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Effectiveness of a Minimal Contact Smoking Cessation Program for Dutch General Practitioners: A Randomized Controlled Trial[1]

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Background. **Until recently, Dutch general practitioners contributed little to tobacco control. This is due to several factors, among which is the lack of a feasible intervention program for adult smokers. Such a minimal contact behavioral intervention, using the Stage-of-Change concept, is now available. Effectiveness was tested in a randomized trial.**

Method. **Twenty-two general practitioners and their practice assistants were trained in applying the program. In all, 530 smoking patients were enrolled, randomly assigned to either the intervention or the usual treatment condition. Analysis of treatment effects was performed with logistic regression analysis. In a backward stepwise procedure confounding effects of baseline differences were eliminated.**

Results. **At 12–month follow-up, self-reported abstinence rates (including nonrespondents as smokers) differed significantly between intervention subjects and controls: 13.4 vs 7.3% point prevalence (odds ratio 1.51, $P < 0.05$). An analysis of consecutive abstinence, defined as being abstinent at both 6- and 12-month follow-up, showed that 8.2% of the intervention group compared to 3.1% of the controls had sustained abstinence for more than 6 months (odds ratio 3.04, $P < 0.001$).**

Conclusions. **Results indicate that an effective smoking cessation program for use in Dutch general practice, already shown to be feasible, is now available. Outcomes are generally consistent with recent international literature.**

Key Words: **smoking; smoking cessation; prevention; physician; general practitioner; RCT; tobacco; health education.**

INTRODUCTION

In The Netherlands the prevalence of adult smoking behavior has declined rapidly from 60% in 1958 to 37% in the late 1980s. However, from 1991 until now smoking prevalence seems to have stabilized at 35% [*1,2*]. Two conclusions can be drawn from this. A remarkable change in an addictive habit has taken place in a relatively short period of 25 years. At the same time the need for effective, innovative ways to promote nonsmoking has become even more apparent.

In The Netherlands smoking cessation is promoted in a number of ways, varying from locally organized group programs to a wide variety of mass-media publicity. In this range of methods a lack of individually oriented interpersonal counseling methods exists, especially those suitable for large-scale use. For several reasons general practitioners seem particularly qualified to fill this gap. General practitioners (GPs) are potentially influential intermediates in smoking cessation: they are seen as a credible source of information [*3,4*] and have regular interpersonal contact with virtually all smokers. It is estimated that in The Netherlands annually 70% of all smokers will visit their GP at least once [*5*].

Numerous studies have shown that the use of theory-based behavioral interventions by general practitioners can be effective [*4,6–13*]. Successful programs include a variety of elements such as motivational counseling,

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providing behavioral change techniques, setting a quitting date, follow-up contacts, written self-help material, nicotine replacement therapy (NRT) [*7,14,15*], and the matching of programs to smokers' readiness to quit [*16*].

Nevertheless, until the 1990s, Dutch GPs contributed very little to the reduction of tobacco consumption. Smoking is not registered systematically, and the frequency of antismoking counseling in general practice is low, usually limited to a straightforward advice to quit smoking, which is nearly always related to the contact reason [*17–21*]. According to the literature several factors may be responsible for this situation:

—GPs seem to be experiencing an increasing work load;

—A lack of financial reimbursement for preventive health education activities carried out by the GP;

—A (perceived) lack of skills to successfully influence patients' lifestyle behaviors;

—A lack of appropriate materials to support patients and doctors.

Apparently, many of these barriers to GPs' adoption of a smoking cessation intervention are similar for other countries (see, for example, a review by Richmond and Anderson [*22*]).

In the early 1990s, a minimal contact behavioral intervention was developed for use in the Dutch general practice, accounting as much as possible for these barriers. A preliminary analysis among a Delphi-panel of GPs revealed that the prevailing attitude and routine of Dutch GPs calls for, in short, the following program characteristics:

—easily applicable (i.e., not complex);

—brief interventions, consuming little of the GPs' consultation time;

—flexible (i.e., can be adapted to the GPs' personal style);

—requiring no major changes in the office organization;

—enables a task division, involving the practice assistant.

In the study reported here, the effect of this intervention program on smoking behavior of a random population of smoking patients visiting their GP was compared with usual treatment in a randomized trial. A prior feasibility study showed that the intervention program, which is described in more detail in the following section, sufficiently met the aforementioned criteria [*23*].

The results of the trial described below have recently led to the dissemination of the intervention program on a national scale [*24*]. At present, it is estimated that 28% of Dutch general practitioners apply this program routinely [*25*].

METHOD

Samples

All approximately 250 general practices in the region were approached directly with a written invitation, authorized by the regional GP association. This was followed by presentations at local meetings of GPs. In all, 25 practices responded, from which 18 enrolled in the study, involving 22 GPs and 19 practice assistants. The sample of practices appeared to match the Dutch population of general practices on relevant variables, such as age, smoking behavior, size of the patient population, and degree of urbanization [*23,26*]. All participants received a 2-h skills training, followed by a detailed introduction of the research goals and procedures. In the skills training, participants received an introduction on smoking behavior, nicotine addiction, stages-of-change theory, and behavioral change processes. Training relevant counseling techniques and other skills in role-playing, after dividing GPs and office assistants in two subgroups, formed the main part of the training. Finally, preparations needed to implement the intervention program into everyday office routine were discussed.

Office assistants were additionally trained in applying the randomization and informed consent procedures. The first 2 weeks in practice were used as a testing period. Patients recruited in this period were not incorporated in the analyses. All procedures, concerning both the study measurements and the interventions, were evaluated after the first 2 weeks by the researchers in telephone interviews with both the office assistant(s) and the GP. By interviewing all participants within one practice separately, answers could be verified. If necessary, the practices received instructions for adjustments. Adherence of the practices in the following months was periodically monitored by short telephone interviews. In the interviews the following questions or themes were addressed:

(a) research procedures: Are patients correctly informed when recruited? Is randomization carried out correctly? Are the pretest questionnaires completed before allocating the patients and starting the intervention protocol?

(b) program fidelity: to what extent is the treatment carried out completely and correctly with each patient in the intervention group? This was assessed with several detailed questions concerning elements of the treatment protocol. This analysis revealed that in general the GPs complied with the intervention protocol, and that the only significant deviation concerned the effort GPs were willing to put into counseling the nonmotivated patients. A minority of GPs considered this a waste of time, whereas the majority briefly tried to motivate this group of patients, in accordance with the original protocol. The former GPs were encouraged to

follow the protocol as much as possible, but were allowed some freedom at this point, as long as they did conclude each consultation with unmotivated patients with an explicit advice to quit.

Smoking patients, ages 18–70 years, were recruited in two ways. First, a poster in the waiting room invited patients to participate in a study on smoking behavior; second, practice assistants proactively approached patients in the waiting room. Subsequently, participants filled in the pretest questionnaire. A separate page added to the questionnaire served as a written informed consent form. The informed consent forms were collected by the research staff. All subjects received general information about the importance of developing new ways of supporting smoking cessation, the number of follow-up measurements, and the confidentiality of the data, but they were not informed about the experimental nature of the study. Controls were thus not made aware of the existence of a cessation program. Both the informed consent procedure and the overall study design were approved by an independent advisory committee and were consistent with the regulations of the national association of Dutch general practitioners (LHV).

After handing over the completed questionnaire, subjects were assigned to one of both groups by the office assistant, according to a prestructured allocation list. Hence, randomization took place within the practices. Since this implies that exposure of the control group to the treatment becomes a possible source of bias, GPs were asked to register each consultation in which smoking was discussed with smokers not allocated to the intervention group. This enabled the identification of control patients who may have been exposed to the treatment, as described in the next section. These cases were subsequently excluded from the analyses.

Another disadvantage of the randomization procedure involves the ethical problem that GPs are knowingly withholding some of their patients from a potentially more effective treatment. This is especially relevant with patients suffering more serious health problems related to tobacco use. GPs were permitted in such cases to use the intervention for control patients. These patients were excluded from the analyses as well.

In all, 537 patients were recruited, 269 in the intervention group and 268 in the control group. Due to above-mentioned problems, only 7 (control) subjects were excluded, leaving 530 eligible subjects (269 intervention and 261 controls).

Treatment

Control group smokers received usual treatment, implying that they received no counseling or advice on smoking at all, except when indicated by the contact reason or when initiated by the patient. In those cases counseling was limited to a straightforward stop-smoking advice, sometimes accompanied by a referral to the local municipal health organization. They received no motivational counseling and no self-help manual and were not offered follow-up care. In all, 45 (17.2%) of the controls reported to have had some conversation about smoking during the 12-month follow-up period with the practice assistant, the GP, or both.

General characteristics of the treatment are brief interventions, taking on average approximately 10 min per patient including follow-up sessions; a task division between GP and the office assistant, in which the assistant caries out most of the intake and administrative procedures, including handing out the written material, while the GP performs the behavioral counseling; and counseling is tailored to the smokers motivational stage, largely in accordance with the stages-of-change concept [*16*]. With four questions (concerning former quit attempts, thinking about ways to quit, planning of a next quit attempt, and frequency of thinking about quitting), subjects were classified as low (precontemplating), moderately (contemplating) or highly motivated (preparation).

Interventions consisted of the following elements, which are shown to be effective in numerous studies [*4,6,7,10,13–15,27–30*]:

(a) assessment of level of nicotine dependence (low or high) and the motivational stage;

(b) if necessary, reinforcement of motivation to quit by discussing outcome expectancies, emphasizing positive (short-term) outcomes;

(c) reinforcement of perceived ability to quit by discussing expected abstinence difficulties and high-risk relapse situations and suggesting strategies to overcome these barriers;

(d) setting a quitting date with smokers ready to quit;

(e) reinforcement of self-management capabilities, by handing out a self-help manual, which was thoroughly pretested [*31*];

(f) advising NRT to dependent smokers (note that in The Netherlands patients received no reimbursement for NRT at the time the study was carried out, and that gum was the only available product);

(g) a follow-up meeting is offered to smokers setting a quitting date.

Measures

Smoking behavior and demographic variables (see Table 1), as well as behavioral determinants (see Table 2), were assessed using a validated written questionnaire. Biochemical validation of self-reported abstinence was not performed.

TABLE 1

Subject Characteristics

Subject characteristic		Study group		Base-line differences
		Intervention	Control	
Age	(years)	35.8	35.6	
Sex	(% female)	58.4	61.6	
	Education			
	% low	15.5	16.7	
	% moderate	63.6	59.9	
	% high	20.9	23.4	
	Smoking			
	Years smoking	18.7	18.1	
	Age onset	16.4	16.4	
	Cigarettes/day			
	% ≤10	13.3	20.4	$F = 4.3$; $P = 0.04$
	% 11–24	70.0	67.9	
	% ≥25	16.7	14.1	
Nicotine dependence[a]	(scale: 4(l) − 13(h); $\alpha = 0.73$	8.4	8.5	
Motivation to quit	(scale: 4(l) − 20(h); $\alpha = 0.82$	14.8	13.8	$F = 6.7$: $P = 0.01$

Note. Subject characteristics of patients in the intervention and control group on socioeconomic variables and smoking behavior. Statistically significant baseline differences between both study groups are indicated.

[a] Nicotine dependence is estimated with a four-item, adapted Fagerströmscale [*35*,*36*].

To enhance the accuracy of post-treatment self-reported smoking behavior and abstinence, a bogus pipeline procedure was introduced in the 1-month follow-up questionnaire. Patients were asked to give the telephone number of a relative or close friend, a so-called confederate, who might be contacted by the research team during the follow-up period. It was expected that respondents would be motivated to give accurate self-reports, being aware that the researchers might verify their questionnaires [*32*]. Telephone contacts with a random selection of these confederates ($n = 20$), shortly after the 1-month follow-up, revealed no discrepancies between smoking status as reported in the questionnaires with that reported by the confederates.

TABLE 2

Treatment Effects

Independent variables	Abstinence at follow-up					
	1 month		12 months		Consecutive (6 + 12)	
	OR (95% CI)	*P*	OR (95% CI)	*P*	OR (95% CI)	*P*
Variables at base-line						
Daily cigarette consumption		ns		ns		ns
Nicotine dependency	1.19 (1.0–1.3)	0.016	1.31 (1.1–1.5)	0.000	1.39 (1.2–1.7)	0.001
Quitting motivation	1.13 (1.0–1.2)	0.004		ns		ns
Social support		ns		ns		ns
Self-efficacy		ns		ns		ns
Attitude		ns		ns		ns
Positive outcome expect		ns		ns		ns
Negative outcome expect	1.15 (1.0–1.3)	0.019	1.13 (1.0–1.3)	0.032		ns
Intervention	2.56 (1.8–3.8)	0.000	1.51 (1.1–2.1)	0.009	3.04 (1.7–5.6)	0.000
Interaction terms						
Intervention ×						
Nicotine dependency		ns		ns		ns
Quitting motivation		ns		ns		ns
Attitude		ns		ns		ns
Positive outcome expect		ns		ns		ns
Negative outcome expect		ns		ns	1.21 (1.1–1.4)	0.009

Note. Effects of treatment on smoking status (including nonrespondents as smokers) in a backward-stepwise logistic regression analysis ($n = 481$), correcting for baseline differences. Odds ratios (OR) are reported with the corresponding 95% confidence interval (95% CI) and probability ($P <$). Base-line variables were recoded in such a way that a high score should, as predicted by theory, be associated with a higher chance of quitting and thus result in an OR > 1.

Abstinence at follow-up was assessed with two variables: smoking status ("do you smoke cigarettes?" yes/none-at-all) and the average daily cigarette consumption (0;1–5;6–10;11–15;16–20;21–25;>25). Only respondents with consistent answers, i.e. smoking no cigarettes at all and smoking zero cigarettes daily, were counted as nonsmokers.

In addition to the point prevalence measures at three follow-ups, a more rigorous measure of consecutive abstinence was constructed by combining the smoking status at all follow-ups. Consecutive abstinence was defined as being a nonsmoker at—at least—both the 6-month and the 12-month follow-up points. Thus, successful quitting implies being abstinent for (probably) at least 26 weeks, starting within 6 months following the intervention. By using this criterion the chance of missing a possible delayed effect, or sleeper effect [*33*], of the intervention was reduced.

Analyses

Analysis of treatment effects on 1 and 12 months point prevalence, as well as on consecutive abstinence, was performed with logistic regression analysis. In a backward stepwise procedure [*34*] confounding effects of baseline differences were eliminated. Additionally, to confirm the effect of the intervention on sustained abstinence an univariate analysis of variance was performed to compare the average number of weeks smoke-free at the final follow-up. The possible confounding effects of a differential exposure to external sources of antismoking messages was tested with χ^2 analysis.

RESULTS

Subjects

The response rate at 1-month follow-up was 74% (n = 393). For the second and third follow-up again all 530 patients were approached. This resulted in a response rate at the 6-month follow-up of 64% (n = 339) and 78% (n = 416) at 12 months. Response rates in both study groups were comparable, except for the first follow-up questionnaire. At 1 month significantly more control patients responded: 81% compared to 67% in the intervention group (χ^2 = 8.5; df = 1; $P < 0.01$).

The relative increase in response rate at 12 months was a result of additional efforts to reach nonrespondents. In all, 95 initial nonrespondents could be contacted by telephone. The interviewers tried to assess patients' smoking status and urged them to return the questionnaire. In this way attrition could be diminished considerably. Approximately half of these patients did not comply. Of the majority of this group only the smoking status is known, assessed by telephone.

The main characteristics of the total population are shown in Table 1. The socio-demographic variables do not vary significantly between intervention and control group. Moreover, with regard to sex, age, and education level, this population can be considered representative for the average Dutch visitor of a general practice [*23*]. This also accounted for the contact reasons: from a registration by the GPs it appeared that in only 19.1% of the contacts with patients allocated to the intervention group was a health problem presented that could in some way be related to tobacco use.

With respect to smoking behavior, both study groups vary significantly on two variables. At baseline patients in the intervention group smoked more cigarettes per day and were more motivated to quit. Since this bias may confound the effect of the intervention, we tested whether these variables were associated with smoking behavior at follow-up. In a univariate analysis of variance, the number of cigarettes smoked daily is significantly associated with smoking status at 1 (F = 6.2; $P < 0.05$), 6 (F = 6.4; $P < 0.05$), and 12 months (F = 13.6; $P < 0.001$): a high daily tobacco consumption at baseline is associated with a lower chance of quitting, especially on the long term. The second confounding variable, motivation to quit smoking, is only associated with smoking status at 1 month (F = 12.5; $P < 0.001$): a high motivation to quit at baseline correlates with a higher chance of short-term quitting. No interaction effects between both variables were found. In following analyses these confounders were corrected for where necessary.

Effects

The practices registered the immediate outcomes of the 269 interventions. This showed that the majority of interventions were successful: 175 patients (65.5%) agreed to set a quitting date. Nicotine chewing gum, which was at the time the only available product for nicotine replacement therapy, was prescribed by the GPs to 25 patients in the intervention group (9.4%). Analyses within the intervention group to test any contribution of nicotine replacement to the intervention effect were not significant, due to both a low statistical power and small differences between gum users and nonusers. Follow-up care was provided to 37 intervention subjects (13.8%) in the 12 months following the intervention.

At 1 month follow-up, abstinence was reported by 27.6% (n = 50) of the responding intervention group and 4.9% (n = 10) of the control respondents. By including the nonrespondents as smokers these rates are estimated more conservatively: 18.6 and 3.8%, respectively. At 6 months the reported cessation rate of responding intervention patients decreased to 19.5%, while the quit rate of control respondents increased to 6.3%. Including nonrespondents this amounts to 11.9 versus 3.8%. At 12 months the reported quit rate in the intervention

group further dropped to 17.6% ($n = 36$). In contrast, the control respondents' quit rate increased again to 9% ($n = 19$). Inclusion of nonrespondents results in quit rates of 13.4 and 7.3%, respectively.

According to the consecutive abstinence criterion 15.3% of the respondents in the intervention group can be considered successful quitters, compared to 5.3% of the control respondents. When including all missing subjects as smokers, success rates are about half as high: 8.2% ($n = 22$) versus 3.1% ($n = 8$) respectively.

As Table 2 shows, quit rates of the intervention group were significantly higher than in the control group at 1-month (odds ratio 2.56) and 12-month follow-up (odds ratio 1.51), as well as according to the more rigorous consecutive abstinence criterion (odds ratio 3.04), after controlling for baseline differences.

In addition to the treatment effect, three baseline variables appear to be associated independently with smoking cessation. First, a low level of nicotine dependence at baseline appears to contribute to a higher chance of quitting as well as sustaining abstinence. Likewise, perceiving fewer cons of quitting, i.e., having less negative outcome expectancies, seems to predict abstinence at 1 and at 12 months. Third, a high motivation to quit at baseline is also associated with a higher chance of quitting, although only at 1-month follow-up. Furthermore, one interaction term was found to be significant. Patients in the intervention group, having less negative outcome expectancies at baseline, seem to have a higher chance of achieving consecutive abstinence.

In an intention-to-treat approach the aforementioned logistic regression analyses were replicated incorporating the seven controls that were excluded from the initial analyses because of their exposure to the intervention. This produced identical outcomes, since all seven subjects appeared to have missing values on some of the baseline variables and were not included in the regression model.

Note that in the second half of the follow-up year, in contrast to the expected decline in the proportion of quitters in the intervention modality, a considerable increase was observed in the control group. Presumably, a relatively large number of control patients undertook a quit attempt later that year, while among the early quitters in the intervention group a normal pattern of relapse took place. If this is the case, one may expect that in the intervention group, nonsmokers at 12 months maintained their abstinence for a longer period. To test this assumption the mean number of smoke-free weeks during the current quit attempt was compared between the 12-month quitters in both study groups ($n = 53$). It appeared that the nonsmokers in the intervention group had at that point sustained abstinence for almost 29 weeks, whereas nonsmokers in the control group reported 17 weeks nonsmoking on average. This resulted in a (univariate) significant variance ($F = 4.3$; $P < 0.05$).

Since the control quit rate at 12 months seems rather high in comparison with literature reports [*6,7,15*], some additional analyses were performed. In the questionnaire subjects were asked about their contacts with their doctor during the follow-up year. This revealed that 18 control patients (8.6%) reported discussing smoking with their GP at least once. More specifically, 4 of the 11 control patients who had quit smoking at 6 months reported discussing smoking with their GP in the preceding 6 months. The nature of these contacts could not be retrieved.

An important external influence occurring at the time of the experiment was a nationwide mass-media stop-smoking campaign [*37*], which started shortly before the second follow-up. The campaign included a weekly broadcasted prime-time television show and a television quitting course of six sessions. Exposure to campaign messages and other sources of information was roughly assessed. At 6 months more control patients were exposed to "other stop-smoking activities" ($\chi^2 = 11.9$; df = 1; $P < 0.001$), and to "stop-smoking leaflets" ($\chi^2 = 8.3$; df = 1; $P < 0.01$). This second difference still existed at 12 months ($\chi^2 = 5.3$; df = 1; $P < 0.05$). Furthermore, two respondents, both in the control group, ordered the course manual that accompanied the television course. One of these patients reported abstinence at 12 months. No further differences were found on specific campaign elements or other activities at 12 months.

DISCUSSION

The results of this study indicate that an effective and easily applicable smoking cessation intervention is available for Dutch general practitioners. Doctors, cooperating with their office assistants, have shown to be able, within a few minutes, to persuade a large proportion of smoking patients to undertake a quit attempt. The significance of this finding is underlined by the fact that the study population consisted of a largely representative sample of smokers, visiting their GP for a wide range of reasons mostly unrelated to smoking, and that NRT was used by only a small minority of intervention subjects. In general, the outcomes suggest further generalizability of the approach to primary care physician-based cessation interventions, which now is becoming the standard in international literature [*13*].

Besides a significant short-term impact, as appears from the conservatively estimated 15% net gain in the quit rate at 1 month, the program seems to be effective on the long term as well. The proportion of patients abstinent at 12 months is roughly doubled by the intervention program. Furthermore, application of the program seems to triple the chance that patients reach

sustained abstinence, as estimated by measuring consecutive nonsmoking at 6 and 12 months follow-up.

These abstinence rates seem to be consistent with comparable international research. The odds ratio of point prevalence quitting at 12 months (1.51) falls within the range reported in the recent Cochrane meta-analysis (odds ratio 1.69; confidence interval 1.45–1.98), while the odds ratio of reaching consecutive abstinence in this study (3.04) suggests a relatively strong long-term effect [*15*]. The absolute gain in the consecutive abstinence rate of 5.1% seems indeed encouraging, when compared to the average 2.5% gain reported in the Cochrane meta-analysis.

Some caution is needed, however, in interpreting these results. First, the absence of biochemical verification of nonsmoking may have caused an overestimation of the point prevalence estimates. It is argued, though, that self-reports of smoking behavior can be fairly accurate [*38*], while the validity of cessation reports tends to increase at later follow-up points [*39*]. Nevertheless, a small overreporting bias of quitting within our outcomes seems likely. More important is that there is evidence that self-report deception rates do not vary systematically between control and intervention groups [*7,32,40–45*]. In this study we applied two ways of enhancing accuracy of self-reports, e.g., a bogus pipeline procedure and checking the consistency between multiple measures.

Second, the measurement of point prevalence of quitting behavior in this study differs from the "past 7-days" measure which is now considered to be standard [*14*]. Despite the collateral verification of abstinence self-reports by combining two alternative measures, this may have resulted in a overestimation of cessation rates in this study. Assuming, though, that this bias affected the cessation rates in both study groups equally, it may not seriously compromise the strength of the treatment effects reported here.

Third, this study showed a rather high quit rate at 12 months among control patients (7.3%), even when accounting for a probable Hawthorne effect or the use of self-reports [*6,7,15*]. Even more so, an increase from 3.8% quitters at 1 and 6 months to 7.3% at 12 months was observed. Two possible explanations for this observation were explored in this study. First, possible interaction of the control group with (elements of) the intervention in some way must be considered. Second, special attention was paid to external influences, which may have had a differential impact on the control group. To avoid interaction between treatment and control subjects, GPs were instructed to provide usual care when smoking came up during consults with nonintervention patients and to register these cases. Thus we were able to identify several control patients who were exposed to intervention elements and were excluded from the analyses. Nevertheless, the data give some reason to believe that several other members of the control group were exposed to the intervention as well. Of course, this is one of the possible consequences of the choice to randomize subjects, instead of randomizing GPs to a control or treatment condition. This procedure was chosen for two reasons: provider-mediated effects are controlled for and the study becomes more efficient since patients are the unit of analysis and only a limited number of practices is required.

Analyses on the influence of other stop-smoking messages, occurring at the time of the follow-up, indicate that the control group may have been more frequently and extensively exposed to these external information sources. What we have observed here is perhaps that participating in a study made control subjects more susceptible to information on smoking cessation, while intervention subjects at that point already had either received this information or acted upon it, e.g., had tried to quit. We are inclined to think that the exposure of controls both to external influences and to the intervention may have contributed to a more conservative estimation of treatment effects.

Fourth, we must consider a selection bias, probably due to irregularities in the randomization procedure, as expressed in pretreatment differences between the study groups in number of cigarettes smoked daily and in level of motivation to quit. Since these two confounding variables will have oppositely affected the difference in cessation rates and were controlled for in the regression model, we expect that this limits the validity of the results reported here only marginally.

Fifth, in this study no data were gathered concerning the smoking patients that were approached but refused to participate in the study. Therefore, no information is available for a refusal rate or the resulting selection of subjects more willing to quit. This may limit the generalizability of the results in this study to a general population. In real life, an average Dutch GP may meet more resistance than the GPs involved in this experimental setting.

We expect that in order to further enhance program effectiveness, we should first look at relapse prevention. In other words, GPs using this program should pay more attention to maintenance of nonsmoking, rather than trying to achieve more quit attempts. Since the amount of follow-up care provided to quitters in this study was minimal (less than 14% of them returned for follow-up), this seems worthwhile. In fact, it is stated that the intensity of cessation counseling has a strong dose–response relation with effectiveness [*13*]. When intensifying the intervention with additional or expanded elements, one should bear in mind the practical limitations of the GP's office. Telephone support counseling by the office assistant, which is not very time-consuming, might be such an extension that GPs would be willing to adopt.

Second, NRT deserves a more prominent role in this program. Note that only 9% of the patients in the intervention group made use of NRT in this study. As a result of the research in the past decade, NRT has now become a regular part of this type of smoking cessation intervention [*13,14*]. To promote the use of NRT, both the current reluctance among Dutch GPs to advise these treatments and the cost for dependent smokers willing to quit need to be lessened.

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