A controlled trial of an expert system and self-help manual intervention based on the stages of change versus standard self-help materials in smoking cessation

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ABSTRACT

Aim To examine the population impact and effectiveness of the Pro-Change smoking cessation course based on the Transtheoretical Model (TTM) compared to standard self-help smoking cessation literature.
Design Randomized controlled trial.
Setting Sixty-five West Midlands general practices.
Participants Randomly sampled patients recorded as smokers by their general practitioners received an invitation letter and 2471 current smokers agreed.
Interventions Responders were randomized to one of four interventions. The control group received standard self-help literature. In the Manual intervention group, participants received the Pro-Change system, a self-help workbook and three questionnaires at 3-monthly intervals, which generated individually tailored feedback. In the Phone intervention group, participants received the Manual intervention plus three telephone calls. In the Nurse intervention group, participants received the Manual intervention plus three visits to the practice nurse.
Measurements Biochemically confirmed point prevalence of being quit and 6-month sustained abstinence, 12 months after study commencement.
Findings A total of 9.1% of registered current smokers participated, of whom 83.0% were not ready to quit. Less than half of participants returned questionnaires to generate second and third individualized feedback. Telephone calls reached 75% of those scheduled, but few participants visited the nurse. There were small differences between the three Pro-Change arms. The odds ratio (95% confidence intervals) for all Pro-Change arms combined versus the control arm were 1.50 (0.85–2.67) and 1.53 (0.76–3.10), for point prevalence and 6-month abstinence, respectively. This constitutes 2.1% of the TTM group versus 1.4% of the control group achieving confirmed 6-month sustained abstinence.
Conclusions There was no statistically significant benefit of the intervention apparent in this trial and the high relapse of quitters means that any population impact is small.

KEYWORDS Smoking cessation, Transtheoretical Model.

INTRODUCTION

The British Government's smoking cessation strategy is to train general practitioners (GPs) to increase the proportion of smokers that they advise to stop smoking and to encourage patients intending to act on this advice to attend smoking cessation clinics (Secretary of State for Health 1998). The guidelines for this strategy suggest that this could increase the number of smokers who attempt to stop each year in England from about 3.4 mil-

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lion to about 4.7 million (Raw, McNeill & West 1998). However, in the financial year 2000–2001, only 127 000 people set quit dates using the network of new smoking cessation clinics to assist them to stop smoking. Consequently, most smokers who try to stop will not use the clinics, but 3% of smokers who try to stop without assistance will succeed, whereas up to 20% of those attending the clinics will succeed (Raw *et al.* 1998). Self-help methods for the majority of smokers quitting unaided could be important adjuncts to the national strategy.

Lennox *et al.* (2001) tested the effect of a one-off letter from GPs to registered smokers, advising smokers to quit and how to quit, which was either tailored or not tailored to individuals' stage of change. There was little difference in the effect of the two letters, but meta-analysis of the two showed that receipt of a letter increased the smoking cessation rate compared to those not sent a letter (Aveyard 2001). In this study, however, the intervention was one-off, and constituted the written equivalent of GPs' brief advice to quit smoking, with which it seems equivalently effective (Silagy & Stead 2002).

Velicer *et al.* (1993) have developed self-help interventions, based on the Transtheoretical Model (TTM), designed as substitutes for skilled smoking cessation counselling. Taking their results at face value, their trials show that over 80% of smokers registered with health maintenance organizations or recruited by cold-call telephone enrolled in self-help smoking cessation courses, perhaps because participants were approached with messages that acknowledged that they may not be ready to quit imminently (Prochaska *et al.* 1993; Velicer *et al.* 1999; Prochaska *et al.* 2001a, 2001b). These courses achieved quit rates equivalent to those achieved using smoking cessation counselling and nicotine replacement therapy (NRT). The intervention included a stage-based manual, which gives a detailed description of where individuals are in the stopping process, and provides exercises that engage the appropriate processes of change to move forward. This was supplemented by an expert system letter. This letter is generated by individuals completing a questionnaire describing their stage of change, processes of change, self-efficacy and decisional balance. This is processed using computerized decision rules to produce individualized smoking cessation strategies (Velicer *et al.* 1993). This process was repeated every few months. This Pro-Change system is available in a UK-wide high street pharmacist, and has been used in health authorities' smoking cessation interventions.

One problem with Prochaska *et al.*'s studies is that the outcome is self-reported point prevalence of smoking cessation. Data from Lennox *et al.* (2001) suggest that even in low-contact trials, this outcome will overestimate the absolute benefit. In this report, we examine the effectiveness of the Pro-Change system in recruiting a large proportion of smokers and in increasing the quit rate over simple smoking cessation advice, with cotinine validation of smoking status.

METHOD

Participants

Participants were recruited in three waves. We wanted to estimate the proportion of smokers that could be recruited from British general practice, so for wave 1 we used random sampling to select participants. West Midlands GP practices were selected with probability proportional to size (number of partners), and then a fixed number of patients (300) were selected randomly for invitation. All practices were eligible to enter the trial, providing they could accomplish this task, and all selected patients were eligible unless they were terminally ill, violent, or other unusual circumstances pertained. In effect, the trial was restricted to practices with computerized lists with smoking status recorded. We assisted practices with the random selection process, while maintaining confidentiality.

Some practices were slow in sending out recruitment packs, but from the first practices in wave 1, it was clear that insufficient participants would be recruited. Consequently, we invited the originally recruited practices to repeat the process of randomly selecting patients (wave 2). When wave 2 failed to reach the target number, non-randomly selected new practices were approached to participate and send out recruitment packs. Wave 3 practices selected potential participants randomly in the same manner as waves 1 and 2. In waves 2 and 3, the number of packs per practice was determined by the practice. The invitation pack contained a covering letter from the GP to patients expressing concern about smoking, assuring patients that it was almost never too late to stop smoking, and offering help to stop smoking at the surgery, if not by trial entry. In all waves, invitees were eligible to participate if they were current smokers and regardless of intention to stop smoking. Participants signalled consent by returning the baseline questionnaire, and no reminder recruitment packs were sent.

Interventions

On receipt of the baseline questionnaire, we sent participants in the control arm four standard items of self-help materials. These were 'Stopping smoking made easier', a 24-page A6-size manual on how to stop, 'The quit guide to stopping smoking', a 12-page A5-size booklet which is a dispassionate consumer review of different smoking cessation aids, and two cards shaped like credit cards. One card gave bullet points covering the benefits of smoking

cessation, and the other gave bullet points concerning tips for staying quit. Both cards and the quit booklet contained the Quitline (smoking cessation helpline) number.

On return of the baseline questionnaire, participants in all three intervention arms were sent the TTM-based 'Pro-Change programme for a healthier lifestyle', a 64-page A5 colour booklet. The introduction enabled participants to stage themselves. Unlike the control literature, the Pro-Change book contained many exercises designed to help participants use the processes of change that were appropriate for moving from their current stage. This booklet was an anglicized version of the one used in the American trials. Participants also received the expert system letter: a personalized six to eight-sided letter based on their responses from the questionnaire. This gave feedback on stage of change, decisional balance, temptations and self-efficacy and the processes of change. On the second and third occasions it described progress from the previous report. The expert system was identical to that used in the American trials (Prochaska *et al.* 1993; Velicer *et al.* 1999; Prochaska *et al.* 2001a, 2001b).

Participants in the three intervention arms were sent the same questionnaire 3 months after returning the baseline questionnaire; this was used to generate a second expert system letter, and 3 months later to generate the third expert system letter. Non-responders to the initial questionnaire were reminded 2 weeks later by letter, 2 weeks later and 2 weeks later still by telephone (or mail if we did not have their number).

Participants in one of the intervention arms ('Manual') received only the interventions described above, but in two others ('Telephone' and 'Nurse'), these interventions were augmented. Participants in the Telephone arm received a telephone call at baseline, 3 months and 6 months, provided that participants had returned these questionnaires. Four attempts per intervention period were made to reach participants on the telephone. The calls were made mainly by postgraduate students who had received 3 hours' training. The calls were made using a 'live' Access database (Microsoft), and although they would have appeared somewhat interactive to recipients, all the text was scripted. The text of each of the three intervention calls varied, but the aim of each call was to explain different elements of the Pro-Change system and how to use the materials. They were designed as reminders, rather than as motivational calls.

Participants in the Nurse arm were asked to make an appointment to see a named member of their practice staff (usually a practice nurse) if they had returned their questionnaire. The practice nurses attended a 2-day training course, conducted by Pro-Change trainers. Practice nurses were sent a copy of the expert system letter. They were asked to stage participants, ensure that participants understood the Pro-Change system and encourage them to use it, and perhaps conduct one of the exercises in the Pro-Change manual with the patient in the clinic. Nurses were asked to send a single reminder postcard if no appointment was made. Apart from this, all the scheduling, reminding, and tracking was automated in a computerized Access database.

The rationale for our intervention choices was as follows. We had an active intervention for the control group because, having had their GP express concern about smoking in a letter, we felt it was appropriate that participants had at least some assistance. The effect of standard self-help literature over no intervention is very low (Lancaster & Stead 2002a). The other three arms replicated the basic Pro-Change system, apparently successful in America. The Telephone augmentation was used because it seemed to enhance the effectiveness of self-help interventions in some trials (Lancaster & Stead 2002), and we felt the National Health Servece (NHS) could implement this intervention, if successful. The Nurse augmentation was used because it capitalized on the relationship between general practice staff and some patients. All participants, regardless of arm, had access to a Freephone number to contact the research team. This was used mainly for administration purposes, but a handful of participants discussed methods of smoking cessation with one of the research team on a one-off basis.

Outcomes

We used the point prevalence of being quit at 12 months as our primary outcome measure. This was because it was the measure reported in most detail in the American trials (Prochaska *et al.* 1993, 2001a, 2001b; Velicer *et al.* 1999), was verifiable by cotinine and was theoretically appropriate. Prochaska *et al.* (1993, 2001b) have claimed that individuals using the stage-based approach continue changing after the end of the intervention in a way that individuals who have experienced traditional interventions do not. Point prevalence of being quit would capture these late changers, which was assessed by responses to the question 'Are you currently a cigarette smoker?' on the questionnaire sent exactly 12 months from return of the first questionnaire. This outcome was confirmed with salivary cotinine, so that we had unconfirmed and confirmed prevalence of quitting. Salivary cotinine was obtained by visit to the participant's house or by post. Participants were reminded of cotinine validation on the covering letter accompanying the 12-month questionnaire. Whether by post or visit, requests for saliva were accompanied by a questionnaire where participants could admit to relapse. The cotinine was analysed by Advanced Bioanalytical Service Laboratories Ltd using capillary gas chromatography, and values over 14.2 ng/ml were taken as indicative of active smoking.

Our secondary outcome was point prevalence of sustained abstinence of at least 6 months. This was defined either by answering 'no' to the question 'Have you smoked any cigarettes in the last 6 months'.

Sample size

We intended to recruit 3600 participants, 900 per arm, but reduced this to 2500 total because of recruitment difficulties. Because of unequal allocation, this provided about 700 in the control arm and 1800 in the three intervention arms, providing over 80% power to detect a relative risk of quitting of 1.40 [equivalent to an odds ratio (OR) of 1.47], assuming 10% quit in the control group and a 5% type 1 error rate, and 80% power to detect a relative risk of quitting of 1.51 (equivalent to an OR of 1.60) for each of the arms versus the control group. The single trial comparing manuals and expert system letters versus standard self-help literature presented data implying larger relative benefits than these (Prochaska *et al.* 1993).

Allocation

Minimization was used to allocate individuals to arms to balance three predictors of smoking cessation success (White & Freedman 1978): stage of change (three stages), addiction score (three groups) and socio-economic status (three groups). Balance was assessed within each practice. Questionnaires were read optically and the data transferred automatically to the Access database that performed the minimization and controlled the contacts. There was no reason and no way that the clerical assistant running the database could alter the questionnaire reading schedule, which would have altered the allocation of particular individuals. Nevertheless, there was a 10% chance that the allocation was assigned randomly to an arm other than that indicated by the minimization algorithm.

Insufficient participants necessitated wave 3 recruitment of new practices. We had insufficient funds to pay for the training of these practice nurses and, in any case, it was clear by then that participants were not coming to see the nurse. Therefore the minimization algorithm was amended to allocate individuals only to the three remaining arms.

Statistical methods

The recruitment of new practices in wave 3 where participants were allocated to only three arms complicated the analysis, because we had no guarantee overall that participants' characteristics were balanced between arms. We therefore analysed the data as though they were two separate trials. We calculated the percentage of quitters in each arm, and performed an overall χ^2 test for the difference between arms. We calculated ORs for the risk of quitting relative to the control arm, and the percentage and OR for quitting in all TTM arms combined relative to the control arm.

We examined whether there was a difference between the four-arm and three-arm trials in the effectiveness of the intervention arms relative to the control arm by adding a multiplicative term for trial (four-arm versus three-arm) × trial arm to a logistic regression equation containing terms indicating arm and trial. This is equivalent to a χ^2 test for heterogeneity. However, we felt that the most appropriate analysis was to combine all arms in logistic regression, adjusting only for trial (four-arm versus three-arm), equivalent to meta-analysis. Finally, we checked that imbalance of important predictors of smoking cessation (in Table 1) did not influence the ORs in logistic regression. The unadjusted and adjusted ORs were similar, so the latter are not reported (but are available on our website, available at http://www.publichealth.bham.ac.uk/berg/).

Ethical committee approval

We obtained approval from the multi-centre and all West Midlands local research ethics committees.

RESULTS

Recruitment

Participants were recruited to wave 1 between 6/8/98 and 26/2/99, wave 2 between 2/1/99 and 7/6/99, and in wave 3 between 2/1/99 and 2/12/99. Invitees who did not want to participate were encouraged to return a decline questionnaire giving reasons (Fig. 1). Some practices participating in waves 1 and 2 mixed up recruitment questionnaires, so that it was not possible to separate responders to these waves in some cases. The effect of this is that the random sample wave 1 was clouded by oversampling from some practices. Having adjusted for the known non-smokers and non-English speakers that replied, the waves 1 and 2 recruitment rate was 9.9%. Wave 3 constituted randomly selected participants from non-randomly selected practices, and had a response rate of 7.8%. The recruitment pack met its goals of enticing a large proportion of smokers (83.0%) who were not yet ready to quit to enter the study (Table 1).

Baseline data

There were no large differences in the distribution of the predictors of smoking cessation or other

Table 1 Distribution of potential confounding factors in four-arm and three-arm trials combined.

	Control		*Manual*		*Phone*		*Nurse*	
	n	%	n	%	n	%	n	%
Baseline age								
Mean age (SD) years	41 (12)		41 (12)		41 (12)		42 (12)	
Baseline sex								
Female	367	53.2	381	55.8	392	57.2	236	57.1
Male	313	45.4	289	42.3	276	40.3	170	41.2
Missing	10	1.4	13	1.9	17	2.5	7	1.7
Baseline education								
Up to age 15/16	357	51.7	322	47.1	333	48.6	207	50.1
Up to age 18/19	40	5.8	52	7.6	41	6.0	29	7.0
Professional, technical diploma	175	25.4	197	28.8	196	28.6	119	28.8
University degree	69	10.0	72	10.5	75	10.9	34	8.2
Still in full-time education	8	1.2	9	1.3	7	1.0	5	1.2
None of the above	18	2.6	21	3.1	15	2.2	9	2.2
Missing	23	3.3	10	1.5	18	2.6	10	2.4
Baseline social class								
Non-manual	284	41.2	309	45.2	294	42.9	183	44.3
Manual	247	35.8	241	35.3	238	34.7	145	35.1
Other	90	13.0	62	9.1	74	10.8	41	9.9
Missing	69	10.0	71	10.4	79	11.5	44	10.7
Baseline ethnic group								
White	659	95.5	651	95.3	662	96.6	405	98.1
Black groups	9	1.3	8	1.2	5	0.7	1	0.2
Asian groups	4	0.6	2	0.3	2	0.3	1	0.2
Other	9	1.3	12	1.8	8	1.2	4	1.0
Missing	9	1.3	10	1.5	8	1.2	2	0.5
Baseline cigarette consumption								
Median cigarettes per day (10th, 90th percentile)	20 (9, 30)		19 (6, 30)		20 (8, 33)		20 (7, 30)	
Baseline nicotine dependence								
Median FTND score (10th, 90th percentile)	4 (1, 7)		4 (1, 7)		4 (1, 7)		4 (1, 7)	
Baseline stage								
Precontemplation	316	45.8	303	44.4	310	45.3	202	48.9
Contemplation	247	35.8	275	40.3	248	36.2	152	36.8
Preparation	94	13.6	69	10.1	86	12.6	40	9.7
Not able to stage	33	4.8	36	5.3	41	6.0	19	4.6
Partner's smoking habits								
Partner does not smoke	248	35.9	263	38.5	257	37.5	178	43.1
Partner smokes	275	39.9	262	38.4	279	40.7	163	39.5
No partner	156	22.6	146	21.4	140	20.4	69	16.7
Missing data	11	1.6	12	1.8	9	1.3	3	0.7

demographic characteristics between the arms (Table 1).

Numbers analysed

In clinical counselling trials, participants who drop out have often returned to smoking and do not want to admit this to their counsellor (May & West 2000). Consequently it is common to assume that dropouts are smokers, a practice adopted by the Cochrane Tobacco Addiction Review Group (Lancaster & Stead 2002a). Prochaska *et al.* (2001a, 2001b) have challenged the legitimacy of this approach in self-help trials, where no relationship with a therapist exists. We present the results with all randomized in the denominator, and only those followed-up in the denominator.

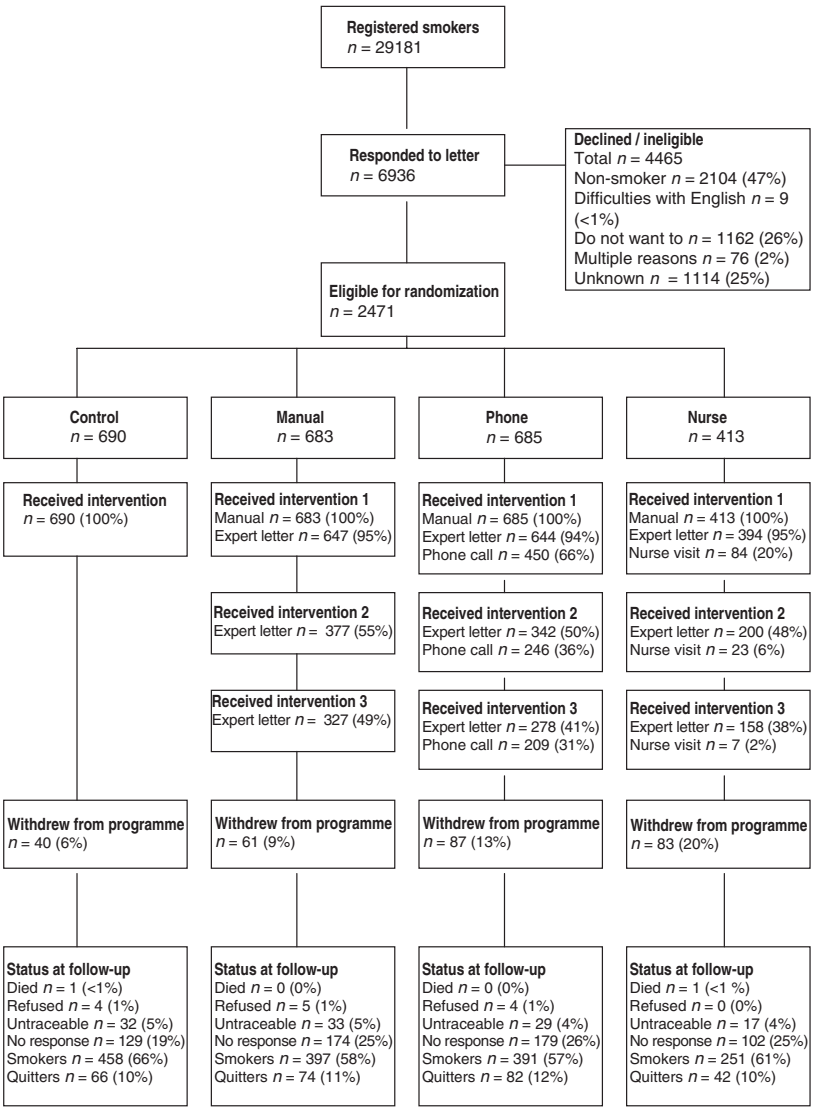

Figure 1 Flow of participants through the trial

Outcomes and estimation

Process data are shown in Fig. 1. Around half of the participants returned questionnaires to allow us to generate the second and third expert letters, which did not vary between the three intervention arms, but this was lower for the third mailing than for the second. Phone calls were only scheduled if a questionnaire was returned, and we made an intervention call with 70–75% of such participants regardless of occasion. The only other process information on this trial relates to the intervention phone calls. Telephonists recorded their impressions of the emotional tone of the intervention call to participants in the Phone arm immediately following the call. They ticked one of seven descriptions plus 'other' directly into a form on the computer database, choosing as many of the following descriptions as applied: keen to talk, warmed up as call proceeded, enthusiastic (positive), neutral, and hostile, uninterested, embarrassed (negative). Positive descriptors were checked in 353 (78%), neutral was checked in 79 (18%), negative descriptors were checked in seven (2%) and other in 11 (2%) first calls. Positive descriptors were checked in 207 (84%), neutral was checked in 25 (10%), negative descriptors were checked in four (2%) and other checked in 10 (4%) second calls. Positive descriptors were checked in 157 (75%), neutral was checked in 40 (19%), negative descriptors were checked in six (3%) and other checked in six (3%) third calls. Nurses reported very low contact rates and, informally, reported that our requests to patients to make appointments caused considerable upset. This arm had the highest withdrawal from intervention.

There was no statistically significant difference between the arms of the trial in the prevalence of self-reported quitting, although all TTM arms showed a

Table 2 Self-reported smoking cessation by trial arm.

	Self-report point prevalence quitting			*Self-report 6-month sustained prevalence quitting*		
	n *(%)*	*Unadjusted OR**	χ^2, P†	n *(%)*	*Unadjusted OR**	χ^2, P†
Intention to treat			2.21, 0.53			4.80, 0.19
Control	66 (9.6)	1.00		40 (5.8)	1.00	
Manual	74 (10.8)	1.15 (0.81–1.63)		43 (6.3)	1.09 (0.70–1.70)	
Phone	82 (12.0)	1.29 (0.91–1.81)		59 (8.6)	1.53 (1.00–2.32)	
Nurse	42 (10.2)	1.07 (0.70–1.63)		30 (7.3)	1.27 (0.76–2.11)	
			4.59, 0.20			6.88, 0.076
Only those followed-up						
Control	66 (12.6)	1.00		40 (7.6)	1.00	
Manual	74 (15.7)	1.29 (0.90–1.85)		43 (9.1)	1.22 (0.77–1.91)	
Phone	82 (17.3)	1.46 (1.02–2.07)		59 (12.5)	1.72 (1.13–2.63)	
Nurse	42 (14.3)	1.18 (0.77–1.82)		30 (10.2)	1.41 (0.84–2.35)	

*Adjusted only for trial (four-arm versus three-arm). †Three degrees of freedom.

Table 3 Cotinine confirmed smoking cessation by trial arm.

	Confirmed point prevalence quitting			*Confirmed 6-month sustained prevalence quitting*		
	n *(%)*	*Unadjusted OR**	χ^2, P†	n *(%)*	*Unadjusted OR**	χ^2, P†
Intention to treat			2.04, 0.56			1.71, 0.64
Control	15 (2.2)	1.00		10 (1.4)	1.00	
Manual	23 (3.4)	1.57 (0.81–3.03)		15 (2.2)	1.53 (0.68–3.42)	
Phone	21 (3.1)	1.42 (0.73–2.78)		14 (2)	1.42 (0.62–3.21)	
Nurse	14 (3.4)	1.54 (0.72–3.31)		9 (2.2)	1.81 (0.69–4.73)	
			3.10, 0.38			2.40, 0.49
Only those followed-up						
Control	15 (2.9)	1.00		10 (9.1)	1.00	
Manual	23 (4.9)	1.74 (0.90–3.38)		15 (3.2)	1.69 (0.75–3.79)	
Phone	21 (4.4)	1.58 (0.80–3.09)		14 (3.0)	1.57 (0.69–3.57)	
Nurse	14 (4.8)	1.69 (0.78–3.64)		9 (3.1)	1.99 (0.76–5.20)	

*Adjusted only for trial (four-arm versus three-arm). †Three degrees of freedom.

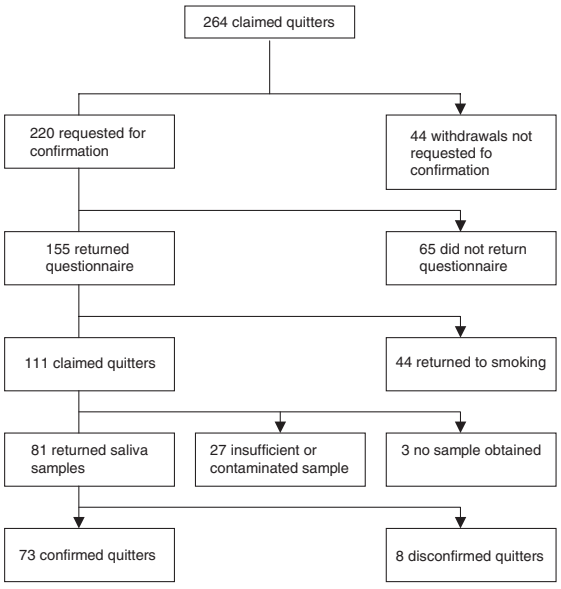

Figure 2 Flowchart detailing attempts to confirm quitting status

small–moderate advantage over the control arm (Table 2). The prevalence of cotinine confirmed that quitting was much lower than self-reported quitting. The major reasons for this were: 44 (17%) quitters were not asked for confirmation as they had withdrawn from the intervention, 65 (25%) did not respond to the request for validation and 44 (17%) admitted to returning to smoking (Fig. 2). These results did not differ between the postal and personal visit methods of saliva collection. (Separate flow diagrams for postal and personal visit methods are available on our website, available at http://www.publichealth.bham.ac.uk/berg/.) Despite the lower absolute prevalence of quitting, the advantage of the TTM arms over the control arm was relatively greater (Table 3). Combination of the TTM arms confirmed this moderate advantage, which was not statistically significant (Table 4).

There was highly statistically significant heterogeneity between the results of the four-arm and three-arm

Table 4 Self-reported and cotinine confirmed quitting in all TTM arms versus the control arm.

	Self-report point prevalence quitting		*Self-report 6-month sustained prevalence quitting*		*Confirmed point prevalence quitting*		*Confirmed 6-month sustained prevalence quitting*	
	n (%)	*Unadjusted OR**	n (%)	*Unadjusted OR**	n (%)	*Unadjusted OR**	n (%)	*Unadjusted OR**
Intention to treat								
Control	66 (9.6)	1.00	40 (5.8)	1.00	15 (2.2)	1.00	10 (1.4)	1.00
TTM	198 (11.1)	1.19 (0.88–1.59)	132 (7.4)	1.30 (0.90–1.86)	58 (3.3)	1.50 (0.85–2.67)	38 (2.1)	1.53 (0.76–3.10)
Only those followed-up								
Control	66 (12.6)	1.00	40 (7.6)	1.00	15 (2.9)	1.00	10 (1.9)	1.00
TTM	198 (16.0)	1.33 (0.99–1.80)	132 (10.7)	1.45 (1.00–2.10)	58 (4.7)	1.67 (0.93–2.97)	38 (3.1)	1.69 (0.83–3.43)

*Adjusted only for trial (four-arm versus three-arm).

studies, which persisted despite adjustment for baseline characteristics (results not shown). Regardless of outcome used or non-adjustment or adjustment for baseline characteristics, in the four-arm study the Phone arm performed best, while the Manual arm performed worse than control. In the three-arm trial the opposite applied. This resulted in statistically significant differences between the arms within trials. The baseline characteristics of trial participants in both trials were similar, the protocol was identical (other than allocating to three or four arms) and the process measures were also similar. Consequently, despite heterogeneity that might suggest that combination of results was unwise, we think that these results were simply unusual happenings, and the combined results are most likely to represent the true effect of the interventions. Tables presenting the baseline characteristics and the results of the three-arm and four-arm trials separately are available on our website, available at http://www.publichealth.bham.ac.uk/berg/.

DISCUSSION

American results showed that a large proportion of smokers could be enrolled into a smoking cessation programme and many would quit (Velicer *et al*. 1999; Prochaska *et al*. 2001a, 2001b). This study aimed to replicate this finding within British general practice, but with rigorous methodology. Proportionately fewer participants were enrolled, fewer quit, and the relative quit rates between the arms were more similar than in the American studies. When asked to confirm their quit status, many self-reported quitters had relapsed. There was little evidence that enhancements to the Pro-Change system were beneficial. The equivalent American trials did not apply such a rigorous method of follow-up and analysis as used in this study. If our results reflect what might have happened had such methods been used, the apparent 'unprecedented impacts on entire populations' (Prochaska & Velicer 1997, p. 47) have been overstated.

Minimization eliminated selection bias and resulted in even distribution of known confounders, and adjustment for these did not change the results. Information bias is also unlikely to have obscured the results of this trial. Contact with participants was by post or telephone according to set scripts, and follow-up was the same in each arm. Prochaska *et al*. (2001a, 2001b) have argued that treating dropouts as continuing smokers is inappropriate. Regardless of whether or not this argument is accepted, whether point prevalence or sustained abstinence, or whether self-report or cotinine confirmed smoking cessation was taken, the results show at best a small benefit for the TTM intervention, which was not significantly different to that of the con-

trol intervention. The method of analysis did not change the results.

Meta-analysis from this study and Prochaska *et al.*'s (1993) study of standard self-help materials versus Pro-Change materials produced an OR (95%CI) of 1.44 (1.03–2.01), with no significant heterogeneity for self-reported point prevalence of quitting. There is therefore some weak evidence that this expert system is effective, but the absolute benefit is low when applied in this way to this population, expressed as the number needed to treat. For every 143 people enrolled on the course, one person achieved long-term (validated) cessation as a result (compared to the number that would have done so had they received standard self-help materials only). However, for every 143 enrolees, 1424 additional people were invited onto the course, but declined. Only 18% of practices approached participated, implying 7247 additional smokers were in practices declining to participate for every 1567 smokers invited in participating practices. Thus, even if the point estimate of the benefit of the intervention is used, we benefited one person in every 8814 people we aimed to help.

What is the role of the Pro-change system in British smoking cessation practice? Currently this system is available in a prominent high street pharmaceutical chain, and our local health authority has invested in this as part of the smoking cessation programme. This system is effective but implementation within primary care, as we tried, was complicated. Several practices needed assistance to send out the recruitment letters despite being paid to do so. The recruitment letter upset a number of patients. The intervention is designed as an alternative to face-to-face counselling, but the OR for such counselling is 1.55 (1.27–1.90) for individual (Lancaster & Stead 2002b) and 2.10 (1.64–2.70) for group counselling compared to brief advice (Stead & Lancaster 2002), implying greater effectiveness than the Pro-Change intervention. Additionally, there is definite evidence that the effects of NRT and counselling are multiplicative (Silagy *et al.* 2002), which is not available for the Pro-Change system. Adding NRT to brief advice from a GP, encouraging GPs to give brief advice to more patients, or increasing the provision of existing smoking cessation services are likely to represent better alternatives for smoking cessation managers (Raw *et al.* 1998). Despite this conclusion, it should be remembered that counselling and NRT are only likely to help those with immediate plans to stop smoking, while the Pro-Change system might benefit a population without such plans (Velicer *et al.* 1999; Prochaska *et al.* 2001a, 2001b). Nevertheless, we conclude that the Pro-Change system is unlikely to provide an important alternative to the current network of smoking cessation clinics and prescription of NRT.

ADDITIONAL INFORMATION

Additional tables and diagrams are available at http://www.publichealth.bham.ac.uk/berg/.

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