An evidence-based programme for smoking cessation: effectiveness in routine general practice

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SUMMARY

Background. *Smoking cessation clinical practice guidelines are based on randomised clinical trials reporting outcomes in persons who participate in these studies. However, many practitioners are sceptical about the effectiveness of these recommendations when applied to the general population in everyday routine consultation.*

Aim. *To evaluate the results of a comprehensive smoking cessation programme in routine primary care practice.*

Method. *All smokers consulting in 10 general practices during one year participated in a non-randomised controlled trial. The percentages of subjects in the intervention (n = 1203, seven practices) and control (n = 565, three practices) groups who reported sustained abstinence between six and 12 months follow-up and were validated biochemically were compared. The effect of the programme was adjusted to baseline differences in both groups by multiple logistic regression analyses.*

Results. *The programme resulted in an increase of five percentage points (95% CI = 3.1%–6.8%) in the validated and sustained one-year abstinence probability, with 7.1% for all of the intervention practices (adjusted OR = 3.7, 95% CI = 2.4–5.7).*

Conclusion. *Programmes that combine advice to stop smoking to all smokers attending general practices with the offering of support, follow-up, and nicotine patches to those willing to stop are feasible and effective in routine practice, as primary care clinicians need only identify 20 smokers to get one additional success attributable to the programme.*

Keywords: smoking cessation; primary health care; effectiveness; nicotine replacement therapy.

Introduction

ALTHOUGH from a public health perspective tobacco interventions are highly relevant,[1] only half of current smokers report having been advised to stop smoking by their health care providers.[2,3] This may be explained in part by clinicians' doubts about the effectiveness of intervention strategies directed to all smoking patients in the framework of time constraints and excessive workload of everyday routine consultation.[4,5]

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Submitted: 5 October 1999; Editor's response: 2 February 2000; final acceptance: 11 May 2000.

Smoking cessation clinical practice guidelines for primary care clinicians[6,7] derived from data of randomised controlled trials[8-10] stress the importance of systematically identifying all smokers at everyday visits, strongly advising all smokers to stop smoking, assisting the patient with motivational intervention, encouraging nicotine replacement therapy, and scheduling follow-up contacts. However, the effectiveness of these recommendations incorporated continuously into everyday clinic visits and delivered universally to all smoking patients has not been previously assessed.

Therefore, a pragmatic trial was designed to assess the outcome of a comprehensive smoking cessation programme that includes all of these actions. The programme was developed in the framework of an actual primary care practice in order to evaluate the whole content of the programme and the effect of the intervention on all smoking patients independently of their motivation to stop smoking.

Method

The design of the study was quasi-experimental (non-randomised controlled trial). Ten general practices from six primary health care centres of the Basque Health Service (Spain) participated in the study. The Basque Health Service provides universal free health care services to every citizen of the Basque Country. Primary care professionals act as gatekeepers to other health care levels and work in group practices responsible for the medical care offered to people living in a given geographical area.

According to the pragmatic objective of the trial[11] all patients attending each general practice had to be included. This prevented random allocation of subjects within each practice to the intervention and control groups. This approach also assured the maintenance of ordinary working conditions and prevented the control group being contaminated throughout the follow-up period.

Physicians for the intervention group were chosen from a group of 22 family physicians who voluntarily attended the first 20-hour course to help patients stop smoking organised by the Basque Health Department in 1995. At the end of the course, the research project was presented and seven agreed to take part in the study. Three practices from the same area, whose general practitioners agreed to delay for three years the implementation of systematic interventions to stop smoking, served as a control group. In these control practices advice against smoking was only given to patients whose reason for consultating or whose health problems were related to tobacco addiction, a regular practice in most primary care consultations.[12]

Screening for tobacco use and intervention

All 6918 patients aged between 15 and 70 years attending the 10 general practices to see a doctor from September 11 1995 to October 1 1996 (4848 in the seven intervention practices and 2070 in the three control practices) had the following question asked by his/her family physician: 'Do you currently smoke?' Of the 2099 subjects who responded affirmatively (n_i [intervention] = 1421, n_c [control] = 678), 251 were excluded (n_i = 180, n_c = 71) owing to the presence of a mental disorder, drug addiction (other than tobacco), terminal illness or no telephone available at

home, and 80 (n_i = 38, n_c = 42) refused to take part in the study (participation = 95.7%). The study population consisted of 1203 smokers in the intervention practices and 565 in the control practices.

After identification, all smokers in the intervention practices were strongly advised by the primary care physician. The patient's receptiveness and answer to the question, 'Are you willing to stop smoking now?' allowed the physician to recognise those persons ready to stop smoking. Smokers who were not prepared to stop smoking received a handout for enhancing motivation to give up smoking. Support was also offered to these 956 subjects for the time when they would be ready to stop and 36 subsequently agreed during the following year. The physician's time dedicated to the programme was measured in a sample of 50 recorded consultations, resulting in a mean of 23 seconds for recognising smokers and three minutes and 28 seconds for counselling, diagnosing motivation, and offering the therapeutic plan. Smokers who were willing to stop smoking carried out a therapeutic plan delivered by his/her doctor over three consultations and two telephone calls and received a printed guide for smoking cessation (Figure 1).

Measures

One month after being included in the study, each smoker was interviewed to register demographic data,[13] smoking history, nicotine dependence,[14] presence of other smokers at home, and

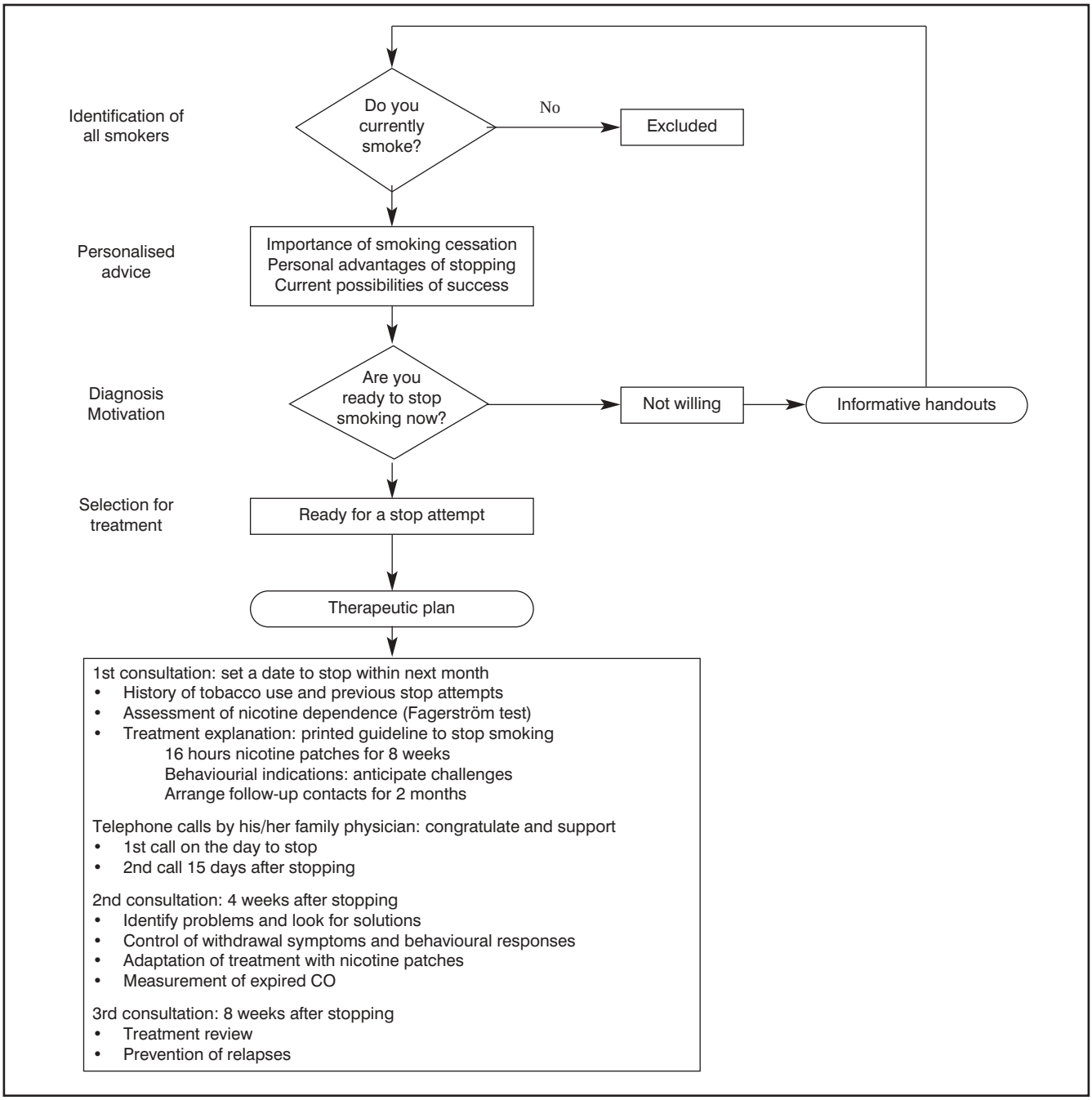

Figure 1. Actions and strategies of the smoking cessation programme in primary care.

prohibition of smoking in the workplace. After six and 12 months, all smokers included were questioned by telephone about their current smoking status. Subjects who were lost during the follow-up (n_i = 40, n_c = 6) and those who refused the 12-month interview (n_i = 11, n_c = 4) were also included in the analysis and counted as smokers. All of those who claimed to be off cigarettes at the 12-month follow-up telephone interview were checked by measurement of expired air carbon monoxide (CO) using a Micro-Smokerlyzer EC50 (Bedfont Scientific Ltd). Levels greater than 10 ppm were attributed to smoking. Those who failed to attend or who did not pass CO testing were counted as continuing smokers. Because it was not expected that smokers included in the programme would stop immediately after being advised by their physicians,[15] the end point outcome measure was the validated and sustained abstinence between the six- and 12-month follow-up.

Analyses

The probability of abstinence in the intervention and control groups was compared on the basis of intention-to-treat. The effect of cluster allocation of subjects to the intervention and control groups was quantified by the intraclass correlation coefficient and the crude comparison between groups was made applying the two-sample *t*-test and the Mann–Whitney–Wilcoxon rank-sum test to the cluster-specific event rates.[16] To control the possible confounding effect of baseline differences between both groups, multiple logistic regression analyses were performed, adjusting the models by the generalised estimating equations approach to take into account the effect of clustering.[16] Analyses were made with the SAS statistical package.

Results

Intervention and control groups were similar in relation to age, gender, social class, characteristics of smoking habit, and presence of other smokers at home. Smokers from control practices were less educated (P = 0.035) and had smoking forbidden in the workplace more frequently (P = 0.005) than smokers from intervention practices (Table 1).

The balance between subjects who stopped smoking and those who relapsed throughout the study period, and therefore the proportion of smokers who self-reported complete abstinence, was progressively greater at the first month, at six months, and at 12 months. In the intervention group, 144 smokers self-reported complete abstinence at six months. At 12 months, 49 of them (34%) had relapsed, whereas 63 new cases of smoking cessation were added during the same period. A total of 158 subjects self-reported complete abstinence at the final follow-up but only 95 smokers self-reported sustained abstinence between six and 12 months. They accounted for 7.9% of the total population, a proportion 2.5 times greater than that reported in the control group (Table 2).

At 12 months, seven of the 95 smokers in the intervention group and four of the 18 in the control group who self-reported sustained abstinence failed to attend CO testing. In addition, three of the 95 subjects in the intervention group and two of the 18 in the control group did not pass CO testing (>10 ppm). Therefore, the aforementioned smoking cessation figures decreased to 85 subjects in the intervention group (7.1% of the total population, 95% CI = 5.7%–8.7%) and 12 subjects in the control group (2.1%, 95% CI = 1.1%–3.7%) who achieved validated and sustained abstinence between six and 12 months. The relative probability of sustained and validated smoking abstinence was 3.3 (95% CI = 1.8–6.0) and the difference between these proportions, which represents the crude effect attributable to the programme, was 5% (95% CI = 3.1%–6.8%) (Table 2). Among all patients who consulted in the intervention practices it was necessary to identify 20 smokers (95% CI = 15–32) to obtain one who achieved sustained and biochemically validated smoking abstinence attributable to the smoking cessation programme implemented in these practices.

The degree of correlation within practices was very low (intraclass correlation coefficient was 0.0031). A *t*-value of 4.9 with

Table 1. Characteristics of subjects at the beginning of the study.

Data	Intervention (n = 1203)	Control (n = 565)	P-value
Women	626 (52%)	275 (48.7%)	0.19
Mean age in years (SD)	36.6 (13.0)	37.3 (13.0)	0.28
University education	302 (25.1%)	116 (20.5%)	0.035
Social class			0.18
Manager larger enterprise[a]	95 (7.9%)	32 (5.7%)	-
Manager small enterprise[b]	128 (10.7%)	60 (10.6%)	-
Intermediate employee	443 (36.8%)	221 (39.1%)	-
Qualified manual workers	331 (27.5%)	145 (25.7%)	-
Semi-qualified manual workers	154 (12.8%)	70 (12.4%)	-
Non-qualified manual workers	52 (4.3%)	37 (6.5%)	-
Age at start of smoking in years (SD)	17.0 (4.7)	16.8 (4.6)	0.25
Duration of smoking in years (SD)	19.6 (12.5)	20.6 (12.3)	0.12
Mean number of cigarettes/day (SD)	16.6 (10.0)	17.3 (10.8)	0.17
Smoke within five minutes of waking	168 (14%)	75 (13.3%)	0.69
Fagerström dependence score ≤5	917 (76.2%)	436 (77.2%)	0.66
Made attempt to stop smoking	565 (47%)	279 (49.4%)	0.34
Previously stopped >2 months	415 (34.5%)	208 (36.8%)	0.34
Last attempt within two years[c]	197/565 (34.9%)	113/279 (40.5%)	0.11
Absence of smokers at home[d]	448/1201 (37.3%)	203/562 (36.1%)	0.63
Prohibition of smoking in workplace[e]	255/813 (31.4%)	143/360 (39.7%)	0.005

[a]Managers in public organisations and enterprises of 10 or more employees, professionals with second and third cycle university degree; [b]managers of enterprises of fewer than 10 employees, professionals with first cycle university degree, superior technicians, artists, and sportsmen/women; [c]number/total subjects who had made some attempt; [d]number/total subjects with available information; [e]number/total patients employed.

Table 2. Probability of tobacco abstinence at different points of follow-up.

Abstinence	Intervention (%) (n = 1203)	Control (%) (n = 565)	Relative ratio (95% CI)	Difference in percentage (95% CI)
Self-reported at:				
First month	70 (5.8)	13 (2.3)	2.5 (1.4–4.5)	3.5 (1.7–5.3)
Six months	144 (12.0)	26 (4.6)	2.6 (1.7–3.9)	7.4 (4.8–9.9)
Twelve months	158 (13.1)	44 (7.8)	1.7 (1.2–2.3)	5.3 (2.4–8.3)
Sustained 6–12 months	95 (7.9)	18 (3.2)	2.5 (1.5–4.1)	4.7 (2.6–6.8)
Validated at 12 months	134 (11.1)	28 (4.9)	2.2 (1.5–3.3)	6.2 (3.7–8.7)
Validated and sustained 6–12 months	85 (7.1)	12 (2.1)	3.3 (1.8–6.0)	5.0 (3.1–6.8)

eight degrees of freedom (P = 0.001) and a rank test P-value of less than 0.01 resulted from the crude comparison of practice-specific proportions of sustained and validated smoking abstinence obtained in intervention and control groups. The effectiveness of the programme was consistent across the seven intervention practices, with no evidence of heterogeneity (χ^2 = 9.98, d.f. = 6, P = 0.13). The crude effect of the intervention was similar to the adjusted effect (adjusted OR = 3.7, 95% CI = 2.4–5.7) and was not modified by the remaining predictive factors (Table 3).

Discussion

Results of this study indicate that the smoking cessation programme incorporated into everyday practice increased the absolute probability of abstinence in a sustained and validated form by 5%, i.e. 7.1% of smokers maintained complete abstinence up to one year, a proportion 3.3 times higher than that found in the control group. This effect size may be overestimated, as 11.2% of smokers were excluded and 3.8% decided not to take part, probably because they were not interested in any programme to help them give up smoking. However, differences in the proportion of abstinent subjects between the intervention and control groups would essentially remain unaffected by re-analysis of data counting those who refused or those excluded as continuing smokers (4.8% and 4.2% respectively). Selection bias was probably negligible since the prevalence of smokers in our study population of 29.9% was similar to the prevalence of smokers (29.4%) in the general population of the Basque Country for 1997.[17] Measurement of expired air CO for all patients self-reporting complete abstinence, counting as continuing smokers the patients who did not attend follow-up or who did not pass CO testing, supports the validity of the results.

Our findings are consistent with those reported by Russell and associates[18] in 1983 in a study carried out in primary care practices that recruited cigarette smokers without taking into consideration tobacco dependence or willingness to stop smoking. Differences between both studies include the prescription of nicotine gum — nicotine patches were not available 17 years ago — and the very short and intense period of recruitment and intervention (26 days). In these circumstances, participating physicians might introduce changes in the course of their everyday work that probably cannot be continuously maintained in the actual practice. The long period of recruitment and intervention in our study — 12 months — provides evidence on the feasibility of including the smoking cessation programme in the primary care setting in a continuous manner.

The lack of randomisation makes necessary the use of multivariate analyses to control the effect of those variables that are systematically different between intervention and control groups. The effect of the programme was adjusted to most known predictors of smoking cessation[19-21] and none of the possible confounding variables was able to modify or to cause a relevant change in the crude effect of the programme. Accordingly, it seems reasonable to expect a similar behaviour for other possible predictors of smoking cessation not measured in this study or still unknown.

It may be argued that the doctors selected were particularly committed to helping patients stop smoking. However, none of them had previous experience with this kind of intervention and they had only attended a 20-hour course on smoking cessation together with eight hours of training to collaborate in the study. We therefore believe that any motivated family physician with minimal training would be able to reproduce the results of this study.

The efficiency of the programme is relatively high, since only 20 smokers must be identified in practices in which the programme has been implemented to result in one abstainer attributable to the programme. The increase in years of life of a smoker who stops smoking at the mean age of subjects in our study is 6.4 years for women and 4.1 for men.[22] If all primary care physicians in Spain were involved in this smoking cessation programme, a decrease of 7% in the prevalence of smokers over one year may be expected, which would result in a reduction of smoking-attributable mortality from 14.7%, estimated for 1992,[23] to 13.8%.

The smoking cessation programme incorporated into routine consultations in general practice is feasible and highly relevant from an epidemiological perspective. Two short questions allow universal identification of smokers and the systematic approach to the problem with a simple and short intervention, such as advice against smoking and help to those ready to stop with a therapeutic plan that includes follow-up contacts and the systematic offer of nicotine patches. Studies on the efficacy of motivational interventions for those not willing to stop smoking are required.[24]

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Table 3. Effectiveness of the programme adjusted by the remaining predictors of smoking cessation.[a]

Variables	Crude OR (95% CI)	Adjusted OR (95% CI)	Likelihood ratio test c^2	d.f.	P-value
Smoking cessation programme	3.5 (2.4–5.2)	3.7 (2.4–5.7)	22.7	1	0.0001
Age (every 10 years)	1.3 (1.2–1.4)	1.4 (1.3–1.5)	18.6	1	0.0001
Fagerström dependence score ≤5	1.7 (0.9–3.3)	1.9 (1.0–3.8)	5.8	1	0.0164
Previously stopped >2 months	1.8 (1.3–2.5)	1.6 (1.2–2.2)	4.8	1	0.0281
University education	1.4 (1.1–1.7)	2.0 (1.4–3.0)	6.4	1	0.0111
Social class					
Manager large enterprise[b]	1	1	11.6	5	0.0409
Manager small enterprise[c]	1.1 (0.3–3.7)	1.3 (0.4–4.3)	-	-	-
Intermediate employee	1.9 (0.6–5.4)	2.9 (0.9–9.5)	-	-	-
Qualified manual workers	1.7 (0.5–5.3)	3.1 (0.8–11.7)	-	-	-
Semi-qualified manual workers	0.7 (0.2–3.1)	1.3 (0.3–6.3)	-	-	-
Non-qualified manual workers	1.4 (0.2–7.5)	2.4 (0.3–17.0)	-	-	-

[a]Final GEE model of multiple logistic regression analyses, response variable: sustained smoking cessation between 6–12 months, biochemically validated at 12 months (expired air CO ×10 ppm); [b]see Table 1; [c]see Table 1.

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Acknowledgements

This study was supported by Fondo de Investigación Sanitaria (FIS grant 95/0987) and by the Department of Health of the Basque Government. We are indebted to Professor M A H Russell for his critical review of the manuscript; to Drs L Aurrekoetxea Bildosola, R Elejalde Llorente, J A Estevez Barrondo, M Fernández Liria, B Goiria Bikandi, M A Hernando Fernández, A Kareaga Uriarte, M A Millán Moneo, and A Ortiz Rubio for their contribution to the study as investigators for their practice; and to Dr Marta Pulido for editing the manuscript.

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