The efficacy and cost-effectiveness of confrontational counselling for smoking cessation in smokers with previously undiagnosed COPD: a randomised controlled trial.

No registrations found.

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

Summary

ID

NL-OMON23106

Source
NTR

Brief title
COSMO

Intervention

Outcome measures

Primary outcome

The primary outcome of this study is biochemically validated prolonged abstinence from smoking during a period of 12 months. A smoker is defined as prolonged abstinent if he/she is a non-smoker (no cigarette smoked during the preceding seven days), at the end of the intervention (day 50), and at the follow-up-visits after 6 months (day 197) and 12 months (day 380. Non-smoking is verified by urine cotinine. Participants with a cotinine-value of > 50ng/mL are regarded as smokers as well as participants who are lost to follow-up.

Secondary outcome

1. Point prevalence of non-smokers (no cigarette smoked during the preceding seven days) at the end of the intervention period and at 6- and 12-month follow-up;
2. Self-reported number of quit attempts and temporary or complete relapse;
3. Attitudes, social norms and self-efficacy with regard to smoking cessation;
4. Lung function (FEV1 post-bronchodilatory and FEV1/FVC) at baseline and at 12-month follow-up;
5. Anthropometry: physical height and weight at baseline, at the end of the intervention period and at 6- and 12-month follow-up;
6. Perceived specific health-related complaints (impairments and functional disabilities in everyday life);
7. Health-related quality of life;
8. Mental health (fear,depression);
9. Smoking related cognitions (risk perception, health concerns, self-exempting beliefs);
10. Number of unplanned visits to the general practitioner or specialized physician due to respiratory complaints and the number, severity and frequency of exacerbations (self-reported and/or reported by the general practitioner or specialist).

Study description

Background summary

Chronic obstructive pulmonary disease (COPD) is a disease state characterized by airflow limitation that is not fully reversible. Although COPD is a major cause of chronic morbidity and mortality worldwide, the true burden of the disease is not usually recognised until it is clinically apparent and moderately advanced. Smoking is the most important risk factor for the development and progression of COPD. Smoking cessation is the single most effective - and cost-effective - intervention to reduce the risk of developing COPD and affecting the outcome in patients at all stages of the disease. Usual care for smoking cessation in the Netherlands involves the use of a protocol for low intensity health education and promotion (the so-called "Minimal Intervention Strategy" for the general practitioner and his/her assistant, H-MIS). Although the H-MIS is an effective aid in helping smokers to quit (8% prolonged abstinence after 12 months compared to 3% in the control group), there is much room for improvement. Smokers with respiratory complaints are more motivated to stop smoking when they know that they are at risk of developing a chronic lung disease such as COPD. Smokers usually minimize their own perceived risk of developing a smoking-related disease, or deny or avoid information about the dangers of smoking in order to reduce cognitive dissonance. We therefore expect that confronting smokers with an objectively (by spirometry) identified negative consequence of smoking (COPD) will positively affect the outcome of their quit attempt. The primary aim of this randomized trial is to analyse the efficacy and cost-effectiveness of confrontational counselling for smoking cessation delivered by specialised pulmonary nurses for smokers with previously undiagnosed mild to moderate COPD with regard to prolonged abstinence from smoking during a period of 12 months. Furthermore, we want to analyse the effect of smoking cessation on lung function, perceived specific health-related complaints, quality of life and mental health. We have therefore

conducted a randomized controlled trial is comparing (1) confrontational counselling delivered by a pulmonary nurse and pharmacotherapy, (2) health education and promotion delivered by a pulmonary nurse and pharmacotherapy and (3) "care as usual" delivered by the general practitioner. Early detection of smokers with mild to moderate COPD is achieved by means of a telephone interview in combination with spirometry.

Study objective

Confrontation with the results from spirometry as part of counselling for smoking cessation in smokers with not earlier diagnosed mild to moderate COPD is effective with regard to prolonged abstinence from smoking during a period of 12 months.

Intervention

Intervention groups:
1. Confrontational counselling delivered by a pulmonary nurse and pharmacotherapy; 2. Health education and promotion delivered by a pulmonary nurse and pharmacotherapy; or 3. "Care as usual" delivered by the general practitioner.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age between 35 through 70 years;

2. Smoker with a smoking history of > 10 pack years of cigarettes;
3. Motivated to stop smoking;
4. One or more of the following symptoms are present: cough, progressive persistent shortness of breath (worse during exercise or respiratory infections) or sputum production;
5. Bronchus obstruction detected by spirometry: FEV1/FVC-ratio < 70% and postbronchodilatory FEV1 > 50% predicted (= mild or moderate COPD / GOLD I or II);
6. Competent enough in speaking the Dutch language.

Exclusion criteria

1. Known by the general practitioner or in the second-line medical care with the diagnosis asthma or COPD (c.q. chronic bronchitis, lung emphysema);
2. Spirometry performed during the preceding 12 months;
3. FEV1 < 50% predicted (= severe or very severe COPD / GOLD III or IV);
4. Contraindications for the intake of the medication such as an acute myocardial infarction and hypersensitiveness for nortriptyline;
5. Current use of antidepressants;
6. Quit smoking attempt(s) using nortriptyline or bupropion during the preceding 6 months;
7. Co-morbidity: hypersensitiveness towards nortriptyline, tuberculosis, porfyrine, epilepsy,Parkinson disease, glaucoma, bronchial carcinoma or any other live threatening disease.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2004
Enrollment:	350
Type:	Actual

Ethics review

Positive opinion

Date:	20-05-2005
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	NL571
NTR-old	NTR627
Other	: N/A
ISRCTN	ISRCTN64481813

Study results

Summary results
N/A