

Does stage-based smoking cessation advice in pregnancy result in long-term quitters? 18-month postpartum follow-up of a randomized controlled trial

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ABSTRACT

Aims To evaluate the effect on quitting smoking at 18 months postpartum of smoking cessation interventions based on the Transtheoretical Model (TTM) delivered in pregnancy compared to current standard care. It has been claimed that TTM-based interventions will continue to create quitters after the end of the intervention period.

Design Cluster randomized trial.

Setting Antenatal clinics in general practices in the West Midlands, UK.

Participants A total of 918 pregnant smokers originally enrolled in the trial, of which 393 women were followed-up at 18 months postpartum.

Interventions One hundred general practices were randomized into the three trial arms. Midwives in these practices delivered three interventions: A (standard care), B (TTM-based self-help manuals) and C (TTM-based self-help manuals plus sessions with an interactive computer program giving individualized smoking cessation advice).

Measurements Self-reported continuous and point prevalence abstinence since pregnancy.

Findings When combined together, there was a slight and not significant benefit for both TTM arms compared to the control, with an odds ratio (OR) 95% confidence interval (CI) of 1.20 (0.29–4.88) for continuous abstinence. For point prevalence abstinence, the OR (95%CI) was 1.15 (0.66–2.03). Seven of the 54 (13%) women who had quit at the end of pregnancy were still quit 18 months later, and there was no evidence that the TTM-based interventions were superior in preventing relapse.

Conclusions The TTM-based interventions may have shown some evidence of a short-term benefit for quitting in pregnancy but no benefit relative to standard care when followed-up in the longer-term.

KEYWORDS Pregnancy, randomized controlled trial, smoking cessation, stages of change.

INTRODUCTION

Between 9% and 45% of women who smoke report stopping smoking in preparation for pregnancy or after their pregnancy is discovered and before contact with any health-care professional [1–4]. Most other women who continue to smoke report reduced consumption [3].

An additional 6% of women continuing to smoke in pregnancy can be persuaded to stop by effective interventions delivered as part of antenatal pregnancy care. This is about double what it might have been without such interventions [5].

However, similar survey data also suggest that most women who stop smoking in pregnancy return to

smoking after they have given birth. Between 50% and 80% return to smoking in the first year after delivery [6–9]. This is much higher than would be predicted by the relapse rates of people who have been quit continuously for usually more than 6 months [10,11].

One reason for the high quit rate but high relapse rate might be because the psychology of stopping while pregnant is different to stopping forever. Pregnant women seem not to use the same processes of change used by non-pregnant women [12] and, indeed, report stopping for the sake of their fetus only and wanting to return to smoking at the end of the pregnancy [13].

Women who stop smoking in response to psychological support provided in smoking cessation programmes in pregnancy might, however, have a different prognosis for remaining quit from those women who stop spontaneously without support. This is because such women may have been guided to use the psychological and social techniques that are known to help people stop smoking, rather than merely 'suspend' their smoking behaviour [12], which appears to be the main method used by most spontaneous quitters in pregnancy. Indeed, Prochaska & Velicer have claimed that the stage-based interventions used in the trial described here result in a 'delayed action effect' [14, p. 46], meaning that the benefit of stage-based interventions is not fully realized until after the formal end of the intervention period. Long-term follow-up of stage-based interventions is needed to assess this claim of superior efficacy.

Few trials to help women stop smoking in pregnancy have followed women beyond the immediate postpartum period to examine whether women quitting in response to these interventions are less likely to relapse as a result of their exposure. In a quasi-randomized trial, Lillington *et al.* found that 43% of the intervention group reported not smoking at the end of pregnancy, which declined to 25% at 6 weeks after birth, while the corresponding rates among the control group were 25% and 12% [15]. Peterson *et al.* however, verified self-report in their quasi-experimental study and found no differences in quit rate in pregnancy or 8 weeks postpartum [16]. Secker-Walker *et al.* found that women randomized to individualized counselling in pregnancy were no more likely to report being quit at either 36 weeks gestation or at 1 year postpartum [17]. In a subsequent trial, Secker-Walker *et al.* found that women randomized to enhanced physician advice were slightly but not significantly more likely to be confirmed as quit at 36 weeks gestation (10.3% versus 7.3%) than women randomized to usual care. At 1 year postpartum, 11.4% of the intervention group and 6.3% of the control group were self-reported quitters, which was again not significantly different [18]. In a quasi-experimental study, Wakefield *et al.* found that demon-

strating self-help booklets led to a significant difference in quit rate in pregnancy, but no significant difference in quit rates at 6 months postpartum [19]. The largest study allocated clinics providing antenatal and postnatal care to either usual care or provided training to deliver enhanced care [20]. At the end of pregnancy and the first postpartum month, there was a significant advantage for women attending enhanced care clinics if women who were not followed were excluded from analysis, but not if they were included as smokers. This advantage declined and was not significant at 6 months postpartum follow-up. Many of these studies lacked power to show that the interventions produced worthwhile benefits in pregnancy or postpartum, so it is unclear whether interventions that succeed in pregnancy have longer-term benefits.

The effects of the interventions in the trial reported here on smoking cessation at the end of pregnancy of have been published previously [21]. The trial compared a standard care intervention with two different programmes based on the Transtheoretical Model (TTM) and we reported cotinine-confirmed smoking cessation. We found that there were small differences between the two TTM arms. Combining the two TTM arms, the odds ratio (OR) 95% confidence intervals (CI) for stopping smoking at 30 gestation weeks were 2.09 (0.90–4.85) for 10-week sustained abstinence and 2.92 (1.42–6.03) for point prevalence abstinence relative to controls. At 10 days after delivery, the OR (95% CI) for quitting were 2.81 (1.11–7.13) and 1.85 (1.00–3.41) for 10-week and point prevalence abstinence, respectively. Some of the apparent advantage of the two TTM arms over standard care was a result of bias in this cluster-randomized trial because midwives in the TTM followed the protocol more assiduously. However, as-yet unpublished results also suggest a within-pregnancy benefit from the TTM interventions on secondary outcomes, which are not subject to the same bias. The aim of this paper is to examine whether the benefit of the TTM-based interventions was sustained in the long-term postpartum period.

METHOD

Recruitment

The methods have been reported previously in detail [21]. Briefly, we recruited 16 of the 19 midwifery services for the West Midlands to participate in the trial. Midwives deliver antenatal care mainly in community settings, meaning general practices rather than hospitals. About half the available general practices were selected to participate, with only one midwife declining. Midwives were asked to attempt to recruit all women aged 16 years and over who were still smoking at

booking for maternity care (about 12 weeks of gestation). We estimate that they recruited approximately 42% of potentially eligible smokers. Full details on these women's socio-demographic and smoking habits are published in the trial report [21]. In brief, nearly all were white, almost two-thirds of women had had a baby previously, were of mean (SD) age 26.5 [5.9] years, of average net household income of £100–200 per week and, on average, left education aged 16 years. Women smoked on average six cigarettes per day at booking, but this increased to 11 cigarettes from mid-pregnancy onward [22]. Two-thirds of women lived with partners who smoked.

Interventions

In this pragmatic trial, we examined the relative effectiveness of three interventions: Arm A, controls; Arm B, manuals; and Arm C, computer. Midwives in each trial arm were aware that they were in one of three trial arms.

Arm A, controls

The intervention in Arm A was intended to be standard smoking cessation advice given by midwives, who would have variable training and variable skills, consistent with a pragmatic trial design [23]. Midwives in Arm A received a half-day training on the research protocol only. They were asked to deliver smoking cessation advice as they would normally do and give women the Health Education Authority (of England) booklet *Thinking about Stopping*. This single-sheet leaflet explains the benefit to stopping smoking for the health of the fetus and gives brief advice on how to stop smoking. We did not record fidelity to the intervention in this arm, but as the leaflet was included in the trial entry pack, completed at enrolment, it is likely that almost all women received the leaflet.

Arm B, manuals

Like the midwives in Arm A, midwives in Arm B received a half-day training on the research protocol. Additionally, they received 2 days training on the TTM. Participants recruited to trial Arm B received a set of six professionally produced 30-page self-help colour manuals, 'Pro-change programme for a healthy pregnancy'. The set consisted of one manual for each stage of change and a further one for 'recycling'. These manuals explained the concepts of stage of change, helped participants to stage themselves, and contained quizzes and exercises to engage the stage-appropriate processes of change. Additionally, at each of three occasions during pregnancy <20 weeks, 23–

25 weeks, and at 28–30 weeks and at 10 days postpartum, the midwife assessed a participant's stage of change, pointed the woman to the appropriate manual in the stage-series and spent no more than 15 minutes ensuring that the participant was familiar with how to use the materials by going through an appropriate exercise with her and discussing it.

We could not record directly the proportion of midwives who assessed stage and gave advice. However, we did record the proportion of women that completed questionnaires. Such completion implies that the midwife raised the topic of the trial with the woman concerned, and gives some indication on fidelity to the interventions. The proportion of women completing questionnaires in this arm was 96%, 74% and 70% at the three in-pregnancy times and 72% at 10 days postpartum, implying good fidelity.

Arm C, computer

The midwives in this arm received the same training as midwives in Arm B. The participants also received the same stage-based self-help manual intervention as Arm B and the midwife explained how to use the stage-based manuals in the same way. Additionally, these participants used a computer program installed on a laptop computer on each of the three intervention occasions (as in Arm B). Women worked alone without the midwife using the computer program. This consisted of questions to stage the woman, and this was followed by on-screen and audio feedback of what stage women were in and what that meant. This format was repeated for the other concepts: decisional balance, temptation and processes of change, with strategies to use to move stage. It took about 20 minutes to complete. On second and third use, women also received feedback on progress or lack of it since the last use. Following each use of the computer, the feedback was printed out and sent to the participant within 1 week of the intervention.

We could record directly the proportion of women who completed the computerized intervention and received written feedback in this arm. This was 97%, 81% and 60% at the three times in pregnancy, and 77% at 10 days postpartum.

Allocation

The midwifery teams in each family practice were allocated by computerized minimization algorithm designed to balance the family practices across arms of the trial. The characteristics balanced by minimization were a measure of the socio-economic status of the population served by the family practice (four groups), urban/rural location (two groups) and birth rate (three groups).

Outcome assessment and analysis

Our original plan was to follow women at 12 months postpartum, but funding for this work was not received until the first women in the cohort were 18 months postpartum. Eighteen months after the final postnatal research contact every woman who had not dropped out of the study and who had given birth to a live child was sent a letter thanking her for her help in the main research and inviting her to give further information about her smoking. She also received a pack consisting of a reminder sheet with pictures of the self-help materials used in the interventions, a consent form, a six-page questionnaire, dental pad and bottle for a saliva sample for cotinine analysis and prepaid Freepost envelope in which to return her questionnaire. A refusal form was also included for women who did not wish to participate. The refusal form included a questionnaire with items concerning current smoking status and stage of change. As an incentive, women were offered a £10 voucher for a large retailer, sent on receipt of the completed questionnaire or refusal questionnaire. If no response to initial contact had been received after a period of 3 weeks a further pack was sent and we telephoned the woman. Over the telephone, women were offered another participant's pack or the opportunity to go through the questionnaire over the phone. If this second contact was unsuccessful, one further full pack was sent, and if still no response a refusal form was sent alone. If it became clear that a trial participant had moved, they were tracked to the responsible health authority and thence to the responsible family doctor and the process of contacting women re-started.

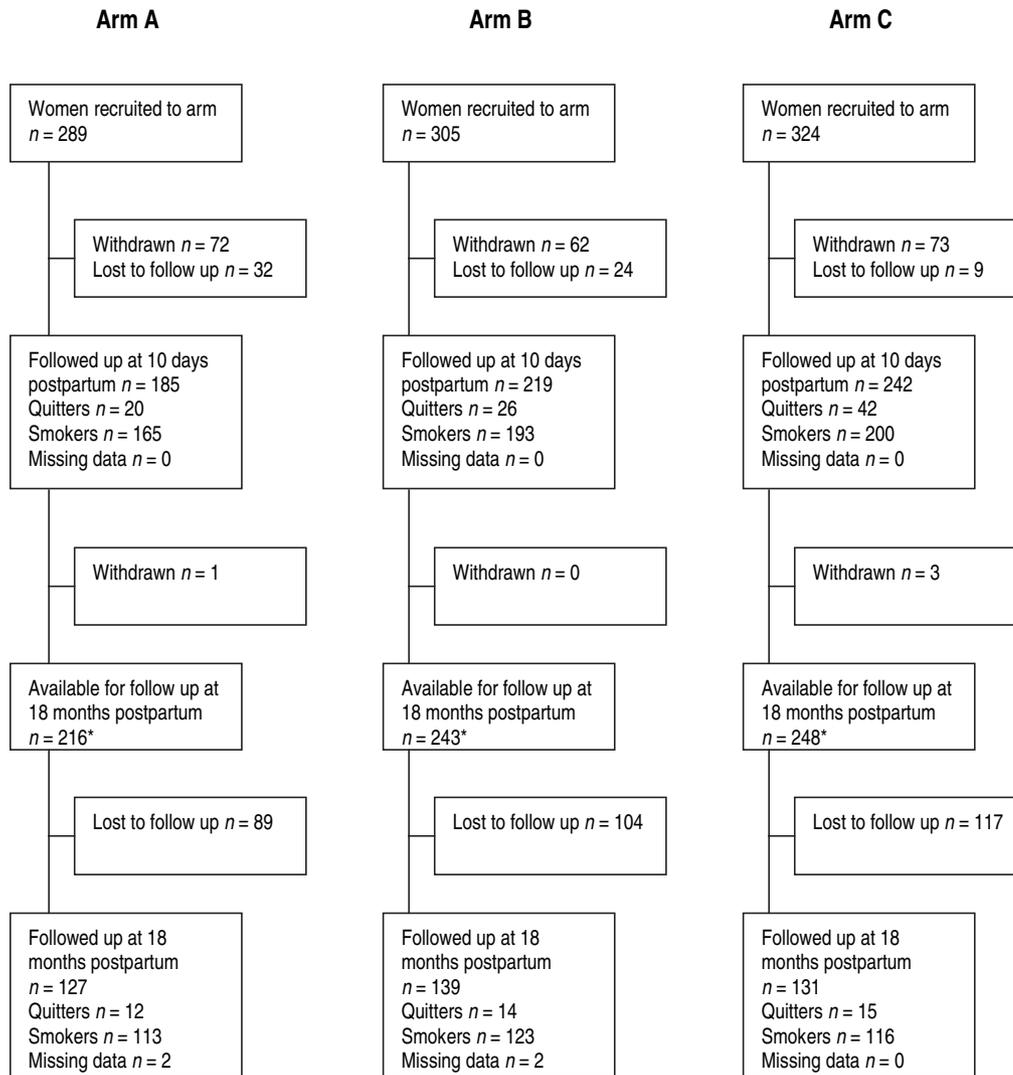
The main outcome examined in this report was continuous self-reported abstinence since pregnancy. The secondary outcome was point prevalence of smoking abstinence, defined as declared non-smoking and no cigarette consumption in the past 24 hours. As previously [21], we examined the data separately for each of the three trial arms and conflated the two TTM arms, as pre-specified in the protocol. The analysis was conducted on the 397 women followed-up. The four women who were followed-up but whose smoking status was unknown were classed as smokers. In sensitivity analysis, we assumed that all those in the original cohort and who were not followed were smokers. We then adjusted for possible baseline differences in the women's characteristics. These were baseline smoking habits, baseline cotinine levels, mean scores on the Fagerstrom Test for Nicotine Dependence [24], stage of change, age, ethnicity, parity, proportion having a partner, proportion whose partner smoked, educational achievement and household net income.

The cluster randomization was accounted for in the analysis using random effects logistic regression in Multilevel Modelling for Windows (MLwiN). In the first analyses, we examined the likelihood of being continuously quit since pregnancy in relation to trial arm, regardless of quit status at 10 days postpartum. In the second analyses, we examined whether those women who had been quitters at the end of pregnancy were more likely to maintain that status in the TTM arms (combined) rather than the control arm. To do so, we created a multiplicative interaction term between trial arm and point prevalence of being quit at 10 days postpartum, examining the χ^2 statistic for inclusion of this term.

A subsidiary outcome assessed in this trial and added to this report in response to a referee's suggestion was change between baseline and 30 weeks gestation, 10 days postpartum and 18 months postpartum in daily self-reported cigarette consumption. Self-reported consumption was based on two questions. One question was 'How many cigarettes do you normally smoke in a day?' with responses in categories: fewer than 5, 5–9, 10–19, 20–29, 30 or more. The second question was 'How many cigarettes have you smoked in the last 24 hours?', where any number between 0 and 99 could be given in response. The mean of these two was used as daily consumption, replacing the categories in the first question by the mid-category value. We also reported change in urinary cotinine concentrations between baseline and 30 weeks gestation and baseline and 10 days postpartum. Urinary cotinine concentration was measured by Wolfson Laboratories, Birmingham University, using a colorimetric assay, expressing the results in micrograms per millilitre ($\mu\text{g/ml}$) [25]. This assay detects all the metabolites of nicotine together (not only cotinine) and calculates the concentration against a cotinine standard curve with the result expressed as a cotinine equivalent concentration. This is then divided by a compensation factor to take into account the dilution of urine. The cut-off dividing smokers from non-smokers is 1.5 $\mu\text{g/ml}$. The cotinine concentrations measured in this way are about eight times those usually reported in other studies. For these analyses, we used random effects linear regression in MLwiN. We adjusted for between group differences in women's baseline characteristics as conducted previously.

RESULTS

In total, 918 women entered the study, 289 in Arm A, 305 in Arm B and 324 in Arm C. The baseline characteristics of both midwives and women did not differ greatly by arm. Two hundred and seven women withdrew from the study prior to the last 'in pregnancy'



*All those not actively withdrawn

Figure 1 Flowchart of follow-up from trial inception to 18 months postpartum

follow-up at 10 days postpartum, and four additional women withdrew after completing that assessment, leaving 707 available for 18 month postpartum follow-up. Of the 707, 397 (56.2%) women returned follow-up questionnaires, of which there were 351 full questionnaires and 46 refuser questionnaires (Fig. 1). Of the 397, four women did not give sufficient information to classify their smoking status. Salivary samples for cotinine analysis were, however, poorly returned with only 45 women returning samples that could be analysed; hence self-report smoking status only is used.

Women who were followed-up successfully at 18 months and all other women initially recruited but who were not followed-up showed few differences in baseline characteristics. Baseline smoking habits, baseline cotinine levels, mean scores on the Fagerstrom Test for

Nicotine Dependence [24], stage of change, ethnicity, parity, proportion having a partner, proportion whose partner smoked and educational achievement were all similar and not statistically significantly different. There were two small but statistically significant differences in the characteristics of women followed-up and not followed-up. Women not followed-up were more likely to be under 20 years of age at booking for pregnancy care (19.4% versus 10.1%) and had lower household net incomes (55.8% had an income less than £200 per week versus 43.0%). Loss to follow-up was also unrelated to all measures of smoking status at 10 days postpartum. Most crucially, however, there was no evidence that follow-up varied much (or significantly) by arm, with 127 (58.8%) followed in Arm A, 139 (57.2%) in B and 131 (52.8%) in C of the 707 women available for follow-up.

Table 1 Effects of trial arm on smoking status at 18 months postpartum.

	Arm A	Arm B		Arm C		χ^2 , P*
	% quitters	% quitters	OR (95%CI)	% quitters	OR (95%CI)	
Only those followed-up						
Point prevalence abstinence	9.4	10.1	1.07 (0.48–2.42)	11.4	1.24 (0.56–2.76)	0.3, 0.86
18 months continuous abstinence	1.6	0.7	0.45 (0.04–5.06)	3.1	1.97 (0.35–10.94)	1.9, 0.39
All in cohort [†]						
Point prevalence abstinence	4.2	4.6	1.11 (0.51–2.44)	4.6	1.12 (0.52–2.44)	0.1, 0.95
18 months continuous abstinence	0.7	0.3	0.47 (0.04–5.23)	1.2	1.79 (0.33–9.87)	1.6, 0.46

*2 degrees of freedom. [†]Those not followed classed as smokers.

Table 2 Examination of whether the TTM intervention was more effective at sustaining abstinence at 18 months postpartum in women who were abstinent at the end of pregnancy.

Point prevalence smoking status at 10 days postpartum	Smoking status at 18 months postpartum			
	n	n followed-up	% of those followed-up	% of original cohort
Outcome = point prevalence of quitting at 18 months				
Control Smoker	7	112	6.3	2.6
TTM Smoker	16	231	6.9	2.9
Control Quitter	5	15	33.3	25.0
TTM Quitter	13	39	33.3	19.1
Outcome = continuous abstinence at 18 months				
Control Smoker	0	112	0.0	0.0
TTM Smoker	0	231	0.0	0.0
Control Quitter	2	15	13.3	10.0
TTM Quitter	5	39	12.8	7.4

The effects of trial arm on smoking status at 18 months postpartum

The prevalence of 24-hour self-reported abstinence did not differ between the arms (Table 1). When combined together, the OR (95% CI) for point prevalence abstinence in the TTM arms compared to the control arm was 1.15 (0.66–2.03) for those followed-up in the denominator. With all in the cohort in the denominator and those not followed-up counted as smokers, the OR (95% CI) was 1.12 (0.56–2.22). Adjustment for baseline differences between arms did not alter these ORs.

The prevalence of continuous abstinence since 10 days postpartum did show some evidence of difference between the arms, with Arm C having more quitters, although this was not significant (Table 1). When combined together, there was a slight and not significant benefit for both TTM arms compared to the Control, with an OR (95% CI) of 1.20 (0.29–4.88) with only those followed-up in the denominator. With all in the cohort in the denominator and those not followed-up counted as smokers, the OR (95% CI) was 1.15 (0.22–5.97). The

adjusted models with continuous abstinence as the outcome did not converge.

The effects of trial arm on sustaining non-smoking status from 10 days postpartum to 18 months postpartum

Among the 397 women followed-up at 18 months postpartum, 54 (13.6%) had been self-reported non-smokers at 10 days postpartum, of whom 29 (7.3%) had been abstinent for at least 10 weeks. Eighteen (33.3%) of the 54 women who were 10-day postpartum quitters were quit at 18 months postpartum, of whom seven (13.0%) had been abstinent continuously since the end of their pregnancies. Six of these seven had also been abstinent continuously for the last 10 weeks of pregnancy. In common with studies reviewed in the Introduction, most smokers who achieved abstinence in pregnancy were smoking again 18 months after pregnancy.

It is clear that the relapse rate in women exposed to the TTM-based interventions was similar to the relapse rate among women exposed to the control intervention, regardless of stratification by quit status at 10 days postpartum (Tables 2 and 3). Tables 2 and 3 give raw

Table 3 Examination of whether the TTM intervention was more effective at sustaining abstinence until 18 months postpartum in women who had been abstinent for the last 10 weeks of pregnancy.

	Point prevalence smoking status at 10 days postpartum	Smoking status at 18 months postpartum			
		<i>n</i>	<i>n</i> followed-up	% of those followed-up	% of original cohort
Outcome = point prevalence of quitting at 18 months					
Control	Smoker	8	118	6.8	2.9
TTM	Smoker	22	250	8.8	3.7
Control	Quitter	4	9	44.4	36.4
TTM	Quitter	7	20	35.0	21.9
Outcome = continuous abstinence at 18 months					
Control	Smoker	0	118	0.0	0.0
TTM	Smoker	1	250	0.4	0.2
Control	Quitter	2	9	22.2	18.2
TTM	Quitter	4	20	20.0	12.5

numbers, rather than the output of the random effects regression. This is because the models with the outcome of continuous abstinence at 18 months postpartum failed to converge because of sparse data. Nevertheless, the tests for interaction between point prevalence smoking status at 10 days postnatal and trial arm with the outcome of point prevalence abstinence were not significant, and it is clear from observation of Table 3 that there is no evidence for an interaction with continuous abstinence either. In other words, there was no evidence that TTM-based interventions served as effective relapse prevention aids after the end of pregnancy. These results are similar whether only those followed-up at 18 months postpartum are used as the denominator or whether all those in the original cohort are used.

The effects of trial arm on change in mean daily cigarette consumption

Women at baseline (around the time of booking for maternity care) reported smoking a mean of six cigarettes per day while, prior to pregnancy, the median reported consumption was 10–19 cigarettes per day. Women's self-reported consumption had increased to about 11 cigarettes per day by 23–25 weeks in all three arms, which change was maintained at 30 weeks and 10 days postpartum [22]. However, this increase was much less marked in Arm C than either Arms A or B: a statistically significant difference between the arms. This difference was much reduced by adjustment for baseline characteristics, but remained significant at both times (Table 4).

At 18 months postpartum, women's self-reported consumption had increased to a mean of about 13 cigarettes per day. This increase was again least in Arm C but, on adjustment, there were no significant differences in change in consumption by trial arm (Table 4).

Differences between the arms in the change in urinary cotinine concentration were much less marked than for change in self-reported cigarette consumption (Table 4). At 30 weeks of gestation, there was a slight increase in urinary cotinine concentration in Arms A and B, commensurate with the reported increase in cigarette consumption, while women in Arm C, despite increasing consumption slightly, showed a slight decrease in urinary cotinine concentration. This difference between the arms was significant and remained so after adjustment. There were, however, no differences between the arms in the change in urinary cotinine concentration from baseline to 10 days postpartum. Women did not supply samples for cotinine estimation at 18 months postpartum.

DISCUSSION

The previously published results of this trial showed a small but just significant benefit for women exposed to a TTM-based intervention for quitting smoking assessed at the end of pregnancy among pregnant women who admitted to smoking at booking for maternity care [21]. When examined 18 months later, this effect was not apparent. Furthermore, there was no evidence that the TTM intervention made relapse to smoking less likely. Relapse to smoking by 18 months postpartum was the most common outcome for both short-term and medium term quitters who stopped in pregnancy. Data not presented in the results showed, however, that women in the TTM arms were more likely to remember the smoking cessation materials, to have valued the materials at the time, to have kept such materials and to have passed them onto others. Many health promotion interventions provide such data only. This report shows that while such materials were more valued, they were not more effective.

Table 4 Changes in self-reported daily cigarette consumption and urinary cotinine concentration by trial arm.

	Arm B			Arm C		Difference between arms χ^2 , P^*
	Arm A Mean	Mean	Difference B-A (95%CI)	Mean	Difference C-A (95%CI)	
Baseline to 30 weeks gestation						
Change cigs/day	5.3	4.4	-0.9 (-2.2-0.4)	1.4	-3.9 (-5.2-2.6)	40.63, <0.001
Change cigs/day (adjusted)			-0.2 (-1.4-1.0)		-2.7 (-4.0-1.4)	19.04, <0.001
Change cotinine concentration [†]	0.98	0.67	-0.31 (-1.73-1.12)	-0.60	-1.57 (-2.97-0.17)	6.85, 0.033
Change cotinine concentration (adjusted) [†]			-0.25 (-1.70-1.20)		-1.85 (-3.32-0.38)	8.40, 0.015
Baseline to 10 days postpartum						
Change cigs/day	6.1	5.7	-0.4 (-1.8-1.0)	1.1	-5.0 (-6.4-3.6)	60.74, <0.001
Change cigs/day (adjusted)			-0.4 (-1.9-1.0)		-3.0 (-4.5-1.4)	16.52, <0.001
Change cotinine concentration [†]	0.62	1.52	0.90 (-0.63-2.43)	0.36	-0.25 (-1.78-1.27)	3.28, 0.194
Change cotinine concentration (adjusted) [†]			0.76 (-0.85-2.37)		-0.92 (-2.60-0.76)	4.55, 0.103
Baseline to 18 months postpartum						
Change cigs/day	8.0	6.3	-1.7 (-3.4-0.1)	4.5	-3.5 (-5.3-1.8)	15.20, 0.001
Change cigs/day (adjusted)			-1.5 (-3.2-0.2)		-0.9 (-2.8-1.0)	3.10, 0.21

*2 degrees of freedom. [†]Micrograms per millilitre.

There is little scope for bias to explain these results. Randomization eliminated selection bias. The assessment of outcome was similar between arms. The biggest potential threat to validity is the extensive loss to follow-up from initial recruitment to follow-up at 18 months postpartum, which was similar to that observed in similar trials reviewed in the Introduction. Younger and less affluent women were less likely to be followed-up, but loss of these women was the same in all three arms. It is unlikely, therefore, that quitters were lost preferentially from one of the trial arms. Furthermore, sensitivity analysis for loss to follow-up by including all those in the original cohort counting those with absent data as smokers did not alter the results. Information bias from this source therefore seems unlikely. One further issue is that we could only follow-up approximately half the women available, which reduces the power to detect differences between the arms. Furthermore, the quit rates were low, further widening the confidence intervals for the ORs for the differences between the arms. It would be a mistake, however, to regard the wide confidence intervals as compatible with a large effect. Given the low quit rates overall, the absolute difference in the long-term quit rates between the arms was less than 1% even at the upper limit of the 95% confidence interval. The TTM-based interventions have therefore resulted in a minimal increase in long-term quitters at best.

One puzzling phenomenon is that most women, including most women that claimed to be quit, either did not return saliva samples or sent them back dry. In a previous trial [26], we found that postal collection of saliva

samples was an effective means of confirming smoking status and it is difficult to know why this method failed on this occasion. There were two methodological differences between the trials. One was the longer gap between trial entry and collection of saliva by postpartum postal follow-up in this trial. The second is that in the first trial, we approached non-smokers only for confirmation, with a subsequent very short questionnaire that allowed participants to admit to relapse to smoking. If this second procedure had been followed, this would probably have resulted in some quitters being re-classified as smokers. It is hard to see, however, why the social desirability of being classified a non-smoker would be particularly strong or vary by arm, when the only contact was by post with researchers 18 months after completing pregnancy. Thus the lack of cotinine confirmation is an unlikely source of bias and probably did not mask the true beneficial effect of belonging to one or other trial arm.

In this paper, we report for the first time data on changes in women's self-reported cigarette consumption, showing that women in Arm C had the lowest increase in consumption throughout pregnancy. This supports data showing that women in Arm C were more likely to quit [21]. These data are, however, equivocal and a variety of interpretations could be placed on them, but we believe that this effect is unlikely to be due to the intervention. The increase in consumption was least in Arm C because the mean reported consumption at baseline was two to three cigarettes per day higher than for women in other arms (a statistically significant difference). We cannot explain this; the method used to record cigarette con-

sumption was identical in all arms, other baseline characteristics of women were well balanced, and the mean baseline cotinine concentrations did not differ significantly by arm. There was some support for an effect of the Arm C intervention on changes in consumption from the data on changes in cotinine concentration at 30 weeks gestation, but not at 10 days postpartum. At 18 months postpartum, the self-reported daily consumption did not differ significantly by trial arm, being 12–13 cigarettes per day. The intervention was not designed to reduce cigarette consumption in women who did not stop smoking, but perhaps midwives gave this advice. Overall, any effect of the intervention on cigarette consumption was at best temporary and had small effects if any on nicotine consumption.

This study provides clearer evidence on the benefits of in-pregnancy interventions on long-term smoking cessation. Compared with the studies reviewed in the Introduction [15–20], it was considerably larger than most. Additionally, three studies were non-randomized [15,16,19], and the benefits of the interventions within pregnancy were modest and mostly not significant, so the absence of good evidence of long-term benefit in these studies is unsurprising. This study showed clearer short-term benefits than these trials (with the exception of Pbert *et al.* [20]), but no evidence at all of any sustained benefit apparent at 18 months postpartum. It needs to be acknowledged that the confidence intervals of the ORs for quitting encompass the possibility of substantial benefit in the relative scale, but this in-pregnancy intervention could generate only a small absolute benefit in numbers of quitters, even taking the upper limit of the confidence interval. However, taking all the literature together, the evidence shows that in-pregnancy programmes may have immediate benefits to the fetus, but do not influence the smoking outcomes of mothers in the medium term. Whether women who have experienced in-pregnancy interventions are better prepared to quit several years into the future has not been investigated.

This study also has implications for the Transtheoretical Model. Prochaska and Velicer claimed that the self-help materials that purport to engage women in the stage-appropriate processes of change will go on working beyond the formal period of the intervention, creating benefits that are larger in the longer term than in the medium term [14]. Stotts *et al.* have argued that many women who stop in pregnancy appear to be suspending their smoking for the sake of their fetus only, and not really quitting in the usual sense [12]. From this perspective, the TTM-based materials have failed. They 'should' have engaged women in the processes of change, rather than merely prompting temporary abstinence through a combination of women's good intentions and guilt. That they did not do so raises the issue of how the TTM-based

interventions achieved their modest benefit [21], which cannot be answered from these data alone.

The issue of smoking in pregnancy continues to be troublesome for policy makers. How can the gains observed in RCTs be translated into effective in-service interventions? Pragmatic attempts to do so have failed to realize the benefits observed in trials designed to show proof of principle [27]. Similarly, return to smoking is the norm for women who suspended smoking during pregnancy [6–9]. Clearly, it is insufficient to approach women with an intervention that is superficially appropriate for their stage of change and expect women to work through the stages. There is something special about women's intentions to smoke in pregnancy [13]. More effort therefore needs to go into understanding these unique intentions, and working with such understanding to develop interventions that are perhaps unique to pregnant women. The TTM-based intervention was similar to that offered to non-pregnant adults, and did not have the same modest benefits in the longer term that, in some trials, it has had in general adult populations [26,28–30].

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References

1. Ershoff, D. H., Quinn, V. P., Boyd, N. R., Stern, J., Gregory, M. & Wirtschafter, D. (1999) The Kaizer Permanente prenatal smoking-cessation trial: when more isn't better, what is enough? *American Journal of Preventive Medicine*, **17**, 161–168.
2. Windsor, R., Lowe, J. B., Perkins, L. L., Smith-Yoder, D., Artz, L., Crawford, M., Amburgy, K. & Boyd, N. R. Jr (1993) Health education for pregnant smokers: its behavioral impact and cost benefit. *American Journal of Public Health*, **83**, 201–206.
3. Owen, L., McNeill, A. & Callum, C. (1998) Trends in smoking during pregnancy in England, 1992–7: quota sampling surveys. *BMJ*, **317**, 728–730.
4. Pirie, P. L., Lando, H., Curry, S. J. & McBride, C. M. & Grothaus, L.C. (2000) Tobacco, alcohol and caffeine use and cessation in early pregnancy. *American Journal of Preventive Medicine*, **18**, 54–61.
5. Lumley, J., Oliver, S. & Waters, E. (2004) Interventions for promoting smoking cessation during pregnancy (Cochrane Review). In: *The Cochrane Library*, Issue, 3.

6. Secker-Walker, R. H., Solomon, L. J., Flynn, B. S., Skelly, J. M., Lepage, S. S., Goodwin, G. D. & Mead, P. B. (1995) Smoking relapse prevention counselling during prenatal and early prenatal care [erratum appears in *American Journal of Preventive Medicine*, 1996, 2, 71–2]. *American Journal of Preventive Medicine*, **11**, 86–93.
7. Fingerhut, L., Kleinman, J. & Kendrick, J. (1990) Smoking before, during, and after pregnancy. *American Journal of Public Health*, **80**, 541–545.
8. Ockene, J. K. (1993) Smoking among women across the lifespan: prevalence, interventions, and implications for cessation research. *Annals of Behavioral Medicine*, **15**, 135–148.
9. Kahn, R. S., Certain, L. & Whitaker, R. C. (2002) A reexamination of smoking before, during, and after pregnancy. *American Journal of Public Health*, **92**, 1801–1808.
10. Stapleton, J. A. (1998) Cigarette smoking prevalence, cessation and relapse. *Statistical Methods in Medical Research*, **7**, 187–203.
11. Jorenby, D. E., Leischow, S. J., Nides, M. A., Rennard, S. I., Johnston, J. A., Hughes, A. R., Smith, S. S., Muramoto, M. L., Daughton, D. M., Doan, K., Fiore, M. C. & Baker, T. B. (1999) A controlled trial of sustained-release bupropion, a nicotine patch or both for smoking cessation. *New England Journal of Medicine*, **340**, 685–691.
12. Stotts, A. L., Diclemente, C. C., Carbonari, J. P. & Mullen, P. D. (1996) Pregnancy smoking cessation: a case of mistaken identity. *Addictive Behaviours*, **21**, 459–471.
13. Abrahamsson, A., Spingett, J., Karlsson, L. & Ottosson, T. (2004) Making sense of the challenge of smoking cessation during pregnancy: a phenomenographic approach. *Health Education Research*, in press. Available at: <http://her.oup-journals.org/cgi/reprint/cyg127v1>
14. Prochaska, J. O. & Velicer, W. F. (1997) The transtheoretical model of health behavior change. *American Journal of Health Promotion*, **12**, 38–48.
15. Lillington, L., Royce, J., Novak, D., Ruvalcaba, M. & Chlebowsky, R. (1995) Evaluation of a smoking cessation program for pregnant minority women. *Cancer Practice*, **3**, 157–163.
16. Petersen, L., Handel, J., Kotch, J., Podedworny, T. & Rosen, A. (1992) Smoking reduction during pregnancy by a program of self-help and clinical support. *Obstetrics and Gynecology*, **79**, 924–930.
17. Secker-Walker, R. H., Solomon, L. J., Flynn, B. S., Skelly, J. M., Lepage, S. S., Goodwin, G. D. & Mead, P. B. (1994) Individualized smoking cessation counseling during prenatal and early postnatal care. *American Journal of Obstetrics and Gynecology*, **171**, 1347–1355.
18. Secker-Walker, R. H., Solomon, L. J., Flynn, B. S., Skelly, J. M. & Mead, P. B. (1998) Smoking relapse prevention during pregnancy. A trial of coordinated advice from physicians and individual counseling. *American Journal of Preventive Medicine*, **15**, 25–31.
19. Wakefield, M. & Jones, W. (1998) Effects of a smoking cessation program for pregnant women and their partners attending a public hospital antenatal clinic. *Australian and New Zealand Journal of Public Health*, **22**, 313–320.
20. Pbert, L. A., Ockene, J. K., Zapka, J. G., Yunsheng, M., Valentine Goins, K., Oncken, C. & Stoddard, A. M. (2004) A community health center smoking-cessation intervention for pregnant and postpartum women. *American Journal of Preventive Medicine*, **26**, 377–385.
21. Lawrence, P. T., Aveyard, P., Evans, O. & Cheng, K. K. (2003) A cluster randomized controlled trial of smoking cessation in pregnant women comparing interventions based on the transtheoretical (stages of change) model to standard care. *Tobacco Control*, **12**, 168–177.
22. Lawrence, T., Aveyard, P. & Croghan, E. (2003) What happens to women's self-reported cigarette consumption and urinary cotinine levels in pregnancy? *Addiction*, **98**, 1315–1320.
23. Roland, M. & Torgerson, D. J. (1998) Understanding controlled trials. What are pragmatic trials? *BMJ*, **316**, 285.
24. Heatherton, T. F., Kozlowski, L. T., Frecker, R. C. & Fagerstrom, K. O. (1991) The Fagerstrom test for nicotine dependence: a revision of the Fagerstrom Tolerance Questionnaire. *British Journal of Addiction*, **86**, 1119–1127.
25. Cope, G., Nayyar, P., Holder, R., Gibbons, J. & Bunce, R. (1996) A simple near-patient test for nicotine and its metabolites in urine to assess smoking habit. *Clinica Chimica Acta*, **256**, 135–149.
26. Aveyard, P., Griffin, C., Lawrence, P. T. & Cheng, K. K. (2003) 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. *Addiction*, **98**, 345–354.
27. Hajek, P., West, R., Lee, A., Foulds, J., Owen, L., Eizer, J. R. & Main, N. (2001) Randomized controlled trial of a midwife-delivered brief intervention in pregnancy. *Addiction*, **96**, 485–494.
28. Prochaska, J. O., Diclemente, C. C., Velicer, W. F. & Rossi, J. S. (1993) Standardized, individualized, interactive, and personalized self-help programs for smoking cessation. *Health Psychology*, **12**, 399–405.
29. Prochaska, J. O., Velicer, W. F., Fava, J. L., Ruggiero, L., Laforge, R. G., Rossi, J. S., Johnson, S. S. & Lee, P. A. (2001) Counselor and stimulus control enhancements of a stage-matched expert system intervention for smokers in a managed care setting. *Preventive Medicine*, **32**, 22–32.
30. Velicer, W. F., Prochaska, J. O., Fava, J. L., Laforge, R. G. & Rossi, J. S. (1999) Interactive versus noninteractive interventions and dose-response relationships for stage-matched smoking cessation programs in a managed care setting. *Health Psychology*, **18**, 21–28.