

# Middle-term effectiveness of a support program for smokers implemented in primary care

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Aim. To determine the middle-term effectiveness of a support program for smokers (SPS) wishing to quit.

Design. Observational, cohort follow-up study. Setting. Primary care.

Participants. Random sample (n=289) of patients older than 14 years who took part in the SPS between 1 July 1998 and 30 September 2001, from among a total of 987 patients who had been seen in the primary care center for any reason during this period. Interventions. Systematic minimal intervention, nicotine replacement therapy (NRT), or both. Main outcome measures. A telephone survey was used to study smoker/ex-smoker status, relapses, mean period of abstention and number of attempts to quit after the study period. Information obtained from the data sheets used in the program included sociodemographic characteristics, smoking habits, chronic illnesses, degree of dependence and motivation, use of NRT, and participation in the program.

Results. Of all patients in the program, 27% guit, with a mean period of abstinence of 23 months at the time of the study. The success rate was higher among older participants, men, participants who has been smokers for longer periods, those who were more highly motivated to quit, and those who did not use NRT. Of all participants, 35.6% failed to quit, and of these, 75% relapsed within the first 6 months.

Conclusions. The SPS offered within the primary care setting was effective and feasible, although participants should be followed closely during the first months so they can be advised to accept the fact that relapses are part of the quitting process.

Key words: Tobacco. Smoking. Support program for smokers. Primary care.

EFECTIVIDAD A MEDIO PLAZO DE UN PLAN DE AYUDA AL FUMADOR DESARROLLADO EN ATENCIÓN **PRIMARIA** 

**Objetivo.** Conocer la efectividad de un plan de ayuda al fumador (PAF) a medio plazo.

Diseño. Estudio observacional de seguimiento de una cohorte.

Emplazamiento. Atención primaria. Participantes. Muestra aleatoria (n = 289) de los pacientes captados en el PAF entre el 1 de julio de 1998 y el 30 de septiembre de 2001, entre aquellos fumadores mayores de 14 años que habían sido atendidos en consulta de atención primaria por cualquier motivo (se incluyeron en ese período 987).

Intervenciones. Intervención mínima sistematizada y/o tratamiento sustitutivo con nicotina.

Mediciones principales. A través de encuesta telefónica, se estudiaron: estado de fumador o ex fumador, recaída, tiempo medio sin fumar y número de intentos de abandono posteriores al estudiado. A partir de las hojas de seguimiento se recogieron datos sociodemográficos, características del hábito tabáquico, patologías crónicas, grado de dependencia y motivación, terapia sustitutiva con nicotina (TSN) y desarrollo del programa. Resultados. El 27% de los pacientes dejó de fumar, con una media de 23 meses de abstinencia en el momento del estudio. La tasa de éxitos es superior entre varones, de mayor edad, que llevan más tiempo fumando, están más motivados y no utilizan TSN. El 35,6% recae, y el 75% de las recaídas se produce en los 6 primeros meses.

Conclusiones. El desarrollo del PAF en el ámbito de atención primaria es efectivo y factible, si bien es necesario intensificar el seguimiento en los primeros meses ayudando a aceptar las recaídas como parte del proceso.

Palabras clave: Tabaco. Tabaquismo. Plan de ayuda al fumador. Atención primaria.

Spanish version available at www.atencionprimaria.com/50.719

A commentary follow this article (pág. 547)

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Manuscript accepted for publication 29 April 2002.

### Introduction

In Spain, smoking is beginning to be considered a socially unacceptable behavior, and its prevalence is decreasing in older age groups, although not in women. However, the decreases are smaller than in other European countries.<sup>2</sup> The benefits of quitting are evident:<sup>3</sup> quitting is the most important step smokers can take to improve their health, therefore patients should be informed about the risks of smoking, the benefits of quitting, and the options available to quit successfully. Given that the effectiveness of these measures is beyond question,<sup>7-9</sup> anti-smoking advice should be provided systematically, as should advice about the most suitable treatment to help smokers quit. 4-6 Because of its coverage and accessibility, primary care is the ideal setting for these interventions. 10-12 In recent years general practitioners have developed programs of systematic intervention aimed at dealing with smoking as a risk factor in public health, 4,13,14 but these programs should be more widely used.

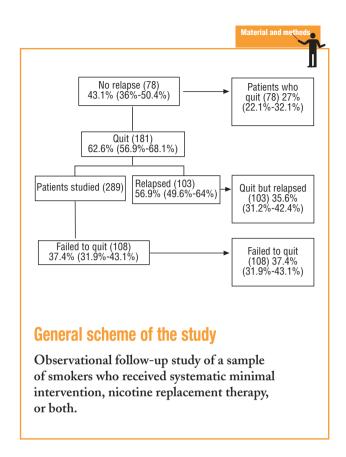
To facilitate the timely contact and interaction with smokers and provide personalized advice and follow-up to the more highly motivated among them, <sup>15,16</sup> the Support Program for Smokers (SPS) was implemented in Health Area VIII of Asturias, Spain. <sup>17</sup> This article reports on the effectiveness of the program in helping smokers to quit. A secondary goal was to determine the mean time to relapse in order to evaluate the need to intensify follow-up measures for smokers who wish to quit.

### **Methods**

The participants were patients older than 14 years who took part in the SPS between 1 July 1998 and 30 September 2001. They were chosen from among a total of 987 patients who had been seen for any reason at primary care centers in Health Area VIII, Asturias. We excluded patients who did not live in Health Area VIII at the time of the study, or who had died. We considered as participants smokers who, having agreed to take part in the program, were given appointments for a number of scheduled activities which consisted of at least Richmond and Fagerström tests. These patients received systematic minimal intervention and – if their degree of dependence was high - nicotine replacement therapy (NRT). A sample size of 400 persons was calculated on the basis of the total number of patients who took part in the SPS, with an expected prevalence of 50%, a precision of 5% and a dropout rate of 35%. To ensure that part of the sample was followed for more than 24 months, the participants were distributed in two equal groups on the basis of date of entry in the SPS. In both groups the sample was chosen randomly from a list of patients included in the SPS and a table of random numbers.

#### Main outcome variables

Smoker/nonsmoker status, relapses, mean duration of abstention and number of attempts to quit after the study period were no-



ted. This information was obtained by health care staff who surveyed participants by telephone.

#### Independent variables

Information obtained from the patient's medical record and noted on the data sheets used in the SPS included age, sex, duration of smoking habit in years, number of cigarettes smoked per day at the time of enrolment, chronic illnesses, previous attempts to quit, score on the Richmond and Fagerström tests, use of NRT, previous telephone reinforcement, and number and mean duration of follow-up visits.

#### Statistical analysis

Quantitative variables are reported as the mean, standard deviation and median; qualitative variables are reported as absolute and relative frequency distributions. Survival analysis is used to describe the findings for relapses, and 95% confidence intervals are reported for each estimator. Differences for each item in comparison to the control variables are evaluated with the chisquared or Student's t test. The differences were considered statistically significant when P was less than 0.05. All analyses were done with SPSS software.

#### Results

Of the 400 patients initially included in the study, we were able to contact 289 (72.3%). There was no statistically significant difference in response rates between ob-

TABLE 1	Participation in the Support Program for Smokers
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	Estimator	95% IC
No follow-up visits (enrolled only)	11%	7.8%-15.1%
Mean number of visits	4.19	3.8-4.58
Only one follow-up visit	26%	20.9%-31.7%
Mean duration of follow-up (months)	8.2	7.1-9.3
Nicotine replacement	32.4%	27.1%-38%
Previous telephone reinforcement	56.6%	47.7%-65.2%

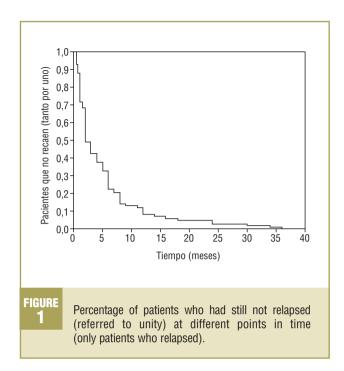
servers. For the group of patients who could not be reached, we recorded all available data from the data sheet and found no statistically significant differences in the distribution of values for any variable. Of the final sample, 143 patients (49.5%) had been included in the SPS before the year 2000. Mean age was 44 years, 75% of the participants were younger than 50 years, and 177 participants (58.9%) were men. Mean duration of the smoking habit was 24 years, with a mean daily consumption of 26 cigarettes. Mean scores on the tests for dependence and motivation to quit were 5.3 and 7.8, respectively. Of all participants, 83.4% had at least one chronic illness, and 67% had tried to quit before. The data sheet was available for 281 patients (97%), 31 (11%) of whom did not attend any of the follow-up visits after initial enrollment («enrolled only»). Mean number of visits, duration of follow-up, use of NRT and previous reinforcement are shown in Table 1. Of the 289 smokers, 181 quit initially, and at the end of the study 78 continued to abstain from smoking.

There were no statistically significant differences in success rates (proportion of patients who said they had quit) between observers, although we did find significant differences in some variables between patients who quit and those who did not (Table 2). Of the 108 patients who fai-

TABLE	Relation between different variables
2	and success rate

Variable	Quit	Did not quit	P
Sex (%)			.017
Men	31.6	68.4	
Women	19.6	80.4	
Mean age	48.06 years	42.05 years	<.0001
Mean duration of smoking habit	28.65 years	22.43 years	.001
Cigarettes/day	24.82	26.04	n.s.
Chronic illness			n.s.
Yes	29	71	
No	22.7	77.3	
Previous attempts to quit			n.s.
Yes	26.7	73.3	
No	31.8	68.2	
Mean Fagerström score	4.88	5.47	.07
Mean Richmond score	8.33	7.64	.007
Previous telephone reinforcement			n.s.
Yes	30.4	69.6	
No	28.3	71.7	
Patients enrolled			.042
Enrolled only	12.9	87.1	
Attended at least one follow-up visit	28.8	71.2	
Mean duration of follow-up in the SPS	319 days	206 days	.001
Mean number of visits for the SPS	5.5	3.1	<.0001
Nicotine replacement therapy			.009
Yes	17.6	82.4	
No	31.6	68.4	

SPS indicates Support Program for Smokers; n.s., nonsignificant difference at 95%.



led to guit, 71.1% (64.7%-76.9%) made no further attempt, and among those who did try again, 58.1% (45.5%-69.8%) tried only once more. Of the 103 patients who relapsed, only 98 recalled how long they had refrained from smoking: the mean was 5.25 months (3.9-6.6 months). Figure 1 shows the survival curves; 50% relapsed within the first 2 months (1.4-2.6 months), and 75% within the first 6 months (4.6-7.4 months).

We found a statistically significant relationship between relapse rates and certain variables (Table 3). Patients who had not resumed smoking at the end of the study had abstained for a mean of 23.19 months (95% CI, 20.8-25.6 months), hence 80% had not smoked for 1 year, and 50% had not smoked for more than 23 months. Considering only smokers who joined the program more than 12 months previously and those who had abstained for at least 1 year, the overall success rate was 27.2% (21.8%-33.1%, ie, 65 of 239 patients).

## Discussion

The relatively high drop-out rate (27.7%) may have skewed the results; however, we believe the patients who could not be contacted for follow-up did not differ significantly in the main outcome variables from those who completed the study program. Comparison of the information obtained about the independent variables from the data sheet failed to reveal any significant differences between the two groups in the distribution of values for these variables, or in the results obtained by different observers.

As in other studies, <sup>18,19</sup> most patients who took part in the SPS were men; mean age was higher than in earlier surveys, as there as no age limit for enrollment. Eleven percent of the participants did not attend any of the followup appointments, and we assumed they had dropped out of the program or that their participation had not been recorded. However, this figure was clearly lower than that reported in an earlier study, <sup>19</sup> in which 32.8% of those initially enrolled did not participate in any further interventions. The SPS was evaluated yearly when the center's regular services were reviewed; this may have contributed to the better rate of participation.

In contrast with at least one earlier study, <sup>19</sup> 56.6% of the participants had received previous reinforcement. In our health area, the SPS is implemented jointly by physicians and nurses, and involvement of the nursing staff is fundamental in this type of program. Success was greatest in smokers who were more highly motivated and who participated in the program for longer, but, in contrast to other studies, 11,20 the program was less successful when NRT was used. We have no explanation for this finding; although patients treated with NRT smoked more and were more dependent on nicotine, they were also more highly motivated.

We did not evaluate adverse effects. The percentage of ex-smokers was greater than in an earlier report 18 on a systematic, opportunistic intervention in a nonselected population, but these participants did not use NRT and their initial level of motivation was clearly lower than in our patients. The percent success rate in the present study was also higher than that found in another study<sup>4</sup> with NRT. However, our results were worse than those obtained by Torrecilla et al.<sup>11</sup> with systematic minimal intervention and NRT. One of the most noteworthy biases in our study arises from the fact that our main outcome variable was evaluated with information obtained by telephone survey, with no further analysis to corroborate the patients' responses, despite the fact that Bedfont breath CO monitors are available at the health centers in our area for use at follow-up appointments. The administration of the study was centralized, and we realized that giving appointments for follow-up visits might have increased the number of drop-outs. This bias may have led us to overestimate the effectiveness of the intervention as a result of underreporting of smoker status. Some have estimated underreporting at 2%-4%, whereas others<sup>21,22</sup> have reported a deception rate of 15% or 17.6%, although we note that these latter surveys were done by staff members of the health center. Our survey was run by four family physicians at different health centers and by a health care technician, hence false positives were unlikely to be due to the patient's desire to please the physician. Moreover, the survey was done outside the health center setting, and no observer-dependent differences were found in drop-out rates. As an added measure, res-

TABLE 3	Relation between different variables and relapse rates
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	Relapsed	Did not relapsed	P
Sex		.017	
Men	50.4	49.6	
Women	67.6	32.4	
Mean age	41.8 years	48.1	<.0001
Mean duration of smoking habit	22.2 years	28.7 years	.001
Cigarettes/day	25.9	24.8	n.s.
Chronic illness			n.s.
Yes	53.6	46.4	
No	61.5	38.5	
Previous attempts to quit			.07
Yes	58.9	41.1	
No	44.9	55.1	
Mean Fagerström score	5.4	4.9	n.s.
Mean Richmond score	8	8.3	n.s.
Previous telephone reinforcement			n.s.
Yes	51.2	48.8	
No	57.1	42.9	
Patients enrolled			n.s.
Enrolled only	56.4	43.6	
Attended at least one follow-up visit	63.6	36.4	
Mean duration of follow-up in the SPS	213 days	319 days	.007
Mean number of visits for the SPS	3.6	5.5	<.0001
UNicotine replacement therapy			<.001
Yes	74.2	25.8	
No	47.4	52.6	

SPS indicates Support Program for Smokers; n.s., nonsignificant difference at 95%.

ponses were checked against the information entered in the data sheet.

Another limitation arises from the characteristics of the study: because no control group was used, we cannot determine whether the success rates were the result of the intervention we set out to evaluate, or of other factors. Among the earlier studies we reviewed, the program most similar to ours was that described by Martín Cantera et al., 19 which achieved an 18% success rate. Although this figure is lower than our success rate, no mention of the use of NRT was made in this study. We achieved an initial success rate of 62.6%, although of those who quit at the start of the program, 56.9% resumed smoking, half within the first 2 months and one-fourth after the first 6 months. It would seem reasonable to follow participants more closely during the first months of the program, and to use telephone reinforcement (especially for participants who skip scheduled appointments), to instill in participants the idea that relapses are part of the quitting process, and to support subsequent attempts to quit.



### What is known about the subject

- The effectiveness of smoking cessation interventions is beyond question.
- Primary care is the ideal setting for such interventions.

### What this study contributes

- The effectiveness of smoking cessation programs was confirmed: 27% of our participants succeeded in quitting.
- Follow-up should be intensified during the first 6 months, as this is when most relapses occur.

The effectiveness of the SPS appears to have been acceptable. Coverage was low: we estimate a target population of 25 109 patients, 15 of whom 987 – 4% of all smokers in the area served by our health centers – were enrolled in the program. Other programs have been implemented individually by physicians interested in smoking prevention and cessation, 5,23 whereas our program forms part of an institutional policy aimed at gradually involving all primary care professionals in attempts to deal with this health problem. Raising their awareness of the problem takes time, and we did not set highly ambitious goals for the primary care teams in this initial study. Despite the low coverage, it should be recalled that smokers who enrolled in the program agreed to take part and attended at least one appointment. However, the SPS aims to identify smokers, inform them about their habit, advise them and offer help. Thus, in addition to the patients initially enrolled, others received advice, and we expect at least 5% of this latter group to quit smoking.<sup>24</sup>

In the light of evidence that the program is effective, more ambitious goals should be considered, and coverage should be extended to make the program available to the large percentage of smokers who intend to quit.<sup>25</sup>

### <u>Acknowledgments</u>

We thank doctors Carlos Fernández Benítez and José Fuentes for their help with the telephone surveys.

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#### COMMENTARY

# Systematic interventions for smoking cessation: current situation and future challenges

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Research on smoking in the primary care setting has traditionally centered on so-called brief interventions. This is because of practical considerations and their low cost, as well as historical tradition going back to Russell in 1979. In addition, brief interventions have been tested more frequently than other procedures, as shown in the review included in the latest edition of the Cochrane Library database (Silagy et al, 2002), which comprises 34 clinical trials involving more than 27 000 smokers. This analysis showed that the role of nursing staff was of fundamental importance (Rice et al, 2002).<sup>2</sup>

More recently, recommendations issued by different agencies such as the Center for Disease Control (CDC 2002)<sup>3</sup> and WHO (2001)<sup>4</sup> have noted the need for brief interventions to add motivational interviews, pharmacological therapy (nicotine replacement therapy [NRT] and bupropion) as strategies of first choice. These studies, however, have also noted the need to ensure that all health professionals (ie, physicians, nursing staff, pharmacists, midwives, and others), as fundamental elements of primary care, are involved in the intervention.

In this issue Alonso Fernández et al. describe an interesting study that centers on systematic minimal intervention with support from the nursing staff and appropriately used NRT. Notably, 27% of the participants in the program quit smoking - a higher success rate than in similar studies. However, the authors caution that this figure was probably due to the better coordination between health professionals (physicians and nurses) and the use of pharmacological treatment (NRT). They also note certain limitations of their study, eg, the lack of a control group. However, this type of study, which is not - strictly speaking - experimental, and which examines results obtained under «normal» conditions during the visit to the physician's office, are enormously valuable in that they enhance the credibility of such findings and support their applicability in our primary care setting.

In addition, the article points out some areas for future research, such as the evaluation of a specific intervention to prevent relapses, and the use of telephone counseling as part of support programs. Similar approaches can be found

- Systematic interventions for smoking cessation, supported by all members of the primary care team, have been shown to be useful and feasible in the Spanish primary care system.
- Future studies should examine the effects of the motivational interview, telephone reinforcement and specific programs to prevent relapses.
- Support programs for smokers implemented in primary care centers should be extended to cover a larger part of the population, with computerized reminder systems forming part of medical record management systems.

in a review of community-level interventions published by the Task Force on Community Prevention Services<sup>5</sup>, which «strongly recommends» the use of «health system strategies to improve the availability of effective cessation therapies» - particularly interventions that provide telephone support - in the context of multicomponent interventions.

A final point worth emphasizing is the authors' own critique of the program's coverage, which they estimated at only 4%. However, it is clear that primary care professionals play a fundamental role in strategies to make treatment of the problem more widely available, because of their contact with the entire population, and because primary care centers are the most appropriate place for such intervention. More active educational policies are probably needed, including specific undergraduate and graduate-level training or continuous medical education (Comité Nacional para la Prevención del Tabaquismo 2002).6 However, it is also necessary to incorporate systems that make it possible to identify smokers more frequently and thus increase the availability of medical help and support. In addition, information technology is likely to be useful, for example, as software programs that manage reminder, follow-up and medical record systems.<sup>3,5</sup>

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