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Smoking cessation in patients with COPD in daily general practice (SMOCC): Six months' results

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Abstract

Background. Chronic Obstructive Pulmonary Disease (COPD) forms an increasing health problem. Despite smoking cessation improving the prognosis of the disease, many patients persist smoking. The present study presents the results of a smoking cessation counseling protocol in general practice (Smoking Cessation in patients with COPD in general practice (SMOCC)).

Methods. A randomized controlled trial of patients with COPD compared smoking cessation counseling according to an intensified minimal intervention strategy with usual care. In total 43 general practices with 392 patients participated in Nijmegen, The Netherlands, in 2001-2002.

Results. Significantly more smokers in the experimental group made a quit attempt (44.9% versus 36.5%) and actually quitted smoking than in the control group (16.0% versus 8.8%). The motivation to stop smoking at baseline was not associated with smoking cessation.

Conclusion. The SMOCC strategy doubled the self-reported quit rates and was complied well by the general practitioners. Implementation in general practice is recommended.

Keywords: Smoking cessation; General practice; Pulmonary disease; Chronic obstructive; Guidelines implementation

Introduction

Chronic Obstructive Pulmonary Disease (COPD), a life threatening and disabling disease, has become an increasing health problem (World Health Organisation, 2000; National Heart, Lung and Blood Institute, 2003). Smoking is the dominant risk factor, smoking cessation remains the major aspect of treatment (National Heart, Lung and Blood Institute, 2003). Quitting smoking reduces ongoing deterioration of the disease and improves the prognosis of COPD related complaints (Scanlon et al., 2000; Anthonisen et al., 1994; Willemse et al., 2004). A number of smoking cessation interventions can be incorporated in general practice: a simple physician's advice to quit (Silagy and Stead, 2003) (in combination with spirometry (Gorecka et al., 2003)), pharmacological therapies (i.e., nicotine replacement therapy (NRT) and antidepressants) (Silagy et al., 2003; Hughes et al., 2003), minimal intervention (counseling) (Pieterse et al., 2001) and pro-active telephone counseling (Stead et al., 2003). In case of stop-smoking support for COPD patients, combinations of pharmacological and behavioral strategies are likely to be effective (van der Meer et al., 2003).

The stages of change (Prochaska and DiClemente, 1982, 1983), a central concept in smoking cessation interventions, divides the process of behavioral change into five steps. Precontemplators do not consider any change (quitting smoking within the next six months). The next stage, contemplation, is the intention to quit smoking within the next six months. In the preparation stage, one is willing to quit within 1 month; the person is preparing to take action. The two other stages, action and maintenance, respectively, relate to the actual change of the behavior and the maintenance of this change.

The Minimal Intervention Strategy (MIS) is a so-called stage-based smoking cessation intervention for general practi-

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tioners (Pieterse et al., 2001). It can be applied during normal practice visits and is effective in decreasing smoking prevalence. Applications of the protocol for risk populations (cardiac patients and pregnant women) also showed effects (Bolman et al., 2002; Bakker, 2001).

Approximately one third of patients with COPD still smokes of which 54% considers to quit smoking within six months or sooner (Hilberink et al., in press). Despite the emphasis in treatment guidelines on smoking cessation, patients with COPD have been found to be a particularly difficult group regarding smoking cessation treatment (Postma and Sluiter, 1989; Crowley et al., 1995; Pederson et al., 1991; Daughton et al., 1980). Since the COPD patient should visit the general practitioner (GP) once in 6 months for a regular control consultation (National Heart, Lung and Blood Institute, 2003), the GP can contribute to the smoking cessation process. Therefore, we changed the MIS into an intensified strategy (SMOking Cessation in COPD in general practice (SMOCC)). The SMOCC program was embedded in normal daily practice as recommended in the COPD treatment guidelines (National Heart, Lung and Blood Institute, 2003).

Implementation of guidelines should be tuned to barriers and stimuli already known and should make use of the knowledge base of effective implementation strategies. Training of health professionals improves their performance of smoking cessation activities, however, organizational factors need also to be addressed (Grol and Grimshaw, 2003). Implementation research shows that interactive education of professionals is mostly effective and suggests that multifaceted interventions and especially outreach visits may be useful to implement guidelines (Grol and Grimshaw, 2003; Thomson O'Brien et al., 2004). Therefore, we designed a multifaceted intervention including professional training and outreach visits to implement a smoking cessation counseling protocol. In the present study, the SMOCC strategy is evaluated on its effectiveness on self-reported quit rates after six months.

Method

Study design

The study is a two-armed randomized controlled trial. General practices in the intervention group received support to implement the SMOCC program, whereas the control group practices delivered usual care. Randomization took place on practice level. Practices were classified in four classes: with high or low task delegation from GP to practice nurses and either or not having experience with smoking cessation counseling. The practices in the classes were then randomly allocated to the groups. Power analysis showed that each group should contain a minimum of 25 general practices and at least 150 patients with COPD per group to find a statistical significant difference of 10% in quit rates (alpha = 0.05, beta = 0.20).

Intervention and protocol

The professional directed intervention consisted of a four h group training on COPD, smoking and smoking cessation. More individual support was provided by an outreach visitor by means of counseling and feedback about performance at the practice location (three visits by a outreach visitor). Furthermore, support materials were delivered. These included:

- Software for detecting patients with COPD;
- Information on COPD and smoking (cessation);
- Letter and patient questionnaire assessing smoking status;
- Smoking cessation counseling protocol (this protocol is available on request); and
- Educational tools for patients.

The patient directed intervention (the SMOCC protocol) consisted of an extended version of the MIS and was specifically aimed at education and support of patients by the general practice. Patients in the intervention group were invited for a control visit in accordance with COPD treatment guidelines (National Heart, Lung and Blood Institute, 2003). The first control visit focused on symptoms, health status and treatment, smoking behavior and the motivational stage to quit smoking. Patients were divided into three categories: (1) preparers (willing to quit within 1 month), (2) contemplators (willing to quit within 6 months) and (3) precontemplators (not willing to quit) (Hilberink et al., in press). Smokers unmotivated to quit received only information about the advantages of quitting. Smokers motivated to quit received self-efficacy enhancing information by discussing how to cope with the various barriers to quit. Depending on their severity of nicotine dependence, they received additional information about NRT. These contemplators were invited again 2 weeks later. When patients were prepared to quit within one month, a next consultation was scheduled to set a quit date and to plan the follow-up visits to the GP (a maximum of two follow-up visits) and proactive telephone calls by the practice nurse/assistant (a maximum of three telephone calls). The patient education tools consisted of a booklet, especially developed for the COPD-population and a videotape; these materials were given to all patients, regardless their motivational stage. To obtain reliable self-report on smoking a Bogus Pipeline procedure was applied (Jones and Sigall, 1971; Aguinis et al., 1993).

Subjects

Recruitment of practices took place in nine districts in the Netherlands amongst practices using one out of four suitable general practice electronic information systems. Forty-nine practices enrolled in the study; one dropped out prior to randomization. By means of a software program using Anatomical Therapeutical Chemical (ATC) prescription codes and International Classification of Primary Care (ICPC) diagnosis codes a selection was made of potential COPD patients. Selection criteria were: (1) age >35 years; (2) diagnosed as having COPD; (3) recorded medication with ICPC code R95/96; (4) prescription of at least three times of bronchodilators in the past year (ATC code R03a/bc); (5) prescription of at least two times of inhaled anti-inflammatory medication in the past year (ATC code R03). To validate the selection results, GPs were asked to confirm the diagnosis. The patients were approached with a letter and a short questionnaire assessing their smoking status. Smokers were requested to give informed consent.

Instruments

The GPs received a questionnaire assessing baseline practice characteristics and policies concerning COPD as well as smoking cessation. The contact persons of each practice also completed a short questionnaire via telephone. At follow-up, GPs received an evaluation questionnaire to assess the compliance with the parts of the protocol.

The patients received two extensive questionnaires at baseline and at 6 months follow-up. The main outcome measure of this study was self-reported point prevalence (did not smoke in the last 7 days). We collected the following data.

- The motivation to quit smoking (Prochaska and DiClemente, 1983).
- Nicotine dependence was measured by the Fagerström Test of Nicotine Dependence (FTND (Heatherton et al., 1991)). A number of studies found support for the validity (Heatherton et al., 1991; Pomerleau et al., 1994).
- Self-efficacy was measured with eleven items on a five-points scale (0–4) (Cronbach's alpha .90). This scale was developed based on previous research (de Vries and Mudde, 1998; de Vries et al., 1995, 1998; Dijkstra and de Vries, 1999; Dijkstra et al., 1996, 1998; Mudde and de Vries, 1999).
- Three constructs of the severity of COPD were measured using the Dutch version of the Medical Research Council Questionnaire (van der Lende and

Orie, 1972): (1) severity of dyspnoea (sum-score range 0–3); (2) chronic coughing (yes/no); and (3) chronic sputum production (yes/no). This questionnaire has good psychometric properties (Toren et al., 1993; Samet, 1978).

Statistical analyses

Bivariate analyses were used to describe group differences. Drop-out analyses were performed with backward logistic regression analysis. Effect analyses were carried out on an intention to treat basis. Because of the hierarchical structure of our study (patients nested within practices), we performed multilevel analyses. SPSS 11.0 and SAS V8.2 (PROC MIXED and GLIMMIX MACRO) were used.

Results

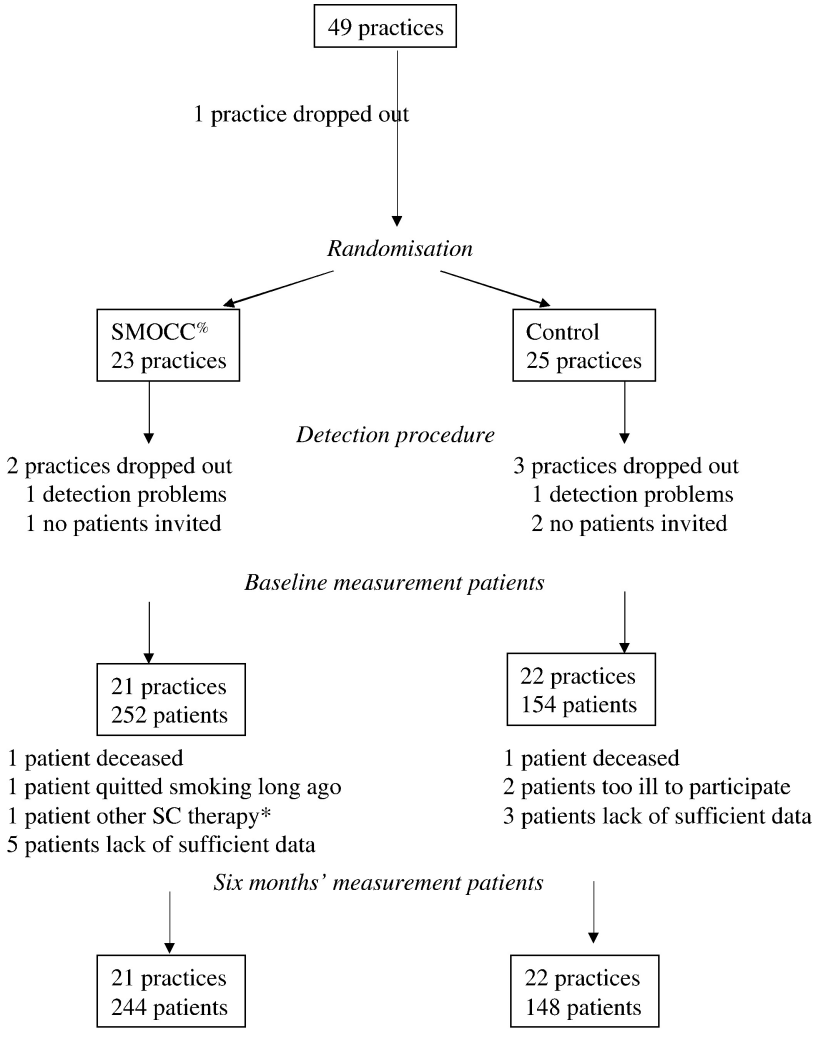
Inclusion of general practices

Twenty-five practices were allocated to the control group and 23 practices to the intervention group, 5 of these practices dropped out (see Fig. 1). Table 1 shows the baseline characteristics of the practices and the GPs, no differences between the arms were observed.

Inclusion of the patients

Of the 406 COPD patients included, two patients died during the study and two patients felt too ill for ongoing participation. After inclusion, 14 patients were excluded from the sample. The total sample consisted of 392 patients (148 in the control group and 244 in the intervention group) (see Fig. 1). This difference between the two groups resulted from the drop out of two large group practices in the control group. Table 2 shows the baseline characteristics of the patients in the two groups. About 50% of the sample was willing to quit smoking within six months; patients in the SMOCC group tended to be slightly more motivated (Chi^2 = 5.7, *df* = 2, *P* = 0.059).

The 6-month questionnaire was returned by 323 patients (82.4%) (131 in the control group and 192 in the intervention



% Smoking cessation in patients with COPD (intervention group)

* Smoking cessation therapy

Fig. 1. Consort figure of the study (Nijmegen, Maastricht, the Netherlands, 2001–2002).

Table 1
Baseline characteristics of the included practices and GPs (Nijmegen, Maastricht, the Netherlands, 2001–2002)

Variable	SMOCC	Control
Practices (*n*)	21	22
Practice form (%)		
Single-handed	43	37
Dual practice	38	45
Group practice	14	9
Health centre	–	5
Number of patients (median (SD))	2900.0 (2946.0)	2975.0 (2291.0)
Number of GPs (median (SD))	2.0 (1.3)	2.0 (0.9)
Number of practice assistants (median (SD))	2.0 (1.3)	2.0 (1.0)
Experience with research concerning COPD (%)	24	14
Experience with smoking cessation intervention research (%)	10	–
GPs (n)	25	30
Male (%)	72	87
Age (mean (SD))	45.8 (7.0)	44.6 (6.8)
Number of working hours in practice (mean (SD))	42.5 (13.7)	41.8 (11.1)
Familiar with the MIS (%)	36	37
Attention to smoking cessation in patients with COPD (% often–always)		
Recommend use of NRT	28	33
Assess the severity of nicotine dependence	60	57
Assess the motivation to quit	80	80

Note. SMOCC: Smoking cessation in patients with COPD (intervention group). GPs: General Practitioners. MIS: Minimal Intervention Strategy. NRT: Nicotine Replacement Therapy. COPD: Chronic Obstructive Pulmonary Disease.

group, $Chi^2 = 6.1$, $df = 1$, $P = 0.013$). Dropped out patients were considered to be smokers to control for biased treatment effects due to patient selection (Fiore et al., 2000). Backward logistic regression analysis showed that drop out was not associated with any main effect.

Compliance with the protocol

19 GPs from 18 practices returned the questionnaire evaluating the SMOCC protocol. Self-reported compliance with the different aspects of the protocol was good in 70–80%.

Smoking cessation

More patients in the intervention group had attempted to quit at 6 months follow-up (44.9% versus 36.5%, $Chi^2 = 10.4$, $df = 1$, $P = 0.003$); these patients also had significantly more quit attempts (median of 1.0 (SD = 1.6) versus 0.0 (SD = 1.3), $U = 8305.5$, $z = -2.9$, $P = 0.019$). Significantly more patients did not smoke in the intervention group (16.0%) than in the control group (8.8%) ($Chi^2 = 4.0$, $df = 1$, $P = .046$; OR = 2.0, 95% CI = 1.0–3.9). The differences in quit rates between the motivational stages were not significant ($Chi^2 = 3.2$, $df = 2$, $P = 0.199$) (Table 3).

Table 2
Baseline characteristics of the included patients with COPD ($n = 392$) (Nijmegen, Maastricht, the Netherlands, 2001–2002)

Variable	SMOCC $N = 244$	Control $N = 148$
Demographics		
Male (%)	46.3	55.4
Age mean (SD)	58.0 (12.1)	60.1 (11.5)
Having a partner (%)	75.8	73.6
Education (%)		
Primary level	47.5	48.0
Secondary level	41.4	38.5
Advanced level	7.4	7.4
Having a (voluntary) job (%)	37.7	34.5
Smoking		
Stages of change (%)		
Preparer	25.8	17.6
Contemplator	32.0	28.4
Precontemplator	39.8	50.7
Self-efficacy (mean (SD))	21.5 (10.5)	19.5 (9.3)
Nicotine dependence[a] (mean (SD))	4.4 (2.3)	4.3 (2.6)
Ever attempted to quit smoking (%)	75.0	71.6
COPD		
Dyspnoea[b,c] (mean (SD))	1.5 (1.2)	1.6 (1.2)
Chronic coughing[b] (%)	33.2	35.1
Chronic sputum[b] (%)	34.8	28.4

Note. SMOCC: Smoking cessation in patients with COPD (intervention group).
[a] Fagerström Test of Nicotine Dependence (FTND) (Grol and Grimshaw, 2003).
[b] Medical Research Council (MRC-ECCS) (Dijkstra et al., 1996).
[c] Sum-score range: 0–3.

Stage transition

Thirteen patients (5.3%) in the intervention group made a shift forward in their stage of change, meaning an increased motivation to quit smoking. In the control group stage transition occurred in 10.9% of the patients ($n = 16$) ($Chi^2 = 1.6$, $df = 1$, $P = 0.215$).

Discussion

The protocol was successfully implemented and doubled the quit rate compared to usual care. Other studies on COPD found continuous abstinence rates at 6 months between 33.3% and 15.7% versus 21.4% and 9.0%, respectively, favoring an

Table 3
Quit rates (point prevalence) specified to baseline motivation to stop smoking (Nijmegen, Maastricht, the Netherlands, 2001–2002)

Stages of change and quit rates	SMOCC $N = 244$	Control $N = 148$
Overall quit rate	16.0	8.8
Preparers (*n*)[a]	63	26
Quit rate among preparers (%)	20.6	15.4
Contemplators (*n*)[a]	78	42
Quit rate among contemplators	16.7	7.1
Precontemplators (*n*)[a]	97	75
Quit rate among precontemplators	13.4	8.0

Note. SMOCC: Smoking cessation in patients with COPD (intervention group).
[a] Due to missing the stage of motivation of some patients, the total sample is greater than the sum of the patients in the three categories.

intervention (Pederson et al., 1991; Tashkin et al., 2001). However, these more intensive interventions compared to the SMOCC strategy took place in a more controlled environment (Pederson et al., 1991; Tashkin et al., 2001), either with patients with severe lung disease (Pederson et al., 1991) or with motivated patients (Tashkin et al., 2001). The present study reports on a smoking cessation program in predominantly less severe patients with different motivational stages, reflecting real life effectiveness in general practice.

Looking at the differences in quit rates per motivational stage, the protocol seemed relatively most successful for less motivated patients. Although recently some critiques on stage-based interventions (Riemsma et al., 2003) and the stages of change construct (Littell and Grivin, 2002; Sutton, 2000) have been published, this might be an indicator of success for a stage-based approach in this population. Application of a stage-based protocol has been proven to be effective in other risk populations as well where smoking formed a direct threat (cancer patients (Bolman et al., 2002) and pregnant women (Bakker, 2001). However, the present study found no intervention effect on stage progression, replicating the results of Cornuz et al. (2002). This raises some doubts about the usefulness of a refined stages of change approach in the COPD-population, the more because the preparators and contemplators in this population do not differ much regarding their determinants of motivation (Hilberink et al., in press). A simplified stages of change model (either motivated or not to stop smoking) may be as effective as the refined version.

The implementation method chosen was well appreciated by the professionals. Outreach visits, small-scale interactive training and delivering support materials effectively contribute to guideline implementation in daily practice, which is in line with other findings (Grol and Grimshaw, 2003; Hulscher et al., 1998; Bero et al., 1998). However, implementation on a national scale could benefit from a less cost- and time-consuming implementation strategy (e.g., personal contacts through telephone helpdesks, e-mail and Internet) and could complement a reduced number of outreach visits. This implementation strategy needs further exploration, especially in educational settings.

Some methodological considerations can be made. Firstly, the size of the effect on quit rate might be distorted by the fact that also relatively many patients in the control group quitted smoking (8.8%) compared to the 6.5% in the general smoking population (Stivoro-smoke Free, 2004). This may be due to the influence of the research setting (i.e., Hawthorne effect (Roethlisberger and Dickson, 1939)) or the detection procedure. Self-selection at practice level possibly affected the quit rate too: 37% of the practices in the control group had experience with the application of the MIS, which is more than the estimated 28% of the Dutch general practitioners at that time (Drossaert et al., 1999). Secondly, although we have self-reported compliance data of the GPs with the protocol, information on the exact performance during the interaction with the patient is not available. Other research methods like videotaping consultations would be needed for that. Thirdly, self-report of smoking behavior is not always reliable, especially populations in which smoking forms an increased risk (pregnant women, patients with cardiovascular diseases) perceive pressure to report non-smoking behavior (Klesges et al., 1995; Secker-Walker et al., 1997; Campbell et al., 2001). However, we applied the Bogus Pipeline procedure (Jones and Sigall, 1971) (briefing the patients that self-reported post-treatment smoking status would be checked by biochemical analysis). This enhances the accuracy of self-reported measures of smoking (Aguinis et al., 1993), especially when subjects perceive a pressure to hide smoking behavior (Gimenes and Adame, 2002).

In spite of the shortcomings, we recommend large scale implementation of the smoking cessation counseling protocol in general practice. As the prevalence of COPD in the Netherlands has been estimated between the 1.4% of the females and 2.4% of the males (Research for Men and Environment, 2002) and approximately one third of them is still smoking (Hilberink et al., in press), the implementation of the protocol on national scale would mean a considerable increase of patients with COPD succeeding in smoking cessation.

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