One year effectiveness of an individualised smoking cessation intervention at the workplace: a randomised controlled trial

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Accepted 12 September
2002
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Aims: To assess the effectiveness of a smoking cessation intervention at the workplace. The intervention was adapted to smokers' tobacco dependence, and included minimal structured counselling at the first visit (5–8 minutes), nicotine patches for three months, and three sessions of counselling for reinforcement of abstinence (2–3 minutes) over a three month period.

Methods: Open randomised trial with two groups: the intervention group, and the control group which was subjected to standard clinical practice, consisting of short (30 seconds to one minute) sporadic sessions of unstructured medical antismoking advice. The trial was carried out among 217 smokers of both sexes, aged 20–63 years, motivated to quit smoking and without contraindications for nicotine patches, who were employees at a public transport company and at two worksites of an electric company. The main outcome measure was self reported tobacco abstinence confirmed by carbon monoxide in expired air ⩽10 ppm. Analysis was performed according to intention-to-treat.

Results: The rate of continuous abstinence at 12 months was 20.2% for the intervention versus 8.7% for the control group (OR: 2.58; 95% CI: 1.13 to 5.90; p = 0.025). In subgroup analyses, effectiveness of the intervention did not vary substantially with age, tobacco dependence, number of cigarettes smoked per day, number of years of tobacco consumption, degree of desire to quit smoking, time spent with smokers, subjective health, and presence of tobacco related symptoms. Weight gain at 12 months was similar for both groups (1.69 kg in the intervention *v* 2.01 kg in the control group; p = 0.21).

Conclusions: A simple and easily generalisable intervention at the workplace is effective to achieve long term smoking cessation. In a setting similar to ours, nine subjects would have to be treated for three months for one to achieve continuous abstinence for 12 months.

Smoking is the leading individual cause of disease, disability, and death in Spain.[1] To control the smoking epidemic, the youth should be prevented from starting smoking. Yet, the benefits of such a measure would only be fully appreciated in the long term. In the short term, greater benefits will be obtained from inducing current smokers to quit.

There are effective ways of quitting available to both the general public[2] and the individual smoker.[3 4] Nevertheless, the effectiveness of smoking cessation interventions vary with the context of the individual smoker, in particular with the prevalence of smoking and the application of smoking policies.[2 5 6] Not only has Spain one of the highest prevalences of tobacco use in Europe—though this has levelled off in recent years[7]—but also enforcement of antismoking policies is rather lenient.[8] Moreover, evaluative investigation of smoking cessation interventions is relatively infrequent in Spain and suffers from certain limitations; for example, assessments that have only been preliminary,[9 10] studies that have lacked a control group,[11 12] or interventions that have either not been randomly assigned[13–21] or not included nicotine patches.[9–16 18 19 22–29] As a result, there is no experimental evidence of the efficacy of nicotine patches in smoking cessation in Spain.

Finally, the workplace is a favourable setting for the implementation of antismoking interventions. In Spain, most workers undergo a medical check up at least once a year, a factor that facilitates intervention and patient follow up. Furthermore, such an approach brings broad sectors of the population within reach, including subjects of both sexes across a wide age range, who have a good state of health and a great variation in tobacco dependence, similar to most smokers in the general population. This distinguishes such subjects from many of those demanding medical attention in primary or specialised healthcare settings, who suffer more frequently from smoking related health problems and display a high degree of nicotine dependence. Nonetheless, in Europe very little experimental evidence is available on the usefulness of medical smoking cessation interventions at the workplace.[30–32]

This paper therefore assessed the effectiveness of a smoking cessation intervention, whose intensity is graduated according to the nicotine dependence of the individual smoker, and was implemented at three worksites in Spain.

METHODS

Participants

This open, randomised clinical trial was conducted at three worksites located in Bilbao, a city in the north of Spain. The first of these worksites was the public transport company, *Empresa de Transportes Colectivos de Bilbao, S.A.*, whose workers were mostly bus drivers in the Bilbao metropolitan area. The remaining two were the Gardoqui and Larrasquitu worksites belonging to an electric utility company, *Iberdrola*, whose workers were mostly engaged in clerical work.

The participants were enrolled during the annual medical check up. Here, the study objectives and procedures were explained and, after verifying that these had been understood by the participants, their written consent was obtained. Subjects were deemed eligible for the study if they were aged 18–63 years, had smoked cigarettes during the preceding month, had a concentration of carbon monoxide in expired air

of >10 ppm at the date of the annual medical check up, and were motivated to quit smoking. Motivation was defined as a score of 4 or over in the test of Richmond and colleagues.[33] Exclusion criteria were as follows: known hypersensitivity to nicotine or nicotine replacement therapy, as well as chronic dermatitis that would hinder transdermal nicotine administration; serious cardiovascular disease, such as myocardial infarction in the preceding four weeks, severe angina, serious arrhythmias, heart failure, cerebrovascular accident, or a transient cerebral ischaemic episode; depression, major behaviour disorder, or treatment with psychotropic drugs; peptic ulcer; insulin dependent diabetes mellitus; hyperthyroidism; pregnancy or breast feeding; nicotine replacement therapy in the preceding three months; consumption of alcoholic beverages or other illegal drugs to the point where, in the researcher's judgement, they might interfere with the subject's ability to comply with the intervention (that is, administer nicotine patches or attend prearranged appointments with the physician); and scant probability, in the researcher's judgement, of the subject's complying with the protocol or being followed up over the 12 month study period.

The study complied with Helsinki Declaration guidelines and Spanish statutory provisions governing clinical research on humans,[34] and was formally approved by the Clinical Research Ethics Committee of the "Basurto" Hospital in Bilbao.

Experimental design and intervention

The trial was made up of two groups: intervention and control. In the latter, the occupational health units at the three study centres applied their standard clinical practice, consisting of short (30 seconds to one minute) sporadic sessions of unstructured medical antismoking advice. Sporadic advice means that counselling to the control group was done usually, but not always and not in a prespecified time schedule, during the annual medical check up and in contacts related with the follow up management of health problems of the worker.

This was a randomised trial in which the randomisation list remained concealed until the time when participants were assigned to their respective intervention or control groups. Once informed consent had been obtained and the participant enrolled, he/she was initially assigned a study entry number. A sealed opaque envelope bearing the participant's number on the outside was then opened by the physician to reveal to which specific trial group the participant was to be assigned. The randomisation list was simple, computer generated, and independent for each study centre. The trial was open, meaning that both the researcher and the patient knew to which intervention group the participant had finally been assigned.

The intervention was conducted by an occupational health physician and included a short session (5–8 minutes) of structured individualised counselling based on material drawn up by the USA National Cancer Institute.[35] The counselling session concluded with the handing over of a brochure on smoking cessation.[36] A further three contacts with smokers were made, at two days, 15 days, and three months respectively of the date designated for quitting ("quit date"). These contacts involved short counselling sessions (2–3 minutes) to reinforce the decision to stop smoking, train the participant in coping with difficult abstinence related situations, and consider any modifications to the intervention guideline.

Pharmacological therapy consisted of nicotine patches (Nicotinell TTS, Novartis Consumer Health). Intensity varied according to participants' nicotine dependence as measured by the Fagerström test.[37] Three grades of intervention were established:

- Grade I, when Fagerström test score was 4 or less. Intervention consisted exclusively of individualised medical counselling.

- Grade II, when Fagerström test score was 5–7. Intervention included individualised medical counselling and nicotine

patches of 14 mg/day for eight weeks, followed by 7 mg/day for four weeks.

- Grade III, when Fagerström test score was more than 7. Intervention consisted of individualised medical counselling and nicotine patches of 21 mg/day for four weeks, followed by 14 mg/day for four weeks, and a final phase of 7 mg/day for four weeks.

If, at 15 days of initiating the intervention, grade I or II participants had not successfully achieved smoking cessation, presented with notable withdrawal symptoms, or regarded the likelihood of maintaining abstinence as highly remote, intervention was "upgraded" to the next immediately higher level.

Measurement of variables

At baseline, all participants underwent a physical examination, routine laboratory tests, and an electrocardiogram. This, along with a review of their occupational clinical history, allowed for identification of exclusion criteria. At baseline, all participants likewise completed the Fagerström test.[37] This is a widely used measure of nicotine dependence, with scores from 0 to 10; a score of 5 or higher indicates greater levels of dependence. For the first two weeks, the participants kept a daily record of tobacco withdrawal symptoms, based on the Hughes and Hatsukami questionnaire.[38] Information on these symptoms was summarised in a composite score, calculated as the average of the following eight symptoms: craving for cigarettes; restlessness; increased appetite; depressed mood; anxiety; difficulty concentrating; irritability, frustration, or anger; and difficulty sleeping. Similarly, during the treatment with nicotine patches, the participants also kept a daily record of possible adverse events accompanying the therapy. On the occasion of the visits at 2 and 15 days and at 3 and 12 months, the patient's weight and tobacco consumption were measured. Self reported abstinence from smoking (not even one puff) in the week preceding each visit was assessed, and confirmed by determination of carbon monoxide in expired air ≤10 ppm at the date of the visit (micro-Smokerlyzer, Bedfont Technical Instruments).

Statistical analysis

The main outcome variable was continuous tobacco abstinence at 12 months, defined as abstinence at this and all preceding visits (including also the week before each visit). Abstinence was assessed as from the prespecified quit date for each subject. Secondary outcomes were: change in tobacco withdrawal symptoms during the first two weeks; and change in weight over 12 months.

We estimated that a total of 110 subjects would be needed in each study group to have a power of 80% to detect a 10% difference in the smoking cessation rate at 12 months, with an alpha level of 0.05. Calculations were based on previous experience at the study centres indicating annual cessation rates around 5%, and data in the literature on the effectiveness of interventions similar to ours applied in primary healthcare settings[39 40] and at the worksite.[16]

Data analysis strategy consisted of two phases. Firstly, the efficacy of randomisation was examined. To this end, the baseline variables in the two groups of the study were compared, using the Student's t and χ^2 tests to analyse continuous and categorical variables respectively. Secondly, we compared abstinence rates between the intervention and control groups by intention-to-treat analysis. For the purpose of analyses, a smoker was defined as anyone without confirmation of abstinence by expired carbon monoxide. The effect of the intervention was summarised with odds ratios (OR) of continuous abstinence, obtained from unconditional logistic regression.[41] The dependent variable was the rate of continuous abstinence, and the independent variables were the intervention and the worksite.

Table 1 Baseline characteristics of subjects by intervention group

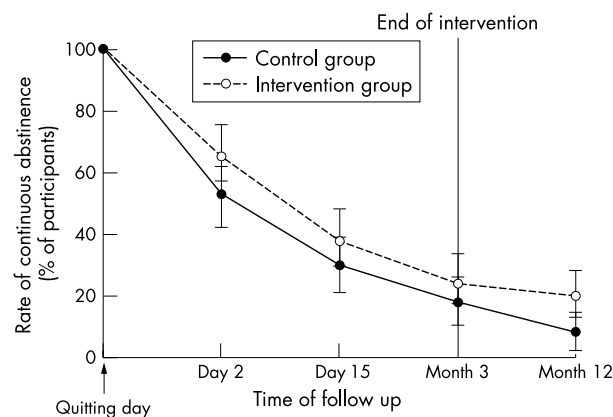|	Control (n=103)	Intervention (n=115)
Sociodemographic data		
Age (years)	43.3 (8.3)	43.1 (8.2)
Sex (% males)	85.4	87.0
Civil status (% married)	81.6	84.2
Occupation (% manual workers)	54.4	54.8
Educational level		
No formal education (%)	24.3	23.5
Primary (%)	17.5	16.5
Secondary (%)	33.0	39.1
University (%)	25.2	20.9
Body mass index (kg/m^2)	27.2 (4.5)	26.4 (3.8)
Tobacco consumption		
Cigarettes per day	27.6 (11.7)	25.0 (10.6)
Expired carbon monoxide (ppm)	37.0 (19.0)	37.0 (17.5)
Reasons for quitting		
If quitting were easy, would be highly likely to quit (%)	97.1	100
Has strong or very strong desire to quit (%)	78.6	76.5
Prospects of this attempt to quit being successful regarded as sure or very probable (%)	57.3	52.2
Quitting regarded as easy or very easy (%)	8.7	13.0
Health reasons or under doctor's orders to quit (%)	86.4	92.2
Smoking history and attempts to quit		
Age at start of smoking regularly (years)	16.6 (4.0)	16.5 (3.3)
Duration of tobacco consumption (years)	26.6 (8.6)	26.9 (8.6)
In the past 5 years has seriously contemplated quitting (%)	78.6	84.3
In the past 5 years has tried to quit smoking:		
Never (%)	35.3	41.7
Once (%)	21.6	32.2
Two or three times (%)	28.4	19.1
Four or more times (%)	14.7	7.0
Maximum time has successfully refrained from smoking at any one attempt to quit		
Less than 2 weeks (%)	49.2	42.6
2 weeks to 6 months (%)	35.4	35.3
More than 6 months (%)	15.4	22.1
Social setting		
Spends major part of the time with other smokers (%)	52.4	53.9
Spouse/companion is a smoker (%)	37.9	42.6
Has first degree family relatives who are smokers (%)	88.3	86.1
During the working day spends major part of the time with smokers (%)	21.4	19.1
During leisure hours spends major part of the time with smokers (%)	43.7	47.0
Assessment of health		
Optimal subjective health in the past year (%)	73.8	69.6
Presence of tobacco related symptoms (%)	65.0	60.0
Dependence		
Fagerström test score	5.1 (2.8)	4.5 (2.4)
Fagerström score ≤4 (grade I intervention) (%)	39.8	42.6
Fagerström score 5–7 (grade II intervention) (%)	36.9	45.2
Fagerström score ≥8 (grade III intervention) (%)	23.3	12.2
Study sites		
Empresa de Transportes Colectivos de Bilbao, S.A. (%)	54.4	59.1
Iberdrola-Gardoqui (%)	28.2	26.1
Iberdrola-Larrasquitu (%)	17.5	14.8

*Mean (SD).

Changes in tobacco withdrawal symptoms were analysed in: (1) all study participants; and (2) participants with a Fagerström test score of 5 or higher. Repeated measures analysis of variance was used to compare the mean change from baseline in composite score for withdrawal symptoms between the intervention and control groups. In these models, the dependent variable was the change in the score, and the independent variables were the intervention group, baseline value of the score, and worksite. Changes in weight at 12 months were analysed in: (1) all study participants; and (2) participants with continuous abstinence from smoking for the full 12 months. For this purpose, a linear regression model was used, in which the dependent variable was the change in weight at 12 months with respect to the baseline weight, and the independent variables were the intervention group, baseline weight, and worksite.

Statistical significance was established as $p < 0.05$ (two sided). Statistical analyses were performed with the SAS package.[42]

RESULTS
Flow of participants and baseline variables
Recruitment and follow up of subjects took place from March 1999 to April 2001. Of the 220 workers that fulfilled the inclusion criteria, one was excluded for presenting with insulin dependent diabetes mellitus, and another for being on nicotine replacement therapy. Of the 218 randomised subjects, 115 were assigned to the intervention and 103 to the control group. Of the 115 participants assigned to the intervention group, all received the assigned intervention. Two subjects initially assigned to grade I intervention were upgraded to grade II, so that ultimately, 49 received grade I, 52 grade II, and 14 grade III interventions. Of the subjects undergoing grade II and III interventions, five and two respectively interrupted nicotine patch treatment because they resumed smoking. However, except for one subject who died of lung cancer, all subjects in both treatment groups, including those who interrupted nicotine patch medication, furnished information for the follow up assessments. Hence, we finally analysed the

Figure 1 Rates of continuous tobacco abstinence, by intervention group.

results of 114 subjects in the intervention and 103 in the control group.

Table 1 shows the baseline characteristics of the study subjects by intervention group. No significant differences (p > 0.05) between the two groups were observed.

Results of the intervention

Throughout the follow up, the rate of continuous abstinence was higher in the intervention than in the control group (fig 1). At 12 months, this rate was 20.2% in the intervention and 8.7% in the control group (OR: 2.58; 95% CI: 1.13 to 5.90; p = 0.025). Effectiveness of intervention remained, even after adjustment for the Fagerström test score with a logistic model (OR: 2.59; 95% CI: 1.12 to 6.0; p = 0.026).

In subgroup analyses, there was a tendency for the effectiveness of the intervention to increase with grade (I, II, and III), though statistical significance was not attained in any of the subgroups (fig 2). Intervention reached statistical significance (p < 0.05) in those subjects who: smoked over 20

cigarettes per day; had smoked for over 25 years; had the strongest desire to quit smoking; and did not spend the major part of their time with smokers. Nevertheless, effectiveness of the intervention did not vary substantially, either with the above variables or with age, subjective health, or presence of smoking related symptoms, because odds ratios for all subgroups were greater than 1 and their confidence intervals overlapped (fig 2). Subgroup analyses were previously specified in the study protocol.

With regard to tobacco withdrawal symptoms during the first two weeks post-cessation, the symptom composite score increased in all subjects during the first days post-cessation, and decreased thereafter. However, there were fewer symptoms in the intervention than in the control group, though the difference failed to reach statistical significance (p = 0.51). While differences between the groups were somewhat greater when analysis was restricted to subjects with a Fagerström test score of 5 or higher (subjects to whom nicotine patches were administered when they belonged to the intervention group), these nevertheless failed to attain significance (p = 0.62).

The subjects in the intervention group gained 1.69 kg, and those in the control group, 2.01 kg over the 12 month follow up period (p = 0.21). Weight gain was greater in both groups among those who managed to refrain from smoking. Among subjects with continuous abstinence over 12 months, weight gain was 3.9 kg in the intervention group versus 3.5 kg in the control group (p = 0.32).

No serious adverse events were observed among the subjects treated with nicotine patches.

DISCUSSION

Our results show that structured medical counselling, accompanied by nicotine patches, results in higher rates of continuous tobacco abstinence than does sporadic unstructured advice at the worksite in Spain. In concrete terms, our findings suggest that, among workers similar to those employed at the workplaces in this study, it would be necessary to treat only
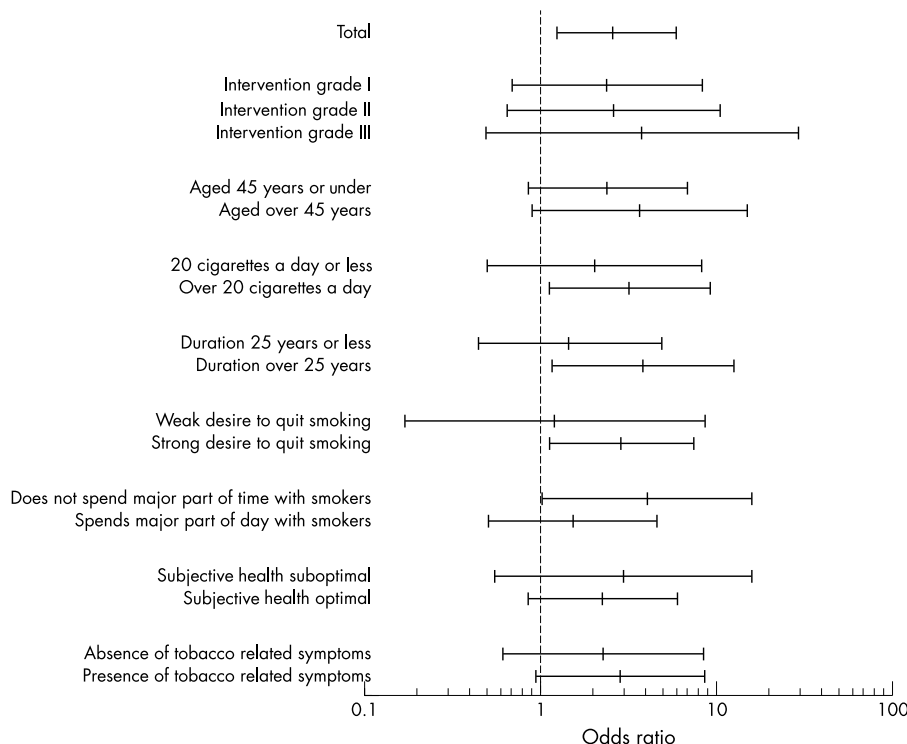
Figure 2 Odds ratios and 95% confidence intervals of continuous tobacco abstinence at 12 months in intervention and control subjects, by subgroup.

nine subjects for three months in order for one to achieve continuous abstinence for 12 months (1/0.202–0.087).[43] Accordingly, this intervention has a clinical effectiveness comparable, or even superior, to that of other widely implemented interventions targeting other morbidity-mortality risk factors.[43]

Moreover, our results are particularly interesting because: (1) they were obtained in an adverse social environment for smoking cessation. Indeed, over 85% of the study participants had first degree family relatives who were smokers, and over half spent the major part of their time with other smokers (table 1). In addition, these results were obtained in a country characterised by widespread social tolerance towards smoking[8]; (2) the study participants registered a wide variation in cigarette smoking intensity and degree of tobacco dependence, including smokers with a Fagerström test score <5 (table 1), whereas most nicotine patch studies have targeted smokers with intakes of over 10–15 cigarettes/day[3][4]; (3) the study subjects had a wide range of educational levels and included manual as well as non-manual workers (table 1); and (4) it is a very simple intervention, which can be extended to many other workplaces.

The intervention achieved a two- to threefold increase in the rate of continuous abstinence compared to that obtained with sporadic unstructured medical counselling. This is consistent with the rates obtained by similar interventions in clinical trials conducted in primary care settings in Anglo-Saxon countries,[39][40] in non-randomised studies in primary care,[18] and at workplaces[16] in Spain. However, absolute abstinence rates are not directly comparable, since every worksite is to a certain degree unique and is characterised by a specific productive activity, work relations, social culture, and in-house smoking policies.[30][31] The 12 month abstinence rates in our study are higher than those usually obtained by medical interventions in primary care[18] and work[16] settings. This may be linked to the fact that we chose subjects who were motivated to quit smoking, that all subjects assigned to intervention grade II or III reported compliance of 80% and over with nicotine patches, and to the smoking policies in place at some of the work sites. Specifically, bus drivers, who accounted for the majority of workers included in the study, are not permitted to smoke while at the wheel and may only do so during the 15 minute break which they are obliged to take for every two hours of work. However, it could also be due to methodological factors. Although the nominal outcome is continuous abstinence at 12 months, what we have actually measured is complete non-use in the week preceding each assessment. This will surely overestimate abstinence, since no allowance is made for lapses during times more than one week prior to an assessment date.

This randomised trial was open, seeking faithfully to reproduce the conditions of administration of the intervention in clinical practice. The certainty of being treated with an "active" medication (nicotine patch) can increase cessation rates and effectiveness relative to what would be obtained in a trial in which the intervention were masked. Yet this could be offset—though by how much we do not know—by co-interventions to enhance cessation in the control group. It is thus difficult to know the extent to which the results of our trial's open design would differ from those that would have been obtained in a double blind trial. It must nonetheless be stressed that determination of the principal outcomes, such as smoking cessation or weight, was not influenced by the open study design, since objective measurements were used for the purpose.

Lastly, in our study, weight gain among subjects who underwent intervention was similar to that among controls, regardless of whether or not they maintained tobacco abstinence. Our results are largely in line with the literature since, in general, nicotine patches have not been shown to substantially reduce weight gain post-cessation,[44–46] though they may delay weight gain during the treatment period.[47]

Main messages

- The effectiveness of smoking cessation interventions vary with the context of the individual smoker, in particular with the prevalence of smoking and the application of smoking policies in and outside the workplace.
- In Spain there is no experimental evidence of the effectiveness of nicotine patches in smoking cessation, while in Europe there is scant experimental evidence on medical interventions for smoking cessation at the workplace.
- Structured medical counselling, accompanied by nicotine patches, results in higher rates of continuous tobacco abstinence than does sporadic unstructured advice at the worksite in Spain. In a setting similar to that of the trial, nine subjects would have to be treated for three months for one to achieve continuous abstinence for 12 months.
- Although study subjects were motivated to quit, results were, nevertheless, obtained in an adverse social environment for smoking cessation. Indeed, most of the study participants had first degree family relatives who were smokers, and over half spent the major part of their time with other smokers.

Policy implications

- A simple and easily generalisable intervention at the workplace is effective to achieve long term smoking cessation.
- This intervention has an effectiveness comparable, or even superior, to that of other widely implemented interventions targeting other morbidity-mortality risk factors.

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