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An observational, longitudinal study on the home environment of people with chronic obstructive pulmonary disease: the research protocol of the Home Sweet Home study

Nienke Nakken,1 Daisy J A Janssen,1,2 Esther H A van den Bogaart,1 Jan H Vercoulen,3 Emiel F M Wouters,1,4 Martijn A Spruit1

ABSTRACT
Introduction: Chronic obstructive pulmonary disease (COPD) represents an important public health challenge. Patients are confronted with limitations during activities of daily living (ADLs). Resident loved ones of patients with COPD may be uniquely positioned to witness these limitations. COPD may have an impact on not only the patients’ life, but also on the lives of the resident loved ones. Furthermore, COPD exacerbation-related hospital admissions often occur in patients with COPD. However, whether and to what extent these admissions influence resident loved ones’ burden and health status remains currently unknown. Therefore, the primary objectives of this study are to investigate the differences between patients with COPD and resident loved ones’ perceptions of patients’ health status and problematic ADLs and to study prospectively the effects of a COPD exacerbation on resident loved ones’ perceptions of patients’ health status and problematic ADLs.

Methods and analysis: An observational, longitudinal study will be performed in 192 patients with COPD and their 192 resident loved ones. Primary outcomes are daily functioning, ADL, disease-specific health status, generic health status and dyspnoea. These will be assessed during home visits at baseline and after 12 months. Additional home visits will be performed when a COPD exacerbation-related hospital admission occurs during the 12-month follow-up period.

Ethics and dissemination: This protocol was approved by the Medical Ethics Committee of the Catharina Hospital Eindhoven, the Netherlands (NL42721.060.12/M12-1280) and is registered in the Dutch Trial Register (NTR3941).

INTRODUCTION
Chronic obstructive pulmonary disease (COPD) is the fourth cause of death in the world1 and represents an important public health challenge.2 Owing to continued exposure to COPD risk factors and aging of the population, the burden of COPD will increase in the upcoming decades.2 This, combined with the shortage in healthcare staffing3 most probably causes a shift towards home care.

Commonly, patients with COPD suffer from multiple symptoms, like dyspnoea, coughing, sputum production, fatigue, anxiety and/or depression.4 Therefore, it is not very surprising that patients with COPD experience symptoms during activities of daily living (ADLs).3,6 Resident loved ones may be uniquely positioned to witness the limitations that patients with COPD experience during (physical and instrumental) ADLs.

The terminology used to refer to the caregiver role is ambiguous.7 The terms ‘family caregiver’ or ‘informal caregiver’ refer to a person, often a family member or friend, who is providing care, but is not a healthcare professional.8 9 However, informal caregivers...
themselves, in particular spouses, do not refer to the notion of being a caregiver, often describing it as an extension of their loving role and commitment to the person requiring support. Therefore, in this study, the term resident loved one will be used. We adopt the following definition: a person living together with a patient with COPD, regardless of whether they provide care to the patient with COPD.

Caring for a loved one with advanced COPD is described as a full-time role that is akin to that of caring for people with severe disability. General day-to-day commitments of resident loved ones are planned around the care of the patient with COPD. Therefore, caregiver burden is common in family caregivers of patients with COPD. However, caregiver burden is not associated with objective measures of the patient’s need for assistance. In fact, caregiver burden seems more associated with the loved ones’ report of need for greater help and symptoms of depression of the patient. It is known that discrepancies exist in spouses’ perceptions of patients’ symptoms and health status and those of the patients themselves. How resident loved ones interact with patients with COPD probably depends on many determinants, such as their perceptions of patients’ limitations in ADLs, the quality of the relationship, as well as the patients’ health status and mood status. On the other hand, spouses’ anxiousness is a predictor for the health status of patients with COPD.

Family caregiving is most probably a dynamic process, in which an escalation in loved ones’ anxiety, depression and psychological distress may occur as the patient’s functional status declines over time or during a hospitalisation due to a COPD exacerbation. In fact, caregivers of patients with heart failure who had fewer emergency department visits felt more positive about caregiving than other caregivers. Whether and to what extent COPD exacerbation-related hospital admissions influence resident loved ones’ burden and health status remains currently unknown.

Objectives of the study

The primary objective of this study in patients with COPD is twofold:

1.1 To investigate the differences between patients with COPD and resident loved ones’ perceptions of patients’ health status and problematic ADLs.

1.2 To study prospectively the effects of a COPD exacerbation on resident loved ones’ perceptions of patients’ health status and problematic ADLs.

Furthermore, the following secondary objectives will be addressed:

2.1 To investigate the differences between patients with COPD and resident loved ones’ perceptions of patients’ mood status, care dependency and daily symptoms.

2.2 To investigate the general well-being of patients when discrepancies exist between the patients’ and resident loved ones’ perceptions of patients’ care dependency.

2.3 To investigate if general well-being of patients and loved ones is influenced by the health or mood status of the significant other.

2.4 To study the relationship between lifestyle factors (like physical activity, smoking habit and fat free mass) in patients with COPD and their resident loved ones.

2.5 To investigate resident loved ones’ burden due to patients care dependency.

2.6 To investigate resident loved ones’ knowledge about COPD and the relationship with anxiety and social support.

3.1 To study prospectively the effects of a COPD exacerbation on resident loved ones’ perceptions of patients’ mood status, care dependency and daily symptoms.

3.2 To investigate whether and to what extent loved ones’ burden and resident loved ones’ health and mood status are influenced by exacerbation-related hospital admissions.

4.1 To capture differences at baseline and 12 months later between patients’ and resident loved ones’ health and mood status and problematic ADLs, mood status, care dependency and daily symptoms.

The objective of this article is to show the rationale and methods of this observational, longitudinal study in patients with COPD and their resident loved ones. Furthermore, this detailed description of the research protocol of the Home Sweet Home study will serve as reference for the method section of future publications of this study. Finally, the current manuscript provides an outline of the possible strengths, weaknesses and clinical consequences.

**METHODS AND ANALYSIS**

**Study design**

An observational, longitudinal study on the home environment of people with COPD has been designed. All data will be collected during home visits at baseline and after 12 months. Additional home visits will be performed when an exacerbation-related hospital admission occurs during the 12-month follow-up period. The resident loved one will be visited extra at home <7 days after admission of the patient with COPD to the hospital. Finally, 2 weeks after discharge, the patient and loved one will be visited once more at home. Figure 1 gives a complete overview of the study design. Data collection will take place from July 2013 until April 2016.

**Eligibility criteria**

Eligible patients are those who satisfy all of the following criteria:

1. Patients with moderate to very severe COPD as main diagnosis (Global initiative for chronic Obstructive Lung Disease (GOLD) grade II, III or IV),

2. Patients 40-80 years of age;

3. Residence in the Netherlands;

4. COPD duration >1 year; and

5. Currently under follow-up by a general practitioner or pulmonologist.

**Data collection**

A comprehensive manual for data collection will be developed and will be given to the research assistants. Data collection will be performed by all members of the research team. The quality of data collection will be assured by the research coordinator and the principal investigator. Data will be entered in a specific SPSS database by the research assistants. Data entries will be checked for quality and consistency.

**Analysis**

The primary objective of this study is to compare the health status and problematic ADLs of patients with COPD and their resident loved ones. Secondary analyses will be performed to investigate the impact of COPD exacerbations and hospital admissions on the health status and problematic ADLs of patients with COPD and their resident loved ones. Additionally, the relationship between lifestyle factors (like physical activity, smoking habit and fat free mass) in patients with COPD and their resident loved ones will be investigated.

The primary outcome of this study is the health status and problematic ADLs of patients with COPD and their resident loved ones. Secondary outcomes will be investigated to assess the impact of COPD exacerbations and hospital admissions on the health status and problematic ADLs of patients with COPD and their resident loved ones. Additionally, the relationship between lifestyle factors (like physical activity, smoking habit and fat free mass) in patients with COPD and their resident loved ones will be investigated.

**Ethical approval**

The Home Sweet Home study will be conducted according to the provisions of the declaration of Helsinki and has been approved by the Ethics Committee of Maastricht University Medical Center (MUMC) and the Board of Directors of MUMC. Patients will be asked to sign an informed consent form before starting the study.
2. No exacerbation of COPD (defined as ‘an acute event characterised by a worsening of the patient’s respiratory symptoms ie, beyond the normal day-to-day variations and leads to a change in medication’ or hospitalisation <4 weeks preceding enrolment);

3. Provided written informed consent;

4. One resident loved one (defined as a person living together with a patient with COPD, regardless of whether they provide care to the patient with COPD) also provided written informed consent to participate.

Patients will be excluded if:
1. Patient and/or resident loved one is unable to complete the study questionnaires because of cognitive impairment (defined as Short Blessed Test score ≥10 point);
2. Patient and/or resident loved one is unable to speak or understand Dutch.

Patients will be equally divided based on gender and GOLD grade. Furthermore, about two-third of the participating patients should be frequent exacerbators (defined as two or more COPD exacerbations, or one or more COPD exacerbation-related hospital admission in the year before baseline measurements).

From eligible non-participating patients, some data like disease severity (GOLD grade), gender, and age will be collected to compare characteristics of participating and non-participating patients.

Outcomes
The following primary outcomes will be assessed at the patients’ home environment: Daily functioning (Canadian Occupational Performance Measure (COPM) and the Instrumental Activities of Daily Living Scale (IADLS)); disease-specific health status (COPD Assessment Test (CAT)); generic health status (12-Item Short Form Health Survey (SF-12) and the EuroQol 5-Dimensions (EQ-5D)); Dyspnoea (modified Medical Research Council (mMRC) dyspnoea scale).

In addition, the following secondary outcomes will be assessed: Symptoms of fatigue (Subjective Fatigue subscale of the Checklist Individual Strength (CIS)); exercise self-efficacy (self-efficacy for home walking questionnaire); symptoms of anxiety and depression (Hospital Anxiety and Depression scale (HADS)); general well-being (Assessment of Quality of Life with 8 dimensions (AQL-I5D)); mobility (Timed-Up-and-Go test); daily symptoms using visual analogue scales (VAS); COPD-specific knowledge (CIROPD knowledge questionnaire); coping (Utrecht Coping List (UCL)); care dependency (Care Dependency Scale (CDS)); and informal and professional care <6 months; physical activity and motivation (validated accelerometer); the Behavioural Regulation in Exercise Questionnaire (BREQ-2); and the social-individual focus; smoking status (self-developed questionnaire, and the Fagerström test for nicotine dependence); social support (Medical Outcome Study Social Support Survey (MOSSSS)); quality of the relationship (Dutch relationship questionnaire (NRV)); cognitive functioning (Short Blessed Test (SBT)); caregiver burden and positive aspects of caregiving (Family Appraisal of Caregiving Questionnaire for Palliative Care (FACQ-PC)); clinical characteristics (fat-free mass (using body impedance assessment (BIA)); body weight and height, post-bronchodilator spirometry, resting blood pressure, resting heart rate and resting transcutaneous oxygen saturation).

Additionally, demographics (such as age, gender, marital status and working status), medical history, (Charlson comorbidity index), current medication and home adaptations and aids will be recorded.

The resident loved one will be asked to contact the study team when an exacerbation-related hospital admission occurs during the 12-month follow-up period. Furthermore, COPD exacerbation-related hospital admissions of participants will be checked weekly in the participating hospitals by the study team.

Figure 1 Timing of the home visits. Home visits will take place in all patients and their loved ones at baseline and after 1-year follow-up. Additional home visits will be planned when a chronic obstructive pulmonary disease exacerbation-related hospital admission occurs.

Besides questionnaires that will be administered about the patient or the resident loved one themselves, residents loved ones will be asked to complete questionnaires regarding their perception of the health status or situation of the patient. Table 1 provides an overview of the measurements per time point.

Questionnaires that were not available in Dutch have been translated into Dutch by the procedure of forward-backward translation.

Sample size
Since no preliminary data are available concerning differences in perception in health status and ADLs, the sample size for the primary objective 1.1 is estimated using G power. A total of 171 patients and 171 resident loved ones are needed to detect an effect size of 0.25 with a significance of 5% and power of 90%. Since we expect about 10% dropout, 10% additional couples will be included. Furthermore, patients will be equally divided based on gender and GOLD grade. Therefore, the study population consists of 192 patients and their resident loved ones.

For objective 1.2, 38 patients with an exacerbation-related hospital admission during follow-up are needed to detect a medium effect size of 0.5 (significance 5% and power 85%). In this study sample, we expect about 46 hospital admissions. Therefore, a sample size of 192 patients and 192 loved ones will also be sufficient to answer objective 1.2.

<table>
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<td>Timed-up-and-go test</td>
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<td>Subjective fatigue scale (CIS)</td>
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<td>COPD knowledge questionnaire (CIROPD)</td>
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<td>Dutch relationship questionnaire (NRV)</td>
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<td>Behavioural Regulation in Exercise Questionnaire (BREQ-2)</td>
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<td>Social-individual focus</td>
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<td>Assessment of Quality of Life with 8 dimensions (AQOL-8D)</td>
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<tr>
<td>Family Appraisal of Caregiving Questionnaire for Palliative Care (FACQ-PC)</td>
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</table>

LO’s perc., loved one’s perception of the person with COPD; LO, loved one; P, patient.
Recruitment
Patients, both with and without COPD exacerbations in the past year, will be recruited by their chest physician or a respiratory nurse during hospital admission or at the outpatient clinic in four hospitals throughout the southern-eastern part of the Netherlands. In addition, patients participating in the study ‘Correlates of CAT’ (NTR3416) who meet the inclusion criteria of the Home Sweet Home study and were willing to participate in further research will be asked to participate in the current study. If patients and their loved ones agree, an appointment for a first home visit will be made. Informed consent will be obtained at the start of this visit.

Data management and statistical analysis
Missing data will be minimised because all questionnaires will be completed in the presence of a researcher or research assistant. Handling of missing data will be carried out according to the guidelines of the different questionnaires. For data-analysis SPSS V2.0 will be used.

Descriptive statistics, including means, SDs, frequencies and medians and IQRs, will be used, as appropriate. Mean scores of continuous variables will be compared between patients and their loved ones using paired sample t tests or Wilcoxon signed rank tests, depending on the variable distribution. Moreover, we will calculate intraclass correlation coefficients to study agreement between patients and loved ones in mean scores and visualise agreement using Bland and Altman plots. Cohen’s \( \kappa \) will be used to determine agreement in categorical variables. These analyses will be performed for the COPM, CAT, mMRC, SF-12, IADLS and EQ-5D. Furthermore, a mixed effect model will be used to estimate longitudinal changes. Covariates such as age and smoking status can be included as fixed effects, whereas time and exacerbation-related hospital admissions can be entered as random effects. A priori, a two-sided level of significance will be set at \( p \leq 0.05 \).

Ethics and dissemination
This project will be conducted in accordance with the declaration of Helsinki and the principles of the Dutch Medical Research Involving Human Subjects Act (‘WMO’).

DISCUSSION
This study will focus on gaining knowledge about resident loved ones, including their role in the disease management and the interaction between the patient and the resident loved one in their lifestyles. This information is necessary to involve resident loved ones in the disease management of patients with COPD. The study has several strengths and limitations, which will be described below.

Strengths
The approach of this study differs from other studies on loved ones of patients with COPD, especially because of the use of unique measurements and concepts. A major strength of this study is the use of an individualised, client-centred outcome to detect problems in ADLs (COPM). A previous study included outcomes only based on physical activity. The current study detects problems in ADLs according to the patient and the loved one using a semistructured interview method. Additionally an accelerometer is used for both the patient as well as for the loved one. Moreover, these problematic ADLs are not only determined during baseline and follow-up measurements, but also 2 weeks after a COPD exacerbation-related hospital admission. The changes in these ADL problems over time and after a hospital admission are a unique point of view in this population. Furthermore, in previous studies, characteristics of the family or loved ones of the patients themselves were determined. In this study, not only characteristics of the patients, and resident loved ones are assessed, but also the resident loved ones’ perception of the patients’ characteristics (such as health status, daily functioning and symptoms of anxiety and depression). Further, capabilities of loved ones (like coping styles and social support) will be investigated. In addition, these measurements are not only performed once, but will be repeated after a COPD exacerbation-related hospital admission of the patient. Moreover, the quality of the relationship between the patient and resident loved one will be assessed. The quality of the relationship could be one of the determinants of the interaction between the resident loved one and the patient. Therefore, this study provides a complete overview of the patient, the resident loved one, and the resident loved ones’ perceptions of the patient.

Other strengths of this study are related to the inclusion of the participants. Many studies focus on male patients with their female partners. In this study an equal number of male and female participants will be recruited and therefore the current study will also provide knowledge concerning female patients and their male resident loved ones. Furthermore, patients will also be equally divided based on GOLD grading. Therefore, this study includes the same number of patients with moderate, severe and very severe COPD, which improves the external validity of this study.

Moreover, the present study is a longitudinal study, which makes it possible to analyse changes over time. Finally, the tests and questionnaires will all be performed at the patients’ home. So participant’s burden is minimised and all data will be collected in their own trusted environment.

Limitations
This study has some limitations. First, it may be possible that patients and/or loved ones are not willing to participate. Although the burden of this study is minimised,
a possible reason for refusing participation could be the time investment. To minimise the burden of this study, all measurements are performed in the patients’ homes and on a day and time of their preference. Furthermore, the home visit can be spread over 2 days. Nevertheless, it may be possible that most burdened patients and loved ones are not willing to participate in (additional) home visits. This could result in an underestimation of the burden, health status and well-being of this population. Therefore, some characteristics of the non-participating patients, like gender, age and GOLD grade, will be collected. Furthermore, it may be possible that participating resident loved ones are more aware of the situation of the patient compared to the non-participating loved ones. This should be taken into account in interpreting the results. Second, it might be challenging to include the same number of male and female patients with COPD. However, collaboration with four hospitals and recruitment of patients admitted to the hospital as well as patients who attend the outpatient clinic, will facilitate recruitment. Third, some loved ones of admitted patients may be unwilling to participate in additional home visits shortly after the patients’ admission to the hospital. This could lead to missing data or even drop-outs. However, the time investment and impact of this visit is minimal. Fourth, the follow-up period is limited to 1 year. This follow-up period could be too short to draw conclusions about long-term changes in patients’ health status and problems during ADLs and the perception of the resident loved ones about these changes. Finally, it may be possible that participation in this study works as a stimulus for patients to talk about COPD with their loved ones. This could result in more understanding and agreement during the measurements after 12 months. However, if participants communicate more about the disease and the problems during daily activities, the expectation is that this will be performed shortly after the first home visit.

Clinical consequences
The present study will gain more knowledge about the resident loved ones of patients with COPD and about their perceptions of the patients’ health status and problematic ADLs. With this information, a more systemic approach in the treatment of patients with COPD could be developed. Healthcare providers should not only focus on the patient, but should see the patient, his/her loved ones and their interaction as a whole. Only by gaining more information about the loved ones themselves, the quality of the relationship, and their perception of the patients’ health status and problematic ADLs, loved ones could be involved in the patient’s treatment. With the knowledge gained in this study, we will learn how to carry out self-management plans in patients and loved ones, so loved ones are able to facilitate and encourage the self-management. Furthermore, this study investigates the impact of a hospitalisation due to an acute COPD exacerbation on the resident loved ones. With this information it may be possible to determine whether and how professional caregivers should give more attention to the resident loved ones during an exacerbation related hospitalisation.

CONCLUSION
In conclusion, COPD may have an impact on not only the patients’ life, but also on the lives of the resident loved ones. As a shift towards home care is anticipated, the Home Sweet Home study is necessary to give more insight in the home situation of patients with COPD.

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Contributors NN, DJAJ, EFMW and MAS designed and established the study. All authors contributed to the writing of this manuscript, read and approved the final version of the manuscript.

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Competing interests None.

Patient consent Obtained.

Ethics approval Ethics approval has been obtained from the Medical Ethical Committee of the Catharina hospital Eindhoven, The Netherlands (NL42721.060.12/M12-1280) and is registered in the Dutch trial register (NTR3941).

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