

Training pharmacists and pharmacy assistants in the stage-of-change model of smoking cessation: a randomised controlled trial in Scotland

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Abstract

Objective—To evaluate a training workshop for community pharmacy personnel to improve their counselling in smoking cessation based on the stage-of-change model.

Design—A randomised controlled trial of community pharmacies and pharmacy customers.

Setting—All 76 non-city community pharmacies registered in Grampian, Scotland, were invited to participate. Sixty-two pharmacies (82%) were recruited.

Subjects—All the intervention pharmacy personnel were invited to attend the training; 40 pharmacists and 54 assistants attended. A total of 492 customers who smoked (224 intervention, 268 controls) were recruited during the 12-month recruitment period (overall recruitment rate 63%).

Main outcome measures—The perceptions of customers and pharmacy personnel of the pharmacy support and self-reported smoking cessation rates for the two groups of customers at one, four, and nine months.

Results—The intervention customer respondents were significantly more likely to have discussed stopping smoking with pharmacy personnel, 85% (113) compared with 62% (99) of the controls ($p < 0.001$). The former also rated their discussion more highly; 34% (45) of the intervention customers compared with 16% (25) of the controls rated it as “very useful” ($p = 0.048$). Assuming non-responders had lapsed, one-month point prevalence of abstinence was claimed by 30% of intervention customers and 24% of controls ($p = 0.12$); four months’ continuous abstinence was claimed by 16% of intervention customers and 11% of controls ($p = 0.094$); and nine months’ continuous abstinence was claimed by 12% of intervention customers and 7% of controls ($p = 0.089$). These trends in outcome were not affected by potential confounders (sex, age, socioeconomic status, nicotine dependence, and type of nicotine replacement product used) or adjustment for clustering.

Conclusions—The intervention was associated with increased and more highly rated counselling, and a trend toward

higher smoking cessation rates, indicating that community pharmacy personnel have the potential to make a significant contribution to national smoking cessation targets.

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Keywords: community pharmacy, health education, smoking cessation

Introduction

The efficacy of nicotine replacement therapy (NRT) in a range of clinical settings has been well documented, and studies have demonstrated that personal motivation^{1,2} and ongoing support³ can further increase smoking cessation rates. The opportunity to increase accessibility to the combination of nicotine replacement and support was initially provided in the United Kingdom in 1991 through the reregulation of the 2 mg strength of nicotine gum from “prescription-only medicine” (POM) to “pharmacy-supervised sale” (P) and the subsequent availability for “over-the-counter” (OTC) sale from community pharmacies.

In a preliminary study to consider outcomes in the community pharmacy setting,³ three-quarters of NRT users interviewed recalled having received some counselling from the pharmacist and/or the pharmacy assistant, and almost all of these customers felt the counselling had been helpful. However, more than a quarter did not recall having received any counselling, and most of these customers would have valued regular counselling from pharmacy personnel. NRT users voiced a preference for individual counselling as opposed to a support group,³ and evidence suggests that brief intervention is more cost effective than clinic-based intervention,⁴ and more effective on a population basis.

Although health education is now a contractual obligation for British community pharmacists, the requirement is only mandatory with respect to the display of health education material.⁵ However, most pharmacists are eager to undertake an extended role in health promotion.⁶⁻⁸ Concerns have been expressed that pharmacists are not trained for smoking cessation counselling and that it may conflict with advice from the general practitioner (GP), who may even feel threatened.^{9,10} Furthermore, a study of the attitudes of GPs, carried out just before the reregulation of nicotine gum, showed that fewer than half were in favour of increasing the range of medicines

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available for sale by pharmacists, and only a quarter thought the introduction of formal pharmaceutical consultations with patients, formalising current OTC advice, would be desirable.¹¹

Following the reregulation of NRTs, a vast array of support material on clinical issues¹²⁻¹³ has been sent to pharmacies; however, the dissemination of guidelines in printed form has been shown to be ineffective in the medical setting,¹⁴ and there is a similar need for a more interactive approach to raising pharmacy personnel's awareness of these issues. In addition it is likely that the healthcare personnel who are helping smokers to change their behaviour are in practice given little or no effective training in how to promote behavioural change.¹⁵ Naidoo and Wills¹⁶ highlight several models of behaviour change that attempt to explain the influence of different variables on a person's health-related behaviour. The "stage-of-change" model of smoking cessation¹⁷⁻¹⁸ has been studied extensively in the United States and the efficacy of the model has been demonstrated under ideal conditions.¹⁹ However, in a recent review, Ashworth²⁰ highlights the need to confirm the superior efficacy of interventions tailored to the stage of change over non-staged interventions and, in particular, to document efficacy in "real-world" conditions in health service settings. This paper describes a pragmatic study set in community pharmacies in Scotland which used a randomised controlled trial to test the effect of training pharmacists and pharmacy assistants in the stage-of-change model of smoking cessation.

Customers seeking help with smoking cessation from community pharmacy personnel are already beyond the "precontemplation" stage of the stage-of-change model. People entering a pharmacy for advice on smoking cessation have reached the "contemplation" or "preparation" stage and many may be intending to purchase an anti-smoking aid. For smokers who decide to stop smoking, NRT increases the chances of success.³⁻²¹ An understanding of the theory and practice of the stage-of-change model could promote more effective counselling by tailoring the advice to the stage the customer is at, which may in turn be expected to optimise the potential of NRT and result in more customers achieving long-term abstinence from smoking. In particular, the use of the model by pharmacy personnel could achieve the following.

- Help move smokers from the contemplation and preparation stages to the action and maintenance stages where the use of NRT is appropriate
- Improve the effectiveness of the treatment by reducing inappropriate use of NRT by targeting it to smokers at the correct stages of the model
- Increase the chance of smoking cessation success by providing important additional support matched to the need of the individual
- Help them remain supportive and positive in encouraging customers who lapse to attempt cessation again when they feel ready

- Be more effective in terms of time by reducing inappropriate intervention.

We hypothesised that community pharmacists and pharmacy assistants who participated in a training workshop based on the stage-of-change model would be more effective than untrained controls in helping people stop smoking and that more of their customers would achieve long-term abstinence from smoking. The study set out to develop and evaluate an interactive training workshop for community pharmacists and their staff based on the stage-of-change model. Unlike similar training for hospital doctors,²² for GPs and practice nurses,²³ and for GPs, practice nurses, and health visitors,²⁴ the training did not include motivational interviewing techniques to encourage smokers to move from precontemplation to contemplation; however, it did include specific content and recommendations pertaining to preparation, action, maintenance, and relapse. The training aimed to give participants an understanding of the stages in the stage-of-change model, and focussed on brief questioning which could enable counsellors to assess the stage of individual customers and to subsequently increase the frequency and effectiveness of the counselling support by tailoring their advice to the current stage of the customer.

Both quantitative (randomised controlled trial) and qualitative methods were used to evaluate the training. Pharmacy personnel's perceptions of the value of the workshop and of changes in job satisfaction following the training is the subject of a separate paper.²⁵ The major focus of this paper is the effect of the training on the pharmacy support process and the subsequent self-reported smoking cessation outcome of intervention and control customers.

Methods

Ethical Committee approval was obtained, and the patient information leaflets complied with the Code of Ethics of the Royal Pharmaceutical Society of Great Britain (RPSGB). A training package based on the stage-of-change model of smoking cessation¹⁷⁻¹⁸ was commissioned from Grampian Health Promotions by the Department of General Practice and Primary Care at the University of Aberdeen, and the School of Pharmacy at the Robert Gordon University, both in Aberdeen, Scotland. The training was piloted in mid-December 1994 on a cross-section of pharmacy personnel from outside the study sample (eight pharmacy assistants and five pharmacists). The training focussed on the stage-of-change model using case studies of pharmacy customers, and on communication skills for negotiating change and providing on-going support and encouragement; it did not focus on smoking cessation products.

In September 1994, all 76 non-city community pharmacies registered in Grampian were invited to participate in the trial; city pharmacies were excluded to prevent contaminating a similar concurrent training initiative for other primary care professionals.²⁴

Non-respondent pharmacies were sent a reminder after three weeks and followed up by telephone after a further three weeks. Pharmacies were not allocated to the intervention or control group until agreement to participate had been obtained, because willingness to co-operate may not have been randomly distributed in the population.²⁶ Pharmacy recruits were stratified by type—national multiple (chain) or proprietor-owned—and ranked according to the pharmacist's level of motivation (as defined by the date their "willingness to participate" proforma was received). They were then randomised to either the intervention or control group by sequential allocation.

All intervention pharmacists and pharmacy assistants who were routinely involved in giving anti-smoking advice or selling NRT products were invited to attend the two-hour training in early January 1995. To optimise participation, eight workshops were scheduled with a choice of dates, times (daytime or evening), and location (Aberdeen or Elgin—the major population centres which are located 70 miles apart at opposite ends of the study region).

During the 12-month customer recruitment period, all smokers who sought advice on stopping smoking or those who bought an OTC anti-smoking product in preparation for a new attempt to stop smoking were eligible for inclusion. Pharmacy personnel offered these customers a patient information sheet specific to their group (intervention or control), informing them that Grampian pharmacists were working with researchers who were studying stopping smoking, and inviting them to join the study (neither leaflet specified inclusion in the intervention or control group). The intervention leaflet noted that, with their agreement, pharmacy staff would maintain a confidential client record which would document their progress in stopping smoking, any product supplied, points raised by the client, and advice given. To minimise inter-group contamination, both leaflets requested customers to return to that same pharmacy for any further advice and for subsequent purchase(s) of anti-smoking products. Customers willing to participate then registered with that pharmacy, so joining either the intervention or control group as determined by the group to which the pharmacy had been allocated; however, the customers were not made aware of their group allocation. To monitor the level of non-recruitment, pharmacies in both groups maintained a tally record of customers who declined to join the study, and their reasons. Intervention personnel offered their customers the Pharmacy Support Programme, which involved client registration, counselling, and record keeping. The control group asked customers to register and then continued to provide standard professional support.

The main outcome measures were self-reported point prevalence smoking cessation rates at one month and self-reported continuous abstinence from zero to four months and from zero to nine months.

Although validation is a controversial area, we chose not to use validation for two reasons²⁷: (a) because validation in this context would have further reduced participation; and (b) because there is no reason why misreporting rates should differ between the two arms of the study. At each of the three time points, two postal reminders and duplicate questionnaires were sent to non-responders.

In addition to self-reported smoking status, the one-month questionnaire recorded demographic characteristics: gender, age, postcode (a proxy for socioeconomic status²⁸), and previous nicotine dependence.²⁹ Information was sought on the subject's experience in the pharmacy when they first bought the product as part of their current attempt to stop smoking (for example, whether they were questioned regarding current health status or advised on product strength and use). The four-month questionnaire assessed the intervention customers' perceptions of the three major components of the support package: registration, counselling, and record keeping. A shorter version of the questionnaire assessed the views of the control customers on registration and the counselling received.

As part of the one-month questionnaire, all the customers were requested to give a contact telephone number if they were willing to participate in a follow-up telephone interview six months after registration. A sub-sample of 25 intervention and 25 control interviewees was selected; customers who provided a contact number were stratified by group, and ranked by date of recruitment; then every fourth subject was selected for interview. The interviews aimed to validate data from the four-month questionnaire and to collect in-depth qualitative information on the customers' perceptions of the support provided in the pharmacy. A semi-structured interview schedule was piloted on two intervention and two control customers; no major amendments were required.

Sixteen months after the training, the intervention personnel were each sent a postal invitation to participate in a semi-structured telephone interview to assess their perceptions of the utility of the training and to identify any problems encountered when implementing the training in the pharmacy setting. A representative sub-sample of 20 personnel was selected; the sample aimed to reflect the range of characteristics: pharmacist/assistant, multiple/non-multiple (chain, non-chain), age, gender, and smoking status. A semi-structured interview schedule was piloted on two pharmacists and two assistants; no major amendments were required.

Permission was sought from the interviewees to tape the telephone interviews. The tapes were transcribed in full and the text read several times to facilitate the identification of themes; quotes were highlighted and grouped by theme. The statistical software SPSS for Windows³⁰ was used to store and analyse questionnaire data, to calculate descriptive statistics, and to demonstrate differences between the intervention and control groups

using parametric tests (*t* tests for quantitative variables) and non-parametric tests (Mann-Whitney tests for quantitative and χ^2 test of association for qualitative variables). Multiple logistic regression was carried out³¹ for the binary outcomes of point prevalence at one month, and continuous abstinence at four and nine months, and to assess the effect of potential confounders (age, sex, socioeconomic status,²⁸ nicotine dependence,²⁹ and the use of OTC anti-smoking products). The effect of cluster randomisation was assessed by firstly calculating the degree of intra-cluster correlation (within-pharmacy correlation) for each of the binary outcomes of abstinence. Secondly, regression techniques, adding the pharmacy as a random factor nested within the treatment groups (intervention and control) to the other fixed effect factors, were considered leading to a generalised linear mixed model (GLMM) approach.^{32 33}

The determinant of sample size was continuous abstinence at the nine-month follow up; this was also the measure likely to show the smallest difference between the intervention and control groups. The most relevant data on outcome in a pharmacy setting reported 15% not smoking at one month and 9% at seven months (assuming non-responders had lapsed).³ This was used to estimate a control group continuous abstinence rate of 7% at nine months. A worthwhile effect of the training intervention was taken as a five percentage point increase in this figure to 12% for the subjects exposed to the intervention. Assuming that subjects lost to follow up had lapsed, the number of subjects required to detect a five percentage point improvement with a power of 80% and a probability of 95% was determined using the formula for calculating sample size for unpaired proportions.³⁴ At least 538 subjects were required in each group to give an 80% chance of detecting a five percentage point difference in smoking cessation success rate (from 7% to 12%), which is statistically significant at the 5% level (two-tailed test).

Results

PARTICIPANT FLOW AND FOLLOW UP

Sixty-two pharmacies were recruited to the study, a recruitment rate of 81.6% (62/76) (intervention, *n* = 31; control, *n* = 31). During the training it was noted that one intervention pharmacist was also in charge of an outlet allocated to the control group. The latter pharmacy was transferred to the intervention group. One control pharmacy withdrew due to pressure of work and one intervention pharmacy withdrew because of major staff changes (no customers had been recruited by either). Thus, as detailed in figure 1, 31 intervention and 29 control pharmacies participated throughout the study.

The study recruited 492 customers (out of a possible 775) (224 intervention, 268 controls), an overall recruitment rate of 63.5%. Customer recruitment, non-recruitment, and response rates at the three postal follow ups are detailed in figure 1. Because the main aim of

the third follow up was to determine the number of subjects who had achieved nine months of continuous abstinence, the 106 intervention and 136 control subjects who were already identified as smoking were not followed up. Nine-month smoking data were provided by a total of 73.2% (347) of the recruited customers: 73.3% (159) intervention and 73.2% (188) controls.

Sixteen months after the training, two pharmacists and eight assistants were no longer employed by the same pharmacy, thus leaving 84 of the 94 workshop participants available for follow up: 38 pharmacists (23 women) and 46 assistants (all women). Following two postal reminders, 30 pharmacists (18 women) and 41 assistants responded; of these, 22 pharmacists (12 women) and 19 assistants were willing and able to participate in a telephone interview.

ANALYSIS

Respondent characteristics

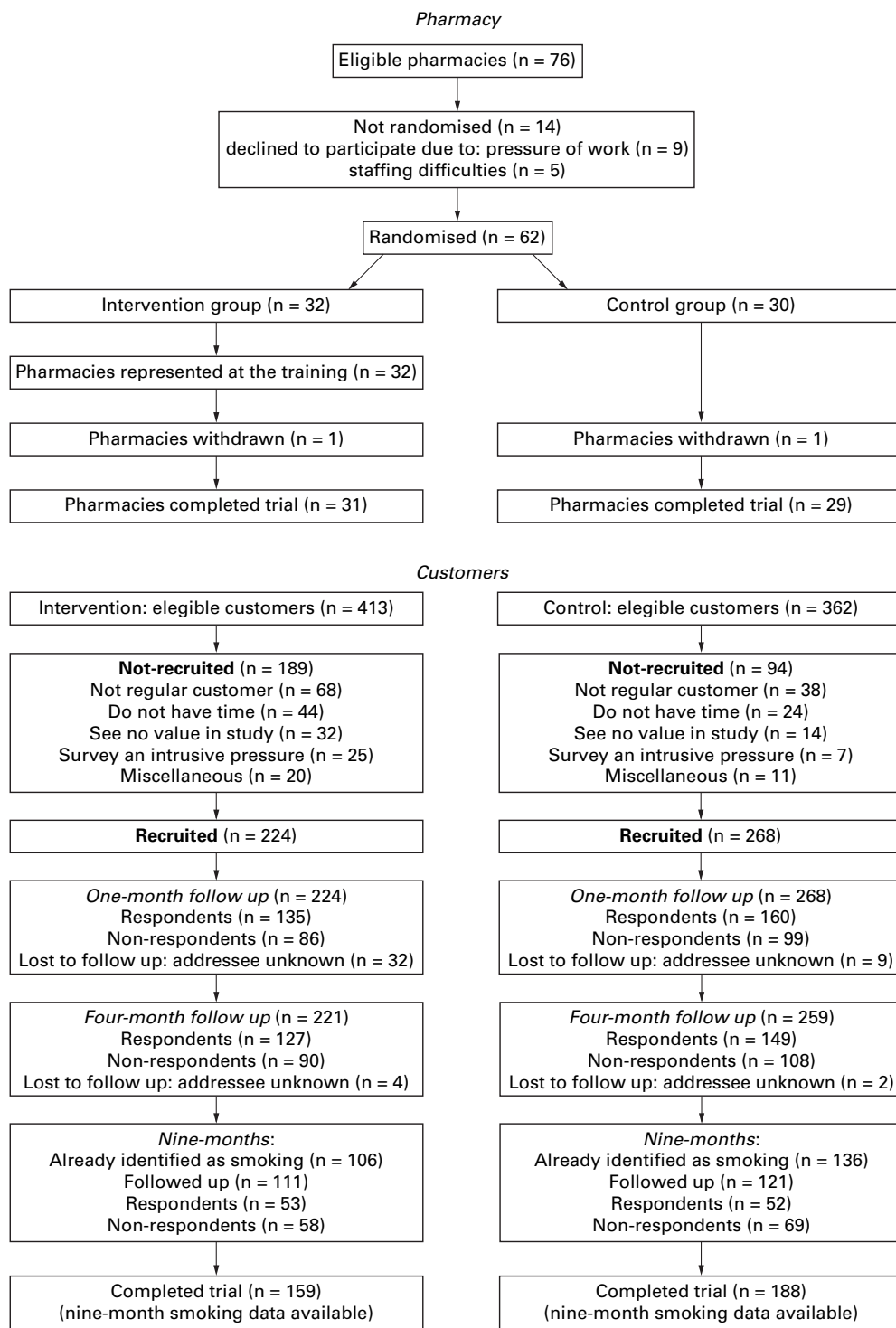
The two arms of the study were well balanced with respect to pharmacy location (rural *vs* urban) and pharmacy type (single outlet *vs* small multiple *vs* large multiple). All the intervention pharmacies were represented at the training, and a total of 94 personnel participated: 54 assistants (all women) and 40 pharmacists (25 women, 15 men). The sociodemographic characteristics of the intervention and control customer recruits are shown in table 1. There was no significant difference between the characteristics of the intervention and control customers who responded to each of the three postal follow ups with respect to gender, age, socioeconomic status, and nicotine dependence. However, the groups differed in their use of anti-smoking aids. Most recruits bought an anti-smoking product at the time of registration; however, intervention subjects were significantly more likely to make a purchase (*p* = 0.0085). Moreover, there was a significantly greater use of nicotine patches relative to nicotine gum in the intervention group compared with the controls (*p* = 0.029). Overall, approximately three-quarters of the customers used patches compared with a quarter using gum.

There was no significant difference between the characteristics of the intervention and control customer interviewees. The 20 pharmacy personnel selected for interview were representative of the study population.

Smoking cessation outcomes

As detailed in table 2, the point prevalence of self-reported abstinence was greatest at one month of follow up with lower continuous abstinence at four months and a gradual reduction at nine months. Assuming that all non-responders had lapsed, the intervention subjects tended to be more likely to report not smoking at each of the follow ups (one month *p* = 0.12; four months *p* = 0.094; nine months *p* = 0.089).

The potential confounders of age, sex, socioeconomic status, and nicotine dependence showed no differences between intervention and controls. At all three time points, there was



Participant flow and follow up.

greater use of patches in those who stopped smoking, but the type of product used was not significantly related to smoking cessation (one month $p = 0.10$, four months $p = 0.45$, nine months $p = 0.53$). The estimates of intra-cluster correlation (ρ) for the outcomes at each time point were calculated. The estimated values were less than 0.0001 and therefore negligible. The design effect (DE) of cluster randomisation is given by $DE = [1+(n-1)\rho]$ ³⁵ and so depends also on the average size of the cluster or pharmacy, which in

this study was approximately 5, on average. Even assuming an intra-cluster correlation of 0.001, this would give a design effect of 1.004, which leaves the variance relatively unchanged. Thus the cluster design had a negligible effect and the analysis could be treated as if by subject.

Pharmacy Support Programme: registration, counselling and recording

The intervention pharmacies recruited fewer customers and recorded more non-recruits

Table 1 Characteristics of the study population

	Intervention recruits		Control recruits		χ^2/t	df	p
	%	n	%	n			
Gender		224		263	$\chi^2 = 0.04$	1	0.85
Men	38.8	87	37.3	98			
Women	61.2	137	62.7	165			
Age (in years)		133‡		158‡			
Range	17–74		17–77		$t = 0.04$	280	0.97
Mean	41.7		41.5				
Standard error	1.12		0.98				
Socioeconomic status*		210		258			
Range	1–7		1–7		$\chi^2 = 9.77$	6	0.13
Mean	3.0		3.4				
Standard error	0.13		0.12				
FTND†		134‡		159‡			
Range	0–10		0–10		$\chi^2 = 1.29$	4	0.86
Mean	5.2		5.2				
Standard error	0.20		0.20				
Very low (0–2)	14.2	19	15.1	24			
Low (3–4)	23.1	31	21.4	34			
Medium (5)	13.4	18	16.4	26			
High (6–7)	32.8	44	28.3	45			
Very high (8–10)	16.5	22	18.9	30			
Anti-smoking aid		224		268			
Product used	97.8	219	92.5	248	$\chi^2 = 6.92$	1	0.0085
No product used	2.2	5	7.5	20			
Type of product		219		248			
Nicotine patch	79.0	173	66.9	166	$\chi^2 = 4.75$	1	0.029
Nicotine gum	19.6	43	25.8	64			
Other	1.4	3	7.3	18			

*Carstairs Morris deprivation score (1992), where 1 is affluent and 7 deprived.²⁸

†Fagerström test for nicotine dependence.²⁹

‡One-month respondent data.

than their control counterparts (figure 1); however, these trends were not statistically significant. The most commonly cited reasons for non-registration were that the subject was not a regular customer (36.0% intervention and 40.4% controls), did not have enough time to get involved (23.3% intervention, 25.5% controls), saw no value in the study (16.9% *vs* 14.0%), or felt the study would be an intrusive pressure (13.2% *vs* 7.4%).

The one-month follow-up data in table 3 showed that the intervention respondents were significantly more likely to have discussed stopping smoking with pharmacy personnel ($p < 0.001$); they also rated their discussion with the pharmacy personnel more highly ($p = 0.048$). At the time of their initial purchase, intervention customer respondents were significantly more likely to report having been asked about their health ($p = 0.0025$) and advised on the strength of NRT ($p = 0.0037$). They were also significantly more likely to report that “helpful support from pharmacy staff” had contributed to their not smoking ($p = 0.013$).

The four-month customer follow up provided data on the Pharmacy Support Programme, the attitudes of intervention and control customers to registration (using the same pharmacy throughout their attempt to

stop smoking and having personal information held by that pharmacy), and intervention customers’ experience of counselling and the recording of their progress. About half in each group thought it would be helpful to always use the same pharmacy. Sixty per cent of the intervention respondents rated the pharmacy counselling as having been helpful, whereas only 40% rated the client records as helpful (table 3).

The semi-structured telephone interviews with pharmacy personnel revealed that half had experienced difficulties when asking local customers to register with the pharmacy; these included customer and pharmacy time constraints, and customer reticence. Customer telephone interviews showed that most interviewees (19/25 intervention, 13/25 controls) felt it was helpful to always use the same pharmacy because it encouraged the development of a long-term supportive relationship with pharmacy personnel. Five intervention customers and 12 controls felt it made “no difference”, the most common reasons being that pharmacies were equally good and that, after learning about the product during the initial consultation, any pharmacy could be used for further supplies.

Most customers (20/25 intervention, 19/25 controls) rated the counselling helpful, particularly appreciating ongoing product advice and friendly interest and encouragement. Several highlighted personal motivation as the most important factor in stopping smoking; however, encouragement from pharmacy personnel was a useful adjunct.

None of the interviewees mentioned dissatisfaction with regard to which member(s) of the pharmacy team provided the counselling. Almost half (12/25 intervention, 10/25 controls) were counselled by the pharmacist and the assistants. The counter assistant was the only point of contact for more than a quarter of interviewees, whereas a quarter were only counselled by the pharmacist. Almost all the pharmacy interviewees (10/10 pharmacists, 9/10 assistants) were positive about counselling. However, in practice, many factors interacted to influence counselling—for example, the smoker’s perceived need for support, pharmacy and customer time constraints, and the practical reality of counselling in the commercial setting of community pharmacy. Some found that commercial advertising encouraged customers to request advice, whereas others found it a barrier to counselling because of customers having firmly held unrealistic expectations of particular products.

Table 2 Smoking cessation outcomes

	Intervention		Control		Difference		p
	%	n	%	n	%	95% CI	
One-month point prevalence	29.9	66	23.6	61	6.3	–1.6–14.2	0.12
Total n		221		259			
Four-months continuous abstinence	16.1	35	10.9	28	5.2	–1.0–11.4	0.094
Total n		217		257			
Nine-months continuous abstinence	12.0	26	7.4	19	4.6	–0.8–10.0	0.089
Total n		217		257			

Table 3 Pharmacy Support Programme: registration, counselling, and client record

	Intervention		Control		χ^2	df	p
	%	n	%	n			
Pharmacy personnel discussed stopping smoking	85.0	133	62.3	159	18.7	1	0.00001
Usefulness of discussion							
1—Very useful	33.8	45	15.7	25			
2	30.8	41	29.5	47			
3	17.3	23	11.3	18			
4—Not at all useful	3.0	4	5.7	9	7.9	3	0.048
Asked about health		131		150			
	63.4	83	45.3	68	9.1	1	0.0025
Advised on product strength		132		149			
	88.6	117	75.2	112	8.4	1	0.0037
Advised on how to use product		135		152			
	77.8	105	71.1	108	1.7	1	0.19
Reason which may have contributed to not smoking		61		65			
Helpful support from pharmacy							
Very much	19.7	12	7.7	5			
Quite a lot	13.1	8	12.3	8			
A little	49.2	30	36.9	24			
Not at all	18.0	11	43.1	28	10.8	3	0.013
Helpful to always use the same pharmacy		123		145			
	55.3	68	46.9	68	2.7	2	0.26
Talking to pharmacy staff helpful		124					
Yes	59.7	74					
It made no difference	32.3	40					
No	8.1	10					
Helpful to know pharmacy keeping a record of progress		124					
Yes	39.4	49					
It made no difference	49.2	61					
No	11.4	14					
Tried before to stop smoking using an anti-smoking product		126		149			
	50.0	63	55.7	83	0.89	1	0.34
Comparison with previous attempt(s):							
Better	49.2	31	19.3	16			
Same	46.0	29	73.5	61			
Worse	4.8	3	7.2	6	14.7	2	0.00064

Pharmacy and customer interviewees were less enthusiastic about the records than the counselling. Pharmacy personnel identified several barriers to maintaining the client records, including pharmacy constraints (in particular, time, privacy, and part-time staff) and customer aversion towards the formality of the record. However, two-thirds of the intervention customers (16/25) felt it had been helpful to know that the pharmacy was recording their attempt; several commented it provided additional encouragement.

Comparison with previous attempt(s)

About half the respondents to the four-month questionnaire in each group had made at least one previous attempt to stop smoking using an anti-smoking product (table 3). When asked to compare the current pharmacy support with previous attempts, the intervention group were significantly more likely to rate their support as "better" whereas the controls were more likely to rate it as the "same" ($p < 0.001$). Eleven intervention interviewees and seven controls rated the pharmacy support this time as having been "better", whereas two intervention and nine controls rated it as the "same". Many highlighted a lack of communication during previous attempts, with the prevailing attitude having been "just another sale". Customers particularly valued talking to the pharmacy personnel to gain information on the various products and the personal interest taken in their attempt.

Discussion

Ideally, the pharmacies should have been unaware as to which group they had been allocated²⁶ and researchers should have remained unaware of the group assigned for as long as possible to prevent the introduction of bias by the investigators, who might interpret the results differently³⁶; however, despite the superiority of this approach, blind allocation of pharmacies was not a practical option because of the training intervention. Furthermore, a possible limit on the external validity of the results was the potential impact of expected follow-up measures on training effectiveness and pharmacist compliance. Intervention pharmacy personnel knew that their performance would be evaluated, building in an accountability factor that would not be present in replications that took place outside the context of a formal evaluation; however, the control pharmacy personnel also knew they were being monitored.

Our study aimed to capture a population representative of smokers who enter community pharmacies to purchase an anti-smoking aid or to seek advice on stopping smoking. The generalisability of the results was compromised by the need to exclude city pharmacies to prevent cross contamination with a similar training initiative for GPs, practice nurses, and health visitors.²³ Comparisons with national data³⁷ highlight the under-representation of urban pharmacies and a higher proportion of single outlets and fewer large multiples (chains) in the study population. However, the

high participation rate means that the results can be said to be representative of the population of non-city Grampian pharmacy personnel.

The study failed to reach its recruitment target, recruiting only half the required number of customers; thus, the power of the study was reduced to the 10% level. This was due to two main factors. Firstly, local wholesale figures for NRT products highlight a major decline in sales during the three-year period from 1993–1996 (personal communication, AAH Pharmaceuticals Ltd, 1996). Secondly, the study failed to recruit all the eligible customers; in both groups the most common reason for non-registration was that the subject was not a regular customer. However, analysis showed that the two arms of the study were well balanced in terms of the potential confounders of age, sex, socioeconomic status,²⁸ and nicotine dependence.²⁹ Thus, despite the indeterminate biases resulting from customer self-selection and selective recruitment of customers by pharmacy personnel and the possible limitations on the external validity of the results, we consider that the descriptive data and self-reported abstinence data are worth reporting, given the dearth of similar research data on the utility of the model in the pharmacy setting.²⁰

The study demonstrated the utility of the stage-of-change model in a pharmacy setting. As reported elsewhere, there was almost unanimous agreement by the workshop participants that the model was a good way of understanding stopping smoking, and that the training had made a difference to the way they counselled customers and had helped them to help their customers.²⁵ This was confirmed by the customers, as both questionnaire and telephone interview data demonstrated that significantly more intervention subjects rated the pharmacy support as better than on previous attempts and subsequently achieved higher smoking cessation rates compared with the controls.

The intervention was associated with increased and more favourably rated counselling; in particular, intervention respondents were significantly more likely to have been asked about their health and advised on the strength of NRT at the time of their initial purchase. Most telephone interviewees reported that talking to pharmacists or pharmacy assistants had been helpful, most highlighting the additional encouragement, whereas others reportedly valued the professional product advice. The study highlighted the key role of pharmacy assistants^{38, 39} in providing much of the product advice and ongoing counselling.

The RPSGB guidelines on smoking cessation advice in the pharmacy¹³ recommend the recording of advice and treatment given. Although customers and pharmacy personnel were more positive about counselling than about client records, ways of publicising new services to customers should be developed because a significant number of intervention customers felt the records had been an

additional encouragement. Pharmacy personnel should offer support; however, while still meeting professional requirements, they should also be sensitive to the wishes of the minority of customers who prefer to make an autonomous purchase without any input from the pharmacy.^{40, 41}

About half the intervention and control respondents thought it was helpful to always use the same pharmacy throughout their attempt to stop smoking, and customer and pharmacy interviewees highlighted the benefits of fostering a long-term supportive rapport. At present, British pharmacies do not have registered populations and their informal accessibility is seen as a major strength.⁴² Registration could potentially damage this positive aspect. However, the wider use of patient-held health cards⁴³ and electronic data interchange could facilitate the provision of seamless care among different community pharmacy outlets and across the primary healthcare team.

The study demonstrated that the intervention produced favourable trends in self-reported smoking cessation outcomes, the results being robust to potential confounders and to the adjustment for clustering. However, these treatment effects did not reach statistical significance. There was a greater use of nicotine patches relative to nicotine gum by the intervention group, but smoking cessation outcome was not strongly related to the type of product used.

The unit of randomisation was the pharmacy; therefore, it could not be assumed that the individuals included in the analysis were independent (a reasonable assumption had the randomisation been by subject). However, the degree of intra-cluster randomisation was shown to be negligible and so the randomisation by pharmacy had no inflationary effect on the variance of the regression coefficients and the results could therefore be treated as if randomisation was by subject.

The response rates of the intervention and control subjects were very similar at each of the follow ups, so the outcome rates were not distorted by numerator biases. For example, a higher response rate in either group would have potentially uncovered more successful subjects and would have given a better smoking cessation outcome rate (the conventional assumption being that non-responders had lapsed).

We hope this study's findings will encourage more widespread use of pharmacy personnel to provide effective ongoing support for patients who are trying to stop smoking.¹¹ The wider adoption of this training programme would be expected to increase the effectiveness of NRT and would make an important contribution to patient care and the achievement of national smoking cessation targets.^{44, 45}

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- 1 Lennox AS, Taylor RJ. Factors associated with outcome in unaided smoking cessation, and a comparison of those who have never tried to stop with those who have. *Br J Gen Pract* 1994;44:245-50.
- 2 Curry S, Thompson B, Sexton M, et al. Psychosocial predictors of outcome in a worksite smoking cessation programme. *Am J Prev Med* 1989;14:23-33.
- 3 Sinclair HK, Bond CM, Lennox AS, et al. Nicotine replacement therapies: smoking cessation outcomes in a pharmacy setting in Scotland. *Tobacco Control* 1995;4:338-43.
- 4 Lichtenstein E, Russell E. Smoking cessation: what have we learned over the past decade? *J Consult Clin Psychol* 1992;60:518-27.
- 5 Royal Pharmaceutical Society of Great Britain. *Medicines, ethics and practice: a guide for pharmacists*. London: RPSGB, 1995.
- 6 Bond CM, Sinclair HK, Winfield AJ, et al. Community pharmacists' attitudes to their advice giving role and the deregulation of medicines. *Int J Pharm Pract* 1993;2:26-30.
- 7 National Audit Office. *Community pharmacies in England*. London: HMSO, 1992.
- 8 Martinez PJ, Knapp J, Kottke TE. Beliefs and attitudes of Minnesota pharmacists regarding tobacco sales and smoking cessation counselling. *Tobacco Control* 1993;2:306-10.
- 9 Eaton G, Webb B. Boundary encroachment: pharmacists in the clinical setting. *Sociol Health Illness* 1979;1:69-89.
- 10 Roberts D. Dispensing by the community pharmacists: an unstoppable decline? *J R Coll Gen Pract* 1988;38:563-4.
- 11 Bond CM, Sinclair HK, Taylor RJ, et al. Pharmacists: a resource for general practice? *Int J Pharm Pract* 1995;3:85-90.
- 12 Anon. Pharmaceutical Journal practice checklist: nicotine replacement therapy. *Pharm J* 1993;255:291.
- 13 Anon. Advising on how to stop smoking: guidelines on smoking cessation advice in the pharmacy. *Pharm J* 1994;252:816.
- 14 Russell IT, Grimshaw JM. The effectiveness of referral guidelines: a review of the methods and findings of published evaluations. In: Roland M, Coulter A, eds. *Hospital referrals*. Oxford: Oxford University Press, 1992.
- 15 Rollnick S, Kinnerley P, Stott N. Methods of helping patients with behaviour change. *BMJ* 1993;307:188-90.
- 16 Naidoo J, Wills J. *1994 health promotion: foundations for practice*. London: Baillière Tindall 1994.
- 17 Prochaska JO, DiClemente CC. Stages and processes of self change of smoking: toward an integrative model of change. *J Consult Clin Psychol* 1983;51:390-5.
- 18 Prochaska JO, Goldstein MG. Process of smoking cessation: implications for clinicians. *Clin Chest Med* 1991;12:727-35.
- 19 Velicer WF, Prochaska JO, Bellis JM, et al. An expert system intervention for smoking cessation. *Addict Behav* 1993;18:269-90.
- 20 Ashworth P. Breakthrough or bandwagon? Are interventions tailored to stage of change more effective than non-staged interventions. *Health Educ J* 1997;56:166-74.
- 21 Mant D, Fowler G. Effectiveness of a nicotine patch in helping people stop smoking: results of a randomised trial in general practice. *BMJ* 1993;306:1304-8.
- 22 Goldberg DN, Hoffman AM, Farinha MF, et al. Physician delivery of smoking cessation advice based on the stages-of-change model. *Am J Prev Med* 1994;10:267-74.
- 23 Stott NCH, Rollnick S, Rees MR, et al. Innovation in clinical method: diabetes care and negotiating skills. *Fam Pract* 1995;12:413-18.
- 24 Lennox AS, Groves J, Silcock J, et al. *The cost effectiveness of brief training for the primary health care team in facilitating smoking behaviour change. Report to the Scottish Office Home and Health Department*. Aberdeen: University of Aberdeen 1996.
- 25 Sinclair HK, Bond CM, Lennox AS, et al. An evaluation of a training workshop for community pharmacists and pharmacy assistants based on the stages of change model of smoking cessation. *Health Educ J* 1997;56:296-312.
- 26 Farmer R, Miller D. *Lecture notes on epidemiology and public health medicine*. Oxford: Blackwell Scientific, 1994.
- 27 Velicer WF, Prochaska JO, Rossi JS, et al. Assessing outcome in smoking cessation studies. *Psychol Bull* 1992;111:23-41.
- 28 Carstairs V, Morris R. *Deprivation and health in Scotland*. Aberdeen: Aberdeen University, 1991:305-17.
- 29 Heatherston TF, Kozlowski LT, Frecker RC, et al. The Fagerström test for nicotine dependence: a revision of the Fagerström tolerance questionnaire. *Br J Addict* 1991;86:1119-27.
- 30 SPSS for Windows v.6.1.3 software manual. Chicago, Illinois: SPSS, 1995.
- 31 Dixon WJ. *BMDP statistical software manual*. Berkeley, California: University of California, 1993.
- 32 Collett D. *Modelling binary data*. London: Chapman & Hall, 1991.
- 33 Genstat 5 Committee. *Genstat 5 reference manual*. Oxford: Clarendon Press, 1993.
- 34 Casagrande JT, Pike MC, Smith PG. The power function of the 'exact' test for comparing two binomial distributions. *Appl Stat* 1978;27:175-80.
- 35 Moser C, Kalton G. *Survey methods in social investigation*. London: Heinemann, 1979.
- 36 Baker TL. *Doing social research*, 2nd ed. New York: McGraw-Hill, 1994.
- 37 Bond CM, Taylor RJ, Sinclair HK, et al. Some characteristics of Scottish community pharmacies: how far has Nuffield been implemented? *Pharm J* 1992;249:R6.
- 38 Jepson M, Jesson J, Kendall H, et al. *Consumer expectations of community pharmacy services*. London: Department of Health, 1991.
- 39 Hassell K, Harris J, Rogers A, et al. *The role and contribution of pharmacy in primary care*. Manchester: National Primary Care Research and Development Centre, 1996.
- 40 Taylor J. Reasons consumers do not ask for advice on non-prescription medicines in pharmacies. *Int J Pharm Pract* 1994;2:209-14.
- 41 Bond CM, Bradley C. The interface between the community pharmacist and patients. *BMJ* 1996;312:758-60.
- 42 Royal Pharmaceutical Society of Great Britain. *Pharmacy in a new age: the new horizon*. London: RPSGB, 1996.
- 43 Hickey F. Innovations in prescribing information report of the UK Drug Utilisation Research Group Regional Meeting, King's Conference Centre, University of Aberdeen, 31 May 1995. *Pharmacoepidemiol Drug Safety* 1996;5:263-7.
- 44 Secretary of State for Health. *The health of the nation: a strategy for health in England (Cm 1986)*. London: HMSO, 1992.
- 45 Scottish Office. *Scotland's health: a challenge to us all*. Edinburgh: HMSO, 1992.