Multiple symptoms in COPD

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Foreword

Since I finished my nursing degree 11 years ago, I have been working with people suffering from lung diseases. This has mainly been at a medical lung ward and at an outpatient unit where I work as a respiratory nurse. Lung function testing and lung rehabilitation have been my main task during the last 10 years. Through my work I have been talking to many people with COPD. Their struggle to live their life in spite of the symptoms they experience has made a strong impression on me and motivated me to get a broader picture of their problems in order to give better help.

I have chosen to write this master thesis in two parts. The first part contains introduction, theoretical background and a presentation of the method used in this cross-sectional study. The second part is written as a paper. The central point here is data, analysis and discussion around the analysis. We have chosen to write the paper tailor made for the Journal of Advanced Nursing (Appendix A).

This work has taught me a lot professionally regarding scientific methods, theory and the more technical aspects of writing a paper.

It would not be possible to do this project or write this master thesis without help.

I gratefully acknowledge my main supervisor Professor Astrid K. Wahl. She has guided me steadily from the start of the project through the accomplishment of the study and the writing of the cape and the paper for this thesis. I would also like to thank Professor Christine Miaskowski from the Schools of Nursing, University of California, San Fransisco. The study for this thesis is part of an expanded project. Christine Miaskowski has taken part in this project with guiding and ideas from the outset and she is also a co-author on the paper of this thesis.
This work was performed at Lovisenberg Diakonale Hospital in Norway. I am grateful to the hospital for making it possible to carry out this work. Anne Marit Tangen, head of Medical Department at the hospital has given me permission to

perform the project on patients at the hospital and has given me time off from my main tasks at work in order to accomplish it. I also wish to thank all the participants who have made this project possible.

Special thanks to the head of the outpatients' ward, respiratory nurse Elise Austegard. She has supported the work through the whole period and positively made it practicable to carry out the work. I gratefully acknowledge Tor E. Erikstad, respiratory physician at the hospital. He has been the main doctor on the project and has taken care of the participants when necessary. Also thanks to Kari L. Johansen, respiratory nurse for checking the plotting of data in SPSS and performing some of the tests of the participants. She has given me grate support as well. Great thanks to my dear colleague with whom I share office, Martha Lein, respiratory nurse who has been very supporting through the process.

My sincere thanks to my family for patience and support all through this work.

Abbreviations

ATS	American Thoracic Society
BIP	Brief Pain Inventory
COPD	Chronic Obstructive Pulmonary Disease
ERS	European Respiratory Society
FEV1	Forced Expiratory Volume in one second
FEV%	Forced expiratory Volume % = FEV1/FVC
FVC	Forced Vital Capacity
GOLD	Global Initiative for Chronic Obstructive Lung Disease
GSDS	General Sleep Disturbance Scale
HAD	Hospital Anxiety and Depression Scale
HRQL	Health Related Quality of Life
LFS	Lee Fatigue Scale
MRC	Medical Research Council scale
RQLQ	Respiratory Quality of Life Questionnaire
SD	Standard Deviation
SF-36	Short Form 36 question
SMM	Symptom Management Model
SGRQ	St.George Respiratory Questionnaire
SpO2	Arterial oxygen saturation measured by pulse oximetry (%)

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Abstract

Aim: The aim of this study was to explore the relationships between demographic and clinical variables, and multiple symptoms such as breathlessness, depression, anxiety, fatigue, insomnia and pain in COPD.

Background: Although research in COPD often has focused on single symptoms there is a lack of knowledge about possible associations with multiple symptoms.

Methods: A total of 154 COPD patients participated in a cross-sectional study from June 2006 to December 2007. All performed pulmonary lung function tests and completed a questionnaire that included demographic variables, Brief Pain Inventory, Hospital Anxiety and Depression Scale, Lee Fatigue Scale, General Sleep Disturbance Scale and Respiratory Quality of Life Questionnaire. Co-morbidity and medication were collected from their medical records. The following analysis method was used: descriptive, bivariate correlation and multiple regression analysis.

Results: With regard to demographic variables, age was significantly related to breathlessness, fatigue, insomnia and pain. Education was significantly related to depression and anxiety. Smoking was significantly related to anxiety, depression and pain. Co-morbidity was significantly related to breathlessness.
Bivariate relationships showed that breathlessness, depression, anxiety, fatigue, insomnia and pain were significantly related to each other. In the multiple regression analysis, lung function was related to breathlessness and insomnia. Breathlessness was the most significant symptom associated with the other symptoms after controlling for demographic and clinical variables.

Conclusion: Breathlessness is a significant symptom associated with depression, anxiety, fatigue, insomnia and pain. Results from this study may suggest an expanded focus on multiple symptoms in COPD guidelines, health care and research.

Sammendrag

Mål: Målet med studien var å undersøke sammenhengen mellom tung pust, depresjon, angst, trøtthet, søvnvansker og smerte hos personer med KOLS

Bakgrunn: Forskning innen KOLS har primært fokusert på ett symptom av gangen, men det er lite kunnskap om mulige sammenhenger mellom flere symptomer. Teoretisk rammeverk som symptomhåndteringsmodellen kan gi innsikt i forståelsen av ulike sammenhenger mellom symptomer.

Metode: Totalt deltok 154 personer med KOLS i tverrsnittstudien i perioden juni 2006-desember 2007. Alle gjennomførte lungefunksjonstest og fylte ut spørreskjema som inkluderte demografiske variable, Brief Pain Inventory, Hospital Anxiety and Depression Scale, Lee Fatigue Scale, General Sleep Disturbance Scale og Respiratory Quality of Life Questionnaire. Informasjon om sykdommer og medisiner ble hentet fra journal. Følgende analysemetoder ble benyttet: deskriptiv statistikk, bivariate korrelasjonsanalyse og multiregresjonsanalyser.

Resultat: Alder viste signifikant sammenheng med tung pust, trøtthet, søvnvansker og smerte. Utdannelse viste signifikant sammenheng med depresjon og angst. Røyking viste signifikant sammenheng med angst, depresjon og smerte. Antall sykdommer viste signifikant sammenheng med tung pust.
Bivariate korrelasjon viste at tung pust, depresjon, angst, trøtthet, søvnvansker og smerte var signifikant assosiert med hverandre. I multiregresjonsanalysen hadde lungefunksjon sammenheng med tung pust og søvnvansker. Tung pust viste størst signifikant sammenheng med de andre symptomene etter å ha kontrollert for demografiske og kliniske variable.

Konklusjon: Tung pust er det mest fremtredende symptomet hos personer med KOLS og viser sammenheng mellom symptomer som depresjon, angst, trøtthet, søvnvansker og smerte. Resultatene fra studien tilsier at det kan være formålstjenlig å fokusere mer på multisymptomer i guidelines, behandling og forskning.

1. Introduction

Chronic Obstructive Pulmonary Disease (COPD) is known to be a slowly progressive disorder with airflow obstruction that does not change (Bourke, 2007). Smoking over time can bring on this obstruction. Until recently there has not been much focus on COPD, even though the term COPD has been known since 1959 (Rabe, et al., 2007). Few people have been familiar with this diagnosis and the consequences smoking has had for it (Petty, 2006). It is estimated that a total of 5.4% (about 200 000) of the Norwegian population suffers from COPD (Helse-og omsorgsdepartementet, 2006). World wide there is estimated to be 80 million people with COPD. Morbidity and mortality are a major result of the disease, and the situation is expected to get worse in the future (Hurd, 2000). COPD is also stated to be a costly disease for the health service (Rabe, et al., 2007).

Global Initiative for Chronic obstructive Lung Disease (GOLD) (Rabe, et al., 2007) and American Thoracic Society (ATS) Standard for the Diagnosis and Management of Patients with COPD (ATS/ERS guidelines, 2004) are guidelines that are used in diagnosing and helping COPD patients. These guidelines have narrow focus on symptoms other than disease characteristics as breathlessness, dyspnea and sputum (Walke, et al., 2007). However the patients themselves subjectively may feel they have got several symptoms. Clinically it is difficult to treat and help COPD patients to live well with their chronic disease. Would it help if the health service to a greater extent could focus on psychosocial symptoms?

Studies show that lung function signs such as FEV1 have less or no association with symptoms of psychological and social characteristics. Dyspnea is almost the only symptom found to be associated with FEV1 (Mahler, et al., 1992). Dyspnea has however shown an association with depression (Kellner, et al., 1992). Another study reports that FEV1 correlated with dyspnea and physical function but not with anxiety (Cully, et al., 2006). Depression and anxiety are also often found to be of close association (Mikkelsen, et al., 2004). Both insomnia (Kutty, 2004) and fatigue

(Theander, et al., 2004) have been reported as highly relevant symptoms in COPD. The amount of 32.2% of persons with end stage COPD have reported pain (Rabow, et al., 2005). Although the symptom pain has not been much focused in COPD science, one study has shown that breathing difficulties have a relationship with pain using a health quality of life questionnaire. Predicted FEV1 and pain showed no significance in the same study (Mahler, et al., 1995).

The studies mentioned above illustrate that most of the research on symptoms in COPD have been directed towards one single symptom or a few symptoms in one and the same study. Actually only one study has focused on the symptoms dyspnea, anxiety, depression, fatigue and sleeping problems in COPD (Kapella, et al., 2006). The symptoms dyspnea, depression, anxiety, insomnia, fatigue and pain in COPD have never been investigated in one and the same study.

Understanding and management of symptoms is complex. One symptom could influence other symptoms and several factors could have an impact (Miaskowski, et al., 2007). Different models have been developed to understand symptoms. The Symptom Management Model is a theoretical framework that may help understanding symptoms in a biopsychosocial approach (Dodd, et al., 2001a). This model is based on earlier research in oncology (Dodd, et al., 2001a).

We know from studies in oncology that multiple symptoms as pain, fatigue and depression are associated (Dodd, et al., 2004). Reports show that multiple symptoms are influenced by demographic variables and sickness characteristics (Miaskowski, et al., 2006). This kind of association may also be found in COPD.

To be able to meet the challenge of helping COPD patients with their problems, we need to know more about multiple symptoms. Focusing on multiple symptoms could help us understand more about their special nature and combinations. This would improve our knowledge about the association with possible signs of illness and the different demographic variables in COPD.

On this background this study will focus on multiple symptoms in COPD such as breathlessness, depression, anxiety, insomnia, fatigue and pain.

1.1 Research question

Through an explorative study we searched for an answer to the question:

1. *What is the relationship between the demographic variables smoking, co-morbidity and lung function and multiple symptoms (breathlessness, depression, anxiety, insomnia, fatigue and pain)?*

2. What is the relationship between breathlessness and depression, anxiety, insomnia, fatigue and pain, controlling for demographic and clinical variables?

2. Theoretical background

2.1 Chronic obstructive Pulmonary Disease (COPD)

Global Initiative for Chronic Obstructive Lung Disease (GOLD) was established in 1998. They have defined Chronic Obstructive Pulmonary Disease as characterized by airflow obstruction that is not fully reversible. The term implies two diseases: obstructive bronchitis and emphysema (Rabe, et al., 2007).
It has been stated that in some individuals with fixed airflow limitation it is difficult to differentiate asthma from COPD (Rabe, et al., 2007). The main difference is that Asthma has periods free from symptoms and shows normal spirometry values. COPD has more chronic characteristics of the symptoms breathlessness, cough, sputum, and it has seldom variable spirometry values. Asthma is believed to be more genetically related than COPD (Bourke, 2007). The study by Charles Fletcher in 1977 showed that smoking was the main reason for chronic airflow obstruction (Fletcher, et al., 1977). Recently other thoughts have been stated. One study shows that genetic factors independent of those related to smoking habits can play a role in development of chronic bronchitis (Hallberg, et al., 2007).

Because of the difficulties of distinguishing asthma from COPD, COPD has often been described as an umbrella term that includes chronic bronchitis, emphysema and chronic asthmatic bronchitis. Asthma is then described as a hyper responsiveness to a variety of stimuli in the airways (Petty, 2006), differing from COPD in pathology and clinical characteristics (Bourke, 2007). Chronic asthmatic bronchitis is in this way considered an overlapping diagnosis, but with different physiological mechanisms (Petty, 2006).

Chronic bronchitis implies that inflammation cells in the airways can lead to mucus hyper secretion, ciliary dysfunction and airflow limitation. The result is small airways causing airflow obstruction. This can again bring on hard breathing, cough and sputum (Bourke, 2007).

Emphysema involves a destruction of the small airways and the alveoli. Loss of elasticity can lead to collapse. The gas exchange between the alveoli and the blood can be altered. When the oxygen levels in the body fall, the respiratory centre in the brain reacts with dyspnoea (Bourke, 2007).

Some people with *asthma* develop fixed airflow obstruction. The reason for these changes is among other things mucous membrane thickening and increased airway smooth muscle. This can lead to the feeling of dyspnoea, cough and sputum. (Bourke, 2007)

The diagnosis of COPD is done by performing a lung function test, spirometry. Spirometry values with the combination of FEV1/FVC (FEV %) (4.3.1).should be under 70% before taking a bronchodilator. In order to confirm the diagnosis, information about medical history on dyspnoea, chronic cough, chronic sputum production and exposure to risk factors such as tobacco, dusts, chemical smoke from home cooking and heating fuels should also be considered (Rabe, et al., 2007). FEV1(4.3.1) is used to classify severity of COPD. GOLD has classified COPD in 4 stages:

- Stage I: Mild FEV1/FVC<70% , FEV1 ≥80% predicted
- Stage II: Moderate FV1/FVC <70%, 50% ≤ FEV1<80% predicted
- Stage III: Severe FEV1/FVC <70%, 30% ≤ FEV1<50% predicted
- Stage IV: Very Severe FEV1/FVC <70%, FEV1<30% predicted or FEV1<50% predicted plus chronic respiratory failure (Rabe, et al., 2007)

2.2 Definition of symptom, multiple symptoms, symptomcluster and sign

Symptom

The word "symptom" descends from Greek "to fall" and "together". In the 19th century it was described as the bodily or mental phenomena that a person experiences (Aronowitz, 2001). The sense of the definition has not been changed very much since the 19th century. It still implies the subjective phenomena. "Symptom" is experienced by the person himself. One definition of the term symptom is: "subjective experience reflecting changes in the biospychosocial functioning, sensations or cognition of an individual" (Dodd, et al., 2001a, p.669). The definition states a subjective feeling that could be associated with thoughts or with a feeling of changes in the body. This could for instance be the feeling of breathlessness as a result of obstruction in the airways (ATS/ERS guidelines, 2004). Symptom could also be changes of psychological function such as depression and anxiety and of sociological function as loneliness (Kara, et al., 2004).

Sign

The term sign was in the 19th century described objectively (Aronowitz, 2001). Today the definition is still objective, but it also contains information that the person himself can detect. The term sign has been defined as "any abnormality indicative of disease that is detectable by the individual or by others" (Dodd, et al., 2001a, p.669). This could be blue lips with dyspnoea or a lung function test as predicted FEV1.

Multiple symptoms

It is necessary to understand the meaning of the concept "multiple", in order to be able to describe the sense of "multiple symptoms". Webster's Dictionary defines the concept multiple as "having numerous aspects or functions" and " more than one" (Webster dictionary, 1983, p.779). Multiple symptoms could thus be understood as several symptoms detected by the person himself. However they are not necessarily synonymous. A person with COPD could for instance suffer from both dyspnea and

depression where dyspnea could be due to the disease and depression could be caused by a social situation, such as financial difficulties.

Symptom cluster

The term symptom cluster has a similar explanation as the concept multiple symptoms. The term symptom cluster is by Dodd et. al defined as three or more symptoms associated with each other and sharing the same variance. The symptoms in the cluster don't have to share the same mechanisms (Dodd, et al., 2004,p.465). This means that the cause of the symptoms could be different. In oncology patients fatigue can for instance be due to medication connected with treatment, pain caused by the disease and insomnia caused by pain. They then don't share the same mechanisms, but the symptoms could still be associated with each other in a cluster and share an explaining variance. Symptom cluster differs in this way from multiple symptoms by the amount of symptoms (being three symptoms or more) and by the fact that symptoms in a cluster should share the same explaining variance.

2.3 Definition of the concept: breathlessness, depression, anxiety, fatigue, insomnia and pain

The symptoms breathlessness, depression, anxiety, fatigue, insomnia and pain focused in this thesis can be described and defined in a different perspective. Several of these symptoms are often known as names of diseases. Depression for instance is one of the most prevalent disorders (Passer, et al., 2008), while generalized anxiety disorder has been found in 5% of people between 15-45 years old (Passer, et al., 2008) and chronic fatigue syndrome has the recent years been more known as a disease (Soderlund, et al., 2005). These sensations may be representative of a pathological state. Likewise breathlessness is known to be a symptom both in heart disorders and lung disorders. The exact difference between symptom and disease will in many circumstances be difficult to distinguish. The actual definition of symptoms concepts is complex and can be described in a biological, psychological and/or sociological perspective. In this study the persons own experience of the symptoms will be in focus.

Breathlessness

Dyspnea has been defined as the "sensation of difficulty of breathing" (Janssens, et al., 2000,p.379). Historically in many Greek texts asthma was described as abnormal breathing. During the 19th and 20th centuries asthma was reformulated from a symptomatic diagnosis to the name of a disease (Aronowitz, 2001).

Other words for dyspnea used in literature, by patients and health care are breathlessness and shortness of breath (Lindsey, et al., 1993). These words will be used synonymously in this master thesis.

Breathlessness or dyspnoea is probably the symptom mostly used within respiratory disease (Ambrosino, et al., 2004). The concept is a subjective experience of difficulties and uncomfortable breathing with a sensation of breathing problems and unpleasant stimuli (Lindsey, et al., 1993). The definition includes a personal reaction as well as a subjective experience.

Dyspnea often occurs with activity as light house work (Isoaho, et al., 1995), shopping and eating (Odencrants, et al., 2005). Dyspnea is often trigged by smoke-filled rooms, stress, environmental factors as weather, pollution, allergens and dust (Lindsey, et al., 1993). It can be difficult to avoid situations like these and the sensation of breathlessness can happen unexpectedly. Inability to manage active and social situations may cause hopelessness and loneliness. These situations can lead to immobility that may bring on worse attacks of breathlessness (Kara, et al., 2004). The subjective experience of breathlessness has been described as invisible symptoms and may be recognized by anxiety symptoms (Bailey, 2004). Continual respiratory infections often involve more breathlessness and can make the disease more severe (Wedzicha, et al., 2003). These are all subjective experiences of breathing difficulties that occur with different stimuli.

Depression

Depression is by Websters dictionary defined as "a state of feeling sad" (Webster dictionary, 1983, p.341). Sad is defined as "affected with or expressive of grief or unhappiness " (Webster dictionary, 1983, p.1035).

The definition of the concept involves the person's sensation of feeling unwell. This could be caused by a sense of loss or worthlessness, lack of support, anger, a feeling of helplessness or a negative self image. Most people experience depression symptoms like these from time to time in life (Atkinson, et al., 1990).
COPD patients can to a great extent feel that they have lost control of their lives. Friends and family who are healthy might react to their depressive symptoms and may withdraw from the depressed person (Kara, et al., 2004).
A lot of people with COPD have smoked or are still in the habit of smoking. People with COPD can have a negative self image due to shame from smoking or having smoked. This might be the reason why people with COPD do not seek medical help (Arne, et al., 2007).

The intensity and occurrence of depression symptoms over a long period could explain clinical depression. However, the specific definition of what is normal or abnormal behavior is vital in order to explain the difference of what is symptom and what is disease. "Abnormal behavior is statistically infrequent or deviant from the norm" (Atkinson, et al., 1990,p.591). A norm is usually a behavior in a certain society. Abnormality occurs when people don't recover when expected (Atkinson, et al., 1990).

Anxiety

Anxiety is defined as "an emotional state characterized by apprehension accompanied by physiological arousal and fearful behaviour"(Passer, et al., 2008, p.G-1).
An interpretation of the definition anxiety could imply a subjective experience of a physiological symptom. The feeling of physical sensations such as heart beat, chest pain, nausea, dyspnoea and headaches are anxiety symptoms. Anxiety can be trigged by fearful and threatening situations. This could be crowds gathered for instance at school or in other social situations. Anxiety can also occur when the person feels unable to cope with everyday settings (Atkinson, et al., 1990). Cognitive processes such as thoughts involving worries and threats can also give anxiety symptoms (Passer, et al., 2008). The anxiety-dyspnea circle illustrates that people who can not

breathe get anxiety symptoms causing more breathlessness (Bailey, 2004). Remembering an anxiety situation can lead to anxiety symptoms (Passer, et al., 2008). When anxiety happens in a situation that most people can handle it is considered abnormal and could be an anxiety disorder. In a stressful or threatening situation where most people feel anxiety this may however be a symptom (Atkinson, et al., 1990).

Depression and anxiety symptoms can often overlap, but it has also been stated that not everyone with depression symptoms experiences the same levels of anxiety (Sitsen, et al., 2003). In fact research has found both situations in COPD (Kellner, et al., 1992).

Insomnia

Insomnia is defined as a "symptom complex consisting of difficulty falling asleep, or staying asleep, or non refreshing sleep in combination with some form of daytime squealae" (Roth, et al., 2003,p.5).
Subjectively this definition implies that insomnia is a symptom caused by dissatisfaction with impaired sleep. It could mean that lack of sleep involves tiredness or not being able to sleep as long as wanted or having a satisfactory period of sleep all night.

Environmental factors such as light and noise can give impaired sleep. Personal worries can interfere with sleep and be the reason for insomnia. This can be due to acute situations as death in the family, conflicts at work, with family or friends, or worries about personal health. It is well known that psychological factors like depression, anxiety and poor quality of life can interfere with sleep quality (Kutty, 2004;Roth, et al., 2003). In fact the most common co- morbidity found among insomnia patients are psychiatric disorders. Insomnia can lead to fatigue, daytime sleepiness, short memory, impaired problem solving/coping (Lindsey, et al., 1993) The symptoms cough, mucus and breathlessness in COPD may give episodes of nocturnal dyspnea and frequent awareness (Roth, et al., 2003). The disruption in gas

exchange between the alveoli and blood in emphysema may increase ventilation, give hypoxemia and then disturb sleep (George, et al., 2003). Also medications such as corticosteroids and β-agonists are known to cause insomnia problems (Kutty, 2004).

Fatigue

Fatigue has been defined as "an overwhelming sustained sense of exhaustion and decreased capacity for physical and mental work" (Lindsey, et al., 1993,p.209). From this definition fatigue implies a sensation of being very tired and not being able to concentrate, remember, think clearly, direct attention and cognitively perform different tasks (Lindsey, et al., 1993). Physical fatigue can involve different parts of the body. This can be a feeling of tiredness in legs when walking or in breathing muscles as a result of heavy breathing in COPD (Lindsey, et al., 1993).

A lot of circumstances can cause fatigue. This can be side effects of medication, diseases like multiple sclerosis, rheumatoid arthritis, cancer, AIDS , chronic fatigue syndrome, but it may also appear as an energy imbalance in daily living activities (Lerdal, et al., 2005).

Pain

Pain has been defined as " an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage"(Merskey, et al., 1994, p.210). The concept has a subjective implication, but limits it to a sensation that can be felt physically or emotionally because of tissue damage.

Pain is in this way a biological response of tissue damage leading to a feeling that may be sharp, squeezing, cramping or burning. The intensity varies widely between individuals in verbal manifestations, with age, and cultural related issues (Lindsey, et al., 1993). The intensity of pain can give other complications as sleep disruption (Merskey, et al., 1994). Pain is known to be very distressing. Depression is also thought to be a pathology causing pain and distress (Lindsey, et al., 1993). Previous experiences may interfere with pain (Atkinson, et al., 1990). People, who have

previously suffered pain, may also have acquired strategies for mastering their discomfort. In this way previous experience may influence cognitive mechanisms of pain experience (Bandura, 1997). Pain experience can also interfere socially in daytime activities. In COPD the feeling of pain can be related to pain in the breast, and be explained by thorax and intercostals muscles (Rabe, et al., 2007) and associated with headaches with hypoxemia (Ozge, et al., 2006).

2.4 Symptom model - Biopsychosocial approach

Different frameworks have been developed to understand and study symptoms. The Middle-Range theory of unpleasant symptoms, The Symptom Experience Model, The Symptom Interaction Framework and The Symptom Management Model are theories that have multiple symptoms interaction (Parker, et al., 2005), but with different goals (table 1). Below you will get an introduction to these multiple symptoms models and thereafter the chosen model will be presented in detail.

Each model can be interpreted to have different components of a biospycosocial approach. George Engel introduced the biopsychosocial model in 1977 (Borrell-Carrio, et al., 2004). The biopsychosocial approach describes health as more than lack of illness. You have to see the relationship between the concepts psychological, sociological and biological situations in order to understand health (Borrell-Carrio, et al., 2004).

Engel described the model as a linear cause-effect model (Borrell-Carrio, et al., 2004;Engel, 1979). There has been a lot of criticism of this model, but one in particular is that the clinical reality is more complex than the linear cause. There may be circular and structural causality (Borrell-Carrio, et al., 2004).

Table 1 -Multiple symptoms model

Model	Goal	Factors that influence the symptoms
The Middle-Range Theory of Unpleasant symptoms An update of The theory of unpleasant symptoms (Lenz, et al., 1997).	Presentation of the complexity and interactive nature of the symptoms experience.	Physiological factors, psychological factors and situational factors influence the symptoms. Intensity distress, quality and duration are the characteristics of the symptoms.
The Symptom Experience Model (Armstrong, 2003).	Understand the meaning of the symptoms experience.	Demographic characteristics, disease characteristics and individual characteristics are antecedents for the symptoms experience. The symptoms experience is influenced by situational meaning and existential meaning. The consequences are suggested to be: adjustment to illness, quality of life, mood, functional status, disease progression and survival.
The symptom Interaction Framework (Parker, et al., 2005).	Increased understanding of the multidimensional mechanisms underlying symptom pairs and cluster. The main focus is to se the interaction cause of symptom.	Biological domains, psychological domains, behavioural domains, sociocultural domains and a combination of mechanisms could explain symptoms experience and multiple symptoms.
The symptom Management model (Dodd, et al., 2001a)	To understand symptoms and use as a direction for interventions, informing research and help to see the association with variety of disease and conditions.	Symptoms experience, management strategies and outcomes are dimensions that are interrelated. Person variables, environment variables, health and illness variables are believed to influence these three dimensions. Person variables contain demographic, psychological, sociological, physiological and developmental characteristics.

The Middle-Range Theory of Unpleasant symptoms is an update of the theory of unpleasant symptoms. It shows a more interactive model than the current model which has been criticised to be linear. The model has a feedback loop from performance of the symptoms to influence of the symptoms, physiologically, psychologically and in situational factors. The theory explains and guides research of multiple symptoms. The model can seem to have a biopsychosocial function where

the biological factors derive from physiological factors, and the sociological factors are equivalent to situational factors (Lenz, et al., 1997). The performance of the symptoms is described as the outcome variables. However, factors as for instance quality of life, morbidity, co-morbidity, self-care and economic state have not been described in the model as outcome variables. These factors may also be important in order to influence the symptom experience and they can be a result of experiencing the symptoms.

The Symptom Experience Model aims for the subjectively perceived understanding of multiple symptoms. The experience of multiple symptoms can influence quality of life, functional state, psychological state, disease progression and survival (Armstrong, 2003). An interpretation of the theory describes factors involving biological domains (as disease characteristics), psychological domains (as mood, individual characteristics) and sociological domains (as demographic characteristics).
The model may be criticized for showing a one way direction of the factors influencing multiple symptoms. Furthermore it has not yet been tested out and it has been suggested to use a qualitative method for this approach (Barsevick, et al., 2006).

The Symptom Interaction Framework tries to focus on bringing in the multi dimensional mechanisms underlying the symptoms. In other words the main goal is to see the interaction cause of the symptoms (Parker, et al., 2005). The theory is related to symptom pairs and clusters and symptom interaction. Physiological, psychological, behavioural and sociocultural mechanisms are described to underlie the symptoms. Environmental and developmental factors are in context of the symptom. All this gives a clinical outcome (Parker, et al., 2005). The theory has not been tested out and interaction has not been defined. This may cause some confusion how to find the interaction.

2.4.1 The Symptom Management Model

The choice of model in table1 depends on the aim of investigation. In this study the purpose is to investigate multiple symptoms and evaluate which predictors can interfere with the symptoms. These situations are complex and therefore we need a model which can present the complexity and interconnection between predictors and symptoms. The Symptom Management Model (SMM) (figure 1) has been chosen because:

1. It illustrates and verbally describes important perspectives of the research questions in this thesis.
2. The model shows that factors of biology, physiology, psychology and sociology can influence a person's experience of symptoms.
3. The model visualizes that symptoms are outcomes of multidimensional indicators more than in the other models reviewed above. The illustration of The Symptom Interactional Framework is for instance not as characteristic as in the SMM. Because of the visual illustration of SMM it immediately seems to give more information which makes it practical to use when planning a research project. This will be shown later in 4.3.
4. The SMM contains more information about factors such as quality of life and co-morbidity than seen in the The Middle-Range Theory of Unpleasant symptoms. These factors are also believed to influence the symptom status (Dodd, et al., 2001a). It dose not have the linear construction found in The Symptom Experience Model.

The SMM has been developed on the basis of various research done in oncology patients (Dodd, et al., 2001a). It has not been tested out in many studies, but several studies have findings that are consistent with the theory. These papers have used the model to understand symptoms in angina (Caldwell, et al., 2000), HIV(Voss, et al., 2006) and oncology (Dodd, et al., 2001b;Dodd, et al., 2001a).

Figure 1. -The symptom Management Model

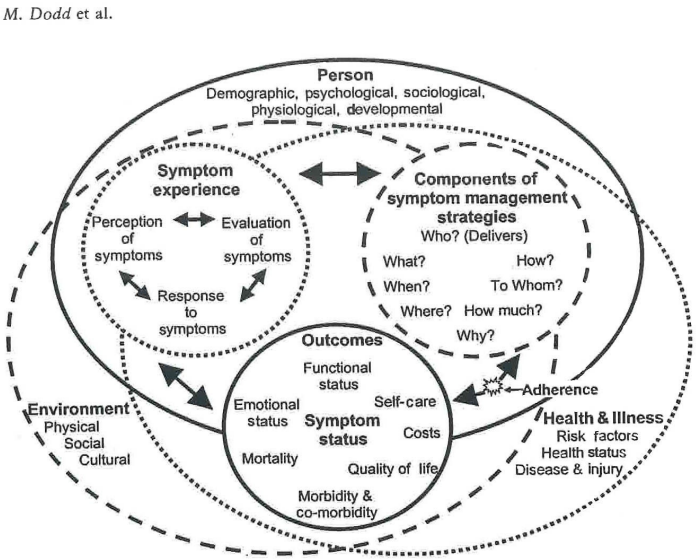


Figure 1 Revised Symptom Management Conceptual Model.

Person variables, environment variables, health and illness variables are believed to influence symptom experience, symptom management strategies and the outcome of the symptoms

Person domain contains variables that are important for an individual in order to discover and to respond to the symptom. These are demographic variables, psychological, sociological, physiological variables and developmental variables. These intrinsic variables may for instance be age and gender.

Health Illness domain includes risk factors, health status, disease and injury. People with genetic asthma are more at risk than others to develop COPD when exposed to smoke (Barnes, 2008). This could have a direct or indirect effect on the three components of the model: symptom experience, management and outcomes.

Environment domain in the model is cultural aspects, physical environment like home and work and social environment like friends. Other relationships could interfere with the three components of the model (Dodd, et al., 2001a). An example of this could be the tradition in some cultures of cooking by open fire inside the houses. Thus people are more at risk to develop symptoms of COPD (ATS/ERS guidelines, 2004).

Symptom experience is about a person's ability to perceive, evaluate and respond to the symptom.
The response to a symptom may be influenced by different causes. Being on sedative medication or being helped by a mechanical ventilator, a person with COPD could for instance fail to recognise the symptom breathlessness. Symptom experience, complexity of intensity, the location, the nature of the symptom, the frequency and the affective impact are factors that evaluate symptoms. Thus the response to the symptom influences the intensity of the symptom. The symptom experience dimension could be related to "illness perception". The equal components imply how a person percepts and responds to illness (Broadbent, et al., 2006) and symptoms (Dodd, et al., 2001a). A theory like this one could be used to further investigate and understand the influences on symptoms in COPD. Illness perception has been shown to be associated with coping strategies in COPD (Scharloo, et al., 1998).

The component of symptoms management strategies includes assessment of the symptom from an individual perspective. This could be efficacy strategies. Specifications of efficacy could be: what symptom, when and where the symptom was experienced, why does the person feel this symptom and how much does he experience of the specific symptom (Dodd, et al., 2001a). How people believe that they will manage to take care of a symptom could be called their self-efficacy thoughts. This is described in Bandura's self-efficacy theory (Bandura, 1977). For instance could a person with COPD get breathing difficulties when waiting for a bus at wintertime (many with COPD experience dyspnea when the weather is cold (Silkoff, et al., 2005)) If the person can manage this situation well this may result in better efficacy next time he is in a similar situation. In this way peoples self-efficacy can influence how to manage a symptom like breathlessness.

The *outcomes variables* emerge from symptom management and symptom experience. These outcome variables could be anxiety, depression, fatigue, insomnia, quality of life, mortality, co morbidity, functional state and the cost of being in need for economic finance from the health state/services (Dodd, et al., 2001a).

These factors could also be influenced by each other. In fact, several studies have found this. One symptom that is unrelieved could again influence other symptoms like in a cluster. The experience of variety of symptoms could also be associated with low score on quality of life (Dodd, et al., 2001a). These associations are also supported in Wilson & Cleary's Quality of life model. Here it is suggested that a person's characteristics and his environmental characteristic could influence biological variables, symptoms, function, general health and global quality of life. The biological variables could influence symptoms. Symptoms could in a two way interaction be associated with function, function with general health and general health with global quality of life (Osoba, 2007).

3. Studies

3.1 Previous research in COPD

The overviews of different symptoms in COPD studies are based on:
1. Symptoms association with each other and lung function
2. That the different symptoms association with demographic variables.

The number of papers illustrated in table 2 show the difficulties of getting a full picture of studies on symptoms in COPD. The literature search could have been done by limiting it to a period of years. However since some of the symptoms are well know (such as dyspnea) in COPD the relevant papers may be older than during the recent years. Table 3 will therefore summarize some of the previous research and papers in COPD

The search presented in table 2 and the papers presented in table 3 show that few studies have focused on more than three symptoms in COPD. Most of the studies performed on three symptoms are done on the symptoms depression, anxiety and dyspnea. Depression and anxiety have often been objects of research in the same study. This may be due to the close relationship of these two symptoms (2.3).

Table 2. PubMed search result

Illustration of search (words) in Pub Med (last search 14 of June 2008)	**Number of papers**
COPD dyspnea symptoms	2115
COPD dyspnea symptoms lung function	1159
COPD depression symptoms	209
COPD depression dyspnea symptoms lung function	64
COPD anxiety symptoms	356
COPD anxiety dyspnea symptoms lung function	64
COPD insomnia	37
COPD insomnia dyspnea symptoms lung function	4
COPD fatigue symptoms	320
COPD fatigue dyspnea symptoms lung function	105
COPD pain symptoms	30
COPD depression anxiety dyspnea symptoms lung function	45
COPD depression anxiety dyspnea fatigue sleep (not insomnia)	4
COPD depression anxiety dyspnea pain lung function symptoms	2
COPD depression anxiety dyspnea pain fatigue symptoms lung function	1
COPD depression anxiety dyspnea pain fatigue insomnia (or sleep) lung function Symptoms	0

Table 3.- Studies on symptoms in COPD

Keyword search in Pub Med	Relevant symptoms and variables	Author year	Research question	Sample	Type of design	Methods	Key findings
COPD dyspnea lung function symptoms	Dyspnea	(Wolkove, et al., 1989)	To investigate the relationship between lung function and dyspnea	93	Cross-sectional	Dyspnea questionnaire and pulmonary function test	Dyspnea is poorly correlated with lung function. The use of dyspnea rating may yield information about bronchodilator responsiveness not appreciated by spirometry alone.
COPD dyspnea lung function symptoms	Dyspnea	(Jones, et al., 2005)	Examines the rationale for quantifying breathlessness, functional status and health status and evaluates their application in COPD alongside measuring lung function and exacerbation frequency..	Not reported	Review	Dyspnea questionnaires and pulmonary function test	Main summery: Lung function and measurements of dypsnea, function status and health status are required to provide a complete picture of COPD. Dyspnoea is the predominant symptom of COPD
COPD depression anxiety dyspnea symptoms lung function	Dyspnea, anxiety and depression	(Schlecht, et al., 2005)	To evaluate the relationship between dyspnea and functional, psychosocial and quality of life parameters in COPD	90	Cross-sectional	Dyspnea, stress, anxiety, depression, personality quality of life questionnaire and pulmonary function test	Dyspnea correlated more strongly with HRQL and with anxiety and depression than with lung function.

COPD depression anxiety dyspnea symptoms lung function	Depres-sion, anxiety, dyspnea	(Chavannes, et al., 2005)	To reveal associations of depressive symptoms with demographic and clinical characteristics in middle to moderate COPD	147	Cross-sectional	Depression, anxiety questionnaire and pulmonary function test	Female and current smoking were associated with depressive symptoms. In a multivariate logistic model only female and dyspnea were independently associated with depressive symptoms
COPD insomnia	Insomnia	(Kutty, 2004)	Review of sleep disturbance in COPD	Not reported	Review of issues related to sleep and COPD	Review of sleep in COPD from different studies	Insomnia common in COPD, sleep apnea in COPD is high, nocturnal oxygen desaturation is common even in mild COPD
COPD insomnia dyspnea symptoms lung function	Sleep, respiratory symptoms as cough and wheeze	(Klink, et al., 1994)	To define the relationship among sleep complaints airways obstructive disease diagnosis and pulmonary function	1358	Epidemiologic study of Chronic Lung Diseases	Lung function and designed questionnaire about what kind of disease and symptoms (cough; wheeze during day and nigh time)	Significant relationship between respiratory symptoms and sleep complaints. Comments: Those with lung function < 60% had more symptoms.

COPD fatigue symptoms	Fatigue	(Theander, et al., 2004)	To describe the prevalence of perceived fatigue on everyday life.	36 patients and 37 controls	RCT	Fatigue questionnaire.	Significantly more fatigue every day, duration of fatigue and worse or one of the worst symptoms they have had in COPD group compared with control group.
COPD fatigue dyspnea symptoms lung function	Fatigue, dyspnea, sleeping difficulties	(Reishtein, 2005)	Use the theory of Unpleasant Symptoms to determine the interrelationships and relative contributions of dyspnea, fatigue and sleep difficulties to functional performance in COPD.	100	Cross-sectional	Functional and sleep questionnaire, fatigue and dyspnea scale and clinical variables collected from the chart.	Only dyspnea was related to fatigue, sleeping difficulties and functional performance. After controlling for age and oxygen only dyspnea was to predict variance.
COPD dyspnea fatigue depression lung symptoms lung function	Fatigue, depression and dyspnea	(Breslin, et al., 1998)	To determine the relationship between fatigue and pulmonary function, exercise tolerance, depression and quality of life in COPD.	41	Cross-sectional	Fatigue, depression and quality of life questionnaire and dyspnea scale and pulmonary function test.	General fatigue and physical function, exercise tolerance, depression and quality of life were associated. Mental fatigue and general fatigue correlated with depression.

COPD pain dyspnea	Pain, dyspnea	(Solano, et al., 2006)	To determine to what extent patients with progressive chronic diseases have similar symptom profiles. (end-stage patients with cancer, AIDS, heart disease, COPD and renal disease).	64 studies	Search in MED-LINE, EM-BASE, Psyc INFO	Studies reporting 11 symptoms (pain, confusion, delirium, cognitive failure, depression, low mood, sadness, anxiety, dsypnoea, dyspnea, breathlessness, fatigue, weakness, anorexia, nausea, diarrhoea, diarrhea, constipation, insomnia poor sleeping).	Pain, breahlessness and fatigue were found among more than 50% of patients for all diseases.
COPD pain dyspnea	Pain, fatigue, dyspnea	(Klinkenberg, et al., 2004)	To investigate symptom burden last week of life.	270	Interview with close relatives	Symptom burden scale conducted (fatigue, shortness of breath, pain, confusion, anxiety depression, nausea and vomiting).	Cancer patients and patients with COPD had the symptoms fatigue, pain and shortness of breath.

COPD quality of life dyspnea	Pain, dyspnea	(Mahler, et al., 1995)	To evaluate health related quality of Life in COPD.	50 male	Observa-tional data at a single point in time	Quality of life and dyspnea respiratory questionnaire and pulmonary function test.	SF-36 is a valid instrument to measure HRQL in COPD. Comment: The pain index was significantly correlated with dyspnea and not with lung function.
COPD fatigue dyspnea sleep depression anxiety symptoms lung function	Fatigue, dyspnea, insomnia, anxiety, depression	(Kapella, et al., 2006)	To describe characteristics of fatigue in COPD and test the theory of unpleasant symptoms of the relationships' among subjective fatigue, dyspnea, function performance, anxious and depressed moods and sleep quality in COPD.	130	Cross-sectional	Fatigue , dyspnea, mood, sleep, functional questionnaires and pulmonary function test.	Dyspnea was slightly greater than fatigue and there was a strong relationship between fatigue and dyspnea. Dyspnea, depressed mood, and sleep quality accounted for 42% of the variance in subjective fatigue. Fatigue, dyspnea, airflow obstruction, and anxious mood accounted for 36% of the variance in functional performance.
COPD dyspnea fatigue sleep anxiety	Fatigue, dyspnea, insomnia, anxiety, depression, age	(Kinsman, et al., 1983b)	Frequency of occurrence of symptoms examined in relation to demographic factors, type of disease, pathophysiologic measures and functional capacity.	146	Cross-sectional	Symptom questionnaire	In decreasing order, symptoms of dyspnea were followed by symptoms of fatigue, sleep disturbance, congestion, irritability, anxiety, decathexis, helplessness-hopelessness, poor memory, alienation. Younger people reported more anxiety and irritability than older people.

Co-morbidity, education, COPD	Co-morbidity, quality of life, education	(van Manen, et al., 2001)	Influence of co.morbidity on health-related quality of life in COPD patients.	659	Cross-sectional	Health quality of life questionnaire, questions about diseases, education and pulmonary lung function test.	Health related quality of life partly explained co-morbidity. Comments: 86% had low education.
Co-morbidity, COPD	Co-morbidity, anxiety, depression, age	(Hynninen, et al., 2007)	Factors associated with health status.	58	Cross-sectional	Anxiety, depression, sleep quality, health related questionnaire and pulmonary function test.	Severity not related to health status. Health status related to anxiety, depression sleep disturbance and daily functioning. Statistically significant differences between men and women on COPD severity, age and anxiety.

3.2 Other studies on multiple symptoms

As for other disabilities like Diabetes Mellitus (Hammer, et al., 2003) and Perimenstrual diseases (Taylor, 2005) there are examples of how multiple symptoms can be clustered. However most of the research done on multiple symptoms the recent years has been done in oncology (Dodd, et al., 2004).

Fox et. al. explored the prevalence and intensity of depression, fatigue, and pain in survivors of lung cancer. Depression, fatigue and pain were found in the majority of the patients. Fatigue was the most intense symptom. The cluster explained 29% of the variance of quality of life in lung cancer (Fox, et al., 2006).

Miaskowski et. al. investigated outpatients with cancer based on their experience on fatigue, sleep disturbance, depression and pain. Four subgroups were found. The subgroup reporting low level of all symptoms also reported best functional status and quality of life (Miaskowski, et al., 2006).
These findings show how multiple symptoms in a complex way can have an impact on circumstances of in life. Osoba has suggested that measuring multiple symptoms are important factors in measuring quality of life (Osoba, 2007).

4. Material and methods

4.1 Setting

This study was performed at an urban community hospital in Norway "Lovisenberg Diakonale Sykehus". The hospital has 293 beds and is one of the largest private hospitals in Norway. The hospital is one of four sector local hospitals in Oslo. Psychiatry, internal medicine and surgery are the main departments in the hospital. The area has a population of about 135 000 among which is an ethnic minority group (Lovisenberg Diakonale Sykehus, 2008)

4.2 Design

The study has a cross-sectional design. The participants filled out a booklet with demographic questions and standardized questionnaire tools (Appendix B). Lung function test, spirometry, was performed.

4.2.1 Project: "Symptomcluster, self-efficacy and quality of life for people who suffer from COPD"

This thesis is part of a larger study: "Symptomcluster, self-efficacy and quality of life for people who suffer from COPD". The symptom management model has been useful in designing the project. In this study the following components of the Symptom Management Model have been covered by different standardised questionnaires: symptom experience, symptom management strategies and the outcome symptoms and quality of life. Further the project patients have performed a 6 Minute walk test.

4.2.2 Analysis

SPSS statistical package version 14.0 was used in the analysis. Descriptive analysis by frequency mean and SD were used on demographic variables. Correlation analysis were used to detect association between the variables. A hierarchic multiple regression analysis was constructed in 3 steps. These steps were based on considerations in the research question. The variables age, gender, education, smoking history, co-morbidity (step 1), + predicted lung function (step 2) and + breathlessness (step 3) were put into the equation on each step.
Statistic normality, linearity and homosecedasiticity were tested and satisfactory assumptions were met (Pallant, 2005). Each independent variable was regressed on all of the others and the level of multi-collinearity ($r>0.70$) was acceptable (Pallant, 2005).

4.2.3 Sample size

There are many variables included in this project. It is therefore difficult to calculate the sample size based on screening instruments. However, in the project "Symptom cluster, self-efficacy and quality of life for people who suffer from COPD" the plan is to identify symptomclusters and in this thesis to perform a multiple regression analysis. The sample size required is therefore based on these analyses. Symptomcluster analyses have not been done in COPD before, but according to SPSS survival manual about 150 participants will be adequate (Pallant, 2005). The question of how many variables will be necessary in a multiple regression analysis is based on the principle of 10 persons per variable (Pallant, 2005). The multiple regression analysis in this thesis has 8 variables. On this background a number of 150 persons is adequate.

4.2.4 Inclusion criteria

The inclusion criteria were:

- All stages of COPD diagnosed in the journal
- Able to read and write Norwegian
- 30 years and older

4.2.5 Data collection procedure

On a list of 507 people with the diagnosis of (number) COPD, 392 matched the criteria to be included in the project. The patients were sent an invitation letter during the period June 2006-December 2007 (Appendix C). Sixty invitations were sent out every time (5 times). In the final round 92 invitations were sent out. After three weeks a reminder was sent to those who had not accepted. Among those who did not accept 31 people declined and 193 did not respond to the invitation. A total of 168 accepted the invitation (Appendix D). Out of these two patients were not able to fill out the questionnaire, 6 patients withdrew the acceptance, 2 patients did not return the questionnaire and 4 patients did not meet for the appointment at the outpatient unit. 154 (response rate 39%) of these participated in the project.

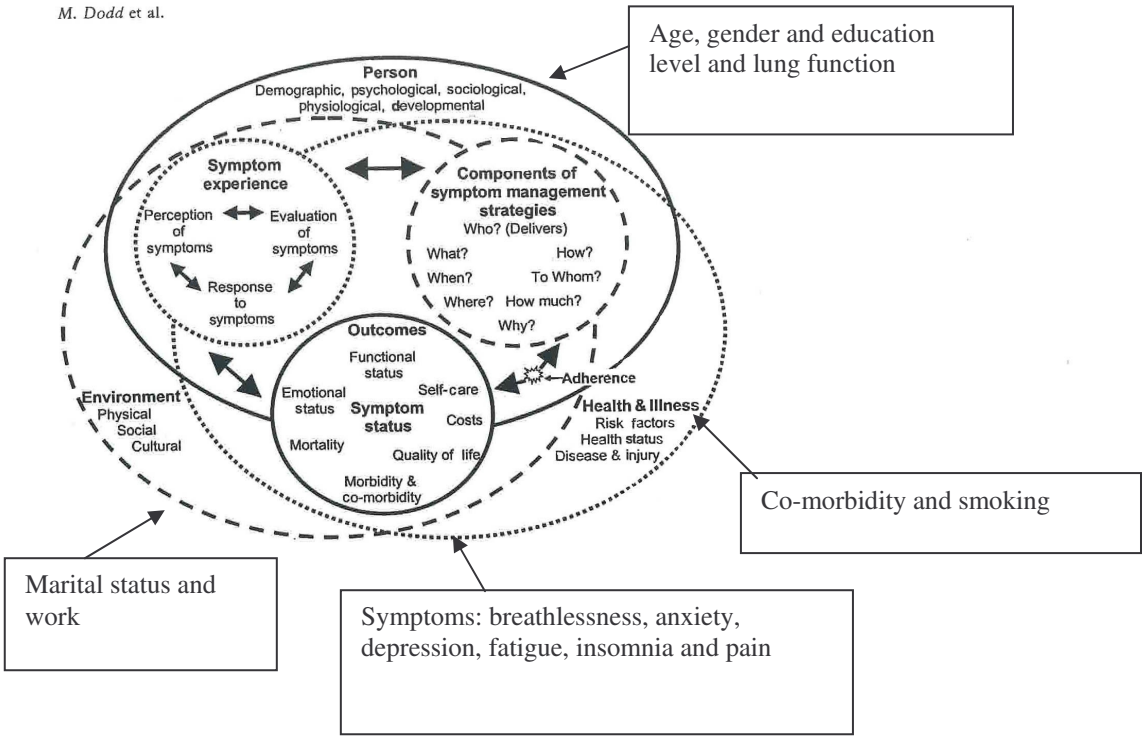
The participants were phoned after having accepted. An appointment was made for taking spirometry before and after a broncodilatator (Ventoline Accuhaler 0.2 mg x 2). A letter with the appointment time and the questionnaire booklet was sent to the participants, which they filled out and brought back to the appointment with a respiratory nurse. It took about one to three weeks from the time the booklet was sent to the appointment at the hospital. Some of the participants cancelled their appointment with the major cause being due to an infection or an exacerbation. Then it took longer from the booklet was filled out until the appointment at the hospital. They were then asked to look over the questionnaire to see if there were questions they would answer differently. If there was a lot of questions they had not filled out, the respiratory nurse pointed them out and left the room for them to answer without interference. It took about 45 min to 1 ½ hours to fill out the questionnaire, but some

of the participants reported that they had needed 2 hours. At the appointment the project patients were able to ask questions about their COPD, medication and spirometry values. If necessary the respiratory doctor was contacted. Some of the patients needed extra treatment and were followed up at the outpatient unit by the respiratory doctor and the respiratory nurse. This was relevant if they could benefit from medication treatment or if respiratory failure was suspected and oxygen treatment would be needed. A note was written in their journal for those who required treatment.

4.3 Instruments

The parts of the symptom management model put to use in this project are illustrated in figure 2. Some of the variables can be interpreted to issues from several parts of the figure. In order to find the variables, lung function test spirometry, self-report of demographic questions and standardized questionnaires were carried out.

Figure 2. – Illustration of variables put to use



4.3.1 Spirometry measurement

Spirometry is a test that measures physiological signs of how an individual inhales and exhales (Pellegrino, et al., 2005). The diagnosis COPD is identified by spirometry with the measurement of FEV1 (forced expiratory volume in one second) , FVC (forced vital capacity) and the ratio between these two measurements FEV% (FEV1/FVC) (Pellegrino, et al., 2005;ATS/ERS guidelines, 2004).
A V-max spirometry was used for performing spirometry. This spirometer has Europeans reference values as standard.
All of the test participants performed the spirometry test in the way the "standard procedure of spirometry" test describes: "1) maximal inspiration; 2) a blast of exhalation; and 3) continued complete exhalations to the end of test".
A nose clip was attached and the lips of the patient were closed around the mouthpiece during the whole test procedure. The test was repeated for a minimum of three times. If the patient felt dizzy the test was stopped or not repeated. To be sure that the spirometer gave correct measurements it was calibrated with measured volume within ± 3,5 % using a 3-L syringe (Pellegrino, et al., 2005). The participants were told not to inhale medication 4 hours before the test. This is a normal procedure to obtain spirometric values that are not influenced by medication, but also to be able to test medication effect (Pellegrino, et al., 2005).

4.3.2 Measure of demographic variables

Sociodemographic characteristic questions about gender, age, material status, education, employment, smoking status and living status were asked in the first part of the questionnaire booklet.

4.3.3 Data from the medical record

A separate worksheet used by the tester contained information about co-morbidity, how long they had been suffering from COPD and about medication. The information was found in the medical record.

4.3.4 Symptom measurement

The second part of the questionnaire booklet contained a selection of instruments measuring the different symptoms (table 4). The instruments were selected on basis of other studies in COPD and multiple symptom research in oncology. It was important that questionnaires were considered relevant to the symptoms. Since we were supposed to investigate many variables it was important to choose instruments that were easy to use. Because few studies have focused on multiple symptoms in COPD it was important to choose instruments of general nature. In this way it would be possible to compare with other populations. The author has asked permission to use the different questionnaires from those responsible for the tools in Norway.

Unanswered questions

Some of the participants had not answered all the questionnaires. These items were left unanswered when plotting this in SPSS. The same procedure was used for those who had answered two places in the same item. In order to calculate a sum score for the different symptom assessment scales respondents needed to answer 80 % of the items within each scale. As for the symptom pain this was not done due to the manual (Klepstad, et al., 2002).

Reliability

To be sure of getting the relevant answer to the research question the tools used in this study must be reliable. Internal consistency using Cronbachs alpha is commented in each questionnaire. Cronbachs alpha involves estimating homogeneity between the different question on the same scale (Polit, et al., 2004). Questions that don't belong to the issue can then disturb the internal consistency. Cronbachs alpha value goes from 0 to +1 (Polit, et al., 2004). A value above 0.7 as in this study is considered satisfactory (Pallant, 2005).

Validation

Instruments with rating scales have limitations caused by the person's capacity to report, the characterization of the measurement and the boundaries imposed by the instrument. This may implicate the study and make the result of a study using instruments like this uncertain. Validation of the tool may give some insurance if the tool measures what it is suppose to do.

RQLQ has only been used once in COPD. The construct validity was performed by comparing association between another health quality of life questionnaire. It was found to be highly correlated(Stavem, et al., 1999)

GSDS has been validated among Chinese American parents with hospitalized infants. Concurrent validity was demonstrated and the instruments were found suitable to measure sleep among Chinese American population(Lee, 2007). It has been used in oncology, but not validated. However it had proved to bee useful in this group to measure sleep disturbance (Miaskowski, et al., 2006).

LFS has been tested in cancer patients. When comparing it with other fatigue instruments LFS has been supported to be valid (Meek, et al., 2000).
BPI was validated in oncology patients in Norway (Klepstad, et al., 2002). Because 2-factors solutions were loaded together, 3-factors were found. This 3- factor model is pain intensity, interference with physical function and interference with psychological functions/sleep (Klepstad, et al., 2002).
Because it seemed to be a tradition to use a 2- factor solution in several other studies this was used in the present study as well.

HADs has been used in several studies including COPD. Concurrent validity of HADS compared to other measuring tools has had various results, but conclusively it can be accepted as a good tool to assess symptoms of depression and anxiety (Bjelland, et al., 2002).

Table 4. – Questionnaires

Questionnaires	Subscale measure	Question	Translation and internal consistency	Why used in this study
Respiratory Quality of Life question-naire (RQLQ) (Stavem, et al., 1999;Marks, et al., 1992)	Breathlessness, mood, concerns, and social	Contains 20 questions scored on a 5 point scale. Range score from 0-10 (higher score more symptoms)	Originally designed for studies in asthma. Translated in to Norwegian and used in COPD. In this study Cronbach's alpha=0.85 (breathlessness score was used in this study)	Few items and easy to use.
Lee Fatigue Scale (LFS) (Miaskowski, et al., 1999;Gay, et al., 2004)	Fatigue and energy	Contains 18 questions scored on a scale from 0-10 (higher score more symptoms).	Used in oncology, and newborn babies and their parents. Translated to Norwegian. In this study Cronbach's alpha =0.85 (fatigue score was used in this study)	First time used in COPD in this study. It's been proved to be easy to use and have a general nature. Can be compared with other populations.
The Hospital Anxiety and Depression Scale (HAD) (Dowson, et al., 2001;Jones, et al., 1992;Bjelland, et al., 2002)	Anxiety and Depression.	Contains 14 questions. 7 question on each subscale. Score range from 0-21 (higher score more symptoms)	Used in several diseases, included COPD. Translated to Norwegian. In this study Cronbach's alpha= 0.86 for anxiety and =0.74 for depression.	Easy to use, few items and there exists reference data from the Norwegian population.
General Sleep Disturbance Scale (GSDS) (Miaskowski, et al., 2006;Gay, et al., 2004;Lee, 2007)	Insomnia	Contains 21 questions on a scale from 0-7 (higher score more symptoms).	Used in oncology and for newborn babies and their parents. Translated to Norwegian. In this study Cronbach's alpha= 0.84	First time used in COPD in this study. Easy to use and has a general nature. Can be compared with other populations
Brief Pain Inventory (BPI)(Stenseth, et al., 2007;Cleeland, et al., 1994;Klepstad, et al., 2002)	Pain intensity and interference. The participants mark on a body map which part of the body they feel pain.	Contains 14 questions. 11 of the questions have a rating scale from 0-10 (higher score more symptoms) The body map was divided into 45 areas and counted by using a template.	Used in oncology. Translated to Norwegian. In this study Cronbach's alpha= 0.92 (pain interference score was used in this study)	First time used in COPD in this study. It's been proved to be easy to use and have a general nature. Can be compared with other populations.

5. Ethics

The study was approved by the Medical Ethics Committee, the Data Inspectorate and the hospital clinic (Appendix E - G).
The selection of instruments to measure symptoms may lead to questions and emotional distress for the participants. Sensibly we therefore wanted the project patients to bring their booklets to the appointment.

The fact that the participants performed the spirometry test at the hospital made it safe to participate. The tester always had a telephone available during the test, and could contact the respiratory doctor if needed. Some participants required further follow-up appointments and some also needed hospitalisation. The tester was certified in advanced cardiopulmonary resuscitation.

The participants were given a number on the questionnaire, spirometry schedule and the separate work sheet. The approval from the participants was marked with the same number. The sample of data from the participants and the sample of approval were stored in separate places to satisfy requirement of anonymity.

6. Discussion

In the paper of this thesis the result of the present study is presented and discussed. The main findings show that breathlessness has the strongest association with all the other symptoms after controlling for demographic and clinical variables. Demographic variables, smoking, co-morbidity and lung function had different association with the different symptoms.

As suggested by the Symptom Management Model these findings show that person variables, health & illness variables and environment variables influence multiple symptoms in various manners.

The following section will contain a discussion and a reflection on theoretical background and methodological considerations around the significance and validity of these findings.

6.1 Discussion of theoretical background

Symptom definition

Several definitions of the different concepts chosen in this study exist. Pain can for instance be defined as "whatever the experiencing person says it is, existing whenever he says it does"(Lindsey, et al., 1993, p. 235). The choice of definitions was difficult, because each definition would give a different approach. Maybe the definition of pain mentioned above would be better in a quality approach. As for the concept depression it was in literature often defined as a disease, even if the common expression would refer to a clinical symptom or to a general feeling. This can give an illustration of confusion of ideas which can make communication difficult. In this study a particular definition of the concepts has been chosen, but when the participants answer the questionnaire they may not have the same definition in mind. The only relationship between the definition and the patient then is if the questionnaire measures what the definition says.

Symptom model

The SMM was chosen because of the visual and verbal illustration of the complex circular understanding of symptoms. It has been useful in planning the project but also in evaluating the result afterwards. However we have not used the entire model and can therefore not give the complete picture of a "circular" understanding. The implied part only explains some of the associations, but other variables of the model could have a stronger impact on the outcome variable. With the variables we have in the multiple regression analysis the Theory of unpleasant symptoms may also be a model that could answer the research questions. This model will however not give an understanding of the missing items such as quality of life. The entire model of the SMM could in this way give ideas of important factors to consider for further investigation.

6.2 Discussion of methods

6.2.1 Setting and sample

Response rate and bias

It can be considered as a strong point that the whole population of COPD patients from the outpatient list in a period was invited to participate in the study. In this way there will be a reduced effect of systematic bias. However the response rate seemed to be low. Polit and Beck state that a response rate of 50% most typically achieved with mailed questionnaires, but with a face-to-face interview the response rate could be higher (Polit, et al., 2004). In this study the response rate was based on the mailed acceptation letter. The participants also had a face-to-face meeting when performing the lung function test. The response rate of 40% in the present study may be due to the fact that "Lovisenberg Diakonale Sykehus" serves patients from various ethnic

minorities and patients with more severe disease may have hesitated to come all the way to the hospital only for the study

The Medical Ethics Committee did not approve collecting data about minority background from the participants or the non-responders (Appendix H). Only names from the list of those patients not responding can to some extent suggest anything about origin. Also data on demographic characteristics such as gender and age can shed light on how representative the respondents are in relation to the population studied. In order to document possible bias on non- responder's analysis of age, gender and minority names were performed. The mean age of non- responders was 67.7 with a SD of 12.4. This differed only by 4.6% in age and 1.8% in SD compared to the participants in the study. The frequency of men and women were also similar to the participants. 48.4% were men and 51.6% were women in the sample of non-responders. In the sample of participants 51.3% were men and 48.7% women. However there was an amount of 14.6% of people with names suggesting a minority-language in the sample of no-responders and this number was 6.4% in the participants.

6.2.2 Design and analysis

Design

A Cross-sectional design was chosen because of the explorative focus of the project. Because this kind of design is known to be easy and relatively economical (Polit, et al., 2004) it was in the start of the project thought practicable to perform in a master thesis. Each participant had one hour appointment at the hospital to perform the pulmonary function test and talk to the respiratory nurse. Some of the participants needed an extra appointment for medical following up. Almost everyone wanted a journal note to be written and sent to their main doctor. Because of this, the study was more time consuming than expected. Most important, this design assured the participants that they would be taken care of if necessary.

The cross-sectional design will not estimate prediction of the direction of the variables. The assumptions in this thesis are therefore to give some ideas of association but this should be further explored in forthcoming studies.

Analysis

Other analysis methods could have been considered to analyse multiple symptoms. This could for instance be factor analysis, cluster analysis or pathway analysis. Methods as these would need other statistical programs than available in SPSS. However the result of using multiple regression analysis is a start that can give ideas for further studies on investigating multiple symptoms. Another approach such as simultaneous regression has been stated to be a commonly used multiple regression analysis (Pallant, 2005;Polit, et al., 2004). However, using a hierarchical multiple approach different steps of relationships may be explored.

6.2.3 Instruments

Performance of spirometry and reference values

Spirometry instruments have reference values predicted by the normal population in their office program. Different reference values are used in different countries. In Norway the reference values from the European Respiratory Society are normally used as predicted spirometry values. Norwegian reference values exist, but they have been reported to be too high (Langhammer, et al., 2001). To consider accurate reference value is difficult and may also predict invariable data because a subjective consideration by the tester is needed for each patient. Performing the test is also a technical procedure. This has proved to be difficult for several patients, probably due to insufficient understanding of the procedure (Ulmer, 2003). However, with trained technicians, and the spirometry test performed in the way illustrated by guidelines,

the test is mostly known as a good way to confirm diagnosis, evaluate disease and treatment (Schermer, et al., 2003).

Use of questionnaires

To an extent the validity of the instrument on other diseases could tell us if it was useful to measure the symptoms in COPD, but the disease could also be different from other conditions so the tools may not measure what they were intended to do. Some of the participants told the tester (author) that they had joined the project in order to measure their lung function and ask questions about their medications and their disease. Because of this they might not have been motivated to answer the questionnaires sincerely.

In our sample some of the participants had a negative reaction to this questionnaire. Numerous questions were of a personal nature and may therefore have been difficult to answer truly.

An evaluation of other questionnaires

Different measurement scales (such as VAS) and various questionnaires have been developed to measure breathlessness (Dorman, et al., 2007). In this thesis the RQLQ subscale "breathlessness" was chosen. Other questionnaires measuring dyspnea could also have been useful, but we preferred this questionnaire because it also measured additional conditions witch would be valuable in further analysis of the data. On the other hand other questionnaires, well known for information on cut points in different groups, could have been a better tool. Tools like the Medical Research Council Scale (MRC) have been shown to give information that could help confirm the diagnosis of COPD and also grade the severity of the disease (Bestall, et al., 1999). This tool is used a lot and might possibly have been a better choice when evaluating this later.

6.3 Further research

The studies give ideas for further investigation. In the expanded project other variables as for instance quality of life, self-efficacy and illness perception have been measured. The participants have also performed a 6 min. walking test with measuring of SpO2. Further analysis on this data could be to identify symptomclusters and find how these may be associated with illness variables such as lung function or SpO2 during walking, self-efficacy and quality of life in COPD.

The lack of connection between predicted lung function FEV1 and multiple symptoms in the present study and in other studies (3.1) raise questions as to why guidelines still focus so much on these signs in diagnosing and helping people with COPD. The author has not found any study investigating if psychosocial issues are points that are discussed with COPD patients during consultations. Using questionnaires this study and several other studies have found people with COPD suffering from symptoms. Could questionnaires for instance be used in clinical meetings between the care worker and the patients in order to approach psychosocial issues? A project with standardized questionnaires in clinical practice might enable bringing these issues into a conversation with COPD patients.

7. Conclusion

This is the first study to focus on multiple symptoms such as breathlessness, depression, anxiety, fatigue, insomnia and pain. Few studies focus on multiple symptoms.

The findings of this study are presented in the paper. These findings showed that breathlessness had the strongest relationship with all the symptoms after controlling for demographic and clinical variables. Among the different symptoms breathlessness and insomnia were the only symptoms to be related to predicted lung function. Significant relationships were also found between demographic variables, smoking, co-morbidity and the different symptoms. The theoretical framework The Symptom Management Model proved useful in planning, accomplishing and evaluating the result of the present study.

The response rate seemed to be low, but this could be due to the population originally invited to participate in the project. However, this result may be of valuable information for further investigation. The results from this study may suggest an expanded focus on multiple symptoms in COPD guidelines, health care and research.

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Multiple symptoms in COPD

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Abstract

Aim: The aim of this study was to explore the relationships between demographic and clinical variables, and multiple symptoms such as breathlessness, depression, anxiety, fatigue, insomnia and pain in COPD.

Background: Although research in COPD often has focused on single symptoms there is a lack of knowledge about possible associations with multiple symptoms.

Methods: A total of 154 COPD patients participated in a cross-sectional study from June 2006 to December 2007. All performed pulmonary lung function tests and completed a questionnaire that included demographic variables, Brief Pain Inventory, Hospital Anxiety and Depression Scale, Lee Fatigue Scale, General Sleep Disturbance Scale and Respiratory Quality of Life Questionnaire. Co-morbidity and medication were collected from their medical records. The following analysis method was used: descriptive, bivariate correlation and multiple regression analysis.

Results: With regard to demographic variables, age was significantly related to breathlessness, fatigue, insomnia and pain. Education was significantly related to depression and anxiety. Smoking was significantly related to anxiety, depression and pain. Co-morbidity was significantly related to breathlessness.

Bivariate relationships showed that breathlessness, depression, anxiety, fatigue, insomnia and pain were significantly related to each other. In the multiple regression analysis, lung function was related to breathlessness and insomnia. Breathlessness was the most significant symptom associated with the other symptoms after controlling for demographic and clinical variables.

Conclusion: Breathlessness is a significant symptom associated with depression, anxiety, fatigue, insomnia and pain. Results from this study may suggest an expanded focus on multiple symptoms in COPD guidelines, health care and research.

Summary statement

What is already known about this topic:

- Breathlessness is a major symptom in COPD.
- Predicted lung function signs are often found associated with breathlessness, but not with other symptoms.
- Research on symptoms in COPD is explored within the scope of single symptoms such as breathlessness, depression, anxiety, insomnia and fatigue.

What this paper adds:

- This is the first study which explores multiple symptoms such as breathlessness, depression, anxiety, fatigue, insomnia and pain in COPD, using The Symptom Management Model.
- Breathlessness has a strong significant association with symptoms such as depression, anxiety, fatigue, insomnia and pain after controlling for demographic and clinical variables.
- Further studies of multiple symptoms in COPD are needed to guide symptom management.

Introduction

Chronic Obstructive Lung Disease (COPD) is a serious chronic disease characterized by airflow limitation that is not fully reversible. About 80 million people in the world suffer from severe COPD which often leads to hospitalization and mortality (Hurd, 2000;ATS/ERS guidelines, 2004).

In COPD patients, breathlessness is a major symptom. Although separate studies have reported that single symptoms such as depression, anxiety, fatigue, insomnia and pain are present (Kellner, et al., 1992;Theander, et al., 2004;George, et al., 2003;Mahler, et al., 1995), no study has focused on multiple symptoms in one and the same study.

Background

The concept symptom can be understood as the subjective experience of a biopsychosocial change in the body (Dodd, et al., 2001a). Multiple is defined as "more than one" (Webster dictionary, 1983). Multiple symptoms can in this way be understood as more than one symptom. Understanding symptoms in a more complex perspective is of great importance in exploring the need for the health care of COPD patients.

The Symptom Management Model (SMM)(Dodd, et al., 2001a) is a conceptual framework resulting from research on oncology patients (Dodd, et al., 2001b). It has also been used to assess symptoms for HIV(Voss, et al., 2006) and angina (Caldwell, et al., 2000). However it has never been used to understand symptoms in COPD patients. The model has three interrelated dimensions; symptoms experience, management strategies and symptom outcomes. Personal, environmental, health and illness variables are believed to influence these three dimensions (Dodd, et al., 2001a). Several studies on oncology patients have suggested how multiple symptoms can appear concurrently and how different variables can interfere, such as social variables like education, personal variables like gender and health & illness

variables like treatment (Miaskowski, et al., 2004;Miaskowski, et al., 2006;Miaskowski, et al., 2006).

We know that the relationship between respiratory signs such as FEV1% and different symptoms is not linear in COPD (Larson, et al., 2006). Breathlessness has shown an association with the predicted lung function FEV1% (Mishima, et al., 1996;Mahler, et al., 1992). Anxiety and depression are associated with dyspnea , but not with FEV1 % (Mishima, et al., 1996;Gift, 1990). Kapella et.al found the same situation with the symptoms of fatigue and insomnia (Kapella, et al., 2006). Despite this situation the focus in guidelines for COPD is mostly on respiratory signs such as FEV1% and on symptoms such as breathlessness, sputum and cough (ATS/ERS guidelines, 2004). Other factors like gender and co-morbidity, education and smoking history (Hynninen, et al., 2007;Chavannes, et al., 2005;Lin, et al., 2005;ATS/ERS guidelines, 2004) have shown to be related to symptoms in COPD patients. However, no study has examined possible relationships between selected demographic and clinical variables in relation to multiple symptoms in COPD. Considering the burden of symptoms for COPD patients and the increasing incidence of this disease (Hurd, 2000) it is important to expand our knowledge about multiple symptoms and the factors that could influence multiple symptoms.

The Study

The present study aims to answer the following questions:

1. What is the relationship between the demographic variables smoking, co-morbidity and lung function, and multiple symptoms (breathlessness, depression, anxiety, insomnia, fatigue and pain)?

2. What is the relationship between breathlessness and depression, anxiety, insomnia, fatigue and pain, controlling for demographic and clinical variables?

Design

This paper is based on data from a cross-sectional study in COPD. The patients were registered at an outpatient unit list at a medium-large hospital in Norway during the period from June 2005- May 2006. The participants answered a questionnaire booklet and came to an appointment at the hospital to perform a lung function test spirometry. It took about one to three weeks from the time that the booklet was sent until the appointment.

Sample

The following inclusion criteria were used to identify suitable respondents: all stages of COPD diagnosed in the medical record, able to read and write Norwegian and more than 30 years old. Out of 502 COPD patients, 387 patients fulfilled the inclusion criteria and were invited to participate in the study during the period from June 2006-December 2007. After three weeks a reminder was sent to those who had not responded. A total of 168 accepted the invitation. Out of these, two patients were not able to fill out the questionnaire, six patients withdrew their acceptance, two patients did not return the questionnaire and four patients did not meet up to the appointment. A total of 154 persons (response rate 40%) participated in the study.

See figure 1 for further information.

Figure 1 about here

Data Collection

Physical tests

Lung function values were measured before and after the inhalation of Salbutamol (0.4 mg). The participants were told not to take inhalation medication less than four hours before the lung function test spirometry (V-Max spirometry with European standard measurement). All the tests were performed in accordance with American Thoracic Society (ATS)/ European Respiratory Society (ERS) standardization for lung function testing (Pellegrino, et al., 2005).

Instruments and scoring procedure

The test instruments for the study included a questionnaire booklet with information on sociodemographic characteristics (gender, age, marital status, education, employment, smoking status and living status) and standardized instruments used in previous studies. Information about co-morbidity and medication was collected from the medical record.

Respiratory Quality of Life questionnaire (RQLQ) measures quality of life specific to COPD. This instrument was originally made and used in studies of asthma patients in Australia (Marks, et al., 1997;Marks, et al., 1992). It has been translated into Norwegian and used in COPD (Stavem, et al., 1999). It contains 20 questions with a range score from 0-10. A higher score indicates a higher intensity of breathlessness. Each item has a five point scale: "not at all, mildly, moderately, severely and very severely". It has four subscales: breathlessness, mood, concerns and social. This study concentrates only on the subscale breathlessness. RQLQ has shown satisfactory internal consistency in previous research (Stavem, et al., 1999). In this sample the Cronbach's alpha was 0.87 for the subscale breathlessness.

Lee Fatigue Scale (LFS) was used to measure fatigue. It consists of 18 questions with a range score from 0 to 10. A higher score indicates higher intensity of fatigue. Thirteen of the questions contain information about the feeling of fatigue. Five questions contain information about energy. Only the fatigue score was used in this study. LFS has not been used in COPD patients but was still chosen because of its general nature. Because the LFS contains questions not directly related to the disease it is possible to compare to other populations and diseases. This instrument has been used in oncology studies (Miaskowski, et al., 2006;Miaskowski, et al., 1999) and with newborn babies and their parents (Gay, et al., 2004b). LFS has shown a satisfactory internal consistency in previous research (Dowson, et al., 2001). In this study the Cronbach's alpha was 0.85 for the subscale fatigue.

Brief Pain Inventory (BPI) was used to measure pain, and consists of four questions related to pain intensity with a rating scale from 0 (no pain) to 10 (excruciating). It also contains seven questions related to pain interference with a rating scale from 0 (does not interfere) to 10 (completely interferes). The score ranges from 0-40 for pain intensity and from 0-70 for pain interference. A high score indicates more severe pain. The participants were asked to mark with a pencil /pen on a body map on which part of their body they experienced pain. The procedure used by Rustoen et. al. was performed to score the marked areas of pain on the body map (Rustoen, et al., 2004). The body map was divided into 45 areas, and each area was scored and counted by using a template. BPI has been used in oncology (Stenseth, et al., 2007;Cleeland, et al., 1994) and translated into Norwegian (Klepstad, et al., 2002). The pain interference subscale was used in this study. BPI has shown satisfactory internal consistency in previous studies (Klepstad, et al., 2002;Paul, et al., 2005). In this study Cronbach's alpha was 0.92 for the subscale pain interference.

The Hospital Anxiety and Depression Scale (HAD) has been used to measure anxiety and depression. It contains 14 items. Each question has a four point scale where seven items on each subscale measure anxiety and depression. The scale ranges from 0-21, with higher scores indicating the presence of anxiety and depression. HAD has been translated into Norwegian and has been used for different disease groups, including COPD (Dowson, et al., 2001;Jones, et al., 1992). HAD has shown satisfactory internal consistency in previous studies (Bjelland, et al., 2002). In this study Cronbach's alpha was 0.86 for the subscale anxiety and 0.74 for the subscale depression.

General Sleep Disturbance Scale (GSDS) was used to measure insomnia. The questionnaire includes 21 items with a range from 0-7 (how many days per week). The scale ranges from 0-147. A higher score indicates a higher degree of sleeping problems. This instrument has been used in oncology research (Miaskowski, et al., 2006) and for measuring the pattern of sleep/fatigue with newborn babies and their parents (Gay, et al., 2004a;Gay, et al., 2004a;Gay, et al., 2004b). The questionnaire has been translated into Norwegian. In previous studies the GDSD has shown a satisfactory internal consistency (Lee, 2007;Gay, et al., 2004a). In this study Cronbach's alpha was 0.84 for the subscale insomnia.

Ethical considerations

The study was approved by the Medical Ethics Committee, the Data Inspectorate and the hospital clinic. The invitation letter contained information about the project and anonymity procedures regarding the participants.

Data analysis

The statistical analyses were performed using the SPSS statistical package version 14.0. Demographic variables and the severity of various symptoms and lung function were analyzed with descriptive analyses (frequency, mean, SD). Analyses of the relationships between lung function, demographic characteristics and the symptoms were performed using bivariate correlation analysis (Pearson's r) and by hierarchic multiple regression analysis (enter method). The hierarchic multiple regression analyses followed three steps:

Step 1:

Independent variables: Age, gender, education, smoking history and co-morbidity.

Dependent variables: Breathlessness, depression, anxiety, insomnia, fatigue and pain.

Step 2:

Independent variables: Age, gender education, smoking history, co-morbidity + predicted lung function FEV1%.

Dependent variables: Breathlessness, depression, anxiety, insomnia, fatigue and pain.

Step 3:

Independent variables: Age, gender, education, smoking history, co-morbidity, predicted lung function FEV1% + breathlessness.

Dependent variables: Depression, anxiety, insomnia, fatigue and pain.

Statistic normality, linearity and homosecedasiticity were tested and satisfactory assumptions were met (Pallant, 2005). Each independent variable was regressed on all of the others and the level of multi-collinearity ($r>0.70$) was acceptable (Pallant, 2005).

Results

Demographic characteristics, smoking history, co-morbidity and location of pain

The demographic characteristics are shown in table 1. Out of 154 participants 51.3% are men and 48.7% are women. The age range is from 36 to 87, with a mean age of 64.6 years. A total of 44.2% are non smokers and 43.5% are still in the habit of smoking. A total of 18.1% have a university education of less than four years, and 9.7% have more than four years. The rest of the participants have attended primary school, vocational school or secondary school. Many of the participants have several diseases. Among these 39% have low or high blood pressure, 31.2% have heart disorders, 22.1% have joint disorders, 16.9% have stomach and kidney disorders and 11.7% have diabetes. A total of 18.8% have no other disorders. The body map shows that 33% mark pain in the shoulders, 29.2% in the lumbar region, 26.6% in the legs, 21.4% in the back, 16.9% in the neck, 16.2% in the thighs and 12.3% in the head.

With regard to the non-respondents the mean age is 67.7 years and 14.6% have a minority background. The relative proportion of men and women is similar between the group of participants and the group of non-participants.

Table 1 about here

Characteristics of lung function and symptoms

Descriptive information on variables such as lung function, symptoms, and the Gobal Initiative for Chronic Obstructive Lung Disease (GOLD) classification of the severity of COPD (Rabe, et al., 2007) is presented in table 2.

Table 2 about here

The relationship between demographic variables, smoking, co-morbidity, lung function and multiple symptoms

Table 3 presents the results of the bivariate analysis (Pearson's r, column r) and the multivariate linear regression analyses of the relationships between independent variables (demographic variables, smoking, co-morbidity and lung function) and multiple symptoms as dependent variables.

The bivariate analyses show that *breathlessness* is significantly negatively related to age ($p<0.05$, $r=-0.19$), education ($p<0.01$, $r=-0.23$) and lung function ($p<0.01$, $r=-0.36$) and positively related to co-morbidity ($p<0.05$, $r=0.16$). In the multivariate analysis only age ($p<0.01$, st.beta = -0.22) and lung function ($p<0.01$, st.beta =-0.34) are significantly related to breathlessness (step 2, table 3).

As for *depression* ($p<0.01$, $r=-0.24$) and *anxiety* ($p<0.01$, $r=-0.26$), the bivariate relationship shows a significant negative relationship with education. Education stays significant ($p<0.05$, st.beta =-0.2) in the model after controlling for the independent variables (step 2, table 3). However, smoking is negatively significantly related to anxiety ($p<0.05$, st.beta =-0.17) and depression ($p<0.05$, st.beta =-0.17) (step 2, table 3).

No bivariate associations are found for the separate independent variables and *fatigue*. However age is negatively significantly related to fatigue ($p<0.05$, st.beta =-0.17) at the second step (step 2, table 3) in the multivariate analysis.

The bivariate relationship also shows that age is negatively related to *insomnia* ($p<0.01$, r=-0.25). After controlling for independent variables, age stays negatively significantly related to insomnia ($p<0.01$, st.beta =-0.23) at the second step (step 2, table 3).

Pain interference is negatively significantly related to age ($p<0.01$, r=-0.24), smoking ($p<0.01$, r=-0.21) and positively related to gender ($p<0.05$, r=0.17). Age ($p<0.05$, st.beta =-0.19) and smoking ($p<0.05$, st.beta =-0.2) remain significantly associated to pain interference when independent variables are controlled for at the second step (step 2, table 3) in the multivariate analysis.

The variance explained within all the models shows a range from 2%-10% at step 1 (table 3) and a range from 1% to 10% at step 2 (table 3).

Table 3 about here

The relationships between breathlessness and depression, anxiety, insomnia, fatigue and pain, controlling for demographic and clinical variables

Table 4 shows a significant positive ($p<0.01$) bivariate relationship between *all the symptoms*. The Pearson r ranges between 0.3 (fatigue-depression) and 0.61 (insomnia-pain interference).

Breathlessness is negatively significantly related to *lung function* ($p<0.01$, r=-0.36).

Table 4 about here

When controlling for demographic and clinical variables, breathlessness is significantly positively related to *depression* ($p<0.01$, st.beta =0.34) and *anxiety* ($p<0.01$, st.beta =0.34), fatigue ($p<0.01$, st.beta =0.39), *insomnia* ($p<0.01$, st.beta =0.45) and *pain interference* ($p<0.01$, st.beta =0.43) (step 3, table 3). However, *lung function* is positively significantly related to *insomnia* ($p<0.05$, st.beta =0.22) after breathlessness entered the equation at the third step (step 3, table 3).

The Adj.R Square for fatigue is 13%, for anxiety 14%, for depression 15%, for insomnia 22% and for pain interference 25%.

Discussion

To our knowledge this project is the first which in one single study includes multiple symptoms such as breathlessness, depression, anxiety, fatigue, insomnia and pain in COPD, and tries to explore the relationships between selected demographic and clinical variables and multiple symptoms.

Our main findings showed that breathlessness had the strongest relationship with all symptoms after controlling for demographic and clinical variables. The various symptoms had a different, significant relationship with demographic variables, smoking, education, co-morbidity and lung function. In accordance with the Symptom Management Model these findings support that personal variables, health & illness and environmental factors influence multiple symptoms in various manners.

Study limitations

The study reported on in this paper may have limitations such as a low response rate and the cross-sectional design. The low response rate (40%) may be due to the fact that the participants were invited by letter and patients with more severe disease of COPD may have hesitated to come all the way to the hospital only for the study. Several of the non-participants also had a minority background. Because of the cross-sectional nature of this study it is not possible to draw conclusions about predictive issues with regard to the relationships found in this study.

Severity of the various symptoms

The five symptoms that are reported commonly in COPD were selected for this analysis. Pain interference has however not been previously investigated in COPD. Because of this, it is surprising that the mean score of pain interference in the present study is similar to the mean score in oncology patients (Klepstad, et al., 2002;Stenseth, et al., 2007). Although fatigue has been found to be a highly relevant symptom in COPD (Kapella, et al., 2006), the instrument used in the present study will make it possible to compare with other diseases. In the present study, the mean score of fatigue and insomnia was found to be similar to the baseline mean score values for male patients with prostate cancer(Miaskowski, et al., 2008) and baselines mean score values of bone metastasis patients(Miaskowski, et al., 1999) before treatment. As for depression and anxiety symptoms, the mean score was similar to other studies of COPD patients getting oxygen therapy (Mishima, et al., 1996). The mean score of breathlessness seemed to be not as high as the mean score Stavem et. al. found with the same breathlessness score (Stavem, et al., 1999). There is however significant uncertainty about how large this difference is. We recommend that further research is conducted to validate the measure of breathlessness with RQLQ.

The relationship between demographic variables, smoking, co-morbidity and lung function and multiple symptoms

Our results suggest that younger people experience more breathlessness, fatigue, insomnia and pain interference. Reishtein also found a negative correlation between age and the symptoms dyspnea and sleep difficulties (Reishtein, 2005), but other studies have reported increased insomnia (Klinkenberg, et al., 2004) and breathing problems with higher age (Hardie, et al., 2005). A study of pain in the Norwegian population showed that the proportion of pain was larger for older people (Rustoen, et al., 2004). Bandura explains aging as an exercise of control. From this perspective getting older will give experience in controlling the symptoms or the biopsychosocial changes in the life of several people (Bandura, 1997). In order to investigate this further one may include components such as "self-efficacy" (Dodd, et al., 2001a).

More women than men are associated with pain interference in the present study. Because many studies have shown a difference between men and women when it comes to the experience of different symptoms, it is surprising that we don't find any association between gender and the other symptoms. For instance Di Marco et. al found that women experienced significantly more anxiety and depression than men (Di, et al., 2006). A Norwegian population study showed that women had a higher fatigue score than men (Loge, et al., 1998). Kapella et.al. found a different score for sleep quality and fatigue between men and women but not with anxiety and depression (Kapella, et al., 2006).

In our study, lower education is connected with a higher score of depression, anxiety and breathlessness and this is supported by Van Manens et. al. study. They found that the majority of people with COPD had lower education (van Manen, et al., 2001).

Our result shows that smoking status is related to depression, anxiety and pain interference. This is supported by others as well. Smoking has been found to have a relationship with depression in the general population in Norway (Klungsoyr, et al., 2006). Some people with anxiety symptoms also tend to use cigarettes as anxiolytic effect (Mikkelsen, et al., 2004). As for pain, it has been reported that people with musculoskeletal pain tend to smoke more. (McBeth, et al., 2007).

Because many of the participants had co-morbidity, one could expect that the relationship between co-morbidity and symptoms would be more pronounced. Van Manen et.al found that pain was influenced by co-morbidity in COPD patients (van Manen, et al., 2003). Walke et. al found the opposite, the amount of co-morbidity showed a non- significant relationship with the severity of symptoms anxiety, depression and pain in COPD (Walke, et al., 2007).

As in our study, several studies have also found low lung function to be associated with increased breathlessness (Mishima, et al., 1996;Mahler, et al., 1992). Our findings suggested that lung function and age have a more pronounced influence on breathlessness than on the other symptoms. This was also shown through no significant associations between lung function and the other symptoms; depression, anxiety, fatigue, insomnia and pain interference. Other studies have found similar results (Mishima, et al., 1996;Mahler, et al., 1992;Gift, 1990;Kapella, et al., 2006). In spite of this it has been stated that people with severe to very severe COPD (lung function FEV1%<50%) can have a high feeling of depression (van Manen, et al., 2002). In our study we focused on all stages of COPD, and the fact that the results showed no connection between lung function and depression may be seen in light of this.

The relationship between breathlessness and depression, anxiety, insomnia, fatigue and pain, controlling for demographic and clinical variables

In this study we have shown that breathlessness is related to all of the symptoms after controlling for demographic and clinical variables.

Because few studies of COPD focus on the symptom pain, it is interesting that breathlessness explained the ultimate variance of pain interference in our study. Pain is however complex and may be caused by many different changes in the body (Lindsey, et al., 1993). Özge et. al. suggested for instance that chronic hypoxemia and associated sleep disorder can be the reason for headaches of a severe to a very severe degree in COPD (Ozge, et al., 2006). Also discomfort in legs during activity and distress in breathing muscles are common in COPD. This condition may be due to changes in the chest wall, diaphragm position, overloading of respiratory muscles or oxidative stress in muscles (MacIntyre, 2006;Orozco-Levi, 2003). Our study reports that most of the pain was situated in shoulders, back, lumbar region, legs and thighs. These factors may explain the variance of pain in association with breathlessness. However it might be necessary to do further investigations of the symptom pain in order to clarify the interrelationship between pain and other factors in COPD.

Breathlessness does not explain the total variance of insomnia in our study. The positive association with lung function can indicate that people with good lung function have more symptoms of insomnia. These results conflict with earlier findings of chronic airflow limitation contributing to sleep disruption (George, et al., 2003). It is well known that inhalation medication as beta 2 stimulating and corticosteroids used twice a day by many COPD patients can interrupt sleep (George, et al., 2003). These medications can also give a better lung function (ATS/ERS guidelines, 2004). This may be the reason for our results.

Several studies suggest that anxiety and depression are associated with breathing difficulties (Bailey, 2004;Kellner, et al., 1992). The reason why anxiety and depression are related to breathlessness is complex. Anxiety is often related to panic and fear and can therefore cause breathlessness which again brings on more anxiety (Bailey, 2004). Feelings of hopelessness because of limitations and lack of energy (Sirey, et al., 2007) in activities such as shopping and cleaning can also develop depression. The feeling of anxiety and depression often results in social isolation, loneliness, helplessness and hopelessness(Kara, et al., 2004). Depression and anxiety can in this way seem to overlap each other (Mikkelsen, et al., 2004). The high correlation between anxiety and depression, and the same explaining variance of breathlessness associated with anxiety and depression shown in our study may explain this.

As with depression and anxiety, fatigue also has smaller explaining variance than insomnia and pain interference. This result is quite surprising since other studies have found dyspnea to be highly related to fatigue (Kinsman, et al., 1983). Dyspnea was also related to anxiety, helplessness and hopelessness in this study (Kinsman, et al., 1983). Kapella et.al demonstrated in a study that dyspnea and fatigue were the most prominent symptoms of disability in functional performance. In their study, other symptoms such as anxiety, depression and sleep quality were also predictors to functioning (Kapella, et al., 2006). Fatigue has also been found to be quite common for those with sleeping difficulties in COPD (Mohsenin, 2005). These studies demonstrate how multiple symptoms can be associated with each other. We can find these associations by bivarite correlation between all of the symptoms. Further analyses are needed to gain more knowledge about multiple symptoms associations with each other.

Clinical implications

ATS/ERS guidelines recommend the use of spirometry to measure the severity and set the diagnosis in COPD. However there are few suggestions to be found about how to investigate and help symptoms such as depression, anxiety, fatigue, insomnia and pain (ATS/ERS guidelines, 2004). This view is supported by others as well (Walke, et al., 2007). Vestbo et. al questioned whether measuring breathlessness was a better tool to classify severity than lung function (Vestbo, et al., 1988). Schlecht et. al suggest dyspnea measuring as a better method of reflecting both function and psychological impact in COPD (Schlecht, et al., 2005). Our results support this view and more focus on multiple symptoms in guidelines and health care is suggested.

Conclusion and further research

Our main findings showed that breathlessness had the strongest relationship with all symptoms after controlling for demographic and clinical variables. The various symptoms had a different, significant relationship with demographic variables, smoking, education, co-morbidity and lung function. This analysis can contribute to investigating how symptoms are associated with each other in clusters (three or more symptoms associated with each other through a common mechanism or etiology through a shared common variance (Miaskowski, et al., 2007). Symptom cluster (of fatigue, sleep disturbance, depression and pain) show an association with the low quality of life of patients with cancer. This kind of association may also be found in COPD. Further research should explore the relationship between several symptoms by looking into symptom cluster analysis to understand more about what kind of predictors can be influenced.

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Author contributions

C. R. Borge and A. K. Wahl were responsible for the study conception, design and analysis. C. Miakowski provided guidance on the concept. C. R. Borge performed the data collection and was responsible for drafting the manuscript. A. K. Wahl and C. Miakowski supervised the content of the paper.

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Figure 1- Flowchart

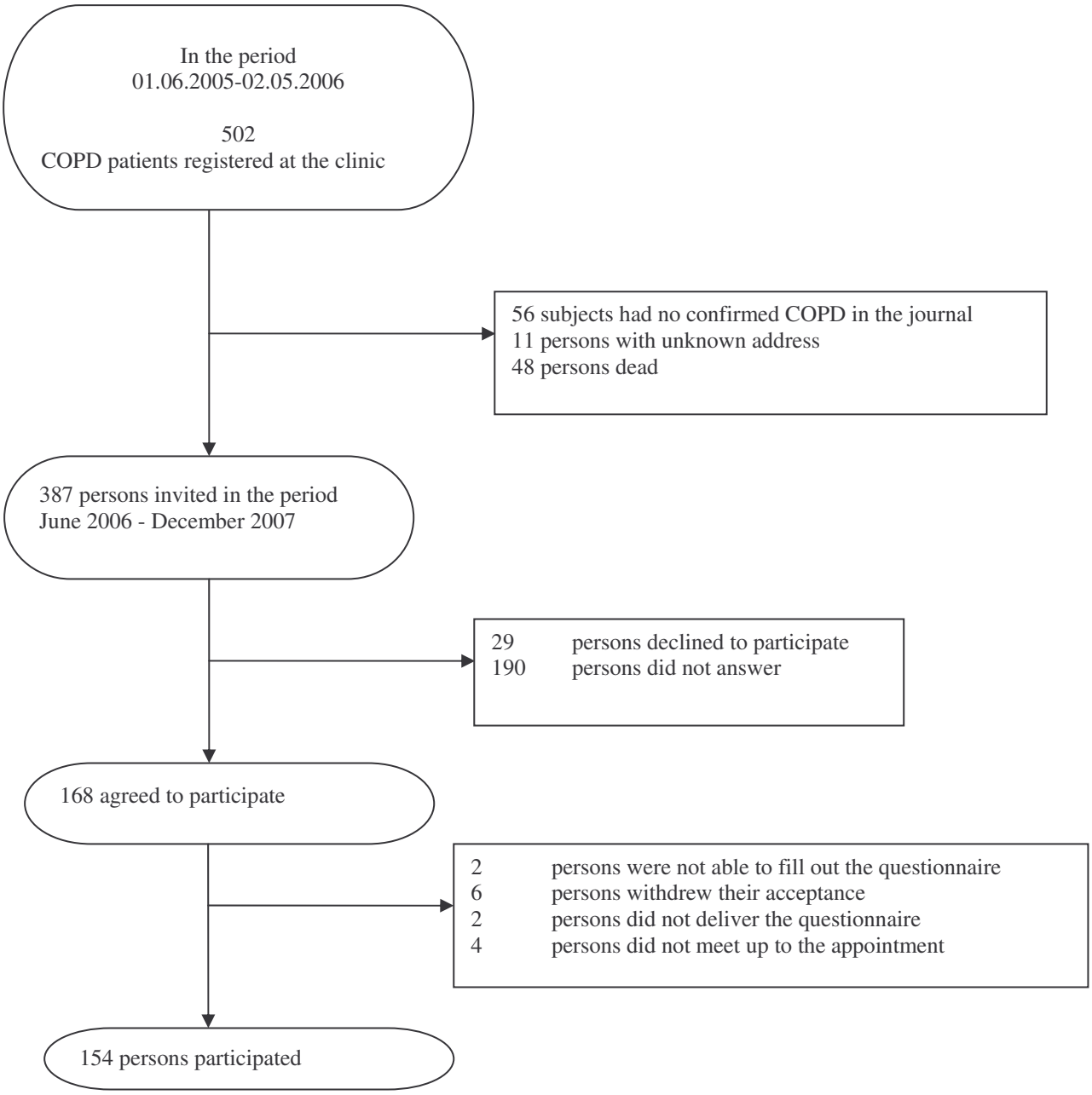

Table 1- Demographic Characteristics of patients with COPD (N=154)

	N %
Age Mean (SD) 64,6 (10,2)	
Min –Max 36-87	
Gender	
Male	79 (51,3%)
Women	75 (48,7%)
Marital status	
Married/partner	68 (44,2%)
Widow	25 (16.2%)
Other	61 (39.6%)
Smoking history	
No Smoker	86 (44.2%)
Smoker	68 (43.5%)
Work	
Working	41 (26,6%)
Retired	67 (43,5%)
Disability insurance	41 (26,6%)
Living	
Living alone (%)	77 (50%)
Living with spouse or partner	69 (44,8%)
Living with others	19 (12,3%)
Education	
Primary school	35 (22,7%)
Vocational school	27 (17,5%)
Secondary school	47 (30,5%)
University <4 year	28 (18,2%)
University > 4 year	15 (9,7%)
Co morbidity[1]	
Heart disorders	48 (31,2%)
Blood pressure	60 (39%)
Diabetes	18 (11,7%)
Stomach and kidney disorder	26 (16.9%)
Stroke	10 (6,5)
Cancer	14 (9,1%)
Psychiatric disorders	15 (9,7%)
Sum joint disorders	34 (22.1%)
Asthma	13 (8,4%)
Other lung diseases	22 (14,3%)
Other diseases	16 (10.4%)
Amount Co-morbidity	
0 disease	29 (18.8%)
1 disease	37 (24%)
2 diseases	39 (25.3%)
3 diseases	31 (20.1%)
4 diseases	11 (7.1%)
5 diseases	4 (2.6%)
6 diseases	2 (1.3)
7 diseases	1(0.6%)
Parts of the body with pain[2]	
Shoulders	51(33%)
Neck	26 (16.9%)
Legs	41 (26.6%)
Thighs	25 (16.2%)
Back	33 (21.4%)
Lumbar region	45 (29.2%)
Head	19 (12.3%)

[1] The total is more than 100% because some participants had from 0-7 diseases

[2] The total is more than 100% because some had pain several places. Results from BPI.

Table 2-Descriptive information from tests and questionnaires

	N	%	Mean	SD	Min-Max	Score form- to
FEV1%	154		59,1	22,6	17-124	
Mild stage	28	18.2				
Moderate stage	72	46.8				
Severe stage	39	25.3				
Very severe stage	15	9.7				
FEV%	154		55,1	13,2	24-82	
Breathlessness	153		2.4	2,1	0-7.5	0-10
Fatigue	153		3.7	1.7	0-9,6	0-10
Anxiety	153		6,2	4,5	0.5-18	0-21
Depression	153		5,4	3,6	0-16	0-21
Insomnia	154		61.3	21.9	16.8-115.5	0-147
Pain interference	152		21.2	18.0	0-64	0-70

Table 3-The relationship between independent and dependent variables by hierarchic multiple regression analysis (r,st.beta, weights, adjusted R2 and significant level)

	Breathlessness			Depression				Anxiety			
		Step 1	Step 2		Step 1	Step 2	Step 3		Step 1	Step 2	Step 3
Independent variable	**R**	**St. beta 1**	**St. beta 2**	**r**	**St. beta 1**	**St. beta 2**	**St. beta 3**	**r**	**St. beta 1**	**St. beta 2**	**St. beta 3**
Age	-0.19*	-0.18*	-0.22**	-0.09	-0.00	-0.012	0.06	-0.23	-0.00	-0.01	0.06
Gender 1= men, 2= women	-0.3	-0.06	0.07	-0.3	-0.07	-0.04	-0.06	0-11	-0.07	-0.04	-0.06
Education (higher scores=higher level and education)	-0.23**	-0.18*	-0.13	-0.24**	-0.22**	-0.2*	-0.16*	-0.26**	-0.22**	-0.2*	-0.16*
Smoking 1= yes, 2=no	-0.01	0.02	-0.04	-0.14	-0.16	-0.17*	-0.16*	-0.06	-0.16	-0.17*	-0.16*
Co-morbidity (higher score= more morbidity)	0.16*	0.17*	0-11	0.05	0.06	0.05	0.1	0.13	-0.06	0.05	0.01
Lung function FEV1% predicted (higher score= higher lung function)	-0.36**		-0.34**	-0.1		-0.08	0.06	-0.6		-0.078	0.06
Breathlessness				0.38**			0.34**	0.34**			0.34**
Adjusted R^2		0.08	0.19		0.06	0.06	0.15		0.1	0.1	0.14

Step1= st. beta weights using age, gender, education, smoking , co-morbidity as independent variables
Step2= st. beta weights using age, gender, education, smoking, co-morbidity and FEV1% as independent variables
Step3= st. beta weights using age, gender, education, smoking, co-morbidity, FEV1% and breathlessness as independent variables (different symptom in each model) as independent variables

* Significant at the 0.05 level
** Significant at the 0.01 level

Continues Table 3-The relationship between independent and dependent variables by hierarchic multiple regression analysis (r,st.beta, weights, adjusted R2 and significant level)

Independent variable	Fatigue				Insomnia				Pain interference			
	r	Step 1 St. beta 1	Step 2 St. beta 2	Step 3 St. beta 3	r	Step 1 St. beta 1	Step 2 St. beta 2	Step 3 St. beta 3	r	Step 1 St. beta 1	Step 2 St. beta 2	Step 3 St. beta 3
Age	-0.18	-0.17*	-0.17*	-0.08	-0.25**	-0.23**	-0.23**	-0.13	-0.24**	-0.19*	-0.19*	-0.1
Gender 1= men, 2= women	0.07	0.03	0.05	0.03	0.09	0.06	0.04	0.01	0.17*	0.14	0.15	0.13
Education (higher scores=higher level an education)	-0.05	-0.01	-0.00	0.05	-0.14	-0.08	-0.09	-0.03	-0.13	-0.07	-0.06	-0.01
Smoking 1= yes, 2=no	-0.1	-0.08	-0.09	-0.07	-0.13	-0.07	-0.07	-0.05	-0.21**	-0.19*	-0.2*	-0.18*
Co-morbidity (higher score= more morbidity)	0.08	0.11	0.1	0.06	0.11	0.12	0.13	0.08	0.11	0.14	0.13	0.08
Lung function FEV1% predicted (higher score= higher lung function)	-0.00		-0.04	0.1	0.07		0.05	0.22*	0.03		-0.05	0.11
Breathlessness	0.37**			0.39**	0.42**			0.45**	0.44**			0.43**
Adjusted R^2		0.02	0.01	0.13		0.06	0.06	0.22		0.1	0.1	0.25

Step1= st. beta weights using age, gender, education, smoking , co-morbidity as independent variables
Step2= st. beta weights using age, gender, education, smoking, co-morbidity and FEV1% as independent variables
Step3= st. beta weights using age, gender, education, smoking, co-morbidity, FEV1% and breathlessness as independent variables (different symptom in each model) as independent variables

* Significant at the 0.05 level
** Significant at the 0.01 level

Table 4-Correlation matrices between the symptoms

	Breathlessness	Fatigue	Anxiety	Depression	Insomnia	Pain interference	FEV1%
Breathlessness	1						
Fatigue	0.38**	1					
Anxiety	0.34**	0.31**	1				
Depression	0.38**	0.3**	0.65**	1			
Insomnia	0.42**	0.4**	0.55**	0.51**	1		
Pain interference	0.44**	0.53**	0.52**	0.54**	0.61**	1	
FEV1%	-0.36**	-0.0	-0.06	-0.1	0.07	0.03	1

** Significant at the 0.01 level

Appendix A- Author information to Journal of Advanced Nursing

JOURNAL OF ADVANCED NURSING

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Guidelines for Qualitative, Quantitative and Mixed Methods Research Papers

Qualitative, quantitative, and mixed methods research papers should not exceed 5000 words for the main text, excluding the abstract, summary statement, tables and references

The following standard headings should be used:

- **Abstract**
  The 250 word abstract should use the following headings: Aims (of the paper), Background, Methods (including year of data collection), Results/Findings, Conclusion.
- **Summary Statement**
  See the Summary Statement guidelines for further information.
- **Keywords** (maximum of six)

Introduction

Rationale, context, international relevance of topic

Background

- Provide a substantial, critical review of relevant theoretical and empirical literature
- For reports of qualitative studies, identify the rationale for selection of the phenomenon studied, such as the conceptual model that guided the study. Note that simply stating that the phenomenon has not yet been studied is not sufficient, as some phenomena may be trivial and, therefore, are not worthy of study.
- For reports of quantitative studies, present the theoretical framework of the research. Identify and provide an overview of the conceptual model and/or theory that guided the study. Explain the connections between the conceptual model or theory and the study variables. Identify and define each study variable. Explain connections between study variables and support those connections with relevant theoretical and empirical literature.
- For reports of mixed methods studies, provide a critical review of relevant theoretical and empirical literature, which should draw conclusions from the theoretical framework and current evidence, and support the need for a mixed methods study.

The Study (subheadings preferably in the following order)

Aim/s

- State the aims of the study as a narrative study purpose or as research questions or hypotheses to be tested.
  For example, *"The aim of the study was to…"*, *"The following hypotheses were tested: …"*

Design / Methodology

- Identify the specific research design used.
- For qualitative studies, this should be, for example, grounded theory, phenomenology, ethnography. For quantitative studies, this should be, for example, descriptive, correlational, experimental, quasiexperimental,

randomised controlled trail, cross-sectional, longitudinal
- For mixed methods studies identify the mixed method approach i.e. primarily qualitative with a quantitative component, or primarily quantitative with a qualitative component. Also identify the specific quantitative and qualitative approaches.

Sample / Participants

- Identify the sampling strategy/ strategies used– random, stratified, convenience, purposive (state what purpose). For example, *"A convenience sample of Registered Nurses was recruited, A random sample of patients was recruited…"*
  Identify the inclusion and exclusion criteria. For example, *"The inclusion criteria were…", "The exclusion criteria were…"*
- Explain how participants were recruited.
- Identify the size of the sample.
- For qualitative studies, provide justification for participant numbers that addresses data saturation or another criterion.
- For quantitative studies, report the power analysis or sample size calculation, if done; if not done, provide another type of justification for the sample size.

Data collection

- *Use subheadings* for different types of data collection techniques if appropriate, e.g. questionnaires, interviews, observation. For example, *"Data were collected using a questionnaire…", "Focus groups were conducted …"*
- *Describe each instrument used to collect the data, including number and type of items and scoring technique, as well as interpretation of scores.*
- Pilot study – if done, what changes (if any) did this lead to for the main study?
  Identify the year of data collection; usually **this should be no more than 5 years between data collection to submission of the paper** .

Ethical considerations

- Provide a statement of ethics committee approval. Do not name the university or other institution from which ethics committee approval was obtained. State only that ethics committee approval was obtained from a university and/or whatever other organisation is relevant.
- Briefly explain what information and guarantees were given to participants
- Indicate what type of informed consent was obtained—written, oral, or implied.
- Note that data cannot be both confidential and anonymous. If the investigators know the identity of the research participants, the data are considered confidential. If the investigators do not know the identity of any research participants, the data can be considered anonymous.

Data analysis

- Describe the techniques used to analyse the data, including computer software used, if appropriate.
- For mixed methods studies, describe analysis processes used for qualitative and quantitative data analysis.
- For example, *"The data were analysed using SPSS version X…", " The data were analysed using thematic content analysis…"*

Validity and reliability / Rigour as appropriate

- *Provide types of and estimates for trustworthiness of qualitative data and/or the psychometric properties of quantitative instruments.*
- *If tools were developed for this study, describe the processes employed, including validity and reliability testing.*

Results / Findings

- Start with a description of actual sample. For example, *"The study participants ranged in age from X to Y years…"*

- Present results explicitly for each study aim or research question or hypothesis. Indicate whether each hypothesis was supported or rejected.
- Use subheadings as appropriate.

Discussion

- Start with study limitations
- Must be in relation to the literature. Do previous research findings match or differ from yours?
- Draw conclusions about what new knowledge has emerged from the study. For example, this new knowledge could contribute to new conceptualisations or question existing ones; it could lead to the development of tentative/substantive theories (or even hypotheses), it could advance/question existing theories or provide methodological insights, or it could provide data that could lead to improvements in practice.

Conclusions

- Provide real conclusions, not just a summary/repetition of the findings
- Draw conclusions about the adequacy of the theory in relation to the data. Indicate whether the data supported or refuted the theory. Indicate whether the conceptual model was a useful and adequate guide for the study.
- Implications / recommendations for international nursing practice/research/education/management as appropriate, and consistent with the limitations

Notes

1. Presentational style
   Do not anthropomorphize inanimate objects, i.e. do not write about 'things' as if they were 'people'.
   For example, do not write *"The study explored ... "* Instead, write something such as: *"The purpose of the study was to explore..."* Alternatively, use the first person, for example: *"In this study we/I explored…", "We interviewed a convenience sample of 20 Registered Nurses".*
2. See also - author guidelines about Readability
3. See also - author guidelines about International Relevance.
4. Authors are cautioned against submitting multiple papers about one study without adequate justification (i.e., avoid "salami slicing") and against including content about background literature and methods that already has appeared in another paper by the same author(s) without appropriate citations (i.e., avoid self-plagiarism). See the Overlapping Publications section in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication, which can be found at http://www.icmje.org/
5. 5. See also http://www.nurseauthoreditor.com/article.asp?id=70, http://www.nurseauthoreditor.com/article.asp?id=42, http://www.nurseauthoreditor.com/article.asp?id=82
   Please note that you will need to register with the site to view the article.

Appendix B- Questionnaire (the questionnaires used in the master thesis only)

Lovisenberg Diakonale Sykehus
Pionér i kompetanse og omsorg

Spørreskjema om sykdom, forventet mestring og livskvalitet

Universitet i Oslo
Institutt for sykepleiervitenskap og helsefag

Kandidat nr. ☐☐☐☐☐☐

Dato: ☐☐☐☐☐☐

DEL A: BAKGRUNNSOPPLYSNINGER

A1. ALDER:_____

A2. KJØNN

Mann: ☐ Kvinne: ☐

A3. SPØRSMÅL OM SIVILSTAND

Gift/ samboer: ☐
Ugift: ☐
Enke/Enkemann: ☐
Skilt: ☐
Separert: ☐

A4. SPØRSMÅL OM HVEM DU BOR SAMMEN MED

Bor alene: ☐
Ektefelle/samboer: ☐
Søsken: ☐
Annen familie/slekt: ☐
Barn/svigerbarn: ☐
Bor på institusjon: ☐
Andre: ☐

A5. SPØRSMÅL OM UTDANNING

Kryss av for høyest gjennomførte utdanning:

Grunnskole: ☐
Yrkesskole: ☐
Videregående skole: ☐
Høyskole/universitetsutdannelse mindre enn 3-4 år: ☐
Høyskole/universitetsutdannelse over 4 år: ☐

A6. SPØRSMÅL OM JOBB

1. Er du pr. dags dato i lønnet arbeid? Ja: ☐ Nei: ☐

2. Hvis ja, hva jobber du med?_____

3. Hvis ja, hvor stor stillingsprosent har du?_____

4. Hvis nei:
Pensjonist: ☐ Uføretrygdet: ☐ Hjemmeværende: ☐ Går på skole: ☐ Sykemeldt: ☐

5. Hva har du eventuelt jobbet med tidligere?_____

A7. SPØRSMÅL OM HENDELSER I LIVET

Kryss av i en eller flere av rutene nedenfor dersom du i din senere tid (siste 4 uker) har opplevd noen av følgende hendelser:

Fått barn: ☐
Giftet deg/flyttet sammen med samboer: ☐
Dødsfall i familien /nære venner: ☐
Alvorlige bomessige eller økonomiske problemer: ☐
Andre betydelige livshendelser: ☐ Beskriv:_____

DEL B: OPPLYSNINGER OM SYKDOM OG FAKTORER RUNDT SYKDOM

B1. SPØRSMÅL OM MEDISINER

Bruker du medisinene dine regelmessig hver dag? Ja ☐ Nei ☐

B2. SPØRSMÅL OM RØYKING

1. Røyker du? Ja: ☐ Nei: ☐

Dersom ja, hvor lenge har du røkt i antall år?_____

Dersom ja, hvor mange sigaretter røyker du hver dag?_____

2. Dersom Nei, har du røkt tidligere? Ja ☐ Nei ☐

3. Hvor lenge er det siden du eventuelt sluttet? _____

B3. SPØRSMÅL OM OPPLÆRING PÅ SYKDOM OG TRENING

1. **Har du deltatt på lungerehabilitering?** Ja: ☐ Nei: ☐

2. **Dersom ja, hvor lenge siden?**
1-6 måneder siden: ☐ 6 måneder til 1 år siden: ☐ 1-3 år siden ☐ Mer enn 3 år siden: ☐

3. **Har du deltatt på annen kurs eller undervisning om din KOLS?** Ja: ☐ Nei: ☐

Dersom ja, spessifiser:_____

4. **Har du fått opplæring av helsepersonell om din lungesykdom?** Ja: ☐ Nei: ☐

Dersom ja, kryss av i en eller flere av rutene av hvem du har fått opplæring av?

Fast lege: ☐ Lungelege: ☐ Sykepleier: ☐ Fysioterapeut: ☐ Ergoterapeut: ☐

5. **Kryss av i en eller flere av rutene om du er i aktivitet i form av:**

Gå tur: ☐ Fysikalskinstitutt: ☐ Hjemmeøvelser: ☐ Helsestudio ☐ Annet ☐_____

_____

6. **Hvor ofte er du i aktivitet:**

Mindre enn 2 ganger i måneden ☐
Fra 2-4 ganger i måneden ☐
En gang i uken ☐
2-3 ganger i uken ☐
Mer enn 3 gagner i uken ☐

B4. SPØRSMÅL OM KOLS

1. **Har du hatt lungebetennelse eller forkjølelse de siste 4 ukene?** Ja ☐ Nei ☐

2. **Har du vært hos lege på grunn av din KOLS det siste året?** Ja ☐ Nei ☐
Eventuelt hvor mange ganger?_____

4. **Har du hatt sykehusinnleggelse det siste året?** Ja ☐ Nei ☐
Eventuelt hvor mange ganger?_____

B5. SPØRSMÅL OM LUNGESYKDOMMEN

Nedenfor følger en serie utsagn, som beskriver hvordan astma og obstruktiv lungesykdom (eller sykdommens behandling) affiseres for noen personer. For hvert utsagn ber vi deg merke av det svaret som passer best for deg i løpet av de siste fire ukene. Sett ring rundt svaret.

	Ikke i det hele tatt	Lett	Middels	Mye	Svært mye
1. Jeg har vært plaget av episoder med kortpustethet	1	2	3	4	5
2. Jeg har vært plaget av anfall med pipende pustelyd	1	2	3	4	5
3. Jeg har vært plaget av en følelse av tranghet i brystet	1	2	3	4	5
4. Jeg har vært hindret i å gå bortover gaten på flat mark eller i å gjøre lett husarbeid pga lungesykdommen	1	2	3	4	5
5. Jeg har vært hindret i å gå oppoverbakke eller å gjøre tungt husarbeid pga. lungesykdommen	1	2	3	4	5
6. Jeg har følt meg trett eller generelt manglet energi	1	2	3	4	5
7. Jeg har vært ute av stand til å sove om natten	1	2	3	4	5
8. Jeg har følt meg trist eller deprimert	1	2	3	4	5
9. Jeg har vært frustrert pga meg selv	1	2	3	4	5
10. Jeg har vært engstelig, spent eller stresset	1	2	3	4	5
11. Jeg har følt at lungesykdommen forhindrer meg i å utføre det jeg ønsker i livet	1	2	3	4	5
12. Lungesykdommen har forstyrret mitt sosiale liv	1	2	3	4	5
13. Jeg har unngått å gå til bestemte steder fordi de er dårlige for min lungesykdom	1	2	3	4	5
14. Jeg har unngått å gå til bestemte steder fordi jeg har vært redd for å få et anfall med pustebesvær og ikke være i stand til å få hjelp	1	2	3	4	5
15. Jeg har måttet begrense meg i sport, hobbyer eller andre fritidsaktiviteter jeg kan delta I pga. min lungesykdom	1	2	3	4	5
16. Jeg har følt at jeg generelt må begrense meg	1	2	3	4	5
17. Jeg har følt at lungesykdommen kontrollerer livet mitt	1	2	3	4	5
18. Jeg har vært bekymret for min nåværende eller fremtidige helse pga. lungesykdommen	1	2	3	4	5
19. Jeg har vært bekymret for at lungesykdommen kan forkorte mitt liv	1	2	3	4	5
20. Jeg har følt meg avhengig av mine astma/KOLS medisiner	1	2	3	4	5

DEL C: SPØRSMÅL OM HVOR TRØTT, DØSIG OG UTMATTET DU ER

Vi ønsker å vite mer om energinivået ditt. Nedenfor er det 18 utsagn vi ber deg svare på. Dette vil ta deg mindre enn ett minutt å gjøre.

INSTRUKSJONER: For hvert av utsagnene nedenfor: sett ring rundt det tallet som best indikerer hvordan du føler deg AKKURAT NÅ (angi klokkeslett: ____:____)

For eksempel: Anta at du ikke har spist siden i går. Vil du være "ikke sulten i det hele tatt", eller vil du være nærmere "svært sulten" helt til høyre på skalaen? Hvilket tall nedenfor vil du sette ring rundt?

ikke sulten i det hele tatt	0	1	2	3	4	5	6	7	8	9	10	svært sulten

Du vil antakeligvis sette ring rundt et tall nærmere "*svært sulten*" helt til høyre på skalaen, slik dette eksempelet viser:

ikke sulten i det hele tatt	0	1	2	3	4	5	6	7	8	[9]	10	svært sulten

VENNLIGST SVAR PÅ FØLGENDE UTSAGN OM HVORDAN DU FØLER DEG AKKURAT NÅ:

1.	ikke **sliten** i det hele tatt	0	1	2	3	4	5	6	7	8	9	10	svært **sliten**
2.	ikke **trøtt** i det hele tatt	0	1	2	3	4	5	6	7	8	9	10	svært **trøtt**
3.	ikke **døsig** i det hele tatt	0	1	2	3	4	5	6	7	8	9	10	svært **døsig**
4.	ikke **utmattet** i det hele tatt	0	1	2	3	4	5	6	7	8	9	10	svært **utmattet**
5.	ikke **utslitt** i det hele tatt	0	1	2	3	4	5	6	7	8	9	10	svært **utslitt**
6.	ikke **utkjørt** i det hele tatt	0	1	2	3	4	5	6	7	8	9	10	svært **utkjørt**
7.	ikke **utslått** i det hele tatt	0	1	2	3	4	5	6	7	8	9	10	svært **utslått**
8.	**å holde øynene åpne** er ikke anstrengende i det hele tatt	0	1	2	3	4	5	6	7	8	9	10	**å holde øynene åpne** er veldig anstrengende

9. **å bevege kroppen** er ikke anstrengende i det hele tatt	0	1	2	3	4	5	6	7	8	9	10	**å bevege kroppen** er veldig anstrengende
10. **å konsentrere seg** er ikke anstrengende i det hele tatt	0	1	2	3	4	5	6	7	8	9	10	**å konsentrere seg** er veldig anstrengende
11. **å holde i gang en samtale** er ikke anstrengende i det hele tatt	0	1	2	3	4	5	6	7	8	9	10	**å holde i gang en samtale** er veldig anstrengende
12. Jeg har absolutt **ikke noe behov for å lukke øynene**	0	1	2	3	4	5	6	7	8	9	10	jeg har et **veldig sterkt behov for å lukke øynene**
13. jeg har absolutt **ikke noe behov for å legge meg nedpå**	0	1	2	3	4	5	6	7	8	9	10	jeg har et **veldig sterkt behov for å legge meg nedpå**

INDIKER HVORDAN DU FØLER DEG <u>AKKURAT NÅ</u> I FORHOLD TIL DE SISTE FEM UTSAGNENE:

14. ikke **energisk** i det hele tatt	0	1	2	3	4	5	6	7	8	9	10	svært **energisk**
15. ikke **aktiv** i det hele tatt	0	1	2	3	4	5	6	7	8	9	10	svært **aktiv**
16. ikke **sprek** i det hele tatt	0	1	2	3	4	5	6	7	8	9	10	svært **sprek**
17. ikke **effektiv** i det hele tatt	0	1	2	3	4	5	6	7	8	9	10	svært **effektiv**
18. ikke **livlig** i det hele tatt	0	1	2	3	4	5	6	7	8	9	10	svært **livlig**

DEL D: SPØRSMÅL OM SØVNFORSTYRRELSE

*Tenk tilbake på den siste **uken**. Hvor mange dager har du* (sett ring rundt det aktuelle tall):

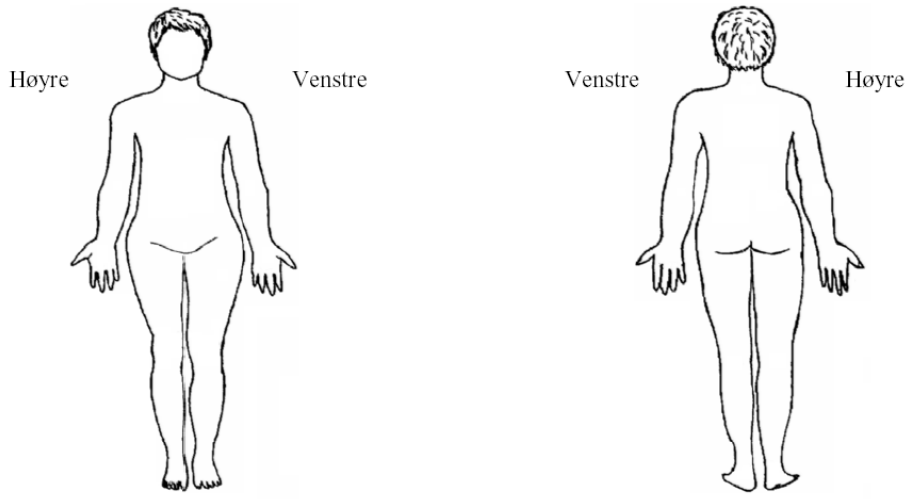
		Aldri							**Hver dag**
1.	Hatt problemer med å sovne	0	1	2	3	4	5	6	7
2.	Våknet i løpet av søvnperioden	0	1	2	3	4	5	6	7
3.	Våknet for tidlig og fikk ikke til å sovne igjen	0	1	2	3	4	5	6	7
4.	Følt deg uthvilt når du våkner på slutten av en søvnperiode	0	1	2	3	4	5	6	7
5.	Sovet dårlig	0	1	2	3	4	5	6	7
6.	Følt deg søvnig i løpet av dagen	0	1	2	3	4	5	6	7
7.	Kjempet for å holde deg våken gjennom dagen	0	1	2	3	4	5	6	7
8.	Følt deg irritabel i løpet av dagen	0	1	2	3	4	5	6	7
9.	Følt deg trøtt eller utmattet i løpet av dagen	0	1	2	3	4	5	6	7
10.	Følt deg tilfreds med søvnkvaliteten	0	1	2	3	4	5	6	7
11.	Følt deg våken og energisk gjennom dagen	0	1	2	3	4	5	6	7
12.	Fått for mye søvn	0	1	2	3	4	5	6	7
13.	Fått for lite søvn	0	1	2	3	4	5	6	7
14.	Tatt en blund til planlagt tid	0	1	2	3	4	5	6	7
15.	Sovnet uten at det var planlagt	0	1	2	3	4	5	6	7
16.	Drukket alkohol for å få til å sovne	0	1	2	3	4	5	6	7
17.	Brukt tobakk for å få til å sovne	0	1	2	3	4	5	6	7
18.	Brukt andre stimuli for å sovne (f.eks. avslapping, musikk, lesing)	0	1	2	3	4	5	6	7
19.	Brukt naturmedisinske midler for å sovne	0	1	2	3	4	5	6	7
20.	Brukt reseptbelagt sovemedisin for å få til å sovne	0	1	2	3	4	5	6	7
21.	Brukt paracet eller annet smertestillende for å sove	0	1	2	3	4	5	6	7

DEL E: SPØRSMÅL OM SMERTE

1. Gjennom livet har de fleste av oss hatt smerter (som lett hodepine, forstuelser eller tannpine). Har du i dag smerter av et annet slag enn slike dagligdagse smerter.

☐ Ja ☐ Nei

2. Vil du skravere de områdene på kroppen hvor du har smerter. Marker med et kryss der du har mest vondt.



3. Vennligst sett ring rundt det tallet som best beskriver de sterkeste smertene du har hatt i løpet av de siste 24 timer.

0 1 2 3 4 5 6 7 8 9 10

Ingen smerter — Verst tenkelige smerter

4. Vennligst sett ring rundt det tallet som best beskriver de svakeste smertene du har hatt i løpet av de siste 24 timer.

0 1 2 3 4 5 6 7 8 9 10

Ingen smerter — Verst tenkelige smerter

5. Vennligst sett ring rundt det tallet som best angir hvor sterke smerter du har i gjennomsnitt.

0 1 2 3 4 5 6 7 8 9 10

Ingen smerter — Verst tenkelige smerter

6. Vennligst sett ring rundt det tallet som best angir hvor sterke smerter du har akkurat nå.

0 1 2 3 4 5 6 7 8 9 10

Ingen smerter — Verst tenkelige smerter

7. Hvilken behandling eller medisiner får du for å lindre smertene dine?

8. I hvor stor grad har behandling eller medisiner lindret smertene dine de siste 24 timene?
Vennligst sett en ring rundt det prosenttallet som viser hvor stor smertelindring du har fått.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Ingen lindring **Fullstendig lindring**

Sett en ring rundt det tallet som for de siste 24 timene best beskriver hvor mye smertene har virket inn på:

9. Daglig aktivitet

0 1 2 3 4 5 6 7 8 9 10

Ikke påvirket Fullstendig påvirket

10. Humør

0 1 2 3 4 5 6 7 8 9 10

Ikke påvirket Fullstendig påvirket

11. Evne til å gå

0 1 2 3 4 5 6 7 8 9 10

Ikke påvirket Fullstendig påvirket

12. Vanlig arbeid (gjelder både arbeid utenfor hjemmet og husarbeid)

0 1 2 3 4 5 6 7 8 9 10

Ikke påvirket Fullstendig påvirket

13. Forhold til andre mennesker

0 1 2 3 4 5 6 7 8 9 10

Ikke påvirket Fullstendig påvirket

14. Søvn

0 1 2 3 4 5 6 7 8 9 10

Ikke påvirket Fullstendig påvirket

15. Livsglede

0 1 2 3 4 5 6 7 8 9 10

Ikke påvirket Fullstendig påvirket

DEL F: SPØRSMÅL OM HVORDAN DU FØLER DEG

HAD

Dette spørreskjemaet er laget for å hjelpe oss til å forstå hvordan du føler deg. Les hver linje og marker i boksen for det svar som beskriver dine følelser DEN SISTE UKEN.

1. Jeg er nervøs eller anspent

- ☐ For det meste
- ☐ Ofte
- ☐ Noen ganger
- ☐ Ikke i det hele tatt

2. Jeg gleder meg fremdeles over ting jeg pleide å glede meg over

- ☐ Avgjort like mye
- ☐ Ikke fullt så mye
- ☐ Bare litte grann
- ☐ Ikke i det hele tatt

3. Jeg har en urofølelse som om noe forferdelig kommer til å skje

- ☐ Helt sikkert og svært ille
- ☐ Ja, men ikke så veldig ille
- ☐ Litt ille, men det bekymrer meg ikke så mye
- ☐ Ikke i det hele tatt

4. Jeg kan le og se det morsomme i situasjoner

- ☐ Like mye som jeg alltid har gjort
- ☐ Ikke like mye nå som før
- ☐ Avgjort ikke så mye nå som før
- ☐ Ikke i det hele tatt

5. Jeg har hodet fullt av bekymringer

- ☐ Veldig ofte
- ☐ Ganske ofte
- ☐ Av og til
- ☐ En gang i blant

6. Jeg er i godt humør

- ☐ Aldri
- ☐ Noen ganger
- ☐ Ganske ofte
- ☐ For det meste

7. Jeg kan sitte i fred og ro og kjenne meg avslappet

- ☐ Ja, helt klart
- ☐ Vanligvis
- ☐ Ikke så ofte
- ☐ Ikke i det hele tatt

8. Jeg føler det som om alt går langsommere

- ☐ Nesten hele tiden
- ☐ Svært ofte
- ☐ Fra tid til annen
- ☐ Ikke i det hele tatt

9. Jeg føler meg urolig liksom jeg har sommerfugler i magen

- ☐ Ikke i det hele tatt
- ☐ Fra tid til annen
- ☐ Ganske ofte
- ☐ Svært ofte

10. Jeg har sluttet å bry meg om hvordan jeg ser ut

- ☐ Ja, helt klart
- ☐ Jeg bryr meg ikke så mye som jeg burde
- ☐ Det kan nok hende at jeg ikke bryr meg nok
- ☐ Jeg bryr meg om utseendet like mye som jeg alltid har gjort

11. Jeg føler meg rastløs som om jeg stadig må være i aktivitet

- ☐ Uten tvil svært mye
- ☐ Ganske mye
- ☐ Ikke så veldig mye
- ☐ Ikke i det hele tatt

12. Jeg ser med glede frem til hendelser og ting

- ☐ Like mye som jeg alltid har gjort
- ☐ Heller mindre enn jeg pleier
- ☐ Avgjort mindre enn jeg pleier
- ☐ Nesten ikke i det hele tatt

13. Jeg kan plutselig få en følelse av panikk

- ☐ Uten tvil svært ofte
- ☐ Svært ofte
- ☐ Ikke så veldig ofte
- ☐ Ikke i det hele tatt

14. Jeg kan glede meg over en god bok eller et radio eller TV-program

- ☐ Ofte
- ☐ Fra tid til annen
- ☐ Ikke så ofte
- ☐ Svært sjelden

Appendix C – Information and invitation letter

Lovisenberg Diakonale Sykehus

Universitet i Oslo
Seksjon for Sykepleiervitenskap
og helsefag

Forespørsmål om deltakelse i prosjekt "Symptomkluster, forventet mestring og livskvalitet"

I et prosjekt ved Lovisenberg Diakonale Sykehus ønsker vi å se nærmere på hvordan personer med KOLS opplever sine symptomer, forventet mestring og livskvalitet. Totalt ønsker vi at ca. 150 personer med KOLS kan delta i prosjektet. Vi håper du har anledning til å delta.

Deltagelse i prosjektet innebærer at du må besvare et spørreskjema, gjennomføre spirometri (lungefunksjonstest) og en 6. minutters gangtest. Spørreskjema vil handle om opplevelse av pust, følelser, utmattelse, søvn, smerte, eventuelle røykevaner, forventet mestring og livskvalitet. Spørreskjema inneholder ca 170 spørsmål. Alle spørsmålene er skrevet på norsk og du må derfor kunne lese og skrive norsk for å delta. Opplysninger om eventuelle andre sykdommer og ulike medisiner du bruker ønsker vi å hente fra din journal ved Lovisenberg Diakonale Sykehus.

Dersom du samtykker i deltagelse, får du tilsendt spørreskjemaet hjem til deg, sammen med en oppsatt time til lungefunksjonsprøve og gangtest på sykehuset. Undersøkelsen på sykehuset vil ta ca. 30 minutter, og besvarelse av spørreskjemaet kan ta opp mot 45 minutter. Ferdig utfylt spørreskjema tar du med deg når du kommer til undersøkelsen.

I etterkant av undersøkelsen får du tilbud om en samtale med lungesykepleier, hvor du kan ta opp eventuelle spørsmål du har i forbindelse med dine lungeplager. Denne samtalen vil ikke være en del av studiet, men fungere som en poliklinisk time. Egen taxi rekvisisjon gjennom folketrygden vil bli tilsendt til de som deltar. Det blir ingen utgifter dersom du har frikort.

Det er frivillig å være med og du har mulighet til å trekke deg når som helst underveis, uten å måtte begrunne dette nærmere. Dersom du trekker deg kontakter du lungesykepleier Christine Råheim Borge som vil sørge for at alle innsamlede data om deg bli slettet.

Opplysningene vil bli behandlet konfidensielt. Det vil ikke være mulig å identifisere deg når resultatene fra studien publiseres. Du har rett til innsyn i opplysningene som er lagret om deg, og til å kreve eventuelle feil rettet opp. Institutt for sykepleiervitenskap og helsefag, Universitet i Oslo er ansvarlig for lagring av data, som sikres mot innsyn.
Dersom du ønsker å delta, signerer du vedlagte samtykkeerklæringen og sender den i den frankerte konvolutten.

Det kan også være aktuelt å kontakte deg på et senere tidspunkt i forhold til å besvare ytterligere spørsmål og å gjennomføre lignende tester som beskrevet ovenfor. Du vil da bli kontaktet innen to år. Samtykkeerklæringen til å delta i denne studien vil også innebære at vi kan ta kontakt med deg i forhold til en eventuell oppfølgingsstudie.
Innsamlet data i denne studien vil bli slettet innen 2012.

Sykehuset eies av stiftelsene Menighetssøsterhjemmet og Diakonissehuset Lovisenberg

Lovisenberg Diakonale Sykehus

Hvis det er noe du lurer på, kan du ta kontakt med;
mastergradstudent/lungesykepleier Christine Råheim Borge
på telefon: 23 22 64 18 eller sende e-post: christineraaheim.borge@lds.no.

Studien er meldt til Regional komité for medisinsk forskningsetikk, REK Sør og Norsk samfunnsvitenskaplig Datatjeneste A/S. Studien er også godkjent av sykehusledelsen ved Lovisenberg Diakonale Sykehus. Veileder for prosjektet er Professor Astrid K. Wahl ved seksjon for Helsefag, Universitet i Oslo.

Men vennlig hilsen

Christine Råheim Borge
Mastergradstudent ved Universitet i Oslo
Lungesykepleier ved Lovisenberg Diakonale Sykehus
Medisinsk Poliklinikk

Astrid K. Wahl
Professor
Universitetet i Oslo, Seksjon for Helsefag

Sykehuset eies av stiftelsene Menighetssøsterhjemmet og Diakonissehuset Lovisenberg

Appendix D – Approval form from the participants

Lovisenberg Diakonale Sykehus

Universitet i Oslo
Seksjon for Sykepleiervitenskap
og helsefag

Samtykkeerklæring

Jeg har mottatt informasjon om studiet: "Symptomkluster, forventet mestring og livskvalitet hos personer med KOLS", og ønsker å delta i prosjektet ved å svare på spørreskjema. gjennomføre en spirometri og en 6. minutters gangtest.

Jeg kan kontaktes igjen for en eventuell oppfølgingsstudie.

Signatur_____

Telefonnummer_____

Sykehuset eies av stiftelsene Menighetssøsterhjemmet og Diakonissehuset Lovisenberg

Appendix E- Approval form from the Medical Ethics Committee

UNIVERSITETET I OSLO
DET MEDISINSKE FAKULTET

KOPI

Professor dr. philos. Astrid Wahl
Institutt for sykepleievitenskap og helsefag
Universitetet i Oslo
Pb. 1153 Blindern

Regional komité for medisinsk forskningsetikk
Sør- Norge (REK Sør)
Postboks 1130 Blindern
NO-0318 Oslo

Telefon: 228 50 670
Telefaks: 228 44 661
E-post: jorunn.lindholt@medisin.uio.no
Nettadresse: www.etikkom.no

Dato: 14.01.08
Deres ref.:
Vår ref.: S-0723

S-07023b Symptomkluster, forventet mestring og livskvaliet hos personer med KOLS [2.2007.73]

Vi viser til e-post mottatt 04.02.2008 vedlagt brev datert 03.01.2008.

I brevet henvises det til REKS svarbrev av 11.12.2007 og tidligere innsendt skjema for protokolltillegg og endringer datert 28.11.2007.

I brevet klargjøres det hva endringen skissert i det tidligere innsendte skjema for protkolltillegg og endringer innebærer. Endringen oppgis å være er to-delt:
1) Prosjektleder ønsker å inkludere personer over 80 år i prosjektet.
2) Prosjektleder ønsker å undersøke informasjom om alder, kjønn, sykdomstilstand og etnisitet på de som ikke har samtykket i å delta i prosjektet, med det formål å forklare hvorfor de ikke har samtykket i deltakelse.

Opplysningene under del to i det ufylte endringsskjemaet ønsket man å innhente fra pasientjournaler.Dette mente komiteen reiste etiske betenkeligheter, så lenge det ikke ble innhentet samtykke til innsyn i journal på forhånd. I brev fra prosjektleder av 3. januar foreslås det derfor i stedet å hente opplysninger fra pasientlister.

Som angitt i forrige brev, ser komiteen ingen betenkeligheter ved å inkludere personer over 80 år i prosjektet. Vi opprettholder også oss vår vurdering vedrørende innhenting av opplysninger fra journal uten å først innhente samtykke fra pasientene dette gjelder. Komiteen finner derimot at opplysninger om *navn* og *alder* å være åpne opplysninger i pasientlister, og mener at disse, men kun disse, kan brukes som mulige forklaringsfaktorer for hvorfor pasientene ikke samtykket til deltakelse.

Vi ønsker fortsatt lykke til med prosjektet

Med vennlig hilsen

Tor Norseth
Leder

Jorunn Lindholt
Fungerende sekretær

Kopi: Mastergradsstudent Christine Råheim Borge, Institutt for sykepleievitenskap og helsefag, Universitetet i Oslo,Pb. 1153

Appendix F- Approval from Data Inspectorate

Norsk samfunnsvitenskapelig datatjeneste AS
NORWEGIAN SOCIAL SCIENCE DATA SERVICES

Astrid Klopstad Wahl
Institutt for sykepleievitenskap og helsefag
Universitetet i Oslo
Postboks 1153 Blindern
0318 OSLO

Harald Hårfagres gate 29
N-5007 Bergen
Norway
Tel: +47-55 58 21 17
Fax: +47-55 58 96 50
nsd@nsd.uib.no
www.nsd.uib.no
Org.nr. 985 321 884

Vår dato: 09.03.2007 Vår ref: 16140/KS Deres dato: Deres ref:

TILRÅDING AV BEHANDLING AV PERSONOPPLYSNINGER

Vi viser til melding om behandling av personopplysninger, mottatt 12.01.2007. All nødvendig informasjon om prosjektet forelå i sin helhet 07.03.2007. Meldingen gjelder prosjektet:

16140	*Symptomkluster, forventet mestring og livskvalitet hos personer med KOLS*
Behandlingsansvarlig	*Universitetet i Oslo, ved institusjonens øverste leder*
Daglig ansvarlig	*Astrid Klopstad Wahl*
Student	*Christine Råheim Borge*

Personvernombudet har vurdert prosjektet, og finner at behandlingen av personopplysninger vil være regulert av § 7-27 i personopplysningsforskriften. Personvernombudet tilrår at prosjektet gjennomføres.

Personvernombudets tilråding forutsetter at prosjektet gjennomføres i tråd med opplysningene gitt i meldeskjemaet, korrespondanse med ombudet, eventuelle kommentarer samt personopplysningsloven/-helseregisterloven med forskrifter. Behandlingen av personopplysninger kan settes i gang.

Det gjøres oppmerksom på at det skal gis ny melding dersom behandlingen endres i forhold til de opplysninger som ligger til grunn for personvernombudets vurdering. Endringsmeldinger gis via et eget skjema, http://www.nsd.uib.no/personvern/endringsskjema. Det skal også gis melding etter tre år dersom prosjektet fortsatt pågår. Meldinger skal skje skriftlig til ombudet.

Personvernombudet har lagt ut opplysninger om prosjektet i en offentlig database, http://www.nsd.uib.no/personvern/database/

Personvernombudet vil ved prosjektets avslutning, 31.12.2012 rette en henvendelse angående status for behandlingen av personopplysninger.

Vennlig hilsen

for
Vigdis Namtvedt Kvalheim

Katrine Utaaker Segadal
Katrine Utaaker Segadal

Kontaktperson: Katrine Utaaker Segadal tlf: 55 58 35 42

Vedlegg: Prosjektvurdering

Kopi: Christine Råheim Borge, Bringebæråsen 16, 1412 SOFIEMYR

Appendix G- Approval from the Medical Clinic

Lovisenberg Diakonale Sykehus

Klinikk for medisin
Klinikkledelsen
Lovisenberg Diakonale Sykehus AS
0440 Oslo
Sentralbord: 23 22 50 00

Besøksadresse:
Lovisenberggt. 17

Direkte telefon: 23 22 56 58
Faks: 23 22 56 51
www.lds.no
Org. nr.: No 965 985 166

Til Regional komité for medisinsk forskningsetikk
Sør-Norge (REK Sør)
Postboks 1130 Blindern
NO-0318 Oslo

Deres ref.:	Vår ref.:	Saksnr.:	Arkivnr.:	Dato:
	anmt			14.2.07

Vedrørende gjennomføring av prosjektet "Symptomkluster, forventet mestring og livskvalitet" S – 07023b

Jeg bekrefter med dette at Lovisenberg Diakonale Sykehus, Klinikk for medisin har godkjent gjennomføringen av ovennevnte prosjekt og at vi betrakter dette som et viktig satsningsområde for pasienter med KOLS.

Lungesykepleier og mastergradsstudent ved Institutt for helsefag UiO, Christine Råheim Borge vil være ansvarlig for innsamling av data.

Til daglig arbeider hun ved vår lungepoliklinikk der hun utfører ulike lungefunksjonsprøver samt er ansvarlig for lungerehabilitering og sykehusets astmaskole.

Klinikksjefen har godkjent at hun kan bruke inntil 30 % av sin ordinære arbeidstid til gjennomføring av studiet. Overlege i lungemedisin Tor Einar Erikstad vil være medisinsk -faglig ansvarlig for respondentene. I tillegg vil de, som et ledd i oppfølgingen, få samtale med en lungesykepleier.

Vennlig hilsen
Anne Marit Tangen
Anne Marit Tangen
Klinikksjef

Appendix H- Approval form Medical Ethics Committee for collecting data on non-participants

UNIVERSITETET I OSLO
DET MEDISINSKE FAKULTET

KOPI

Professor dr. philos. Astrid Wahl
Institutt for sykepleievitenskap og helsefag
Universitetet i Oslo
Pb. 1153 Blindern

Regional komité for medisinsk forskningsetikk
Sør- Norge (REK Sør)
Postboks 1130 Blindern
NO-0318 Oslo

Telefon: 228 50 670
Telefaks: 228 44 661
E-post: jorunn.lindholt@medisin.uio.no
Nettadresse: www.etikkom.no

Dato: 14.01.08
Deres ref.:
Vår ref.: S-0723

S-07023b Symptomkluster, forventet mestring og livskvaliet hos personer med KOLS [2.2007.73]

Vi viser til e-post mottatt 04.02.2008 vedlagt brev datert 03.01.2008.

I brevet henvises det til REKS svarbrev av 11.12.2007 og tidligere innsendt skjema for protokolltillegg og endringer datert 28.11.2007.

I brevet klargjøres det hva endringen skissert i det tidligere innsendte skjema for protkolltillegg og endringer innebærer. Endringen oppgis å være er to-delt:
1) Prosjektleder ønsker å inkludere personer over 80 år i prosjektet.
2) Prosjektleder ønsker å undersøke informasjom om alder, kjønn, sykdomstilstand og etnisitet på de som ikke har samtykket i å delta i prosjektet, med det formål å forklare hvorfor de ikke har samtykket i deltakelse.

Opplysningene under del to i det ufylte endringsskjemaet ønsket man å innhente fra pasientjournaler.Dette mente komiteen reiste etiske betenkeligheter, så lenge det ikke ble innhentet samtykke til innsyn i journal på forhånd. I brev fra prosjektleder av 3. januar foreslås det derfor i stedet å hente opplysninger fra pasientlister.

Som angitt i forrige brev, ser komiteen ingen betenkeligheter ved å inkludere personer over 80 år i prosjektet. Vi opprettholder også oss vår vurdering vedrørende innhenting av opplysninger fra journal uten å først innhente samtykke fra pasientene dette gjelder. Komiteen finner derimot at opplysninger om *navn* og *alder* å være åpne opplysninger i pasientlister, og mener at disse, men kun disse, kan brukes som mulige forklaringsfaktorer for hvorfor pasientene ikke samtykket til deltakelse.

Vi ønsker fortsatt lykke til med prosjektet

Med vennlig hilsen

Tor Norseth
Leder

Jorunn Lindholt
Fungerende sekretær

Kopi: Mastergradsstudent Christine Råheim Borge, Institutt for sykepleievitenskap og helsefag, Universitetet i Oslo,Pb. 1153