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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25530

Source
NTR

Brief title
Silver or Gold

Health condition

COPD
motivation
smoking cessation
contract

Sponsors and support

Primary sponsor: Julius Centre for Health Sciences and Primary Care
Source(s) of monetary or material Support: Picasso

Intervention

Outcome measures

Primary outcome

Point prevalence after 24 months, measured by self-reported smoking and urinary cotinine measurement

Secondary outcome

Smoking abstinence, functional status, motivation for smoking cessation, illness perception, quality of life, social stimulation, self-efficacy, smoking habits and pulmonary function

Study description

Background summary

Rationale:

Smoking cessation is the cornerstone of COPD treatment since it reduces the decline in pulmonary function. However, this intervention is barely implemented in everyday practice. To obtain maximum profit of COPD care, motivated patients should be offered ‘result-focused’ care, in which treatment goals are signed up in a doctor-patient contract, instead of the current ‘effort-focused’ care. ‘Result-focused’ behavioural interventions are already applied successfully in rehabilitation programs, psychiatric treatments and addiction care.

Objective:

To evaluate a ‘result-focused’ smoking-cessation-program (‘Golden care’) in which treatment goals are signed up in a doctor-patient contract.

Study design:

A two-arm, cluster randomised controlled trial, with general practice as unit of randomization.

Study population:

720 smoking COPD patients

Intervention:

All patients of the intervention group receive ‘Silver care’. When
motivated to initiate a quit attempt, treatment goals are composed in a doctor-patient contract and the patient attends an intense smoking-cessation-program (‘Golden care’). After

6, 12 and 24 months goals will be evaluated. Noncompliant patients will again receive ‘Silver care’ for at least three months to get motivated for smoking cessation once more. Patients unmotivated to quit smoking will continuously receive ‘Silver care’.

Main endpoints:

Primary endpoint: point prevalence after 24 months, measured by self-reported smoking and urinary cotinine measurement.
Secondary endpoint: smoking abstinence, functional status, motivation for smoking cessation, illness perception, quality of life, social stimulation, self-efficacy, smoking habits and pulmonary function.

Statistical analysis:

Intention-to-treat analysis. Primary outcome is measured by logistic regression analysis. Differences in secondary outcome measures are measured by co-variation analysis.

Study objective

The objective of this study is to evaluate a ‘result oriented’ smoking cessation program (‘Silver or Gold’) for COPD patients in which treatment goals are signed up in a doctor-patient contract.

Study design

Baseline, 1 year, 2 years

Intervention

Intervention group:

All patients of the intervention group receive ‘Silver care’. When
motivated to initiate a quit attempt, treatment goals are composed in a doctor-patient contract and the patient attends an intense smoking-cessation-program (‘Golden care’). After 6, 12 and 24 months goals will be evaluated. Noncompliant patients will again receive ‘Silver care’ for at least three months to get motivated for smoking cessation once more. Patients unmotivated to quit smoking will continuously receive ‘Silver care’.

Control group:

Patients in the control group receive care as usual

Contacts

Public
Julius Centre for Health Sciences and Primary Care
P.O. 85500

M.J. Warnier
Huispost STR. 6.131 (kamer 4.143)

Utrecht 3508 GA
The Netherlands
+31 (0)88 7555102
Scientific
Julius Centre for Health Sciences and Primary Care
P.O. 85500

M.J. Warnier
Huispost STR. 6.131 (kamer 4.143)

Utrecht 3508 GA
The Netherlands
+31 (0)88 7555102

Eligibility criteria

Inclusion criteria

1. COPD patient

2. Age 40 – 75 year

3. Smoker. A smoker is someone who says to smoke daily or incidentally.

Exclusion criteria

1. Terminally stage of a (chronic) disease

2. Not speaking Dutch

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2008
Enrollment:	720
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-05-2008
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	NL1259
NTR-old	NTR1305
Other	: ABR 15530
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A