The Home Sweet Home study.

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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'...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24106

Bron
NTR

Aandoening

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

Ondersteuning

Primaire sponsor: Prof. E.F.M. Wouters, MD, PhD
Ciro+, centre of expertise for chronic organ failure
Overige ondersteuning: Lung Foundation Netherlands
Boehringer Ingelheim Nederland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

Program Development Centre
CIRO+, centre of expertise for chronic organ failure
Hornerheide 1
Martijn A. Spruit
Horn 6085 NM
The Netherlands
+31 (0)475 587726

Wetenschappelijk

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Horn 6085 NM
The Netherlands
+31 (0)475 587726

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2013
Aantal proefpersonen:	384
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	08-04-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41466
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A