Papers

Randomised controlled trial of home based motivational interviewing by midwives to help pregnant smokers quit or cut down

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Abstract

Objective To determine whether motivational interviewing—a behavioural therapy for addictions—provided at home by specially trained midwives helps pregnant smokers to quit.
Design Randomised controlled non-blinded trial analysed by intention to treat.
Setting Clinics attached to two maternity hospitals in Glasgow.
Participants 762/1684 pregnant women who were regular smokers at antenatal booking: 351 in intervention group and 411 in control group.
Interventions All women received standard health promotion information. Women in the intervention group were offered motivational interviewing at home. All interviews were recorded.
Main outcome measures Self reported smoking cessation verified by plasma or salivary cotinine concentration.
Results 17/351 (4.8%) women in the intervention group stopped smoking (according to self report and serum cotinine concentration <13.7 ng/ml) compared with 19/411(4.6%) in the control group. Fifteen (4.2%) women in the intervention group cut down (self report and cotinine concentration less than half that at booking) compared with 26 (6.3%) in the control group. Fewer women in the intervention group reported smoking more (18 (5.1%) *v* 44 (10.7%); relative risk 0.48, 95% confidence interval 0.28 to 0.81). Birth weight did not differ significantly (mean 3078 g *v* 3048 g).
Conclusion Good quality motivational interviewing did not significantly increase smoking cessation among pregnant women.

Introduction

Cigarette smoking damages the health of pregnant women and unborn babies and has been linked with increased risk of cot death, miscarriage, perinatal death, low birth weight, childhood asthma, and adult cardiovascular disease.[1] The increased cost to the NHS of pregnancy per smoker may be £1500,[2] and the cost of cigarettes impacts on household income. Smoking is a common factor linking ill health and low social class.[3 4] A third of pregnant women smoke,[1] and a quarter of smokers quit while they are pregnant.[5] Most have stopped before maternity booking, and 7.5% give up between booking and delivery.[6] This compares with 2% of all smokers who stop each year,[7] reflecting different incentives to change during pregnancy.

The NHS Centre for Reviews and Dissemination recommends that "pregnant women should be offered intensive advice and support to stop smoking" and advises that "prenatal counselling of at least 10 minutes person to person contact, combined with written materials tailored to pregnancy, can double the quit rate to about 15%."[6]

A Cochrane review of 64 trials from 1975-2003 concluded that "programmes are effective at increasing smoking cessation, and reducing low birth weight, so interventions should become routine antenatal practice."[8] However, the interventions reviewed were a heterogeneous mixture of cognitive behavioural therapy and motivational interviewing augmented by written advice. There remains no standard intervention, and the use of nicotine replacement therapy, widely recommended as part of general smoking cessation guidelines, remains controversial during pregnancy.[8]

Motivational interviewing is a one to one counselling style designed for treating addictions.[9] Its "stages of change" model is widely taught on smoking cessation training courses but may not apply during pregnancy.[10 11] We used a randomised controlled trial to determine whether the quit rate for pregnant smokers increases with motivational interviewing provided at home by specially trained midwives.[12]

Methods

Women booking at two hospitals in Glasgow were eligible to participate if they were smokers at booking and were ≤ 24 weeks' gestation (to allow for 12 weeks of intervention before follow-up).

We planned to recruit 930 women (310 intervention, 620 controls) to give 90% power to detect, at the 5% significance level, an improvement in quit rate from 7.5% in the control group[6] to 15% in the intervention group. After six months the 1:2 intervention:control ratio was modified to 1:1 as pilot recruitment rates were not achieved.[10] From 1 March 2001 to 31 May 2003 we recruited 351 women in the intervention group and 411 in the control group (figs 1 and 2), providing 89% power for a quit rate in the control group of 7.5%.[6]

Four dedicated midwives enrolled smokers at booking clinics. They phoned the administrator, who provided random allocation using sealed envelopes after entering details on the database. Random allocation used balanced stratification for three levels of smoking before pregnancy (<10, 10-20, >20 cigarettes a day (level of smoking)) and cutting down (smoking half or less of the amount before pregnancy at the time of book-

P+ *A copy of the patients' information sheet and details of the two interviews can be found on bmj.com*

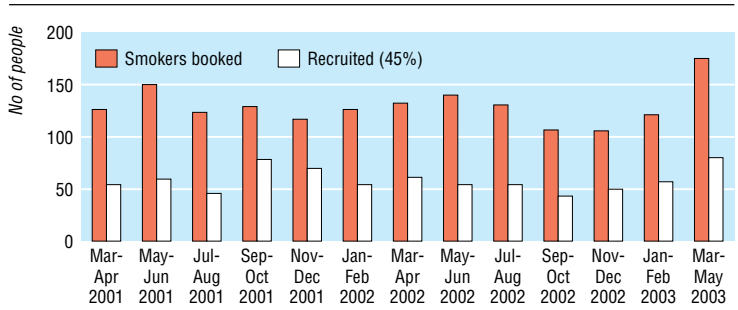

Fig 1 Enrolment of women over time

ing (change already)). A third party made up envelopes in batches. Intervention and control groups were similar at baseline (table 1). Participants and midwives were aware of group assignment.

A consultant provided five days of training in motivational interviewing followed by one day a month throughout the study, using midwives' own recorded interviews to focus development of skills.

Midwives provided standard health promotion including information on smoking and pregnancy from a health education book given to all pregnant women in Scotland (www.hebs.com/readysteadybaby). Women in the intervention group were offered two to five additional home visits of about 30 minutes' duration from the same study midwife. Midwives made six attempts to contact women, including the home visit arranged at enrolment, two to three telephone calls, one or two "cold" calls to the house, and sending a letter asking them to telephone a free number.

All 625 home visits were recorded and stored as digital files. A 10% (n=63) random sample of interviews was transcribed and sent to the Center for Alcoholism Substance Abuse and Addictions, University of New Mexico[13] for content analysis using the motivational interviewing skills code (MISC).

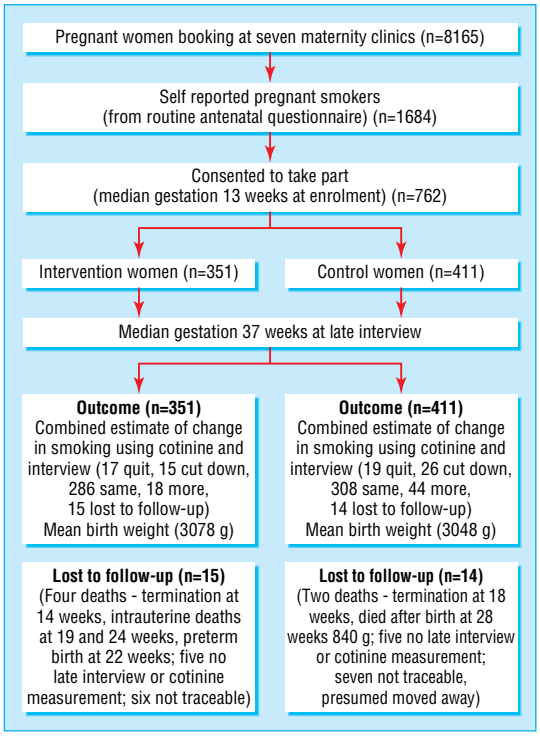

Fig 2 Movement of women through study

Table 1 Baseline individual variables at enrolment in pregnant smokers. Numbers in parentheses indicate number of women for whom data were available. Figures are means (SD) unless stated otherwise

Variable	Intervention (n=351)	Control (n=411)
Age (years)	26.5 (5.8)	26.9 (6.6)
Gestation (weeks)	13.3 (2.2)	13.5 (2.7)
Living with partner	235 (67%)	278 (68%)
No of previous children (n=350, 411):		
0	146 (42%)	177 (43%)
1	105 (30%)	143 (35%)
≥2	99 (28%)	91 (22%)
Deprivation category*:		
1-3	38 (11%)	28 (7%)
4-5	72 (21%)	81 (20%)
6-7	241 (69%)	302 (73%)
Height (cm) (n=347, 409)	162.4 (6.4)	162.3 (6.4)
Weight (kg) (n=347, 409)	65.4 (14.4)	63.8 (13.4)
Smoking		
Age (years) started smoking (350, 411)	15.1 (8-26)	14.7 (6-28)
Cigarettes smoked yesterday (351, 411)	11.7 (0-40)	11.3 (0-45)
Maximum smoked per day (350, 410)	27.0 (5-80)	27.5 (5-80)
Minutes to first cigarette (323, 386)	40.6 (1-660)	47.1 (1-720)
Made at least one previous attempt to quit (349, 411)	231 (66%)	286 (70%)
One full day smoke-free in previous attempts (222, 277)	3 (1%)	0
Usually or always smoke when ill (341, 401)	125 (37%)	164 (41%)
At least one other smoker in house (351, 409)	228 (65%)	268 (66%)
At least one "close other" who is smoker (351, 411)	320 (91%)	379 (92%)
Smoking level before pregnancy (351, 411):		
<10	57 (16%)	67 (16%)
10-20	190 (54%)	215 (53%)
>20	104 (30%)	129 (31%)
Cutting down or quitting		
Commitment to cut down (n=288, 360)†:		
Not considering	41 (14%)	67 (19%)
Considering in next 6 months but not next 30 days	53 (18%)	50 (14%)
Considering in next 30 days, no 24 hour attempt in past year	63 (22%)	98 (27%)
Considering in next 30 days with 24 hour attempt	77 (27%)	84 (23%)
Have cut down at present for at least 24 hours	54 (19%)	61 (17%)
Commitment to quit (n=327, 360)†:		
Not considering at present	87 (27%)	98 (27%)
Considering in next 6 months but not next 30 days	119 (36%)	121 (34%)
Considering in next 30 days, no 24 hour attempt in past year	67 (20%)	69 (19%)
Considering in next 30 days, with 24 hour attempt	54 (17%)	72 (20%)

*According to mailing address in seven categories in ascending order of severity,[19] taking account of overcrowding, male unemployment, low socioeconomic status, and lack of car.
†Numbers reduced because ambiguity was present in these questions such that initially midwives only completed either cut down or quit rather than both and we did not go back to clients already enrolled to ask questions again.

Table 2 Summary of rating scales for 63 randomly selected interviews

Variable	Mean (SD)	Range	Proficient*	Expert*
Global therapist ratings	5.68 (0.68)	2-7	>5.0	>6.0
Ratio of reflections to questions	1.47 (0.68)	0.35-3.38	>1.0	>2.0
% of open questions	43.89 (14.0)	13.3-72.0	>50%	>70%
% of complex reflections	59.26 (19.7)	25.8-100	>40%	>50%
Total reflections per 10 minutes	19.9 (7.9)	4.1-39.7	>10	>15
% of consistent responses	98.00 (3.6)	82.1-100	>80%	>90%
% of therapist talk time (n=61)	53.06 (12.7)	27.9-85.3	<60%	<50%

*Target criteria: talk less than your client; your most common response to what client says should be reflection; on average, reflect twice for each question you ask; when you reflect use complex reflections more than half the time; when you do ask questions ask mostly open questions; avoid getting ahead of your client's level of readiness (warning, confronting, giving unwelcome advice or direction, taking the "good" side of the argument).

A second administrator blinded to random allocation established a primary outcome (quit, cut down, same, more) soon after the routine 36 week antenatal visit using a structured telephone interview. A health visitor went to the woman's home if telephone contact failed. This self report was corroborated by cotinine concentration in residual routine blood or saliva samples. Cotinine is a nicotine metabolite and reflects cigarettes smoked over a few days. Routine blood samples were collected at booking and at visits in mid and late pregnancy and analysed with gas liquid chromatography.[14] We augmented late pregnancy blood samples for 290/351 (83%) women in the intervention group and 364/411 (89%) in the control group with saliva samples from a further 27 (8%) and 20 (5%) women, respectively.

We defined quitting as self report plus cotinine concentrations of <13.7 ng/ml serum or <14.2 ng/ml saliva.[15] Cutting down was self report of smoking half that at booking plus cotinine concentrations half the previous measurement.[16] "Same" was as self report unless cotinine concentration was twice the previous level. "More" was cotinine concentration twice that at booking or self report of twice the amount smoked. We allocated the 15/351 (4%) women in the intervention group and the 14/411 (3%) in the control group who were lost to follow-up (fig 2) to the category of same. We also asked women about use of nicotine replacement therapy during pregnancy.

Our secondary outcomes were attempts to quit and cut down during pregnancy, changes in commitment to quit and cut down, birth weight, and costs of maternity care measured as days in hospital for mother or infant, or both, which were available for 308/351 (88%) in the intervention group and 378/411 (92%) in the control group.

We collected data on adverse events, including antenatal admissions, miscarriage, termination of pregnancy, preterm delivery (<37 weeks' gestation), very low birthweight (<1500 g), neonatal death, assisted delivery (forceps or caesarean section), and admission to neonatal unit.

Statistical analysis

We used SPSS version 12 for Windows and confidence intervals analysis.[17] The primary response variables were quit, cut down, same, or more, based on cotinine concentration alone, questionnaire alone, and a combination of both. We compared groups using χ^2 tests for trend and computed the ratio of rates of quitting, cutting down, and smoking more (with 95% confidence intervals). Multiple logistic regression was used to estimate the odds ratio of quitting and of smoking more with adjustment for potential confounders and variables used in stratification. We compared mean cotinine concentrations and mean birth weights using two sample t tests and confidence intervals and used multiple linear regression to adjust for confounders and variables used in stratification. The main analysis was performed on an intention to treat basis. In addition, we obtained an unbiased "compliance" estimate of the benefit of receiving motivational interviewing, as opposed to just being offered it, for the primary response variables using the method of Cuzick et al.[18]

Results

We successfully carried out 625 interviews in 259 (74%) of the intervention group; 97 women had one interview, 58 had two, 26 had three, 61 had four, and 17 had five or more. Median intervention time was 56 minutes (range 9-219). Table 2 summarises the motivational interviewing skills ratings for the 63 (10%) interviews randomly selected for external assessment. Nearly all measures were "proficient" and two thirds were rated as "expert" level. A good standard of motivational interviewing was provided throughout the study.

We then assessed if the intervention had worked. There were no significant differences in change in smoking behaviour in the intervention group compared with the control group for any of the three primary response variables (table 3), although the wide confidence intervals mean that some differences may have been present. Fewer women in the intervention group reported that they were smoking more, and this was significant for the combined outcome (5.1% (18/351) v 10.7% (44/411); relative risk 0.48, 95% confidence interval 0.28 to 0.81) and for the questionnaire only outcome (5.1% (18/351) v 10.2% (42/411); 0.50, 0.26 to 0.86). These results were unchanged after we used logistic regression to adjust for age, level of deprivation,[19] living with a partner, having previous children, smoking level before pregnancy, and cutting down before enrolment. Similarly, there was no significant difference between the groups in cotinine concentrations at booking or mid or late pregnancy (table 4).

Assessment of secondary outcome measures showed that birth weight, although 30 g greater on average in the intervention group, did not differ significantly even after standardisation for gestation and sex (table 5). Birth weight was low (<2500 g) in 44/332 intervention and 59/400 control infants (relative risk 0.90, 0.63 to 1.29).

In the two groups 30% (intervention) and 28% (control) attempted to quit (24 hours without a cigarette) (relative risk 1.08, 0.86 to 1.35) and 44% and 46% attempted to cut down (24 hours smoking less than at booking) (0.97, 0.83 to 1.14). The

Table 3 Effect of motivational interviewing on smoking in pregnancy according to how smoking was determined

Variable	No (%) in intervention (n=351)	No (%) in control (n=411)	Relative risk (95% CI) (intervention/control)
Combined (cotinine concentration and questionnaire)*			
Quit	17 (4.8)	19 (4.6)	1.05 (0.55 to 1.98)
Cut down	15 (4.3)	26 (6.3)	0.68 (0.36 to 1.25)
Same	301 (85.8)	322 (78.3)	1.10 (1.02 to 1.17)
More	18 (5.1)	44 (10.7)	0.48 (0.28 to 0.81)
Cotinine concentration†			
Quit	26 (7.4)	36 (8.8)	0.85 (0.52 to 1.37)
Cut down	14 (4.0)	26 (6.3)	0.63 (0.33 to 1.19)
Same	303 (86.3)	334 (81.3)	1.06 (0.99 to 1.13)
More	8 (2.3)	15 (3.6)	0.62 (0.27 to 1.46)
Questionnaire‡			
Quit	24 (6.8)	31 (7.5)	0.91 (0.54 to 1.51)
Cut down	31 (8.8)	52 (12.7)	0.70 (0.46 to 1.06)
Same	278 (79.2)	286 (69.6)	1.14 (1.05 to 1.24)
More	18 (5.1)	42 (10.2)	0.50 (0.26 to 0.86)

*χ^2 for trend 0.93, P=0.34, χ^2 non-linear 9.08, P=0.01 (2 df).
†χ^2 for trend 0.68, P=0.41, χ^2 non-linear 3.47, P=0.18 (2 df).
‡χ^2 for trend 0.01, P=0.98, χ^2 non-linear 11.26, P=0.004 (2 df).

Table 4 Analysis of cotinine concentrations in pregnant smokers during trial of intervention to aid quitting. Figures are means (SD) unless stated otherwise

Cotinine concentration (Nos with available data)	Intervention (n=351)	Control (n=411)	Difference (95% CI) (intervention–control)
At enrolment (216, 241)	128 (71)	135 (82)	–7 (–21 to 7)
At baseline* (249, 281)	128 (72)	134 (80)	–6 (–19 to 7)
At 25-31 weeks (224, 299)	126 (74)	128 (74)	–2 (–15 to 10)
In late pregnancy (290, 364)	113 (70)	117 (83)	–4 (–16 to 7)
Adjusted mean† at 25-31 weeks (162, 211)	129	124	5 (–5 to 15)
Adjusted mean† in late pregnancy (211, 249)	114	114	0 (–9 to 10)

*Obtained either at enrolment or at next antenatal visit.
†Adjusted by analysis of covariance, using baseline cotinine as covariate.

Table 5 Birth weight and gestation in infants born to mothers after trial of intervention to aid quitting. Figures are means (SD)

Variable (Nos with available data)	Intervention (n=351)	Control (n=411)	Difference (95% CI) (intervention–control)
Birth weight (g) (332, 400)	3078 (602)	3048 (642)	30 (–60 to 121)
Standardised birth weight* (332, 400)	–0.62 (1.02)	–0.66 (1.10)	0.04 (–0.12 to 0.19)
Gestation at delivery (weeks) (342, 402)	38.7 (4.1)	39.1 (2.8)	–0.39 (–0.91 to 0.13)

*Standardised for gestation and sex using recent cohort of 1000 babies from Newcastle.[25] In both groups mean birth weight was 3042 g for infants of mothers who made no measurable change (same). Only those women who quit had significantly heavier infants (mean 3445 g, P<0.001). Mean birth weights associated with cutting down (3112 g, P=0.23) and more (3009 g, P=0.36) were not significantly different from same.

level of commitment to cut down in late pregnancy and the level of commitment to quit did not differ significantly between groups (χ^2 for trend 0.01 (P = 0.95) and 0.02 (P = 0.89)).

Table 6 gives details of adverse events. None was causally attributable to the intervention. There were 166 antenatal admission days for 308 women in the intervention group (mean 0.54 per woman) and 188 for 377 women in the control group (mean 0.50). The numbers of delivery admission days were 1061 (mean 3.44) and 1334 (mean 3.44). Neither set showed significant differences. Babies of women in the intervention group spent fewer days in the neonatal unit (325 *v* 832), though in the control group 334 days were from four sets of premature twins.

Nicotine replacement therapy is not routinely recommended during pregnancy, except for women who would not otherwise stop as it is considerably safer than continuing to smoke.[20] Some forms, however, are available without prescription and women are free to buy them. Two out of 389 women in the control group used nicotine replacement therapy during the study, with one continuing at late interview; both were still smoking 15 cigarettes a day. Four out of 329 women in the intervention group used nicotine replacement therapy but had stopped doing so by late interview. Three of these women stopped smoking, two of whom had taken part in the intervention.

Table 6 Details of adverse events in pregnant smokers during trial of intervention to aid quitting

Variable	Intervention (n=351)	Control (n=411)	Relative risk (95% CI) (intervention/control)
No of antenatal admissions	75	75	*P=0.196
No of women admitted	57/351 (16.2%)	53/411 (12.9%)	1.26 (0.89 to 1.78)
Neonatal death/termination†	4/351 (1%)	2/411 (1%)	2.34 (0.43 to 12.71)
Assisted delivery‡	107/332 (32%)	153/399 (39%)	0.84 (0.69 to 1.03)
Very low birth weight <1500 g	6/331 (2%)	8/400 (2%)	0.91 (0.32 to 2.59)
Preterm gestation <37 weeks	35/342 (10%)	43/402 (11%)	0.96 (0.63 to 1.46)
Special care baby unit	32/351 (9%)	53/411 (13%)	0.71 (0.47 to 1.07)

*Mann-Whitney U test compared median numbers of admissions per baby as some babies had multiple admissions that could not be treated as independent observations.
†One termination in each group; two intrauterine deaths and one preterm neonatal death in intervention group; and one preterm neonatal death in control group.
‡In intervention/control group: 15 (4%)/17 (4%) ventouse, 22 (7%)/34 (9%) forceps, 24 (7%)/31 (8%) elective caesareans, 46 (14%)/71 (18%) emergency caesareans.

We could not get 92/351(26%) women to take part in the home intervention. These women were less likely to be cohabiting (58% *v* 70%), more likely to be primagravida (54% *v* 37%), and less likely to live in severely deprived areas (deprivation score 6 or 7; 59% *v* 72%).[19] There were no significant differences in smoking at baseline, commitment to quit or cut down, or any outcome variables (although non-compliers tended to have lower cotinine concentrations throughout). We used results for the primary outcome variables in table 3 to provide an unbiased estimate of the benefit of receiving motivational interviewing, as opposed to just being offered it.[18] The ratio of quit rates (intervention/control) in this compliance analysis was 1.07 (0.42 to 2.69) for the combined outcome, 0.79 (0.41 to 1.53) for cotinine alone, and 0.87 (0.43 to 1.76) for questionnaire alone—similar to the results of the intention to treat analysis. The lowered rate of smoking more among women in the intervention group was more pronounced in the compliance analysis—0.36 (0.18 to 0.72) for combined outcome, 0.59 (0.24 to 1.49) for cotinine alone, and 0.38 (0.19 to 0.77) for questionnaire alone.

Discussion

We have shown that good quality motivational interviewing provided by midwives in smokers' own homes did not significantly increase smoking cessation among pregnant women who were still smoking at the time of maternity booking. Fewer women in the intervention group reported an increase in their smoking between booking and late pregnancy. As nicotine is metabolised more quickly during pregnancy and its half life is shorter,[21] women may smoke more heavily at the end of pregnancy to maintain the same level of nicotine. Preventing such as increase may be important, although this outcome was not part of our prior hypothesis.

We ensured that the intended intervention took place to the highest possible standard, using intensively trained midwives who were continuously assessed. We recorded and analysed exactly what took place during the home based intervention and the motivational interviewing was of good quality. The intervention delivered and the time available for the midwives to follow up subjects were better than could be expected in routine practice. Compliance did not compromise the outcome. Our study's power was 89% to show an increase in smoking cessation from 7.5% in the control group to 15% in the intervention group. Only 19/411 (4.62%) women in the control group quit smoking, which therefore provided 90% power to show an increase in quit rate from 4.62% to 11.25%, meaning that a change of this magnitude, if present, would have been missed in only one in 10 studies of this size. We cannot rule out a smaller improvement in quit rate. The Cochrane review suggest an absolute difference of six in 100 women continuing to smoke,[8] which we could not replicate (0.2 in 100; – 2.8 to 3.2). Such a change in quit rate is probably not possible when an intensive behavioural intervention designed for addictive behaviours is offered to pregnant smokers by skilled midwives with plenty of resources in Glasgow an area of severe material deprivation.[19]

The Cochrane review spans 1975-2003, during which time general awareness of the dangers of smoking increased, the sup-

What is already known on this topic

Behavioural intervention can help pregnant smokers to quit

Motivational interviewing, a behavioural therapy designed for addictions, has been taught to many healthcare workers to help smokers without specific evidence that it works or is being provided to a good standard

What this study adds

A good standard of motivational interviewing provided by midwives did not help women who were smoking at maternity booking to stop smoking

port available to smokers who want to stop greatly improved, and rates of smoking in the general population fell. Most women who are able to quit for reasons related to pregnancy probably do so by the time of maternity booking, meaning that our study probably included heavier, more dependent smokers. This view is supported by the mean birth weight of control infants (3048 g) being much lower than that found in the Cochrane review (mean 3260 g).

This study gives information to clinicians and policy makers in Glasgow and other areas of the United Kingdom and beyond that behavioural intervention alone for those heavily addicted women who continue to smoke at maternity booking is unlikely to be effective enough to provide good value for money. More potent therapy must be considered. The use of nicotine replacement therapy in pregnancy can avoid exposure to teratogens such as carbon monoxide in tobacco smoke. So far few trials have been published that demonstrate safety[8] and efficacy.[22 23] In the general population behavioural therapy plus nicotine replacement therapy have proved more effective than either alone.[24] Midwives have legitimate access and the confidence to provide close supervision of nicotine replacement therapy during pregnancy. Acceptability, effectiveness, and adverse events must be carefully examined before its widespread use is recommended.

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Contributors: DMT was involved in conception, design, and implementation of study, analysis and interpretation of data, and drafting, revising, and final approval of the article. MAL and WHG were involved in conception, design, and implementation of study, interpretation of data (final report writing), and drafting, revising, and final approval of the article. MAL was also responsible for the study intervention process. K Cooper produced the envelopes for random allocation with supervision from WHG. RW was involved in conception and implementation of study. FC was involved in conception, design, and implementation of study, and interpretation of data. DHS was involved in conception, design, and implementation of study, and drafting, revising, and final approval of the article. DM was involved in conception and design. S MacIndoe was involved in implementation of study and provided random allocation by telephone. E Mohammed was involved in implementation of study. P Meldrum gave advice on information needed for financial analysis. J Allison trained the midwives in motivational interviewing and mentored the midwives on one day a month throughout the study period. T Thornton and E Mitchell collected late pregnancy information. D Barnett, S McGuigan, and L Jarvie (research midwives) provided home based motivational intervention. L Govan assisted with the statistical analysis. Ian White, MRC Biostatistics Unit Cambridge, provided guidance on compliance analysis. DMT is guarantor.

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Ethical approval: Ethics committees for the Queen Mother's and the Princess Royal Maternity hospitals approved the study.

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