Interventions to support smoking cessation in pregnancy: a systematic review of reviews

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Introduction
This is the second in a series of articles about improving health and wellbeing for parents and their children during the perinatal period. This review describes the effectiveness of interventions that aim to help women stop smoking during pregnancy or shortly afterwards using systematic reviews of randomised controlled trials (RCTs).

Background
Pregnancy is a time when women and their partners are often motivated to address issues affecting their health in order to give their baby a good start in life. Antenatal care and support sessions provide an opportunity to influence health-related behaviours. As well as the chance to improve the outcome of the pregnancy, there is also an opportunity to influence long-term health.

Even though there is clear evidence that smoking adversely affects outcomes for women and their babies, around 13% of mothers in England are smokers at the time their babies are born. Smoking is more common in low-income households and less common in high-income households, and women who have experienced greater disadvantage, for example leaving education early or having a low income, are more likely to smoke before pregnancy. Effective interventions in this area could, therefore, potentially address health inequalities.

It is, therefore, important that professionals and NCT practitioners are aware of the latest evidence in this area. This overview sets out evidence on the effectiveness of smoking cessation interventions during pregnancy or shortly afterwards and summarises relevant evidence-based guidance. An intervention is any action that is designed to effect change ranging from, for example, simple advice to complex health promotion programmes.

Method
Medline was searched to identify systematic reviews of RCTs that were published during the last 10 years and aimed to determine the effectiveness of interventions to help women stop smoking during pregnancy or shortly afterwards. The search strategies are available on request. The focus was on systematic reviews because of limited space and the expected large number of trials, but a search was also made for RCTs from the last five years to identify those that had not yet been incorporated into a review. The Cochrane Database of Systematic Reviews was also searched by looking for reviews under relevant topic headings.

Studies involving interventions of any type were eligible as long as they related to smoking cessation in pregnancy or shortly afterwards. Studies addressing smoking cessation among partners were eligible if the aim was to help the mother quit and they otherwise met the inclusion criteria. Recently, some studies have looked at establishing smoke-free homes, but such studies were excluded if the outcome was smoking in the presence of an infant, rather than cessation.

Results
Systematic reviews
Forty-eight titles were retrieved from Medline. After considering the abstracts, eight eligible reviews were identified. One examined the role of men in supporting cessation among their pregnant partners and this is summarised in the box at the end of this article. Two had the same authors. As all the trials included in the earlier review were included in the later review plus another trial, only the later review has been described. Two of the remaining reviews were a Cochrane review and its update and only the update has been described. The resulting five reviews, which address related but different research questions, are described chronologically, starting with the earliest. They include the two reviews that were identified by searching the Cochrane database of systematic reviews.

Self-help
A fairly high quality review (7.5/10 on CASP checklist) from 2008 evaluated self-help, that is ‘structured materials that assist the individual in making a quit attempt and sustaining abstinence without significant assistance from a health professional or group support’. Twelve trials (about 4,700 women) from the UK, USA, Norway, Sweden and Australia compared self-help interventions (usually a booklet with or without other aids such as videos, audiocassettes, computer programs or other written material) with usual care. Eight were assessed as having a high risk of bias and two did not validate cessation with a biochemical test. After excluding one trial that was a major source of heterogeneity, indicating that it may be inappropriate to combine its results with the others, the pooled odds ratio was 1.99 (95% confidence interval CI 1.42–2.80). This suggests that self-help interventions on average nearly...
double the odds of quitting compared with usual care. There was no significant difference between subgroups based on the length of face-to-face contact, intensity of materials, or whether they were tailored to a woman’s personal characteristics, although the authors felt that there was a lack of relevant trials.

**Any intervention**
A high quality 2009 Cochrane review (8.5/10 on CASP checklist) considered any intervention.13 Trials with biochemically validated or self-reported cessation were eligible, but the authors recommended that in future this should be validated. The outcome was the proportion of women who continued smoking in the intervention group compared with the control group, unlike most other reviews, which used the proportion of women who stopped. The trials, including about 21,000 women, were grouped according to what the authors considered was the most important component of the intervention:

- The pooled result for four trials evaluating incentives, for example vouchers, was significantly larger than that for other interventions (risk ratio 0.76, 95% CI 0.71 to 0.81: a risk ratio of less than one means that women in the intervention group are less likely to continue smoking than women in the control group).
- The pooled effect for the 31 trials involving cognitive behavioural therapy was significant (risk ratio 0.95, 95% CI 0.93 to 0.97).
- There was a significant pooled effect for the five trials, including one quasi-randomised trial, involving nicotine replacement therapy (NRT) (risk ratio 0.95, 95% CI 0.92 to 0.98).
- The 11 trials based on stages-of-change theory (risk ratio 0.99, 95% CI 0.97 to 1.00) and the four trials based on feedback (risk ratio 0.92, 95% CI 0.84-1.02) were not significantly effective.

However, heterogeneity was high when studies were grouped by intervention type, suggesting that the results should be treated with caution. Although the effects were modest, the authors felt that they were important because of the substantial impact of smoking on babies and mothers.

The authors felt, however, that the safety of NRT in terms of birth outcomes remained unproven. Finally, many trials did not disclose how many women declined to take part and substantial proportions of women were lost to follow-up or left trials. This limits the usefulness of their results as the women who contributed to them may be a very select group, for example women who were very motivated to stop smoking.

**Counselling**
A review from 2011 evaluated counselling.15 Although it scored highly on most other points from the CASP checklist (B/10), the authors did not mention assessing the quality of included trials. Eight RCTs (over 3,000 women) from the UK or USA were included, all with biochemically validated cessation. They compared face-to-face or telephone counselling with brief advice from a clinician with or without self-help material.

‘NICE advises cognitive behavioural therapy can support women to quit smoking in pregnancy.’

The number of counselling sessions ranged from three to nine lasting in total from 180 to 600 minutes, but no other details were provided. Although all the odds ratios favoured the intervention, there were no significant differences when results were pooled from:

- All the trials (odds ratio 1.08, 95% CI 0.84-1.40)
- The six trials involving face-to-face counselling (odds ratio 1.12, 95% CI 0.81-1.56), or
- The two trials involving telephone counselling (odds ratios 1.03, 95% CI 0.68-1.55).

**Pharmacotherapy**
A medium-quality review (6.5/10 on CASP checklist) from 2012 looked at pharmacotherapy, that is, drug treatments.16 Five RCTs, one quasi-RCT and one prospective controlled study (about 1,400 women) were included, although only four biochemically validated cessation.

- Pharmacotherapy had a significant effect when all results were pooled (relative risk 1.80, 95% CI 1.32 to 2.44).
- Studies were grouped by study design, presumably because the randomisation used in RCTs generally results in less biased estimates for effectiveness. Although the individual RCTs found no significant effects (nicotine compared with placebo patches - two trials - nicotine patches plus counselling compared with counselling only, choice of nicotine gum or patch or lozenge plus cognitive behavioural therapy versus cognitive behavioural therapy only, nicotine versus placebo gum), they all favoured the intervention and the pooled result was significant (relative risk 1.48, 95% CI 1.04 to 2.09).

Several studies reported serious adverse events, although there was no evidence linking them to the pharmacotherapy. Two RCTs reported that the intervention group had a significantly higher mean birthweight than the comparison group, whereas one RCT, the quasi-RCT and the prospective study reported no significant difference.

The authors pointed out the lack of relevant trials and short follow-up of most existing trials and concluded that larger trials are needed to confirm the efficacy and safety of pharmacotherapy.

**Nicotine replacement therapy (NRT)**
A high quality 2012 Cochrane review (B/10 on CASP checklist) assessed NRT.16 Six RCTs (1,745 women) that all validated cessation biochemically were included: four compared a nicotine patch or gum with a placebo, one compared a patch plus behavioural support with behavioural support alone, and one compared a patch or gum or lozenge plus behavioural support with behavioural support alone.

- NRT was not significantly effective in a pooled analysis (risk ratio 1.33, 95% CI 0.93 to 1.91).
- The authors felt that the pooled result from the placebo-controlled studies (risk ratio 1.20, 95% CI 0.93 to 1.56) was more relevant and reliable because of unmeasured placebo effects in non-placebo-controlled trials.
- There was no statistically significant difference in stillbirths, miscarriages, preterm births, neonatal intensive care unit admissions or neonatal deaths when results were pooled from studies that provided data on those outcomes.
- Results related to birthweight from individual studies were mixed.
- The overall conclusion was that there was insufficient evidence to determine whether NRT was effective or safe in pregnancy.

The authors felt that low adherence could be due to increased metabolism of nicotine in pregnancy and more marked withdrawal symptoms and suggested qualitative research exploring low adherence and placebo-controlled RCTs with higher doses.

**More recent RCTs**
Thirty-three titles were retrieved from Medline. After reviewing the abstracts, eight eligible trials were identified. The oldest three had been included in the eligible systematic reviews, leaving five trials. They are described chronologically, starting with the earliest.
A medium quality study (6.5/11 on CASP checklist) from 2009 evaluated feedback during ultrasound and motivational interviewing. Women from Texas were randomised to best practice (n=120), best practice plus an ultrasound with messages incorporated into the discussion (n=120), or the ultrasound plus a motivational interview and personalised letter and telephone session two weeks later (n=120). Best practice consisted of the 5As (ask, advise, assess, assist, arrange) and standard literature. There were differences between the groups, for example a higher proportion of women in the best practice and ultrasound group (80%) had a partner who smoked than in the best practice-only group (68%). At the end of pregnancy, the validated quit rate was 10.8%, 14.2% and 18.3% respectively in the three groups, but the differences were not significant. Quit rates were higher among women who originally smoked ten or fewer cigarettes per day, whereas women who smoked more were unaffected.

A small medium-quality trial (6.5/11 on CASP checklist) from 2010 from the USA looked at enlisting supporters. Women in intervention (n=54) and comparison groups (n=28) saw a counsellor and identified supporters, but only supporters of the intervention group saw a counsellor followed by monthly telephone sessions. Only 53% of eligible women participated and there were differences between the groups, for example a higher proportion of women in the intervention group had other children. In an intention-to-treat analysis, the validated quit rate at the end of pregnancy was higher in the intervention (13.6%) than the comparison group (7.8%), but the result was non-significant. Only 22 of 58 women assigned to CM-Lite had initiated testing of at least one urine sample by 10 weeks and most were not abstinent. The CD-5As intervention led to significantly increased abstinence as measured by urinary cotinine (odds ratio 10.195% CI 1.4-75.0) but not seven-day point prevalence confirmed by carbon monoxide (odds ratio 5.795% CI 0.9-34.3). The authors concluded that the intervention based on giving vouchers did not affect smoking in this sample, but that the intervention based on the 5As warranted further investigation.

A preliminary English study from 2012 focused on text messages. Women in the intervention group (n=102) were sent a self-help leaflet and up to two texts per day, both tailored to their characteristics, for example whether they lived with other smokers. They could text HELP for support texts or STOP to stop all texts. Women in the comparison group (n=105) received a non-tailored self-help leaflet. Although the study was well-designed and reported (8.5/11 on CASP checklist), there were limitations: for example, most midwives returned very few referral forms and a higher proportion of women in the comparison (59%) than the intervention group (44%) had smoked in a previous pregnancy. At three months, only 9% of women had stopped the texts and the validated quit rate was higher in the intervention (12.5%) than the comparison group (7.8%), but the result was non-significant (odds ratio 1.68, 95% CI 0.66-4.31) and adjusting for prenatal smoking history made no difference.

Evidence-based guidance
One relevant document was found on the RCM website. In 2008, the RCOG, the Royal College of Midwives (RCM), the Royal College of Anaesthetists, and the Royal College of Paediatrics and Child Health set out desired standards for maternity care based on recommendations and guidelines from reputable national bodies. They stated that all pregnant women and their partners who smoke should receive clear information about the risks and support available to them to help them stop, such as NHS Stop Smoking Services.

There were two relevant documents on the NICE website. The NICE antenatal care guideline CG62 (last modified 2010) includes recommendations about smoking in pregnancy, but there is also public health guidance specifically on quitting smoking in pregnancy (PH26 issued 2010). The first two recommendations, for midwives and others in the public, community and voluntary sectors, concern identifying women who smoke and referring them to NHS Stop Smoking Services. For the benefit of NHS Stop Smoking Services specialist advisers, subsequent recommendations set out effective interventions, namely:

- Cognitive behavioural therapy
- Motivational interviewing
- Structured self-help and support from NHS Stop Smoking Services
- Interventions that are ineffective or where the evidence is unclear were also detailed:
  - Incentives to quit – although found to be effective elsewhere, research is needed to see whether they work in this country.
  - Stages-of-change-based interventions – mixed results.
  - Giving feedback on the effects of smoking – not effective.
  - NRT – mixed results, with the most robust trial to date finding no evidence of effectiveness in terms of quitting or increased baby’s birthweight.

The Scottish guidance about how to help pregnant women stop smoking, published in 2010, is based on this NICE public health guidance.

Discussion
Main findings
Three reviews evaluated pharmacotherapy (nicotine replacement therapy with or without other interventions). The later Cochrane review concluded that NRT was not significantly effective. This review is likely to be most trustworthy as it includes the most recent data and its conclusion is based on pooling results from placebo-controlled RCTs only.

One of the Cochrane reviews looked at other interventions. Stages-of-change-based interventions were not significantly effective, but there were significant pooled
effects for cognitive behavioural therapy and incentives. A small trial from the USA found that few women agreed to pharmacological testing with incentives, and most of those who did participate were not found to test positive for nicotine, but this may reflect how the intervention was delivered or the population in which it was tested. A high-quality review found that, although the odds ratio favoured the intervention, face-to-face and/or telephone counselling was not significantly effective. Unfortunately, this review gave few details about the form or quantity of ‘counselling’, such as cognitive behavioural therapy. The Cochrane review also reported that feedback, for example of the health of the baby, was not significantly effective. A medium-quality trial from the USA reported that the validated quit rate was higher among women who received feedback during ultrasound than among other women, but this was not significant and women who had smoked more heavily were unaffected.

The last review, which was fairly high-quality, reported that self-help nearly doubles the odds of quitting compared with usual care. The remaining trials considered a range of interventions. One high-quality trial reported that women who received a tailored leaflet and texts were more likely to quit than women who received a non-tailored leaflet.

The difference was non-significant, but the study was preliminary. Two small trials found that there were no significant effects of tailored Video Doctor sessions plus a prompt sheet for clinicians or recruiting supporters.

‘NICE recommends that all pregnant women who smoke should be referred by their midwife or GP to NHS Stop Smoking Services.’

No evidence was found on addressing smoking cessation in a group antenatal course setting. Peer support may contribute to supporting health-related behaviour, such as breastfeeding, but it is important to avoid embarrassing or stigmatising individuals when working in groups, particularly around sensitive issues.

NICE guidance emphasises the importance of accepting the answer of women who decline a referral to NHS Stop Smoking Services in an impartial manner. Provided there is no negative pressure or judgement, a group setting could potentially provide support for women and their partners who have decided to stop smoking. Any focus on support to stop smoking in an antenatal course setting should, however, be carefully evaluated as there is potential to do harm as well as to have a positive impact.

Limitations
This review aimed to identify evidence by systematically searching key sources. Time and resource constraints meant it was not possible to exhaustively search all possible sources. Some minor reviews and trials may, therefore, have been omitted. Nor was it possible for two independent researchers to assess articles for eligibility and quality, which would be preferable, but eligibility criteria and widely accepted checklists for assessing quality have been used to ensure transparency and limit bias.

Comparisons with other studies
One of the pieces of work on which the NICE public health guidance PH26 was based was a briefing paper that summarised key evidence, notably the 2009 Cochrane review and the 2008 review of self-help interventions. Ten studies were also described: most were descriptive or qualitative and the only RCT had been included in the 2009 Cochrane review.

The results of this review are in line with the briefing paper, which concluded that there is good evidence for the effectiveness of incentives (although further research should explore applicability in the UK), mixed evidence for the effectiveness of NRT and insufficient data on perinatal outcomes, and good evidence from one review (although mostly not from this country) on the effectiveness of self-help interventions. It also reported, based on four UK mixed methods or qualitative studies, that there was evidence that NHS Stop Smoking Services are effective at helping pregnant women to quit.

Key points
- Cognitive behavioural therapy is effective in helping pregnant women to stop smoking.
- Access to self-help materials on average nearly double the odds of quitting compared with usual care, and incentives are also promising.
- In contrast, the safety and effectiveness of nicotine replacement therapy remains unproven.
- Midwives and others working with pregnant women are recommended by NICE and the Scottish guidance to refer women who smoke to NHS Stop Smoking Services (also called smoking cessation services). Any focus on support to stop smoking in an antenatal course setting should be carefully evaluated as there is potential to do harm as well as to have a positive impact.

- None of the trials or reviews concentrated on women from disadvantaged backgrounds, even though they are more likely to smoke and continue smoking during pregnancy. Research on interventions that are acceptable to and effective for these women is urgently needed.

Fathers are important too
The characteristics and smoking status of a pregnant woman and other regular contacts appear to be important. A review from 2007 examined the role of men in supporting smoking cessation among their pregnant partners. The descriptive studies found indicated that women were more likely to continue smoking or relapse if their partner smoked and more likely to quit if their partner quit compared with women whose partner continued smoking.

Two intervention studies described the impact of a partner’s behaviour. The first measured perceived support from their partner for stopping among 688 women enrolled in a cessation trial. It suggested that women were significantly more likely to quit if their partner was a non-smoker or a smoker trying to quit and that women who did quit had received greater positive support from their partners than women who continued smoking. A follow-up study aimed to encourage support from partners by providing them with information, but this did not increase the women’s cessation rates.

A review on which the NICE public health guidance PH26 was based considered which interventions are effective in encouraging partners to support cessation and which are effective in encouraging partners who smoke to stop. However, this found that very few studies had demonstrated significant results, highlighting the need for further research.


