

Rapid review of interventions to prevent relapse in pregnant ex-smokers

Report to National Institute for Health and Clinical Excellence

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Executive Summary

Introduction and aims: This review examines the effectiveness of relapse prevention (RP) interventions for pregnant smokers. It summarises the conclusions of the two Cochrane Reviews of the relevant outcome trials; and reviews studies which did not pass the criteria for inclusion in the Cochrane Reviews, but which may include data useful for informing further work in this area.

Method: A comprehensive literature search was conducted. 1231 titles and abstracts were screened, from which 54 papers were selected for further review. From these papers, 35 (14 studies already included in the Cochrane RP review, 4 further outcome studies and 17 papers providing other information) were identified as providing information related to the questions of interest.

Note: As the task of the review was to explore the grey literature for any practical lessons and pointers for future developments, only some of the findings are amenable to be presented as evidence statements. The rest are presented in a narrative form and as suggestions for future work. (The evidence statements are graded using a code ‘++’ and ‘+’ based on the extent to which the potential sources of bias had been minimised).

Findings:

1. Which interventions have been evaluated so far?

We reviewed the interventions used in the 17 existing randomised trials and noted that two types of methods were evaluated so far: Efforts to strengthen women's determination to remain abstinent by education, motivational interviewing, and persuasion; and teaching them to identify relapse situations and put in place coping strategies.

2. What is the evidence of the efficacy of these interventions from randomised controlled trials with at least 6-months follow-up?

Evidence statement 1: Two Cochrane Reviews of relapse prevention (RP) interventions with women who stopped smoking during pregnancy found that the types of interventions examined so far had no effect on relapse (++).

3. What is the evidence from trials not included in the Cochrane reviews?

Four evaluative studies were found which did not qualify for inclusion in the Cochrane Review on RP. One non-randomised cohort comparison found a significant effect, but three randomised studies produced negative results.

Evidence statement 2: Overall, the results are consistent with the Cochrane negative verdict (+).

4. Are there any other interventions which may hold a promise in this area?

We reviewed data on the use of incentives with pregnant smokers. These seem to have at least a short-term effect on smoking cessation (+), and have not yet been studied in

the context of relapse prevention. The most promising approach involves progressive monetary incentives contingent on continuing abstinence. This poses some challenges, such as finding ways to promote an incentive scheme without encouraging potential pregnant quitters to delay a quit attempt until they get paid; or even encouraging light smokers or non-smokers to increase or initiate smoking to qualify for the rewards. Using incentives for relapse prevention with smokers successfully treated earlier may avoid at least some of these problems. The incentives may prove to be attractive especially for women from lower socioeconomic groups who are a priority target group, and if effective, they may exert an effect across the various groups of pregnant ex-smokers including those not interested in other types of help. In this field where promising interventions are lacking, this approach may warrant a formal randomised evaluation.

5. Are there any practical barriers to implementing RP interventions with pregnant ex-smokers?

The main barriers to intervention implementation were problems with recruiting the women, and low adherence to procedures by front-line Health Care Professionals (HCPs) asked to implement such interventions within routine care. Possible reasons included HCP's priorities and time pressure.

It also appears that only the women keen to remain abstinent and worried about their capacity to do so are likely to be receptive to RP efforts. Those who had successfully stopped smoking and have no intention of going back to it are unlikely to seek help or to be receptive to the existing advice. Even those who plan to go back to smoking after delivery may not be overly keen to go along with the existing interventions. The proportion of such groups among pregnant ex-smokers is unknown and no study screened women for these characteristics. There thus appears a gap in the evidence regarding tailoring the intervention to women's intentions. One obvious research recommendation is to only randomise women in the first of the three categories above.

This however is likely to prove impractical. Recruitment for pregnancy studies is slow and difficult, and a selection like this is likely to reduce the numbers further.

Conclusions and recommendations

Relapse prevention interventions evaluated so far are not effective and so investment in them is not recommended. The use of incentives may be worth randomised evaluation. Otherwise, until new interventions are developed and shown effective, it would seem best to focus resources on helping pregnant smokers quit. Even short-term abstinence from smoking benefits the foetus, and increased initial abstinence rates can be expected to generate higher long-term effects even if no effective RP intervention is available.

Introduction

About one-fifth of pregnant smokers in the UK are able to quit smoking during their pregnancy (Owen et al., 1998, Madeley et al., 1989). Relapse rates are high, with some 70% of these women returning back to smoking within the first six month postpartum (Hajek et al., 2001). International data indicate that approximately half of all postpartum relapse occurs within the first three months (Carmichael and Ahluwalia, 2000, Fang et al., 2004, Ratner et al., 1999), with some evidence this level may be approached by the end of the first two weeks after delivery (Suplee, 2005). Numerous studies have examined the efficacy of smoking cessation treatments in pregnancy, but comparatively few have explored relapse prevention (RP) interventions for either the pregnancy or postpartum periods (Fang et al., 2004, Mullen, 2004).

Two Cochrane systematic reviews of randomised controlled trials (RCTs) have included sub-sections on relapse prevention for pregnant women (Hajek et al., 2009, Lumley et al., 2009). Both concluded that no effective relapse prevention approaches currently exist for this population.

To see if there are any approaches which may be worth investigating further and to explore possible ways forward, the present review was commissioned by NICE to examine any experimental literature which did not meet the inclusion criteria for the Cochrane reviews, and to review qualitative and descriptive studies to identify factors which may promote or inhibit the success of relapse prevention interventions in pregnancy.

The report starts with a brief overview of the different RP approaches evaluated to date (Chapter 1). This is followed by a summary of the findings from the two Cochrane

Reviews (Chapter 2). We then present the details of the search strategy used to identify literature not included in the Cochrane documents, and present the results of four outcome studies (Chapter 3). Next we include a review of studies on use of incentives in smoking cessation with pregnant women as this approach may pose a promise for RP (Chapter 4). The existing literature suggested a range of possible barriers to intervention implementation, and proposed potential areas for future research. These topics are covered in Chapter 5. Finally, we offer our overall conclusions and recommendations (Chapter 6).

Note: As the task of the review was to explore the grey literature for any practical lessons and pointers for future developments, only some of the findings are amenable to be presented as evidence statements. The rest are presented in a narrative form and as suggestions for future work. The evidence statements are graded using a code ‘++’ and ‘+’ based on the extent to which the potential sources of bias had been minimised.

Chapter 1: Interventions evaluated so far

Only a limited range of relapse prevention interventions has been evaluated so far.

Table 1 provides their details. The counselling sessions, written materials, tapes, and videos typically included the following elements: Information about the health impact of smoking during pregnancy and postpartum, discussion of the advantages and disadvantages of maintaining cessation; discussion of high-risk situations and triggers for relapse and how to cope with them; barriers to maintaining abstinence specific to the transition to motherhood; countering of stress-reduction belief about smoking; written anecdotes from successful long-term abstainers; non-smoking gifts (water bottles, fridge magnets, etc) with suggestions for non-smoking activities; written 'contracts' to remain smoke-free; attempts to elicit social support; relaxation exercises; praise for success and encouragement for maintenance; and patient chart reminders for clinic staff to carry out the intervention.

In general terms, the interventions outlined above can be categorised into two main approaches: Motivational interventions aiming to strengthen the women's resolve to remain abstinent (motivational interviewing, praising women for abstinence, checking smoking status at every visit, elaborating on health risks of smoking for the foetus/baby, eliciting peer/social support); and an approach grounded in Marlatt and Gordon's (1985) thoughts on relapse prevention, attempting to teach women to identify risky situations and prepare coping responses other than smoking. Both interventions were delivered via face-to-face sessions, booklets, tapes and videos.

As the next chapter will reveal, these methods lacked efficacy across the type of intervention and mode of delivery.

Table 1 – Interventions evaluated for relapse prevention in pregnancy

Paper	Interventions
Lowe 1997	Face-to-face counselling session, written materials, non-smoking gifts (including diaper coupons) + praise for continued abstinence by staff at all clinic visits.
Hajek 2001 Secker-Walker 1995	Face-to-face counselling session + written materials
Secker-Walker 1998	Physician advice + referral to a relapse prevention councillor
Ershoff 1995	Booklets given at clinic visit with a brief outline of the content given by health educator + a further 4 booklets sent weekly
Severson 1997	Brief advice and encouragement at each visit + written materials + video
Van't Hof 2000	Counselling + reinforcement sessions
McBride 2004	Relapse prevention kit (booklet and gifts) + multiple counselling call + partner assisted intervention aimed at encouraging communication between couples + booklet + video. Partners received six separate contacts.
McBride 1999	Relapse prevention kit sent to participants which included a booklet + personalised letter + multiple counselling telephone calls
Morasco 2006	Psychotherapy session (to help women recognise the link between psychological and/or interpersonal problems and relapse back to smoking) + multiple telephone calls
Ruger 2008	Motivational interviewing given at several home visits + written materials
Hannöver 2009	Face-to-face counselling (incorporating motivational interviewing) + 2 telephone counselling calls
Pbert 2004	System developed for office in order for staff to prompt women on smoking status + counselling by trained staff

Ratner 2000	A brief in-hospital intervention following birth + written materials + multiple telephone contact
Peterson 1992	Written materials + audiocassette tapes + clinicians used tracking sheets at each visit as a prompt to ask about smoking status
French 2007	Brief in-hospital intervention + home visits and phone calls + written materials
Suplee 2005	Brief in-hospital intervention involving motivational interviewing + skills-based relapse prevention + health risk education
Lillington 1995	Face-to-face counselling session + self help guide + booster postcards + incentivised homework activities

Chapter 2: Précis of Cochrane Reviews

Hajek et al. (2009) reviewed all relapse prevention interventions and provided a sub-section on RP with pregnant smokers. Lumley et al. (2009) reviewed interventions for pregnant smokers and also provided a sub-section on relapse prevention in this population.

Relapse prevention interventions for smoking cessation (Hajek et al., 2009)

Fourteen studies involving more than 3500 participants randomised pregnant (Secker-Walker et al., 1998, Hajek et al., 2001, Secker-Walker et al., 1995, Lowe et al., 1997, McBride et al., 1999, McBride et al., 2004, Morasco et al., 2006, Ruger et al., 2008, Pbert et al., 2004, Ershoff et al., 1995) or post- postpartum (Hannover et al., 2009, Van't Hof et al., 2000, Ratner et al., 2000, Severson et al., 1997) ex-smokers for interventions designed to assist them in remaining abstinent throughout their pregnancy and/or after the delivery. Figures 1 and 2 present the results of the meta-analysis.

The results were negative, showing no benefit of motivational and 'skills-based' interventions (RR 1.04, 95% CI 0.98 - 1.11). The same result was found for non-pregnant smokers, and studies randomising participants before they actually stopped smoking. It was concluded that at present there is insufficient evidence to support the use of any specific behavioural intervention to avoid relapse in smokers who managed to quit for a short period of time.

Figure 1. Behavioural interventions for abstinent pregnant/postpartum women. Not smoking at longest follow-up after delivery(Hajek et al., 2009).

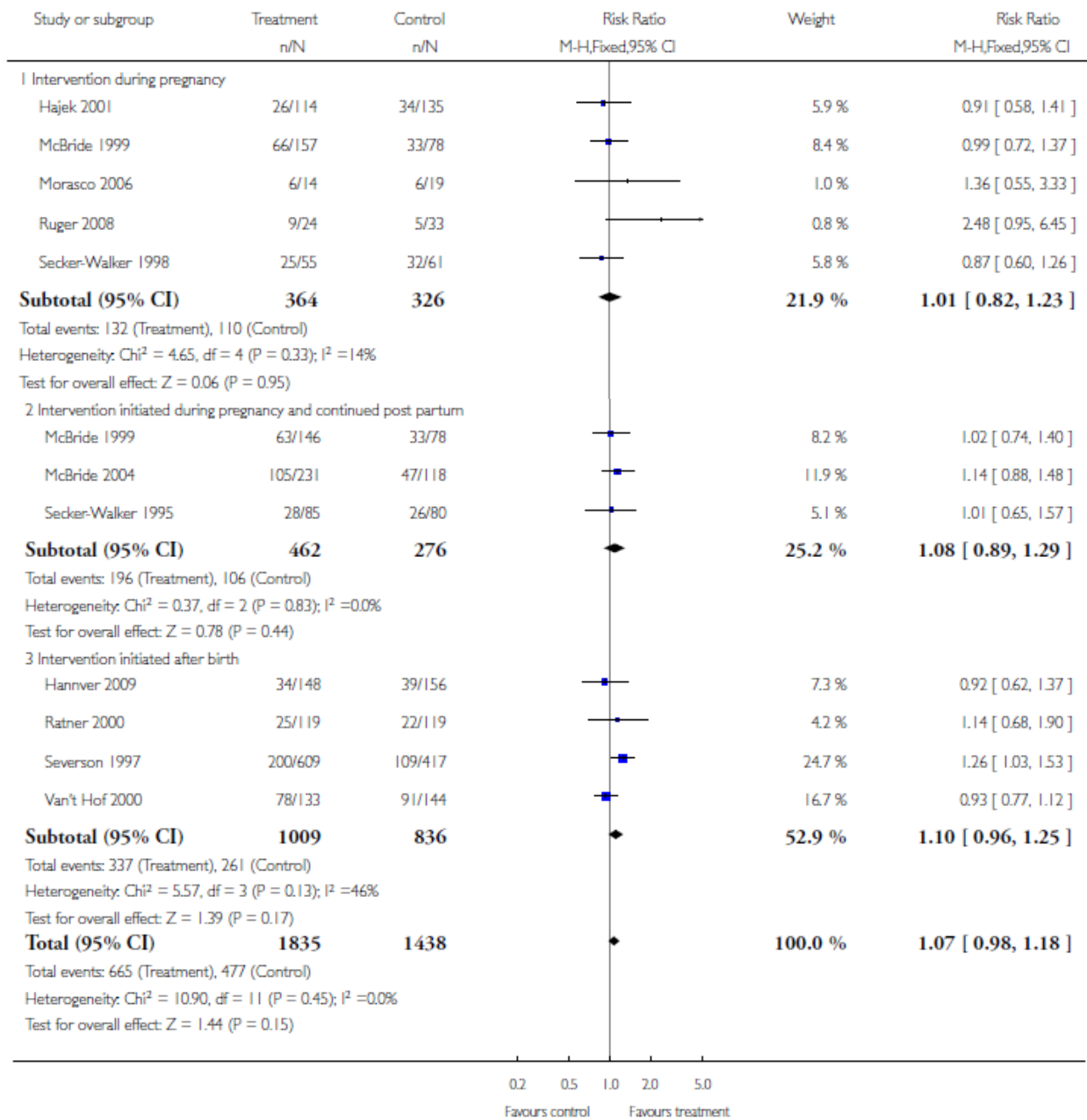


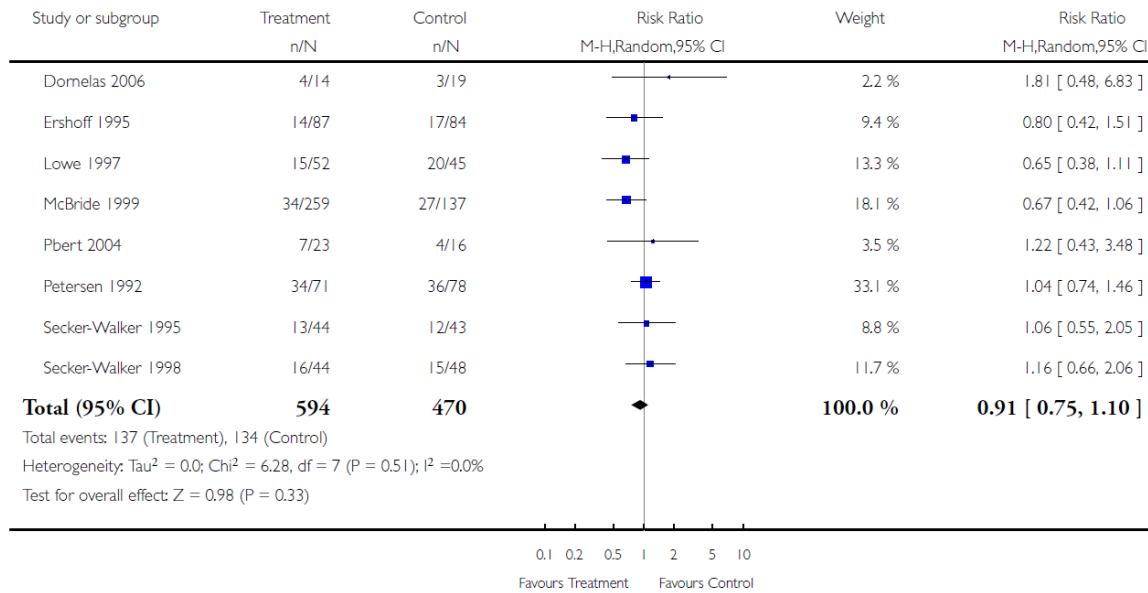
Figure 2. Behavioural interventions for abstinent pregnant/postpartum women. Not smoking at delivery/last follow-up prior to delivery (Hajek et al., 2009)

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Self help intervention Ershoff 1995	73/87	67/84		13.3 %	1.05 [0.91, 1.21]
2 Individual counselling Lowe 1997	32/40	29/38		5.8 %	1.05 [0.83, 1.33]

For one study (Pbert et al., 2004), it was not possible for the authors of the review to extract data in a comparable format to be pooled with other studies in the meta-analyses. Consistent with the overall picture, the intervention from this study was ineffective.

Interventions for promoting smoking cessation during pregnancy (Lumley et al., 2009)

A review of smoking cessation in pregnant women identified eight trials involving more than 1000 pregnant ex-smokers that looked at relapse prevention (Pbert et al., 2004, Secker-Walker et al., 1998, Secker-Walker et al., 1995, Petersen et al., 1992, McBride et al., 1999, Lowe et al., 1997, Ershoff et al., 1995, Morasco et al., 2006). The meta-analysis detected no significant improvement in relapse rates. (RR 0.91, 95% CI 0.75 - 1.10). Figure 3 presents the results of the meta-analysis.

Figure 3: Effects of RP interventions with pregnant smokers (Lumley et al., 2009)

Evidence Statement 1: The interventions evaluated thus far seem ineffective in preventing relapse back to smoking in women who manage a period of abstinence during their pregnancy (++).

Chapter 3: Review of outcome trials not included in Cochrane reviews

To see if there were any more hopeful signs and pointers in other literature, we conducted a comprehensive review of studies which did not meet the Cochrane Review inclusion criteria (explained for each study below), or were looking at different variables and outcomes.

Literature search

NICE conducted the literature searches for this rapid review in May 2009. The literature searches covered published papers in the following standard databases: MEDLINE, EMBASE, PSYCHINFO, EBSCO CINAHL, and CRD NHS EED. The database searches produced a total of 1231 citations. A full description of the search terms and processes that were used is presented in Appendix 1. Studies published in languages other than English were not included in the review.

Selection of studies for inclusion

Once the literature searches were completed by the team at NICE, the project team at QM selected relevant studies using the procedure outlined in section 5 of the *Public Health Guidance Methods Manual*. The titles that emerged from the literature searches were initially scanned by two reviewers who removed studies that were clearly irrelevant to the research questions or outcomes of interest. Abstracts were obtained for the remaining papers. These abstracts were scrutinised in relation to the research questions by two reviewers and those that did not directly deal with the research questions or outcomes were eliminated. Once this sifting process was complete, full copies of the selected studies and reviews were acquired for assessment.

In total 1231 references were produced by the initial search and full texts were obtained for 54 papers. Of these, 15 were included in the Cochrane Reviews covered in Chapter

2, 4 were outcome studies covered in Chapter 3, and 17 provided qualitative discussion of relapse and barriers to intervention which are covered in Chapter 5. The remainder were not relevant to the review.

Outcome trials not included in Cochrane reviews

We identified three studies not included in either Cochrane Review for reasons stated in each trial's description below (Lillington et al., 1995, Suplee, 2005, French et al., 2007). One further study (Petersen et al., 1992) did not focus on RP and reported smoking cessation data mixed with RP data, but the intervention included a 'maintenance' component and the trial was included in Lumley et al. (2009) review. The four studies and their result are described below.

Suplee et al. (2005):

Reason for not being included in Cochrane Reviews: Less than 6 month follow up.

Study design: RCT. **Participants:** 20 (control group) and 17 (intervention group)

verified non-smokers at baseline. **Intervention:** 10-20 minutes RP intervention delivered immediately post-partum, including 1) 'Empowering patient-practitioner relationship' 2) Motivational interviewing 3) Skills-based relapse prevention, 4) Education on health risks to both mother and infant. This was in addition to standard postpartum teaching. **Control group:** Standard postpartum teaching. **Results:**

Abstinent 4-8 weeks postpartum: Intervention 53%, control 40%, $p=.4$, NS. **Key**

methods features: *Validation:* Yes, urine cotinine; *Point prevalence or sustained abstinence:* Not clear; *Lost to follow-up:* Included as smoking.

Finding summary: In a small trial, RP intervention delivered immediately post-partum had no significant effect on relapse 4-8 weeks later.

French et al. (2007):

Reason for not being included in Cochrane Reviews: Non RCT pilot study. **Study design:** Non-randomised comparison of two time periods. **Participants:** 97 (control group) and 121 (intervention group) women who reported quitting smoking during pregnancy and were abstinent for at least 7 days before delivery, **Intervention:** During hospital stay women were congratulated and encouraged to remain smoke free; During a home visit 1 week post-partum women were asked about smoking status and reminded of the effects of environmental tobacco smoke on the baby. Stop smoking merchandise and written information given to the mother; phone calls or visits to reinforce the message were made at 1 and 2 months post-delivery. **Control group:** Usual care. **Results:** Abstinent at 3 and 6 months postpartum: Intervention 5 (5%), control 22 (18%), $p \leq .01$. **Key methods features:** *Validation:* Yes, salivary cotinine; *Point prevalence or sustained abstinence:* 7 day point prevalence: *Lost to follow-up:* Included as smoking.

Finding summary: The study found a significant difference between the two cohorts. However, there were significant differences between the cohorts (e.g. the women in the control group had more prior failed quit attempts and were less likely to be married) which were not controlled for, and the cohorts were not randomised.

Lillington et al. (1995):

Reason for not being included in Cochrane Reviews: Less than 6 month follow up. **Study design:** Cluster randomised study. **Participants:** 548 (control group) and 207 (intervention group) minority women who were current smokers or reported quitting smoking up to one year prior to the first pregnancy contact. **Intervention:** Face-to-face counselling reinforcing abstinence, self-help guide with behaviour change strategies, reinforcement booster post cards, incentive contest (weekly draws for inexpensive baby items and a grand prize of \$100), and baby bib to decorate to replace smoking activities. **Control group:** Usual care including written information about the risks of smoking. **Results:** The authors report 79% and 62% abstinence rates in the

intervention and control groups at 6-weeks postpartum ($p < 0.01$). However, they limited the analysis to those reached at follow-up, included those refusing validation as not-smoking, and did not adjust the data to differential deception rates in the two groups. An intention-to-treat analysis including the validation results shows 44% and 40% abstinence rates in the two groups (NS). **Key methods features:** *Validation:* Yes, salivary cotinine; *Point prevalence or sustained abstinence:* 7 day point prevalence; *Lost to follow-up:* Excluded from analyses.

Finding summary: The study did not find a significant effect of the relapse prevention procedures.

Petersen et al. (1992):

Reason for not being included in Hajek et al. (2009) Cochrane Review: The focus of the study was not on relapse prevention. **Study design:** Intervention 1 vs control: RCT; Intervention 2 vs control: not randomised. **Participants:** 317 baseline smokers and spontaneous quitters: **Intervention 1:** Pregnancy specific self-help manual with a maintenance section for the postpartum period (this included relaxation and exercise), and audiocassette tapes mailed to the participants; **Intervention 2:** As intervention 1 + progress sheet attached to patient's medical record to facilitate checking of smoking status at routine visits. Support materials and reinforcement letters signed by physicians were mailed at eight month of pregnancy and again within the first month postpartum. **Control group:** Routine care + mailed a list of community-based smoking cessation resources. **Results:** Abstinent 6 months pregnancy: Intervention 1: 88%, intervention 2: 85%, control: 86%, NS. Abstinent 8 weeks postpartum: Intervention 1: 61%, intervention 2: 79%*, control: 57%*, $p < .0.05^*$. **Key methods features:** *Validation:* Yes, urine cotinine but not included in results; *Point prevalence or sustained abstinence:* Not clear; *Lost to follow-up:* Excluded from analysis.

Finding summary: The study found no effect of the randomised intervention, but reported a positive finding from a non-randomised comparison. This however only

reached borderline significance if the 25% deception rate was ignored and patients lost to follow-up were excluded from the sample.

Evidence Statement 2: One pilot study reported a positive result, but it was a non-randomised comparison of two cohorts. The three randomised studies produced negative results. Overall, the studies reviewed above are consistent with the findings of the Cochrane Review which found the RP procedures ineffective in preventing relapse in pregnant smokers (+).

Chapter 4: Use of incentives with pregnant smokers

The above evidence shows that the common RP interventions evaluated so far are ineffective. A question arises whether there are any other approaches not yet evaluated which may hold a promise in this area.

No pharmacological interventions were evaluated with pregnant ex-smokers so far. Given the problems with instigating pharmacotherapy in people who are currently not smoking, and the concerns about using smoking cessation medications in pregnancy, it is unlikely that relevant trials will be instigated.

Another approach which may be more practicable is the use of incentives. Such an intervention has not yet been tested in the context of RP in pregnancy, but it has been evaluated for smoking cessation in pregnant women, and it is currently attracting considerable interest within the UK health service. The DoH has already invested £100,000 into a cash rewards scheme of up to £200 in 12 Stop Smoking services in the Yorkshire and Humber areas, and other PCTs are implementing 'home grown' incentive schemes.

We searched EMBASE, MEDLINE, PSYCINFO and CINAHL using the terms “preg* AND smok* AND (incentiv* OR contingency management)”. A total of 19 papers were found, 3 of which directly investigated incentives to stop smoking in pregnant women. We review below these three US studies and present the details of each with a brief summary at the end.

Donatelle et al. (2000)

Study design: RCT. **Participants:** 207 pregnant women (102 in control group, 105 in intervention group). **Intervention:** \$50 retail vouchers were given each month throughout pregnancy to 2 months postpartum, contingent upon biochemically verified abstinence. Participants designated a close, female, non-smoking friend to provide ‘natural peer support’. Supporters received \$50 of vouchers in the first month, \$25 in subsequent months, and \$50 in the final month (contingent upon biochemically verified abstinence). **Control:** Usual care, including information on the importance of smoking cessation during pregnancy. **Results:** Abstinence at 32 weeks pregnancy: Intervention 32%, control 9%, $p < 0.001$; Abstinence at 2 months post-partum: Intervention 21%, control 6%, $p < 0.001$. **Key methods features:** *Validation:* Yes, urinary cotinine; *Point prevalence or sustained abstinence:* 7-day point prevalence; *Lost to follow-up:* Included as smoking.

Finding summary: The study demonstrated a significant benefit of an intervention combining incentives and social support. No follow-up was conducted after the incentives were discontinued.

Higgins et al. (2004)

Study design: Mixed study design (randomised and consecutive study admissions). **Participants:** 53 women (23 in control group, 30 in intervention group). **Intervention:** Vouchers exchangeable for retail items, contingent upon CO-verified abstinence

assessed daily for the first 5 days, twice a week for the next 7 weeks, once weekly for the next 4 weeks and then bi-weekly until birth. Post-partum abstinence assessment once a week for the first month, then bi-weekly for 2 months. Vouchers began at \$6.25 and escalated by \$1.25 per consecutive negative specimen up to a maximum \$45. Smoking or missed session re-set the value to \$6.25; 2 consecutive negative tests restored to the pre-reset value. **Control:** Vouchers, independent of smoking status, \$11.50 per visit pre-partum and \$20 post-partum. **Results:** End of pregnancy abstinence: 37% intervention and 9% control group ($p < .05$). 12 weeks post partum: 33% versus 0% ($p < .05$); 24 weeks postpartum: 27% versus 0% ($p < .05$). Voucher earnings were \$397 in the intervention group and \$313 in the control group (NS).

Key methods features: *Validation:* Yes, urinary cotinine; *Point prevalence or sustained abstinence:* 7-day point prevalence; *Lost to follow-up:* Not clear.

Finding summary: This small study showed a significant long-term effect, but the control procedure may have had a detrimental effect (0% success rate)

Heil et al. (2008)

Study design: RCT. **Participants:** 77 pregnant women (37 in intervention group and 40 in control group). **Intervention and Control:** The same schedule of incentives was used as in Higgins et al. (2004). **Results:** End of pregnancy abstinence: 41% in the intervention versus 10% in the control group ($p < .01$). 12 weeks post-partum: 24% versus 3% ($p < 0.1$). 24 weeks post-partum: 8% versus 3%, NS. Voucher earnings were \$461 and \$413 in the two groups, NS>

Key methods features: *Validation:* Yes, urinary cotinine; *Point prevalence or sustained abstinence:* 7-day point prevalence; *Lost to follow-up:* Included as smoking.

Finding summary: The intervention showed efficacy while it lasted, but the effect became non-significant when the vouchers were discontinued.

All three studies are of a good methodological standard. Their results broadly confirm the findings from using incentives with non-pregnant smokers (Tevyaw et al., 2009, Shoptaw et al., 2002), namely that incentives are effective but the efficacy tends to diminish when the rewards stops. Financial incentives seem to be needed. 'Goodie bag' type of presents, not contingent on smoking status, were included in some RP trials and lacked efficacy (Severson et al., 1997, Lowe et al., 1997). There are obvious limits to the size and duration of such payments. However, even if incentives only generated a short term effect, due to the nature of health risks of maternal smoking to the foetus, this could be valuable.

Using incentives with current smokers may generate additional practical problems, e.g. it is not clear how the services can advertise an incentive scheme without encouraging potential pregnant quitters to delay a quit attempt and continue smoking until they get paid; or even encourage light smokers or non-smokers to increase or initiate smoking to qualify for the rewards. Using incentives for relapse prevention with smokers who were successfully treated earlier may avoid at least some of these problems. In the relapse prevention field where promising interventions are lacking, this approach may warrant a formal randomised evaluation.

Chapter 5: Literature on Factors Influencing Implementation of Interventions

A number of articles discuss qualitative problems with instigating and implementing RP interventions, present suggestions for work with pregnant ex-smokers, and propose further research. We review this literature below.

Barriers to interventions

Two problems were common. Recruiting the women was difficult (Hannover et al., 2009, Van't Hof et al., 2000), and a number of studies reported poor adherence of health care professionals (HCPs) to the delivery of the interventions (Ershoff et al., 1995, Lando et al., 2001, Valanis et al., 2001, McBride et al., 1992, Secker-Walker et al., 1995, Groner et al., 2005, Ratner et al., 2000, Pbert et al., 2004). In several instances the discussion points quoted below concern not just RP but smoking cessation as well. The following barriers to implementation were suggested.

Patient/practitioner relationship

HCPs may have been concerned that patients may react negatively to discussing smoking (Ratner et al., 2000, Lando et al., 2001). One approach suggested to counter this problem is to use smoking cessation specialists to provide the treatment, e.g. (Lopez et al., 2008). Other commentators worried that such specialists would not be able to develop therapeutic alliance such as that elicited by midwives and health visitors (Chalmers et al., 2004). An evaluation of the UK pregnancy service however showed no difference in efficacy of smoking cessation specialists who had or had not got a background in midwifery (Taylor et al., 2001). One study reported HCPs did not meet resistance to raising the topic of smoking from post-partum women (Groner et al., 2005). The majority of patients provided positive evaluations of a nurse home visit in which relapse prevention was discussed, although only 40% reported that the advice was useful (Groner et al., 2005).

Attitudes of HCPs

Several commentators have noted that HCPs do not view discussion of smoking as a priority (Zapka et al., 2004, Pbert et al., 2004) or even as a part of their role (Zapka et al., 2004, Lando et al., 2001, Groner et al., 2005). On the other hand, one report noted that home care nurses (US equivalent of health visitors) viewed relapse prevention as a natural extension of their work (Groner et al., 2005). Other barriers suggested include lack of self-efficacy to deliver the intervention (Zapka et al., 2004) and a possibility that once women stop smoking, HCPs may view them as 'cured' and so unlikely to raise the issue of relapse (McBride et al., 1992). Some HCPs have questioned the efficacy of relapse prevention interventions (Zapka et al., 2004).

Organisational Barriers

Demands on HCP time have been considered to be a major barrier for implementation of relapse prevention interventions (Zapka et al., 2004, Lando et al., 2001, Hajek et al., 2001, Pbert et al., 2004, Groner et al., 2005). For this reason, the suitability of midwives as providers of relapse prevention advice has been questioned (Bakker et al., 2003). Frequent changes in personnel were also mentioned (Lando et al., 2001), together with lack of financial incentives to engage in smoking treatments (Roske et al., 2008).

In different health care systems, other barriers may include poor communication among staff members and with patients, lack of involvement of key stakeholders, and inadequate monitoring and documentation of patient smoking status (Lando et al., 2001, Secker-Walker et al., 1995).

Timing of Intervention

RP interventions may be needed especially towards the end of pregnancy. Two commentators noted difficulty recruiting women around the time of delivery (Van't Hof et al., 2000, Hannover et al., 2009). However, in a number of studies of smoking cessation

interventions in pregnancy, recruitment of women, in whatever stage of pregnancy, has been difficult (Lopez et al., 2008, Park et al., 2007).

Practical suggestions made in existing literature

Several papers included practical suggestions for RP work. Routine recording and tracking of smoking status is considered of paramount importance (Hajek et al., 2001, Lowe et al., 1997, McBride et al., 1992, Groner et al., 2005, Petersen et al., 1992, Severson et al., 1997). RP interventions need to be timed close to delivery to address the risk of women relapsing shortly after delivery (Groner et al., 2005, McBride et al., 1999, McBride et al., 1992). Effort can be made to involve partners (Bakker et al., 2003). Booster training sessions may improve staff compliance (Valanis et al., 2001, Groner et al., 2005). In view of difficulties encountered when trying to involve routine front line staff (priorities, time pressure, demands on training, staff turn-over, etc.), dedicated specialists delivering such interventions may be a way forward (Mullen, 2004, Lando et al., 2001, Lopez et al., 2008).

Suggestions for further research made in existing literature

Authors of the reviewed papers typically state that further research is needed in enhancing self-efficacy (Gaffney, 2006, Van't Hof et al., 2000, Fang et al., 2004), behavioural and cognitive skills training (Ershoff et al., 1995, Edwards and Sims-Jones, 1998, Fang et al., 2004, Pletsch, 2006, Secker-Walker et al., 1998) and motivational interviewing (Pletsch, 2006, Fang et al., 2004).

Other suggestions were more relevant to pregnancy.

Research could explore the effects and modification of social support from women's partner, family, and friends, (Edwards and Sims-Jones, 1998, McBride et al., 1999,

McBride et al., 1992, Lando et al., 2001, Ratner et al., 2000, Fang et al., 2004, Van't Hof et al., 2000) including its quantity, nature and timing.

There is a possibility that different interventions may be needed for those who choose to quit only for the duration of their pregnancy versus those who intend to remain smoke free post-partum (Edwards and Sims-Jones, 1998). Research could also consider tailoring interventions according to the circumstances in which women quit during pregnancy (e.g. spontaneous quitters versus women who had treatment) (Morasco et al., 2006). As women who relapse may be more sensitive to immediate versus delayed rewards, interventions to enhance self-control may be worth exploring (Yoon et al., 2007).

The issue of the focus of educational input at different stages of pregnancy and delivery has been raised. During pregnancy, the information focuses primarily on the foetus, but at delivery a partial shift towards the mother may be warranted, but without leaving out the issue of risks of exposing the baby to environmental tobacco smoke (ETS) (Severson et al., 1997, Groner et al., 2005).

Other pregnancy specific factors suggested as candidates for further research included effects of sleep deprivation, post-natal depression, and breast feeding (Mullen et al., 2004).

Chapter 6: Conclusions and recommendations

1. Which interventions have been evaluated so far?

We reviewed the interventions used in the 17 existing randomised trials of relapse prevention in pregnancy and noted that two types of methods were evaluated so far: Efforts to strengthen women's determination to remain abstinent by education, motivational interviewing, and persuasion; and teaching them to identify relapse situations and put in place coping strategies.

2. What is the evidence of the efficacy of these interventions from randomised trials with at least 6-months follow-up?

Evidence statement 1: Two Cochrane reviews of relapse prevention (RP) interventions with women who stopped smoking during pregnancy found that the types of interventions examined so far had no effect on relapse (++).

The interventions identified in the first chapter seem to have been ineffective across levels of intensity and the type of provider.

3. What is the evidence from trials not included in the Cochrane reviews?

We undertook a comprehensive review of wider literature on the topic. Apart from 15 studies included in the Cochrane reviews, we identified 20 other publications providing data on relapse prevention in pregnancy or discussing such interventions. Four evaluative studies were found which did not qualify for inclusion in the main Cochrane Review, but provided some outcome data. One non-randomised cohort comparison found a significant effect, but three randomised studies produced negative results.

Evidence statement 2: Overall, the results of studies which did not qualify for inclusion in the Cochrane review are consistent with the Cochrane negative verdict (+).

4. Are there any other interventions which may hold a promise in this area?

There is currently a great deal of interest in the use of incentives as a smoking cessation intervention for pregnant women. We reviewed three existing outcome studies and concluded that the intervention seems to have at least a short-term effect on smoking cessation (+). The approach has some intuitive validity in relapse prevention as well. Despite the challenges intrinsic in using monetary incentives for behaviour change, in this field where promising interventions are lacking, this approach may warrant a formal randomised evaluation. The incentives may prove to be attractive especially for women from lower socioeconomic groups who are a priority target group, and if effective, they may exert an effect across the various groups of pregnant ex-smokers including those not interested in other types of help.

5. Are there any practical barriers to implementing RP interventions with pregnant ex-smokers?

Implementation of the interventions with pregnant women was sometimes difficult for two reasons which were usually related. Studies which used front-line staff to deliver the interventions often struggled with low HCP compliance, and there were problems with recruiting the women. A number of barriers were identified, such as HCP's priorities and time pressures. The existing literature offered various practical suggestions and proposals for further research, including e.g. the issues of the timing of the intervention, a need for specialists providing the intervention as opposed to involving the front-line staff on a large scale, social support issues, etc.

An important issue concerns recruitment of women. It has been pointed out that the target of the intervention is somewhat unclear ((Lopez et al., 2008, Mullen, 2004)). Among pregnant ex-smokers, it would seem that only the women keen to remain abstinent and worried about their capacity to do so are likely to be receptive to RP efforts. Those who had successfully stopped smoking and have no intention of going

back to it are unlikely to seek help or attend a series of sessions. They may listen politely to arguments for staying abstinent, but as they want to do this anyway, both parties may feel the exercise somewhat superfluous. Even those who plan to go back to smoking after delivery, or are unsure, may not be overly keen to go along with the existing interventions. What proportion of pregnant ex-smokers belong to each of these groups is unknown and no study screened women for these characteristics. One obvious recommendation for future RP trials is to only randomize women keen to remain abstinent and worried about their capacity to do so. This however is likely to prove impractical. Recruitment for pregnancy studies is slow and difficult, and a selection like this is likely to reduce the numbers further.

Conclusions and recommendations

The commonly used RP interventions for pregnant ex-smokers lack efficacy and so investment in them is not recommended. Interventions based on incentives may warrant randomized evaluation. Until new interventions are developed and shown effective, it would seem best to focus resources on helping pregnant smokers quit. Even short term abstinence during pregnancy benefits the fetus and increased short-term quit rates can be expected to generate higher long-term effects even if the problem of relapse remains unsolved.

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Appendices

Appendix 1 – Search strategy

Smoking in pregnancy – relapse prevention

Ovid Medline 1950 to April Week 4 2009

Searched 6th May 2009 by Sarah Glover

- 1 (smok* or nicotin* or tobacco or cigar* or hand-roll* or bidi or paan or gutkha or snuff or betel nut* or betel).ti,ab. (190686)
- 2 nicotine/ (17195)
- 3 tobacco/ (17812)
- 4 "tobacco use disorder"/ (5210)
- 5 tobacco, smokeless/ (2121)
- 6 smoking/ (91749)
- 7 or/1-6 (218707)
- 8 pregnancy/ (591149)
- 9 pregnan*.ti,ab. (280766)
- 10 Postpartum period/ (13906)
- 11 pregnant women/ (4271)
- 12 (post-partum or post partum or postpartum).ti,ab. (29452)
- 13 or/8-12 (647760)
- 14 recurrence/ (127236)
- 15 (relaps* adj3 (prevent* or interven*)).ti,ab. (4462)
- 16 smoking cessation/ (13118)
- 17 behavior therapy/ (19928)
- 18 chewing gum/ (1625)
- 19 cessation.ti,ab. (36854)
- 20 or/14-19 (191021)
- 21 (evaluat* or effect* or study or studies or trial* or implement* or follow?up or review* or program* or impact* or intervention).ti,ab. (7288333)
- 22 7 and 13 and 20 and 21 (978)
- 23 Animals/ (4363592)
- 24 Humans/ (10674272)

- 25 23 not (23 and 24) (3270634)
- 26 22 not 25 (970)
- 27 limit 26 to english language (868)
- 28 limit 27 to yr="1990 - 2009" (826)

Ovid Embase 1980 to 2009 Week 18

Searched 6th May 2009 by Sarah Glover

- 1 (smok* or nicotin* or tobacco or cigar* or hand-roll* or bidi or paan or gutkha or snuff or betel nut* or betel).ti,ab. (151186)
- 2 Nicotine/ (20770)
- 3 Tobacco/ (11409)
- 4 Tobacco Dependence/ (4782)
- 5 Smokeless Tobacco/ (938)
- 6 Smoking/ (55330)
- 7 cigarette smoking/ (34599)
- 8 Smoking Habit/ (8160)
- 9 or/1-8 (177654)
- 10 Pregnancy/ (154650)
- 11 pregnan*.ti,ab. (197273)
- 12 puerperium/ (10570)
- 13 pregnant woman/ (4933)
- 14 (post-partum or post partum or postpartum).ti,ab. (20358)
- 15 or/10-14 (265016)
- 16 9 and 15 (8727)
- 17 maternal smoking/ (675)
- 18 16 or 17 (8980)
- 19 Relapse/ (24152)
- 20 (relaps* adj3 (prevent* or interven*)).ti,ab. (4528)
- 21 smoking cessation/ (17727)
- 22 behavior therapy/ (21162)
- 23 Chewing Gum/ (599)
- 24 cessation.ti,ab. (31527)
- 25 or/19-24 (86527)
- 26 (evaluat* or effect* or study or studies or trial* or implement* or follow?up or review* or program* or impact* or intervention).ti,ab. (5870461)

- 27 18 and 25 and 26 (810)
- 28 Animal/ (18273)
- 29 Human/ (6477405)
- 30 28 not (28 and 29) (14487)
- 31 27 not 30 (810)
- 32 limit 31 to yr="1990 -Current" (788)
- 33 limit 32 to english language (697)

Ovid PsycInfo 1806 to May Week 1 2009

Searched 6th May 2009 by Sarah Glover

- 1 (smok* or nicotin* or tobacco or cigar* or hand-roll* or bidi or paan or gutkha or snuff or betel nut* or betel).ti,ab. (32079)
- 2 Nicotine/ (5522)
- 3 Tobacco Smoking/ (15677)
- 4 Smokeless Tobacco/ (356)
- 5 or/1-4 (32308)
- 6 Pregnancy/ (9857)
- 7 pregnan*.ti,ab. (20717)
- 8 Expectant Mothers/ (459)
- 9 (post-partum or post partum or postpartum).ti,ab. (5103)
- 10 or/6-9 (25077)
- 11 Relapse Prevention/ (1341)
- 12 (relaps* adj3 (prevent* or interven*)).ti,ab. (3262)
- 13 smoking cessation/ (5856)
- 14 behavior therapy/ (11279)
- 15 Behavior Modification/ (9396)
- 16 cessation.ti,ab. (8777)
- 17 or/11-16 (33808)
- 18 (evaluat* or effect* or study or studies or trial* or implement* or follow?up or review* or program* or impact* or intervention).ti,ab. (1634640)
- 19 5 and 10 and 17 and 18 (364)
- 20 limit 19 to yr="1990 -Current" (354)
- 21 limit 20 to english language (350)

EBSCO CINAHL

Searched 6th May 2009 by Sarah Glover

- S1 TI (smok* or nicotin* or tobacco or cigar* or hand-roll* or bidi or paan or gutkhs or snuff or betel nut* or betel)
- S2 AB (smok* or nicotin* or tobacco or cigar* or hand-roll* or bidi or paan or gutkhs or snuff or betel nut* or betel)
- S3 (MH "Nicotine")
- S4 (MH "Tobacco")
- S5 (MH "Tobacco, Smokeless")
- S6 (MH "Smoking")
- S7 S1 or S2 or S3 or S4 or S5 or S6
- S8 (MH "Pregnancy")
- S9 TI pregnan*
- S10 AB pregnan*
- S11 (MH "Postnatal Period")
- S12 (MH "Expectant Mothers")
- S13 TI (post-partum or postpartum or post partum)
- S14 AB (post-partum or postpartum or post partum)
- S15 (S8 or S9 or S10 or S11 or S12 or S13 or S14)
- S16 (MH "Recurrence")
- S17 TI (relaps* AND prevent*)
- S18 AB (relaps* AND prevent*)
- S19 TI (relaps* AND interven*)
- S20 AB (relaps* AND interven*)
- S21 (MH "Smoking Cessation")
- S22 (MH "Behavior Therapy")
- S23 (MH "Chewing Gum")
- S24 TI cessation
- S25 AB cessation
- S26 S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24 or S25

S27 TI (evaluat* or effect* or study or studies or trial* or implement* or follow?up or review* or program* or impact* or intervention)

S28 AB (evaluat* or effect* or study or studies or trial* or implement* or follow?up or review* or program* or impact* or intervention)

S29 S27 or S28

S30 S7 and S15 and S26 and S29

S31 S7 and S15 and S26 and S29

Limiters - Published Date from: 199001-200912; Language: English

CRD NHS EED

Searched 6th May 2009 by Sarah Glover

- 1 (smok* OR nicotin* OR tobacco OR cigar* OR hand-roll* OR bidi OR paan OR gutkha OR snuff OR betel AND nut* OR betel)
- 2 MeSH Nicotine
- 3 MeSH Tobacco
- 4 MeSH Tobacco Use Disorder
- 5 MeSH Tobacco, Smokeless
- 6 MeSH Smoking
- 7 #1 or #2 or #3 or #4 or #5 or #6
- 8 MeSH Pregnancy
- 9 pregnan*
- 10 MeSH Postpartum Period
- 11 MeSH Pregnant Women
- 12 (post-partum OR (post AND partum) OR postpartum)
- 13 or/8-12
- 14 MeSH Recurrence
- 15 (relapse* AND (prevent* OR interven*))
- 16 MeSH Smoking Cessation

17 MeSH Behavior Therapy

18 MeSH Chewing Gum

19 cessation

20 #14 or #15 or #16 or #17 or #18 or #19

21 (evaluat* OR effect* OR study OR studies OR trial* OR implement* OR follow?up OR review* OR program* OR impact* OR intervention)

22 #7 and #13 and #20 and #21