Secondary prevention of problems in health status in patients with COPD by early detection, motivational intervention to engage in treatment by the patient and by individualized treatment

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24431

Source
Nationaal Trial Register

Health condition

Chronic Obstructive Pulmonary Disease (COPD), Health Status, Quality of Life, Intervention, Patient-tailored treatment, gezondheidstoestand, kwaliteit van leven, interventie, zorg op maat

Sponsors and support

Primary sponsor: PICASSO-Partners in Care Solutions
Radboud University Nijmegen Medical Centre, department of Medical Psychology and department of Pulmonary Diseases
Sponsor / Initiator: Radboud University Nijmegen Medical Centre, Department of Medical Psychology & Department of Pulmonary Diseases, Postbus 66, Nijmeegsebaan 31, 6560 AB Groesbeek

Source(s) of monetary or material Support: PICASSO-Partners in Care Solutions

Intervention

Outcome measures

Primary outcome

1. Physiological Functioning: TLC%p predicted, RV% predicted, FEV1% predicted, BMI;

2. Symptoms:

A. Physical Activity Rating Scale Dyspnoea;

B. Global Dyspnoea Activity and Global Dyspnoea Burden;

C. Dyspnoea Emotions Questionnaire;

D. Frustration and Anxiety;

E. Checklist Individual Strength;

F. Fatigue.

3. Quality of Life:

A. Beck Depression Inventory Primary Care;

B. Satisfaction with Life Scale;

C. Satisfaction Physical, Satisfaction Future, Satisfaction Spouse and Satisfaction Social.

4. Functional Impairment:

A. Quality of Life for Respiratory Illness Questionnaires;

B. General Activities;

C. Sickness Impact Profile;

D. Home Management and Ambulation.

5. The number of additional treatments in both groups.

Secondary outcome

1. Smoking status;

2. Patient satisfaction with treatment;

3. Accuracy of diagnostic properties of the PatientProfileChart;

4. Sociodemographic variables (sex, age, education, personal situation, work situation);

5. Clinical variables (comorbidity, previous and current treatments, hospitalization).

Study description

Background summary

Chronic Obstructive Pulmonary Disease (COPD) is a disease state characterized by airflow that is not fully reversible. Besides problems in phsyiological functioning, the patient also can experience symptoms, functional impairment and a diminished quality of life. Problems in the three latter domains of health status are hardly recognized in usual care, and remain untreated until escalated. This is mainly caused by two phenomena: doctor delay and patient delay. Doctor delay: the physician does not directly identify symptoms, functional impairment, and problems in quality of life. Patient delay: the patient does not report problems in these health status domains. What is necessary is a screening instrument that can be used in routine care and identifies patients with problems in the four domains of health status. If clinically relevant problems exists, and additional treatment is recommended, an intervention by the pulmonary nurse is indicated. This intervention is directed at increasing awareness of existing problems and motivating the patient for additional treatment. By means of the screening and intervention, problems in health status are detected and treated early, before escalation. Treatment is patient-tailored, based on the existing problems in the four domains of health status, eventually leading to an improved health status. A randomized controlled trial is conducted to test this hypothesis, comparing (1) patients with no clinically relevant problems in health status (usual care as delivered by the outpatient clinic), (2) patients with clinically relevant problems in health status (usual care as delivered by the outpatient clinic), (3) patients with clinically relevant problems in health status receiving an intervention by a pulmonary nurse.

Study objective

In a sample of COPD patients with clinically relevant problems in four main domains of health status (physiological functioning, symptoms, functional impairment and quality of life) a motivational intervention conducted by a pulmonary nurse will lead to patient-tailored treatment and an improved health status.

Study design

1. T0 (baseline);

2. T1 (after 6 months);

3. T2 (after 12 months).

Each timepoint measurement of primary and secondary outcomes.

T0: group I/II/III;

T1: group II/III;

T2 group I/II/III.

Intervention

Based on the indepent clinical interpretation of the PatientProfileChart by three professionals, patients are assigned to one of the following groups:

1. Patients with no clinically relevant problems in health status (group I);

2. Patients with clinically relevant problems in health status (group II/III).

Patients with clinically relevant problems in health status are randomized to a control group (group II: usual care as delivered by the outpatient clinic) and the experimental group (group III: intervention conducted by a pulmonary nurse, directed at increasing awareness of problems in health status, increasing motivation to engage in additional treatment, and improving health status).

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Eligibility criteria

Inclusion criteria

Diagnosis COPD according to GOLD-criteria.

Exclusion criteria

1. Not competent enough in understanding Dutch language;

2. Participation in pulmonary rehabilitation program within the previous six months.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2007

Enrollment:	120
Type:	Actual

Ethics review

Positive opinion Date:	08-06-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1733
NTR-old	NTR1844
CCMO	NL15356.091.06
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A