

A randomised controlled trial of weekly versus basic smoking cessation support in primary care

Authors

Paul Aveyard^{*1,2}, National Institute of Health Research Career Scientist
Karen Brown², Research Nurse
Cas Saunders², Research Nurse
Avril Alexander², Research Nurse
Elaine Johnstone², Research Fellow
Marcus R. Munafò³, Lecturer
Mike Murphy⁴, Consultant Epidemiologist

Affiliations

1 Department of Primary Care & General Practice
University of Birmingham
Birmingham B15 2TT
UK

2 Cancer Research UK General Practice Research Group
Department of Clinical Pharmacology
University of Oxford
Radcliffe Infirmary
Woodstock Road
Oxford OX2 6HE
UK

3 Department of Experimental Psychology
University of Bristol
12a Priory Road
Bristol BS8 1TU
UK

4 Childhood Cancer Research Group
University of Oxford
57 Woodstock Road
Oxford OX2 6HJ
UK

*** Corresponding author**

Email p.n.aveyard@bham.ac.uk
Tel: 0121 414 8529
Fax 0121 414 6571

the Corresponding Author has the right to grant on behalf of all authors and does grant on behalf of all authors, an exclusive licence (or non exclusive for government employees) on a worldwide basis to the BMJ Publishing Group Ltd and its Licensees to permit this article (if accepted) to be published in [THORAX] editions and any other BMJPG Ltd products to exploit all subsidiary rights, as set out in our licence (<http://thorax.bmjournals.com/fora/licence.pdf>).

Abstract

Background

There is insufficient and conflicting evidence about whether more intensive behavioural support is more effective than basic behavioural support for smoking cessation and whether primary care nurses can deliver effective behavioural support.

Methods

In this randomised controlled trial in 26 UK general practices, 925 smokers of 10 or more cigarettes per day were randomly allocated to basic or weekly support. All participants were seen prior to quitting, telephoned around quit day, and seen one and four weeks after initial appointment (basic support). In weekly support, participants had an additional telephone call at 10 days and three weeks after initial appointment and an additional visit at 2 weeks to motivate adherence to nicotine replacement and renew quit attempts. 15mg/16 hour nicotine patches were given to all participants. The outcome was assessed by intention to treat analyses of the percentage confirmed sustained abstinence at 4, 12, 26, and 52 weeks after quit day.

Results

Of the 469 and 456 participants in the basic and weekly arms, the numbers (percentages) quit and the percentage difference (95% confidence intervals) were 105 (22.4), 102 (22.4), 0.1 (-5.3-5.5) at 4 weeks, 66 (14.1), 52 (11.4), -2.6 (-6.9-1.7) at 12 weeks, 50 (10.7), 40 (8.8), -1.9 (-5.7-2.0) at 26 weeks, and 36 (7.7), 30 (6.6), -1.1 (-4.4-2.3) at 52 weeks.

Conclusions

The absolute quit rates achieved are those expected from nicotine replacement alone, implying that neither basic nor weekly support were effective. Primary care smoking cessation treatment should provide pharmacotherapy with sufficient support only to ensure it is used appropriately and refer those in need of support to specialists.

Key words

Smoking cessation, randomised controlled trial, primary care, behavioural support

Trial registration ISRCTN 05689186

Introduction

Most unassisted attempts to stop smoking end in relapse, mostly within the first few weeks¹. The primary reason for early failure is nicotine withdrawal; low mood, irritability, cravings and other symptoms². Medication alleviates withdrawal symptoms, but does not eliminate them³, and roughly doubles the odds of cessation^{4,5}. Behavioural support includes advice on how to quit, encouragement to cope with withdrawal, and increasing the social cost of relapse⁶. It also doubles the likelihood of cessation^{7,8}. The active components of behavioural support are unknown and it is also unclear how much behavioural support is necessary for its effect and whether more behavioural support is more effective than less support^{7,8}. Three trials examined the effects of intensity of one-to-one support for smoking cessation, summarised in the Cochrane review⁷. Meta-analysis of the results produces an odds ratio (OR) and 95% confidence interval (95%CI) of 0.98 (0.68–1.56), which suggests no benefit of more intensive support but is compatible with a clinically important benefit.

All primary care trusts (PCTs) in England must provide behavioural support and medication to smokers who want to give up, in one of two ways⁹. Specialists, often nurses, provide cessation treatment as their main role, frequently in groups of about 20 participants meeting weekly for an hour seven times. Alternatively, treatment is given by primary care staff trained and monitored by stop smoking services' managers. PCTs vary in the extent to which they provide specialist or primary care nurse support. Guidelines recommend NHS services provide weekly contact⁹, but this intensity is uncommon in primary care cessation programmes. We examined whether weekly behavioural support increased the quit rate relative to basic support in primary care.

Methods

Participants were eligible if they were aged 18 years and over and smoked 10 cigarettes per day or more and were recruited from 26 general practices in Buckinghamshire and Oxfordshire. GPs recruited patients attending for other reasons (n=60, 6.5%), or patients volunteered having seen posters or heard about the study (n=15, 1.6%). In some practices we wrote to every registered smoker offering trial entry (n=850, 91.9%).

Practice nurses excluded only those with contra-indications to nicotine replacement therapy (NRT). Nurses did not record the number of exclusions or people who, on discussion, decided against trial entry, but both were uncommon. All nurses were trained to give NHS smoking cessation support and manage NRT. In Oxfordshire and Buckinghamshire, NHS stop smoking training took two days, with an annual update day and mentoring. Practice nurse provision is the main method of smoking support in Oxfordshire and Buckinghamshire. Nurses received one hour additional training on the trial protocol and documentation.

The trial contrasted primary care nurses' usual level of cessation support with what the NHS stop smoking service recommends as best practice (Figure 1). Normal practice is to see a patient for an initial 20-40 minute assessment, at which medication is prescribed. The patient stops smoking, typically the next day, with follow up by the nurse one to two weeks after the initial assessment (10-20 minutes), and then follow up two to three weeks later (10-20 minutes) to assess the NHS standard four week cessation outcome and prescribe the second half of the eight weeks of medication. In practice, three visits are usual and, if satisfactory appointments cannot be made, the support is delivered by telephone. With the addition of a telephone call around quit day, this comprised the basic support intervention. In this trial, weekly support supplemented basic support with an additional visit at 14 days and additional calls at 10 and 21 days.

The protocol did not specify the nature of the support offered, as this was a trial designed to test NHS practice and protocols and hence fidelity checks were left to the NHS stop smoking services. In NHS practice, telephone support is given as an alternative to a face-to-face consultation and there was no intended difference in the content of visits and calls. Unique to weekly support, because the additional contacts took place later into the quit attempt, a participant whose quit attempt was failing was encouraged to set a new quit date. At NV1, all participants were given and instructed in use of a 15mg nicotine patch to be worn for 16 hours per day for eight weeks, dispensed in two packs four weeks apart (NV1 and NV4).

The primary outcomes were confirmed sustained abstinence at 1, 4, 12, and 26 weeks from quit day. Sustained abstinence was defined as self-reported total abstinence from NV2 providing NV2 was undertaken 14 or fewer days from quit day^{10;11}. At each visit, participants' exhaled carbon monoxide (CO) was measured. Participants were telephoned at 12 weeks (TC4), 6 months (TC5), and 1 year (TC6) from quit day to assess smoking status and those claiming at least 7-day abstinence were asked to return a salivary sample for cotinine concentration measurement. Confirmation of abstinence was defined as an exhaled CO less than 10 parts per million (ppm), or salivary cotinine concentration less than 15ng/ml on each occasion¹². Participants who were withdrawn (which was commonly due to reverting to smoking) or who were lost to follow up (unless they moved to an untraceable address or had died) were counted as smokers, as is standard¹⁰.

We also report NRT use. At the first telephone call (quit day), participants were asked whether they were using NRT and, at NV4, it was also recorded whether the second four-week pack of patches was dispensed. At every other contact up to NV4, the side-effects of NRT were recorded, or left blank if someone was not on NRT. To be classed as using NRT, a person had to have contacted the nurse during the relevant period and be recorded as using NRT at every contact during that period. People who switched to non-trial supplied NRT were counted as using NRT. These data record whether NRT was being used in general and not the degree of adherence.

Based on two similar trials^{13;14}, we anticipated that 35-40% of the smokers would maintain abstinence for one week, 25% at one month, 15% at three months, and 8% at six months. The recruitment target was reduced to 900 because of difficulties. This provides more than 80% power to exclude a 1.5-fold increase in quit rate up to three months, and 52% power at 6 months.

A random number sequence and sealed numbered envelopes were generated by a statistician in Cancer Research UK Medical Statistics Group, Oxford. Nurses opened the envelopes in sequence following eligibility assessment and consent. Participants attending together, such as husbands and wives, were allocated to the same arm. In some cases, envelopes were opened slightly out of sequence, which was inadvertent and not due to dislike of the allocation. The trial statistician was informed and was unconcerned. Participants and nurses were necessarily not blind to allocation, although research staff making follow up phone calls at 3, 6, and 12 months were.

In the analysis, we compared the proportion of smokers quit in each arm, calculating risk differences and ORs and 95% CIs using standard formulae. Logistic regression was used to examine for effect modification.

Results

925 smokers were recruited between July 2002 and March 2005. Although only cigarette smokers were eligible, seven cigar smokers and two pipe smokers were recruited and retained. Likewise, 13 participants reporting fewer than ten cigarettes per day were enrolled, although all reported 10 or more to the nurse assessing eligibility. Mean nicotine dependence scores were similar to those of comparable studies^{13;15} and this and other key confounders were balanced (Table 1).

Table 1 Baseline characteristics of trial participants

	Basic (n=469)	Weekly (n=456)
Female	247 (52.7)	229 (50.2)
Age	42.9 (11.9)	44.3 (11.7)
Ethnic background		
White	431 (98.0)	423 (97.2)
Oriental	0 (0.0)	4 (0.9)
Indian, Pakistani, Bangladeshi	7 (1.6)	8 (1.8)
Other	2 (0.5)	0 (0.0)
Has partner	301 (74.1)	293 (71.5)
Live with smoker	202 (48.1)	189 (44.4)
Weekly units of alcohol ²	8 (18)	6 (15)
Daily cigarette consumption		
1-9	7 (1.6)	6 (1.4)
10	22 (5.1)	27 (6.4)
11-20	221 (50.9)	222 (52.5)
21-30	146 (33.6)	122 (28.8)
>30	38 (8.8)	46 (10.9)
FTND ¹	5.1 (2.2)	5.1 (2.1)
Baseline CO (ppm) ¹	22.6 (10.4)	22.3 (10.0)
Baseline plasma cotinine concentration ¹ (ng/ml)	284 (126)	280 (120)
Longest duration of past quit attempt (days) ²	28 (177)	21 (178)
Age started smoking ¹	16.5 (3.6)	16.3 (3.6)
Smoking product		
Manufactured cigarette	379 (80.8)	360 (78.9)
Roll up cigarette	86 (18.3)	91 (20.0)
Cigar	4 (0.9)	3 (0.7)
Pipe	0 (0.0)	2 (0.4)

1 Mean (SD), 2 Median (IQR)

The number of participants asked by their GPs to participate and who declined and the number of ineligible participants were not recorded. In two practices where we knew the number of smokers invited by letter, 11% and 13% were recruited. Five people were recruited but excluded from the analysis, three because they entered the study twice (their second entry was excluded) and two because the randomisation envelope was not opened and they were not allocated to either arm. There were 431 months of recruitment, meaning that, on average, nurses provided support for 2.1 patients per month.

The most popular quit day was one day after the initial visit, with two-thirds setting quit days within four days of the initial visit. Fifty-eight (12.4%) basic and 49 (10.7%) weekly arm participants did not make a quit attempt. There was some contamination with a few participants in the basic intervention arm making additional visits or calls, but insufficient to alter the results (Figure 2). Only 53% (TC2), 68% (NV3) and 42% (TC3) of participants allocated to the additional support received it, but these were 68%, 95%, and 67% of those participants whose quit attempts were continuing at these times. One effect of weekly contacts might have been to motivate NRT use or manage side-effects resulting in improved

concordance. However, rates of use of NRT were high and not different between arms (Table 2),

Table 2 Use of NRT at various times after quit day in those whose quit attempt was continuing at the relevant time and who had a contact in the relevant period

	Basic			Weekly		
	Using n (%)	Not using n (%)	Missing data n (%)	Using n (%)	Not using n (%)	Missing data n (%)
Days 1-14	335 (97.7)	8 (2.3)	0 (0.0)	333 (97.1)	10 (2.9)	0 (0.0)
Days 15-35	227 (90.4)	23 (9.2)	1 (0.4)	255 (90.1)	28 (9.9)	0 (0.0)
Issued for final 4 weeks	243 (89.0)	18 (6.6)	12 (4.4)	231 (87.8)	14 (5.3)	18 (6.8)

The timing of the support offered differed from the protocol and between participants, with only 63 (13.4%) participants in the basic arm and 35 participants (7.7%) in the weekly arm making all the contacts at the times (+/-4 days) specified. There was evidence of slight significant variation between practices too, with inter-quartile range (IQR) for median days between quit day and NV4 by practice being 2 days (Kruskal Wallis $\chi^2=38.4$, $df=24$, $p=0.032$) (Table 3).

Table 3 Median (25th, 75th centile) for days from quit day for visits and calls WEB

	Basic	Weekly
TC1	2 (1, 3)	2 (1, 3)
NV2	6 (4, 9)	5 (3, 7)
TC2	19 (10, 25)*	10 (8, 14)
NV3	25 (22, 27)*	13 (11, 20)
TC3	27 (21, 31)*	23 (19, 29)
NV4	26 (24, 31)	30 (25, 37)

* Based on 12, 12, and 5 cases (see Figure 2)

At one week, confirmed sustained abstinence was higher for those in the weekly contact arm with a risk difference (95%CI) of 11.6% (5.4%-17.8%) (Table 4, Figure 3). This effect is due to bias because NV2 was scheduled about 3 days after quit day, so that in 75% of participants, the information about week 1 quit status came from visits other than NV2, and there were more early visits in the weekly contact arm. At 4, 12, 26, and 52 weeks, there was no evidence that those in the weekly contact arm were more likely to be quit, with the point estimate of the quit rates favouring the basic support arm. There was no evidence that the confirmed sustained abstinence rate varied by practice ($\chi^2=28.6$, $df=25$, $p=0.28$ at 4 weeks, $\chi^2=30.9$, $df=25$, $p=0.19$ at 6 months). The quit rate at four weeks is considerably lower than the English or local smoking cessation service average (>50%) during these years. One explanation could be that GP referred patients (as is normal in smoking cessation services) were more motivated than those recruited by GP letter. There was little evidence to support this, with 26.4% of those recruited by GPs exhibiting confirmed sustained abstinence at 4 weeks and 22.1% in those responding to invitation letters ($\chi^2=0.50$, $df=1$, $p=0.50$).

Table 4 Confirmed sustained abstinence¹

	Basic n=469 n (%)	Weekly n=456 n (%)	Risk difference (95% CI)	OR (95% CI)
1 week	148 (31.6)	196 (43.0)	11.6 (5.4-17.8)	1.65 (1.26-2.16)
4 weeks	105 (22.4)	102 (22.4)	0.1 (-5.3-5.5)	1.00 (0.74-1.37)
12 weeks ²	66 (14.1)	52 (11.4)	-2.6 (-6.9-1.7)	0.79 (0.54-1.17)
26 weeks ²	50 (10.7)	40 (8.8)	-1.9 (-5.7-2.0)	0.81 (0.52-1.25)
52 weeks ²	36 (7.7)	30 (6.6)	-1.1 (-4.4-2.3)	0.85 (0.51-1.41)

¹ Allows a grace period of smoking prior to NV2 providing NV2 took place within 14 days of quit day

² No participants were taking NRT at any of these follow up points

Eleven (2.3%) in the basic arm and 49 (10.7%) participants in the weekly arm set renewed quit dates. However, only one person (weekly contact) sustained continued abstinence for six months or more.

Length of previously achieved smoking abstinence predicted success, as did nicotine dependence (FTND) scores, as observed in other studies^{13;16} (Table 5). However, there was no evidence that those who were least likely to succeed because of high dependence or short previous quit attempts were more likely to benefit from the weekly support over basic support (Table 5).

Table 5 Predictors of confirmed sustained abstinence and modification of the effect of weekly support by those predictors

	FTND ¹		Length of previously achieved abstinence	
	OR (95% CI) for a 1 point increase in FTND	χ^2 , p for modification of effect of weekly support by FTND ²	OR (95% CI) for a 100 day increase in previous longest abstinence	χ^2 , p for modification of effect of weekly support by length of previous abstinence ²
4 weeks	0.89 (0.83-0.96)	0.4, 0.95	1.05 (1.02-1.07)	0.0, 0.95
12 weeks	0.92 (0.84-1.01)	0.0, 0.97	1.05 (1.02-1.08)	0.0, 0.90
26 weeks	0.93 (0.84-1.03)	0.1, 0.72	1.04 (1.01-1.07)	0.1, 0.77
52 weeks	0.91 (0.81-1.02)	0.0, 0.94	1.05 (1.02-1.08)	0.0, 0.94

¹ Fagerstrom test for nicotine dependence, scored on a scale of 0-10.

² 1 degree of freedom

Discussion

There was no benefit from an additional visit and two additional supportive telephone calls, which was the difference between basic and weekly support. Rates of use of NRT were uniformly high and additional quit attempts failed swiftly in 59/60 cases. Although an ideal pattern of smoking cessation support was recommended, few patients adhered to it.

This study had 50% more participants than all three previous trials combined in the Cochrane review of intensity of behavioural support⁷. However, the evidence is compatible with a small but worthwhile advantage. At six months, using the confidence intervals as bounds, sustained abstinence rate could be 2% higher in absolute terms with moderate support. The marginal cost of this additional support (30 minutes of nurse time) could be no more than £30, making this intervention highly cost-effective (a maximum of £1500 per additional six-month quitter or around £750 per life year saved¹⁷). No single trial could exclude cost-effective benefits of additional behavioural support in smoking cessation. Adding these results to the two trials contrasting moderate versus low intensity support^{18;19}, the combined OR (95% CI) is 0.71 (0.47-1.07).

The sustained abstinence rates at four and 52 weeks were half those achieved by NHS stop smoking services studied in the national evaluation²⁰, and similar to those achieved by NRT supplied with no behavioural support²¹. Two explanations are possible. The first is that some inherent characteristic of NHS patients in Oxfordshire and Buckinghamshire makes them less likely to stop than the services in the national evaluation (North Cumbria and Nottingham). However, given that Oxfordshire and Buckinghamshire are more affluent, and that affluence is related to success in stopping^{16;20}, this seems unlikely. The second explanation is that treatment was more effective. In Cumbria and Nottingham, it was given on a true weekly schedule by NHS advisors working directly for the stop smoking service to their protocol. In Oxfordshire and Buckinghamshire, we reported great variation in practice and only 1 in 13 assigned weekly support received it as intended. The sustained abstinence rate at one year is not quite double that which would be expected from smokers stopping without any assistance (4%¹), whereas with effective behavioural support and medication it should be three to four times higher⁵- about 15% observed in the national evaluation. Given NRT is effective with only minimal support^{5;21} and NRT was used by nearly all participants, we conclude that the behavioural support offered by primary care nurses was only minimally effective. Perhaps this was because the throughput was low (2.1 patients per month), or because practice appointment systems make weekly contact difficult. The quit rate in this study was similar to that in the only other study of primary care NHS stop smoking services (Table 6).

Table 6 Sustained validated abstinence rates in those taking NRT in relation to intensity of behavioural support provided by primary care staff **WEB**

Study	Contacts in first four weeks	4 week quit rate	26 week quit rate	52 week quit rate
Fagerstrom (high) ²³	4			27%
Fagerstrom (low) ²³	2			22%
Marshall (high) ²⁶	3			17%
Marshall (low) ²⁶	1			14%
GPRG ¹⁴	3			9.0%
Stapleton ¹³	3	38.0%	12.6%	9.6%
Daughton ²⁷	2		18.5%	14.7%
West ²⁸	3	12.0%		4% ¹
McEwen ¹⁵	4+	32%		8% ¹
PIP	3 +1 phone call	22.4%	9.7%	7.1%

¹ Expected based on usual probability of relapse

Randomisation eliminates selection bias and balanced confounders in this trial. However, information bias may have played a role. The assessment of smoking status during the first four weeks was not identical, with more assessments in the weekly support arm. This biased the OR in favour of weekly support for the one-week quit rates considerably and four-week quit rates slightly because NV4 took place a median of four days earlier, at 26 days, in the basic support arm. This would not bias the assessment of abstinence subsequently. The results could be biased against weekly support if individuals were less likely to report lapses occurring more than a week prior to their visit, because lapses were forgotten or not salient. In the basic arm, the median time between NV2 and NV4 was 21 days whereas in the weekly support arm, the median time between last assessment and NV4 was 7 days. Any slips reported after NV2 meant the person was counted as a smoker. There was some evidence that slips may have been unreported in the basic arm; 37% of participants who were quitting and had a CO<10ppm at NV4 reported slips in the past seven days, but only 13% who had

not slipped in the past seven days reported slips in the seven days preceding these, although this is confounded. The rates of use of NRT may have been slightly higher than in reality. We excluded data from those who had no contact during the relevant period, as there was no way of ascertaining their use of NRT. This would exclude those who did not attend because they did not need NRT dispensing. Only 9.2% of people who were point prevalent abstinent at TC4 and 0% of those with sustained abstinence missed NV4, so the bias was minimal.

Although we do not know how many participants declined to participate, our pragmatic trial provided the only vehicle for NHS cessation support in some practices. The results generalise to primary care-based stop smoking services and show that, in such a context, extra support is ineffective. These results have implications for NHS stop smoking services. Even basic support leads to high rates of use of the nicotine patch. The National Institute of Clinical Excellence recommends that patients choose their preferred form of NRT²². However, other forms of NRT require good technique to use properly and perhaps a trial of additional contacts using these other forms of NRT may show a greater benefit of the additional contacts. In support of this, Table 6 shows that both Fagerstrom and Raw²³ found modest advantages of more frequent contact early in the quit attempt when participants used nicotine gum. This should push primary care prescribers towards the patch. The ineffectiveness of behavioural support given by primary care nurses implies that stop smoking services might provide only sufficient support to ensure medication is used most effectively. Patients who require more intensive support should be referred to specialists, as intensive support will probably not be provided in primary care. Finally, attempting to set a quit date again soon after the original one led to failure is unproductive. Halting that quit attempt and returning to the stop smoking services later would be preferable.

We do not believe, however, that the results imply that basic support would be as effective as the usual one hour weekly seven-session group treatment provided in specialist clinics. The effectiveness of behavioural interventions in smoking cessation depends upon context, exemplified by buddying. Buddying links the fortunes of two quitters so they feel responsible for each other's success. In primary care, where there is no inter-linking of quitters, buddying had an OR of 2.6 ($p < 0.05$) for 4-week continuous abstinence²⁴, but the same intervention in group-based programmes produced an OR (95% CI) of 1.16 (0.76-1.78) for the same outcome²⁵. This difference in effectiveness may reflect the higher commitment felt in group programmes without buddying that would be undermined by fewer visits. This might explain the higher quit rates achieved by specialist group programmes than primary care-based support in the PIP trial, or weekly one-to-one support provided by specialists^{15:16}.

Primary care professionals have a key role in providing support for smoking cessation and reaching public health goals, but the PIP trial results emphasise that this role is providing medication and sufficient support to ensure it is taken appropriately. Primary care smoking cessation services should reach broadly, rather than give in-depth support.

Acknowledgments

We are grateful to Cancer Research UK for the programme grant funding for this study. United Pharmaceuticals supplied the nicotine patches for the study free to be given without charge to the participants. A longer version of this paper is available by emailing Paul Aveyard.

Contributors

The protocol was designed and written by Mike Murphy, Marcus Munafo', Robert Walton, Mike Bradburn, Ed Peile, and Mark Drury. The clinical protocol was designed by Mark Drury, Karen Brown, and Mike Murphy. Karen Brown and Cas Saunders recruited and trained the practice nurses. Karen Brown, Cas Saunders, and Avril Alexander monitored the practice nurses. Kate Hey provided organisational and computing support. Viv Crombie and Victoria Johansen provided administrative support. Elaine Johnstone, Katherine Elliott, and Dominic Sweeney processed the samples. The cotinine concentrations were measured by ABS Labs Ltd, London. Karen Brown, Mark Drury, and Paul Aveyard monitored the study. Mike Bradburn, Louise Linsell, and Sharon Love provided statistical support. Paul Aveyard cleaned and analysed the data and wrote the first draft of the study. All authors commented and revised the draft and it was agreed by all authors. Paul Aveyard acts as the guarantor of the study.

The smoking cessation co-ordinators of Milton Keynes (Pam Berry), Buckinghamshire (Jane Giles, Val Mills), and Oxfordshire (Laura Wardak) Stop Smoking Services provided valuable support. The following nurses and surgeries participated in the clinical care of patients: Edwina Humm, Mill Stream Surgery, Benson; Lesley Boler, Church Street Practice, Wantage; Sheila Long, 19 Beaumont Street, Oxford; Lesley Cook, Temple Cowley Health Centre, Oxford; Fran Kelly, Donnington Health Centre, Oxford; Sue Lynch, Health Centre, Bicester; Louise Ross, Aston Clinton Surgery, Aston Clinton; Louise Ross, Wendover Health Centre, Wendover; Nicole Coulon, Jericho Health Centre, Oxford; Kathy Gould, The Health Centre, Thame; Dianne Alley, Boughton House Surgery, Aylesbury; Avril Alexander, Bury Knowle Health Centre, Oxford; Jenny Molloy, Oakfield Health Centre, Aylesbury; Ruth Dowthwaite, Poplar Grove Practice, Aylesbury; Chris Townsend, Bedgrove Surgery, Bedgrove; Lynn Murphy, Whitehill Surgery, Aylesbury; Avril Alexander, The Malthouse, Abingdon; Avril Alexander & Cas Saunders, The Health Centre, Didcot; Chris Malins & Cas Saunders, Marcham Road Health Centre, Abingdon; Karen Brown, Woodstock Surgery, Woodstock; Val Lewis, Blackbird Leys Health Centre; Avril Alexander, Mably Way Surgery, Wantage; Ruth Thompsett, Central Milton Keynes Surgery, Milton Keynes; Mary Ellis, Bedford Street Surgery, Milton Keynes; Avril Alexander, Central Oxford Research Clinic; Avril Alexander, Bloxham Surgery, Bloxham. We are grateful to them all.

Competing interests

Paul Aveyard has received free nicotine replacement products from Novartis and nortriptyline from King Pharmaceuticals for distribution to trial participants. Paul has received personal income for advice to Xenova, a biotechnology company investigating a nicotine vaccine. He has received small gifts and had numerous meals paid for by drug companies, including those producing medications for smoking cessation. He has received travel grants to attend conferences from the Society for Research in Nicotine and Tobacco. Karen Brown, Cas Saunders, and Avril Alexander have received small gifts and had meals paid for by drug companies, including those manufacturing medications for smoking cessation.

Marcus Munafo has received fees for invited lectures from the National Health Service, GlaxoSmithKline, Novartis, the Moffitt Cancer Research Center and the Karolinska Institutet, and received benefits in kind (hospitality etc.) from various pharmaceutical companies. He has received research and travel support from the European Research Advisory Board, GlaxoSmithKline, Pfizer Consumer Healthcare and Novartis. Consultancy has been provided to the European Commission, The American Institutes for Research, the National Audit Office and G-Nostics Ltd.

Elaine Johnstone has received consultancy income from European Network for Smoking Prevention.

Mike Murphy has received consultancy income from the European Network for Smoking Prevention and has provided scientific consultancy services through the University of Oxford ISOS Innovation to the National Audit Office and G-Nostics Ltd.

The Childhood Cancer Research Group and the Cancer Research UK General Practice Research Group have received unrestricted educational grants, research project grants, and consultancy fees from Ciba Geigy/Novartis, Glaxo Smith Kline, Pharmacia/Pfizer, Ares-Serono, Sanofi-Synthelabo, Third Wave Technologies, Astra-Zeneca, and G-Nostics.

Figure Legends

Figure 1 Timing of behavioural support in the basic and weekly support arms

Figure 2 Trial flow diagram

Figure 3 Duration of confirmed sustained abstinence by trial arm¹ WEB

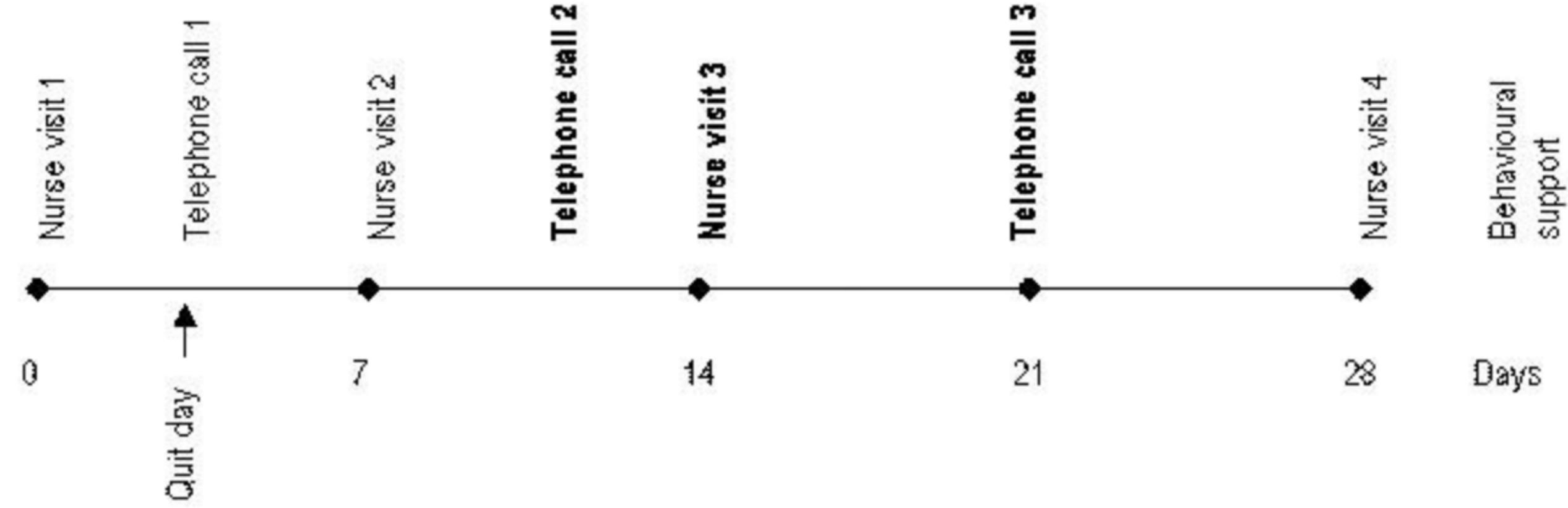
Reference List

- (1) Hughes JR, Keely J, Naud S. Shape of the relapse curve and long-term abstinence among untreated smokers. *Addiction* 2004; 99(1):29-38.
- (2) Piasecki TM, Fiore MC, McCarthy DE, Baker TB. Have we lost our way? The need for dynamic formulations of smoking relapse proneness. *Addiction* 2002; 97(9):1093-1108.
- (3) West R, Shiffman S. Effect of oral nicotine dosing forms on cigarette withdrawal symptoms and craving: a systematic review. *Psychopharmacology (Berl)* 2001; 155(2):115-122.
- (4) Hughes JR, Stead LF, Lancaster T. Antidepressants for smoking cessation. Hughes JR, Stead LF, Lancaster T Antidepressants for smoking cessation *The Cochrane Database of Systematic Reviews: Reviews* 2004 Issue 4 John Wiley & Sons, Ltd Chichester, UK DOI: 10 1002/14651858 CD000031 pub2 2004;(4).
- (5) Silagy C, Lancaster T, Stead L, Mant D, Fowler G. Nicotine replacement therapy for smoking cessation. Silagy C, Lancaster T, Stead L, Mant D, Fowler G Nicotine replacement therapy for smoking cessation *The Cochrane Database of Systematic Reviews: Reviews* 2004 Issue 3 John Wiley & Sons, Ltd Chichester, UK DOI: 10 1002/14651858 CD000146 pub2 2004;(3).
- (6) Hajek P. Withdrawal-oriented therapy for smokers. *Br J Addict* 1989; 84(6):591-598.
- (7) Lancaster T, Stead LF. Individual behavioural counselling for smoking cessation. Lancaster T, Stead LF Individual behavioural counselling for smoking cessation *The*

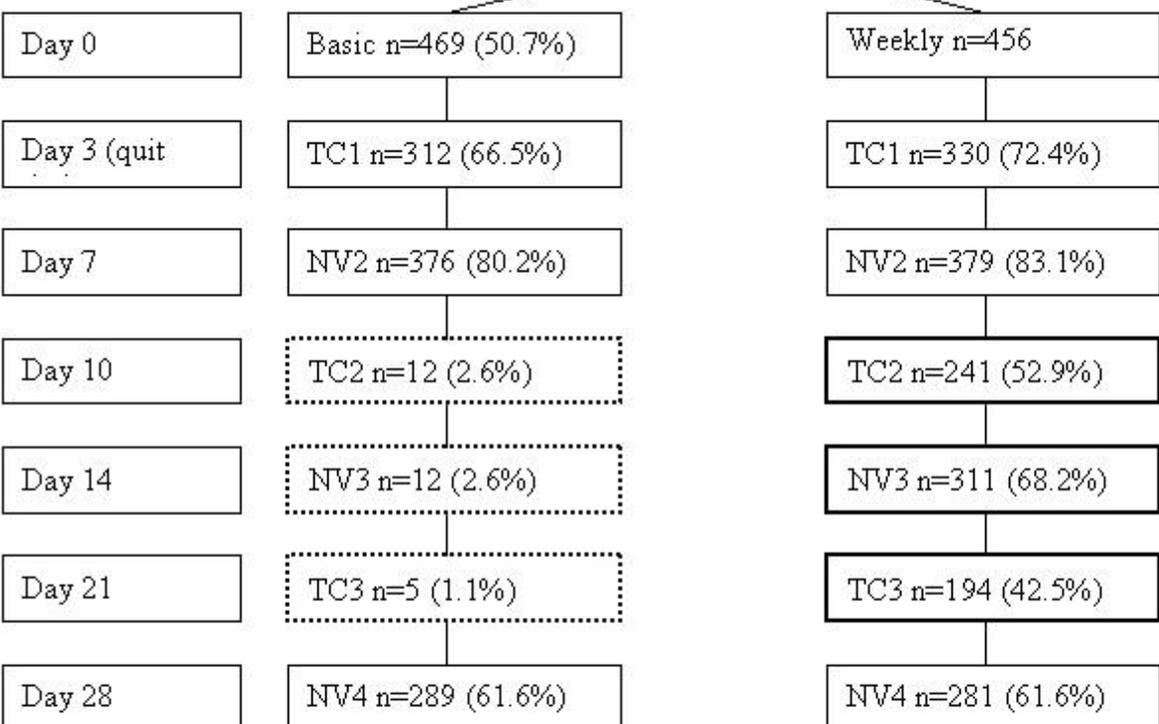
Cochrane Database of Systematic Reviews: Reviews 2005 Issue 2 John Wiley & Sons, Ltd Chichester, UK DOI: 10 1002/14651858 CD001292 pub2 2005;(2).

- (8) Stead LF, Lancaster T. Group behaviour therapy programmes for smoking cessation. Stead LF, Lancaster T Group behaviour therapy programmes for smoking cessation The Cochrane Database of Systematic Reviews: Reviews 2005 Issue 2 John Wiley & Sons, Ltd Chichester, UK DOI: 10 1002/14651858 CD001007 pub2 2005;(2).
- (9) West R, McNeill A, Raw M. Smoking cessation guidelines for health professionals: an update. *Thorax* 2000; 55:987-999.
- (10) West R, Hajek P, Stead L, Stapleton J. Outcome criteria in smoking cessation trials: proposal for a common standard. *Addiction* 2005; 100(3):299-303.
- (11) Hughes JR, Keely JP, Niaura RS, Ossip-Klein DJ, Richmond RL, Swan GE. Measures of abstinence in clinical trials: issues and recommendations. *Nicotine & Tobacco Research* 2003; 5(1):13-25.
- (12) SRNT Sub-Committee on Biochemical Verification. Biochemical verification of tobacco use and cessation. *Nicotine and Tobacco Research* 2002; 4:149-159.
- (13) Stapleton JA, Russell MA, Feyerabend C, Wiseman SM, Gustavsson G, Sawe U et al. Dose effects and predictors of outcome in a randomized trial of transdermal nicotine patches in general practice. *Addiction* 1995; 90(1):31-42.
- (14) Imperial Cancer Research Fund General Practice Research Group. Randomised trial of nicotine patches in general practice: results at one year. *BMJ* 1994; 308(6942):1476-1477.
- (15) McEwen A, West R, McRobbie H. Effectiveness of specialist group treatment for smoking cessation vs. one-to-one treatment in primary care. *Addict Behav* 2006; In Press.
- (16) Judge K, Bauld L, Chesterman J, Ferguson J. The English smoking treatment services: short-term outcomes. *Addiction* 2005; 100(s2):46-58.
- (17) Song F, Raftery J, Aveyard P, Hyde C, Barton P, Woolacott N. Cost-effectiveness of pharmacological interventions for smoking cessation: a literature review and a decision analytic analysis. *Med Decis Making* 2002; 22:s26-s37.
- (18) Alterman AI, Gariti P, Mulvaney F. Short- and long-term smoking cessation for three levels of intensity of behavioral treatment. *Psychology of Addictive Behaviors* 2001; 15(3):261-264.
- (19) Weissfeld JL, Holloway JL. Treatment for cigarette smoking in a Department of Veterans Affairs outpatient clinic. *Arch Intern Med* 1991; 151(5):973-977.
- (20) Ferguson J, Bauld L, Chesterman J, Judge K. The English smoking treatment services: one-year outcomes. *Addiction* 2005; 100(s2):59-69.
- (21) Hughes JR, Shiffman S, Callas P, Zhang J. A meta-analysis of the efficacy of over-the-counter nicotine replacement. *Tob Control* 2003;(1):21-27.

- (22) Anonymous. Guidance on the use of nicotine replacement therapy (NRT) and bupropion for smoking cessation. National Institute of Clinical Excellence [2002
- (23) Fagerstrom K. Effects of nicotine chewing gum and follow-up appointments in physician-based smoking cessation. *Prev Med* 1984; 13:517-527.
- (24) West R, Edwards M, Hajek P. A randomized controlled trial of a "buddy" systems to improve success at giving up smoking in general practice. *Addiction* 1998; 93(7):1007-1011.
- (25) May S, West R, Hajek P, McEwen A, McRobbie H. Randomized controlled trial of a social support ("buddy") intervention in smoking cessation. *Patient Educ Couns* 2006; in press.
- (26) Marshall A, Raw M. Nicotine chewing gum in general practice: effect of follow up appointments. *Br Med J* 1985; 290:1397-1398.
- (27) Daughton D, Susman J, Sitorius M, Belenky S, Millatmal T, Nowak R et al. Transdermal Nicotine Therapy and Primary Care: Importance of Counseling, Demographic, and Participant Selection Factors on 1-Year Quit Rates. *Arch Fam Med* 1998; 7(5):425-430.
- (28) West R, Edwards M, Hajek P. A randomized controlled trial of a "buddy" system to improve success at giving up smoking in general practice. *Addiction* 1998; 93(7):1007-1011.



Recruited n=925



3 month call

- Smoking status known n=351 (74.8%)
- Withdrawn n=18 (3.8%)
- Lost to follow up n=99 (21.1%)
- Moved 1 (0.2%)

3 month call

- Smoking status known n=349 (76.5%)
- Withdrawn n=30 (6.6%)
- Lost to follow up n=77 (16.9%)
- Moved 0 (0.1%)

6 month call

- Smoking status known n=338 (72.1%)
- Withdrawn n=21 (4.5%)
- Lost to follow up n=108 (23.0%)
- Moved 2 (0.4%)

6 month call

- Smoking status known n=332 (72.8%)
- Withdrawn n=35 (7.7%)
- Lost to follow up n=88 (19.3%)
- Moved 1 (0.2%)

12 month call

- Smoking status known n=321 (68.4%)
- Withdrawn n=21 (4.5%)
- Lost to follow up n=123 (26.2%)
- Moved 2 (0.4%)

12 month call

- Smoking status known n=316 (69.3%)
- Withdrawn n=37 (8.1%)
- Lost to follow up n=101 (22.1%)
- Moved 1 (0.2%)

