

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

Women are known to be more motivated to stop smoking during pregnancy and are usually in regular contact with health services. Four reviews that sought to identify effective methods to reduce the prevalence of smoking among pregnant women¹⁻⁴ 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, and none investigated their effectiveness when applied by health-care professionals within routine antenatal care.

Available materials used in previous American and Swedish self help studies,⁵⁻¹⁰ 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 within routine antenatal care, was evident.

Methods

Randomisation and recruitment

All 128 community midwives working in three NHS trusts participated in the study. The midwives were 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 trial procedure, including the need to minimise contamination between the trial arms. Within each stratum midwives were randomly allocated to be either an "intervention midwife" or a "normal care midwife." Intervention midwives were 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*

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for *Good*, should be delivered in addition to, and not instead of, normal care.

All pregnant women attending their first antenatal appointment were asked by midwives using a "show card" to indicate which best described their smoking status. The options were "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", and "I do not smoke". Women who smoked before becoming pregnant (first three categories) were eligible for recruitment if they were aged 16 years or over, less than 17 weeks pregnant, and able to speak sufficient English.

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).

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 and carried out a further power calculation from which we calculated that we would require 1560 participants. To achieve this, the trial was extended to include trust C, from which we began recruiting in January 2000 (see bmj.com).

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. A research midwife 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.

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

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. Twenty two in-depth interviews were conducted with women drawn from the three participating trusts and from both arms of the trial. Shortly after the trial ended, 17 participating midwives, similarly sampled, were interviewed. Brief semi-structured interviews were conducted with every participating midwife at the beginning and end of the trial. In addition, 16 first antenatal appointments were observed conducted by 14 midwives participating in the trial.

Data analysis

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. 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.

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 (see bmj.com). 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.

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 (see bmj.com). Of these, 363 reported that they were non-smokers, and we obtained a cotinine assay for 341 (94%) of them. The primary outcome, validated smoking cessation, was therefore obtained for 1295 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 1 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. 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. Again, the difference between the two groups was not statistically significant. Cigarette consumption among daily smokers in the two groups was similar.

Table 2 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.

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; rather, they remembered 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. This lack of

Table 1 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.

Table 2 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.

verbal reinforcement would have attenuated the potential effect of the intervention.¹¹

The content and delivery of normal care also varied between midwives in both arms of the trial; it is not surprising, therefore, that the degree of clustering at the midwife level in the smoking outcomes was substantial. We can be confident, however, that the trial was not underpowered.

The external validity of the trial should be high, given that 85% of eligible pregnant women were recruited. The groups differed 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 the estimated intervention effect indicated a slight, but not statistically significant, benefit. There was some potential for contamination, especially where midwives were working within teams, although data collected suggested that any contamination was minimal. 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. Our trial remains the only methodologically rigorous evaluation of a brief self help intervention in normal clinical practice (see bmj.com).

Context

The transferability of a successful intervention may depend on the context in which it is delivered.¹² Strong

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

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.¹³

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.¹⁴ The discrepancy between biochemically validated and self reported quit rates highlights the importance of biochemical validation. This 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.¹⁵

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Contributors: See bmj.com

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- 1 Health Education Authority. *Smoking and pregnancy: guidance for purchasers and providers*. London: HEA, 1993.
- 2 Dolan-Mullen P, Ramirez G, Groff JY. A Meta-analysis of randomized trials of prenatal smoking cessation interventions. *Am J Obstet Gynaecol* 1994;171:1328-34.
- 3 Walsh R, Redman S. Smoking cessation in pregnancy: do effective programmes exist? *Health Promot Internation* 1993;8:111-27.

- 4 Lumley J. Strategies for reducing smoking in pregnancy. In: Enkin MW, Keirse MJNC, Renfrew MJ, Neilson JP, eds. *Pregnancy and Childbirth Module*. *Cochrane Library*. Oxford, Update Software, 1994 (Review Nos 03312 and 03397).
- 5 Sexton M, Hebel JR. A clinical trial of change in maternal smoking and its effect on birth weight. *JAMA* 1984;251:911-5.
- 6 Windsor RA, Cutter G, Morris J, Reese Y, Manzella B, Bartlett EE, et al. The effectiveness of smoking cessation methods for smokers in public health maternity clinics: a randomised trial. *Am J Public Health* 1985;75:1389-92.
- 7 Windsor RA, Lowe JB, Perkins LL, Smith-Yoder D, Artz L, Crawford M, et al. Health education for pregnant smokers: its behavioral impact and cost benefit. *Am J Public Health* 1993;83:201-6.
- 8 Petersen L, Handel J, Kotch J, Podedworny T, Rosen A. Smoking reduction during pregnancy by a program of self-help and clinical support. *Obstet Gynecol* 1992;79:924-30.
- 9 Hjalmarsen AIM, Hahn L, Svanberg B. Stopping smoking in pregnancy: effect of a self-help manual in controlled trial. *Br J Obstet Gynaecol* 1991;98:260-4.
- 10 Ershoff DH, Mullen PD, Quinn VP. A randomised trial of a serialized self-help smoking cessation program for pregnant women in an HMO. *Am J Public Health* 1989;79:182-7.
- 11 Fitzmaurice DA. Written information for treating minor illness. *BMJ* 2001;322:1193-4.
- 12 Mant D. Health promotion and disease prevention. In: Peckham M, Smith R, eds. *Scientific basis of health services*. London: BMJ Publishing Group, 1996:170-8.
- 13 Oliver S, Oakley L, Lumley J, Waters E. Smoking cessation programmes in pregnancy: systematically addressing development, implementation, women's concerns and effectiveness. *Health Educ J* 2001;60:362-70.
- 14 Secretary of State for Health. *Smoking kills. A white paper on tobacco*. London: Stationery Office, 1998.
- 15 Owen L, McNeill A. Saliva cotinine as indicator of cigarette smoking in pregnant women. *Addiction* 2001;96:1001-6.

Corrections and clarifications

Work stress and risk of cardiovascular mortality: prospective cohort study of industrial employees

A lapse in concentration at proof stage of this paper by Mika Kivimäki and colleagues (19 October, pp 857-60) led us to assign the wrong address to some authors. The correct affiliation for Päivi Leino-Arjas, Ritva Luukkonen, and Hilikka Riihimäki is the Department of Epidemiology and Biostatistics, Finnish Institute of Occupational Health, Helsinki, Finland, and for Jussi Vahtera is the Turku Regional Institute of Occupational Health, Finland. Our apologies for getting these wrong.

Career focus

Two editorial errors crept into the article "Induction courses for international doctors" by Martha Swierczynski (16 November, p s159). In trying to clarify the meaning of the phrase "international doctors," we added (in the opening paragraph) "doctors who have trained in the United Kingdom." This is clearly wrong; what we had intended to add was "doctors who have trained outside the United Kingdom." Also, in the last paragraph of the section "Eligibility for induction courses" the penultimate sentence should read "Trusts [not deaneries] are advised to make the courses as accessible as possible."

Nurse led follow up and conventional medical follow up in management of patients with lung cancer: randomised trial

In this paper by Sally Moore and colleagues (16 November, pp 1145-7), the affiliation for Mary Wells was out of date. She has informed us that for the past three years she has been a clinical research fellow in cancer nursing at the School of Nursing and Midwifery, University of Dundee.