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Original Paper

Maintaining Abstinence from Cigarette Smoking: Effectiveness of Group Counselling and Factors Predicting Outcome

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The aim of the study was to assess the effectiveness of worksite group counselling interventions designed to prevent smoking relapse after abstinence has been achieved following 3 months therapy using group support and/or transdermal nicotine replacement therapy. After 3 months, abstinent subjects were randomly allocated either to a counselling group led by professional psychologists (PG), to a counselling group led by former smokers (SG) or to no intervention group (NG). The 3 and 12 months abstinence were defined, respectively, as a sustained smoking cessation during the last month, and the last 9 months. Complete abstinence was confirmed by expired carbon monoxide and by urine cotinine concentrations. The abstinence rate at 3 months was 35.1%. After 12 months abstinence rates were not statistically different in the PG, the SG and the NG (respectively 57.8, 53.4 and 49.6% of those randomised). In multivariate analyses, baseline variables associated with 12 months abstinence were non-smoking family, gender (male), lower daily intake of nicotine and better psychological adjustment. Mean weight gain at 3 months in abstinent versus relapsed subjects was, respectively, 4.1 and 2.4 kg. Baseline variables associated with weight gain at 3 months were higher Fagerström score, gender (male) and professional status (blue collar worker). Group support after abstinence has been achieved did not significantly improve the abstinence. This study shows the difficulty of preventing smoking relapse with monthly group counselling. The results indicate the need to investigate further specific programmes focusing on factors such as gender, family, nicotine dependence, psychological and weight concerns/issues which may precipitate relapse. © **1999 Elsevier Science Ltd. All rights reserved.**

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INTRODUCTION

THE EFFECTIVENESS of worksite group counselling interventions designed to prevent smoking relapse after abstinence using group support and transdermal nicotine replacement therapy has been poorly studied. Transdermal nicotine replacement treatment is now established as an aid to stop smoking [1–4]. Success rates are approximately twice as high with transdermal nicotine than with placebo.

Two studies [5, 6] have been performed with transdermal nicotine (Nicotinell TTS) in Switzerland. The first [5], which did not involve special psychological backup, was carried out by general practitioners over a 3 month period in 199 well-motivated nicotine dependent subjects without a history of cardiovascular disease. The rate of tobacco abstinence was significantly higher in the group receiving nicotine TTS (41, 36 and 36% after 1, 2 and 3 months respectively) than in the

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placebo control group (19.4, 20.4, and 22.5%, respectively). The second study [6], which was also without special psychological backup, lasted 9 weeks and comprised 112 well motivated, nicotine dependent smokers under the age of 30 years. After 3, 6 and 9 weeks, the rate of tobacco abstinence was 52, 43 and 39%, respectively, in the group given nicotine TTS and 29, 25 and 20%, respectively, in the placebo group. However, 9% of the subjects suffered distressing but reversible local erythema.

Factors associated with better outcome have not been adequately studied in large populations. Factors associated with smoking relapse are [7–12]: heavy smoking, shorter interval between wakening and the first cigarette, young age and low education level. Among factors associated with a better outcome, consolidation programmes designed to prevent smoking relapse, although often recognised as useful, have not been assessed for their effectiveness. Some studies have also assessed baseline factors associated with abstinence achieved with transdermal nicotine treatment [1, 13].

The primary aim of this study was to assess the effectiveness of worksite group support designed to prevent smoking relapse. More precisely the aim of this study was to assess the relative effectiveness of two support programmes designed to prevent smoking relapse after maximal short term abstinence has been achieved using an intensive group support programme with transdermal nicotine substitution. The relative effectiveness of three follow-up regimes:

1. No formal follow-up (NG);
2. Follow-up by professionals (PG); or
3. Follow-up by ex-smokers (SG) were assessed.

The secondary aim of the study was to assess psychosocial factors which may be associated with a better outcome and weight gain after 3 and 12 months.

MATERIALS AND METHODS

Study design

This was an open label randomised study. 993 smokers wishing to stop smoking were recruited by contacting companies by mail and inviting them to participate in the programme. For companies interested in the programme, an internal mailing to employees assessing their interest in participating in this study was scheduled.

The study was planned to have a 12 month follow-up from the time of inclusion for each participant, and included two phases (Figure 1): first phase included a preparatory visit with screening, an initiation period of 1 month and a detoxification period of 2 months including weaning. Consenting smokers with a Fagerström score of 5 or more i.e. indicating probable nicotine dependence and, therefore, eligibility for nicotine replacement therapy [17], who fulfilled the inclusion criteria and had none of the exclusion criteria began the programme and received Nicotine TTS. Other smokers with a Fagerström score of four or less could start the programme but were not treated with Nicotine TTS. Those abstaining from smoking at the end of the Nicotine TTS treatment phase (month 3) were randomised into one of the three follow-up groups. The second phase was a 9 months consolidation period, using the different follow-up regimes according to randomisation (relapse prevention programmes: a no intervention group (NG), a former smokers intervention group (SG) and a professional counselling intervention group (PG)). Randomisation was carried out according to the company so that all participants from one company were assigned the same intervention group.

Transdermal administration of nicotine (TTS) is available in three active forms (30, 20 and 10 cm^2), each steadily delivering an average of 0.7 mg nicotine per cm^2 per 24 h (system A: TTS 30 cm^2 containing 52.5 mg nicotine delivering 21 mg/24 h; system B: TTS 20 cm^2 containing 35 mg nicotine delivering 14 mg/24 h; system C: TTS 10 cm^2 containing 17.5 mg nicotine delivering 7 mg/24 h). The initial dose of nicotine TTS was determined from the number of cigarettes smoked daily. Those smoking 20 cigarettes per day or more were started on System A, and those smoking less than 20 cigarettes per day were started on System B. Active treatment with Nicotine TTS continued for 3 months.

During the first month of the study, the dose could be changed if necessary from B to A if the subject was still smoking or had withdrawal symptoms, and from A to B if

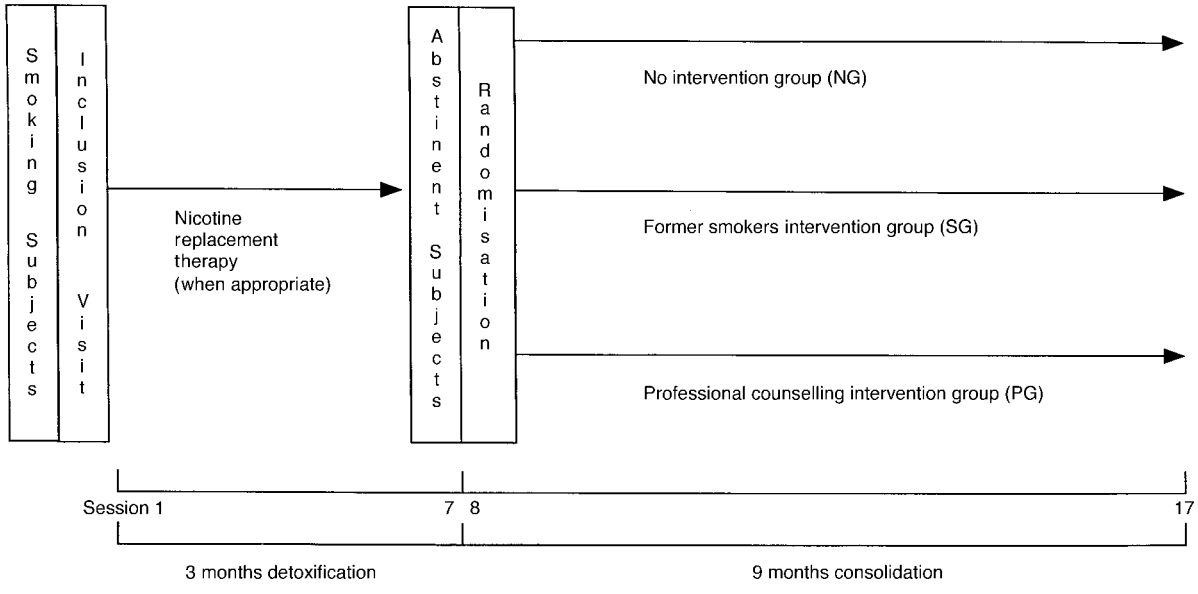

Figure 1. Flow diagram illustrating the study design.

side-effects were observed. The reasons for a change of dose had to be recorded in the case report form. After 1 month, a weaning phase was scheduled for subjects using A with a downward titration from A to B to C reducing the TTS size each 4 weeks; and those using B reducing to C using C for 1 month. Nicotine substitution was thus stopped 3 months after initiation.

Subjects

To be included in the first phase of the study, subjects had to be cigarette smokers aged 18 to 65 years, wishing to stop smoking, with a significant smoking behaviour. Furthermore they had to be sufficiently motivated to participate seriously in the entire study. To be included in the second phase of the study, subjects had to have stopped smoking completely during the last month.

Exclusion criteria were: cigar or pipe smokers (other than occasional use), hypersensitivity to any adhesive cutaneous application, current skin diseases which may contra-indicate use of nicotine TTS (psoriasis or active eczema), difficulty in attending the planned visit schedule, pregnant women or women who were not using a recognised method of birth control during the trial, history of severe somatic problems (renal, hepatic, neurological, cardiac or chronic pulmonary disease, or active cancer), history of severe neuropsychiatric problems (chronic alcoholism, or abuse of drugs) in the previous year, unacceptable concomitant medication, clinically significantly abnormal laboratory values.

Concomitant medications

Any concomitant medication administered regularly or for a limited period had to be recorded. Medication affecting tobacco withdrawal was not allowed: e.g. nicotine (chewing gum, cigar or pipe smoking), clonidine or any substances with centrally stimulating alpha activity. Subjects taking psychotropic drugs were only included if these drugs could safely be discontinued before the start of the study. However, if the subject chronically used low-dose benzodiazepines (more than 1 year) the dose was kept constant and carefully monitored throughout the trial.

Assessment

Inclusion visit. Subjects were screened for inclusion in the study. General medical history, physical examination (including blood pressure, pulse rate and weight) and interview were performed to ensure that the relevant exclusion criteria were not present. Subjects were also asked to complete the Fagerström Tolerance Questionnaire [17], two subscales of the Reasons for Smoking Questionnaire of Horn–Russell [18], the Demaria and Grimaldi Motives for Quitting Scale [19], the Brief Symptom Inventory (BSI) [15] of Hopkins and Life Events Scale [16].

Introduction to problems related to smoking, methods to stop smoking were made, and a convenient date for session one was scheduled. Subjects were asked not to change intentionally their smoking habit until session one. Informed written consent was obtained, emphasising the length of the study and the required commitment.

Sessions 1–7. Sessions 1–7 were scheduled every 2 weeks. Subjects were clearly instructed to stop smoking completely. The use of diaries was discussed; subjects were asked to bring this completed to subsequent sessions, as well as all used and unused nicotine TTS. At each visit, weight, blood pressure and pulse rate were recorded. The size of nicotine TTS was adjusted as described above. Concomitant therapy, medical problems, compliance and tolerability were recorded at each visit. The self-reported smoking habit, caffeine and alcohol intake of the subject, from their diary and/or direct questioning, were also recorded at each visit. At each visit breath carbon monoxide was assessed. Subjects who had reverted to smoking were asked for the main reason which could explain relapse.

Session 7 *(randomisation visit)*. The same data as during the previous sessions were recorded. Subjects were again asked to complete the Brief Symptom Inventory and the Life Event Scale (assessing life events having occurred during the last 3 months). The smoking status of the subjects was assessed. Abstinent subjects were randomised into the follow-up consolidation phase of the study.

Randomisation was performed by using a provided list of random number (hidden by a label) to assign the follow-up regime. The label hid a printed randomisation list. Treatment was either follow-up with professional support, or with support by trained volunteers of ex-smokers, or with no follow-up support.

Sessions 8–17. Sessions 8–17 were scheduled every month. Supportive therapy according to randomisation group was organised. Weight, blood pressure and pulse rate, concomitant therapy and medical problems were recorded at each visit. At session 17, a laboratory screen was repeated and subjects were again asked to complete the BSI and the Life Event Scale (assessing life events having occurred during the last 9 months).

Assessment of efficacy. The objective for each individual subject was complete abstinence from smoking. Abstainers by self-report were requested to attend for validation if possible. When no data were available, it was assumed that the subjects continued to smoke. The definition of abstinence at 3 months was: the subject should report no use at all of tobacco in the previous 4 weeks (self-report), and should have a confirmatory breath carbon monoxide of 10 ppm or less. The definition of abstinence at 12 months was: the subject should report no use of tobacco at all since randomisation (i.e. for 9 months), and should have a confirmatory breath carbon monoxide of 10 ppm or less. In case of missing expired carbon monoxide assessment, subjects were considered as non-abstinent.

Breath carbon monoxide (CO) was measured using the Bedfont EC50 Micro smokerlyser portable carbon monoxide monitor (available from Bedfont Technical Instruments, Kent, U.K.). The manufacturers guidelines on calibration and use were followed. A second success rate calculation was obtained by adding to the definition above of abstinence that an abstinent subject should have a urinary cotinine level of 317 ng/ml or less. The assessment of the urine cotinine level was thus added to the conditions above beside the measurement of carbon monoxide for the definition of abstinence. In case of missing urinary cotinine determinations, subjects were considered as non-abstinent in the success rate calculation. Urine cotinine levels were analysed by a radioimmunoassay procedure [14].

Other assessments. Psychological adjustment was assessed by the Hopkins Brief Symptom Inventory (BSI) developed to reflect global adjustment as well as nine specific patterns or concepts within that adjustment [15]. The BSI is a 53 item self-report symptom inventory. Each item of the BSI is rated

on a five-point scale. The BSI is scored and interpreted in terms of three global indices of distress. Global measures are labelled the global severity index (GSI), the positive symptoms distress index (PDSI), and the positive symptoms total (PST). The GSI combines information on the numbers of symptoms and the intensity of perceived distress. The summed distress score divided by 53 provides the GSI score. The PST is simply a count of the number of symptoms the subject reports experiencing to any degree. Counting the number of positive symptom responses gives the response style, i.e. whether the subject is 'augmenting' or 'attenuating' symptomatic distress in the style in which he or she reports the disorder. The PSDI score is obtained by dividing the grand total by the PST. Lower scores thus mean fewer symptoms.

Life events before stopping smoking was assessed by a Life Events Scale of 47 different items [16]. Nicotine dependence was assessed by the modified Fagerström Tolerance Questionnaire [17]. Motives for smoking were assessed by two selected subscales of the Reasons for Smoking Scale measuring automatic and addictive smoking [18]. Motives for stopping smoking were assessed by a self-report questionnaire, the Demaria and Grimaldi scale [19]. Number of previous attempts to stop, longest period without smoking, and daily intake of nicotine (number of cigarettes smoked per day $\times$ content of nicotine per cigarette) were also recorded.

Assessment of tolerability. Concomitant illnesses and adverse experiences were recorded routinely at each session. Serious adverse experiences (death, hospitalisation, prolongation of hospitalisation, persistence of significant disability or incapacity, life-threatening conditions, congenital anomaly, cancer, etc.) were reported immediately. All adverse reactions were assessed for their severity (mild, moderate, severe) and their relationship with nicotine TTS (not related, unlikely, possible, probable and highly probable). Local reaction of the skin were specifically assessed by the modified Draize rating scale from sessions 2–7. If severe skin reactions occurred the subjects were referred to a dermatologist and followed up until the reaction cleared.

Laboratory assessment. Laboratory tests were performed at the inclusion visit, at 3 and 12 months. These laboratory tests were designed to detect major renal or hepatic disease.

Other assessments. Compliance with nicotine TTS was assessed by a count of all used and unused patches, before dispensing the supply to be used until the next session.

Premature discontinuation. For all subjects who were withdrawn from the trial, or declined to continue their participation, a final evaluation was performed if possible. The results of this evaluation, and the primary reasons for withdrawing from the study were recorded.

Reasons for removing a subject from the trial were: intolerable adverse experiences, serious intercurrent illness, lack of compliance with the protocol, lost to follow-up, unsatisfactory response (e.g. complete failure to reduce smoking after 4–6 weeks of active therapy). A subject was not considered to have discontinued the trial prematurely if only up to two visits between sessions 1 and 7 were missed provided that nicotine TTS was continued, and/or up to three visits were missed after session 8. Smoking status and reason for discontinuing for those subjects discontinuing prematurely or not attending the final visit was sought at 3 and 12 months.

Data analysis. The primary analysis of the study was a comparison of the abstinence rates at 12 months in the three groups, in subjects previously treated with nicotine TTS and abstinent at 3 months using an intent to treat analysis. Any subjects discontinuing their treatment prematurely were included in the final (12 month) analysis as if they had continued that treatment. Smoking status was determined by attendance or by telephone contact when this could be confirmed by breath CO measurement. With a risk of 5% and β risk of 20%, using the arc tan approximation, it has been calculated that 95 patients per group would be required to detect a difference in sustained abstinence rates of 65 to 45% using two-tailed Binomial tests. The likely study numbers estimated as follows: 1000 smokers recruited; 600 smokers treated with nicotine TTS; 300 abstinent at 3 months; 100 randomised to each consolidation phase follow-up group.

Subsidiary descriptive analyses were performed to assess baseline medical, sociodemographic and psychosocial data which could be associated with abstinence at 3 and 12 months.

Abstinence was a potential dependent variable for a multivariate analysis. The following baseline independent variables were considered as potential predictors of abstinence: daily intake of nicotine, age at onset of smoking, time between wakening and first cigarette (minutes), duration of last smoking cessation period (months), time since last attempt to stop smoking (months), number of previous attempts to stop smoking. Abstinence was assessed using forward stepwise logistic regression. Forward stepwise multiple linear regression was used to analyse weight change. All statistical tests were two-tailed, at the 5% level of significance. The statistical analysis was performed with the SAS programme.

Subject consent and ethical considerations. This trial was conducted in accordance with the Declaration of Helsinki, the study protocol having been approved by the ethical committee of Institut Jules Bordet, Cancer Centre of the University of Brussels. Subjects included in this trial were informed of its design and purpose, and gave written consent.

Support programme

A psychosocial support programme was designed to provide smokers with group support during the pre- and post-randomisation phase. A manual included the detailed content of the programme. All the information and the education part of the programme were provided to group participants by videotaped lectures developed by the authors.

Pre-randomisation phase. Each session of the pre-randomisation programme included professional support such as facilitation of emotion expressions and ventilation of emotions of participants (30 min per session), group discussion (90 min per session) and information and education about nicotine substitution (5–15 min per session). More precisely some sessions included information about relaxation (20 min during the third session), education about relaxation (15 min during the third session), relaxation exercises (30 min at the third session), education about stress control (30 min at the fourth session), information about role playing technique (15 min at the sixth session) and role playing exercises about a common smoking relapse risk situation (15 min at the sixth session).

Post-randomisation phase (sessions 8–17*).* The following were included in the Professional Counselling Intervention Group (PG): group discussion (90 min per session), role

Table 1. *Abstinence at* 3 *and* 12 *months*

	Abstinence based on	
	Subject report and expired carbon monoxide	Subject report, expired carbon monoxide and cotinine
	n (%)	*n* (%)
Abstinence at 3 months ($n = 993$)	349 (35.1)	190 (19.1)
Abstinence at 12 months		
Professionals (PG) ($n = 135$)	78 (57.8)	59 (43.7)
Ex-smokers (SG) ($n = 88$)	47 (53.4)	33 (37.5)
No follow-up (NG) ($n = 121$)	60 (49.6)	43 (35.5)
Total ($n = 344$)	185 (53.8)	135 (39.2)

playing exercises about common smoking relapse situations (at sessions 9, 11, 13, 15, 16), information and education session about relapse and possible compensatory behaviour (at session 10), information and education about peer pressure (at session 14); for the Former Smokers Intervention Group (SG), the programme included group discussion led by former smokers; and in the No Intervention Group (NG), no intervention was planned.

RESULTS

Participation

50 companies were contacted in order to invite them to participate in the study. 32 (64%) companies agreed to participate. Approximately 22 000 subjects were assessed by mailed questionnaire for their motivation to stop smoking, of which 1800 subjects attended sessions to receive information about the smoking cessation programme and the aim of the study. Following these sessions, 1200 subjects (65%) were interested in stopping smoking. All were invited to an individual interview scheduled to assess their eligibility, and to complete baseline questionnaires. 993 (4.5%) subjects were eligible and included in the study (inclusion visit).

Nicotine replacement therapy and compliance

145 subjects did not attend session one. 751 subjects with a Fagerström score of five or more attending session one received nicotine TTS substitution. The abstinence rate of the 97 subjects with a Fagerström score of four or less attending session one and thus not receiving nicotine substitution treatment was 49% compared with 40% for the subjects who received nicotine substitution treatment. Compliance to the use of the pharmacological treatment could be considered good during the first 8 weeks starting after session one. Thereafter compliance decreased considerably. During the initiation and detoxification phases, 2 weeks were foreseen between visits, implying that 14 patches had to be used. The median use of patches was 14 at sessions two, three, four and five. It then declined for session six to the median use of 10.5 patches and for session seven to the median use of only one patch. This reduction in patch use can probably be explained by discouragement of subjects not achieving abstinence.

During the period of patch use from session 1–7. 949 side-effects were reported in a total of 498 subjects. 263 side-effects were possibly, probably or highly probably related to the trial treatment. The most frequent reported and related side-effects in decreasing order of importance were: sleep disorder, insomnia, constipation, rash, agitation and headache. It is not known if these adverse events are due to the use of nicotine TTS since the same symptoms are also reported as withdrawal symptoms. Skin rash was clearly related to the use of the patch. However, local tolerability was good since only 5% of the subjects reported erythema at the start of the treatment and only 2% at the end of treatment with nicotine TTS. There was a small decrease in pulse rate in randomised groups, in contrast to the non randomised group where the pulse rate increased. Some fluctuation in blood pressure was observed but no great nor significant differences were observed during patch treatment nor during the consolidation phase. The lack of a significant effect on these cardiovascular parameters indicates that nicotine TTS was well tolerated. The laboratory results also indicated a good safety and tolerability profile of nicotine TTS (data not shown).

Table 2. *Sociodemographic data*

	3 months		12 months	
	Abstinence $n = 349$ (%)	Relapse $n = 644$ (%)	Abstinence $n = 185$ (%)	Relapse $n = 808$ (%)
Age, mean ± S.D. (years)	39 ± 8.5	39 ± 8.9	39 ± 7.9	39 ± 8.9
Gender*				
Male ($n = 542$)	217 (40.0)	325 (60.0)	121 (22.3)	421 (77.7)
Female ($n = 451$)	132 (29.3)	319 (70.7)	64 (14.2)	387 (85.8)
Weight (kg), mean ± S.D.	71 ± 13.1	69.5 ± 14.1	71 ± 12.7	69.7 ± 14
Height (cm), mean ± S.D.†	172.2 ± 9.2	170.6 ± 9.0	173.2 ± 9.0	170.7 ± 9.1
BMI (kg/m^2), mean ± S.D.	23.9 ± 3.7	23.7 ± 3.7	23.8 ± 3.6	23.7 ± 3.7
Educational status‡				
Primary ($n = 65$)	20 (30.8)	45 (69.2)	9 (13.8)	56 (86.2)
More than primary ($n = 915$)	324 (35.4)	591 (64.6)	173 (18.9)	742 (81.1)
Professional status‡				
Blue collar ($n = 108$)	37 (34.3)	71 (65.7)	13 (12.0)	95 (88.0)
White collar ($n = 879$)	310 (35.3)	569 (64.7)	171 (19.5)	708 (80.5)

*$P = 0.001$ (chi-square test) at 3 and 12 months. †$P = 0.008$ and 0.001 (t-test), respectively, at 3 and 12 months. ‡Missing data for some subjects. S.D., standard deviation; BMI, body mass index.

Table 3. Psychosocial data

		3 months		12 months	
		Abstinence $n=349$	Relapse $n=644$	Abstinence $n=185$	Relapse $n=808$
Fagerström tolerance					
Questionaire score*	Mean ± S.D.	6.3 ± 1.7	6.8 ± 1.9	6.3 ± 1.6	6.7 ± 1.9
Demaria and Grimaldi scale†	Mean ± S.D.	15.3 ± 2.0	15.0 ± 2.0	15.4 ± 2.0	15.1 ± 2.0
Horn–Russell scale	Mean ± S.D.	15 ± 4.3	15.4 ± 4.5	14.8 ± 4.3	15.4 ± 4.5
Brief symptom inventory (BSI)					
GSI‡	Mean ± S.D.	0.54 ± 0.44	0.64 ± 0.51	0.51 ± 0.41	0.62 ± 0.51
PST§	Mean ± S.D.	17.9 ± 11.2	19.8 ± 11.9	17.2 ± 11.1	19.5 ± 11.8
PSDI‖	Mean ± S.D.	1.45 ± 0.47	1.54 ± 0.52	1.43 ± 0.48	1.53 ± 0.51
Life event scale¶	Mean ± S.D.	135.3 ± 119.5	165.4 ± 132.7	132.7 ± 116.8	159.9 ± 131.1

*$P<0.001$ and 0.002 (t-test), respectively, at 3 and 12 months. †$P=0.024$ and 0.028 (t-test), respectively, at 3 and 12 months. ‡$P=0.002$ and 0.001 (t-test), respectively, at 3 and 12 months. §$P=0.015$ and 0.016 (t-test), respectively, at 3 and 12 months. ‖$P=0.005$ and 0.014 (t-test), respectively, at 3 and 12 months. ¶$P<0.001$ and 0.010 (t-test), respectively, at 3 and 12 months. S.D., standard deviation; GSI, global severity index; PST, positive symptoms total; PSDI, positive symptom distress index.

Abstinence at 3 and 12 months

The abstinence rate based on statement of subject, expired carbon monoxide assessment and urinary cotinine determination (less than 317 ng/ml) are shown in Table 1. If data on expired carbon monoxide assessment or urinary cotinine were missing, subjects were considered as non-abstinent.

349 subjects out of 993 subjects were abstinent after 3 months (35.1%). 5 subjects decided not to continue the programme. After 3 months, 344 subjects, who have been completely abstinent during the last month, were randomised into one of the three follow-up programmes: 135 in the PG, 88 in the SG and 121 in the NG. Randomisation by site (company) explains the differences in repartition among each of the follow-up programmes. 185 subjects out of the 344 (53.8%) subjects randomised after 3 months were abstinent after 1 year (18.6% out of the 993 subjects included in the study). The number of abstinent subjects and the rate of abstinence after 1 year in the different randomised groups is shown in Table 1. The differences in abstinence rates in the three arms were not statistically significant (Chi-square test).

Outcome Predictors

Several baseline variables of abstinent and non-abstinent subjects were compared (Table 2). The comparison of baseline sociodemographic data indicated that the abstinence rate was higher in men than women ($P=0.001$; Chi-square test).

The comparison of baseline psychosocial data (Table 3) showed that abstinent subjects had slightly lower Fagerström Tolerance Questionnaire scores ($P<0.001$ and $P=0.002$ respectively, at 3 and 12 months; student t-test), higher

Table 4. Smoking habit data

		3 months		12 months	
		Abstinence $n=349$ (%)	Relapse $n=644$ (%)	Abstinence $n=185$ (%)	Relapse $n=808$ (%)
Age at onset of smoking (years)	Mean ± S.D.	17 ± 4	17 ± 4	17 ± 3	17 ± 4
Number of previous attempts to stop smoking	Mean ± S.D.	2.5 ± 2.8	2.4 ± 2.7	2.4 ± 2.3	2.5 ± 2.8
Time since last attempt to stop smoking (month)	Mean ± S.D.	80 ± 105	80 ± 103	84 ± 100	79 ± 105
Duration of last smoking cessation period (month)	Mean ± S.D.	8 ± 21	6 ± 16	9 ± 23	6 ± 17
Time between wakening and 1st cigarette (min)	Mean ± S.D.	47 ± 55	44 ± 95	48 ± 57	45 ± 88
Daily intake of nicotine (mg*)	Mean ± S.D.	23 ± 13	27 ± 15	22 ± 12	26 ± 14
Daily intake of alcohol (>1 glass/day)					
No ($n=599$)		217 (36.2)	382 (63.8)	106‡ (17.7)	493‡ (82.3)
Yes ($n=394$)		132 (33.5)	262 (66.5)	79 (20.1)	315 (79.9)
Daily intake of coffee (>1 cup/day)					
No ($n=52$)		17 (32.7)	35 (67.3)	12 (23.1)	40 (76.9)
Yes ($n=941$)		332 (35.3)	609 (64.7)	173 (18.4)	768 (81.6)
Smoking in the family†‡					
No ($n=448$)		172 (38.4)	276 (61.6)	105 (23.4)	343 (76.6)
Yes ($n=537$)		176 (32.8)	361 (67.2)	80 (14.9)	457 (85.1)
Smoking in the work environment‡					
No ($n=221$)		68 (30.8)	153 (69.2)	39 (17.6)	182 (82.4)
Yes ($n=763$)		280 (36.7)	483 (63.3)	146 (19.1)	617 (80.9)

*$P<0.001$ (t-test) at 3 and 12 months. †$P=0.077$ and $P=0.001$ (chi-square test), respectively, at 3 and 12 months. ‡Missing data for some subjects. S.D., standard deviation.

Table 5. *Multivariate analysis of abstinence at* 12 *months*

	Subject report and expired carbon monoxide (all subjects)		
	Coefficient	(*P*)	OR (95% CI)
Intercept	− 0.395		
Smoking in the family	0.528	(*P* = 0.003)	1.695 (1.200–2.395)
Gender	0.562	(*P* = 0.002)	1.754 (1.225–2.512)
Daily intake of nicotine	0.023	(*P* = 0.001)	1.023 (1.009–1.037)
BSI GSI score	0.008	(*P* = 0.024)	1.008 (1.001–1.016)

OR, odds ratio. CI, confidence interval; BSI, brief symptom inventory; GSI, global severity index.

Table 6. *Univariate comparison of changes at* 3 *and* 12 *months*

		Baseline—month 3 changes		Month 3—month 12 changes	
		Abstinence *n* = 349	Relapse *n* = 644	Abstinence *n* = 185	Relapse *n* = 159
Brief symptom inventory (BSI)					
GSI score*	Mean ± S.D.	0.16 ± 0.39	0.10 ± 0.43	0.05 ± 0.37	0.01 ± 0.38
PST†	Mean ± S.D.	4.3 ± 8.5	2.1 ± 9.8	0.2 ± 9.4	0.3 ± 9.8
PSDI	Mean ± S.D.	0.17 ± 0.56	0.14 ± 0.55	0.09 ± 0.53	0.07 ± 0.60
Weight change (kg)‡	Mean ± S.D.	4.1 ± 3.0	2.4 ± 2.9	2 ± 3.6	− 1 ± 4
Alcohol intake (%)§‖					
Increase *n* = 55		31 (56.4)	24 (43.6)	*n* = 26 17 (65.4)	9 (34.6)
No change *n* = 718		290 (40.4)	428 (59.6)	*n* = 259 150 (57.9)	109 (42.1)
Decrease *n* = 86		28 (32.6)	58 (67.4)	*n* = 36 18 (50.0)	18 (50.0)
Coffee intake (%)‖					
Increase *n* = 14		5 (35.7)	9 (64.3)	*n* = 13 6 (46.2)	7 (53.8)
No change *n* = 821		331 (40.3)	490 (59.7)	*n* = 301 173 (57.5)	128 (42.5)
Decrease *n* = 24		13 (54.2)	11 (45.8)	*n* = 2 1 (50.0)	1 (50.0)

*$P = 0.03$ and 0.375 (*t*-test), respectively, at 3 and 12 months. †$P < 0.001$ and $= 0.973$ (*t*-test), respectively, at 3 and 12 months. ‡$P < 0.001$ (*t*-test) at 3 and 12 months. §$P = 0.019$ and 0.471 (Chi-square test), respectively, at 3 and 12 months. ‖Data missing for some subjects. GSI, global severity index; PST, positive symptoms total; PSDI, positive symptom distress index; S.D., standard deviation.

Table 7. *Univariate analysis of weight change at* 3 *months (abstinent subjects)*

Continuous variables	Pearson correlation		Categorical variables	Mean ± S.D.	Min; max	*n*	*t*-test
Age	− 0.030	*P* = 0.575	Gender				*P* = 0.019
Weight	0.019	*P* = 0.730	Males	4.39 ± 3.05	− 7.6; 12.3	217	
Height	0.121	*P* = 0.024	Females	3.61 ± 2.78	− 6.0; 15.0	129	
BMI	− 0.064	*P* = 0.233	Education status				*P* = 0.253
Fagerström score	0.167	*P* = 0.002	Elementary	4.03 ± 2.90	− 7.6; 15.0	321	
Demaria and Grimaldi score	0.043	*P* = 0.425	Others	5.16 ± 4.21	− 6.0; 11.0	20	
Horn–Russell score	0.051	*P* = 0.349	Professional status				*P* = 0.014
BSI GSI	0.003	*P* = 0.951	Blue collar	5.24 ± 2.68	− 1.0; 11.7	37	
BSI PST	− 0.010	*P* = 0.852	White collar	3.96 ± 2.99	− 7.6; 15.0	307	
BSI PDSI	− 0.014	*P* = 0.798	Use of caffeine				*P* = 0.810
Life event scale	− 0.010	*P* = 0.858	No	3.93 ± 2.51	− 1.0; 8.3	17	
Age at onset of smoking	− 0.066	*P* = 0.219	Yes	4.11 ± 3.00	− 7.6; 15.0	329	
Time since last attempt	0.016	*P* = 0.766	Use of alcohol				*P* = 0.981
Duration cessation	− 0.027	*P* = 0.616	No	4.09 ± 3.04	− 7.6; 15.0	214	
Number of previous attempts	0.002	*P* = 0.965	Yes	4.10 ± 2.86	− 2.5; 11.0	132	
Time to first cigarette	− 0.118	*P* = 0.029	Smoking in the family				*P* = 0.489
Daily intake of nicotine	0.109	*P* = 0.049	No	3.99 ± 2.77	− 7.6; 12.3	172	
VAS scales			Yes	4.21 ± 3.17	− 6.0; 15.0	173	
Need to smoke	0.029	*P* = 0.590	Smoking in the work environment				*P* = 0.630
Need of gesture	0.030	*P* = 0.575	No	4.25 ± 2.60	− 2.0; 10.0	68	
Appetite	− 0.109	*P* = 0.044	Yes	4.06 ± 3.06	− 7.6; 15.0	277	

BSI, brief severity index; GSI, global severity index; PST, positive symptoms total; PDSI, positive symptom distress index; BMI, body mass index; S.D., standard deviation.

Table 8. Analysis of weight change at 3 months. Global analysis with univariately significant variables (abstinent subjects)

Variable	Coefficient	Significance
Intercept	4.901	
Fagerström score	0.346	$P<0.001$
Gender	−0.784	$P=0.018$
Professional status	−1.039	$P=0.040$

Demaria and Grimaldi scale scores ($P=0.024$ and 0.028 respectively, at 3 and 12 months; student *t*-test), lower BSI GSI scores ($P=0.002$ and 0.001, respectively, at 3 and 12 months; student *t*-test), lower BSI PST scores ($P=0.015$ and 0.016, respectively, at 3 and 12 months; student *t*-test), lower BSI PSDI ($P=0.005$ and 0.014, respectively, at 3 and 12 months; student *t*-test) scores, and lower Life Event Scale scores ($P<0.001$ and 0.01, respectively, at 3 and 12 months; student *t*-test).

A comparison of smoking habits (Table 4) showed that abstinent subjects had a lower mean daily intake of nicotine (23 versus 27 mg at 3 months and 22 versus 26 mg at 12 months; $P<0.001$; student *t*-test), and that the rate of abstinence at 12 months was 14.9% among patients with a smoker in the family, whilst it was 23.4% if there was no smoker in the family ($P=0.001$, chi-square test).

For the analysis of abstinence at 12 months, the definition was based on a statement by the subject and expired carbon monoxide. A subject was classified as not abstinent if any variable used in the definition was missing (which includes a subject withdrawing). The analysis of abstinence at 12 months was based upon data from all subjects ($n=993$). A global multivariate analysis of abstinence at 12 months was performed (stepwise logistic regression) based upon the variables recorded at the onset of the study that were univariately significant at the 5% level of significance (Table 5). The following variables (see Tables 2–4 for univariate results) were used in the analysis: daily intake of nicotine, Fagerström total score, Demaria and Grimaldi scale total score, BSI GSI score, BSI PST score, BSI PSDI score, Life Event Scale total score, smoking in the family, and gender. A positive coefficient for the variable 'smoking in the family' indicates more abstinent subjects in non-smoking families, whilst the positive coefficients for the variables 'daily intake of nicotine' and 'BSI GSI score' indicate lower average values for these variables for the abstinent subjects. The positive coefficient for 'gender' indicates more abstinence among male subjects.

Mean weight (± standard deviation, S.D.) gain in abstinent versus relapsed subjects was respectively 4.1 kg (S.D. 3.0) and 2.4 kg (S.D. 2.9) at 3 months (Table 6). A mean weight gain of 2 kg (S.D. 3.6) was observed in abstinent randomised subjects and a mean loss of weight of 1 kg (S.D. 4.0) in relapsers. Abstinent men gained more weight than abstinent women (4.4 versus 3.6 kg).

The analysis of weight change at 3 months is based upon the data of the 346 abstinent subjects for whom weight was recorded at 3 months (abstinence based on statement of subject and expired carbon monoxide). Table 7 shows the results of the univariate analysis of weight change. This analysis included all variables recorded at the onset of the study. For continuous variables, the Pearson correlation coefficients are given and for categorical variables, descriptive statistics are given.

For the multivariate analysis of weight change at 3 months, the change in weight between baseline 1 and 3 months was analysed by means of stepwise multiple linear regression. The analysis was performed on the basis of all of the variables included in Table 7 which were significantly related to weight change, at the 5% level of significance. From the multiple linear regression analysis, the variables: 'Fagerström score', 'gender' and 'professional status' were significant predictors of the change in weight.

Table 8 describes the results of the regression analysis. The model obtained has an r^2 equal to 0.079. This indicates that

Table 9. Univariate analysis of weight change at 12 months (abstinent subjects)

Continuous variables	Pearson correlation		Categorical variables	Mean ± S.D.	Min; max	*n*	*t*-test
Age	0.033	$P=0.666$	Gender				$P=0.665$
Weight	−0.141	$P=0.060$	Males	6.14 ± 4.05	−8.5; 19.0	118	
Height	0.084	$P=0.266$	Females	5.85 ± 4.42	−6.0; 19.1	61	
BMI	−0.221	$P=0.003$	Education status				$P=0.535$
Fagerström score	0.230	$P=0.002$	Elementary	6.08 ± 4.25	−8.5; 19.1	167	
Demaria and Grimaldi score	−0.009	$P=0.902$	Others	5.19 ± 3.36	−1.0; 10.0	9	
Horn–Russell score	0.256	$P=0.001$	Professional status				$P=0.706$
BSI GSI	0.048	$P=0.524$	Blue collar	6.45 ± 3.27	1.7; 13.2	13	
BSI PST	0.018	$P=0.814$	White collar	6.00 ± 4.25	−8.5; 19.1	165	
BSI PDSI	0.071	$P=0.348$	Use of caffeine				$P=0.843$
Life event scale	0.018	$P=0.814$	No	5.81 ± 3.71	−1.0; 10.0	12	
Age at onset smoking	0.040	$P=0.594$	Yes	6.06 ± 4.21	−8.5; 19.1	167	
Time since last attempt	−0.049	$P=0.516$	Use of alcohol				$P=0.473$
Duration cessation	0.020	$P=0.788$	No	6.23 ± 4.51	−6.0; 19.1	103	
Number of previous attempts	−0.005	$P=0.946$	Yes	5.78 ± 3.68	−8.5; 14.0	76	
Time to first cigarette	−0.128	$P=0.087$	Smoking in the family				$P=0.651$
Daily intake of nicotine	0.204	$P=0.008$	No	5.91 ± 4.10	−8.5; 19.0	101	
VAS scales			Yes	6.20 ± 4.28	−6.0; 19.1	78	
Need to smoke	0.205	$P=0.006$	Smoking in the work environment				$P=0.901$
Need of gesture	−0.50	$P=0.511$	No	5.96 ± 4.10	−0.8; 14.0	35	
Appetite	−0.106	$P=0.160$	Yes	6.06 ± 4.20	−8.5; 19.1	144	

BMI, body mass index; BSI, brief severity index; GSI, global severity index; PST, positive symptoms total; PDSI, positive symptom distress index.

Table 10. *Analysis of weight change at* 12 *months. Global analysis with univariately significant variables (abstinent subjects)*

Variable	Coefficient	Significance
Intercept	4.703	
Need to smoke	0.038	$P = 0.047$
Fagerström score	0.468	$P = 0.035$
BMI	− 0.190	$P = 0.042$

the inclusion of the three variables yielded a significant but not a strong prediction of weight change. The positive sign for the variable 'Fagerström score' indicates greater weight increase for larger values for the Fagerström scores. The negative signs for the variables 'gender' and 'professional status' indicate greater weight increase for male subjects and more weight increase for blue collar workers.

The analysis of weight change at 12 months was based upon data of 179 abstinent subjects for whom weight was recorded at 12 months. Table 9 shows the results of the univariate analysis of weight change. This analysis considers all variables recorded at the onset of the study.

For the multivariate analysis, the evolution of weight between baseline 1 and 12 months was analysed by means of stepwise multiple linear regression. The analysis was performed on the basis of all of the variables included in Table 9 which were significantly related to weight change, at the 5% level of significance. From the multiple linear regression analysis, the variables 'VAS evaluation of need to smoke', 'Fagerström score' and 'body mass index' (BMI) were significant predictors of the change in weight. Table 10 describes the results of the regression analysis (coefficients of the regression equation and their *P*-values). The model obtained has an r^2 equal to 0.116. This indicates that the inclusion of the three variables yielded a significant but not a strong prediction of weight change. The positive sign for the variables 'need to smoke' and 'Fagerström score' indicates greater weight increase for larger values for these variables, whilst the negative sign for 'BMI' indicates greater weight increase for subjects with a smaller BMI.

DISCUSSION

There is some interest from companies willing to organise worksite smoking cessation programmes [20]. Programmes as described in this study are feasible. However, the rate of participation in initial information sessions was low (8%), although we consider the number of participants ($n = 1200$) sufficient to continue to promote programmes using regularly scheduled group sessions and nicotine replacement therapy. The number of white collar workers attending the programme was significantly higher than the number of blue collar workers (approximately 89 versus 11%). The lower rate of blue collar participation may be explained by more strict work rotation, by a reluctance to join group sessions with white collar workers or, by the cognitive behavioural content of the programme. This indicates the need to design specific programmes for blue collar workers.

Because all participants from one company were assigned to the same intervention group, an interaction between company and treatment cannot be excluded. A randomisation procedure by group would have been theoretically preferable because smoking policy of companies, the way in which participants are recruited and the work environment of a company may influence smoking cessation programmes' success rate. However, in practice, randomisation by group of individuals from the same company could have been perceived by some participants as neglect if they were not receiving the treatment given to other participants. Therefore, a randomisation procedure by company was more preferable than by group; moreover the number of companies participating in the study allowed this type of randomisation.

The comparison of abstinence rates based on a subject's report and expired carbon monoxide versus a subject's report, expired carbon monoxide and cotinine assay showed that success rates may be significantly over-reported in worksite smoking cessation programmes.

The abstinence rates based on a report by the participant and expired carbon monoxide at 3 and 12 months were comparable to those reported in other studies using nicotine replacement therapy [5, 6]. Looking at the results of the three different follow-up regimes, no statistically significant differences were observed. Because all participants were informed that they would be invited to an assessment session at 12 months, it is possible that all subjects even those in the no follow-up regime, knowing the aim of the study, were challenged to remain abstinent. The slight but not statistically significant advantage observed for the professional intervention arm could be explained by the professional's commitment to the programme—organising the ex-smokers follow-up proved difficult due to numerous practical difficulties.

The question of the feasibility and effectiveness of more intensified worksite smoking cessation programmes should be investigated in future studies. The appropriate type (cognitive, behavioural, etc.) and timing (first weeks, first months, etc.) of counselling and psychological support intensification should also be investigated. The similar success rate found in this study in the three follow-up regimes may indicate the need to design and to test other prevention relapse programmes or 'rescue' programmes for relapsers.

Men, those with a lower daily nicotine intake and those with no smokers in their family were more likely to stop and remain abstinent at 12 months. The gender difference found here is consistent with the results of other studies [1, 22, 23] showing that women in particular have difficulty stopping smoking. Women's concern for weight gain [24–28] should be considered as a possible explanation for this gender difference. A high nicotine dependence, low motivation and a low level of psychological adjustment (being confronted with many stressful events) made stopping smoking more difficult despite the intention and the attempt to stop. The influence of psychological adjustment on abstinence rates in a working population could be even more pronounced because psychological distress (as assessed by the BSI) may be under-reported at the worksite for social reasons. Although those with psychiatric disorders were excluded from this study, it should be noted that a link between major depression, for example, and smoking cessation has been described [21].

A significant weight gain was observed in this study while using nicotine replacement therapy. Abstinent as well as relapsed subjects gained a significant amount of weight by 3 months, but by 12 months only the abstinent continued to gain weight, whilst relapsed subjects lost some of the weight gained. It is interesting to notice that, although subjects relapsed, they lost only a part of the amount of weight gained. At 3 months, nicotine dependence, professional status and gender were linked to the amount of weight gained (a higher

weight gain for males, blue collar, and highly nicotine dependent subjects). At 12 months a greater weight gain was observed in subjects with a greater need to smoke, a higher nicotine dependence and a smaller BMI. Nicotine is known to influence metabolism and appetite [29–33]. Moreover abstinent women gained less weight than men at 3 months (3.6 versus 4.4 kg). This can be explained either by the fact that women who gained weight relapsed and/or by the fact that men, and maybe blue collar workers in particular, are less concerned by weight gain [24–28]. As weight gain may be an important barrier to stopping smoking [27, 34–37] the relationship between weight gain and smoking cessation should be studied carefully in order to improve not only the success rate of smoking cessation programmes but also quality of life of those who stop smoking.

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