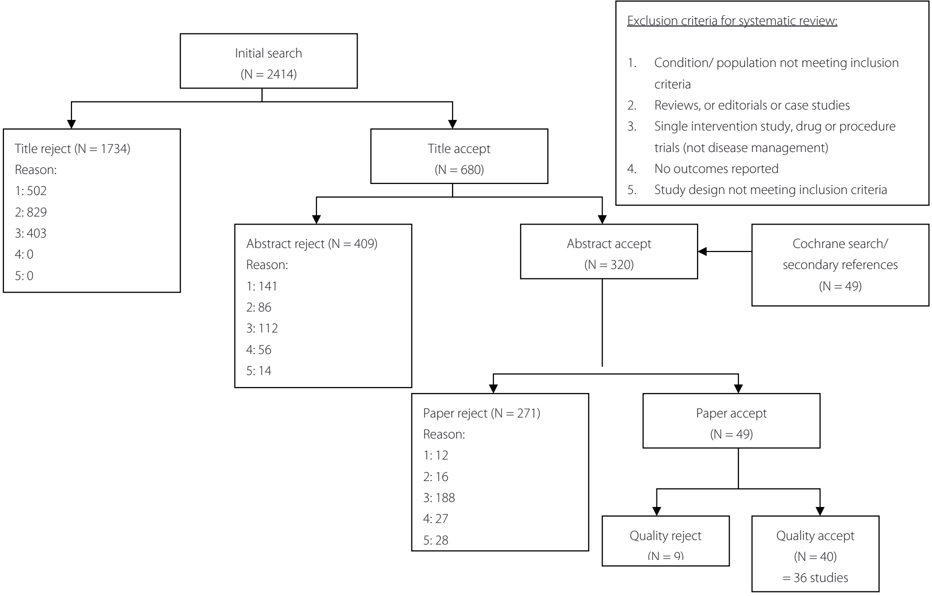


Figure 3.1 Selection process for including studies in systematic review

We present results based on combinations of interventions as outlined in the protocol. Seventeen studies used both patient-related and organisational interventions[51 55 56 61 63 64 67 70 72 73 75 77 78 81-84] and another 19 used triple interventions (patient-related, professional-directed, and organisational).[47-49 52-54 58 60 62 65 68 69 71 74 76 79 80 85 86] No studies that combined patient-related and professional-directed or professional-directed and organisational interventions passed the selection criteria (Table 3.2). As expected, the intervention groups were generally compared to control patients receiving 'usual care'. Control patients in three studies received patient education[55 78 81]; another two studies used two control groups: one given usual care and one given patient education.[54 86]

Most studies reported quality of life and health care utilisation measures. Instruments for measurement of quality of life differed widely among the studies. Reported clinical outcomes, lung function and symptoms, generally demonstrated no significant differences between intervention and control groups. But, studies directed at asthma patients frequently showed a significant decline in symptoms.[48 53 60 70 71] Various studies reported quality of care measures (satisfaction), a great variety of instruments found mostly significant beneficial differences for multiple interventions. Significant improvements on process measures were reported, as well. Improved compliance, enhanced knowledge, and inhalation technique were frequently found, often combined with significant improvement in quality of care.

Patient education in combination with case management (and professional education)

Nine studies examined patient education in combination with case management compared to usual care[51 56 61 64 73 77 78 82 84] showing mixed results. We noted an apparent variation in intensity and duration of the interventions, ranging from home visits after 1 and 4 weeks to weekly calls and monthly visits for 1one year. Similarly, duration of the follow-up period largely varied; from 6 weeks to 2 years.

Most of these studies reported quality of life parameters[51 56 61 73 77 82 84]; three studies reported significant beneficial differences for multiple interventions. Bourbeau et al.[51 57] found statistically and clinically significant differences on the SGRQ impact and total score at 4 months favouring the intervention group, whereas at 12 months only the impact score reached clinical significance. Egan et al.[56] showed significant improved scores for the activity domain of the SGRQ and the anxiety dimension of the HADS in the intervention group. Smith et al.[82] reported evidence of significant effects on asthma specific quality of life and SF-36 mental subscales at 12 months, no results were found on SF-36 physical subscales.

Six studies evaluated the impact of the interventions in terms of changes in health care utilisation.[51 56 61 64 73 84] Only the study by Gadoury et al.[57] revealed strong indications for improvements in health care utilisation, i.e. statistically significant and clinically relevant reduction of emergency room visits and hospitalisations over a 2 year period. None of the other studies detected statistical significant changes on these parameters.

Table 3.2 Key Features of Studies Included in a Systematic Review of Multiple Interventions in Patients with Asthma and COPD

Study	Setting	Study[I] Design/ Quality	Interventions	Follow-up (Months)[II]	Outcome[III] / process Indicators[IV]	Results[V]
Multiple interventions versus usual care						
Aiken et al. 2005 "Intensive Home-based Case Management"	COPD patients in a hospice > 18 years with an estimated 2 year life-expectancy, Phoenix, Arizona (U.S.)	RCT Moderate	I: Provider education, patient education, continuity of care (case management) (N=33) C: Usual care (N=28)	9	**QOL:** SF36 (8 domains) **HCU:** ED **PROCESS:** Behaviour; Knowledge	Sign. better on 3 domains: Physical functioning, General health and Vitality NS Sign. better outcomes on self-management of illness and knowledge on illness
Armour et al. 2007 "Pharmacy Asthma Care Programme"	Asthma patients 18-75 registered in a pharmacy in New South Wales, Victoria and Queensland (Australia)	RCT Moderate	I: Provider education, patient education, expansion or revision of professional roles (pharmacist plays more active role in patient monitoring) (N=191) C: Usual care (N=205)	6	**LUNG:** FEV1 **SYMP:** Perceived Control of Asthma (PCAQ) **QOL:** AQLQ (4 domains) **PROCESS:** Knowledge; Technique; Behaviour	NS Sign. better asthma control Sign. more beneficial effects in Total score Sign. more asthma knowledge; Sign. increase of correct inhalation technique and usage action plan (no data control)
Barbanel et al. 2003 "Community Pharmacist-based Programme"	Adults, 18–65, with a general practitioner diagnosis of asthma who regularly visited the pharmacy for collection of prescribed medication (U.K.)	RCT Moderate	I: Provider education, patient education, expansion or revision of professional roles (pharmacist plays more active role in patient monitoring) (N=12) I: C: Usual care (N=12)	3	**SYMP:** North of England Symptoms Questionnaire	Sign. better symptom score
Bourbeau et al. 2003 Gadoury et al. 2005 Bourbeau et al. 2006 "Multi-component self-Management Programme"	COPD patients ≥ 50 years in 7 hospitals with advanced COPD with at least 1 hospitalisation for exacerbation in the previous year (Canada)	RCT Good	I: Patient education, continuity of care (case management) (N=96) C: Usual care (N=95)	12	**LUNG:** FEV1 **QOL:** SGRQ (4 domains) **SYMP:** 6MWT; MRC; Sputum; Exacerbations **HCU:** Hosp; ED; Cost	NS Sign. better on Impact domain, other domains NS NS; NS; NS; Borderline sign. more decrease in No. of exacerbations Sign. more reduction in No. of hospitalisations (acute exacerbations/ all cause), frequency hospitalised, No. of hospital days; Reduction in emergency visits (acute exacerbations) and scheduled GP visits; cost savings with increased patient caseload and rising costs of hospitalisation.

				24	**HCU:** Hosp; ED	Stat. sign. and clinically relevant reduction in all-cause hospitalisations and in all-cause emergency visits
Casas et al. 2006 "Integrated Care"	COPD patients recruited in two tertiary hospitals immediately after the patients' hospital discharge for an exacerbation > 48 hours (Spain and Belgium).	RCT Good	I: Provider education, self-management, continuity of care (case management; follow-up) (N=65) C: Usual care (N=90)	12	**HCU:** Readm; Visits	Significantly lower No. of readmissions, rate of readmission, and mean No. of readmissions; NS
Cordina et al. 2001 "Community Pharmacist-based Programme"	Patients ≥ 16 registered at the asthma clinic cared for by community pharmacies (Malta)	RCT Good	I: Provider education, patient education, expansion or revision of professional roles (pharmacist plays more active role in patient monitoring) (N=86) C: Usual care (N=66)	12	**LUNG:** PEFR **QOL:** SF36 (8 domains); LWAQ (11 domains) **SYMP:** Wheeze **QOC:** Satisfaction **HCU:** Hosp; Days off **PROCESS:** Technique; Compliance	NS Sign. better on Vitality domain, other domains NS; Borderline sign. better Total score Sign. more patients reported no wheezing Sign. more patients reported approachable pharmacist/ questioned their pharmacist Sign. fewer self-reported hospitalisations; NS Sign. higher improved inhaler technique; NS
Coultas et al. 2005 "Nurse-Assisted Home Care"	COPD patients in primary care clinics associates with an urban academic health center, aged ≥ 45 cared for by primary care physicians (U.S.)	RCT Moderate	I: Provider education, patient education, continuity of care (follow-up) (N=72) C: Usual care (N=73)	6	**QOL:** SF36; SGRQ; Illness intrusiveness scale **HCU:** ED; Hosp; Visits	NS; NS; Sign. more improvement in perceived illness intrusiveness NS; NS; NS
Egan et al. 2002 "Nursing-Based Case Management"	COPD patients ≥ 18 years, admitted to a major private hospital (Australia)	RCT Moderate	I: Patient education, continuity of care (case management) (N=33) C: Usual care (N=33)	1,5	**QOL:** SGRQ (4 domains); HADS (2 domains) **SYMP:** SWB **HCU:** Readm **PROCESS:** Support	Sign. better on Activity domain, other domains NS; Sign. less anxiety (not sustained), depression NS NS NS NS

Study	Setting	Study[I] Design/ Quality	Interventions	Follow-up (Months)[II]	Outcome[III] / process Indicators[IV]	Results[V]
Garcia-Aymerich et al. 2007 "Integrated care intervention"	COPD patients recruited in a tertiary hospitals immediately after the patients' hospital discharge for an exacerbation > 48 hours (Spain).	RCT Good	I: Provider education, self-management, continuity of care (case management; follow-up) (N=44) C: Usual care (N=69)	12	**LUNG:** FEV1 **QOL:** SGRQ; EQ-5D **SYMP:** Dyspnoea **PROCESS:** Knowledge; Compliance; Behaviour	NS NS; NS NS All variables related to knowledge and behaviour were better, mostly sign.; Compliance NS
Herborg et al. 2001 "Community-Based Programme for Pharmaceutical Care"	Asthma patients aged 16-60 who purchased medication at the participating community pharmacies in the area (Denmark)	CBA Good	I: Provider education, patient education, expansion or revision of professional roles (pharmacist plays more active role in patient monitoring)/ monitoring system (N=264) C: Usual care (N=236)	12	**LUNG:** PEFR **QOL:** NHP; LWAQ **SYMP:** Asthma Symptom Status **QOC:** Satisfaction **HCU:** ED; Hosp; Visits **PROCESS:** Knowledge; Compliance	NS Sign. more improvement on both measures Sign. better improved asthma status NS NS; NS; Clinically relevant less use of services Sign. more knowledge on asthma (medications); Sign. less inhalation errors
Hermiz et al. 2002 "Home-Based Care by Community Nurse"	COPD patients in Health Services 30-80 years, attended to ED or admitted to the hospitals (Australia)	RCT Moderate	I: Patient education, continuity of care (follow-up) (N=84) C: Usual care (N=93)	3	**QOL:** SGRQ **QOC:** Satisfaction **HCU:** Hosp; ED **PROCESS:** Knowledge; Behaviour; Follow	NS Sign. more satisfied with their care NS; NS Sign. greater knowledge of COPD; NS; Sign. more follow-up
Hernandez et al. 2003 "Home Hospitalisation"	COPD patients with exacerbations admitted to ER or two tertiary hospitals (Spain)	RCT Moderate	I: Provider education, self-management, continuity of care (follow-up) (N=121) C: Usual care (N=101)	2	**QOL:** SGRQ (4 domains) **QOC:** Satisfaction **HCU:** Readm; ED; LOS; Cost **PROCESS:** Knowledge; Compliance	Sign. higher improvement in Total score Sign. higher satisfaction NS; Sign. less ED admissions; Sign. lower LOS; Sign. lower overall health care cost per patient Sign. more improvement in knowledge and compliance to inhalation technique
Hesselink et al. 2004 "Education Programme"	Patients aged 16-75 from GP practices in with asthma or COPD (The Netherlands)	RCT Good	I: Patient education, team changes (professional roles; nurse) (N=139) C: Usual care (N=137)	12	**QOL:** QOL-RIQ **SYMP:** MRC **PROCESS:** Efficacy; Technique; Coping; Compliance; Behaviour	NS NS NS; Inhalation technique was significantly better; NS; NS; NS

				24	**QOL:** QOL-RIQ **SYMP:** MRC **PROCESS:** Efficacy; Technique; Coping; Compliance; Behaviour	NS NS NS; Inhalation technique was significantly better; NS; NS; NS
Jeffs et al. 2005 "Post Acute Respiratory Outreach Service"	All patients with COPD in a regional hospital (Australia)	CBA Moderate	I: Patient education, continuity of care (follow-up) (N=28) C: Usual care (N=25)	12	**HCU:** ED; Hosp; LOS	NS; NS; Sign. higher increase in hospital bed days
Johnson et al. 2005/ Johnson et al. 2007 "Disease Management"	Patients in the McKesson Asthma Care Support Advisor programme (U.S.)	CBA Moderate	I: Provider education, self-management, continuity of care (case management) (N=196) C: Usual care (N=196)	12	**HCU:** ED; Hosp; LOS; Adm **PROCESS:** Compliance	Sign. fewer ED visits, hospitalisations, bed days, and asthma-related admissions. Sign. higher rates of medication usage
Knoell et al. 1998 "Outpatient Pharmaceutical Care"	Adult asthma patients referred to a specialty outpatient clinic (U.S)	CBA Moderate	I: Patient education, team changes (professional roles/pharmacist) (N=45) C: Usual care (N=55)	3	**QOL:** SF12; AQLQ **QOC:** Satisfaction **HCU:** Hosp; ED; Visits; Cost **PROCESS:** Compliance; Process	NS; sign. more improvement in quality of life Sign. more satisfaction with care NS: NS; NS; NS Sign. more compliant and better informed patients
Kritikos et al. 2007 "Interactive Small-group Education in a Community Pharmacy Setting"	Asthma patients ≥ 16 registered in a pharmacy in the Central Sydney Area (Australia)	RCT Moderate	I: Provider education, patient education, expansion or revision of professional roles (pharmacist plays more active role in patient monitoring) (N=16) C: Usual care (N=16)	3	**SYMP:** Asthma control **QOL:** AQLQ **PROCESS:** Knowledge; Technique; Compliance	Sign. less patients in the severe asthma/ poor control category Sign. more improvement in quality of life Sign. higher asthma knowledge scores; Sign. more increase of correct inhalation technique; NS

Study	Setting	Study[I] Design/ Quality	Interventions	Follow-up (Months)[II]	Outcome[III] / process Indicators[IV]	Results[V]
Lee et al. 2002 "Care Protocol by Community Nurses"	COPD patients ≥ 65, resident of 45 nursing homes in Hong Kong (China)	RCT Moderate	I: Provider education, self-management, continuity of care (follow-up) (N=48) C: Usual care (N=41)	6	**LUNG:** FEV1 **QOL:** GHQ (4 domains); Barthel Index (BI) **QOC:** Satisfaction **HCU:** ED; Hosp; LOS	NS Sign. less anxiety and insomnia and sign. improved overall psychological well-being; NS Sign. more increase in level of satisfaction NS; NS; NS
McLean et al. 2003 "Community Pharmacy Programme"	Uncontrolled asthma patients in from pharmacies in the community (Canada)	RCT Good	I: Patient education, team changes (professional roles/pharmacist) (N=191) C: Usual care (N=214)	12	**LUNG:** PEFR **QOL:** AQLQ (4 domains) **SYMP:** Dyspnoea; cough; wheeze; phlegm **HCU:** ED; Hosp; Days off; Visits **PROCESS:** Knowledge; Compliance	Sign. improvement in mean PEFR Sign. greater improvement in all domains Sign. greater improvement in all symptoms NS; NS; NS; Sign. reduction in No. of medical visits Sign. greater improvement in knowledge and compliance
Mehuys et al. 2008 "Pharmacist Intervention for Asthma Control"	Asthma patients 18-50 registered in pharmacies, located in diverse areas of Flanders (Belgium)	RCT Moderate	I: Provider education, patient education, expansion or revision of professional roles (pharmacist plays more active role in patient monitoring) (N=107) C: Usual care (N=94)	6	**QOL:** AQLQ **SYMP:** Asthma Control Test (control, rescue medication, awakenings); Exacerbations **PROCESS:** Compliance; Technique; Knowledge; Behaviour	NS NS, Sign. higher reduction in need of rescue medication, Sign. less night-time awakenings; NS Sign. higher adherence to controller medication; Sign. better inhalation technique; NS; NS
Meulepas et al. 2007 "Integrated primary care management model"	COPD patients ≥ 40 in general practice (The Netherlands)	CBA Moderate	I: Patient education, team changes (professional roles; nurse) (N=137) C: Usual care (N=123)	24	**SYMP:** Exacerbations **PROCESS:** Process; Technique; Compliance	NS Sign. more improvement of No. of planned visits and periodical lung function measurement; Sign. more improvement in correct inhalation technique; NS
Pilotto et al. 2004 "Nurse-Run Asthma Clinics"	Asthma patients aged ≥ 18 years attended nurse-run asthma clinics (Australia)	RCT Good	I: Patient education, continuity of care (follow-up) (N=80) C: Usual care (N=90)	9	**LUNG:** FEV1 **QOL:** SGRQ (4 domains) **HCU:** ED; Hosp; Days off; Visits **PROCESS:** Behaviour	NS NS NS; NS; Sign. less time off work; Sign. more hospital outpatient department visits NS

Poole et al. 2001 “Case Management”	All patients who had been admitted to Auckland hospital for COPD for ≥ 4 in the previous 2 years (with ≥ 2 in the previous 12 months) (New Zealand)	CBA Moderate	I: Provider education, self-management, continuity of care (follow-up) (N=16) C: Usual care (N=16)	12	**QOL:** CRQ (4 domains) **HCU:** Hosp; LOS	Clinically relevant improvement in all CRQ scores and stat. sign. for total and fatigue for the intervention group (no data control) NS; Sign. more decrease in LOS
Premaratne et al. 1999 “Nurse specialists in asthma management”	All registered asthma patients aged 1550 years of 41 general practices in Greenwich with a practice nurse (U.K.)	RCT Moderate	I: Patient education, team changes (professional roles; nurse) (N=43436) C: Usual care (N=57932)	36	**QOL:** AQLQ **HCU:** ED; Hosp **PROCESS:** Compliance	NS NS; NS NS
Rea et al. 2004 “Chronic Disease Management”	COPD patients from four general practices (New Zealand)	RCT Moderate	I: Patient education, continuity of care (case management) (N=83) C: Usual care (N=52)	12	**LUNG:** FEV1 **QOL:** SF36; CRQ (4 domains) **SYMP:** SWT **HCU:** Hosp; LOS **PROCESS:** Compliance	Stat. but not clinically sign. improvement NS; Stat. and clinically sign. improvement in 2 domains (fatigue, mastery) NS NS; NS NS
Rootmensen et al. 2008 “Additional Pulmonary Nurse Care”	Asthma and COPD patients ≥ 18 from the pulmonary outpatient clinic at the Academic Medical Centre in Amsterdam (the Netherlands)	RCT Good	I: Patient education, continuity of care (case management) (N=97) C: Usual Care (N=94)	6	**QOL:** SGRQ; SF36 **SYMP:** Exacerbations **QOC:** Outpatient satisfaction **PROCESS:** Knowledge; Behaviour; Technique	NS; NS NS NS Sign. higher increase in knowledge; NS; NS
Schonlau et al. 2005 “Quality Improvement Collaborative”	Asthma patients of 6 rural and urban asthma clinics (U.S.)	CBA Good	I: Provider education, self-management, continuity of care (case management) (N=101) C: Usual care (N=64)	12	**QOL:** SF12 **QOC:** Satisfaction **HCU:** ED; Days off **PROCESS:** Knowledge; Behaviour; Compliance; Process	NS Sign. more likely to be satisfied with clinician NS; NS NS; Sign. better self-management; NS; Sign. Process improvement

Study	Setting	Study[I] Design/ Quality	Interventions	Follow-up (Months)[II]	Outcome[III] / process Indicators[IV]	Results[V]
Schulz et al. 2001 "Pharmaceutical Asthma Care Services"	Asthma patients registered in a pharmacy in the city of Hamburg (Germany)	CBA Moderate	I: Provider education, patient education, expansion or revision of professional roles (pharmacist plays more active role in patient monitoring) (N=191) C: Usual care (N=205)	12	**LUNG:** FEV1; PEFR **SYMP:** Dyspnoea **QOL:** SF36 (2 domains); LWAQ (11 domains) **PROCESS:** Knowledge; Technique; Efficacy	NS; NS NS Sign. more improvement in mental scale, physical scale NS; Sign. more improvement in summary and all subscales Sign. more improvement in knowledge, inhalation technique and self-efficacy
Smith et al. 2005 "Home-Based Nurse-led Psycho Educational Intervention"	Adult patients registered at the asthma clinic (U.K.)	RCT Good	I: Patient education, continuity of care (follow-up) (N=47) C: Usual care (N=45)	12	**QOL:** SF36 (2 domains); LWAQ **SYMP:** Asthma Symptom Status **PROCESS:** Behaviour; compliance	Sign. more improvement in mental health score, physical functioning NS; Sign. better asthma quality of life score NS NS; Sign. more increase in PEF monitoring
Solomon/ Gourley 1998 "Pharmaceutical Care Model"	Ambulatory COPD patients > 40 years of 10 departments of Veterans Affairs medical centres and 1 academic medical centre (U.S.)	RCT Moderate	I: Patient education, team changes (professional roles/pharmacist) (N=43) C: Usual care (N=55)	6	**QOL:** HSQ **SYMP:** Dyspnoea **QOC:** Satisfaction **HCU:** ED; Hosp; Visits **PROCESS:** Compliance; Knowledge; Process	NS NS Sign. better satisfaction NS; NS; NS NS; NS; NS
Sridhar et al. 2008 "Nurse-led intermediate care package"	COPD patients previously admitted to community and hospital care in west London (U.K.)	RCT Good	I: Patient education, continuity of care (follow-up) (N=61) I: C: Usual care (N=61)	24	**SYMP:** Mortality **QOL:** CRQ (4 domains) **SYMP:** Exacerbations **HCU:** Hosp; Visits; Cost **PROCESS:** Behaviour	Sign. lower No. of COPD-related deaths NS NS NS; Sign. less unscheduled GP contacts; NS Sign. better self-management of exacerbations

Vrijhoef et al. 2007 "Transfer of Care"	Patients with previously documented COPD attending the respiratory outpatient clinic (The Netherlands)	RCT Good	I: Provider education, patient education, team changes (professional roles; nurse), continuity of care (follow-up) (N= 91) C: Usual Care (N=83)	9	**LUNG:** FEV1; FVC **QOL:** SGRQ; COOP/ WONCA **QOC:** Satisfaction **HCU:** Visits **PROCESS:** Behaviour; Knowledge	NS; Sign. more improvement in mean FVC NS; NS Sign. better satisfaction NS Self care behaviour was mostly NS with exception of sign. better coping and sign. lower condition maintenance; Sign. bigger improvement of knowledge
Weinberger et al. 2002 "Pharmaceutical Care Programme"	Asthma and COPD patients > 18 years with reactive airways disease at 36 community drugstores in Indianapolis (U.S)	RCT Good	I: Provider education, patient education, expansion or revision of professional roles (pharmacist plays more active role in patient monitoring) (N=447) C: Usual care (N=303)	12	**LUNG:** PEFR **QOL:** CRQ; AQLQ **QOC:** Satisfaction **HCU:** ED; Hosp **PROCESS:** Process	Sign. higher peak flow rates NS (COPD); NS (asthma) Sign. more satisfied with pharmacist NS; NS (COPD); Sign. more breathing-related ED and hospital visits (asthma) NS
Multiple interventions versus single intervention						
Donald et al. 2008 "Telephone based Asthma Management"	Adults aged 18–55 years admitted to one or both of two metropolitan Melbourne (Victoria) teaching hospitals with a primary diagnosis of asthma (Australia)	RCT Moderate	I: Patient education, continuity of care (follow-up) (N=36) C: Patient education (N=35)	12	**LUNG:** Morbidity **HCU:** ED; Readm; Visits	NS NS; Sign. less readmissions; NS
Coultas et al. 2005 "Nurse-Assisted Home Care"	COPD patients in primary care clinics associates with an urban academic health center, aged ≥ 45 cared for by primary care physicians (U.S.)	RCT Moderate	I: Provider education, patient education, continuity of care (follow-up) (N=72) C: Patient education (N=72)	6	**QOL:** SF36; SGRQ; Illness intrusiveness scale **HCU:** ED; Hosp; Visits	NS; NS; NS NS; NS; NS

Study	Setting	Study [I] Design/ Quality	Interventions	Follow-up (Months) [II]	Outcome [III] / process Indicators [IV]	Results [V]
Schatz et al. 2006 "Care Manager"	Asthma patients 18-56 of the San Diego Kaiser Permanente Medical Care Programme (U.S.)	RCT Moderate	I: Patient education, continuity of care (follow-up/ case management) (N=31) C: Patient education (N=31)	12	**QOL:** AQLQ **SYMP:** Symptom free days **PROCESS:** Knowledge	NS NS Sign. better rating of asthma knowledge
Smith et al. 1999 "Respiratory Home Nurse Intervention"	Patients > 40 years with severe COPD attending a teaching hospital (Australia)	RCT Moderate	I: Patient education, continuity of care (follow-up) (N=48) C: Patient education (N=48)	12	**LUNG:** FEV1 **QOL:** COOP **HCU:** Hosp; Visits; LOS	Sign. deterioration (no data control) Sign. improvement in total quality of life (no data control) NS; NS; NS
Weinberger et al. 2002 "Pharmaceutical Care Programme"	Asthma and COPD patients > 18 years with reactive airways disease at 36 community drugstores in Indianapolis (U.S)	RCT Good	I: Provider education, patient education, expansion or revision of professional roles (pharmacist plays more active role in patient monitoring) (N=447) C: Patient education (N=363)	12	**LUNG:** PEFR **QOL:** CRQ; AQLQ **QOC:** Satisfaction **HCU:** ED; Hosp **PROCESS:** Process	NS NS (COPD); NS (asthma) Sign. more satisfied with pharmacist NS; NS NS

[I] Research designs: RCT: Randomised Controlled Trial; CBA: Controlled Before-After study

[II] When the follow-up period is longer then 12 months, the 12-months results as well as the final results are presented

[III] Outcome indicators: Main: LUNG= lung function; QOL= quality of life; SYMP: symptoms; QOC: quality of care; HCU: health care utilisation. Measures: FEV1=forced expiratory volume in 1 second; PEFR=peak expiratory flow rate; MRC=Medical Research Council; Exacerbations= number of exacerbations; SWB=Subjective Well-Being; 6MWD=6-Minute Walking Distance; SWT=Shuttle Walk Test; CRQ=Chronic Respiratory Questionnaire; SGRQ=St. George's Respiratory Questionnaire; QWB=Quality of Well-being Scale; SF36/12=Short-Form 36/12; NHP=Nottingham Health Profile; COOP/WONCA=; LWAQ= Living With Asthma Questionnaire; QOL-RIQ=Quality-of-life for Respiratory Illness Questionnaire; AQLQ=Asthma Quality of Life Questionnaire; GHQ= General Health Questionnaire; HSQ= Health Status Questionnaire; VAS=Visual Analogue Scale; EQ-5D=Euro-Quol-5D; HADS=Hospital and Anxiety Depression Scale; ED= number of emergency department visits; Hosp=number of hospitalisations; Days off= number of days off work/ school; Visits=number of visits to health care services; (Re)adm= number of (re)admissions; LOS=length of stay; Cost= costs.

[IV] Process indicators: Main: PROCESS=Process indicators. Measures: Behaviour= self-management behaviour; Compliance= (medication) compliance; Knowledge=patient knowledge; Efficacy=self-efficacy; Technique=inhalation technique; Support=social support; Process=process performed; Follow=follow-up.

[V] All results are presented compared to "usual care".

Eleven studies examined patient education and case management in combination with professional education.[47 52 54 58 62 65 69 74 76 79 85] All but two studies concerned COPD care. Quality of life measures were reported in most studies. Four studies reported improvement on the SGRQ score in favour of the multiple intervention groups, however not constantly significant. Rea et al.[76] reported a significant improvement for two dimensions of the CRQ (fatigue and mastery), but no significant difference was found on the SF-36 score. Conversely, another study by Aiken et al.[47] showed better physical functioning, vitality and total function on the SF-36 in favour of the intervention group. Lee et al.[69] showed a significant greater improvement in psychological wellbeing (GHQ) in the intervention group. Of the ten studies reporting health care utilisation three studies[52 62 65] demonstrated significant reductions in readmissions and emergency department visits.

Overall, no significant differences between intervention and control groups were found on clinical outcomes, namely lung function and symptoms. Reports on satisfaction showed significant more increase in satisfaction in intervention groups compared to control groups. Processes measures also showed positive results: most studies reported significantly better scores on knowledge and self-management in the intervention groups.

Meta-analyses demonstrated statistically significant improvements on the SGRQ total and impact scores in favour of multiple interventions (Figure 3.2). The differences on the SGRQ activity score reached statistical significance in the triple intervention studies. Pooled SGRQ data showed better effects in triple intervention compared to double intervention studies. Moreover, clinically relevant differences for triple interventions were found in SGRQ total, activity and impact scores. No significant difference or clinically relevant was found on the SGRQ symptom score. Nine studies reporting hospitalisations in COPD-care were pooled (Figure 3.3). For a few studies standard deviations were not available[56 62 77], however they did show similar mean scores.

	Multiple			Usual Care				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Fixed, 95% CI**
2.1.1 Double interventions versus Usual Care								
Bourbeau	50.6	17.8	81	54.2	17.6	76	19.9%	-3.60 [-9.14, 1.94]
Hermiz	59.39	20.3	67	57.68	19.75	80	14.4%	1.71 [-4.80, 8.22]
Pilotto	27	15.9	71	27.3	17.1	82	22.3%	-0.30 [-5.53, 4.93]
Subtotal (95% CI)			**219**			**238**	**56.7%**	**-0.95 [-4.23, 2.34]**
Heterogeneity: Chi² = 1.58, df = 2 (P = 0.45); I² = 0%								
Test for overall effect: Z = 0.57 (P = 0.57)								
2.1.2 Triple interventions versus Usual Care								
Coultas	55	16.4	51	58.5	16.4	51	15.1%	-3.50 [-9.87, 2.87]
Garcia-Aymerich	37.5	22.3	20	49.8	18.4	41	4.8%	-12.30 [-23.58, -1.02]
Vrijhoef	28.1	15.1	81	31.8	16.6	69	23.4%	-3.70 [-8.81, 1.41]
Subtotal (95% CI)			**152**			**161**	**43.3%**	**-4.59 [-8.34, -0.83]**
Heterogeneity: Chi² = 2.02, df = 2 (P = 0.36); I² = 1%								
Test for overall effect: Z = 2.39 (P = 0.02)								
Total (95% CI)			**371**			**399**	**100.0%**	**-2.52 [-5.00, -0.05]**
Heterogeneity: Chi² = 5.64, df = 5 (P = 0.34); I² = 11%								
Test for overall effect: Z = 2.00 (P = 0.05)								
Test for subgroup differences: Chi² = 2.04, df = 1 (P = 0.15), I² = 51.0%								

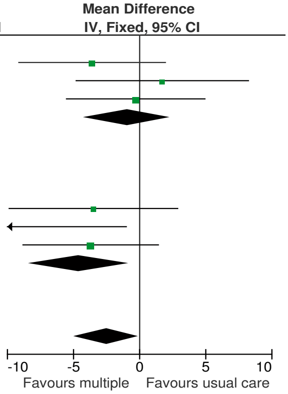
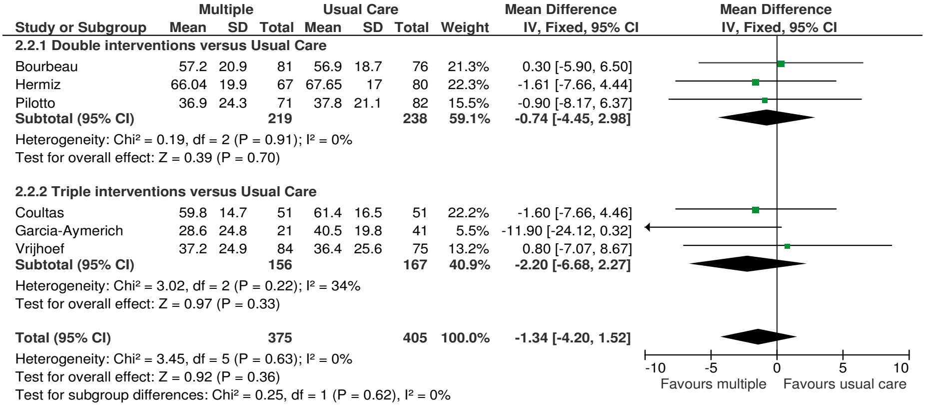
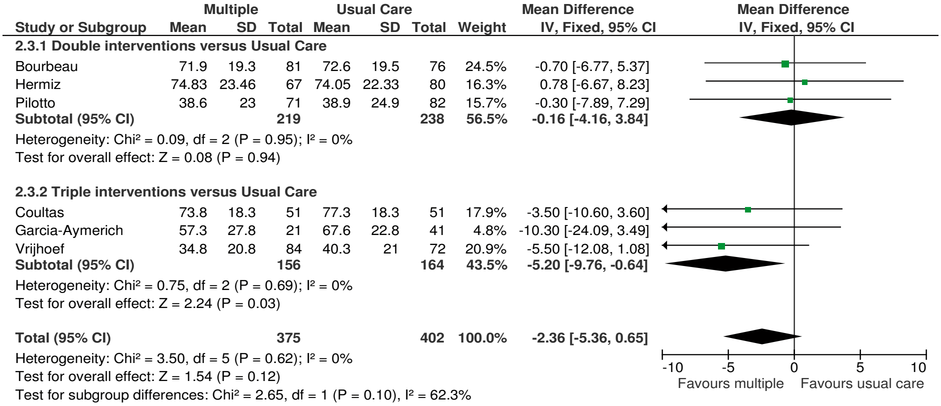


Figure 3.2a Multiple interventions including case management versus usual care, Quality of Life (SGRQ Total) post intervention



Study or Subgroup	Multiple Mean	Multiple SD	Multiple Total	Usual Care Mean	Usual Care SD	Usual Care Total	Weight	Mean Difference IV, Fixed, 95% CI
2.2.1 Double interventions versus Usual Care								
Bourbeau	57.2	20.9	81	56.9	18.7	76	21.3%	0.30 [-5.90, 6.50]
Hermiz	66.04	19.9	67	67.65	17	80	22.3%	-1.61 [-7.66, 4.44]
Pilotto	36.9	24.3	71	37.8	21.1	82	15.5%	-0.90 [-8.17, 6.37]
Subtotal (95% CI)			**219**			**238**	**59.1%**	**-0.74 [-4.45, 2.98]**
Heterogeneity: Chi^2 = 0.19, df = 2 (P = 0.91); I^2 = 0%								
Test for overall effect: Z = 0.39 (P = 0.70)								
2.2.2 Triple interventions versus Usual Care								
Coultas	59.8	14.7	51	61.4	16.5	51	22.2%	-1.60 [-7.66, 4.46]
Garcia-Aymerich	28.6	24.8	21	40.5	19.8	41	5.5%	-11.90 [-24.12, 0.32]
Vrijhoef	37.2	24.9	84	36.4	25.6	75	13.2%	0.80 [-7.07, 8.67]
Subtotal (95% CI)			**156**			**167**	**40.9%**	**-2.20 [-6.68, 2.27]**
Heterogeneity: Chi^2 = 3.02, df = 2 (P = 0.22); I^2 = 34%								
Test for overall effect: Z = 0.97 (P = 0.33)								
Total (95% CI)			**375**			**405**	**100.0%**	**-1.34 [-4.20, 1.52]**
Heterogeneity: Chi^2 = 3.45, df = 5 (P = 0.63); I^2 = 0%								
Test for overall effect: Z = 0.92 (P = 0.36)								
Test for subgroup differences: Chi^2 = 0.25, df = 1 (P = 0.62), I^2 = 0%								

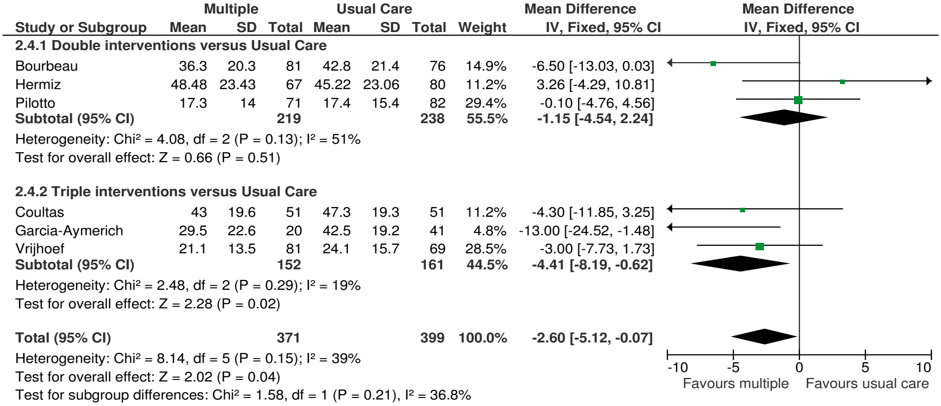
Figure 3.2b Multiple interventions including case management versus usual care, Quality of Life (SGRQ Symptoms) post intervention



Study or Subgroup	Multiple Mean	Multiple SD	Multiple Total	Usual Care Mean	Usual Care SD	Usual Care Total	Weight	Mean Difference IV, Fixed, 95% CI
2.3.1 Double interventions versus Usual Care								
Bourbeau	71.9	19.3	81	72.6	19.5	76	24.5%	-0.70 [-6.77, 5.37]
Hermiz	74.83	23.46	67	74.05	22.33	80	16.3%	0.78 [-6.67, 8.23]
Pilotto	38.6	23	71	38.9	24.9	82	15.7%	-0.30 [-7.89, 7.29]
Subtotal (95% CI)			**219**			**238**	**56.5%**	**-0.16 [-4.16, 3.84]**
Heterogeneity: Chi^2 = 0.09, df = 2 (P = 0.95); I^2 = 0%								
Test for overall effect: Z = 0.08 (P = 0.94)								
2.3.2 Triple interventions versus Usual Care								
Coultas	73.8	18.3	51	77.3	18.3	51	17.9%	-3.50 [-10.60, 3.60]
Garcia-Aymerich	57.3	27.8	21	67.6	22.8	41	4.8%	-10.30 [-24.09, 3.49]
Vrijhoef	34.8	20.8	84	40.3	21	72	20.9%	-5.50 [-12.08, 1.08]
Subtotal (95% CI)			**156**			**164**	**43.5%**	**-5.20 [-9.76, -0.64]**
Heterogeneity: Chi^2 = 0.75, df = 2 (P = 0.69); I^2 = 0%								
Test for overall effect: Z = 2.24 (P = 0.03)								
Total (95% CI)			**375**			**402**	**100.0%**	**-2.36 [-5.36, 0.65]**
Heterogeneity: Chi^2 = 3.50, df = 5 (P = 0.62); I^2 = 0%								
Test for overall effect: Z = 1.54 (P = 0.12)								
Test for subgroup differences: Chi^2 = 2.65, df = 1 (P = 0.10), I^2 = 62.3%								

Figure 3.2c Multiple interventions including case management versus usual care, Quality of Life (SGRQ Activity) post intervention

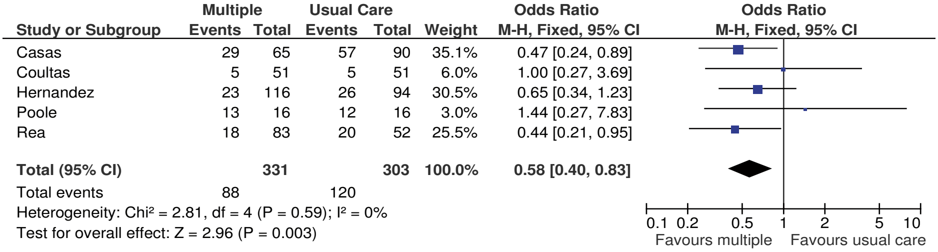
There was a statistically significant reduction of the probability of at least one hospital admission among patients receiving multiple interventions compared to usual care. Data on double interventions showed statistical heterogeneity (I^2=67.4%) and were therefore excluded from further analyses. Subgroup analyses of triple interventions revealed a significant effect. Meta-analysis of emergency department visits per person did not show a statistically significant effect in favour of treatment (Figure 3.4). The level of statistical heterogeneity for this outcome was related to the outlying effect reported in Bourbeau[57] (only double intervention); its removal led to a lower I^2 statistic (93.7% versus 21.2%).



Study or Subgroup	Multiple Mean	Multiple SD	Multiple Total	Usual Care Mean	Usual Care SD	Usual Care Total	Weight	Mean Difference IV, Fixed, 95% CI
2.4.1 Double interventions versus Usual Care								
Bourbeau	36.3	20.3	81	42.8	21.4	76	14.9%	-6.50 [-13.03, 0.03]
Hermiz	48.48	23.43	67	45.22	23.06	80	11.2%	3.26 [-4.29, 10.81]
Pilotto	17.3	14	71	17.4	15.4	82	29.4%	-0.10 [-4.76, 4.56]
Subtotal (95% CI)			**219**			**238**	**55.5%**	**-1.15 [-4.54, 2.24]**
Heterogeneity: Chi² = 4.08, df = 2 (P = 0.13); I² = 51%								
Test for overall effect: Z = 0.66 (P = 0.51)								
2.4.2 Triple interventions versus Usual Care								
Coultas	43	19.6	51	47.3	19.3	51	11.2%	-4.30 [-11.85, 3.25]
Garcia-Aymerich	29.5	22.6	20	42.5	19.2	41	4.8%	-13.00 [-24.52, -1.48]
Vrijhoef	21.1	13.5	81	24.1	15.7	69	28.5%	-3.00 [-7.73, 1.73]
Subtotal (95% CI)			**152**			**161**	**44.5%**	**-4.41 [-8.19, -0.62]**
Heterogeneity: Chi² = 2.48, df = 2 (P = 0.29); I² = 19%								
Test for overall effect: Z = 2.28 (P = 0.02)								
Total (95% CI)			**371**			**399**	**100.0%**	**-2.60 [-5.12, -0.07]**

Heterogeneity: Chi² = 8.14, df = 5 (P = 0.15); I² = 39%
Test for overall effect: Z = 2.02 (P = 0.04)
Test for subgroup differences: Chi² = 1.58, df = 1 (P = 0.21), I² = 36.8%

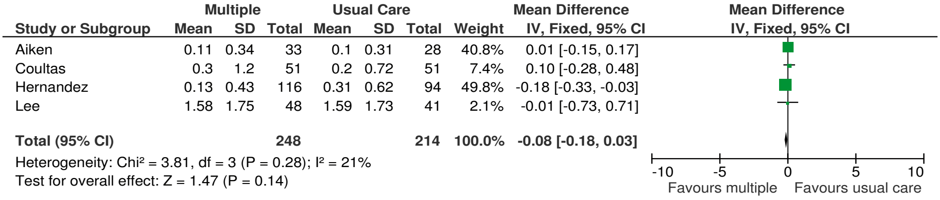
Figure 3.2d Multiple interventions including a case management versus usual care, Quality of Life (SGRQ Impact) post intervention



Study or Subgroup	Multiple Events	Multiple Total	Usual Care Events	Usual Care Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Casas	29	65	57	90	35.1%	0.47 [0.24, 0.89]
Coultas	5	51	5	51	6.0%	1.00 [0.27, 3.69]
Hernandez	23	116	26	94	30.5%	0.65 [0.34, 1.23]
Poole	13	16	12	16	3.0%	1.44 [0.27, 7.83]
Rea	18	83	20	52	25.5%	0.44 [0.21, 0.95]
Total (95% CI)		**331**		**303**	**100.0%**	**0.58 [0.40, 0.83]**
Total events	88		120			

Heterogeneity: Chi² = 2.81, df = 4 (P = 0.59); I² = 0%
Test for overall effect: Z = 2.96 (P = 0.003)

Figure 3.3 Multiple interventions including case management versus usual care, hospital admissions



Study or Subgroup	Multiple Mean	Multiple SD	Multiple Total	Usual Care Mean	Usual Care SD	Usual Care Total	Weight	Mean Difference IV, Fixed, 95% CI
Aiken	0.11	0.34	33	0.1	0.31	28	40.8%	0.01 [-0.15, 0.17]
Coultas	0.3	1.2	51	0.2	0.72	51	7.4%	0.10 [-0.28, 0.48]
Hernandez	0.13	0.43	116	0.31	0.62	94	49.8%	-0.18 [-0.33, -0.03]
Lee	1.58	1.75	48	1.59	1.73	41	2.1%	-0.01 [-0.73, 0.71]
Total (95% CI)			**248**			**214**	**100.0%**	**-0.08 [-0.18, 0.03]**

Heterogeneity: Chi² = 3.81, df = 3 (P = 0.28); I² = 21%
Test for overall effect: Z = 1.47 (P = 0.14)

Figure 3.4 Multiple interventions including a case management versus usual care, emergency department visits per person per year

Patient education in combination with revision of professional roles (and professional education)

Six studies focussed on patient education as well as on revision of professional roles. Two forms of revision could be distinguished: substitution of physicians by nurses[63 72 75] and pharmacists providing (drug) counselling that was formerly provided by nurses and physicians.[67 70 83] Substitution of physicians by nurses was not associated with any significant benefits, other than process improvements mainly of inhalation technique. Of the studies involving a pharmacist, two studies[67 83] showed significantly more satisfaction with care. Knoell et al.[67] also reported significant between-group differences in quality of life and process measures. Moreover, McLean and colleagues[70] found significant improvements on clinical, quality of life and all process measures, but could not detect significant differences on health care utilisation between groups. They applied intense patient education: at least 3 1-hour appointments every 2 or 3 weeks, followed by 1-hour sessions every 3 months.

Interventions in another eight studies constituted of professional and patient education in combination with pharmacists playing a more active role in patient monitoring.[48 49 53 60 68 71 80 86] All studies concerned asthma patients, apart from one study which focussed on both diseases. The numerous outcomes measured showed positive results: in the intervention groups significantly better symptom scores, quality of life scores and improvement in process indicators, such as knowledge and inhalation technique, were found in most studies. Overall, no significant improvements were found in lung function. Results on health care utilisation and satisfaction were ambiguous.

Meta-analysis of studies that included a pharmacist[67 70 71 86] demonstrated a significant improvement on the Asthma Quality of Life Questionnaire (AQLQ) (Figure 3.5). However, statistical heterogeneity was apparent. Subgroup analyses showed a significant effect of double interventions.[67 70] Triple interventions[71 86] compared to usual care did not reach statistical significance. Yet, a qualitative comparison on all quality of life instruments and other outcomes suggest more significant effects of triple rather than double interventions. Data measured by the Living With Asthma Questionnaire (LWAQ)[53 60 80] could not be pooled due to instrument differences, caused by use of an adjusted version of the original; all studies reported significantly improved outcomes.

	Multiple			Usual Care				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
3.1.1 Double interventions versus Usual Care								
Knoell	5.62	1.22	45	4.95	1.44	55	8.0%	0.67 [0.15, 1.19]
McLean	5.13	1.19	119	4.4	0.93	105	28.1%	0.73 [0.45, 1.01]
Subtotal (95% CI)			**164**			**160**	**36.0%**	**0.72 [0.47, 0.96]**
Heterogeneity: Chi² = 0.04, df = 1 (P = 0.84); I² = 0%								
Test for overall effect: Z = 5.72 (P < 0.00001)								
3.1.2 Triple interventions versus Usual Care								
Mehuys	6	0.7	80	5.8	0.9	70	31.9%	0.20 [-0.06, 0.46]
Weinberger	5	1.3	225	4.9	1.2	142	32.0%	0.10 [-0.16, 0.36]
Subtotal (95% CI)			**305**			**212**	**64.0%**	**0.15 [-0.03, 0.33]**
Heterogeneity: Chi² = 0.28, df = 1 (P = 0.59); I² = 0%								
Test for overall effect: Z = 1.59 (P = 0.11)								
Total (95% CI)			**469**			**372**	**100.0%**	**0.35 [0.21, 0.50]**
Heterogeneity: Chi² = 13.43, df = 3 (P = 0.004); I² = 78%								
Test for overall effect: Z = 4.71 (P < 0.00001)								
Test for subgroup differences: Chi² = 13.10, df = 1 (P = 0.0003), I² = 92.4%								

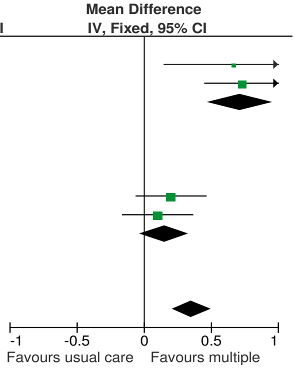


Figure 3.5 Multiple interventions including a pharmacist versus usual care, Quality of Life (AQLQ) at 6 months

Multiple versus single interventions

In five studies multiple interventions were compared to single interventions.[54 55 78 81 86] Four studies reported complete quality of life data, demonstrating better, however non-significant, quality of life in the multiple intervention group. Data on quality of life could not be included in a meta-analysis due to heterogeneity of instruments. Data reported on other outcomes in these studies was too diverse to interpret.

Discussion

This study was performed to understand the effectiveness of multifaceted disease-management interventions in improving care or reducing costs for patients with asthma or COPD. Although relevant reports are limited in number and show great heterogeneity, some cautious conclusions can be drawn. The studies showed significant improvements on quality of life in pharmacist programmes and COPD care programmes. Qualitative analyses of other quality of life measures partially confirmed this finding. Meta-analyses on hospitalisations showed a significant reduction in the number of patients with one or more hospital admissions within triple interventions. No effects were found in emergency department visits per person. Qualitative assessment of the studies showed significant improvements in process measures in several studies. Moreover, for satisfaction, a positive trend was seen. Inconclusive results were reported on symptoms; no effects were found in lung function.

In particular, combining patient and professional education with an active role of the pharmacist in patient monitoring led to improvements in patient outcomes as compared with usual care. Bravata et al.[87] also reported statistically significant improvements in processes and outcomes when pharmacists were actively involved. Education provided by pharmacists rather than by nurses seemed to achieve better results. Taylor et al.[88] also found little evidence to support nurse-led management of COPD patients in the community. A factor contributing to this effect might be the lower intervention intensity of nurse education compared with pharmacist education. Overall the provision of education as a result of revision of roles seemed to have a positive impact on patient satisfaction.

This review included asthma as well as COPD studies; these differed in several respects. Asthma studies focused on adult patients from the age of 16 years; in some cases the population was constrained to a maximum age. Studies with regard to COPD patients, on the other hand, mostly restricted their populations to older patients, from the age of 30 years. All asthma studies were in community settings; COPD studies took place in various settings. Results on asthma seemed to achieve more favourable results of multiple interventions than COPD studies, albeit not consistently across all studies.

The multifaceted interventions also targeted various populations ranging from mild to severe patients. It was apparent that studies including more severe patients showed greater tendency to success on the short run. Another recurring theme was that studies that reported a positive effect on quality of life often concerned programmes with more intense interventions of longer duration. This supports the continuous character of disease management: multifaceted interventions should frequently interact with the patients therein; the chronic care model approach provides a promising manner to shape long-term care for chronic patients.

The complexity of multiple disease-management interventions makes rigorous evaluation and determining their practical feasibility quite problematic. Although RCTs are the gold standard in clinical research, in organisational research it is difficult to set up RCTs.[89] In general, a design should be chosen that minimises potential bias (internal validity) and maximises generalisability (external validity).[90-92] Therefore, this review concentrated on quasi-experimental and experimental study designs. It was apparent that many studies that failed to meet the quality criteria on research methodology, concerned asthma disease-management studies.[43-45] In these studies, participants were offered commercial disease-management programmes. However, using total costs as the primary outcome measure to demonstrate programme effectiveness and return on investment poses a significant threat to the validity of outcomes in the evaluation of disease management.[93]

While almost all studies measure outcome parameters, less attention is paid to structure and process indicators. Since multifaceted interventions interfere in the structure and the process of care delivered, these are important aspects to be measured. Nevertheless, nine studies did not report process measures and merely one study reported structure measures. For example, geographical differences reflected in diverse organisational structures are considered to influence the design and performance of the programmes. We would like to make a plea for more attention to the use of structure and process parameters, as well as to considerable (minimum) duration of data collection. Although the major effects of disease-management interventions may be expected to occur in the long-term, the follow-up period in fifteen15 of 36 studies was less than 1one year after allocation of the subjects or start of the interventions. Sixteen studies lasted 12 months. No studies reported simulation models to extrapolate measurements over time.

Limitations of the study

As with all systematic reviews, this study has several limitations. Most importantly, it may be criticised for the widely ranging quality and heterogeneity of the original studies. These encompass a wide range in (combinations of) interventions used, process and outcome variables, and patient populations. Programme interpretation according to the EPOC criteria was hampered by the imprecise descriptions of the interventions. Next to that, lack of data impeded the determination of the incremental benefits of the various components of each intervention. Moreover, an informative description of each intervention is extremely important in disease management, because of the comprehensiveness and the complexity of disease-management interventions. Furthermore, the intensity of the interventions was often unclear. When described, various interventions could be characterised as being of low intensity, in particular professional-directed interventions. In many cases the intervention consisted of a minimal level of education, which Grimshaw and colleagues advised against.[18] They concluded that occasional education had only short-term effects. From a methodological point of view, restrictions in search strategies, such as databases, could have influenced the study findings. Furthermore, the absence of publication bias cannot be guaranteed. Consequently, the effectiveness of combinations of interventions may appear too positive.

Practice and research implications

Measuring at outcome as well as process levels contributes to a better understanding of ways to improve quality of care. Measuring the process of care contributes to understanding heterogeneity in patient outcomes. In addition to outcomes measures, process measures should be collected in future research. Structure indicators are largely missing in this literature review. Since most multifaceted interventions involve some form of organisational change resulting in structural change, information about the structure of healthcare is essential. Future research should attempt to set up practical, multicentre clinical trials; a wider range of physicians and settings is bound to improve external validity.[94] International comparative studies can gain a better understanding of the effects of disease management in relation to the health care system.

A wide variety of indicators were used to evaluate the interventions. The indicators in the studies included in this review were frequently not related to the interventions that were evaluated. This holds true for process measures in particular: although present in many studies, they did not cover the degree of successful implementation of the interventions. A plea has been made, therefore, to choose process indicators that are sensitive to the specific interventions and are associated with the expected changes in outcomes of care.[35]

More research on the long-term effectiveness of multifaceted interventions is needed, as follow-up in most of the studies in the present review was short. Lack of hard evidence of effectiveness of multiple interventions may in part be due to inadequate length of follow up. To deal with this issue, future studies need to evaluate sustainability of multiple interventions on the longer term. Finally, as variation in follow-up periods and reporting of data complicate comparability of studies, we would recommend to standardising reporting periods and data sets.

Conclusions

Current evidence on disease-management programmes in asthma and COPD shows improvements in quality of life and reductions in hospitalisations in triple interventions. No effects on emergency department visits were found. Qualitative analysis demonstrated small, albeit no consistent, improvements in process and outcome indicators. Estimates of the effectiveness of multifaceted interventions are limited by the wide range of outcomes measured, the diverging combinations of interventions, the different study designs and the many different settings in which care was delivered. Still, this review points at promising combinations of interventions. Improvement in comparison with usual care was notably found for interventions in which pharmacists can liaise with the patient and the professional, provide education and play an active role in patient monitoring.

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Chapter 4

Identifying Potentially Cost Effective Chronic Care Programmes for People with COPD

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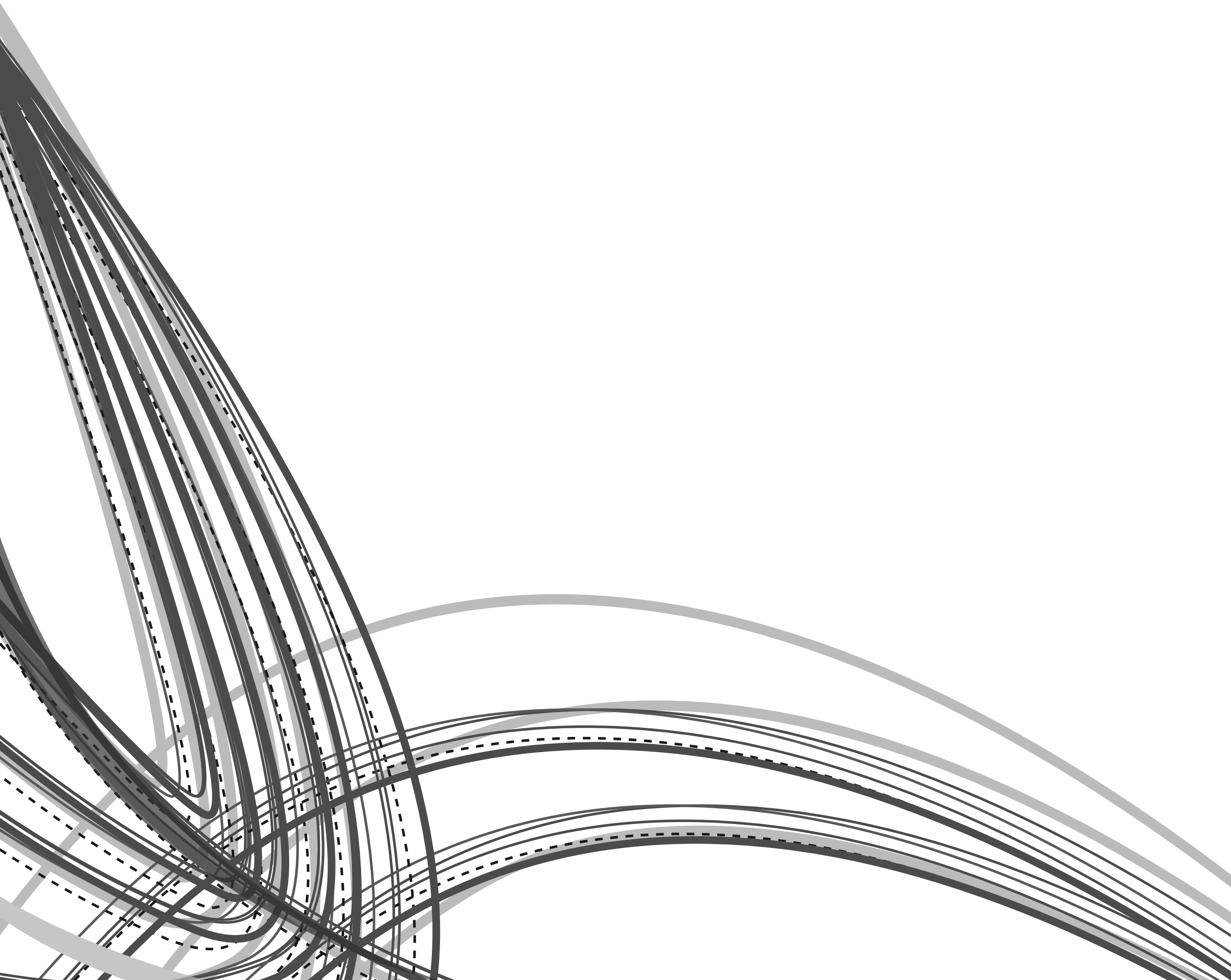

Abstract

Objective: To review published evidence regarding the cost effectiveness of multi-component COPD programmes and to illustrate how potentially cost effective programmes can be identified.

Methods: Systematic search of Medline and Cochrane databases for evaluations of multi-component disease-management or chronic care programmes for adults with COPD, describing process, intermediate, and end results of care. Data were independently extracted by two reviewers and descriptively summarised.

Results: Twenty articles describing 17 unique COPD programmes were included. There is little evidence for significant improvements in process and intermediate outcomes, except for increased provision of patient self-management education and improved disease-specific knowledge. Overall, the COPD programmes generate end results equivalent to usual care, but programmes containing ≥3 components show lower relative risks for hospitalisation. There is limited scope for programmes to break-even or save money.

Conclusion: Identifying cost effective multi-component COPD programmes remains a challenge due to scarce methodologically sound studies that demonstrate significant improvements on process, intermediate and end results of care. Estimations of potential cost effectiveness of specific programmes illustrated in this chapter can, in the absence of 'perfect data', support timely decision-making regarding these programmes. Nevertheless, well-designed health economic studies are needed to decrease the current decision uncertainty.

Introduction

Chronic care programmes for people with chronic obstructive pulmonary disease (COPD), such as the chronic care model[1] and disease-management programmes[2] are increasingly implemented in daily health care[3 4] in response to the growing burden of COPD on societies worldwide.[5] The aim of these programmes is, generally, to improve processes and outcomes of care whilst making a more efficient use of scarce health care resources, or even generate cost savings.

The disease-management approach as described by the Disease-management Association of America (DMAA) highlights three components: the central care delivery and leadership roles of the primary care physician; the critical importance of patient activation, involvement and personal responsibility; and the patient focus and capacity expansion of care coordination provided through wellness, disease and chronic care management programmes.[2] The chronic care model (CCM) identifies essential components that encourage high-quality chronic disease care, involving the community and health system and including self-management support, delivery system design, decision support, and clinical information systems.[6]

Notwithstanding the intuitive appeal of these approaches, the current evidence regarding their efficacy, effectiveness and cost effectiveness is severely limited by the amount and quality of well-designed studies and the evidence that has been published so far reveals results that are far below expectations.[7] Indeed, the systematic reviews of Weingarten[8], Ofman[9], and Mattke[10] consistently show that disease management is less effective for COPD than it is for chronic conditions such as diabetes, congestive heart failure and depression.

By specifically focusing on COPD, however, the systematic review of Adams and colleagues[11] demonstrated that patients who received two or more CCM components had lower rates of hospitalisations and emergency/unscheduled visits, and shorter length of hospital stay compared with control groups. This may indicate that, despite earlier less encouraging findings, a scope for COPD care programmes to generate the necessary improvements in COPD care does exist, providing these packages are truly comprehensive, multi-faceted and well coordinated. However, since even the proven effective but less comprehensive disease-management and chronic care programmes struggle to demonstrate their economic benefits[7 9-11] and because more comprehensive programmes are likely to come at an even higher opportunity cost than the less comprehensive ones, the need for rigorous studies and timely economic evaluations can hardly be underestimated. Furthermore, with innovative industries and health care practices greatly outpacing academic research in this area and considering the mounting health care costs, there is a need to estimate the potential cost effectiveness of COPD care programmes, even in the absence of the 'ideal' clinical and economic data.[12] This study therefore first provides an update of the published evidence regarding the effectiveness and cost effectiveness of multi-component COPD care programmes (i.e., programmes consisting of ≥2 components of disease-management or the chronic care model). Secondly, we illustrate how the likely short and long term cost effectiveness of a particular programme can be estimated with limited data available; the latter mainly with the aim to support timely decision-making, rather than providing the most precise estimates possible.[13 14]

Methods

Literature search

Medline and Cochrane databases were electronically searched for English-language articles published between January 1995 and September 2007 describing evaluations of disease-management or chronic care model interventions for adults with mild, moderate, severe, or very COPD. Search terms included combinations of MeSH terms and text words, as described in Table 4.1. The search was further expanded by hand searching the references of identified articles.

Study selection and data extraction

Two reviewers (KL and LS) independently selected studies for inclusion based on the following predetermined criteria: (1) interventions included at least two components of disease-management as defined by the DMAA[2] or the CCM as described by Wagner[1] and Bodenheimer and colleagues[15 16]; (2) studies included a control or comparison group or at least one outcome measured at two points in time (before/after designs), and (3) evaluated relevant process (i.e., number of scheduled follow-up contacts with care providers and medication prescribing patterns); intermediate (i.e., patients' disease specific knowledge, self-efficacy and self-management skills, medication compliance, and social support) or end outcomes (i.e., mortality, quality of life, exacerbations, lung function, dyspnoea, symptoms, overall clinical condition, hospital admissions, readmissions and bed days, emergency care admissions, unscheduled outpatient visits, health-related quality of life (HRQL), days off work, COPD-related health care resource use and total costs for COPD-related care). Agreement was examined and disagreements resolved by consensus. Articles describing the impact of specific therapeutic regimens, such as different forms of bronchodilator therapy, pulmonary rehabilitation, oxygen therapy etcetera, were excluded because these interventions are individual parts of clinical guidelines and therefore beyond the scope of this review. Two reviewers (KL and AN) independently extracted the data using a standardised form created for this review; assessed methodological quality of the articles with the so called 'HTA-DM instrument,[17] and scored this on a 0 to 100 scale with a score < 50 points indicating poor quality, whilst 50 to 69 points was considered as moderate quality and ≥70 points as good quality. Articles of poor quality were excluded from the review.

Interventions were categorised based on (1) the setting in which they were carried out (i.e., community, primary care, secondary care, tertiary care or a combination of these); (2) the population of COPD patients included (i.e., at risk, mild, moderate, severe or very severe); (3) the type and number of intervention components (i.e., self-management support [SMS]; delivery system design [DSD]; decision support [DS]; clinical information systems [CIS]). As regards the latter we also noted

Table 4.1 Search strategy

Combinations of MeSH and text words searched
1. “Disease management”[MeSH]
2. “Disease management”
3. “Disease state management”
4. “Delivery of Health Care, Integrated”[MeSH]
5. “Comprehensive Health Care”[MeSH:NoExp]
6. “Patient Care Planning”[MeSH] NOT “Advance Care Planning”[MeSH]
7. “Primary Health Care”[MeSH] NOT “Refusal to Treat”[MeSH]
8. “Patient Care Team“ [MeSH:NoExp]
9. “Critical Pathways“ [MeSH]
10. “Case Management“ [MeSH]
11. “Continuity of Patient Care“ [MeSH]
12. “Practice Guidelines“ [MeSH]
13. “Guidelines” [MeSH]
14. “Clinical protocols“ [MeSH:NoExp]
15. “Patient education“ [MeSH]
16. “Self Care“ [MeSH:NoExp]
17. “Reminder systems“ [MeSH]
18. “Health Education“ [MeSH]
19. “Health Promotion“ [MeSH:NoExp]
20. “Community Health Planning“ [MeSH]
21. “Ambulatory Care”[MeSH]
22. (Patient OR providers) AND feedback
23. (Patient OR providers) AND reminder
24. (Patient OR providers) AND monitor$
25. OR/1-24
26. “Epidemiologic Research Design”[MeSH] NOT “Sensitivity and Specificity”[MeSH]
27. “Clinical Trials” [MeSH:NoExp]
28. “Controlled Clinical Trials” [MeSH]
29. “Randomised Controlled Trials” [MeSH]
30. “Multicenter Studies” [MeSH]
31. “Epidemiologic Studies”[MeSH] NOT “Seroepidemiologic Studies”[MeSH]
32. “Pilot Projects” [MeSH]
33. “Sampling Studies” [MeSH]
34. “Programme evaluation” [MeSH]
35. “Intervention Studies” [MeSH]
36. “Evaluation studies” [MeSH:NoExp]
37. OR 26-36
38. Controlled clinical trial [pt]
39. Clinical trial [pt]
40. Multicenter study [pt]
41. Randomised controlled trial [pt]
42. Evaluation studies [pt]
43. Meta-analysis [pt]
44. OR 38-43
45. 37 OR 44
46. “Pulmonary Disease, Chronic Obstructive”[MeSH]
47. 25 AND 45
48. limit 47 to human
49. limit 48 to yr 1995-2007
50. limit 49 to English

whether the article explicitly named the intervention as being a disease-management programme or a CCM intervention. If the intervention was stated to be a disease-management programme and encompassed a clinical information system, it was additionally registered whether this information system facilitated (a) population identification processes; (b) process and outcome measurement, evaluation and management; and/or (c) routine reporting and/or feedback loops.[2]

Data analysis

Extracted data were entered into a spreadsheet (Excel®; Microsoft, Redmond (WA), US) and analysed in a descriptive way (i.e., numbers, frequencies, and percentages). To determine the impact of the interventions, included studies were analysed for statistically significant differences (considering the p-value as applied in the study's analysis). In addition we noted whether the study was sufficiently powered (i.e., $\beta \leq 0.2$) to detect a statistical significant difference of a 'meaningful' size on the primary study outcome (with 'meaningful' as determined by the authors of the included studies). Further, where the presented data allowed us to, we calculated relative risks (RRs) and their associated 95% confidence intervals for hospitalisation, emergency department visits and other unplanned visits, and mortality. Finally, to illustrate the potential financial viability of the COPD programmes, it was explored at what opportunity costs a programme might be expected to demonstrate a cost effective use of resources (1) within one year; or (2) in the long term (i.e., over the expected remaining life time of the patient population) from a health system's perspective. The exploration was carried out for a selection of programmes that reported the necessary data for these analyses.

The short term cost effectiveness analysis was based on the reported changes in hospital and emergency department (re)admissions within one year of follow-up and the associated cost per hospital and/or emergency department (ED) admission. The long-term analysis was based on reported changes in survival and HRQL and evaluated against a range of societal willingness-to-pay (WTP) thresholds for one 'quality-adjusted life year'(QALY).[18 19]

Results

Study retrieval

The search identified 308 no duplicative titles. After independent assessment of abstracts and full-texts by two reviewers regarding eligibility, 288 articles were excluded because these (1) did not concern disease or chronic care management in accordance with the definitions of the DMAA or Wagner and colleagues (n = 166); or (2) were single component interventions (n = 72); or (3) did not employ a control group or report more than one measurement (n = 42); or (4) were of poor methodological quality (n = 8). The 20 included articles described 17 unique COPD programmes. Most articles originate from the US (n = 6; describing five programmes)[20-25] followed by Australia (n

= 4)[26-29] and New Zealand (n = 2)[30 31]; Canada (n = 3; describing one programme)[32-34] the Netherlands (n = 2)[35 36]; Spain (n = 2[37 38]; one including a Belgian comparator group[37]); and China (n = 1).[39]

Study designs and methodological quality

The 17 studies include 14 randomised controlled trials (RCTs), two nonrandomised controlled trials[28 30] and one before–after study[36] (Table 4.2). In 11 of the 14 RCTs randomisation was performed on the patient level, whereas three RCTs randomised on the level of care delivery centres, i.e., general practices[31], nursing homes[39], or drugstores.[25]

Although 15 studies report the impact of the intervention on resource use, only three evaluated this impact in monetary terms[32 36 38] and can therefore be considered an economic evaluation. Poole and colleagues[30] conducted a limited return-on-investment analysis by investigating the reduction in bed days per patient needed in order to pay off the salary costs of the main care providers involved in the programme.

Reported study follow-up varies from eight weeks[38] to two years[23 24 35], with most articles reporting a follow-up of 12 months (n = 9).[25 28-33 36 37] Study sample size at baseline varies from n = 32[30] to n = 453[25], with a mean (±SD) sample size of n = 163 (±104) and a median of n = 155. Average proportion of patient follow-up is 81% (±14%) in intervention arms and 78% (±16%) in control arms. Six of the 17 included studies demonstrate at least 80% power for detecting a meaningful statistical significant change in their primary outcome measure[25 29 31-34 36 37] and four studies failed to include sufficient patient numbers as determined by their sample size calculations.[20 21 27 35] Seven studies did not mention whether their study was sufficiently powered[22-24 26 28 30 38 39], but three of these studies include less than 40 patients in each study arm[26 28 30] and are most likely underpowered.

Methodological quality of studies is mostly moderate (Table 4.2), with an overall mean (±SD) quality score of 67.6 (±9.4) points and a median of 65 points. The most frequently observed flaw in included articles is that information on the programme itself and the characteristics of the region or institution in which the programme has been implemented is lacking or described too briefly, herewith hindering the assessment of external validity of the findings. Further, the time horizon of the evaluations is in almost 50% of the studies considered too short (i.e., less than one year) to adequately capture the potential benefits of essentially non pharmacological interventions in a patient population suffering from an irreversible and progressing chronic condition.

Study setting and population

Most programmes are implemented in secondary care and three programmes have been implemented across multiple settings (Table 4.2). The study settings reflect the subgroups of COPD patients enrolled in the programme, as characterised by the staging system of Global Initiative for Chronic Obstructive Lung Disease (GOLD).[40] For example, all programmes include patients with severe COPD (GOLD 3) who are commonly treated in secondary care, whereas multiple setting programmes encompass a broader range of patients (e.g., GOLD 1 to 4).[28 35 36] The mean age (±SD)

Table 4.2 Characteristics of studies included in the systematic review (clustered where) describing unique COPD programmes.

Study	Location	Setting (CC; PC; SC; TC)[1]	Population		Programme type (CCM; DMP; not explicitly stated)[2]	No. / type of components (2 to 4)[3]	Study design	Study quality score (0-100)	Length of follow-up	Sample size at baseline		No. completed	
			Mean age (yrs±SD)	GOLD stage						I1 /I2[4]	C	I1 /I2[4]	C
Aiken et al. 2006[20]	United States	TC	68.5 (±13.5)	3&4	Not stated	3 (SMS; DS; DSD)	RCT	60	18mo	100	90	43	30
Bourbeau et al. 2003; 2006[32 33]	Canada	SC	69.5 (±7.0)	2&3	Not stated	3 (SMS; DS; DSD)	RCT	80 (both)	12mo	95	95	86[B]	79[B]
Gadoury et al. 2005[34]								65	24mo			91[G]	84[G]
Casas et al. 2006[37]	Spain I Belgium	TC	71.2 (±9.0)	3&4	Not stated	4 (SMS; DS; DSD; CIS)	RCT	80	12mo	65	90	48	72
Coultas et al. 2005[21]	United States	PC	69.0 (±8.2)	2&3	Not stated	3 (SMS; DS; DSD)	RCT	55	6mo	72/ 72	73	51/ 49	51
Egan et al. 2002[26]	Australia	SC	67.5 (SD not stated)	1-3	DMP	4 (SMS; DS; DSD; CIS)	RCT	60	3mo	33	33	25	28
Hermiz et al. 2002[27]	Australia	CC & PC	49.3 (SD not stated)	2&3	Not stated	2 (SMS; DSD)	RCT	65	3mo	84	93	67	80
Hernandez et al. 2003[38]	Spain	SC & TC	70.8 (±9.7)	2&3	Not stated	2 (SMS; DSD)	RCT	65	8wk	121	101	116	94
Hesselink et al. 2004 [35]	The Netherlands	PC	47.3 (±13.9)	1-4	Not stated	2 (SMS; DSD)	RCT	80	24mo	46	38	32	22
Jeffs et al. 2005[28]	Australia	SC	67.5 (SD not stated)	1-4	Not stated	2 (SMS; DSD)	CCT	55	12mo	28	25	28	25
Lee et al. 2002[39]	China	TC	80.4 (±6.3)	1-3	Not stated	3 (SMS; DS; DSD)	RCT	65	6mo	48	41	48	41
Poole et al. 2001[30]	New Zealand	SC	69.7 (±7.1)	3	Not stated	2 (SMS; DSD)	CCT	55	12mo	16	16	15	13

Rea et al. 2004[31]	New Zealand	PC	68 (range 44-84)	2&3	DMP	4 (SMS; DS; DSD; CIS)	RCT	75	12mo	83	52	71	46
Ries et al. 2003[23]	United States	TC	67.1 (±8.2)	3	Not stated	2 (SMS; DS)	RCT	70	24mo	87	87	82	73
Smith et al. 1999[29]	Australia	SC	69.9 (±1.2)	3	Not stated	2 (SMS; DS)	RCT	80	12mo	48	48	36	36
Solomon et al. 1998[24]/ Gourley et at 1998[22]	United States	SC	69.3 (±7.8)	3&4	DMP	2 (SMS; DS)	RCT	60/60	6mo	43	55	43	54
Steuten et al. 2006[36]	The Netherlands	PC & SC	61 (±14)	1-4	DMP	4 (SMS; DS; DSD; CIS)	CBA	70	12mo	317	NA	222	NA
Weinberger et al. 2002[25]	United States	CC	62.4 (±11.1)	1-3	Not stated	3 (SMS; DS; DSD)	RCT	80	12mo	185/ 130	138	149/ 105	111

[1] CC=Community care, PC=Primary care, SC=Secondary care, TC=Tertiary care;

[2] CCM=Chronic Care Model, DMP=Disease-Management Programme

[3] SMS=self-management support, DSD=delivery system design, DS=decision support, CIS=clinical information systems

[4] I_2 = the 2nd intervention for trials with three study arms

[B] denotes study of Bourbeau et al.; [G] denotes study of Gadoury et al.

of the included study samples ranges from 47.3 (±13.9)28 to 80.4 (±6.3)21 years. Across all included studies, the mean age is 66.4 (±7.9) with a median of 68.5 years.

Types of programmes and included interventions

All programmes include the components self-management and delivery system design. Five programmes additionally encompass the component decision support[20 21 25 32-34 39] and four also include clinical information systems.[26 31 36 37] Of the four programmes that are explicitly referred to as disease-management programmes, three operate a clinical information system that serves to support process and outcomes measurement, evaluation and management.[26 31 36] In two of these programmes this system also facilitates routine reporting and feedback loops[26 36], and in one programme[31] the system is further used for population identification processes.

Results on process measures

The majority of studies describing the number of scheduled outpatient visits and home visits reported no significant changes for general practitioner (GP), specialist or nurse visits (Table 4.3). Medication prescribing patterns (i.e., type and amount of COPD medication prescribed) also remained largely the same, except for one study that found a statistical significant lower cost for COPD prescriptions (31% lower) associated with the intervention.[38] The amount of patient education provided increased significantly in all studies reporting this process measure. Results for coordination of care were mixed, depending on how coordination was defined and measured, whereas one study reported improved accessibility of care.[36]

Results on intermediate outcomes

Disease-specific knowledge has been found to improve in four out of five studies measuring this.[20 27 36 38] Further, patient reported outcomes indicated advanced technical skills (inhalation technique) and self-efficacy in two studies[27 38], whereas one study showed improved self-management and medication adherence.[36] The majority of studies, however, did not detect statistical significant changes as far as self-management behaviour, medication compliance, technical skills/self-efficacy and social support are concerned (Table 4.3).

Results on end outcomes

For all reported end results, the dominating finding is that COPD care management programmes generate equivalent outcomes in comparison to usual care and less intense forms of chronic care or disease management. Nevertheless, a few studies have detected a positive impact of their intervention on lung function (n = 2)[25 31], physical functioning (n = 3)[20 23 29], and mental functioning (n = 3).[23 29 39] Furthermore, eight[20 23 29-31 33 36 38] out of 15 studies reporting on HRQL find statistical significant improvements for (at least some aspects of) this parameter, although these are not always sustained in the longer term.[23 33] As regards health care utilisation, seven studies (eight articles)[23 24 30 33-37] out of 15 studies (19 articles) report a decrease in exacerbation related health care

Table 4.3 Reported intermediate and end outcomes: measures used and summary of findings

Outcome (n=number of studies reporting the outcome)	**Measures§**	**Summary of findings**
Process measures		
Scheduled outpatient visits (n=7)	Physician (GP) office visits[21,27,33,36,38]; Specialist/ outpatient hospital visits[23,33,36-38]; Nurse home visits[27,37,38]	+ [27] (nurse home visits), [36] = [21,27,33,37] (GP visits), [23,38] (12 month follow-up) – [23] (24 month follow-up)
Medication prescriptions (n=5)	Total prescribed COPD-related medication[36,38]; new medications prescribed[24]; antibiotics[28,31]; oral steroids[28,31]; domiciliary oxygen[28]; inhaled bronchodilators[28]	+ [38] (oxygen and nebulizer), [36] = [24,28,31,38]
Amount of patient education provided (n=5)	Self-management education[20,36]; COPD education[20-22,27]	+ [20-22,27,36]
Coordination of care (n=2)	Number of GP-arranged follow-ups[27]; Patient assessed change in coordination of care[36]	+[36] = [27]
Accessibility of care (n=1)	Patient assessed change in accessibility of care[36]	+[36]
Intermediate outcomes		
Disease specific knowledge (n=5)	Deenen's respiratory knowledge questionnaire [M1,36]; Self-designed questionnaire (not validated)[20,22,27,38]	+ [20,27,36,38] = [22]
Self-management behaviour (n=4)	Self-designed questionnaire (not validated)[27,31,35,36]; Patient-reported smoking cessation[31,35,36]; physical activity[36]; influenza vaccination[27]; pneumococcal vaccination[27]	+ [36] = [27,31,35]
Medication compliance (n=4)	Self-designed questionnaire (not validated)[25,35,36,38] ; Single-item [M2,25] and 4-point Likert scale questionnaire [M3,25]	+ [36] = [25,35,38]
Technical skills / self-efficacy (n=4)	COPD Self-Efficacy Scale [M4,21,35]; Coping style questionnaire [M5,35]; Inhalation checklist [M6,35] ; Walking self-efficacy [M7,23]; Self-designed questionnaire (not validated)[38]	+ [35,38] (inhalation) = [21,35] (self-efficacy & coping), [23]
Social support (n=2)	MOS social support survey [M8,21,26]	= [21,26] (tangible & emotional support, positive social interaction)] – [26] (affectionate support)
End outcomes		
Lung function (n=7)	Post bronchodilators FEV_1 (litres)[23,29,31,33] ; FEV_1 (% predicted)[23,29,31,36,39] ; FVC (litres)[33]; FEV_1/FVC (%)[33,36]; PEF rate (% predicted)[25]	+ [25,31] = [33,36,39] – [23,29]
Dyspnoea (n=7)	MRC dyspnoea questionnaire [M9,35] CRQ-dyspnoea dimension [M10,25,30,31]; UCSD Shortness of Breath Questionnaire [M11,23]; Baseline and Transition Dyspnoea Indices (interview administered) [M12,23]; BORG scale [M13,24]; Self-developed questionnaire (not validated)[29]	= [24,25,29-31,35] – [23]

Table 4.3 will be continued on the next page

Outcome (n=number of studies reporting the outcome)	Measures[§]	Summary of findings
Symptoms (n=9)	SGRQ-symptoms [M25 21 26 27 33 38]; Memorial Symptom Assessment Scale [M26 20]; General Health Questionnaire [M23 39]; Symptoms checklist [M27 35]; Self-developed questionnaire (not validated)[24]	= [20 21 24 26 27 33 35 38 39]
Physical functioning (n=10) => Questionnaire based (n=8)	SF-36 physical functioning [M14 20 21 31]; SF-12 physical functioning [M15 38]; Barthel Index [M16 39]; RAND-36 physical component [M17 23]; COOP (adapted physical functioning item) [M18 29]; Health Status Questionnaire [M19 22]	+ [20 29] = [21-23 31 38 39]
=> Performance based (n=2)	6-minute walk test [M20 23 33]; Shuttle Walk Test [M21 31]; Treadmill Test[23]	+ [23 (12 month follow-up)] = [23 31 33 (24 month follow-up)]
Mental functioning (n=11)	SF-36 mental health [M14 20 21 31]; HAD [M22 26 30]; Health Status Questionnaire [M19 24]; SF-12 mental health [M15 38]; General Health Questionnaire [M23 39]; CRQ-emotion dimension [M10 25 30 31]; CED-Depression Scale [M24 23]; RAND-36 mental component [M17 23]; COOP emotion components [M18 29]	+ [23 39 (12 month follow-up), 29] = [20 21 23 26 30 31 38 (24 month follow-up), 24 25 29]
Health-related Quality of Life	SF-36 [M14 20 21 31]; SGRQ-total [M25 21 26 27 33 36 38]; CRQ-total [M10 23 25 30 31]; Subjective Well Being Scale [M28 26]; Health Status Questionnaire [M19 24]; SF-12 [M15 38]; QOL-RIO [M29 35]; General Health Questionnaire-total [M23 39]; Quality of Well Being Scale [M30 23]; COOP-total [M18 21]; EQ-5D [M31 36]	+ [20 33 (4 month follow-up), 38 (SGRQ), 30 31(CRQ-fatigue & mastery), 23 (12 month follow-up), 29 36 (EQ-5D)] = [33 (12 month follow-up), 21 26 27 38 (SF-12), 31 35 39 (SF-36), 23 (24 month follow-up), 36 (SGRQ), 25]
Health care utilisation and costs (n=19)	Hospital (re)admission[21 24-31 33 34 36-39]; Hospital LOS[23 28 30 31 38 39]; ED-visits[20 21 23-25 27-29 31 33 34 38 39]; Unscheduled outpatient visits[21 23 24 29 33 36-38]; Prescriptions[24 28 31 36 38]; Home visits[37]; Phone calls[23]; Sick leave[36]; Total costs[32 36 38]	+ [38(prescriptions), 28 (hospital LOS), 36 (prescriptions)] = [20 21 26 27 32 35 37 (outpatient visits), 28 30 31 39 23 (ED-visits), 24 29 36 (total costs), 25] – [33 34 37 (readmissions), 30 35 (hospital LOS), 23 24 (outpatient visits), 36]
Mortality (n=14)	All causes death [20 21 23 25 27 29-35 37 38]	= [20 21 23 25 27 29-35 37 38]

[§] References to included studies that applied this measure are indicated numerically; References to papers describing the validity/reliability of the measure or questionnaire are indicated with Mx.
MI Deenen TAM. Patient health-education and self-management. Dissertation. Rijksuniversiteit Groningen, the Netherlands, 1996. [M2] Inui TS et al. Med Care 1981;19:1061-64. [M3] Morisky DE, et al. Med Care 1986;24:67-74. [M4] Wigal JK,et al. Chest 1991;99:1193-6. [M5] Ketelaars CA,et al. Thorax 1996;51:39-43. [M6] Hesselink AE, et al. Scand J Prim Health Care 2001;19-255-60. [M7] Kaplan RM, et al. Health Psychol 1984;3:223-42. [M8] Sherbourne CD, et al. Soc Sci Med 1991;32(6):705-14. [M9] Bestall JC, et al. Thorax 1999;54;581-6. [M10] Wijkstra PJ, et al. Thorax 1994;49(5):465-7. Ml1 Eakin EG, et al. Chest 1998;113:619-24. [M12] Mahler DA, et al. Chest 1984;85:751-8. [M13] Borg G. Med Sci Sports Exerc 1982;14:377-81. [M14] Ware JE, et al. Med Care 1992;30:473-83. [M15] Ware JE, et al. Med Care 1996;34:220-33. [M16] Collin C, et al. Int Disabil Stud 1988;10:64-7. [M17] Hays RD, et al. Health Econ 1993;2:217-27. [M18] Nelson E, et al. JAMA 1983;249:3331-8. MI9 Radosevich DM, et al. Health Status Questionnaire (HSQ) 2.0. Bloomington, Minn; Health Outcomes Institute, 1994. [M20] Borg G. Med Sci Sports Exerc 1982;14:377-81. [M21] Singh SJ, et al. Thorax 1992;47:1019-

24. [M22] Zigmond AS, et al. Acta Psychiatr Scan 1983;67~6):361-70. [M23] Goldberg DP, et al. Psychol Med 1979;9:139-45. [M24] Radloff LS. Appl Psychol Meas 1977;1:385-401. [M25] Jones P, et al. Am Rev Respir Dis 1992;145:1321-7. [M26] Portenoy RK, et al. Eur J Cancer 1994;30A: 1326-36. [M27] Wijnhoven HA, et al. Chest 2001;119:1034-42. [M28] Bradburn N. The structure of psychological well-being. Chicago:Aldine, 1969. [M29] Maille AR, et al. Respir Med 1997;91:297-309. [M30] Kaplan RM et al. J Chron Dis 1984;37:85-95. [M31] The EuroQol Group. Health Policy 1990;16:199-208.

utilisation, including ED-visits, hospital (re)admissions and other unscheduled outpatient visits. Three studies[32 36 38] presented cost data and showed that differences were found on individual cost parameters including higher costs for prescriptions[36 38], lower hospitalisation-related costs[38] and lower sick leave costs.[38] However, none of these studies reported significant changes in total costs.

Negative findings associated with the interventions have also been reported. These include: deteriorated lung function, increased dyspnoea, increased medication use and longer hospital length of stay in comparison with the control groups. An overview of results on end outcomes is presented in Table 4.3.

Relative risks for hospitalisations, emergency department / unscheduled visits, and mortality

The observed relative risks (RRs) for hospitalisation of intervention patients versus control patients vary widely (from 0.64 to 1.50; Table 4.4) and only three[31 33 37] are statistically significant at a 95% confidence interval (95% CI). The findings from these three studies all favour the intervention group. Moreover, these three programmes include three chronic care components (i.e., DS on top of SMS and DSD) or four[31 37] (i.e., DS and CIS in addition to SMS and DSD) components, whereas all other programmes for which a RR could be calculated encompass SMS and DSD only. As regards ED and other unplanned outpatient visits, the RRs vary from 0.28 to 2.28 (Table 4.4), with two studies[33 38] observing a statistical significant reduction in ED-visits favouring the intervention. The RRs for mortality vary from 0.31 to 1.20 (Table 4.5), and none of these reach statistical significance at a 95% CI.

Illustration 1a: potential short term cost effectiveness based on reduced hospital admissions only

In the study of Rea and colleagues, a RR for hospital admissions in the intervention group of 0.81 (95% CI: 0.59–0.83) was observed.[31] Also the mean length of hospital stay was reportedly shorter in the intervention group than in the control group (1.1 vs 4.0 days). The cost of a hospital bed day was approximately NZ$700 in 2003. From this it can be calculated that the average cost of hospitalisation per COPD patient per year for the conventional care strategy would be:

4 * NZ$ 700 = NZ$ 2800

Table 4.4 Relative Risks of hospitalisation and Emergency Department / unscheduled visits for intervention patients versus control patients

Source	Study setting	Included GOLD-stages	Number of components	Relative Risk of hospitalisation (95% Confidence Interval)	Relative Risk of ED / unscheduled visits (95% Confidence Interval)
Bourbeau et al. 2003	Secondary care	2&3	3	0.64 (0.45 - 0.91)	0.64 (0.48 - 0.86)
Casas et al. 2006	Tertiary care	3&4	4	0.67 (0.49 - 0.91)	NA
Gourley et al. 1998	Secondary care	3&4	2	NA	1.12 (0.44 - 5.43)
Hermiz et al. 2002	Community and primary care	2&3	2	1.27 (0.66 - 2.43)	0.28 (0.06 - 1.27)
Hernandez et al. 2003	Secondary and tertiary care	2&3	2	0.74 (0.45 - 1.21)	0.44 (0.22 - 0.86)
Jeffs et al. 2005	Secondary care	1 - 4	2	1.50 (0.84 - 2.67)	NA
Poole et al. 2001	Secondary care	3	2	1.08 (0.75 - 1.57)	NA
Rea et al. 2004	Primary care	2&3	4	0.81 (0.59 - 0.83)	0.46 (0.16 - 1.37)
Smith et al. 1999	Secondary care	3	2	1.01 (0.82 - 1.26)	2.28 (0.96 - 5.43)

Table 4.5 Relative Risks of mortality for intervention patients versus control patients

Source	Study setting	Included GOLD-stages	Number of components	Relative Risk (95% Confidence Interval)
Aiken et al. 2006	Tertiary care	3&4	3	1.20 (0.60 – 2.40)
Bourbeau et al. 2003	Secondary care	2&3	3	0.56 (0.19 – 1.60)
Casas et al. 2006	Tertiary care	3&4	4	1.19 (0.59 – 2.39)
Coultas et al. 2005	Primary care	2&3	4	1.01 (0.21 – 4.86)*
Gadoury et al. 2005	Secondary care	2&3	3	0.71 (0.37 – 1.38)
Hermiz et al. 2002	Community and primary care	2&3	2	1.00 (0.43 – 2.33)
Hernandez et al. 2003	Secondary and tertiary care	2&3	2	0.60 (0.20 – 1.82)
Poole et al. 2001	Secondary care	3	2	0.33 (0.04 – 2.87)
Rea et al. 2004	Primary care	2&3	4	0.31 (0.26 – 1.65)
Ries et al. 2003	Tertiary care	3	2	0.98 (0.43 – 2.22)
Smith et al. 1999	Secondary care	3	2	1.14 (0.45 – 2.90)

* RR for case management versus usual care

whereas the average annual cost of hospitalisation per COPD patient in the intervention group would be:

0.81 * (1.1 * NZ$ 700) = NZ$ 623.7

Thus, based on the observed reduction in hospital admissions and hospital length of stay, and assuming all else equal, a cost effective use of resources from a health systems perspective for this programme will be achieved if it can be delivered in a way that the incremental costs of the programme are lower than NZ$ 2800 – NZ$ 623.7 = NZ$ 2176.3 per patient per year.

Illustration 1b: potential short term cost effectiveness based on changes in hospital admission and ED visits

In the study of Hermiz and colleagues[27], a RR for hospital admissions of 1.27 (95% CI: 0.66–2.43) and a RR for ED visits of 0.28 (95% CI: 0.06–1.27) was observed for the intervention group as compared for the controls. The cost of a hospital bed is approximately AUS$ 320 and the costs of an ED visit AUS$ 100.[41] Assuming the length of hospital stay is 2.4 days[41] and is equal in COPD care management and usual care, the average cost of hospitalisations per patient per year in a usual care strategy would be:

2.4 * AUS$ 320 = AUS$ 768

Further, assuming an average of 0.5 ED visits per COPD patient per year[41], the cost of ED visits in a usual care strategy would be:

0.5 * AUS$ 100 = AUS$ 50

In the COPD care programme, the annual cost of hospitalisations per patient would be:

1.27 * (2.4 * AUS$ 320) = AUS$ 975.36

and the average annual cost of ED visits per COPD patient would be:

0.28 * (0.5 * AUS$ 100) = AUS$ 14

Based on the observed increase in hospital admissions and reduction in ED visits, and assuming all else equal, this COPD programme would be considered cost effective from a health systems perspective if its incremental costs would be lower than AUS$ 818 – AUS$ 989.36 = – AUS$ 171.36 per patient per year. This means that on other aspects of the programme savings of at least AUS$ 171.36 per patient per year should be generated in order to set off the additional hospitalisation costs, and even more to potentially achieve a return on investment.[42]

Illustration 2a: Potential long term cost effectiveness based on changes in health-related quality of life only

The study of Steuten and colleagues reports an increase in HRQL of 0.02 (from 0.67 at baseline to 0.69 at 12 months follow-up).[36] Assuming 1) no difference in mortality between usual care and the intervention; 2) an average life expectancy of 75 years (i.e., plus 14 years from the sample's baseline age of 61 years); and 3) a sustained relative intervention effect on HRQL over the life time of a patient, then, all else equal, the incremental QALYs over the remaining life time of one patient in the intervention versus the control strategy would be:

14 * 0.02 = 0.28 QALYs[1]

At a societal WTP of €30,000 per QALY this means that the programme would be considered cost effective if its incremental costs do not exceed 0.28 * €30,000 = €8,400 per patient over his/her remaining lifetime or on average €600 per patient per year (€8,400/14). Similarly, if the WTP for a QALY would be €50,000 then the cost effectiveness gap for the programme, given its incremental effectiveness on HRQL of 0.28, would be as high as €14,000 per patient over his/her remaining lifetime (or €1,000 annually) and at a WTP of €20,000 only €5,600 over lifetime (or €400 per year).

Illustration 2b: Potential long term cost effectiveness based on changes in health related quality of life and survival

From the paper of Hernandez and colleagues[38], it can be derived that the average score on the physical component of the Short Form 12 (SF-12) is 0.3770 in the intervention group and 0.3590 in the control group (scores converted from a 0–100 to a 0–1 scale). The incremental HRQL for the interventions group on the physical domain is thus +0.0180. On the mental domain of the SF12, the average scores are 0.4600 and 0.4395 in the intervention and control group respectively, thus an incremental HRQL for the intervention group of 0.0205 on the mental domain. It is assumed that the incremental and physical domains are additive.[43] Given that the average age of the study subjects is 71 years at baseline, the RR for mortality is 0.6 for intervention vs control group, and assuming an average life expectancy of 75 years when receiving conventional care (so +4 years from baseline), then, all else equal, the mean difference in QALYs over the remaining life time of one patient in the intervention versus the usual care strategy would be:

(4/0.6) * (0.0180 + 0.0205) = 6.66676 * 0.03085 = 0.256 QALYs[2]

At a societal WTP of €30,000 per QALY this means that the programme would be considered cost effective if its incremental costs would not exceed 0.256 * €30,000 = €7,680 per patient over his/her expected lifetime of 6.7 years. At a WTP of €50,000 the cost effectiveness gap would be €12,800 and at a WTP of €20,000 this gap would be €5,120 per patient over the expected lifetime.

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[1] For reasons of simplicity, future benefits and costs are not discounted in this illustration.

[2] For reasons of simplicity, future benefits and costs are not discounted in this illustration.

Discussion

Notwithstanding their relentless efforts and investments, the innovators behind chronic care programmes for people with COPD keep struggling to articulate the value of these programmes to patients, care providers and payers in terms of 'proof' rather than 'belief'. This study therefore aimed to update and critically review the current evidence base as regards the impact of multi-component COPD care programmes on process, intermediate and end results of care. Furthermore, in order to support timely decision-making regarding (further) investment in such programmes, we illustrated how potentially cost effective programmes can be identified, even in the absence of full-blown health economic evaluations.

Starting with the effectiveness of multi-component COPD programmes on processes and intermediate outcomes of care, we find little evidence of significant improvements. Although significantly more patient self-management education is provided as part of the COPD programmes, and patient's disease-specific knowledge indeed improves as a result of this, on the whole there is little proof that this better knowledge actually translates into significant and sustained behavioural changes, as for example smoking cessation, or in better medication adherence and self-efficacy within one or two years follow-up. This finding is in accordance with results from previous reviews[11] [44], but nevertheless dissatisfying. Since smoking cessation is still regarded the most effective way to slow down the disease progression, more emphasis should be placed on other ways to encourage smokers to quit than purely providing education. Reimbursing the costs of smoking cessation therapy, for example, has been proven an efficacious[45] and cost effective[46] way to significantly increase the prolonged abstinence rate.

Also on end outcomes of care (including clinical outcomes, dyspnoea, symptoms and physical and mental functioning, HRQL, mortality, health care utilisations and costs), the COPD care programmes merely demonstrate equivalence to usual care. As regards hospital (re)admissions, which are commonly the primary outcome of evaluation, it is worth noting that only for the three programmes that encompass ≥3 components of chronic care management, the associated RRs for hospital readmission were statistically significant, and favoured the intervention strategy, whereas for programmes encompassing two components no statistical significant changes were detected. Given that the patient populations included in these studies were comparable to the other studies in terms of sample size, COPD severity and age, and that all programmes encompassed the components 'delivery system design' and 'self-management support', this might suggest that programmes that additionally encompass the components 'clinical information system' and/or 'decision support' are more likely to be effective in reducing hospital (re)admissions than the more limited packages. Although this suggestion should be interpreted with caution since the programmes were not compared head to head and RRs could only be calculated for nine of the 17 studies, this may start to shed more light on the important issues raised in the review of Adams and colleagues[11] about the relative value of each of the chronic care components for COPD, and the incremental value of combining more than two components in one COPD programme. Further, the fact that the component 'decision-support' is lacking in most programmes might indicate that clinical guidelines, which have shown to reduce unjustified variety in care and improve delivery of cost effective care, are still underused. A possible explanation for this is that most guidelines focus more on decision-making by individual professionals than on such multi-disciplinary care processes.[47] As such, this points out the responsibility for health professionals and care managers to intensify their efforts for developing and implementing such multidisciplinary decision-support tools as part of their COPD programmes.

As regards HRQL, about half of the studies reporting this outcome observed statistical significant improvements on (limited) aspects of quality of life, but it was not always clear whether these improvements exceeded the minimal clinically meaningful difference. Moreover, the studies of Bourbeau and colleagues[33] and Ries and colleagues[23] showed that the positive impact did not sustain over time. Nevertheless, no studies reported a deterioration in HRQL and also there seemed to be no relation with the COPD severity of the included population or the setting in which the programme was implemented. The latter is in contrast with a previous review of Niesink and colleagues[48], concluding that improved HRQL resulting from COPD disease management is limited to programmes that are (at least partly) implemented in primary care.

Since only three studies undertook a (partial) economic evaluation, and the programmes differ largely in terms of their contents as well as in the way they are operated in daily practice, the extent to which COPD care programmes deliver value-for-money could not convincingly be demonstrated at the aggregate level. The provided illustrations on the potential cost effectiveness of specific COPD programmes, however, may help to indicate whether there is sufficient opportunity for the programme to be considered a worthwhile spending of scarce resources or to deliver a return on investment in the short or longer term. Although the illustrations are deliberately kept simple and therefore the figures should not be taken at face value, they do suggest that there is a fairly limited scope for the programmes to save money or break-even. Again, similar observations have been published previously as well as reasons why this might be the case.

Linden and Adler-Milstein[12] for example point out that "the main opportunity for chronic care programmes to realise short-term medical cost savings is via reductions in costly and avoidable hospital admissions" and "a focus on avoiding the first admission during the intervention period is critical given that hospitalisations are relatively rare events for the majority of the population" and that "individuals may only experience one over the entire course of the programme." Therefore, close patient monitoring and effective integrated care delivery across community, primary, secondary and tertiary care are crucial to pick up exacerbation signs more timely and respond more pro-actively to achieve the desired cost effectiveness target. However, when having a closer look at the programmes included in this review, it can be seen that only three are characterised by some degree of integration between care settings, whereas the majority is aimed at secondary care only, and therefore after the first hospitalisation. As regards the disease severity of the included populations a similar observation can be made: most programmes focus on the sicker part of the population, i.e., GOLD stage 3. Of course, in a sicker population with higher hospitalisation rates, a relatively lower number of admissions need to be avoided for the programme to break even. But, such a narrowly focused programme addresses only a small part of the population in a too late stadium to achieve the long term goal of chronic care management, which is reducing the increasing burden of COPD on society.

Finally, a couple of limitations of this review have to be taken into account when interpreting its results. First, determining whether a programme consisted of two or more components was complicated by the fact that some papers only provided a limited description of their intervention. In case of doubt the paper was excluded and this may conservatively have limited the sample of included papers. However, when comparing the number of included studies in our review (i.e., 20 studies) with the review of Adams and colleagues[11] (n = 37) that also considered single component studies, the amount of included papers seems reasonable. Moreover, the multi-component programmes included by Adams and colleagues[11] were also picked up by our search. Finally, the results of this review should be interpreted in the light of the moderate methodological quality of its underlying studies, including for example at least seven studies that were underpowered to detect meaningful and statistical significant changes, as well as the lack of economic evaluations in the existing evidence base. Although the currently published data can be used to provide some indication about the potential cost effectiveness of COPD care programmes, more and better health economic information will be needed to reduce uncertainty regarding the real impact of COPD care programmes in daily practice. To obtain this, well-designed but practical multicentre health economic studies including broad representative patient samples, should be performed across care settings.[49 50]

Conclusion

This systematic review shows that identifying potentially cost effective multi-component COPD care programmes remains a challenge given the scarcity of methodologically sound studies that demonstrate significant improvements on process, intermediate and end results of care. Nevertheless, also in the absence of 'perfect data', decisions regarding (future) investments in such care programmes have to be made, and will be made, with the information that is available today. Estimations of potential cost effectiveness of specific programmes as illustrated in this chapter might support decision-makers in doing so. Further research, however, is needed to, firstly, substantiate the finding of this study that programmes including three or more chronic care components are likely to be more cost effective than programmes that only include the components 'delivery system design' and 'self-management support'. Finally it is recommended to carefully investigate whether programmes that are more strongly based on multidisciplinary guidelines will indeed deliver more value for money than the current COPD care programmes, especially when implemented across care settings and including broader patient samples.

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Chapter 5

Designing Patient-Related Interventions in COPD Care: Empirical Test of a Theoretical Model

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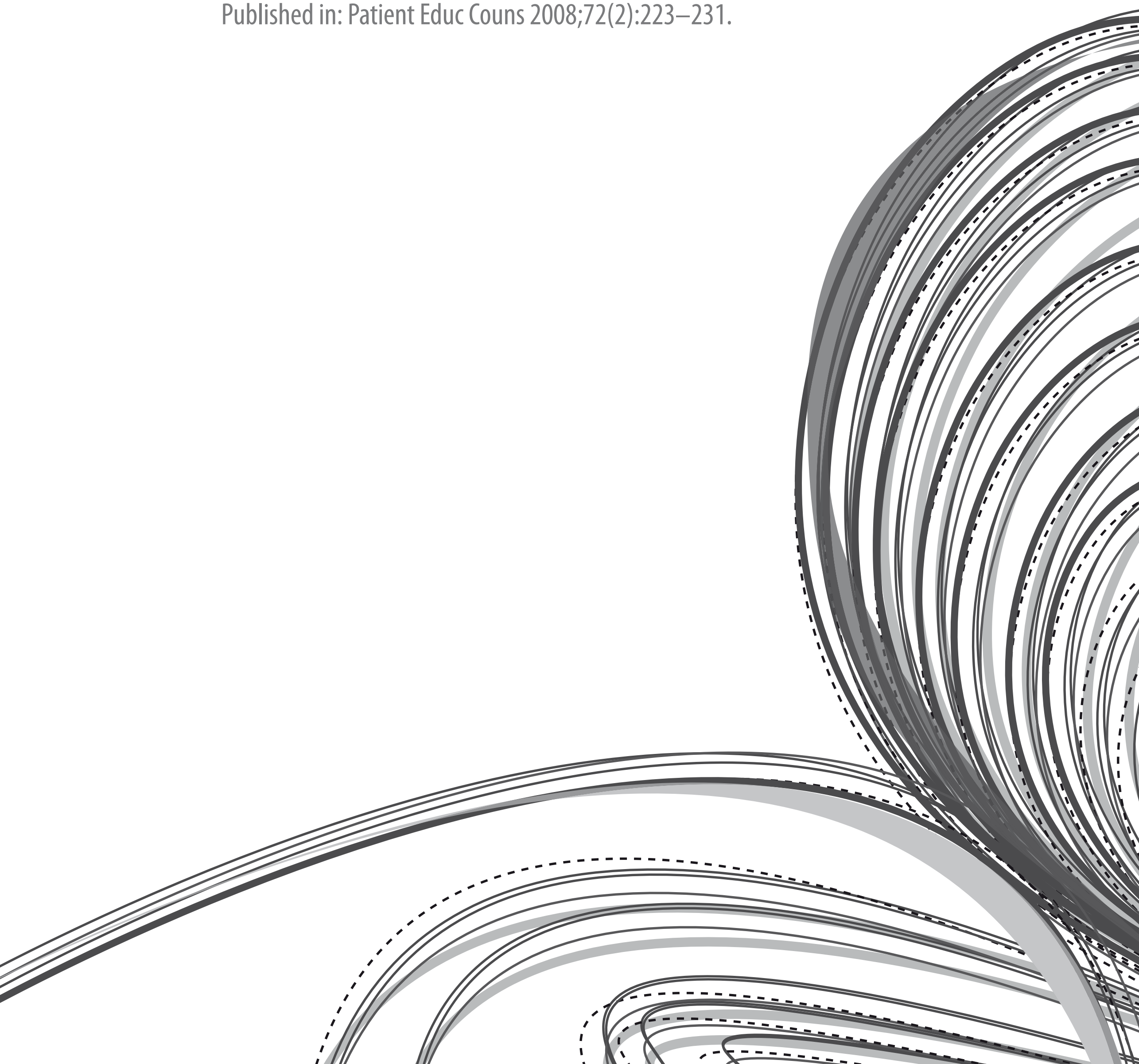

Abstract

Objectives: The aim of this exploratory study was to test the applicability of a theoretical model to develop patient-related interventions. In this model knowledge, psychosocial mediators, self-efficacy and behaviour are determinants of patient-related interventions.

Methods: The model was tested on 278 patients with mild or moderate chronic obstructive pulmonary disease (COPD), recruited in a primary care setting. Hierarchical regression analyses were applied using data from self-reported questionnaires and clinical data from an electronic data registry.

Results: Knowledge, psychosocial mediators, self-efficacy and behaviour proved to be, to a moderate degree, predictors of outcomes in COPD care. Moreover, physical activity appeared to be a significant predictor for all clinical and functional outcomes.

Conclusion: Theoretically expected associations of patient-related interventions are existent in patients with mild or moderate COPD. The application of theoretical models in designing patient-directed interventions in COPD care is therefore feasible.

Practice implications: More attention should be paid to the patterns of physical activity in patients with mild to moderate COPD. The results of this study are also useful in the development of patient-related interventions. Future interventions should be designed along the lines of theory on behavioural change, such as social cognitive theory.

Introduction

Chronic obstructive pulmonary disease (COPD) is a major cause of chronic morbidity and mortality affecting adults worldwide.[1] Listed as the fifth leading cause of death in the world, its prevalence and mortality rates are expected to go up in the coming decades. Health-care providers and patients often underestimate the substantial morbidity associated with COPD; likewise, COPD is frequently under diagnosed and under treated.[2] The clinical course of COPD is one of gradual impairment and episodes of acute exacerbations that contribute to deterioration of health.[3] Evidence-based guidelines aim to improve COPD management through a comprehensive approach: patient education, pharmacologic treatment and non-pharmacologic treatment.[4] Patient-related interventions, such as patient education and self-management interventions are expected to improve a patient's self-management skills, ability to cope with illness, and health status.

Patient-related interventions in COPD care increasingly focus on self-management strategies[5], with mixed results so far. A meta-analysis[6] demonstrated a significant reduction of hospitalisations, but no improvements on emergency visits, or lung function. Results for quality of life and COPD symptoms were inconclusive.[6] Other studies showed improved health status and reduced hospitalisations.[3 7-9] The various programmes, however, show apparent heterogeneity in content. Another important limitation is the poorly documented use of outcomes or even the use of inappropriate outcome measures.[10] Thus, there is still much to be learned about the specifics of patient-related interventions in COPD. At this point, we first need to gain insight in determinants for change in health behaviour and outcomes in COPD care. Then, we might be able to design more effective patient-related interventions and to implement strategies for long-term maintenance.

To gain a deeper understanding of the underlying processes of patient-related interventions for COPD requires insight in behaviours related to self-management of a disease.[11] Opening the "black box" of patient-related interventions may be key to optimising health. Elsewhere, a case has already been made for more systematic use of theories in planning and evaluating interventions in clinical practice.[12 13] Several theoretical frameworks have been proposed to better understand patient-related interventions, such as the social cognitive theory and the health belief model.[14] Social cognitive theory offers both predictors and principles of behavioural change. It specifies a core set of determinants and the mechanisms through which they work.[14] Applying this theoretical model for COPD patients would suggest a model as shown in Figure 5.1. A patient having knowledge of health risks and benefits creates the precondition for change. Psychosocial mediators, such as beliefs of a patient towards his or her ability to take action, affect health behaviour. Stronger self-efficacy is bound to positively influence health behaviour and eventually health status, as borne out by the findings of many relevant studies.[15 16] Together, enhanced knowledge, psychosocial beliefs, and self-efficacy are thought to result in behavioural change, which in turn determines the effects of a self-management programme on clinical and functional outcomes.[17-19] The presented theory on patient-related interventions is part of a broader model on disease management.[13]

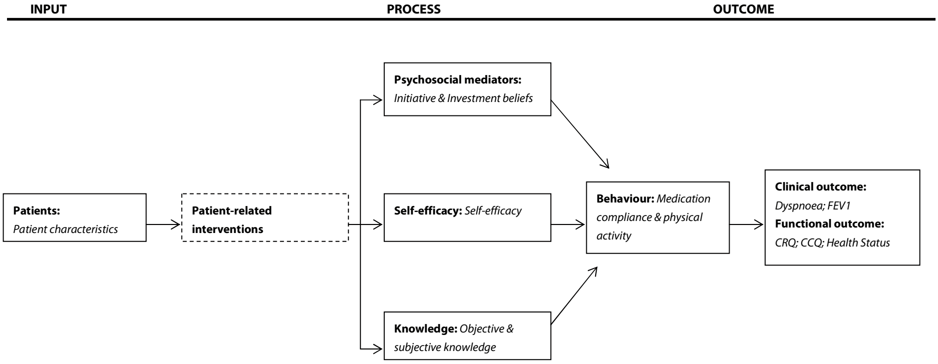

Figure 5.1 Theoretical model on patient-related interventions and its empirical test

The current chapter, however, presents the preliminary results of a cross-sectional, empirical study that tested the model's propositions on patient-related interventions. Accordingly, we tested whether theoretically expected associations between determinants and outcomes of patient-related interventions could be found. Moreover, these associations are tested with self-reported data by COPD patients and data from electronic registries. Insight into these associations can be used to design patient-related interventions.

Methods

Setting and design

This study is a part of a larger longitudinal evaluation study on COPD disease-management programmes in the Netherlands. Between April 2006 and August 2006, patients were recruited from seven general practices (12 general practitioners) in the region 'Gelderse Vallei' in the centre of the Netherlands. These general practitioners cooperate with the regional hospital within a disease-management programme, and are supported by practice nurses of a regional home care organisation. Patients with a confirmed diagnosis of COPD, according to Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria[4] were invited to participate in the study. The practice nurse identified eligible patients supported by the GP and an electronic protocol. Patients with serious co-morbidity, e.g. congestive heart failure, were not eligible for inclusion.

A cross-sectional design was used[20] to collect data on patient characteristics, process and outcome data (Figure 5.1). The process was specified by the determinants underlying the intervention: knowledge, psychosocial mediators, self-efficacy and behaviour. The outcome included functional and clinical outcomes; we expected effects on the following outcomes: quality of life, health status, dyspnoea and lung function.[21] Studying whether these variables influence one another is essential before implementing the intervention.

Data collection and measures

Data were collected by means of a postal questionnaire including process variables and quality of life measures. The questionnaire also asked for demographic characteristics, such as age, sex, education, marital status, domestic status and daily activities. Clinical outcome data were obtained from the electronic registry within the general practice (Table 5.1).

Table 5.1 Overview of measurement instruments per variable and model element

Model element[1]	Variable(s)	Instrument	No. of items	Range	Source[2]	Cronbach's α	Mean (± SD)	Actual range
Knowledge	Subjective	Instrument by Deenen	6	1 – 5	Q	0.91	2.73 (± 0.83)	1 – 4.60
	Objective	Instrument by Deenen	22	0 – 10	Q	0.76	4.49 (± 2.12)	0 – 9.55
Self-efficacy	Self-efficacy	SMAS	5	1 – 6	Q	0.82	4.19 (± 0.77)	1.20 – 6
Psychosocial mediators	Initiative beliefs	SMAS	5	1 – 6	Q	0.72	4.07 (± 0.78)	1.20 – 6
	Investment beliefs	SMAS	5	1 – 6	Q	0.75	4.04 (± 0.80)	1.40 – 6
Behaviour	Medication compliance	Instrument by Deenen	3	1 – 5	Q	0.53	4.40 (± 0.65)	1 – 4.67
	Physical activity	Instrument by Deenen	5	1 – 5	Q	0.65	2.82 (± 0.55)	1.5 – 4.57
Functional outcome	Dyspnoea	CRQ	5	1 – 7	Q	0.82	5.75 (± 1.29)	1.5 – 7
	Emotional function	CRQ	7	1 – 7	Q	0.90	5.30 (± 1.06)	2 – 7
	Fatigue	CRQ	4	1 – 7	Q	0.85	4.73 (± 1.23)	1 – 7
	Mastery	CRQ	4	1 – 7	Q	0.76	5.61(± 1.07)	2.5 – 7
	Total health	CCQ	10	0 – 6	Q	0.91	4.61(± 0.84)	0 – 4.30
	Symptoms	CCQ	4	0 – 6	Q	0.78	4.12 (± 0.95)	0 – 5
	Functional state	CCQ	4	0 – 6	Q	0.89	4.68 (± 1.09)	0 – 6
	Mental state	CCQ	2	0 – 6	Q	0.80	5.37 (± 0.90)	0 – 5.25
	Health Status	VAS	1	0 – 10	Q		7.06 (± 1.32)	3 – 10
Clinical outcome	Dyspnoea	MRC Dyspnoea	1	0 – 5	E		3.39 (± 1.07)	0 – 5
	Lung function (FEV$_1$ % predicted)	Spirometry	1		E		77.90 (± 19.93)	

[1] Scores are arranged so that a higher score on each indicator indicates a better health outcome or a more positive score.

[2] E = Electronic registry of GP; Q = Questionnaire

Process variables

A validated instrument was used to measure disease-specific knowledge and compliance behaviour.[22] This instrument was also used and tested for less severe COPD patients.[23] Disease-specific objective knowledge was measured by means of 22 true or false questions about COPD and expressed as the proportion of correct answers, transformed into a 0-10 scale. Subjective knowledge was assessed by six questions on a five-point scale. Medication compliance and physical activity (general physical condition enhancement) were both measured by numeric rating (0-10) in combination with questions on a five-point scale that were expressed as one overall score. The physical activity scale was originally developed by Baecke and is often used for epidemiological research.[24 25] Measurement of psychosocial mediators, investment (the ability to invest in longer-term benefits) and initiative beliefs (the ability to be self-motivating regarding the realisation of the dimensions of well-being), as well as self-efficacy was performed with three dimensions of the Self-Management Ability Scale (SMAS).[26] The subscales each consist of five items rated on a six-point scale.

Patient outcomes

Quality of life was measured with a validated Dutch version of the self-reported Chronic Respiratory Questionnaire (CRQ-SR).[27] The CRQ-SR is made up of 20 questions and measures four dimensions relating to dyspnoea (5), emotional function (7), fatigue (4), and mastery (4). For every question there are seven response categories that score from 1 to 7. Furthermore, the Clinical COPD Questionnaire (CCQ) was used, a self-administered multidimensional clinical control questionnaire that includes 10 questions in three domains: symptoms, functional and mental state.[28] The total CCQ score, and the score on each of the three domains, varies between 0 (very good health status) to 6 (extremely poor health status). Perceived health status was measured by the EQ-5D visual analogue scale (VAS), a "thermometer" for eliciting a self-rating of health status. Patients indexed their value for health status ranging from 0 (worst imaginable health state) to 100 (best imaginable health state) on a line.[29] In Table 5.1 the Cronbach's alphas which refer to the reliability of the scales are reported.

The Medical Research Council (MRC) scale, a commonly used, validated, ordinal scale, was used for grading the type and magnitude of dyspnoea according to five grades of increasing severity: 0 indicating 'breathlessness with strenuous exercise' to 5 representing 'breathlessness keeping patients from leaving the house'.[30] Lung function was assessed by measuring the forced expiratory volume in one second (FEV_1) with the use of spirometry and expressed as FEV_1 percentage predicted, according to established criteria.[31] FEV_1 was measured from a series of at least three forced expiratory curves that had an acceptable start of test and were free from artefact. In addition, all spirograms in the general practice were reviewed by the pulmonologist through telespirometry.

Data analyses

Hierarchical regression analyses were used to determine if the propositions depicted in the model are consistent with the data. The order of entering variables was determined by the theoretical model (Figure 5.1). At the first step knowledge (subjective and objective), psychosocial mediators (initiative and investment beliefs) and self-efficacy were assumed to affect patient behaviour: medication compliance and physical activity (dependent variable). At the second step, these variables including patient behaviour were thought to affect health outcomes (dependent variable).

Patient characteristics such as age and sex can also influence relationships between process variables and outcome achievement. For example, advanced age can be related to lower quality of life.[32] This should be controlled for when assessing the impact of the interventions on health outcomes. Therefore, a third step with age, age square and sex was added to the regression analysis. The age square variable is centred. This means that the square is calculated after the mean is subtracted from the score on this variable.[33]

Furthermore, descriptive analysis was performed on patient demographics and study variables. Data from both the database and questionnaire were extracted and analysed in the statistical package SPSS 13 for Windows. A prior significance level of 0.05 was used for all statistical tests.

Results

Response and sample characteristics

Three hundred and ninety-one patients met the study inclusion criteria. Of those patients 278 consented to participate; a response rate of 74%. The commonest reason for refusal was unwillingness to complete the questionnaire. Patient characteristics are presented in Table 5.2. A non-response analysis showed no significant differences between the two groups.

The characteristics and psychometric properties of the measures are also described in Table 5.1. Overall, mean scores were relatively high. Table 5.3 presents zero-order correlations between all variables of the model. Scores are arranged so that a higher score on each indicator indicates a better health outcome or a more positive score. Therefore, negative correlations indicate a negative relation. It appears that most model variables correlate significantly with each other.

Predictors of behaviour

According to the evaluation model, knowledge (subjective and objective), psychosocial mediators (initiative and investment beliefs) and self-efficacy are assumed to affect patient behaviour. Since medication compliance did not correlate significantly with knowledge, psychosocial mediators and self-efficacy, no regression was done with medication compliance as a dependent variable. All variables, except for subjective knowledge, correlated significantly with physical activity (Table 5.3). However, only investment beliefs appeared to significantly predict physical activity (depen-

Table 5.2 Patient characteristics (n = 278)

Characteristic	% (n)
Age (Mean ±SD)	63 ± 11 years
Sex	
Male	56 (156)
Female	44 (122)
Marital status	
Married or equivalent	80 (219)
Widowed	10 (28)
Divorced	3 (9)
Never married	18 (7)
Educational level greater than high school diploma	26 (73)
Smoking status	
Non or Ex-smoker	74 (205)
Current smoker	26 (73)
Pack years (Mean ±SD)	31 (± 28)
COPD severity	
Mild	53 (141)
Moderate	37 (97)
Severe	10 (26)
Dyspnoea (Mean ±SD)	1.61 (± 1.07)
Body Mass Index (Mean ±SD)	27.46 (± 4.69)

dent variable) (β=0.42, p<0.01) in the regression analysis. Explained variance by investment beliefs in physical activity was 24% (data not shown).

Predictors of quality of life

Table 5.4 shows results of our regression analyses. Physical activity appeared to be a significant predictor for all clinical and functional outcomes. This finding was consistent with the correlations found (Table 5.3). In the multiple regression model, physical activity (β=0.38, p<0.001) and age (β=-0.15, p<0.05) significantly determined CRQ dyspnoea. Total explained variance in dyspnoea was 20%.

In the regression model for CRQ emotional function significant effects of objective knowledge, initiative beliefs, self-efficacy and physical activity were found in step 2. Age (β=0.19, p<0.05) and sex (β=-0.17, p<0.01) were added as significant predictors in step 3, indicating that lower age and being female are related to lower emotional functioning. In the final model, initiative beliefs, self-efficacy, physical activity, age and sex had significant standardised regression coefficients of respectively -0.19, 0.38, 0.17, 0.19 and -0.17. Total explained variance in emotional functioning was 23%.

Significant effects of subjective knowledge, objective knowledge, self-efficacy and physical activity were found on CRQ fatigue in the second step. In the final regression model subjective knowledge (β=0.15, p<0.05), self-efficacy (β=0.18, p<0.05), physical activity (β=0.43, p<0.01), sex (β=-0.20, p<0.01) and age square (β=-0.13, p<0.05) were significant predictors of CRQ fatigue. Total explained variance in fatigue was 29%.

In the regression analyses subjective knowledge (β=0.23, p<0.01), investment beliefs (β=-0.25, p<0.05) and physical activity (β=0.19, p<0.01) significantly determined CRQ mastery; total explained variance in mastery was 14%.

In addition to the CRQ, we also analysed quality of life outcomes obtained with the CCQ questionnaire. Significant effects of objective knowledge, respectively β=-0.16 (p<0.05) and β=-0.15 (p<0.05), and physical activity, respectively β=-0.16 (p<0.05) and β=-0.15 (p<0.05), for both CCQ symptoms and CCQ mental state were found. In addition, sex significantly influenced CCQ mental state. Total explained variance in CCQ symptoms and CCQ mental state was respectively 11% and 15%. The results on CCQ mental state validate the previously found association between knowledge and CRQ emotional functioning. In the regression models for CCQ functional state, physical activity (β=0.44, p<0.001) and age (β=-0.15, p<0.05) were significant predictors, accounting for 23% of the variance.

In the regression analyses, physical activity (β=0.43, p<0.001) was a significant predictor of health status, accounting for 22% of the variance.

Predictors of clinical outcomes

The regression analyses for MRC Dyspnoea showed a picture similar to CRQ Dyspnoea: significant effects of physical activity (β=0.20, p<0.01) and age (β=-0.28, p<0.001) were found. In addition sex (β=-0.21, p<0.01) significantly predicted MRC Dyspnoea. The MRC and CRQ dyspnoea scores correlated significantly at p<0.01 level (*r* =0.60) (Table 5.3). With respect to lung function, objective and subjective knowledge, and physical activity were significant predictors in step 2. Subjective knowledge, physical activity and age had significant standardised regression coefficients of respectively -0.14 (p<0.05), 0.17 (p<0.05) and -0.17 (p<0.05) in the final model. Noteworthy is the fact that objective knowledge is positively correlated to lung function, whereas subjective knowledge correlated negatively. Total explained variance in lung function was, however, small (10%).

Discussion and conclusion

Discussion

Our goal was to detect associations of patient-related characteristics and functional and clinical outcomes, and to test these associations with data from self-report questionnaires by COPD patients and from GPs' electronic registries. Knowledge on associations of patient-related aspects helps to target the specific interventions. Our exploratory results provided support for the proposed associations in our theoretical model. Knowledge, psychosocial mediators and self-efficacy were indeed associated with physically active behaviour. However, regression analyses showed

Table 5.3 Correlations between study measures

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Independent variables																
1.Subjective knowledge																
N																
2. Objective knowledge	.399**															
N	258															
3. Self-efficacy	.156*	.170**														
N	253	268														
4. Initiative beliefs	.129*	.187**	.655**													
N	253	269	265													
5. Investment beliefs	.177**	.164**	.712**	.724**												
N	256	270	267	266												
6. Medication compliance	.113	.035	.019	.100	-.035											
N	255	272	267	267	269											
7. Physical activity	.111	.126*	.339**	.404**	.482**	-.128*										
N	244	258	253	253	255	256										
Dependent variables																
8. CRQ dyspnoea	.117	.051	.067	.048	.091	-.125	.359**									
N	234	245	243	240	244	243	231									
9. CRQ emotional function	.118	-.044	.308**	.100	.235**	-.052	.213**	.444**								
N	246	261	257	255	259	260	246	244								
10. CRQ fatigue	.166**	-.023	.197**	.109	.190**	-.074	.410**	.571**	.707**							
N	241	256	252	250	254	254	240	239	255							
11. CRQ mastery	.280**	.155*	.144*	.119	.076	.113	.174**	.468**	.449**	.350**						
N	238	251	247	245	249	249	237	235	251	250						

12. CCQ symptoms	.002	-.123*	.029	-.041	.001	-.046	.231**	.450**	.341**	.438**	.261**					
N	248	262	256	256	258	259	247	238	253	253	248					
13. CCQ mental state	.081	-.119	.092	-.012	.081	.086	.198**	.429**	.491**	.457**	.449**	.507**				
N	244	257	253	252	254	254	242	236	248	248	243	257				
14. CCQ functional state	.088	.020	.115	.097	.127*	-.124*	.419**	.784**	.460**	.601**	.429**	.564**	.522**			
N	247	261	255	255	257	258	247	238	252	252	247	259	255			
15. Health Status	.082	.047	.206**	.182**	.206**	-.117	.426**	.520**	.445**	.592**	.337**	.483**	.350**	.491**		
N	233	245	242	242	242	243	232	222	236	231	229	235	231	234		
16. MRC dyspnoea	.092	.075	.078	.129*	.129*	-.127*	.255**	.597**	.233**	.376**	.255**	.393**	.278**	.613**	.427**	
N	228	241	238	236	240	240	227	225	239	233	230	234	230	234	222	
17. Lung function	-.075	.107	.049	.134*	.093	-.038	.195**	.432**	.082	.134*	.274*	.182**	.176**	.361**	.330**	.362**
N	258	275	269	270	271	274	259	245	262	256	251	262	257	261	246	242

** Correlation is significant at the 0.01 level (2-tailed); * Correlation is significant at the 0.05 level (2-tailed). PAIRWISE

Table 5.4 Hierarchical regression analysis of patient behaviour on outcome

	CRQ Dyspnoea			CRQ Emotional			CRQ Fatigue			CRQ Mastery			CCQ Symptoms		
	β			β			β			β			β		
	Step 1	Step 2	Step 3	Step 1	Step 2	Step 3	Step 1	Step 2	Step 3	Step 1	Step 2	Step 3	Step 1	Step 2	Step 3
1. Knowledge (O)	.00	-.01	-.08	-.13*	-.14*	-.07	-.13	-.14*	-.11	.04	.03	.06	-.15*	-.16*	-.16*
Knowledge (S)	.10	.11	.10	.12	.12	.10	.18**	.18**	.15*	.26**	.24**	.23**	.06	.05	.04
Investment beliefs	.09	-.07	-.02	.15	.09	.03	.13	-.04	-.08	-.14	-.22*	-.25*	.02	-.12	-.11
Initiative beliefs	-.04	-.11	-.10	-.23*	-.26**	-.19*	-.09	-.15	-.09	.09	.09	.11	-.10	-.14	-.11
Self-efficacy	.01	.03	.02	.36**	.37**	.38**	.15	.18*	.18*	.14	.14	.15	.10	.11	.10
2. Med. compliance		-.10	-.06		-.06	-.08		-.05	-.05		.11	.10		-.02	-.01
Physical activity		.40**	.38**		.15*	.17*		.42*	.43**		.18*	.19**		.32**	.31**
3. Age			-.15*			.19*			.12			.10			-.03
Age square			-.12			-.02			-.13*			-.04			-.01
Sex (M=0; F=1)			-.09			-.17**			-.20**			-.06			-.09
Δ R^2		.14	.04		.02	.07		.14	.07		.03	.01		.08	.01
R^2	.02	.16	.20	.14	.16	.23	.08	.22	.29	.10	.13	.14	.03	.10	.11
Sign. F change	0.89	18.59**	3.61*	7.88**	3.02*	6.90**	4.00**	21.06**	7.00**	4.99**	4.23*	1.26	1.21	10.22**	0.67
df_1/df_2	5/225	2/223	3/220	5/238	2/236	3/233	5/234	2/232	3/229	5/231	2/229	3/226	5/238	2/236	3/233

*p < .05; **p < .01 (2-tailed) PAIRWISE

Table 5.4 Hierarchical regression analysis of patient behaviour on outcome (continued)

	CCQ Mental state β			CCQ Functional state β			Health Status β			MRC Dyspnoea β			Lung function β		
	Step 1	Step 2	Step 3	Step 1	Step 2	Step 3	Step 1	Step 2	Step 3	Step 1	Step 2	Step 3	Step 1	Step 2	Step 3
1. Knowledge (O)	-.18**	-.19**	-.15*	-.03	-.05	-.11	-.01	-.03	.02	.03	.02	-.05	.14*	.14*	.09
Knowledge (S)	.13	.12	.10	.08	.08	.07	.05	.05	.04	.06	.07	.04	-.14*	-.15*	-.14*
Investment beliefs	.11	.01	-.03	.08	-.11	-.06	.09	-.08	-.12	.09	.00	.08	.05	-.03	.03
Initiative beliefs	-.16	-.17	-.12	.00	-.07	-.06	.04	-.02	.01	.09	.04	.08	.14	.12	.09
Self-efficacy	.13	.13	.14	.05	.08	.06	.11	.13	.14	-.06	-.04	-.09	-.08	-.07	-.09
2. Med. compliance		.10	.09		-.08	-.05		-.07	-.09		-.10	-.05		.01	.02
Physical activity		.24**	.25**		.46**	.44**		.42**	.43**		.23**	.20**		.18*	.17*
3. Age			.11			-.15*			.11			-.28**			-.17*
Age square			-.06			-.08			.05			.03			.05
Sex			-.17*			-.11			-.05			-.21**			.08
Δ R^2		.05	.04		.18	.03		.14	.02		.06	.08		.03	.03
R^2	.06	.10	.15	.02	.20	.23	.05	.20	.22	.03	.08	.16	.05	.07	.10
Sign. F change	2.78*	6.30**	3.82*	1.10	25.77**	3.19*	2.49*	20.00**	1.88	1.20	6.58**	6.77**	2.32*	3.24*	2.75*
df_1/df_2	5/236	2/234	3/231	5/238	2/236	3/233	5/226	2/224	3/221	5/221	2/219	3/216	5/238	2/236	3/233

*p < .05; **p < .01 (2-tailed) PAIRWISE

that investment beliefs remained the only significant predictor of physical activity. The results of the multiple regression analyses showed that knowledge, psychosocial mediators, self-efficacy and behaviour were predictors of health outcomes to a moderate degree. Especially physical activity is associated with positive outcomes. These findings support the application of theory in designing patient-directed interventions. So far, patient-related interventions in COPD care have not been based on theoretical models aimed at behavioural change.[34] Furthermore, other measures than outcome indicators are often disregarded. Although a recent study by McGeoch and colleagues[35] on self-management programmes in primary care found better self-management knowledge in the intervention group but no difference in quality of life or health outcomes. In asthma care, a review on the application of evidence-based theoretical principles that guide learning and behaviour modification showed results consistent with improved education in processes and outcomes.[36] Hence, theoretically derived indicators can provide better understanding of interventions and their actual effects.

The present study shows that knowledge on COPD is positively correlated to a patient's emotional or mental state. This would seem to imply that this helps patients to manage their emotional state, perhaps by improving coping strategies. In previous research emotional wellbeing was found to be significantly related to coping patterns.[37] Even so, it was found that COPD patients with an inferior mental state have difficulty with learning and applying self-management plans.[38] Teaching adequate coping strategies therefore seems instrumental in improving emotional wellbeing. So far, only few studies have examined and shown associations between self-management education and improvement in disease knowledge.[39] Of the wealth of studies exploring the relationships between beliefs, self-management behaviour and outcomes, only very few have addressed beliefs in COPD.[40] In accordance with our findings, one study found that patient's beliefs (perceived control over COPD) influenced self-management behaviour.[38]

Several studies underline the importance of self-efficacy in the process of managing the disease and its consequences, since higher self-efficacy enhances the likelihood of positive health behaviour.[5 14 41] Previous findings confirm increased self-efficacy in COPD patients after an educational and supportive telephone follow-up programme.[42] Therefore, in the present study self-efficacy was expected to be an important predictor of behaviour and outcomes. Significant associations were nevertheless found only for CRQ emotional function and CRQ fatigue. The sample of this study contained patients with mild to moderate COPD, including newly diagnosed patients, preliminary to intervention. This may have reduced the role of self-efficacy. The associations of self-efficacy with emotional and fatigue quality of life components for these patients suggests that patients' disease perceptions mainly affect their emotional state. Self-efficacy theory seems to support this conclusion, as it holds that sources of self-confidence are obtained primarily through performance accomplishment, vicarious experience, verbal persuasion and self-evaluation of physiological and emotional states.[15] In the present study in patients with mild and moderate disease, physical activity was the most consistent factor associated with clinical and quality of life outcomes: it was a significant predictor in each multiple regression analysis. Previous research in (very) severe COPD patients already showed positive effects of physical activity on health outcomes such as quality of life, lung function and dyspnoea.[43-47] Physical activity has not been shown to significantly benefit quality of life and dyspnoea of patients with mild or moderate COPD.[48 49] While current primary care guidelines in the Netherlands recommend changes in lifestyle, such as physical activity, for patients with mild or moderate COPD, these are often not included in the care plan. The associations found in this study would seem to stress the importance of this recommendation in order to prevent further deterioration.

As expected, higher age was related to lower quality of life, except for emotional functioning. As to the influence of sex, women scored lower than men on health outcomes. Apart from dyspnoea this relation was mainly found on emotional domains. Variance in psychological and social cultural factors between men and women might explain these differences.[50] A recent study also demonstrated sex differences in quality of life and dyspnoea in patients with COPD; health related quality of life was significantly worse in women.[51 52]

Our study contained clinical data and self-reported outcome measures. Both types of outcome were significantly associated with patient-related characteristics. This provides objective validation of our findings, even though the explained variance of clinical measures, such as lung function, was smaller. Clinical measures are indeed more difficult to influence. Lung function was found to correlate with other features of the disease, such as quality of life and dyspnoea. Previous research demonstrated poor correlations with these features.[21] This may be due to the specific population, patients with mild to moderate COPD. Since COPD is a multi component disease, there is a need for outcome measures other than FEV_1 that independently capture severity.

Findings of this study must be interpreted in the light of several limitations. First, this study was an exploratory cross-sectional analysis, which has implications for conclusions about causality of the effects. The ideal test would be a longitudinal test of the theoretical model, as this allows detecting changes in associations as well. Secondly, self-reported instruments were used. Self-reporting of medication and exercise behaviour must be interpreted as an estimate of particular behaviours. Yet, as early as 1988 Ley[53] found positive correlations of self-report with other methods of measurement. Thirdly, the nature of the study sample, with all subjects having mild to moderate COPD, may limit the generalisability of these results. Nevertheless, eighty-two percent of all patients with COPD show a mild or moderate phenotype.[54] Fourthly, we tested 10 different independent variables in the regression models. The risk of finding positive results because of mass significance is always the risk in these kind of analyses and therefore also in our study. However, we explicitly tested associations derived from a theoretical model. To avoid type one errors, we already set the significance level at 0.01 (two-tailed). And finally, we aimed at identifying those aspects of patient-related interventions important for targeting the appropriate patient-related interventions. We did not study the exact nature or intensity of the interventions. So, there remains much debate and research about the most effective way to execute strategies to educate and involve people to deal effectively with their COPD.[10]

Conclusion

The present exploratory study has provided support for the proposed associations in our theoretical model of COPD care. Knowledge, psychosocial beliefs, self-efficacy and behaviour proved to determine clinical and functional outcomes. Systematic use of theories is important in developing and evaluating patient-related interventions. To achieve benefits of patient-related interventions, behavioural change and learning principles must be incorporated. Next to that, selection of indicators for evaluation of patient-related interventions should be determined through linkage with the specific elements of the theoretical model.

Practice Implications

From this chapter it can be concluded that more attention should be paid to the patterns of physical activity in patients with mild to moderate COPD. Furthermore, studies on patient-related interventions rarely report process indicators, such as self-efficacy and behavioural change. But, effects on outcomes are often not found.[6 9] Findings from our study suggest the desirability of including measures on knowledge, psychosocial beliefs, self-efficacy and behaviour, since they determine clinical and quality of life outcomes. Moreover they may be more sensitive in picking up relevant changes specific to self-management. This brings us to our second practice implication; future patient-related interventions should be designed along the lines of theory on behavioural change, such as social cognitive theory, as these offer both predictors and principles of behavioural change.

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Chapter 6

Professional Commitment to Changing Chronic Illness Care: Results from Disease Management Programmes.

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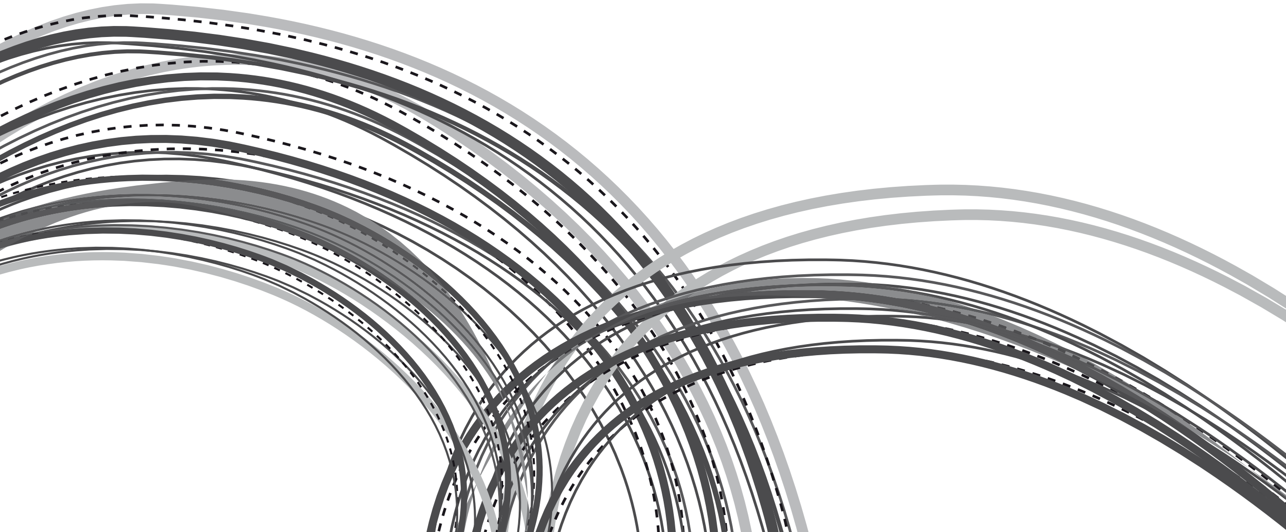

Abstract

Objectives: The aim of this exploratory study was to investigate to what extent primary care professionals are able to change their systems for delivering care to chronic obstructive pulmonary disease (COPD) patients and which professional and organisational factors are associated with the degree of process implementation.

Design: Quasi-experimental design with one year follow-up after intervention.

Setting: Three regional COPD disease-management programmes in the Netherlands, in which general practices cooperated with regional hospitals.

Participants: All participating primary care professionals (n = 52).

Intervention: COPD disease-management programme.

Main Outcome Measures: Professional commitment, organisational context and degree of process implementation.

Results: Professionals significantly changed their systems for delivering care to COPD patients, namely self-management support, decision support, delivery system design and clinical information systems. Associations were found between organisational factors, professional commitment, and changes in processes of care. Group culture and professional commitment appeared to be, to a moderate degree, predictors of process implementation.

Conclusions: COPD disease management was effective; all processes improved significantly. Moreover, theoretically expected associations between organisational context and professional factors with the implementation of COPD disease management were indeed confirmed to some extent. Group culture and professional commitment are important facilitators.

Introduction

Chronic diseases are the main cause of death and disability worldwide, and as the population ages, prevalences of chronic conditions will increase.[1] Chronic obstructive pulmonary disease (COPD) is a common multi-component disease that imposes an enormous burden on the patient, medical professionals and society in terms of morbidity, mortality, healthcare resource utilisation and cost.[2] Highly prevalent already, COPD is projected to become the third most common cause of death by 2020.[1] Efforts to improve quality and efficiency of health care have been given high priority. Disease management, defined as "an approach to patient care that emphasises coordinated, comprehensive care along the continuum of disease and across health care delivery systems"[3], has emerged as a new strategy to achieve improvement. Disease management has three key features: it uses empowerment strategies (patient-oriented) and decision support tools (professional-directed), preferably supported by changes in the organisational system.[4]

A growing body of literature argues that improving the delivery of primary care is an effective approach to implement disease management[5 6], since chronic illness care is largely performed within a primary care setting. Primary care professionals are therefore at the forefront of COPD diagnosis and management.[2] Their motivation to redesign care is one of the keys to successful disease management.[7] However, most professionals lack the time, information technology, and financial resources to systematically improve the quality of care provided to these patients.[6] There is a gap between what professionals do for patients with chronic diseases (e.g. COPD) and what should be done.[8] This raises questions about professional commitment in changing chronic illness care. There are currently no research reports, however, examining professionals' roles in implementing disease management within primary care.

In general, variations in degree of implementation of changes can been attributed to characteristics of the professionals, but also to the organisational context.[9 10] The aim of this exploratory study is to investigate to what extent primary care professionals are able to change their processes for delivering care to COPD patients and which professional and organisational factors are associated with the degree of process implementation.

Theoretical framework

The framework is based on theoretical approaches by Cretin and colleagues[9] and Lin and colleagues.[7] Both papers argue that a multilevel approach is needed to improve quality; they focus on professional level as well as organisational context. This study combines the approaches by relating professional and organisational factors to changes in processes of care (Figure 6.1). At professional level, professional commitment is approached in terms of motivation, using the expectancy theory.[11 12] This theory acknowledges the multi-faceted nature of professional commitment by distinguishing valence, instrumentality and expectancy. Valence is the attractiveness

Figure 6.1 Theoretical model on professional commitment to changing chronic illness care

that professionals assign to the outcomes associated with successful implementation of disease management. These outcomes induce both intrinsic and extrinsic rewards, such as improvement in patient health and satisfaction or higher professional self-esteem. Instrumentality refers to the belief that disease management implementation will lead to these targeted outcomes. Expectancy concerns the association between effort and success in disease management implementation. Thus, the product of an individual's assessment of valence, instrumentality, and expectancy is the professional commitment towards implementing disease management.[7 12]

Culture, organisational commitment to quality improvement and climate are considered to be important conditions in the organisational context. They provide information on the setting and contingencies that professionals are confronted with in their work environment.[13] Culture concerns the norms, values, beliefs, and behaviours of an organisation reflecting "how we do things around here". The Competing Values Framework (CVF) distinguishes four types of culture: group culture (teamwork and participation), developmental culture (risk-taking, innovation, and change), hierarchical culture (rules, regulations, and bureaucracy), and rational culture (efficiency, goal attainment, and achievement).[14 15] Previous research on chronic care improvement showed that having a group culture is related to higher commitment from professionals.[16] The core principles of disease management emphasise change and teamwork efforts, hence group culture may be a facilitator for chronic care improvement. A higher degree of the practice group's commitment to quality improvement is expected to positively influence professional commitment as well, since quality activities are hypothesised to support implementation of disease management. Climate refers to an individual's perception of the environmental and organisational contingencies between individual behaviours related to COPD disease management and anticipated collegial responses.[15] Professionals are hypothesised to be more committed to implementing COPD disease management when they perceive a supportive climate.[7] A group culture, a supportive climate, and commitment to quality tend to create a positive workplace with dedicated professionals working together effectively.[17] This supports the development and implementation of system changes that improve processes and, ultimately, patient outcomes.

Previous research[9 18] suggests that it is the interplay between professional level factors and the organisational context that explains the success or failure of the implementation of disease-management programmes. This study explores associations between professional commitment, organisational context and perceived degree of implementation of changes within current practice groups of COPD (Figure 6.1).

Methods

Setting and design

This study evaluates professionals' commitment within three regional pilots of COPD disease-management programmes in the Netherlands. The pilot studies were supported by Partners in Care Solutions (PICASSO) for COPD, a national programme that aims to optimise COPD care by supporting the implementation of disease management. The programmes were carried out in twenty-one general practices in central Netherlands: the 'Gelderse Vallei' region, Doetinchem and Nijmegen. The practices cooperated with the regional hospital(s) and were supported by their own practice nurses or practice nurses of a regional home care organisation.

The COPD disease-management programme consisted of patient-education, protocolised assessment and treatment of COPD, and coordination of care. Practice nurses systematically educated patients on smoking behaviour, medication usage, nutrition and physical activity so as to increase their understanding of COPD and self-management skills. Next to that, professionals were educated on the guidelines and programme. These interventions were supported by organisational interventions. A multidisciplinary team (general practitioner, practice nurse and a pulmonologist) coordinated diagnostic procedures, treatment, and ongoing patient management. Team members' tasks and responsibilities were described in a guideline-based protocol. Practice nurses performed lung function tests, assessed patients' conditions, provided disease-related education and advice, coordinated care, and organised follow-up meetings. They acted in conjunction with the general practitioner who consulted the specialist when needed. Figure 6.2 shows the specific characteristics of these programmes and specific differences between the regions. It shows that the programmes are rather similar.

An exploratory study was performed as a part of a larger evaluation study on COPD disease-management programmes in the Netherlands. Data were collected by means of postal questionnaires at baseline and one year after intervention. Both the researcher and the programme manager invited the professionals involved in these programmes to complete the questionnaire. The characteristics and psychometric properties of the measures are described in Table 6.1.

Questionnaire

Professionals completed a questionnaire based on the Improving Chronic Illness Care questionnaire (ICIC).[7] Areas covered were 1) general professional characteristics, 2) COPD disease man-

Table 6.1 Descriptive statistics of theoretical constructs and instruments per variable

Construct	Variable(s)	Instrument	No. of items	Range	Cronbach's α	T0 Mean (SD)	T1 Mean (SD)	Change (95% CI)	P-value
Organisational factors	Culture	CVF[1]	20	0 – 100					
	Group					40.8 (17.0)	40.6 (18.6)	-0.3 (-3.7 to 3.1)	0.88
	Developmental					27.7 (14.3)	26.2 (12.2)	-1.4 (-5.6 to 2.8)	0.49
	Hierarchical					16.3 (9.8)	19.0 (11.1)	2.7 (-0.3 to 5.6)	0.07
	Rational					15.1 (10.9)	14.0 (9.7)	-1.1 (-4.1 to 1.8)	0.44
	QI commitment	EFQM[2]				3.8 (0.5)	3.8 (0.6)	0.0 (-0.2 to 0.2)	0.89
	Policy and strategy		5	1 – 5	0.69	3.9 (0.6)	4.0 (0.7)	0.1 (-0.2 to 0.3)	0.77
	Quality development		5	1 – 5	0.78	3.8 (0.6)	4.0 (0.6)	0.1 (-0.1 to 0.3)	0.23
	Employee involvement		4	1 – 5	0.78	3.9 (0.6)	3.8 (0.7)	-0.1 (-0.4 to 0.1)	0.23
	Customer satisfaction		5	1 – 5	0.76	3.4 (0.6)	3.4 (0.6)	0.0 (-0.2 to 0.2)	0.97
	Climate	ICIC	4	1 – 4	0.48	3.0 (0.3)	3.5 (0.5)	0.5 (0.4 to 0.7)	<0.001
Professional commitment	Professional commitment					124.8 (28.0)	135.7 (33.8)	10.9 (1.6 to 20.3)	0.02
	Valence	ICIC	9	1 – 5	0.87	3.6 (0.5)	3.8 (0.5)	0.2 (0.1 to 0.3)	0.009
	Instrumentality	ICIC	9	1 – 7	0.78	5.7 (0.5)	5.8 (0.5)	0.1 (0.0 to 0.2)	0.16
	Expectancy	ICIC	1	1 – 7		6.1 (0.8)	6.2 (0.8)	0.1 (-0.2 to 0.4)	0.58
Changes in care processes	Self-management support	ACIC	4	0 – 11	0.94	4.8 (2.5)	7.2 (1.7)	2.4 (1.7 to 3.1)	<0.001
	Decision support	ACIC	4	0 – 11	0.85	5.8 (1.9)	7.5 (1.3)	1.7 (1.1 to 2.3)	<0.001
	Delivery system design	ACIC	6	0 – 11	0.94	4.8 (2.3)	7.7 (1.3)	3.0 (2.3 to 3.6)	<0.001
	Clinical information systems	ACIC	5	0 – 11	0.91	4.5 (2.3)	6.7 (1.6)	2.3 (1.7 to 2.9)	<0.001

[1]CVF: Competing Values Framework; [2]EFQM: European Foundation for Quality Management; [3]ICIC: Improving Chronic Illness Care; [4]ACIC: Assessing Chronic Illness Care

	Gelderse Vallei	*Doetinchem*	*Nijmegen Milbergen*
Intervention period	April 2006 – November 2007	September 2006 – March 2008	August 2006 – February 2008
Professionals	7 General practices: 14 GPs, 8 practice nurses	10 General practices: 17 GPs, 10 practice nurses	4 General practices: 8 GPs, 2 practice nurses/ 2 practice assistants, 2 physiotherapists
Patient-related intervention Systematic use of patient education, including: smoking behaviour, medication usage, nutrition and physical activity	• Frequency: every 3 months • Duration: First contact ten minutes, follow-up meetings at least fifteen minutes • Provision of information booklet	• Frequency: at least twice a year • Duration: Fifteen to twenty minutes • Provision of information workbook and booklet	• Frequency: Four times a year • Duration: At least fifteen minutes • Provision of information booklet • Reactivation or advice by physiotherapist
Professional-directed intervention Educational meetings GPs and practice nurses on: COPD management according to guidelines and application of spirometry	• Frequency: GP – three times a year; practice nurse – six days at the start • Duration: GP – two hours; practice nurse – eight hours (each session)	• Frequency: GP – ones a year; practice nurse – at least three times at the start • Duration: GP – two hours; practice nurse – four hours (each session)	• Frequency: GP – ones a year; practice nurse – at least three times at the start • Duration: GP – two hours; practice nurse –four hours (each session)
Active distribution of clinical practice guidelines	• Supported by an electronic registry system	• A regional care protocol	• A regional care protocol
Audit and feedback by lung specialist/ peers	• To confirm diagnosis every spirometry was seen by the lung specialist. In follow-up spirometry tests could be send to the lung specialist when necessary	• Spirometry tests could be send to the lung specialist when necessary	• Spirometry tests could be send to the lung specialist when necessary
Organisational intervention Arrangements for structural follow-up with practice nurse	• Frequency: 3, 6 and 12 months	• Frequency: 3, 6 and 12 months	• Frequency: 1, 6 and 12 months
Multidisciplinary collaboration between GP, practice nurse and a lung specialist	• Multidisciplinary care teams	• Multidisciplinary care teams	• Multidisciplinary care teams, including physiotherapist
Revision of professional roles	• Delegation of care from GP to practice nurse, from lung specialist to GP	• Delegation of care from GP to practice nurse, from lung specialist to GP	• Delegation of care from GP to practice nurse, from lung specialist to GP
Case management	• Care coordination by the practice nurse in collaboration with the GP	• Care coordination by the practice nurse in collaboration with the GP	• Care coordination by the practice nurse in collaboration with the GP

Figure 6.2 Disease-management interventions in the disease-management programmes

agement implementation and 3) factors associated with changing chronic COPD care. The first part related to background characteristics, such as duration of professional activity. Secondly, the Assessing Chronic Illness Care (ACIC) survey[19] aimed to determine the perceived degree of actual implementation of the programme. Only the elements reflecting the interventions within the disease-management programme were included: self-management support (patient-related intervention), decision support (professional-directed intervention), delivery system design and clinical information systems (both evaluating implementation of the organisational intervention) (Figure 6.2). The 4 to 6 items per element were rated on a 0 to 11 response scale, with higher scores indicating more complete implementation. Mean scores for each element were obtained. To validate self-reports by professionals we compared changes in ACIC elements to available data on structural changes in care practices and to available process measures, namely application of patient education for changes in self-management support, provision of inhalation-instruction and application of spirometry for changes in decision support and regularity of follow-up for changes in delivery system design. The process measures were expressed as percentages of patients within practices that received a specific intervention.

The third part of the questionnaire measured professional commitment in implementing COPD disease management (valence, instrumentality and expectancy; professional level) and identified relevant contextual factors (culture, commitment and climate; organisational level). Valence is measured on a 9-item scale; professionals are asked to report the importance of each of the described outcomes, for example improving continuity of care. Response categories range from 1 (not important) to 5 (extremely important). Instrumentality is made up of 9 items; response categories range from 1 (strongly disagree) to 7 (strongly agree). Expectancy is a single item to be rated from 1 (strongly disagree) to 7 (strongly agree) in response to a statement on the association between effort and success in disease management implementation. Consistent with Vroom's conceptualisation of the expectancy framework[12], these scales add up to one professional commitment score.

Culture was assessed using the CVF[13], which asks respondents to distribute 100 points across series of four statements on the culture of their practice group. These statements reflect the four culture types. Commitment to quality improvement is measured by an overall average score on quality improvement questions by the European Foundation for Quality Management (EFQM) scale adapted for primary care.[13 20] Response categories range from 1 (strongly disagree) to 5 (strongly agree). The scale covers four subjects: policy and strategy, quality development, employee involvement and customer satisfaction. Examples of items are: 'the practice group uses data from patients to improve services' and 'professionals are recognised for improving quality'. Climate is measured as the average of four questions assessing expected collegial responses to initiating behaviours and performing tasks related to COPD disease management.[7] Response categories range from 1 (admonition or disapproval) to 4 (reward or approval).

Table 6.2 Professional characteristics at baseline

Characteristic	% (n)
Sex	
Male	50 (27)
Female	50 (27)
Profession	
General Practitioner	61 (33)
Practice nurse	31(17)
Practice assistant	4 (2)
Physiotherapist	4 (2)
Years in practice	
0 – 1 year	6 (3)
1 – 5 years	26 (14)
5 – 10 years	19 (10)
Longer than 10 years	50 (27)
Specific COPD education	
Yes	63 (34)
No	37 (20)
Number of hours a week working with COPD patients	
Less than 8 hours	68 (35)
8 to 15 hours	12 (6)
16 to 22 hours	12 (6)
More than 22 hours	8 (4)
Participating in regional multidisciplinary COPD meetings	
Yes	64 (35)
No	36 (19)

Statistical analyses

For all study variables comparisons were made between baseline (T0) and post-intervention (T1) data using paired-sampled *t*-tests and Wilcoxon signed rank tests (one-sided; $\alpha = 0.05$) where appropriate. Process changes in ACIC were validated by comparing them to process measures using Pearson's correlation coefficients. Differences between groups determined by professional characteristics were explored with Mann-Whitney U tests. To determine if the theoretical model propositions are consistent with the data, regression analyses were applied in two steps. The associations between organisational context, professional commitment and degree of process changes were explored using professional commitment as a mediator variable (Figure 6.1).[21] Baseline as well as change scores were entered into the model to account for the individual baseline levels and to control for regression to the mean effects.[22] Data were analysed in the statistical package SPSS 13 for Windows. A prior significance level of 0.05 was used for all statistical tests.

Results

Response and characteristics

The eligible study population consisted of sixty professionals. Initial responses were received from fifty-four professionals; as two professionals were lost to follow-up, the final response rate was 87%. Professional characteristics at baseline are presented in Table 6.2. We explored the differences between general practitioners and practice nurses. Overall, the latter tended to score more positively; differing significantly on instrumentality and the implementation of information systems. Furthermore, professionals with specific COPD education had significantly higher scores on COPD disease management implementation, except for decision support. After the implementation of the disease-management intervention these differences dissipated.

Professional commitment

At baseline, attractiveness assigned to the outcomes associated with successful implementation of COPD disease management (valence) was rated a mean 3.57 (±0.44) on a 1-5 scale. This indicates that professionals attach importance to these outcomes. The statement that implementation of disease management leads to the targeted outcomes was rated a mean of 5.69 (±0.51) (1-7 scale), denoting that professionals believe they can successfully implement COPD disease management. Expectancy was rated a mean of 6.10 (±0.75) (1-7 scale), which implies that disease management is seen as an effective tool in improving outcomes. These measures add up to an overall professional commitment score of 124.8 (±28.0). Comparing baseline and post intervention scores showed that professional commitment ($p=0.02$) and valence ($p=0.009$) had improved significantly after intervention (Table 6.1).

Organisational context

At baseline, most professionals (62%) indicated that their practice is best characterised by a group culture; 23% indicated their practice culture as developmental. A rational culture and a hierarchical culture each were perceived by only eight per cent. Questions related to commitment to quality improvement were rated with a mean of 3.79 (±0.47) on a 1-5 scale; scores for the four items ranged from 3.40 (±0.57) to 3.91 (±0.57). These scores indicate a relatively high commitment to quality, involving staff members and supported by strategy. With regard to climate, professionals gave a rating of 2.96 (±0.29) on a 1-4 scale for the expectation of a somewhat positive collegial response when they would initiate behaviours and perform tasks related to COPD disease management. After the intervention, the climate had improved significantly ($p<0.001$). No significant changes were found on culture and commitment to quality improvement (Table 6.1).

Programme implementation

Table 6.1 also summarises the extent to which the professionals felt that the disease-management programme was actually implemented (process changes). Overall, subscale scores at baseline

Table 6.3 Zero-order correlations between independent en dependent variables (N=52)

	1. Group culture T0	2. QI Commit-ment T0	3. Climate T0	4. Δ Group culture	5. Δ QI Commit-ment	6. Δ Climate	7. Professional commitment T0	8. Δ Professional commitment	9. Δ Self-management support	10. Δ Decision support	11. Δ Delivery system design	12. Δ Clinical information systems
2. QI Commitment T0	-0.17											
3. Climate T0	0.01	0.15										
4. Δ Group culture	-0.20[3]	-0.07	0.26[2]									
5. Δ QI Commitment	-0.02	-0.48[1]	-0.03	0.14								
6. Δ Climate	0.22[3]	-0.07	-0.25[2]	-0.17	0.08							
7. Professional commitment T0	-0.06	0.07	0.24[2]	-0.18	-0.04	0.31[2]						
8. Δ Professional commitment	-0.00	0.18	-0.14	0.02	0.23[3]	-0.04	-0.41					
9. Δ Self-management support	0.35[1]	-0.10	0.22[3]	0.05	0.04	0.07	0.18[3]	-0.03				
10. Δ Decision support	0.21[3]	0.04	0.22[3]	-0.12	0.14	0.03	0.13	0.19[3]	0.43[1]			
11. Δ Delivery system design	0.46[1]	-0.09	0.18	0.07	0.07	0.06	0.13	0.14	0.79[1]	0.66[1]		
12. Δ Clinical information systems	0.21[3]	0.08	0.18	-0.17	-0.02	0.11	0.35[2]	-0.02	0.72[1]	0.57[1]	0.77[1]	
13. Δ Disease management	0.36[1]	-0.02	0.23[3]	-0.04	0.06	0.06	0.22[3]	0.08	0.87[1]	0.76[1]	0.94[1]	0.89[1]

[1] Correlation is significant at the 0.01 level (1-tailed); [2] Correlation is significant at the 0.05 level; [3] Correlation is significant at the 0.10 level (1-tailed).

Table 6.4 Determinants of process changes from hierarchical regression analyses (standardised regression coefficients)

Variables	Self-management support	Decision support	Delivery system design	Clinical information systems	Disease management
Group culture T0	0.38[2]	0.21	0.52[1]	0.22	0.40[2]
QI Commitment T0	-0.11	0.03	-0.10	0.03	-0.05
Climate T0	0.15	0.23	0.08	0.12	0.16
Δ Group culture	0.12	-0.14	0.19	-0.09	0.03
Δ QI Commitment	-0.03	0.13	-0.05	0.00	0.01
Δ Climate	-0.03	-0.04	-0.10	-0.03	-0.07
Professional commitment T0	0.26	0.19	0.34[2]	0.38[2]	0.34[3]
Δ Professional commitment	0.12	0.27	0.31[3]	0.15	0.25
Adjusted R^2	0.07	0.04	0.22	0.05	0.12

[1] = $p < 0.01$; [2] = $p < 0.05$; [3] = $p < 0.10$ (1-tailed) PAIRWISE.

ranged from 4.45 (information systems) to 5.80 (decision support). This indicates that basic support for COPD disease management was present, for example facilitating access to evidence based guidelines or providing educational materials to patients.[19] Scores for all elements – self-management support, decision support, delivery system design and clinical information systems – improved significantly after intervention, with delivery system design to the highest degree. Changes in self-reported self-management support and actual application of patient education in practice correlated significantly (*r* =0.38, p<0.01). Changes in decision support correlated significantly with provision of inhalation-instruction (*r* =0.52, p<0.01) and changes in delivery system design correlated significantly with the proportions of patients regularly followed-up (*r* =0.42, p<0.01). In addition, process measures showed that all patients did get spirometry as indicated by guidelines, validating reported improvements in decision support.

Professional commitment to changing chronic illness care

Table 6.3 presents zero-order correlations between all variables of the model (Figure 6.1). It shows that climate baseline (*r* =0.24, p<0.05) and climate change scores (*r* =0.31, p<0.05) correlate significantly with professional commitment at baseline. Changes in commitment to quality improvement and changes in professional commitment correlate marginally significantly with each other (*r* =0.23, p<0.10). No significant correlations were found between group culture and professional commitment. Furthermore, (marginal) significant correlations are found between organisational or professional factors and process changes, except for decision support.

Table 6.4 shows the results of the regression analyses that explored whether organisational context and professional commitment could be predictors of changes in processes of care. In order to compare the magnitude of the effects of various independent variables, we presented the standardised regression coefficients from the models. In the final model, group culture at baseline appeared to be a significant predictor of process changes in self-management support, delivery system design and disease management (total score), with standardised regression coefficients of 0.38, 0.52 and 0.40, respectively. In the multiple regression models for process changes in delivery system design, clinical information systems and disease management, (marginally) significant effects of professional commitment at baseline were found in the final model as well, with standardised regression coefficients of 0.34, 0.38 and 0.34, respectively. Total explained variance after adjustment was small; except for delivery system design (22%). Professional commitment was not identified as a mediator of organisational factors in influencing process changes.

Discussion

The aim of this study was to explore factors that contribute to success or failure of the implementation of disease-management programmes. COPD disease management was effective; all processes changed significantly. Furthermore, these exploratory results provide some support for the theoretically proposed associations between organisational, and professional factors, and the degree of process changes. The presence of a group culture and professional commitment were indeed associated with positive changes in processes of care. Moreover, these factors were found to be significant predictors of process changes to a moderate degree. The significant effect of group culture on process changes can be explained by a more autonomous way of working within a group culture; fewer rules and agreements enhance implementation of improvements. Health care cultures that emphasise group affiliation, teamwork, and coordination have been associated with more complete implementation of quality improvement.[17 23] Accordingly, professional commitment was associated with more complete disease management implementation. As this association was not confirmed for all process changes, it would seem that the professionals' commitment to change is determined by particular characteristics of the interventions (self-management, guidelines, information technology) which may promote or hamper their actual adoption. This is widely discussed in various theories on involving professionals in implementation of innovations.[24]

Previous research identified a number of barriers to professionals' commitment in changing chronic illness care.[25] The present study finds some evidence that a supportive climate is associated with professional commitment, implying that peer support is an important motivator of professional commitment. In contrast to culture, climate is an individual perception of the day-to-day practice group environment. It is therefore interesting that a supportive climate stimulates professionals to engage in improving chronic illness care. The finding that change in commitment to quality improvement is associated with change in professional commitment confirms our initial hypothesis; quality activities within a practice group do support implementation of disease management. Various associations were found between organisational factors and professional commitment on the one hand, and changes in processes of care on the other, providing support for our theoretical model. No associations were found between professional and organisational factors and changes in decision support, probably due to only small changes in this parameter. A high baseline score left little room for improvement. General practices apparently are rather used to working with guidelines, as a major tool for making clinical decisions and improving patient care.[26]

One of the critical factors for better chronic disease management is the effective use of specialised practice nurses.[27] This study shows that practice nurses strongly believe that one can really achieve the desired change in general practice, an attitude that may act as a catalyst to adapting disease management in primary care. Previous research showed that lack of outcomes expectancy was a possible barrier in implementing changes in health care. There was great variation, however, among patient groups, with positive results in the case of alcohol abuse prevention but not for clinical breast screening.[28] The present study shows that disease management is seen as an effective tool in improving outcomes in COPD care, as can be derived from high scores on expectancy and valence. Furthermore, significantly improved professional commitment and valence suggest that professionals' exposure to disease-management programmes may positively influence professionals' behavioural intention to implement disease management, which is confirmed by previous findings.[29]

To date, most health care improvements have been targeted at factors related to individual professionals.[30] Still, achieving changes in health care typically will require interplay between a range of factors at different levels, i.e. professional level, organisational context, and the economic and political context.[24] To determine whether and to what extent change is achieved, we will need information on all levels.[9] This study provides a first empirical test of a theoretical model on professional *and* organisational aspects important in changing chronic illness care. By combining two models, this multilevel approach was effectuated. Yet, more research is needed, including research on internal and external incentives, such as financial support or quality targets.

Findings of this study must be interpreted in the light of several limitations. First, this study was an exploratory analysis as part of a research project on COPD disease-management programmes. Consequently, the sample of the study was small, leaving limited predictive power of organisational and professional factors in process changes. Furthermore, mass significance in the regression analyses may have led to too positive results. However, we explicitly tested associations derived from a theoretical model. To avoid type one errors, we set the significance level at 0.05 (one-tailed). Secondly, self-reported instruments were used. The ACIC measures professionals' perceptions; these perceptions may have been influenced by the professionals' expectations in addition to the actual implementation. However, professionals' perceptions were validated by available process measures. Even though these process measures only reflect part of the change in practice, we found associations between these measures and reported changes in related ACIC domains: self-management support, decision support and delivery system design. Whereas ACIC is a multidimensional survey, process measures only measure fragments of changes. In addition, structural changes within the programmes were also apparent, such as COPD consulting hours, specialised nurses, and a COPD registry within practices, which supports the changes reported by professionals by pointing to actual implementation of the programme. Thirdly, this study concerned pilot programmes. This may have biased the results, since professionals participating in pilot programmes may be assumed to have a fair degree of commitment right from the start. Yet, despite high baseline scores significant improvements in these pilots were found, which suggests improvement possibilities for practices which are less far ahead in disease management implementation. Hence, large-scale follow-up research is needed.

In conclusion, the present exploratory study showed that professionals significantly changed their systems for delivering care to COPD patients. Organisational context and professional factors proved to be instrumental to these changes. Group culture and professional commitment are important facilitators for implementation of COPD disease management in primary care.

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Chapter 7

Evaluating COPD Disease Management: Application of a Theoretical Model

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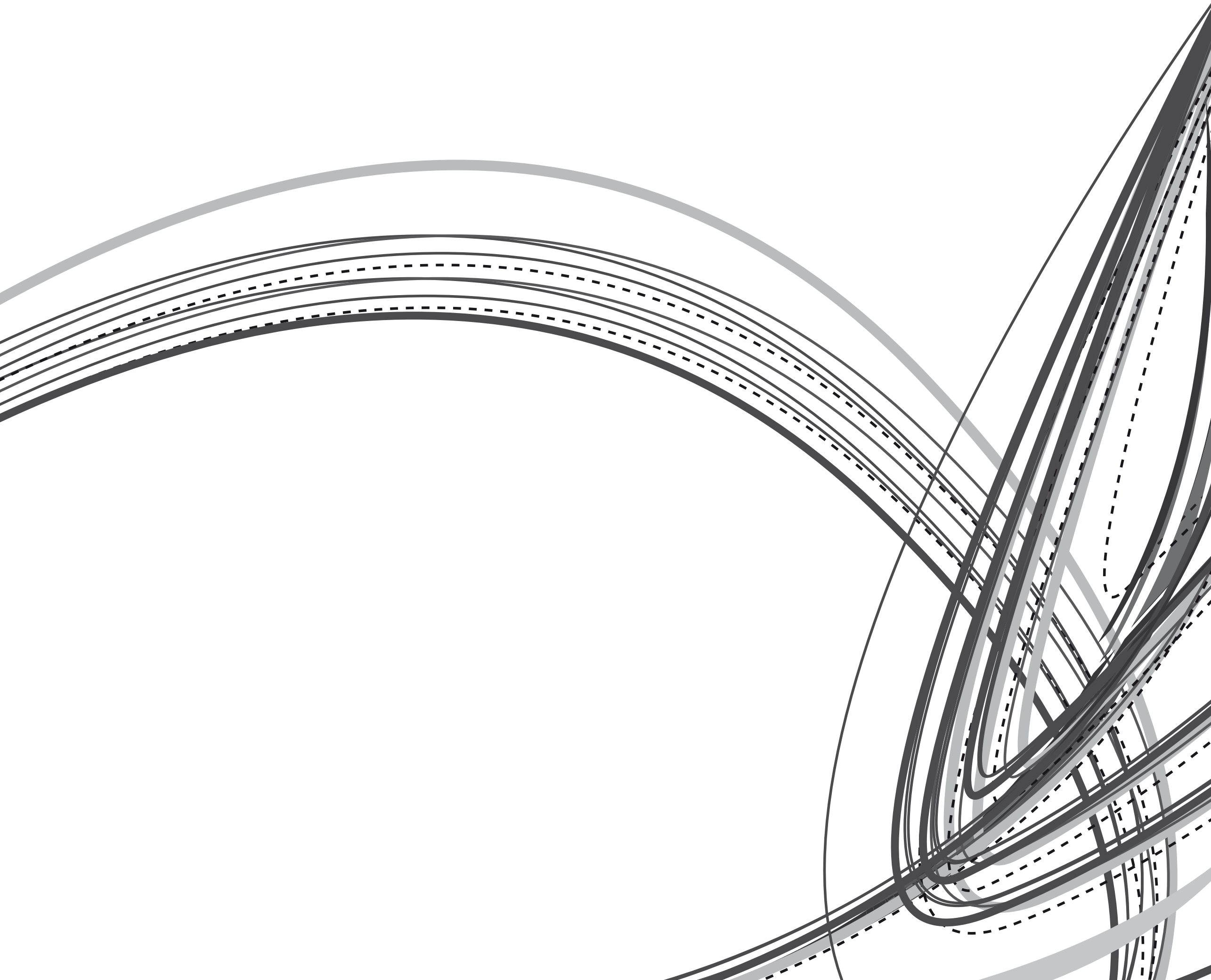

Abstract

Background: Disease-management programmes are heterogeneous in nature and often lack a theoretical basis. An evaluation model has been developed and tested empirically in which theoretically driven inquiries link disease-management interventions to outcomes. The aim of this study is to methodically evaluate the impact of a disease-management programme for patients with chronic obstructive pulmonary disease (COPD) on process, intermediate and final outcomes of care in a general practice setting.

Methods: A quasi-experimental research was performed with 12-months follow-up of 189 COPD patients in primary care in the Netherlands. The programme included patient education, protocolised assessment and treatment of COPD, structural follow-up and coordination by practice nurses at 3, 6 and 12 months. Data on intermediate outcomes (knowledge, psychosocial mediators, self-efficacy and behaviour) and final outcomes (dyspnoea, quality of life, measured by the CRQ and CCQ, and patient experiences) were obtained from questionnaires and electronic registries.

Results: Implementation of the programme was associated with significant improvements in dyspnoea ($p<0.001$) and patient experiences ($p<0.001$). No significant improvement was found in mean quality of life scores. Improvements were found in several intermediate outcomes, including investment beliefs ($p<0.05$), disease-specific knowledge ($p<0.01$; $p<0.001$) and medication compliance ($p<0.01$). Overall, process improvement was established. The model showed associations between significantly improved intermediate outcomes and improvements in quality of life and dyspnoea.

Conclusions: The application of a theoretical model enhances the design and evaluation of disease-management programmes aimed at improving health outcomes. This study supports the notion that a theoretical approach strengthens the evaluation designs of complex interventions. Moreover, it provides prudent evidence that the implementation of COPD disease-management programmes can positively influence outcomes of care.

Background

Due to aging of the population, numbers of persons suffering from chronic conditions are growing at astonishing rates. Chronic illnesses will be the primary cause of death and disability in the world by 2020.[1] Among the most common chronic diseases is chronic obstructive pulmonary disease (COPD), which represents an enormous burden on individuals, families and societies, by its impact on quality of life, health resource utilisation, and mortality.[2-4] The causes and maintaining factors of chronic conditions are complex; therefore a multifaceted, multidisciplinary and multi-institutional response is needed.[1] Models of care coordination, such as disease management, capture the complexity of providing health care for chronic conditions in a coordinated manner. They also underscore the importance of using multifaceted approaches as opposed to “magic bullet” or single interventions.[5] Multifaceted programmes offer different combinations of interventions directed at patients, professionals or the organisation of care.[6] Although these programmes vary widely in structure and style, the primary goals – to improve disease outcomes while containing overall healthcare costs – tend to be consistent.

Yet it is the very heterogeneity of the programmes that makes it hard to evaluate them and compare them on results. An evaluation model has therefore been developed to structurally evaluate disease-management programmes, in which theoretically driven inquiries link disease-management interventions to outcomes achievement.[6] In this chapter this model was applied to a COPD disease-management programme implemented in the ‘Gelderse Vallei’ region in central Netherlands. Seven general practices to that aim cooperated with the regional hospital and home care organisation. The programme includes three main features: patient education, protocolised assessment and treatment of COPD, and coordination of care. This study reports on the effects of the implementation of this programme on process, intermediate and final outcome indicators as derived from the evaluation model. It is hypothesised that patient-related and professional-directed interventions influence intermediate and eventually final outcomes of care.

Theoretical framework

Determining the effectiveness of complex interventions requires understanding of the components of an intervention and their interrelationships (“black box”).[6 7] The theoretically derived evaluation framework, which is based on social learning theories, links the disease-management components with the underlying mechanisms by which they influence outcomes, and proposes direct and indirect relationships among them. The framework has been described in detail elsewhere[6] and includes three key components: patient-related and professional-directed interventions, supported by the organisational design (Figure 7.1). Both patient-related and professional-directed interventions aim to alter behaviour through mechanisms such as gaining knowledge, skills and/or self-efficacy. Behavioural change is presumed to contribute to or to facilitate the attainment

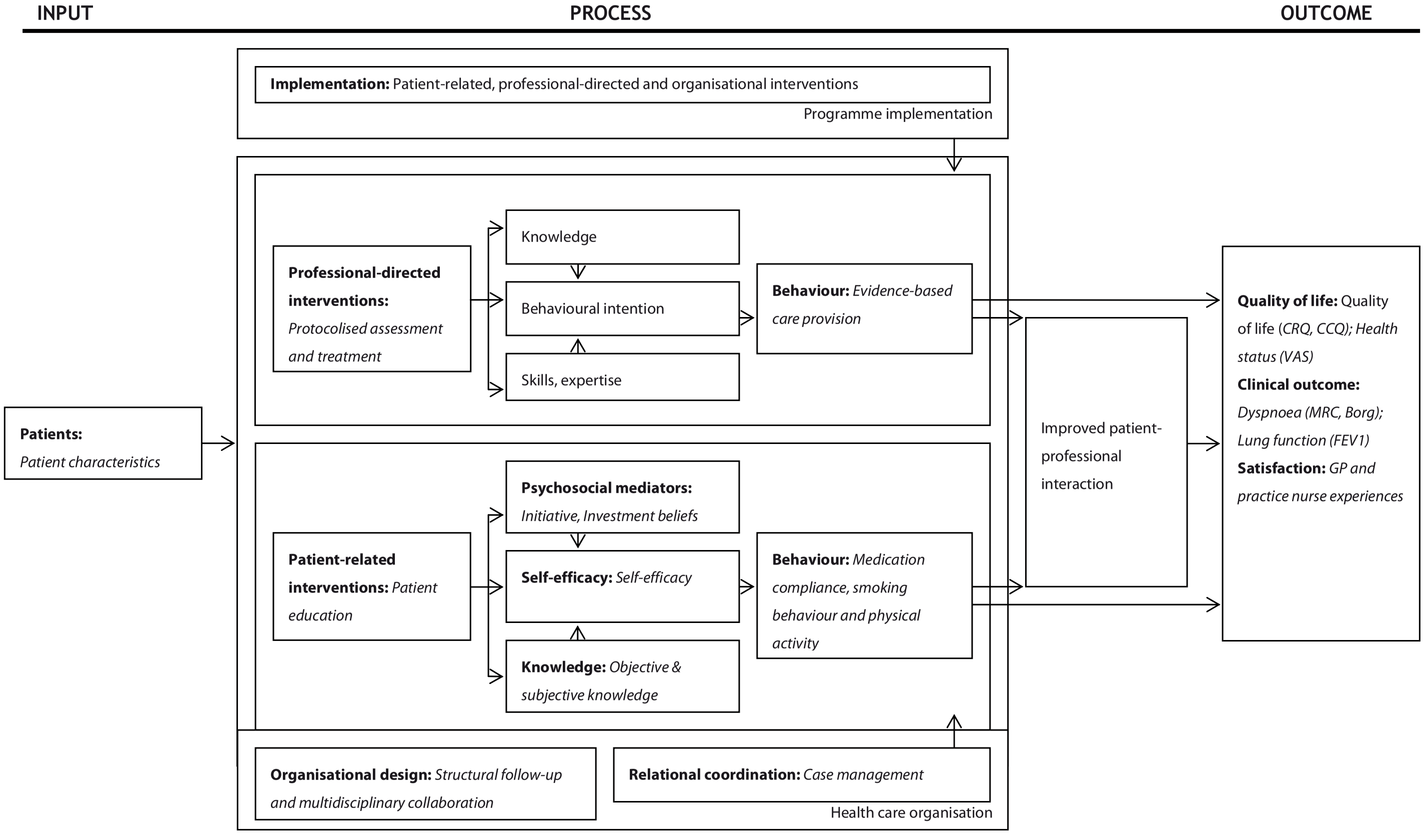

Figure 7.1 Disease management evaluation model for the 'Gelderse Vallei' region

of expected outcomes. The model also shows that organisational support may facilitate learning; moreover it can act as a catalyst to behavioural change. Next to that, the actual implementation of the COPD disease-management programme in the 'Gelderse Vallei' region will be examined through process evaluation. The various components and indicators defined are shown in Figure 7.1. A distinction was made between process (what is done), intermediate (procedural end point, i.e. behavioural change) and final outcome (end results of care, i.e. change in patient health status) indicators.[8] This is described in the method section.

Methods

Study design

The study was designed as an one-group pre-post test study.[9] Patient characteristics were assessed at baseline and controlled for. This exploratory design was chosen to test the theoretical basis and components of this complex intervention. An exploratory trial is also an opportunity to determine the consistency with which the intervention is delivered.[10] It was not possible to include a control group, because potential control regions were also working on COPD management, which would bias the measure of usual care.

Participants and setting

The programme was carried out in seven general practices (12 general practitioners (GPs)) in the 'Gelderse Vallei' region in central Netherlands. These practices cooperated with the regional hospital. The practices were supported by practice nurses of a regional home care organisation. Patients were recruited between April 2006 and August 2006. All known COPD patients, as well as individuals who satisfied predefined criteria (aged ≥ 40, previous use of COPD or asthma medication and International Classification of Primary Care (ICPC) codes COPD (R95) or asthma (R96)), were invited for diagnostic assessment. The practice nurses identified eligible patients supported by the GP and an electronic protocol. Patients with a confirmed diagnosis of COPD, according to Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria which include confirmation by spirometry[11], were invited to participate, and informed consent was obtained. Patients with serious co-morbidity, for instance congestive heart failure, were not eligible for inclusion.

Disease-management interventions

The COPD disease-management programme consisted of three facets (Figure 7.2): One, a *patient-related intervention* designed to increase patients' understanding of the condition and to teach them specific prevention or treatment strategies on smoking behaviour, medication usage, nutrition and physical activity. In practice this intervention was offered during each contact for at least fifteen minutes (patient-education). An information booklet was provided as well. Secondly, a *professional-directed intervention* designed to educate professionals on the guidelines and pro-

Patient-related intervention: *Patient education*

- More emphasis on systematic use of patient education, including the following topics: smoking behaviour, medication usage, nutrition and physical activity
  - Frequency: every 3 months
  - Duration: First contact ten minutes, follow-up meetings at least fifteen minutes
  - Provision of information booklet

Professional-directed intervention: *Protocolised assessment and treatment of COPD*

- Educational meetings GPs and practice nurses on the following topics: COPD management according to guidelines and application of spirometry. Practice nurses also concentrated on the provision of patient education: smoking behaviour, medication usage, nutrition and physical activity
  - Frequency: GP - three times a year; practice nurse – 6 days at the start
  - Duration: GP – two hours; practice nurse eight hours (each session)
- Active distribution of clinical practice guidelines
  - Supported by electronic registry system
- Audit and feedback by lung specialist/ peers
  - Every spirometry test to confirm COPD diagnosis was seen by the lung specialist for confirmation, additionally other spirometry tests could be send to the lung specialist when necessary
  - GPs received feedback data from their practice after the start of the programme and after 12 months

Organisational intervention: *Coordination of care*

- Arrangements for structural follow-up
- Periodical follow-up meetings at 3, 6 and 12 months with practice nurse. Multidisciplinary collaboration
  - Multidisciplinary care teams, each composed of a GP, practice nurse and a lung specialist
  - Revision of professional roles; more delegation of care from GP to practice nurse, and from lung specialist to GP. The practice nurses discussed their findings with GPs
- Case management
  - Care coordination by the practice nurse in collaboration with the GP

Figure 7.2 Disease-management interventions in the 'Gelderse Vallei' region

gramme (protocolised assessment and treatment of COPD). Over twelve months, GPs attended three courses on standardised COPD management and spirometry training. Before the introduction of the programme the practice nurses received six days of training in standardised COPD management and the provision of medical and non-medical treatment. The training was designed to reinforce knowledge on diagnosing COPD, assessing COPD severity, patient self-management, smoking cessation, follow-up, and planning possible action against exacerbations. Both GPs and practice nurses were trained in the application of spirometry. The implementation of the guidelines was supported by an electronic diagnostic and treatment protocol. Third, these interventions were supported by *organisational interventions* consisting of structural follow-up, case management and multidisciplinary collaboration. A multidisciplinary team cooperated in a system for coordinating diagnostic procedures, treatment, and ongoing patient management (coordination of care). The tasks and responsibilities of the members (GP, practice nurse and a pulmonologist) were described in a guideline-based protocol. The practice nurses performed diagnostic tests such as lung function measurements, assessed patients' conditions, provided disease-related education and advice, coordinated care, and organised follow-up meetings at 3, 6 and 12 months. They acted in conjunction with the GP who consulted the specialist when needed. Generally, telespirometry was used to confirm the diagnosis; the test results in the general practice were dispatched through a simple telephone call to the pulmonologist who was able to make a functional diagnosis.

Data collection

Data on patient intermediate outcomes as well as quality of life and satisfaction were collected by means of postal questionnaires. The following patient characteristics were also gathered: age, gender, education and marital status. Professional behaviour and clinical outcome data were obtained from an electronic registry, which was part of the software protocol for treatment and monitoring of COPD patients in participating practices. Process data were gathered by means of a survey among professionals.

Process

Actual exposure to the disease-management programme was evaluated by the Assessing Chronic Illness Care (ACIC) survey.[12] In this study, only the process elements reflecting the programme's interventions were included: self-management support (patient-related intervention), decision support (professional-directed intervention), as well as delivery system design and clinical information system (both organisational interventions). Professionals rated the 4 to 6 items per element on a 1 to 11 scale, with higher scores indicating greater implementation. A mean score for each element was obtained.

Intermediate outcomes

Compliance and disease-specific knowledge were measured using a validated Dutch-language instrument.[13] Objective knowledge was measured by means of 22 true or false questions about COPD and expressed as the proportion of correct answers, transformed into a 0-10 scale. Subjective knowledge was assessed by six questions on a five-point scale. Self-reported medication compliance and physical activity practice were both measured by numeric rating (0-10) in combination with questions on a five-point scale that were expressed as one overall score. Next to that, self-reported smoking behaviour was measured on a dichotomous scale. Psycho-social mediators and self-efficacy were assessed using three dimensions of the Self-Management Ability Scale (SMAS): investment (the ability to invest in longer-term benefits) and initiative beliefs (the ability to be self-motivating regarding the realisation of the dimensions of well-being), as well as self-efficacy.[14 15] The subscales each consist of five items rated on a six-point scale. A higher score indicated better ability.

Professional behaviour was measured from the degree to which GPs applied evidence-based care after the intervention. Professional adherence to protocolised assessment and treatment of COPD was measured by four main guideline aspects: GOLD classification with each COPD diagnosis, application of spirometry, prescription of airway medication and inspection of patients’ medication usage and technique. The application of patient education was evaluated from the proportions of patients reporting they had received clear information and information booklets. Continuity of care was assessed from the proportions of patients regularly followed. The indicators are expressed as percentage of patients that received a specific intervention.

Final outcomes measures

A validated Dutch version of the self-reported Chronic Respiratory Questionnaire (CRQ-SR) was used to measure quality of life.[16 17] The CRQ-SR is made up of 20 questions and measures four dimensions relating to dyspnoea (5), emotional function (7), fatigue (4), and mastery (4). For every question there are seven response categories that score from 1 to 7; higher scores indicated better quality of life. A change of 0.5 in each dimension has been calculated as being the minimum clinically important difference (MCID).[17]

Additionally, the Clinical COPD Questionnaire (CCQ) was used, a self-administered multidimensional symptom control questionnaire that includes 10 questions in three domains: symptoms (4), functional (4) and mental state (2).[18] The total CCQ score, and the score on each of the three domains, varies between 0 (very good health status) to 6 (extremely poor health status). An average change in score of 0.4 for the total score has been shown to be the MCID.[18]

The EQ-5D visual analogue scale (VAS), a “thermometer” for eliciting a self-rating of health status, was used. Patients mark their perceived health status on a line with anchors 0 (worst imaginable health state) and 100 (best imaginable health state).[19]

The Medical Research Council (MRC) scale is a commonly used, validated, ordinal scale on which patients rate the type and magnitude of their dyspnoea according to five grades of increasing severity: 0 indicating ‘breathlessness with strenuous exercise’ to 5 representing ‘breathlessness keeping patients from leaving the house’.[20] Dyspnoea was also measured by the modified Borg scale, a 0 to 10 rated scale to measure and evaluate patients’ dyspnoea.[21]

Lung function was assessed by measuring the forced expiratory volume in one second (FEV^1) with the use of spirometry and expressed as FEV^1 percentage predicted, according to established criteria.[11] FEV^1 was measured from a series of at least three forced expiratory curves that had an acceptable start of test and were free from artefact.

Patients’ experiences on quality of care were measured using a self-administered questionnaire, the QUOTE (QUality Of care Through the patients’ Eyes) COPD.[22] In this study, only indicators reflecting aspects of quality of care specifically targeted by the programme’s interventions were included, namely coordination and accessibility of care, education on medication use and non-medical self-care.

Statistical analyses

Comparisons for all study variables were made between baseline and 12 months post-intervention using paired-sampled *t*-tests and Wilcoxon signed rank tests (two-sided; α= 0.05) where appropriate. Next to that, baseline and post-intervention data were compared with regard to changes in intermediate and outcome measures, using regression analyses to determine if the model's propositions depicted are consistent with the data. Regression analyses were performed based on changes in indicators; all significant differences in intermediate indicators (independent variables) were related to differences in clinical outcomes, functional outcomes and patient satisfaction, as subsequent dependent variables. Zero-order correlations were calculated to assess the strength of the relationships between significantly changed independent variables (investment beliefs, subjective and objective knowledge, and medication compliance) and dependent variables. When significant correlations were found the independent variables entered the regression model. Additional analyses showed within group variation in quality of life making it feasible to perform these regression analyses. Scores are arranged so that positive correlations indicate a positive relation. All analyses were performed at patient level. Data processing and analysis were performed using SPSS 13 for Windows. A prior significance level of 0.05 was used for all statistical tests.

Results

Patient inclusion, assignment and follow-up

Two hundred fifty-nine patients were found eligible to participate in the disease-management programme, of whom 189 (73%) consented to participate in the study. Participants did not significantly differ at baseline from the patients that did not participate in the study. Most were males, over 65 years old, and suffered from mild or moderate COPD.

Table 7.1 shows baseline characteristics of all participants and those for whom data collection was complete (150/189; 79%). A comparison of drop-outs with patients that completed the study revealed no clinical differences on any baseline characteristics and quality of life measures. The most common reason for dropping out of the study was unwillingness to complete questionnaires.

Process evaluation

Table 7.2 summarises the extent to which the caregivers felt that the disease-management programme was actually implemented. Although all scores increased, those for decision support and self-management support changed the least and were not significant. Scores on organisational interventions, delivery system design and clinical information system, had improved significantly after 12 months ($p=0.012$ and $p \leq 0.001$, respectively).

Table 7.1 Baseline characteristics

Baseline characteristics	Total population (n = 189)	Completed data (n = 150)
	Mean ±SD	Mean ±SD
Age	66 (± 11)	66 (± 11)
Lung function (FEV_1)	75.7 (± 18.6)	75.4 (± 18.6)
Tiffeneau	63.6 (± 11.4)	63.9 (± 11.1)
Dyspnoea	1.68 (± 1.09)	1.65 (± 1.07)
Body Mass Index	27.0 (± 4.2)	27.1 (± 4.3)
	% (n)	% (n)
Sex		
Male	65 (122)	67 (100)
Female	35 (67)	33 (50)
Marital status		
Married or equivalent	80 (149)	81 (120)
Widowed	10 (19)	11 (16)
Divorced	2 (3)	2 (3)
Never married	8 (15)	6 (9)
Educational level greater than high school diploma	24 (46)	26 (39)
Smoking status		
Non or Ex-smoker	74 (139)	77 (115)
Current smoker	26 (50)	23 (35)
COPD severity		
GOLD 1 (Mild)	47 (90)	46 (69)
GOLD 2 (Moderate)	40 (75)	43 (64)
GOLD 3 (Severe)	13 (24)	11 (17)

Table 7.2 Process improvement

Dimension[†]	Baseline (Mean ±SD)	12 months (Mean ±SD)	Change (95% CI)	p-value
Patient-related (Self-management support)	5.97 (± 2.44)	6.93 (± 2.11)	0.95 (-0.46 ; 2.36)	p = 0.163
Professional-directed (Decision support)	6.88 (± 1.40)	7.86 (± 1.63)	0.98 (-0.13 ; 2.09)	p = 0.079
Organisational (Delivery system design)	6.67 (± 1.45)	7.97 (± 1.51)	1.30 (0.35 ; 2.24)	p = 0.012*
Organisational (Clinical information system)	5.83 (± 1.17)	7.03 (± 1.23)	1.20 (0.68 ; 1.73)	p = 0.000*

[†] Positive change means improvement

Intermediate outcomes

Objective and subjective measurement of knowledge improved significantly (p=0.002 and p≤0.001, respectively). Variables related to self-efficacy and psychosocial beliefs remained the same or improved, the difference in investment beliefs being statistically significant (p=0.049). Compliance with the medication regimen has improved after 12-months follow up (p=0.003), unlike smoking status or physical activity practice (Table 7.3).

With regard to professional behaviour, all patients were diagnosed with spirometry and were classified according to the GOLD criteria. Airway medication was mostly prescribed in line with guideline recommendations (92%). Correct use of medication by patients was checked for 92% of the patients. Seventy-eight percent of the patients reported to have received clear information (78%), however only 56% had received an information booklet. Ninety-two percent of patients regularly attended follow-up meetings.

Final outcomes of care

Table 7.4 summarises the findings for all clinical outcomes, quality of life variables and patient experiences, comparing the baseline measurement with the 12-month measurement and determining statistical significance of the difference. Dyspnoea had improved significantly on both MRC ($p \leq 0.001$) and Borg scale ($p \leq 0.001$). A significant decline with regard to lung function was found. Clinically and statistically significant improvements were not found on quality of life scores (according to the CRQ, CCQ and VAS). Overall, patient experiences with practice nurses, as measured by QUOTE, had improved ($p < 0.001$). More specifically, improvements were found on the subscales accessibility, education on medication use and on non-medical self care. Improvement on patient experiences with GPs was only found for the subscale on accessibility ($p = 0.016$).

Table 7.3 Changes in intermediate outcomes

Indicator	Baseline (Mean ±SD)	12 months (Mean ±SD)	Change (95% CI)	p-value
Psycho-social mediators[2]				
Initiative beliefs (scale 1-6)	4.04 (± 0.74)	4.10 (± 0.77)	0.06 (-0.06 ; 0.18)	p = 0.335
Investment beliefs (scale 1-6)	4.13 (± 0.76)	4.24 (± 0.74)	0.10 (0.01 ; 0.20)	p = 0.049*
Self-efficacy[2]				
Self-efficacy (scale 1-6)	4.24 (± 0.74)	4.23 (± 0.78)	-0.01 (-0.11 ; 0.10)	p = 0.865
Knowledge on COPD[2]				
Subjective knowledge (scale 1-5)	2.84 (± 0.84)	3.22 (± 0.82)	0.38 (0.24 ; 0.51)	p = 0.000*
Objective knowledge (scale 1-10)	4.49 (± 2.10)	4.92 (± 2.03)	0.43 (0.16 ; 0.69)	p = 0.002*
Behaviour				
Smoking status[1] (% smoking)	23%	22%	1%	p = 0.180
Medication compliance[2] (scale 1-5)	4.41 (± 0.63)	4.58 (± 0.58)	0.17 (0.05 ; 0.28)	p = 0.003*
Physical activity[2] (scale 1-5)	2.80 (± 0.54)	2.85 (± 0.53)	0.05 (-0.02 ; 0.12)	p = 0.167

[1] Negative change means improvement; [2] Positive change means improvement

Testing the Evaluation Model's propositions

Table 7.5 presents only those intermediate indicators for which statistically significant associations were found in the hierarchical regression analyses. Since medication compliance did not correlate significantly with any of the model variables, it was excluded from the analyses.

Table 7.4 Changes in outcomes of care

Outcome indicator	Baseline (Mean ±SD)	12 months (Mean ±SD)	Change (95% CI)	p-value
Quality of life				
CRQ[2] (scale 1-7)				
CRQ (dyspnoea)	5.68 (± 1.33)	5.70 (± 1.33)	0.02 (-0.13 ; 0.16)	p = 0.823
CRQ (emotional function)	5.39 (± 1.05)	5.34 (± 1.10)	-0.04 (-0.19 ; 0.10)	p =0.551
CRQ (fatigue)	4.79 (± 1.27)	4.85 (± 1.27)	0.53 (-0.10 ; 0.21)	p = 0.515
CRQ (mastery)	5.63 (± 1.07)	5.64 (± 1.07)	0.01 (-0.17 ; 0.19)	p = 0.895
CCQ (total)[1] (scale 0-6)	1.38 (± 0.84)	1.45 (± 0.92)	0.07 (-0.05 ; -0.19)	p = 0.237
CCQ (symptoms)	1.86 (± 0.94)	1.83 (± 1.03)	-0.03 (-0.17 ; -0.11)	p = 0.686
CCQ (functional)	1.34 (± 1.11)	1.47 (± 1.16)	0.13 (-0.02 ; 0.28)	p = 0.087
CCQ (mental state)	0.54 (± 0.83)	0.66 (± 0.86)	0.11 (-0.02 ; 0.24)	p = 0.088
Health Status (VAS)[2] (scale 0-10)	6.99 (± 1.34)	6.97 (± 1.54)	-0.03 (-0.22 ; 0.16)	p = 0.758
Symptoms				
Dyspnoea (MRC) (scale 0-5)[1]	1.61 (± 1.06)	1.30 (± 1.07)	-0.31 (-0.47 ; -0.15)	p < 0.001*
Dyspnoea (Borg) (scale 0-10)[1]	2.42 (± 1.62)	2.01 (± 1.28)	-0.41(-0.65 ; -0.17)	p = 0.001*
Lung function (FEV_1 % predicted)[2]	76.93 (± 17.96)	73.59 (± 18.53)	-3.34 (-4.94 ;-1.75)	p < 0.001*
Patient experiences[2]				
General practitioner (scale 0-10)	6.95 (± 1.69)	7.00 (± 1.70)	0.46 (-0.32 ; 0.41)	p = 0.804
Practice nurse (scale 0-10)	5.60 (± 1.87)	7.15 (± 1.44)	1.55 (0.82 ; 2.28)	p < 0.001*

[1] Negative change means improvement; [2] Positive change means improvement

Changes in CRQ dyspnoea could be predicted by investment beliefs (β=0.26, CI=0.01 to 0.51, p=0.04). Subjective knowledge (β=0.24, CI=0.01 to 0.47, p=0.038) and investment beliefs (β=0.31, C=0.01 to 0.61, p=0.047) were, in turn, predictors of CRQ Mastery. In addition to the CRQ, we also analysed quality of life outcomes obtained with the CCQ questionnaire. Changes in CCQ Total (β=0.15, CI=0.01 to 0.30, p=0.045) and CCQ mental (β=0.18, CI=0.01 to 0.34, p=0.036) could be predicted by subjective knowledge. Subjective knowledge and investment beliefs both were predictors of CCQ functional state (β=0.30, CI=0.11 to 0.48, p=0.002 and β=0.27, CI=0.03 to 0.51, p=0.001, respectively). The regression analyses with health status as a dependent variable showed correlations with subjective knowledge (β=0.29, CI=0.05 to 0.53, p=0.019). MRC dyspnoea as a dependent variable showed no significant predictors, on the other hand objective knowledge was a significant predictor (β=0.19, CI=0.02 to 0.36, p=0.030) of Borg dyspnoea.

Table 7.5 Association between significantly improved intermediate outcomes and final outcomes of care

Outcome Indicators	Associated Intermediate indicators	β (95% CI)	R^2
CRQ Dyspnoea	Investment beliefs*	0.26 (0.01-0.51)	.06
CRQ Mastery	Subjective knowledge* Investment beliefs*	0.24 (0.01-0.47) 0.31 (0.01-0.61)	.08
CCQ Total	Subjective knowledge*	0.15 (0.01-0.30)	.07
CCQ Mental state	Subjective knowledge*	0.18 (0.01-0.34)	.04
CCQ functional state	Subjective knowledge* Investment beliefs*	0.30 (0.11-0.48) 0.27 (0.03-0.51)	.13
Health Status (VAS)	Subjective knowledge*	0.29 (0.05-0.53)	.08
Borg	Objective knowledge*	0.19 (0.02-0.36)	.07

*p < .05; **p < .01 (2-tailed) PAIRWISE

Discussion

The objective of this study was to evaluate the effectiveness of a disease-management programme for COPD patients according to the evaluation model and to explore associations between the model elements. Implementation of the programme was associated with significant improvements in dyspnoea and patient experiences with the practice nurses, whereas quality of life measures remained stable. It would seem, therefore, that symptoms may improve despite worsening of lung function parameters.[23] COPD is a progressive disease and lung function can be expected to worsen over time.[24]

Improvements were also found in several intermediate outcomes, including investment beliefs, disease-specific knowledge and medication compliance. The model associations were examined, and investment beliefs and subjective knowledge proved to be predictors of quality of life and dyspnoea. Some were not tested due to absence of significant improvements in intermediate outcomes.

The findings in our study are to some extent consistent with results from other studies on the effectiveness of COPD disease management, which are limited in number. Many studies focus on only one component.[25] Disease-management programmes have often been reported to improve patient satisfaction and process measures[26], but results on quality of life were inconclusive.[25]

This study presents an example of a theory-based evaluation of disease management. This in contrast with studies on other complex interventions that are often defined pragmatically and lack any clear theoretical basis.[27] Unfolding the black box of disease management, by the application of an evaluation framework, clarified the content, application, and setting of the programme and helped the interpretation of the outcome results. Furthermore, process, intermediate as well as final outcome indicators were selected on theoretical grounds.

Several factors might have influenced the effect size of the programme in this study. The multidimensional and multidisciplinary nature of disease management in addition to the amount of time it takes to detect changes, presents further challenges in developing an evidence base within a time and financially limited research project. The 12 months follow-up period may have been too brief to observe all changes resulting from the intervention, since major effects of disease-management interventions are expected to occur in the long term.[28] Over time, changes found in intermediate outcomes may be predictors of improvements, particularly in quality of life. Moreover, the patients in this study had less severe disease than those in some other studies, potentially reducing possibilities to detect improvement in our sample. And finally, even though all process implementation measures improved, full implementation of the programme was not always reached. For example, evidence-based care provision by professionals was hindered by distribution problems of the information booklet to the practice nurses.

Furthermore, intensity of the patient-related intervention, which is crucial for improving skills, ability to cope with illness, and health status[11], may have been too low. This would explain why changes in self-efficacy were not observed. And even though physical activity is an important predictor of outcomes in COPD care[29], it did not change significantly as a result of the intervention. Greater attention to physical activity and smoking cessation is indicated, therefore. Comprehensive self-management programmes seem most promising to this end.[30]

It is difficult to isolate elements of the programme that were more important than others. Easy access to the GPs and practice nurses, as well as more focused objectives, are likely to be beneficial. A critical factor was the development of the patient's relationship with their practical nurses, as shown from significantly improved satisfaction. The perception of continuity of care and consistency of patient support enabled knowledge gain, better use of medication and investment beliefs.

Findings of this study must be interpreted in the light of several limitations. First, the lack of a control group means that it can not be assumed that positive effects of this study were solely due to the programme. Theoretically, the observed changes could also have been caused by other factors.[31] There is no reason to assume, however, that elements such as the introduction of new medication or changes in the insurance system occurred that could have caused improvements of comparable magnitude. A randomised controlled trial would be required to give a definitive answer to this question, but the natural heterogeneity of the intervention makes experimental methods less helpful in understanding the effectiveness.[32] Yet, a theoretically driven approach, as used in this study, to understanding complex social interventions and their effects is very valuable. Second, self-reported instruments were used. Self-reporting of medication and exercise behaviour must be interpreted as an estimate of particular behaviours. Still, the multi-item scales used met standards for reliability, and support for validity has been reported for several measures.[13 14 17 18] And finally, not all proposed model associations could be tested. Since the implementation of the electronic registry was part of the intervention, we were able to measure final professional behaviour only. On the other hand, the evaluation of process changes led to valuable information on changes in care provision.

Conclusions

The application of a theoretical model improves the design and evaluation of disease-management programmes. It helps to understand the context and the processes of the intervention, and to select the appropriate indicators for evaluation. Although results have to be interpreted with caution due to the research design, this study provides prudent evidence that the implementation of disease management for patients with COPD can positively influence outcomes of care. Moreover, stronger effects are expected in the long run.

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Chapter 8

Evaluating Bottom-Up Implementation of Three Regional Disease-Management Programmes

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Abstract

Purpose: To evaluate a bottom-up implementation of three regional disease-management programmes on chronic obstructive pulmonary disease (COPD) based on bottlenecks experienced in professional practice.

Methods: We performed a multi-site comparison of three Dutch regional disease-management programmes combining patient-related, professional-directed and organisational interventions. Process (Assessing Chronic Illness Care (ACIC) survey) and outcome (disease specific quality of life (clinical COPD questionnaire, CCQ; chronic respiratory questionnaire, CRQ), MRC dyspnoea, and patients' experiences) data were collected of 370 COPD patients and their care providers.

Results: Bottlenecks in region A were mostly related to patient involvement, in region B to organisational issues and in region C to both. Selected interventions related to identified bottlenecks were implemented in all programmes, except for patient-related interventions in programme A. Within programmes significant improvements were found on dyspnoea and patients' experiences with practice nurses. Outcomes on quality of life differed between programmes: programme A did not show any significant improvements; programme B did show significant improvements on CCQ total ($P<0.001$), functional ($P=0.011$) and symptom ($P<0.001$), CRQ fatigue ($P<0.001$) and emotional scales ($P<0.001$); in programme C CCQ symptom ($P<0.001$) improved significantly, whereas CCQ mental score ($P<0.001$) deteriorated significantly. Regression analyses showed that programmes with better implementation of selected interventions resulted in relatively larger improvements in quality of life (CCQ).

Conclusions: Bottom-up implementation of COPD disease-management programmes is a feasible approach, which in multiple settings leads to significant improvements in outcomes of care. Programmes with better fit between implemented interventions and bottlenecks showed more positive changes in outcomes.

Introduction

Disease-management programmes have emerged as a new strategy to enhance quality of care for patients suffering from chronic conditions and to control health care costs. Integration of multiple interventions is essential to these programmes[1]; patient-related, professional-directed and organisational interventions have been found key components for success.[2 3] Until recently, they were usually implemented through top-down approaches in which the organisation of current practices and processes is basically redesigned with a standard set of interventions, rather than having professionals select the interventions that fit best with the desired changes in their practices.[4] It has been put forward, however, that organisational change in health care requires substantial effort and typically needs to be driven by enthusiastic groups and individuals.[5] Therefore, implementation of change should be linked to professionals' needs and motivation based on problems experienced in practice.[6] A bottom-up approach is thought to ensure that programmes are geared to current bottlenecks and based on evidence, as well as on professional commitment. This bottom-up approach contrasts with previous models of innovation by taking the bottlenecks in professional practice as points of departure. It focuses on locally supported interventions and stimulates professional ownership to flexibly configure their practices. However, to evaluate such complex multi-component interventions is a challenge.[7] This would seem to require more systematic use of theories in planning and evaluating the effects of disease-management programmes.[6] We developed an evaluation model that allows to determine relations between the implemented interventions and specific outcomes, such as improvement in quality of life.[2]

To investigate the usefulness of a bottom-up approach that combines the actions of professionals with those of scientific evaluation, we present our research on disease-management programmes in chronic obstructive pulmonary disease (COPD). COPD is a multi-component disease with a high prevalence that imposes an enormous burden on the patient, medical professionals and society in terms of morbidity, mortality, healthcare resource utilisation and costs.[8] Despite this burden and the availability of recommendations for better care, COPD remains a condition that is suboptimally managed.[9] It thus presents opportunities for quality improvement.

The aim of this chapter is to evaluate the bottom-up implementation of three regional COPD disease-management programmes in the Netherlands. The three programmes are captured in one single conceptual framework explicating the associations between existing bottlenecks, implementation of selected interventions and outcomes of care.

Methods

We performed a multi-site comparison of the effects of three different disease-management programmes. Data were collected before and after implementation of the programmes. This design has been found helpful to better understand relations between problems defined by professionals, implementation of the selected interventions, and effects of disease management in multiple representative settings.[10]

Disease-management programmes

The disease-management programmes studied are part of a Dutch national programme - Partners in Care Solutions (PICASSO) for COPD - that aims to optimise COPD care by supporting regional COPD projects. It offers a unique bottom-up approach for inducing and sustaining organisational change. This is based on bottleneck analyses with regional stakeholders (such as general practitioners, pulmonologists and patient platforms), consensus on corresponding disease-management interventions by local professionals, strategic planning and change management support, and structured evaluation through a theoretically derived framework for understanding how interventions affect outcomes of care.[2]

Bottleneck analysis

A standard, two-stage bottleneck analysis was performed for each of the three regions, named A, B, and C hereafter. First, project leaders invited regional stakeholders to select potentially missing preconditions for optimal COPD care and rank the ten most important ones on an online portal (1 point for the least important and 10 points for the most important one). Thirty-one professionals participated in region A; 47 in region B; 30 in region C. Second, the professionals prioritised the obtained regional bottleneck top-10 on the grounds of three aspects: 1) complexity: how complex is it to solve this bottleneck; 2) speed: how long does it take to implement the solution; and 3) impact: what degree of impact on patients' health is the solution expected to have. This was done

Table 8.1 Existing bottlenecks

Mean (SD)	**Complex**	**Speed**	**Impact**	**Score[1]**
Programme A (n = 31)[2]				
1. Smoking cessation is difficult	1.69	3.04	3.92	129
2. Smoking cessation programmes and medication gain too little effects	2.19	3.52	3.68	73
3. Insufficient awareness towards COPD as a treatable disease	2.75	3.50	3.42	72
4. Underestimation of COPD symptoms by patients	2.08	3.36	3.88	69
5. Care provider has insufficient time or means for instruction and education	2.83	4.40	4.50	69
6. Patients are not convinced of/ do not experience advantages of complying with therapy and lifestyle instructions	3.13	3.52	3.84	67
7. Division between primary and secondary care	2.19	4.04	4.21	64
8. Too little attention for / knowledge on specific COPD characteristics	3.31	3.68	4.09	63
9. No clear guidelines for care plans	3.23	3.67	3.71	49
10. The general public is unaware of COPD	2.54	3.38	3.95	47

Mean (SD)	**Complex**	**Speed**	**Impact**	**Score**[1]
Programme B (n = 47)				
1. No multidisciplinary approach to COPD care	2.31 (0.91)	3.27 (0.94)	3.86 (0.68)	131
2. Smoking cessation is difficult	1.75 (0.63)	3.33 (1.04)	3.77 (0.79)	126
3. Insufficient awareness towards COPD as a treatable disease	2.33 (0.83)	3.29 (1.03)	4.00 (0.46)	102
4. No clear agreements on responsibilities for instruction and information	3.46 (1.15)	3.89 (0.86)	3.79 (0.56)	97
5. Little / no attention for multidisciplinary COPD approach	2.33 (0.98)	4.04 (0.50)	4.11 (0.31)	96
6. No multidisciplinary follow-up of COPD (particularly physiotherapy and dietetics)	2.86 (1.03)	4.00 (0.46)	3.90 (0.40)	92
7. Spirometry is not standard performed with all COPD patients	3.07 (1.10)	4.28 (0.45)	4.18 (0.47)	80
8. Organisation of practice (no standard COPD follow-up system)	2.52 (1.13)	3.46 (1.05)	3.24 (0.95)	79
9. No clear guidelines for care plans	3.38 (1.03)	3.79 (0.67)	3.92 (0.27)	76
10. Care providers have insufficient time or means for instruction and education	2.66 (0.84)	4.24 (0.43)	4.13 (0.80)	72
Programme C (n = 30)				
1. Little / no attention for multidisciplinary COPD approach	1.67 (0.85)	3.31 (1.26)	3.54 (1.28)	133
2. No multidisciplinary follow-up of COPD (particularly physiotherapy and dietetics)	1.92 (1.00)	3.00 (1.11)	3.42 (1.04)	101
3. Underestimation of COPD symptoms by patients	2.00 (0.96)	3.15 (1.17)	3.62 (0.92)	62
4. No clear agreements on responsibilities for instruction and information	2.23 (1.05)	3.92 (1.14)	4.00 (0.46)	60
5. Insufficient awareness towards COPD as a treatable disease	1.54 (0.50)	3.08 (1.21)	3.31 (1.07)	56
6. The general public is unaware of COPD	1.83 (0.80)	2.33 (1.03)	2.00 (0.71)	55
7. Care providers have insufficient time or means for instruction and education	2.46 (1.45)	3.77 (1.25)	3.54 (1.08)	54
8. Organisation of practice (no standard COPD follow-up system)	1.62 (0.49)	3.15 (1.10)	3.92 (1.00)	45
9. Patients are not convinced of/ do not experience advantages of complying with therapy and lifestyle instructions	2.15 (1.10)	3.31 (1.07)	3.62 (0.92)	45
10. Smoking cessation is difficult	1.85 (0.36)	3.31 (1.07)	3.31 (1.07)	44

[1] Sum of distributed points by professionals in bottleneck analysis.

[2] Due to technical problems with the online scoring system, data on SD of programme A were lost.

using a 5-point scale. This prioritisation guided the selection by the local professionals of disease-management interventions to be incorporated in a strategic plan of action; ideally a combination of long-term goals and quick wins. Regions varied on complexity and themes, but hardly on speed and impact (Table 8.1). Region C assessed bottlenecks as more complex.

Setting and participants

Table 8.2 describes the three settings, the bottlenecks and the COPD disease-management interventions designed to tackle these bottlenecks. In each region, general practices cooperated with regional hospital(s) and were supported by their own practice nurses/ physician assistants or by practice nurses of a regional home care organisation. Regional settings determined inclusion of the stakeholders in the programmes, such as home care organisations. All programmes combined patient-related, professional-directed and organisational interventions, but the focus differed. Patients were systematically educated to increase their understanding of COPD and self-management skills. Professionals were educated on the guidelines and programme. These interventions were supported by organisational interventions, such as structural follow-up of COPD patients and revision of professional roles.

Study patients were those registered with the participating general practices, aged 40 or over with a confirmed diagnosis of COPD according to Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria, which are primarily based on spirometry.[11] Patients were recruited between April 2006 and December 2007. Informed consent was obtained. Patients with serious co-morbidity, for instance congestive heart failure, were excluded by the general practitioner according to protocol.

Data collection and measures

Process data were collected from (electronic) practice registrations after the introduction of the disease-management programme. The process measures were expressed as percentages of patients within practices who actually received a specific intervention, for example attending follow-up meetings. Furthermore, participating professionals completed the Assessing Chronic Illness Care (ACIC) survey[12] at baseline to identify areas for improvement and again at the end of the programme to assess process improvement. Process elements that reflected the programmes' interventions were included: self-management support (patient-related intervention), decision support (professional-directed intervention), as well as delivery system design and clinical information system (both organisational interventions).

The patients twice completed a set of outcome questionnaires – before the intervention and 12 months after the intervention. Quality of life was measured by disease-specific questionnaires (CCQ[13] and CRQ[14]). Dyspnoea was measured by the MRC Dyspnoea scale.[15] Patients' experiences with quality of care were assessed by means of a questionnaire, the QUOTE (QUality Of care Through the patients' Eyes) COPD.[16]

Statistical analysis

We used paired-sampled *t*-tests and Wilcoxon signed rank tests (two-sided; $\alpha= 0.05$), where appropriate, to analyse within-programme changes between baseline and 12 months post-intervention. We used multiple regression analyses for the between-programme comparisons with health outcomes (quality of life (CCQ) and MRC dyspnoea) as dependent variables. At the first step we entered dummy variables for the different programmes in the overall analysis. At the second step, process changes were added to these programme dummy variables. Finally, age, sex, smoking status and lung function (FEV_1 percentage predicted) were added to control for patient characteristics. Data

Table 8.2 Regional selection of disease-management interventions in the programmes

Setting	Bottlenecks[1]	Disease-management interventions
Programme A • 14 General practitioners 8 Practice nurses • 7 General practices 1 Hospital 1 Home care organisation • Rural area • Social-economic status: average	**Patient involvement** 1. Smoking cessation is difficult 2. Smoking cessation programmes and medication gain too little results 4. Underestimation of COPD symptoms by patients 6. Patients are not convinced of/ do not experience advantages of complying with therapy and lifestyle instructions	**Patient-related intervention:** Structured patient education • Education on smoking behaviour, medication usage, nutrition and physical activity by a practice nurse: Frequency: every 3 months; Duration: First contact ten minutes, follow-up meetings at least fifteen minutes. • Provision of purpose developed information booklet.
	Diagnostics and treatment 9. No clear guidelines for care plans	**Professional-directed intervention:** Regional diagnostic and treatment protocol supported by ICT • Implementation of clinical practice guidelines supported by an electronic registry system based on national standards. • Educational meetings GPs and practice nurses on COPD management according to guidelines and application of spirometry: Frequency: GP – three times a year; practice nurse – six days at the start; Duration: GP – two hours; practice nurse – eight hours (each session). • Audit and feedback by pulmonologist/ peers. To confirm diagnosis every spirometry was assessed by the pulmonologist. In follow-up spirometry tests could be sent to the pulmonologist when necessary. Peer feedback by benchmark report.
	Multidisciplinary collaboration 5. Care provider has insufficient time or means for instruction and education 7. Division between primary and secondary care	**Organisational intervention:** Regional arrangements for referral and task delegation • Revision of professional roles: Delegation of care from GP to practice nurse, from pulmonologist to GP • Arrangements for structural follow-up with practice nurse: Frequency: 3, 6 and 12 months • Multidisciplinary collaboration between GP, practice nurse and a pulmonologist. Care coordination by the practice nurse in collaboration with the GP
Programme B • 17 General practitioners 10 Practice nurses • 10 General practices 1 Hospital 1 Home care organisation • Rural area • Financial support of health care insurer • Social-economic status: average	**Patient involvement** 2. Smoking cessation is difficult 4. No clear agreements on responsibilities for instruction and information	**Patient-related intervention:** Patient education and information • Education on smoking behaviour, medication usage, nutrition and physical activity by a practice nurse according to a regional protocol: Frequency: at least twice a year; Duration: Fifteen to twenty minutes. • Provision of information brochures and patient diary. • Referral to smoking cessation sessions (group or nurse).
	Diagnostics and treatment 7. Spirometry is not standard performed with all COPD patients 8. Organisation of practice (no standard COPD follow-up system) 9. No clear guidelines for care plans 10. Care provider has insufficient time or means for instruction and education	**Professional-directed intervention:** Regional diagnostic and treatment protocol • Educational meetings GPs and practice nurses on: COPD management according to guidelines and application of spirometry: Frequency: GP – once a year; practice nurse – at least three times at the start; Duration: GP – two hours; practice nurse – four hours (each session). • Active distribution of clinical practice guidelines: A regionally developed guideline-based care protocol. • Audit and feedback by pulmonologist/ peers: Spirometry tests could be sent to the pulmonologist when necessary.

	Multidisciplinary collaboration 1. No multidisciplinary approach to COPD care 4. No clear agreements on responsibilities for instruction and information 5. Little / no attention for multidisciplinary COPD approach 6. No multidisciplinary follow-up of COPD (particularly physiotherapy and dietetics) 8. Organisation of practice (no standard COPD follow-up system)	**Organisational intervention:** Protocol for collaboration between primary and secondary care. • Arrangements for structural follow-up with practice nurse: Frequency: 1, 6 and 12 months. • Multidisciplinary collaboration between GP, practice nurse and a pulmonologist: Multidisciplinary care teams, including physiotherapist. • Revision of professional roles: Delegation of care from GP to practice nurse, from pulmonologist to GP. Care coordination by the practice nurse in collaboration with the GP.
Programme C • 8 General practitioners 2 Practice nurses 2 Practice assistants 2 Physiotherapists • 4 General practices 2 Hospitals 1 Physiotherapy practice • Rural/ urban area • Social-economic status: average	**Patient involvement** 3. Underestimation of COPD symptoms by patients 4. No clear agreements on responsibilities for instruction and information 9. Patients are not convinced of/ do not experience advantages of complying with therapy and lifestyle instructions 10. Smoking cessation is difficult	**Patient-related intervention:** A quit smoking programme and education by practice nurse • Education on smoking behaviour, medication usage, nutrition and physical activity by a practice nurse: Frequency: Four times a year; Duration: At least fifteen minutes. • Referral to smoking cessation group sessions. • Provision of information brochures. • Reactivation or advice by physiotherapist.
	Diagnostics and treatment 4. No clear agreements on responsibilities for instruction and information 8. Organisation of practice (no standard COPD follow-up system) 7. Care provider has insufficient time or means for instruction and education	**Professional-directed intervention:** Regional diagnostic and treatment protocol • Educational meetings GPs and practice nurses on: COPD management according to guidelines and application of spirometry: Frequency: GP – ones a year; practice nurse – at least three times at the start; Duration: GP – two hours; practice nurse – four hours (each session). • Active distribution of clinical practice guidelines: A regionally developed guideline-based care protocol. • Audit and feedback by pulmonologist/ peers: Spirometry tests could be sent to the pulmonologist when necessary.
	Multidisciplinary collaboration 1. Little / no attention for multidisciplinary COPD approach 2. No multidisciplinary follow-up of COPD (particularly physiotherapy and dietetics) 4. No clear agreements on responsibilities for instruction and information 8. Organisation of practice (no standard COPD follow-up system)	**Organisational intervention:** Regional arrangements for referral and task delegation • Multidisciplinary collaboration between GP, practice nurse, physiotherapist and a pulmonologist. Care coordination by the practice nurse in collaboration with the GP. • Arrangements for structural follow-up with practice nurse: Frequency: 3, 6 and 12 months. • Revision of professional roles: Delegation of care from GP to practice nurse, from pulmonologist to GP. Care coordination by the practice nurse in collaboration with the GP.

[1] Number of bottleneck corresponds to bottleneck top-10.

processing and analysis were performed using SPSS 15 for Windows. A prior significance level of 0.05 was used for all statistical tests.

Results

Patient inclusion, assignment and follow-up

Hundred and eighty-nine (73%) of the eligible patients in region A participated in the disease-management programme; 137 in region B (73%); 121 in region C (68%). Table 8.3 shows baseline characteristics of those participants for whom data collection was fully completed, 150 (79%), 112 (82%) and 108 (89%), respectively. There were no significant differences in baseline characteristics and quality of life measures between these participants and the "drop-outs". Most of the latter had been found unwilling to complete questionnaires. Significant differences between regions were found for sex, smoking status and COPD severity.

Table 8.3 Baseline characteristics

Baseline characteristics		**Programme A (n = 150)**	**Programme B (n = 112)**	**Programme C (n = 108)**	**Overall (n = 370)**
Mean (SD)					
Age		65.7 (10.7)	65.0 (11.5)	63.0 (10.8)	64.8 (11.0)
Lung function (FEV$_1$)		76.9 (18.0)	75.4 (16.1)	71.7 (16.3)	74.8 (17.0)
Tiffeneau		63.9 (11.1)	62.7 (12.6)	63.0 (8.7)	63.4 (10.9)
Dyspnoea		0.75 (0.90)	0.82 (0.91)	0.89 (0.95)	0.81 (0.92)
N (%)					
Sex	Male	100 (67)	70 (63)	55 (51)	244 (61)
	Female	50 (33)	42 (37)	53 (49)	144 (39)
Marital status	Married or equivalent	120 (81)	86 (77)	74 (70)	280 (77)
	Widowed	16 (11)	14 (12)	16 (15)	46 (12)
	Divorced	3 (2)	3 (3)	9 (8)	15 (4)
	Never married	9 (6)	9 (8)	7 (7)	25 (7)
Educational level	> high school diploma	39 (26)	30 (27)	24 (26)	93 (25)
Smoking status	Non or former smoker	115 (77)	73 (65)	55 (52)	243 (66)
	Current smoker	35 (23)	39 (35)	51 (48)	125 (34)
COPD severity	GOLD 1 (Mild)	69 (46)	45 (40)	41 (38)	155 (42)
	GOLD 2 (Moderate)	64 (43)	61 (54)	67 (62)	192 (52)
	GOLD 3 (Severe)	17 (11)	6 (5)	0 (0)	23 (6)

From bottlenecks to results

Table 8.4 summarises the findings for processes (ACIC) and clinical outcomes, quality of life variables and patients' experiences, comparing the baseline measurement with the 12-month measurement.

Table 8.4 Changes in processes and outcomes of care for COPD patients

	Programme A			**Programme B**			**Programme C***			*Overall*		
Mean (SD)	*pre*	*post*	*P value*	*pre*	*post*	*P value*	*pre*	*post*	*P value*	*pre*	*post*	*P value*
Chronic Illness Care (ACIC)†,§												
Self-management support	5.97 (2.44)	6.93 (2.11)	0.163	3.81 (2.14)	7.65 (1.50)	<0.001	4.33 (2.50)	6.48 (1.68)	0.008	4.77 (2.46)	7.15 (1.73)	<0.001
Decision support	6.88 (1.40)	7.86 (1.63)	0.079	5.61 (1.84)	7.57 (1.19)	<0.001	5.03 (2.69)	7.40 (0.94)	0.012	5.80 (1.95)	7.51 (1.29)	<0.001
Delivery system design	6.67 (1.45)	7.97 (1.51)	0.012	3.75 (1.71)	7.86 (1.02)	<0.001	4.11 (2.80)	7.50 (1.18)	0.002	4.78 (2.32)	7.74 (1.27)	<0.001
Clinical information system	5.83 (1.17)	7.03 (1.23)	<0.001	3.53 (1.75)	6.33 (1.52)	<0.001	4.18 (3.10)	6.73 (2.12)	0.017	4.45 (2.32)	6.70 (1.59)	<0.001
	n = 150			n = 112			n = 108			n = 370		
Quality of life†												
CRQ† - Dyspnoea (scale 1-7)	5.68 (1.33)	5.70 (1.33)	0.832	6.20 (0.95)	6.28 (0.85)	0.276				5.91 (1.19)	5.96 (1.17)	0.365
Emotional function	5.39 (1.05)	5.34 (1.10)	0.551	5.11 (1.16)	5.53 (0.90)	<0.001				5.27 (1.11)	5.43 (1.02)	0.011
Fatigue	4.79 (1.27)	4.85 (1.27)	0.515	5.04 (1.35)	5.47 (0.94)	<0.001				4.90 (1.31)	5.12 (1.17)	0.001
Mastery	5.63 (1.07)	5.64 (1.07)	0.895	5.54 (1.18)	5.75 (1.20)	0.090				5.59 (1.12)	5.69 (1.13)	0.177
CCQ‡ - Total (scale 0-6)	1.38 (0.84)	1.45 (0.92)	0.237	1.20 (0.71)	0.91 (0.62)	<0.001	1.26 (0.72)	1.13 (0.73)	0.038	1.29 (0.77)	1.18 (0.81)	0.005
Symptoms	1.86 (0.94)	1.83 (1.03)	0.686	1.90 (1.06)	1.43 (0.89)	<0.001	1.92 (0.87)	1.33 (0.84)	<0.001	1.88 (0.96)	1.56 (0.95)	<0.001
Functional	1.34 (1.11)	1.47 (1.16)	0.087	0.90 (0.81)	0.72 (0.72)	0.011	0.95 (0.87)	0.85 (0.92)	0.202	1.09 (0.97)	1.05 (1.02)	0.417
Mental state	0.54 (0.83)	0.66 (0.86)	0.088	0.39 (0.67)	0.24 (0.55)	0.053	0.54 (0.74)	1.29 (0.80)	<0.001	0.50 (0.76)	0.71 (0.86)	<0.001
Symptoms												
Dyspnoea (MRC) (scale 0-5)‡	0.75 (0.90)	0.50 (0.87)	0.001	0.82 (0.91)	0.57 (0.81)	0.002	0.89 (0.95)	0.63 (0.80)	0.001	0.81 (0.92)	0.56 (0.83)	<0.001
Lung function (FEV_1 % predicted)†	76.9 (18.0)	73.6 (18.5)	<0.001	75.4 (16.1)	76.0 (17.3)	0.545	71.7 (16.3)	73.0 (14.1)	0.304	74.8 (17.0)	74.2 (16.8)	0.314
Patient experiences†												
General practitioner (scale 0-10)	6.95 (1.69)	7.00 (1.70)	0.804	7.02 (1.85)	7.25 (1.58)	0.318	4.17 (2.76)	5.58 (2.69)	0.181	6.46 (2.23)	6.73 (2.05)	0.109
Practice nurse (scale 0-10)	5.60 (1.87)	7.15 (1.44)	<0.001	6.66 (1.71)	7.13 (1.42)	0.081	1.69 (2.37)	6.68 (2.47)	0.008	5.73 (2.35)	7.09 (1.54)	<0.001

*CRQ score were not obtained in programme C.

† Positive change means improvement; ‡Negative change means improvement

§range 0 - 11: 0 - 2 = limited support for chronic illness care; 3 - 5 = basic support; 6 - 8 = reasonably good support; 9 - 11 = fully developed chronic illness care

Most bottlenecks in region A were related to (organising) patient involvement (Table 8.2), and they were also ranked highest. Core of the programme was an ICT supported diagnostic and treatment protocol, including patient education. Process evaluation showed that all patients had been diagnosed by spirometry and were classified according to the GOLD criteria (n=150). Smoking status had been registered for all. Most of the patients were prescribed airway medication (92%). Inhalation instruction, when applicable, was given to 92% of the patients. However, only 56% received written information material. Ninety-two percent of patients regularly attended follow-up meetings. All ACIC sub-scores increased in programme A, but differences for decision support and self-management support did not reach statistical significance. With regard to programme outcomes, a significant decline in lung function was found; dyspnoea improved significantly. Quality of life scores did not significantly improve. Overall, patients' experiences with practice nurses improved.

Region B mostly identified and highly ranked organisational problems related to multidisciplinary collaboration (Table 8.2). This programme focussed on developing a multidisciplinary diagnostic and treatment protocol, including patient education and smoking cessation referral. All patients (n=112) had been diagnosed by spirometry and were classified by GOLD criteria. Smoking status had been registered for all. Information material was provided to 68% and 90% received inhalation instruction. Most of the patients regularly attended follow-up meetings (91%). Scores for all ACIC items improved significantly after intervention. As to programme outcomes, lung function did not change but dyspnoea improved significantly. Statistically significant improvements in CCQ total, functional and symptom, CRQ fatigue and CRQ emotional scales were found. The change in CCQ symptom score was also clinically relevant. Changes in patients' experiences did not reach statistical significance.

Bottlenecks identified for region C related to both patient involvement and organisational problems. Referral for smoking cessation and education by practice nurses were essential parts of the regional diagnostic and treatment protocol. Furthermore, patients were referred to a physiotherapist who gave reactivation or advice depending on patients' needs. All patients (n=108) had been diagnosed by spirometry and were classified by GOLD criteria. Smoking status had been registered for all. Airway medication was prescribed to 82% of the patients; 91% received inhalation instruction. Eighty-two percent received information material. Almost all patients regularly attended follow-up meetings (98%). As in programme B, scores on all ACIC items improved significantly after intervention. In this programme, no changes in lung function were found, whereas dyspnoea improved significantly. Statistically significant and clinically relevant improvements were found in CCQ symptom score as well. However, CCQ mental score deteriorated significantly. Patients' experiences with practice nurses improved significantly.

Regression results for programme outcomes

Table 8.5 shows the results of the regression analyses for changes in quality of life (CCQ) and dyspnoea. Programme A served as a reference, since it showed the smallest changes in quality of

Table 8.5 Regression analyses for changes in quality of life and dyspnoea

	Programme A														
	CCQ Total change			CCQ Symptoms change			CCQ Functional state change			CCQ Mental state change			MRC Dyspnoea change		
	β			β			β			β			β		
	Step 1	Step 2	Step 3	Step 1	Step 2	Step 3	Step 1	Step 2	Step 3	Step 1	Step 2	Step 3	Step 1	Step 2	Step 3
1. Programme B	0.25**	0.22**	0.22**	0.22**	0.20**	0.21*	0.18**	0.15*	0.15*	0.15**	0.12	0.11	0.00	0.02	0.00
Programme C	0.13*	0.12	0.10	0.28**	0.27**	0.25**	0.12*	0.11	0.09	-0.35**	-0.37**	-0.34**	0.01	0.01	-0.03
2. ACIC change		0.10	0.10		0.07	0.06		0.10	0.10		0.05	0.05		-0.05	-0.03
Medication (Y=1; N=0)		0.04	0.05		0.06	0.07		0.04	0.05		-0.03	-0.04		-0.02	0.03
Information (Y=1; N=0)		-0.03	-0.04		-0.03	-0.04		-0.04	-0.05		0.02	0.02		0.08	0.10
Follow-up (Y=1; N=0)		-0.07	-0.08		-0.05	-0.06		-0.07	-0.08		-0.02	-0.02		-0.03	-0.01
3. Age			-0.06			-0.01			-0.09			-0.05			-0.02
Sex (M=1; F=0)			0.04			0.00			0.04			0.07			-0.20**
Smoking status (Y=1; N=0)			0.09			0.09			0.11			-0.04			0.07
Lung function baseline			-0.02			-0.04			-0.01			-0.01			0.13*
ΔR^2		0.02	0.02		0.01	0.01		0.01	0.03		0.00	0.01		0.01	0.06
R^2	0.05	0.07	0.09	0.07	0.09	0.09	0.03	0.04	0.07	0.19	0.19	0.20	0.00	0.01	0.07
Sign. F change	8.65	1.21	1.23	12.77	0.89	0.84	4.60	1.81	2.08	35.90	0.37	0.64	0.00	0.61	4.51
df_1/df_2	2/315	4/311	3/307	2/319	4/315	3/311	2/319	4/315	3/311	2/316	4/312	4/308	2/292	4/288	4/284

*p < 0.05; **p < 0.01 (2-tailed) PAIRWISE life. The analyses showed a more positive effect of programme B on changes in CCQ total and CCQ functional state as compared with programme A. Both programme B and C had relatively larger improvements in CCQ symptom change. However, a decrease in CCQ mental state was found in programme C. Changes in MRC dyspnoea were associated with sex and lung function, in so far that being female and better lung function at baseline are related to improvements in dyspnoea. All programmes resulted in significantly improved MRC dyspnoea; there were no differences in this respect between programmes. Process measures such as structural follow-up meetings and perceived decision support based on the ACIC instrument correlated significantly with changes in quality of life (data not shown); these correlations disappeared in the regression analyses, however, due to the inclusion of programmes as independent variables.

Discussion

Principal findings

In this study, bottom-up implementation of COPD disease-management programmes led to statistically significant improvements in various quality of life dimensions, dyspnoea and patients' experiences with practice nurses. In each region, interventions were geared to perceived bottlenecks; quantitative analyses showed that programmes with better implementation of selected interventions were associated with more positive changes in outcomes. Consequently, this study suggests that bottlenecks in professional practice can well be used as points of departure for the implementation of disease-management programmes. Although patient baseline characteristics between programmes differed, regression analyses showed that these differences did not explain differences in quality of life changes between programmes. Dyspnoea improved in all three programmes, but CCQ symptoms only improved in programmes B and C. This might be explained by better implementation of patient-related interventions focussing on the improvement of self-management. But analyses also showed deterioration in CCQ mental state in programme C; this might be due to low baseline scores (indicating better quality of life) which reduced possibilities to detect improvement. Programme B performed best, which might be explained by well implemented interventions in relation to the perceived bottleneck.

This study showed that a multifaceted perspective on disease management is indeed effective: all programmes combined patient-oriented, professional-directed and organisational interventions. Previous studies focussed on single components or on programmes that did not include all three components. Meta-analyses of previous study results already suggested that patients in programmes with two or more components had lower health care use compared with controls.[17] Furthermore, multifaceted COPD programmes were found to lead to improvements in quality of life and hospital admissions.[18 19] The present study was the first to test the premise of triple intervention programmes within multiple real-life settings. It is not yet possible to specify what aspects of disease-management interventions are most beneficial to COPD patients. Nevertheless, findings from this study show that combining patient-related, professional-directed and organisational interventions is recommendable.

Disease-management interventions selected by the regional professionals mostly concerned rather traditional interventions, such as provision of education instead of motivational interviewing.[20] This might be explained by the fact that diffusion of innovation models do not provide a framework for assessing the conditions in which such interventions become practically workable in healthcare settings.[21] What's more, increasing sense of ownership of professionals does not necessarily bring about more creativity. On the other hand, autonomy to refine innovations and improve their fitness for purpose will accelerate adoption.[22]

Strengths and limitations

This study combined the best available evidence and appropriate theory with a bottom-up approach suitable for widespread implementation in real-life settings. It fills a gap identified by the Medical Research Council (MRC) for more research into complex interventions – starting with pilot studies targeted at each of the key uncertainties in the design, and moving on to an exploratory evaluation (and then a definitive evaluation).[23] Furthermore, this bottom-up approach demonstrated that well implemented interventions geared to perceived bottlenecks are associated with changes in outcomes of care. By measuring processes and multiple outcomes, selected on theoretical grounds, we were able to assess the success of disease-management programmes across a range of domains and to provide insights into why programmes will work out well or will have unexpected consequences. For example, outcomes in programme A improved the least, probably because insufficient implementation of patient-related interventions in relation to the perceived bottleneck with regard to patient involvement. Data on patients that did not participate in the study were not readily available; representativeness can therefore not be assured. Such data were available for programme C, however, and no significant differences were found in baseline data between those participating and those who are not.

The purpose of this study was to evaluate bottom-up implementation of disease management. Randomisation by selecting a control region was not feasible, since this approach does not provide for a standard programme. Regional bottlenecks are likely to differ. Consequently, regions will differ as to selected interventions. Individual randomisation was not feasible, either.[7] A quasi-experimental design in multiple settings was therefore applied. Since disease management essentially is applied in real-life settings, this design is an adequate method for understanding the effectiveness of interventions in different clinical settings and in broader patient populations.[24] Nevertheless we fully acknowledge that, results have to be interpreted with caution.

Indications for further research

As mentioned in the previous section, this study is an example of a comprehensive evaluation of bottom-up implementation of multiple disease-management pilots. The MRC recommended next step is a definitive evaluation in which randomisation, such as a cluster randomised trial, should be considered in combination with qualitative research to explore further opportunities for, and barriers to, change.[25]

From our study we learned that disease management should be geared to perceived bottlenecks in a region. Still, it is not yet clear what specific characteristics of disease-management interventions (such as intensity, duration, or components) are most beneficial to COPD patients. Previous research in other chronic diseases found that effects appeared to be somewhat stronger for delivery system design and self-management support.[26] Adams et al.[17] deduced from a review that self-management interventions were more powerful. Future research should therefore focus on multifaceted interventions that include more robust self-management interventions.

Knowledge that underpins the adoption, dissemination, and implementation of a complex intervention within health care settings is either not objective or lacking.[22] Engaging professionals by creating ownership of a problem and involving them in the selection of (complex) solutions (i.e. innovation) should be further explored as a factor in the associations between innovation, dissemination, diffusion and adoption.

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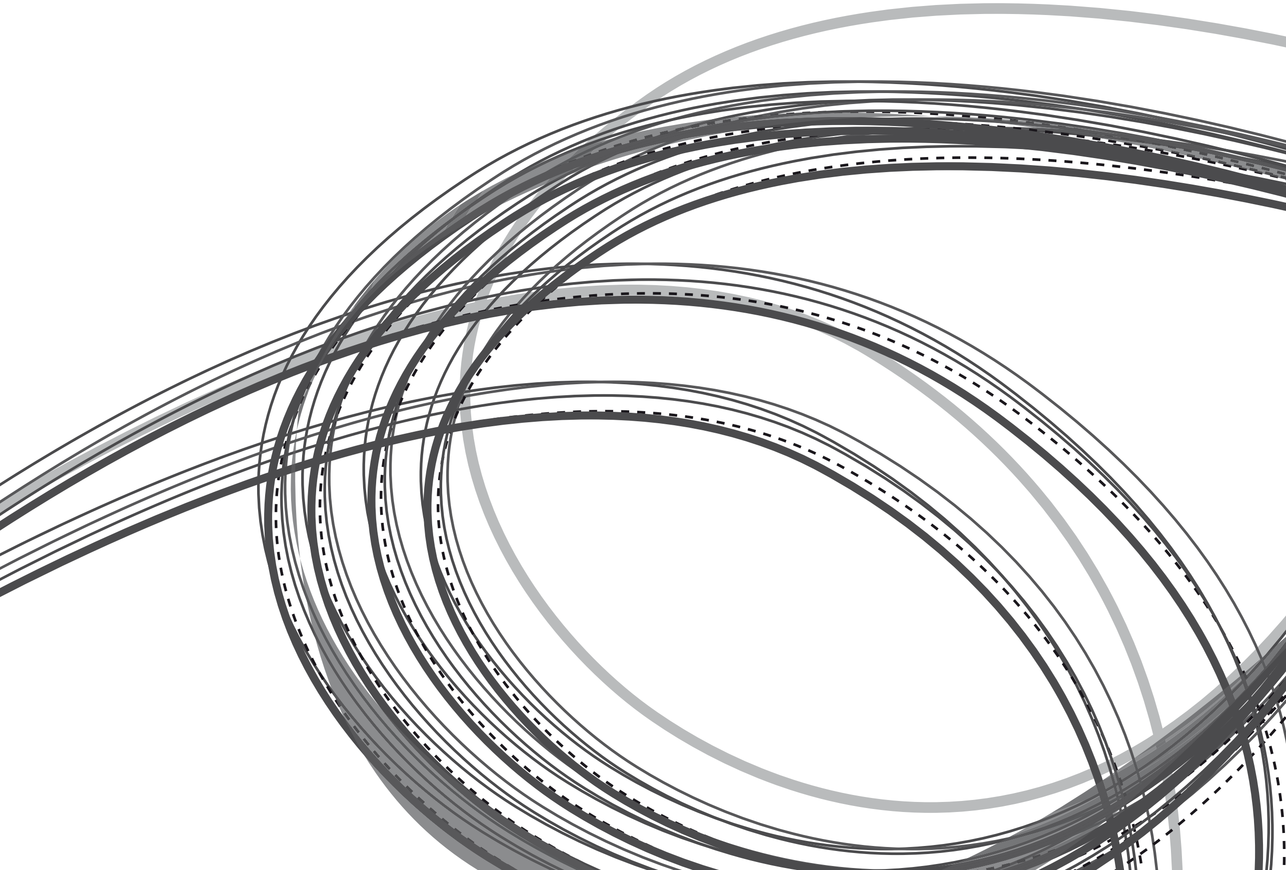
Chapter 9

General Discussion



Introduction

The overall aim of this thesis was to determine the core elements of disease management and to understand how they operate and interact in order to effectively evaluate disease-management programmes, in this instance for patients with chronic obstructive pulmonary disease. The increasing burden of chronic illness has altered medical care irrevocably.[1] However, large proportions of people with chronic illness do not receive either proven biomedical or behavioural interventions or adequate information and support for self-management.[2 3] Disease-management programmes have emerged to level off the rising trend in chronic diseases and, most importantly, to postpone or even prevent complications and co-morbidities, thus leading to better quality of life of chronic patients.[2] Yet, adequate interpretation of the effects of multiple disease-management programmes that have already been implemented is still lacking. It would seem essential to gain insight into the mechanisms by which these programmes work – if, why and how? This thesis contributed to the evidence on these mechanisms and the effectiveness of disease-management programmes in real-life settings.

This chapter first presents the main findings of the studies following the research questions. Next, theory and methodology of the current study are discussed. Finally, the implications of this research for policy and practice as well as recommendations for future research are described.

Main Findings

Question 1: How does a comprehensive, integrated model for disease management enable evaluation of chronic care?

Disease-management programmes are multifaceted in nature and should consist of three components: patient-related, professional-directed and organisational interventions. Hence, evaluations should focus on the effects of multiple interventions. We developed an evaluation model – based on social learning theories – that relates programme components with the underlying mechanisms (e.g. knowledge and behaviour) by which they influence outcomes, and proposes direct and indirect relationships among them.

The evaluation model thus provided a heuristic for understanding how disease-management interventions affect outcomes of care. Both patient-related and professional-directed interventions aim to alter behaviour through mechanisms such as gaining knowledge and improving skills and/or self-efficacy. Behavioural change is presumed to contribute to or to facilitate the realisation of expected outcomes. The model also showed that organisational support may facilitate learning; moreover this support can act as a catalyst to behavioural change.

Application of the evaluation model enables to compare efficiency and outcomes of disease-management programmes in a valid manner, so that we may learn more about the effectiveness of particular programmes. Moreover, a valid set of indicators for disease-management programmes could be determined by linking indicators to the elements of the model.

Question 2: What is the effectiveness of multiple disease-management interventions in improving care and cost effectiveness for patients with asthma or COPD?

Disease-management programmes should comprise all three components, namely patient-related, professional-directed and organisational interventions. Our review identified promising combinations of interventions. In the first place, the combination of patient education, professional education and case management in COPD care. Secondly, pharmacist-led programmes consisting of professional and patient education in combination with a more active role for pharmacists in patient monitoring. Disease-management programmes in asthma and COPD showed significant improvements in quality of life and significant reductions in numbers of patients with one or more hospital admission in triple intervention studies.

Current knowledge is still insufficient to formulate clear recommendations regarding the structure and contents of disease-management programmes in COPD care. The main reason is that these programmes are often poorly described and that the evidence is anything but standardised. Heterogeneity in (combinations of) interventions was found on study populations, follow-up time, settings, programme intensity and outcome measures.

Question 3: Are COPD disease-management programmes potentially cost effective?

Data on cost effectiveness of specific COPD disease-management programmes are scarce. Even so, we were able to provide illustrations of potential cost effectiveness, a factor that might help to indicate whether a programme could to be considered a worthwhile spending of scarce resources and deliver sufficient return on investment in the short or longer term.

Question 4: Are theoretically expected associations between determinants and outcomes of patient-related interventions existent?

Our study showed that – consistent with our evaluation model – knowledge, psychosocial mediators and self-efficacy were indeed determinants of behaviour (physical activity) and that this behaviour is significantly associated with positive outcomes (clinical and functional outcomes). Physical activity appeared to be an important predictor of clinical and functional outcomes in patients with mild or moderate COPD. Insight in determinants of patient-related interventions in COPD care is needed to design appropriate self-management programmes and properly evaluate their effectiveness. Patient-related interventions should be aimed at behavioural change and include learning principles.

Question 5: To what extent are primary care professionals able to change their processes for delivering care to COPD patients and which professional and organisational factors are associated with the degree of process implementation?

Group culture and professional commitment contributed significantly to successful implementation of disease-management programmes. However, total explained variance was small. Professionals should nevertheless be involved in changing chronic illness care. Furthermore, our exploratory study found some evidence that a supportive climate is a determinant of professional commitment, with peer support as an important motivator.

Organisational factors are indeed associated with the degree of process changes. Structured quality activities within a practice group seemed to support implementation of disease management, since commitment to quality improvement is significantly associated with change in professional commitment. Furthermore, it appeared that practice nurses strongly believe that one can really achieve the desired change in general practice, an attitude that might act as a catalyst to adopting disease management in primary care.

Question 6: What are the effects of the implementation of this programme on process, intermediate and final outcome indicators as derived from the evaluation model?

Disease-management programmes can be thoroughly evaluated by application of our evaluation model. Changes in processes and intermediate outcomes have been related to changes in final outcomes of care. By measuring processes and multiple outcomes, selected on theoretical grounds, we were able to assess the success of programmes across a range of domains and to provide valuable insights into why programmes work or have unexpected consequences. Moreover, evaluation of a particular disease-management programme showed that intermediate outcomes, namely investment beliefs and subjective knowledge, significantly predicted changes in quality of life and dyspnoea. This finding stresses the importance of theory-based evaluation of complex interventions.

Question 7: What is the impact of bottom-up implementation of three regional COPD disease-management programmes and how are existing bottlenecks, implementation of selected interventions and outcomes of care associated?

A multifaceted approach to disease management was indeed effective; all programmes combined patient-oriented, professional-directed and organisational interventions. Bottom-up implementation of COPD disease-management programmes led to statistically significant improvements in various quality of life dimensions, dyspnoea and patient experiences with practice nurses. Moreover, bottlenecks in professional practice proved to be useful points of departure. All three programmes employed interventions based on their bottlenecks. However, programmes with better fit between implemented interventions and bottlenecks showed more positive changes in outcomes. A bottom-up approach based on existing bottlenecks appeared to be suitable for widespread implementation of disease-management programmes in real-life settings.

Interestingly, the regional professionals mostly selected rather traditional interventions, such as provision of education instead of motivational interviewing. Thus, increasing sense of ownership of professionals does not necessarily bring about more creativity. On the other hand, autonomy to refine innovations and improve their fitness for purpose will accelerate adoption.

Theoretical and Methodological Considerations

Theoretical reflections

The evaluation model presented in this thesis has been geared to the multifaceted nature of disease-management programmes, for which so far no sound analytic evaluation method was available. Earlier theories on disease management, such as the chronic care model (CCM)[3 4] and Disease Management Association of America (DMAA)[5], failed to reveal these programmes' working mechanisms. They rather provided a definition of (components of) disease management. Grounded in theory as well as tested in various empirical studies, the evaluation model appeared a sound base for the evaluation of disease-management programmes. Although most model associations were detected, explained variance was often low (around 20%). Still, the application of theoretical principles proved a feasible approach. Other studies discussed the importance of the use of theory of behaviour in patient-related[6 7] or professional-directed[10 11] interventions. The model suggested that disease-management programmes should focus on cognitive and behavioural changes in patients and professionals, on organisational changes, and on multiple outcomes of care. However, it did not elaborate on how the larger health care system influences outcomes of disease-management programmes. Contextual factors should be assessed more accurately since they intervene in various parts of the model.

Our meta-analyses showed promising improvements in health-related quality of life and number of hospital admissions, which is consistent with the review by Peytremann-Bridevaux and colleagues.[8] Similarly, Adams and colleagues[9] found that COPD patients who received interventions with two or more CCM components had lower rates of hospitalisations and emergency/ unscheduled visits and a shorter length of stay compared with control groups. However, Niesink and colleagues[10] found inconclusive results on quality of life. Most of the included studies focussed on pulmonary rehabilitation; we excluded such programmes because these therapies are considered to be "standard care". Our results add to those of other systematic reviews in that we identified promising combinations of interventions supported by quantitative analyses. We also found relatively strong indications that triple interventions are more successful in improving outcomes than double interventions. Moreover, our review established that professional-directed interventions are lacking in most programmes. This might point at underuse or unavailability of multidisciplinary guidelines, which have shown to reduce unjustified variety in care and improve delivery of cost effective care.[11] Finally, we evaluated comprehensive programmes, directed at multiple elements of chronic care within the continuum of care.

Our empirical study found support for associations between existing bottlenecks, implementation of selected interventions, and outcomes of care. This was achieved by applying a bottom-up approach to the evaluation of disease management. Such an approach is unique. True, previous studies already suggested that multifaceted disease-management programmes could lead to improvements in quality of life and reductions in hospitalisations.[8] So far, however, most of these studies had been performed in clinical rather than real-life settings[12 13] and did not include all three recommended components.[14 15] Results of one of the most comprehensive interventions, performed in a real-life setting, were equivalent to those of our study.[16] Comparison is somewhat compromised, however, as that study concerned a single site.

Systematic literature reviews

Our systematic reviews aimed to identify all relevant studies on the (cost) effectiveness of disease-management programmes in COPD (and asthma) care. However, topics related to health care delivery, organisation, and financing pose inherent challenges for systematic reviews: problem formulation may be difficult, evaluative studies may be scarce, and the common quantitative approaches for meta-analysis may not be applicable.[17] To minimise bias we used an a piori established protocol.[18] Interpretation of studies was complicated by the fact that some papers only provided a limited description of their disease-management interventions; this is often a problem in reviews related to organisational topics. Furthermore, meta-analyses could only be applied to a limited number of outcomes and studies due to heterogeneity of outcome measures. Studies also largely lacked economic evaluations. Yet, within performed meta-analyses comparisons could be made between double and triple interventions and heterogeneity was acceptable. Finally, publication bias is known to occur in systematic reviews because research with statistically significant results from large well funded studies, or of higher quality is potentially more likely to be submitted and published than work without such characteristics.[19] To minimise publication bias, we set up a broad search strategy and reference lists from papers identified as meta-analyses, reviews or others studies were searched for additional studies. But included papers were restricted to English publications and 'grey' literature was not taken into account. All in all, the apparent effectiveness of some of the interventions may have been overestimated due to the possibility of publication bias.

Study design

Several limitations need to be considered when interpreting the results of our empirical studies. First, randomised controlled trials are the gold standard method for evaluating healthcare interventions.[20] Through random allocation it is ensured that both known and (particularly important) unknown factors (confounders) that may independently affect the outcome of an intervention are likely to be distributed evenly between the intervention and control groups. However, in organisational research it is difficult to set up randomised controlled trials.[21] Multiple causation and contingent causes may create problems in the evaluation of disease-management programmes for which hardly any satisfying solution exists.[22] We therefore carefully considered the trade-off between the importance of the intervention and the value of the evidence that can be gathered given these constraints.[23] Aim of our study was to evaluate a bottom-up approach to the implementation of disease management. A bottom-up approach excludes standardisation of the programme due to differences in regional bottlenecks; the regions would thus select different interventions. Randomisation by selecting a control region was not feasible therefore. Individual randomisation was not feasible, either.[24] We performed a non-randomised comparison of three regional disease-management programmes in an endeavour to apply the best possible rigorous research design. This strategy allowed for evaluating the effects of complex programmes in real-life multiple settings. Since disease management essentially is applied in such settings, this design is an adequate method for understanding the effectiveness of that intervention in different clinical settings and in broader patient populations.[25] Theoretically, the observed changes could also have been caused by other factors.[20] We turned the burden of proof around and found no reason to assume that elements such as the introduction of new medication or changes in the insurance system occurred that could have caused improvements of comparable magnitude. Yet, we are well aware of the limitations of quasi-experimental methods and interpreted our findings with due caution.

But then again, our research design also held a considerable strength. A theoretically driven approach is important, indeed, to understand complex social interventions and their effects. In our study, we combined the best available evidence and appropriate theory with a bottom-up approach suitable for widespread implementation in real-life settings. Herewith, our study filled a gap identified by the Medical Research Council (MRC) for more research into complex interventions starting with a series of pilot studies targeted at each of the key uncertainties in the design, and moving on to an exploratory evaluation.[23] Drawing on theories helped to conceptualise the problem and to understand interactions with patient, professional, and organisational factors.[26] Understanding the mechanisms of disease-management programmes enabled a thorough evaluation of a concept which until now was only marginally defined in the literature.

Setting and participants

The programmes evaluated in this thesis participated in PICASSO for COPD, a national disease-management programme. The setting and participants – patients as well as professionals – in this study were therefore determined by regional settings, participating professionals in the disease-management programmes and the willingness of their patients to participate.

With regard to patients, we did not apply formal eligibility criteria. Such criteria are not used in routine practice, except for serious co-morbidity, which the general practitioner assessed according to protocol. This adds to the generalisability of the findings.[24] Response and completion rates within the three programmes were moderate to good; an average of 72% of patients responded and 83% of those completed the study. We compared drop-outs with patients who completed the study; no selective loss to follow-up was found. Since patients were recruited in primary care, most patients had mild to moderate COPD. Nevertheless, this is in line with the finding that 82% of all patients with COPD show a mild or moderate phenotype.[27] Moreover, primary care is attributed an important role in organising disease management.[28 29]

Professionals included in the study participated in disease-management programmes. As a consequence, the sample might not be representative since professionals participating in such programmes may be assumed to have a fair degree of commitment right from the start. Given that response and completion rates were high, 90% initially participated of which 96% completed the study, we are confident that representative representations within these regions were provided.

Role of the researcher

Furthermore, structured evaluation of selected disease-management programmes was part of the support provided by PICASSO. Accordingly, the researcher played an active role beforehand; after selection of the interventions advice was given on evaluation and elements of the interventions. However, there was no active interference throughout programme implementation. This approach enabled structured evaluation and selection of comparable indicators within multiple settings.

Recommendations for practice and research

This thesis revealed several implications for practice and research. First of all, multifaceted disease-management programmes for COPD patients are indeed effective within various settings. They provided support for the identified triptych of patient-related, professional-directed and organisational interventions. Consequently, the recommendations described below are organised according to these key components. Furthermore, we will discuss the implications for the macro and meso organisation of health care. This section therefore ends with recommendations for future research.

Patient-related interventions

Patient-related interventions are key to disease-management programmes. Until now, however, most patient-related interventions were rather traditional, such as sole patient education.[30] Behavioural change is an essential determinant in improving outcomes. Moreover, greater attention to physical activity and smoking cessation is indicated. Hence, more robust methods than purely providing education are needed in practice. Comprehensive self-management programmes seem most promising to these ends.

The disease-management paradigm seeks to promote a fuller understanding of the patient's life and preferences, activation or empowerment of patients, and tailoring of management to patient preferences. These are concepts often associated with the term patient-centred care.[31] Patient-centred care has implications for the organisation of primary care (e.g. close to the patient's home), financing (demand steering), multidisciplinary approach, et cetera. Although many care organisations claim to work patient-centred, so far this is often not reality, notably when patients need integrated care arrangements. Given the increased attention to and evidence for patient activation, further efforts should be directed at establishing true patient-centred care.

Professional-directed interventions

So far, most guidelines have focused more on decision-making by individual professionals than on multidisciplinary decision-making processes. As such, the health professionals and care managers prove to need to intensify their efforts on developing and implementing such multidisciplinary decision-support tools as part of their COPD programmes. Demand-oriented care standards are a good example of combining patient-centred and evidence-based care.[32]

Just like patient-related interventions, most professional-directed interventions so far were rather non-innovative, as they consisted of providing educational materials, courses, and conferences.[33] Professional involvement is crucial in improving outcomes. Professionals should thus be supported in selecting improvement strategies in the context of disease management. Evidence is available that a more individualised approach, based on personal learning strategies and active participation, effectively stimulates learning and improvement.[34] Professional organisations should provide a framework for assessing the conditions in which such interventions become practically workable in healthcare settings.[35] In this respect researchers could also play a role; once bottlenecks have been identified they could more purposefully advise on intervention selection.

Organisational interventions

Practice nurses and assistants play important roles in caring for chronic patients. Assigning new professional roles all of a sudden may lead to confusion and impede implementation.[36] Organisations such as the "College Opleidingen en Beroepen in de Gezondheidszorg" (Healthcare education and professions board; COBG) should provide clear job descriptions for these new professionals, with clearly stated tasks, responsibilities and qualifications. Moreover, role extension for practice nurses and assistants calls for regulation by law. For the patient it should be clear which care professional is eventually responsible for the delivery of care.[37]

Close patient monitoring and effective, integrated care delivery across community, primary, secondary and tertiary care are crucial to pick up early signs (e.g. exacerbations) more timely and to respond more pro-actively so to achieve the desired (cost) effectiveness target. Monitoring systems and outcome measurement (e.g. quality of life and dyspnoea) seem promising in supporting professionals to this end. In addition to the previous point on demand-oriented care standards[32], these standards may serve for the definition of monitoring parameters.

Health care system

This thesis demonstrated that bottom-up implementation of disease-management programmes is an effective, feasible approach. Yet, system support is needed; the health care organisation forms the foundation on which patient-related, professional-directed and organisational interventions rest.[38] Barriers within the studied programmes were found to involve financing systems, organisational structures, and information technology. General recommendations with regard to these aspects are given in the following section.

Changes in interorganisational structures and financing systems are needed to accomplish patient-centred care provided by multidisciplinary care teams. Well-organised and integrated primary care is then fundamental to the possibility implementing disease-management programmes to the full.[39] Diagnosis Treatment Combinations in primary care are evolving; primary care groups are setting up regional "care group" organisations. Yet, these organisations are not by definition patient-centred. Strict division of care into primary and secondary care will have to disappear. Moreover, great differences exist in secondary care involvement in Diagnosis Treatment Combinations in primary care. A value based system is needed to achieve patient-centeredness: (1) the goal is value for patients, (2) medical practice should be organised around medical conditions and care cycles, and (3) results – risk-adjusted outcomes and costs – must be measured.[40] Functional descriptions of the benefit package (*functionele bekostiging*), as recently proposed by the Dutch Ministry of Health, seem well fit for this purpose.[41] Functional descriptions start with patients' care needs (demand steering) as opposed to being based on the care provider or organisation (supply steering). Moreover, to cover the entire care continuum in a patient-centred way, care packages (*zorgzwaartepakketten*) in outpatient care should also be based on patient profiles. In so doing, the financing system will fit patients' care needs. Patients and professionals will then not become entangled in the web of financing structures, such as Diagnosis Treatment Combinations, inpatient care arrangements, outpatient care arrangements, and so on.

One of the programmes in our evaluation applied an Information and Communication Technology (ICT) system to support decision making by general practitioners and nurse practitioners. Although ICT is increasingly being used in management of chronic illness, there is still much room for improvement, notably in its structural and cohesive application. ICT can play an important role in all pillars of disease management: supporting patient self-management (patient-related interventions), supporting professional decision making (professional-directed intervention) and supporting the organisation of care, e.g. patient monitoring, evaluation of care or data feedback.

Recommendations for future research

Based on the findings from this thesis, a number of recommendations for future research on evaluation of disease-management programmes can be given. We have seen that rigorous evaluation and determining the practical feasibility of multiple disease-management interventions often is quite problematic.[23] In this thesis we performed a comprehensive evaluation of bottom-up implementation of disease-management programmes in multiple settings. According to the MRC the next step is a definitive evaluation of such programmes in which randomisation should be considered in combination with qualitative research to explore further opportunities for, and barriers to, change.[42]

First, when feasible a cluster randomised design should be used to quantitatively assess the impact of programmes on processes and outcomes of care, where clusters are caregiver practices, regions, hospital departments, et cetera. Well-designed but practical clinical trials including broad representative patient samples in multiple settings are also suggested.[42 43] Our research was performed in multiple settings and reported setting, context and multiple outcome data.[25] But practical clinical trials adhere to designs relying on replication, such as interrupted time-series or delayed treatment designs. Such designs could also be applied in future disease-management evaluation to fit the culture of ongoing quality improvement.[43]

Second, qualitative research can be used to show how the intervention works and to find potential barriers to change in patient or professional behaviour.[24] So far, it is unclear which specific characteristics of disease-management interventions, such as intensity, duration, or combination of interventions, bring the most benefit to COPD patients. Qualitative research could elucidate this and therefore be of help in optimising combinations of interventions. It can also add to a more in depth description of programme organisation and the possible effects of contextual factors (e.g. finance, culture). The context of care delivery is thought to be decisive for the emergence of problems with chronic illness care, as well as for the feasibility of intervention to remedy these problems.[42]

Disease-management programmes for the chronically ill aim at improving quality of care and mitigating healthcare costs.[44] Evidence on the latter aspect is still very limited however. Prevention of exacerbations and complications, as the result of improved disease control, is expected to lead to better health-related quality of life in the long term, while mitigating healthcare costs.[22] Considering that ever tightening budgets cannot meet the continuously increasing demand for healthcare, it is important to assess the costs and cost effectiveness of disease-management programmes. This will facilitate decision making on the inclusion of a disease-management programme into the benefit package of health care insurance, conditional reimbursement for specific indications and/ or capacity planning at regional and/ or national level.

In this thesis we applied the evaluation model to disease-management programmes directed at COPD patients. It was developed as a general model, however, which could also be applied to other chronic conditions, such as diabetes mellitus or heart failure. The fact remains that approximately 36 percent of patients with chronic conditions suffer from two or more conditions.[45] Recognition of this large extent of multi-morbidity also has implications for the way in which health care is organised. For example, the risk of an avoidable inpatient admission or a preventable complication in an inpatient setting increases dramatically with the number of chronic conditions.[46] Better primary care, especially coordination of care, could reduce avoidable hospitalisation rates, especially for individuals with multiple chronic conditions.[47]

Conclusion

It is concluded that bottom-up implementation of COPD disease-management programmes is a feasible approach, which leads to significant improvements in various quality of life dimensions, dyspnoea, and patient experiences with practice nurses in multiple settings. Disease-management programmes should preferably include the triptych of patient-related, professional-directed and organisational interventions. Achieving change in the behaviour of patients as well as professionals is essential in disease-management programmes. Organisational structures to this end should also be modified by case management, follow-up systems and/ or multidisciplinary care provision. But, top-down support and connection to the broader system is needed. Policy should seek to adjust macro and meso organisation of care and financing systems to guarantee broad implementation and sustainability. Moreover, to tackle the future burden of chronic disease, innovations initiated by professionals should be actively encouraged and supported in a productive dialogue with researchers.

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Summary

The purpose of this thesis was to determine the core elements of disease management and to understand how they operate and interact in order to effectively evaluate disease-management programmes, particularly for patients with chronic obstructive pulmonary disease.

In **chapter 2** a framework has been presented for valid evaluation of disease-management programmes. Although current models define the concept of disease management, they do not provide a systematic development or an explanatory theory of how disease-management programmes affect outcomes of care. In this chapter we explored how a comprehensive, integrated model for disease management enables evaluation of chronic care. This has resulted in a theoretically derived evaluation framework including three key components, namely patient-related, professional-directed and organisational interventions. The framework has been built upon the conceptualisation of these interventions. Analysis of the underlying mechanisms of these interventions revealed that learning and behavioural theories support the core assumptions of disease management. Insight was gained in both patient-related and professional-directed interventions, which aim to alter behaviour through mechanisms such as gaining knowledge, skills and/or self-efficacy. It appeared that behavioural change is presumed to contribute to or to facilitate the attainment of expected outcomes. The model also explained that organisational support may facilitate learning; moreover it could act as a catalyst to behavioural change. The evaluation model is useful for the identification of disease-management components and the mechanisms behind them. Its consistent application should thus enable comparisons among disease-management programmes. Next to that, this model should guide definition of indicators that are suitable to assess disease-management components.

A systematic review was performed in **chapter 3** to examine the effectiveness of multiple interventions, as compared to single interventions or usual care, on health outcomes and health care utilisation within the context of integrated disease management in COPD and asthma. MEDLINE and the Cochrane Library were searched from January 1995 to May 2008 for controlled trials. Thirty-six studies were included; seventeen targeted double interventions, namely patient-related and organisational interventions, and nineteen studies concerned triple interventions, namely patient-related, professional-directed and organisational interventions. Heterogeneity was found in terms of (combinations of) interventions, measured outcomes, study design and settings. Meta-analyses showed promising improvements in quality of life and reductions in hospitalisations, especially for triple intervention disease-management programmes. No significant effects were found on the number of emergency department visits. Qualitative analysis demonstrated small, albeit no consistent, improvements in process and outcome indicators. Inconclusive results were reported on symptoms; no effects were found in lung function. Despite the heterogeneity of disease-management programmes, this review pointed at promising combinations of interventions.

Effects in comparison with usual care were notably found for COPD programmes in which patient education, professional education and case management are combined and for pharmacist-led programmes consisting of professional and patient education in combination with a more active role for pharmacists in patient monitoring.

In **chapter 4** published evidence was reviewed regarding the (cost) effectiveness of multi-component COPD programmes and it was illustrated how potentially cost effective programmes could be identified. MEDLINE and Cochrane databases were systematically searched between January 1995 and September 2007 for evaluations of multi-component disease-management or chronic care programmes for adults with COPD. Twenty articles describing seventeen unique COPD programmes were included. The review found little evidence for significant improvements in process and intermediate outcomes, except for increased provision of patient self-management education and improved disease-specific knowledge. Overall, the included COPD programmes generated outcomes of care equivalent to usual care, but programmes containing three components showed lower relative risks for hospitalisation. Thus, limited scope was found for programmes to break even or save money. This review illustrated that identifying cost effective multi-component COPD programmes remains a challenge due to scarce methodologically sound studies that demonstrate significant improvements on process, intermediate and end results of care. It was illustrated that, in the absence of 'perfect data', estimations of potential cost effectiveness of specific programmes can support timely decision-making regarding these programmes.

The exploratory study described in **chapter 5** aimed to test the applicability of a theoretical model to develop patient-related interventions. The model was tested on 278 patients with mild or moderate COPD, recruited in a primary care setting. This study showed that knowledge, psychosocial mediators, self-efficacy and behaviour proved to be predictors of outcomes in COPD care, albeit to a moderate degree. Moreover, physical activity appeared to be a significant predictor for all clinical (lung function and dyspnoea) and functional outcomes (health-related quality of life). Theoretically expected associations of patient-related interventions appeared to be existent in patients with mild or moderate COPD. Patient-related interventions should therefore be designed along the lines of theories on behavioural change, such as social cognitive theory. It could also be concluded that patterns of physical activity in patients with mild to moderate COPD deserve more attention.

Chapter 6 described an exploratory study which aimed to investigate first, to what extent primary care professionals are able to change their systems for delivering care to COPD patients and second, which professional and organisational factors are associated with the degree of process implementation. This study was performed in three regional COPD disease-management programmes in the Netherlands, in which general practices cooperated with regional hospitals. It was found that professionals significantly changed their systems for delivering care to COPD patients, namely self-management support, decision support, delivery system design and clinical information systems. These professionals' perceptions were validated by available process measures. Theoretically expected associations between organisational context and professional factors with the implementation of COPD disease management were indeed confirmed to some extent. Group culture and professional commitment appeared to be, to a moderate degree, predictors of adequate process implementation.

Disease-management programmes are heterogeneous in nature and often lack a theoretical basis; a framework has been developed for their valid evaluation (chapter 2). The aim of **chapter 7** was to systematically evaluate the impact of a disease-management programme for COPD patients on process, intermediate and final outcomes of care in a general practice setting. This programme included patient education, protocolised assessment and treatment of COPD, structural follow-up and coordination by practice nurses at 3, 6 and 12 months. Implementation of the programme was associated with significant improvements in dyspnoea and patient experiences. No significant improvement was found in mean quality of life scores (CRQ and CCQ). Improvements were found in several intermediate outcomes, including investment beliefs, disease-specific knowledge and medication compliance. Overall, process improvement was established. Furthermore, significantly improved intermediate outcomes were associated with improvements in quality of life and dyspnoea. Support was found for the notion that a theoretical approach strengthens the evaluation design of complex interventions. Additionally, prudent evidence was found that the implementation of COPD disease-management programmes can positively influence various outcomes of care.

In **chapter 8** a bottom-up implementation of three regional COPD disease-management programmes was evaluated. In each region, interventions were geared to perceived bottlenecks in professional practice. Bottlenecks in region A were mostly related to patient involvement, in region B to organisational issues and in region C to both. Selected interventions related to identified bottlenecks were implemented in all programmes, except for patient-related interventions in programme A. This approach led to statistically significant improvements in dyspnoea and patients' experiences with practice nurses. Outcomes on quality of life differed between programmes: programme A did not show any significant improvements; programme B did show significant improvements on various disease-specific quality of life dimensions (total, functional state, symptoms, fatigue and emotional dimension); in programme C quality of life scores on the symptom dimension improved significantly, whereas mental scores deteriorated significantly. Quantitative analyses revealed that programmes with better implementation of selected interventions were associated with more positive changes in outcomes. Consequently, this study suggested that bottlenecks in professional practice can well be used as points of departure for the implementation of disease-management programmes. Programmes with better fit between the implemented interventions and the bottlenecks showed more positive changes in outcomes.

In the general discussion the main finding of this thesis are presented and discussed. The conclusions are described following the research questions. Subsequently, methodological issues are reviewed. It was brought forward that this thesis contributes to the current body of evidence on the evaluation of disease-management programmes. Imperfections of systematic reviews, such as publication bias and the application of reviews to organisational interventions, were discussed. We reflected on design limitations of this study, addressing controlled designs and the application of theory in the evaluation of complex interventions. Finally, remarks were made on characteristics of the participants in this study. Practice implications were addressed regarding the design of disease-management interventions and top-down support of their implementation. The discussion ends with some recommendations for future research, notably considering cluster randomisation, qualitative research, economic evaluations and multi-morbidity.

This thesis showed that bottom-up implementation of COPD disease-management programmes is a feasible approach, which led to significant improvements in various quality of life dimensions, dyspnoea and patient experiences with practice nurses in multiple settings. Disease-management programmes should consist of multiple interventions including patient-related, professional-directed and organisational interventions. Achieving behavioural changes in patients as well as professionals appeared essential. To this end, organisational structures should also be modified by case management, follow-up systems and/ or multidisciplinary care provision. But, top-down support and connection to the broader system are needed too. Policy should seek to adjust the macro and meso organisation of care and financing systems to guarantee broad implementation and sustainability. Moreover, to tackle the future burden of chronic disease, innovations initiated by professionals should be actively encouraged and supported in a productive dialogue with researchers.

Samenvatting

Disease management is een programmatische en systematische aanpak van specifieke ziekten door middel van het gebruik van meerdere geïntegreerde interventies met als doel de kwaliteit en de doelmatigheid te bevorderen. Het doel van dit proefschrift is om de kernelementen van disease-management programma's vast te stellen en inzicht te krijgen in hoe deze programma's werken om vervolgens op doeltreffende wijze disease-management programma's voor COPD patiënten te evalueren.

In **hoofdstuk 2** wordt een evaluatiemodel voor disease-management programma's gepresenteerd. In bestaande modellen ontbrak het aan een systematische aanpak of verklarende theorie over de manier waarop disease-management programma's uitkomsten van zorg beïnvloeden. In dit hoofdstuk is onderzocht hoe een integraal evaluatiemodel voor disease management kan bijdragen aan het inzichtelijk maken van de effecten van dergelijke programma's. Het evaluatiemodel is theoriegestuurd en bestaat uit drie componenten: patiëntgerelateerde, professionalgerichte en organisatorische interventies. De verschillende disease management interventies zijn geconceptualiseerd door de onderliggende mechanismen, die de uitkomsten van het programma beïnvloeden, bloot te leggen. Leer- en gedragstheorieën zijn toegepast om te verklaren waarom disease management werkt. Zowel patiëntgerelateerde als professionalgerichte interventies richten zich op het beïnvloeden van gedrag door het vergroten van kennis, vaardigheden en zelfvertrouwen. Het model maakt inzichtelijk waarom gedragsverandering bijdraagt aan betere uitkomsten van zorg. Het laat ook zien dat organisatorische ondersteuning gedragsverandering bij patiënten en professionals kan ondersteunen. Het evaluatiemodel kan worden gebruikt voor het identificeren van disease-management componenten en hun achterliggende mechanismen. De toepassing van het model maakt het bovendien mogelijk om programma's met elkaar te vergelijken. Het model kan leidend zijn in het definiëren van indicatoren die geschikt zijn voor de evaluatie van disease-management programma's.

In **hoofdstuk 3** wordt een systematische literatuurstudie naar de effectiviteit van geïntegreerde disease-management programma's voor astma en COPD patiënten beschreven. In MEDLINE en de Cochrane Library is voor de periode januari 1995 tot mei 2008 gezocht naar gecontroleerde studies waarin meerdere interventies zijn toegepast in de context van disease management. Dit leverde 36 studies op. Zeventien studies waren gericht op dubbele interventies, namelijk patiëntgerelateerde en organisatorische interventies. Negentien studies richtten zich op drievoudige interventies, namelijk patiëntgerelateerde, professionalgerichte en organisatorische interventies. De studies verschilden van elkaar wat betreft de (combinaties van) interventies, de indicatoren, het onderzoeksontwerp en de setting. Meta-analyses van de resultaten van soortgelijke studies lieten veelbelovende verbeteringen zien in kwaliteit van leven en in vermindering van het aantal ziekenhuisopnamen. Vooral disease-management programma's die bestaan uit drievoudige interventies lieten positieve resultaten zien. Er zijn geen significante effecten gevonden in het aantal bezoeken aan de eerste hulp. Kwalitatieve analyses lieten geringe verbeteringen zien in zorgprocessen en kwaliteit van zorg. Uiteenlopende resultaten zijn gevonden met betrekking tot symptomen, zoals benauwdheid. Er zijn geen effecten gevonden in de verandering van de longfunctie. Veelbelovende combinaties van interventies die in deze literatuurstudie naar voren zijn gekomen zijn COPD programma's waarin patiënteducatie, professionaleducatie en case management gecombineerd werden. Zij lieten significante verbeteringen zien ten opzicht van controle groepen. Interventies die bestonden uit educatie voor patiënten en professionals waarin bovendien apothekers een actieve rol spelen in het monitoren van de patiënt zijn eveneens veelbelovend.

In **hoofdstuk 4** is een overzicht gegeven van de beschikbare literatuur ten aanzien van de kosteneffectiviteit van COPD programma's die uit meerdere componenten bestaan. Hierbij is aangegeven hoe potentieel kosteneffectieve programma's herkend kunnen worden. In MEDLINE en de Cochrane Library is gezocht naar evaluatieonderzoeken van disease-management programma's voor volwassen COPD patiënten die gepubliceerd zijn tussen januari 1995 en september 2007. Twintig artikelen waarin zeventien verschillende studies worden beschreven zijn meegenomen in dit onderzoek. In deze literatuurstudie is beperkt bewijs gevonden voor verbeteringen in proces, intermediaire uitkomsten en eindresultaten van zorg. Zelfmanagementeducatie en ziektespecifieke kennis bleken wel te verbeteren. De resultaten van de onderzochte COPD programma's waren vergelijkbaar met de resulaten van standaard zorg. Programma's bestaand uit drie of meer componenten lieten echter wel kleinere relatieve risico's zien voor ziekenhuisopnames. Het onderzoek heeft dus wel laten zien dat er mogelijkheden zijn voor COPD programma's om kostenneutraal of kostenbesparend te zijn. Het identificeren van COPD programma's die uit meerdere componenten bestaan en kosteneffectief zijn is een uitdaging. Er zijn weinig methodologisch goede onderzoeken die significante verbeteringen laten zien in proces, intermediaire uitkomsten en eindresultaten van zorg. Deze literatuurstudie heeft ook laten zien dat schattingen van de kosteneffectiviteit van COPD programma's, in afwezigheid van 'perfecte data', kunnen bijdragen aan tijdige besluitvorming ten aanzien van deze programma's.

Het explorerende onderzoek in **hoofdstuk 5** is er op gericht om het theoretische model toe te passen voor de ontwikkeling van patiëntgerelateerde interventies. Het model is getest op milde of matige COPD patiënten in een eerstelijnssetting. De studie heeft laten zien dat kennis, psychosociale variabelen, zelfvertrouwen en gedrag voorspellers zijn van uitkomsten in de COPD zorg. Daarnaast is gebleken dat lichaamsbeweging een significante voorspeller is van alle klinische (longfunctie en benauwdheid) en functionele uitkomsten (ziektegerelateerde kwaliteit van leven). Dit onderzoek laat zien dat theoretische modellen moeten worden toegepast bij het vormgeven van patiëntgerelateerde interventies voor COPD patiënten. Daarnaast kan er geconcludeerd worden dat er meer aandacht moet worden besteed aan bewegen bij patiënten met milde en matige COPD.

Hoofdstuk 6 beschrijft een verkennend onderzoek naar de mate waarin eerstelijnsprofessionals in staat zijn hun zorgsystemen aan te passen voor zorg aan COPD patiënten. Daarnaast is gekeken welke professionele en organisatorische factoren er samenhangen met de mate van procesimplementatie. Dit deel van het onderzoek is uitgevoerd in drie regionale COPD disease-management programma's in Nederland. In deze programma's werkten huisartsenpraktijken samen met regionale ziekenhuizen. Er zijn significante veranderingen gevonden in zorgprocessen voor COPD patiënten die zich richten op zelfmanagementondersteuning, beslissingsondersteuning, organisatie van zorg en klinische informatiesystemen. De gerapporteerde ervaringen van professionals zijn gevalideerd door ze te vergelijken met procesmaten, zoals het percentage patiënten met een vervolgafspraak. Relaties tussen de organisatorische context en kenmerken van de professionals en de implementatie van COPD disease management zijn deels bevestigd. Groepscultuur en professionele betrokkenheid bleken in redelijke mate voorspellers van procesimplementatie.

Disease-management programma's verschillen doorgaans van elkaar en in veel gevallen ontbreekt het aan een theoretische basis. Om een goede evaluatie van disease-management programma's mogelijk te maken is een evaluatiemodel ontwikkeld (hoofdstuk 2). Het doel van **hoofdstuk 7** is om in een eerstelijnssetting het effect te meten van een disease-management programma voor COPD patiënten op proces, intermediaire uitkomsten en eindresultaten van zorg. Het geëvalueerde disease-management programma omvatte patiënteducatie, geprotocolleerde diagnose en behandeling van COPD, structurele vervolgafspraken en coördinatie door praktijkverpleegkundigen na 3, 6 en 12 maanden. Het onderzoek heeft laten zien dat de implementatie van het programma samenhing met significante verbeteringen in benauwdheid en betere patiëntervaringen. Er zijn geen significante verbeteringen gevonden in gemiddelde ziektespecifieke kwaliteit van leven scores. Wel zijn verbeteringen aangetroffen in verschillende intermediaire uitkomsten, waaronder investeringsgedrag, ziektespecifieke kennis en het naleven van medicatievoorschriften door patiënten. Significante veranderingen in de zorgprocessen zijn ook gerealiseerd. Daarnaast zijn er relaties gevonden tussen intermediaire uitkomsten en verbeteringen in kwaliteit van leven en benauwdheid. Dit onderzoek heeft laten zien dat een theoriegestuurd ontwerp de evaluatie van complexe interventies versterkt. Daarnaast zijn er aanwijzingen gevonden dat de implementatie van COPD disease-management programma's een positieve invloed kan hebben op de uitkomsten van zorg.

In **hoofdstuk 8** is de bottom-up implementatie van drie regionale COPD disease-management programma's geëvaluateerd. In elke regio zijn de in de praktijk ervaren knelpunten door professionals geanalyseerd en zijn de interventies hierop afgestemd. Knelpunten in regio A waren vooral gerelateerd aan het betrekken van patiënten, in regio B betrof het organisatorische problemen en in regio C zijn beide typen knelpunten aangetroffen. De interventies die geselecteerd zijn op basis van de knelpunten moesten in de programma's geïmplementeerd worden. In programma A zijn de patiëntgerelateerde interventies echter onvoldoende geïmplementeerd. De bottom-up aanpak heeft duidelijk geleid tot verbeteringen in benauwdheid en patiëntervaringen met de praktijkverpleegkundigen. De uitkomsten in ziektespecifieke kwaliteit van leven verschilden echter tussen de programma's. Programma A liet geen significante verbeteringen zien; programma B verbeterde significant op verschillende kwaliteit van leven dimensies (algemeen, functionele status, symptomen, vermoeidheid en emotionele status); in programma C verbeterde de symptoomdimensie significant, terwijl de mentale status dimensie significant achteruitging. Kwantitatieve analyses laten zien dat programma's met een betere implementatie van de geselecteerde interventies samenhingen met positievere veranderingen in uitkomsten. Dit onderzoek laat zien dat knelpunten in de praktijk van de professional gebruikt kunnen worden als startpunt voor de implementatie van disease-management programma's. Programma's met een betere afstemming tussen geïmplementeerde interventies en knelpunten lieten positievere veranderingen in uitkomsten zien.

De methodologische beperkingen van het onderzoek worden in de discussie besproken. De beperkingen van systematisch literatuuronderzoek zijn publicatiebias en het uitvoeren van dergelijke onderzoeken bij organisatorische interventies. Daarnaast zijn de (on)mogelijkheden van een gecontroleerd onderzoeksontwerp besproken en het gebruik van theorie bij de evaluatie van complexe interventies. Er worden aanbevelingen voor de praktijk gegeven over de opzet van disease management interventies en het inbedden van disease-management programma's in de dagelijkse zorgpraktijk middels ondersteuning vanuit de meso- (regionale organisatie) en macro-organisatie van zorg (beleid, wet- en regelgeving, financiering). Het hoofdstuk wordt afgesloten met een aantal suggesties voor verder onderzoek.

Dit proefschrift heeft laten zien dat bottom-up implementatie van COPD disease-management programma's een haalbare aanpak is die leidt tot significante verbeteringen in verschillende kwaliteit van leven dimensies, benauwdheid en patiëntervaringen met praktijkverpleegkundigen. Disease-management programma's moeten daartoe uit meerdere interventies bestaan: patiëntgerelateerde, professionalgerichte en organisatorische interventies. Het veranderen van het gedrag van de patiënten en dat van de professionals is essentieel gebleken in disease-management programma's. Om dit mogelijk te maken moeten organisatorische structuren worden aangepast bijvoorbeeld door de invoering van case management, structurele vervolgafspraken en/ of multidisciplinaire zorgverlening. Echter, top-down ondersteuning en aansluiting met het gezondheidszorgsysteem is ook noodzakelijk. Beleid moet zorgen voor aansluiting tussen de macro- en meso-organisatie van zorg en de financieringssystemen om brede implementatie en borging te garanderen. Innovaties die geïnitieerd worden door professionals moeten actief worden aangemoedigd en ondersteund om de toekomstige toename van chronisch zieken op te vangen.

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Dit onderzoek is uitgevoerd in opdracht van PICASSO voor COPD en was nooit tot dit einde gekomen zonder de bijdrage van de ‘spil’ van PICASSO voor COPD: Javier, Therese en Edmee. Het enthousiasme, de bevlogenheid en de visie waarmee jullie PICASSO voor COPD tot stand hebben gebracht is bewonderenswaardig. Bedankt voor de fantastische samenwerking! Jullie zijn hèt voorbeeld dat een ‘open mind’ en samenwerking tot zoveel meer kunnen leiden.

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Curriculum Vitae

Karin Lemmens was born in Alkmaar, the Netherlands, on August 7, 1979. In 1997 she graduated from secondary school (Athenaeum) at Newman College in Breda. From 1997 to 2001 she studied at the institute of Health Policy and Management at the Erasmus University Rotterdam, where she graduated with a Master's dissertation on information needs of patients in addiction care. After graduation she travelled in South-America for 2 months.

In 2002 she started as a junior research fellow at the institute of Health Policy and Management at the Erasmus University Rotterdam. She worked on a project on the validity of quality systems in health care. In addition, she worked as a quality consultant in a mental health institution (GGZ Delfland), from 2003 until 2004. She co-edited a book on performance management in health care and wrote a workbook on this topic together with Astrid van Dijk and Jan Walburg. In 2005 she started to work on her PhD thesis on the evaluation of disease-management programmes for COPD patients, which resulted in this dissertation. Furthermore, as a teacher, she coordinates and lectures performance management and supervises Master theses in the Master in Health Care Management. She also lectures Integrated Care in the Bachelor of Health Sciences.

Currently, she is a researcher fellow at the institute of Health Policy and Management. She will continue her research aimed at disease-management programmes by working on the evaluation of 22 practice projects assigned by the Netherlands Organisation for Health Research and Development (ZonMw).

PhD Portfolio Summary

PhD portfolio

PhD student:	Karin Lemmens
Department:	Institute of Health Policy and Management
PhD period:	2005 – 2009
Promotor:	Prof. Dr. Robbert Huijsman
Supervisor:	Dr. Anna Nieboer

PhD training

Training

Forces of Change: Intensive Seminar for New and Emerging Leaders – Harvard School of Public Health	2008
Working visit to MacColl Institute for Healthcare Innovation – Seattle	2007
Various courses and seminars on Health Care Management	2002 – now
Academic writing for PhD students	2005
Erasmus Summer Programme	2003

Presentations

Presentation "Evaluating COPD Disease Management: Application of a Theoretical Model" ISQUA's 25th International Conference; Copenhagen Denmark	2008
Poster "Evaluation of a COPD Disease-Management Programme" European Respiratory Society; Berlin Germany	2008
Poster "A review on the use of integrated disease-management interventions" Academy Health Annual Research Meeting; Orlando US	2007
Presentation "Improving Chronic Care: The Role of Disease Management" The Routledge Health Management Conference; London UK	2006
Workshop "Improving professional quality by feedback on outcomes: team oriented approach" 8th European Forum on Quality Improvement in Health Care; Bergen Norway	2003
Poster "Methodological issues of the effects of certification and accreditation on healthcare." ISQUA's 20th International Conference; Dallas US	2003

Teaching qualifications and experience

Lecturing

Bachelor in Health Policy and Management: Integrated care; lecturer	2003 – now
Master in Health Care Management: Performance Management; coordinator, lecturer	2003 – now
Nihes master's programme in Health Services Research: Quality of Care Research, Addiction and Substance Use; lecturer	2005 – 2006

Supervising Master's theses

Master in Health Care Management (ZoMa): supervisor	2003 – now