Optimizing COPD care in primary care: going for Silver or for Gold?

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To evaluate a result oriented smoking cessation program in which treatment goals are signed up in a doctor-patient contract.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON31653

Source
ToetsingOnline

Brief title
Silver or Gold

Condition

- Respiratory disorders NEC

Synonym
COPD

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: PICASSO-ZonMw,Agis Zorgverzekeringen

Intervention

Keyword: contract, COPD, motivation, smoking cessation

Outcome measures

Primary outcome

Primary study endpoint: point prevalence after 24 months, measured by self-reported smoking and biochemical verification (urinary cotinine measurement).

Secondary outcome

Secondary study endpoint: abstinence after 12 en 24 months, functional status, quality of life, attitude, social stimulation, self-efficacy, patiënt perception, motivation, smoking habits and pulmonary function.

Study description

Background summary

Smoking cessation is the cornerstone the treatment of COPD since it reduces the deterioration of pulmonary function. Apart from smoking cessation, physical activity and proper use of medication lead to better quality of life and functional status. However, these interventions are barely implemented in everyday practice, most importantly due to lack of motivation of patients as well as general practitioners. To obtain maximum profit out of COPD care, motivated patients should be offered *result oriented* care instead of the current *care oriented* care. Result oriented behavioural interventions with treatment goals signed up in a doctor-patient contract are already applied successfully in cardiac and lung rehabilitation programmes, treatment of psychiatric diseases and in addiction care. With these interventions, improvement of patients* adherence to treatment and self-management due to shared decision making and patient empowerment is perceived. The use of a doctor-patient contract targeting on smoking cessation and improvement of quality of life and functional status of COPD patients has never been investigated in primary care.

Study objective

To evaluate a result oriented smoking cessation program in which treatment goals are signed up in a doctor-patient contract.

Study design

This is a two arm cluster randomised controlled trail, with general practice as the unit of randomisation.

Intervention

All patients in the *result oriented* group will be asked, when motivated to initiate a quit attempt, to compose treatment goals in a contract and attend an intense smoking-cessation program.
After 6, 12 and 24 months the goals will be evaluated. Noncompliant patients will again receive *care oriented care* for at least three months. During this period they can again get motivated to participate once more in the smoking-cessation program. When patients are not motivated to quit smoking they will continuously receive *care oriented care* and are repeatedly point out the advantages of *result oriented care*.

Study burden and risks

The burden and risks associated with participation: The participating patients fill in questionnaires, undergo pulmonary function tests and 6 minutes walk tests and their urinary cotinine level will be measured. The patients will repeatedly consult the doctor (*care oriented care: 4 times in 2 year; *result oriented* care(voluntarily):22 times in 2 year). All included patients will be treated according to the Dutch College of General Practitioners guidelines *COPD* and *smoking cessation*. There are no risks associated with participation of this trial.

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 patients (FEV1/FVC < 70% predicted) Gold I - IV; age: 40-75 yrs; smokers.

Exclusion criteria

not familiar with the Dutch language
patients in the end stage of a disease

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-03-2008
Enrollment:	720
Type:	Actual

Ethics review

Approved WMO Date:	08-01-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-03-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	03-06-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL15530.041.07