Self help smoking cessation in pregnancy: cluster randomised controlled trial

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Abstract

Objectives To evaluate the effectiveness of a self help approach to smoking cessation in pregnancy.
Design Pragmatic cluster randomised controlled trial with community midwife as the unit of randomisation.
Setting Three NHS hospital trusts in England.
Participants 1527 women who smoked at the start of pregnancy.
Intervention A series of five self help booklets comprising a step by step programme to increase motivation for quitting smoking and to teach strategies for cessation and relapse prevention. The first booklet was given to the women by a midwife at the earliest opportunity in antenatal care, together with a booklet for partners, family members, and friends. The remaining four booklets were mailed directly to the women.
Main outcome measures The primary outcome was smoking cessation validated by cotinine measurement at the end of the second trimester of pregnancy. Other outcomes were self reported smoking status and cigarette consumption among daily smokers. Qualitative data exploring the acceptability of the intervention and the way that smoking cessation advice was delivered in both trial arms were also collected.
Results Smoking cessation rates were low: the cotinine validated rates were 18.8% (113/600) in the intervention group and 20.7% (144/695) in the normal care group (difference 1.9%, 95% confidence intervals −3.5% to 7.3%). Self reported quit rates were higher. In the intervention group, 156 (25.6%) women reported not smoking for at least seven days, compared with 207 (29.1%) in the normal care group. In both groups, median self reported daily cigarette consumption among daily smokers was 10 cigarettes per day. Pregnant women and midwives approved of the intervention, but the way in which it was delivered varied considerably. For the primary smoking outcome, the degree of clustering at the midwife level was non-trivial (intracluster correlation coefficient 0.031).
Conclusion The self help intervention was acceptable but ineffective when implemented during routine antenatal care. More intensive and complex interventions, appropriately targeted and tailored, need to be developed and evaluated. Validated smoking cessation rates among pregnant women are substantially lower than the self reported rates on which current smoking policy is based.

Introduction

The substantial long term health benefits achieved from reducing smoking in pregnancy have made this an explicit health policy objective in many countries. Women are known to be more motivated to stop smoking during pregnancy and are usually in regular contact with health services. The means by which increases in quit rates can be secured, however, are less apparent. Four reviews that sought to identify effective methods to reduce the prevalence of smoking among pregnant women[1–4] concluded that the efficacy of interventions adopting a self help behavioural strategy for quitting smoking in pregnancy had been shown in a small number of well designed trials. Most of these studies, however, involved staff who were assigned specifically to the intervention. None of the studies had attempted to investigate the effectiveness of such an approach when applied by healthcare professionals within routine antenatal care.

Previous studies showing the efficacy of a self help approach all used an initial face to face session in which the pregnant smoker was introduced to literature specifically designed for pregnant women. The women then used the literature as a self help resource to help them quit smoking and maintain cessation. The studies varied in terms of the length of the introductory session, who conducted it (health educator, nurse, or doctor), whether or not there were additional personal or telephone contacts, and whether the materials were delivered as a one-off guide[5–9] or as a series of booklets mailed separately at intervals.[10] The materials used in these American and Swedish studies were not suitable for direct application in the United Kingdom, and none of the leaflets available in the United Kingdom for use by midwives fully embraced the self help approach that had been found to work in these studies. A need to develop self help materials for use in the United Kingdom, and for a pragmatic trial to assess their effectiveness and acceptability when implemented within routine antenatal care, was evident.

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Methods

Randomisation and recruitment

Three NHS trusts agreed to participate in the study, and we obtained approval from relevant local research ethics committees. All 128 community midwives in the three trusts participated. Data on smoking prevalence for each midwife's caseload were taken from the mothers' self reported smoking behaviour collected at the time of the first appointment with the midwife, and recorded in the notes by the midwife. They were further stratified according to whether the smoking rate among their caseload was above or below the average for their respective trust. All participating midwives were given detailed training on the procedure to identify, recruit, and obtain written informed consent from participants. They were also instructed on the rationale of a randomised controlled trial, the importance of maintaining recruitment in both trial arms, and the need to minimise contamination by continuing with normal care in both arms and by not allowing midwives in the normal care group to see the intervention materials. Once this training was complete, RC produced six pre-numbered lists of midwives within strata. From these lists, half of the midwives within each stratum were randomly allocated to be an "intervention midwife" using computer generated random numbers produced by LM. The remaining midwives were allocated to provide normal care. Midwives were then informed of the group to which they had been allocated. Intervention midwives were subsequently introduced to the intervention materials and instructed to spend at least five minutes introducing the first booklet to the pregnant women. It was emphasised that the series of booklets, called *Stop for Good*, should be delivered in addition to, and not instead of, normal care. Details of the procedure used to recruit women to the trial are given in box 1.

The *Stop for Good* self help intervention

The intervention consisted of a series of five self help booklets that incorporated a step by step programme to increase motivation for quitting and that imparted behavioural strategies for cessation and relapse prevention (box 2). They were based primarily on the eight booklets of the *Stop Smoking!* programme used by Ershoff et al,[10] but also drew on the materials specific to pregnancy used by others.[6 7 9]

Box 1: Recruiting women to the study

- All pregnant women attending their first antenatal appointment in the three participating trusts were asked by midwives using a "show card" to indicate which best described their smoking status: "I smoke now"; "I smoke now but have cut down since I thought I might be pregnant"; "I have stopped smoking since I thought I might be pregnant"; "I do not smoke"
- Women who smoked before becoming pregnant (first three response categories above) were eligible for recruitment if they were aged 16 years or over, less than 17 weeks pregnant, and able to speak sufficient English
- All eligible women provided written consent to participate in the trial

Box 2: Delivery of the *Stop for Good* intervention

- Midwives in the normal care group continued with the first antenatal appointment as usual, giving (or not giving) advice and information on smoking cessation according to their usual practice
- Midwives in the intervention group also continued to give their usual normal care. In addition, they introduced the pregnant women to the *Stop for Good* self help booklets on smoking cessation and gave them a copy of the first booklet
- Subsequent booklets were mailed directly to participants at weekly intervals
- The booklets were specifically tailored for pregnancy and included activities and props that allowed women to use the programme flexibly and in a personalised way. A booklet for partners, family members, and friends was also included with the first booklet
- The booklets had been developed by the study team in consultation with midwives, doctors, and pregnant women and subjected to thorough formative evaluation and field testing
- The booklets were awarded the Plain English Campaign's crystal mark for their clarity

Sample size

We began recruiting from trusts A and B in May 1998 with an initial target of 1122 participants. In February 1999 we undertook a blinded analysis of self reported smoking rates from the first 332 recruits, obtaining an estimated intracluster correlation of 0.0123. The updated Cochrane review[11] showed absolute differences in cessation rates between 6.6% and 9.2% in a pooled analysis of various subsets of previous studies on smoking cessation in pregnancy. The estimated differences were higher in better quality studies with validated smoking cessation status. We then calculated that, to achieve 80% power to detect a difference in cessation rates of 8.5%, and on the basis of an expected cessation rate of 27% in the control group[12] and a participant dropout rate of 15%, we would require 1560 participants. To achieve this, the trial was extended to include trust C, from which we began recruiting in January 2000.

Outcome measures

The primary outcome was validated smoking cessation at the end of the second trimester of pregnancy. At 26 weeks' gestation we sent each participant a self completion postal questionnaire. Women who had failed to reply within 10 days were sent a reminder, with further intensive follow up, including telephone calls and personal visits by the research midwives at the participants' homes or at antenatal clinics. A research midwife (PL, EM, or JF) visited all participants who stated that they had not smoked for at least seven days to collect a urine sample, which was sent for cotinine assay.

Data on gestation and birth weight at delivery were abstracted for all participants from maternity units' delivery notes. We obtained data on stillbirths, and on perinatal, neonatal, and childhood deaths occurring among study participants from the Confidential Enquiry into Stillbirths and Deaths in Infants (CESDI). These data are not included in our paper, but are available on request.

Process evaluation

We used qualitative research methods to investigate how the intervention was delivered in practice and what constituted normal care; we also used the methods to explore the acceptability of the intervention from the point of view of pregnant women and midwives. NM and PL conducted 22 in-depth interviews with women drawn from the three participating trusts and from both arms of the trial. AW interviewed in depth 17 participating midwives, similarly sampled, shortly after the trial ended. Brief semistructured interviews were conducted with every participating midwife by PL, EM, and JF at the beginning and end of the trial. In addition, 16 first antenatal appointments undertaken by the pregnant women, conducted by 14 midwives participating in the trial, were observed by AW.

Data analysis

All statistical analysis was undertaken according to a prespecified analysis plan. The primary outcome was validated smoking cessation, with 80 ng/ml used as the cut-off value of urinary cotinine concentration to distinguish between smokers and non-smokers. Other outcomes analysed were self reported smoking status and cigarette consumption among daily smokers. Confidence intervals for differences in smoking cessation rates were estimated in Stata 7 using design weighted survey estimators. For each outcome the primary analysis was a regression model, with the two stratifying variables (NHS trust and smoking prevalence of the midwife's caseload) included as covariates. For each outcome, we also undertook secondary analyses, adjusting for cigarette consumption before pregnancy and cigarette consumption at recruitment, and sensitivity analyses investigating the potential impact of missing data and different cotinine cut-off points to confirm self reported cessation (60 ng/ml and 100 ng/ml, respectively). To take account of midwife level clustering effects, all these analyses used random effects models, using Stata 7 procedures xtlogit and xtreg.

Results

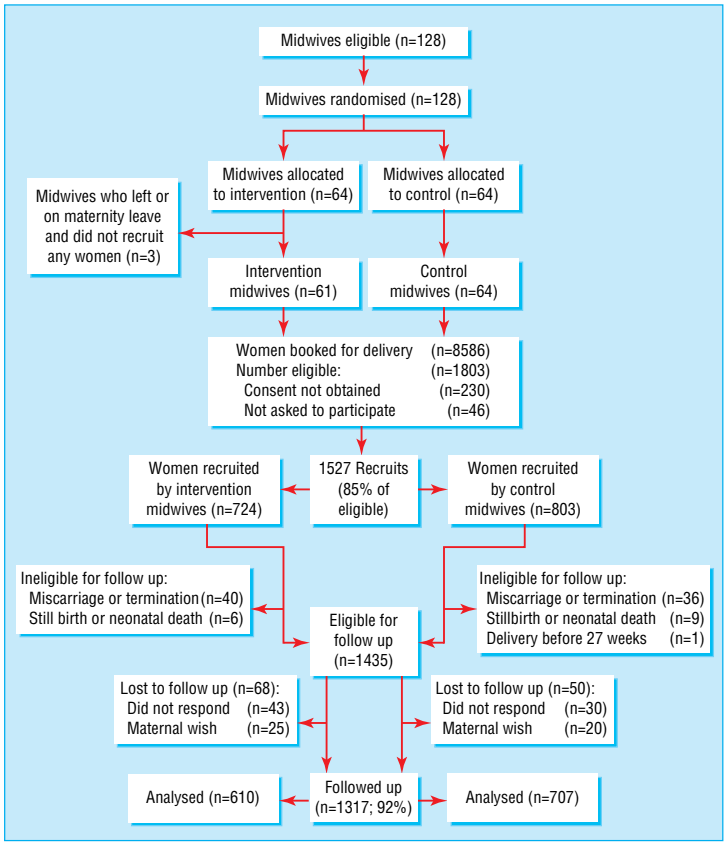
Participant flow and follow up

Recruitment took place from May 1998 to September 1999 in trusts A and B and from January to July 2000 in trust C. Intervention midwives recruited a total of 724 women, and midwives giving normal care recruited 803 women. Women in the two groups were similar in terms of age, age on leaving full time education, gravidity, and gestational age (table 1). Women in the normal care group were more likely to have stopped smoking since they first thought they might be pregnant; also, their cigarette consumption before becoming pregnant and at recruitment was lower than that of women in the intervention group.

The figure shows the structure of the trial. Of the 1527 women recruited to the trial, 92 subsequently became ineligible for follow up due to miscarriage, termination, delivery before 27 weeks, stillbirth, or neonatal death. Self reported data on smoking behaviour were provided by 1317 (92%) of the remaining 1435 eligible women. Of these, 363 reported that they were non-smokers, and we obtained a cotinine assay for 341 (94%) of them (15 refused to provide a urine sample, two samples were lost in transit to the biochemistry laboratory, and five participants were lost to further follow up). The primary outcome, validated smoking cessation, was therefore obtained for 1295

Table 1 Characteristics of participants recruited. Values are numbers (percentages) unless otherwise specified

Characteristic	Intervention	Normal care
NHS trust where booked for maternity care and recruited to trial:	(n=724)	(n=803)
Trust A	191 (26.4)	263 (32.8)
Trust B	317 (43.8)	386 (48.1)
Trust C	216 (29.8)	154 (19.2)
Age left full time education:	(n=706)	(n=784)
16 years	431 (61.0)	499 (63.6)
17-18 years	162 (22.9)	179 (22.8)
>18 years	109 (15.4)	100 (12.8)
Currently in full time education	6 (0.8)	4 (0.5)
Maternal age:	(n=723)	(n=803)
Mean (SD)	27.2 (6.0)	26.7 (5.6)
First pregnancy:	(n=724)	(n=803)
Yes	224 (30.9)	280 (34.9)
No	500 (69.1)	523 (65.1)
Gestational age in weeks at recruitment:	(n=724)	(n=803)
Mean (SD)	11.8 (2.3)	11.8 (2.3)
No of cigarettes smoked (per day) before pregnancy:	(n=721)	(n=797)
Mean (SD)	16.0 (8.5)	15.1 (8.0)
No of cigarettes smoked (per day) at recruitment:	(n=722)	(n=803)
Mean (SD)	6.4 (6.6)	5.5 (5.8)
Maternal smoking at recruitment:	(n=724)	(n=803)
Smoke now	97 (13.4)	97 (12.1)
Smoke now but cut down since thought might be pregnant	445 (61.5)	464 (57.8)
Stopped smoking since thought might be pregnant	182 (25.1)	242 (30.1)



Structure of the trial

Table 2 Smoking outcomes at end of second trimester. Values are numbers (percentages) unless otherwise specified

	Intervention	Normal care
Validated smoking status*:	(n=600)	(n=695)
Non-smoker	113 (18.8)	144 (20.7)
Smoker	487 (81.2)	551 (79.3)
Self reported smoking status (unvalidated):	(n=610)	(n=707)
"I have not smoked for 7 days—not even a puff"	156 (25.6)	207 (29.3)
"I don't really smoke but do have an occasional puff on a cigarette"	35 (5.7)	42 (5.9)
"I smoke occasionally but not every day"	65 (10.7)	54 (7.6)
"I smoke every day"	354 (58.0)	404 (57.1)
Cigarettes smoked per day:		
Mean (SD)	10.3 (5.6)	10.1 (5.4)
Median	10	10
Total responses from daily smokers†	(n=353)	(n=403)

*Reported as not having smoked for 7 days; validated by urinary cotinine <80 ng/ml.
†In each group there was one daily smoker who did not report the number of cigarettes they smoked each day.

participants, of whom 600 were in the intervention group and 695 were in the normal care group.

Of the 610 women in the intervention group who completed a questionnaire, 564 (92.5%) recalled having seen the *Stop for Good* booklets; of these, 502 (89.0%) reported that they had read the booklets, and 404 (71.6%) had read the booklets and found them useful. Of the 707 women in the control group, 29 (4.1%) reported seeing the booklets, of whom 18 had read them and 13 found them useful.

Table 2 gives details of each of the smoking outcomes by intervention group. For the primary outcome, the validated cessation rates of the intervention group and the normal care group were not significantly different (18.8% and 20.7%, respectively; difference 1.9%, 95% confidence intervals −3.5% to 7.3%). The degree of clustering at the midwife level (intracluster correlation) for validated smoking cessation was estimated as 0.031 (0 to 0.063). Self reported quit rates were higher. In the intervention group, 156 (25.6%) women reported that they had not smoked a cigarette for at least 7 days, whereas in the normal care group 207 (29.3%) women reported that they had stopped smoking; this difference was not significant (3.7%, −1.1% to 8.5%). Cigarette consumption among daily smokers in the two groups was similar (median of 10 cigarettes per day in both groups).

Table 3 shows the results of the random effects logistic regression analyses for the primary outcome. We found no significant difference in validated smoking prevalence between the two groups, either in the primary analysis or in the secondary analyses, adjusting for cigarette consumption before pregnancy and at recruitment. We found no significant intervention effect when different cotinine thresholds were used, nor when those for whom no follow up data were obtained were assumed to be smokers at follow up. No statistically significant intervention effect was found in any of the estimated models when self reported smoking cessation and self reported mean daily cigarette consumption were analysed.

Table 3 Cotinine validated smoking cessation status at end of second trimester of pregnancy. Results are odds ratios of being a smoker (95% confidence intervals)

Analysis	Intervention group *v* control group	P value
Primary*	1.13 (0.80 to 1.60)	0.50
Secondary (additional adjustment for smoking before pregnancy)	1.03 (0.74 to 1.43)	0.87
Secondary (additional adjustment for smoking at recruitment)	0.87 (0.63 to 1.21)	0.40

*Adjusted for stratifying variables (trust and midwives' catchment smoking prevalence at baseline) and clustering by midwife.

Delivery of the intervention

The qualitative findings indicated that the delivery of the intervention varied. Training emphasised that midwives should spend about five minutes introducing the first booklet, but some midwives reported that they spent much more time than this; others spent much less. None of the women interviewed could recall the midwife taking them through the first booklet in the first antenatal appointment; rather, they remembered being given the booklet and going through it on their own later. The amount of smoking cessation advice and support provided to women in the normal care group was similarly variable.

Midwives and pregnant women said that they found the booklets used in the intervention acceptable. Midwives indicated that the booklets prompted them to give consistent and coherent smoking cessation advice and introduce what they perceived to be a difficult issue in a non-judgmental and positive way. All the women interviewed were generally supportive of any initiative to help pregnant women stop smoking. None of the women in the intervention group said that the booklets had helped them to quit. The booklets were seen as a useful resource for others but not for themselves.

Discussion

The *Stop for Good* intervention was well received by the midwives and by pregnant women but failed to affect smoking behaviour at the end of the second trimester of pregnancy. The delivery of the intervention varied between midwives, with many of them spending less than five minutes introducing the booklets. Given the growing body of evidence that written materials on their own are ineffective,[13] this lack of verbal reinforcement would have attenuated the potential effect of the intervention when the programme was implemented within the busy first antenatal appointment.

The content and delivery of normal care also varied between midwives in both arms of the trial; and it is not surprising, therefore, that the degree of clustering at the midwife level in the smoking outcomes was substantial. We can be confident that the trial was not underpowered, however, because the lower limit of the 95% confidence interval (−3.5%) in the analysis of the difference in the primary outcome indicates that the true effect of the intervention is unlikely to have been sufficiently large to merit its implementation, even if the intervention was beneficial.

The trial took place in three hospital trusts in England, and all community midwives participated, recruiting 85% of eligible pregnant women during the recruitment period. The external validity of the trial should therefore have been high. There were a number of threats to the internal validity of the trial, which may have led to some bias. There were some differences between the two treatment groups at baseline, most notably in the numbers of women who had stopped smoking before the booking appointment and in the quantity of cigarettes consumed before the pregnancy

and at the time of booking. When these variables were included in the analysis as covariates the negligible estimated intervention effect switched from one suggestive of a counterproductive impact on smoking cessation to one indicating a slight benefit, but in no case was the difference between the two groups statistically significant. There was some potential for contamination, especially where midwives were working within teams. In practice, however, only 29 (4.1%) of control women reported seeing the intervention materials, of whom 18 said that they had read them. Furthermore, only 32 of the 128 midwives were in teams. Researchers and midwives were not blind to treatment allocation, and this may have led to some differences in the content and delivery of normal care, and also in data collection and analysis. However, follow up rates were high in both groups, and all data coding and cleaning was undertaken blind to treatment allocation.

Other attempts to evaluate brief interventions to promote smoking cessation in pregnancy within routine antenatal care have been met with considerable difficulty. A large cluster trial in the United States included several clusters that were not randomised and which had a high rate of loss to follow up (45%) and a low rate of cotinine validation (34%).[14] A cluster randomised trial in the United Kingdom randomised 290 midwives to intervention or control but only 178 (61%) of these midwives actually recruited women and average recruitment per midwife was substantially less than expected.[15] An individually randomised trial of a brief intervention among low income African-American women had a very low rate of follow up (53%).[16] Also, a randomised design was rejected in another study because of the way in which antenatal care was organised[17]; thus, our trial remains the only methodologically rigorous evaluation of a brief self help intervention in normal clinical practice.

Context

The transferability of a successful intervention may depend on the context in which it is delivered.[18] It could be argued that brief interventions to encourage smoking cessation may have been effective when smoking prevalence was high and the health risks of smoking were becoming widely known. Such interventions, however, may not be as effective when smoking is confined to a subgroup of smokers who find it difficult to stop smoking, despite wanting to quit. Strong associations between social inequality and continued smoking by pregnant women show that more complex interventions that take full account of the social and cultural circumstances of this target group are required.[19]

Implications for policy

Midwives will always have an important role in encouraging pregnant women to stop smoking, but if the government's target of a reduction from 23% to 15% in the percentage of women who smoke during pregnancy is to be met by the year 2010, more intensive interventions or interventions provided by dedicated staff will be required.[20] Generic specialist services for smoking cessation are now being introduced throughout the NHS, and one of its priorities is to reduce smoking in pregnancy. A variety of models of service organisation are being used, but how effective and acceptable these are for pregnant women remains to be evaluated, particularly as the main client group for these services are people motivated to stop smoking.[21]

This study provides the largest dataset of biochemically validated smoking behaviour among women in the United Kingdom who were smokers at the start of pregnancy. Our validated quit rate of 19.8% is very close to the rate found in the previous largest prospective study.[15] However, the self reported quit rate was 27.4%, which is the same as the average rate recorded in several studies conducted throughout the 1990s.[12] This discrepancy highlights the importance of biochemical validation and calls into question the adequacy of monitoring of the government's target for smoking in pregnancy, which currently relies on retrospective self reported smoking behaviour in the infant feeding survey.[22] It would therefore seem premature to conclude, on the basis of recent evidence from the infant feeding survey, that progress towards achieving targets is being made.[23]

What is already known on this topic

The most recent systematic review evidence suggests that self help interventions designed specifically for pregnant smokers can be effective in increasing cessation rates

These reviews, however, are based mainly on efficacy trials involving staff who are specifically employed to provide the intervention

In other attempts to assess the effectiveness of such an approach within routine antenatal care, it has been difficult to implement scientifically rigorous evaluations

What this study adds

A low cost, self help intervention was ineffective when implemented during routine antenatal care, even though it was acceptable to midwives and pregnant women

Validated smoking cessation rates among pregnant women are substantially lower than the self reported rates on which current smoking policy is based

Conclusion

Validated smoking cessation rates among pregnant women are substantially lower than the self reported rates on which current smoking policy is based. A low cost, self help intervention was acceptable to pregnant women and midwives but was not consistently implemented by all midwives. The assumption that such an approach would be effective when integrated into routine antenatal care has proved to be false. Interventions developed in trials with dedicated staff cannot be assumed to be applicable to routine care.

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Contributors: LM and RC designed the study. AW, LM, and RC developed, tested and finalised the intervention. PL, EM, and JF trained the midwives and collected follow up data, supervised by AW and NM, who acted as trial coordinators. RC, AW, NM, and PL collected and analysed the qualitative data. LM undertook quantitative data analysis. LM and RC wrote the first draft of the paper, and all authors contributed to the final manuscript. LM and RC are the guarantors. The Department of Social Medicine is a lead centre of the Medical Research Council Health Services Research Collaboration.

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