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

Gepubliceerd: 25-02-2010 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24119

Bron
NTR

Verkorte titel
REDUQ study

Aandoening

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

Ondersteuning

Primaire 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

Overige ondersteuning: Nederlands Astma Fonds (NAF; Netherlands Asthma Foundation)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

University of Twente, building citadel, P.O.Box 217

Marcel Pieterse
Enschede 7500 AE
The Netherlands
+31 (0)53 4896066

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2010
Aantal proefpersonen:	262
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	25-02-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2110
NTR-old	NTR2227
Ander register	MEC MST / Netherlands Asthma Foundation : P09-22 / AF 3.4.08.036 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A