

RESEARCH REPORT

Randomized controlled trial of a midwife-delivered brief smoking cessation intervention in pregnancy

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Abstract

Objective. To evaluate the efficacy of a brief smoking cessation intervention with pregnant women practicable routinely by midwives. **Design.** Midwives were randomized to deliver the experimental intervention or usual care. The 10–15-minute intervention was based on brief counselling, written materials, arrangements for continuing self-help support and feedback on expired-air carbon monoxide levels. The intervention was tailored to the women's needs: those who did not want to stop smoking received a brief motivational intervention, those who wanted to stop received an intervention designed to assist them and those that had stopped recently (recent ex-smokers) received a relapse prevention intervention. **Setting.** Booking interviews with pregnant women in nine hospital and community trusts. **Subjects.** A total of 1120 pregnant women in the third month of pregnancy (249 recent ex-smokers and 871 current smokers). **Main outcome measures.** Three indicators of biochemically validated abstinence were collected. Continuous abstinence for at least 3 months prior to delivery, point prevalence abstinence immediately post-delivery, and continuous abstinence from 3 months pre-delivery to 6 months post-delivery. **Results.** Only a small proportion of the women who would have been eligible to take part in the trial were actually recruited by 178 recruiting midwives, with lack of time being cited as the main barrier. The intervention and usual care groups differed in post-delivery point prevalence abstinence rates for recent ex-smokers (65% vs. 53%, $p < 0.05$, one-tailed), but not in other outcome measures. Overall, 54% of 'recent ex-smokers' at booking and 7% of 'current smokers' at booking had been abstinent for at least 3 months at the time of delivery, and 23% and 3%, respectively, were still abstinent by the time the child was 6 months old (i.e. 12 months post-intervention). Smoking status at follow-up was predicted by dependence indexed by time to first cigarette in the morning. **Conclusions.** A brief 'one-off' smoking cessation intervention by midwives does not seem to be a practicable or effective method of helping pregnant smokers to stop. Other options such as tailored self-help materials and telephone counselling and other specialist treatments should be examined. Current smoking cessation rates in pregnancy are very low.

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Introduction

Some 25% of women in the United Kingdom smoke at the time they become pregnant.¹ Of these, only one-fifth report that they stop smoking.^{1,2} Apart from health risks to women, smoking in pregnancy damages the fetus, leading to low birth weight and in some cases to spontaneous abortion or perinatal death. Children whose mother smoked during pregnancy have a higher risk of learning and behaviour problems and cot death.³⁻⁵ Encouraging and helping women to stop smoking during pregnancy remains a high priority.

Previous research has indicated that counselling by dedicated staff can lead up to 10% of women to stop smoking during pregnancy in addition to those who would have done so anyway, and that this is a relatively inexpensive way of reducing morbidity.⁶ If the intervention could be undertaken by routine health-care staff, it would be even more cost-effective. Midwives are well placed to deliver anti-smoking advice because they interview the mother early in the pregnancy and often maintain contact until the early postnatal period. Survey data indicate that most midwives are keen to play a part in encouraging pregnant smokers to stop,⁷ but any midwife-delivered intervention needs to be brief enough to be fitted into their existing activities. Little is known about whether it is practicable or effective for midwives to deliver brief smoking cessation counselling. A recent study carried out in Denmark suggests that it is not⁸ but definitive evidence is lacking. This study sought to answer this important question.

In addition to looking at smoking status at birth as in the previous trials, subjects were followed up for 6 months post-delivery as over half of women abstinent at delivery resume smoking within 3 months.⁹

Subjects and method

Midwifery services in nine hospital and community trusts were recruited to take part in the study. Midwives (MWs) were informed that they may be assigned either to a control condition in which they would deliver their usual anti-smoking advice or the intervention condition in which they would be asked to deliver an experimental intervention.

The allocation schedule was generated by drawing of folded tags with Intervention or Con-

trol designations and assigning them to consecutive names on the list of midwives. MWs were invited to training sessions lasting either 1 hour (control group) or 2 hours (intervention group). Training sessions involved a discussion and a video of the study procedures, and practice in collecting study data. For the intervention group, this also included using the CO monitor and administering the intervention. MWs in the control group were asked to record their usual procedures with smokers and recent ex-smokers. They were then asked to continue with their usual practice, but to avoid including any other interventions for the duration of the study. The usual care normally included access to standard anti-smoking leaflets. Research workers were available for refresher sessions throughout the study.

Pregnant women who were current smokers or recent ex-smokers (see below) were invited to take part in the study at their first 'booking interview' with MWs. This takes place usually around the 12th week of pregnancy. The first follow-up took place about 6 months after the intervention, usually during a MW visit at 10 days after delivery. Those claiming abstinence and passing a CO validation (see Measures) were contacted again 6 months later (1 year after the intervention). Women claiming abstinence were visited to provide an expired-air CO reading.

Subjects

Women were eligible to take part in the study if they were current smokers or stopped smoking up to 3 months previously (recent ex-smokers), and provided informed consent. A total of 1287 subjects were recruited. This was estimated to yield an 80% chance of detecting a 5% difference in abstinence rates between the intervention and control groups in the sample as a whole, assuming minimal loss of power due to some midwives having significantly better success rates than others.

Intervention

Smokers were asked about their intentions concerning smoking cessation (see 'Other measures' below). Those not considering any change were given a three-page booklet aiming to enhance motivation and combat likely barriers to considering cessation (the 'Choice is yours' booklet).

Smokers wanting to stop and recent ex-smokers received the full intervention.

The intervention consisted of the following:

- Advice by the MW which included an interpretation of the carbon monoxide (CO) reading.
- Written material produced for this study in two slightly different versions for current smokers and for recent ex-smokers ('How to stop smoking for good' and 'How to stay off smoking for good'). This (1) explained the effects of smoking on the fetus and the effects of passive smoking on the new-born child, (2) explained why abstinence may be difficult to maintain, (3) combated the belief that smoking reduces stress and (4) advised on ways to stop smoking and to avoid relapse. It emphasized the importance of complete cessation as opposed to smoking reduction.
- Each of the four parts of the six-page leaflet were summarized into several simple points, and at the end of the booklet there was a four-item 'quiz' checking the key points. After clients had read the booklet, midwives conducted a brief interview correcting and discussing any incorrect answers.
- The last page of the booklet provided space for specifying a quit date and registering a commitment to stop smoking, to be 'witnessed' by MW's signature and a woman's partner or friend.
- Women were invited to be paired with another pregnant smoker for mutual support, and guidelines on managing the process were provided by means of a 'Buddy Card'.
- Women's notes were marked to encourage reinforcement of the intervention during future contacts. It was also explained to women that their smoking status would be ascertained again after 6 and 12 months.

The reason for tailoring the intervention to the smoker's motivational state was to alleviate MWs' concerns that an anti-smoking intervention may alienate unmotivated women. The relapse prevention component represented a significant addition to normal practice, where little attention is given to recent ex-smokers. Regarding the social support element, we have demonstrated recently that a 'buddy system' can be effective in primary care interventions.¹⁰

The intervention was developed in consultation with midwives and was piloted prior to the

study initiation. The following set of criteria was used to make sure the intervention was suitable for incorporation into routine care: cost of no more than £4.00 per smoker (including materials, administration and training, but excluding midwives' time); duration of no more than 10 minutes of midwife's time on average per smoker (15 minutes with informed consent and study questionnaire); practicable enough to allow it to be incorporated into a midwifery protocol.

The control group received the usual care in the MW's individual style (see above).

Measures

Outcome measures

The two main outcome measures were:

- (1) 'Continuous abstinence' at birth determined at the postnatal interview. This was defined as self-reported abstinence during the last 12 weeks of the pregnancy and up to the interview, and an expired air carbon monoxide reading at that interview of less than 10 p.p.m.
- (2) 'Continuous abstinence' at 6 months post-delivery determined at the 6-month post-birth interview. This was defined as continuous abstinence at birth (see above), self-reported lapse-free abstinence from birth until the 6-month post-birth interview, and an expired air carbon monoxide reading of less than 10 p.p.m. at that interview.

A further outcome measure, 'point prevalence abstinence at birth', was included, defined as self-reported abstinence at the time of the post-birth interview and an expired air carbon monoxide concentration of less than 10 p,p,m, at the interview.

Other measures

At booking interview, subjects filled in a questionnaire, which covered marital and employment status, occupation and education. They were asked to rate their desire to stop smoking on four-point scale, i.e. I am desperate to give up, I would quite like to give up, I am not sure, and I am not really interested in giving up. Answers to this question dichotomized current smokers into motivated (first two answers) and non-motivated ones. Other smoking variables included time to first cigarette in the morning. MWs recorded their compliance with individual

study procedures and the duration of the intervention.

At follow-ups, subjects filled in a form checking their smoking status and their recall and ratings of the intervention components. Those smoking rated their desire to stop. Birth weight of the babies was also recorded. At the end of the study, midwives were asked to fill in forms providing feedback on the intervention components and their feasibility in routine care.

Data analysis

Logistic regression analyses were undertaken to assess whether midwives differed in terms of their patients' outcomes. Similar tests were carried out to check for differences between the trusts on outcome measures. Intervention and control groups were compared on all baseline measures using chi-squared tests for categorical measures and *t*-tests for quantitative measures. Logistic regression analyses were carried out to assess the extent to which individual baseline measures predicted outcomes. The effect of the intervention was assessed for each outcome measure by chi-squared tests and logistic regression. It was planned to use random effects logistic regression analyses if differences between midwives in outcome had been observed or a conventional logistic regression otherwise. The logistic regression would control for any baseline differences between the intervention and control groups. All *p* values are two-tailed except for tests of intervention effects which are one-tailed, the prediction being that the intervention would lead to more abstainers than the control condition. Outcome analyses were completed on an intention-to-treat basis.

Results

A total of 290 midwives from nine NHS trusts agreed to assist with the trial. Of these, 20% were hospital midwives, 78% were community midwives and 2% were both. Their average age was 37 years and they had been practising for an average of 11 years. They reported that they performed on average five bookings per week. There were no differences between the midwives in the two groups in age, years of practice, number of bookings per week or smoking status. It would be expected that they would each undertake bookings with at least 20 smokers and

recent ex-smokers over a 6-month period allowing for absences. This would provide a pool of 8700 eligible patients during that period. In the event only 178 (61%) actually recruited any patients, 86 in the control group and 92 in the intervention group. These will be referred to as 'participating midwives'. As subject recruitment was slow, some sites were offered payments for each smoker recruited. This appeared to boost recruitment. In hospitals that were paid, 77% of midwives recruited at least one patient, compared with 54% in hospitals that were not paid ($\chi^2 = 6.0, p < 0.05$). Fifteen per cent of the midwives were smokers, but smoking midwives were equally likely to recruit participants as those who were not smokers. Participating midwives recruited an average of seven women each (SD = 8.9).

Fifty-one women did not respond to the call for the first follow-up after the birth of the child or withdrew from the study. These were counted as smokers. A further 167 (83 in the control group and 84 in the intervention group) had moved away and were untraceable or were deemed unsuitable for follow-up (e.g. because of miscarriage). These were excluded from analyses. Thus the sample for analysis was 1120. There were no differences in baseline characteristics between those who were successfully followed up and those that were not.

Of the 1120 women, 249 (22%) were recent ex-smokers and 871 (78%) were current smokers. Among current smokers, 189 (22%) were not motivated to stop smoking.

Table 1 shows the baseline characteristics of the intervention and control groups. The groups differed significantly in the proportion of women who wanted to stop and who smoked within 30 minutes of waking (used to index dependence), with the control group being slightly more interested in stopping and less dependent. Ex-smokers had higher educational levels and were less dependent than current smokers. Among current smokers about a quarter were unemployed and, despite the low average self-reported smoking rate (10 cigarettes per day), over half smoked within 30 minutes of waking.

Table 2 shows associations between baseline variables and abstinence at each follow-up point. Among current smokers, desire to stop and dependence were associated with abstinence up to birth but only dependence was significantly associated with abstinence 6 months later. Also, for

Table 1. Baseline characteristics of intervention and control groups

	Smokers		Ex-smokers	
	Intervention	Control	Intervention	Control
Sample size	431	440	114	135
Percentage married/living with partner†	71.9	71.1	77.2	81.5
Percentage unemployed†	24.3	24.6	16.0	14.5
Percentage non-manual occupation†	20.1	14.5	34.9	37.9
Percentage looking after the home†	35.6	35.3	22.6	21.8
Percentage who want to stop smoking	75.9*	80.7*	–	–
Percentage who smoke within > 30 min of waking†	39.4*	58.0*	67.6	76.6
Percentage with no educational qualifications†	27.4	26.1	9.8	15.8
Mean (SD) daily cigarette consumption†	10.1 (6.2)	9.7 (6.7)	12.6 (7.0)	10.9 (6.9)
Mean (SD) weeks since last cigarette	–	–	6.6 (3.6)	7.3 (3.6)
Mean (SD) age	27.6 (6.0)	26.9 (6.1)	28.2 (5.3)	27.7 (5.5)

† Current smokers differed from ex-smokers by chi-squared test, $p < 0.05$. * Current smokers in Intervention and Control groups differed, $p < 0.05$ by chi-squared test

abstinence at birth a multiple logistic regression showed that only dependence was significantly independently predictive. For ex-smokers several variables were associated with abstinence up to the birth of the child. There were no significant predictors of smoking status at the last follow-up. There was no evidence that either midwives or trusts differed significantly in terms of the outcomes of their patients.

Table 3 shows abstinence rates in the intervention and control groups at the two follow-up points. There were no significant differences between intervention and control groups except for point-prevalence at the postnatal interview, where the ex-smokers in the intervention group did slightly better. There was no evidence that the intervention was effective in the subgroup of current smokers who were motivated to stop and received the full intervention; 7.8% of the intervention group and 5.8% of the control group were continuously abstinent at postnatal follow-up, 11.6 and 11.4% were abstinent at this point using point prevalence, and 2.9 and 2.5% were abstinent at the 6-month post-birth follow-up.

When controlling for desire to stop and time to first cigarette (on which the intervention and control groups had differed at baseline), again the only effect found was on point prevalence among ex-smokers at the postnatal interview (odds ratio 6.11, $p < 0.05$, one-tailed test)

There was no significant interaction between

intervention effects and socio-economic status of the smokers, nor was there any interaction between intervention effects and dependence (indexed by time to first cigarette of the day).

The intervention significantly increased desire to stop smoking at the postnatal interview (mean ratings of 2.75 vs. 2.51 for intervention and control groups respectively, $F = 5.8$, $p < 0.02$ for analysis of covariance with motivation to stop at baseline as a covariate).

Table 4 shows the percentage of mothers at the postnatal interview recalling intervention elements in the intervention and control conditions. The extent to which intervention midwives followed the protocol was variable.

Table 5 shows implementation rates of elements of the intervention as recorded by midwives on the log forms. It appears that handing out the booklet and asking the client to blow into the CO monitor was implemented comprehensively, but other elements were not. A quit date was negotiated by only 56% of the midwives for current smokers, and the social support 'buddy' system was generally not initiated.

The intervention took an average of 15 minutes, including obtaining consent to take part in the study and filling in the study questionnaire. Midwives were asked to comment on the practicability of the intervention. Of 52 midwives who gave comments, 65% said the intervention could not be undertaken in the time available.

Table 2. Associations between baseline variables and outcome measures

	Continuous abstinence at birth	Point prevalence at birth	Continuous abstinence 6 months post-birth
Current smokers			
Unemployed	1.09	1.01	1.56
Homekeeper	1.21	1.07	2.89
Non-manual occupation	0.64	0.76	0.25
Married	0.91	1.06	0.74
No educational qualifications	0.99	0.82	1.20
Want to stop	1.52*	1.45*	1.59
1st cig after 30 min from waking	3.88***	2.75***	3.76*
Ex-smokers			
Unemployed	0.63	0.74	1.02
Homekeeper	0.49*	0.58	0.46
Non-manual occupation	1.87*	1.61	1.82
Married	1.90*	1.21	1.20
No educational qualifications	0.41*	0.44*	0.53
1st cig after 30 min from waking	1.16	0.97	1.08
Weeks since last cigarette at booking	1.09*	1.07	1.07

The figures in the table are odds ratios from logistic regression analyses (one for each figure) examining the bivariate relationship between the predictor variable and the outcome variable. Some of the predictor variables are not independent of each other (i.e. homekeeper, unemployment and non-manual occupation). The odds ratios give the increase in odds of abstinence for each unit increase in the predictor variable. * $p < 0.05$; *** $p < 0.001$,

Table 3. Abstinence rates (percentage) in intervention and control groups at each follow-up among current smokers and ex-smokers at booking interview

	Point prevalence at birth	Continuous abstinence at birth	Continuous abstinence 6 months post-birth
Intervention group: current smokers, $N = 431$	11	6	3
Control group: current smokers, $N = 440$	10	7	3
Intervention group: ex-smokers, $N = 114$	65*	58	23
Control group: ex-smokers, $N = 135$	53	50	25
Intervention group: all $N = 545$	22	17	7
Control group: all $N = 575$	20	17	8

* Significantly different from control by chi-squared test, $p < 0.05$, one-tailed.

Regardless of whether the mothers were in the intervention or control groups, babies born to mothers who were abstinent at the birth weighed more than those who were not—118 ounces (SD = 19.9) vs. 111 ounces (SD = 19.4), $t = 26.9$, $p < 0.0001$. A similar size of difference

was observed in babies whose mothers were abstinent for 12 weeks leading up to the birth versus those that were not—118 ounces (SD = 20.4) vs. 111 ounces (SD = 19.3), $t = 21.1$, $p < 0.0001$.

We were interested to know how birth weight

Table 4. Percentage of mothers in intervention and control groups who at the first postnatal visit recalled advice given by midwives

	Unmotivated smokers		Motivated smokers		Ex-smokers	
	Int N = 100	Cont N = 81	Int N = 287	Cont N = 303	Int	Cont
Midwife						
Discussed smoking	100	100	99	98	100	99
Discussed smoking more than once	50*	38	47	40	33	24
Advised to set a date and stop abruptly	29*	13	64***	13	20	11
Advised to stop in their own time or cut down	74	73	48***	69	43	39
Offered to find a 'buddy'	42***	5	68***	8	35***	5
Given a booklet to read	86***	35	92***	46	95***	33
Checked understanding of the booklet	68***	16	81***	26	82***	20
Measured CO in the breath	87***	9	93***	7	90***	12
Explained that smoking is dangerous	94**	78	95***	81	94***	63
Explained why stopping may be difficult	53**	34	66***	33	60***	31
Advised on how to avoid relapsing	24	12	41***	10	48***	16
Explained why is it difficult to stay off cigs	31	23	49***	17	48***	12
Discussed coping with difficult situations	40**	16	43***	14	45***	15
Mother						
Found the advice helpful	64***	38	72***	55	66*	55
Resented the advice given	3	5	3	4	2	3

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$ for comparison between Intervention and control conditions by chi-squared test.

related to smoking history and so entered continuous abstinence, prior cigarette consumption and smoking status (current vs. ex-smoker) at booking together into a multiple regression analysis predicting birth weight. We also included measures of deprivation that were related to birth weight. These were being single ($R = -0.11, p < 0.001$) and having no educational qualifications ($R = 0.08, p = 0.02$). The

results are shown in Table 6. It appears that there were independent 'effects' of smoking status at time of booking, abstinence in the last 12 weeks of the pregnancy and cigarettes per day at booking (for ex-smokers at booking this was previous cigarette consumption).

Discussion

The smoking cessation intervention by midwives did not influence continuous abstinence rates in recent ex-smokers or current smokers at any of the two follow-up points. The intervention

Table 5. Percentage implementation of elements of the intervention as logged by midwives

	Current smokers	Ex-smokers
Asked to blow into CO monitor	95	95
Given booklet to read	100	100
Asked questions about the booklet	69	89
Agreed a quit date	56	-
Put sticker on records	72	74
Offered to put in touch with a 'buddy'	23	3
Explained that there would be a follow-up	72	75

Table 6. Results of regression using smoking history variables to predict birth weight

Predictor	Beta	p value
Smoking status at booking (0 = smoker, 1 = ex-smoker)	0.08	0.04
Cigarettes per day when smoking	-0.08	0.02
Continuous abstinence for 12 weeks up to birth	0.08	0.05
Married/living with partner	0.06	0.07
No educational qualifications	-0.08	0.02

seems to have influenced women's readiness to quit at follow-ups, but such self-reported effects in the absence of behavioural change can be due to 'demand characteristics' of the study,¹¹ and are of little practical significance.

Before discussing the implications of the findings it is important to consider their limitations. Given the low recruitment rate by the midwives, it is possible that the results were biased by midwives attempting to select women who they felt would be most amenable to receiving an intervention. However, if that were the case, it should work in favour of finding an 'intervention effect', albeit spurious. This was not the case. Another possible limitation was that there was no attempt to check the skills of the midwives following the training, and indeed the training may have been too brief. Even with the brevity of training used, however, it was very difficult to arrange the training sessions and, without better structures in place in the Health Service to support training, including locum cover, this is a practical problem that will be difficult to overcome.

The lack of effect cannot be attributed to the control 'usual care' procedure being too powerful to allow the study intervention to improve on it. The overall success rates were low, close to those observed in spontaneous quit attempts.^{12,13}

Client feedback and MWs' log forms suggest that some parts of the intervention were implemented comprehensively, but some of the key elements designed to instigate continuing motivational support were not. To counteract the limitation of a 'one-off' intervention, several mechanisms were designed to be put in place for extended support. This included, in addition to self-help materials, a reminder in the client's notes to reinforce the intervention at future contacts, a signed commitment to quit date, and an initiation of a social support system. The reminder stickers were not used in a quarter of cases, and the last two elements were poorly implemented. Midwives felt uneasy about pairing strangers, and very few used the 'buddy system' with their clients. More surprisingly, the compliance with setting up the quit date was low. There seems to be a tradition in midwifery of using a permissive approach with regard to smoking, and the recommendation to 'cut down' seems much more congenial to this ethos than a more 'authoritarian' advice to set up

a concrete quit date and stop smoking altogether.

A more intensive intervention spread over multiple sessions or telephone contacts could be more successful, but would not be practicable. Even the current intervention taking 15 minutes inclusive of the study questionnaire and consent form was generally considered too long. In fact, a sizeable proportion (39%) of midwives who expressed willingness to take part in the study were unable to recruit a single client.

Midwives' verbal feedback queried whether the booking interview, which is generally busy, is the optimal time for the intervention. However, there is no other more suitable occasion available, as this is the only session that all women attend, and it takes place at the beginning of pregnancy at the most opportune time to consider life-style changes.

The recruitment and implementation difficulties experienced during this study correspond closely with the experience of initiating routine smoking cessation procedures with other groups of primary care professionals. It seems very difficult to sustain even simple routine procedures in this area.¹⁴⁻¹⁶ Primary care staff have other pressing priorities, and interventions with smokers can be demoralizing, as well over 90% of patients who receive any type of routine intervention will continue to smoke. In addition to this, patients may feel embarrassed and compelled to avoid their health care providers or to misreport their smoking status. Some have expressed concern that smoking interventions may strain relationships between patients and primary care staff.¹⁷

One possible solution would be for midwives to refer motivated smokers to specialist counselors for help.¹⁸ This was indeed the most preferred option in the midwifery survey mentioned above.⁷ Pregnant smokers seem reluctant to attend clinics (e.g. Lichtenstein & Hollis¹⁹), but seem more receptive to receiving help on an individual basis from a counsellor who can see them during visits to antenatal sessions or in their home.⁶ Other areas worth further investigation are targeted and tailored self-help interventions which can be administered centrally and economically by post.²⁰ Finally, there is a growing sense that nicotine replacement should be made available to pregnant women.²¹

The study provided some interesting information on smoking and birth weight. Even when

smoking status at the time of the birth and cigarette consumption were controlled for, smoking status at the time of the booking was related to birth weight. This suggests that perhaps some of the damage to the fetus occurs early in pregnancy, before the booking interview. This study was able to address this question with greater precision than some others because of biochemical checks of smoking status at booking and at the postnatal follow-up. This issue needs further clarification.

The study provides the largest prospective dataset to date on changes in smoking status in pregnant smokers with all self-reports biochemically validated. Only 24% of 'recent ex-smokers' and 3% of 'current smokers' managed to remain abstinent by the time the child was 6 months old. These figures are low and there clearly remains a pressing need to find practicable and effective interventions in this area.

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