Patterns and processes of cognitive and behavioural changes in patients with COPD receiving smoking reduction treatment - The REDUQ II study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41681

Source
ToetsingOnline

Brief title
REDUQ II study

Condition

- Other condition
- Pulmonary vascular disorders

Synonym
COPD (smoker's lung), tobacco addiction

Health condition

nicotineafhankelijkheid/ tabaksverslaving/rookverslaving

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Longfonds (voorheen Astmafonds)

Intervention

Keyword: Chronic Obstructive Pulmonary Disease (COPD), single case experimental design (SCED), smoking cessation, smoking reduction

Outcome measures

Primary outcome

The main study parameter of the RCT is continuous abstinence (cotinine validated) after 18 months, for at least the last full year (also see REDUQ protocol P09-22)

The main study parameters of the SCED are factors addressed in the smoking reduction intervention: smoking behaviour (change) and (psychological) factors thought to be predictive of behaviour change. The study parameters are (changes in):

• Smoking status

• Motivation/Intention to quit

• Self-efficacy

• Attitudes towards smoking cessation

Secondary outcome

Secondary parameters of the RCT are (also see REDUQ protocol P09-22):

- point prevalence abstinence rates

- sustained reduced smoking at 6, 12, and 18 monhts

- disease specific quality of life

- lung function (FEV1)

- anxiety and depression

- nicotine dependence

- exacerbations defined as needing treatment with a course of oral steroids or

antibiotocs

- use of health care services (to enable a cost-effectiveness analysis)

Secondary parameters of the SCED are:

- Social influence

- Desire or urge to smoke

- Treatment adherence (scheduled reduced smoking)

- Use of NRT and/or anti-smoking medication

Study description

Background summary

Smoking cessation is 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 such strategy would be to prepare a patient for a new serious cessation attempt by first successfully reducing the number of cigarettes smoked per day. In the REDUQ study (P09-22/NL30620.044.09) such a smoking reduction programme, which combines behavioural counselling with Nicotine Replacement Therapy (NRT), is compared to a brief (placebo) self-help intervention (a single information meeting on smoking reduction and cessation combined with a self-help manual).
The main hypothesis of the REDUQ trial was that the smoking reduction

intervention leads to an increased likelihood of sustained abstinence after 18 months, compared to a the brief (placebo) self-help intervention. Intermediate analyses have shown, however, that the reduction intervention has no effect on the smoking cessation rate at 6 months follow-up (8%, 3 out of 36 patients) compared to controls (10%, 4 out of 39). Moreover, the percentage of participants who undertake at least one serious quit attempt during the first 6 months is, in contrast with our hypothesis (i.e. 75% of the experimental group and 25% of the control group), comparable: 25% (3 out of 36 patients) of the reduction intervention arm vs. 21% (8 out of 39 patients) in the control arm. Extrapolating these outcomes to 12-month and 18-month follow-up, we expect no significant differences between groups will be found.
Three conclusions can be drawn from the intermediate outcomes. First, by offering COPD patients, unmotivated to quit, a reduction intervention, even a brief one, an abstinence rate of up to 10% after six months is observed in this sample. Second, a very brief reduction intervention appears to be able to re-motivate a fairly high number of smoking COPD patients who were initially unmotivated quit. And third, a considerably more intensive reduction intervention does not seem to add to the effect of the brief reduction intervention.
These conclusions support the initial idea that for smokers who have become resistant to smoking cessation therapies (after repeated failures), offering a reduction approach may have some beneficial effect. Yet, unclear is how to explain the aforementioned conclusions. Can the quit attempts undertaken in the brief intervention group be attributed to a re-motivating effect of trying reduction first? And if so, by what mechanisms does the brief intervention re-motivate some of the participants? We have no detailed data on the extent to which participants in this arm even consider applying the reduction techniques provided to them, whether they actually try to reduce their smoking, or whether this precedes subsequent quit attempts. Also, data are lacking on the cognitive changes these patients undergo during this phase, and which may help to explain when re-motivation to quit occurs in some participants and what elicits this change. Similarly, although many participants in the REDUQ intervention arm initially do engage in a scheduled reduction process, it is unclear whether this contributes to favourable changes in their expectations towards cessation. And if so, why this does not elicit more (successful) quit attempts?
To gain a better insight into this issue, we need to collect more detailed longitudinal data on the trajectories of smoking behaviour (and underlying cognitions) of patients in the REDUQ trial than is currently provided for. According to the REDUQ study protocol, patients receive measurements at baseline and at 6, 12, and 18 months follow-up. However, to explain a lack of treatment effects during the first six months, data on week-to-week changes in their experiences and their behaviour are needed. A final group of 32 patients is yet to be enrolled into the trial (see amendment 8 to REDUQ protocol), which enables us to collect additional prospective data among these subjects.

Study objective

The REDUQ II study will be conducted to help us to complete data on the secondary endpoints of the REDUQ study (P09-22) and arrange and examine relationships occurring between and among intervention elements of the REDUQ study, behavioural and cognitive variables, and confounding and extraneous variables, by means of a single case experimental design (SCED). The primary objective of the SCED is to:
a) gain insight into the nature of the psychological processes (including cognitive as well as behavioural changes) that participants experience during the first six months of the trial;
b) assess whether these processes are casually related to smoking cessation (attempts); and to what extent components of both interventions (i.e., reduction techniques, NRT use) contribute to successful reduction and quitting.

The main study question is: What are the psychological patterns and processes of cognitive and behavioural change in patients with COPD receiving smoking reduction treatment? In order to answer the main question, several sub questions are formulated.
- Are there any patterns and processes of changes in the target variables of the study (main study parameters: smoking status, motivation to quit, self-efficacy, attitudes towards smoking (cessation)?
- When do these patterns and processes of change emerge?
- Are these patterns and processes of change unique for each participant in the study
- Are the patterns and processes of change linked to (components of) the smoking reduction intervention?
- Are the patterns and processes of change linked to other (independent) variables (e.g. treatment adherence, social influence, NRT use, urges to smoke)?
- Are there differences in patterns and processes of change between the experimental and control group?

Study design

The protocol concerns a combination of a randomized controlled trial (RCT) on the (cost)effectiveness of a smoking reduction intervention for patients with COPD (see REDUQ study, P09-22) with an 18 month follow-up, and a randomized single case experimental design (SCED) with seven to eight months follow-up in patients with COPD.

In the RCT the cost-effectiveness of an intensive smoking reduction group intervention and a self-help smoking reduction intervention will be compared. In addition to the RCT, a single case experimental design (SCED) will be conducted to explore patterns and processes of cognitive and behavioural changes in COPD patients receiving smoking reduction treatment. A combination of an ABA design and multiple-baseline design is applied.

Patients will be randomly assigned into one of eight study groups (i.e.,

experimental or control smoking reduction condition and one of four baseline conditions) using a computer-generated schedule. Outcomes will be assessed at baseline, during a 26-week period (*ABA phase*) with weekly repeated measures, and six, 12 and 18 months after treatment start.

Intervention

Participants of the REDUQ II receive the intervention offered in the REDUQ study. The intervention has been described in detail in the REDUQ study protocol (P09-22/NL30620.044.09)
In brief: patients in the intervention group receive an intensive reduction-to-quit smoking programme, which combines behavioural counselling and NRT. It consists of eight small-group sessions and four telephone contacts between meetings. NRT is offered free of charge for a period of 12 weeks. Patients in the control group receive one single information meeting on smoking reduction and quitting, and 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.

Study burden and risks

The possibility of reducing or alleviating symptoms of COPD by smoking cessation or reduction outweighs the (minimal) burden of participating in the study. Smoking reduction counselling may prove to be an alternative treatment option for COPD patients experiencing problems with quitting abruptly. Both participants and non-participating patients can benefit from this study and its outcome, but it is also possible that participants will not receive any benefit from treatment. It is expected that there are no (extra) risks for patients participating in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Clinical diagnosis of COPD (GOLD criteria stage I-IV);
Currently smoking 10 or more cigarettes per day;
Age between 40 and 80 years;
Two or more failed lifetime quit attempts (abstinentie > 24 hours);
Motivated to reduce the number of cigarettes smoked.

Exclusion criteria

Motivated to quit smoking 1 month from baseline (= ready to quit);
Not able to speak, read and write Dutch;
Contra-indication for the use of all forms of Nicotine Replacement Therapy (NRT);
Serious psychiatric morbidity (not only depressive symptoms);
Pregnancy.

Study design

Design

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

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-11-2013
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO Date:	17-09-2013
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	17-11-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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
CCMO	NL45791.044.13