The development and evaluation of a new burden of disease instrument for COPD.

No registrations found.

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

Summary

ID

NL-OMON26129

Source
NTR

Brief title
CIS

Health condition

Chronic Obstructive Pulmonary Disease (COPD)

Sponsors and support

Primary sponsor: C.P. van Schayck, Research Institute CAPHRI, Maastricht University.
Source(s) of monetary or material Support: Achmea, CZ, AstraZeneca, GSK, Takeda, Novartis, Picasso voor COPD, Boehringer Ingelheim

Intervention

Outcome measures

Primary outcome

The difference in health-related quality of life between baseline and 18-months follow-up, measured by the St George’s Respiratory Questionnaire.

Secondary outcome

1. The difference in health-related quality of life between baseline and 6-months and 12-months follow-up, measured by the St George's Respiratory Questionnaire;

2. The difference in health-related quality of life between baseline and 18-months follow-up, measured by the COPD Assessment Test;

3. Differences will be calculated between baseline and 18-months follow up on the EuroQol 5d;

4. Number of exacerbations at 12 months and 18 months.

Study description

Background summary

Chronic Obstructive Pulmonary Disease (COPD) is an irreversible lung disease and an increasing health problem worldwide. On the basis of morbidity records of general practices, the number of COPD patients know by the GPs can be estimated. Each year two new COPD patients are found per 1000 patients who are registered, while there are already 20 patients being treated for COPD amongst this 1000 patients.
COPD imposes a great burden on patients. It is a major cause of morbidity and mortality. Many patients suffer from it for years, and die prematurely due to complications arising from the disease. Approximately 6000 people die every year due to COPD. It is expected that prevalence of COPD will increase with 76% within approximately twenty years.

As COPD cannot be cured, it is important to focus on patient-reported outcomes, to address the progression of disease, complaints, limitations, and quality of life, in order to provide optimal treatment.

In order to improve health care in the Netherlands, Health Care Standards are developed. Health Care Standards offer a functional description of the multidisciplinary organization of prevention, care, and self-management support for a chronic condition from a patient perspective, during the full continuum of care. These are based on actual and, as far as possible, scientifically- funded insights. The 'Dutch Health Care Standard COPD' describes a new concept, namely the "burden of disease". The burden of COPD is considered to be attributed to more than simply the airway obstruction: it is defined by a Dutch national expert research team, commissioned by the Dutch Lung Alliance (Long Alliantie Nederland; LAN), as: "The physical, psychological, emotional and/or social burden as experienced by the patient."
This new concept is intended to guide management of COPD patients and can also classify

the patients' burden of disease as a mild, moderate or severe burden of disease.
Therefore, the Dutch national expert research team created the COPD Impact Scale (CIS) using literature and input from both patients and health care professionals. Furthermore an algorithm was written that includes instructions and advices to assist the health care professional in providing the patient with the care they need.

This study aims to assess the effectiveness of the CIS in the management of patients with COPD.
This study is a 2-armed, cluster randomized controlled trial (RCT) comparing an intervention group using the CIS and algorithm-based COPD management, to a control group receiving usual care.

The duration of the follow-up period is 18 months. During the first part of the study the intervention arm will also deliver data on the reproducibility and validity of the COPD Impact Scale (CIS).

The trial will be conducted amongst General Practitioners and pulmonologist throughout the Netherlands.

Study objective

COPD management using the COPD Impact Scale and an treatment algoritm, will be more effective in improving the health related quality of life of COPD patients, meausured by the Saint George Respiratory Questionnaire, than usual care, over a period of 18 months.

Study design

1. Baseline;

2. 6 months follow up;

3. 12 months follow up;

4. 18 monhts follow up.

Intervention

Participants in the intervention group will receive treatment, based on the newly developed COPD Impact Scale (CIS) and a treatment-algorithm. Patients will fill out the CIS, and additionally the caregiver will add some more relevant parameters. A computer based algorithm will visually display the outcomes and provides advices the patients and caregivers can discuss and put in the treatment plan.

Participants in the control group will receive care as usual.

Contacts

Public
PO Box 616
Annerika Slok
Research Institute CAPHRI, Department of General Practice
Maastricht University
P. Debyeplein 1
Maastricht 6200 MD
The Netherlands
+31 (0)43 3882997
Scientific
PO Box 616
Annerika Slok
Research Institute CAPHRI, Department of General Practice
Maastricht University
P. Debyeplein 1
Maastricht 6200 MD
The Netherlands
+31 (0)43 3882997

Eligibility criteria

Inclusion criteria

1. Spirometrically confirmed diagnosis of COPD (post-bronchodilatatoir FEV1/FVC < 0.7);

2. Age 40+;

3. Patient is competent enough to understand and read the Dutch language.

Exclusion criteria

1. Exacerbations < 6 weeks;

2. Hard drug addiction;

3. Life-threatening co-morbid condition;

4. Pregnancy.

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):	01-02-2013
Enrollment:	360
Type:	Actual

Ethics review

Positive opinion

Date:	11-01-2013
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	NL3622
NTR-old	NTR3788
Other	METC Atrium Orbis Zuyd : 12-N-93
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

The Assessment of Burden of COPD (ABC) Scale: A Reliable and Valid Questionnaire.
Slok AH, Bemelmans TC, Kotz D, van der Molen T, Kerstjens HA, In 't Veen JC, Chavannes NH, Asijee GM, Rutten-van Mölken MP, van Schayck OC.
COPD. 2016 Aug;13(4):431-8.

Effectiveness of the Assessment of Burden of COPD (ABC) tool on health-related quality of life in patients with COPD: a cluster randomised controlled trial in primary and hospital care.
Slok AH, Kotz D, van Breukelen G, Chavannes NH, Rutten-van Mölken MP, Kerstjens HA, van der Molen T, Asijee GM, Dekhuijzen PN, Holverda S, Salomé PL, Goossens LM, Twellaar M, In 't Veen JC, van Schayck OC.
BMJ Open. 2016 Jul 11;6(7):e011519.

[Effectiveness of the Assessment of Burden of COPD tool: a cluster-randomised controlled trial].
van Schayck OC, Slok AH, Kotz D, van Breukelen G, Chavannes NH, Rutten-van Mölken MP, Kerstjens HA, van der Molen T, Asijee GM, Dekhuijzen PN, Holverda S, Salomé PL, Goossens LM, Twellaar M, In 't Veen JC.
Ned Tijdschr Geneeskd. 2016;160(0):D955.

Effectiveness of the Assessment of Burden of Chronic Obstructive Pulmonary Disease (ABC) tool: study protocol of a cluster randomised trial in primary and secondary care.
Slok AH, In 't Veen JC, Chavannes NH, van der Molen T, Mölken MP, Kerstjens HA, Asijee GM, Salomé PL, Holverda S, Dekhuijzen RP, Schuiten D, van Breukelen G, Kotz D, van Schayck OC.
BMC Pulm Med. 2014 Aug 7;14:131.

Development of the Assessment of Burden of COPD tool: an integrated tool to measure the burden of COPD.
Slok AH, in 't Veen JC, Chavannes NH, van der Molen T, Rutten-van Mölken MP, Kerstjens HA,

Salomé PL, Holverda S, Dekhuijzen PN, Schuiten D, Asijee GM, van Schayck OC.
NPJ Prim Care Respir Med. 2014 Jul 10;24:14021

Slok, Annerika HM, et al. "'To use or not to use': a qualitative study to evaluate experiences of healthcare providers and patients with the assessment of burden of COPD (ABC) tool." npj Primary Care Respiratory Medicine 26 (2016): 16074.