The Home Sweet Home study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24106

Source
NTR

Health condition

Patients with Chronic Obstructive Pulmonary Disease (COPD) + their resident loved ones.

Sponsors and support

Primary sponsor: Prof. E.F.M. Wouters, MD, PhD
Ciro+, centre of expertise for chronic organ failure
Source(s) of monetary or material Support: Lung Foundation Netherlands
Boehringer Ingelheim Nederland

Intervention

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:

1. Problematic ADLs using the Canadian Occupational Performance Measure (COPM);

2. COPD Assessment Test (CAT);

3. mMRC dyspnea scale;

4. Short-Form 12;

5. Instrumental Activities of Daily Living Scale (IADLS);

6. EQ-5D;

7. Fatigue using the Subjective Fatigue subscale of the Checklist Individual Strength;

8. Self-efficacy for home walking.

Secondary outcome

The secondary study parameters will be:

1. Hospital Anxiety and Depression scale (HADS);

2. Care Dependency Scale (CDS);

3. Daily symptoms checklist;

4. Current smoking status and smoking history;

5. Fat-free mass (using BIA), body weight and height;

6. Physical activity (using validated accelerometer);

7. Informal and professional (medical) care <6 months;

8. Perceived social support using the Medical Outcome Study Social Support Survey (MOSSSS);

9. Post-bronchodilator spirometry;

10. Blood pressure, heart rate and oxygen saturation at rest;

11. Timed-up-and-go test;

12. Utrecht Coping List;

13. Caregiver burden and positive aspects of caregiving using the FACQ-PC;

14. A 35-item COPD knowledge questionnaire (self-developed, currently tested);

15. Dutch relationship questionnaire 2003 (Uitgever: Pearson Assessment and Information B.V.).

Other study parameters will be:

16. Demographics, including marital status;

17. Data on relationship of the loved one to the patient;

18. Medical history;

19. Current medication;

20. Charlson co-morbidity index.

Study description

Background summary

Background of the study:

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, 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.

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.

Study design:

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

Study population:

The study population consist of 192 persons with COPD (Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage II, III and IV) and one resident loved one for each person with COPD.

Primary study parameters/outcome of the study:

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.

Study objective

1. To investigate the differences between patients’ and resident loved ones' perceptions of patients’ health status and problematic ADLs;

2. To study prospectively the effects of an acute COPD exacerbation on resident loved ones' perceptions of patients’ health status and problematic ADLs.

Study design

Baseline and after 12 months. Only for patients who are admitted to the hospital because of an exacerbation, 2 additional visits are planned. The first visit, only for the loved one, within 7 days after hospital admission of the patient. The other visit, for both the patient and loved one, within 2 weeks after hospital discharge.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. COPD as main diagnosis (GOLD stage II, III or IV according to GOLD guidelines);

2. No exacerbation or hospitalization <4 weeks before enrolment;

3. Providing written informed consent;

4. One resident loved one also provided a written informed consent to participate.

Exclusion criteria

1. 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;

2. Unable to speak or understand Dutch, for both the patient as well as the loved one.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2013
Enrollment:	384
Type:	Actual

Ethics review

Positive opinion

Date:	08-04-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41466
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3776
NTR-old	NTR3941
CCMO	NL42721.060.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41466

Study results

Summary results
N/A