Primary care nursing for COPD patients: a biopsychosocial perspective

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PhD thesis Utrecht University, the Netherlands

ISBN: 978-94-91602-72-6
Cover: Rianne Witteveen (www.Riannewitteveen.nl)
Layout: Robin Deckert, Sinds 1961 grafisch ontwerp (www.sinds1961.nl)
Printed by: Printservice Ede, Ede (www.proefschriftprinten.nl)

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Verpleegkundige zorg voor COPD patiënten in de eerste lijn:
een biopsychosociaal perspectief

(met een samenvatting in het Nederlands)

Proefschrift

ter verkrijging van de graad van doctor aan de Universiteit Utrecht
op gezag van de rector magnificus, prof.dr. G.J. van der Zwaan,
ingevolge het besluit van het college voor promoties
in het openbaar te verdedigen op
donderdag 3 november 2016 des middags te 12.45 uur

door

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geboren op 5 Januari 1971
te Vianen

Promotoren: Prof. dr. J.W.J. Lammers
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Parts of the studies presented in this thesis were financially supported by PICASSO (Partners In Care Solutions) and Hart & Long Stichting Utrecht

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Content

General introduction

Living with COPD

"One day you realize that having COPD has changed into "a way of life". You did not remember when it started, but you realize that you have avoided riding your bike for a while." (Woman, 62 years old, severe COPD)

"I realize that I'm short of breath when I work in the garden. I can hold on for 10 minutes, then I must stop. My lungs are so bad, I'm worried. But luckily I don't have cancer." (Man, 55 years old, moderate COPD)

"I need time to recover when I walk the stairs. My general condition was decreasing, but I did not give it attention because I was busy with daily life." (Woman, 63 years old, severe COPD)

"One part of having COPD is the medication aspect, but that's not all. One of the biggest problems is that you cannot do what you're used to do or what you want to do, you feel isolated and no one takes that into account." (Woman, 62 years old, mild COPD)

Caring for COPD patients

"My role as a nurse is guiding patients but after several year of caring for COPD patients I still feel empty handed. I have no tools that describe how I can care for COPD patients with depressive symptoms."
(Practice nurse, 54 years old)

"It is hard to motivate COPD patients to come the consultation, and when they finally visit you there is, besides the spirometry and medication information, not much time left for guiding the patient." (Respiratory nurse, 48 years old)

Chronic Obstructive Pulmonary Disease

Chronic Obstructive Pulmonary Disease (COPD) is a common progressive chronic disease characterized by persistent airflow limitation and respiratory complaints such as dyspnea, chronic cough and chronic sputum production mainly caused by non-reversible airway obstruction[1]. Besides pulmonary complaints, COPD patients face other limitations in daily life caused by muscle dysfunction and comorbidities[1,2]. The course of COPD is unpredictable and characterized by periods in which the patient's condition worsen[2].

The first and foremost causal risk factor for developing COPD is tobacco smoking. In addition, it has been assumed that external risk factors, such as secondary smoking, indoor and outdoor air pollution, and occupational related exposure to dust and noxious particles increases the occurrence of COPD[3]. It is estimated that approximately 328 million people (160 million women and 168 million men) have COPD worldwide[3, 4]. Mortality predictions suggest that COPD will become the fourth leading cause of death in 2030[5]. Together with other chronic diseases (diabetes, dementia and cancer) COPD accounts for most of the burden of disease and COPD will continue to be a major health problem leading to high social and economic burden[3].

Impact of COPD

Pulmonary and extra pulmonary complaints affect the physical, emotional and social quality of life of COPD patients[6,7]. Many patients are confronted with daily life limitations. Some COPD patients are able to manage and cope with their condition. However, for many other patients coping with the limitations caused by COPD is very demanding.

Although the clinical diagnosis to characterize COPD is based upon the degree of airflow limitation (i.e., the decrease in the forced expiratory volume in one second (FEV_1)), individual differences in daily functioning and health related quality of life (HRQoL) are not explained by airflow limitations as measured by the FEV_1[8]. The degree of airflow limitation has poor correlations with symptoms and HRQoL[9,10]. To explain these individual differences in HRQoL and daily activities in chronic patients, other models in addition to biomedical perspectives, are increasingly used[11-13]. These biopsychosocial models assume that besides biological aspects, psychological and social factors play an important role in adjustment to chronic disease[12,13]. To understand the complexity of living with COPD, it is important to understand which factors, in addition to physical complaints are related to daily activities and HRQoL[7,14,15].

Nursing care for COPD

Because COPD cannot be cured, treatment objectives focus on relieving and reducing the impact of symptoms, improving participation in everyday activities, improving HRQoL, and reducing adverse events in the future (i.e, exacerbations or so called "lung attacks")[1]. During the last decade patients with COPD are increasingly treated in primary care instead of in hospitals in the Netherlands as well as in many other European countries, the United States, Canada and Australia[16,17]. General practitioners, respiratory nurses and practice nurses play a crucial role in the integrated chronic care for COPD patients[18,19]. In particular, the role of nurses is becoming increasingly important, because nursing care is characterized by continuity of care. Specifically, nurses are involved at all stages of care, from prevention to end-of-life care[18,19]. Nurses have considerably expanded their practice in recent years and efforts have been made to develop care that is coordinated or delivered by nurses[17,18,20-22]. Despite the efforts and positive results, the effectiveness of nursing care on health outcomes remains inconclusive[23,24]. Moreover, most of the time nurses are lacking knowledge and skills to guide COPD patients in living with the disease, to prevent negative consequences and to strengthen daily activities. Research on the role of nurses in COPD care in primary care should therefore be further extended and elucidated[18].

Scope of the thesis

The major challenges of COPD care are guiding patients with the consequences of their disease, reducing impact of symptoms, improving participation in daily activities and improving HRQoL[1,18]. Against this background the scope of this thesis is how to improve the effectiveness of primary care nursing to reduce the impact of COPD in terms of improving HRQoL and daily activities. A biopsychosocial perspective served as the framework for our studies.

Outline of the thesis

First, starting from desired outcomes we systematically reviewed the literature concerning the content and psychometric properties of available instruments used to measure HRQoL as an outcome measure in COPD patients **(Chapter 1)**.

In addition, it is essential to measure and evaluate daily activities. The Functional Performance Inventory (FPI) is an example of an instrument that measures not only physical activities, but also social, occupational and spiritual activities that individuals perform in their daily life and that are considered as important. We translated the English version of the FPI into Dutch and validated the translated questionnaire in Dutch COPD patients **(Chapter 2)**.

Subsequently, looking for points of action from a biopsychosocial perspective, we explored to which extend the combination of several psychological factors (depressive symptoms, proactive coping and illness perceptions) and physical factors (airflow

limitation, dyspnea and co-morbidities) contribute to daily activities and HRQoL in COPD patients in primary care **(Chapter 3)**. As an extension of this study, we analyzed the specific role off illness perceptions in relation to HRQoL **(Chapter 4)**.

Based on the findings regarding outcomes and points of action, we developed a comprehensive nursing intervention that takes into account psychosocial aspects. This resulted in the COPD Guidance, research on Illness Perception (COPD-GRIP) intervention which translates the theory and evidence regarding illness perceptions and HRQoL into a practical guide which nurses can use to provide individualized COPD care. **Chapter 5** presents the barriers and facilitators of the newly developed intervention from the perspective of the nurses. An explanatory mixed-method study was conducted, nested within a cluster randomized trial which is described in chapter 7. Quantitative (questionnaires) and qualitative (focus groups) research methods were used. In addition to the nurses' evaluations, we conducted a qualitative interview study in COPD patients to evaluate their experiences regarding the COPD-GRIP intervention **(Chapter 6)**. Finally, we conducted a cluster randomized trial to determine if the COPD-GRIP intervention, implemented by nurses in primary care settings, leads to improved HRQoL and daily activities in COPD patients compared to usual nursing care **(Chapter 7)**.

Chapter 8 presents the general discussion, which critically reflects on the series of studies in primary care regarding the challenges, outcomes and points of action that can guide nursing interventions. This reflection may provide valuable insights for nurses, researchers, other clinicians and policymakers in this field, resulting in the implications and the next steps in COPD care and research.

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Chapter 1

Evaluation of quality of life instruments for use in COPD care and research: a systematic review

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Published in International Journal of Nursing Studies 50 (2013)

Abstract

Objective: Quality of Life (QoL) measurements to quantify disease burden have become an important outcome measure in Chronic Obstructive Pulmonary Disease (COPD) research and treatment. A large variety of QoL instruments is available. The objective of this review was to comprehensively evaluate content and psychometric properties of available QoL instruments used in COPD care and research.

Design: A systematic literature search was performed.

Databases: The databases PubMed, Embase, CINAHL, and the Cochrane Library were used.

Review method: Two researchers independently identified eligible studies. Methodological quality of the studies and data on measurement properties were assessed by using the Consensus based Standards for selection of health Measurement Instruments (COSMIN). A best evidence synthesis for each instrument was performed.

Results: 77 studies describing 13 disease-specific and 10 generic QoL instruments were identified. The content of the instruments showed a great variety. 20 instruments measured mobility. Pulmonary symptoms were measured in 11 disease specific instruments. Pain, vitality, and spiritual activities were domains seen only in generic instruments. Social and emotional functioning were domains seen in disease specific instruments as well as in generic instruments. The methodological quality of the studies was mostly rated fair, according to the COSMIN checklist. The psychometric properties of the instruments (validity, reliability and responsiveness) were in general rated positive. The best evidence synthesis showed the strongest positive evidence for the disease specific instruments Chronic Respiratory Questionnaire (CRQ), COPD Assessment Test (CAT), Saint George Respiratory Questionnaire (SGRQ), and Living with COPD questionnaire (LCOPD). The generic instruments received less favorable ratings.

Conclusion: Despite the comprehensive overview we could not uniformly recommend the best instrument to evaluate QoL in COPD patients. However, we could recommend the disease specific instruments CRQ, CAT, SGRQ, or LCOPD. In addition to the best evidence synthesis, the decision to use one instrument over another, will be driven by study purpose and research questions in combination with the domains of the instrument. Given the large availability of instruments we discourage to develop new instruments, instead we encourage to design studies according the COSMIN standards to evaluate the psychometric properties of the existing instruments.

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is one of the leading causes for morbidity and mortality worldwide[1]. The prevalence of social and economic burden continues to increase[1]. COPD patients face functional decline and daily life limitations caused by dyspnea, airflow limitation, skeletal muscle dysfunction, and co-morbidities[1]. One of the therapeutic goals in COPD care is to reduce disease burden[2,3]. In order to measure disease burden and the impact of COPD on daily life, Quality of Life (QoL) assessment can be used[2]. In the last decade, the evaluation of QoL in COPD patients has become an important outcome measure in COPD research and treatment[1-4]. The number of articles that use the term "Quality of Life" and "COPD" has grown substantially. In 2007, a PubMed search of all past years using "COPD" and "Quality of Life" keywords, yielded 1607 references[2] whereas in June 2012 the same search yielded 3329 references.

Despite the absence of an agreed definition of QoL, it is usually defined as an individual's perception of the position in life or life satisfaction[5], affected in a complex way by physical health, psychological state, level of independence, social relationships and personal beliefs[6-8]. These perceptions can vary between individuals faced with ostensibly the same circumstances, and within an individual and over time[6].

Health status, functional status, and QoL are often used interchangeably[5,9,10]. However, according to Reardon[11], Moons[5], and Jones[10] these constructs are not equal and should therefore not be used interchangeably, moreover perceptions of health, health status, and functional status should be interpreted as aspects of Quality of Life[5]. Health-related QoL should be operationalised in instruments that assess physical, social, and psychological domains[5,6].

Since QoL is a significant aspect in COPD care and research, it is important to use valid and reliable instruments to evaluate QoL in COPD patients. At present many QoL instruments are available. Besides generic QoL instruments, which can be used to evaluate QoL in any population, there are disease specific instruments which can be used in patients with a particular disease. QoL instruments are used to assist in designing COPD management by prioritizing patient problems, screening potential problems, and taking decisions about treatment[12]. To select an appropriate QoL instrument for use in COPD practice or in COPD research, the measurement properties (validity, reliability, and responsiveness) must be evaluated and considered adequate[13]. Instruments for evaluation of an intervention must be responsive over time and instruments for distinguishing patients must be reliable[13].

Although a large variety of instruments is available, a comprehensive overview is lacking. Therefore, it remains difficult for clinicians and researchers to compare the quality of the various instruments and to determine what the most suitable instrument is, given the measurement objective.

Objective

The purpose of this systematic review was to identify and evaluate the content and measurement properties of QoL instruments used in COPD care and research in order to help clinicians and researchers in their choice of the most suitable instrument.

Methods

Search strategy

A systematic literature search (8 June 2012) was done to identify eligible studies, using the keywords chronic obstructive pulmonary disease, chronic bronchitis, emphysema, and Quality of Life in combination with questionnaire, instrument, and derivates of these terms. A detailed overview of the search strategy is presented in Appendix A. The databases PubMed, Embase, CINAHL, and the Cochrane Library were used without limit features. Reference lists of included studies were screened to identify additional relevant studies.

Selection criteria

All titles and abstracts were read independently by two investigators (SW, RL) to assess whether the retrieved study was eligible for review. Disagreements were resolved in a consensus meeting. Where necessary, any remaining disagreements were resolved by other reviewers (MJS, JWJL). A paper was included if (1) it was a full text original article, (2) published in English, (3) in a peer reviewed journal, (4) described the development or evaluation of the measurement properties or validation of a QoL instrument, and (5) was conducted in a COPD population. Studies in which a QoL instrument was evaluated in other patient groups than COPD patients, were excluded. Etiologic studies or studies concerning QoL determinants, studies where the objective was the evaluation of an intervention or treatment, case reports, abstracts, editorials, opinions, dissertations, reviews, and studies published in languages other than English, were also excluded.

Assessment methodological quality of the studies

The evaluation of QoL instruments requires assessment of the methodological quality of the studies in which the instrument is evaluated[14-16]. If the quality of the study is adequate, the results are reliable and valid, and the instrument could be a useful tool in research and care. However, when the methodological quality of a study is inadequate the results cannot be trusted and the quality of the instrument remains unclear[15,16]. In order to assess the methodological quality of the included studies the recently developed COSMIN checklist (Consensus-based Standards for selection of health Measurement Instruments) was used[14]. This is the only specific tool for methodological evaluation of measurement properties (psychometric properties) on patient reported

outcomes and it is operationalized into a user-friendly and easily applicable checklist; available on the website www.cosmin.nl. It is already used in other reviews[17,18] and the inter-rater agreement has been described as adequate[19].

The COSMIN checklist evaluates the methodological quality of studies on three measurement properties: validity, reliability, and responsiveness. Validity contains content validity and construct validity, which includes structural validity, hypothesis testing, and cross-cultural validity. Reliability is divided into internal consistency and reliability[14]. The methodological quality was assessed on a number of items (5-18 per measurement property), measured on a nominal scale of excellent, good, fair and poor[14-16]. An overall score for the methodological quality of a study was determined for each measurement property separately by taking the lowest rating of any item ('worst score counts')[16]. Two independent reviewers (SW, RL) determined which measurement properties were investigated in the included studies. Disagreements were discussed and resolved in a consensus meeting. Where necessary, any remaining disagreements were resolved by the other reviewers (MJS, JWJL).

Quality assessment of instruments

In order to determine the quality of the instruments, the rating system for measurement properties as proposed by Terwee[20] was used. For each measurement property a criterion is defined for a positive, negative, or indeterminate rating, depending on the outcomes of the studies. For a detailed description see Table 1.

Measurement properties

The measurement properties that were assessed are divided over three domains: validity, reliability, and responsiveness.

Validity refers to the degree to which an instrument measures the construct it is intended to measure[20,21] and is divided into content validity and construct validity. *Content validity* means the degree to which the content of an instrument is an adequate reflection of the construct to be measured. It is important to assess whether all items are relevant for the construct and if no items are missing[21]. *Construct validity* is divided into structural validity, hypothesis testing, and cross cultural validity[21]. *Structural validity* refers to the instrument's structure. Factor analysis is the preferred statistic to determine structural validity[13]. *Hypothesis testing* refers to the extent to which instrument scores relate to other measures in a way that is consistent with a theoretically derived hypothesis concerning the concept that is measured[13]. *Cross-cultural* validity refers to the degree to which the items' performance on a translated scale or culturally adapted instrument, is an adequate reflection of the items' performance of the instrument's original version[13]. *Reliability* is the extent to which scores for stable patients are the same for repeated measurement under several conditions[21]. Reliability contains *internal consistency*, which refers to the extent to which items in an instrument are correlated and is expressed by Cronbach's α[13]. *Reliability* refers to the degree to which repeated measures in stable

subjects provide similar results. Reliability concerns the degree to which patients can be distinguished from each other[20,21].

Responsiveness refers to the ability to detect changes over time in the construct to be measured[13]. Therefore, it is considered as a measure of longitudinal validity[20]. The evaluation should be assessed by testing predefined hypotheses about expected correlations between changes in measures or between groups[20].

Best evidence synthesis

A best evidence synthesis was performed in order to summarize all the evidence on the measurement properties of the different instruments taking into account the number of studies, methodological quality (according to the COSMIN criteria)[14] and the consistency of the results[17,18,22]. *Strong evidence* was defined as consistent findings in multiple studies of good methodological quality *or* in one study of excellent methodological quality. *Moderate evidence* was defined as consisting finding in multiple studies of fair methodological quality *or* in one study of good methodological quality; *a limited level of evidence* was defined as one study of fair methodological quality; *conflicting level of evidence* was defined as conflicting findings. When there were only studies of poor methodological quality or other statistics than recommended by the COSMIN checklist used, *a lack of evidence* was noted.

Results

Selection of studies

The literature search yielded 3432 papers (figure 1). The main search was supplemented by a manual search of reference lists of included studies, which yielded 11 additional papers meeting the selection criteria[23-30,30-33].

Removal of duplicates led to the exclusion of 1471 papers. After reviewing the abstracts, 1862 papers were excluded, 100 references met the selection criteria and after reviewing the full-text articles, an additional 23 papers were excluded. In the qualitative synthesis 77 studies were included.

Table 1. Quality criteria for measurement properties[20]

Property	Rating†	Quality Criteria
Reliability		
Internal consistency	+	Cronbach's alpha(s) ≥ 0.70
	?	Cronbach's alpha not determined
	-	Cronbach's alpha(s) < 0.70
Reliability	+	ICC / weighted Kappa ≥ 0.70 OR Pearson's r ≥ 0.80
	?	Neither ICC / weighted Kappa, nor Pearson's r determined
	-	ICC / weighted Kappa < 0.70 OR Pearson's r < 0.80
Validity		
Content validity	+	The target population considers all items in the questionnaire to be relevant AND considers the questionnaire to be complete
	?	No target population involvement
	-	The target population considers items in the questionnaire to be irrelevant OR considers the questionnaire to be incomplete
Construct validity - *Structural validity*	+	Factors should explain at least 50% of the variance
	?	Explained variance not mentioned
	-	Factors explain < 50% of the variance
- *Hypothesis testing*	+	Correlation with an instrument measuring the same construct ≥ 0.50 OR at least 75% of the results are in accordance with the hypotheses AND correlation with related constructs is higher than with unrelated constructs
	?	Solely correlations determined with unrelated constructs
	-	Correlation with an instrument measuring the same construct < 0.50 OR < 75% of the results are in accordance with the hypotheses OR correlation with related constructs is lower than with unrelated constructs
	+	Original factor structure confirmed OR no important DIF between language versions
- Cross-cultural validity	?	Confirmatory factor analysis not applied and DIF not assessed
	-	Original factor structure not confirmed OR important DIF found between language versions
Responsiveness		
Responsiveness	+	Correlation with an instrument measuring the same construct ≥ 0.50 OR at least 75% of the results are in accordance with the hypotheses OR AUC ≥ 0.70 AND correlation with related constructs is higher than with unrelated constructs
	?	Solely correlations determined with unrelated constructs
	-	Correlation with an instrument measuring the same construct < 0.50 OR < 75% of the results are in accordance with the hypotheses OR AUC < 0.70 OR correlation with related constructs is lower than with unrelated constructs

ICC = intraclass correlation coefficient, DIF = differential item functioning, AUC = area under the curve

† + = positive rating, ? = indeterminate rating, - = negative rating

Instruments

To measure QoL in COPD patients 23 instruments were identified; 13 disease specific and 10 generic instruments. Table 2a shows the instrument characteristics (number of items, response options, completion time, and administration) while Table 2b shows the instruments' domains. In 20 instruments, meaning all except the Hyland scale, the Chronic Respiratory Questionnaire (CRQ), and the Living with Chronic Obstructive Pulmonary Disease questionnaire (LCOPD), mobility was measured. In 11 disease specific instruments, meaning all except de LCOPD and the Maugeri Respiratory Failure (MRF-28), COPD specific symptoms such as dyspnea, cough, phlegm, chest tightness, and wheezing were measured. Invalidity, mastery, fatigue, and cognition were only measured in disease specific instruments. Pain, vitality, and spiritual activities were domains seen only in generic instruments. Social and emotional functioning were domains seen in disease specific instruments as well as in generic instruments.

The methodological quality per study (poor, fair, good, or excellent) and the quality of the measurement properties of the instruments (negative, intermediate, or positive) are presented in Table 3. The characteristics of the included studies are presented in Table 4. The synthesis of the results per instrument is presented in Table 5. Below the results per instruments are described.

The Chronic Respiratory Questionnaire (CRQ) was studied in 23 papers (Table 3) in different settings (community, hospital, and pulmonary rehabilitation) (Table 4).

Validity: as can be seen in Table 3 hypothesis testing was performed in 17 studies. Most methodological ratings were fair. One study had poor quality[34], two studies had good quality[35,36,36] and one had excellent quality[27]. Except for three studies[34,37,38], all studies were rated positive for the measurement property hypothesis testing. Content validity was rated excellent in one study regarding methodological quality and rated positive for the accompanying measurement property[39]. Methodological ratings for structural validity were good in two studies[35,40] and excellent in one study[38]. The measurement property was rated positive in those three studies. Cross cultural validity was studied in five studies[37,39,41-43]. It was rated poor for methodological quality and rated intermediate for this measurement property in these studies.

Reliability: internal consistency was studied in 12 studies (Table 3). Despite the fact that it was rated poor for methodological quality in seven studies, the measurement property was rated positive in all studies. Reliability was studied in ten studies (Table 3). One study had good quality[41], three had fair quality[39,43,44] and the remaining studies had poor quality. In seven studies this measurement property was rated positive, in one study negative[37], and in one study it was rated intermediate[34].

Responsiveness was studied in ten studies (Table 3). All of these studies were rated fair for methodological quality, except for two studies which were rated good[36,40]. This measurement property was rated negative in two studies[45,46], rated positive in three

studies[36,40,47] and rated intermediate in the remaining studies.

Best evidence synthesis resulted in strong evidence for content validity, structural validity, hypothesis testing, and internal consistency. It resulted in moderate evidence for reliability and responsiveness. For cross cultural validity there were no results due to the lack of evidence (Table 5).

St George Respiratory Questionnaire (SGRQ) was studied in 26 papers (Table 3) in different settings (community, hospital, and pulmonary rehabilitation) (Table 4).

Validity: hypothesis testing was studied in 20 papers (Table 3). One study's quality was rated poor[28], three were rated good[48-50], the remaining studies were rated fair. In 17 studies the measurement property hypothesis testing was rated positive (Table 3). In one study[51] it was rated negative and in two studies[52,52,53] it was rated intermediate.

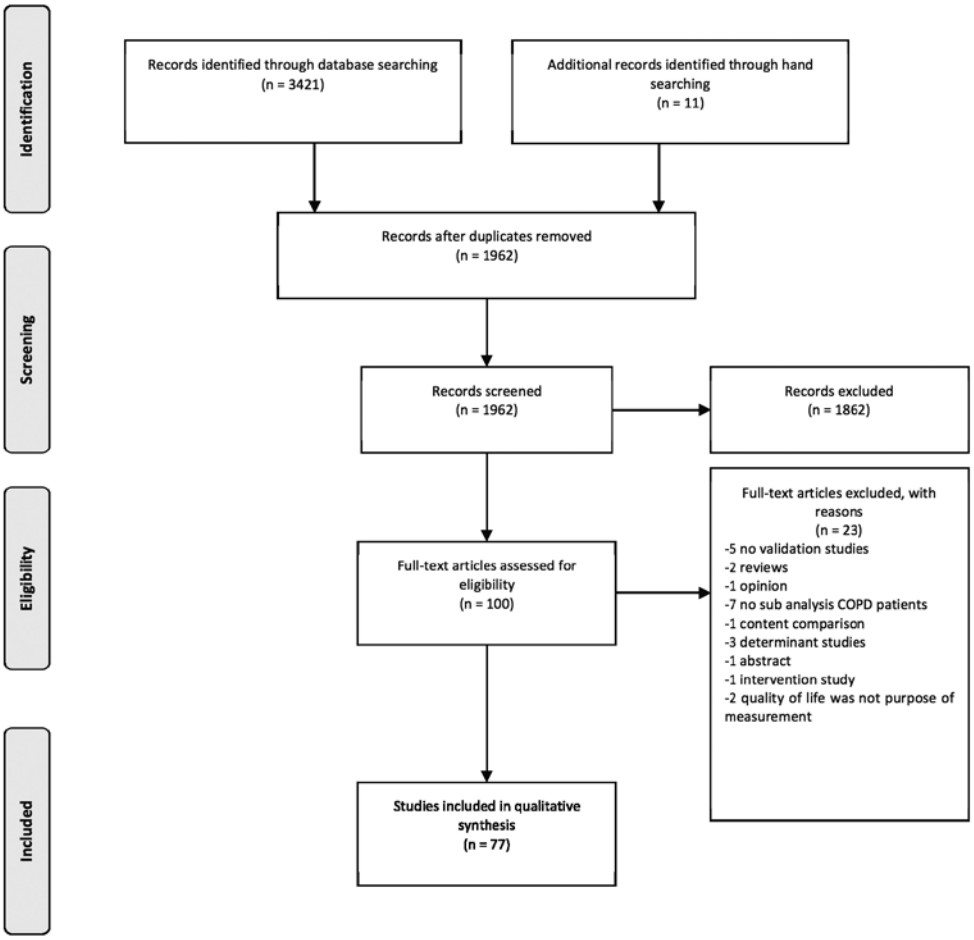
Methodological quality for structural validity was rated excellent in one study[54], it was rated good in one study[40] and rated fair in a different study[55]. The measurement property was rated positive in all three studies. Cross cultural validity was studied in six studies which were all of poor quality (Table 3). This measurement property was rated intermediate (Table 3). Content validity was not assessed.

Reliability: internal consistency was studied in eight studies of poor quality (Table 3), two studies of fair quality[28,56], and one study of good quality[55]. In all studies the measurement property internal consistency was rated positive. Reliability was studied in eight studies. Two studies had poor quality[23,24], three had fair quality[53,54,57], two had good quality[28,55] and one had excellent quality[58]. Reliability was rated positive, except in one study[53], which was rated intermediate for this measurement property.

Responsiveness was studied in 12 studies (Table 3). Study quality was rated poor in one study[59], rated good in three studies[28,40,48] and rated fair in eight studies (Table 3). Responsiveness was assessed positive in one study[40] negative in two studies[28,59] and intermediate in the remaining studies (Table 3).

Best evidence synthesis resulted in strong evidence for structural validity and reliability. It resulted in moderate evidence for hypothesis testing, internal consistency, and responsiveness. For cross cultural validity there were no results due to the lack of evidence. Content validity was not assessed (Table 5).

Figure 1. Flow diagram of search results



Tabel 2a. Instrument characteristics

Instrument	*Reference*	*Number of items*	*Response options*	*Completion time (minutes)*	*Administration*
Disease specific					
CRQ	Guyatt et al, 1987 [107]	20	7-point modified Likert Scale	10 (int) 15-25 (sa)	Interview (int) self-administration (sa)
SGRQ	Jones et al, 1991 [108]	76	5-point Likert and Dichotomous (yes/no)	10	Supervised self-administration
AQ20/30	Chen et al, 2006 [72]	20/30	Yes, No, Not applicable	1-3	Self-administered
AQ 20 R	Chen et al, 2006 [72]	20	Yes, Unable, No, Not applicable	1-3	Self-administered
CAT	Jones et al, 2009 [73]	8	5-point Likert scale	1-3	Self-administered
CCQ	Molen vd et al, 2003 [30]	10	7-point Likert scale	1-3	Self-administered
MRF-28	Duiverman et al, 2008 [74]	28	Dichotomous true/ false	10	Self-administered
SRI	Duiverman et al, 2008 [74]	49	5 point Likert scale	20	Self-administered
LAS/VAS-8	Nishiyama et al, 2000 [77]	8	Horizontal line 10 cm with extrems in words on end	3	Self-administered
VSRQ	Perez et al, 2009 [78]	8	Horizontal numerical scale 0-10 grades /1cm	3	Interview
RQLQ	Stavem et al, 1999 [79]	20	5-point Likert scale	10-15	Self-administered
LCOPD	McKenna et al, 2011 [100]	22	Dichotomous True/ not true	10	Self-administered
McGill COPD	Pakhale et al, 2011 [102]	29	5-point Likert Scale	10-15	Self-administered
Generic					
SF-36	Ozalevli et al, 2008 [81]	36	5 level response choices	10-15	Interview/ self-administered
SF-12	Menn et al, 2010 [67]	12	5 level response choices	5	Interview/ self-administered
DartmCoop	Eaton et al 2005 [83]	9	5 –point ordinal scale (words and graphically)	5	Interview/ self-administered
SIP	Hutter et al, 1997 [84]	136	Dichotomous Yes/ no	20-30	Interview/ self-administered
NHP	Ozalevli et al, 2008 [81]	45	Dichotomous Yes/ no	10-15	Self-administered
WHOQOLBREF	Liang et al, 2008 [52]	26	5- point Likert scale	10	Self-administered
QWBSA	Kaplan et al, 2004 [66]	10	Preference weighted 0-1	12 – 20	Self-administered
Hyland Scale	Nishimura et al, 2008 [68]	1	1 scale extremes on end (0-100)	<5	Interview/ self-administered
MYMOP	Paterson et al, 2000 [85]	3	Choosing problematic symptom and ADL /7- point scale	< 10	Interview/ self-administered
EQ-5 D	Rutten-van Molken et al, 2006 [86]	15	3 levels: no problems, some problems and severe problems	8	Self-administered

CRQ (Chronic Respiratory Questionnaire), **SGRQ** (St George Respiratory Questionnaire), **AQ-20/30** (Airway Questionnaire 20/30), **AQ-20R** (Airway Questionnaire 20 Revised), **CAT** (COPD assessment Test), **CCQ** (Clinical COPD Questionnaire), **MRF-28** (Maugeri Respiratory Failure Questionnare-28), **SR**I (Severe Respiratory Insufficiency), **LAS/VAS-8** (Linear Analogue Scale/Visual Analogue Scale), **VSRQ** (Visual Simplified Respiratory Questionnaire), **RQLQ** (Respiratory Quality of Life Questionnaire), **LCOPD (**Living with Chronic Obstructive pulmonary disease questionnaire), **McGill COPD** (McGill COPD Quality of Life Questionnaire), **SF-12** (Short-Form Health Survey-12), **SF-36** (Short-Form Health Survey-36), **DartmCoop** (The Dartmouth Northern New England Primary Care Cooperative Information Project chart system), **SIP** (Sickness Impact Profile), **NHP** (Nottingham Health Profile**), WHOQOLBREF** (World Health Organization Quality of Life short version list), **QWBSA** (Quality of Well Being Self-Administered), **MYMOP** (Measure Yourself Medical Outcome Profile), **EQ-5D** (EuroQol 5D)

Tabel 2b. Instrument's domains

Instrument	Dyspnea	Cough	Phlegm	Chest Tightness	Wheezing	Symptoms	Mobility	Invalidity	Energy, vitality, fatigue	Mastery	Social functioning	Feelings/ Emotional Functioning	Anxiety	Impact on daily life	Sleep	Cognition	Pain	Appetite	Spiritual	Sexual Life	Overall Healthwell-being
Disease specific																					
CRQ	X								X	X		X									
SGRQ	X	X	X		X		X							X							
AQ20/30		X					X		X			X									
AQ20-R		X					X		X			X									
CAT	X	X	X	X			X		X						X						
CCQ	X	X	X				X				X	X									
MRF-28							X	X								X					
SRI	X	X	X	X		X	X				X		X		X						X
LAS/VAS-8	X					X	X				X	X	X					X			X
VSRQ	X						X		X		X	X	X		X					X	
RQLQ	X			X	X	X	X		X	X	X	X	X	X	X						
LCOPD														X							
McGill COPD						X	X					X									
Generic																					
SF-36							X		X		X	X					X				X
SF-12							X		X		X	X					X				X
DartmCoop							X				X	X					X				X
SIP							X				X	X			X			X			
NHP							X		X		X	X			X		X				
WHOQOLbref							X				X	X							X		
QWBSA	X	X			X	X	X				X										
Hylandscale																					X
MYMOP						X	X														X
EQ-5 D							X						X				X				

CRQ (Chronic Respiratory Questionnaire), **SGRQ** (St George Respiratory Questionnaire), **AQ-20/30** (Airway Questionnaire 20/30), **AQ-20R** (Airway Questionnaire 20 Revised), **CAT** (COPD assessment Test), **MRF-28** (Maugeri Respiratory Failure Questionnare-28), **SR**I (Severe Respiratory Insufficiency), **LAS/VAS-8** (Linear Analogue Scale/Visual Analogue Scale), **VSRQ** (Visual Simplified Respiratory Questionnaire), **RQLQ** (Respiratory Quality of Life Questionnaire), **SF-12** (Short-Form Health Survey-12), **LCOPD (**Living with Chronic Obstructive pulmonary disease questionnaire), **McGill COPD** (McGill COPD Quality of Life Questionnaire **SF-36** (Short-Form Health Survey-36), **DartmCoop** (The Dartmouth Northern New England Primary Care Cooperative Information Project chart system), **SIP** (Sickness Impact Profile), **NHP** (Nottingham Health Profile), **WHOQOLBREF** (World Health Organization Quality of Life short version list), **QWBSA** (Quality of Well Being Self-Administered), **MYMOP** (Measure Yourself Medical Outcome Profile), **EQ-5D** (EuroQol 5D)

Table 3. Rating standards for methodological and measurement properties

		Validity								Reliability		Responsiveness			
		Content Validity		Construct Validity											
				Structural validity		*Hypothesis testing*		*Cross cultural*		Internal consistency		Reliability		Responsiveness	
Instrument	Author	M	Q	M	Q	M	Q	M	Q	M	Q	M	Q	M	Q
Disease specific															
CRQ	Aaron et al., 2002 [44]					**Fair**	+					**Fair**	+	**Fair**	?
	Al Moamary and Tamim 2011 [43]							**Poor**	?			**Fair**	+		
	Al-Ghimlas et al., 2011 [42]							**Poor**	?						
	Bourbeau et al., 2004 [23]					**Fair**	+			**Poor**	+	**Poor**	+	**Fair**	?
	Chan et al., 2006 [39]	**Excellent**	+			**Fair**	+	**Poor**	?	**Poor**	+	**Fair**	+		
	Desikan et al., 2002 [56]									**Fair**	+				
	Guell et al., 1998 [37]					**Fair**	-	**Poor**	?	**Poor**	+	**Poor**	-		
	Hajiro et al., 1998 [61]					**Fair**	+			**Poor**	+				
	Harper et al., 1997 [24]					**Fair**	+			**Poor**	+	**Poor**	+	**Fair**	?
	Martin, 1994 [34]					**Poor**	?					**Poor**	?		
	Puhan et al., 2004 [41]					**Fair**	+	**Poor**	?	**Good**	+	**Good**	+		
	Puhan et al., 2007 [62]													**Fair**	?
	Reda et al., 2010 [36]					**Good**	+			**Poor**	+			**Good**	+
	Ringbaek et al., 2012 [91]					**Fair**	+								
	Rutten-van Molken et al., 1999 [40]			**Good**	+	**Fair**	+			**Good**	+			**Good**	+
	Schunemann et al., 2005 [47]					**Fair**	+							**Fair**	+
	Singh et al., 2001 [45]					**Fair**	+							**Fair**	-
	de Torres et al., 2002 [46]													**Fair**	-
	Williams et al., 2001 [27]					**Excellent**	+					**Poor**	+		
	Tsai et al., 2008 [38]			**Excellent**	+	**Fair**	-			**Poor**	+	**Poor**	+	**Fair**	?
	Tsukino et al., 2002 [63]													**Fair**	?
	Wijkstra et al., 1994 [64]					**Fair**	+			**Poor**	+				
	Wyrwich et al., 1999 [35]			**Good**	+	**Good**	+			**Excellent**	+				
SGRQ	Alonso et al., 1998 [65]					**Fair**	+	**Poor**	?						
	Aslani et al., 2008 [51]					**Fair**	-								
	Barr et al., 2000 [28]					**Poor**	+	**Poor**	?	**Fair**	+	**Good**	+	**Good**	-
	Bourbeau et al., 2004 [23]					**Fair**	+			**Poor**	+	**Poor**	+	**Fair**	?
	Desikan et al., 2002 [56]									**Fair**	+				
	Doll et al., 2003 [48]					**Good**	+							**Good**	?
	Engstrom et al., 1998 [59]					**Fair**	+	**Poor**	?	**Poor**	+			**Poor**	-
	Ferrer et al., 1996 [49]					**Good**	+	**Poor**	?	**Poor**	+				
	Harper et al., 1997 [24]					**Fair**	+			**Poor**	+	**Poor**	+	**Fair**	?

		Validity								Reliability				Responsiveness	
		Content Validity		Construct Validity											
				Structural validity		*Hypothesis testing*		*Cross cultural*		Internal consistency		Reliability		Responsiveness	
Instrument	**Author**	M	Q	M	Q	M	Q	M	Q	M	Q	M	Q	M	Q
	Hajiro et al., 1998 [61]					**Fair**	+			**Poor**	+				
	Kaplan et al., 2004 [66]					**Fair**	+								
	Katsoulas and Skordilis, 2010 [57]					**Fair**	+					**Fair**	+	**Fair**	?
	Liang et al., 2008 [52]					**Fair**	?			**Poor**	+				
	Maly and Vondra, 2006 [53]					**Fair**	?			**Poor**	+	**Fair**	?	**Fair**	?
	Meguro et al., 2007 [54]			**Excellent**	+							**Fair**	+	**Fair**	?
	Menn et al., 2010 [67]					**Fair**	+							**Fair**	?
	Nishimura et al., 2008 [68]					**Fair**	+								
	Pickard et al., 2011[50]					**Good**	+								
	Puhan et al., 2007 [62]													**Fair**	?
	Ringbaek et al., 2012 [91]					**Fair**	+								
	Rutten-van Molken et al., 1999 [40]			**Good**	+	**Fair**	+			**Good**	+			**Good**	+
	Fallah Tafti et al., 2009 [69]							**Poor**	?	**Poor**	+				
	de Torres et al., 2002 [46]													**Fair**	-
	Xu et al., 2009 [58]					**Fair**	+	**Poor**	?			**Excellent**	+	**Fair**	?
	Yu et al., 2004 [55]			**Fair**	+	**Fair**	+			**Good**	+	**Good**	+		
AQ20/30	Alemayehu et al., 2002 [70]					**Fair**	+								
	Hajiro et al., 1999 [71]					**Fair**	+			**Poor**	+			**Poor**	+
	Blanco-Aparicio et al., 2010 [89]					**Fair**	+			**Poor**	+	**Fair**	+		
	Mazur et al., 2011 [90]					**Good**	+								
AQ-20 R	Chen et al., 2006 [72]					**Fair**	+			**Poor**	+				
CAT	Dodd et al., 2011 [94]													**Good**	+
	Dodd et al., 2012 [93]													**Good**	+
	Jones et al., 2009 [73]	**Excellent**	+	**Excellent**	+					**Excellent**	+	**Good**	+		
	Jones et al., 2011 [33]					**Fair**	+								
	Jones et al., 2012 [106]													**Fair**	+
	Mackay et al., 2012 [95]													**Good**	+
	Ringbaek et al., 2012 [91]					**Fair**	+								
	Tsiligianni et al., 2012 [92]					**Fair**	+			**Poor**	+	**Good**	+		
CCQ	Vd Molen et al., 2003 [30]					**Fair**	+			**Poor**	+	**Poor**	+	**Fair**	+
	Damato et al., 2005 [29]					**Fair**	+			**Poor**	+	**Good**	+	**Fair**	+
	Ställberg et al., 2009 [32]					**Good**	+			**Poor**	+	**Fair**	+		
	Kocks et al., 2010 [31]					**Fair**	+								
	Reda et al., 2010 [36]					**Good**	+			**Poor**	+			**Good**	+
	Papadopoulos et al., 2011 [96]					**Poor**	+	**Poor**	?	**Poor**	+	**Poor**	+	**Poor**	+
	Ringbaek et al., 2012 [91]					**Fair**	+								

Instrument	Author	Validity						Reliability		Responsiveness			
		Content Validity		Construct Validity									
				Structural validity		*Hypothesis testing*		*Cross cultural*		Internal consistency		Reliability		Responsiveness	
		M	Q	M	Q	M	Q	M	Q	M	Q	M	Q	M	Q
	Tsiligianni et al., 2012 [92]					Fair	+			Poor	+	Good	+		
MRF-28	Duiverman et al., 2008 [74]					Good	+					Poor	+		
SRI	Windisch et al., 2008 [75]			Fair	+					Fair	+				
LAS/VAS-8	Katsura et al., 2003 [76]					Fair	-			Poor	+			Fair	+
	Nishiyama et al., 2000 [77]					Fair	+			Poor	+			Fair	+
VSRQ	Perez et al., 2009 [78]					Fair	+			Excellent	+	Excellent	+	Fair	?
RQLQ	Stavem et al., 1999 [79]					Fair	+	Poor	?	Poor	+	Good	+	Fair	?
LCOPD	McKenna et al., 2011 [100]	Excellent	+			Fair	+			Good	+	Good	+		
	McKenna et al., 2012 [101]	Excellent	+			Fair	+	Poor	?	Good	+	Good	+		
McGill COPD	Pakhale et al., 2011 [102]	Excellent	+												
Generic															
SF-36	Harper et al., 1997 [24]					Fair	+			Poor	+	Poor	-	Fair	?
	Mahler and Mackowiak, 1995 [80]					Fair	+								
	Ozalevli et al., 2008 [81]					Fair	?								
	Pickard et al., 2011 [50]					Good	+								
	Prieto et al., 1997 [82]			Fair	+	Fair	+			Fair	+				
	Alonso et al., 1998 [65]					Fair	+	Poor	?	Poor	+				
	Aslani et al., 2008 [51]					Fair	-								
	Desikan et al., 2002 [56]									Fair	+				
	Kaplan et al., 2004 [66]					Fair	+								
	Maly and Vondra, 2006 [53]					Fair	?			Poor	+	Fair	?	Fair	?
	Puhan et al., 2007 [62]													Fair	?
	de Torres et al., 2002 [46]													Fair	?
	Wyrwich et al., 1999 [35]					Good	+			Excellent	+			Good	?
SF-12	Menn et al., 2010 [67]					Fair	+							Fair	?
Darthmouth COOP	Eaton et al., 2005 [83]					Fair	+					Poor	-	Fair	?
	Stavem and Jodalen, 2002 [26]					Fair	+					Fair	+		
SIP	Hutter and Wurtemberger, 1997 [84]					Fair	-			Poor	+				
	Engstrom et al., 1998 [59]					Fair	+							Poor	-
NHP	Doll et al., 2003 [48]					Good	+							Good	+
	Jans et al., 1999 [25]					Fair	?			Poor	+				
	Ozalevli et al., 2008 [81]					Fair	+								

Instrument	Author	Validity						Reliability				Responsiveness			
		Content Validity		Construct Validity						Internal consistency		Reliability		Responsiveness	
				Structural validity		*Hypothesis testing*		*Cross cultural*							
		M	Q	M	Q	M	Q	M	Q	M	Q	M	Q	M	Q
	Prieto et al., 1997 [82]			**Fair**	+	**Fair**	+								
	Tsukino et al., 2002 [63]													**Fair**	**?**
WHQOL-BREF	Liang et al., 2008 [52]					**Fair**	**?**			**Poor**	+				
QWBSA	Kaplan et al., 2004 [66]					**Fair**	+								
Hyland Scale	Nishimura et al., 2008 [68]					**Fair**	+	**Poor**	**?**			**Fair**	+		
MYMOP	Paterson et al., 2000 [85]													**Fair**	**?**
EQ5D	Rutten-van Molken et al., 2006 86					**Fair**	+								
	Harper et al., 1997 [24]					**Fair**	+			**Poor**	+	**Poor**	-	**Fair**	**?**
	Menn et al., 2010 [67]					**Fair**	+							**Fair**	**?**
	Pickard et al., 2011 [50]					**Good**	+								
	Stavem, 1999 [87]					**Fair**	**?**					**Fair**	+	**Fair**	**?**

M= methodological quality of the study: "excellent", "good", "fair" and "poor" **Q = Quality criteria of measurement property +** = positive rating,**?** = indeterminate rating or another statistical analysis than preferred by the COSMIN criteria, **-** = negative rating.

CRQ Chronic Respiratory Questionnaire, **SGRQ** St George Respiratory Questionnaire, **AQ-20/30** Airway Questionnaire 20/30 , **AQ-20R** Airway Questionnaire 20 Revised, **CAT** COPD assessment Test, **CCQ** Clinical COPD questionnaire, **MRF-28** Maugeri Respiratory Failure Questionnare-28, **SRI** Severe Respiratory Insufficiency, **LAS/VAS-8** Linear Analogue Scale/ Visual Analogue Scale, **VSRQ** Visual Simplified Respiratory Questionnaire, **RQLQ** Respiratory Quality of Life Questionnaire, **LCOPD** Living with Chronic Obstructive pulmonary disease questionnaire, **McGill COPD** McGill COPD Quality of Life Questionnaire, **SF-12** Short-Form Health Survey-12, **SF-36** Short-Form Health Survey-36, **DartmCoop** The Dartmouth Northern New England Primary Care Cooperative Information Project chart system, **SIP** Sickness Impact Profile, **NHP** Nottingham Health Profile**, WHOQOLBREF** World Health Organization Quality of Life short version list, **QWBSA** Quality of Well Being Self-Administered, **MYMOP** Measure Yourself Medical Outcome Profile, **EQ-5D** EuroQol 5D

Airway Questionnaire (AQ 20/30) was studied in four studies (Table 3) in different settings (Table 4).

Validity: the validity (hypothesis testing) of the AQ20/30 was studied in three papers of fair quality[71,88,89], one paper of good quality[90], and assessed positive for this measurement property. The remaining measurement properties were not assessed (Table 3).

Reliability: internal consistency was assessed in two studies of poor quality[71,89]. The measurement property was rated positive (Table 3).

Responsiveness was rated positive, but the quality of the study was poor[71] (Table 3).

Best evidence synthesis resulted in moderate evidence for hypothesis testing. For reliability there were no results due to the lack of evidence. Other properties were not assessed (Table 5).

The Airway Questionnaire AQ 20-R was studied in one study[72] in the community (Table 4).

Validity (hypothesis testing) was rated fair for study quality and positive for measurement property (Table 3).

Reliability (internal consistency) was rated poor for methodological quality and positive for measurement property (Table 3).

Best evidence synthesis resulted in limited evidence for hypothesis testing and for internal consistency there were no results due to the lack of evidence (Table 5).

COPD Assessment Test (CAT) was studied in eight studies in mainly pulmonary rehabilitation patients and in one study in primary care patients[33] (Tables 3 and 4).

Validity: the validity (hypothesis testing) of the CAT was studied in three studies of fair methodological quality[91,92] and was rated positive for this measurement property. Content- and structural validity was assessed in one study[73], rated excellent for methodological quality and positive for measurement property.

Reliability: internal consistency was assessed in two studies, one of excellent methodological quality[73] and one of poor methodological quality[92]. Both studies were assessed positive for measurement property. Reliability was studied in the same studies and rated good for methodological quality and positive for measurement property.

Responsiveness was studied in three studies of good methodological quality[93,94] and one of fair quality[95]. The measurement property was rated positive in all of these studies.

Best evidence synthesis resulted in strong evidence for content validity, structural validity, internal consistency and responsiveness. It resulted in moderate evidence for hypothesis testing and reliability (Table 5).

Clinical COPD Questionnaire (CCQ) was studied in eight studies, mainly in primary care patients (Tables 3 and 4).

Validity: the validity (hypothesis testing) was assessed in eight studies. One study was rated poor for methodological quality[96], two were rated good[32,36], and the remaining studies were rated fair for methodological quality. One study[96] of poor quality studied the cross cultural validity and was rated intermediate for this measurement property.

Reliability: internal consistency was studied in six studies (Table 3) of poor methodological

quality, however rated positive in all studies for measurement property. Reliability was assessed in five studies (Table 3). Two were rated poor for methodological quality[30,96], two were rated good[29,92], and one was rated fair[32]. The measurement property was rated positive in all of these studies.

Responsiveness was studied in four studies. One of poor study quality[96], two of fair quality[29,30], and one of good methodological quality[36]. The measurement property was assessed positive in all of these studies.

Best evidence synthesis resulted in strong evidence for hypothesis testing and reliability. Moderate evidence for responsiveness and lack of evidence for internal consistency and cross cultural validity due to poor methodological quality and other used statistics than recommended by the COSMIN checklist (Table 5).

Maugeri Respiratory Failure (MRF-28) was studied in one study[97] in patients with stable conditions in respiratory failure (Tables 3 and 4).

Validity: methodological quality was assessed good for v*alidity (hypothesis testing)* and the measurement property was rated positive (Table 3).

Reliability was rated poor for methodological quality. The measurement property was assessed positive. Other properties were not assessed (Table 3).

Best evidence synthesis resulted in moderate evidence for hypothesis testing and for reliability no results were available due to the lack of evidence (Table 5).

Severe Respiratory Insufficiency (SRI) instrument was studied in one study[75] in oxygen dependent COPD patients (Table 4) and was assessed for *structural validity* (fair study quality and positive measurement property) *and reliability* (fair study quality and positive measurement property) (Table 3).

Best evidence synthesis resulted in limited evidence for structural validity and internal consistency (Table 5).

Linear Analogue Scale/Visual Analogue Scale (LAS/ VAS-8) was studied in two studies[76,98] in community and rehabilitation patients (Tables 3 and 4).

Validity: both studies studied hypothesis testing (study quality fair). The measurement property was rated negative in one study[76] and positive in the other study[98] (Table 3).

Reliability (internal consistency) was rated poor for methodological quality in both studies, but was assessed positive for its measurement property (Table 3).

Best evidence synthesis resulted in conflicting evidence for hypothesis testing and unavailability of results due to the lack of evidence for internal consistency (Table 5).

Visual Simplified Respiratory Questionnaire (VSRQ) was studied in one study[99] in mild and severe patients (Table 4).

Validity (hypothesis testing) was rated fair for methodological quality, but positive for measurement property (Table 3).

Reliability: internal consistency and reliability were rated excellent for study quality and positive assessed for the measurement property (Table 3).

Responsiveness was rated fair for study quality and was rated intermediate for

measurement property (Table 3).

Best evidence synthesis resulted in limited evidence for hypothesis testing and strong evidence for internal consistency and reliability. There were no results due to the lack of evidence for responsiveness (Table 5).

Respiratory Quality of Life Questionnaire (RQLQ) was studied in one study in outpatient patients[79] (Table 4).

Validity was rated fair for methodological quality (hypothesis testing) and rated positive for measurement property. Cross cultural validity was rated poor for methodological quality and intermediate for measurement property (Table 3).

Reliability: internal consistency was assessed poor for methodological quality, but positive for measurement property. Reliability was rated good for methodological quality and positive for measurement property (Table 3).

Responsiveness was rated fair for study quality and intermediate for measurement property (Table 3).

Best evidence synthesis resulted in limited evidence for hypothesis testing, no results due to lack of evidence for cross cultural validity, internal consistency, and responsiveness and moderate evidence for reliability (Table 5).

Living with Chronic Obstructive Pulmonary Disease Questionnaire (LCOPD) was studied in two studies[100,101] in mild to severe COPD patients.

Validity: content validity was assessed excellent for study quality in the two studies[100,101] and rated positive for measurement property. Hypothesis testing was rated fair for methodological quality but rated positive for this measurement property[100,101]. Cross cultural validity was assessed poor for study quality and intermediate for this measurement property.

Reliability: internal consistency and reliability were rated good for methodological quality and positive for measurement property in both studies.

Best evidence synthesis resulted in strong evidence for content validity, internal consistency and reliability, moderate evidence for hypothesis testing, and a lack of evidence for cross cultural validity (Table 5).

McGill COPD Quality of Life Questionnaire (McGillCOPD) was studied in one study[102].

Validity: content validity was assessed and rated excellent for methodological quality and positive for this measurement property. The other properties were not assessed.

Best evidence synthesis resulted in strong evidence for content validity (Table 5).

Short-Form Health Survey (SF-36) was studied in outpatient and hospital patients (Table 4).

Validity: hypothesis testing was studied in ten studies (Table 3). All studies were of fair methodological quality, except for two studies which were of good quality[35,50]. The measurement property was rated positive in seven studies, intermediate in two studies[53,103] and negative in one study[51] (Table 3). Structural validity was studied in one study[82]. The methodological quality was rated fair and the measurement property was rated positive. Cross cultural validity was rated poor for study quality and intermediate

for measurement property[65].

Reliability: internal consistency was studied in six studies (Table 3). The methodological quality was rated poor in three studies[24,53,65], rated fair in two studies[56,82], and excellent in one study[35]. The measurement property was rated positive in all of these studies. Reliability was studied in one study of poor quality[24] and one study of fair quality[53]. The measurement property was rated negative in one study[24] and intermediate in one study[53].

Responsiveness was assessed in four studies of fair quality (Table 3) and in one study of good quality[35]. It was rated intermediate for measurement property in all of these studies.

Best evidence synthesis resulted in limited evidence for structural validity, conflicting evidence for hypothesis testing and reliability, no results due to lack of evidence for responsiveness and cross cultural validity, and strong evidence for internal consistency (Table 5).

Shorter form SF-12 (SF-12) was studied in one study in exacerbation patients[104] (Table 4).

Validity (hypothesis testing) was rated fair for methodological quality, but rated positive for measurement property (Table 3).

Responsiveness was rated fair for methodological quality and rated intermediate for measurement property (Table 3).

Best evidence synthesis resulted in limited evidence for hypothesis testing and no results due to the lack of evidence for responsiveness (Table 5).

Dartmouth-Northern New England Primary Care Cooperative Information Project chart system (Dartmouth COOP) was studied in two studies in outpatients and oxygen dependent patients[26,83] (Table 4).

Validity: the methodological quality was rated fair for hypothesis testing in both studies[26,83]. The measurement property was rated positive[26,83] (Table 3).

Reliability was rated poor for methodological quality in one study[83] and fair in one study[26]. The measurement property was rated negative in one study[83] and positive in the other study[26].

Responsiveness was rated fair for study quality and intermediate for measurement property[83] (Table 3).

Best evidence synthesis resulted in moderate evidence for hypothesis testing, conflicting evidence for reliability, and no results due to lack of evidence for responsiveness (Table 5).

Sickness Impact Profile (SIP) was studied in two studies[59,84] (Table 4). One study was in end-stage oxygen dependent patients[84] and one in stable hospital patients[59].

Validity: hypothesis testing was rated fair for methodological quality and rated negative for measurement property in one study[84] and positive in the other study[59] (Table 3).

Reliability was rated poor for methodological quality, but rated positive for measurement property[84] (Table 3).

Responsiveness was studied in one study[59] and rated poor for methodological quality

and negative for measurement property (Table 3).

Best evidence synthesis resulted in limited evidence for hypothesis testing and no results due to the lack of evidence for internal consistency (Table 5).

The Nottingham Health profile (NHP) was studied in five studies (Table 3) in different settings (hospital, community, and outpatient patients) (Table 4).

Validity: hypothesis testing was assessed in four studies (Table 3). Three studies were rated fair for methodological quality[25,82,103] and one was rated good[48]. The measurement property was assessed positive in three studies[48,82,103] and intermediate in one study[25]. Structural validity was studied in one study[82] and assessed fair for methodological quality and positive for measurement property.

Reliability (internal consistency) was rated poor for methodological quality[25], but positive for measurement property (Table 3).

Responsiveness was rated good for methodological quality and positive for measurement property in one study[48], but rated fair for methodological quality and rated intermediate for measurement property in a different study[3] (Table 3).

Best evidence synthesis resulted in limited evidence for structural validity, moderate evidence for hypothesis testing and responsiveness, and no results were available due to the lack of evidence for internal consistency (Table 5).

World Health Organization Quality of Life short version list (WHOQOL-BREF) was studied in one study[52] in an outpatient clinic (Table 4).

Validity: hypothesis testing was rated fair for study quality and intermediate for measurement property (Table 3).

Reliability: internal consistency was rated poor for study quality, but positive for measurement property (Table 3).

Best evidence synthesis had no results due to the lack of evidence for validity and reliability (Table 5).

Quality of Well Being Self-Administered (QWBSA) was studied in one study[66] in pulmonary rehabilitation patients (Table 4).

Validity: hypothesis testing was rated fair for methodological quality and intermediate for measurement property (Table 3).

Best evidence synthesis resulted in limited evidence for hypothesis testing (Table 5).

Hyland Scale was studied in one study[68] in stable patients (Table 4).

Validity: hypothesis testing was rated fair for methodological quality and positive for measurement property (Table 3). Cross cultural validity was rated poor for methodological quality and intermediate for measurement property.

Reliability was rated fair for methodological quality and positive for measurement property (Table 3).

Best evidence synthesis resulted in limited evidence for hypothesis testing and reliability, and no results were available due to the lack of evidence for cross cultural validity (Table 5).

Measure Yourself Medical Outcome Profile (MYMOP) was studied in one study in a general practice setting[85] (Table 4).
Responsiveness was rated fair for methodological quality and intermediate for measurement property (Table 3). This led to unavailability of results due to the lack of evidence (Table 5).
Utility measure EuroQol EQ5D was studied in five studies in hospital patients (Table 4).
Validity: hypothesis testing was studied in five studies. Four studies were rated fair for methodological quality (Table 3) and one was rated good[50]. Four studies were rated positive for measurement property[24,50,86,104]. One study was rated intermediate for measurement property[87].
Reliability (internal consistency) was rated poor for methodological quality[24] and rated positive for measurement property[24]. *Reliability* was rated poor for methodological quality in one study[24] and fair in a different study[87]. The measurement property was assessed negative in one study[24] and positive in the other study[87] (Table 3).
Responsiveness was studied in three studies[24,87,104] and rated fair for methodological quality and intermediate for measurement property (Table 3).
Best evidence synthesis resulted in moderate evidence for hypothesis testing, limited evidence for reliability, and absence of results due to lack of evidence for responsiveness and internal consistency (Table 5).

Tabel 4. Characteristics of included studies

Instrument	Author	Setting	N	Country
CRQ	Aaron, 2002 [44]	Acute exacerbation, Emergency Department	66	Canada
	Al Moamary, 2011 [43]	Stable patients, outpatient clinic	45	Saudi Arabia
	Al-Ghimlas, 2011 [42]	Stable patients, outpatient clinic	5	Kuwait
	Bourbeau, 2004 [23]	Stable patients	65	Canada (French)
	Chan, 2006 [39]	Stable patients, community and hospital	155	China
	Desikan, 2002 [56]	Stable patients, community	40	USA
	Guell, 1998 [37]	Stable patients, outpatient clinic	60	Spain
	Hajiro, 1998 [61]	Stable patients, outpatient clinic	143	Japan
	Harper, 1997 [24]	Chest clinic	156	United Kingdom
	Martin, 1994 [34]	Pulmonary rehabilitation	15	USA
	Puhan, 2004 [41]	Stable patients, Pulmonary rehabilitation	162	Germany
	Puhan, 2007 [62]	Pulmonary rehabilitation	177	Canada
	Reda, 2010 [36]	Stable patients, community	269	The Netherlands
	Ringbaek, 2012 [91]	Severe patients, Pulmonary rehabilitation	90	Denmark
	Rutten-van Mölken, 1999 [40]	Outpatient clinic	133	The Netherlands
	Schünneman, 2005 [47]	Pulmonary rehabilitation	177	USA & Canada
	Singh, 2001 [45]	Stable patients, Pulmonary rehabilitation	79	United Kingdom
	De Torres, 2002 [46]	Severe patients, Pulmonary rehabilitation	37	USA
	Tsai, 2008 [38]	Exacerbation, Emergency Department	301	USA & Canada
	Tsukino, 2002 [63]	New patients, outpatient clinic	82	Japan
	Williams, 2001 [27]	Pulmonary rehabilitation	52	United Kingdom
	Wijkstra, 1994 [64]	Severe patients, Hospital, Pulmonary rehabilitation	40	The Netherlands
	Wyrwich, 1999 [35]	Outpatient clinic	471	USA
SGRQ	Alonso, 1998 [65]	Outpatient and primary health clinic	321	Spain
	Aslani, 2008 [51]	Outpatient clinic	58	Iran
	Barr, 2000 [28]	Pulmonary rehabilitation	102	United States
	Bourbeau, 2004 [23]	Stable patients	65	Canada (French)
	Desikan, 2002 [56]	Stable patients, Community	40	USA
	Doll, 2003 [48]	Acute and stable patients, Ambulatory setting	320	Germany
	Engstrom, 1998 [59]	Stable patients, hospital	149	Sweden
	Ferrer, 1996 [49]	Outpatient clinic, primary care center, hospital	318	Spain
	Harper, 1997 [24]	Chest clinic	156	United Kingdom
	Hajiro, 1998 [61]	Stable patients, Outpatient clinic	143	Japan
	Kaplan, 2004 [66]	Moderate/severe patients, Pulmonary rehabilitation	1218	USA
	Katsoulas, 2010 [57]	Exacerbation patients	72	Greece
	Liang, 2008 [52]	Male patients, Outpatient clinic	211	Taiwan
	Malý, 2006 [53]	Stable and therapeutic patients	175	Czech
	Meguro, 2007 [54]	Pulmonary rehabilitation	1992	United Kingdom
	Menn, 2010 [67]	Exacerbation patients	117	Germany
	Nishimura, 2008 [68]	Stable patients	161	Japan
	Pickard, 2011 [50]	In/outpatient clinic	120	USA
	Puhan,2007 [62]	Pulmonary rehabilitation	177	Canada
	Ringbaek, 2012 [91]	Severe patients, Pulmonary rehabilitation	90	Denmark
	Rutten- van Mölken,1999 [40]	Outpatient clinic	133	The Netherlands
	Tafti, 2009 [69]	Hospital patients	55	Iran
	DeTorres,2001 [46]	Severe patients, Pulmonary rehabilitation	37	USA
	Xu, 2009 [58]	Stable patients hospital	491	China
	Yu, 2004 [55]	Hospital patients	54	China
AQ20/30	Alemayehu, 2002 [70]	Health Management Program	181	USA
	Hajiro, 1999 [71]	Mild- severe patients Outpatient	251	Japan
	Blanco-Aparicio, 2010 [89]	Outpatient clinic	100	Spain
	Mazur, 2011 [90]	Hospital patients	739	Finland
AQ-20R	Chen, 2006 [72]	Community	135	USA
CAT	Dodd, 2011 [94]	Pulmonary Rehabilitation	118	United Kingdom
	Dodd, 2012 [93]	Pulmonary Rehabilitation	261	United Kingdom
	Jones, 2009 [73]	Stable and exacerbation patients	296	USA, Europe*
	Jones, 2011 [33]	Primary care	1817	Europe
	Jones, 2012 [106]	Exacerbation patients/Pulmonary Rehabilitation	123	USA, Canada
	Mackay, 2012 [95]	Exacerbation patients	161	United Kingdom
	Ringbaek, 2012 [91]	Severe patients, Pulmonary rehabilitation	90	Denmark
	Tsiligianni, 2012 [92]	Primary Care, hospital patients	90	Greece

CCQ	Molen vd, 2003 [30]	Community and outpatient clinic, primary care	119	The Netrherlands
	Damato, 2005 [29]	Community and outpatient clinic	175	Italy
	Ställberg, 2009 [32]	Primary Care	111	Sweden
	Kocks, 2010 [31]	Outpatient Clinic	44	The Netherlands
	Reda, 2010 [36]	Stable patients, community	269	The Netherlands
	Papadopoulos, 2011 [96]	Outpatient Clinic	93	Greece
	Ringbaek, 2012 [91]	Severe patients, Pulmonary rehabilitation	90	Denmark
	Tsiligianni, 2012 [92]	Primary Care, hospital patients	90	Greece
MRF28	Duiverman, 2008 [74]	Stable conditions in respiratory failure	72	The Netherlands
SRI	Windisch, 2008 [75]	Community oxygen dependant patients	162	Germany
LAS/VAS	Katsura, 2003 [76]	Mild, severe patients Outpatient	102	Japan
	Nishiyama, 2000 [77]	Pulmonary rehabilitation	75	Japan
VSRQ	Perez, 2009 [78]	Mild, severe patients	1009	France
RQLQ	Stavem, 1999 [79]	Outpatients	59	Norway
LCOPD	McKenna, 2011 [100]	Mild/moderate and severe patients	342	United Kingdom, USA
	McKenna, 2012 [101]	Mild/moderate and severe patients	262	Italy, Spain, Russia
McGillCOPD	Pakhale, 2011 [102]	Pulmonary Rehabilitation	142	Canada
SF-36	Harper, 1997 [24]	Chest clinic	156	United Kingdom
	Mahler, 1995 [80]	Outpatient clinic	50	Lebanon
	Ozalevli, 2008 [81]	Outpatient, moderate to severe patients	130	Turkey
	Pickard, 2011 [50]	In/outpatient clinic	120	USA
	Prieto, 1997 [82]	Outpatient clinic	321	Spain
	Alonso, 1998 [65]	Outpatient and primary health clinic	321	Spain
	Aslani, 2008 [51]	Outpatient clinic	58	Iran
	Desikan, 2002 [56]	Stable patients, Community	40	USA
	Kaplan, 2004 [66]	Moderate / severe patients, Pulmonary rehabilitation	1218	USA
	Menn, 2010 [67]	Exacerbation patients GOLD 3, 4 Hospital	117	Germany
	Malý, 2006 [53]	Stable and therapeutic patients	175	Czech
	Puhan,2007 [62]	Pulmonary rehabilitation	177	Canada
	De Torres, 2002 [46]	Severe patients, Pulmonary rehabilitation	37	USA
	Wyrwich, 1999 [35]	Outpatient	471	USA
SF-12	Menn, 2010 [67]	Exacerbation patients GOLD 3, 4 Hospital	117	Germany
Darthmouth COOP	Eaton, 2005 [83]	Outpatient clinic oxygen patients	50	New Zealand
	Stavem, 2002 [26]	Outpatient	59	Norway
SIP	Hutter, 1997 [84]	Oxygen dependant- end stage	58	Germany
	Engstrom, 1998 [59]	Stable patients, hospital	149	Sweden
NHP	Doll, 2003 [48]	Acute and stable patients, Ambulatory setting	320	Germany
	Jans, 1999 [25]	General practice setting	170	The Netherlands
	Ozalevli, 2008 [81]	Outpatient, moderate to severe patients	130	Turkey
	Prieto, 1997 [82]	Outpatient clinic	321	Spain
	Tsukino, 2002 [63]	New patients, outpatient clinic	82	Japan
WHQOLBREF	Liang, 2008 [52]	Male patients, Outpatient clinic	211	Taiwan
QWBSA	Kaplan, 2004 [66]	Moderate / severe patients, Pulmonary rehabilitation	1218	USA
Hyland scale	Nishimura, 2008 [68]	Stable patients	161	Japan
MYMOP	Paterson, 2000 [85]	exacerbation General Practice setting	81	United Kingdom
EQ5-D	Rutten-van Mölken, 2006 [86]	Patients from medication trial	1235	Europe and USA
	Menn, 2010 [67]	Exacerbation patients GOLD 3, 4 Hospital	117	Germany
	Harper, 1997 [24]	Chest clinic	156	United Kingdom
	Pickard, 2011 [50]	In/outpatient clinic	120	USA
	Stavem, 1999 [87]	Outpatient clinic	59	Norway

CRQ (Chronic Respiratory Questionnaire), **SGRQ** (St George Respiratory Questionnaire), **AQ-20/30** (Airway Questionnaire 20/30), **AQ-20R** (Airway Questionnaire 20 Revised), **CAT** (COPD assessment Test), **CCQ** Clinical COPD questionnaire **MRF-28** (Maugeri Respiratory Failure Questionnare-28), **SRI** (Severe Respiratory Insufficiency), **LAS/VAS-8** (Linear Analogue Scale/Visual Analogue Scale), **VSRQ** (Visual Simplified Respiratory Questionnaire), **RQLQ** (Respiratory Quality of Life Questionnaire), **LCOPD** Living with Chronic Obstructive pulmonary disease questionnaire, **McGill COPD** McGill COPD Quality of Life Questionnaire, **SF-12** (Short-Form Health Survey-12), **SF-36** (Short-Form Health Survey-36), **DartmCoop** (The Dartmouth Northern New England Primary Care Cooperative Information Project chart system), **SIP** (Sickness Impact Profile), **NHP** (Nottingham Health Profile), **WHOQOLBREF** (World Health Organization Quality of Life short version list), **QWBSA** (Quality of Well Being Self-Administered), **MYMOP** (Measure Yourself Medical Outcome Profile), **EQ-5D** (EuroQol 5D).

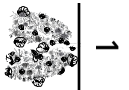
**Germany, French, The Netherlands, Spain, Belgium*

Tabel 5. Best Evidence Synthesis

Instrument	*Content Validity*	*Structural Validity*	*Hypothesis Testing*	*Cross cultural validity*	*Internal Consistency*	*Reliability*	*Responsiveness*
Disease specific							
CRQ	+++	+++	+++	?	+++	++	++
SGRQ	.	+++	++	?	++	+++	++
AQ20/30	.	.	++	.	?	+	?
AQ 20 R	.	.	+	.	?	.	.
CAT	+++	+++	++	.	+++	++	+++
CCQ	.	.	+++	?	?	+++	++
MRF-28	.	.	++	.	.	?	.
SRI	.	+	.	.	+	.	.
LAS/VAS-8	.	.	±	.	?	.	++
VSRQ	.	.	+	.	+++	+++	?
RQLQ	.	.	+	?	?	++	?
LCOPD	+++	.	++	?	+++	+++	
McGillCOPD	+++	.	.	.	.	.	.
Generic							
SF-36	.	+	±	?	+++	±	?
SF-12	.	.	+	.	.	.	?
DartmCoop	.	.	++	.	.	±	?
SIP	.	.	±	.	?	.	-
NHP	.	+	++	.	?	.	++
WHOQOLBREF	.	.	?	.	?	.	.
QWBSA	.	.	+	.	.	.	.
Hyland Scale	.	.	+	?	.	+	.
MYMOP	.	.	.	.	.	.	?
EQ-5 D	.	.	++	.	?	+	?

+++ or --- strong evidence positive/ negative result, ++ or -- moderate evidence positive/ negative result, + or – limited evidence positive/ negative result,
± conflicting evidence, ? lack of evidence due to poor methodological quality or other statistics than recommend by COSMIN checklist, . no information available

CRQ (Chronic Respiratory Questionnaire), **SGRQ** (St George Respiratory Questionnaire), **AQ-20/30** (Airway Questionnaire 20/30), **AQ-20R** (Airway Questionnaire 20 Revised), **CAT** (COPD assessment Test), **CCQ** Clinical COPD questionnaire , **MRF-28** (Maugeri Respiratory Failure Questionnare-28), **SRI** (Severe Respiratory Insufficiency), **LAS/VAS-8** (Linear Analogue Scale/Visual Analogue Scale), **VSRQ** (Visual Simplified Respiratory Questionnaire), **RQLQ (**Respiratory Quality of Life Questionnaire), **LCOPD** Living with Chronic Obstructive pulmonary disease questionnaire, **McGill COPD** McGill COPD Quality of Life Questionnaire,**SF-12** (Short-Form Health Survey-12), **SF-36** (Short-Form Health Survey-36), **DartmCoop** (The Dartmouth Northern New England Primary Care Cooperative Information Project chart system), **SIP** (Sickness Impact Profile), **NHP** (Nottingham Health Profile**), WHOQOLBREF** (World Health Organization Quality of Life short version list), **QWBSA** (Quality of Well Being Self-Administered), **MYMOP** (Measure Yourself Medical Outcome Profile), **EQ-5D** (EuroQol 5D)



Discussion

This review identifies and evaluates the content and measurement properties of 23 QoL instruments that were studied in COPD populations. As far as can be assessed, this is the first study to provide a comprehensive and systematic overview of the studies' methodological quality and the quality of the measurement properties of QoL instruments in COPD patients, using the COSMIN checklist. It is the only tool available to evaluate the studies' methodological quality on measurement properties in a standardized way.

The content of the instruments showed a great variety. 20 instruments measured mobility. Pulmonary symptoms were measured in 11 disease specific instruments. Pain, vitality, and spiritual activities were domains seen only in generic instruments. Social and emotional functioning were domains seen in disease specific instruments as well as in generic instruments.

Overall the methodological quality of the studies was rated fair. In the studies that evaluate the validity of the instruments, two studies were rated poor, 28 fair, 16 good, and nine excellent for methodological quality. All studies that evaluate the cross cultural validity were rated poor for methodological quality. In the studies that evaluate the reliability, 45 studies were rated poor, 17 fair, 16 good, and five excellent for methodological quality. In the studies assessing the responsiveness, three studies were rated poor, 36 fair, and 11 good for methodological quality. The assessment of the methodological quality of the studies does not imply that the included instruments are inadequate. It does mean however, that the reliability and validity of the results achieved with the instrument can be questioned.

The psychometric properties of the instruments (validity, reliability, and responsiveness) were in general rated positive. Validity was rated positive in 88 studies, intermediate in 24 studies, and negative in six studies. Reliability was rated positive in 83 studies, intermediate in three studies, and negative in four studies. Responsiveness was rated positive in 16 studies, intermediate in 29 studies, and negative in six studies.

In order to appreciate the findings of this comprehensive review, some limitations need to be considered. This review focused on measurement properties of QoL instruments in COPD care and research. Consequently, to be transparent, in the search strategy we searched for papers describing the evaluation of QoL instruments in the title or the abstract. Given the debate on the concept of QoL[5,6] implication of this choice could be that some instruments describing health status and not QoL, are not covered. Moreover, only papers in the English language were included, language bias could be an issue in our study.

Most studies included in this review were completed before consensus was reached about the criteria for health measurement standards as described in the COSMIN checklist. This influenced the overall ratings given the fact that some criteria were hardly ever used in studies.

Despite the comprehensive overview we could not uniformly recommend the best instrument.
However, based on the best evidence synthesis we could recommend the instruments with the strongest positive evidence like the disease specific instruments CRQ, CAT, SGRQ, and LCOPD. Since the best evidence synthesis shows less favorable ratings for the generic instruments, we recommend using a disease specific instrument to evaluate QoL in COPD patients.
In addition to the best evidence synthesis, the decision to use one instrument over another, will be driven by study purpose and the domains of the instrument most salient to the research question of each individual study. Responsiveness is essential when the purpose of the study is evaluation of treatment[14,20,21]. Responsiveness was studied in most instruments. There was strong positive evidence of responsiveness in the CAT, moderate evidence of responsiveness in the CRQ, SGRQ, CCQ, LAS/VAS, and NHP. Reliability is important if the study purpose is discrimination among patients[14,20]. There was strong positive evidence of reliability in the SGRQ, CCQ, VSRQ, and LCOPD. There was moderate evidence of reliability in the CRQ, CAT, and RQLQ and limited evidence in the QWSA and EQ5D.
If the instruments are used in clinical practice, a wider range of properties is required[12]. An instrument must not only be valid and reliable, it must be interpretable in clinical practice, simple, quick and easy to score[12]. Over the last decade there has been a growing interest in the development of simple and short questionnaires to assess the QoL in COPD patients[30,73,105]. The CCQ and CAT are examples of these short instruments covering domains of mobility, respiratory complaints, sleep and emotional functioning.

Conclusion

This review has provided a comprehensive overview of the content and measurement properties of QoL instruments in COPD care and research. This study shows strong positive evidence for disease specific instruments CRQ, CAT, SGRQ, and LCOPD. Since this study shows less favorable ratings for the generic instruments, we recommend using a disease specific instrument to evaluate QoL in COPD patients. In addition to the best evidence synthesis, the decision to use one instrument over another, will be driven by study purpose in combination with the domains of the instrument most salient to the research question of each individual study.
Given the large availability of instruments to evaluate QOL in COPD patients we discourage to develop new instruments, instead we encourage to design studies

according the COSMIN standards to evaluate the psychometric properties of the existing instruments. This additional research of good methodological quality is necessary in order to contribute to advancements in the field of QoL measures in COPD care and research.

Appendix 1 Search strategy

chronic obstructive pulmonary disease [tiab] OR copd [tiab] OR chronic bronchitis [tiab] OR emphysema [tiab])

AND

quality of life [tiab]

AND

questionnaire [tiab] OR test [tiab] OR instrument [tiab] OR inventory [tiab] OR scale [tiab].

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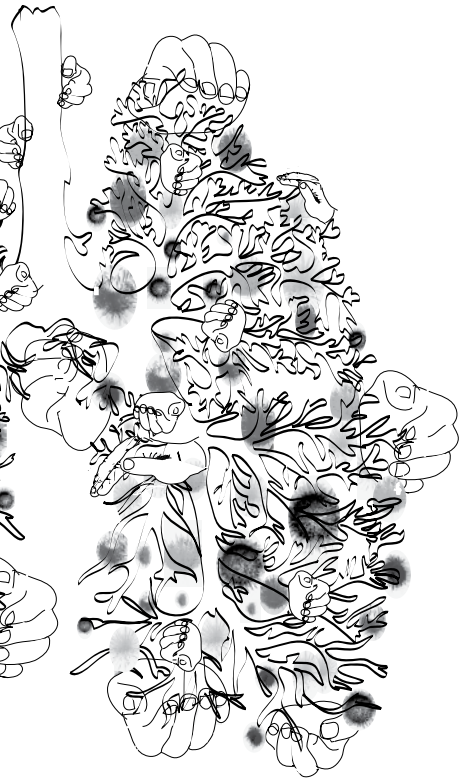

Chapter 2

The Dutch Functional Performance Inventory Validity and reliability in patients with Chronic Obstructive Lung Disease

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Published in Nursing Research, January/February 2015

Abstract

Background: Performing activities of daily living (ADLs) is an important outcome measure in Chronic Obstructive Pulmonary Diseases (COPD). The Functional Performance Inventory (FPI) can be used to measure ADL performance in people with COPD.
Objective: The aims are to report translation of the FPI into the Dutch language and evaluate the validity and reliability of the translated version in a Dutch COPD population.
Methods: The FPI was translated, after which validation and test-retest reliability studies were conducted. The Consensus-Based Standards for Selection of Health Status Measurement Instruments checklist was used. The Clinical COPD Questionnaire (CCQ), the self-administered Chronic Respiratory Questionnaire-Standardized, and the Medical Research Council Dyspnea Scale were used in the validation study. Test-retest reliability was estimated across 2 weeks in patients with stable COPD.
Results: Participants were patients with COPD from the Netherlands who took part in either the validation (n = 90) or reliability study (n = 60). The validity analyses showed that, as hypothesized, the household maintenance and physical exercise subscales of the Dutch version of the FPI had high correlations with the CCQ functional status domain; the total FPI had a correlation of -.44, with CCQ functional status domain. Across the subscales, score reliability estimated with Cronbach's alpha ranged from .55 (Body Care) to .97 (Household Maintenance); total score alpha was .98. Intraclass correlations (ICCs) ranged from .84 (Social Activities) to .97 (Body Care and Household Maintenance); total scale ICC was .98. Recreation and Spiritual Activity subscales varied significantly on retesting at 2 weeks.
Discussion: Scores on the Dutch FPI were reliable and reproducible. Evidence for validity was reasonable, but less strong than reported in studies from other populations.

Introduction

Chronic obstructive pulmonary disease (COPD) is a debilitating and progressive disease characterized by dyspnea and coughing, persistent airflow limitation, skeletal muscle dysfunction, and comorbidities[1]. COPD causes substantial limitations in ability to perform daily activities[2-4]. One of the most common complaints of COPD patients is that their condition prevents them from completing their favorite daily activities[4-6].

Performing physical activities is an important outcome measure in COPD care and research and refers to the ability to perform self-care behaviors that require physical activity[7] such as feeding, toileting, dressing, bathing and instrumental activities of daily living (IADL) such as shopping, cooking, housework, and transport around the environment[7,8]. However, performing activities is not limited to ADL and instrumental ADLs; it includes also activities performed for personal satisfaction and recreational activities, such as hobbies and social activities, and spiritual activities[8,9]. Fatigue interferes with functional activity, and is associated with hospitalization among persons with COPD[10].

Because inactivity is associated with many consequences, including mortality[11], poor general health[12] and hospital admissions[13], an important goal in COPD care and research is improving and easing the performance of daily activities (Global Initiative for Chronic Obstructive Lung Disease)[14,15]. Valid and reliable instrumentation is essential, but development of valid patient-reported outcome measures to assess limitations in daily activities is still challenging, partly because of lack of consensus regarding measurement and conceptual frameworks of limitations in daily activities[8,16].

Several generic and disease-specific instruments for measuring limitations in daily activities are available. The Duke Activity Status Index[17] and Functional State Questionnaire[18] are generic instruments. The Manchester Respiratory ADL Questionnaire[19], the Clinical COPD Questionnaire (CCQ (functional state domain)[20] and the St. George Respiratory Questionnaire[21] are examples of COPD-specific questionnaires.

In contrast to other COPD-specific instruments for evaluating daily activities, the functional performance inventory is based on an explicit theoretical framework. According to this framework, functional performance is defined as: "The physical, psychological, social, occupational, and spiritual activities that people do in their normal lives"[22,23]. The FPI is a self-report measure of the extent to which individuals perform specific daily activities to meet basic needs, fulfill usual roles and maintain their health and well-being[22,24]. The questionnaire captures elements of daily activities that individuals themselves identify as important, meaningful and possibly difficult to fulfill.

In this study, the FPI was selected over other COPD- specific instruments because the FPI is an instrument based on a conceptual framework and comprises a broad spectrum of activities chosen by a patient[16,23]. The FPI is available in a 65-item questionnaire[24] or a 32-item version[25]. In English, scores on both questionnaires have exhibited evidence of validity and reliability[14,24,26,27]. The FPI-65 item FPI has been translated and validated in Turkish[28] and the Short form has been translated and validated in Chinese[29]. However, the FPI has not been translated and validated in a Dutch population. This article reports the translation process of the English FPI 65-item questionnaire into the Dutch language and the evaluation of the validity and reliability of the translated version in a Dutch COPD population.

Methods

The study was carried out in three stages: (a) translation of the FPI to Dutch; (b) validation; and (c) 2-week test-retest reliability assessment. The Consensus-Based Standards for Selection of Health Status Measurement Instruments (COSMIN) checklist was used[30] to guide study design[31].

Sample and Setting

Two separate groups of patients with COPD were recruited for the validity and reliability portions of the study. To be eligible for inclusion in the studies, patients had to be diagnosed with COPD according to the GOLD criteria[15]. The GOLD criteria classification of severity of airflow limitation in COPD is based on post bronchodilator forced expiratory volume at 1 minute (FEV1), converted to a percentage of normal for age, height, and race (GOLD grades I, II, III and IV). They also had to be physically and mentally able to fill out the questionnaires, had Dutch as the first or "daily" language, and be at least 40 years old. Patients were excluded if they concurrently participated in another study than this validation study or our previous study[32], if they were unable to read or write the Dutch language, and if they had a primary diagnosis of asthma or a life-threatening disease other than COPD.

Validation study. Patients in the validation study consisted of COPD patients with a diagnosis of mild, moderate, or severe COPD (GOLD I, II, or III) receiving care from 10 general practices throughout the Netherlands. These patients participated in a cross-sectional study in which we explored the extent to which psychological factors contribute to daily activities and health related quality of life (HRQoL) in COPD patients[32]. The validation sample was a subset from the sample we used in this previous study.

Reliability study. Patients in the test-retest reliability study had clinically stable COPD and were receiving care from the outpatient clinic of the Department of Respiratory Diseases of the University Medical Center Utrecht in the Netherlands. These patients were diagnosed with mild, moderate, severe, or very severe COPD (GOLD grades I, II, III, or IV).

Protection of human subjects in research in the Netherlands, biomedical research

that does not involve treatment is considered but not "approved" by research ethics committees. The protocols for the research reported here were considered by the Medical Ethical Research Committee of the University Medical Center Utrecht to ensure that investigators had taken all necessary and appropriate measures to safeguard the protection of participant privacy, including the adaptation of data to ensure sufficient anonymity. Medical Ethical Research Committee also ensures that participants had been adequately informed that their data would only be used for research purposes. All participants signed an informed consent document.

Procedures

Translation of the FPI. Using principles of good practice for translation of patient-reported outcomes[33], we followed a sequential translation approach in four phases: forward translation, backward translation, cognitive debriefing, and review of cognitive debriefing according to the principles of good practice for translation of patient reported outcomes[33]. The first phase involved preparation, forward translation of the FPI from English into Dutch, and reconciliation. After obtaining permission to use the instrument from the developer (N.K. Leidy), two native Dutch translators familiar with chronic care, COPD, and nursing independently translated the FPI from English to Dutch. In a consensus meeting with an independent observer, one of the translators, and the first author (SW), the two translations were reconciled into a single forward translation. In the second phase, the reconciled translation of the FPI was then back translated from Dutch into English. Two native English translators experienced in chronic care, nursing, and COPD independently prepared the backward translation—unaware of the original English FPI. In a consensus meeting with an independent observer, one of the translators, and the first author (SW), the back translation was compared with the original English FPI to check for conceptual discrepancies. These discrepancies were resolved in consultation with the developer of the FPI. The third translation phase involved cognitive debriefing by three COPD patients from the outpatient clinic to ensure that the final Dutch FPI draft was clear and understandable. The final translation phase included review of the cognitive debriefing results, proofreading, and finalization of the Dutch FPI. On the basis of the comments, the Dutch FPI was finalized in a meeting with an independent observer, one of the forward translators, and the first author (SW).

Assessment of Validity. After providing written informed consent, participants completed several questionnaires at home and returned them to our center. Questionnaires included: The Dutch version of the FPI, the Clinical COPD Questionnaire (CCQ)[20], the Chronic Respiratory Questionnaire-standardized (CRQ-SAS)[34], and the Medical Research Council (MRC) Dyspnea Scale[35]. Data were collected from June 2010 to April 2011.

Assessment of Reliability. Patients participating in the reliability study completed the questionnaires at home twice—at approximately 2-week intervals—and returned them

to our center by mail. As a reminder, the patients were called by phone and they were explicitly asked if they were still in a clinically stable condition. Data were collected from January to May 2012.

Instruments

Functional Performance Inventory

The FPI is a self-administered questionnaire designed to measure the extent to which people engage in daily activities[24]. The FPI consists of 65 items and has six subscales: body care (9 items), household maintenance (21 items), physical exercise (7 items), recreation (11 items), spiritual activities (5 items), and social activities (12 items). For each activity, response options range from 1 = *the activity can be performed easily, with no difficulty at all* to 4 = *the activity is no longer performed for health reasons*; there was also an option to answer "the activity is not performed for reasons other than health". The instructions ask patients to encircle the number that best describes how difficult it is for them to perform each activity. In the analyses, scores are reversed so higher scores represent higher levels of function. Total and subscale scores are expressed as mean values, with an 80% completion rate required for calculation per subscale. The newly translated Dutch version was used.

Clinical COPD Questionnaire

The CCQ is a self-administered questionnaire developed to measure health status[20]. The four-item functional state domain subscale was used in this study. Respondents are asked how much their respiratory problems limit activities. Response options for the functional domain items of strenuous activities, moderate activities, daily activities at home, and social activities range from 0 = *not limited at all* to 6 = *totally limited/unable to do*. A high score is indicative of low functional status. There is strong evidence for the validity of the CCQ[36].

Chronic Respiratory Questionnaire—Standardized

The CRQ- SAS is a 20-item, self-administered questionnaire designed to measure HRQoL. The questionnaire consists of four domains: dyspnea, fatigue, emotional function, and mastery[34]. The response options range from 1 *maximum impairment* to 7 = *no impairment* for each question. There is also an 8 = *activity not performed* for the dyspnea domain. The dyspnea and fatigue domains were used to assess validity. The scores for each question of each dimension were added together and divided by the number of questions answered. Higher scores indicate better HRQoL. There is strong evidence for the validity of the CRQ-SAS[36].

Medical Research Council

The MRC Dyspnea Scale. The MRC Dyspnea Scale[35] was used to assess functional dyspnea. The MRC Dyspnea Scale consists of six statements about perceived breathlessness. Patients read the statements and select the item that best describes them. Items are scored with 0 = *I don't suffer from shortness of breath;* 1 = *I only get breathless with*

strenuous exercise; 2 = *I get short of breath when hurrying on the level or up a slight hill*; 3 = *I walk slower than people of the same age on the level because of breathlessness or have to stop for breath when walking at my own pace on the level*; 4 = *I stop for breath after walking 100 yards or after a few minutes on the level*; and 5 = *I am too breathless to leave the house*. Scores from the MRC Dyspnea Scale have been associated with variation in variables used to measure the severity and impact of COPD[35].

Pulmonary function and demographics.

Data on pulmonary function were collected: the forced expiratory volume in one second (FEV1 in litres) and the forced vital capacity (FVC in litres). To calculate the predicted forced expiratory volume percentage (FEV1% predicted) and the GOLD grade, data on height were collected. Sociodemographic variables including age, gender, education level[37], employment status, and marital status were also collected.

Statistical Analyses

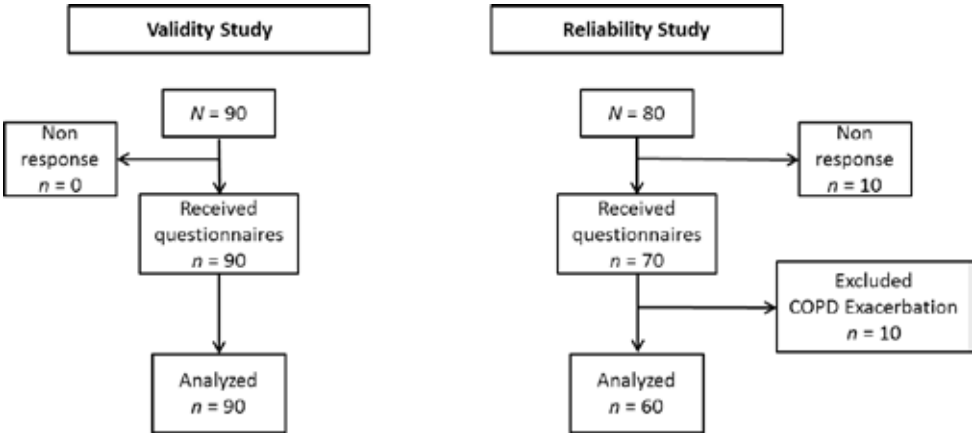
All analyses were performed with Statistical Package for the Social Sciences (SPSS 20.0 for Windows). Descriptive statistics (frequencies, means, and standard deviations) were used to present patient background and medical characteristics. Subscale scores were calculated as the mean of the responses scores across all items comprising the subscales. Floor and ceiling effects were defined as 15% or more of the patients with the lowest or highest possible score, respectively, on the Dutch FPI scale[30,38].

Validation. Construct validity was assessed using the COSMIN hypothesis testing approach, which refers to the extent to which instrument scores relate to other measures in theoretically-consistent ways[30,38]. To assess construct validity of scores from the Dutch version of the FPI, hypotheses about relationships with the CCQ[20], the self-administered CRQ-SAS[34], and the MRC Dyspnea Scale[35] were formulated. Pearson correlations were estimated. On the basis of the review of the literature, the following patterns of association were expected, where a correlation between .30 and .50 in absolute value was considered "medium" and a correlation >.50 in absolute value was considered "large"[39]:

- Correlations of FPI Body Care, Household Maintenance, Physical Exercise, and Social Activities subscales with the CCQ functional status domain scores would be large in magnitude and negative in direction.
- Correlations between the total FPI and the CCQ functional status domain would be large and in the negative direction.
- Correlations of FPI subscales Body Care, Household Maintenance, and Physical Exercise with the dyspnea and fatigue domain of the CRQ-SAS would be medium and in positive direction
- Correlations of FPI subscales Body Care, Household Maintenance, Physical Exercise with the MRC Dyspnea Scale would be medium and in negative direction.

Reliability. We evaluated reliability of scores using Cronbach's alpha[30,40]. Test-retest reliability for the Dutch version of the FPI was estimated using intraclass correlations (ICCs; agreement, two-way random effects model) and by applying a paired samples t-test with log-transformed data using a nominal p-value of .05,[41,42]. The log transformation was used to make the patterns in the skewed data more interpretable. A log transformation gives interpretable results after a back transformation[41,42]. Taking the difference between the logarithms of the two geometric means resulted in the logarithm of their ratio; the logarithm of a pure number. We took the antilog to give the dimensionless ratio of the two geometric means. This is the best estimate of the ratio of the mean pre and post and the confidence interval for a difference in the log scale becomes a confidence interval for a ratio in the original scale[41,42].

Figure 1. Flow of participants through the validity and reliability studies



Results

Characteristics of the Samples

Figure 1 describes participant recruitment and participation. A total of 90 patients participated in the validation study. In the reliability study, 80 participants were recruited, but 10 did not respond and 10 were determined to have had exacerbation of COPD, so data from 60 participants were analyzed. Sample characteristics are presented in Table 1. Of the 90 patients in the validation study, 54.5% were men; ages in the sample ranged from 47 to 87 (*M* = 65.2, *SD* = 9.0). Most patients in the validity study had GOLD grade II (66.7%) and had experienced symptoms from 0 to 40 years (*M* = 5.0, *SD* = 8.1). In the reliability study, 65.0% were men; ages in the sample ranged from 40 to 91 years (*M* = 68.8, *SD* = 9.9). Most patients in the reliability study had GOLD grade III (43.3%) and had experienced symptoms from 0 to 35 years (*M* = 17.7, *SD* = 18.6).

As can be seen in Table 2, the mean score of the total FPI was 1.80 (*SD* = .40) in the validation study and 1.50 (*SD* = .55) in the reliability study. Floor and ceiling effects were present in the Body Care subscale (58.9% and 25% of the patients reported the highest score) and in the Spiritual Activities subscale (60% and 58.3% of the patients reported the lowest score).

Table 1. Patient Characteristics

	Validity study [a] (N = 90)		Reliability study (N = 60)	
Characteristic	***n***	**(*%*)**	***n***	**(*%*)**
Gender (male)	49	(*54.4*)	39	(*65.0*)
GOLD stage				
Mild	18	(*20.0*)	4	(*6.7*)
Moderate	60	(*66.7*)	23	(*38.3*)
Severe	12	(*13.3*)	26	(*43.3*)
Very severe	0	(*0.0*)	7	(*11.7*)
Marital status				
Married	59	(*65.6*)	41	(*68.3*)
Single	15	(*16.7*)	7	(*11.7*)
Widowed	8	(*8.9*)	10	(*16.7*)
Divorced	8	(*8.9*)	2	(*3.3*)
Educational level[b]				
Low	13	(*14.4*)	39	(*65.0*)
Medium	56	(*62.2*)	10	(*16.7*)
High	21	(*23.3*)	10	(*16.7*)
Paid work	20	(*22.1*)	14	(*23.3*)
Retired	46	(*51.1*)	39	(*65.0*)

Note. GOLD = Global Initiative for Chronic Obstructive Lung Disease.

[a] Based on and adapted with permission from Weldam, Lammers, Decates, & Schuurmans (2013).

[b] Categories are based on the International Standard Classification of Education (ISCED)

Table 2. Dutch Version of the Functional Performance Inventory: Means, Standard Deviations, Floor and Ceiling Effects

Study	FPI domain	*n*	*M*	(*SD*)	Floor (%)	Ceiling (%)
Validity	Body care	90	2.88[a]	(*0.20*)	0.0	58.9
(*N = 90*)	Household maintenance	90	2.30[a]	(*0.50*)	1.1	5.6
	Physical exercise	89	1.51[a]	(0.*51*)	1.1	0.0
	Recreation	89	1.92[a]	(*0.57*)	1.1	1.1
	Spiritual activities	89	0.52[a]	(*0.90*)	60.0	7.8
	Social activities	89	1.69[a]	(*0.72*)	1.1	3.3
	Total score	89	1.80[b]	(*0.40*)	1.1	0.0
Reliability	Body care	60	2.51[a]	(*0.59*)	1.7	25.0
(*N = 60*)	Household maintenance	60	1.63[a]	(*0.75*)	1.7	5.0
	Physical exercise	59	1.10[a]	(*0.71*)	5.0	1.7
	Recreation	59	1.62[a]	(*0.67*)	1.7	1.7
	Spiritual activities	59	0.60[a]	(*0.92*)	58.3	6.7
	Social activities	59	1.40[a]	(*0.75*)	1.7	1.7
	Total score	56	1.50[b]	(*0.55*)	1.7	0.0

Note. FPI = Functional Performance Inventory. *SD* = standard deviation. Floor and ceiling percentages reflect the number of patients with scores at the minimal and maximum, respectively.
[a]Possible score range is 0-3. [b]Possible score range is 1-3.

Table 3. Correlations of Scores on the Dutch FPI with CCQ, CRQ, and Dyspnea Scores

Criterion	FPI total	FPI BC	FPI HM	FPI PE	FPI RA	FPI SA	FPI SI
CCQ functional	-.44**	-.48**	-.50**	-.57**	-.35**	-.00	-.30**
CRQ dyspnea	.32*	.28**	.39**	.37**	.24*	-.08	.17
CRQ fatigue	.44**	.35**	.53**	.52**	.34**	.05	.28**
MRC dyspnea	-.37**	-.25*	-.43**	-.39**	-.22	-.12	-.24*
FEV1 % pred	.15	-.08	.30**	.21	.14	-.02	.08

Note. BC = body care; CCQ = Clinical COPD Questionnaire, CRQ = Chronic Respiratory Questionnaire, FEV1% pred = percentage predicted forced expired volume, HM = Household Maintenance, FPI = Functional Performance Inventory, MRC = Medical Research Council Scale, PE = Physical Exercise, RA = Recreation, SA = Spiritual Activities, SI = Social Activities, $^{*}p < .05$. $^{**}p < .01$.

Validity

Correlations associated with the hypotheses are summarized in Table 3. (The complete correlation matrix is available as Supplemental Digital Content.) All coefficients were in the predicted direction. For the subscales Body Care, Household Maintenance, Physical Exercise and the total FPI score, all correlations were significant. In the subscale Social Activities, the correlation with the CRQ Dyspnea was not significant.

As hypothesized, correlations of the FPI subscale scores for Body Care, Household Maintenance, and Physical Exercise, with CCQ Functional State were large. The

correlation between the Social Activity FPI subscale and the CCQ functional status score was lower in magnitude than expected (r = -.30).

The total FPI scale and the functional state domain of the CCQ had a correlation of -.44, which was slightly lower in magnitude than hypothesized (-.50).

As hypothesized, the FPI Body Care, Household Maintenance, and Physical Exercise, had medium correlations with the dyspnea domain of the CRQ. As hypothesized, the subscales Body Care, Household Maintenance and Physical Exercise had medium correlations with CRQ fatigue scores and the MRC Dyspnea Scale

The subscales Recreation, Spiritual Activities, and Social Activities had the lowest correlations. The subscale Spiritual Activities had no significant correlations with criterion instruments. The Physical Exercise domain of the FPI and the CCQ functional status domain had the highest correlation (r = .57). There was no significant correlation with FEV1% predicted, except for the Household Maintenance scale (r = .30).

Reliability

Score reliability and test-retest reliability estimates for the six subscales and the total score for the Dutch version of the FPI are provided in Table 4. Cronbach's alpha ranged from .55 (Body Care) to .97 (Household Maintenance) and .98 (Body Care). Cronbach's alpha for the total score was .91 in the validation study and .98 in the reliability study. ICCs ranged from .84 (Social Activities) to .97 (Body Care and Household Maintenance); the total scale ICC was .98. The paired sample t-test with log transformed data—to estimate the 2-week reproducibility—showed only a significant difference in the subscales Recreation and Spiritual Activities. In the other subscales, there were no significant differences—reflecting stability over time.

Table 4. Reliability: Dutch Version of the Functional Performance Inventory

		Cronbach's alpha		Test-retest (stability)			
		Validation	Reliability				
Scale	Items	Study	Study	*ICC*	*M*[a]	*p*	95% *CI*[b]
Total FPI	65	.91	.98	.98	100.6	.52	[99.1, 102.1]
Bodycare	9	.55	.98	.97	100.3	.63	[99.1, 101.6]
Household maintenance	21	.84	.97	.97	99.7	.83	[97.7, 101.8]
Physical exercise	7	.69	.94	.86	102.3	.13	[99.8, 104.8]
Recreation	11	.72	.81	.94	103.6	.03	[101.0, 107.0]
Spiritual activities	5	.87	.93	.93	93.7	.04	[88.9, 98.8]
Social activities	12	.79	.94	.84	103.9	.09	[100.0, 107.3]

Note. *CI* = confidence interval; *ICC* = intraclass correlation.

[a]Mean is antilog of log-transformed scores. [b]*CI* is for the paired t-test for log-transformed scores.

Discussion

The FPI was designed to quantify patient-reported physical, recreational, social, and spiritual daily activities[24]. This study evaluated the validity and reliability of the translated version in a Dutch COPD population.

The results of the construct validity analyses were mostly consistent with the general pattern of expectations that we expected. This means that the results for the construct validity are positive, according to the rating system for measurement properties as proposed by Terwee[38]. However, the magnitude of many correlations was below .50, meaning that the validation evidence is not very strong. Although this evidence was not very strong, the strongest correlations were observed in the subscales Body Care, Household Maintenance and Physical Exercise, as hypothesized. The lowest correlations were found with the subscales Spiritual Activities and Social Activities.

Using criteria proposed by Terwee[38], these data suggest that scores on the Dutch FPI are reliable and that scores are stable over time when underlying COPD status has not changed. However, values for Cronbach's alpha in the validation study were lower than the alpha values in the reliability study—where alpha for the Body Care subdomain was the lowest (alpha= .55). This low alpha indicates a lack of correlation in the Body Care subscale in the primary care population from which the validity study sample was drawn. However, it has been suggested that both very low and very high alpha values can mean either unidimensionality or multidimensionality[43]. The paired sample t-test, to estimate the two-week reproducibility, showed only a significant difference in the subscales Recreation and Spiritual Activities. The other subscale domains showed no differences.

A strength of this study is the use of the recently developed COSMIN criteria in designing the study. These guidelines provided the opportunity to develop a psychometric study according to recent guidelines. Another strength is its generalizability. In our study population, 55.3% of the patients had GOLD grade II, indicating moderate COPD and 25 % had severe COPD. Moreover, we did not exclude patients with comorbidities. Therefore, our study population is representative for GOLD grade II and GOLD grade III COPD population in primary care. However, it is not generalizable to patients with very severe COPD (Gold grade IV).

In contrast to our expectations, we did not find correlations above 0.5 between the total FPI and the functional state domain of the CCQ and the dyspnea and fatigue domain of the CRQ. However, in the validation studies by Larson[26] and Leidy[24,27], the magnitude of correlations of the FPI and instruments that assess daily activities, were above 0.5, meaning good evidence for construct validity. These findings could be explained by the use of other instruments which are maybe more comparable to the FPI, such as Functional Status Questionnaire[24,27], Duke activity Status Index[24,27], KATZ scale[24,27],

Sickness Impact Profile[26] and Physical Activity Scale for the Elderly[26]. In the study by Leidy and Knebel[27], the correlation between FPI and the Duke Activity Status Index were nevertheless not significant. Another explanation could be that the population in these studies[24,26,27] had moderate to severe COPD, and the population in our validation study had a mild to moderate COPD.The lowest correlations were found in the spiritual subscale and het social activity subscale, which is comparable to the findings in other studies[24,27].

The reliability estimates of the Dutch FPI (Chronbach's alpha is between .91 and .95 and ICC is .98) in our study are comparable to the estimates in Larson et al[26] (Chronbach's alpha = .89) and in Leidy[24] (Chronbach's alpha= .96; ICC=85), indicating that scores on the FPI are reliable.

Limitations

Some limitations need to be considered. First, because of the cross-sectional nature of the validation study, it was not possible to investigate the full spectrum of psychometric properties of the scores obtained using the instrument, such as responsiveness. Second, a different set of instruments was used for validation than in other FPI studies[24,26,27]; therefore, results were not fully comparable.

Third, although recommend by the COSMIN criteria, our data did not allow performing a confirmatory factor analysis to evaluate and confirm the structure of the Dutch FPI compared to the original English FPI, which had a modest fit of the model to the data[24].

Conclusions

Scores from the newly translated Dutch version of FPI seem reproducible and reliable. Evidence for validity of the Dutch version of the FPI was less strong than reported for versions in other languages used in other populations, but was nevertheless reasonable. The assessment of validity of scores from an instrument is a continuing process. Further evaluation of psychometric properties in a wider and lager range of participants is recommended, including the evaluation of the full spectrum of psychometric properties, such as the responsiveness, construct validity, and reliability. Using current international standards, the results of this study suggest that scores on the Dutch version of the FPI can be used as valid outcome measures that gauge the extent to which individuals with COPD perform specific daily activities.

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Chapter 3

Daily activities and health-related quality of life in patients with chronic obstructive pulmonary disease: psychological determinants: a cross-sectional study

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Published in Health and Quality of Life Outcomes (11) 2013

Abstract

Background: Chronic obstructive pulmonary disease (COPD) patients are confronted with reduced daily activities (DA) and reduced health-related quality of life (HRQoL) caused by dyspnea and systemic effects such as skeletal muscle dysfunction and co-morbidities. To understand the complexity of living with COPD, it is important to understand which factors, in addition to physical functioning, are associated with DA and HRQoL. In this study, we explored the extent to which the combination of illness perceptions, proactive coping, and depressive symptoms contribute to DA and HRQoL in COPD patients.

Methods: In a cross-sectional study in primary care, 90 COPD patients (GOLD I-III) completed questionnaires: The Brief Illness Perception Questionnaire, the Utrecht Proactive Coping Competence scale, the Centers for Epidemiologic Studies Depression scale, the Medical Research Council dyspnea scale, the Functional Performance Inventory (FPI), and the Clinical COPD Questionnaire (CCQ). The analyses were performed with multiple linear regression analyses.

Results: More adequate and positive illness perceptions ($\beta = .61$, $p < .001$) and less depressive symptoms ($\beta = .21$, $p = .010$) were associated with better HRQoL (CCQ). Significant relations between psychological factors and DA were not found.

Conclusion: The results of this study demonstrate that psychological factors are related to HRQoL, but not to DA. These results contribute to understanding the complexity of living with COPD and provide starting points for the development of interventions focusing on psychological factors to support COPD patients in disease management.

Introduction

Chronic obstructive pulmonary disease (COPD) is one of the leading causes of morbidity and mortality in the world[1]. The prevalence of the social and economic burden that results from this illness continues to increase[1,2]. Previous research on COPD has shown that COPD patients are confronted with daily life limitations, reduced daily activities (DA), and reduced health-related quality of life (HRQoL) caused by complaints such as dyspnea, skeletal muscle dysfunction, and co-morbidities[2-7].

In the last decade, in the Netherlands and in many other countries, care for patients with COPD has increasingly moved from hospitals to primary care[8]. According to the COPD guidelines in the Netherlands, general practitioners and practice nurses play a key role in care for COPD patients in primary care[9]. Education and counseling are the most important tasks of practice nurses. These nurses have become essential in the integrated care for COPD patients in the Netherlands[8]. Although research is being conducted among COPD populations in primary care[10-12], much of the research on COPD patients is conducted in hospital-based populations.

To understand the complexity of living with COPD, it is important to understand which factors, in addition to physical functioning and complaints, are associated with DA and HRQoL[13,14]. Psychological factors, such as illness perceptions, depressive symptoms, and ability to cope with the illness, may complicate living with COPD and participation in everyday activities[15-18].

According to the Common Sense Model by Leventhal[19], patients' beliefs and perceptions about illness guide individuals' efforts to cope with illness. Studies of the rehabilitation of COPD patients[20] and patients who attended outpatient clinics[21] show that COPD patients with positive beliefs about the impact of their disease on daily life and those with more positive thoughts about the effect of their treatment have a better HRQoL than patients who have more negative perceptions. Concerns about COPD are negatively related to walking test results[22] and general functioning[23]. Although research is being conducted among COPD populations in primary care[11,12,24], knowledge of the associations among illness perceptions, HRQoL, and DA in COPD patients in primary care is scarce.

To adjust to life with COPD and to prevent further physical deterioration, it is important that patients participate in everyday activities and physical exercises and that they anticipate potential threats[25]. In this respect, proactive coping, which refers to efforts undertaken to prevent or modify a potential threat to a person's health, may play an important role[26,27]. Some studies show that people who have the ability to anticipate and address potential threats to their health have better outcomes in goal achievement and general health behavior[27,28]. However, proactive coping has not been studied in COPD patients.

Furthermore, multiple studies covering a variety of medical settings have shown that

depressive symptoms are prevalent among COPD patients and that these symptoms are related to inactivity and lower HRQoL[29-31]. Prevalence estimates of depressive symptoms vary (10%-42%) due to the use of varied measurement tools[30,31]. A meta-analysis revealed that the prevalence of depressive symptoms was two times higher in COPD patients than in healthy controls[31].

In this cross-sectional study, we will explore the extent to which the combination of these psychological factors (illness perceptions, proactive coping, and depressive symptoms) contribute to DA and HRQoL in COPD patients in primary care. We hypothesize that positive illness perceptions (i.e., positive beliefs about the effects of the illness on daily life), adaptive proactive coping competencies, and low levels of depressive symptoms are associated with better DA and better HRQoL in COPD patients.

Methods

Study design and participants

This cross-sectional study was conducted in primary care settings in the Netherlands. COPD patients from ten general practices throughout the Netherlands who regularly visited the consulting hours of the practice nurses were asked to participate. To be eligible for inclusion, patients had to be diagnosed with COPD GOLD grades I, II, or III[25] and be physically and mentally able to complete the questionnaires. The patients were excluded if they participated in another study or if they had COPD GOLD grade IV or a primary diagnosis of asthma. The study was approved by the Medical Ethical Committee of the University Medical Center Utrecht (UMC Utrecht), and all participants provided written informed consent.

Procedure

Practice nurses working in the participating general practices included the COPD patients who visited their consulting hours. After providing written informed consent, the participating patients completed the questionnaires at home and returned them to our center. Data were collected from June 2010 to April 2011.

Measures

Illness Perceptions

The Brief Illness Perception Questionnaire (B-IPQ)[32] was used to assess illness perceptions concerning consequences, timeline, personal control, treatment control, identity, concern, understanding, emotional representations, and causal representations. The B-IPQ is a self-administered scale consisting of nine items (range: 0-10). To assess the degree to which COPD is perceived as threatening or benign, an overall summary score was computed. Three items (personal control, treatment control, and understanding) were reversed and added to the other items. A higher score reflects a more threatening view of COPD.

A lower score reflects a more positive and adaptive view of COPD.

Proactive coping

The Utrecht Proactive Coping Competence questionnaire (UPCC)[33] was used to assess individuals' competency with regard to the various skills associated with proactive coping. The questionnaire is self-administered and consists of 21 items that together form one factor. The response options range from 1 ("not competent") to 4 ("very competent"). A higher score reflects more proactive coping competencies.

Depressive symptoms

The Centers for Epidemiologic Studies Depression Scale (CES-D scale)[34] was used to assess depressive symptoms. The CES-D scale was not developed to diagnose depression; rather, it aims to identify depressive symptoms. It is a self-administered questionnaire consisting of 20 items related to situations during the previous week. The response options range from 0 ("seldom") to 3 ("mostly/ always"). High scores indicate more depressive symptoms.

Dyspnea

The Medical Research Council (MRC) scale[35] was used to assess dyspnea. Dyspnea was rated by the patient with five increasing scores with option ranges from 0 ("not breathless except for exertion") to 4 ("too breathless to leave house or breathless when dressing or undressing").

Daily Activities

Daily activities (DA) were measured by the Functional Performance Inventory (FPI)[36]. This self-administered questionnaire measures the extent to which people engage in their usual day-to-day activities. The FPI consists of 65 items and has six subscales: body care (9 items), household maintenance (21 items), physical exercise (7 items), recreation (11 items), spiritual activities (5 items), and social activities (12 items). Response options range from 1 ("the activity can be performed easily, with no difficulty at all") to 4 ("the activity is no longer performed for health reasons") with an option to answer "the activity is not performed for reasons other than health". In the total score, the items are recoded to indicate that high scores represent high performance.

Quality of Life

The Clinical COPD Questionnaire (CCQ) was used to measure HRQoL[37]. The CCQ is a self-administered questionnaire and consists of ten questions covering three domains: functional state, symptoms, and mental state. Response options range from 0 ("no limitations/asymptomatic") to 6 ("totally limited/extremely symptomatic").

Data were collected on height and weight (according to the local general practitioner registry), and BMI was calculated as weight (kg)/height (m) squared. Data on pulmonary function (FEV1 in liters, FEV1% predicted, FVC in liters, and FEV1/FVC ratio), co-morbidities (Charlson co-morbidity Index)[38], and demographic variables (age, gender, illness duration, medication, education level, working status, smoking status, and marital status) were also collected.

Analyses

Descriptive statistics (frequencies, mean, and standard deviation) were used to present patients' background and medical characteristics. Linear regression analyses (adjusted for the confounders age, gender, dyspnea, FEV_1, smoking status, and co-morbidity) were applied to quantify the associations between illness perceptions, proactive coping, and depressive symptoms, on the one hand, and DA and QoL, on the other hand. First, a crude model was developed with the separate psychological determinants (illness perceptions, proactive coping, and depressive symptoms) (model 1). In the second model (model 2), the three psychological variables were combined in one model and corrected for the confounders age and gender. The third model (model 3) was additionally adjusted for dyspnea, FEV_1, smoking status, and co-morbidity. In the regression models, the standardized βs were used to compare the strength of the various independent variables. The explained variance per model was analyzed. Because the amount of missing data was only 3%, a complete case analysis was performed. All analyses were performed with Statistical Package for the Social Sciences (SPSS 20.0 for Windows).

Results

Study Sample

Sample characteristics are presented in Table 1. A total of 98 patients completed the questionnaires. In the analyses, eight patients were excluded because they appeared to have GOLD stage 0 with an FEV_1/FVC ratio >70%. Most patients had GOLD grade II (n= 60, 67%). Of the patients in this study, 46% were women, and mean age of the sample was 65 (SD 9.0). Most of the patients had a medium educational level (n=56; 62%), and approximately half of the patients were retired (51%). Of the non-retired population (n=44), 45% (n=20) had a full-time job.

The means, standard deviations, range of illness perceptions, proactive coping, depressive symptoms, dyspnea, FEV_1, DA, and HRQoL are presented in Table 2.

The average on the FPI scale was 1.8 (range: 1.0-2.9, reference range 1-3), indicating intermediate levels of DA[36]. The average on the CCQ was 1.4 (range: 0-3.8, reference range 0-6), meaning that the HRQoL was good, on average[37].

The mean of illness perceptions was 33.2 (range: 10-68, reference range 0-100), indicating that the patients had, on average, a more positive and adequate perception of their COPD[32]. The mean of proactive coping was 3.0 (range: 1.8-4.0, reference range 1.0-4.0), which is similar to healthy adults[33]. The mean of depressive symptoms was 10.2 (range: 0-42, reference range 0-60). Twenty patients had a score >16, indicating that 22.2% of the patients studied were possible cases of depression (three patients with GOLD grade I, 15 with GOLD grade II, and two patients with GOLD grade III)[34].

Table 1. Patient Characteristics

Variables	*Total Population N=90*
Gender	
Male	49 (54.4%)
Female	41 (45.6%)
Age, years	
Mean	65.19 (*SD* 9.0)
≤ 50	5 (5.6%)
51-60	26 (28.9%)
61-70	31 (34.4%)
71-80	23 (25.6%)
> 80	5 (5.6%)
Years diagnosed with COPD	8.13 (*SD* 8.11)
Disease Severity	
GOLD[a] I	18 (20.0%)
GOLD[a] II	60 (66.7%)
GOLD[a] III	12 (13.3%)
FEV_1 mean	1.86 (1.02-3.70) (*SD* .59)
FEV_1 % pred	67.0 (36.54-101.22) (*SD* 14.4)
Educational Level [b]	
Low	13 (14.4%)
Medium	56 (62.3%)
High	21 (23.3%)
Retired	46 (51.1%)
Paid work	20 (22.22%)
Marital status	
Married	59 (65.6%)
Widowed	8 (8.9%)
Divorced	8 (8.9%)
Single	15 (16.7%)
Smoking Status	
Current smoker	36 (40.0%)
Former smoker	49 (54.4%)
Never smoked	5 (5.6%)
Medication use	82 (91.1%)
Polypharmacy [c]	28 (31.1%)
Charlson comorbidity index, ≥1	28 (31.1%)

a Global Initiative for Chronic Obstructive Lung Disease
b Categories are based on the International Standard Classification of Education (ISCED)
c Defined by using five or more different types of medication

Table 2. Means, standard deviations, range of illness perceptions (B-IPQ), proactive coping (UPCC), depressive symptoms (CES-D), dyspnea (MRC-dyspnea), FEV1, daily activities (FPI), and health-related quality of life (CCQ) N= 88-90

	Mean (SD)	***Range***	***Ref Range***
B-IPQ	33.21(11.3)	10 - 68	0 - 100
UPCC	3.0 (0.4)	1.9 - 4.0	1 - 4
CES-D	10.2 (7.4)	0 - 42	0 - 60
MRC-dyspnea	1.7 (1.0)	0 - 5	0 - 6
FEV_1 (liters)	1.86 (0.59)	1.0 - 3.7	
FEV % pred	67.0 (14.4)	36.54 - 101.22	
FPI	1.80 (0.4)	1.0 - 2.9	1 - 3
CCQ	1.4 (0.8)	0.0 - 3.8	0 - 6

B-IPQ= Brief Illness Perception Questionnaire, UPCC= Utrecht Proactive Coping Competence scale,
CES-D= Centers for Epidemiologic Studies Depression scale, MRC dyspnea= Medical Research Council dyspnea scale,
FEV_1= Forced Expiratory Volume in one second, FEV% pred= Forced Expiratory Volume Percentage from predicted,
FPI= Functional Performance Inventory, CCQ= Clinical COPD Questionnaire.

Regression analyses

Daily Activities

As shown in Table 3, in the univariate models (model 1), illness perceptions (β= -.25) and depressive symptoms (β= -.21) were associated with DA measured by the Functional Performance Inventory. Proactive coping was not associated with DA. In model 2, where the psychological determinants illness perceptions, proactive coping, and depressive symptoms were combined and corrected for the confounders age and gender, only illness perceptions (β= -.22) and age (β= -.25) were associated with DA. In the third model, the combination of the psychological determinants illness perceptions, proactive coping, and depressive symptoms were corrected for the confounders age, gender, dyspnea, FEV_1, smoking status, and co-morbidity. The psychological determinants were not associated with DA. Only age (β= -.21) and dyspnea (β= -.29) were significantly associated with DA (Table 3).

Quality of Life

As shown in Table 4, illness perceptions (β= .61) and depressive symptoms (β= .21) were associated with HRQoL (CCQ) in the univariate models (model 1), in model 2 (the combination of illness perceptions, proactive coping, and depressive symptoms, corrected for the confounders age and gender), and in model 3, which is corrected for age, gender, dyspnea, FEV_1, smoking status, and co-morbidity. Thus, COPD patients with a more positive view of their illness and fewer depressive symptoms had a better HRQoL. Illness perceptions and depressive symptoms together with dyspnea explained 60% of the variance in HRQoL. Proactive coping was not associated with HRQoL.

Table 3. Regression model of illness perceptions (B-IPQ), proactive coping (UPCC), and depressive symptoms (CES-D) and the dependent variable daily activities (FPI) N=87

	Model 1 (Block 1) univariate			Model 2 (Block 1 and 2)			Model 3 (Block 1, 2, 3)		
	R2	β	95% CI	R2	β	95% CI	R2	β	95% CI
Block 1				.15			.24		
B-IPQ	.06	-.25*	-.02 - .00		-.22*	-.02 - .00		-.11	-.01 - .00
UPCC	.03	.182	-.03 - .36		.04	-.17 - .24		.00	-.20 - .21
CES-D	.05	-.21*	-.02 - .00		-.11	-.02 - .01		-.09	-.02 - .01
Block 2									
Age					-.25*	-.02 - .00		-.21*	-.02 - .00
Gender					-.03	-.19 - .14		.00	-.16 - .17
Block 3									
MRC dyspnea								.29**	-.20 - -.03
Fev_1								.12	-.00 - .01
Smoking status								.02	-.15 - .18
Co-morbidities								-.06	-.22 - .13

* P≤0.05 ** P≤ 0.01

Model 1: Crude model (univariate) separate: Illness perceptions (B-IPQ), Proactive coping (UPCC), Depressive symptoms (CES-D)
Model 2: B-IPQ, UPCC and CES-D corrected for confounders age and gender.
Model 3: B-IPQ, UPCC and CES-D additionally adjusted for dyspnea, FEV_1, smoking status, and co-morbidities

Table 4. Regression model of illness perceptions (B-IPQ), proactive coping (UPCC), and depressive symptoms (CES-D) and the dependent variable health-related quality of life (CCQ) N=87

	Model 1 (Block 1) univariate			Model 2 (Block 1 and 2)			Model 3 (Block 1, 2, 3)		
	R2	β	95% CI	R2	β	95% CI	R2	β	95% CI
Block 1				.55			.60		
B-IPQ	.48	.69***	.04 - .06		.68***	.039 - .06		.61***	.03 - .06
UPCC	.04	-.20	-.80 - .03		.09	-.142 - .513		.12	-.08 - .55
CES-D	.10	.32**	.014 - .06		.22**	.008 - .049		.21**	.01 - .05
Block 2									
Age					.01	-.013 - .015		-.00	.02 - .01
Gender					.03	-.205 - .311		-.01	-.26 - .25
Block 3									
MRC dyspnea								.26***	.09 - .35
Fev_1								-.03	-.01 - .01
Smoking status								-.00	.27 - .25
Co-morbidities								-.04	-.35 - .19

** P≤ 0.01 ***P≤0.001

Model 1: Crude model (univariate) separate: Illness perceptions (B-IPQ), Proactive coping (UPCC), Depressive symptoms (CES-D)
Model 2: B-IPQ, UPCC and CES-D corrected for confounders age and gender.
Model 3: B-IPQ, UPCC and CES-D additionally adjusted for dyspnea, FEV_1, smoking status, and co-morbidities.

Discussion

This study indicates that in COPD patients in primary care, psychological factors contribute to HRQoL. More positive perceptions about COPD and lower levels of depressive symptoms were associated with better HRQoL. Significant relations between psychological factors and DA (measured by FPI) were not found.

To appreciate the findings of this study, some limitations need to be considered. First, the cross-sectional nature of our study prohibits conclusions on causal relationships. Longitudinal data will facilitate the explanation of the relationships among psychological determinants, DA, and HRQoL in more detail. Second, the βs in the regression models were small, indicating small clinical changes per unit change.

Third, although our sample size was adequate given the research question, it did not allow us to conduct subgroup analyses per GOLD grade. Therefore, we could not describe the associations in the different stages of COPD.

The strength of the present study is its generalizability. In our study population, 60% of the patients had GOLD grade II, indicating mild to moderate COPD, which is in line with the population of COPD patients in primary care[8]. Moreover, we did not exclude patients with co-morbidities. Therefore, our study population is representative of the primary care population.
The multivariate approach (i.e., including the combination of different types of psychological factors) to explain the complexity of living with COPD represents another strength of this study.

The findings of our study are in accordance with results from previous studies concerning illness perceptions in COPD patients. Scharloo et al.[21] demonstrated that COPD patients with more positive beliefs about the effect and outcomes of their illness and with fewer strong emotional reactions to the illness had higher HRQoL scores. In a study by Fischer et al.[22], COPD patients' beliefs about the effectiveness of medical (pharmacological) treatment in COPD were shown to be related to better outcomes in COPD.
Whereas in other patient groups, such as patients with diabetes, proactive coping has been related to better outcomes in health behavior[27,33], we could not confirm the hypothesis that COPD patients with proactive competencies have better DA and HRQoL. Possible explanations may include our relatively small sample and the mild COPD population we studied. It is unknown what this association is for COPD patients with GOLD grade III and IV, who have more potential threats to their health.
In this study, 22.2% of the patients had depressive symptoms, which is comparable to the prevalence of depressive symptoms (24.6%) in a meta-analysis study by Zhang[31]. However, contrary to other studies[39,40], daily activities were not associated with depressive symptoms

in our study. This finding may partially be explained by the use of other DA and dyspnea measurement tools. Nevertheless, in line with other studies[13,41], depressive symptoms were associated with HRQoL.

The finding of our study that dyspnea contributes to HRQoL is comparable to other studies regarding the association between dyspnea and HRQoL[41-43]. Moreover, our study revealed that 60% of the variance in HRQoL was explained by the combination of illness perceptions, depressive symptoms, and dyspnea.

Although the level of daily activities of COPD patients in this study (1.80) was in line with levels of activity in other studies using the FPI in COPD patients (2.2 in a study by Kapella[44] and 1.87 in study by Wall[39]), in contrast to our hypothesis, we did not find associations between psychological factors and DA. This finding is in contrast to the results from previous studies concerning relationships between psychological factors and DA[45-47]. This finding could be explained by the use of different measurement tools for DA. Fischer et al.[20] used walking test results as the outcome parameter, in contrast to our study, which used the FPI questionnaire. A possible explanation is that a walking test measures the physical capacity or ability to participate in day-to-day activities[48,49], whereas the functional performance inventory measures self-reported activities in daily life[36].

In other studies, concerning factors affecting health status[40,45], other DA measurement tools (Saint George's Respiratory Questionnaire and the Pulmonary Functional Status Tool) were used. Obviously, other factors are likely to influence the activities people choose to perform on a daily basis, such as environmental factors, medical history, and other personal characteristics[44]. In our study, dyspnea was significantly associated with DA, which is in line with results from other studies[50,51].

Conclusions and implications

The results of this study indicate that in COPD patients, the combination of illness perceptions and depressive symptoms contribute to HRQoL. More positive illness perceptions about COPD and lower levels of depressive symptoms were associated with better HRQoL. This study contributes to the understanding of the complexity of living with COPD.

Although small βs in the regression models indicate a small clinical contribution, these results provide starting points for the development of interventions focusing on psychological concepts to support COPD patients in their daily life and disease management. Patients' perceptions of COPD, depressive symptoms, and dyspnea should be explored (e.g., with questionnaires), discussed with the patient, and, if necessary, corrected at an early stage. Positive (realistic) beliefs should be stimulated, and negative beliefs should be prevented or challenged[52-54]. Depressive symptoms and dyspnea should also be identified and treated properly. These approaches may result in better HRQoL in COPD patients. However, because interventions focusing on these psychological concepts have only recently been described in patients with other chronic diseases[55-57], it is important to develop and test the effectiveness of these interventions for COPD patients.

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Chapter 4

Perceived quality of life in Chronic Obstructive Pulmonary Disease Patients: a cross-sectional study in primary care on the role of illness perceptions

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Published in BMC Family Practice (15) 2014

Abstract

Background: Previous research has shown that in Chronic Obstructive Pulmonary Disease (COPD) patients, it is important to consider not only physical functioning and complaints but also psychological factors, such as illness perceptions, to explain differences in Health-Related Quality of Life (HRQoL). The objective of this study is to analyse the extent to which the specific dimensions of illness perceptions according to the Common Sense Model (corrected for airflow limitation, dyspnoea and comorbidities) contribute to HRQoL.

Methods: In a cross-sectional study in primary care, 90 COPD patients completed questionnaires: The Brief Illness Perception Questionnaire, the Medical Research Council dyspnoea scale, the Clinical COPD Questionnaire (CCQ) and the Chronic Respiratory Questionnaire (CRQ). Analyses were performed with multiple linear regression.

Results: When corrected for confounders (airflow limitation, dyspnoea and comorbidities), identity (β=.42) and comprehensibility (β=-.16) were associated with HRQoL (CCQ). Identity, comprehensibility and dyspnoea explained 56% of the variation in HRQoL (R^2=.56). Consequences (β=-.50) and treatment control (β=.20) were associated with HRQoL (the CRQ's physical domain). They explained 59% of the variation in the CRQ physical (R^2=.59) domain. Treatment control (β=.19) and emotional response (β= -.33) were associated with the CRQ emotional domain.

Conclusions: Patients who experience fewer symptoms attributed to COPD, who have a better understanding of the disease, who experience less impact of COPD in daily life, who experience better treatment control and who have less of an emotional response have better HRQoL. This study indicates that the HRQoL of COPD patients is associated with illness perceptions as well as with the severity of dyspnoea as experienced by patients. Airflow limitation measures or comorbidities do not add to the explanation of HRQoL. The results of this study provide starting points for the development of interventions focusing on illness perceptions to support COPD patients in their disease management and to improve HRQoL.

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is a chronic disease characterised by progressive and persistent airflow limitation[1]. In the Netherlands, more than 360,000 people have been diagnosed with COPD[2]. The prevalence is estimated at 2.3% of men and 2.1% of women[2]. COPD patients may face limitations in daily activities and reduced quality of life caused by dyspnoea, airflow limitation, skeletal muscle dysfunction, and comorbidities[1,3]. Three major goals of COPD care and treatment are to reduce symptoms, increase participation in daily activities and improve health-related quality of life (HRQoL)[1]. In primary care settings in the Netherlands and many other countries, care for patients with COPD has increasingly moved from hospitals to primary care settings. Practice nurses have become essential in supporting COPD patients in their disease management[4].

The pulmonary and extrapulmonary effects of the disease have an impact on physical, emotional, and mental well-being in COPD patients[5,6]. Although the assessment of COPD relies mainly on the degree of airflow limitation (i.e., the decrease in forced expiratory volume in one second (FEV1)), there is evidence that FEV1 has a relatively poor correlation with symptoms, HRQoL and daily functioning[7-9]. Therefore, other models in addition to strict medical models are increasingly used to explain differences in daily functioning and HRQoL in chronically ill patients. These models presume that biological factors as well as psychological and social factors play a significant role in the explanation of functioning and HRQoL in chronic illnesses[10,11]. One of the psychological factors that is considered important in this context is illness perceptions. Illness perceptions are the central concept of the Common Sense Model (CSM)[12,13]. This model suggests that people have personal beliefs about their illness that often do not match medical views but that nevertheless determine, to a large extent, how people respond to their illness. These illness perceptions include beliefs about consequences, the timeline of the disease, ability to control the disease and the extent to which the treatment helps in controlling the disease. They also include perceptions of symptoms attributed to the disease (identity), understanding of the disease, concerns and emotional response to the disease[12-14]. The CSM presumes that these various dimensions of illness perceptions are logically related to health behaviors and HRQoL. Therefore, these perceptions are considered key elements for understanding the ways that people attempt to manage threats to their health[12,13]. The CSM is depicted in Figure 1[13,15].

Previous research in outpatient and clinical populations has demonstrated that COPD patients who believe that the impact of the disease on daily life is less serious, who have positive beliefs about the treatment and who have less strong emotional reactions have better HRQoL than patients who have more negative beliefs[16-18]. Our previous

study of COPD patients in a primary care setting, which explored the extent to which the combination of illness perceptions, proactive coping and depressive symptoms contribute to daily activities and HRQoL, revealed that illness perceptions are associated with HRQoL. More positive perceptions of illness were related to better HRQoL[9]. In this study, we will expand on our earlier research by analysing the extent to which the specific dimensions of illness perceptions contribute to HRQoL. Investigating these dimensions of illness perceptions in patients with mild to severe COPD allows us to test the assumption of the CS Model that specific beliefs about consequences, the timeline of the disease, ability to control the disease, ability to control the disease by treatment, symptoms, comprehensibility of the disease, emotional response and concerns are related to HRQoL.

Methods

Study design and participants

This cross-sectional study was conducted in ten general practices throughout the Netherlands between June 2010 and April 2011. The study sample consisted of COPD patients who attended the participating general practices and visited the practice nurses during consulting- hours. The patients included in the study complied with the following criteria: a diagnosis of mild COPD (GOLD I), moderate COPD (GOLD II) or severe COPD (GOLD III)[1]. The GOLD (Global initiative for chronic Obstructive Lung Disease) is a classification of severity of airflow limitation in COPD based on post-bronchodilator forced expiratory volume in one second (FEV_1) and the forced vital capacity (FVC)[1]. Furthermore, they had to be both physically and mentally able to complete the questionnaires. Patients were excluded if they had participated in another study or if they had a primary diagnosis of asthma. The Medical Research Ethics Committee (MREC) of the University Medical Center Utrecht concluded that the Medical Research Involving Human Subjects Act (WMO) does not apply to this study; therefore, no WMO approval by the MREC was needed. The MREC ensured that the individuals involved in the study were adequately informed that their data would be used for research proposes. All participants provided written informed consent to participate in the study.

Procedure

Eleven practice nurses working in ten participating general practices asked eligible COPD patients who visited them during consulting-hours if they would be willing to participate in the study. Eligible patients who expressed willingness to participate received a standardised letter explaining the aims of the study, particularly that the study would investigate the impact of COPD in daily life. After giving written informed consent, the participating patients completed the questionnaires at home and then returned them in a stamped addressed envelope to our center.

Measures

Illness Perceptions

To assess the various dimensions of illness perceptions, the Brief Illness Perception Questionnaire (B-IPQ)[19] was used. This brief version was used because it is more suitable, less taxing, much quicker and much easier to complete than the long version IPQ-R[20]. The B-IPQ is a self-administered scale consisting of eight items on an 11-point scale (range 0-10). Each item represents a dimension of the CSM (Figure 1). Five items assess cognitive representations of the illness, and three items assess the emotional representation of the illness. The dimensions and implications of the scores are depicted in Table 1. A higher score on these dimensions implies that patients believed in a stronger influence of illness upon daily life *("consequences"),* held stronger belief in a chronic time course *("timeline"*), had greater perceived personal control of illness *("personal control"),* had greater perceived control of the disease by treatment *("treatment control"),* and had a greater experience of severe symptoms as a result of the illness *("identity")*. Two of the items assess emotional representations of illness. A higher score implies that patients had greater feelings of concern about the illness *("concern")* and a stronger emotional response to the illness *("emotional response")*. One questionnaire item assesses *"comprehensibility"*; a higher score implies a better understanding of the illness. One open-ended item assesses causal beliefs about COPD. This item asks patients to list their views on the three most important causal factors of their illness.

Dyspnoea

The MRC dyspnoea scale is a questionnaire that consists of six statements about perceived breathlessness: grade 0, "I don't suffer from shortness of breath" grade 1, "I only get breathless with strenuous exercise"; grade 2, "I get short of breath when hurrying on the level or up a slight hill"; grade 3, "I walk slower than people of the same age on the level because of breathlessness or have to stop for breath when walking at my own pace on the level"; grade 4, "I stop for breath after walking 100 yards or after a few minutes on the level"; and grade 5, " I am too breathless to leave the house"[21]. Patients selected the grade that applied to them.

Health-Related Quality of Life

To measure HRQoL, the Clinical COPD Questionnaire (CCQ)[22] and the Chronic Respiratory Disease Questionnaire Self-Administered Short version (CRQ-SAS)[23] were used. The CCQ is a self-administered questionnaire consisting of 10 questions. Response options range from 0 ("no limitations/asymptomatic") to 6 ("totally limited/extremely symptomatic"). The total score is computed by summing the scores and dividing the total score by the number of items. Higher scores indicate lower HRQoL.

The CRQ-SAS is a 20-item self-administered questionnaire covering four dimensions: dyspnoea, fatigue, emotional function and mastery. The response options for each question range from 1 (maximum impairment) to 7 (no impairment). The total score per domain is computed by summing the scores and dividing the total score by the

number of items. In the analyses, the CRQ-SAS was divided into two domains: the CRQ-SAS physical domain (the mean of the dyspnoea and fatigue domains) and the CRQ-SAS emotional domain (the mean of the emotional function and mastery domains). Higher scores indicate better HRQoL.

In addition, data on pulmonary function were collected: FEV1 in litres and FVC in litres. To calculate the predicted forced expiratory volume percentage (FEV1% predicted), data on height and weight (according to the local general practitioner registry) were collected. Co-morbidities were measured by the Charlson comorbidity index[24]. This index is a validated method of classifying comorbidity from medical records and measures 17 conditions. The index score is the total of assigned weights and represents a measure of the burden of comorbidity[24,25].

Sociodemographic variables, such as age, gender, education level (based on the International Standard Classification of Education: ISCED)[26], working status, marital status and disease-related variables (medication use, smoking status) were also collected.

Analyses

Descriptive statistics were used to present patients' backgrounds, medical characteristics and their causal beliefs about COPD.

Linear regression analyses (adjusted for the confounders age, gender, dyspnoea, airflow reduction and comorbidities) were performed to quantify the associations between illness perceptions and HRQoL[27].

First, a crude model with the eight specific dimensions of illness perceptions (model 1) was analysed. In the second model (model 2), illness perceptions were corrected for the confounders of age and gender. In the third model (model 3), illness perceptions were adjusted for dyspnoea, airflow reduction (FEV1%predicted) and comorbidities. In the regression models, the standardised βs were used to compare the strength of the various independent variables. The adjusted explained variance (adjusted R2) per model was then analysed. Because only 3% of the data was missing, a complete case analysis was performed. All analyses were performed with the Statistical Package for the Social Sciences (SPSS 20.0 for Windows).

Results

Sample characteristics

A total of 98 patients completed the questionnaires. In the analyses, it was found that eight patients had no COPD; they had a GOLD stage of 0 with an FEV1/FVC ratio >70%. Therefore, these patients were excluded from the analyses. The sample characteristics of the 90 patients are presented in Table 2. The mean age of the patients in the study sample was 65, with a standard deviation (SD) of 9.0. Forty-six percent of study sample was women. Most patients (n=60, 67%) had moderate COPD (GOLD grade II). Half of the patients were retired (51%). In the non-retired population (n=44), 20 patients (22% from the total population) had full-time jobs. Most of the patients had a medium educational level (62%).

Illness perceptions and disease-related characteristics

The means, standard deviations, range of various dimensions of illness perceptions, dyspnoea, airflow limitations (FEV1), and HRQoL are presented in Table 3. In general, given their mean scores on the dimensions of illness perceptions, participants in this study considered their COPD chronic but not very serious, easily controlled by medical care or self-care, and with only minor consequences for daily life (Table 3). Most patients believe that smoking caused their COPD (71%), followed by heredity (22%), air pollution (16%) and allergy (8%).

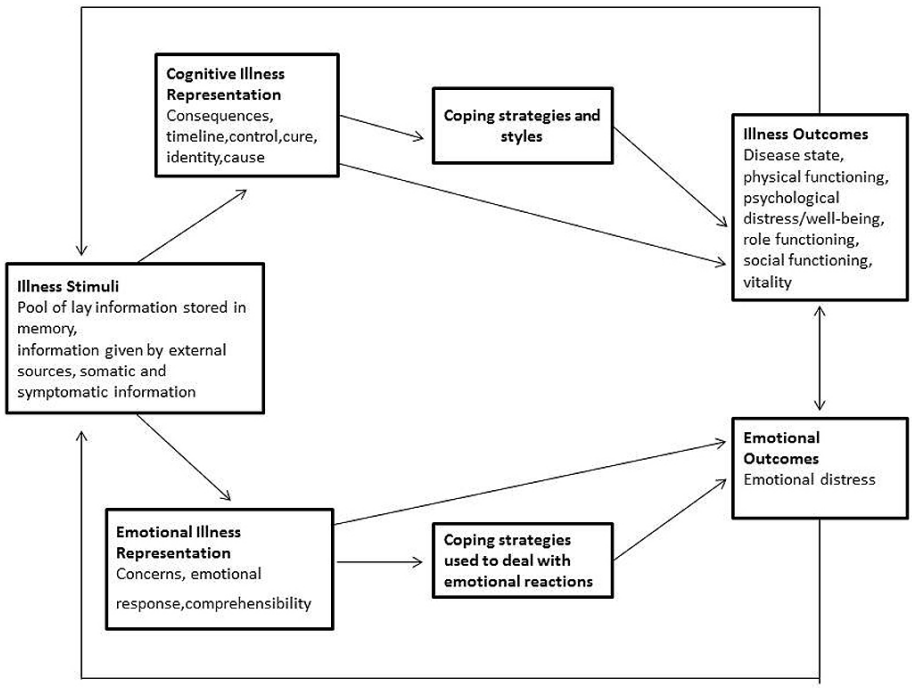

Figure 1. The Common Sense model (Adapted from Hagger et al, and Kaptein et al)[13,15]

Illness perceptions and HRQoL

As shown in the crude regression model, which is not corrected for confounders (model 1, Table 4), *consequences* (β=.26), *identity* (β=.43) and *comprehensibility* (β=-.16) were associated with HRQoL as measured by the CCQ. When corrected for the confounders of age and gender (model 2), only *identity* (β=.44) was associated with HRQoL. In model 3, corrected for the confounders of dyspnoea, FEV1%predicted and comorbidities, *identity* (β=.42) and *comprehensibility* (β=-.16) were associated with HRQoL. *Identity, comprehensibility* and dyspnoea explained 56% of the variation in HRQoL in model 3 (R^2=.56). FEV%pred and comorbidity were not associated with the CCQ. These results indicate that COPD patients with weaker perceptions of *identity* and greater understanding *(comprehensibility)* of the disease have better HRQoL.

As shown in Table 5 (model 1 and model 2), *consequences* (β=-.55) and *treatment control* (β=.16) were associated with HRQoL as measured by the CRQ-SAS physical domain. When corrected for the confounders of dyspnoea, FEV1%predicted and comorbidity (Table 5, model 3), *consequences* (β=-.50) and *treatment control* (β=.20) were associated with the CRQ-SAS's physical domain. *Consequences, treatment control* and dyspnoea explained 59% of the variation in the CRQ-SAS's physical domain (R^2=.59). These results indicate that COPD patients with weaker perceived consequences and more perceived effectiveness of the treatment have better HRQoL as measured by the CRQ-SAS's physical domain (the mean of the dyspnoea and fatigue domains).

As shown in table 6 (model 1, 2 and 3), *treatment control* (β=.19) and *emotional response* (β=-.33 - -.40) were associated with the CRQ-SAS's emotional domain. *Treatment control, emotional response* and dyspnoea explained 35% of the variation in the CRQ-SAS's emotional domain. These results indicate that COPD patients with better treatment control and a weaker emotional response to their disease have better HRQoL as measured by the CRQ-SAS's emotional domain (the mean of the emotional function and mastery domains).

Table 1. The dimensions of the Brief-Illness Perception Questionnaire (B-IPQ)[19]

Dimensions B-IPQ	Higher score Implies:
Consequences	greater perceived influences of COPD
Timeline	a stronger belief in a chronic time course
Personal control	greater perceived personal control
Treatment control	greater perceived control by treatment
Identity	greater experience of severe symptoms as a result of COPD
Concern	greater feelings of concern about COPD
Emotional response	a stronger emotional response
Comprehensibility	a better understanding of the illness

Table 2. Patient Characteristics

Variables	Total Population (N=90)
Gender	
Male	49 (54.4%)
Female	41 (45.6%)
Age, years	
Mean	65.19 (SD 9.0)
≤ 50	5 (5.6%)
51-60	26 (28.9%)
61-70	31 (34.4%)
71-80	23 (25.6%)
> 80	5 (5.6%)
Years diagnosed with COPD,	8.1 (SD 8.11)
mean disease severity	
GOLD[a] I	18 (20.0%)
GOLD II	60 (66.7%)
GOLD III	12 (13.3%)
FEV1 mean	1.9 (1.0-3.7) (SD .59)
FEV1% predicted	67.0 (36.5-101.2) (SD 14.4)
Educational Level [b]	
Low	13 (14.4%)
Medium	56 (62.3%)
High	21 (23.3%)
Retired	46 (51.1%)
Paid work (among ≤ 64 years)	20 (22.2%)
Marital status	
Married	59 (65.6%)
Widowed	8 (8.9%)
Divorced	8 (8.9%)
Single	15 (16.7%)
Smoking status	
Current smoker	36 (40.0%)
Former smoker	49 (54.4%)
Never smoked	5 (5.6%)
Medication use	82 (91.1%)
Charlson comorbidity index, ≥1	28 (31.1%)

[a] Global Initiative for Chronic Obstructive Lung Disease

[b] Categories are based on the International Standard Classification of Education (ISCED)[26]

Table 3. Descriptions of illness perceptions (B-IPQ), MRC dyspnoea, FEV1 and Health-Related Quality of Life (CCQ and CRQ) N= 88-90

	Mean (SD)	***Range***	***Ref Range***	***Percentage***
Illness Perceptions (B-IPQ)				
Consequences	3.6 (2.5)	0-9	0 – 10	
Timeline	9.1 (2.1)	0-10	0 – 10	
Personal control	6.0 (2.5)	0-10	0 – 10	
Treatment control	6.8 (2.7)	0-10	0 – 10	
Identity	4.0 (2.6)	0-10	0 – 10	
Concern	4.1 (3.1)	0-10	0 – 10	
Comprehensibility	7.6 (2.7)	0-10	0 – 10	
Emotional response	3.0 (3.1)	0-10	0 – 10	
Causes of COPD				
Smoking				71%
Heredity				22%
Air pollution				16%
Allergy				8%
Other				42%
MRC dyspnoea	1.7 (1.0)	0 - 5	0 - 6	
FEV1 (litres)	1.9 (0.6)	1.0 - 3.7		
FEV_1% pred	67.0 (14.4)	36.5 - 101.2		
HRQoL: CCQ	1.4 (0.8)	0.0 - 3.8	0- 6	
HRQoL: CRQ:				
CRQ-SAS Physical	5.6 (1.3)	2.70-7.00	1-7	
CRQ-SAS Emotional	5.60 (1.0)	2.73-7.00	1-7	

B-IPQ= Brief Illness Perception Questionnaire, CCQ= Clinical COPD Questionnaire, CRQ-SAS= Chronic Respiratory Disease Questionnaire Self-Administered Short version, CRQ-SAS physical= CRQ-SAS dyspnoea domain and CRQ-SAS fatigue domain, CRQ-SAS emotional= CRQ-SAS emotional domain and CRQ-SAS mastery domain, FEV1= Forced Expiratory Volume in 1 second, FEV%pred= Forced Expiratory Volume Percentage from predicted, HRQoL= Health-Related Quality of Life, MRC dyspnoea= Medical Research Council dyspnoea scale

Table 4. Regression models between various illness perception items and dependent variable health-related quality of life (CCQ) N=86

	Model 1 (Block 1)		Model 2 (Block 1 and 2)		Model 3 (Block 1 and 3)	
	R^2	β	R^2	β	R^2	β
Block 1:Perceptions	.53		.54		.56	
Consequences		**.26***		.26		.21
Timeline		.01		-.01		-.03
Personal control		.03		.02		.04
Treatment control		-.11		-.16		-.15
Identity		**.43****		**.44****		**.42****
Illness concern		.02		.03		-.01
Comprehensibility		**-.16***		-.13		**-.16***
Emotional response		.16		.09		.13
Block 2: Demographic characteristics						
Age				.06		
Gender				.10		
Block 3: Clinical characteristics						
MRC dyspnoea						**.23****
FEV%pred						.01
Comorbidity						-.10
F-change model		**13.9*****		**1.00**		**2.3*****

R2 is an adjusted R2. β is a standardised β
* P≤0.05 ** P≤ 0.01
FEV%pred= forced expiratory volume percentage from predicted, MRC dyspnoea= Medical Research Council dyspnoea scale

Table 5. Regression models between various illness perceptions items and dependent variable health-related quality of life (CRQ physical) N=87

	Model 1 (Block 1)		Model 2 (Block 1 and 2)		Model 3 (Block 1 and 3)	
	R^2	β	R^2	β	R^2	β
Block 1: Perceptions	.49		.49		.59	
Consequences		**-.55*****		**-.55*****		**-.50*****
Timeline		-.16		-.14		-.08
Personal control		-.09		-.08		-.06
Treatment control		**.16***		**.16***		**.20****
Identity		-.09		.11		-.06
Illness concern		.01		.02		.06
Comprehensibility		.07		.04		. 07
Emotional response		-.15		-.14		-.17
Block 2: Demographic characteristics						
Age				-.01		
Gender				-.10		
Block 3: Clinical characteristics						
MRC dyspnoea						**-.35****
FEV%pred						-.11
Comorbidity						.05
F-change		**11.25*****		**7.69**		**6.47*****

R^2 is an adjusted R^2. β is a standardised β

* P≤0.05 ** P≤ 0.01

FEV%pred= forced expiratory volume percentage from predicted, MRC dyspnoea= Medical Research Council dyspnoea scale

Table 6. Regression models between separate illness perception items and dependent variable health-related quality of life (CRQ emotional) N=87

	Model 1 (Block 1)		Model 2 (Block 1 and 2)		Model 3 (Block 1 and 3)	
	R^2	β	R^2	β	R^2	β
Block 1: Perceptions	.32		.32		.35	
Consequences		-.17		-.17		-.14
Timeline		.01		.03		.05
Personal control		.03		.05		.05
Treatment control		.17		.17		.19*
Identity		-.08		-.10		-.07
Illness concern		-.03		-.01		-.00
Comprehensibility		-.53		-.09		-. 06
Emotional response		**-.40****		**-.39****		**-.33***
Block 2: Demographic characteristics						
Age				-.02		
Gender				-.14		
Block 3: Clinical characteristics						
MRC dyspnoea						**-.23***
FEV%pred						-.10
Comorbidity						.05
F-change model		**6.01*****		**1.08**		**1.74**

R^2 is an adjusted R^2. β is a standardised β

* P≤0.05 ** P≤ 0.01

FEV%pred= forced expiratory volume percentage from predicted, MRC dyspnoea= Medical Research Council dyspnoea scale

Discussion

This study shows that specific dimensions of illness perceptions are associated with HRQoL in COPD patients with mild to severe COPD (GOLD I-III) who receive medical support from a primary care physician and a practice nurse in primary care. COPD patients have better HRQoL when they experience fewer symptoms attributed to COPD (identity), experience less impact in daily life (consequences), experience fewer emotional consequences (emotional response), have stronger beliefs about control of their treatment and have a greater understanding of the disease (comprehensibility). When corrected for dyspnoea, airflow limitation and comorbidity, *identity, comprehensibility*

and dyspnoea explained 56% of the variation in HRQoL (CCQ). *Consequences, treatment control* and dyspnoea explained 59% of the variation in HRQoL (the CRQ-SAS's physical domain), and *emotional response* and dyspnoea explained 35% of the variance in HRQoL (the CRQ-SAS's emotional domain).

The findings of our study are in line with the results of other studies regarding illness perceptions in COPD patients. Scharloo[28] and colleagues have concluded that outpatient COPD patients who have a strong illness identity and strong beliefs regarding the consequences of their illness have worse general functioning and HRQoL. In another study by Scharloo[16] of outpatient COPD patients, decreased symptoms, more positive beliefs about the effects and outcomes of treatment and less strong emotional reactions were associated with higher HRQoL. Our data support these findings. Our findings are also in line with findings regarding illness perceptions in COPD patients undergoing rehabilitation; more positive and adaptive attitudes about treatment are related to better outcomes and general functioning[17,29,30].

Although some studies show that coping with illness mediates the relationship between illness perceptions and the overall outcome of the illness[13], our previous research[9] and research by Heijmans et al.[31,32] has revealed that HRQoL is more influenced by illness perceptions than by coping strategies.
Our study lends support to the Comon Sense Model (CSM)[12], which suggests that people hold views and beliefs about their illness that are associated with their HRQoL. These illness perceptions are the key elements for understanding how people manage threats to their health and experience their HRQoL[12].

To appreciate the findings of this study, some aspects require further consideration. The current study has some limitations. First, because of the cross-sectional nature of this study, the associations between the dimensions of illness perceptions and HRQoL should not be understood as implying a causal relationship. In light of these findings, it is important to address the possibility of some conceptual overlap between the specific dimensions of illness perceptions and HRQoL. There were some significant correlations between the illness perception dimensions and the HRQoL measures, but they were too low to determine collinearity. Longitudinal data will enable us to explain the relationship between illness perceptions and HRQoL in more detail. Second, the βs in the regression models were small, indicating small clinical changes per unit change. Third, the sample size did not allow for subgroup analyses per GOLD grade. Therefore, we could not describe the associations in the different stages of COPD. Furthermore, all measures were questionnaires. It could be questioned whether a questionnaire is the best measure of illness perceptions because the development of perceptions is partially an unconscious process. Qualitative interviews might be preferable to

questionnaires. However, the aim of the study was to quantify the relationship between illness perceptions and HRQoL, for which regression analysis is the preferred method. Furthermore, patient-reported outcome measures of illness perceptions (B-IPQ)[19,33] and HRQoL[34] have been shown to be valid and reliable.

The strength of the present study is its generalisability. In our study population, 20% of the patients had mild COPD (GOLD grade I), and almost 70% of the patients had moderate COPD (GOLD grade II). This sample is in line with the distribution of COPD patients in primary care[4]. Moreover, we did not exclude patients with comorbidities. Therefore, our study population is representative of the primary care population.

Conclusion

This study highlights the importance of patients' beliefs about their illness and symptoms in relation to HRQoL. The results of this study indicate that the HRQoL of COPD patients is associated with illness perceptions together with the severity of dyspnoea as experienced by patients. More objective measures, such as airflow limitation measures or comorbidities, do not add to the explanation of HRQoL.

A major goal of COPD treatment is to improve HRQoL[1], and this study contributes to the existing knowledge concerning the associations between illness perceptions and HRQoL. Despite their importance, patients' beliefs and views of their symptoms and illness are rarely discussed in consultations[14]. The results of this study confirm the existing knowledge and provide starting points for the development of interventions focusing on illness perceptions both to support COPD patients in their disease management and to improve HRQoL. Because evidence suggests that the degree of physician-patient concordance regarding perceptions of symptoms is poor[35,36] and that addressing illness perceptions is more important than interpersonal skills in relation to patient adherence[37], the starting point should be to explore these illness perceptions (e.g., with questionnaires)[38]. The second step should be to discuss these perceptions and, if necessary, to correct them at an early stage. Realistic positive beliefs should be encouraged, and negative beliefs should be prevented or challenged[18,39,40]. This approach may result in better HRQoL in COPD patients. Because interventions focusing on illness perceptions have only recently been described in patients with other chronic diseases[41-43], it is important to develop and test an illness perception intervention for COPD patients in primary care settings.

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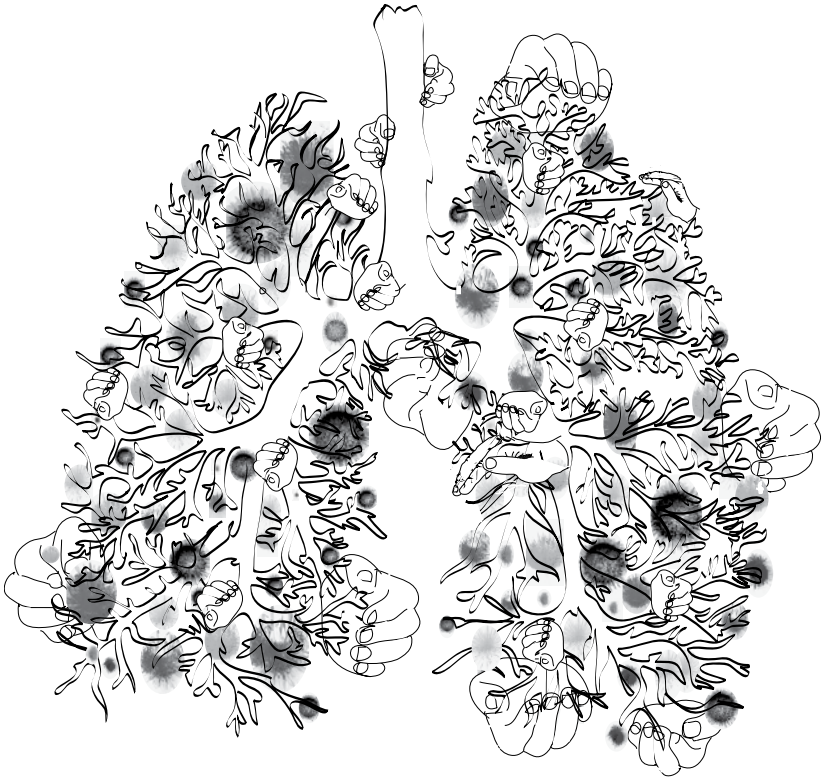

Chapter 5

Facilitators and barriers of a new individualized nursing care intervention in Chronic Obstructive Pulmonary Disease patients in primary care: a mixed method study from the perspective of nurses

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Under Review

Abstract

Background: The major challenges in Chronic Obstructive Pulmonary Disease (COPD) care are guiding a patient in daily living with the consequences of the disease, reducing the impact of symptoms and improving Health Related Quality of Life (HRQoL). The new nurse-led COPD-Guidance, Research on an Illness Perception (COPD-GRIP) intervention translates the evidence concerning illness perceptions and Health Related Quality of Life (HRQoL) into a practice nurse intervention.
The aim is to explore facilitators and barriers in applying the COPD-GRIP intervention from the perspective of the nurses.
Methods: An explanatory mixed-method study nested in a cluster randomized trial in primary care was conducted. Pre- intervention questionnaires were sent to all participating nurses (N=24) to identify expectations. Post-intervention questionnaires identified experiences after applying the intervention followed by two focus groups to further extend exploration of findings. Questionnaires were analyzed by descriptive analyses. To identify themes, the audio-taped and transcribed focus groups were independently coded by two researchers.
Results: The nurses described the intervention as a useful, structured and individualized tool to guide COPD patients in living with the consequences of COPD. Applying the intervention took less time than the nurses initially expected. The intervention enables to provide patient- centered care and to address patient needs. Barriers were encountered, especially in patients with a lower social economic status, in patients with a lower health literacy and in patients with another cultural background.
Conclusion: Nurses perceived the COPD-GRIP intervention as a feasible, individualized tool which is a valuable improvement in the care for COPD patients.

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is a progressive chronic disease characterized by persistent airflow limitation resulting in breathlessness, limitations in daily activities and reduced quality of life[1]. It is estimated that 328 million people worldwide have COPD[2] and the prevalence of the physical, social and economic burden that results from this disease continues to increase[3]. COPD patients experience several unmet health needs, such as the need of a better understanding of the sustained symptom burden, physical limitations, and psychological impact of COPD[4,5]. These developments highlight the importance to develop new interventions in COPD management[4-6].

Treatment and care for COPD patients has increasingly moved from hospitals to primary care during the last decade in the Netherlands as well as in many other countries[7]. General practitioners, practice nurses and respiratory nurses play a key role in the care for COPD patients in primary care[7,8]. Particularly nurses can make a substantial contribution to the long-term care of COPD patients because of their unique position: nurses are involved in all stages of the disease, from prevention to end-of life-care[6]. Moreover, their contribution is characterized by continuity of care[6,8,9]. The major challenges in COPD care are guiding a patient in daily living with the consequences of the disease, reducing the impact of symptoms and improving Health Related Quality of Life (HRQoL)[1,6]. Evidence show that illness perceptions are associated with HRQoL in COPD patients[10-15]. These illness perceptions guide individuals' efforts to cope with COPD. Despite their importance, patients' illness perceptions are rarely discussed in consultations with general practitioners and nurses[16,17]. Although several COPD disease management programs[18,19] and nurse-led interventions[20-23] have been developed, specific guidelines for nurses how to discuss illness perceptions with COPD patients are lacking. Therefore, we have developed a new nursing intervention that translates the evidence concerning illness perceptions into a practical guide that nurses can use in clinical care. According to the Medical Research Council (MRC) for developing and evaluating complex interventions it is important to evaluate the experiences of the providers of new interventions in order to improve the intervention and to enable implementation in practice[24-27]. Therefore, the purpose of the study is to evaluate the nurses' experiences with this new intervention.

Background

The COPD-Guidance Research on Illness Perception (COPD-GRIP) intervention[28] is based on the Leventhal's Common Sense model (CSM) of self-regulation of health and illnesses[29]. The CSM suggests that people have personal beliefs about their illness which determine to a large extent how people respond to their illness[29]. Based on this CSM and the existing evidence on the relationship between illness perceptions and

HRQoL[12-15,30], a first draft of the intervention was written. The structure developed by Petrie et al[30] of identifying, discussing and evaluating illness perceptions was taken as a starting point in developing the intervention, followed by a description of specific building blocks which can be used by nurses to guide COPD patients in primary care. Subsequently, the face validity of this first draft of the COPD-GRIP intervention was assessed in a team of experts (4 respiratory nurses, an expert in health psychology, a pulmonologist (JWL), a nursing scientist (MS) and a general practitioner). Based on their comments an adjusted version of the COPD-GRIP intervention was written. The COPD-GRIP intervention is currently being tested on its' effectiveness in terms of health status, quality of life and daily activities with a nine-month follow-up period in a cluster randomized trial in primary care in the Netherlands. This COPD-GRIP trial includes 37 participating nurses from primary care practices and 221 COPD patients (COPD-GRIP trial, Netherlands Trial Registry (NTR) 3945).

COPD-GRIP intervention

The COPD-GRIP intervention is an individualized tailor-made intervention. It starts with assessing and discussing illness perceptions with the Brief Illness Perception Questionnaire (B-IPQ)[31] as a guide for tailoring the intervention. It is subsequently followed by improving patient's understanding of the relationship between their perceptions and their behavior, by challenging them to draw up an individualized care plan and finally, by evaluating the action they have taken to change their perceptions and behavior. The COPD-GRIP intervention consists of three face-to face consultations, each lasting approximately half an hour. Because of the sequential structure and content of the intervention the consultations are planned with an interval of three weeks.

The intervention is entirely described in a booklet[28]. It has an equivalent structure for all patients. The specific content is individualized, based on the patients' responses on the B-IPQ, and based on the needs of the patient. An English version of the booklet can be found on our website www.umcutrecht.nl/griponderzoek.

The COPD-GRIP intervention has been applied within the COPD-GRIP trial in primary care in context of regular contacts between the COPD patient and the participating nurses at the primary care-office or at the patient's home. The participating nurses were practice nurses who mainly contacted the patients in the primary care office, or respiratory nurses who mainly visited the patients at home. All nurses of the 19 participating practices were trained in an educational session which was developed by a health psychologist and a researcher/nurse (SW). During this session the above-mentioned stages of the intervention were explained and discussed step by step. Moreover, the content of the booklet in which the COPD-GRIP intervention is described, was discussed and a short animation movie was used to explain the content of the booklet. This movie can be found on our website www.umcutrecht.nl/griponderzoek

Aim

The aim of this study was to explore facilitators and barriers in applying the COPD-GRIP intervention from the perspective of the nurses.

Methods

Study design

An explanatory mixed-method study on nurses' perceptions of facilitators and barriers of the COPD-GRIP intervention, nested in a cluster randomized trial in primary care was conducted. As can be seen in Figure 1 quantitative and qualitative research methods were used. The study design was guided by the proposed Criteria for Reporting the Development and Evaluation of Complex Interventions in health care; the CReDECI guidelines[25].

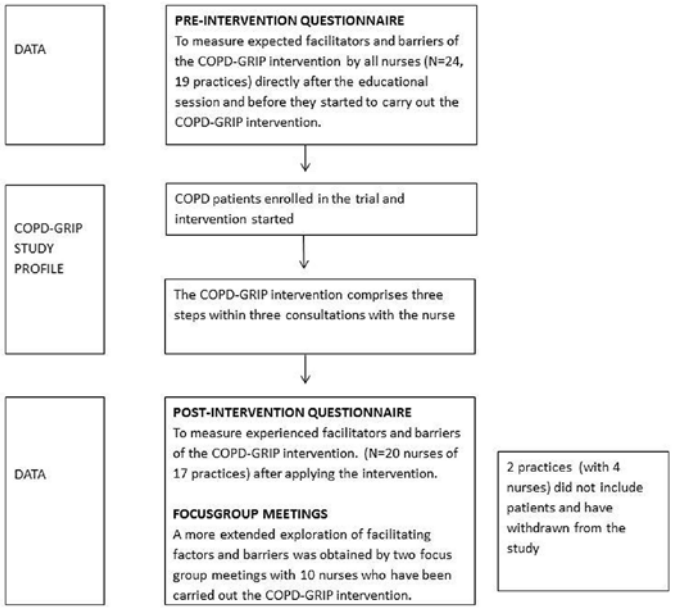
Study sample

The study sample consisted of 24 nurses of 19 practices in primary care who participated in the COPD-GRIP trial. The primary care practices were situated all around the Netherlands.

Data collection

Quantitative data of the nurses' perceptions of facilitators and barriers related to the COPD-GRIP intervention were collected by a questionnaire at two moments in time and the qualitative data concerning facilitators and barriers were collected by two focus group meetings with the nurses (Figure 1).

Figure 1. Study profile and data collection



Questionnaires

Facilitators and barriers with respect to the COPD-GRIP intervention were explored by a pre-intervention and a post-intervention questionnaire. The nurses filled in the pre-intervention questionnaire directly after the educational session and before they started to carry out the COPD-GRIP intervention. The post-intervention questionnaire was filled in after carrying out the COPD-GRIP intervention at least one time in all patients, which means three consultations in every patient (Figure 1). The questionnaire was adapted from van Eijken et al[32] and based on a structured list of barriers and facilitating factors[33]. The content validity was assessed by a group of experts[32] and formerly used in two other studies evaluating new interventions for practice nurses in primary care[32,34]. The questionnaire included items with respect to expectations and experiences concerning knowledge, organizational context, performing the intervention, time, patient characteristics and nurse perspectives. The response options range from 5 (strongly agree) to 1 (strongly disagree).

Focus group meetings

A more extended exploration of facilitators and barriers was obtained by two focus group meetings with the nurses who carried out the COPD-GRIP intervention at least one time in all patients, which means three consultations in every patient. The first author (SW) wrote the protocol and selected topics for discussion concerning facilitators and barriers. She also observed the process and took notes during the focus groups. The moderator (MZ) introduced the groups, led the discussion and ensured that all predefined topics were discussed. A study nurse observed the discussion and took notes. The two focus group meetings took place in June 2014 at the University Medical Center Utrecht in the Netherlands and lasted one and a half hours each. The nurses who were not able to participate in the focus group meetings were asked by mail to fill in some open questions in the post-intervention questionnaire concerning facilitators and barriers of the COPD-GRIP intervention.

Ethical considerations

This study is nested in a cluster randomized trial assessed and approved by the Medical Ethics Review Committee (MERC) of the University Medical Center Utrecht (UMCU) with protocol ID 13-026/C. The questionnaires were analyzed anonymously and audio-recorded verbal consent was acquired at the beginning of each focus group.

Data analyses

Descriptive analyses of the quantitative data derived with the questionnaires were performed with the Statistical Package of the Social Sciences (SPSS version 20.0). Continues data were presented as means with the corresponding standard deviations. Categorical data were presented as numbers with the corresponding percentages who

agreed and strongly agreed with an item on the questionnaire.

To allow for systematic data–analyses the qualitative data from the focus group meetings were audio taped, transcribed verbatim and analyzed anonymously[35]. The transcripts were studied repeatedly and independently by two researchers (MZ and SW). Subsequently open coding analyses, performed independently by the same researchers, were used to discover important themes concerning facilitators and barriers of the COPD-GRIP intervention. The results from the open answers from the post-intervention questionnaire were incorporated in this analysis. Subsequently the themes that turned out to be important were further analyzed, described and discussed in consensus meetings by SW and MZ. The data were analyzed in a systematic and transparent way by using triangulation, segmenting and reassembling[36]. The quantitative and qualitative results were used in the interpretation of the results to increase validity.

Results

Results from the pre-intervention and post-intervention questionnaires

All the nurses from the 19 participating practices (N=24) filled in the pre-intervention questionnaire. During the study four nurses of two practices have withdrawn from the study without including any patient. Therefore, the post-intervention questionnaire was sent to 20 nurses of the remaining 17 participating practices. 15 nurses (75%) completed and returned the questionnaire.

All the nurses were women, the mean age was 45.5 years (standard deviation (SD) 9.8) and their mean work experience in COPD care was 9.1 years (SD 10.8).

Facilitators

Multiple facilitators were identified by the nurses. As can be seen in Table 1 the nurses indicated in the pre-intervention questionnaire that they had sufficient knowledge and training to provide the COPD-GRIP intervention. They also mentioned that the lay-out of the intervention enabled them to use it in their daily practice (95.9%). However, after working with the COPD-GRIP intervention a lower percentage of the nurses, but still 80% indicated that the lay-out is easy applicable.

Another facilitator that is described by the nurses is the good fit of the intervention into their work style (91.7% and 97.3%, respectively). Moreover, a high percentage of the nurses expected, and even a higher percentage experienced after working with the intervention, that the intervention improves patient satisfaction (70.9% and 93.4%, respectively), improves quality of life of the patient (70.9% and 93.4%, respectively), and changes the perception of the patient (67.7% and 73.4%, respectively).

Although 33.4% of the nurses estimated in the pre-intervention questionnaire that performing the intervention will take much time, after actually working with the intervention a lower percentage (20%) indicated that the intervention is time consuming.

Table 1. Experiences of the nurses: results from the pre-intervention and post-intervention questionnaire

Domains	Pre-intervention N=24 (%)	Post-intervention N=15 (%)
Knowledge. The COPD-GRIP intervention		
... Provides enough freedom to make my own decisions	22 (91.7)	15 (100)
...provides enough freedom to incorporate patients' wishes	24 (100)	15 (100)
...is a good start of my self-study	20 (83.3)	11 (73.3)
...s' lay out makes it feasible to work with	23 (95.9)	12 (80)
I did not read the intervention enough or I did not remember the intervention	2 (8.3)	0 (0)
I need to know more about the intervention before I decide to use it	1 (4.2)	4 (26.7)
I think that several parts of the intervention are wrong	0 (0)	0 (0)
I'm not trained to accomplish this intervention	0 (0)	0 (0)
I'm not involved in developing/spread out this intervention	2 (8.3)	1 (6.7)
Organisational		
Colleagues do not work with this intervention	4 (16.6)	1 (6.7)
The GP does not work with this intervention	4 (16.6)	4 (28.5)
Supervisor do not cooperate in this intervention	4 (16.6)	3 (20.3)
Performing the COPD -GRIP intervention is difficult, because		
…there is insufficient supporting personnel	1 (4.2)	1 (6.7)
...there is a lack of several instruments	1 (4.2)	0 (0)
…the time at which the intervention is performed is impractical	0 (0)	1 (6.7)
…the spaces are insufficient	2 (8.3)	1 (6.7)
Time		
Performing this intervention will take a lot of time	8 (33.4)	3 (20)
Patient characteristics		
Patients do not cooperate in performing this intervention	0 (0)	1 (6.7)
it is difficult to perform the COPD-GRIP intervention:		
…on patients with a different cultural background	16 (16.6)	9 (60)
…on patients who are mainly healthy	8 (33.3)	6 (40)
…on patients with a low social economic status	7 (29.2)	9 (60)
...on older patients	2 (8.3)	0 (0)
…on patients who visit the practice not regularly	9 (37.5)	6 (40)
… on male patients	1 (4.2)	1 (6.7)
…on patients with multimorbidity	5 (20.8)	6 (40)
… on patients who are willing to change	1 (4.2)	1 (6.7)
Nurse perspective		
The intervention does not fit with my work style or style in my practice	2 (8.3)	1 (6.7)
I have difficulties with changing my "old routines"	2 (8.3)	0 (0)
In general I experience resistance in working with guidelines	1 (4.2)	0 (0)
This intervention		
…requires a financial compensation	14 (58.3)	8 (53.4)
…improves patient satisfaction	17 (70.9)	14 (93.4)
…improves quality of life of the patient	17 (70.9)	14 (93.4)
…changes the perception of the patient	16 (67.7)	11 (73.4)

Barriers

Several barriers were identified. Some nurses described that they experienced more barriers after applying the intervention than they estimated in the pre-questionnaire. Before using the intervention 4.2% estimated they need to have more information before they decide to use the intervention. However, after working with the intervention, a higher percentage (26.7 %) indicated they want to know more about the intervention before they decide to use it. Other barriers were encountered in patients with a different cultural background, (16.6 % in the pre-questionnaire and 60% in the post questionnaire, respectively), in patients with a lower social economic status (29.2 and 60%, respectively), and in patients with multiple problems (20.8 and 40%, respectively).

Results from the focus group meetings

Prior to completing the post-intervention questionnaires all the 20 nurses were invited to participate in a focus group meeting to share their experiences of working with the COPD-GRIP intervention. From these 20 nurses 10 nurses were willing and able to participate in one of the two focus group meetings. The nurses who were not able to participate in the focus group (N=10) were asked to fill in four additional open questions concerning their experiences of facilitators and barriers of the COPD-GRIP intervention. From the 10 nurses, seven nurses filled in these open questions.

The mean age of the nurses who participated in the focus group was 47.4 (SD 10.01) and their mean working experience was 10 years (5.98).

Facilitators

As shown in Table 2 several facilitators of the COPD-GRIP intervention emerged from the data analyses of the focus groups. The intervention is experienced as a good structured method to start a dialogue with a COPD patient. It enables to provide patient- centered care and to address the patient needs. Moreover, the nurses experienced the intervention as the essence of nursing care. The B-IPQ questionnaire at the start of the intervention provides a focused way to ask the patient questions. The booklet in which the intervention is described was experienced as a clear handhold. The COPD-GRIP intervention appeared to be a valuable tool to provide individualized care, to discuss many topics in more detail, and to accomplish a situation of openness and sincerity, which was experienced as the starting point of nursing care. The nurses concluded that the COPD-GRIP intervention is an important added value in their work as a nurse because of the structured way of providing individualized care.

Barriers

Although the nurses were very positive, they experienced also some barriers (Table 2). Even though it was feasible to accommodate the frequency of three consultations for each individual patient within six weeks in the context of participating in the cluster randomized trial, the nurses explained that they questioned if they could arrange this in the context of their daily practice because of their busy workload and other work

obligations. However, under the condition that the general practitioner authorize them and that payment models will be developed, they highly recommend to enroll the COPD-GRIP- intervention in daily practice. Finally, the nurses experienced some barriers in applying the COPD-GRIP intervention in patients with a lower health literacy, especially in filling in the B-IPQ questionnaire and drawing up an individualized care plan. These barriers were solved by taking more time to fill in the questionnaire together and by taking more time to discuss possible actions within the care plan. The nurses experienced also barriers in patients with a lower social economic status. They observe more and more that low financial resources of the patients complicate their COPD management. Financial costs can be, for example an obstacle for a healthy lifestyle. The nurses mentioned that a growing number of patients could not afford to visit fitness clubs to enlarge their physical activities and a growing number of patients could not pay their medication because of the own contribution within their health assurance.

Table 2. Facilitators and barriers that emerged from the focus group analyses

Themes	Facilitators
Dialogue	A good and structured method to start a dialogue with the patient which enables the nurses to provide individualized, patient centered care which addresses the perceptions and needs of the patient. It is the essence of the nursing profession.
Start of the intervention	The Brief-Illness Perception Questionnaire provides a focused way to ask questions to the patient. The questions go beyond the topics the nurses normally discuss about complaints and giving the advice of quit smoking. Some patients interpret the questions in diverse or wrong ways. The questions elicited the patient to answer the questions and to think about the topics.
The booklet	The booklet is clear and structured and a good handhold in applying the intervention because it guides the nurse through the intervention, step by step with clear examples of the questions which they can ask the patient.
Added value	A useful, structured and individualized tool to get to know the patient and to learn what is important for a patient. It gives the tools to discuss many topics in more detail, enhancing patient knowledge, enhancing understanding and awareness. Intervention is helpful in asking accurate questions. By applying this intervention, the nurses are able to accomplish a situation of openness and sincerity, which is the starting point of nursing care. The nurse appreciated working in a structured way by asking questions, formulate goals and care plans based on shared decision making.
	Barriers
Time and financial models	Within the context of normal practice, it will be difficult to accommodate the frequency of three consultations for each patient within six weeks. Applying the COPD-GRIP intervention means that the first consultation-hour took 30 to 60 minutes which is longer than within regular care. Financial models need to be developed and the general practitioner should authorize the nurses to apply the intervention.
Specific patients	Applying the COPD-GRIP intervention is difficult in patients with a with a lower health literacy and in patients with lower social economic status.
	Recommendations
Digital system	The nurses would like to integrate the intervention in the digital general practitioner system in order to use it on a computer or a mobile device.
Education in future	Nurses would like to be more trained in applying the intervention in the future.

Table 3. Summary of the facilitators and barriers of the COPD-GRIP intervention

Facilitators	Barriers
Sufficient knowledge to provide intervention within the trial.	Lack of time and financial models to accommodate three consultations within six weeks within normal practice.
Took less time than expected.	In patients with a different cultural background.
Structured tool to provide individualized patient-centered care.	In patients with lower social economic status.
Good method to address perceptions and needs of the patient. Essence of nursing profession.	In patients with lower health literacy.
Booklet is clear handhold.	
Intervention is a tool to discuss many topics in more detail, enhancing patient knowledge, enhancing understanding and awareness.	

Recommendations

The nurses gave some recommendations for the future. Firstly, in order to make the COPD-GRIP intervention more feasible, the nurses recommended to integrate the COPD-GRIP intervention into the digital general practitioner system so they can use it on the computer or mobile device. Secondly, to apply the intervention in the future the nurses would like to receive more training and education.

Summary

A summary of the facilitators and barriers as described in the questionnaires and in the focus groups is provided in Table 3.

Discussion

In this study we evaluated the nurses' experiences with the new COPD-GRIP intervention. To our knowledge this is the first nursing intervention that translates the evidence concerning illness perceptions into a practical guide that nurses can use in clinical care. The study revealed that the COPD-GRIP intervention is experienced as a worthwhile tool that provides structured, individualized and patient centered care to guide the patient with the COPD. Several facilitating factors were identified. Firstly, according to almost all nurses in this study, the COPD-GRIP intervention is a good method to address perceptions and the needs of COPD patients. Secondly, applying the COPD-GRIP intervention took less time than they expected. Thirdly, the COPD-GRIP intervention as a valuable tool to discuss many topics in detail and to improve the care for COPD patients. Barriers were encountered, especially in patients with another

cultural background, in patients with a lower social economic status, and in patients with a lower health literacy. Furthermore, the nurses described that if the COPD-GRIP intervention will be implemented in the future, extra attention should be paid to the development of financial and authorization models.

The key strength of the present study is that we used a mixed-method procedure to obtain an in-depth exploration and understanding of the nurses' experiences with the intervention in order to identify facilitators and barriers in applying the COPD-GRIP intervention in clinical nursing practice.

Another strength is that this study was nested within a cluster-randomized trial. Although comprehensive process evaluations alongside randomized trials are increasingly carried out[34,37,38] it remains a relatively uncommon procedure in trials of complex interventions in general[24,27] and specific in studies concerning illness perceptions interventions in other chronic disease patients[30,39-41]. To prevent bias in interpreting the results the current evaluation study should be conducted before the results of the trial are known.

The findings of this study will provide nurses, other health care professionals and policy makers with vital information about how the new COPD-GRIP intervention can be implemented and used in daily practice.

Although the questionnaires and focus groups provided a great deal of rich data, the study has some limitations. One limitation is that we have not measured treatment fidelity. Although all nurses received the same educational session by the same researcher we could not provide information on how the nurses applied the intervention during their consultations. Secondly, we did not collect data concerning the experiences of the nurses with the educational sessions. Evaluating these sessions might have provided us with recommendations to develop the educational sessions in the future.

Some identified barriers of applying the COPD-GRIP intervention in this study are in line with barriers described in other studies. The identified barrier of financial- and authorization models in the future, is also described as a barrier in a study where primary care nurses applied a telephone-delivered health monitoring in COPD patients[23] and in a study focussing on nursing interventions for frail elderly people in primary care[34]. Other studies show that not only financial models are important to implement chronic care management in primary care, but organizational priorities could hinder a successful collaborative patient- practitioner relationship[42,43].

Other barriers in the current study are in line with the barriers reported in two studies in which a new intervention in primary care was evaluated[32,34]. Although these studies evaluated nursing interventions that focuses on frail elderly patients, we can compare the barriers at the level of the nurses, because the studies used the same questionnaire based on a structural list of barriers and facilitators[33]. Bleijenberg and colleagues[34] indicate that in line with our results, barriers were encountered in patients

with multimorbidity, in patients with different cultural backgrounds, in patients with a lower social economic status. In the study by van Eijken[32] as well as in the study by Bleijenberg[34] the same barriers concerning time and financial compensation were identified.

The finding that nurses in our study experienced barriers in patients with a different cultural background, in patients with a lower social economic status and in patients with a low health literacy is not surprising. Chronic illness case management in these patient groups require high level competencies[44,45]. Although the basic assumption of the COPD-GRIP intervention is to explore the perceptions and needs of the patient, the intervention does not describe in detail how to use the intervention in these specific patients. Even though the Common Sense model and self- regulation theory[29] takes the social context into account, this approach to health and illness is predominantly a Western world approach[46]. The cultural setting defines explicit features of illness perceptions[46]. To explore these features the COPD-GRIP intervention might be helpful. However, to apply this intervention in patients with another cultural background and to detect cultural variations, adjustments should be made by adding a cultural assessment as described by Clark[47] and Bauman[46]. This means that in order to understand cultural variations in illness perceptions, it should be emphasized that the context, the underlying premises (such as causes of a disease) of behavior and the meaning of specific behaviors should be explored in more detail[46,47].

In patients with a lower social economic status and a lower health literacy it is likewise important to understand the context and needs of an individual patient by asking which problems patients encounter in daily life before starting to assess the illness perceptions[44,48]. These patients could experience problems which dominate the health problems. Therefore, it remains very important to explore their situation and identify their problems in daily life. Hence, we need to adjust the COPD-GRIP intervention by describing simple supportive interventions as to ask "What concerns do you have in your daily life" or "Are there issues you like to discuss with me?", or to use a question prompt list. A recent study shows that low literate patients themselves feel less confident and perceive more obstacles in the communication in medical consultations as well[49]. Therefore, it is important to pay extra attention that patients feel confident within the consultations[45,49].

Implications for nursing practice

To enhance implementation of the COPD-GRIP intervention, we have defined three recommendations based on the results of this study. First, the nurse should be well educated and trained in applying the COPD-GRIP intervention. Second, models for financial compensation and authorization need to be developed. Third, adjustments in applying this intervention in specific patient groups need to be made.

Conclusion

The current study meets the emerging need for research regarding development and evaluation of nursing interventions in COPD care that addresses patient unmet needs and takes illness perceptions into account. Although adjustments in applying the intervention in specific patients' groups should be made and financial and authorization models should be developed, the outcomes in this study show that a nursing intervention which takes illness perceptions into account is a valuable improvement in providing individualized COPD care.

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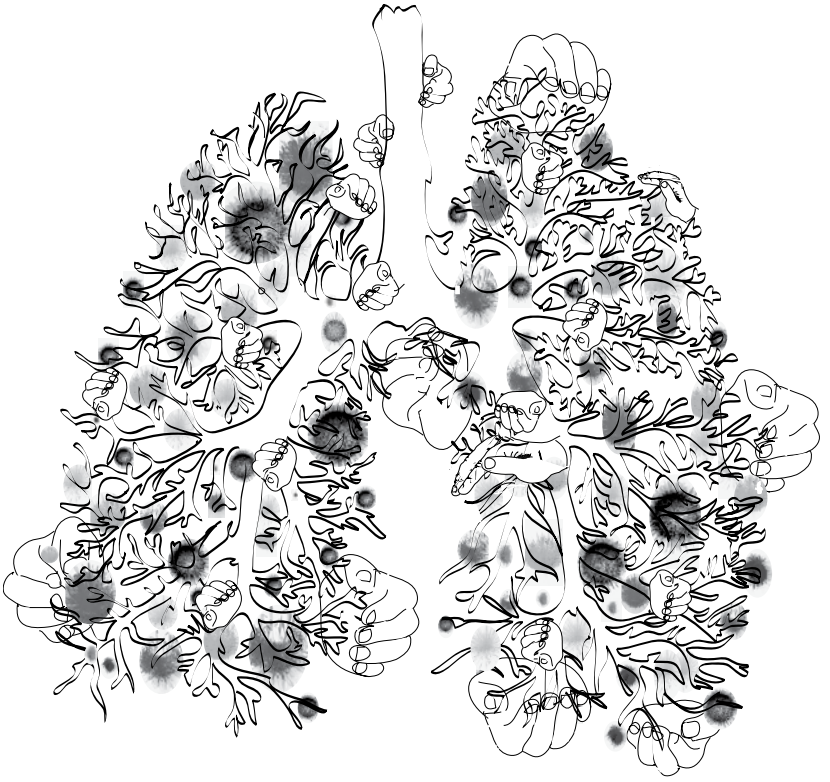

Chapter 6

Patient perspectives on the COPD-GRIP intervention, a new nursing care intervention for Chronic Obstructive Pulmonary Disease patients

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Submitted

Abstract

Objective: To explore patients' experiences regarding the COPD-GRIP intervention.
Background: Improving health-related quality of life (HRQoL) is one of the main goals of Chronic Obstructive Pulmonary Disease (COPD) care. The nurse-led COPD-Guidance Research on Illness Perception (COPD-GRIP) intervention was developed to incorporate illness perceptions into COPD care with the intention of improving the HRQoL of COPD patients. This individualized intervention, which identifies illness perceptions using the Brief Illness Perception Questionnaire, consists of three consultations with a practice nurse and results in a personal care plan.
Design: A qualitative interview study nested in a cluster randomized trial in primary care.
Methods: One-time semi-structured individual interviews with COPD patients who were guided with the COPD-GRIP intervention in 2015. During data collection, the constant comparative approach was used. To identify themes, audio-taped and transcribed interviews were independently coded by two researchers.
Results: Sixteen patients were interviewed. All patients were positive and experienced an additional value of the intervention in different areas. Three main themes were identified: being listened to and be acknowledged (1), gaining awareness (2) and making lifestyle changes (3). Some patients suggested that the individualized care plan could be improved and starting the intervention immediately after being informed of the COPD diagnosis. All patients recommended this intervention.
Conclusion: The results of this study indicate that the COPD-GRIP intervention is a promising tool for providing individualized COPD care.
Relevance to clinical practice: Our findings on patients' experiences illustrated that according to the patients, this nurse-led intervention is a useful tool to improve the guidance during the course of the disease.

Introduction

Practice nurses in primary care play a key role in supporting patients with chronic obstructive pulmonary disease (COPD) in the management of their disease throughout its entire course[1-3]. Improving health related quality of life (HRQoL) is one of the main goals of COPD care and treatment[1,4]. However, there aren't guidelines or interventions which nurses could use to guide COPD patients with the consequences of the disease and to improve HRQoL. Therefore, a new nurse-led intervention is developed[5]. In the development of a new intervention, qualitative approaches to evaluate the perspective of the target group contribute to the development and implementation of the intervention[6-8]. Therefore, the aim of this study was to explore patients' experiences regarding the COPD-Guidance Research on Illness Perception (COPD-GRIP) intervention and to inform the health care professionals about the value of the COPD-GRIP intervention from the perspectives of the target group.

Background: Previous research has shown that patient perceptions about COPD are associated with HRQoL[9-12]. Illness perceptions determine to a large extent how patients respond to their illnesses[13]. However, despite the importance of illness perceptions, they are rarely discussed during consultations[14-16]. To incorporate illness perceptions in clinical care for COPD patients, the nurse-led COPD-GRIP intervention has been developed[5]. This COPD-GRIP intervention translates theory and evidence concerning illness perceptions and HRQoL into a practical guide that nurses can use to provide proper individualized COPD care and to guide COPD patients throughout the entire course of their disease[5].

The COPD-GRIP intervention is applied by practice nurses trained in delivering the COPD-GRIP intervention in primary care. As can be seen in Figure 1, the intervention consists of three face-to-face consultations, each lasting approximately half an hour, at intervals of three weeks. During the first consultation, illness perceptions are identified with the Brief Illness Perception Questionnaire (B-IPQ)[17]. In the second consultation, a connection is made between the illness perceptions and the behavior of the patient. This results in a written individualized care plan consisting of a short-term goal and a long-term goal. Strategies to achieve the goals are identified by the practice nurse and the patient. During the last consultation, this individualized care plan is evaluated by the patient. An English version of the COPD-GRIP intervention can be found on our website www.umcutrecht.nl/griponderzoek.

The effectiveness of the COPD-GRIP intervention in terms of health status, quality of life and daily activities is currently being investigated in a cluster randomized trial in primary care settings in the Netherlands (Netherlands Trial Registry NTR3945). In addition to a quantitative evaluation, this qualitative study was performed. This additional study makes a substantial contribution to the current understanding of the COPD-GRIP intervention.

Figure 1. COPD-GRIP intervention

Three face-to-face consultations, each lasting approximately half an hour, at intervals of three weeks.	
First consultation	Understanding patient's illness perceptions. Assessing and discussing illness perceptions with the Brief Illness Perception Questionnaire (B-IPQ).
Second consultation	Identifying the link between illness perceptions and behavior. Improving patient's understanding of the relationship between their perceptions and their behavior, by challenging them to draw up an individualized care plan.
Third consultation	Evaluation and discussion of the individualized care plan. Evaluating and assessing whether the care plan was successful and what new actions are necessary for the future.

Methods

A qualitative study nested within the COPD-GRIP trial was performed. Data were collected using semi-structured interviews.

Participants

Potential participants were identified within the database of the COPD-GRIP trial. COPD patients were invited to participate in this qualitative study if they had received the COPD-GRIP intervention within the COPD-GRIP trial. The intervention arm of that trial included patients at 19 general practices throughout the Netherlands.

To be eligible to participate in the COPD-GRIP trial, patients had to be diagnosed with mild (gold 1), moderate (gold 2), severe (gold 3) or very severe COPD (gold 4) according to the GOLD guidelines[4]. The other inclusion criteria were as follows: age of 40 years or above, lung function test performed no more than one year prior to enrollment, ability to understand and read the Dutch language, and physical and mental ability to complete the questionnaires. Patients were excluded if they had a life-threatening co-morbid condition or if they had a primary diagnosis of asthma.

A patient was eligible if their last consultation within the COPD-GRIP intervention was three to five months before the interview. This time period was chosen because it decreases the possibility of recall bias and it prevents bias in interpreting the results because the study was conducted before the results of the trial regarding the effectiveness of the COPD-GRIP intervention were known. To obtain a heterogeneous sample for the qualitative study and to ensure diversity, purposeful sampling was performed. Sampling was based on the selection criteria of age, gender, level of education, disease severity and employment. By using these criteria, maximum variation with widely different experiences was obtained. Sampling was continued until the point of saturation was reached, meaning that no new information that would improve the understanding of patients' experiences with the COPD-GRIP intervention could be obtained. The expectation was that saturation would be reached when 16 participants

were included[18-20]. The patients (N=24) who fulfilled the criteria were contacted by telephone by the first author (MZ). If the patient was interested in participation, a patient information form was sent to the patient. After two weeks, the first author (MZ) contacted the patient again, and if he/she was interested, an appointment for an interview was made. Written consent was obtained from the patient before starting the interview.

Data collection

Data were collected during semi-structured interviews lasting approximately 45 minutes between May 2014 and December 2014. The interviews were conducted at a time and location of the patient's choice and were audio-tape recorded.

All interviews were conducted by MZ, a researcher with experiences in performing interviews, and started with the same question: "What is your experience with the three consultations you have had within the context of the COPD-GRIP trial?" After the first question, a topic list based on expert knowledge and previous studies[2,21,22] was followed. The topic list consisted of questions about the frequency and duration of the consultations, the B-IPQ questionnaire, the individualized care plan, the period from diagnosis to the initiation of the COPD-GRIP intervention and the subjects discussed during the COPD-GRIP intervention. The topic list also consisted of questions to extrapolate the patients' experiences with the COPD-GRIP intervention.

Before the start of the interview, patients' demographics (age, gender, employment, gold stage and level of education) were collected.

Ethical considerations

The Medical Research Ethics Committee (MREC) of the University Medical Center Utrecht concluded that the Medical Research Involving Human Subjects Act (WMO) did not apply to either the COPD-GRIP trial or this qualitative evaluation. Therefore, no WMO approval by the MREC was needed. The MREC had ensured that the individuals involved in the study were adequately informed that their data were being used for research proposes. All participants provided written informed consent to participate in the study before starting the data collection.

Data analyses

All interviews were transcribed verbatim. The constant comparative approach of data collection and analysis were applied during the study process, which allowed emerging themes to be identified in an early stage of the study and then explored in later interviews[20].

The three phases of coding described by Strauss and Corbin (1998), open, axial and selective, were applied[23]. In the open coding process, the transcripts were read and coded independently by two authors (MZ and SW). Memos were used to document

initial thoughts and ideas that emerged during the coding process. The codes and analytical memos were compared and discussed in a meeting by the same two authors. During this process, concepts and themes were identified and named. The codes were then organized into categories based on thematic similarities[19,20]. Subsequently, axial coding was performed, which involved comparing the subthemes to determine common links and differences. Finally, selective coding was conducted by analyzing the relationship between the subthemes and subordinate themes and determining the main themes.

The qualitative software MAXQDA was used to manage the data[24]. In addition, an audit trail was performed to meet the requirements of dependability and confirmation.

Results

From the patients who were eligible for this qualitative study (n=24), 16 agreed to participate. The reasons for not taking part in the study (n=8) were as follows: no time to participate (n= 4), no interest (n=2), no problems with COPD (n=1), not wanting to say anything negative about the nurse who performed the intervention (n=1).

As presented in Table 1, the age of the patients was between 54 to 80 years, and half of the patients were female. Most of the participants had moderate COPD, four patients had severe COPD and one patient had very severe COPD. Four included patients had paid jobs. The interviews were conducted at the homes of the patients (14 times) or elsewhere (general practice or neighborhood center).

Generally, patients were pleased with the three consultations with the practice nurse within the COPD-GRIP intervention and they did experience an added value. Moreover, all patients stated that they would recommend the consultations to other COPD patients. One patient illustrated this as follows:

"People need guidance. They need to know they are able to slow it down" (patient 11).

Table 1. Patients demographics

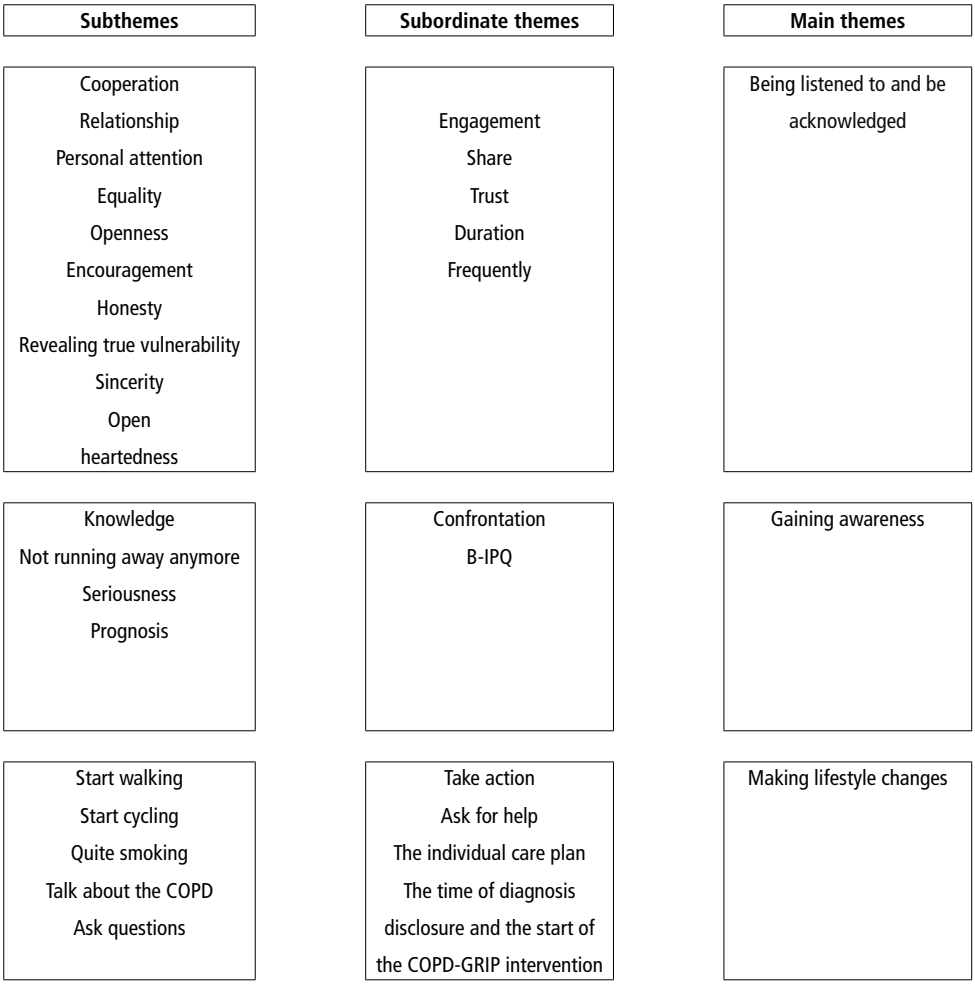
Patient	Gender	Age	GOLD-stage	Employment Yes/No	Education[33*]
1	M	80	2	No	Low
2	V	62	3	Yes	Medium
3	M	80	2	No	Medium
4	V	66	2	No	Medium
5	V	55	2	Yes	Medium
6	M	65	2	Yes	Medium
7	V	56	2	No	Medium
8	M	67	3	No	Medium
9	V	77	3	No	Medium
10	M	54	2	Yes	Medium
11	V	65	4	No	High
12	M	81	2	No	Medium
13	V	65	2	No	Medium
14	M	59	2	No	Medium
15	M	75	3	No	Medium
16	V	59	2	No	Medium

* Low: junior general secondary education for adults
Medium: vocational education, professional training diploma, senior general secondary education for adults, vocational education, middle management training diploma
High: Bachelor

Table 2. The discussed subjects during the consultations with the practice nurse within the COPD-GRIP intervention

Knowledge of COPD (n=14)	Activities (n=12)	Psychosocial items (n=8)	Remaining subjects (n=9)
What is COPD?	Intention of movement	Stress	Nutrition
Prognosis	Spread activities	Fear	Quite smoking
Medication	Kind of movement	Standing up for yourself	Teeth
Dyspnea	Home care		Incontinence
Inhalation Technique	Condition		Cooking
			Vacation
			Preparation for an operation

Figure 2. Subthemes, superordinate themes and main themes that emerged from open coding, axial coding and selective coding



Main Themes

Three main themes were identified based on the experiences and views of the interviewed patients: (1) being listened to and be acknowledged (2) gaining awareness and (3) making lifestyle changes (Figure 2).

Being listened to and be acknowledged

Within the consultations of the COPD-GRIP intervention, the patients experienced encouragement, trust, and openness and found that they could

talk on an equal level with the practice nurse. Moreover, patients expressed that the frequency of the consultations helped to build a confidential relationship based on trust, which allowed them to reveal their vulnerabilities. *"Because if you met someone once a year, as it regularly is, you need time to get used to each other. That was not the case now." (patient 5).* The finding that the patients were able to reveal their vulnerabilities was supported by their reports of feeling free to express their feelings, such as embarrassment, fear, sadness, and happiness, during the consultations. Despite differences in the durations of the consultations between patients, all patients felt comfortable asking questions when something was unclear and sharing their experiences concerning COPD, as presented in Table 2.

Most patients reported receiving personal attention during the consultations of the COPD-GRIP intervention. This personal attention was reported by the patients as follows: *"To be listened to"* (patient 11), *"To tell one's story"* (patient 8) and, *"To share and discuss your experiences and problems with someone else because you do have difficult times."* (patient 2). Another patient described the personal attention as pleasant (patient 9).

In general, the patients experienced personal engagement with the practice nurse, which they did not experience with other persons.

"If you do not succeed in giving up smoking, a friend might say: Try it again tomorrow", but with a nurse you have an agreement." (patient 10).

This personal engagement resulted in helpful cooperation of the patient with the practice nurse and adherence to the agreement they made. For example, giving up smoking, improving daily activities (walking and cycling), and expressing their feelings. Furthermore, patients experienced a feeling of no longer being alone in dealing with their COPD.

Gaining awareness

The COPD-GRIP intervention starts with identifying and assessing illness perceptions by completing the B-IPQ questionnaire. Twelve patients mentioned that the assessment was easy to use and thought that the assessment was comprehensive. However, other patients (n=3) found the questions difficult and experienced some difficulties with scoring their answers between zero and ten. Three patients wished some topics would be added to the B-IPQ, namely hobbies and how the weather and the patient's emotions influence their illness. Lastly, a few patients stated that completing the questionnaire allowed them to reflect on their illness. In addition, the patients mentioned that it provided them with a deeper understanding and awareness of their COPD. This awareness was mentioned in several areas, such as the seriousness of COPD, the patient's prognosis and the effect of lifestyle on COPD. The patients described that this awareness prevented them from avoiding their illness any longer. Awareness was seen as a result of increased knowledge about COPD, which was mentioned as the

major effect of the COPD-GRIP intervention. Eleven patients said that their knowledge about COPD and the medications and treatments for it improved with this intervention. However, the degree of the increase in knowledge varied between patients. One patient expressed the increase in knowledge as follows: *"I became wiser. I didn't even know the word COPD."* Another patient said that the consultations only refreshed their knowledge of the subject.

According to the patients, better awareness could also be obtained through confrontation with the seriousness of COPD, which was achieved by the nurse telling stories about COPD, by showing pictures of the lungs of COPD patients or by discussing statistics. In this regard, patients also mentioned the importance of nursing expertise in COPD. In other words, a practice nurse should be able to answer questions about COPD.

Making lifestyle changes

Seven patients wrote an individualized care plan in cooperation with the practice nurse. A minority of these patients were satisfied with the care plan. One patient who was satisfied said that the care plan felt like a contract and, thus, required respect. A patient who was not satisfied with the care plan made the suggestion of formulating a more specific goal and writing it in their agenda. Another patient said that the care plan was unnecessary. However, that patient said that the care plan could be useful for passive patients because it might help draw attention to the goals. A few patients could not remember the care plan and stated that it may be useful to have a copy of it. Three patients did receive a copy of the care plan and were positive about it.

The majority of patients (n=13) said that they made lifestyle changes after the consultations of the COPD-GRIP intervention. For example, several patients started to improve their physical condition. Some patients began cycling and others started to walk with their dog. Some patients made appointments with a physical therapist to try to improve their condition. Some patients quit smoking. Additionally, some patients started to talk with their friends about COPD and some asked the practice nurse and doctor questions. In general, the consultations of the COPD-GRIP intervention revealed opportunities to the patients for decreasing the burden of COPD (actions that could be taken); thus, they made positive lifestyle changes and asked for help if necessary.

According to the interviewed patients, the time between diagnosis and start of the COPD-GRIP intervention also influenced the execution of lifestyle changes. Nine patients said they would have preferred the consultation shortly after they were diagnosed with COPD. Those patients mentioned that after COPD diagnosis, initiation of treatment, which requires being advised about COPD, is important. One patient did undergo the first COPD-GRIP consultation immediately after diagnosis and that patient felt it was the correct time for that consultation. However, a few patients (n=4) stated that they would prefer to start the consultations when they experienced an increased burden of COPD because they did not want to confront the disease at an earlier stage.

Discussion

This study presents the experiences of COPD patients regarding the COPD-GRIP intervention with the aim of informing health care professionals about the value of the COPD-GRIP intervention from the patients' perspectives. Generally, the patients welcomed the consultations of the COPD-GRIP intervention and recommend them to other COPD patients. The experiences of the patients can be outlined in three main themes: the COPD-GRIP intervention made the patients feel 'being listened to and be acknowledged', the intervention improved their "awareness" of the disease and its management and helped them make lifestyle changes. In addition to these positive experiences, some patients suggested that the individualized care plan could be improved. Furthermore, they suggest starting the intervention directly after diagnosis, which is in line with the theory concerning the development of illness perceptions[13]. The theory is that illness perceptions are developed directly after the patient is confronted with the diagnosis of COPD[13]. Therefore, starting the COPD-GRIP intervention by identifying and discussing illness perceptions in an early stage of the disease seems appropriate. Nevertheless, not every patient wants to be confronted with the disease at an early stage; therefore, it is vital for long-term care to be individually tailored to the needs of every COPD patient.

The results of this study show that COPD patients experience the relationship with the practice nurses as important. Moreover, patients felt personal engagement with the nurses based on trust and sharing their experiences. This is in line with the literature concerning the role of the nurse in primary care[1,21,25,26], especially in COPD care and is supported by the recent findings of a study by Barello & Graffina[27] The results of this study suggest that the ability of patients to engage in the care process leads to adjustments in their quality of life.

As described by Smolowitz et al.[26] and Fletcher and Dahl[1], nurses play a significant role in the continuity of chronic disease management at all stages and are responsible for the quality of care. Previous research has shown that patients find it easier to talk to nurses than to doctors because, they perceive nurses to have more time available[28]. Within this context, nurses perform several roles, including chronic illness case management and health coaching. These roles require a professional attitude, meaning that nurses need to be good listeners and must have the ability to act upon observations[26].

Some strengths and limitations of this study should be considered when interpreting its findings. Enrollment for this qualitative study started a half year after the start of the trial. As a consequence, patients enrolled in the beginning of the trial could not participate in this qualitative study. However, starting this qualitative study later gave the nurses the opportunity to learn how to perform the COPD-GRIP intervention. The strength of this study is that it characterized the intervention through the experiences of the patients who received the COPD-GRIP intervention. In the last decade, different programs for patients other than COPD patients have been developed to translate

the theory about illness perceptions into clinical practice[29-31]. However, little attention has been paid to the experiences of the patient with the intervention. Some studies performed a qualitative evaluation of an intervention, but focused only on effects, not patient experiences[22,32]. As a result, those studies did not provide insight into the value of the intervention from the patients' perspectives. In the process of evaluating a complex intervention, such as the COPD-GRIP intervention, it is important to explore its effects and usefulness and the experiences of all persons involved in the intervention[6,7]. Therefore, the experiences of the patient were explored in this study. The experiences of the nurses who worked with the COPD-GRIP intervention have been described elsewhere[5]. Another strength of this study is that it was conducted before the results of the trial regarding the effectiveness of the COPD-GRIP intervention were known. This prevents bias in interpreting the results of this study of patient perceptions.

Practical implications

The findings of this study support the usefulness of the COPD-GRIP intervention. They indicate that the intervention should be used by a nurse in the primary care of COPD-patients and that the nurse should start the consultations of the COPD-GRIP intervention directly after the patient is diagnosed with COPD. Additionally, the results of this research show that the nurses in primary care need to invest in a professional relationship with the COPD patient to improve the quality of care.

Conclusion

In conclusion, the COPD-GRIP intervention is a promising tool for improving COPD nursing care. Although the adjustments of starting the intervention directly after diagnosis and applying the individualized care plan at that time should be made, this study shows that taking part in the COPD-GRIP intervention made the patients feel 'listened to and be acknowledged', improved their awareness of the disease and its management and helped them make lifestyle changes.

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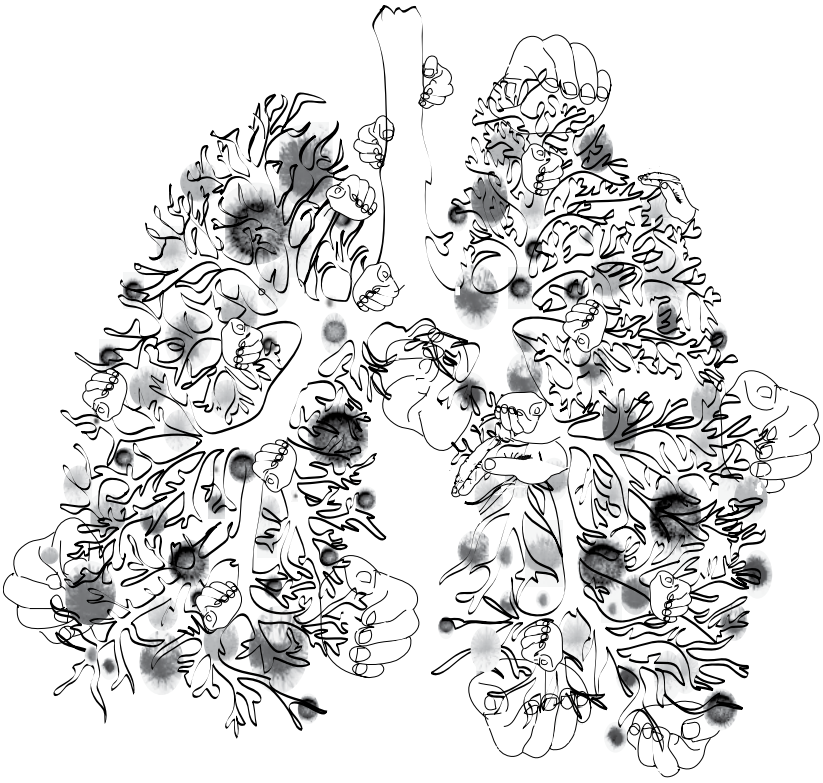

Chapter 7

The effectiveness of a nurse-led illness perception intervention in Chronic Obstructive Pulmonary Disease patients: a cluster randomized trial in primary care

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Submitted

Abstract

Background: The new nurse-led COPD-Guidance, Research on Illness Perception (COPD-GRIP) intervention translates evidence regarding illness perceptions and Health Related Quality of Life (HRQoL) into a care plan to guide COPD patients and to improve health outcomes.

Objective: This study aimed to assess the effectiveness of the intervention in primary care.

Methods: A cluster randomized controlled trial was conducted within 35 general practices including 204 COPD patients. 103 patients were randomly assigned to the intervention group and 101 patients to the usual care group. To assess differences, repeated multilevel linear mixed modelling analyses were used. Primary outcome was change in health status on the Clinical COPD Questionnaire (CCQ) at nine months. Secondary outcomes were HRQoL, daily activities, health education impact and changes in illness perceptions.

Results: There was no significant difference between the groups in the CCQ at nine months. We found a significant increase in health directed activities at six weeks and in personal control at nine months in favour of the intervention group.

Conclusion: The COPD-GRIP intervention, practiced by nurses, could not improve health status in COPD patients in primary care. The intervention does influence the ability to control the disease and health related behaviours in the short term. Taking illness perceptions into account when stimulating healthy behaviours in COPD patients should therefore be considered. Further study on influencing the health status and HRQoL is needed. **Trial registration** Netherlands Trial Register NTR 3945

Introduction

Chronic obstructive pulmonary disease (COPD) is a common chronic disease characterized by respiratory complaints like dyspnea and cough, pulmonary function abnormalities mainly due to non-reversible airway obstruction, and limitations in daily life[1]. It is estimated that approximately 328 million people worldwide have COPD[2], and their numbers are still increasing leading to high social and economic burden[2,3].

Three major challenges of COPD care are to reduce the impact of symptoms, to improve health status and Health Related Quality of Life (HRQoL) and to guide patients in their daily life with the consequences of the disease[4,5]. In the Netherlands as well as in other countries the care for COPD patients has increasingly moved from hospital to primary care settings[6,7]. In this context, practice nurses in primary care play an important role in the integrated care for COPD patients[6,8,9].

Evidence revealed that personal perceptions of COPD patients about their disease are associated with HRQoL[10-16]. These personal perceptions about illness are the central concept of Leventhal's Common Sense model (CSM) of self-regulation[17]. The CSM assumes that people have personal perceptions which determine to a large extent how they respond to their illness. These perceptions include beliefs about consequences, the duration of the disease, beliefs about the ability to control the disease and the extent to which the treatment helps in controlling the disease, comprehensibility of the disease, emotional responses and concerns[17]. Evidence highlights the importance of addressing patients' illness perceptions in order to influence illness related behaviour and HRQoL[13,15,18-20]. However, specific guidelines how to discuss illness perceptions with COPD patients in clinical practice are lacking. Given the central role of nurses in guiding COPD patients, we developed the nurse-led COPD-Guidance, Research on Illness Perception (COPD-GRIP) intervention[21]. This intervention translates the theory and evidence regarding illness perceptions and HRQoL into a practical care plan which nurses can use to provide individualized COPD care.

This cluster randomized trial aimed to assess whether the COPD-GRIP intervention in primary care is effective in improving health outcomes of COPD patients.

Methods

Study design and participants

A two arm, cluster randomized controlled trial with an intervention period of 6 weeks and follow-up period of 9 months, was performed to test whether the nurse-led COPD-GRIP intervention leads to more improved health outcomes in COPD patients in primary care compared to usual nursing care (Netherlands Trial Register NTR 3945). A cluster consisted of a general practice or a home care service.

General practices and home care services (n=40) were recruited throughout the Netherlands. A practice or home care service was eligible to participate in the study if

a practice nurse or respiratory nurse provided consulting-hours or home visits to guide COPD patients according to the standard COPD care as described in the Dutch COPD guidelines[22,23]. COPD patients were eligible if they were diagnosed by their general practitioner with mild to severe COPD, grades I to IV, according to the GOLD guidelines (Global initiative for chronic Obstructive Lung Disease)[4]. Other inclusion criteria were age of 40 years or above, a lung function test performed no more than one year prior to enrollment, both physically and mentally able to complete the questionnaires, and ability to understand and read the Dutch language. Patients were excluded if they had a life-threatening co-morbid condition or if they had a primary diagnosis of asthma.
The Medical Research Ethics Committee (MREC) of the University Medical Center Utrecht concluded that the Medical Research Involving Human Subjects Act (WMO) does not apply to this study; therefore, no WMO approval by the MREC was needed. All participants provided written informed consent to participate in the study.

Setting

Recruitment of general practices and home care services started in December 2012 and was finished in October 2014. The inclusion of patients started in May 2013 and was closed in December 2014. The follow-up period ended in November 2015.
The practice nurses affiliated in the participating practices and home care services identified eligible COPD patients. Written informed consent was obtained from all patients before entry in the study.
The COPD-GRIP intervention was applied by the practice nurses within the context of three extra consultations within approximately six weeks. After three consultations the intervention was completed. The nurses in the control group were asked to continue their usual nursing care, based on the Dutch general practices COPD guidelines[23], in line with the GOLD guidelines[4].

Intervention

The COPD-GRIP intervention was applied individually for each participant and consisted of three extra face-to-face consultations, each lasting approximately half an hour. These consultations were planned within an approximately three-week interval after inclusion in the study. The intervention has an equivalent structure for all patients. The specific content is individualized, based on the patients' questions, responses and the needs of the patient.
Within the first consultation illness perceptions were assessed and discussed with the Brief Illness Perception Questionnaire (B-IPQ)[24]. In the second consultation patient's understanding of the relationship between their perceptions and their behaviour was improved and challenged in writing an individualized care plan. In the last consultation the action the patients had taken to change their perceptions and behaviour were evaluated. The COPD-GRIP intervention is entirely described in a booklet. An English

version of the booklet can be found on our website www.umcutrecht.nl/griponderzoek. The nurses working in the intervention practices were trained in an educational session how to apply the COPD-GRIP intervention. The first consultation of the intervention started shortly after each patient was included.

Randomisation and masking

Randomization was performed on the level of the primary care practices/home care services before the inclusion of patients. A practice was randomized to the intervention group or control group using a computer generated randomization program with block randomization, developed by an independent data manager (N. Boekema) from the University Medical Center Utrecht.

Because of the nature of the intervention, participating nurses and patients could not be blinded to allocation.

Outcomes

All patient outcomes were collected by postal questionnaires at baseline, at six weeks, at three months, and nine months, respectively. To prevent missing data, patients received one reminder for the questionnaires by a telephone call if they did not return the questionnaire within three weeks.

The primary outcome was health status on the Clinical COPD Questionnaire (CCQ)[25] at nine months. Secondary outcomes were HRQoL as measured by the Chronic Respiratory Disease Questionnaire Self-Administered Short version (CRQ-SAS) covering four dimensions: dyspnoea, fatigue, emotional function, and mastery[26]. Other secondary outcomes were: daily activities, as measured by the Functional Performance Inventory Short Form (FPI Short form)[27], and illness perceptions, as measured by the Brief Illness Perception Questionnaire (B-IPQ)[24]. In addition, we measured impact of health education by the Health Education Impact Questionnaire (HeiQ)[28] and dyspnea was assessed with the MRC dyspnea score[29].

Statistical analysis

Sample size estimates were based on the mean difference in the total CCQ score (primary outcome) between intervention and control groups at nine months. Sample size estimates for trials that randomize at the level of the individual were first used. Subsequently to account for cluster randomization a single inflation factor to the usual sample size was used in the power calculation[30]. The inflation factor is a function of cluster size m and intraclass correlation ρ: $N^* = N(m) \times m = N\,[\,1 + (m-1)\,\rho]$. The usual sample size of N=100 per trial arm was based on the estimated effect size of .39 of the CCQ[31] with α =.05 and power =.80[32]. Using the usual sample size, an upper estimated value of the intra class correlation of ρ= 0.1[30], and the inflation factor, power calculations, indicated that we needed 38 clusters of practices with an average of 10 participants per

cluster, leading to a total of 380 participants with a power of .80 and α=0.5.
The primary effectiveness analysis was an intention to treat analysis of the difference in mean CCQ score between groups at nine months. Because of repeated measurements for all patients, we used multi-level repeated linear mixed modelling (LMM) analyses[33]. We assessed the differences between the intervention and usual care group, the effects of measurement time points, and whether group differences were dependent on measurement time points by defining a group by time interaction. If this group by time interaction is not significant, then the development of the outcome over time is not significant, meaning that there is no effect of the intervention. The primary explanatory parameters were the measured time points and the group allocation. These two parameters constitute the basic model. Other parameters (age, sex, MRC dyspnea, CRQ, FPI, B-IPQ, and Hei-Q) were added to the model in order to see if the model improved. This analysis process was first conducted with the primary outcome HRQoL (CCQ). Subsequently it was repeated with the secondary outcomes HRQoL (CRQ), daily activities (FPI), illness perceptions (B-IPQ), and health education impact (HEI-Q). The cluster was represented by a random intercept and a random slope model. The within patient covariance was set as variance components. All analyses were performed with the Statistical Package for the Social Sciences (IBM SPSS version 23.0 for Windows).

Results

A total of 40 practices and 202 patients were included in the study. Drop-out rates at nine months were almost similar in the two groups (17 % in the intervention group and 14 % in the usual care group, respectively) (Figure 1). Patients who dropped out at nine months had significantly worse scores on the CCQ, MRC, CRQ dyspnea, CRQ fatigue, FPI, B-IPQ (consequences, concern, and emotional response) questionnaires at baseline (P=<0.05).
The mean age was 68 in the intervention group and 65 in the usual care group. The mean FEV1 (% predicted) was also similar in both study groups (60.6 in the intervention group and 60.5 in the usual care group). Most of the patients had moderate COPD (n=61 in the intervention group and n=63 in the control group). There were no significant differences between the two groups at baseline, meaning that the two trial arms were well balanced on all variables at the patient level (Table 1 and 2).

Figure 1. Flow Chart

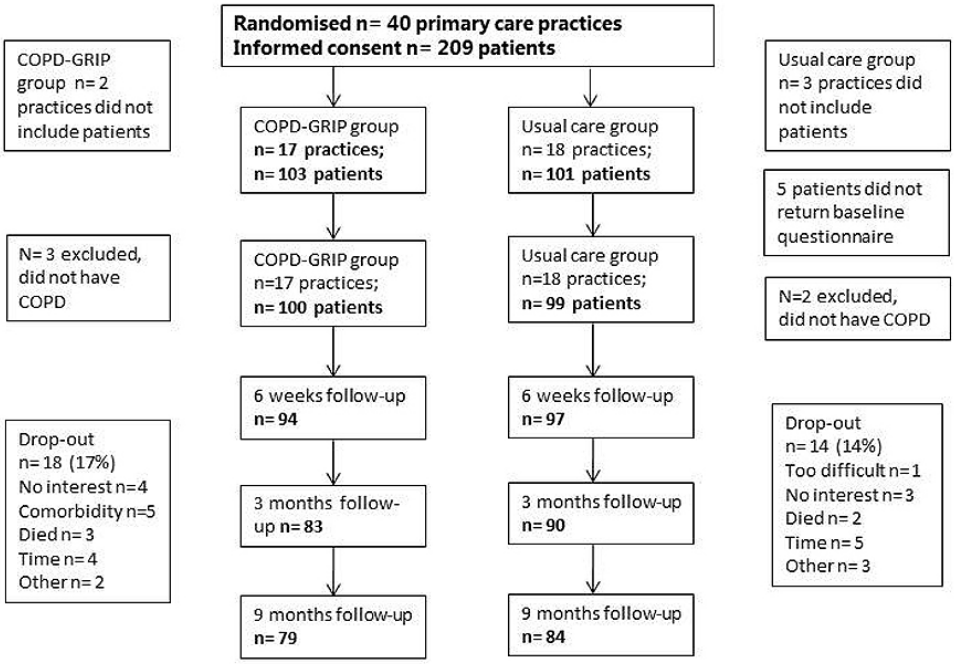


Table 1. Patient characteristics

	Intervention (n= 98; 17 clusters)	Usual care (n= 99; 18 clusters)
Age (years, mean (SD))	68.04 (9.64)	65.78 (9.61)
Male sex	45	45
FEV_1% of predicted (Mean (SD))	60.6 (17.6)	60.5 (20.1)
GOLD-stage		
I (mild)	9	9
II (moderate)	61	63
III (severe)	23	18
IV (very severe)	5	9
Education level	61	67
Lower secondary or less	71	65
Upper secondary	18	21
College /University	10	8
Current smoker	27	32
Living alone	44	39

Table 2. Baseline measurements

	Intervention Group Mean (SD)	Ususal Care Group Mean (SD)	Reference range
CCQ Total (SD)	1.9 (1.2)	1.6 (1.1)	0-6
Symptoms	2.2 (1.2)	2.0 (1.1)	
Functional state	2.0 (1.5)	1.7 (1.4)	
Mental state	1.0 (1.3)	0.9 (1.1)	
B-IPQ			
Consequences	5.5 (2.9)	4.9 (2.8)	0-10
Timeline	9.5 (1.6)	9.6 (1.7)	0-10
Personal control	5.5 (2.7)	6.4 (2.3)	0-10
Treatment control	7.0 (2.6)	7.0 (2.0)	0-10
Identity	5.4 (2.5)	4.9 (2.7)	0-10
Concern	5.0 (3.0)	5.4 (3.1)	0-10
Comprehensibility	7.6 (2.4)	7.1 (2.6)	0-10
Emotional response	3.9 (3.2)	3.6 (2.9)	0-10
MRC dyspnea	2.2 (1.3)	1.9 (1.4)	0-5
CRQ SAS (SD)			
Dyspnea	5.8 (1.4)	5.6 (1.5)	1-8
Fatigue	4.5 (1.4)	4.7 (1.4)	1-7
Emotional	5.0 (1.2)	5.2 (1.2)	1-7
Mastery	5.4 (1.2)	5.4 (1.3)	1-7
FPI total score (SD)	1.7 (0.7)	1.8 (0.6)	1-3
Hei-Q mean (SD)			
Health Directed Activity	2.9 (0.7)	3.1 (0.7)	1-4
Positive and active engagement in life	3.0 (0.6)	3.1 (0.5)	1-4
Emotional distress	3.1 (0.7)	3.1 (0.7)	1-4
Self-monitoring and insight	3.1 (0.4)	3.1 (0.4)	1-4
Constructive attitudes and approaches	3.2 (0.6)	3.3 (0.5)	1-4
Skill and technique acquisition	3.0 (0.4)	3.0 (0.5)	1-4
Social integration and support	3.0 (0.6)	3.0 (0.6)	1-4
Health Service navigation	3.2 (0.4)	3.2 (0.4)	1-4

CCQ= Clinical COPD Questionnaire, B-IPQ= Brief illness Perception Questionnaire,
MRC= Medical research Counse dyspnea scorel, CRQ-SAS= Chronic Obstructive Pulmonary Questionnaire Self-administered short form,
FPI= Functional Performance Inventory, Hei-Q= Health Education Impact Questionnaire. SD= standard deviation

CCQ: lower score means better HRQoL
B-IPQ: lower score on consequences, timeline, identity, concern, emotional response means more positive perceptions.
B-IPQ: higher score on personal control, treatment control, and comprehensibility means more positive perceptions.
MRC: lower score means less burden of dyspnea.
CRQ-SAS, FPI, and HEI-Q: Higher score means better HRQL, functional performance, and Health Education Impact, respectively.

Primary outcome

No statistically significant differences have been detected between both groups concerning the CCQ at week 6, and after 3 and 9 months, respectively (Table 3).

The group * time interaction with the outcome CCQ was also not significant (p=0.197), meaning that the COPD-GRIP intervention could not improve Health status over time (Figure 2).

Secondary outcomes and subgroup analyses

Also no statistically significant differences between both groups has been detected in the secondary outcomes HrQoL as measured by the CRQ (p= 0.162- 0.631) and daily activities as measured by the FPI (p=0.074; Table 3). We did find a statistical significant treatment effect on "Health Directed Activities "domain of the HEI-Q at 6 weeks (p=0.024) as shown in Table 3. This means that the COPD-GRIP intervention improved health behaviour shortly after the intervention, but this effect was not preserved over time (Figure 4).

Furthermore, there was a statistically significant treatment effect on the "Personal Control" domain of the B-IPQ (p= 0.005 at nine months), meaning that the COPD-GRIP intervention improved the perception of the ability to control the disease. However, at three months there was a decrease of the perception of control (Figure 3), meaning that this result is clinically difficult to interpret.

A posteriori defined subgroup analysis (MRC dyspnea score <2 or >2 and male/female) showed no significant effect of the intervention (Table 4).

The analysis using the minimal clinical important differences (MCID) of 0.4 for the CCQ[31] revealed that 15, 7% (n= 16) of the patients within the intervention group and 12.9 % (n= 13) of the patients within the control group had a MCID of 0.4 or more.

Table 3. Clinical Outcomes, corrected for clustering, time, treatment and MRC dyspnea score

Outcome	Mean (SD) T= 0	Mean (SD) T=6 weeks	Mean (SD) T= 3 months	Mean (SD) T= 9 months	P values Treatment*time interaction at 9 months
CCQ –total					
I	1.9 (1.2)	1.8 (1.1)	2.0 (1.3)	2.0 (1.2)	0.197
U	1.6 (1.1)	1.7 (1.1)	1.8 (1.1)	1.7 (1.1)	
CRQ fatigue					0.631
I	4.5 (1.4)	4.5 (1.5)	4.5 (1.5)	4.4 (1.4)	
U	4.7 (1.4)	4.8 (1.4)	4.7 (1.3)	4.7 (1.4)	
CRQ dyspnea					0.162
I	5.8 (1.4)	5.6 (1.6)	5.6 (1.5)	5.5 (1.6)	
U	5.6 (1.5)	5.6 (1.5)	5.6 (1.4)	5.7 (1.5)	
CRQ emotional					0.463
I	5.0 (1.2)	5.2 (1.3)	5.2 (1.3)	5.1 (1.3)	
U	5.2 (1.2)	5.3 (1.2)	5.2 (1.1)	5.3 (1.2)	
CRQ mastery					0.375
I	5.4 (1.0)	5.4 (1.1)	5.3 (1.3)	5.3 (1.2)	
U	5.4 (1.3)	5.4 (1.3)	5.4 (1.2)	5.5 (1.2)	
FPI					0.074
I	1.7 (0.7)	1.6 (0.7)	1.6 (0.7)	1.5 (0.7)	
U	1.8 (0.6)	1.8 (0.7)	1.7 (0.7)	1.8 (0.7)	
B-IPQ (Control)					0.005
I	5.5(2.7)	6.5 (2.1)	6.1 (2.5)	6.6 (2.2)	
U	6.4 (2.3)	6.5 (2.1)	6.9 (1.7)	6.2 (2.3)	
HEI-Q (HDA)					0.024 (6 weeks)
I	2.8 (0.7)	3.1 (0.7)	3.0 (0.5)	2.9 (0.8)	
U	3.1 (0.7)	3.1 (0.6)	3.1 (0.6)	3.1 (0.6)	

CCQ= Clinical COPD Questionnaire, B-IPQ= Brief illness Perception Questionnaire,
CRQ= Chronic Obstructive Pulmonary Questionnaire Self-administered short form,
FPI= Functional Performance Inventory. Hei-Q= Health Education Impact Questionnaire. HDA= Health directed activities/ behavior,
SD= Standard Deviation, CI= Confidence Interval, I= COPD-GRIP intervention group, U= Usual care group.

CCQ: lower score means better HRQoL
B-IPQ: lower score on consequences, identity, concern, emotional response means more positive perceptions.
B-IPQ: higher score on timeline, personal control, treatment control, and comprehensibility means more positive perceptions.
MRC: lower score means less burden of dyspnea.
CRQ-SAS, FPI, and HEI-Q: Higher score means better HRQL, functional performance, and Health Education Impact, respectively.

Table 4. Subgroup analyses: differences between Intervention group and usual care group in CCQ scores

Group	N	Mean (SD) T= 0	Mean (SD) T=6 weeks	Mean (SD) T= 3 months	Mean (SD) T= 9 months	P values Treatment*time interaction at 9 months
MRC score ≤2						0.595
I	64	1.3 (0.7)	1.3 (0.7)	1.3 (0.9)	1.5 (.8)	
U	68	1.2 (0.8)	1.2 (0.8)	1.3 (0.8)	1.3 (0.7)	
MRC score >2						0.165
I	20	3.0 (1.1)	3.0 (1.1)	3.2 (1.1)	3.2 (1.1)	
U	23	2.7 (0.9)	2.9 (1.0)	3.0 (0.9)	3.0 (1.0)	
Male						0.811
I	33	1.8 (1.3)	1.4 (0.9)	1.8 (1.3)	1.7 (1.0)	
U	41	1.7 (1.0)	1.9 (1.1)	1.8 (1.1)	1.8 (1.3)	
Female						0.126
I	51	2.2 (1.3)	2.1 (1.2)	2.3 (1.4)	2.2 (1.3)	
U	53	1.6 (1.1)	1.6 (1.2)	1.8 (1.1)	1.6 (1.0)	

MRC= Medical research Counsel dyspnea score
SD= standard deviation
I= COPD-GRIP intervention group, U= Usual care group

Figure 2. Mean Score CCQ over time

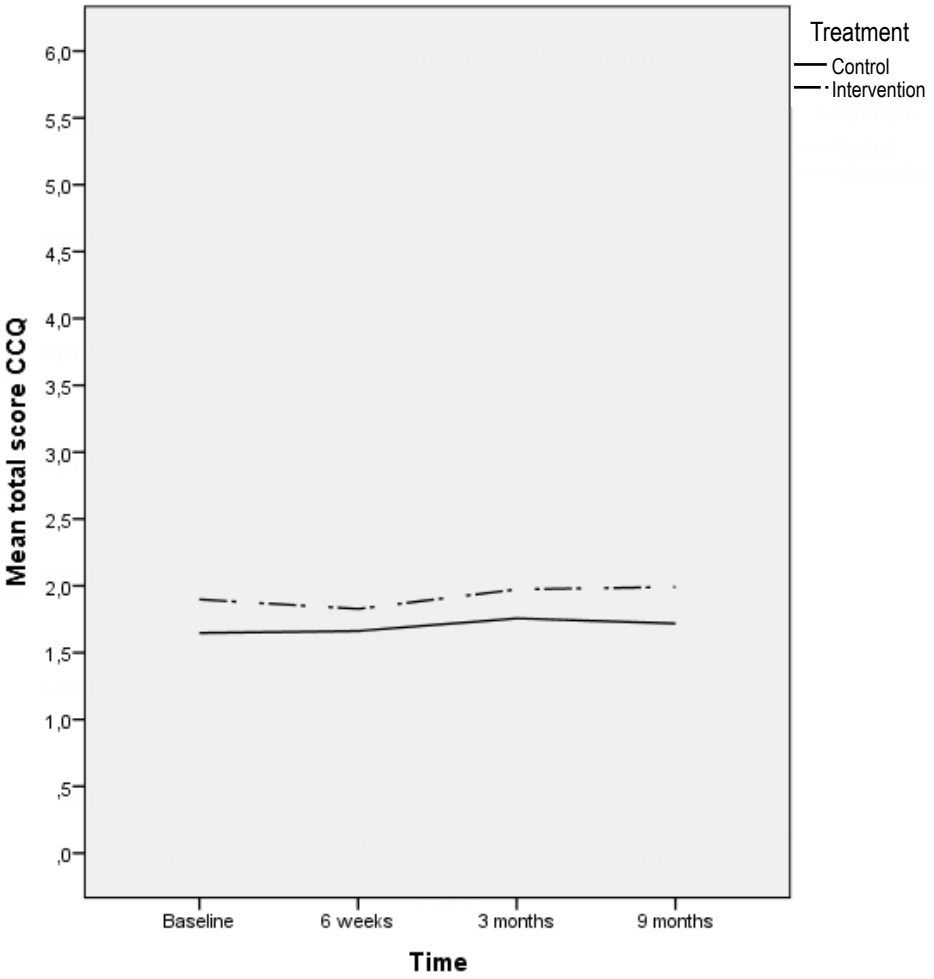


Figure 3. Mean Score B-IPQ personal control over time

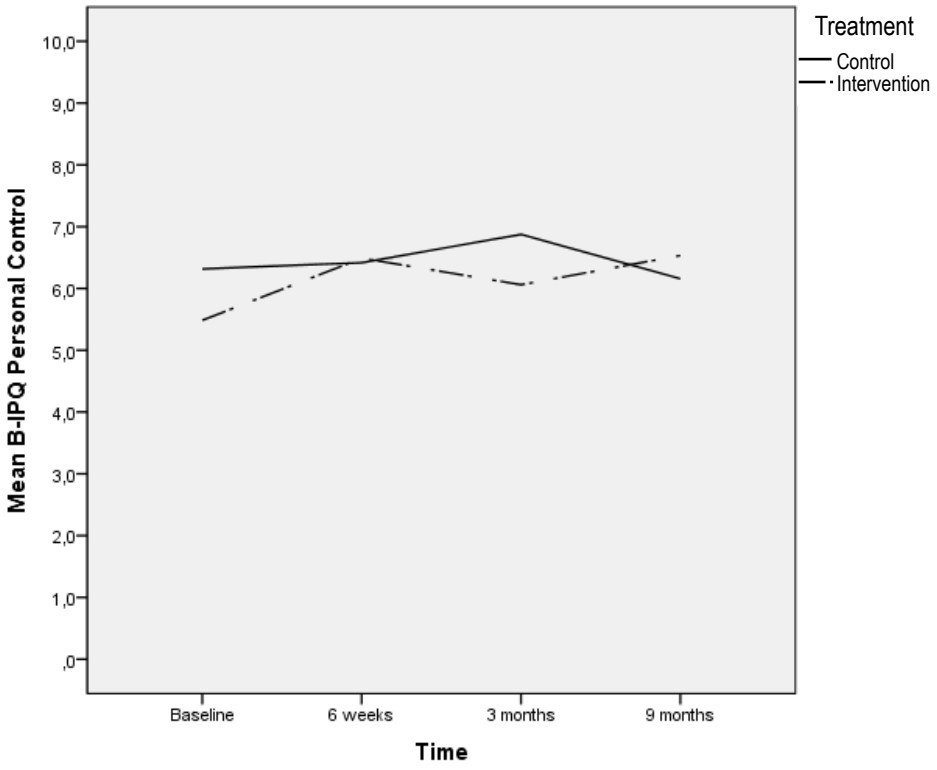
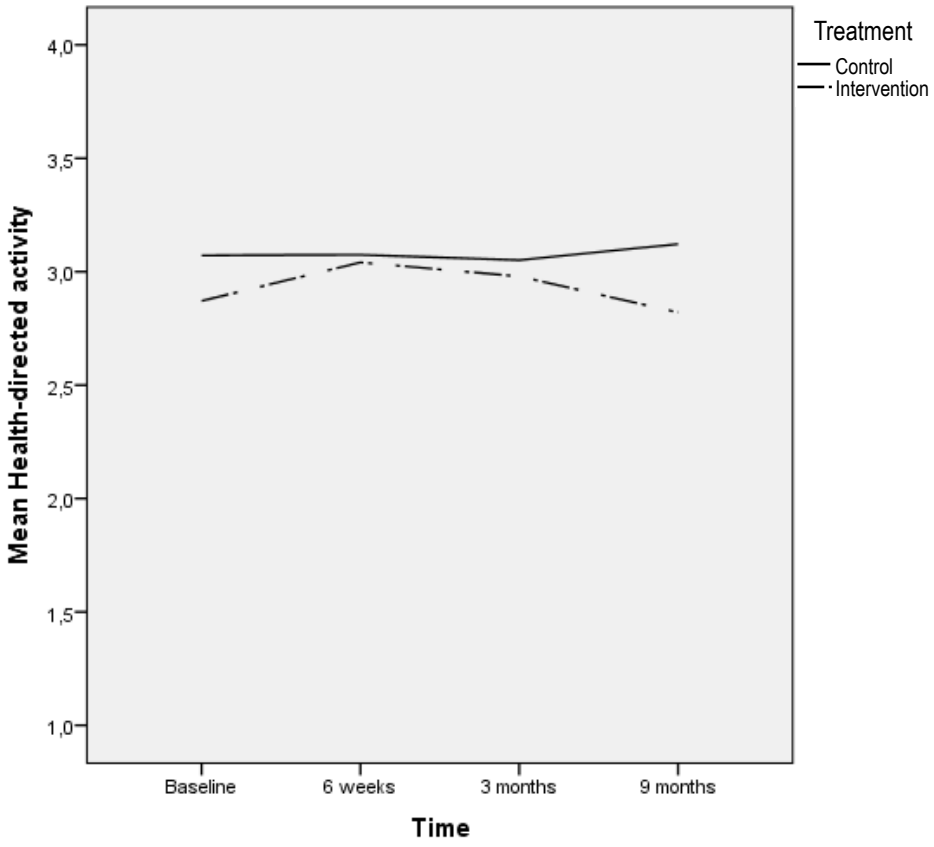


Figure 4. Mean score Health Directed Activities over time



Discussion

This cluster randomized trial revealed that the COPD-GRIP intervention which focuses on identifying, discussing and evaluating illness perceptions could not improve health status (as measured by the CCQ) and HRQoL (as measured by the CRQ) in COPD patients in primary care in the Netherlands. The intervention did demonstrate advantages on the perception of the ability to control the disease and on health-related behaviours in the short run. Nevertheless, these gains were not persisted on the long term.

While the intervention is based on the evidence regarding illness perceptions, health outcomes[11,13,15,16], and recent developments concerning patient-centered care[34,35], we could not show benefits on health status and HRQoL in COPD patients.

There are some considerations for not identifying these benefits. Firstly, it could be likely that the time-period of the intervention was too short. In order to achieve a more comprehensively guidance and results on the long term, some ongoing support and an extension of the follow-up period of the intervention could be needed. This is in line with the recent findings of a Cochrane review concerning personalized care planning, which shows that the effects appeared to be larger when the intervention was more comprehensive and better incorporated into regular practice[35]. Likewise, the results of a recent individual patient data meta-analysis concerning the characteristics of effective self-management interventions in COPD show that a longer duration of the intervention is associated with a reduction in hospital admissions[36]. Although the COPD-GRIP intervention was applied in real nursing practice, it is conceivable that incorporating the intervention in a more elaborated way, supported by a much more intensive training on the job for the nurses, could have resulted in more benefits on the long term.

Secondly, although the CCQ is a highly recommended outcome measure in COPD care and research[37] it could be discussed if the CCQ is the best possible outcome measure to capture the perceived benefits of the COPD-GRIP intervention that the individual patient may achieve. The CCQ measures health status within three domains: symptoms, functional state and mental state. Because the impact of COPD on daily life varies among individuals and symptoms may change over time caused by disease progression, it could be questioned if more multidimensional response measures, including domains such as adaptability, adjustment with disease, and resilience should be more appropriate. Of particular relevance to this discussion is the recent debate concerning multidimensional measures in COPD by Spruit et al[38] and Ambrosino et al[39] who bring up the urgent need to develop measures in COPD research that take into account the large heterogeneity of clinical manifestations and individual differences in COPD to do justice to individual responses to therapies.

The finding that the intervention improved health activities (as measured by the HEI-Q) in the short term means that patients changes some aspects of their health behaviours. These activities may include changes in diet, exercise and relaxation routines[28].
Furthermore, we did find an effect on the perceived ability to control the disease. However, this result is difficult to interpret clinically. The perception of disease control improved at six weeks, declined between 6 weeks and 3 months, in order to improve again at nine months.
These gains of the intervention are reflected in two qualitative studies that we performed during the trial, in order to identify the experiences of the patients and nurses with the COPD-GRIP intervention[40,41].
Patients within the intervention group expressed that they were more aware of the consequences of COPD and they were willing to enhance a more active lifestyle. Simultaneously, the nurses described the intervention as a very useful tool. It gave them the opportunity to give psychosocial care in a structured and patient-centered way. In the light of the findings of this trial and the positive experiences of the patients as well as the nurses regarding the intervention, it seems reasonable to rethink the process of the intervention by expanding the time-period of the intervention and an intensive training on the job for nurses.

Whereas in other patient groups, such as patients recovering from a heart attack[42] and poorly controlled type 2 diabetes patients[43] an illness perception intervention improved health-related outcomes, we could not draw comparable conclusions. Petrie[42] conducted the intervention within heart attack patients at a very early stage after a heart attack and prior to hospital discharge and Keogh[43] studied the intervention within poorly controlled diabetes patients. However, there are some important differences between our study and these studies. Firstly, the patient groups are not comparable. Whereas heart attack patients were confronted with a life threatening acute disease, COPD patients are being confronted with a mostly slow progressive disease. Secondly, the outcome measures are not comparable. Petrie[42] used recovery and return to work as an outcome measure where Keogh[43] used, glycated hemoglobin in addition to psychological well-being and beliefs. In addition, a large cluster randomized trial, recently performed in COPD patients in primary care in the Netherlands assessing the effectiveness of integrated disease management on HRQoL could also not show an improvement on the outcome (CCQ)[44]. More or less the same pattern of change in health status improvements in the first follow-up period but no preservation over time was revealed in a large medication study in COPD patients[45]. These studies show some similarities in the pattern of responses of COPD patients. Based on these results, the question arises what can be done to improve HRQoL in a complex disease such as COPD and to sustain health status improvements after initial treatment.

Strengths and limitations of this study

To the best of our knowledge, this is the first study assessing the effect of an individualized illness perception intervention in COPD patients in primary care. Strength of this study is embedding of a clinical trial in regular nursing practice and the inclusion of a wide range of patient outcome measures relevant for primary care nursing. Another strength is the operationalization of the crucial but rather neglected theoretical concept of illness perceptions within patient-centred care by identifying, discussing and evaluating illness perceptions. Additionally, we applied sophisticated multilevel and longitudinal analyses to assess the effectiveness of the intervention.

Unlike our expectations and our efforts, we did not succeed in including the amount of patients we calculated in the power calculation, which is a limitation of this study. Recruitment of patients was performed by the practice nurses by professional invitation. Despite the commitment by the GP's and the practice nurses, the heavy workload for practice nurses in primary care may have contributed to a suboptimal recruitment of patients. Subsequently it could be possible that we missed a real effect by including insufficient numbers. The drop-outs after nine months were low, however their scores at baseline were significantly worse. This could raise questions about the generalizability. However, incorporating baseline scores in the analyses did not result in treatment effects, indicating that it is unlikely that drop-out rates have biased the results. Furthermore, we have no information about the patients who did not take part in the trial, in other words: we cannot identify characteristics of the non-responders.

Another limitation is the lack of a detailed description of the treatment fidelity in this study. Although we used a standardized approach within the educational sessions and within the protocol of the intervention, there is no insight into the exact content and nature of the consultations.

Conclusion

The COPD-GRIP intervention, practiced by nurses, could not improve health status and HRQoL in COPD patients in primary care in the Netherlands. The intervention does influence the ability to control the disease and health directed activities in the short term. Taking illness perceptions into account when stimulating healthy behaviors in COPD patients should therefore be considered. Further study on influencing health status and HRQoL is needed.

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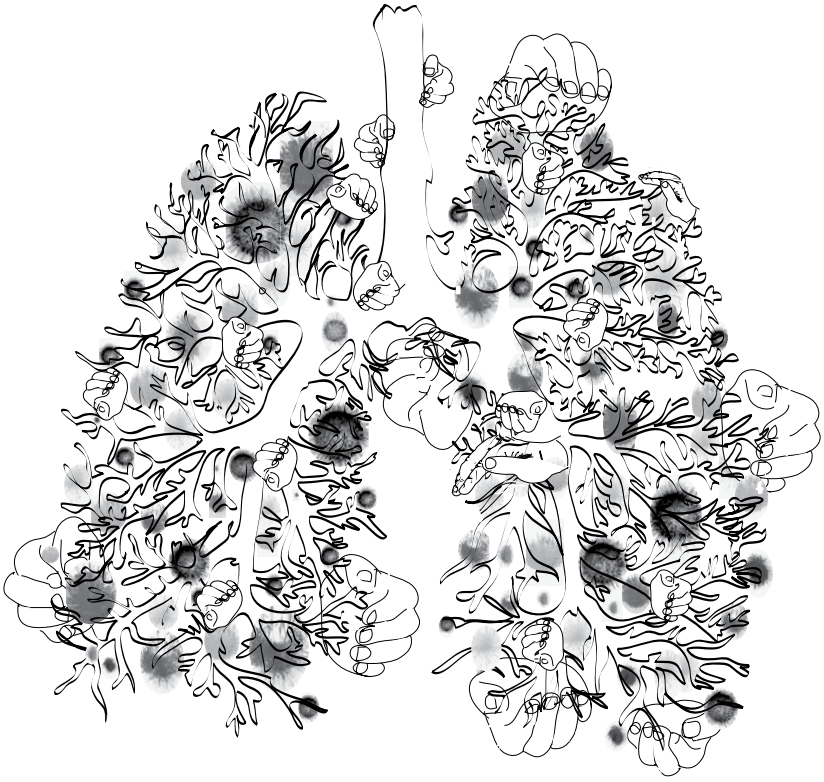

Chapter 8

Primary care nursing for COPD patients from a biopsychosocial perspective:

A call for change

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Submitted

Living with COPD

"One day you realize that having COPD has changed into "a way of life". You did not remember when it started, but you realize that you have avoided riding your bike for a while." (Woman, 62 years old, severe COPD)

"One part of having COPD is the medication aspect, but that's not all. One of the biggest problems is that you cannot do what you're used to do or what you want to do, you feel isolated and no one takes that into account." (Woman, 62 years old, mild COPD)

Caring for COPD patients

"My role as a nurse is guiding patients but after several years of caring for COPD patients I still feel empty handed. I have no tools that describe how I can care for COPD patients with depressive symptoms." (Practice nurse, 54 years old)

"It is hard to motivate COPD patients to come to consultation, and when they finally visit you there is, besides the spirometry and medication information, not much time left for guiding the patient." (Respiratory nurse, 48 years old)

Introduction

The impact of Chronic Obstructive Pulmonary Disease

Chronic Obstructive Pulmonary Disease (COPD) is a common chronic progressive disease characterized by respiratory complaints, such as dyspnea and cough and by pulmonary function abnormalities mainly caused by nonreversible airway obstruction. COPD is expected to increase to the fourth leading cause of death by 2030[1,2]. The course of COPD is unpredictable and characterized by periods of worsening of the patient's condition[2]. Pulmonary and extrapulmonary complaints influence not only the physical domain of quality of life, but also the emotional and social domains of quality of life[3-5]. Many patients are confronted with daily life limitations[3]. Some COPD patients are able to manage and cope with their condition. However, for many other patients, coping with the limitations caused by COPD is very demanding[5].

The clinical diagnosis of COPD is based upon the degree of airflow limitation (i.e., the decrease in the forced expiratory volume in one second (FEV_1)). Although the FEV_1 has been assumed to be an important marker of disease severity, the severity of airflow limitation does not track the path of experienced Health Related Quality of Life (HRQoL) in COPD patients at an individual patient level[6,7]. To explain these individual differences in HRQoL and daily activities in chronic patients, psychosocial models, in addition to biomedical perspectives are emerging[8-10]. These models take into account psychological- and social factors, as well as biological aspects, when explaining individual differences in adjustment to chronic disease[9,10].

Health care for patients with COPD

Because COPD cannot be cured, COPD care and treatment need to focus on the short-term and long- term impacts of the disease on each COPD patient. They consist of relieving and reducing the impact of symptoms, improving participation in daily life, improving HRQoL, and reducing adverse events in the future (i.e., exacerbations or so called "lung attacks")[11].

The care for COPD patients has increasingly moved from hospital to primary care settings in the Netherlands and in other European countries, the United States, Canada and Australia[12-15]. In this context, general practitioners, practice nurses and respiratory nurses in primary care can make a crucial contribution to the integrated, patient-centered care for COPD patients[13-15]. In particular, the nursing role is becoming increasingly important. Nursing care is characterized by continuity of care[16]. Specifically, nurses are involved at all stages of care, from prevention to end-of-life care[15,16]. Several tasks characterize nursing care, for example: education about the disease, giving advice concerning nutrition, medication instruction, smoking cessation advice, healthy life style promotion, and breathing techniques[16-18]. In addition to these primarily educational tasks, there are other challenges in COPD nursing care, like guiding patients in addressing the consequences of their disease in daily life, reducing the impact of symptoms and improving HRQoL[2,19,20].

Nurses have considerably expanded their practice in recent years, and efforts have been made to develop care that is coordinated or delivered by nurses[14,16,21-23]. Despite the efforts and positive results, the effectiveness of nursing care on health outcomes remains inconclusive [16,24,25]. Moreover, nurses often experience a lack of knowledge and skills to address the needs of this specific group of patients, as described in their quotes cited above.

To address the major challenges of COPD care and to explore how nurses in primary care can contribute to reduce the impact of COPD in terms of improving HRQoL and daily activities, we conducted a series of studies in COPD patients in primary care. A biopsychosocial perspective served as the framework for our studies. In these studies, we looked at outcomes and points of action that can guide nursing interventions. Based on these insights we developed and tested a comprehensive nursing intervention. The present paper will first address the data sources and current evidence provided by our studies. Subsequently, a critical reflection may provide valuable insights for nurses and other clinicians, researchers and policymakers in this field, resulting in a description of the implications and the next steps in COPD care and research.

Current evidence

Data sources

First, starting from desired outcomes we systematically reviewed the literature concerning the content and psychometric properties of available instruments used to

measure HRQoL in COPD patients[26]. In addition, we validated a specific questionnaire that measures daily activities in COPD patients. Subsequently, looking for points of action, in a cross sectional study, we explored the extent to which the combination of several psychological factors and physical factors contribute to daily activities and HRQoL in COPD patients in primary care. As an extension of this study, we analyzed the specific role of illness perceptions in relation to HRQoL. Based on these analyses, we developed a comprehensive nursing intervention that takes into account psychosocial aspects, especially illness perceptions. We conducted a cluster randomized trial to determine if this intervention, implemented by nurses in primary care settings, leads to improved HRQoL and daily activities in COPD patients compared to usual nursing care. Finally, the experiences of the patients and the experiences of the nurses regarding this intervention were evaluated in a qualitative interview study and a mixed –method study nested within the cluster randomized trial.

Outcomes in COPD care and research

Measuring Health Related Quality of Life (HRQoL) in COPD

HRQoL is usually defined as an individual's perception of the complex effects of health and psychosocial issues on their position in life[27,28], but there is a lack of consensus on the definition[29]. The absence of an agreed-upon definition is reflected in the large number of available instruments to measure HRQoL in COPD[26]. To guide researchers and clinicians in choosing the best instrument to evaluate HRQoL in COPD patients, we systematically reviewed the literature concerning the content and psychometric properties of available instruments used to measure HRQoL in COPD[26]. Our review showed that various domains, such as mobility, fatigue, emotional and social functioning are measured in generic as well as in disease specific instruments. The added value of COPD specific instruments is the inclusion of the COPD specific symptoms domains. Our review showed strong evidence, especially for disease specific instruments: Chronic Respiratory Questionnaire (CRQ), COPD Assessment Test (CAT), St George Respiratory Questionnaire (SGRQ), and the Living with COPD questionnaire (LCOPD) [26]. However, an optimal instrument was not identified. Therefore, the decision to choose one instrument over another should be guided by the results to be obtained in a study or in clinical practice in relation to the domains included in the instrument and the psychometric properties[26].

Measuring daily activities with the Dutch Functional Performance Inventory in COPD patients

COPD patients are confronted with substantial limitations in ability to perform daily activities[2,3,30]. Inactivity is associated with many consequences, such as poor general health[31,32]. Poor general health prevents COPD patients from performing their favorite daily activities[33,34]. Improving and easing the performance of these activities is an

important goal in COPD care. These activities do not only include self-care behaviors such as dressing, bathing and cooking, but also activities that are performed for personal satisfaction and recreational activities[35,36]. Within the context of care and research in COPD patients it is essential not only to measure physical capacity and ability, but also to measure self-reported activities in daily life. The Functional Performance Inventory (FPI) is an instrument that is based on a theoretical framework and especially developed for COPD patients[37]. It measures a broad spectrum of self-reported activities; not only physical activities, but also social, recreational, occupational and spiritual activities that individuals perform in their daily life[37,35]. Moreover, the instrument takes into account what activities are considered important for an individual[37,35]. This instrument therefore seems to be valid as a nursing outcome measure. We translated the English version of the FPI into Dutch and validated the translated questionnaire in 150 Dutch COPD patients[38]. Our results show that the translated version of the FPI was reliable and reproducible[38]. While the validity scores were lower than those in other studies, they were nevertheless acceptable, meaning that the FPI can be used as a valid outcome measure[38]. However, further evaluation of its psychometric properties is recommended[38].

Exploring points of action

Psychological aspects in COPD patients

To explain individual differences in HRQoL and daily activities in chronic patients, psychosocial models in addition to biomedical models are increasingly used[8-10]. These models assume that besides biological aspects psychological and social factors play an important role in adjustment to chronic disease[9,10]. Especially, illness perceptions, depressive symptoms and proactive coping influence outcomes in COPD patients [39]. In exploring the points of action that can guide nursing interventions in COPD care, we studied in 90 COPD patients in primary care the extent to which the combination of these psychological aspects are associated with daily activities and HRQoL[39]. Besides psychological aspects, dyspnea and airflow limitation were measured. Our study revealed that illness perceptions, depressive symptoms and dyspnea are related to HRQoL. Moreover, our study confirmed that more objective measures, such as airflow limitation did not contribute to the individual differences in HRQoL. In contrast to our expectations, we could not confirm an association between psychological factors and daily activities, as measured by the FPI in COPD patients in primary care[39,40]. This could be explained by the relatively small study population with mild COPD.

Additionally, we analyzed the specific role off illness perceptions in relation to HRQoL[40]. Illness perceptions are individual perceptions and beliefs about illness, described within the Common Sense Model by Leventhal[8], a theoretical model used in medical psychology. The essence of this model is the assumption that more positive perceptions in combination with clinical characteristics are related to better health outcomes[8]. Our analyses revealed that specific dimensions of illness perceptions contribute to HRQoL.

In particular, patients who perceived fewer symptoms attributed to COPD, who had a better understanding of COPD, who experienced more treatment control and had less of an emotional response to COPD had a better HRQoL[40]. Our studies therefore indicate that addressing psychosocial aspects, and more specifically illness perceptions, should be an essential part of nursing interventions.

A comprehensive nursing intervention

Based on the findings regarding outcomes and points of action, we developed a comprehensive nursing intervention that takes into account psychosocial aspects, in particular illness perceptions. This resulted in the COPD Guidance, research on an Illness Perception (COPD-GRIP) intervention as described elsewhere[41]. This intervention translates the theory and evidence regarding illness perceptions and HRQoL into a practical guide that nurses can use to provide individual patient-centered care. The intervention focuses on identifying, discussing and evaluating illness perceptions. It consists of three face-to face consultations with the practice nurse. Within the first consultation, illness perceptions are assessed and discussed with the guidance of by the Brief Illness Perception Questionnaire (B-IPQ)[42]. During the second consultation, the link between the personal illness perception and behavior is discussed by improving the patient's understanding of the relationship between their perceptions and their behavior. Subsequently, the patient is challenged to develop an individual care plan based on their own needs and preferences. Finally, in the last consultation, the success of the care plan is evaluated and new action points necessary for the future are identified.

Evaluation of the nursing intervention from the perspective of the nurse

In order to enable successful implementation of comprehensive interventions in clinical practice, it is important to perform a transparent and detailed evaluation from the providers' perspective[43,44]. Twenty-four nurses throughout the Netherlands implemented the newly developed intervention[41]. All nurses were trained prior to application of the intervention. In an educational session all stages of the intervention were explained and discussed step by step[41]. In order to provide a thorough understanding of how these nurses experienced the COPD-GRIP intervention, we performed a mixed-method study (questionnaires and focus group meetings). Barriers and facilitators in applying the intervention were identified. The study revealed that nurses appreciated the intervention very much. The intervention, proved to be a feasible tool for providing tailored, patient-centered care and they would like to incorporate the intervention in daily care[41]. The nurses defined the intervention as the heart of the nursing care[41]. Applying the COPD-GRIP intervention means that nurses do not only focus on tasks and documentation, but it allows them to give attention to relational and personal aspects[41]. Many nurses in our study experienced that the intervention improved the HRQoL and patient satisfaction with care to a greater degree than they initially expected[41].

Furthermore, the intervention took less time than initially expected[41]. Nevertheless, the nurses experienced barriers in proving care to patients with lower social economic status, lower health literacy and in patients from other cultural backgrounds, indicating that adjustments for implementing the intervention in these specific groups must be developed[41]. Additionally, the nurses recommended that to implement the intervention in their busy practice, authorisation by the general practitioner is needed. Furthermore, it was recommended to develop remuneration models and organization models.

Evaluation of the nursing intervention from the perspective of the patient

To enhance development and implementation of the intervention, the experiences of the patients with the intervention were also explored. In a qualitative study 16 COPD patients were interviewed[45]. The results show that patients appreciated the consultations of the COPD-GRIP intervention. The intervention made them feel "listened to and acknowledged", it improved their "awareness" of the disease and it assisted them in the process of "making lifestyle changes" [45]. A small number of patients (n=4) advised to start with the intervention at the moment that the symptoms of COPD started to increase, because they did not want to be confronted with COPD at an early stage. Nevertheless, most of the patients (n=9) recommended the opposite. They advised to start the intervention directly after the diagnosis of COPD, because that way, the awareness of the disease could be built up from the beginning.

Effectiveness of the intervention

In a cluster randomized trial in primary care we studied if the intervention, implemented by nurses leads to improved HRQoL and more daily activities in COPD patients compared to usual nursing care. The results show that the COPD-GRIP intervention influenced the patient's ability to control the disease and health- related behaviors in the short term[46]. In other words, the patients in the intervention group experienced an improvement in their ability to control COPD. Also their health behavior improved shortly after the intervention, but this effect was not preserved over time.

The intervention did not demonstrate advantages with respect to improving health status (as measured by the Clinical COPD Questionnaire), HRQoL (as measured by the Chronic Respiratory Disease Questionnaire) and daily activities (as measured by the Functional Performance Inventory)[46].

Critical reflection on outcomes

In response to our study results, the following question arose: "What are the desired outcomes of COPD care and research?" Although the enormous number of instruments available for the measurement of HRQoL covers many domains ranging from symptoms such as dyspnea and cough to physical (mobility and fatigue), social and emotional domains[26], it could be questioned if the existing instruments are able to capture the

individual experiences and desired outcomes of COPD patients.
Although the current measures are "patient reported outcome measures" (PROMS), they are standardized, not individualized, instruments. The effectiveness of tailored interventions is still measured with standardized methods. Because COPD patients are confronted with individual disease courses and many individual challenges, it is more suitable to use other outcome measures. To reflect individual differences, it is of the greatest importance to take into account adaptability and adjustment to disease. Recently, development of multidimensional outcome measures has been identified an urgent need in COPD care[47,48]. Although these recommendations were described within a pulmonary rehabilitation setting, our studies show that individual differences need to be addressed in primary care settings as well.
Another current dilemma is choosing the most suitable outcome measure with respect to the instrument length and the time required for the completion of the available questionnaires. Most of the available questionnaires are long and are therefore not suitable for use as an outcome measure in daily care or even in research settings. Additionally, these questionnaires are standardized and not tailored to patient needs. A possible solution could be the use of a digital questionnaire that is tailored to an individual, such as Computerized Adaptive Testing (CAT)[49]. This modern method of using and developing questionnaires allows more flexibility because the selection of questions using CAT method depends on a patient's response to previous items[49,50]. Recently, promising advances have been made by Paap et al [50,51]. They are developing a CAT for assessing HRQoL in COPD, including physical activities, by identifying important domains of HRQoL from the patient's perspective[51]. Asking patients about their desired outcomes is extremely important in defining outcomes of COPD care and research.

Critical reflection on points of action

Starting from a biopsychosocial perspective in our studies, we addressed psychological aspects as point of action that can guide nursing interventions specifically illness perceptions and depressive symptoms. However, there are studies focusing on complementary aspects of the biopsychosocial perspective, such as family support[22,52,53], social support[54], and self-efficacy[55]. Given the results of these studies, these aspects should serve as additional points of action to guide nursing interventions in COPD care. Future studies should integrate the full spectrum of the biopsychosocial perspective to further strengthen the changes for success. As described by David Richards, chair of the European Academy of Nursing Science, amalgamation of apparently marginal gains, produced by tiny changes leads to world class nursing[56].
Our studies, however, show the benefits of a feasible nursing intervention focusing on illness perceptions. Other studies urgently called to develop interventions focusing on illness perceptions[57,58] and patient needs[59] in COPD. Until now there were some small trials which studied the effectiveness of an illness perception intervention in heart

attack patients[60] and diabetes patients[61], we are the first who actually developed and studied the effectiveness of a comprehensive nursing intervention focusing at illness perceptions in a larger trial in COPD patients.

The COPD-GRIP intervention provides nurses with a structured way to address illness perceptions in daily clinical care. Nurses in our studies indicated that the training on this intervention provided them with new insights. Working with this intervention diminished their feeling of being empty handed. Although the COPD-GRIP intervention does not cover the full spectrum of integrative COPD care, it describes the starting point of COPD care by exploring patients' perceptions in a structured individualized way. Our research is supporting the conclusion that an illness perception intervention applied by nurses has benefits in improving health behavior and improving the ability to control the situation of living with COPD. However, the benefits were not sustained on the long term. It could be likely that the time period of the intervention should be extended by some ongoing support. This is in line with the recent findings of a Cochrane review concerning personalized care planning[62] and an individual patient data analysis study concerning the effectiveness of self-management interventions among COPD patients[63]. Both studies[62,63] conclude that longer intervention durations and more comprehensive interventions lead to better outcomes. Training nursing in providing this type of care is pivotal, because nurses need to develop skills to integrate a biopsychosocial perspective in care. The need for education is supported by our study[41] and by other studies in primary care nursing for COPD patients[16,64] and patients with other chronic conditions[65,66].

Although we did not find an effect of the COPD-GRIP intervention on health status and HRQoL as measured by the CCQ and CRQ, respectively, we should not prematurely dismiss the intervention. Our qualitative studies[41,45] show that patients and practice nurses experienced various benefits. Furthermore, our research supports the conclusion that "one size does not fit all"[67] in regard to interventions and outcome measures. Interventions and outcome measures alike need to be tailored to the patient's needs and specific context of each patient. An assessment of needs and preferences is a critical component of tailoring interventions[52,68].

Implications and next steps

A call for change in COPD nursing care and research

Nurses should be at the forefront of patient care for complex diseases, such as COPD, as they are involved in patient care from prevention to end-of life care. In collaboration with the general practitioner and other health care workers, nurses therefore can substantially contribute to COPD care. A vital aspect of this care is understanding patient perceptions by inquiring about how they perceive the disease and their needs. However, there is an urgent need for a reconsideration of nursing outcome measures. Despite the enormous number of instruments available for outcome measurements, we

still do not have the optimal outcome measures that are tailored to the patient needs. One of the most important questions for nurses and scientists in the near future is: "How do we define outcomes in nursing care for COPD patients?" Within the context of the recently proposed definition of health as the ability to adapt[69], it is vital that nursing scientists and nurses develop, endorse and adapt new flexible and patient-centered outcome measures in COPD care and research. The proposed health indicators by Huber et al[70] can serve as a starting point in developing these new outcome measures. These indicators include bodily-, mental-, spiritual- and social functioning, as well as quality of life and daily functioning[70]. We must take into account the adaptability and adjustment with disease reflecting individual differences.

Meanwhile, in the absence of optimal flexible outcome measures, we should focus on nursing outcomes that represent patient's perspective. A simple way of doing so is by asking what his or her desired outcomes are.

Within nursing, research and practice are sometimes considered as worlds apart with a gap in between that needs to be bridged[71,72]. To ensure validity of findings and to sustain impact of research findings in practice, nurses and nurse researchers need to share their perspective. Collaboration on local, national and international level between nurses, researchers but also educators in nursing is vital to ensure high quality of care based on evidence. With regard to COPD nursing care an international forum is urgently needed to enable nurses to debate new outcome measures and interventions from a biopsychosocial perspective. The first step in this process is establishing a scientific nursing journal for respiratory diseases, which is currently lacking. This encourages nurses and nursing scientists in respiratory research to publish their studies and to debate new developments in nursing care for COPD patients.

Besides the debate on outcome measures, nurses and scientist should develop, endorse and evaluate the effectiveness of personalised care interventions for COPD patients. There is an ongoing need for scientific evidence in nursing COPD care and the mutual effort to change practice. Nurses need to strengthen their role in their daily clinical practice to address the challenges in COPD care. However, they should not take this responsibility in isolation, but in collaboration with colleagues, researchers and educators on a national and international level.

Conclusions

It is important to recognize and acknowledge individual differences in COPD patients, as described by patients themselves. Nurses can be at the forefront of patient care for COPD patients. A vital aspect of this care is to understand how patients perceive their illness. To address these issues, nurses can use a comprehensive nursing intervention focusing on illness perceptions. Moreover, integrating a biopsychosocial perspective in COPD care provides further window of optimizing outcomes and interventions.

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Chapter 9

Summary

Impact of Chronic Obstructive Pulmonary Disease

Pulmonary and extra pulmonary complaints affect the physical, emotional and social quality of life of patients with Chronic Obstructive Pulmonary Disease (COPD). Many patients are confronted with daily life limitations. Some COPD patients are able to manage and cope with their condition. However, for many patients disease management and coping with the limitations caused by COPD are very demanding. To explain this type of individual differences, biopsychosocial models are increasingly used. These models assume that besides biological aspects, psychological and social factors play an important role in managing chronic diseases.

Health care for patients with COPD

Because COPD cannot be cured, COPD care and treatment focuses on the individual short-term and long-term impacts of the disease on each COPD patient. In the past decade the care for COPD has increasingly moved from hospital towards primary care settings. In this context, general practitioners, practice nurses and respiratory nurses in primary care can make a crucial contribution to the integrated, patient-centered care for COPD patients. In particular, the nursing role has gained importance. Efforts have been made to develop care that is coordinated or delivered by nurses. Despite the efforts and some positive results, the effectiveness of nursing care on health outcomes remains inconclusive. Research on primary care nursing and patient outcomes should therefore be extended and elucidated.

The major challenges of COPD care are guiding patients with the consequences of their disease, reducing impact of symptoms, improving participation in daily activities and improving health related quality of life (HRQoL). Against this background the scope of this thesis is how to improve the effectiveness of primary care nursing to reduce the impact of COPD in terms of improving the patients' quality of life and daily activities. A biopsychosocial perspective served as the framework for the studies presented in this thesis. In these studies, patient outcomes and points of action that can guide nursing interventions were investigated. Based on these insights a comprehensive nursing intervention was developed and evaluated.

Outcomes in COPD care and research

Measuring Health Related Quality of Life

Starting from desired outcomes as HRQoL, a systematic review concerning the content and psychometric properties of available instruments to measure HRQoL in COPD patients was performed (Chapter 1). HRQoL is usually defined as an individual's perception of the complex effects of health and psychosocial issues on their position in life. However, there is a lack of consensus on the definition. The absence of an agreed-upon definition is reflected in the large number of available instruments to measure HRQoL in COPD. The results described in chapter 1 show that there is strong psychometric

evidence for disease specific instruments. The Chronic Respiratory Questionnaire (CRQ), the COPD Assessment Test (CAT), the St George Respiratory Questionnaire (SGRQ), and the Living with COPD questionnaire (LCOPD) had the best ratings. However, an optimal instrument could not be identified. Therefore, the decision to choose one instrument over another should be guided by the results to be obtained in a study or in clinical practice in relation to the domains included in the instrument and the psychometric properties.

Measuring daily activities with the Dutch Functional Performance Inventory in COPD patients

COPD patients are confronted with substantial limitations in the ability to perform daily activities. Improving and easing the performance of these activities in an important goal in COPD care. These activities do not only include physical activities, but also social, occupational and spiritual activities. Within the context of COPD care and research it is therefore essential not only to measure physical capacity, but also self-reported activities in daily life. The Functional Performance Inventory (FPI) is an instrument which measures these activities that individuals perform in their daily life. Moreover, the FPI takes into account what activities are considered important for an individual. Therefore, this instrument seems to be valid as a nursing outcome measure. The original English version of the FPI was translated into Dutch **(Chapter 2)**. Subsequently this version of the instrument was validated in 150 Dutch COPD patients. The results, show that the translated version of the FPI is reliable and reproducible. Although the validity scores were lower compared to other studies, they were nevertheless acceptable, meaning that the FPI can be used as a valid outcome measure. However, further evaluation of its psychometric properties is recommended.

Exploring points of action

Psychological aspects in COPD patients

Looking for points of action that can guide nursing interventions in COPD care, the extent to which the combination of several psychological factors (depressive symptoms, proactive coping, illness perceptions) and physical factors (airflow limitation, dyspnea, co-morbidities) contribute to daily activities and HRQoL in 90 COPD patients in primary care, was explored **(Chapter 3).** The study revealed that illness perceptions, depressive symptoms and dyspnea are related to HRQoL. Moreover, the study confirmed that more objective measures, such as airflow limitation did not contribute to the individual differences in HRQoL. In contrast to the expectations, an association between psychological factors and daily activities could not be confirmed. As an extension of this study, the specific role off illness perceptions in relation to HRQoL was analyzed **(Chapter 4)**. Illness perceptions are individual perceptions and beliefs about illness, described within the Common Sense Model by Leventhal, a theoretical model used in medical psychology. The essence of this model is the assumption that more positive perceptions

in combination with clinical characteristics are related to better health outcomes. The study shows that patients who attributed fewer symptoms to COPD, who had a better understanding of COPD, who experienced more treatment control and had less of an emotional response to COPD had a better HRQoL. The studies in Chapter 3 and Chapter 4 therefore indicate that addressing psychosocial aspects, and more specifically illness perceptions, should be an essential part of nursing interventions aimed at improving HRQoL.

A comprehensive nursing intervention

Evaluation from perspective of nurses and patients

Based on the findings regarding outcomes (Chapter 1 and Chapter 2) and points of action (Chapter 3 and Chapter 4), a comprehensive nursing intervention that takes into account psychosocial aspects, was developed. This resulted in the COPD Guidance, Research on Illness Perception (COPD-GRIP) intervention which translates the theory and evidence regarding illness perceptions and HRQoL into a practical guide for nurses to provide individualized COPD care.

The COPD-GRIP intervention was used by 24 nurses in primary care. In an explanatory mixed-method study, nested within a cluster randomized trial, the barriers and facilitators as experienced by these nurses were evaluated **(Chapter 5).** Quantitative (questionnaires) and qualitative (focus groups) research methods were used. The study revealed that the intervention, proved to be a feasible tool for providing tailored, patient-centered care. The nurses would like to incorporate the intervention in daily care. The nurses described the intervention as a useful, structured and individualized tool to guide COPD patients in living with the consequences of COPD. Applying the intervention took less time than the nurses initially expected. Barriers were encountered, especially in patients with a lower social economic status, in patients with a lower health literacy and in patients with a different cultural background. The nurses also recommended that to successfully implement the intervention in their busy practice, authorisation by the general practitioner is needed. Furthermore, they proposed to develop remuneration models and organization models.

In addition to the nurses' evaluations, a qualitative interview study in 16 COPD patients to evaluate their experiences regarding the COPD-GRIP intervention was conducted **(Chapter 6)**. Patients appreciated the consultations of the COPD-GRIP intervention. The essence of their experiences can be described as: the intervention made them feel "being listened to and being acknowledged", it improved their "awareness" of the disease and it helped them "making lifestyle changes".

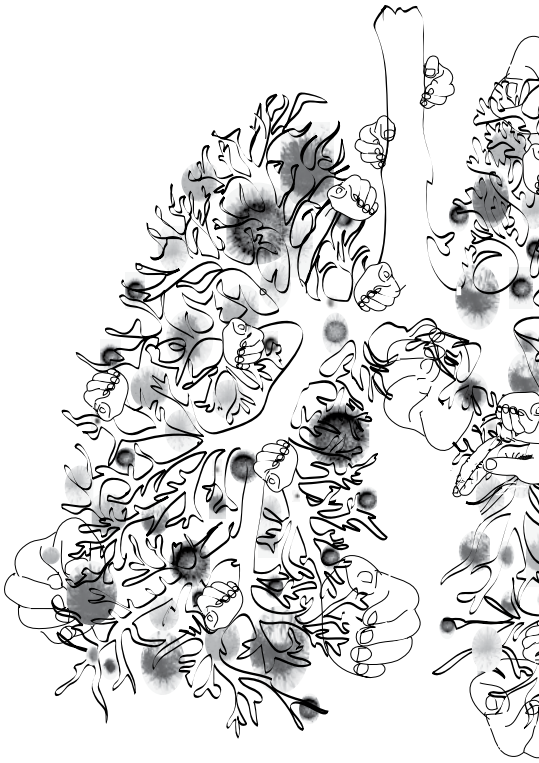
Effectiveness of the intervention

In a cluster randomized trial it was determined if the COPD-GRIP intervention, implemented by nurses in primary care settings leads to improved HRQoL and daily activities in COPD patients compared to usual nursing care **(Chapter 7)**. The trial was

conducted within 35 primary care practices, including 204 patients.
The intervention could not improve health status (as measured by the Clinical COPD Questionnaire), HRQoL (as measured by the Chronic Respiratory Disease Questionnaire) and daily activities (as measured by the Functional Performance Inventory). The COPD-GRIP intervention did influence the patient's ability to control the disease and health-related behaviours in the short term. In other words, the patients in the intervention group experienced an improvement in their ability to control COPD. Also their health behaviour improved shortly after the intervention, but this effect was not preserved over time.

Critical reflection on outcomes and points of action: a call for change

Chapter 8 offers a general discussion, which critically reflects on the studies presented in this thesis.
Firstly, a critical reflection on outcome measures in COPD care and research is presented. Although the enormous number of instruments available for the measurement of HRQoL cover many domains, it could be questioned if the existing instruments are able to capture the individual experiences and desired outcomes of COPD patients. Although the current measures are "patient reported outcome measures" (PROMS), they are standardized, not individualized, instruments. The effectiveness of tailored interventions is still measured with standardized methods. To reflect individual differences, it is of the of the utmost importance to develop multidimensional outcome measures.
Secondly, a critical reflection on points of action is presented. The studies in this thesis show that psychological aspects as points of action can guide nursing interventions. Although an effect on HRQoL could not be detected, the intervention should not be dismissed prematurely. The qualitative studies showed various benefits and marginal gains, produced by tiny changes which could lead to positive outcomes.
Future studies should focus on interventions that provide an ongoing support over time. Interventions and outcome measures alike need to be tailored to the patient's needs and specific context of each patient.
To address the issues of outcome measures and tailored interventions, nurses, scientists and educators should take the responsibility in collaboration to debate, develop, endorse and evaluate scientific evidence in nursing COPD care in order to improve patient outcomes and change clinical practice.



Chapter 9

Samenvatting

Impact van Chronisch Obstructieve Longziekte

Zowel klachten van de longen als andere klachten beïnvloeden de fysieke, emotionele en sociale kwaliteit van leven van patiënten met een chronische obstructieve longziekte (COPD). Veel patiënten worden geconfronteerd met beperkingen in het dagelijkse leven. Sommige mensen met COPD zijn in staat om met hun situatie om te gaan en hun leven met COPD goed te organiseren. Voor velen is echter het organiseren van het leven met COPD en omgaan met de beperkingen die veroorzaakt worden door COPD, een grote opgave. Om deze individuele verschillen te verklaren worden in toenemende mate modellen vanuit een biopsychosociaal perspectief gebruikt. Deze modellen gaan ervan uit, dat naast biologische aspecten, psychologische en sociale factoren een belangrijke rol spelen in het omgaan met een chronische ziekte.

Gezondheidszorg voor mensen met COPD

Omdat COPD niet te genezen is, richt de zorg en behandeling van COPD zich op de individuele gevolgen van de ziekte op korte en lange termijn. In het afgelopen decennium is de zorg voor mensen met COPD in toenemende mate verschoven van het ziekenhuis naar de eerste lijn. Binnen deze context kunnen huisartsen, praktijkverpleegkundigen en eerstelijns longverpleegkundigen een cruciale bijdrage leveren aan de geïntegreerde, patiëntgerichte zorg voor mensen met COPD. In het bijzonder is de verpleegkundige rol steeds belangrijker geworden. Er zijn veel inspanningen verricht om zorg te ontwikkelen die wordt gecoördineerd of geleverd door de verpleegkundige. Ondanks deze inspanningen en een aantal positieve resultaten is het effect van de verpleegkundige zorg op de gezondheidsuitkomsten toch nog niet voldoende duidelijk. Onderzoek naar verpleegkundige zorg in de eerste lijn en patiëntgerichte uitkomstmaten moet uitgebreid en verhelderd worden.

De grootste uitdagingen in de COPD-zorg zijn: het begeleiden van patiënten met de gevolgen van de ziekte, het verminderen van de impact van symptomen, verbeteren van deelname aan dagelijkse activiteiten en het verbeteren van de gezondheidgerelateerde kwaliteit van leven (HRQoL). Met deze achtergrond richt dit proefschrift zich op de vraag hoe de effectiviteit van verpleegkundige zorg in de eerste lijn verbeterd kan worden, gericht op het verminderen van de impact van COPD op mensen met deze ziekte en het verbeteren van hun kwaliteit van leven en dagelijkse activiteiten. In de onderzoeken die beschreven staan in dit proefschrift is het biopsychosociale model het uitgangspunt geweest. Er is onderzocht welke patiëntgerichte uitkomstmaten en welke aangrijpingspunten er zijn om de verpleegkundige zorg en interventies te ontwikkelen. Op basis van de verworven inzichten is een uitgebreide verpleegkundige interventie ontwikkeld en geëvalueerd.

Uitkomsten in COPD-zorg en onderzoek

Meten van kwaliteit van leven

Met gezondheidgerelateerde kwaliteit van leven als startpunt en als uitkomstmaat is een systematische review gedaan. Deze richt zich op de inhoud en de psychometrische eigenschappen van de beschikbare instrumenten om kwaliteit van leven bij COPD-patiënten te meten (Hoofdstuk 1). Kwaliteit van leven wordt normaal gesproken gedefinieerd als de individuele perceptie van de complexe effecten van gezondheid en psychosociale aspecten op de positie in het leven. Er is echter geen consensus over de definitie. De afwezigheid van een gezamenlijk overeengekomen definitie weerspiegelt zich in het grote aantal beschikbare instrumenten om kwaliteit van leven te meten bij mensen met COPD. De resultaten die beschreven staan in hoofdstuk 1, laten zien dat er een sterk psychometrisch bewijs is voor ziekte specifieke instrumenten. De "Chronic Respiratory Questionnaire" (CRQ), de "COPD Assessment Test"(CAT), de "St George Respiratory Questionnaire" (SGRQ), en de "Living with COPD questionnaire" (LCOPD) hadden de beste scores en beoordelingen. Een optimaal instrument kon echter niet geïdentificeerd worden. De keuze voor een instrument boven een ander instrument zal daarom bepaald worden door de resultaten en doelen van de studie of klinische praktijk in relatie tot de domeinen van de instrumenten en hun psychometrische eigenschappen.

Het meten van dagelijkse activiteiten met de Nederlandse "Functional Performance Inventory" bij COPD-patiënten

COPD-patiënten worden geconfronteerd met substantiële beperkingen in hun mogelijkheden tot het uitvoeren van dagelijkse activiteiten. Een belangrijk doel in de COPD-zorg is het verbeteren en vergemakkelijken van het uitvoeren van dagelijkse activiteiten. Deze activiteiten beperken zich niet alleen tot fysieke activiteiten, maar omvatten ook sociale, werkgerelateerde en spirituele activiteiten. Binnen de context van COPD-zorg en onderzoek is het daarom essentieel om niet alleen fysieke capaciteit te meten, maar ook zelf gerapporteerde dagelijkse activiteiten. De Functional Performance Inventory (FPI) is een instrument dat deze activiteiten die mensen in hun dagelijkse leven uitvoeren, meet. Daarnaast meet het instrument welke activiteiten voor iemand persoonlijk belangrijk zijn. Daarom lijkt dit instrument als verpleegkundige uitkomstmaat valide. De originele Engelse versie is vertaald naar het Nederlands **(Hoofdstuk 2)**. Vervolgens is deze versie van het instrument gevalideerd in 150 Nederlandse COPD- patiënten. De resultaten laten zien dat de vertaalde versie betrouwbaar en reproduceerbaar is. Hoewel de scores op validiteit lager waren dan in andere onderzoeken, waren ze echter acceptabel wat betekent dat de FPI gebruikt kan worden als een valide uitkomstmaat. Echter, verdere evaluatie van de psychometrische eigenschappen wordt aanbevolen.

Onderzoeken van aanknopingspunten

Psychologische aspecten bij mensen met COPD

Op zoek naar aanknopingspunten voor de ontwikkeling van verpleegkundige interventies in de COPD-zorg, is de mate waarin de combinatie van verschillende psychische factoren (depressieve symptomen, proactieve coping, ziektepercepties) en fysieke factoren (beperkingen van de luchtstroom in de longen, kortademigheid, comorbiditeit) bijdragen aan dagelijkse activiteiten en kwaliteit van leven bij 90 COPD- patiënten in de eerste lijn, onderzocht **(Hoofdstuk 3)**. Het onderzoek liet zien dat ziektepercepties, depressieve symptomen en kortademigheid gerelateerd zijn aan kwaliteit van leven. Tevens bevestigde het onderzoek, dat meer objectieve maten, zoals de beperkingen in de luchtstroom, niet bijdragen aan de individuele verschillen van kwaliteit van leven. In tegensteling tot de verwachting kon een relatie tussen psychologische factoren en dagelijkse activiteiten niet worden bevestigd. In een uitbreiding van dit onderzoek is de specifieke rol van ziektepercepties in relatie tot kwaliteit van leven geanalyseerd **(Hoofdstuk 4)**. Ziektepercepties zijn individuele percepties en overtuigingen over ziekte. Deze ziektepercepties zijn beschreven binnen het "Common Sense Model" van Leventhal, een theoretisch model dat gebruikt wordt binnen de medische psychologie. De essentie van het model is de aanname dat meer positieve percepties in combinatie met klinische karakteristieken gerelateerd zijn aan betere gezondheidsuitkomsten. De studie laat zien dat patiënten, die minder aan COPD toegeschreven symptomen ervaren, hun COPD beter begrijpen, meer controle over de behandeling ervaren en minder emotionele reacties hebben op COPD, een betere kwaliteit van leven ervaren. De onderzoeken in Hoofdstuk 3 en Hoofdstuk 4 laten zien dat het aanpakken van psychologische aspecten en in het bijzonder ziektepercepties, een essentieel onderdeel zou moeten zijn van verpleegkundige interventies om daarmee de kwaliteit van leven te verbeteren.

Een verpleegkundige interventie

Evaluatie vanuit het perspectief van verpleegkundigen en patiënten

Gebaseerd op de bevindingen met betrekking tot uitkomsten (Hoofdstuk 1 en 2) en de aanknopingspunten (Hoofdstuk 3 en Hoofdstuk 4), is een uitgebreide verpleegkundige interventie ontwikkeld die rekening houdt met psychologische aspecten. Dit resulteerde in de Guidance, Research on Illness Perception (COPD-GRIP) interventie. Deze interventie vertaalt de theorie en het bewijs met betrekking tot ziektepercepties en kwaliteit van leven in een praktische handleiding voor verpleegkundigen om individuele COPD-zorg te geven.

De COPD-GRIP interventie is gebruikt door 24 verpleegkundigen in de eerste lijn. In een verkennend onderzoek binnen een cluster gerandomiseerd onderzoek zijn met verschillende methoden de door de verpleegkundigen ervaren barrières en bevorderende factoren geëvalueerd **(Hoofdstuk 5)**. Kwantitatieve (vragenlijsten) en

kwalitatieve (focusgroepen) onderzoeksmethoden zijn in dit onderzoek gebruikt. De resultaten lieten zien dat de interventie een haalbare interventie is en gebruikt kan worden om afgestemde, patiëntgerichte zorg te geven. De verpleegkundigen zouden de interventie graag in hun dagelijkse praktijk willen invoeren. De verpleegkundigen beschreven de interventie als bruikbaar, gestructureerd en als mogelijkheid om individueel afgestemde zorg te bieden. Het gebruik van de interventie nam minder tijd in beslag dan vooraf verwacht. Er werden ook barrières ervaren, met name bij patiënten uit een lagere sociaaleconomische klasse, bij patiënten met lagere gezondheidsvaardigheden en bij patiënten met een andere culturele achtergrond. Om de interventie in de toekomst succesvol in hun drukke praktijk in te voeren, adviseerden de verpleegkundigen dat de huisarts bij wie zij werken hen autoriseert deze zorg te bieden. Verder stelden zij voor om financieringsmodellen en organisatiemodellen te ontwikkelen.

In aanvulling op de evaluatie met de verpleegkundigen is een kwalitatief onderzoek bij 16 patiënten uitgevoerd. In persoonlijke interviews werden hun ervaringen met de COPD-GRIP interventie geëvalueerd **(Hoofdstuk 6)**. Patiënten waardeerden de consultgesprekken van de COPD-GIP interventie. De essentie van hun ervaringen kan als volgt omschreven worden: door de interventie voelden zij zich "gehoord en erkend". De interventie vergrootte het bewustzijn van het hebben van COPD en het hielp hen "leefstijlveranderingen in gang te zetten".

Effectiviteit van de interventie

In een cluster gerandomiseerd onderzoek is bepaald of de COPD-GRIP interventie, zoals geïmplementeerd door de verpleegkundigen in de eerstelijnszorg, tot verbetering van kwaliteit van leven en dagelijkse activiteiten heeft geleid in vergelijking tot de reguliere verpleegkundige COPD-zorg (Hoofdstuk 7). Het onderzoek is uitgevoerd binnen 35 huisartspraktijken bij 204 patiënten.

De interventie kon de gezondheidssituatie (gemeten met de "Clinical COPD Questionnaire"), de kwaliteit van leven (gemeten met de "Chronic Respiratory Disease Questionnaire") en dagelijkse activiteiten (gemeten met de "Functional Performance Inventory") niet verbeteren. De COPD-GRIP interventie beïnvloedde wel het vermogen om controle te hebben over de ziekte en gezondheidbevorderende activiteiten. Met andere woorden, de patiënten in de interventiegroep ervaarden een verbetering in hun gevoel controle te hebben over de ziekte. Het gedrag om de gezondheid te bevorderen verbeterde ook kort na de afronding van de interventie, maar dit hield echter na enige tijd geen stand.

Kritische reflectie op uitkomst maten en aanknopingspunten: oproep tot verandering

Hoofdstuk 8 biedt een algemene discussie waarin kritisch gereflecteerd wordt op de onderzoeken die in dit proefschrift beschreven staan.

Ten eerste wordt een kritische reflectie gegeven op de uitkomstmaten in COPD-zorg en onderzoek. Hoewel er een enorm aanbod is van meetinstrumenten om kwaliteit van leven te meten waarin vele domeinen opgenomen zijn, kan de vraag gesteld worden of de bestaande instrumenten wel in staat zijn om individuele ervaringen en gewenste uitkomsten van COPD-patiënten te meten. Hoewel de huidige meetinstrumenten weliswaar door de patiënt gerapporteerde uitkomsten ("PRO"s) zijn, zijn het toch gestandaardiseerde en niet geïndividualiseerde instrumenten. Het effect van individueel afgestemde interventies wordt alsnog geëvalueerd met gestandaardiseerde methodes. Om individuele verschillen weer te geven is het van het grootste belang om multidimensionale uitkomstmaten te ontwikkelen.

Ten tweede wordt een kritische reflectie gegeven op de aanknopingspunten. De onderzoeken in dit proefschrift laten zien dat psychologische aspecten als aanknopingspunt kunnen dienen voor verpleegkundige interventies. Hoewel er geen effect op kwaliteit van leven gevonden is, moet de interventie niet op voorhand afgewezen worden. De kwalitatieve onderzoeken lieten zien dat er positieve effecten en kleine opbrengsten van de interventie waren die mogelijk kunnen leiden tot positieve uitkomsten.

Onderzoeken in de toekomst zullen zich moeten richten op interventies die langer ondersteuning geven. Zowel interventies als uitkomstmaten zullen afgestemd moeten zijn op de individuele patiënt in zijn of haar specifieke context.

Om de aandachtspunten van de uitkomstmaten en de op maat gemaakte interventies aan te pakken, moeten verpleegkundigen, onderzoekers en opleiders de verantwoordelijkheid nemen om gezamenlijk over de verpleegkundige COPD-zorg te discussiëren en het belang hiervan te onderschrijven om daarmee deze zorg te ontwikkelen en te evalueren. Hiermee kan het mogelijk gemaakt worden om patiëntuitkomsten en de klinische praktijk te verbeteren.

Chapter 9

Dankwoord

Met ontzettend veel plezier heb ik de afgelopen jaren onderzoek gedaan. Terugblikkend op deze tijd, realiseer ik mij dat mijn drijfveer om dit te doen altijd is geweest: het verder ontwikkelen en verbeteren van goede verpleegkundige zorg aan mensen met COPD, gebaseerd op wetenschappelijke inzichten. In de tijd dat ik als verpleegkundige op de longafdeling werkte en verplegingswetenschap studeerde, voelde ik altijd al de 'drive' om me verder te verdiepen. De vraag, hoe wij als verpleegkundigen mensen met een chronische longziekte kunnen bijstaan, bleef mij altijd bezighouden. Ik voel me dan ook bevoorrecht dat ik de mogelijkheid kreeg om deze verdieping daadwerkelijk vorm te geven door onderzoek te doen op dit gebied. Daarmee kan ik bijdragen aan het bouwen van de zo broodnodige brug tussen de wetenschap en de dagelijkse zorg. En dan "ineens" is het zover. De onderzoeken zijn gedaan en het proefschrift is klaar. Naast alle positieve ervaringen in het onderzoek doen en het opschrijven, waren er natuurlijk ook momenten dat het even minder leuk was en er tegenvallers op mijn pad kwamen. Maar met de support en inspiratie van zoveel mensen om mij heen, kon ik altijd wel weer het pad begaanbaar maken of een nieuwe weg vinden. Daarom is het nu tijd om iedereen die erbij betrokken is geweest te bedanken. Een aantal van hen wil ik graag in het bijzonder bedanken.

Mijn beide promotoren, prof. dr. Jan-Willem Lammers en prof. dr. Marieke Schuurmans wil ik als eerste bedanken.
Beste Jan-Willem, ik zie mijzelf nog als leerling-verpleegkundige op de longafdeling mijn eerste visite langs patiënten met je lopen. Wat vond ik dat spannend! Destijds kon ik nog niet vermoeden dat je jaren later een promotieplek voor mij mogelijk zou maken. Ik ben je enorm dankbaar voor het vertrouwen dat je in me hebt gesteld en de ruimte die je me hebt gegeven om het onderzoek uit te voeren. In onze overleggen gingen we steeds op zoek naar verbindingen tussen wetenschap, dagelijkse praktijk en goede zorg voor mensen met COPD. Op deze manier kwamen vele wegen samen. Ik zal de inspirerende gesprekken in deze context best gaan missen.
Beste Marieke, ik leerde jou voor het eerst kennen toen ik als leerling-verpleegkundige op de afdeling interne geneeskunde werkte en jij een klinische les kwam geven over een delier bij oudere mensen. Wat had je een verfrissende visie op zorg voor kwetsbare ouderen. Dat gaf mij zoveel inspiratie! De jaren die volgden kwamen we elkaar steeds weer tegen. Ik herinner me nog goed, dat je me een keer een aanbod deed dat voor mij helaas niet op het goede moment kwam. Ik zal nooit vergeten dat je zei: "Sas, geen zorgen, er komt voor jou echt nog wel iets anders voorbij!" En dat kwam er dus! Ik heb zoveel van je geleerd. Dank, dat je altijd ruimte had als ik even vastliep of om gewoon even de stand van zaken te bespreken. Ik kom altijd met zoveel energie en inspiratie uit onze overleggen. Je gaf me de ruimte om me vast te bijten in details, maar wist me altijd weer op tijd de grotere verbanden te laten inzien.

Furthermore, I would like to thank the assessment committee consisting of prof.dr. Jet Smit, prof.dr. Theo Verheij, prof.dr. Thys van der Molen, prof. dr. Rinie Geenen and prof. dr. Helga Jónsdóttir for reading and assessing my thesis. Dear prof. Dr. Helga Jónsdóttir, thank you for your time to travel from Iceland to Utrecht and to participate as an opponent during the defense. I really look forward to discussing the findings with all of you on the 3th of November.

Beste Robert van Barneveld, dank dat je me de afgelopen jaren de tijd en ruimte hebt gegeven om mij te verdiepen en te focussen op onderzoek binnen een promotieplek die jij samen met Jan-Willem gecreëerd hebt. Mede door jouw steun, vertrouwen en de faciliteiten die je creëerde heb ik mij verder kunnen ontwikkelen. Dank daarvoor! Ik kan altijd even bij je binnen lopen om kleine en grote gebeurtenissen in het leven en in het onderzoek met je te delen. Voor de komende tijd wens ik je vooral heel veel kracht toe. Ik verheug me op de blijvende samenwerking in het uitbouwen van onderzoek in de zorg.

Alle mensen met COPD die deelgenomen hebben aan de verschillende onderzoeken. Zonder u was dit proefschrift niet tot stand gekomen. Ik hoop hiermee een stukje te kunnen bijdragen aan de ontwikkelingen in de zorg voor u. Dank voor het invullen van de vele vragenlijsten en het delen van uw ervaringen met het leven met COPD.

Simone Sluis en Marieke Zwakman, wat had ik zonder jullie gemoeten? Jullie bewaakten als onderzoeksverpleegkundigen het "COPD-GRIP fort" in alle opzichten. Dankzij jullie liep de logistiek van het COPD-GRIP onderzoek vlekkeloos! En als zich toch een "gek" probleem voordeed, dan hadden jullie altijd wel een passende oplossing voor de pakketjes, nieuwsbrieven, dubbele vragenlijsten, reminders, DBM, enveloppen etc. Soms leek het op Q05 meer op een postorderbedrijf dan een onderzoekskamer, maar door jullie organisatietalenten kwam er altijd weer orde. Jullie stonden altijd klaar om praktijken te bezoeken, mee te gaan naar de scholingen voor de verpleegkundigen, congressen te bezoeken om verpleegkundigen enthousiast te maken voor deelname aan het COPD-GRIP onderzoek. Mijn dank daarvoor!
Lieve Simone, we hebben veel gedeeld in vreugdevolle en soms verdrietige gebeurtenissen in ons leven. Dat blijven we vast doen! Maar ik hoop ook zeker dat we in de nabije toekomst weer samen aan nieuw onderzoek kunnen werken. Dank voor je nauwkeurige controle op de lay-out!
Lieve Marieke, zet 'm op! Je werkt toe naar het schrijven van je eigen proefschrift. Heel veel succes!

Gertie, Rita, Liesbeth, Karin, Annemieke, Elisabeth, Roos, Matty, Ingrid, Jojanneke, Jolien, Inge, Cynthia, Susan, Moniek, Geanne, Levina, Sylvia, Irma, Simone, Ellen, Tieke,

Karin, Clara, Astrid, Phyllis, Annemiek, Monique, Janneke, Yvonne, Marja, Jennifer, Ingrid, Astrid, Petra, Wendy, Lenneke, Corry, Margreet, Erna, Barbara en Corrie. Dank dat jullie als praktijkverpleegkundige, longverpleegkundige of als POH bereid waren om mee te werken aan de onderzoeken. Ik realiseer mij heel goed, dat het onderzoekswerk naast jullie dagelijkse drukke werkzaamheden moest gebeuren. Maar zonder jullie had dit allemaal niet kunnen plaatsvinden. Ook dank aan de huisartsen en thuiszorgorganisaties waar jullie werkzaam zijn.

Caroline Veelers, Anne Botermans en Rani Liu, jullie kwamen als student een stage bij mij lopen en hebben daarmee bijgedragen aan de verschillende onderzoeken. Dank jullie wel. Marlous Reeder, dank voor de administratie binnen een van de eerste onderzoeken. Lisanne Sluis, dank voor het bewaken van het GRIP fort in de zomervakantie.

In het bijzonder wil ik hier Rogier Decates noemen. Als enthousiaste 6e jaars geneeskunde student kwam je bij mij praten over mogelijkheden voor je wetenschappelijke stage. Je wilde je graag verdiepen in de psychosociale aspecten bij mensen met longziekten. In 3 maanden tijd heb je bergen werk verzet voor mijn onderzoek. Dit resulteerde in een co-auteurschap bij een van mijn artikelen. Je bleef enthousiast en we maakten plannen om tijdens je opleiding tot longarts nieuw onderzoek op te gaan zetten. Het mocht niet zo zijn. Je werd ziek. Tot aan mijn allerlaatste bezoek aan jou, een maand voordat je overleed, bleef je enthousiast over mogelijke nieuwe onderzoeksplannen. Dank dat ik je heb mogen leren kennen.

Marjorie, Larissa en Carien, jullie input vanuit verpleegkundig perspectief in de ontwikkelfase van de COPD-GRIP interventie was essentieel. Dank jullie wel hiervoor.

Pieter Zanen, ik heb genoten van het samenwerken aan de statistische analyses en de discussies over de ontwikkelingen in het longonderzoek en de longzorg die erop volgden. Dank dat je altijd klaar stond als ik graag weer een analyse met je wilde doorspreken of als ik vastliep in SPSS. Door jouw geduld en heldere uitleg kon ik uiteindelijk heel veel syntaxen in SPSS zelf maken. Ik heb veel van je geleerd.

Marloes van Beurden en Nicole Boekema, dank voor jullie hulp in het datamanagement. Marloes, als datamanager en de lay-outontwerper van de teleform lijsten en de Deelnemer Beheer Module (DBM) was je nauw betrokken bij een belangrijk stuk van het COPD-GRIP onderzoek. Door jouw werk bleef de logistiek zeer goed gewaarborgd. Jij kon het proces omzetten in een DBM. Dank dat je hierover altijd zo makkelijk en snel bereikbaar was.

Ariane van Wamel, we kennen elkaar al weer een hele tijd en delen de passie voor goede zorg. Dank voor de terugkerende lunches en wandelingen. Het is heerlijk om met enige regelmaat onze ervaringen en ideeën met elkaar te delen. Ik verheug me op de komende periode waarin we onze ideeën over kruisbestuivingen tussen onderzoek en praktijk tot bloei kunnen laten komen.

Frank van Lent, jij bent degene die als een leeuw onze COPD-GRIP website bewaakt heeft, toen deze dreigde te moeten verdwijnen door een herstructurering van de internetsites van het UMC Utrecht. Ik ben je daar erg dankbaar voor. En weet je nog: de gedelete channels vlak voor de scholingen. Dankzij jou kwam het goed.

Rob Schouten, de animatiefilm die je gemaakt hebt over de COPD-GRIP interventie gebruiken we nog steeds en mensen glimlachen nog steeds op dezelfde momenten!

Berry en Mariken, zonder jullie als het gouden duo op het secretariaat was er zeker een en ander misgegaan. Dank voor jullie bijdrage en hulp.

Ik wil ook heel graag alle onderzoekers van de onderzoeksgroep VW en collega's van het KGW en VW onderwijs bedanken voor de inspirerende discussies zowel in de researchbijeenkomsten als daarbuiten. In het bijzonder: Agnes, Thóra, Jita, Judy, Janneke, Roelof, Jaap, Heleen, Yvonne, Jacqueline, Nienke, Irina, Sigrid, Pieterbas, Marlies, Irene, Wietske, Debbie, Nini, Mariska en Harmieke. Dank voor alle input en overwegingen gedurende de afgelopen jaren.

Sandra van Duijn en Marjan Veltman, tot voor kort waren jullie de voorzitters van respectievelijk de V&VN Longverpleegkundigen en de V&VN POH/ praktijkverpleegkundigen. In deze rollen hebben jullie je altijd hard gemaakt voor verpleegkundig onderzoek en mijn onderzoek ook altijd van harte ondersteund. Dank daarvoor. Sandra, ik wens je heel veel succes en inspiratie met je promotietraject! Ik zie ernaar uit om onze ervaringen en passie voor het vak te blijven delen.

Onno van Schayck, Walter Litsenburg, Frans Toben en Denise Schuiten, dank voor de financiële en inhoudelijke support vanuit PICASSO. Zonder die support was het COPD-GRIP onderzoek nooit van de grond gekomen.

Beste Alfred Sachs, ik heb een enorme waardering voor je. Je hebt me de afgelopen jaren geïnspireerd in het onderzoek naar ziektepercepties. Jouw heldere kijk als huisarts en als mens op zorg en onderzoek voor mensen met COPD was voor mij altijd een mooie spiegel voor mijn eigen gedachten. Ik ben je dankbaar dat je je wilde verbinden aan het COPD-GRIP onderzoek en mee wilde schrijven aan het artikel hierover.

Monique Heijmans, je bent later in het traject ingestapt. Ik ben enorm blij met je kritische blik en waardevolle adviezen. Zij zetten mij aan het denken. Dank dat je mee wilde schrijven aan twee artikelen.

Prof. dr. Ad Kaptein, dank voor je waardevolle input in de ontwikkelfase van het COPD-GRIP onderzoek.

Marijke Kars, wat een mooie tijd was de periode dat wij onze kamer in het Q-gebouw deelden. Jij schreef in jouw dankwoord over de mixed-methods op onze kamer die ons denken over zorg en onderzoek voedden. Alhoewel we de kamer niet meer delen, is de intentie gebleven. Gelukkig delen we nog steeds onze ideeën en ervaringen, zowel over onderzoek, zorg als andere gebeurtenissen in ons leven. Dat is voor mij van grote waarde, dank je wel.

Prof. dr. Mieke Grypdonck, destijds hebben we samengewerkt aan de ontwikkeling van een behoefte gestuurde richtlijn voor de vochtbeperking bij dialysepatiënten. Dat was een enorm inspirerende tijd waarin ik ontdekte dat ik me heel graag vastbijt in het wetenschappelijk onderbouwen van de verpleegkundige zorg. Dank dat u destijds het vertrouwen in mij had, en mij inspireerde om verder te gaan met onderzoek dat geleid heeft tot dit proefschrift.

Lieve Rianne, dank voor de prachtige omslag! Je bent in staat om woorden in beeld om te zetten.

Lieve vrienden en vriendinnen: Ellis, Richard, Dominique, Ineke, Gaby, Reneé, Ilse, Manon, Marc, Iris en Heleen, met jullie deel ik al heel lang lief en leed. Dank voor jullie medeleven in goede en minder goede tijden. Door de etentjes, koffiemomentjes, telefoongesprekjes, fietstochtjes en alle andere ontspanningsmomenten kon ik vaak alles weer veel beter relativeren. Het is een rijkdom jullie om mij heen te hebben!
Lieve Belinda, Lilian, Cathalijne, Petra en Jacqueline, dank voor alle bemoedigende en gezellige gesprekjes op het schoolplein en thuis aan de keukentafel.

Lieve Marieke Verkleij, ooit zijn we samen begonnen aan de faculteit Sociale Wetenschappen. Herinner je je nog ons eerste tentamen filosofie van wetenschap? Hadden we beiden alle verbanden en achtergronden bestudeerd, gingen de vragen alleen over de feiten. We zijn beiden onze richting gegaan en recent kruisten onze wegen weer binnen onderzoek bij mensen met longziekten. Ik hoop dat we nog lang vriendinnen zullen zijn!

Lieve Chantal, jaren geleden ontmoetten wij elkaar tijdens de epidemiologieopleiding. We bleken meer gemeen te hebben: we wonen vlakbij elkaar, en jij was ooit lid geweest van de zwemvereniging Aquarijn waar Yara ook zwemt. En niet alleen dat, ik herkende je ook van een foto met je behaalde bronzen zwemmedaille op de Paralympische spelen van Beijing. Sindsdien zijn we veel (levens)gebeurtenissen blijven delen, zelfs nu binnen het onderwijs van KGW. Jij weet als geen ander wat het betekent om onderzoek te doen, daarom vind ik het superfijn dat je 3 november achter me staat!

Lieve Evert, we delen veel in het leven. Zowel de liefde voor de zorg, de wetenschap als de liefde voor het leven. Ik ben zo blij dat ik je destijds tijdens de opleiding VW op de rug tikte met de vraag of je met mij wilde samenwerken aan een opdracht. Er is veel moois uit voort gekomen. Dank, dat je met Rajna en mij het avontuur wilde aangaan.

Lieve Emilia, je bent niet alleen mijn schoonzus, maar ook mijn steun en toeverlaat als ik weer eens worstel met een Engelse zin! Dank ook voor je enorme bijdrage in de vertaling van het FPI-instrument en de eerste CRF's.

Lieve Paul en Kata, ik vind het zo ontzettend jammer, dat jullie dit moment niet meer kunnen meemaken. Ik weet zeker dat jullie ervan hadden genoten. Paul vooral van de discussie tijdens de verdediging. Toen ik je destijds vertelde van mijn onderzoek, kwam je ineens heel trots je afstudeerscriptie van de studie geneeskunde laten zien. Voor die tijd was het iets heel nieuws, maar het zou me vast interesseren, zei je. Het ging over de vijf fases van rouwverwerking van de psychiater Elisabeth Kübler-Ross. Kata zou vooral genieten van alle feestelijkheden. In gedachten zijn jullie erbij!

Lieve Yvonne, lieve zus! Ik ben zo blij met jou! Jij voelt altijd precies aan wat ik nodig heb. Bij jou kan ik altijd (ook midden in de nacht) terecht. Daarom ben ik ook zo blij en trots dat je 3 november als paranimf achter me staat! Dank voor alles wat je voor me gedaan hebt. Ik zie uit naar alle mooie momenten die nog komen gaan.

Lieve pap en mam, dank voor alle steun in alle vormen de afgelopen jaren! Mam, toen mijn afstuderen in het gedrang leek te komen, stond jij klaar om op de meiden te passen zodat ik mijn scriptie kon afronden! Pap, jij stond altijd klaar om ons te helpen met allerlei klusjes waar wij niet altijd de tijd voor hadden. Jullie hebben altijd in mij geloofd, mij de ruimte gegeven om me te ontwikkelen en mijn keuzes in het leven gerespecteerd. Dat is zo waardevol! Ik ben zo ontzettend dankbaar dat jullie erbij zijn.

Lieve Jeroen, lieve broer, vanuit het voor mij vaak onbekende perspectief van marketing en brandmanaging heb je mij vaak onbewust aan het denken gezet over mijn onderzoek. Dank daarvoor! En dank voor je altijd luisterende oor als ik tot in

detail mijn ervaringen met je wil delen. Het is fijn om jou als broer te hebben!

Lieve Tom, Coen, Pepijn, Caroline, Lieve, Flore, Keeke, Tim en Matthew, dank voor alle support en de leuke en gezellige momenten! Het is een rijkdom om zoveel lieve familie om me heen te hebben.

En dat brengt me bij mijn drie dierbaren die het dichtst bij mij staan en dit hele proces het dichtste bij hebben meegemaakt. Yara, Dunja en Rajna weten als geen ander hoe onderzoek doen mij blij, gelukkig, boos of gefrustreerd kan maken. Jullie zijn er altijd om alle momenten hierin met mij te delen en laten mij ervaren wat er werkelijk toe doet in het leven. Wat een rijkdom om iedere dag bij jullie thuis te komen en het leven met jullie te delen! Ik hou van jullie!
Lieve Yara, je hebt een enorm analyse talent. Zo en passant tijdens het eten heb je me al een aantal mooie vragen gesteld, die zouden passen in een proefpromotie! En wat was ik blij dat je mij hielp met de opmaak van het manuscript voor de leescommissie en het maken van de adreslijsten. Dank je wel. Het is een heerlijkheid om te zien hoe jij verder groeit en je ontwikkelt! Geniet van het zwemmen en het avontuur in het leven.
Lieve Dunja, met jouw grote gevoel voor humor weet je niet alleen mij, maar ook Rajna en Yara altijd aan het lachen te brengen. Dat is fijn, want het geeft een mooi evenwicht als ik soms weer eens te serieus ben. Het is fijn en leerzaam om aan jou mijn onderzoek uit te leggen. Het is een genot om te zien hoe groot je wordt en je je ontwikkelt. Geniet van het paardrijden, het dansen en het avontuur in het leven.
Lieve Rajna, wat leven we toch een mooi leven! Samen hebben we zoveel mogelijk gemaakt! Dank voor meelopen op dit pad van mijn promotie. Je steunt me onvoorwaardelijk, stimuleert me om door te gaan en geeft me de ruimte die nodig is. Je bent mijn grote liefde en ik weet zeker dat we samen nog meer mooie avonturen gaan beleven!

Chapter 9

Curriculum Vitae

Saskia Weldam was born January 5th 1971 in Vianen, the Netherlands. After graduating from the secondary school at 'Cals College' in Nieuwegein, she worked as a volunteer in a shelter for homeless women and children at the Convent of the Sisters 'Augustinessen of Saint Monica' in Paris, France. Subsequently, she obtained her propaedeutics in Social Sciences at the University of Utrecht and started her nursing education ('A-In service' program) at the University Medical Center Utrecht in 1993. Her interest in respiratory nursing science was aroused during her work as a nurse student at the respiratory department of the University Medical Center Utrecht. After finishing her nursing education in 1997 she continued working at this department for five years. She continued her studies at Maastricht University, obtaining her Master of Science degree in Health Science (Cum Laude) in 2004, having specialized in Nursing Science. During this study she got the opportunity to focus more on research. Under supervision of professor Mieke Grypdonck she completed a qualitative research project on developing and testing a clinical guideline for self-management related to fluid restriction in dialysis patients. From 2003 to 2005 she participated as a junior researcher in a research project on the development of evidence-based nursing guidelines for stroke patients. In 2005 she started working as a nursing scientist at the respiratory department of the University Medical Center Utrecht and in 2010 she was invited to start a PhD project, under supervision of professor Jan-Willem Lammers and professor Marieke Schuurmans, which resulted in this thesis. In the summer of 2012 she received a grant from Partners in Care Solutions (PICASSO) for development and evaluation of a comprehensive nursing intervention in COPD patients. She obtained a Master of Science degree in Epidemiology at the Utrecht University Graduate School of Life Sciences in 2012.

Since 2013 she is also a lecturer in the Masters program of Clinical Health Sciences in Utrecht and since 2016 she participates in the Professional Advisory Committee of the European Lung Foundation.

Saskia Weldam continues her research activities at the respiratory department of the University Medical Center Utrecht.