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Original Scientific Paper

The effect of a minimal intervention strategy in addition to nicotine replacement therapy to support smoking cessation in cardiovascular outpatients: a randomized clinical trial

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Background **Smoking is an important risk factor for recurrent events in cardiovascular patients. Evidence exists that nicotine replacement therapy (NRT) approximately doubles smoking cessation rates. The minimal intervention strategy (MIS) has been used successfully to assist patients to quit smoking in general practice, and was recently adapted for cardiology inpatients (C-MIS). It is hypothesized that in cardiovascular outpatients the combination of C-MIS and NRT significantly increases the number of quitters compared to NRT alone.**

Methods **A randomized clinical trial in 385 smoking patients who attended the cardiovascular outpatient departments in the Academic Medical Centre, Amsterdam for the treatment of atherosclerotic disease. Patients were allocated to either NRT + C-MIS or NRT alone. Self-reported and biochemically validated abstinence rates were measured at 12 months' follow-up.**

Results **Including patients with incomplete follow-up as smokers, abstinence was reported by 19% of the NRT + C-MIS group and 14% of the NRT group [absolute risk reduction (ARR) = 0.05; 95% confidence interval (CI) = −0.02; 0.12]. According to biochemical markers, abstinence rates were 28 and 24%, respectively (ARR = 0.04, 95% CI = −0.06; 0.14). Hence, no significant differences between groups were found. The number of cigarettes smoked a day decreased significantly at 12 months: from 21 to 15 a day in the experimental group, and from 21 to 14 in the control group ($P < 0.001$), but did not differ between groups ($P = 0.32$).**

Conclusions **The effectiveness of a minimal contact intervention was investigated in order to reach as many cardiovascular patients as possible in the setting of outpatient departments. This intervention was not found to be effective.** ***Eur J Cardiovasc Prev Rehabil*** **13:931–937 © 2006 The European Society of Cardiology**

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Introduction

Although smoking is one of the most important risk factors for recurrent events in cardiovascular patients, smoking behaviour receives only limited attention from treating physicians [1–3]. This is mainly due to lack of time and inadequate smoking cessation programmes.

In 1998 the Health Education Authority in the UK developed evidence-based recommendations [4,5] regarding smoking cessation, based on evidence from the US Agency for Health Care Policy and Research

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(AHCPR) guideline [6] and Cochrane Reviews. According to these guidelines, key components of successful cessation programmes are the combination of nicotine replacement therapy (NRT) and supportive care. Prescription of NRT to smokers who attempt to quit should be standard practice, since it increases the odds of quitting approximately 1.5 to 2-fold, regardless of setting [7].

Supportive care is an additional tool for influencing patients' smoking behaviour. In the absence of an effective and feasible behavioural smoking cessation programme as a primary prevention tool, the minimal intervention strategy (MIS) was developed. The MIS is an individualized short intervention, and has proven its efficacy and feasibility in general practice in a large, randomized, controlled trial. It resulted in a point prevalence abstinence rate of 11.9%, compared to 3.8% in the control group at 6 months, and 13.4 versus 7.3% at 12 months [8]. The theoretical assumptions of the attitude–social influence–efficacy model [9,10] and the transtheoretical model [11,12] (suggesting that patients go through motivational stages before they change their health behaviour) form the basis of the MIS. The intervention is in line with the smoking cessation guidelines of the UK [4,5].

These days, the MIS is propagated by several health institutions [e.g. the Dutch Expertise Centre on Tobacco Control (STIVORO), and the Dutch College of General Practitioners (NHG)] to support smoking cessation in specific patient populations. For the purpose of secondary prevention, the MIS programme has been adapted for cardiology inpatients (C-MIS) [13] with nurses largely being responsible for the intervention [13,14]. Currently, 45% of the 121 Dutch cardiology inpatient wards are using the C-MIS [15]. However, its incremental effect in addition to NRT in cardiovascular outpatients is unknown. A Cochrane Review [16] also showed that insufficient data are available on the combination of nurse-led interventions and NRT as compared to NRT alone.

The aim of the current study was to contribute to the secondary prevention of cardiovascular disease by attempting to improve smoking cessation rates. We thereby carried out a randomized clinical trial and tested the hypothesis that the combination of C-MIS and NRT, as performed by a nurse in the outpatient clinic, significantly increases the number of quitters as compared to NRT alone.

Methods

Participants

Consecutive patients were recruited at the outpatient departments of vascular surgery, cardiology and vascular medicine of the Academic Medical Centre, Amsterdam, The Netherlands. Patients were eligible if they were ≥ 18 years old, smoked ≥ 5 cigarettes a day, and suffered from documented peripheral arterial disease (PAD) or coronary artery disease (CAD). Exclusion criteria were having an acute myocardial infarction in the previous month, unstable angina, serious arrhythmia, recent stroke, skin allergy, pregnancy and insufficient comprehension of the Dutch language.

Randomization

Patients just diagnosed with a smoking-related illness may be more receptive to participate in a smoking cessation programme, compared to patients who attend the outpatient clinic for a routine follow-up visit. Therefore, a distinction was made between types of clinic attendance. Patients diagnosed with PAD/CAD within the first three visits were considered 'newly diagnosed/first visit'. All other potential cardiovascular patients were identified on the basis of the hospital information system, and the presence of PAD/CAD was verified by physicians.

During a regular consultation, eligible patients received advice to quit smoking from their treating physician and were invited to participate in the study. Consenting patients were referred to a nurse practitioner, and received information about the study procedure. Patients were not informed about the behavioural intervention, in order to avoid a Hawthorne effect [17]. After follow-up, patients received a letter containing this withheld information [18]. While patients completed their baseline questionnaire (and signed a written informed consent), nurses randomly assigned patients to either the control or the experimental group. A computerized balanced randomization programme was designed, taking prognostic factors (e.g. clinic attendance, age and gender) into account. Randomization was stratified by clinic attendance and outpatient department (vascular medicine, vascular surgery or cardiology).

Interventions

Following randomization, 8 weeks of free NRT [transdermal nicotine patches: < 20 cigarettes/day ($20\,cm^2 = 14\,mg/24\,h$) or ≥ 20 cigarettes/day ($30\,cm^2 = 21\,mg/24\,h$)] was offered to all patients, accompanied with intensive application instructions from the nurse practitioner. NRT was only presented when patients were planning to quit, because smoking and using NRT simultaneously may cause serious health problems in patients with cardiovascular disease.

Patients in the control group received usual care only, i.e. no additional motivational counselling or self-help materials. In the experimental group, patients were offered the behavioural intervention (C-MIS). In the C-MIS, during a 15–30-min counselling session, six steps

were performed by the nurse practitioner. First, the nurse assessed the patients' smoking profile, including nicotine dependency and motivation to quit. Based on patients' readiness to change, the nurse would: increase motivation by stressing the adverse effects of smoking and the benefits of quitting; discuss perceived barriers of quitting; set a date to quit smoking; offer NRT and self-help materials such as brochures and information on support groups; and plan at least one follow-up contact by telephone 2 weeks following the quit date. A second behavioural counselling session was provided on patients' request.

Outcomes

The primary endpoint was point prevalence abstinence at 12 months' follow-up as indicated by patients' self-report and biochemically validated measures (nicotine, cotinine and thiocyanate levels from urine and saliva samples). Secondary outcomes included possible interaction effects of treatment condition and baseline characteristics (education, type of disease, nicotine dependence, clinic attendance) on abstinence, and change in the number of cigarettes/day.

Measures

Measurements of patients' baseline characteristics included age, gender, level of education, marital status, type of disease (PAD, CAD), number of cigarettes smoked a day, severity of nicotine dependence, and outpatient clinic attendance (first or routine follow-up visit). We used the Fagerström Test for Nicotine Dependence (FTND), which measures smoking habits with six questions (Cronbach's $\alpha = 0.62$). Sum scores (range 0–10) are used to categorize patients into low (≤ 5) and high (≥ 6) nicotine dependency [19,20].

Smoking status was assessed at baseline and 12 months follow-up using a 7-day point prevalence abstinence measure: 'Have you been smoking during the past 7 days?' (yes; yes, but only one puff; no). Patients were considered to be abstinent when they had not been smoking, not even one puff. When patients did not respond to the 12 months' follow-up questionnaire or the reminder (both by postal mail), smoking status was obtained by telephone interview. Follow-up was blind to allocation.

With the 12-month follow-up questionnaire, patients were asked to bring along a urine sample, and/or to provide saliva when they arrived at the outpatient clinic for a routine follow-up visit. The samples were frozen at -20°C until analysis. Nicotine, cotinine and thiocyanate are widely used biomarkers, but misclassification (such as classifying passive smokers as daily smokers) occurs relatively frequent when applying a single biomarker for the analysis of smoking status [21]. Therefore, Sastre Torano and van Kan [22] developed an analytical method for the simultaneous determination of three biomarkers in urine and two nicotine-related biomarkers (nicotine and cotinine) in saliva (93.2% correct classification). We used their discriminant function [22] to distinguish objectively between smokers and non-smokers. Due to financial restrictions, saliva samples were only used for classification when no urine sample was available.

Sample size

The power calculation was based on data in *Thorax* [4], and the *British Medical Journal* [5], as well as data from the Cochrane Reviews [7,16] and MIS studies [12–14]. We hypothesized an 11% cessation rate for NRT alone, and 21% for the combination of NRT and C-MIS. The hypothesis was tested one-sided, i.e. we did not expect the C-MIS to increase the number of smoking patients. If $\alpha = 0.05$, 188 patients per treatment group (total of 376) are needed to obtain a statistical power of 80%. Analyses were based on the intention-to-treat principle. Patients with incomplete follow-up were considered to be persisting smokers.

Statistics

Point prevalence of abstinence at 12 months was calculated by means of a logistic regression. Accordingly, we calculated absolute risk reductions (ARR), number needed to treat (NNT), odds ratios (OR) and associated confidence intervals (CI). Possible interaction effects of treatment condition and baseline characteristics (education, type of disease, nicotine dependence, clinic attendance and number of cigarettes/day) on abstinence were tested with logistic regression analyses. To investigate whether the C-MIS affected the number of cigarettes/day, a repeated-measures analysis of variance was used.

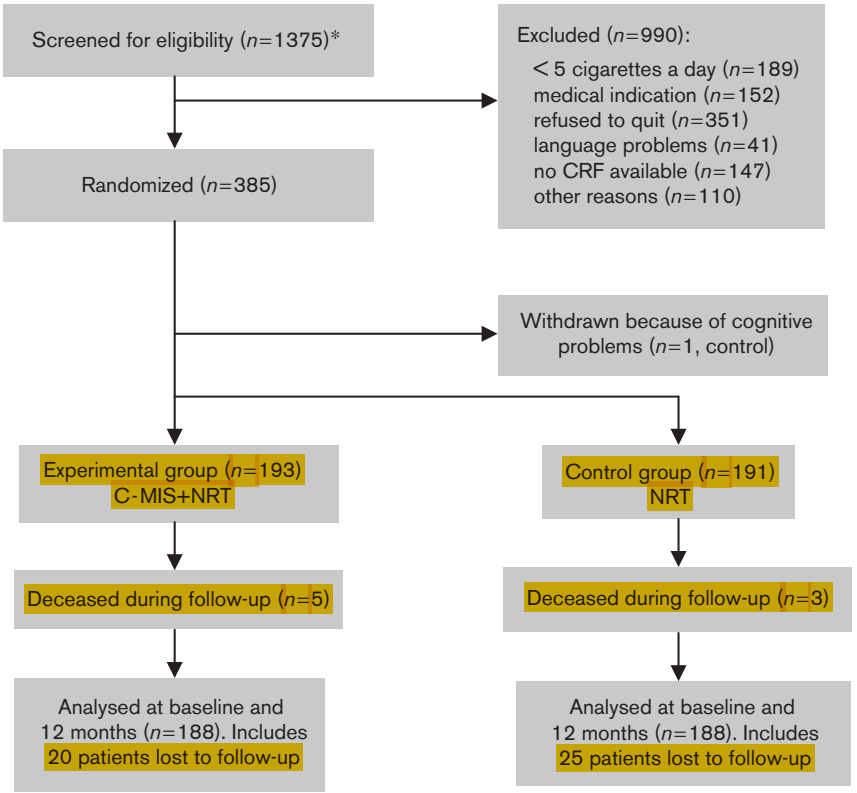
Results

Response and sample

Of the approximately 1375 smoking atherosclerotic patients who were screened for eligibility from September 2001 until May 2004, 385 (28%) met the inclusion criteria and agreed to participate in this study (Fig. 1). After randomization, one patient was withdrawn from the study because of cognitive problems, and eight patients died during follow-up, leaving 376 patients for analyses.

The trial ended in May 2005 when we received the 12-months' follow-up questionnaire of the last included patient. Questionnaire response rates were 99% ($n = 372/376$) at baseline, and 70% ($n = 263/376$) at 12 months. Response rates in both treatment groups were comparable. Those who did not respond to the 12-month questionnaire were reached through telephone interview (18%; $n = 68/376$), or were lost to follow-up (12%; $n = 45/376$). No differences in baseline characteristics were

Fig. 1



Flow chart of participants through the trial. *The number of screened eligible patients ($n=1375$) is an extrapolation from percentages for the total cohort of patients ($n=2725$). Of this total cohort, 28% (119/421) of the smoking atherosclerotic patients agreed to participate. In this trial, we included 385 smoking atherosclerotic patients. Therefore, approximately 1375 patients ($385/28 \times 100 = 1375$) were screened for their eligibility [24]. CRF, case report form; NRT, nicotine replacement therapy; C-MIS, minimal intervention strategy adapted for cardiology inpatients.

found between those who did ($n = 331/376$) and those who did not respond at 12 months (lost to follow-up, $n = 45/376$), except for a small effect of marital status: more unmarried patients were lost to follow-up (chi-squared (1 df) = 2.84, $P = 0.06$). We collected 265 urine and 237 saliva samples (71 and 63%, respectively). A total of 269 samples were used for analysis (265 urine and four saliva). Table 1 presents patients' baseline characteristics.

Data on the number of patients who had used NRT and whether they used the patches as prescribed, have been reported elsewhere [23].

Abstinence rates according to self-report measures

At follow-up, 21% ($n = 35/168$) of the experimental group and 17% ($n = 27/163$) of the control group reported abstinence. Including patients lost to follow-up as smokers, these rates are 19% ($n = 35/188$) and 14% ($n = 27/188$), respectively: 81% smokers in the experimental and 86% in the control group yields an ARR of 0.05 (95% CI = −0.02; 0.12). Point prevalence abstinence rates were not significantly different between treatment groups (Table 2). Experimental patients were more, although not significantly, likely to quit smoking than control patients (OR = 1.44, 95% CI = 0.83; 2.50; one-sided Fisher's exact test, $P = 0.17$).

No interaction effects of treatment and patients' characteristics on abstinence were found. The number of cigarettes/day decreased significantly at 12 months: from 21 to 15 cigarettes in the experimental group, and from 21 to 14 in the control group [$F(1,194) = 90.2$, $P < 0.001$]. The effect did not differ between the two treatment groups [$F(1,194) = 1$, $P = 0.32$].

Abstinence rates according to urine or saliva samples

According to biochemical markers, abstinence rates were 28% ($n = 38/137$) in the experimental and 24% ($n = 32/132$) in the control group (ARR = 0.04, 95% CI = −0.06; 0.14) (Table 2). Table 3 presents a comparison of self-reported and biochemical validated abstinence. The classification model for the biochemical markers [22] matched self-reported abstinence and biochemical validated abstinence in 87% (71% + 16%) of the 269 cases.

When taking self-reported smoking status as a reference, 3% (9/269) were false positive, whereas 10% (26/269) were false negative. One of these misclassified (false-negative) patients reported using NRT at 12 months' follow-up.

To gain insight into the unexpectedly high percentage of misclassified patients, we decided to analyse saliva (when available) from discrepant cases. Of the 35 misclassified patients, 25 saliva samples were available. Abstinence obtained from the saliva test [22] corresponded in 12% of the cases (3/25) with the urine test, and with self-reported abstinence in 88% of the cases (19/25). Only three false positive cases remained. In case of reclassification of the 25 misclassified patients on the basis of their saliva, 7% (20/269) misclassifications remained (Table 3).

Table 1 Baseline characteristics of patients assigned to C-MIS + NRT or NRT

	Experimental	Control	
$n=372$	$n=186$ (%)	$n=186$ (%)	P*
Age (mean, SD)	59 (12)	58 (12)	0.76**
Gender			0.42
Male	118 (63)	115 (62)	
Female	68 (37)	71(38)	
Education†			0.14
Low	107 (57)	125 (67)	
Middle	57 (31)	42 (23)	
High	22 (12)	19 (10)	
Marital status			0.42
Married	105 (57)	108 (58)	
Unmarried	81 (43)	78 (42)	
Ethnicity			0.50
Dutch	167 (90)	166 (89)	
Other	19 (10)	20 (11)	
Type of disease			0.38
PAD	115 (62)	111 (60)	
CAD	71 (38)	75 (40)	
Outpatient attendance			0.46
Routine follow-up visit	55 (30)	58 (31)	
First visit	131 (70)	128 (69)	
Nicotine dependency			0.30
Yes	79 (43)	73 (39)	
No	107 (57)	113 (61)	
No. cigarettes/day (mean, SD)	21 (10)	21 (10)	0.53**

NRT, nicotine replacement therapy; C-MIS, minimal intervention strategy adapted for cardiology inpatients. PAD, peripheral arterial disease; CAD, coronary artery disease. *P value was obtained from chi-squared test unless indicated otherwise. **P value was obtained from t-test. †Low, vocational training; middle, advanced vocational training; high, high vocational or university training. Note: $n=372$ instead of 376 because four patients did not respond to the baseline questionnaire.

Discussion

We could not prove that the nurse-led C-MIS offered to cardiovascular outpatients was effective. Based on the literature, we assumed an 11% cessation rate for NRT alone and 21% for the combination of C-MIS and NRT, but found 14 and 19% – a non-significant difference. However, according to the wide confidence intervals around the point estimates, we can not definitely exclude that the C-MIS might have an effect.

In a previous C-MIS study [13], a significant difference between the C-MIS and usual care with respect to point prevalence abstinence was only found when patients lost to follow-up were excluded from the analyses (OR = 1.63; 95% CI = 1.13; 2.34). A second C-MIS study [14] reported no difference in quitting rates after 12 months among cardiac outpatients (22% in experimental versus 20% in the control group, $P = 0.95$). Comparison with these studies is hindered by differences in applied methodologies. Both studies compared the C-MIS with a usual care group that did not include pharmaceutical support such as NRT, and no biochemical validation was used. Also, one study [13] involved cardiac inpatients instead of outpatients, and did not randomize the complete sample.

Biochemically validated abstinence was higher than self-reported, but still did not differ between intervention groups. The discriminant function we used after urine analysis was previously shown to have high discriminating power (93.2% correct classification). However, the number of discrepancies in our study was substantial (13%). This resulted in higher estimates of overall abstinence rates. Different explanations for these observations can be given. First, although the method of determining three biomarkers in urine, or two in saliva simultaneously seems to be better than applying only one single biomarker, the model still may not be sensitive enough. Second, patients in the false-negative group (10%) (reported to be smokers, but classified as quitters) did not collect morning urine, but afternoon or evening urine instead. In this case, biomarker concentrations can be considerably lower, potentially classifying smokers as quitters. Third, patients in the false-positive group (3%) (reported to be quitters, but classified as smokers) did not report their true smoking status. It is not likely that

Table 2 Abstinence rates at 12 months

	Quitters (n; %)					
Abstinence	Experimental group	Control group	ARR (95% CI)	NNT (95% CI)	OR (95% CI)	P*
Self-report	35/168 (21)	27/163 (17)	0.04 (−0.04; 0.12)	25 (8–infinity)	1.30 (0.75; 2.25)	0.20
Self-report + lost to follow-up	35/188 (19)	27/188 (14)	0.05 (−0.02; 0.12)	20 (9–infinity)	1.44 (0.83; 2.50)	0.17
Urine†	38/137 (28)	32/132 (24)	0.04 (−0.06; 0.14)	25 (7–infinity)	1.23 (0.71; 2.13)	0.30

ARR, absolute risk reduction; NNT, number needed to treat; OR, odds ratio; CI, confidence interval. *Probability associated with a one-sided Fisher's exact test. †Including four saliva samples due to absence of urine.

Table 3 A comparison of self-report and biochemical validated abstinence ($n=269$)

		Self-report	
		Smoker	Quitter
Urine[†]	Smoker	190 (71%)	9 (3%)
	Quitter	26 (10%)	44 (16%)
Urine[†] + 25 saliva samples	Smoker	193 (72%)	6 (2%)
	Quitter	14 (5%)	56 (21%)

[†]Including four saliva samples.

patients who quit smoking report that they are still smoking (false-negative group). This idea is supported by a study of Caraballo *et al.* [25]. They found that variation in smoking patterns, including the extent of nicotine dosing, may explain most of the false negatives, whereas deception regarding smoking status may explain most of the false positives.

A few possible explanations for the lack of effectiveness of the C-MIS can be given. First, patients may not have received the treatment they were allocated to, or nurse specialists did not deliver the C-MIS correctly. However, evaluation of the C-MIS [26] showed that patients in the experimental group were offered all required components of the C-MIS, whereas patients in the control group were not [$F(1;58) = 392.27$, $P < 0.001$]. Also, no differences in counselling quality between nurse specialists [$F(2;57) = 0.07$, $P = 0.93$] and in C-MIS delivery over time were found [$F(4;55) = 0.31$, $P = 0.87$], which demonstrates that the first as well as the last treated patients were exposed to the same intervention [26].

Second, since the C-MIS attempts to change patients' cognition in order to achieve smoking cessation, the extent to which cognitions are indeed affected is of interest and was subject of our previous study [27]. In that study [27] we found no main effects of the C-MIS on the development of cognitions, but we did find that higher-educated patients, those who received the C-MIS, had higher intentions to quit smoking and higher self-efficacy levels than patients who did not receive the C-MIS. We therefore assume that the low or average level of education of our population (88%) might contribute to the ineffectiveness of C-MIS. Our assumption is supported by a study of Wray *et al.* [28] who examined the extent to which education influences the decision to quit in middle-aged adults following a myocardial infarction. They found that each additional year of educational attainment beyond high school raised the probability of quitting. Escobedo *et al.* [29] postulated that higher-educated persons are more aware of the detrimental effects of smoking on health and that smoking has become less socially accepted. They also argued that in order to better reach individuals of lower socio-economic status with the quit-smoking message, it is necessary to understand why these individuals continue to smoke.

Finally, our population consists of relatively old patients (mean age = 58 (SD = 12)). Even if research has shown that older smokers are interested in cessation [30], the majority of them hold the belief that quitting smoking will provide few additional health benefits.

Some limitations of our investigation need to be addressed. First, the absence of an additional control group in which only usual care was offered. Consequently we were unable to compare abstinence rates of patients who only received usual care to rates of those who additionally received NRT. Second, our biochemical validation of self-reported abstinence was limited because we did not collect urine and/or saliva from the entire study population. Unfortunately, only 72% of the patients responded to the request to provide urine and saliva at 12 months' follow-up.

In conclusion, we set out to investigate the effectiveness of a short, relatively easy to implement intervention. With such an intervention we reach as many patients as possible in the setting of a cardiovascular outpatient department. We found this intervention to be feasible. However, it did not lead to a significant increase in cessation rates. Taking these disappointing results and other C-MIS studies into account, we conclude that C-MIS is not effective in supporting cardiovascular patients in their efforts to quit smoking.

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