The Home Sweet Home study: An observational, longitudinal study on the home environment of people with chronic obstructive pulmonary disease (COPD).

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Primary objectives:1.1 To investigate the differences between patients* and resident loved ones' perceptions of patients* health status and problematic ADLs.1.2 To study prospectively the effects of an acute COPD exacerbation on resident loved…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON41466

Source
ToetsingOnline

Brief title
The Home Sweet Home study.

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic obstructive pulmonary disease, COPD

Research involving
Human

Sponsors and support

Primary sponsor: Ciro+, expertisecentrum voor chronisch orgaanfalen

Source(s) of monetary or material Support: Boehringer Ingelheim,Nederlands Astma Fonds

Intervention

Keyword: COPD, Home environment, Loved one, Spouse

Outcome measures

Primary outcome

The resident loved one, their perception of the person with COPD, and the

person with COPD will be compared by using the :

* Problematic ADLs using the Canadian Occupational Performance Measure (COPM)

* COPD Assessment Test (CAT)

* mMRC dyspnea scale

* Short-Form 12

* Instrumental Activities of Daily Living Scale (IADLS)

* EQ-5D

* Fatigue using the Subjective Fatigue subscale of the Checklist Individual

Strength

* Self-efficacy for home walking

Secondary outcome

The secondary study parameters will be:

* Hospital Anxiety and Depression scale (HADS)

* Care Dependency Scale (CDS)

* Daily symptoms checklist

* Current smoking status and smoking history

* Fat-free mass (using BIA), body weight and height

* Physical activity (using validated accelerometer)

* Informal and professional (medical) care <6 months

* Perceived social support using the Medical Outcome Study Social Support

Survey (MOSSSS)

* Post-bronchodilator spirometry

* Blood pressure, heart rate and oxygen saturation at rest

* Timed-up-and-go test

* Utrecht Coping List

* Caregiver burden and positive aspects of caregiving using the FACQ-PC

* A 35-item COPD knowledge questionnaire (self-developed, currently tested)

* Dutch relationship questionnaire 2003 (Uitgever: Pearson Assessment and

Information B.V.)

Other study parameters will be:

* Demographics, including marital status;

* Data on relationship of the loved one to the patient;

* Medical history;

* Current medication;

* Charlson co-morbidity index.

Study description

Background summary

Resident loved ones (mostly spouses or resident family members) are uniquely positioned to witness the abilities/limitations that patients with Chronic

Obstructive Pulmonary Disease (COPD) experience during day-to-day life. Moreover, resident loved ones can play an important role in COPD patients* management and well-being. To date, however, limited data are available specifically focussing on the resident loved ones' perception of the COPD patient*s health status, the resident loved ones' lifestyle and their possible interaction. Furthermore, loved ones' burden and health in relation to exacerbation-related hospital admission of the person with COPD are not investigated until now.

Study objective

Primary objectives:
1.1 To investigate the differences between patients* and resident loved ones' perceptions of patients* health status and problematic ADLs.
1.2 To study prospectively the effects of an acute COPD exacerbation on resident loved ones' perceptions of patients* health status and problematic ADLs.

Secondary objectives:
2.1 To investigate the differences between patients* and resident loved ones* perceptions of patients* mood status, care dependency and daily symptoms.
2.2 To study the relationship between lifestyle factors in COPD patients and their resident loved ones.
2.3 To study prospectively the effects of an acute COPD exacerbation on resident loved ones* perceptions of patients* mood status, care dependency and daily symptoms.
2.4 To investigate resident loved ones* burden due to patients care dependency.
2.5 To investigate the general wellbeing of patients when discrepancies exist between the patients* and resident loved ones* perceptions of patients* care dependency.
2.6 To investigate if general wellbeing of resident loved ones is influenced by the health status of patients.
2.7 To investigate if general wellbeing of patients is influenced by the mood status of their resident loved ones.
2.8 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.
2.9 To investigate resident loved ones* knowledge about COPD and the relationship with anxiety and social support.
2.10 To explore causes for a difference in perception between patients and loved one*s about the problems in everyday life of the patient.

Study design

The Home Sweet Home study is an observational, longitudinal study.

Study burden and risks

To minimize participants* burden, all tests and questionnaires will be assessed during home visits. A minimal of two visits is planned, one visit at baseline and one visit after 12 months. Both visits take about 2.5 hours for the person with COPD and 3 hours for the resident loved one. Two additional home visits will be planned when an exacerbation-related hospital admission occurs during 12 months follow-up. Within seven days after admission, the loved one will be visited at home. This visit will take about 2 hours. Two weeks after discharge, the second visit will take place. The duration of this visit, in which both the person with COPD and the loved one are participating, is equal to the duration of the baseline visit. All procedures in this study are in use in everyday clinical practice. Only the post-bronchodilator spirometry could give some risks. Side effects only occur in minimal cases. Possible side effects are: irritation of the mouth and throat, nausea, vibrations of fingers and hands, headache, restlessness, rapid heartbeat, palpitations and high blood pressure. About ten patients with COPD and ten loved ones will be asked to participate in one qualitative interview after completing the baseline and follow-up visits of the Home Sweet Home study. This qualitative interview with both the patient and the loved one will be done during an additional home visit. The duration of the follow-up measurement will be approximately one hour.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- COPD as main diagnosis (GOLD stage II, III or IV according to GOLD guidelines);
- No exacerbation or hospitalization <4 weeks before enrolment;
- Providing written informed consent;
- One resident loved one also provided a written informed consent to participate.

Exclusion criteria

- Unable to complete the study questionnaires because of cognitive impairment as determined by the *Short Blessed Test*, for both the patient as well as the loved one;
- Unable to speak or understand Dutch, for both the patient as well as the loved one;

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-07-2013
Enrollment:	384
Type:	Actual

Ethics review

Approved WMO Date:	26-04-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-10-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-05-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24106
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL42721.060.12
OMON	NL-OMON24106