Effects of a reduction-to-quit smoking programme in patients with COPD: the REDUQ study.

No registrations found.

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

Summary

ID

NL-OMON24119

Source
NTR

Brief title
REDUQ study

Health condition

Chronic Obstructive Pulmonary Disease
COPD
Lung emphysema and chronic bronchitis
Smoking
Tobacco addiction
Nicotine dependence
Smoking cessation
Smoking reduction

Sponsors and support

Primary sponsor: University of Twente, Dept. Psychology & Communication of Health & Risk; Depts Pulmonolgy of University Medical Center Groningen, Slotervaart Hospital, Catharina Hospital and Medisch Spectrum Twente
Source(s) of monetary or material Support: Nederlands Astma Fonds (NAF; Netherlands Asthma Foundation)

Intervention

Outcome measures

Primary outcome

The primary outcome parameter is the percentage of patients with continuous cotinine-validated abstinence after two years from baseline, for at least the last full year.

Continuous abstinence is defined as having salivary cotinine levels < 20ng/mL at measurements at 12 and 24 months.

Secondary outcome

1. Smoking reduction / decrease of the daily cigarette consumption;

2. Behavioural prognostic determinants of smoking reduction and cessation (e.g. attitude, self-efficacy, nicotine dependence);

3. Point prevalence abstinence rates at 12, 18, and 24 months;

4. Disease-specific QoL;

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

6. Frequency and severity of exacerbations;

7. Disease-specific symptoms (breathlessness, coughing, sputum production);

8. Motivation/readiness to quit smoking;

9. Cost-effectiveness data.

Study description

Background summary

Rationale:

Chronic obstructive pulmonary disease (COPD) is a major cause of chronic morbidity and mortality and represents a substantial economic and social burden throughout the world.

Smoking is the most common cause of COPD and smoking cessation the most effective means of favourably modifying the course of COPD. However, due to several failed quit attempts, many smoking COPD patients are convinced that they are unable to quit smoking. Other avenues to convince these patients to try again to quit smoking are therefore urgently needed. One of such strategies would be to prepare a patient for a new serious attempt by first successfully reducing the number of cigarettes smoked per day. Although total abstinence of smoking is the ultimate goal in COPD patients, sustained smoking reduction might be a valuable interlude which limits health damage until the next serious quit attempt.

Objective:

The primary objective of this study is to evaluate the (cost-)effectiveness of a reduction-to-quit smoking programme, which combines behavioural counselling with nicotine replacement therapy, by comparing it to a single information meeting on smoking reduction and a self-help manual.

Study design:

The REDUQ study is a multicenter, randomised, controlled (non-blinded, parallel groups) trial with 18-months follow-up in patients with COPD. Patients will be randomly assigned (1:1) to an intervention and a control group. Outcomes will be assessed at baseline, and after 6, 12, and 18 months.

Study population:

262 patients with COPD (GOLD stage I-IV), 40-80 years old, currently smoking 10 cigarettes or more per day, are recruited from the outpatient departments of pulmonary medicine of five hospitals in the Netherlands. Only smoking COPD patients, who have failed at least two previous cessation attempts, and are unwilling or perceive themselves to be unable to quit smoking, but are motivated to reduce their cigarette consumption, are enrolled.

Intervention:

Patients in the intervention group receive an intensive reduction-to-quit smoking programme, which combines behavioural counselling and nicotine replacement therapy (NRT). It consists of eight small-group sessions, provided by pulmonary nurses, and four telephone contacts between meetings. NRT is offered free of charge for a period of 12 weeks. Patients in the control group attend to a single information meeting on smoking reduction and cessation, and receive a self-help manual with reduction strategies. As soon as patients in both groups

express readiness to quit, they will be referred to an intensive smoking cessation programme.

Main study parameters/endpoints:

The primary outcome parameter is the percentage of patients with continuous cotinine-validated abstinence after 18 months, for at least the last full year. Continuous abstinence is defined as having cotinine levels < 20 ng/mL at 6, 12 and 18 months, respectively. Secondary endpoints are point prevalence abstinence rates and sustained reduced smoking at 6, 12 and 18 months. Other outcomes are disease specific quality of life, motivation/readiness to quit smoking, lung function, and exacerbations defined as needing treatment with a course of oral steroids or antibiotics. Finally, the use of health-care services is evaluated to enable a cost-effectiveness analysis.

Country of recruitment: the Netherlands.

Study objective

A reduction-to-quit smoking intervention for COPD patients, that combines behavioural counselling with nicotine replacement therapy (NRT), leads to an increase in sustained abstinence after 18 months, compared to a brief self-help smoking reduction intervention.

Study design

Primary timepoints: Baseline, 12 and 24 months.

Secondary timepoints: 6 and 18 months.

Change in follow-up from 24 months to 18 months and corresponding change in time points (6, 12 and 18 months instead of 12 and 24 months).

Intervention

Intervention arm (Reduction-to-Quit Smoking Intervention):

Patients in the intervention group receive an intensive reduction-to-quit smoking programme, which combines behavioural counselling with nicotine replacement therapy (NRT). The programme consists of 8 group sessions (provided by pulmonary nurses) and 4 telephone contacts between meetings. NRT (nicotine patches and/or gum and/or tablets) is provided free of charge for a period of 12 weeks.

Control arm (Brief Self-Help Intervention):

Patients in the control group attend to a single information meeting on smoking reduction and cessation + receive a self-help manual.

Smoke Stop Therapy:

As soon as a patient, regardless of study group, expresses readiness to quit, he or she will be referred to the SmokeStopTherapy (SST), an intensive smoking cessation programme for COPD patients, consisting of group sessions, individual sessions and telephone consults.

Contacts

Public
University of Twente, building citadel, P.O.Box 217
Marcel Pieterse
Enschede 7500 AE
The Netherlands
+31 (0)53 4896066
Scientific
University of Twente, building citadel, P.O.Box 217
Marcel Pieterse
Enschede 7500 AE
The Netherlands
+31 (0)53 4896066

Eligibility criteria

Inclusion criteria

1. COPD, GOLD stage I-IV;

2. Age 40-80 years;

3. Smoking 10 or more cigarettes daily;

4. Motivated to reduce smoking;

5. 2 failed lifetime quit attempts (abstinence > 24 hours)

Exclusion criteria

1. Motivated to quit smoking within 1 month from baseline (= ready to quit);

2. Not able to speak, read and write Dutch;

3. Contra-indication for the use of NRT;

4. Serious psychiatric morbidity (not only depressive symptoms);

5. 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:	Recruiting
Start date (anticipated):	01-06-2010
Enrollment:	262
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-02-2010
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	NL2110
NTR-old	NTR2227
Other	MEC MST / Netherlands Asthma Foundation : P09-22 / AF 3.4.08.036 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A