SMOKE study.

No registrations found.

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

Summary

ID

NL-OMON23457

Source
NTR

Brief title
N/A

Intervention

Outcome measures

Primary outcome

Biochemically validated (salivary cotinine) continuous abstinence rate (defined as validated abstinence at six months and twelve months after the start of the intervention);
biochemically validated point prevalence abstinence rate at 12 months after the start of SmokeStopTherapy (point prevalence).

Secondary outcome

1. Quality of life, measured by the St.Georges’s Respiratory Questionnaire;

2. Lung function (FEV1, IVC, FEV1/IVC, FEV1% predicted);

3. The frequency and severity of exacerbations. The following severity-scale will be used:

Mild exacerbation:
Increased use of pulmonary medication by more than two occasions within a 24 hour period on three or more consecutive days, compared to the stable situation.

Moderately severe exacerbation:

a. Treatment with antibiotics and/or oral steroids.

b. Evidence of a chest infection.

c. An increase in symptoms and increased use of pulmonary medication by more than four occasions within a 24 hour period on three or more consecutive days, compared to the stable situation.

Severe exacerbation:
Requirement of emergency hospital treatment/ hospital admission;

4. Disease-specific symptoms:
Breathlessness, coughing, sputum production and sputum colour. Symptom scores will be used to indicate the severity of the symptoms;

5. Additional secondary data for economic evaluation (cost-effectiveness):

a. Number of visits at the outpatient clinic;

b. Number of hospital-admissions and admission-days;

c. Number of visits to the emergency room;

d. Days lost of work;

e. Medication costs (from pharmacy records);

f. Euroqol 5D.

Study description

Background summary

Background:

Chronic Obstructive Pulmonary Disease (COPD) is a widespread and growing health problem merely due to the smoking trends of the last decades; smoking is the only avoidable cause of the disease.

Approximately 15% of the cases develop COPD and only 5% of the COPD patients never smoked. Smoking cessation is the only evidence based intervention that reduces the accelerated decline of pulmonary function and improves the prognosis of COPD. The urgency

of developing an effective smoking cessation programme is therefore high. Previous research also indicates that the quality of life will increase if a smoker becomes an ex-smoker.

COPD patients generally have a long smoking history and are heavily addicted to smoking. COPD patients have a strong nicotine dependency which is illustrated by the fact that they maintain their smoking behaviour despite the fact that they experience smoking related complaints. In addition, most COPD patients have undertaken several quit attempts. The LMIS is currently recommended in the Netherlands as the preferred smoking cessation programme in COPD patients. Unfortunately, this intervention seemed to be unsatisfying for this specific target group. A more intensive smoking cessation programme might be more effective for these outpatients.

The SMOKE study is a randomised controlled multi-centre trial. This trial compares the effectiveness of a new developed high-intensity smoking cessation programme targeted at COPD outpatients, the SmokeStopTherapy (SST), with the Minimal Intervention Strategy for Lung patients (LMIS). Both interventions are based on theories of behavioural change: the Attitude-Social influence-Efficacy-model (ASE-model), the Transtheoretical Model (TTM), and Marlatt's Relapse Prevention model. Motivational Interviewing (MI) was used as a counselling tool throughout the whole intervention.

Effectiveness of the new developed intervention:

Outpatients with moderate to severe COPD, willing to quit smoking, were randomly assigned to the SST or LMIS. 234 patients were randomised but due to 9 drop outs before the baseline measurements, 225 patients were eventually followed up. The SST consists of both individual and group counselling, telephone contacts and bupropion free of charge. Additionally, patients can re-enter the individual sessions after they experienced a lapse within three months after the start of the intervention ('recycling') to prevent a total relapse. The LMIS consists of individual counselling and telephone contacts which could be combined with pharmacological support at the patients' own expenses.

Primary outcome measures:
continuous and point prevalent abstinence from smoking after one year, validated by salivary cotinine. Analysis was by intention-to-treat.

The cotinine validated continuous abstinence rates after 12 months are 19% for SST and 9% for the LMIS (RR= 2.22; 95% CI: 1.06-4.65; p=0.03). The 12-month point prevalent abstinence rates are 22% for patients receiving SST versus 12% for patients receiving LMIS (RR= 1.80; 95% CI: 0.97-3.37; p=0.06). Discrepancy between the self-reported and validated smoking status was found in 12% in the SST group and in 20% in the LMIS group. The SST is therefore concluded to be more effective than the LMIS after one year follow-up based on validated continuous abstinence rates.

Baseline characteristics predicting continuous abstinence.

Another aim of this study was to identify characteristics of smoking COPD patients participating in a smoking cessation programme that predict successful quitting.

A wide range of social-cognitive, demographic, smoking related and medical characteristics were measured at baseline. Only variables that showed a (marginally) significant ($p < .20$) univariate relationship with cotinine-validated continuous abstinence at 12 months were included in a full logistic regression model. Subsequently, variables that did not remain independent predictors of continuous abstinence were removed, one by one.

A positive attitude with regard to smoking cessation (OR 11.8; 95% CI: 1.7-81.5) and the cotinine level at baseline (OR 2.1; 95% CI: 1.08-3.93) were independent predictors of continuous abstinence for the LMIS. For the SST subjects no independent significant predictor for continuous abstinence remained. It can be concluded that the LMIS is only suitable for COPD patients with a strong positive attitude regarding smoking cessation at baseline. The SST can be seen as an alternative for patients not possessing such baseline characteristic. This stepwise approach may be useful in clinical practice and will lead to increased efficiency by matching the interventions to the patients' needs.

Study objective

1. The SmokeStopTherapy (SST) is twice as effective than the Minimal Intervention Strategy for Lung patients (LMIS) 12 months after the start of the intervention based on validated continuous abstinence rates in patients with Chronic Obstructive Pulmonary Disease (COPD);

2. After one year the SST is more cost-effective than the LMIS;

3. The secondary aim was to investigate the prospective determinants of smoking cessation in patients with COPD within the two separate smoking cessation programmes. Based on the ASE model, it was expected that Attitude, Social Support and Self-efficacy would be important predictors within both interventions.

Study design

N/A

Intervention

Minimal Intervention Strategy for Lung patients (LMIS) -> Control group

SmokeStopTherapy (SST) -> Experimental group.

Contacts

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Eligibility criteria

Inclusion criteria

1. Outpatients of Medisch Spectrum Twente (Enschede), Slotervaart hospital (Amsterdam), or Catharina hospital (Eindhoven);

2. Current smoker;

3. Motivated to quit smoking;

4. 40-75 years (1961-1826);

5. Clinically treated COPD. Moderate COPD (% predicted FEV1=50-69) or severe COPD (% predicted FEV1=<50 as defined by the ATS criteria.

Exclusion criteria

1. Hypersensitivity for elements of Bupropion SR;

2. (Past history of) serious psychiatric co-morbidity;

3. Liver cirrhosis / alcoholism;

4. (Past history of) epilepsy / fits;

5. Tumor in the central nervous system;

6. Quitting the use of alcohol and / or benzodiazepines during the course of the study;

7. (Past history of) diabetes;

8. Eating disorder(s);

9. Usage of monoamine oxidase inhibitors (MAO-inhibitors);

10. A serious other disease with a low survival rate;

11. Not able to understand, read or write Dutch;

12. Women who are pregnant, breastfeeding or intending to conceive during the course of the study;

13. Participant of the COPE study in the Medisch Spectrum Twente.

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):	15-02-2002
Enrollment:	234
Type:	Actual

Ethics review

Positive opinion

Date:	05-04-2005
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	NL72

Register	ID
NTR-old	NTR103
Other	: Dutch Asthma Foundation: 3.4.01.67.
ISRCTN	ISRCTN43240264

Study results

Summary results
N/A