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Interventions for promoting smoking cessation during pregnancy

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ABSTRACT

Background
Tobacco smoking in pregnancy remains one of the few preventable factors associated with complications in pregnancy, low birthweight, preterm birth and has serious long-term health implications for women and babies. Smoking in pregnancy is decreasing in high-income countries and increasing in low- to middle-income countries and is strongly associated with poverty, low educational attainment, poor social support and psychological illness.

Objectives
To assess the effects of smoking cessation interventions during pregnancy on smoking behaviour and perinatal health outcomes.

Search methods
We searched the Cochrane Pregnancy and Childbirth Group’s Trials Register (June 2008), the Cochrane Tobacco Addiction Group’s Trials Register (June 2008), EMBASE, PsycLIT, and CINAHL (all from January 2003 to June 2008). We contacted trial authors to locate additional unpublished data.

Selection criteria
Randomised controlled trials where smoking cessation during pregnancy was a primary aim of the intervention.

Data collection and analysis
Trials were identified and data extracted by one person and checked by a second. Subgroup analysis was conducted to assess the effect of risk of trial bias, intensity of the intervention and main intervention strategy used.
Main results

Seventy-two trials are included. Fifty-six randomised controlled trials (over 20,000 pregnant women) and nine cluster-randomised trials (over 5000 pregnant women) provided data on smoking cessation outcomes.

There was a significant reduction in smoking in late pregnancy following interventions (risk ratio (RR) 0.94, 95% confidence interval (CI) 0.93 to 0.96), an absolute difference of six in 100 women who stopped smoking during pregnancy. However, there is significant heterogeneity in the combined data ($I^2 > 60\%$). In the trials with the lowest risk of bias, the interventions had less effect (RR 0.97, 95% CI 0.94 to 0.99), and lower heterogeneity ($I^2 = 36\%$). Eight trials of smoking relapse prevention (over 1000 women) showed no statistically significant reduction in relapse.

Smoking cessation interventions reduced low birthweight (RR 0.83, 95% CI 0.73 to 0.95) and preterm birth (RR 0.86, 95% CI 0.74 to 0.98), and there was a 53.91g (95% CI 10.44 g to 95.38 g) increase in mean birthweight. There were no statistically significant differences in neonatal intensive care unit admissions, very low birthweight, stillbirths, perinatal or neonatal mortality but these analyses had very limited power.

Authors’ conclusions

Smoking cessation interventions in pregnancy reduce the proportion of women who continue to smoke in late pregnancy, and reduce low birthweight and preterm birth. Smoking cessation interventions in pregnancy need to be implemented in all maternity care settings. Given the difficulty many pregnant women addicted to tobacco have quitting during pregnancy, population-based measures to reduce smoking and social inequalities should be supported.

Plain Language Summary

Interventions to help women to stop smoking in pregnancy

Smoking during pregnancy increases the risk of the mother having complications during pregnancy and the baby being born too small (with low birthweight) and too early (prematurely, before 37 weeks). Low birthweight has been associated with coronary heart disease, type 2 diabetes, and being overweight in adulthood. Tobacco smoking also has serious long-term health risks for both the women and their babies. Tobacco smoking during pregnancy is relatively common, although the trend is toward becoming less frequent in high-income countries and more so in low to middle-income countries. Many mothers find it hard to stop or reduce smoking during pregnancy even knowing the benefits of doing so as the nicotine in tobacco is very addictive. Smoking in pregnancy is also strongly associated with poverty, low levels of education, poor social support, depression and psychological illness.

The interventions offered to promote smoking cessation in pregnancy are generally given individually and include cognitive behaviour and motivational interviewing; offering incentives; interventions based on stages of change; giving feedback to the mothers on fetal health status or nicotine by-products measurements; nicotine replacement therapy, bupropion or other medications. The review of trials found a total of 72 controlled trials involving over 25,000 women. These were conducted from 1975 to 2008 and nearly all were in high-income countries. Interventions were effective in helping women to stop smoking during pregnancy (overall by approximately 6%). The most effective intervention appeared to be providing incentives, which helped around 24% of women to quit smoking during pregnancy. The smoking cessation interventions reduced the number of babies with low birthweight and preterm births, confirming that smoking cessation can reduce the adverse effects of smoking on newborn infants.

Women in the control groups of most trials received information about the risks of smoking in pregnancy and were advised to quit as part of usual care. The intensity of both that information and the interventions has increased over time.

Background

Interventions for promoting smoking cessation during pregnancy (Review)
Risks associated with smoking in pregnancy

Tobacco smoking during pregnancy is the most important potentially preventable cause of a range of adverse pregnancy outcomes, including placental abruption, miscarriage, preterm birth (less than 37 weeks' gestation) and low birthweight (less than 2500 g) (Hammoud 2005; Salihu 2007; US DHHS 2004). Nicotine and other harmful compounds in cigarettes restrict the supply of oxygen and other essential nutrients, retarding fetal growth (Crawford 2008) and neuro-development (Herrman 2008). Preterm birth is the leading cause of neonatal mortality (Hammoud 2005; Kramer 1987) and morbidity, with up to half of all paediatric neuro-developmental problems ascribed to preterm birth (Green 2005). Low birthweight is a surrogate measure of the harmful impact of tobacco smoking on fetal development and there is growing evidence of the association between low birthweight and adult morbidities, including coronary heart disease, type 2 diabetes, and adiposity (Gluckman 2008).

Tobacco smoking also has many long-term health impacts for women and their children, and is a major risk factor for six of the eight leading causes of death globally (WHO 2008a). Tobacco addiction is caused by the nicotine in tobacco which produces a cascade of actions, including release of “pleasure enhancing” dopamine, which strengthens associations of positive feelings with smoking behaviour and appears to be involved in all addictive behaviours (Schmidt 2004).

Epidemiology of smoking in pregnancy

Tobacco smoking is associated with low socioeconomic status and has been cited as one of the principal causes of health inequality between rich and poor (Wireless 2004). In high-income countries, such as the United States (US), Denmark and Sweden, the prevalence of smoking in pregnancy has declined from 20% to 35% in the 1980s to 12% to 25% in 2001 (Cnattingius 2004; US DHHS 2004). However, the decline has not been consistent across all sectors of society, with lower rates of decline across the lower socioeconomic sector (US DHHS 2004). There are marked socioeconomic differences between women who continue to smoke in pregnancy and those who do not. Women who continue to smoke in pregnancy generally have a low income, have high parity, are without a partner, have low levels of social support, receive publicly funded maternity care, have limited education and are more likely to feel criticised by society (Ebert 2007; Frost 1994; Graham 1977; Graham 1996; Tappin 1996; US DHHS 2004). There is a significantly higher prevalence of smoking in pregnancy in several indigenous and ethnic minority groups, which is in accord with their social and material deprivation (Chan 2001; Hunt 2003; Kaplan 1997; US DHHS 2004; Wiemann 1994). Despite the high prevalence, there is a paucity of evidence-based literature into interventions to reduce antenatal smoking in indigenous groups (Gilligan 2007). In some migrant groups, cultural differences may cut across this social gradient. Women who are migrants or refugees to the United Kingdom, Northern America, North Australia who originate from South East Asia retain a lower prevalence of smoking, despite major social disadvantage (Bush 2003; Porter 1996; Small 2000). In the US, African American, Hispanic, and Pacific-Islander women have a lower prevalence of smoking in pregnancy than white women (Andreski 1995; Wiemann 1994; US DHHS 2004).

The global tobacco smoking epidemic is shifting from high-income countries to low- and middle-income countries, where the prevalence of tobacco smoking among women is increasing (rather than decreasing) and is expected to rise to 20% by 2025 (Richmond 2003; Samet 2001). The World Health Organization has identified this rise of tobacco use in young females in low-income, high population countries as one of the most ominous developments of the tobacco epidemic (WHO 2008a). There is marked variation in prevalence of smoking in pregnancy. For example, in Poland the prevalence is estimated at 30% (Polanska 2004), while the prevalence in countries such as the Democratic Republic of Congo is still very low (Richmond 2003). However, given the aggressive nature of tobacco marketing there is concern that prevalence will increase with economic development (WHO 2008a), with subsequent health impacts on countries with already high disease burdens and limited resources to provide health care, particularly neonatal care (Cnattingius 2004).

In addition to the socioeconomic factors associated with continued smoking, there is a growing understanding of psychological associations, especially depression and stress (Aveyard 2007; Blalock 2005; Crittenden, 2007). Depressed women are up to four times more likely to smoke during pregnancy than non depressed women (Blalock 2005). There is limited information available about the effects of smoking and interventions in pregnant women with psychological symptoms, as they are often excluded from trials (Blalock 2005). Two reviews in the general population (Stead 2006a; Toi 2008), and several included trials in this review report stress and depression outcomes in randomised controlled trials of smoking in pregnancy (Aveyard 2007; Blalock 2005; Crittenden, 2007).

A higher proportion of women stop smoking during pregnancy than at other times in their lives. Up to 45% of women who smoke before pregnancy “spontaneously quit” or stop before their first antenatal visit (Quinn 1991; Woodby 1999), a quit rate substantially higher than reported in the general population (Ershoff 1999; McBride 2003). 'Spontaneous quitters’ usually smoke less, are more likely to have stopped smoking before, to have a non-smoking partner, to have more support and encouragement at home for quitting, be less seriously addicted, or to have stronger beliefs about the dangers of smoking (Baric 1976; Cinciripini 2000; Ryan 1980). But only a third of these quitters remain abstinent after one year (CDCP 2002). McBride 2003 hypothesises that pregnancy may be a “teachable moment” for smoking cessation, describing an increased perception of risk and personal outcomes in pregnancy which prompts strong affective or emotional responses,
and redefines a woman’s self-concept or social role, especially when failure to comply with a social role results in social stigmatisation.

Description of the intervention
The range of interventions offered to promote smoking cessation in pregnancy are primarily individual strategies which currently include:

- provision of advice and counselling, using various tools (written and electronic resources and telephone support) and theoretical basis’, such as cognitive behavioural therapy and motivational interviewing;
- advice and counselling based on assessment of the women’s ‘stage of change’;
- feedback of fetal health status or measurement of by-products of tobacco smoking to the mother;
- provision of pharmacological agents, such as nicotine replacement therapy and bupropion;
- social support and encouragement, including the use of rewards for cessation;
- other interventions such as hypnosis.

At the time of this publication there were over 50 Cochrane reviews assessing the effectiveness of smoking cessation interventions in the general population. These include reviews on population wide measures (smoking bans, mass media) organisational interventions (workplace and school-based interventions), community interventions (including family-based programmes, group behaviour interventions), individual strategies (aversive smoking, acupuncture, hypnotherapy, self-help, exercise, individual behavioural counselling, motivational interviewing, stage based interventions, competitions and incentives, telephone counselling, mobile-phone based interventions (protocol only), nursing and physician advice, enhancing partner support), pharmacotherapies (antidepressants, anxiolytics, nicotine replacement therapy, clonidine, mecamylamine, nicobrevin, nicotine agonists, opioid agonists, silver acetate and nicotine vaccines) and relapse prevention.

O B J E C T I V E S
The review evaluated the effect of interventions designed to promote smoking cessation in pregnant women. We tried to address the following questions.

- Are interventions designed to promote smoking cessation in pregnancy effective in assisting pregnant women to quit?
- Do smoking cessation interventions in pregnancy have an impact on health outcomes for the mother and baby?
- What is the differential effectiveness between types of intervention strategies?
- Is there a difference in effectiveness dependent on the intensity of the intervention?

M E T H O D S

Criteria for considering studies for this review

Types of studies
All randomised and quasi-randomised controlled trials where the primary aim of the study was smoking cessation in pregnancy were considered. Trials which combine strategies for smoking cessation with other interventions in pregnancy were considered for the review for smoking cessation and reduction outcomes but not for outcome measures such as birthweight, preterm birth, breastfeeding and perinatal mortality which might be attributable to other components of an intervention package.

Cluster randomisation
There are good reasons for considering random allocation of midwives, clinics, health educators, hospitals, general practitioners, or antenatal classes to intervention or comparison group, rather than random allocation of pregnant women. It may be difficult for those providing pregnancy care to treat women differentially according to the intervention or usual care protocol, and not to introduce co-interventions in one or other group. As women within a cluster will be more like one another, and less like the women in another cluster, outcomes were adjusted for intracluster correlation for the data to be included in this review.

Types of participants
1. Women who are pregnant, in any care setting.
2. Women seeking a pre-pregnancy consultation.
3. Health professionals in trials of strategies to change knowledge, attitudes and behaviour with respect to smoking cessation.

Types of interventions
1. Cognitive behaviour therapy, educational and motivational interviewing strategies (using a range of media). These educational interventions were grouped separately from stage-
based interventions as they were offered to all women in the intervention group.

2. Interventions based on stages of change (using a range of media). These interventions were grouped separately from other educational strategies as they involve assessment of ‘readiness’ to change and exposure to the intervention may be more selective.

3. Feedback of fetal health status or measurement of by-products of tobacco smoking to the mother.

4. Provision of rewards and incentives for smoking cessation.

5. Provision of pharmacotherapies (nicotine replacement therapy, bupropion or other pharmacological agents).

6. Other strategies, including hypnosis.

Types of outcome measures

1. Smoking cessation (continued smoking in late pregnancy, self-reported and validated).

2. Smoking reduction from the first antenatal visit to late pregnancy, self-reported and validated.

3. Smoking cessation in the puerperium, self-reported and validated.

4. Birthweight (mean birthweight, proportion less than 2500 g, less than 1500 g).

5. Gestation at birth (proportion less than 37 weeks, less than 32 weeks, less than 30 weeks).

6. Perinatal mortality (stillbirths, neonatal deaths, all perinatal deaths).

7. Mode of birth.

8. Proportion of women initiating breastfeeding; breastfeeding at three and six months after birth.

9. Measures of anxiety, depression and maternal health status in late pregnancy and after birth.

10. Participants’ views of the interventions, both women and intervention providers.

11. Measures of family functioning in late pregnancy and postpartum.

12. Measures of knowledge, attitudes and behaviour of health professionals (obstetricians, midwives and family physicians) with respect to facilitating smoking cessation in pregnancy.

To complement what is known from research literature about smoking in pregnancy, direct contributions to this review were sought from women who smoked before or during pregnancy in 1999. Women were identified through community networks, and their views emphasised the need to focus attention on potential adverse effects of smoking cessation programmes; in particular, the consequent guilt, anxiety and additional stress experienced by those who continue to smoke, especially through ‘high risk’ pregnancies, and the detrimental effect on their relationships with their family and maternity care providers.

Search methods for identification of studies

This is the fourth update of this review and the methods for previous searches are described in other published versions of this review (Lumley 1995a; Lumley 1999; Lumley 2004).

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group’s Trials Register by contacting the Trials Search Co-ordinator (June 2008).

The Cochrane Pregnancy and Childbirth Group’s Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);

2. weekly searches of MEDLINE;

3. handsearches of 30 journals and the proceedings of major conferences;

4. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL and MEDLINE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the ‘Specialized Register’ section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

In addition, we searched the Cochrane Tobacco Addiction Group’s Trials Register (June 2008) and a qualified librarian searched EMBASE, PsycLIT, and CINAHL (January 2003 to June 2008) using the search strategy detailed in Appendix 2.

Searching other resources

We also checked cited studies while reviewing the trial reports and contacted trial authors to locate additional unpublished data.

We did not apply any language restrictions.

Data collection and analysis

Data extraction and management

Data from included studies was independently extracted from the published reports by two review authors without blinding as to journal, author, or research group. For each trial the following aspects were documented.
Methods

- Country of origin and year of trial.
- Brief description of trial methodology.
- Risk of bias assessment.

Participants

- Description of participants/study population, including pre-pregnancy cigarettes per day.
- Inclusion and exclusion criteria.
- Participation rate of eligible study population.
- Timing within pregnancy of recruitment and outcome measurement.

Interventions

- A description of the intervention(s) and the control.
- Intervention provider.
- Main intervention strategy (as described in ‘types of interventions’).
- Intensity rating of intervention and controls.

1 to 2 = low intensity (1: provision of leaflet, posters or self-help materials available, 2: ++ advice to quit and written or verbal information on risks);
3 = medium intensity (2 + self-help materials on strategies for quitting);
4 = high intensity (3 + other forms of support, such as personal contacts, reminders, incentives, pharmacological agents).

Outcomes

- Outcome measures including smoking cessation and reduction, birthweight, mode of birth, perinatal outcomes, breastfeeding, gestation, psychological measures.
- Withdrawals.

Notes

- Process evaluation of the intervention(s).
- Women’s and provider views

Assessment of risk of bias in included studies

We assessed the methodological quality of the included studies as recommended in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2008). The ‘quality assessment’ from previous reviews has been replaced with the ‘risk of bias’ assessment.

(1) Sequence generation (checking for possible selection bias)

We have described for each included study the methods used to generate the allocation sequence, and have assessed the methods as:

- adequate (any truly random process, e.g. random number table; computer random number generator);
- inadequate (any non random process, e.g. odd or even date of birth; hospital or clinic record number); or
- unclear.

(2) Allocation concealment (checking for possible selection bias)

We have described for each included study the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment. We have assessed the methods as:

- adequate (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- inadequate (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear.

(3) Blinding (checking for possible performance bias)

We have described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. With educational interventions (such as those assessed in this review) it is often not possible to blind women or their care-givers to group allocation. It is possible for outcome assessors to be blind to group allocation and we have noted where there was partial blinding. We have assessed the methods as:

- adequate, inadequate or unclear.

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)

We have described for each included study and for each outcome or class of outcomes the completeness of data including attrition and exclusions from the analysis. We have noted whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups. Where sufficient information has been reported or has been supplied by the trial authors, we have re-included missing data in the analyses. We have indicated where an intention-to-treat (or available case) analysis was carried out for the smoking cessation outcome.
(5) Selective reporting bias
We have described for each included study how the possibility of selective outcome reporting bias was examined by us and what we found. We assessed the methods as:
- adequate (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- inadequate (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear.

(6) Detection bias
We have described for each included study whether the outcome of smoking cessation was biochemically validated or assessed by self-report only, as there is evidence that there may be substantial misclassification by self-report.

Overall risk of bias
We made explicit judgements about whether studies were at high, moderate or low risk of bias, according to the criteria given in the Handbook (Higgins 2008). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it likely to impact on the findings.

Measures of treatment effect

Dichotomous data
All data were entered into review manager software (RevMan 2008) for analysis. For dichotomous data, we have presented results as summary risk ratio with 95% confidence intervals.

Continuous data
For continuous data, we have used the mean difference if outcomes have been measured in the same way between trials. We used the standardised mean difference to combine trials that measured the same outcome, using different methods.

We used the statistical methods described in the Handbook (Higgins 2008). Adjustment for clustering was conducted using a reported intra-cluster correlation (ICC) if available, and if not, a range of ICCs (from 0.003 to 0.20) was assumed and a sensitivity analysis conducted as recommended by Meolo 2005. A conservative ICC value of 0.10 was used for the primary analysis and the cluster trials were included by adjusting the sample sizes and numbers of events.

In all pooled analyses, we examined levels of heterogeneity (Cochran 1954). We used the I² statistic to quantify heterogeneity among the trials in each analysis (Higgins 2008). We explored heterogeneity by pre-specified secondary analysis.

Subgroup analysis and investigation of heterogeneity

Unit of randomisation (individual versus cluster randomisation)
The main analyses (comparison tables) combine data from all trials to produce an overall treatment effect, subgrouped into trials where the individual woman was randomised and cluster trials where the service or provider was randomised. These were subgrouped separately as it is possible there is a difference in the degree of exposure the participants have to the intervention, with cluster trials more closely resembling implementation trials, with potentially less scrutiny on the intervention for each woman.

There is likely to be significant heterogeneity between trials and that by pooling results the combined treatment effect is likely to be biased towards interventions with the most data (cognitive behavioural therapy (CBT) based interventions). We considered carrying out separate comparisons for different types of interventions (e.g. where the main strategy was motivational interviewing as opposed to rewards). However, trials frequently used more than one approach (e.g. nicotine replacement therapy and CBT) and there were many other variables to consider: the intensity of interventions, the high risk of bias in some trials and the unit of randomisation. Therefore, we explored the impact of risk of bias and heterogeneity through undertaking analyses for the following subgroups.

Risk of bias
In the context of this review, the factors which were assessed as posing the greatest risk of bias were misclassification by self-report, lack of treating trial “drop outs” as continuing smokers, followed by the adequacy randomisation. Very few trials reported allocation concealment methods clearly, so this was not included in the criteria for this update of the review.

1. Trials with the lowest risk of bias:
- trials with biochemical validation of smoking status;
- have complete outcome data addressed (intention-to-treat), as attrition is a major problem with trials;
- are adequately randomised.

2. Trials with moderate risk of bias
- biochemical validation of smoking status only.
3. Trials with the highest risk of bias

- no biochemical validation, as misclassification of smoking status by self-report one of the most significant risks of bias (Donovan 1977; Kendrick 1995).

Main intervention strategy

(as described under 'types of interventions'). While many trials incorporated several interventions (described in detail in the characteristics of included studies), the authors have made an assessment of the primary strategy. As this is the only smoking review which collates data on perinatal outcomes, subgroup analysis was conducted on smoking cessation outcomes and birthweight (as it had the largest volume of data) subgrouped by main intervention strategy.

Intensity of the intervention

(as described under 'data extraction/intervention') subgrouped by low, medium, high.

Other aspects of intervention quality, including women's and provider's views, and whether trials were well implemented are presented in the results.

To assess any differences between subgroups we examined forest plots for overlap of confidence intervals; non-overlapping confidence intervals indicating a significant difference in treatment effect between subgroups.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification; Characteristics of ongoing studies.

Results of the search

Eight-hundred and seventy-eight papers related to pregnancy and smoking published between 2003 and 2007 were identified in the most recent search conducted in September 2007. An Ovid auto alert conducted up until 1 April 2008 identified a further 20 papers. The abstracts of these papers were reviewed (C Chamberlain (CC) and 35 papers co-reviewed (CC and J Lumley) for consideration for inclusion in the review. Eleven new randomised controlled trials from 2003 to 2008, which included 4 new cluster RCTs, were identified and added to this update of the review.

The results of previous searches are described in previous publications of this review (Lumley 1999; Lumley 2004).

Included studies

Outcomes reported

A total of 72 trials, conducted between 1975 and 2008 and comprising over 25,000 women, provided outcome data for this review. Fifty-six randomised and quasi-randomised controlled trials and nine cluster-randomised trials reported the principal outcome measure of continued smoking in late pregnancy (21,258 women). The women included in this analysis were assessed as "smokers" at recruitment. The criteria used to assess a woman as a "smoker" varies significantly between trials, and is detailed for each study in the characteristics of included studies.

Eight trials reported continued cessation at end of pregnancy separately for women who had quit spontaneously before the intervention (relapse prevention), three of which were separate trials not included in the primary outcome trial reports. The women included in this analysis are not included in the analysis of continued smoking in women who were assessed as smokers at recruitment. Twenty-one trials reported mean birthweight (15,119 women), four of which were new trials not included in the primary outcome trial reports.

Sixteen trials reported rates of low birthweight babies (< 2500 g) and four reported rates of very low birthweight babies (< 1500 g). Other trials reporting birth outcomes included: perinatal deaths (3), preterm births (14), stillbirths (6), neonatal deaths (3), neonatal intensive care unit (NICU) admissions (4). Twenty-four trials reported various measures of smoking reduction in late pregnancy, including self-reported reduction (8), self-reported reduction >50% (3), biochemically validated reduction (4). Three trials recorded both self-reported and biochemically validated reduction; in these cases we have included only the validated data in the analysis. Other measures of reduced smoking included mean biochemical cotinine or thiocyanate (4), or mean cigarettes per day (10).

Twenty-two trials reported continued cessation in the postpartum period.

Thirteen trials discussed participant views of the intervention, and sixteen trials discussed provider views of the intervention.

Nine trials assessed a range of psychological health measures. Two trials reported mode of birth, two trials reported breastfeeding initiation in women and four reported NICU admissions.

No trials measured any effect of smoking cessation on family functioning or the well-being of other family members.

Other outcome measures which were measured, but not included in this review were fetal growth (1), fetal length (1), maternal weight gain (1), mean gestation (1), shifts in stages of change, and descriptions of all adverse outcomes (1).

Trial countries

Interventions for promoting smoking cessation during pregnancy (Review)

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Almost all trials were conducted in high-income countries. This includes the USA (39), the United Kingdom (14), the Netherlands (7), Australia (6), New Zealand (2), and Canada (2). Only two trials have been conducted in middle-income countries. Belizan 1995 conducted a trial in four Latin American countries (Argentina, Brazil, Cuba and Mexico). Polanska 2004 conducted a cluster-randomised trial in the Lodz district of Poland. Neither trial had biochemically validated smoking outcomes and have therefore, been assessed as being at high risk of bias in this review.

Participants

Participants were generally healthy pregnant women and the usual setting was a hospital or community antenatal clinic. Many trials reported interventions aimed at specific socio-demographic sub-populations.

Interventions

Women in the control arms in 55 of the 72 trials received information about the risks of smoking in pregnancy and were advised to quit as part of ‘usual care’ (controls/low intensity). Interventions ranged from low intensity or usual care (3), medium intensity with provision of materials or support for developing strategies for quitting (18) or high intensity with other forms of support including follow up and reminders, home visits, personal contacts, incentives or provision of pharmacological therapy (45). As would be expected, the median intensity of interventions and controls has increased over time (Figure 1).

Many interventions were multimodal, but the main intervention strategies identified were based on cognitive behavioural therapy (31), stages of change (11), feedback (4), incentives (4), pharmacological therapy (5) and other miscellaneous strategies (11), such as hypnosis.
Two dissemination trials were identified, carried out in Australia (Campbell 2006; Lowe 2002). Data for Campbell 2006 are included under cluster-randomised trials.

Excluded studies
Forty-nine studies were excluded from the review, for the following reasons:
- outcome data were not reported in format or detail to enable inclusion in analysis;
- design not adequately randomised (e.g. cohort studies, pre-post design, quasi experimental designs with matched controls);
- primary population was not pregnant women (e.g. postpartum interventions, intervention for partners, non-pregnant women).

Risk of bias in included studies

Allocation
The method of randomisation was rarely described in sufficient detail to permit assessment of whether the allocation was concealed at the time of trial entry. For example, a common statement was that “a computer-generated list of random numbers was used”. Quasi-randomisation was not uncommon even in large trials. Where pregnancy caregivers were involved in the provision of the intervention or its reinforcement - something expected by many commentators to enhance the effectiveness of the intervention - allocation to intervention or comparison group could not be concealed and the possibility of co-interventions could not be excluded.

Blinding
Very few trials had any blinding of participants or providers, largely due to pragmatic issues associated with administering an educational intervention. We have noted in the Characteristics of included studies tables where there was blinding of outcome assessors.

Incomplete outcome data

Withdrawals
Withdrawals from the trials were common. When women were recruited at their first antenatal visit some participants had a miscarriage or a termination of pregnancy before the time when smoking behaviour was reassessed. Others moved out of the area or changed to another provider of care. The latter was a common cause of attrition in those trials carried out among populations characterised by severe poverty and the receipt of special needs benefits such as Medicaid, or WIC (food program for women, infants and children) clinics. In studies where there was longer-term follow up, attrition was sometimes high; approximately half of the included studies had high levels of missing data (> 20%) for some outcomes. Where possible, women lost to attrition were included in this analysis as continuing smokers. Attrition is potentially a serious risk of bias in these studies. Levels of attrition for each study, and information about any intention-to-treat analysis has been provided in the ‘Risk of bias tables’.

Exclusions
Two groups of women that were often excluded from outcome measurement were those who had a perinatal death or a preterm infant. This means that important outcomes linked in observational studies to smoking exposure were not ascertained. Assessing smoking at 20 to 28 weeks instead of at 36 to 38 weeks would reduce the need to exclude women with particularly adverse outcomes, since their smoking status in mid-pregnancy would have been ascertained before preterm birth or a perinatal death had occurred.

Selective reporting
It was not clear in many trials the extent of outcome data which were collected and therefore, difficult to assess whether the outcomes have been selectively reported.

Other potential sources of bias

Detection bias from misclassification by self-report
The unreliability of self-report as a measure of smoking status in healthcare settings, especially in maternity care, was noted even in the first pregnancy trial (Donovan 1977), though not found by others in the 1980s (Fox 1989). Findings in other trials (Kendrick 1995; Mullen 1991; Petersen 1992; Walsh 1997) show substantial misclassification by self-report with up to a quarter or a third of women who describe themselves as non-smokers having levels of salivary or urine cotinine (a metabolite of nicotine) incompatible with that self-description. There may also be differential misclassification between intervention and control groups, though no investigations have published this effect. This finding means that trials which do not validate smoking status are likely to have substantial measurement errors, and may be biased if women receiving the intervention are more likely to misreport their smoking status than those in the control group. These trials have been classified as “high risk of bias” in this review. Later trials more often relied on a definition of smoking cessation requiring biochemical validation.
Change in 'usual care'
In many cases the comparison/control group was described as receiving 'usual care' without specifying further what constituted usual practice (at a particular time and in a particular setting) with respect to advice and assistance. It can be seen from Figure 1 that current 'usual care' may be a more substantial intervention than the defined intervention in some of the earliest trials (for example, MacArthur 1987).

Intervention exposure
Smoking cessation interventions implemented during pregnancy differ substantially in their intensity, their duration, and the people involved in their implementation. Process evaluation of the intervention occurred in only some trials and in some of these the implementation was less than ideal (Hajek 2001; Kendrick 1995; MacArthur 1987).

The timing of the final antenatal assessment of smoking status varied considerably between trials between the second and third trimester. This may affect the amount of time the participants were exposed to the intervention (if it involved ongoing support), as well as the number of those lost to follow up and measurement of perinatal outcomes.

A summary of risk of bias assessments in the included trials are set out in Figure 2 and Figure 3.
Figure 2. Risk of bias summary: review authors' judgments about each risk of bias item for each included study.
Effects of interventions

I. Smoking cessation outcomes

Pooled data from 65 trials revealed a significant reduction in continued smoking in late pregnancy in the intervention groups (pooled risk ratio (RR) 0.94, 95% confidence interval (CI) 0.93 to 0.96). This equates to an absolute difference in the proportion continuing to smoke of 6%. In trials where the unit of randomisation was individual women, intervention RR for smoking cessation was 0.94, (95% CI 0.92 to 0.96) and in cluster trials where the unit of randomisation was a clinician or service, the intervention RR was 0.97, (95% CI 0.94 to 1.00); these results showed no evidence of a difference in treatment effect between types of randomisation. The heterogeneity amongst both individually and cluster-randomised trials was high ($I^2 > 60\%$) and results should be interpreted with caution.

Cluster trials

Nine cluster-randomised trials were included as a subgroup of the combined comparison table of all trials. No studies reported individual cluster data to enable calculation of clustering effect using generic inverse variance method. Three trials reported the clustering effect (Kendrick 1995; Lawrence 2003; Moore 2002) and these figures were used in the tables. One trial reported cluster variance which was used to derive the intracluster correlation (ICC) (Merlo 2005). One trial reported the design effect (McLeod 2004) which was used in the outcome tables. Five trials had no clustering effect reported (Campbell 2006; Hajek 2001; Manfredi 1999; Pbert 2004; Polanska 2004). A sensitivity analysis was conducted for these trials, using four ICC effects: of 0.003, 0.05, 0.1 and 0.2, as recommended by Merlo 2005. There was minimal difference in effect (RR 0.94, 95% CI 0.91 to 0.99 when calculated using ICC of 0.003, to RR 0.98, 95% CI 0.95 to 1.01 when calculating using ICC of 0.2). Therefore, a conservative median ICC of 0.1 has been used in this review, which provides a pooled RR 0.97, 95% CI 0.94 to 1.00 for randomised cluster trials.

Subgroup analysis (risk of bias)

Trials with the ‘lowest risk of bias’ had an intervention effect corresponding to a RR of 0.97 (95% CI 0.94 to 0.99) with a decrease in heterogeneity ($I^2 = 36\%$), which was the lowest of any of the sensitivity analyses conducted. Trials with the highest risk of bias (no biochemical validation) showed an RR of 0.91 (95% CI 0.87 to 0.95). Trials with ‘moderate risk of bias’ showed an effect of RR 0.94 (95% CI 0.92 to 0.97); these results showed no evidence of a difference in treatment effect between types of randomisation.

Figure 3. Risk of bias graph: review authors’ judgments about each risk of bias item presented as percentages across all included studies.
of a significant difference in treatment effect between trials with differences in the assessed risk of bias.

Subgroup analysis (intervention intensity)
The 45 trials assessed as 'high intensity' (provision of strategies and continued support to quit) demonstrated an intervention RR 0.94, (95% CI 0.92 to 0.96), while the three trials assessed as 'low intensity' (provision of written or verbal advice to quit, or both) demonstrated an intervention RR of 0.95 (95% CI 0.93 to 0.96); these results showed no evidence of a significant difference in treatment effect according to the assessed intensity of the intervention. All these groups showed significant heterogeneity.

Subgroup analysis (main intervention strategy)
When trials were subgrouped by intervention strategies, only one group (those including an incentive component) showed a significantly larger effect (RR 0.76, 95% CI 0.71 to 0.81). Their results were consistent but comprised only four trials. The CBT group, showed a similar pooled effect to that of the whole group (RR 0.95, 95% CI 0.93 to 0.97) compared with pooled data from all trials, which is what would be expected as it was the largest (31 trials). The five trials of nicotine replacement therapy were as effective as the CBT group (RR 0.95, 95% CI 0.92 to 0.98), though there is still no clear evidence of safety in terms of perinatal outcomes (discussed below). The intervention RR for the eleven trials using stages of change theory was RR 0.99, (95% CI 0.97 to 1.00), which is not significantly different from CBT or NRT. The four trials using feedback were not significantly effective (RR 0.92, 95% CI 0.84 to 1.02).

Even when different interventions were separated into subgroups heterogeneity for subgroups remained relatively high, particularly for the large group of trials using CBT as the main intervention strategy (I² = 55%).

2. Relapse prevention
Eight trials (more than 1000 women) included a specific intervention for smoking relapse prevention among women who had stopped smoking by the first antenatal visit. The women in this analysis were not included in the analysis of women counted as smokers. In these, the pooled risk ratio indicated that fewer women receiving the intervention relapsed to smoking in late pregnancy but the effect did not reach statistical significance (RR 0.91, 95% CI 0.75 to 1.10).

3. Smoking reduction
There was limited evidence that women in intervention groups reduced smoking in late pregnancy, but the evidence was weak and not consistent. Pooled data from studies collecting self-reported information on reduced smoking (where women were asked if they had cut down at all in smoking) showed significant evidence of a difference between intervention and control groups (RR 1.52, 95% CI 1.29 to 1.78). However, studies where women reported that they had cut down their smoking by more that half showed no significant differences between intervention and control groups (RR 1.23, 95% CI 0.91 to 1.67). Where reductions were biochemically validated there was no significant evidence of reduced smoking in the intervention group (RR 1.27, 95% CI 0.84 to 1.91). (Where studies recorded both self-reported and biochemically validated data we have included only the validated data in the analysis). There was no significant difference in self-reported mean cigarettes per day, and the skewed distribution of the data suggests there is a lack of precision with these self-reported estimates (the mean and standard deviations are very similar).

4. Continued smoking cessation in the postnatal period
Ten individually randomised trials and five cluster trials examined continued smoking cessation at between one to five months postpartum. The time of data collection varied in different studies and the results included both self-reported and validated smoking cessation outcomes. Overall, there was a statistically significant difference between intervention and control groups for continued smoking cessation in the early postpartum period (RR 1.65, 95% CI 1.22 to 2.24). However, there was no evidence of difference between groups in smoking cessation rates at longer-term follow up (RR 1.39, 95% CI 0.82 to 2.38). Eight trials (all individually randomised) reported smoking cessation at between six and 12 months postpartum (again there was variation between trials in terms of when data was collected and in how this outcome was measured).

5. Perinatal outcomes
The 21 trials with information on perinatal outcomes revealed a reduction in low birthweight (RR 0.83, 95% CI 0.73 to 0.95), a reduction in preterm birth (RR 0.86, 95% CI 0.74 to 0.98), and an increase in mean birthweight of 39.26 g (95% CI 15.77 g to 62.74 g) in the treatment group. There was adequate power to detect differences for these outcomes (n = > 10 000).

Trials using CBT and incentives as the main intervention strategy demonstrated statistically significant improvements in mean birthweight. There were no significant differences in very low birthweight, stillbirths, neonatal deaths, NICU admissions or total perinatal mortality. The subset of trials in which those outcomes were assessed had a very low power to detect clinically important differences in these outcomes (n = < 5000). A number of trials excluded women who had a perinatal death or a preterm birth from the study population.

A follow up of MacArthur’s trial which had reduced smoking and increased birthweight assessed subsequent child growth and de-
development at nine to 10 years (MacArthur 1987). Neither height nor weight, nor intelligence quotient (IQ) or a screening test for 'soft' neurological signs identified any differences between the intervention and control groups (insufficient data for tabulation). Two trials measured mode of delivery (Tappin 2005; Thornton 1997) and showed no significant difference in outcome by intervention group.

Two trials measured breastfeeding initiation (McLeod 2004; Panjari 1999) and showed no significant difference in initiation or duration of breastfeeding in control or intervention arms.

Other perinatal outcome measures reported in trials included adverse perinatal outcomes (Pollak 2007); fetal growth (Heil 2008); fetal length (MacArthur 1987); maternal weight gain (Rush 1992) and shifts in stages of change (Solomon 1996 and Solomon 2000).

6. Psychosocial effects

Thirteen trials included women's views of intervention and 16 included midwives' views of the intervention. Some studies asked about women's views of the intervention (DeVries 2006; Hajek 2001; Thornton 1997), sometimes focussing specifically on the use of intervention materials (Ershoff 1999; Hotham 2005; Strecher 2000; Valbo 1994; Wisborg 2000) or providers' activities (Tappin 2000; Thornton 1997), and whether they thought the intervention was helpful for giving up smoking (Cinciripini 2000; Cope 2003; Ershoff 1999; Hajek 2001; Rigotti 2006; Valbo 1994; Walsh 1997). There were few direct comparisons. Women offered personal contact and a manual considered the personal contact the most important element; the two together were more effective than the usual care of information provision at the time of routine ultrasound examination (Valbo 1994). Similarly, women offered motivational interviewing for relapse prevention were more likely to be satisfied than those offered a booklet, although the motivational interviewing was no more effective (Ershoff 1999). Cinciripini 2000 found that women appreciated printed materials much less if they were also offered a video, although the video combined with printed materials was more effective than the printed materials alone. As mentioned above, subgroup analyses of trials showed no statistically significant difference between the effects of more and less intense interventions.

In a trial of cessation advice and feedback from a point-of-care urine test for the products of nicotine, women were asked to sub-
jectively evaluate the influence of the smoking test on changes in their behaviour. A majority thought the test was a good idea and had helped them to appreciate more about their smoking (Cope 2003).

Case study reports associated with a trial of NRT reported participants' views suggesting significant resistance of women to using NRT in pregnancy. Only 25% of women in the treatment group (n = 5) complied with the treatment protocol (Hotham 2005). A recurrent theme in the trials reporting providers' views was their concern about the time taken by the intervention. 65% of mid-
wives asked to use a carbon monoxide monitor and provide 'stage of change' based advice considered that this could not be achieved in the time available (Hajek 2001). Midwives reported time pressures for counselling in other trials (Lowe 1998a; Lowe 1998b). The use of existing staff to deliver the new interventions and to collect data seemed to affect the study negatively especially given the time needed to process questionnaires and urine samples. This led to less than full implementation and variable motivation to promote smoking cessation counselling among staff (Kendrick 1995).

Nine studies reported baseline psychological well-being though not all of them reported findings post-intervention (Belizan 1995; Ershoff 1999). The findings suggest there are significant psychological symptoms amongst pregnant women who smoke. More than 50% of pregnant women who smoked had current or previous psychological symptoms, and approximately 20% reported major depression based on CES-D scale assessments (Blalock 2005; Dornelas 2006).

Consultation with health promotion specialists identified concerns about adverse effects of quitting, or increased guilt over continued smoking, on women's psychological well-being and capacity to cope with adverse circumstance, with flow-on effects to the women's families (Oliver 1997). Women who smoke report that smoking helps them to deal with stress and quitting may require expenditure of emotional energy which they may not have whilst meeting the demands of a young family (Ebert 2007). Pregnant women are vulnerable to social pressures to conform to the image of 'good mother' (Ebert 2007) and report feeling judged by others. Despite these concerns, five trials have demonstrated that smoking cessation interventions in pregnancy do not increase stress and psychological symptoms for women (Aveyard 2007; Lawrence 2003; Manfredi 1999; Panjari 1999; Rigotti 2006; Solomon 2006), Bullock 1995 reported that women in the intervention group had significant decreases in stress and depression scores, and an improvement in self-esteem scores.

Critenden, 2007 analysed the Manfredi 1999 data and found that smoking outcomes are negatively mediated by stress in low SES women.

7. Other outcomes measures

Heil 2008 reported significant increases in fetal growth measures including birthweight, fetal femur length and fetal abdominal circumference, but no significant difference in lean thigh area, head circumference or biparietal diameter, between control and intervention groups.

MacArthur 1987 reported a small difference in mean infant length at birth, but no difference in head circumference.

Only one trial (Rush 1992) measured maternal weight gain during pregnancy (despite this being identified as a major area of concern for women) which showed a non significant difference of 0.04 kg/week increase in the intervention group.


**Discussion**

**Summary of main results**

There is approximately 6% difference in the combined effect of interventions to promote smoking cessation in pregnancy. However, heterogeneity remained high, even following subgroup analyses of intervention strategy and intensity ($\Gamma^2 > 55\%$). Subgroup analyses of trials at low risk of bias had the largest effect on reducing the heterogeneity, but some heterogeneity remained ($\Gamma^2 = 36\%$). The treatment effect in those trials at low risk of bias was more modest, but still demonstrated an absolute difference of 3% of women in the intervention group who quit smoking during pregnancy (risk ratio 0.97, 95% confidence interval (CI) 0.94 to 0.99).

**Public health impact of the interventions**

Reducing smoking in pregnancy reduces the population attributable risk of preterm birth and low birthweight (Hammoud 2005; Kramer 1987). It is this that makes a focus on interventions to promote smoking cessation in pregnancy an important public health issue, as there are significant impacts on the immediate and long-term health of newborn babies.

The close to 15% reductions in preterm birth and low birthweight in the intervention arm of smoking cessation trials confirm that smoking cessation can reverse the adverse effects of smoking on perinatal outcomes. If all women in the intervention groups stopped smoking and none of those in the control groups did, the expected mean difference in birthweight would have been about 200 g. The weighted difference in mean birthweight in these trials was 53 g. The expected mean difference from the extent of smoking cessation alone would have been about 12 g. This suggests that smoking reduction is also happening to a greater extent in the intervention than the comparison groups, in line with self-reported changes. Windsor 1993 has proposed using a halving of the cotinine level from trial entry as a measure of smoking reduction, and in 1999 promoted the use of biochemical measurement as a new behavioural indicator of ‘harm reduction’ (Windsor 1999), though this finding was not supported by Secker-Walker’s subsequent (Secker-Walker 2002a) analysis of infant birthweight in relation to maternal cotinine from a different trial. The latter makes the point that for a heavy smoker a halving of the cotinine level may still represent a level of tobacco consumption hazardous to the fetus. Secondary analysis of data from the trial of Kendrick 1995 suggests that reduction in smoking to fewer than eight cigarettes a day is necessary to avoid reduction in infant birthweight (England 2001).

The impacts of smoking cessation on birthweight alone provide rapid and significant “returns on investment” from smoking cessation interventions in pregnancy. Miller 2003 2001 estimated birth and first year costs for both mothers and infants attributed to smoking were $1142 to $1358 per smoking woman. Infant costs are approximately 10 times maternal costs and account for 90% of costs in the first year. Low birthweight produces the highest economic burden as it is the most common adverse outcome (Miller 2001). In contrast with that finding, the quality of diet in pregnancy (in high-income countries) has not been shown to affect the mean birthweight of infants over 32 weeks’ gestation (Rogers 1998). Adams 1998, Melvin 2000, and Ayadi 2006 estimated the additional costs of maternal conditions attributed to smoking in pregnancy (preterm prelabour rupture of membranes (PPROM), ectopic pregnancy, placenta praevia, placental abruption, spontaneous abortion, and taking into account a protective effect against pre-eclampsia) at a total of $135 to $167 million per annum in the US, based on 1993 US healthcare cost and dollar estimates. As well as being a critical public health intervention for the baby’s immediate health, pregnancy and motherhood is a major milestone in a woman’s lifespan. The quit rate for smoking during pregnancy is up to eight times that of the general population. There are significant lifelong benefits for children growing up in a smoke-free environment, and smoking is the major preventable cause of premature mortality for the mother.

**Psychosocial considerations**

Smoking has been identified as a major preventable cause of the health and life expectancy inequalities experienced by women who suffer psychosocial disadvantage, including psychological illness, low educational attainment, young early motherhood, lack of social support, and limited employment (Graham 2006). While the importance of reducing smoking in all women is clear, the reduction in smoking has not been as effective in women experiencing psychosocial disadvantage. Graham 2009 suggests that some of the reasons that individual behavioural interventions may not as effective may be that:

- they are unable to change the environmental factors that increase the risk of smoking;
- they may have the effect of being judgemental and alienate women;
- they are unable to change generational patterns.

Therefore, there is a need to gain greater insight into the experiences and vulnerabilities of women who continue to smoke during pregnancy and develop sensitive effective interventions which support women and reduce vulnerability, without increasing risks. Despite these concerns, the evidence from the included trials in this review suggests that there are no negative psychological impacts from behavioural interventions and that the psychological impact may be positive, with responses from women feeling that “somebody cared”.

**Implementation and process issues identified**

The first trials of anti-smoking interventions during pregnancy were published more than 30 years ago (Baric 1977; Donovan 1986).
1977). The first trial to demonstrate the reversibility of the birth-weight reduction associated with smoking by an intensive intervention during pregnancy was published in 1984 (Sexton 1984). The US, UK and Australia have developed guidelines recommending all pregnant women receive interventions to promote smoking cessation in pregnancy (Aveyard 2007). These guidelines generally incorporate a number of interventions, and are currently based on the "5 As", which involves:

- asking all pregnant women if they smoke;
- advising all pregnant women who smoke about the risks of smoking in pregnancy and emphasising the benefits of quitting;
- assisting all pregnant women who smoke to quit, using a range of interventions;
- assessing the pregnant woman's readiness to change and setting a quit date;
- asking and assisting again at each subsequent encounter.

However, despite evidence of effectiveness of interventions in pregnancy and development of guidelines, widespread implementation of smoking cessation interventions in pregnancy in clinical settings remain the exception (DeVries 2006; Lowe 2002; McLeod 2004; Windsor 2000b) rather than the norm (Abatemarco 2007; Lumley 2002; McDermott 2006; NICS 2003). Walsh 1997 argues that evaluation of any preventive intervention should include monitoring as to whether it has been implemented as planned, and if not, why not?

Data from the two dissemination trials demonstrate challenges to implementation in routine practice. Campbell 2006 showed uptake of the intervention, but not at levels sufficient to have a significant impact on smoking outcomes in women. Lowe 2002 found a significantly higher program implementation rate when using an intervention based on Rogers' 'Diffusion of Innovation' theory (43% compared with only 9% implementation in the control group after one year), but there were no data on the impact on smoking outcomes. Five of the six cluster trials implemented in routine care by midwives reported difficulties with implementation (DeVries 2006; Dunkley 1997; Hajek 2001; Lowe 1998b; Moore 2002). Some of the issues which arose included: variable perceptions of smoking cessation as part of the midwives role (DeVries 2006), midwives stating they were too busy and did not have enough time to complete the intervention (Dunkley 1997; Hajek 2001), difficulty recruiting midwives to the study (Lawrence 2003), women unable to recall intervention from a midwife (Moore 2002), and lack of acceptability of resources (Lowe 1998a).

Three of the four physician implemented trials also reported implementation problems (MacArthur 1987; Valbo 1994; Walsh 1997). Three US cluster trials using routine staff to deliver the intervention reported similar challenges (Kendrick 1995; Manfredi 1999; Wisborg 2000). In comparison, smaller trials may benefit from greater enthusiasm of local champions. An analysis of health promotion trials has concluded that where the providers are also the researchers (more likely in single centre studies than multi-centre studies) they appear to be better providers for influencing behavioural outcomes and about the same as other providers for other outcome domains (Oliver 2008). The larger, multicentre trials may therefore be a more accurate representation of implementing policy than smaller, single centre.

There are numerous papers which confirm that the major barriers to implementation of evidence based interventions include:

- lack of time, with many competing pressures on clinicians (Haines 1998; Leviton 2003), also reported by providers in studies included in this review (Hajek 2001; Lowe 1998a; Lowe 1998b);
- staff attitudes and perceptions of interventions, with pessimism over interventions (McLellan 2000), a focus on the 90% failure rate rather than the 10% success rate (Moore 2002), and peer pressure playing an important role (Grol 1999);
- perceived lack of skills and training (DeVries 2006);
- organisational and administrative barriers (Strand 2003);
- lack of high-quality programs which are acceptable to women and care providers (Cabana 1999; Haynes 1998).

Offering additional group sessions for smoking cessation, even in otherwise successful trials (O'Connor 1992; Sexton 1984; Windsor 1985) was a very poorly accepted intervention, but appeared to be accepted better in Northern Europe (Hegaard 2003; Valbo 1991).

### Effectiveness of interventions

#### Nicotine replacement therapy (NRT) during pregnancy

NRT in this review does not appear to have a significant advantage over other types of interventions in terms of smoking cessation in subgroup analysis, but there has been no direct comparison of NRT outcomes with any other strategy. There are still concerns about the safety of prescribing a neurotoxicant in pregnancy, and the possibility of adverse effects of nicotine on the fetus, through alterations in uterine, placental or blood flow or directly on the brain (Slotkin 2008).

The safety of NRT in terms of effect on fetal development and birth outcomes remains unclear in pooled data from this review. Only three of the five NRT trials recorded birth outcomes (Hegaard 2003; Pollak 2007; Wisborg 2000). One trial (Pollak 2007) suspected study enrolment due to a recommendation by the Data and Safety Monitoring Board following a statistically significant increase in serious adverse events between study arms (30% in intervention group and 17% in control group: risk difference = 0.13, 95% CI 0.00 to 0.26 P = 0.007). The adverse events are individually listed in the trial report and include pre-eclampsia, placental abnormality, preterm birth, small for gestational age, neonatal intensive care unit admissions and fetal loss. A large Danish cohort study identified a slight increase in rates of congenital malformations in used nicotine substitutes over women who smoked (Morales-Suarez-Varela 2006).
The pooled birth outcome data from these trials are not significant (birthweight increase 33.96 g, 95% CI -125.5 to 193.43), low birthweight babies odds ratio (OR) 0.95, 95% CI 0.42 to 2.42, and preterm birth OR 0.97, 95% CI 0.61 to 1.53. However, the only trial measuring non-significant positive birth outcomes (Wisborg 2000) reported only 17% compliance in the intervention group. The other two trials (Hegaard 2003; Pollak 2007) which had high compliance rates (approximately 80%) reported non significant negative trends in birthweight and low birthweight babies. Most NRT trials in pregnancy to date have used mainly nicotine patches with continuous use formulations (over 80%). Pollak 2007 used continuous and intermittent dose formulations, but did not report outcomes by type of formulation. Two small (physiological) randomised trials have compared the effects of nicotine gum (Oncken 1996) or transdermal nicotine (Oncken 1997) with maternal smoking in relation to blood concentrations of nicotine and cotinine and to maternal-fetal haemodynamics.

Dempsey 2001 recommend doses of prescribed nicotine in pregnancy should be similar to a smoking dose, and that intermittent forms of NRT (gum, spray, inhaler) are preferred to continuous use formulations as the total dose of nicotine will be less. In some countries, though not in all, nicotine gum and nicotine patches may not be sold without a prescription and in others there are packet warnings against their use in pregnancy, though the appropriateness of this has been debated (Benowitz 1991; Hughes 1993).

Other challenges for NRT trials have included apparent reluctance amongst pregnant women to use NRT (Hotham 2005; Rigotti 2008; Wisborg 2000), and for doctors to prescribe NRT (Vogt 2006). Some trials reported other adverse effects, including low rates of skin irritation and headaches (Hotham 2005; Wisborg 2000), which were given as reasons why women chose to discontinue with the treatment.

Ther has been one randomised controlled trial of Bupropion in pregnancy (Miller 2003), which did not demonstrate a significant difference in smoking cessation. This study is included in “ongoing studies” in this review as the available trial report had insufficient details for inclusion. Cohort studies suggest that it may be safe to use in pregnancy (Chan 2005).

As there are still too few trials to assure safe use in pregnancy, and animal studies suggest nicotine may be toxic to the developing central nervous system, Dempsey 2001 recommend registries of women using NRT be established to gather more outcome data.

Other associated factors

There was no significant difference in rates of smoking initiation or duration in the intervention arms of the two trials measuring breastfeeding outcomes in this review. However, smoking is associated with low rates of breastfeeding initiation, and reduced duration (Horta 1997; Sayers 1995), an association which persists in some, but not all studies, after adjustment for social and reproductive factors. This is likely to be due to motivational rather than physiological causes (Donath 2004).

There is a growing interest in interventions to increase smoking cessation among the partners of pregnant women, with the additional aim of facilitating cessation by the women themselves (Gage 2007; Stanton 2004). In some cases this reflects cultural and demographic patterns of smoking, where smoking rates are still highest amongst men. A review by Park 2004 evaluates the effect of interventions to promote partner support on smoking cessation.

Overall completeness and applicability of evidence

There was limited data for some types of interventions and for some types of outcomes. The review includes a relatively large number of studies focusing on educational and counselling interventions but relatively few focusing on other approaches, such as the use of nicotine patches and rewarding women for giving up smoking. Relatively few of the included trials provided information on perinatal outcomes other than birthweight, and there was very little evidence on the effect of interventions on maternal psychosocial outcomes such as anxiety.

Many of the studies did not provide information on the number of women who were eligible for inclusion or were approached to take part in trials, but who were not randomised. This information is useful to interpret the findings; if only a small proportion of those approached take part in a trial the results may only be applicable to a self-selected part of the smoking population. The high levels of attrition in many of these studies also limits the applicability of findings, those women lost to follow up may be different in a number of ways from those providing complete data.

Most of the included studies were carried out in western Europe and North America and it is not clear that the results are applicable in other contexts. The transfer of an intervention from one setting to another may reduce its effectiveness if elements are changed or aspects of the materials are culturally inappropriate. Examples in these trials are the performance of the Windsor self-help manual. This was developed and shown to be effective in Birmingham, Alabama (Windsor 1985; Windsor 1993). However, when it was used in Baltimore with peer counsellors who received minimal training (Gielen 1997), instead of trained health educators, the effectiveness was much lower. In addition, aspects of the intervention recommended in the same manual were shown to have very poor acceptability in Brisbane (Australia) and a very low level of effectiveness (Lowe 1998a).

Quality of the evidence

The studies included in the review were of mixed quality and we would emphasise the need to consider the risk of bias tables when interpreting results. For educational and counselling interventions...
blinding of participants, clinical staff and outcome assessors was frequently not feasible and rarely attempted. This is likely to be a source of bias. Levels of attrition were generally high, particularly for outcomes where information was collected by postal questionnaire months after the initial intervention; high levels of attrition may mean that it is difficult to interpret results. We have also mentioned problems associated with detection bias when smoking outcomes relied on maternal self-report.

There is a very high level of heterogeneity amongst the trial results ($I^2$ generally greater than 60%), hence we urge caution when interpreting the combined effect of the interventions. Subgroup analysis of trials at low risk of bias had the greatest effect on reducing heterogeneity, though this was still high at 36%.

In addition, at a more general level, there are some criticisms in the literature of smoking cessation programs, including failure to consider the following.

- Relevant health promotion theory and knowledge (Solomon 1996; Stotts 1996). However, there have been some recent studies which have investigated the applicability of theories to smoking cessation in pregnancy (Riemsma 2003; Slade 2006).

- Views of women (Ebert 2007; Gilligan 2007; Jayaweera 2006; McDermott 2006) or caregivers (McLeod 2003; Vogt 2006) or inadequate implementation and little or no process evaluation (Herbert 2005; Windsor 1998). However, there has been some discussion of women’s preferences for cessation support in recent years (Coleman 2004; Usher 2004).

- Weight concerns, with women being asked both to control weight gain and relinquish an addictive drug with weight suppressing effects; yet there is limited research into strategies to help women address this dilemma. There is some evidence women are more likely to smoke to control their weight, and female body image is extensively targeted by tobacco marketing campaigns (CDCP 2002; Levine 2006; Pomerleau 2000). A recent review by Shraim 2006 has assessed the impact of interventions to prevent weight gain after smoking cessation.

- Women’s fears that smoking reduction will, by increasing fetal size, increase the probability of a difficult labour or an operative delivery have been taken into account very rarely (Sexton 1984) in the design and implementation of smoking cessation programs. A small cohort study in the US found that smoking cessation was associated with protection against lower birthweight through mechanisms other than increased maternal weight gain or different weight gain patterns (Groff 1997). One study modelled increases in birthweight (from 2450 g to 2550 g) in Guatemala and found an increased risk of caesarean section due to obstruction by eight in every 1000 cases, but this was outweighed by a reduction in risk of caesarean section due to fetal distress by 34 per 1000 cases (Merchant 2001).

Potential biases in the review process

Impact of population based interventions over time

Population-based campaigns to encourage smoking reduction and smoking cessation during pregnancy are now widespread in high-income countries (Campion 1994; Eriksson 1996). Tappin 2005 reported a modest reduction in smoking in the intervention arm, and notes that the inability of the study to replicate the results of this review may be due to the fact that women continuing to smoke in pregnancy in later studies, despite widespread population based campaigns, may be more seriously addicted, and have lower self-efficacy to quit.

Misclassification of smoking by self-report

A very high proportion of pregnant women describe themselves as having “cut down” but given the problems of self-report described previously, important questions about the effectiveness of interventions in facilitating smoking reduction remain unanswered at present: only biochemically validated smoking cessation can be regarded as a reliable outcome measure. The sensitivity of screening and disclosure of smoking status can be improved by adjusting the question format, from yes or no to multiple options including “I used to smoke”, and “I have cut down” (Mullen 1991).

Agreements and disagreements with other studies or reviews

Stages of change

The data from Solomon 1996 suggest that the transtheoretical model of stages of change in readiness to stop smoking (pre-consideration, contemplation, preparation and action) may not apply in pregnancy, and that stage changes in early pregnancy are not sustained. Pooled analyses showed no evidence for a significant effect with stages of change based interventions, compared with interventions based on other theories. A systematic review of smoking cessation also concluded that stage-based interventions are no more effective in general than interventions which do not tailor the intervention according to the stage of change (Riemsma 2003).

NRT

NRT in pregnant women does not appear to be as effective as is reported in the general population.
AUTHORS’ CONCLUSIONS

Implications for practice

As smoking cessation programs have been shown to increase smoking cessation, reduce preterm birth and low birthweight, and increase mean birthweight, smoking cessation programs need to be implemented in all maternity care settings. Attention to smoking behaviour together with support for smoking cessation and relapse prevention needs to be as routine a part of antenatal care as the measurement of blood pressure. Local piloting of programs shown elsewhere to be effective would be a good place to begin. The use of the NNT (number needed to treat) as a counter to views that smoking cessation interventions do not work in pregnancy, may be a useful strategy.

Given the clear difficulties which most women still smoking at the first antenatal visit have in stopping smoking, midwives, general practitioners, and obstetricians need to support population-wide strategies for smoking control in the whole community to reduce the initiation of smoking by young people: action to prevent sales of tobacco products to young people, prohibition of smoking in all public places, increases in tobacco taxation, workplace smoking cessation programs and bans on tobacco sponsorship of prestigious sporting and cultural events as outlined in the WHO MPOWER package (WHO 2008a).

In order to avoid ‘victim-blaming’, or the perception of ‘victim-blaming’, and compounding issues of social disadvantage closely associated with smoking, attention needs to be given to the consumer concerns and to supporting these population based measures which are non-discriminatory.

Given the strong association between social inequality and continued smoking by pregnant women, and bearing in mind that smoking is the major preventable cause of inequalities in life expectancy, strategies in the wider community to reduce social inequalities, as recommended in the Closing the Gap in a generation: Health Equity through Action on the Social Determinants of Health (WHO 2008b).

Implications for research

Future trials need to include the following elements.

- A description of the intervention in sufficient detail for its replication even if the detail requires a separate paper.
- Process data as evidence of implementation.
- A relapse prevention component for those who have stopped smoking before the first antenatal visit.
- Biochemical validation of non-smoking status.
- The collection of perinatal outcome data on birthweight, preterm birth and perinatal deaths, particularly for nicotine replacement therapy trials.
- Collection of outcome data on breastfeeding, operative delivery, maternal psychological well-being, and the perceived impact of the intervention on family functioning.
- In order to assess the effect of clustering and include cluster-randomised trials in meta-analysis, the impact factor or intracluster correlation needs to be reported.

The strong results from trials using incentive strategies is encouraging, but as yet the trials are small scale and there are no trials in routine practice or discussion papers of the policy implications of implementing such an intervention at population level.

There are two aspects of smoking cessation interventions in which there are mixed messages. These are likely to detract from the overall effectiveness of programs, since simple and explicit messages are a key aspect of effective health promotion.

- Is there a place for including smoking reduction as one of the goals, in line with ‘harm minimisation’ strategies for other harmful substances and practices? Research in this area, including better measures of tobacco exposure is necessary.
- Facilitating smoking cessation in pregnancy is worthwhile to improve pregnancy and infant outcomes and reduce maternal complications of pregnancy. Some programs promote stopping smoking in pregnancy primarily as a strategy for stopping smoking altogether, that is as a strategy for reducing cancer and chronic diseases in later life. An unambiguous recommendation that stopping smoking in pregnancy is an important and worthwhile goal for the fetus is necessary.

As smoking rates have decreased in the general population in high-income countries, it is becoming increasingly recognised that smoking has become more closely correlated with entrenched social disadvantage and psychological co-morbidity. Studies are needed which refine interventions to address the specific needs of these subpopulations, without compounding problems of social alienation and lack of self-efficacy. There is currently very limited applied research into interventions in indigenous (Gilligan 2007) and ethnic minority populations, whose unique perspectives would need to be incorporated into a culturally appropriate intervention. Population wide interventions have not been effective in reducing smoking rates amongst many indigenous and ethnic minority groups, and the appropriateness of messages needs careful review. Given the shifting demographics and burden of diseases from tobacco smoking from high- to low- and middle-income countries, more research is needed to develop strategies which are culturally appropriate for these settings. The authors of this review are frequently asked whether there is evidence of differential effectiveness of interventions by social, economic or demographic factors, particularly poverty or lack of support. If there is adequate reporting of subgroup analysis in trials, we will
attempt to apply an “equity lens” (Murray 2005) to trials in the next update to answer these important questions.

In the next update we will attempt to define measures of “intervention quality”, such as whether the interventions have considered or addressed the views of women and/or providers, and whether they were well implemented. To assess these issues, trials will need to report:

- a developmental phase for the intervention materials and methods to be carried out with women similar to those who will be exposed to the intervention, taking full account of women’s concerns (negative impact on the woman herself and therefore on her family of stopping smoking because of its role in stress management and coping, perceived advantages of smaller babies such as shorter labours and less likelihood of operative delivery, the good outcomes of previous pregnancies despite smoking, or the good health of babies born to other women who smoke), and assessing the cultural appropriateness of material developed elsewhere;

- full involvement of staff who will be involved in any aspects of the intervention to ensure, in a similar way, that their concerns have been addressed, and to increase their understanding, active participation and support;

- a process evaluation identifying the extent of implementation in terms of its reach and the satisfaction of clients/consumers and staff;

- any theories which are used to inform the development of the intervention.

ACKNOWLEDGEMENTS

We thank the Collaborative Review Group Offices (Pregnancy and Childbirth, Tobacco Addiction) and the Australasian Cochrane centre (ACC) for assistance with the retrieval of recent relevant publications and technical support with the review. We would also like to thank staff from the Medical Library, Royal Women’s Hospital and the Borchardt Library, La Trobe University (Melbourne, Victoria) for assistance with searching and providing additional references.

We are grateful to Katherine Crouch, Sally Crowe, Marilyn Fairbairn, Christine Glossop, Sarah Jones and Sue Palmer-Simmons for their time in discussing this review from the perspectives of pregnant women in 1999.

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We thank Ewa Wisniewska for translating Polanska 2005.

As part of the pre-publication editorial process, this updated review has been commented on by two peers (an editor and referee who is external to the editorial team) and the Group’s Statistical Adviser.

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Rush 1992 [published data only]

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Sexton 1984 [published data only]

Sexton 1985 [published data only]

Sexton 1986 [published data only]

Sexton 1987 [published data only]

Sexton 1988 [published data only]

Price 1991 [published data only]

RUSH 1995 [published data only]

Rigotti 2006 [published data only]

Rush 1992 [published data only]

Secker-Walker 1994 [published data only]

Secker-Walker 1995 [published data only]

Secker-Walker 1995 [published data only]

Secker-Walker 1997 [published data only]

Secker-Walker 1998 [published data only]

Secker-Walker 1999 [published data only]
Valbo 1996 \{published data only\}

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Interventions for promoting smoking cessation during pregnancy (Review)

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Lumley 1995d

Lumley 1995e
Lumley 1999

Lumley 2004

* Indicates the major publication for the study
Characteristics of included studies  *(ordered by study ID)*

### Albrecht 1998

| **Methods** | A randomised pilot study including two different interventions and UC provided to “pregnant teens” recruited through local prenatal clinics and public schools in Pittsburgh, USA. The hypothesis was that an intervention including peer support would be more effective than the intervention alone. The aim was to develop an effective intervention which could be implemented by clinics and schools |
| **Participants** | Inclusion criteria were: 12 to 20 years of age; 4 to 28 weeks’ gestation; reported smoking at least 1 cigarette a day; single; no previous live birth; able to read and write English. Exclusion criteria: pregnancy complications preventing attendance at group sessions or participation in a home study program. 84 women recruited (not known how many were eligible or approached), 53 African-American heritage, 31 European-American heritage. 29 randomised to UC, 29 to TFS and 26 to TFSB. 46/84 had outcome data post-intervention. Mean cigarettes/day at first visit: UC = 6.44; TFS = 5.87; TFSB = 6.81 |
| **Interventions** | UC: 30 minutes individual educational session with project nurse including information about the risks of smoking to the mother and the fetus and brochures on smoking and pregnancy. TFS: cognitive behavioural group model designed specifically for adolescents: 8 modules to heighten awareness and attention to smoking messages; build and enhance smoking cessation skills; teach skills for maintenance of smoking control; includes experiential learning and round robin discussion. TFS was modified to include additional information on smoking and the fetus, body image changes and overall health. The intervention also included social activities, immediate rewards and adult modelling. TFS plus peer support (TFSB) utilised all the components of TFS plus one-to-one support through a non-smoking peer (buddy) chosen by the young woman. Buddies were asked to attend all 8 sessions and to be available at other times for reinforcement of techniques learned and encouragement for continued cessation. Intensity rating: I = 4, C = 3 |
| **Outcomes** | Smoking cessation at 4-6 weeks’ post baseline, validated by exhaled CO. Reduction in expired CO. Modified Fagerstrom Tolerance Questionnaire for adolescents to assess nicotine dependence |
| **Notes** | TFS and UC outcomes were combined in this preliminary paper. |

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Described as randomly assigned.</td>
</tr>
</tbody>
</table>
Allocation concealment? | Unclear | No information.
---|---|---
Blinding? | No | Provider and participants unable to be blinded to educational intervention
Women and clinical staff | | |
Incomplete outcome data addressed? | No | Only 46/84 had complete outcome data (high attrition rate = 45%), UC = 12 (41%), TFS = 13 (46%), TFSB = 13 (50%). No explanation for attrition. ITT analysis not mentioned
All outcomes | | |
Free of selective reporting? | Unclear | Only smoking outcomes reported.
Free of detection bias? | Yes | Exhaled CO levels.

Baric 1976

Methods | A randomised pilot study of the effect of medical advice on smoking cessation in pregnancy, in 2 public antenatal clinics in Bolton and District General Hospital, England
---|---
Participants | Women smokers or ex-smokers, at their first antenatal visit, less than 20 weeks' gestation. 110 women, mostly working-class, mostly long-term and heavy smokers. I: n = 63; C: n = 47
Interventions | Control group received UC, which was advice at the discretion of the doctor. Intervention group received one to one counselling from a senior medical student which involved discussion of the disadvantages of smoking during pregnancy: risk to the fetus; long-term risks of physical and intellectual impairment and possible reasons for this; possible effects on the mother's own health; costs of smoking; special dangers of smoking in late pregnancy; various ways to help someone to stop smoking. Given strong encouragement to quit and to make a commitment to do so. If this was not agreed then reduction to less than 5 cigarettes a day. Half the intervention group were given a diary to record each cigarette smoked and a gift of a free smoking diary. No theoretical basis of intervention specified. Intervention intensity I = 3, C = 2
Outcomes | Smoking cessation assessed by self-report in a home interview 11 weeks after baseline visit. Discusses participants' views of intervention
Notes |

Risk of bias

| Item | Authors' judgement | Description |
---|---|---|
Adequate sequence generation? | Unclear | No information provided. Described as "randomly divided". |
Baric 1976

Allocation concealment? | Unclear | No information provided.
---|---|---
Blinding? | No | Educational intervention at first antenatal visit.
Women and clinical staff | | |
Incomplete outcome data addressed? | Unclear | There are some missing data in the tables. It is not clear if there was any overall loss to follow up or whether missing data relate to specific outcomes only. 110/142 analysed. No explanation as to reason for attrition. No ITT analysis
All outcomes | | |
Free of selective reporting? | Unclear | No other outcomes reported.
Free of detection bias? | No | Smoking outcomes were reported by participants. There was no biochemical validation

Bauman 1983

Methods
Randomised trial of effectiveness of use of exhaled carbon monoxide feedback for promoting smoking cessation in pregnancy, in Guildford County, North Carolina. Trial over 6 months in 1981. No sample size justification

Participants
Women currently or recently smoking, attending public clinics. No exclusion criteria details or characteristics of participants in each group. 47% were current smokers, 43% had completed high school education, 56% were black, 80% classified as having no pregnancy risks other than smoking. 38% in the first trimester and 46% in the second trimester of pregnancy. 88 women were included in the analysis for the main outcome

Interventions
Experimental group provided breath specimen in which carbon monoxide was measured, with feedback of the result, and a 135 word script describing the relationship between CO and cigarette smoking and the harmful effects of smoking during pregnancy, by health educator. Women in the control group were read the script only. Intervention carried out by regular health educators. Theoretical basis: feedback. Intensity rating I = 2, C = 1

Outcomes
Smoking cessation 6 weeks after intervention confirmed by subsequent CO <= 9 ppm in breath specimen

Notes
Not clear whether this was a group intervention - in which case there was no adjustment for clustering

Risk of bias

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<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
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Interventions for promoting smoking cessation during pregnancy (Review)

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### Bauman 1983 (Continued)

<table>
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<tr>
<th>Adequate sequence generation?</th>
<th>Yes</th>
<th>Random number table.</th>
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<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>No information provided.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Intervention was carried out by UC staff, no participant blinding</td>
</tr>
<tr>
<td>Incomplete outcome data addressed? All outcomes</td>
<td>No</td>
<td>High rate of attrition (24.8%). The authors report that those lost to follow up had similar characteristics in the experimental and control groups. Analyses included only those remaining at follow up</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>None apparent.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Biochemical validation of reported smoking behaviour for those followed up</td>
</tr>
</tbody>
</table>

### Belizan 1995

#### Methods
Randomised trial of psychosocial support in pregnancy in 4 hospitals in Latin America (Argentina, Brazil, Cuba, Mexico). January 1989 - March 1991

#### Participants
High-risk women whose antenatal care began at 15-22 weeks’ gestation, singleton pregnancy, 1 or more of the following: prior LBW infant; preterm birth; perinatal/infant death; < 18 years; body weight <= 50 kg; height <= 150 cm; low family income (local definitions applied); < 3 years school; crowded household (4 or more persons/bedroom) ; smoking; not living with husband or partner. 2235 women recruited 1115 to intervention 1120 to control.

Exclusions: heart or renal failure; diastolic BP > 100 mmHg; history of cervical cerclage; Rh negative; mental disease or any chronic disease that might interfere with pregnancy

#### Interventions
Control group received routine antenatal care. Intervention involved flexible use of a standardised manual, based on site-specific ethnographic studies of needs, fears, expectations, social support networks, including detailed descriptions of situations likely to occur during home visits. 4 to 6 home visits of 1 to 2 hours with emphasis on psychosocial support, education on health habits including better nutrition, reducing smoking alcohol and other drugs, reducing their physical workload, recognition of alarm signs and symptoms, improved access to hospital facilities, reinforcement of health service utilization. Additional components were a poster, a booklet, hotline to project office, guided tour of hospital, encouragement of family support and participation. Intervention was provided by specially trained female social workers or obstetric nurses with previous experience of childbirth. Theoretical basis: reinforcement of social support networks. Intensity rating: I = 4, C = 1

#### Outcomes
Self-reported smoking cessation, no biochemical validation. Multiple perinatal and maternal health outcome data were collected
Baseline state anxiety score.

Notes
Sample size was planned for the primary trial objective.
Process evaluation showing good implementation is reported.

Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
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<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Centrally prepared, method not stated.</td>
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<tr>
<td>Allocation concealment?</td>
<td>Yes</td>
<td>Allocation was by opening sealed, opaque envelopes.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Home visitors were aware of group allocation. Social support intervention with home visits.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed? All outcomes</td>
<td>No</td>
<td>Nine per cent lost to follow up. No ITT analysis of drop-outs as continuing smokers.</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>None apparent.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>No</td>
<td>No biochemical validation of reported smoking behaviour.</td>
</tr>
</tbody>
</table>

Bullock 1995

Methods
Trial of telephone support for improving outcomes in late pregnancy, in the outpatient department of a large maternity hospital in New Zealand, or its associated GP practices, or self-referral, from March to December 1993

Participants
Women with telephone access, who were either single or with an unemployed partner, were recruited before 20 weeks' gestation. The eligible population was 221 women of whom 131 took part (103 OPD, 22 from GPs, 6 self-referred). 49 were never located, 23 were not interested, 10 refused after explanation, 8 moved away, did not speak English or had a miscarriage. Over 50% of women smoked at recruitment.

Interventions
Introductory letter, phone call, full discussion of “Healthy Mothers/Healthy Babies”, Controls: package of publicly available educational material on healthy behaviours during pregnancy, High intensity intervention: package plus weekly telephone call from trained volunteer with the aim of providing minimal support until 12 weeks after birth; aim “to be a friend and a good listener”; to ask about symptoms; signs; alcohol; drugs; smoking and meals in every call; to encourage attendance at antenatal clinic appointments and to ask about “feeling stressed”. Intervention provided by 19 female volunteers, trained for the project with a “case load”
### Bullock 1995 (Continued)

| Outcomes | Smoking cessation at 34/40. Anxiety and depression scores at baseline and 34/40. There were other intervention components which might have influenced these outcomes |
| Notes | No process evaluation is reported. No sample size justification |

#### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Computer-generated random assignment to control or intervention in balanced blocks of 50</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>No information provided.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>Yes</td>
<td>Caregiver blinded to allocation. Women not blinded to intervention</td>
</tr>
<tr>
<td>Incomplete outcome data addressed? All outcomes</td>
<td>Unclear</td>
<td>Attrition was relatively low (9 of 131 women were lost to follow up) but there was a high non-participation rate. Attrition = 7%. Women lost to follow up were included in the analysis as continuing smokers</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>None apparent.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>No</td>
<td>No biochemical validation of reported smoking behaviour.</td>
</tr>
</tbody>
</table>

### Burling 1991

| Methods | Trial of CO assessment and brief directive feedback, in a large US municipal hospital antenatal clinic, over an 18 month study period |
| Participants | All attending women screened for smoking by questionnaire + CO breath measurement (>= 9 ppm). Pregnant women, currently smoking, at any stage of gestation. Over 50% were current smokers; 40% of women were Black. Exclusion criteria were very young age (not specified) or “complications” (not specified). 139 women included in the analysis |
| Interventions | Control group (UC): clinic nurse provided health education, including smoking. Intervention: UC and a personal letter from the Chief (physician) of the prenatal clinic within 3 days of the visit, mentioning the CO test, discussing the risks of smoking to herself and the fetus and urging her to stop plus the American Cancer Society pamphlet (“Why start life under a cloud?”) about the negative effects of smoking and simple guide-
### Burling 1991 (Continued)

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>No information provided.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>No information provided.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>Unclear</td>
<td>The authors state that clinic staff were unaware of group allocation. Women would not have been blind to educational intervention</td>
</tr>
<tr>
<td>Incomplete outcome data addressed? All outcomes</td>
<td>Yes</td>
<td>No loss to follow up apparent.</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>None apparent.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Biochemical validation of reported behaviour by exhaled CO.</td>
</tr>
</tbody>
</table>

### Risk of bias

<table>
<thead>
<tr>
<th>Methods</th>
<th>Cluster-randomised trial in Newcastle, New South Wales, Australia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Women attending 22 public antenatal clinics (unit of randomisation). Exclusion criteria: under 16 years of age, too sick, non-English speaking, illiterate, attendance was first visit. 194 women included in the analysis</td>
</tr>
<tr>
<td>Interventions</td>
<td>Intensive dissemination of programme (Intervention group) included written information and feedback about programme benefits to managers, provision of programme resources, offers of visits to explain programme and provide training, sample smoking cessation policy, regular contacts to offer support, and computerised feedback on activities. Simple dissemination of programme to clinics (control group) included mail out of written information on programme benefit and resources. The cessation programme “Fresh Start for you and your baby”, developed by Windsor, based on CBT, was used Intervention intensity: I = 4, C = 4 (same intervention in both groups, only dissemination method differed)</td>
</tr>
</tbody>
</table>
Outcomes | Biochemically validated smoking cessation at end of pregnancy, recall of smoking advice received  
Participants and provider views of interventions discussed.

Notes | Process evaluation showed good implementation in intervention group. No intracluster correlation or impact factor reported, so sensitivity analysis conducted using four ICCs and figures adjusting using ICC of 0.1 in outcome tables

Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Method of random allocation not specified, but taken within strata based on clinic size and baseline smoking rates</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Not specified.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>Unclear</td>
<td>Educational intervention. Neither women nor providers would have been blind to the intervention</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td>One clinic excluded as did not report final data and some missing data for post-dissemination measures. No ITT of women dropping out of study. Only women completing study measures included in analysis</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>Smoking status and recall of intervention reported.</td>
</tr>
</tbody>
</table>

Cinciripini 2000

Methods | Trial of provision of videotaped vignettes for promoting smoking cessation and relapse prevention in a community-based university setting, Texas, US

Participants | Volunteers who were willing to quit within 2 weeks, were recruited through local media, such as newspaper, radio, subscriber letters, community business flyers, waiting room posters. Exclusion criteria: women smoking < 3 cigarettes per day; < 18 years; > 30 weeks' pregnant; do not have a working video recorder (approximately 12% Americans); not depressed. Participants n = 82. Mean cigarettes/day at first visit I = 17.3, C = 14.5. No significant difference in socioeconomic variables between groups

Interventions | The control group received a quit calendar and tip guide. Intervention group were also mailed a video with 6 x 25-30 minute vignettes covering
Cinciripini 2000  (Continued)

<table>
<thead>
<tr>
<th>a range of topics and strategies from initial quitting to relapse prevention. Theoretical basis: videos to teach coping skills/ cognitive behavioural techniques. Intensity rating: I = 3, C = 1</th>
</tr>
</thead>
</table>

**Outcomes**
- Self-reported smoking abstinence obtained within 2-3 days of quit date, 4-5 weeks after the quit date and one month postpartum. Biochemically validated with salivary cotinine.
- Participant evaluation of intervention materials.
- Associated references report association of quitting and depressive disorders CES-D scores at baseline only.

**Notes**
- Authors say women in this study tend to be heavier smokers than described in previous studies.
- Process evaluation showed only 53% of the intervention group viewed 1-3 of the 6 videos. 47% did not view them

**Risk of bias**

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Not stated.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Not stated.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Video mailed to participants. Not clear if UG givers were aware of group allocation</td>
</tr>
<tr>
<td>Incomplete outcome data addressed? All outcomes</td>
<td>No</td>
<td>Only 61% of participants completed all assessments. All those with missing data were treated as continuing smokers</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>Pre-specified outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>All reports of abstinence were validated by measurement of salivary cotinine</td>
</tr>
</tbody>
</table>

Cope 2003

<table>
<thead>
<tr>
<th>Methods</th>
<th>Randomised controlled trial in 3 large inner city hospital antenatal clinics, Birmingham, UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>“Current smokers” (&gt; 10 mg/ml in preliminary urine cotinine result) were enrolled in study. No exclusion criteria specified. Intervention group = 447 allocated, with 164 current smokers identified. Control group = 298, with 116 current smokers identified. An average consumption of 11.8 cigarettes per day in intervention group (not reported in control group). No demographic variables between groups reported</td>
</tr>
</tbody>
</table>
### Interventions

Control group: urine measured at initial visit, but no feedback given to women about results. Routine counselling about smoking in pregnancy from doctor or midwife, at 36 weeks' gestation, women had an interview to explain study, and obtain verbal consent to participate.

Intervention group: all allocated women seen at initial visit and given brief explanation of test and asked for consent to participate. After consent, they were asked for sample of urine, and 6 minute test completed in their presence. Results given as number and graphic illustration. A specific "quit date", usually within 14 days, set by mutual agreement and written on result sheet. Women were given printed leaflet on advice of how to quit and invited for further urine measurement and repeated support at subsequent visits.

Theoretical basis: feedback. Intensity rating: I = 4, C = 2

### Outcomes

Biochemically validated cessation (urine cotinine) at 36 weeks' gestation.

Self-reported smoking status and consumption at 36 weeks' gestation.

Proportion with "significant reduction" (20-80%) in urine cotinine.

Birthweight and length. SD for birthweight not provided, assumption of $P = 0.03$ used to calculate SD.

Gestation, type of delivery and Apgar scores (collected but results not reported).

Participants' views of intervention included.

### Notes

Process evaluation feedback from participants suggests that the "majority thought the test was good idea and had helped them to appreciate more about their smoking". Few women in the control group recalled receiving advice about smoking in pregnancy.

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>No</td>
<td>Sequence generation based on odd or even hospital numbers.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>No</td>
<td>Group allocation could be anticipated.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Neither providers nor women were blind to the intervention.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td>One table states that 298 were allocated to control group, but in the text, it states 409 (which would add up to correct total of eligible patients in table). However, the text states that only 280 were current smokers (I = 164, C = 116). Of these, only 192 completed the trial, but the above figures have been used in this analysis. Attrition = 55 in intervention group and 33 in control group (included in this analysis as continuing smokers).</td>
</tr>
</tbody>
</table>
### Cope 2003 (Continued)

<table>
<thead>
<tr>
<th>Free of selective reporting?</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
</tr>
<tr>
<td>Smoking status validated with urine cotinine. &gt;10 mg/ml indicates active smoker. Lower rates of self-reported cessation at 36/40 than biochemically validated (I = 16, C = 0). Biochemically validated used in this analysis</td>
<td>----</td>
</tr>
</tbody>
</table>

### DeVries 2006

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Women using public health services, who smoke more than 1 cigarette per day, literate in Dutch, and gravidity less than or equal to 4. 80% eligible population approached. Participation rate 72% (n = 318). Mean cigarettes per day at intake I = 9.1, C = 7.7. Mean gestation at intake I = 12.4, C = 13.5. (ii) included women from trial (i) and spontaneous quitters; n = 253 (I) and 303 (C); 80% approached. 72% participation</td>
</tr>
<tr>
<td>Interventions</td>
<td>Control group received routine smoking cessation counselling and a folder about smoking cessation in pregnancy. (Both trials i and ii) Intervention group received routine care plus a minimum of 2 counselling sessions from their midwife (who received a 3 hour training session on smoking cessation counselling and a booklet); a video; self-help guide; partner booklet and post-delivery booklet. Information was based on the stages of change model. Intensity rating: I = 4, C = 3</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Self-reported quit attempts at 6 weeks' postpartum, with urine cotinine biochemical validation in a small proportion of participants (n = 14). Self-reported partner smoking status. Detailed assessment of participant and midwifery views of interventions, including an analysis of psychosocial motives which are thought to be associated with implementation</td>
</tr>
<tr>
<td>Notes</td>
<td>Inconsistent information on gravidity criteria. Significant clustering identified at midwife level. The reported inter-cluster variance of 0.82 was used to derive ICC for adjusting reported outcome figures used in analysis. A separate detailed paper published on process evaluation issues which reports poor implementation in some aspects. Only 16.7% of women received the post-delivery booklet. No validation of longer-term self-reported smoking. Only 24.2% of chairs of midwifery agreed to approach midwives in their region to participate</td>
</tr>
</tbody>
</table>

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>No</td>
<td>The first 40 practices (118 midwives) were selected, from 4 provinces, which were then matched (by location and level of urban-</td>
</tr>
</tbody>
</table>
### DeVries 2006 (Continued)

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation</td>
<td>allocation?</td>
<td>unclear</td>
</tr>
<tr>
<td>concealment?</td>
<td></td>
<td>not reported.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>women and clinical staff</td>
<td>no</td>
</tr>
<tr>
<td></td>
<td></td>
<td>neither providers nor women were blinded for this counselling intervention</td>
</tr>
<tr>
<td>Incomplete</td>
<td>outcomes</td>
<td>unclear</td>
</tr>
<tr>
<td>outcome data</td>
<td>addressed?</td>
<td>not clear, figures are not consistent, as well as loss to follow up there are missing data for some variables</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td>when all drop-outs included as smokers 7-day abstinence I = 19% of 141 and C = 7% of 177, included in this analysis</td>
</tr>
<tr>
<td>Free of</td>
<td>selective</td>
<td>unclear</td>
</tr>
<tr>
<td>reporting?</td>
<td>reporting?</td>
<td>none apparent.</td>
</tr>
<tr>
<td>Free of</td>
<td>detection bias?</td>
<td>no</td>
</tr>
<tr>
<td>detection bias?</td>
<td></td>
<td>biochemical validation for a small sub-sample only</td>
</tr>
</tbody>
</table>

### Donatelle 2000

<table>
<thead>
<tr>
<th>Methods</th>
<th>trial of “significant other supporter” (SOS) program, of bolstered social support and direct financial rewards, for low-income high-risk women in 4 Oregon WIC program sites, US. Conducted between June 1996 and June 1997</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>women smoking (even a puff in the last 7 days); less than 28 weeks' gestation; over 15 years of age; literate in English. Participation rate 71%. Mean salivary cotinine at baseline: I: 45.4 (n = 112); C: 45.7 (n = 108).</td>
</tr>
<tr>
<td>Interventions</td>
<td>control group received verbal and written information on the importance of smoking cessation, a pregnancy specific smoking cessation self-help kit, and were telephoned monthly for self-reports on their smoking status. The intervention group received as for the control group plus were asked to designate a social supporter (preferably a female non-smoker), and were advised both she and her supporter would receive an incentive: participants were given $50 voucher for each month biochemically confirmed as quit. Supporter received $50 voucher in first month and at 2 months postpartum, and $25 voucher for other months. The intervention was delivered by trained program staff or research staff. Theoretical basis: rewards and social support. Intensity rating: I = 4, C = 3</td>
</tr>
<tr>
<td>Outcomes</td>
<td>smoking cessation biochemically validated with salivary cotinine at 34 weeks' gestation and 2 months postpartum</td>
</tr>
<tr>
<td>Notes</td>
<td>data in outcome tables is inconsistent.</td>
</tr>
</tbody>
</table>
### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>No information provided.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>No information provided.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Neither providers nor women were blinded for this educational intervention with incentives</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Unclear</td>
<td>High attrition rates $I = 32%$; $C = 51.5%$, but drop-outs included as smokers in this analysis. Those lost to follow up were considered to be smokers.</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>Main outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Reported quitting validated by salivary cotinine analysis.</td>
</tr>
</tbody>
</table>

### Donovan 1977

**Methods**
Randomised trial of advice to stop smoking in pregnancy, provided by a (public health) doctor, reinforced by the woman's own GP and other providers involved in shared antenatal care, in 3 UK maternity units.

**Participants**
Pregnant women $< 35$; currently smoking $\geq 5$ cigarettes/day and had been smoking $\geq 1$/day at the onset of pregnancy; $< 30$ weeks' gestation at first visit; no prior perinatal death; not seeking, nor sought termination. Other exclusions: not pregnant; refused consent; miscarriage or termination of pregnancy; moved to another care provider; twin pregnancy or birth before 28 weeks. 552 women enrolled in the study.

**Interventions**
Control group received ANC usually provided by the hospital, including any anti-smoking advice which may have been given routinely. Intervention: individualised medical advice by clinic doctor, (i) tell the woman the facts about smoking in pregnancy; (ii) encourage questions about these facts; (iii) once the woman has agreed to try, discuss how she may best give up; (iv) follow up the advice at all later contacts. Medical records labelled asking other staff to reinforce advice. Theoretical basis - not clear/ stages of change. Intensity rating: $I = 3$ (advice reinforced at each clinic visit), $C = 2$.

**Outcomes**
Self-reported smoking in cigarettes/day at four stages of pregnancy; mean birthweight; low birthweight; preterm birth ($< 36$ weeks); perinatal deaths. No data on smoking cessation.
Donovan 1977

Continued

No biochemical validation of smoking status.

Notes
Details of the intervention are in Donovan 1975. Good discussion of common problems identified when advising women to stop and on the contextual factors which encourage the continuation of smoking. Process evaluation of the reinforcement of advice showed little difference between the groups in recall of advice being given. Major inconsistency in smoking reports pre and post-birth is a problem in this trial.

Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Table of random numbers.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Information not provided.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Notes labelled. Caregivers asked to reinforce information. Educational intervention</td>
</tr>
<tr>
<td>Incomplete outcome data addressed? All outcomes</td>
<td>Yes</td>
<td>No loss to follow up apparent.</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Smoking cessation rates not reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>No</td>
<td>No biochemical validation of reported smoking behaviour.</td>
</tr>
</tbody>
</table>

Dornelas 2006

Methods

Participants
Inclusion criteria: pregnant women, over 18 years old, less than 30 weeks’ gestation, current smokers (recent quitters included in associated relapse prevention paper), no recent history of abuse or dependence on alcohol or other non-nicotine substance, no major psychiatric illness, access to a telephone
105 women enrolled in study (I = 53, C = 52).

Interventions
Intervention: one 90 minute psychotherapy session at the clinic, followed by bi-monthly prenatal telephone calls from the therapist during pregnancy, and monthly calls after delivery. Therapists were masters-prepared mental health counselors trained in smoking cessation. The theoretical basis of the intervention was CBT
Control: all participants also received UC according to standard smoking cessation guidelines, including provision of a booklet, a chart prompt to remind providers to provide quit messages at each visit, and audit to ensure the advice was documented
Intensity rating: I = 4, C = 3.
**Outcomes**

Abstinence for smokers at end of pregnancy, aggregated by week of gestation to enter study. An associated study reports abstinence rates for recent quitters (relapse prevention) Abstinence at 6 months postpartum. Cost-effectiveness of “cost per quitter”.

**Notes**

Process evaluation showed 17/53 did not receive the phone calls as planned

### Risk of bias

<table>
<thead>
<tr>
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<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>No description of methods of randomisation.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>No description.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Educational intervention so blinding not feasible.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Unclear</td>
<td>Attrition rate = 0% at 36 weeks' gestation and 18% at 6 months postpartum</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>All outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Biochemical validation with expired carbon monoxide readings (less than 4 ppm)</td>
</tr>
</tbody>
</table>

---

**Dunkley 1997**

**Methods**

Trial of midwifery counselling around the "stages of change" model", in a large UK maternity service

**Participants**

100 women; pregnant and booked for maternity care; < 18 weeks' gestation; currently smoking 1 or more cigarettes/day. 13 midwives selected for the intervention group and 13 for the control group

**Interventions**

Intervention midwives were trained to assess the stages of change and provide a behavioural intervention, using the Health Education Authority material “Helping pregnant smokers quit: training for health professionals”, 1994. Few details of intervention provided. Intensity rating: I = 2. C = not clear (0)

**Outcomes**

Smoking cessation: cigarettes/day; "stage of change" at 11 to 18 weeks vs 37 weeks. No biochemical validation of smoking status. Care providers' views discussed

**Notes**

3700 births/year at the hospital, all women who smoked were eligible to take part so it is not clear why only 100 took part (described as “all 100”). No process evaluation reported.
Dunkley 1997  (Continued)

**Risk of bias**

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Not stated.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Described as ‘randomly allocated’.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Different midwives caring for women in the experimental and control groups.</td>
</tr>
<tr>
<td>Women and clinical staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Unclear</td>
<td>94 of 100 women recruited followed up. No ITT analysis.</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>All outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>No</td>
<td>No biochemical validation of reported smoking status.</td>
</tr>
</tbody>
</table>

Ershoff 1989

**Methods**  
Prospective randomised controlled trial in 5 health centres of the same HMO in Los Angeles, 1985-87

**Participants**  
English-speaking women < 18 weeks’ gestation; still smoking ≥ 7 cigarettes a week (n = 323, 165 + 158, with losses due to termination (7 + 11); miscarriage (12 + 13); disenrolment or transfer to another HMO (20 + 18); leaving 126 + 116

**Interventions**  
Control group: 2 page pamphlet on hazards of smoking and on the need to quit; 2 minutes discussion with a health educator (within a 45 minutes individual conference); advised of free 5 session smoking cessation program available through the HMO. Coverage in antenatal classes remained unchanged.  
Intervention group: as for the control group + first of series of 8 self-help booklets aimed to increase motivation for quitting; teach behavioural strategies for cessation and relapse prevention; 3 minutes introduction to these by health educator; asked to make a commitment to read the first one and list reasons for not smoking; others mailed weekly. Booklets were pregnancy-specific, multi-ethnic, and at a 9th Grade reading level. Theoretical basis - aimed to increase motivation and teach behavioural change strategies. Intensity rating: I = 3, C = 2

**Outcomes**  
Smoking cessation validated with urine cotinine; birthweight; low birthweight; preterm birth (< 37 weeks); stillbirths

**Notes**  
Process evaluation showed good implementation.

**Risk of bias**
Ershoff 1989 (Continued)

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>No information</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>No</td>
<td>The authors state that women had been randomised in advance of their visit. It was not clear how women were recruited to the study or gave consent for participation. The health educator turned over a ‘preassigned card’ to randomise women</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>The authors state that the health educator delivering the intervention was not aware of group allocation, but materials were provided to the experimental group at the clinic visit</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Unclear</td>
<td>Attrition I = 39/165, C = 44/158 not included in analysis (due to miscarriage, abortion or dis-enrolment from the HMO)</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>None apparent.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Biochemical validation by urinary cotinine levels.</td>
</tr>
</tbody>
</table>

Ershoff 1995

Methods

Ershoff 1989 trial data of relapse prevention in the women who had spontaneously quit smoking in early pregnancy

Participants

The pre-pregnancy smokers who had quit spontaneously before the first antenatal contact: 110 + 108, with losses due to termination (5); miscarriage (17) and transfer to alternative prenatal care (25) leaving 87 + 84

Interventions

See Ershoff 1989 except that the intervention group received the first 4 booklets at the first interview with booklets 5 to 8 mailed weekly thereafter; control group were congratulated on quitting and given a tip sheet on “staying quit”. Intensity rating: I = 3, C = 2

Outcomes

Smoking data validated with urinary cotinine measurement, no perinatal data

Notes

Detailed process evaluation and analysis of factors promoting or inhibiting cessation and maintenance of non-smoking

Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
</table>
### Adequate sequence generation?

No

No information.

### Allocation concealment?

No

See Ershoff 1989 above.

### Blinding?

Women and clinical staff

No

Neither caregiver nor women were blinded.

### Incomplete outcome data addressed?

All outcomes

No

22% attrition. No ITT analysis.

### Free of selective reporting?

Unclear

None apparent.

### Free of detection bias?

Yes

Biochemical validation by urinary cotinine levels.

---

### Ershoff 1999

**Methods**

Trial of 3 alternative methods of smoking cessation interventions, in a large group model managed care organisation in Los Angeles, California, USA

**Participants**

Smokers were identified at first visit as women who self-report "smoking now", "smoke but have cut down since pregnancy", or "smoke from time to time". Researchers attempted to phone all women over 18 years and less than 26 weeks' gestation (n = 931). 150 could not be contacted and 90 refused to be interviewed. 233 were excluded as they did not speak English (n = 44), smoked less than 7 cigarettes per week pre-pregnancy (n = 114) or experienced miscarriage (n = 34). 380/458 women (82%) agreed to participate. 60% white, approximately 50% college educated, with a mean age of 29.4. Mean cigarette/day at first visit = 6.6

**Interventions**

3 interventions, based on stages of change model.

- **Group 1:** received a self-help booklet "living smoke-free".
- **Group 2:** (n = 120): received the same self-help booklet and had access to a computerised interactive telephone support system, which provided customised messages from a voice model.
- **Group 3:** (n = 101): received the same self-help booklet and 4-6 x 10-15 minute telephone counselling sessions by nurse educators trained in motivational interviewing. A personalised postcard sent to reinforce verbal communication. Intensity rating: I = 4, C = 1

**Outcomes**

Smoking cessation in the third trimester "not even a puff in the last 7 days", biochemically validated with urine cotinine. Smoking reduction in cigarettes/day. Baseline mental health index and Cohen's perceived stress scale. Number of quit attempts and movement in stages of change.

### Notes

Data from group 1 and group 3 only compared in outcome tables. Good process evaluation of each of the methods.

---

**Risk of bias**
<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Described as “random assignment”</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>No information.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>Unclear</td>
<td>Authors state that care providers were blind to group allocation. Educational intervention so blinding women not feasible</td>
</tr>
<tr>
<td>Women and clinical staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Unclear</td>
<td>15% attrition but data available for some outcomes from those lost to follow up. Lost to follow up not included as continuing smokers in analysis as attrition from each study group not reported separately</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Results were difficult to interpret.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Biochemical validation by urinary cotinine levels.</td>
</tr>
</tbody>
</table>

**Gielen 1997**

**Methods**
Randomised trial of a smoking cessation and relapse prevention intervention in an urban, prenatal clinic in Baltimore, USA. Nov 1996-June 1997

**Participants**
Pregnant women currently smoking (even 1 puff in the past 7 days); < 28 weeks’ gestation; African-American or white; 85% of whom were on medical assistance, attending the Outpatient Department at John Hopkins. No other exclusions specified. 2319 women assessed, 32% currently smoking by above definition, 1585 non-smokers, 72 (gestation, ethnicity, not interviewed at their first visit or changing to another care provider) leaving 662 eligible of whom 510 agreed to take part. 25 quit prior to first visit, 18 did not wish to quit, leaving 467 (232 + 235) reduced by withdrawals, miscarriage, termination and change of care provider to (193 + 193). Mean cigarettes/day at intake I = 9.7, C = 7.5 (P = 0.01)

**Interventions**
Control: a brief discussion with a nurse/health counsellor about the risks of smoking; a recommendation to quit and pamphlets from the area’s voluntary agencies.
Intervention: peer health counsellors recruited from local communities, received 2 sessions training from PIs who explained content, rationale and how it was to be provided, then observed in practice by PIs with feedback to her.
(i) A Pregnant Woman’s Guide to Quit Smoking (RA Windsor), 6th Grade level.
(ii) 15 minutes 1:1 counselling session with peer health counsellor on how to use the Guide, showing how it is organised to be used daily, and discussing women’s thoughts and concerns about quitting, targeting cessation or relapse prevention, as appropriate.
(iii) Educational materials for cessation support persons included with the Guide.
(iv) Reinforcement at each clinic visit from doctors and nurses, written prescription to stop smoking provided directly from doctor to woman; 2 letters of encouragement (from
Gielen 1997

Continued

<table>
<thead>
<tr>
<th>Theoretical basis: social learning theory. Intensity rating: I = 4, C = 2</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking cessation in third trimester, validated by salivary cotinine. Proportion cotinine reduction &gt; 50%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guide developed through needs assessment with pregnant women, constructs from the PRECEDE/PROCEED diagnosis and social learning theory, tested with focus groups, additional section on relapse prevention, and on passive smoking postpartum. Process evaluation showing good implementation. Discussion by authors of the extremely disadvantaged population in inner city, with major neighbourhood level factors of unemployment, poverty, drug use, violence and crime. Results show high rate of misclassification by self-report (I = 37%, C = 48%)</td>
</tr>
</tbody>
</table>

### Risk of bias

<table>
<thead>
<tr>
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<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>No information provided.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Described as “randomly assigned”.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Educational intervention.</td>
</tr>
<tr>
<td>Women and clinical staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td>Almost 50% attrition for some outcomes. Attrition: I = 35.2%, C = 35.3% Those remaining available to follow up but failing to provide saliva samples were treated as continuing smokers but those lost for other reasons were not included in the analysis (number excluded not reported separately to be able to include)</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>None apparent.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Biochemical validation by salivary cotinine.</td>
</tr>
</tbody>
</table>

Haddow 1991

<table>
<thead>
<tr>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomised trial in physicians offices and clinic sites within Maine, USA, 1984-7, of providing feedback on cotinine measured in maternal serum screening programme (for the identification of open neural tube defects) as part of an smoking cessation intervention</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnant women with a singleton live pregnancy; having maternal serum AFP screening at 15-20 weeks' gestation; who smoked &gt;= 10 cigarettes a day. 25,628 screened, 97% answered question on smoking, about 3,000 met smoking criteria (17%). 1423 inter-</td>
</tr>
<tr>
<td>Interventions</td>
</tr>
<tr>
<td>Outcomes</td>
</tr>
<tr>
<td>Notes</td>
</tr>
</tbody>
</table>

**Risk of bias**

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Computer-generated random numbers.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Information not provided.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Caregivers aware of group allocation. Experimental group given feedback on serum cotinine levels</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td>Small loss to follow up for some outcomes but 48% of the intervention group did not provide follow-up samples for serum cotinine analysis. No ITT analysis</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Results difficult to interpret. Smoking cessation not recorded</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Unclear</td>
<td>Serum cotinine measurement at baseline for both the experimental and comparison groups but it was not clear that any follow up measurements were made for the comparison group</td>
</tr>
</tbody>
</table>
Cluster-randomised trial of a brief midwife-delivered smoking cessation intervention in 9 hospital and community trusts in the UK. 290 midwives randomised to provide intervention or control care.

Women recruited at first visit (approximately 12 weeks' gestation) and considered eligible if they reported current smoking or having stopped within the last 3 months (n = 1287). 189 current smokers not motivated to stop therefore, received no intervention.

Control group midwives received 1 hour of training to discuss the study and were asked to provide UC and any usual pamphlets. Intervention midwives received 2 hours training which included using the CO monitor and providing 'stage of change' based advice, CO assessments. Intervention group also received written advice and motivational materials for current and recent smokers, including designating a 'quit date', a 'quiz' and the offer of 'buddying' to another pregnant smoker for support. Intensity rating: I = 4, C = 2.

Smoking cessation biochemically validated with exhaled CO in the early postnatal period and at 6 months postpartum. Birthweight for smokers and ex-smokers recorded. Participants and midwives views of interventions reviewed.

Good process evaluation showed poor implementation in some areas, with only 61% of midwives actually recruiting any women for the study. Financial incentives paid to service to improve recruitment. Discussion of barriers includes 65% of midwives reporting the intervention could not be undertaken in the time they had available. Sample size justification.

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>No</td>
<td>Consecutive names on a list of midwives.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>No</td>
<td>Midwives randomised.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Midwives aware of allocation group. Educational intervention. Blinding women not feasible</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Unclear</td>
<td>Approximately 9% of women were lost to follow up. Non-respondents were treated as smokers in the analysis but those lost to follow up for other reasons were excluded from the analysis</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Clustering effect not reported, so sensitivity analysis conducted using four ICCs and outcome figures adjusted using conservative intracluster correlation of 0.1</td>
</tr>
</tbody>
</table>
### Hartmann 1996

**Methods**
Trial of medical smoking cessation counselling and peer support, in a teaching hospital (academic) clinic in North Carolina, USA. 1991-1993

**Participants**
All women receiving prenatal care at the University of North Carolina residents clinic were surveyed: 842/846 completed survey; 793/846 provided a carbon monoxide breath sample; 2 were excluded as > 36 weeks' gestation; 1 for psychiatric diagnosis; leaving 266 eligible smokers (smoked at least once in the prior week) of whom 12 refused, 4 were missed, 2 were not pregnant and 1 was a private patient; 247 recruited, losses were 40 (-4 miscarriage first trimester, -3 miscarriage second trimester, - 3 terminations, -15 moved to alternative care, -12 lost to follow up) leaving 107 intervention and 100 control

**Interventions**
- All 1-4 year residents given didactic and role play training for smoking cessation counselling, including self-assessment of current techniques and skills, which they were asked to continue with for the control group.
- Control group: standard care; residents reminded not to alter amount or time of this; help was provided if woman sought it and prenatal classes included discussion of substance abuse including cigarettes.
- Intervention: (i) residents provided counselling at each visit, and a brief script aimed at setting a quit date or negotiated an alternative assignment such as a smoking diary at every contact;
  - (ii) given Windsor's self-directed 7 day smoking cessation guide;
  - (iii) quit date patients given written prescription to quit, letter of support from doctor, contacted by volunteer smoking cessation counsellor to review the quit plan and encourage follow-through charts flagged, prompts with flow sheet, most recent CO and self-report included for care provider;
  - (iv) successful quitters sent an encouraging postcard each week
- Theoretical basis: feedback and reinforcement. Intensity rating: I = 4, C = 2 (not clear)

**Outcomes**
Smoking cessation biochemically validated by exhaled CO at each visit. Proportion > 50% reduction in CO

**Notes**
Concerns about residents having to treat similar/consecutive patients differently, and self-help manuals accidentally given to some controls

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Computer-generated random numbers.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>No</td>
<td>State that neither the enrolling nurse nor the patient were aware of allocation, but experimental group notes were flagged</td>
</tr>
</tbody>
</table>
### Hartmann 1996

(Continued)

<table>
<thead>
<tr>
<th>Blinding?</th>
<th>No</th>
<th>Case notes flagged. States patient not aware of randomisation status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women and clinical staff</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Incomplete outcome data addressed?</th>
<th>No</th>
<th>Attrition 16%. Drop-outs not reported by intervention group so not able to be included in analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Free of selective reporting?</th>
<th>Unclear</th>
<th>Not apparent.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Expired CO measured at each visit for the experimental group and at 3 visits for the comparison group</td>
</tr>
</tbody>
</table>

Hegaard 2003

**Methods**

Trial of multimodal intervention to promote smoking cessation in pregnancy in a large midwifery centre in the Netherlands, 1996-1998

**Participants**

Pregnant women attending first antenatal visit (approximately 16 weeks' gestation) who identified as "daily smokers" were invited (n = 905). Exclusion criteria: inability to speak Danish; age > 18 years; gestation > 22 weeks; verified psychiatric disease, and alcohol or drug abuse. Participation rate 77% (n = 696). I = 348, C = 347. 87 in the intervention group accepted intensive smoking program (81 group and 6 individual). 75 opted to use NRT. Withdrawals = 48 (miscarriage, moving and premature birth) excluded from the smoking cessation outcomes. Mean cigarettes/day = 11 in both groups. Significant difference in partner smoking I = 67%, C = 77% (P = 0.03)

**Interventions**

Control group received standard smoking cessation counselling from their midwife about risk of smoking and general advice on cessation or reduction, within the standard 30 minute booking consultation.

The intervention group all received an extended first antenatal visit of 40 minutes, which included a dialogue, and written information on hazards of smoking in pregnancy and for newborns. This information was reinforced in the following 5-6 antenatal visits, within the normal 20 minute visit.

Women were invited to join the intensive smoking program, based on cognitive behaviour modification program, with 9 group (90 minutes) or individual sessions (15-30 minutes), conducted over 14 weeks, by specifically trained midwives. Exhaled CO levels taken at each visit, the first 3 weekly sessions prepared women for quitting, with the final 6 sessions designed to assist women to maintain cessation and provide an NRT regime tailored to Fagerstrom nicotine dependence assessments

Intensity rating: I = 4, C= 1.

**Outcomes**

Self-reported smoking cessation at 37 weeks' gestation. Mean birthweight; low birthweight (< 2500 g); preterm births (< 37 weeks). A subsequent paper measures smoking cessation at 1 month and 1 year postpartum
**Hegaard 2003**  
*(Continued)*

| Notes | Sample size justification. Process evaluation shows 86% of intervention group used patches |

**Risk of bias**

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>No</td>
<td>Quasi-randomised, allocation of even/un-even birth dates to designated clinic days</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>No</td>
<td>Possible for those recruiting to anticipate allocation. Educational intervention by usual caregiver</td>
</tr>
<tr>
<td>Blinding?</td>
<td>Women and clinical staff</td>
<td>No</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>All outcomes</td>
<td>Unclear</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Birthweight and low birthweight data provided. No other adverse outcomes reported</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Salivary cotinine measured to verify reported abstinence.</td>
</tr>
</tbody>
</table>

**Heil 2008**

<table>
<thead>
<tr>
<th>Methods</th>
<th>Randomised controlled trial in Greater Burlington, Vermont, USA, 2001-2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Participants were recruited from 1 of 4 large obstetric practices. Inclusion criteria: self-reported smoking (even a puff in the last 7 days), gestational age less than 20 weeks, living within study clinic county and not planning to move until at least 6 months postpartum, English speaking, not incarcerated and not previously participating in the study or living with anyone who has previously participated in the study 182 women were eligible for the study, and 82 (45%) agreed to participate. 5 women withdrew from the study due to fetal demise or termination of pregnancy and were not included in the final analysis (I = 3, C = 2) There was no significant difference in baseline characteristics of the groups, including pre-pregnancy cigarettes per day (I =18.7, C =18.4), health insurance (I =19, C =13), and timing of recruitment (I = 8.9, C = 9.5)</td>
</tr>
</tbody>
</table>
Interventions

Intervention (contingent voucher): participants chose a quit date, and reported daily to the clinic for CO monitoring for 5 days, then urine cotinine monitoring twice weekly for 7 weeks, weekly for 4 weeks, and then every 2 weeks for the remainder of the pregnancy. Vouchers were given dependent on biochemical validation, beginning at US$6.25 and escalated by US$1.25 to a maximum of US$45.00. Positive test results reset voucher back to original value, but two consecutive negative tests restored value to pre-reset value. Control (non-contingent voucher): Participants received voucher independent of smoking status. US$15.00 per antenatal visit and US$20.00 per postpartum visit, to result in a comparable average earnings to the contingent group. Both groups received routine advice from the clinic. It is unclear who delivered the intervention. The theoretical basis on the intervention is rewards and feedback. The intensity rating: I = 4, C = 4.

Outcomes

Smoking cessation at 28 weeks' gestation, 12 weeks and 24 weeks' postpartum. Reduction in mean cotinine. Mean birthweight, gestational age, fetal growth measures (US), and proportion of NICU admissions and low birthweight babies.

Notes

Sample size justification. Process evaluation not reported. Some discussion of cost implications.

Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Described as “randomisation stratified to clinics”. Details of randomisation not described</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>No information.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Participants and providers not blinded as receiving incentives for participation</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Yes</td>
<td>Small loss to follow up due to pregnancy termination or fetal death. Available case analysis</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>Detailed birth outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Exhaled CO for 5 days (&lt; 6 ppm) and then urine cotinine (&lt; 80 ng/ml)</td>
</tr>
</tbody>
</table>
Pilot study in Greater Burlington, Vermont, USA during 2001-2003

Participants
Inclusion criteria: currently smoking (even a puff in the last 7 days), living within city limits of clinic, planning to remain for 6 months postpartum, English-speaking, not incarcerated and not having previously participated in the study or living with anyone who has participated in the study.

100 women were eligible to participate, 58 consented (58% participation rate), with 5 excluded from analysis due to fetal demise or termination of pregnancy.

There was no significant difference between the intervention and control groups in baseline characteristics, including number of pre-pregnancy cigarettes per day ($I = 23.3$, $C = 22.7$); health insurance ($I = 10, C = 13$). The attendance rate was similar between groups ($I = 63.7\%, C = 63.3\%$).

Interventions
Intervention (contingent voucher): participants chose a quit date, and reported daily to the clinic for CO monitoring for 5 days, then urine cotinine monitoring twice weekly for 7 weeks, weekly for 4 weeks, and then every 2 weeks for the remainder of the pregnancy.

Vouchers were given dependent on biochemical validation, beginning at US$6.25 and escalated by US$1.25 to a maximum of US$45.00. Positive test results reset voucher back to original value, but 2 consecutive negative tests restored value to pre-reset value.

Control (non-contingent voucher): participants received voucher independent of smoking status. US$11.50 per antenatal visit and US$20.00 per postpartum visit, to result in a comparable average earnings to the contingent group.

Both groups received routine advice from the clinic. It is unclear who delivered the intervention.

The theoretical basis of the intervention is rewards and feedback.

The intensity rating: $I = 4, C = 4$.

Outcomes
Smoking cessation at 36 weeks of pregnancy, 12 weeks' postpartum and 24 weeks' postpartum.

Notes
There is no sample size justification for this pilot study and no process evaluation reported. There is some discussion of cost implications.

Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>No</td>
<td>37/53 were consecutively assigned (quasi-randomised) as part of pilot study, and 16/53 were randomised.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>No</td>
<td>Group allocation could be anticipated.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Unable to blind participants or providers in this trial.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Yes</td>
<td>Very low loss to follow up (10% at end of pregnancy). Those lost to follow up were counted as continuing smokers.</td>
</tr>
</tbody>
</table>
Free of selective reporting? | Unclear | Only smoking status reported.
---|---|---
Free of detection bias? | Yes | Biochemically validated with exhaled CO (abstinence < 6 ppm) for 5 days, then urine cotinine (abstinence < 80 ng/ml)

Hjalmanson 1991

**Methods**

**Participants**
Women who spoke Swedish, smoking >= 1 cigarette/day, gestational age < 12 weeks at first antenatal visit, (no other exclusion criteria specified), leaving n = 745 of whom 22 had quit by the second antenatal visit. 15% refused to take part (-75) leaving 417 in the intervention and 231 in the control group

**Interventions**
All women were advised to quit by the midwife at the first antenatal clinic; pre-intervention. Control: basic information sheet given to women by the doctor with basic facts about smoking and pregnancy and recommendation to quit. Intervention: self-help manual based on Windsor 1985, revised and with new parts added, distributed by the obstetrician at the second antenatal visit. Self-help tasks were based on principles of behavioural therapy. Intensity rating: I = 3, C = 2

**Outcomes**
Smoking cessation data; biochemically validated (blood thiocyanate < 100 ng/ml) at first and second antenatal visit and in late pregnancy, and 8 weeks' postpartum; mean birthweight; low birthweight; preterm birth (< 36 weeks) Smoking reduction in mean cigarettes per day (the standard deviation for the mean was not provided so in the analysis it was calculated from the confidence intervals given in the paper)

**Notes**

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>No</td>
<td>By birthday. Uneven groups.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>No</td>
<td>Possible to predict allocation.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Neither provider nor women blinded to this educational intervention</td>
</tr>
<tr>
<td>Women and clinical staff</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
Incomplete outcome data addressed? All outcomes | No | Attrition in both groups, approximately 15% in the experimental group at the outset and 11% later. No ITT analysis. Some loss to follow up but where data were available all cases were included

Free of selective reporting? | Unclear | Not apparent.

Free of detection bias? | Yes | Serum thiocyanate analysis at 30-34 weeks' gestation and postpartum

Hotham 2005

Methods | Randomised controlled trial of use of nicotine patches in Adelaide, South Australia, 1999-2000

Participants | Inclusion criteria: self-reported smokers (greater than 15 cigarettes per day), between 12-28 weeks' gestation, and not planning shared antenatal care with a general practitioner. 1462 women were screened and 72 were eligible to participate in the study. 39 (54%) agreed to participate in the study (I = 20, C = 19). There was no apparent significant difference in baseline characteristics, including pre-pregnancy cigarettes per day (I = 19.8, C = 19.6)

Interventions | The intervention group received nicotine patches 15 mg for 16 hours, for 12 weeks, with optional weaning to lower strengths. Control: no placebo patches were available. All participants received counselling at the initial and follow-up visits, with CO measurements and salivary samples. High attrition rate: I = 7/20 (35%), C = 7/19 (37%). Theoretical basis: Nicotine replacement therapy. Intervention intensity: I = 4, C = 3

Outcomes | Smoking cessation and smoking reduction (> 50% cotinine levels)

Notes | Detailed process evaluation in associated case study reports of participants' views suggests significant resistance of women to using NRT in pregnancy. Only 25% of women in the treatment group (n = 5) complied with treatment protocol

Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
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<tbody>
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<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Computer-generated sequence.</td>
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<tr>
<td>Allocation concealment?</td>
<td>Yes</td>
<td>Described as “sealed envelope system”. Unclear whether envelopes opaque</td>
</tr>
</tbody>
</table>
**Kapur 2001**

**Methods**
Canadian double-blind, placebo controlled trial of nicotine replacement therapy (patches) in pregnancy

**Participants**
Women recruited from the Motherisk Program at 12-24 weeks' gestation, smoked > 15 cigarettes/day, and who reported they wanted to quit, but could not do so, in the first trimester

**Interventions**
Intervention group received a 12 week NRT patch regimen: 18 hour 15 mg patch for 8 weeks; 10 mg patch for 2 weeks, and 5 mg patch for 2 weeks + counselling with a video presentation at baseline, 1, 4 and 8 weeks.
Control group received as for intervention group, with a placebo patch. Weekly telephone support was given from 1 investigator to encourage continuation with the program, enquire about adverse effects and to co-ordinate clinic visits. All women were encouraged to call the investigative team for advice, reassurance and support

Intensity rating: I = 4, C = 3.

**Outcomes**
Smoking cessation during second trimester, biochemically validated with serum and salivary cotinine levels. No neonatal outcomes provided

**Notes**
Study ceased after only 30/40 women recruited due to severe fetal withdrawal symptoms in the 30th recruit. The code concealment was broken to reveal the allocation of the woman to placebo. The trial was discontinued due to concerns of providing placebo patches

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**Risk of bias**

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Described as &quot;randomised&quot;.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Yes</td>
<td>Placebo controlled trial.</td>
</tr>
</tbody>
</table>
| Blinding? Women and clinical staff | Yes | Placebo controlled trial. Described as double-blind. Placebo provided but most of the

---

**Hotham 2005** (Continued)

| Blinding? Women and clinical staff | No | No placebo patches available. |
| Incomplete outcome data addressed? All outcomes | No | 14/40 withdrew from the study (35% attrition). All withdrawals included in this analysis as continuing smokers |
| Free of selective reporting? | Unclear | No birth outcomes reported. |
| Free of detection bias? | Yes | Exhaled CO and salivary samples |
Kapur 2001  (Continued)

<table>
<thead>
<tr>
<th>Incomplete outcome data addressed?</th>
<th>No</th>
<th>Biochemical validation data was missing for approximately a third of the sample. Not clear if there was ITT analysis</th>
</tr>
</thead>
</table>

Kendrick 1995

Methods

Cluster-randomised trial of smoking cessation in public prenatal and WIC clinics in Maryland, Colorado and Missouri, USA, 1987-89

Participants

5262, 6087 and 4943 pregnant women screened in Colorado, Missouri and Maryland respectively, with nearly 50% of women in each State smoking. Smoking defined as “even a puff within the last 7 days before the women knew she was pregnant” (includes recent quitters). Consent for data collection ranged from 66% to 79%. High proportions were young, < 12 years education, White, unmarried and poor. Mean gestation at enrolment = 15.2 - 16.6 weeks. Mean cigarettes/day at enrolment combined for smokers = 12 cigarettes/day

Interventions

Control: UC not otherwise specified by usual clinic staff. Interventions based on stages of change, but differed by State, locally adapted with some detailed development. Colorado: 1-5 minutes counselling; assessing smoking status; quitting tips; supportive statements by nurse-clinicians; healthcare providers’ Guide; 8 brochures for pregnant smokers; additional one for women postpartum. Maryland: brief clinic-based counselling program + self-help material focussing on the stages of quitting. Missouri: “becoming a life-long smoker” 6 minutes with clinic patient brochures, flip charts; 1-2 minutes at WIC clinics training staff, chart documentation and forms. All included effects of smoking on the fetus; benefits of quitting; quitting techniques; developing social support; preventing relapse and limiting exposure to environmental tobacco smoke. All materials were at 6th Grade reading level. Intensity rating: I = 3, C = 1 (not clear and varied)

Outcomes

Smoking cessation biochemically validated with urine cotinine. The necessary adjustment for clustering means that the data cannot be put into the standard table of comparisons. Adjusted data showed no differences in verified quitting, mean birthweight or low birthweight

Notes

Intracluster correlation of 0.003 reported and used for adjusting outcome figures in analysis. Substantial misclassification of self-report as non-smoking: 28% at enrolment;
35% at 8th month; 49% of self-reported quitters at intervention clinics; 32% of self-reported quitters at control clinics. Process evaluation suggested less difference between I and C clinics than might have been expected. Project staff felt that the use of existing staff to deliver the new interventions and to collect data affected the study negatively especially given the time needed to process questionnaires and urine samples. This led to less than full implementation and variable motivation to promote smoking cessation counselling among staff.

**Risk of bias**

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Clinics stratified by size of clinic and also by prior low birthweight programme (Colorado) or % minority clients (Maryland), and randomly assigned to deliver either intervention or continue with standard care. No details of randomisation provided</td>
</tr>
<tr>
<td>Blinding?</td>
<td>Unclear</td>
<td>Unclear whether participants and providers were aware of clinic allocation.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Unclear</td>
<td>Records used to collect some outcome data for respondents lost to follow up. Loss to follow up balanced in experimental and control groups. Varying enrolment and attrition rates in different centres. No ITT analysis</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>High rates of non-disclosure for smoking outcomes.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Biochemical validation by urinary cotinine.</td>
</tr>
</tbody>
</table>

**Lawrence 2003**

Methods

Cluster-randomised trial of 2 different interventions, in community midwife clinics in the West Midlands region of the UK.

Participants

Inclusion criteria were all women seen in routine antenatal appointments who were aged 16 years or over, a current smoker at booking. Women not fluent in English were excluded. Initial target of 1440 participants was reduced to 900 due to slow recruitment (particularly in standard care arm). Eligible smokers approached A = 34%, B = 47%, C = 75%. Refusal rate A = 13.4%, B = 7.2%, C = 22.5%. Mean cigarettes per day at baseline were similar between groups 207 women (22.5%) withdrew from the study, 77 due to early end of pregnancy, 38
changed practice, 32 declined further participation and 60 left for other reasons, with similar rates of withdrawal between groups, except for failure to complete the questionnaire and provide a urine sample, with highest compliance in Group C.

### Interventions

Control group (A) received standard care. Midwives received a half day training on research protocol, and asked all midwives to give women the Health Education Authority booklet "Thinking about stopping". Group B midwives received 2 and a half days training on theory of transtheoretical model. Participants received a set of 6 stage based self-help manuals "Pro-Change programme for a healthy pregnancy". The midwife assessed each participant’s stage of change and pointed the woman to the appropriate manual. No more than 15 minutes was spent on the intervention. Group C midwives received the same training as for Group B, and participants received the same self-help manual and intervention as group B. Additionally the participants used a computer programme, which consisted of questions and auto feedback of what stage they were in and what this meant, and a range of other concepts. It took about 20 minutes for the woman to complete. Printed information of the feedback was sent to the participant within a week of the intervention.

Intensity rating: I = 4, C = 2.

### Outcomes

Biochemically validated smoking cessation at 28-30 weeks' gestation and 10 days post-birth. Point prevalence and sustained abstinence of 10 weeks or more were calculated. Arms B+C combined for intervention figures in this analysis.

Effect of midwife training (attitudes, expectations, confidence, concerns and routine practice) was assessed by pre-post training questionnaires.

Subsequent papers measure and describe smoking cessation at 18 months postpartum, movement in stage of change, partner quitting, social support mobilization, and the stress of receiving the intervention.

### Notes

Intracluster correlation of 0.003 reported and used for adjusting outcome data included in this meta-analysis. Sample size calculation given, but unable to recruit sufficient numbers. 17 practices added to arm A, 12 to arm B and 0 to arm C to increase recruitment.

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>A computerised minimisation programme was used to stratify 72 eligible practices into 3 equal groups from 101 available practices</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>No</td>
<td>Further practices were added to the sample because of slow recruitment - these were not randomly allocated</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Neither providers nor women blinded to this educational intervention</td>
</tr>
<tr>
<td>Women and clinical staff</td>
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<td></td>
</tr>
</tbody>
</table>

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*Interventions for promoting smoking cessation during pregnancy (Review)*

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Incomplete outcome data addressed?

| All outcomes | No | Different rates of recruitment and follow up in different arms of the trial. 22% withdrew and data on smoking status were only available for 67% of women. Where there was no urine sample available women were treated as continuing smokers. There was a sensitivity analysis carried out for those lost to follow up, and these figures were used in this analysis. |

Free of selective reporting?

| Unclear | Not apparent. |

Free of detection bias?

| Yes | Urinary cotinine analysis. |

Lilley 1986

Methods

| A randomised trial in Newcastle Hospital antenatal clinic (UK) and with other shared antenatal care providers of individual counselling to promote smoking cessation over 3 months in 1982 |

Participants

| All pregnant women currently smoking >= 1 cigarette a day at the time of the first antenatal clinic, and < 28 weeks’ gestation. 156 contacted, 5 > 28 weeks leaving 151, 5 exclusions (not pregnant, guilt over previous stillbirth, and 3 miscarriages), leaving 72 (I) + 73 (C) |

Interventions

| Control: usual antenatal care with possible exposure to a concurrent television series (6 x 10 minute programme on stopping smoking in pregnancy). Intervention: (i) 10 minutes anti-smoking advice from SHO (Resident) based on Health Education Council Booklet “So you want to stop smoking... for you and your baby”, an additional leaflet from the same source, and copies of the booklet for other family members; (ii) woman’s GP sent a letter describing the purpose of the study and a booklet, asked to reinforce the information at usual contacts; (iii) 2 weeks later a letter of reinforcement was sent to the woman; (iv) 4 weeks later there was a preplanned home visit to provide anti-smoking advice with a letter of the same advice sent if the woman was not at home; (v) possible exposure to the concurrent TV series. Intensity rating: I = 4, C= -2 (not clear). |

Outcomes

| Smoking status and smoking/day assessed 6 weeks later. Reduction in mean cigarettes/day (the standard deviation used in the analysis in this review was calculated from a P value of 0.05 given in the paper) |

Notes

| Short interval between intervention and assessment. |
### Lilley 1986  (Continued)

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Described as balanced “simple random allocation” in blocks.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Information not provided.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Neither women nor providers blinded to this educational intervention</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Unclear</td>
<td>Small loss to follow up, some missing data but balanced across groups. No ITT analysis</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>None apparent.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>No</td>
<td>No biochemical validation of reported smoking behaviour.</td>
</tr>
</tbody>
</table>

### Loeb 1983

**Methods**

Trial of anti-smoking interventions (individual and group) based on the MRFIT trial, carried out in Oregon (USA) where 95% of pregnant women attending one of the two hospitals were enrolled in the Kaiser Permanente HMO, 1979-1980

**Participants**

Pregnant women contacted at first antenatal visit: 3856 asked about smoking; 963 self-reported current smokers (25%). 21% of them in receipt of public assistance but only 7% of non-smokers. Poor participation in the study: 83.6% contacted; refusal rate 37%

**Interventions**

Control group - routine care. Planned intervention: (i) letter of invitation with sac, reminder letter; (ii) group information meeting on programme for respondents with short information session by physician; (iii) individual session with trained smoking counsellor; (iv) 6 x 1.5 hour group sessions, once a week; (v) subsequent support groups, individual sessions and phone calls

Theoretical basis for intervention: behavioural techniques to encourage cessation

Intensity rating: I = 4, C = not clear.

**Outcomes**

Smoking cessation by late pregnancy, biochemically validated with cord blood thiocyanate in a subsample, but no misclassification of self-reported non-smoking

**Notes**

Very poor response to group sessions so intervention changed over the course of the trial to individual counselling, which also had very low participation overall: 18% active; 25% dropped out; 38% did not participate; 18% could not be contacted

**Risk of bias**
**Loeberg 1983**

(Continued)

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>No details of randomisation.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Described as “randomly assigned”.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Women and clinical staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td>Attrition rates high at all stages of this study. Approximately 45% lost to follow up. Questionnaire response rate 25%. No intention to treat analysis and high attrition rates</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Birth outcomes reported by smoking status, not intervention group.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Unclear</td>
<td>Biochemical validation at delivery on a small sub-sample.</td>
</tr>
</tbody>
</table>

**Lowe 1997**

Methods

A randomised trial of relapse prevention among women who had stopped smoking since the beginning of pregnancy, in the public maternity clinics of a large hospital in Birmingham, Alabama 1987-1989, USA

Participants

Pregnant women recruited at their first prenatal visit reporting as having quit since conception, no exclusions mentioned, n = 115, 9 refused to participate leaving 106 of whom 3 had a miscarriage, 4 moved and 2 had babies for adoption, leaving 54 (I) and 45 (C). Follow-up data were available on 80%

Interventions

Control: nurses’ advice to all women not to smoke.

Intervention: 10 minute counselling by health educator using smoking relapse prevention materials on effects of smoking; benefits of maintaining cessation; possible problems; smoking triggers; solutions to smoking cues; strategies for staying quit, contract, and flip chart (5th Grade reading material, “stay quit buddy” encouragement = non-smoking gifts and pamphlets) plus clinic reinforcement by prenatal staff through reminder form in the notes and staff training to confirm abstinence, praise, encourage continuing cessation

Intensity rating: I = 4, C = 2.

Outcomes

Continued smoking cessation in late pregnancy, biochemically validated with salivary thiocyanate. Included in relapse prevention outcome tables only

Notes

Concurrent trial with Windsor 1993.

Process evaluation showed good implementation.

Issues of possible ‘contamination’ in clinics with individual randomisation discussed
Lowe 1997  (Continued)

<table>
<thead>
<tr>
<th>Risk of bias</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Described as “randomly assigned”.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>No information provided.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Notes flagged.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Notes flagged.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Unclear</td>
<td>Approximately 20% attrition. Intention to treat analysis for main outcome, those lost to follow up treated as continuing smokers</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Unclear what data were collected. Only smoking outcomes reported</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Salivary thiocyanate analysis.</td>
</tr>
</tbody>
</table>

Lowe 1998a

Methods
Controlled clinical trial in antenatal clinic of a large metropolitan public hospital in Brisbane (Queensland, Australia) to assess the effectiveness of a self-help booklet developed by Windsor (for women of low socioeconomic status - mostly black women - in Alabama), in urban Australian women. This first trial (i) was followed by a second one (ii) with a modified intervention, but no other change to the methods.

Participants
All pregnant women attending for a first antenatal clinic, who identified themselves as current smokers, had no current pregnancy complications and were not planning to have the child adopted, were approached at their first antenatal clinic appointment (n = 244 - 27 who declined = 217). (ii) Participation rate of 91%, 108 women recruited, 8 had a miscarriage or fetal death or discontinued care at the hospital; 2 withdrew from the study and 19 were lost to follow up (LTFU) by 20 weeks. All those LTFU were counted as continuing smokers.

Interventions
Control: given the self-help booklet and a midwife caution against smoking. Intervention: as for control plus a 15 minutes 1:1 motivational counselling session provided by the midwife, focusing on the booklet (based on cognitive behaviour strategies), a flip chart which demonstrated the effects of smoking on the fetus, being shown how to use the manual, two contracts developed (partner and non-smoking friend) and these people contacted to sign. Aim was to increase self-efficacy and create a social support structure for women during her attempts to quit and motivating her to use the booklet. (ii) Booklet modified through focus groups with input from health promotion specialists, medical specialists and GPs, to a glossy format with coverage of additional topics (growth and development of the fetus, enjoyment of certain foods and sex during pregnancy, emotional and physical aspects of pregnancy and stopping smoking. (C): only
Lowe 1998a  (Continued)

| Outcomes | Smoking reduction and cessation assessed at the 20 week visit. Biochemical validation of smoking status in self-reported non-smokers, same for (i) and (ii) |
| Notes | Process evaluation showed poor response to the booklet. Focus groups with women from I and C identified problems with the material and made suggestions about changes. Discussions with staff showed time pressures over counselling component. Trial stopped and redesigned, see (ii). Second trial (ii) had a positive process evaluation though staff identified a range of barriers to implementing smoking cessation counselling |

**Risk of bias**

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>No</td>
<td>Quasi randomised trial with alternate weekly allocation.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>No</td>
<td>Not specified.</td>
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<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Educational intervention, so providers not able to be blinded</td>
</tr>
<tr>
<td>Incomplete outcome data addressed? All outcomes</td>
<td>Unclear</td>
<td>Loss to follow up 28%. All women lost to follow up assumed to be continuing smokers</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Unclear what data collected. Only smoking outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Urinary cotinine analysis for those reporting quitting.</td>
</tr>
</tbody>
</table>

Lowe 1998b

**Methods**

See Lowe 1998a for setting as this trial followed immediately after the first one

**Participants**

See Lowe 1998a. The participation rate was 91% with 108 women recruited of whom 8 had a miscarriage, or a fetal death or discontinued care at the hospital. 2 more withdrew and 19 were lost to follow up by 20 weeks. All those lost to follow up were counted as continuing smokers

**Interventions**

Booklet modified from the one used in Lowe 1998a, through focus group discussions with input from health promotion specialists, medical specialists and GPs to a glossy format with coverage of other topics (growth and development of the fetus, enjoyment
of certain foods and sex during pregnancy, emotional and physical aspects of pregnancy and stopping smoking).
Control group: only the midwifery caution against smoking.
Intervention: the midwife provided the booklet without any additional discussion or counselling. Intensity rating: I = 3, C = 2

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Smoking behaviour/reduction (self-report) and smoking cessation at 20 weeks, biochemically validated</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Notes</th>
<th>Process evaluation of materials was positive, though staff identified a range of barriers to implementing smoking cessation counselling</th>
</tr>
</thead>
</table>

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Quasi-randomised trial with alternate weeks allocated to control and intervention</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Not specified.</td>
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<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Educational intervention, so providers not bliders.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed? All outcomes</td>
<td>Yes</td>
<td>Loss to follow up 28%. All women lost to follow up assumed to be continuing smokers</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Unclear what data collected. Only smoking outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Urinary cotinine analysis for those reporting quitting.</td>
</tr>
</tbody>
</table>

### MacArthur 1987

**Methods**

Quasi-randomised trial in a large English city maternity hospital to identify effects on fetal size at birth mediated by an anti-smoking intervention, 1981-1982. MacArthur 2001 reported follow up when the children were 9.

**Participants**

Pregnant women smoking at booking: 29% had been pre-pregnancy smokers, 23% were smoking at booking. 1008/1156 women identified as smokers interviewed, 48 lost (early discharge, infection/isolation, changed surname); exclusions were multiple births (6 (I) + 8 (C); records not linked to hospital data 8 (I) + 4 (C)) leaving 493 (I) and 489 (C). Mean cigarettes/day at booking I = 14.4, C = 13.7
### Interventions

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention: advice to stop smoking + information or discussion of the effects of smoking on the fetus offered by the obstetrician at the first antenatal (booking) visit, supported by giving her a leaflet to be shared with the partner, family and friends. If leaflet not given by obstetrician, the midwife was asked to give it to the woman and advise her to stop smoking.</td>
</tr>
<tr>
<td>Control: routine advice, not specified further.</td>
</tr>
<tr>
<td>Intensity rating: I = 2, C = 0 (not clear).</td>
</tr>
</tbody>
</table>

### Outcomes

<table>
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<th>Description</th>
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<tbody>
<tr>
<td>Smoking cessation and reduction - biochemical validation commenced, but abandoned when it became clear it did not distinguish levels of smoking. Birthweight, length and head circumference; Height, weight, IQ and neuromaturity at 9.4 years. Experimental results only discussed in this review (data according to group allocation).</td>
</tr>
<tr>
<td>Report includes observational data (according to smoking behaviour) smoking status not biochemically validated</td>
</tr>
</tbody>
</table>

### Notes

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent not sought from individual women, implementation of the trial across all clinics routinely. Process evaluation shows poor implementation, with only 10% receiving “full intervention”. No details of the content of the leaflet. Follow-up data not sufficient for tabulation.</td>
</tr>
</tbody>
</table>

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>No</td>
<td>Based on date of booking visit.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>No</td>
<td>Alternation of 4 week blocks to intervention or control. Group allocation could be anticipated</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Caregivers not blinded to this educational intervention.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed? All outcomes</td>
<td>Yes</td>
<td>No loss to follow up apparent.</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>Detailed smoking and birth outcomes reported up to 9 years post intervention</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>No</td>
<td>No biochemical validation of reported smoking behaviour.</td>
</tr>
</tbody>
</table>
Methods

Trial of effects of peer counselling on smoking cessation and reduction in a large urban clinic in Hartford Hospital, USA, Jan 1998-Feb 2000

Participants

Low-income, uninsured women, who smoke at least 1 cigarette per day before pregnancy, less than 20 weeks' gestation, literate in English or Spanish, and intending to carry to term. High smoking prevalence in pregnancy (29%). Recruited n = 142 (I = 67, C = 75). Mean cigarettes/day at baseline significantly higher in intervention group. I = 13.3, C = 11.2

Interventions

The control group received routine care, which included the program of “Ask, Advise, Arrange and Assist”, based on cognitive behaviour, described by Windsor et al 2000. The intervention received as for the control group + peer counselling from lay community health outreach workers (telephone or home visits). Peer counsellors received 2 x 3 hours of training. Intensity rating: I = 4, C = 3

Outcomes

Smoking cessation and reduction (cigarettes/day) at 36 weeks' gestation, biochemically validated with urine cotinine and exhaled CO. Nicotine addiction assessments (Fagerstrom Tolerance Questionnaire), and breastfeeding at 6 months postpartum. Infant birthweight correlated with cigarettes/day in late pregnancy. Reduction data not included in review as adjusted data only used and high attrition

Notes

Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Computer-generated list.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Information not provided.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>Unclear</td>
<td>State that caregivers were masked but educational/counselling support intervention that women may have discussed with caregivers</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td>High attrition rates (I = 43%, C = 36%) , ITT analyses for whole sample and for those remaining at follow up</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Birth outcomes only reported by smoking status not intervention group</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Urinary cotinine levels at baseline and at 36 weeks' gestation. Exhaled CO at each prenatal visit</td>
</tr>
</tbody>
</table>
Cluster-randomised trial of a smoking cessation program in 33 prenatal, family planning and paediatric services within 12 public clinics in Chicago, Illinois, USA, 1994-6

Clinics matched on size, type, location, and racial mix of clientele. Smokers in intervention group more likely to be African-American. Participation rate I = 76% (n = 1025), C = 86% (n = 784). Mean cigarettes/day at intake

Control group received smoking cessation advice and available brochures, dependent on the clinician. The intervention group received brief advice to quit (from a variety of clinicians), a written agreement on a quit date, a take home motivational self-help booklet "Its Time", a reminder letter, and a 15 minute telephone motivational interview. High intensity intervention based on stages of change theory and Miller 2003's brief motivational interviewing approach. Intensity rating: I = 4, C = 2 (variable)

Self-reported smoking cessation and reduction (not biochemically validated) at 2, 6, 12 and 18 months post intervention. Movement in stages of change

A subsequent paper describes long-term (18 month) cessation and stress/anxiety measures at baseline and end of pregnancy by intervention group

Data from this study have not been included in the pooled analysis as it was not possible to separate out those data relating to pregnant women (as opposed to women recruited via family planning and well child clinics). Further, data were collected a specific time points post intervention; women were not recruited at a particular stage in pregnancy, so it was not clear at what stage of pregnancy or postpartum women had reached at the various follow up points. There was good process analysis and outcomes were analysed by exposure to intervention and there was a discussion of provider views

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Cluster randomisation. Described as “randomly assigned”</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Matched pairs of clinics with one allocated to experimental condition</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Educational intervention.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td>Very high attrition rates. Attrition rate I = 38%, C = 41%. For example, in the experimental group less than half of those recruited completed follow up. Outcomes only reported on participants who were exposed to the intervention, not on all in the intervention group. No ITT analysis and no discussion of reasons for high attrition</td>
</tr>
</tbody>
</table>

Risk of bias
### Manfredi 1999  (Continued)

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Described as “randomly assigned”.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Not stated.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Caregivers not blinded to this educational intervention.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed? All outcomes</td>
<td>No</td>
<td>15% attrition at follow up, but missing data for many variables. Those lost to follow up were treated as continuing smokers in the analysis</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>Not apparent.</td>
</tr>
</tbody>
</table>

### Mayer 1990

#### Methods
Trial comparing 3 smoking cessation interventions in WIC clinics in Grand Rapids, Michigan, USA, 1985-86

#### Participants
Women currently smoking (>= 1 cigarette/day) comprised 271/641 attending the clinics (42%), 219 agreed to take part, data on 186. Losses to follow up were that a quarter refused, and the rest either moved, changed their source of antenatal care or had a miscarriage (no details of numbers). Mean cigarettes/day prior to pregnancy $I = 19.9$, $C = 20.3$

#### Interventions
Control: printed information about the risks of smoking in pregnancy.
Intervention (a) risk information: 10 minute discussion with a health educator using a flip chart and a brochure but with no behaviour change counselling or self-help manual.
Intervention (b) multi-component: 20 minute 1:1 counselling including risk information (“Because I Love My Baby” Am Lung Assoc, flip chart and brochure to take away), and behavioural change manual adapted from RA Windsor and the Am Lung Assoc “Freedom from Smoking” focusing on contracting and self-monitoring (CBT)
Intensity rating: $I = 3$, $C = 2$.

#### Outcomes
Smoking cessation in late pregnancy and postpartum, biochemically validated with salivary thiocyanate in approximately a third of participants, but no adjustment for misclassification

#### Notes
No process evaluation.
McBride 1999

Methods

Randomised trial of relapse prevention at the Group Health Cooperative of Puget Sound (Seattle, USA) (HMO), and Park-Nicollet of Minnesota (USA), a multispecialty group practice. Years of data collection not stated.

Participants

Women booked for a first prenatal visit were offered, by letter, study participation and unless they opted out were given a baseline telephone interview. Women who had completed the baseline survey, were < 20 weeks of pregnancy, were currently smoking or had smoked in the 30 days before pregnancy but had quit at the time of the baseline survey. They were stratified by baseline smoking status. 9152 approached, 714 ineligible because of miscarriage, pregnancy termination, inability to speak English; 697 refused; 262 could not be reached by telephone after repeated attempts. 7479 completed survey. 1007 were randomised: 88 miscarried and were excluded; 22 were sent wrong intervention material; 897 participated (457 from Seattle, 440 from Minnesota). Mean cigarettes/day 4.8 in intervention and control groups.

Interventions

There were 3 stages of change based interventions, all delivered by mail or telephone without involving prenatal care providers. (1) Self-help booklet “Stop now for your baby”; 5th grade reading level; health effects of smoking during pregnancy; specific suggestions for quitting (setting date, enlisting support). For recent quitters: stress reduction techniques; suggestions for handling high-risk situations; pregnancy-appropriate behavioural alternatives to smoking. 2 and 3. High intensity interventions in pre and postpartum groups also received: (i) a personalised letter acknowledging baseline readiness for change, personal health concerns, motivation to quit, comparison with other pregnant women who had successfully quit. (ii) relapse prevention kit within 2 weeks of completing the 28 week follow-up survey. (iii) a booklet which discussed transition from pregnancy and factors that influence cessation and relapse; practical tips for high-risk situations, strategies for avoiding self-defeating reactions to slips, personal anecdotes from women who quit. (iv) 3 antenatal counselling phone calls: 2 weeks after the booklet and 1 and 2 months later. Calls were open-ended but with standardised protocol based on motivational interviewing and with stage-based objectives average 8.5 min. 3. The pre-post group received an additional 3 counselling calls in the first four months after birth reinforcing themes from the Relapse Prevention booklet; 3 newsletters at 2, 6 and 12 months postpartum about health effects of environmental tobacco smoke and the importance of being a non-smoking parent. Intensity rating: I = 4, C = 3.

Outcomes

Smoking cessation; relapse prevention and patterns of smoking; biochemically validated with salivary cotinine at 28 weeks’ gestation; 8 weeks’ PP; 6 months PP; and 12 months PP. Response rates were 92% at 28 weeks; 91% at 8 weeks’ postpartum; 89% at 6 months postpartum; 87% at 12 months postpartum. Salivary cotinine requested from all who reported abstaining for 7 days (< 20 ng/ml as cut off).
A subsequent paper reports partner abstinence.

**Notes**
Process evaluation describes participation in specific intervention components, including relapse prevention.

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Not described.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>No information provided.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Caregivers not blinded to this educational intervention.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed? All outcomes</td>
<td>Unclear</td>
<td>Approximately 10-15% but higher levels of missing data for some variables</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Smoking outcomes only reported. Not clear what data were collected. For self-reported smoking status non-respondents were treated as continuing smokers</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Salivary cotinine analysis.</td>
</tr>
</tbody>
</table>

## McLeod 2004

**Methods**
Cluster-randomised trial of smoking and breastfeeding education in the Lower North Island, New Zealand, recruited from June 1999-September 2000

**Participants**
The midwifery team was the unit of randomisation, which were stratified by locality and randomised into 1 of 4 groups. All 121 midwives in selected localities in the lower north island were invited to take part. Midwives asked all women who had smoked at the time they conceived to take part in the study. 80 midwives consented to take part and received training, and 61 midwives recruited women to the study (76%). 46/349 women approached declined to take part in the study

**Interventions**
(1) Control group received UC; (2) Smoking education group received midwife training to implement education and support; (3) breast-feeding group received training and support to implement education and support for BF; (4) combined group midwives received training to implement smoking education and BF programmes. Stratified by breastfeeding group for analysis (2x2) with control and BF only group (n = 120) and smoke education and combined group (n = 177)
Smoking education included motivational interviewing provided by a midwife (who was allocated an extra funded visit and given 4 hours training with a counsellor), flip-chart, video-tape
Intensity rating: I = 4, C = 3.
### McLeod 2004  
*(Continued)*

| Outcomes                                                                 | Smoking cessation and reduction at 28 and 36 weeks' gestation, and 6 weeks and 4 months postpartum  
Breastfeeding outcomes.  
Intervention developed with provider input and detailed discussion of provider views included |
<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>Notes</td>
<td>Refusal rate approximately 20%. Design effect for clustering reported, so outcome figures used</td>
</tr>
</tbody>
</table>

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Random sequence generation using excel for each stratum.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Yes</td>
<td>Group allocation by external statistician.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>Women and clinical staff: No</td>
<td>Not possible to blind midwives to allocation group. Women were not aware of midwife group allocation</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td>Missing data for most outcomes, 28% attrition for 4 month postnatal follow up. Available case analysis, only women who moved from the area were excluded</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Smoking status only reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Cotinine serum assay.</td>
</tr>
</tbody>
</table>

### Moore 2002

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Participants</td>
<td>128 community midwives in 3 trusts were randomly allocated to 6 strata. Inclusion criteria: women attending first visit; &gt; 16 years; &lt; 17 weeks’ gestation; literate in English. Smokers counted as those who reported “I smoke now”, “I smoke now but have cut down since I thought I might be pregnant”, or “I have stopped smoking since I thought I might be pregnant”. Mean number of cigarettes per day at baseline I = 16, C = 15.1</td>
</tr>
<tr>
<td>Interventions</td>
<td>Control group midwives continued to give routine advice according to usual practice. Intervention midwives gave their UC and spent at least 5 minutes introducing a series of 5 self-help booklets “Stop for Good”, based on stages of change theory, and gave them a copy of the first booklet. Subsequent booklets were mailed directly to the woman Intensity rating; I = 3, C = 2 (not clear).</td>
</tr>
</tbody>
</table>
Outcomes

Self-reported smoking cessation validated by urine cotinine (94%). Perinatal outcomes: birthweight, gestation at birth. Stillbirths, perinatal, neonatal and childhood deaths not reported but available on request. Smoking reduction in mean cigs/day.

Notes

Reported intracluster correlation of 0.031 used to adjust outcome data for inclusion in outcome tables. Detailed qualitative and quantitative process analysis of participants' and midwives' views of the intervention, which suggested poor implementation in some areas. Some concerns about contamination of control group. Sample size justification.

Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Stratified random allocation by computer-generated random numbers. 118 midwives stratified according to workload and randomly allocated to provide intervention or control care</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>No information.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Yes</td>
<td>Some attrition: 8%. Drop-outs included in denominator for ITT analysis</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>No adjustment for clustering.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Urinary cotinine levels analysed.</td>
</tr>
</tbody>
</table>

O'Connor 1992

Methods

Quasi-randomised (allocation by alternate days) trial of a new smoking cessation programme provided by public health nurses in the antenatal clinic of an Ontario (Canada) teaching hospital, compared with previous standard care. Dates of data collection not specified.

Participants

1028 women screened, 267 daily smokers (673 non-smokers, 88 spontaneous quitters). Ineligible (39) late gestation; miscarriage; missed abortion; termination; malformation; mental illness; mental retardation. Refusal (4). 224 at baseline; 202 at 1 month follow up; 174 at 36 weeks; 190 at 4 weeks' postpartum. Reasons for dropout: miscarriage (17), no further clinic visit (3), subsequent refusal (2), and preterm birth (16 - all of these seen postpartum), and 12 lost to follow up. Mean cigarettes/day at intake I = 13, C = 12.8.
Interventions
Control: 3-5 minutes explanation of the risks of smoking during pregnancy and a pamphlet inviting women to a 2 hour cessation class in the evenings where the Windsor self-help manual would be taught and provided.
Intervention (provided in English or French): 20 minutes 1:1 session with a public health nurse going through the Windsor self-help manual program + follow-up telephone call at a mutually agreed time. High intensity intervention. Intervention intensity: I = 4, C = 2

Outcomes
Smoking cessation biochemically validated by urine cotinine at end of pregnancy and 6 weeks' postpartum

Notes
No one attended the evening group class which was offered and was free.
Interesting discussion of women’s perceptions of risk based on personal experiences.
Process evaluation showed 93% received the intervention by second visit

Risk of bias

<table>
<thead>
<tr>
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<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>No</td>
<td>Alternate according to the day of the week.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>No</td>
<td>Nurse delivering the intervention attended on alternate days. Authors state the appointments were made by a person who was unaware of the intervention days</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Educational intervention by designated nurse.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td>Full data available for 76%.</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Unclear what data were collected. Smoking cessation outcomes only reported ITT analysis (with drop-outs treated as continuing smokers) was not set out in the paper but authors state that this had been performed, and that this did not change the size of the treatment effect. Women lost to follow up not included in this review</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Reported smoking validated by urinary cotinine levels.</td>
</tr>
</tbody>
</table>
Olds 1986

Methods
Randomised trial with 4 arms whose aims were to improve the uptake of prenatal care and pregnancy outcomes, especially low birthweight, in a semi-rural county of New York State, USA, 1978-1980

Participants
Active recruitment of pregnant women with no prior live births + any of the following: < 19 years; single; low socioeconomic status, and any other women with no prior live births who wished to participate in the program. Exclusions were > 25 weeks' gestation (though some were enrolled at 25-29 weeks). Recruitment was through private obstetricians' offices, planned parenthood, public schools health department antenatal clinics and other health and human service agencies. 10% of target population entered prenatal care too late, 10% were not referred from private care, 500 interviewed, 400 participated; 47% < 19, 62% single, 61% low SES. Non-Whites (46) excluded because too few; serious maternal or fetal conditions (20) excluded. Mean cigarettes per day at intake: C = 6.94, I = 7.65

Interventions
Control (i) health and developmental screening of the baby at 12 and 24 months; (ii) (i) + free transport to pregnancy and well-child visits (control); (iii) (i) + (ii) + nurse home visits during pregnancy (intervention); (iv) (i) + (ii) + (iii) + nurse home visits in child's first 2 years.
The focus of the home visiting was individualised from a detailed curriculum dealing with information on fetal and infant development; improvement of maternal diet; monitoring weight gain; elimination of cigarettes, alcohol and drugs; identifying pregnancy complications; encouraging rest, exercise and hygiene; preparing for labour birth and early newborn care. The intervention was also described as enhancement of informal support systems and linkage of parents to community services. Intensity rating: I = 4, C = 0.

Outcomes
Smoking cessation with biochemical cotinine validation in a subsample (n = 116). Data not included in high intensity outcome tables, as smoking was not the focus of the intervention

Notes

Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>No information provided.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Not specified.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff?</td>
<td>No</td>
<td>Home visitation programme.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed? All outcomes</td>
<td>No</td>
<td>Very high attrition. Smoking outcomes only reported on less than 50% (141/354 recruited). No explanation for reason the outcome was not reported in the remaining participants. No ITT analysis</td>
</tr>
</tbody>
</table>
Olds 1986  (Continued)

<table>
<thead>
<tr>
<th>Free of selective reporting?</th>
<th>Yes</th>
<th>Detailed range of outcomes reported.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Serum cotinine analysis on sub-sample of 116/354.</td>
</tr>
</tbody>
</table>

Panjari 1999

<table>
<thead>
<tr>
<th>Methods</th>
<th>Randomised controlled trial of personalised smoking cessation interventions in a low socioeconomic population in Melbourne, Victoria, Australia. Data collected from April 1994-June 1996</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Women who identified as “current smokers” at their first antenatal visit at approximately 12 weeks’ gestation (“even a puff in the last 7 days”). Exclusion criteria: &gt; 20 weeks’ gestation; not literate in English; drug dependency. Mean cigarettes per day = 11 in both groups. Participation rate = 52% (n = 1013), with the majority of eligible non participants refusing to enter the study</td>
</tr>
<tr>
<td>Interventions</td>
<td>Control group received UC, which included advice at the discretion of the caregiver, a group counselling session, and a pamphlet “Smoking &amp; Pregnancy”. The intervention group received as for the control group plus 4 counselling sessions by a midwife specifically trained and employed to provide smoking cessation counselling, using CBT. Sessions included video presentation, interactive discussion and strong verbal messages. These were followed up with a 5 - 10 minute personalised counselling session. High intensity intervention: I = 4, C = 2</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Self-reported smoking cessation biochemically validated with urine cotinine at 36 weeks’ gestation, 6 weeks’ postpartum, and 6 months postpartum. Breastfeeding at 6 weeks’ and 6 months postpartum. General health assessment at first visit and 36 weeks. Preterm delivery rate, mean birthweight, proportion LBW (&lt; 2500 g) Reduction in mean cigarettes/day and cotinine levels. General health questionnaire (including stress and depression measurement) at baseline and end of pregnancy</td>
</tr>
<tr>
<td>Notes</td>
<td>Process evaluation showed 71% women in the intervention group received the full intervention</td>
</tr>
</tbody>
</table>

Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>No information.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Described as “randomly allocated”.</td>
</tr>
<tr>
<td>Blinding?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women and clinical staff</td>
<td>No</td>
<td>Educational intervention delivered by clinic midwife.</td>
</tr>
</tbody>
</table>
Incomplete outcome data addressed? | No | Only 52% eligible agreed to participate, and 22% attrition. Only women available for follow up included in the analysis.

Free of selective reporting? | Yes | A detailed list of birth outcomes reported.

Free of detection bias? | Yes | Urinary cotinine levels measured at baseline and in late pregnancy.

**Methods**
Cluster-randomised trial in Massachusetts, USA of implementation of the “Quit Together” study. Data were collected from May 1997 to November 2000.

**Participants**
Unit of randomisation was 6 community health centers. Eligibility: pregnant women, English or Spanish speaking, less than 32 weeks' gestation, current smoker or spontaneous quitter, planning to remain in area for 6 months after delivery.

**Interventions**
The dissemination intervention consisted of provider training based on national clinical practice guidelines, an office practice management system for routine screening and follow-up reminders, and establishment of program boards. The intervention to women was based on motivational interviewing and the “4As” and the trial conducted by Windsor 2000a.

Intervention intensity: I = 3, C = 3.

**Outcomes**
Biochemically validated smoking cessation at end of pregnancy, and 3 and 6 months postpartum.
Reduction in mean cigarettes/day.

**Notes**
No estimates of clustering effect reported, so sensitivity analysis conducted and intra-cluster correlation of 0.10 used to adjust data for inclusion in outcome tables.

**Risk of bias**

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
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<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>No information provided.</td>
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<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>No information provided.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Sites aware of allocation status.</td>
</tr>
<tr>
<td>Women and clinical staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td>One clinic dropped out due to poor recruitment.</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Petersen 1992

**Methods**  
A randomised trial comparing the impact on smoking cessation of 2 different packages of material mailed to current smokers and recent quitters at a large Boston HMO, USA, 1986-1988

**Participants**  
English-speaking women enrolling in prenatal care; >= 18 years; < 24 weeks’ gestation who reported themselves as currently occasional or regular smokers or who had quit smoking in the previous 3 months. 1439/1442 screened (3 refused), 317 current/recent smokers, 93 dropped out because of miscarriage, termination, moved away or left the HMO; 274 at second assessment and 224 at 8 weeks' postpartum. 78 control and 71 intervention at baseline

**Interventions**  
UC: routine obstetric care, mailed list of community-based smoking cessation resources other pregnancy-related health education materials.  
Intervention: pregnancy-specific self-help manual (Am Lung Assoc and Harvard Community Health Plan (HMO)) and audiotape on safe aerobic exercise and pregnancy-related relaxation, mailed with other health-related education. Smoking component emphasised behavioural strategies for quitting, issues and concerns specific to pregnant women, non-smoking as part of a continuum of care in pregnancy; included a maintenance section for the postpartum period. Intervention based on CBT. Brief repeated counselling by obstetricians and midwives for both groups as part of routine care. Intensity rating: I = 3, C = 2

**Outcomes**  
Smoking cessation for smokers and spontaneous quitters at mid-pregnancy and 6 months, postpartum. Biochemical validation in 50% women  
Mean birthweight, low birthweight (< 2500 g) and very low birthweight (< 1500 g) outcomes

**Notes**  
Refusal of urine test = coded as smoking.  
Substantial misclassification of non-smoking self-report at 6 months gestation 24% controls 21% intervention (and 30% in clinic where the intervention was more intensive). Data from two interventions combined in relapse prevention outcomes, so not included in tables

### Risk of bias

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<th>Description</th>
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</table>

Interventions for promoting smoking cessation during pregnancy (Review)

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### Petersen 1992 (Continued)

<table>
<thead>
<tr>
<th>Adequate sequence generation?</th>
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<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
</tr>
<tr>
<td>Blinding?</td>
<td>Unclear</td>
</tr>
<tr>
<td>Women and clinical staff</td>
<td>State that caregivers were blind as materials to the intervention group were mailed. Not feasible to blind women</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
</tr>
<tr>
<td>All outcomes</td>
<td>224 of 317 randomised completed the study. 30% attrition. Those refusing urine testing were treated as continuing smokers but not clear that analysis included all randomised women</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
</tr>
<tr>
<td>Polanska 2004</td>
<td></td>
</tr>
</tbody>
</table>

**Methods**

Cluster-randomised trial in the Lodz district, Poland. Data collected 2000-2001

**Participants**

15/33 maternity units were allocated to intervention (10) or control (5) groups
Eligibility criteria: current smokers or women who quit 1 month before the visit. Exclusions: miscarriage (I = 5.1%, C = 6.2%)

**Interventions**

Control group: received standard written information about health risks of smoking
Intervention group women received 4 midwife home visits, based on a booklet translated from English (Ottawa) to Polish "How to talk about smoking with high risk pregnant smokers"
Intervention intensity rating: I = 4, C = 1.

**Outcomes**

Smoking cessation (spontaneous quitters and smokers), mean birthweight

**Notes**

No estimates of clustering effect reported, so sensitivity analysis conducted and intracluster correlation of 0.10 used to adjust data for inclusion in outcome tables. High refusal rate
### Pollanska 2004 (Continued)

<table>
<thead>
<tr>
<th>Adequate sequence generation?</th>
<th>Unclear</th>
<th>Notes random allocation, but no description of how this occurred. Only 15/33 eligible clinics allocated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Not specified.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>Women and clinical staff</td>
<td>No Caregivers not blinded to this educational intervention.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Yes</td>
<td>Refusals and those lost to follow up included in analysis of smoking outcomes</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Birthweight and smoking outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>No</td>
<td>Self-reported smoking status only.</td>
</tr>
</tbody>
</table>

### Pollak 2007

#### Methods
Randomised controlled trial of Nicotine Replacement Therapy. Conducted in 3 clinical sites and 5 sites which provide services for military personnel, in North Carolina, USA. Trial period May 2003-August 2005

#### Participants
Inclusion criteria: initial assessment: Pregnant women 13-25 weeks' gestation, who have smoked over 100 cigarettes in their lifetime, currently smoking 5 or more cigarettes per day, enrolled in prenatal care, equal to or greater than 18 years old, English speaking, with no evidence of cognitive or mental health problems. Secondary assessment: no evidence of alcohol or drug addiction, no history of placental abruption, hypertension, cardiac arrhythmia, myocardial infarction, previous pregnancy with congenital abnormality or family history with congenital abnormalities

1219 women eligible smokers identified, 926 approached as met inclusion criteria at initial assessment. 181 randomised as met secondary assessment and did not refuse (79% refusal rate). A further 102 withdrew from the study or were unable to be contacted before the end of pregnancy assessment, but were included as continuing smokers in the analysis (participation rate = 43%)

Control (CBT only) n = 59, Intervention (CBT+NRT) n = 122. (1:2 randomisation)

Care program and baseline characteristics were similar for both groups

#### Interventions
Control: received a “Quit kit” (which contained a booklet, water bottle, straws, candy, exercise band, and stress management tape), as well as 3 counselling sessions from a “support specialist” based on motivational interviewing, transtheoretical model and social cognitive theory

Intervention: as above plus an option of NRT by patch, gum or lozenge. Participants could change mode of administration if they wished

Intensity rating: C = 4, I = 4.

Theoretical basis: NRT.
Outcomes measured included 7-day point prevalence abstinence after 7 weeks, at 38 weeks' gestation, and 3 months postpartum. Birthweight and mean gestation reported. A range of perinatal outcomes reported, including preterm births, NICU admissions, small for gestational age, placental abruption, fetal demise.

Notes
Sample size calculation justified, but aimed for 300. Only 181 included in final analysis, with 102 of those having withdrawn before final analysis. Associated reference discusses challenges to recruitment and the high refusal rate.

Risk of bias

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<tr>
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<th>Authors' judgement</th>
<th>Description</th>
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<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Computerised-random number generation.</td>
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<td>Allocation concealment?</td>
<td>No</td>
<td>Described as “open label randomised trial”.</td>
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<td>Blinding?</td>
<td>No</td>
<td>Caregivers and women not blinded.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td>Participation rate only 19.5%. Loss to follow up low for perinatal outcomes but more than 30% attrition for assessment of smoking status at the postnatal follow up. No birth outcome data for 10/181 women. Women lost to follow up included as smokers.</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>All adverse outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Salivary cotinine</td>
</tr>
</tbody>
</table>

Price 1991

Methods
A randomised comparison of two different minimal contact interventions to encourage smoking cessation and reduction during pregnancy, in women of low SES and low education, compared with UC in an inner urban setting, Toledo, Ohio, USA, 1987-89.

Participants
“Typically low income, single and poor”. 1164 approached, 486 (42%) were current smokers; 60% not enrolled (exclusion criteria not listed, though includes gestation > 28 weeks and refusal); 193 entered the study.

Interventions
Control: UC not specified or assessed but “usual for physicians to address this issue with participants at least 1 prenatal visit”. Intervention (i): tailored educational videotape 6.5 minutes, potential fetal risks, benefits if mother quit + pamphlet on how to quit and opportunity to ask questions of the health professional or nurse.
educator.

Intervention (ii): American Lung Association self-help booklet (with brief overview and explanation) emphasising behaviour modification skills, relation techniques and the support of significant others, + opportunity to ask questions of the health educator. Intensity rating: I = 3, C = 1

**Outcomes**

Smoking reduction (mean cigarettes/day) and cessation, validated by exhaled CO monitoring

**Notes**

Program was developed with input from a questionnaire and open-ended questions about the advantages and disadvantages of smoking when pregnant from local population to inform Health Belief Model used in program.

Commentary on the contextual factors in the lives of indigent women which lead them to have different perceptions about the relative importance of smoking

### Risk of bias

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<tbody>
<tr>
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<td>Unclear</td>
<td>Not reported.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>No</td>
<td>Tossed die (allocation could therefore be changed). Method resulted in three unequal groups, so randomisation to only 2 groups for some of the study period</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Educational intervention in antenatal clinics.</td>
</tr>
<tr>
<td>Women and clinical staff</td>
<td></td>
<td>Relatively low participation and high attrition (57% dropout) from enrolment to completion. Differential drop-out rate in the three study groups. No ITT</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td></td>
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<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Low participation and high attrition.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Biochemical validation by exhaled CO.</td>
</tr>
</tbody>
</table>

### RADIUS 1995

**Methods**

An analysis within a subset of births in the RADIUS trial (births in Missouri, USA) to see whether ultrasound of the fetus at 18-21 weeks and 31-33 weeks decreased adverse perinatal outcomes, including smoking in pregnancy. Data were collected from November 1987-May 1991

**Participants**

53,367 pregnant women; 32,317 ineligible or excluded; leaving 21,050 -3163 refused; -2357 had miscarriage or change of provider; leaving 15,530 (7812 intervention + 7718 controls). subsequently - 64 + 63 miscarriage, -131+121 records lost or women moved,
leaving 7617 + 7534; 1768 smoking (I) and 1,803 smoking (C). Smoking defined as any smoking within the year before their enrolment. Inclusion criteria = last menstrual period known within 1 week, gestational age < 18 weeks, no plans to change providers. Exclusion criteria include medical or obstetric complications, planning an ultrasound for other reasons, twin pregnancy, not intending to continue pregnancy. Intensity rating: 1 = 0, C = 0

**Interventions**
Ultrasound only, at 18-20 and 31-33 weeks, no details about feedback to the mother or others. The women in the control group only had ultrasounds if ordered by their physician for medical reasons

**Outcomes**
Self-reporting smoking cessation, recorded on birth certificate, not biochemically validated (not included in outcome tables). Mean birthweight, preterm birth (< 36 weeks) and very preterm birth (< 33 weeks)

**Notes**

**Risk of bias**

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<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
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<tr>
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<td>Yes</td>
<td>Stratified computer randomisation.</td>
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<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Information not provided.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>Unclear</td>
<td>Smoking status not revealed to sonographer. Intervention not explicitly about smoking cessation</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Yes</td>
<td>Small loss to follow up (approximately 2%). Available case analysis but smoking cessation was not a primary outcome</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>None apparent.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>No</td>
<td>No biochemical validation.</td>
</tr>
</tbody>
</table>

**Reading 1982**

**Methods**
A randomised comparison of the effects on health behaviours (including smoking) of providing specific verbal and visual feedback to the mother about fetal size, shape and movement during an ultrasound examination (or having the screen not visible and providing no specific feedback) at the first antenatal visit, in London, UK

**Participants**
Pregnant women at 10-14 weeks’ gestation; 18 to 32 years; stable relationship; Caucasian; 85% had planned pregnancy, at low risk of complications; 86% nulliparous. Exclusions: prior miscarriage or extended infertility investigations
Interventions
Control: no/low feedback.
Intervention: high feedback about the fetus, with the fetus visible. No clear smoking cessation component
Intensity rating: I = 0, C = 0.

Outcomes
Self-reported smoking cessation at 16 weeks' gestation, without biochemical validation

Notes
Not clear whether quitting was recent or not - no time period specified.
3/62 low feedback group did not attend next visit at 16 weeks.

Risk of bias

<table>
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<th>Description</th>
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<td>Described as “assigned at random”.</td>
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<td>Allocation concealment?</td>
<td>Unclear</td>
<td>No information.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>Unclear</td>
<td>Intervention with verbal feedback, so not feasible to blind women. State that those providing care were not involved in the study</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td>Small loss to follow up, but considerable amounts of missing data for some variables. Those lost to follow up not included in ITT analysis. Only smoking outcomes for approximately 50% participants are reported</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Data collected not specified.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>No</td>
<td>No biochemical validation.</td>
</tr>
</tbody>
</table>

Rigotti 2006

Methods
Randomised controlled trial of a telephone counselling intervention. Trial conducted in Massachusetts, New England, USA, between September 2001 and July 2004

Participants
Study conducted in a network-managed care organisation and a group of 65 community based prenatal care practices
Inclusion criteria: pregnant smoker (at least 1 cigarette in the past 7 days), At least 18 years of age, 26 weeks or less gestation, willing to consider altering smoking during pregnancy, reachable by telephone, English speaking and expected to live in New England for the next year
1444 pregnant smokers were referred to the study and 665 assessed as eligible. 223 refused to participate (refusal rate 34%). 442 were randomised (I = 220, C = 222)
21 women were excluded from the analysis due to miscarriage. I = 209, C = 212. 113 women did not have final assessment due to refusal (22%), baby born before assessment or lost to follow up, but were included in the final analysis (ITT analysis). Baseline characteristics of both groups were similar, though the intervention group had a significantly higher proportion of women who had made a quit attempt this pregnancy and had social support to quit from partner.

### Interventions

In addition to UC, the control group were mailed a validated pregnancy-tailored smoking cessation booklet, and their prenatal care providers were sent the ACOG smoking cessation practice guideline, with a reminder to address smoking at the subject’s visits. The enrolment call concluded with a trained counsellor providing brief smoking counselling (less than 5 minutes). Smokers who requested further assistance were referred to the Massachusetts telephone quitline.

The intervention group received as above, as well as a series of telephone calls accompanied by additional mailed written materials. Each subject had a dedicated counsellor who offered up to 90 minutes of counselling during pregnancy and up to 15 minutes over the 2 months postpartum. The trained counsellor tailored the call to the subjects needs, consistent with the 5-step smoking cessation guideline, and drew on social learning theory and the transtheoretical model of change, the health belief model, and the principles of motivational interviewing.

Intensity rating: I = 4, C = 3.

Theoretical basis: Motivational interviewing, stages of change, by telephone.

### Outcomes

Self-reported and biochemically validated 7-day point prevalence nonsmoking at end of pregnancy, and 3 months postpartum. Also measured reduction in smoking (proportion >50% reduction) and number of quit attempts.

Self-efficacy and social support at baseline and follow up.

Women’s satisfaction with the intervention.

### Notes

Initial recruitment in a managed care organisation did not yield a sufficient sample size, so 140 community-based prenatal care practices were invited to participate in the study.

### Risk of bias

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<tr>
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<th>Description</th>
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<tbody>
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<td>Yes</td>
<td>Computer generated.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Yes</td>
<td>Stated that recruiters were not aware of group allocation.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>All providers and women sent smoking cessation practice guideline.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td>Missing data (up to 30%) for outcomes measured in the postnatal period. Women lost to follow up were included as continuing smokers in this review.</td>
</tr>
</tbody>
</table>
### Rigotti 2006  (Continued)

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<tr>
<th>Item</th>
<th>Authors’ judgement</th>
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</thead>
<tbody>
<tr>
<td>Free of selective reporting?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Salivary cotinine confirmation in 66%.</td>
</tr>
</tbody>
</table>

### Rush 1992

#### Methods
Quasi-randomised study (allocation by alternate weeks) of the effectiveness of a health education intervention provided by a psychologist from booking to birth, compared with standard care, at a large maternity hospital in England, 1978-1979

#### Participants
Pregnant women registering for maternity care: 371/1645 were currently smoking at least 1 cigarette/day, 25 refused participation and 27 were lost because of miscarriage, termination or transfer to another care provider, leaving 319. No exclusions were mentioned or mean cigarettes/day pre-pregnancy

#### Interventions
Control: standard care not otherwise specified.
Intervention: counselling begun in antenatal clinic at 1st visit, with follow-up visit 2 weeks after booking at home, then monthly to the birth, each visit 15-20 minutes, (5 on average). Focus of counselling was help and support to change smoking, focus also on short and long-term benefits; advice on stopping/cutting down, strategy planned with woman, follow up planned with clear objectives, involvement of other family members, friends and partner in support. Counselling by psychologist. Intensity rating: I = 4, C = 0 (not clear - routine care)

#### Outcomes
Smoking cessation, biochemically validated with exhaled CO and serum thiocyanate. Mean birthweight in subgroup smoking >= 5 cigarettes at booking
Smoking reduction in mean cigarettes per day.
Maternal weight gain and discussion of participants' views.

#### Notes
Detailed account of the intervention in King 1981.
Subgroup analysis seems not to have been a pre-specified one.
Apparent problems with the thiocyanate measures and with loss of some data files (see paper)

### Risk of bias

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<th>Authors’ judgement</th>
<th>Description</th>
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<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>No</td>
<td>Alternation (group allocation on alternate weeks).</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Not specified.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Caregivers not blinded to counselling intervention.</td>
</tr>
</tbody>
</table>
Incomplete outcome data addressed? | Unclear | Attrition 8% and missing data for some variables. Available case analysis Those lost to follow up were included in this review as continuing smokers
---|---|---
Free of selective reporting? | Unclear | Those who discontinued counselling were analysed separately and were different at baseline from those continuing (drop outs were heavier smokers and less likely to be married)
Free of detection bias? | Yes | Exhaled CO measured at each clinic visit.

Secker-Walker 1994

Methods
A randomised trial comparing the effectiveness of individualised, but protocol-based smoking cessation counselling provided by a specially trained health educator, compared with UC, at the University of Vermont, Burlington, USA, 1984-1987

Participants
Women receiving prenatal care from obstetricians + nurse-midwives, or residents; private and public including Maternal, Infant & Child clinic for under-insured or non-insured women (23% Medicaid in study); < 25 weeks pregnant (mean gestation 13/40), smoking at least 1 cigarette a day, no exclusions mentioned. 808 interviewed, 33 refused, 175 spontaneous quitters went into separate study of relapse prevention, leaving 300 + 300; (-49: 27 miscarriage, 7 fetal deaths, 5 infant deaths), further losses were 24 + 24 changed care provider, 37 (I) + 4 (C) withdrew and 31 + 28 were lost to follow up. Mean cigarettes/day pre-pregnancy I = 24.4, C = 25.1

Interventions
Control: UC, not otherwise specified. Intervention, from a trained health educator: addressed concerns re smoking and pregnancy, health benefits of stopping, perception of the advantages and disadvantages of stopping, problem solving around those issues and coming to a decision, if yes to quitting formulating a plan, skills rehearsal + pregnancy-specific booklet. Follow up at second antenatal clinic, 36 weeks and 6 week check (where infant health and parental role modelling was discussed) and re-encouraged to quit. Health educators given selected readings, discussion, rehearsal with psychologist + health educator (both former smokers) about smoking and smoking cessation counselling techniques + American Lung Association training group for class leaders + 4 week pilot. Intensity rating I = 4, C = 1 (not clear)

Outcomes
Smoking cessation at 36 weeks’ gestation (75% biochemically validated with cotinine), 8-15 weeks’ pp, 16-24 pp, and 25-54 pp (self-reported). Mean birthweight, low birthweight, other smoking-related complications (PPROM, placental abruption and placenta praevia)
Reduction in mean cotinine at 36 weeks’ gestation. Separate paper (Secker-Walker 1995) evaluates relapse prevention.
Notes

Sample size calculated for 10% increase (from 10% to 20%) in quitting. Differential withdrawal in I and C groups a concern; good information collected on drop-outs being different. Allocation for fetal and infant deaths not reported. No adjustment for misclassification. Separate paper (Secker-Walker 1992) evaluates training program for residents.

Risk of bias

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<tr>
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<td>Described as “randomly assigned”.</td>
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<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Not stated. Unclear when randomisation took place.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>Women and clinical staff No</td>
<td>Educational intervention in antenatal clinics.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed? All outcomes</td>
<td>No</td>
<td>26% lost to follow up during pregnancy. 39% lost to follow up in the longer term. Significant difference in pregnancy drop out rates for I (13% drop out rate) and C (1.4% drop out rate). Those lost to follow up smoked more. Voluntary drop-outs treated as continuing smokers for some analyses. Women lost to follow up were included as continuing smokers in this review.</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Data collected not specified. Only smoking outcomes reported</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Urinary cotinine levels measured at 36 weeks.</td>
</tr>
</tbody>
</table>

Secker-Walker 1995

Methods

Randomised controlled trial of relapse prevention counselling for spontaneous quitters, Burlington, Vermont, USA, May 1984-June 1987

Participants

Those from Secker-Walker 1994 who had stopped smoking spontaneously before their first prenatal clinic visit (n = 175). Attrition: 5 miscarriages, 1 termination, 1 fetal death and 1 infant death leaving I = 85 and C = 80. 15 were transferred to other care, 9 dropped out and 8 were lost to follow up.
### Interventions

**Control:** UC by provider.

**Intervention:** See Secker-Walker 1994 for training of health educators and cessation planning. Concerns dealt with included staying away from smoking, perceptions of advantages and disadvantages of maintaining cessation, problem-solving and skills practice, infant risks and benefits. Women were also given a booklet

Intensity rating: I = 4, C = 0 (not clear - routine care).

### Outcomes

Smoking cessation, biochemically validated at end of pregnancy

Mean birthweight, low birthweight, preterm birth.

### Notes

Exclusion of fetal and infant deaths.

Biochemical validation showed substantial misclassification at 36 weeks in this study, more so than for the continuing smokers.

### Risk of bias

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<td>Described as ‘randomly assigned’.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Not stated. Unclear when randomisation took place.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Educational intervention in antenatal clinics.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td>Data included on approx 65% of participants who had biochemical validation of smoking status. Voluntary drop-outs treated as continuing smokers for some analyses</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Only smoking outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Urinary cotinine levels measured at 36 weeks.</td>
</tr>
</tbody>
</table>

### Secker-Walker 1997

**Methods**

Trial comparing the added effectiveness for smoking cessation during pregnancy of a free videotape using peer role models, Burlington, Vermont, USA, 1992-1993

**Participants**

Women in a state supported clinic for underinsured women, currently smoking at least 1 cigarette/day, 7/67 refused leaving 30 (I) + 30 (C), 4 had miscarriage leaving 26 + 30, 3 lost to follow up and 7 moved to another care-provider leaving 17 + 27 seen at 36 weeks. Mean cigarettes per day pre-pregnancy = 22.6
Interventions
Control: advice from obstetrician or nurse-midwife + tip sheet on quitting.
Intervention: as above + 29 minute videotape of 4 women going through the process of quitting during pregnancy; talking about feelings; coping with weight gain; getting support, which could be borrowed and taken home. Based on social learning theory.
Intensity rating: I = 3, C = 2

Outcomes
Smoking cessation in late pregnancy (36/40), biochemically validated with exhaled CO measurements

Notes
Process evaluation included perceptions of the videotape contents and showed 53% viewed the videotape. 17% had no VCR, and 10% reported having no time

Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Described as “randomly assigned”.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>No information provided.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Educational intervention.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td>20% attrition after randomisation. Loss to follow up not balanced, greater loss from the intervention group Those lost to follow up for reasons other than miscarriage (4) were included in the analysis for this review as continuing smokers</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Not apparent.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Exhaled CO measured at 36 weeks’ gestation.</td>
</tr>
</tbody>
</table>

Secker-Walker 1998

Methods
A trial of structured physician’s advice supported by individual counselling (I) provided to pregnant women during prenatal care compared with UC, Vermont, USA, 1988-92. The study included a relapse prevention component, reported separately

Participants
Woman attending the state-supported (Maternal and Infant Care) prenatal clinic for underserved women or attending the Adolescent clinic for women 12 to 18 years. 544 women smoking at pregnancy onset approached: 21 refused; 124 had quit spontaneously- relapse prevention trial; 399 into cessation trial - 197 (I), 202 (UC);
14 miscarriages, 5 fetal deaths 5 infant deaths (allocation not reported);
34 in each group moved or transferred their care;
12 women withdrew from study (7 (I), 5 (UC));
17 delivered before 36 weeks (9 (I), 8 (UC));
135 (I) and 141 (UC) remained;
114 (I) and 110 (UC) were contacted 1 year after birth, including 16 (I) and 18 (UC)
lost to follow up during pregnancy.
Mean cigarettes/day pre-pregnancy I = 26.1, C = 25.1.

Interventions
All participants received:
baseline questionnaire, measurement of exhaled CO, and brief standardised health risk
message from a research nurse about the effects of smoking on the fetus and pregnancy.
UC was: physician acknowledged women’s smoking, gave a rationale for quitting, strong
recommendation to quit and provided smoking cessation booklet designed for pregnant
women.
I was: smoking cessation protocol provided by physicians trained in its use (Secker-Walker
1992): acknowledging the woman’s smoking, her exhaled CO level, any progress towards
quitting, rationale for & unambiguous recommendation to quit, asking how she felt
about quitting and acknowledging her response, asking how she could be helped and
telling her about the counsellor, eliciting a commitment to change smoking behaviour
before the next prenatal visit and referring her to the counsellor. The aim was to gain her
agreement to set a quit date, a date when she would quit for 24 hours or a date when she
would cut her consumption by half. Counsellor advised women on ways to accomplish
the behaviour change.
2nd visit same with praise for those who had quit with referral to counsellor for help in
staying quit, 3rd 5th 7 36 week visits a briefer protocol was followed with referral for
those who wanted to change, praise for success and referral. Intensity rating: I = 4, C = 2

Outcomes
Smoking cessation maintained in late pregnancy (36/40) and 1 year postpartum, bio-
chemically validated with exhaled CO and urine cotinine.
Mean birthweight.
Low birthweight.

Notes
Methods included a detailed process evaluation of participants’ views and recall of
provider advice. Sample size justification

Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Described as “randomly assigned”.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>No details provided.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Intervention by clinic staff. Notes flagged.</td>
</tr>
<tr>
<td>Secker-Walker 1998  (Continued)</td>
<td></td>
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<tr>
<td>-----------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td>High attrition rate. More than 25% lost to follow up in pregnancy and more than 30% lost to longer-term follow up. There were further missing data for some outcomes</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Only smoking outcomes reported. Women with adverse outcomes were not included in the analysis. Women lost to follow up were not included in an ITT analysis</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Validation by exhaled CO and urinary cotinine levels</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sexton 1984</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
</tr>
<tr>
<td>Participants</td>
</tr>
</tbody>
</table>
| Interventions | Control: UC, not further specified.  
Intervention: at least 1 personal visit, supplemented by frequent mail and telephone contacts (at least 1 visit and 1 call/month) from 1 of 2 health educators (MEd level, trained in pregnancy counselling and smoking intervention), providing information, support, practical guidance and behavioural strategies for quitting.  
Information on quitting and health risks of smoking was mailed every 2 weeks with “homework” linked to telephone calls; group sessions were also available. There was a monthly lottery and in the last year of the study a monthly newsletter. Intensity Rating: I = 4, C = 1 (not clear) |
| Outcomes | Smoking in late pregnancy, 97% biochemically validated with salivary thiocyanate.  
Misscarriage; fetal deaths; mean birthweight; low birthweight; very low birthweight; % Apgar scores < 7 at 1 minute and 5 minutes; length and head circumference  
Reduction in mean cigarettes per day and mean thiocyanate |
| Notes | Change of criteria for enrolment after the first 185 as 35% of these had smoked <10/day and 71% of that group had quit spontaneously with little relapse.  
Detailed account of the intervention is in Nowicki 1984.  
Group sessions in the intervention were not readily accepted |

**Risk of bias**
### Sexton 1984

(Continued)

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Not stated.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>No information.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Educational intervention.</td>
</tr>
<tr>
<td>Women and clinical staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Unclear</td>
<td>11% attrition overall but missing data for some outcomes including smoking status. Women lost to follow up included as continuing smokers in this review</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>Extensive range of outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Validated by salivary thiocyanate.</td>
</tr>
</tbody>
</table>

### Solomon 1996

Methods
A randomised trial of a smoking cessation intervention on women’s “stages of change” (precontemplation, contemplation, preparation and action) in Vermont, USA. Dates of study enrolment not specified

Participants
Low-income pregnant women enrolled in a state-supported service for uninsured and under-insured women, receiving care in a large obstetric group practice. 521 women smoking >= 1 cigarette/day at the onset of pregnancy enrolled, 349 (67%) completed assessments at 1st, 2nd and 36 week visits. Mean cigarettes/day pre-pregnancy I = 22.8, C = 23.6

Interventions
Control: 3 minute physician-delivered protocol at first visit, acknowledging her smoking, concerns re quitting or staying quit; strong recommendation to quit and a cessation pamphlet designed for pregnant women.
Intervention: as control plus quit date or date to cut down set with on-site counselling, 10-30 minutes at 1st, 2nd, 3rd 5th and 36 week visits from trained obstetric nurse: encouragement and reinforcement of small changes, problem solving around barriers to cessation, and prevention of relapse, including dealing with other smokers, coping with the urge to smoke, withdrawals symptoms, weight gain, eliciting support for quitting. Intensity rating: I - 4, C - 2

Outcomes
Shifts in ‘stage of change’ at 2nd visit and 36 weeks’ gestation. No smoking cessation data to include in tables.

Notes
Comment made that stages of change at the first visit are not sustained. “Enthusiasm for behaviour change may wane towards the end of the gestational period when attention may be focused on labour and delivery”.
Pattern of stages’ at first visit different from community-based studies, i.e. more women
Solomon 1996 *(Continued)*

were in the later stages than would be expected at the study onset.
No difference in late pregnancy.

| Risk of bias |
|-----------------|-----------------|----------------------------------|
| Item                        | Authors' judgement | Description                          |
| Adequate sequence generation? | Unclear          | Described as “randomised”.            |
| Allocation concealment?      | Unclear          | No information.                      |
| Blinding?                   | No               | Caregivers not blinded to this educational intervention. |
| Incomplete outcome data addressed? | No               | 33% attrition for questionnaire follow up. Not clear if loss was balanced across groups. Smoking outcomes not reported |
| Free of selective reporting? | Unclear          | Several outcomes not reported in this paper. |
| Free of detection bias?      | Unclear          | Smoking outcomes not reported.        |

**Solomon 2000**

**Methods**

Trial of proactive telephone peer support in a large obstetric practice in Burlington, Vermont, USA, 1996-7

**Participants**

Women reporting smoking at least 1 cigarette in the past week at their first antenatal visit, were approached. Refusal rate = 19%. Women tended to be white, English speaking, and of lower income and education. No exclusion criteria specified. Control n = 74, intervention n = 77. Mean cigarettes/day before pregnancy I = 22.6, C = 20.2

**Interventions**

Control group received brief smoking cessation advice from a MW/Obst at each of the 3 prenatal visits and stage appropriate printed materials. MWs/Obst were provided with a 45 minute training session. The intervention group received the same as the control group plus they were offered telephone peer support from a female ex-smoker, who received 8 hours of training who called the participant within several days to provide support for positive changes in smoking behaviour. Intensity rating: I = 4, C = 3

**Outcomes**

Self-reported abstinence at 28-34/40 gestation, defined as no smoking for the past 7 days, biochemically validated with urine cotinine measurement. Movement in stages of change and proportion of smoking reduction by more than 50%

**Notes**

Process evaluation showed 53% received the peer intervention
Solomon 2000  (Continued)

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>States participants were randomised into either experimental or control condition</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>No information.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Educational intervention by care providers.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Unclear</td>
<td>Approximately 11% attrition at follow up. Report that all were analysed according to randomisation and drop-outs were treated as continuing smokers</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Only smoking outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>End of pregnancy urinary cotinine assessment to confirm smoking status</td>
</tr>
</tbody>
</table>

Stotts 2002

Methods

Trial of individualized stage of change, motivational smoking cessation intervention (“one-to-one”), with personalized feedback for “resistant” pregnant smokers, in 3 large multispecialty clinics in Texas, USA. Enrolment over a 17 month period, dates not specified

Participants

Women who continue to smoke at 28 weeks’ gestation, after having counselling and 8 self-help booklets earlier in pregnancy care. Inclusion criteria were women fluent in English, over 18 years, over 20 weeks’ gestation at first an visit, and smoke more than 5 cigarettes per week prior to pregnancy. All women had group insurance. Eligibility interview participation rate 97%. All eligible included in randomised sample (n = 269), as data collection and implementation were adopted as routine procedures, and required to formal written consent. Women in the intervention group had significantly higher proportion of women smoking > 61 cigarettes/week before pregnancy (I = 57.9%, C = 43%) and a higher proportion of partners who smoke (I = 69.6%, C = 62.5%)

Interventions

All women smoking at intake (< 20 weeks), were provided with MI counselling and motivational self-help books, based on “stage of change” program shown to be effective by Ershoff 1995. Women still smoking at 28 weeks were randomised to this study. The high intensity intervention group (and their partners) then received: a 20-30 min MI telephone counselling call (conducted by trained counsellors and nurse health educators), a personalised, stages of change based feedback letter, and a final MI-base telephone call conducted 4-5 days after the feedback letter was sent. Intensity rating: I = 4, C = 3

Outcomes

Self-reported smoking cessation at 34 weeks’ gestation, validated by an anonymous urine cotinine subsample. Postpartum follow up (6 w, 3 m, 6 m) interview response rate 61% (data collected from a separate survey, with financial incentives). Movement in “stages
### Stotts 2002  (Continued)

| Notes | Only 55% of the experimental group received the full intervention (32% were never able to be reached). Implementation analysis suggested an effect in women who received full implementation: 43% vs 34% control group. Discussion of provider views |

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Computer-generated random number list.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>No details provided.</td>
</tr>
</tbody>
</table>
| Blinding?  
Women and clinical staff | Unclear | Described as “single blind”. Cotinine analysis performed blind but other care providers and women may have been aware of group allocation |
| Incomplete outcome data addressed?  
All outcomes | No | 35% attrition for cotinine testing. 39% attrition for 6 weeks' postpartum follow up. All women lost to follow up for cotinine validated smoking status at 36/40 were included in this review as continuing smokers. |
| Free of selective reporting? | Unclear | Only smoking outcomes reported. |
| Free of detection bias? | Yes | Urinary cotinine analysis for a subset of the sample. |

### Strecher 2000

| Methods | Trial of personalised, computer generated, smoking cessation messages, in 2 university hospitals in North Carolina & Michigan, USA, Dec 1996-97 |
| Participants | Women who have “smoked 100 cigarettes in their lifetime and still smoking” or “had quit since becoming pregnant”, completed a self-administered computer screening program to determine eligibility (no details of inclusion or exclusion criteria). 173 women participated. Mean cigarettes/day smoked before pregnancy I = 20.3, C = 18.7 (ns) |
| Interventions | Control group received “a pregnant woman's guide to quit smoking” at the first visit. The intervention group entered personal data into a hand-held computer at antenatal visits, which subsequently generated personalized tailored messages, which were posted to the woman. Intensity rating: I = 3, C = 1 |
### Outcomes
Self-reported smoking cessation validated by urine cotinine at first visit, 24/40 and 6 weeks' postpartum. Attrition rate 14% in control group, and 15.2% in experimental group.

### Notes
Numbers in paper inconsistent: I = 88, C = 85 in methods section, I = 104, C = 87 in results section. No justification for change of denominators. Participant evaluation of using hand-held computers and reactions to computerised materials.

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>By computer algorithm.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Not described.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Caregivers not blinded to intervention.</td>
</tr>
<tr>
<td>Women and clinical staff</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td>Figures are inconsistent. More than 30% of the control group were lost to follow up. Figures for the intervention group were not clear. Figures not consistent. Figures from results used in analysis in this review.</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Results are conflicting.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Urinary cotinine analysis at 24 weeks' gestation and at 6 weeks' postpartum</td>
</tr>
</tbody>
</table>

### Tappin 2000

**Methods**
Pilot study of home based motivational interviewing for smoking cessation in a Glasgow Hospital, Scotland, March-May 1997

**Participants**
Self-reported women who identified as smokers on a questionnaire at antenatal clinic booking. Participation rate 75%, 27 refused. (n = 100). Mean cigarettes/day pre-pregnancy I = 19.6, C = 18.1

**Interventions**
The control group received usual advice from their prenatal providers, which should include information about smoking. The intervention group received 2-5 motivational interviewing sessions, based on stages of change, in the clients’ home conducted by a midwife trained in smoking cessation counselling. High intensity intervention. Intensity rating: I = 4, C = 2
**Tappin 2000  (Continued)**

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Self-reported smoking cessation, at 27/40 or more, with urine cotinine validation in 93%. Mean birthweight, preterm births. Ranking interviews measured movement around the ‘cycle of change’. Detailed evaluation of participant and midwifery views of interventions. Attrition rate 2%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notes</td>
<td>Good process evaluation of implementation quality according to Miller 2003’s rating tool, showed 79% of women in the intervention group received at least 2 counselling sessions, and less than 20% of the control group recalled being given smoking information at the time of booking</td>
</tr>
</tbody>
</table>

**Risk of bias**

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Random numbers stratified by deprivation.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Yes</td>
<td>Group allocation by telephone.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Midwife intervention.</td>
</tr>
<tr>
<td>Women and clinical staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Yes</td>
<td>Low attrition. Some missing data for cotinine validation. Smoking outcome results reported for all of those randomised</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>Detailed outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Serum cotinine levels measured.</td>
</tr>
</tbody>
</table>

**Tappin 2005**

<table>
<thead>
<tr>
<th>Methods</th>
<th>Randomised controlled trial of home-based motivational interviewing by midwives. Trial conducted in Glasgow, Scotland, from March 2001 to May 2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Women were recruited from two hospitals. Inclusion criteria: Pregnant smokers, less than 24 weeks’ gestation 1684 women eligible, 762 consented to take part (55% refusal rate). I = 351, C = 411 29 women lost to follow up due to termination, preterm birth, or unable to contact. Attrition rate 2% Baseline characteristics similar in both groups.</td>
</tr>
<tr>
<td>Interventions</td>
<td>The control group received counselling from a midwife who had received counselling training. Midwives provided standard health promotion including information on smoking in pregnancy from a book given to all women in pregnancy in Scotland The intervention group also were offered 2-5 additional home visits of about 30 minutes duration from the same study midwife Intensity of intervention: C = 3, I = 4</td>
</tr>
</tbody>
</table>
Outcomes
Biochemically validated and self-reported quitting at end of pregnancy, reduction (mean cotinine), birthweight. Data collected on adverse events including miscarriage, termination of pregnancy, preterm delivery, very low birthweight, neonatal death, assisted delivery and admission to NICU.
Discussion of participant and provider views of intervention and thorough process evaluation showed good implementation.

Notes
Sample size calculated by recruitment to achieve sufficient power not able to be achieved.

Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Stratified central randomisation.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Yes</td>
<td>Group allocation provided by central administrator.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Midwife intervention, with caregivers not blinded.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Yes</td>
<td>Low attrition. Some missing data for cotinine validation. Results reported for all of those randomised.</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>Detailed outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Serum cotinine levels measured.</td>
</tr>
</tbody>
</table>

Thornton 1997

Methods
Trial of smoking cessation counselling and information packs in a large public antenatal clinic, in Rotunda Ireland, during 3 months in 1995.

Participants
Inclusion criteria: women who currently smoke or had spontaneously quit since becoming pregnant; have a viable pregnancy; and intend to deliver in the hospital. Intervention group were less likely to have spontaneously quit, or be employed. Mean gestation at first visit I = 15.5, C = 15.3. Number of daily cigarettes at intake: 1-9 I = 61, C = 54; 10-19 I = 74, C = 73; 20+ I = 68, C = 65.

Interventions
The control group completed a questionnaire at first visit, followed by routine prenatal advice on a range of health issues, from midwives and obstetricians. The intervention group received as for the control group + structured one to one counselling by a trained facilitator (based on stages of change theory); partners invited to be involved in the program; an information pack; and invited to join a stop smoking support group. A
carbon monoxide monitor was available for the intervention group, to quantify smoking habit and act as a motivational tool. High intensity intervention. Intensity rating: I = 4, C = 1 (not clear)

Outcomes
Smoking cessation at delivery and 3 months postpartum, biochemically validated by exhaled CO. Reduction in mean cigarettes/day, quit attempts, comparisons of quitters and non quitters at various stages. Infant outcomes (singleton births): delivery type, mean gestation, mean birthweight, proportion LBW (2500 g), preterm births, NICU admissions, infant outcomes at 3 months

Notes
Good process analysis and participant feedback of program implementation. A high baseline smoking prevalence rate (58.7%). Limited exhaled CO measurement on postnatal ward

Risk of bias

<table>
<thead>
<tr>
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<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Random number tables with restricted randomisation in groups of ten</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Yes</td>
<td>Sealed opaque envelopes.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>Yes</td>
<td>Intervention provided by trained facilitator, with staff unaware of allocation</td>
</tr>
<tr>
<td>Women and clinical staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Yes</td>
<td>Participation rate = 81% (n = 418). Low attrition at delivery: I = 6.2%, C = 8.6%</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td>Women lost to follow up included as continuing smokers in this review</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>All outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Exhaled CO.</td>
</tr>
</tbody>
</table>

Valbo 1991

Methods
Quasi-randomised trial of smoking cessation interventions (allocation to 1 of 4 arms, 3 intervention and 1 control, by date of enrolment for care, with the four time blocks assigned randomly) in women smoking at the time of the 18 week ultrasound scan, at a regional hospital in Norway, 1988

Participants
283 women reported current smoking and wanted to quit. (mean 9-11 cigarettes/day) at the 18 weeks scan: 200 recruited, 50 in each arm. 1/3 receiving private obstetric care

Interventions
Control: not specified. Intervention (i): information provided by a physician to women in groups of 10 about
the harmful effects of smoking on mother and child;
(ii) 2 page pamphlet mailed 3 weeks after the ultrasound scan, with information on the harmful effects of smoking plus advice on how to quit;
(iii) smoking cessation group of 12 - 13 people; 5 x 2 hour meetings over 5 weeks, offered a cognitive behaviour modification program, including self-monitoring, stimulus control, response control, reinforcement control and maintenance strategies, run by a clinical psychologist
Intensity rating: I = 3 (variable), C = 0 (unclear).

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Smoking cessation and reduction assessed immediately after the intervention, biochemically validated but not reported</th>
</tr>
</thead>
</table>

| Notes              | Biochemical validation of smoking status using salivary thiocyanate was carried out but not reported in the paper. Doctor information group treated as 'control' for the other interventions because of minimal impact at either time. Smoking assessed 12 months (96% response rate to questionnaire) after the intervention showed sustained differences by allocation though more than half the quitters had relapsed in the behaviour modification group. Process evaluation showed 20% women attended only the first of the 6 group meetings, and 12% of the women in the brochure group did not read them |

<table>
<thead>
<tr>
<th>Risk of bias</th>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adequate sequence generation?</td>
<td>No</td>
<td>Described as “randomly chosen by drawing lots”. But recruitment to different arms over 4 separate periods</td>
</tr>
<tr>
<td></td>
<td>Allocation concealment?</td>
<td>No</td>
<td>Quasi- randomised design. 3 months recruitment for each of 4 arms</td>
</tr>
<tr>
<td></td>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Group educational intervention.</td>
</tr>
<tr>
<td></td>
<td>Incomplete outcome data addressed? All outcomes</td>
<td>Yes</td>
<td>Low attrition. All drop-outs treated as continuing smokers.</td>
</tr>
<tr>
<td></td>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Smoking outcomes only reported.</td>
</tr>
<tr>
<td></td>
<td>Free of detection bias?</td>
<td>Unclear</td>
<td>Salivary thiocyanate tested but results not reported.</td>
</tr>
</tbody>
</table>
Valbo 1994

<table>
<thead>
<tr>
<th>Methods</th>
<th>Quasi-randomised trial of cognitive-behavioural modification, (using RA Windsor’s self-help manual translated into Norwegian) to promote smoking cessation in women smoking heavily at the time of the 18 week ultrasound scan, in Oslo, Norway, 1990-1991</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Pregnant women attending the National University Hospital Oslo at 18 weeks for ultrasound, and smoking 10 cigarettes/day. No exclusion criteria mentioned and no refusals. 112 women recruited (1800 births/year, study over 15 months). Pre-pregnancy mean cigarettes/day: I = 8, C = 11</td>
</tr>
<tr>
<td>Interventions</td>
<td>Control: information on the negative effects of smoking and encouragement to quit, reinforced by a pamphlet, provided at the time of the ultrasound examination. Intervention: offered the Windsor self-help manual describing a 10 day program, 2 weeks later reminder. Letter and encouragement and appointment for 32 week scan with reinforcement at the 32 weeks scan and 2 weeks later a further letter. Both intervention and control information were provided by obstetrician or midwife. Intervention intensity: I = 4, C = 2</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Smoking cessation and reduction in late pregnancy. No biochemical validation</td>
</tr>
<tr>
<td>Notes</td>
<td>Evidence is provided for an increase in smoking compared with 18 weeks, especially in the control group. Process evaluation suggested that the acceptance of the manual was low (mean score 2.6 on 7 point scale) and that it was staff involvement which had the most impact</td>
</tr>
</tbody>
</table>

**Risk of bias**

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>No</td>
<td>Described as “consecutively randomised”.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>No</td>
<td>Women consecutively randomised into 2 groups.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Educational intervention and ultrasound.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Unclear</td>
<td>Attrition approximately 10%. All drop-outs included in analysis as continuing smokers</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Only smoking outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>No</td>
<td>No biochemical validation and difference in smoking rates between groups at baseline</td>
</tr>
</tbody>
</table>
Valbo 1996

### Methods
Randomised trial of hypnosis for smoking cessation and reduction among women still smoking at the time of the 18 week ultrasound scan in a Norwegian hospital, 1990-1993

### Participants
Women were offered participation if still smoking at 18 week ultrasound visit, (after explanation including potential allocation to control) and then randomised after signing. Expected numbers of women in the recruitment period were 630, 158 (25%) agreed to participate. Of 80 allocated to intervention 13 did not receive an appointment in time, 15 did not attend leaving 52. Mean cigarettes/day prior to pregnancy I = 15.6, C = 15.0

### Interventions
Control: “routine pregnancy health care”. Intervention: anaesthesiologist provided 2 x 45 minute sessions at 2 week interval of a protocol-based script (Handbook of the American Society of Clinical Hypnosis); the tape played after hypnosis was established emphasised the unpleasant effects of smoking, affirmed her wish to quit, encouraged her will and capacity to quit, and instructed her in meeting cravings with relaxation techniques and self-hypnosis, explained during the session. Second visit tape was different with more weight on her capacity and taking control. Both tapes avoided “moralizing about her responsibility for pregnancy outcome”. Intensity rating: I = 4, C = 1 (not clear)

### Outcomes
Self-reported smoking cessation, reduction (mean cigarettes/day, the standard deviation used in the analysis in this review was calculated from a P value = 0.2 given in the paper) and increase at end of pregnancy, not biochemically validated. Perinatal deaths.

### Notes
Process evaluation did not rate the intervention highly: mean score of 2.05 on a 7 point scale. Norway.

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Random numbers.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Women allocated to groups by drawing lots (it was not clear when this took place)</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>Unclear</td>
<td>Psychological intervention, authors state that usual caregivers were not aware of group allocation</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?All outcomes</td>
<td>No</td>
<td>High levels of attrition in the intervention group. Intention to treat analysis for the main outcome (smoking cessation)</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Only smoking outcomes reported.</td>
</tr>
</tbody>
</table>
### Valbo 1996

(Continued)

| Free of detection bias? | No | No biochemical validation. Only 25% of those eligible agreed to participate |

### Walsh 1997

**Methods**

Trial of a structured, cognitive-behavioural, smoking cessation program for pregnant women delivered by UC providers in a public hospital antenatal clinic in Newcastle, Australia, 1990-1991

**Participants**

1909 pregnant women were screened at the first visit (approximately 12 weeks’ gestation). Classified as a smoker if they answered yes to the question “Are you a smoker?”: 725 smokers (38%), - 187 ineligible > 26 weeks, - 47 too ill or disturbed, -11 other reasons left 538. 293 agreed to take part. 7 (I) + 7 (C) withdrew, 10 + 10 had a miscarriage or termination, 4 + 3 gave birth preterm, leaving 125 + 127. Baseline smoking data not specified

**Interventions**

Control: doctor and Midwife both informed women that smoking was an important cause of pregnancy problems and they should stop; Midwife provided a package (sticker, pamphlet on risks of smoking and 2 page cessation guide), none of which were specifically tailored to pregnant women.

Intervention based on CBT: (i) 2-3 minute standardised risk information from Doctor plus 14 minute video on risk information rebuttal of barriers to quitting, cessation tips and 10 minute standardised information and counselling from Midwife after the video, using a flip chart, with negotiation of a quit date whenever possible and self-help manual on risks, barriers and cessation plus 4 packets of confectionary gum and lottery chance (4 prizes) for biochemically validated abstainers at the next visit, plus social support from accompanying adult (partner/friend/other) via support tip sheet, contract and form letter, chart, reminder sticker in the medical record, form-letter and sticker from 1st visit Midwife mailed within 10 days + 2nd visit and 34 to 36 week visit 5 minute counselling from Midwife and 1-2 minute risk advice from Doctor. Women still smoking at 34-36 weeks were advised to attend an external cessation course

Intensity rating: I = 4, C = 2.

**Outcomes**

Smoking status at mid and late pregnancy and 6-12 weeks’ postpartum, biochemically validated with salivary cotinine (I = 86%, C = 78%)

Discussion of provider views.

**Notes**

Midwives involved in recruitment to the trial had variable 'success'.

Overall participation was quite low (54%).

Cotinine data inconsistent with self-report were 52% in controls and 12% in the intervention group

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Computer generated.</td>
</tr>
</tbody>
</table>
### Allocation concealment?
Yes
Described as “precoded questionnaires in manila envelopes”.

### Blinding?
Women and clinical staff
No
Educational intervention by UC providers and notes flagged.

### Incomplete outcome data addressed?
All outcomes
No
Consent rates for different midwives very varied (9%-76%). 25% lost to follow up and further missing data for some variables including cotinine validation. Those with missing data were treated as continuing smokers in the analysis.

### Free of selective reporting?
Unclear
Only smoking outcomes reported.

### Free of detection bias?
Yes
Urinary cotinine was measured and revealed discrepancy with self-reported smoking status.

---

### Windsor 1985

**Methods**
A randomised trial, comparing the effectiveness of 2 smoking cessation interventions with standard care, in public health clinics in Birmingham, Alabama, USA 1983-1984

**Participants**
1838 pregnant women were screened, 460 current smokers (“>= 1 cigarette in the last 7 days”), -30 antenatal care entry >= 32 weeks, -9 left system or moved, -10 miscarriage or termination -10 went to group discussions (this intervention abandoned), leaving 102 (I1), 103 (I2) and 104 (SC). No baseline data on cigarettes/day

**Interventions**
Control: 2-3 minutes within a group prenatal education session at the 1st visit, when maternity clinic staff recommend quitting.
I1: 10 minute standardised counselling session from a health educator (B Comm H Ed) + Am Lung Assoc “Freedom from smoking” (ALA) manual (17 day self-directed plan for quitting) + “Because you love your baby” pamphlet on the dangers and risk of smoking and the benefits of quitting.
I2: as for I1 except that the manual was “A pregnant woman’s self-help guide to quit smoking” (instead of the ALA manual)
Intensity rating: I = 3, C =1.

**Outcomes**
Smoking cessation or reduction (by 30% cotinine levels), biochemically validated by salivary thiocyanate, at mid-pregnancy and within 48 hours of birth

**Notes**
“Multiple attempts were made to bring pregnant smokers together for a peer-led, focused group discussion: not feasible in this setting”. Pre-trial assessment showed no nurses (n = 80) had smoking cessation training and less than 20% felt confident to advise women on how to stop
Windsor 1985

(Continued)

Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Computer generated.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>No information provided.</td>
</tr>
<tr>
<td>Blinding?</td>
<td>No</td>
<td>Educational intervention by health educators in antenatal clinics</td>
</tr>
<tr>
<td>Women and clinical staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data addressed? All outcomes</td>
<td>Unclear</td>
<td>15% lost to follow up. Women lost to follow up were treated as continuing smokers</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Only smoking outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Salivary cotinine measured.</td>
</tr>
</tbody>
</table>

Windsor 1993

Methods

Trial of an enhanced cognitive behaviour therapy intervention, to assist in smoking cessation and smoking reduction during pregnancy in women attending public maternity clinics at a large hospital in Birmingham, Alabama, USA, 1986-91

Participants

4352 pregnant women screened at approximately 4 weeks' gestation, 1381 (31.7%) reported smoking at conception, 1171 current smokers (smoked 1 cigarette even a puff in the last 7 days), 110 ineligible by entry to care > 32 weeks, did not complete first visit, did not return, in earlier trial, prisoner reading level too poor, leaving 1061 of whom 67 refused leaving 493 (I) and 501 (C), 93 + 87 miscarriage, termination or withdrawal from public care, leaving 400 (I) + 414 (C). NS difference in baseline cotinine

Interventions

Control: 2 minute talk in 30 minute group session at first antenatal visit in which women were urged to quit and given 2 pamphlets: “Smoking and the two of you” + “Where to find help if you want to stop” including the name, contact phone number and cost of their local program.

Intervention based on cognitive behaviour therapy: 15 minute standardised cessation skills and risk counselling session from trained female health education counsellor + 7 day self-directed cessation guide on how to quit written at 6th Grade level + reinforcement (chart sticker) + letter from Doctor within 7 days + ‘buddy’ letter, contract and tip sheet + monthly newsletter with testimonials, cessation tips and additional information on risks

Intensity rating: I = 4, C = 2.

Outcomes

Smoking cessation at 32 weeks' gestation and postpartum, biochemically validated with salivary thiocyanate. “Significant” reduction
Notes
Separate paper on spontaneous quitters (Lowe 1997). All those lost to follow up were counted as continuing smokers. Data on gestation and birthweight were collected but the published analysis is by stopping smoking and the timing of cessation rather than by allocation, so not included in outcome tables.

Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Computer generated.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Not reported.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed? All</td>
<td>Unclear</td>
<td>18% attrition due withdrawal from the service, miscarriage or abortion not included in analysis 15% lost to follow up survey or cotinine analysis included as continuing smokers in this review</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Only smoking outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Saliva samples analysed.</td>
</tr>
</tbody>
</table>

Windsor 2000a

Methods

Participants
Inclusion criteria: smoker (1 puff in last 30 days), less than 27 weeks pregnant, access to a telephone, English or Spanish speaking. Both groups smoked approximately 10 cigarettes/d at baseline. Participation rate = 57%.

Interventions
Women screened at first visit (9-12 weeks' gestation) for self-reported smoking, validated by salivary cotinine (n = 1065), who were randomised to one of 3 treatment groups. 2 separate phases: participation rate phase one (1997) = 95% (n = 93), phase 2 (1998) participation rate = 60% (n = 172). Phase one and 20% phase 2 group combined to form control group (n = 126), which received only self-help materials. 80% phase 2 group (n = 139) formed intervention group 2 who received the quit kit and were enrolled in a monetary incentive lottery. Group 3 received the quit kit, the lottery program and up to three motivational in-
terviewing calls. A subsequent paper report 358 persons in this group, which does not correlate with the original paper trial reports.

Nurses, social workers and WIC administrators received orientation sessions. Trained motivational interviewing counsellors provided the intervention.

Intervention intensity: I = 4, C = 3.

Outcomes

Self-reported smoking status at 60 days after first visit, validated by salivary and urinary cotinine. Significant (> 50%) reduction in baseline cotinine (harm reduction measures).

Number of quit attempts reported, and aggregated by number of calls received. Attrition rate 13% (n = 34), counted as smokers.

Subsequent paper assesses cost effectiveness, as “cost per quitter”.

Notes

Mixture of RCT/sequential study with main control group being recruited in phase one of the study to identify representative sample, and small additional control group recruited in phase 2 with the intervention group. Good process evaluation showed nearly 100% experimental group received the intervention, confirming the feasibility of routine delivery by regular staff.

An associated reference details formative evaluation of the intervention materials.

Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>No</td>
<td>Quasi-randomised design with 80% of the control group not randomly assigned</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>No</td>
<td>Many of the control group were historical controls.</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>No</td>
<td>Notes flagged.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed? All outcomes</td>
<td>Unclear</td>
<td>13% not available to follow up. Those lost to follow up treated as continuing smokers (but many in control group not randomly allocated)</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Unclear</td>
<td>Only smoking outcomes reported.</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Salivary cotinine measured.</td>
</tr>
</tbody>
</table>

Wisborg 2000

Methods

Double-blind, placebo controlled trial of nicotine replacement therapy (patches) in pregnant women in a Danish obstetric hospital.
### Participants
Healthy women less than 22 weeks' gestation who smoked more than 10 cigarettes per day after the first trimester, were invited to participate. n = 611. Participation rate 41% (n = 250). Mean cigarettes per day at intake I: n = 13.4, C: n = 14.2

### Interventions
Both groups received strong smoking cessation advice and counselling from a midwife, reinforced with printed materials. The control group received a placebo patch. The intervention group received 16 hour 15 mg nicotine patches for 8 weeks and 10 mg for 3 weeks. Intensity rating I: 4 C: 3.

### Outcomes
Self-reported abstinence of at least 7 days at 2nd, 3rd, and 4th prenatal visits, validated by salivary cotinine measurement. Reduction in mean cigarettes per day (the standard deviation used in the analysis in this review was calculated from a P value = 0.59 given in the paper). Telephone follow up at 3 and 12 months postpartum (self-report). Mean birthweight, low birthweight (<2500 g), preterm delivery.

### Notes
Very low recruitment, with non-participants smoking more cigarettes per day. Low compliance with treatment (28% in NRT group and only 7-8% in the placebo group) who may have guessed allocation. Limited details on 3 months and 1 year follow up.

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Randomisation list in balanced blocks.</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Yes</td>
<td>Placebo controlled trial with allocation coded until the end of data collection</td>
</tr>
<tr>
<td>Blinding? Women and clinical staff</td>
<td>Yes</td>
<td>Double blind placebo controlled study.</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Unclear</td>
<td>Small loss to follow up but 13% missing data for smoking outcomes Where data were missing women were treated as smokers.</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>Appears that adverse outcomes and birth outcomes are reported</td>
</tr>
<tr>
<td>Free of detection bias?</td>
<td>Yes</td>
<td>Salivary cotinine analysis.</td>
</tr>
</tbody>
</table>

AFP: alpha fetoprotein
ALA: American lung association
AN: antenatal
BP: blood pressure
C: control group
CBT: cognitive behavioral therapy
CO: carbon monoxide
GP: general practitioner
HMO: Health Maintenance Organisation
I: intervention group
ITT: intention to treat
LBW: low birthweight
MI: motivational interviewing
min: minutes
MRFIT: randomised trial of health promotion carried out in the US
MW: midwife
NICU: neonatal intensive care unit
NRT: nicotine replacement therapy
OPD: out-patient department
PIs: principal investigators
ppm: parts per million
PPROM: preterm, prelabour rupture of the membranes
sae: stamped addressed envelope
ses: socioeconomic status
SHO: senior house officer
TFS: teen fresh start
TFSB: teen fresh start + peer support
UC: usual care
WIC: Food program for Women, Infants and Children in the US

**Characteristics of excluded studies** [ordered by study ID]

<table>
<thead>
<tr>
<th>Study</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albrecht 2006</td>
<td>Outcome data not reported in format to include in meta-analysis. No reply from authors to request for numerical outcome data</td>
</tr>
<tr>
<td>Boshier 2003</td>
<td>Cohort study, not a randomised study design.</td>
</tr>
<tr>
<td>Britton 2006</td>
<td>Quasi-experimental design. Control and experimental convenience samples collected consecutively</td>
</tr>
<tr>
<td>Byrd 1993</td>
<td>There are no data provided by trial allocation.</td>
</tr>
<tr>
<td>Chan 2005</td>
<td>Controlled observational study of Bupropion for smoking cessation in pregnancy</td>
</tr>
<tr>
<td>Cook 1995</td>
<td>Abstract reports interim findings (outcomes for 43/151 patients at time of publication) of trial of discussion of smoking risks by physician and nutritionist in Louisville, USA. No further results published and no response to letter to author in 2008 requesting final data</td>
</tr>
<tr>
<td>Cope 2001</td>
<td>This paper described an observational study looking at the validity of self-reported smoking measures in pregnancy and the relationship of reported smoking levels on blood parameters</td>
</tr>
<tr>
<td>Reference</td>
<td>Design Description</td>
</tr>
<tr>
<td>--------------------</td>
<td>-------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Culp 2007</td>
<td>Controlled trial/evaluation of “The Community-Based Family Resource and Support” (CBFRS) Program. Control group not randomised</td>
</tr>
<tr>
<td>Emmons 2000</td>
<td>Controlled trial/evaluation of the “Healthy Baby Second Hand Smoke Study” uses historical controls. Good documentation of implementation problems</td>
</tr>
<tr>
<td>Ershoff 1983</td>
<td>The intervention took place in one HMO clinic with historical controls from the same clinic and concurrent controls from a second clinic. There was no randomisation of clinics and no adjustment of the data for clustering</td>
</tr>
<tr>
<td>Ferreira-Borges 2005</td>
<td>Pre-test post-test control group design (not randomised).</td>
</tr>
<tr>
<td>French 2007</td>
<td>Controlled clinical trial of postpartum relapse prevention. Excluded as not a trial during pregnancy, and not randomised</td>
</tr>
<tr>
<td>Gebauer 1998</td>
<td>Study of effect of one 15 minute counselling session and a follow-up telephone call, performed 1994-95, using historical controls from 1993-1994</td>
</tr>
<tr>
<td>Gillies 1987</td>
<td>In this controlled clinical trial the intervention was carried out in 1 hospital with another hospital in the same city acting as a control, after a prior descriptive study which showed the similarity between the 2 in terms of social and demographic factors including smoking. There was no randomisation and recruitment differed substantially across the 2 sites. Data for smoking reduction and smoking cessation are combined in the paper with no separate data on cessation and no adjustment for clustering</td>
</tr>
<tr>
<td>Graham 1992</td>
<td>Although the multicomponent intervention included a smoking change component there are no smoking data in the paper</td>
</tr>
<tr>
<td>Grange 2005</td>
<td>Cohort study design.</td>
</tr>
<tr>
<td>Hahn 2005</td>
<td>Controlled trial with a volunteer sample of contest registrants, compared with a randomly selected group of smokers not exposed to the campaign/contest. Context registrants not randomised and there is evidence of differences between groups</td>
</tr>
<tr>
<td>Haug 1994</td>
<td>General practitioners, rather than individual women, were randomly allocated to provide the intervention or not. There was no adjustment for cluster randomisation in the analysis of the study findings</td>
</tr>
<tr>
<td>Haug 2004</td>
<td>Actual outcome smoking cessation figures are not reported. No reply from author to written request for outcome data</td>
</tr>
<tr>
<td>Heil 2003</td>
<td>Non-pregnant population.</td>
</tr>
<tr>
<td>Hiett 2000</td>
<td>Insufficient recruitment data in abstract to include in meta-analysis. No reply to letter sent to author for additional information in 2008</td>
</tr>
<tr>
<td>Hughes 2000</td>
<td>Insufficient outcome data reported for meta-analysis</td>
</tr>
<tr>
<td>Hymowitz 2006</td>
<td>Postpartum trial only which measures paediatrician implementation of smoking cessation and relapse prevention interventions</td>
</tr>
<tr>
<td>Study</td>
<td>Description</td>
</tr>
<tr>
<td>---------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Jaakola 2001</td>
<td>Controlled study, not randomised, of effects of a population-based smoking cessation program and its impact on smoking in pregnancy. Controls were matched on inclusion criteria from another district</td>
</tr>
<tr>
<td>Kaper 2006</td>
<td>Non-pregnant population.</td>
</tr>
<tr>
<td>Kienitz 2006</td>
<td>Pretest post test control group design (not randomised).</td>
</tr>
<tr>
<td>Langford 1983</td>
<td>Prenatal classes, rather than individual women, were randomly allocated to provide the intervention or not. The intervention was provided in late pregnancy with no outcome data collected during pregnancy but only data four months after birth. There was no adjustment for cluster randomisation in the analysis of the study findings</td>
</tr>
<tr>
<td>Lillington 1995</td>
<td>Four WIC clinics in Los Angeles were matched and randomised within pairs to intervention or control status. There was no adjustment for clustered data. All those not contacted at postpartum visit (28%) were excluded even though they should be counted as smokers; their allocation is not stated so adjustment cannot be made for this. There was significant misclassification of self-reported non-smoking status and 44% did not provide a sample for cotinine analysis so that verified non-smoking cannot be calculated</td>
</tr>
<tr>
<td>Loke 2005</td>
<td>Intervention aimed at smoking cessation in men (husbands of pregnant women)</td>
</tr>
<tr>
<td>Lowe 2002</td>
<td>Data are available on uptake of programs at a hospital level but not at present on smoking cessation effectiveness or perinatal outcomes</td>
</tr>
<tr>
<td>Messimer 1989</td>
<td>Primary care practices, rather than individual women, were randomly allocated to provide the intervention or not. There was no adjustment for cluster randomisation in the analysis of the study findings</td>
</tr>
<tr>
<td>Moore 1998</td>
<td>Not specifically a smoking cessation trial. Data does not include the proportion of smokers which continue to smoke after the intervention</td>
</tr>
<tr>
<td>Mullen 1990</td>
<td>Data are provided on those who stopped smoking only, not data by trial allocation</td>
</tr>
<tr>
<td>Mullen 1991</td>
<td>This was a study designed to test different ways of eliciting smoking behaviour information. In this randomised trial a multiple choice format was compared with asking women whether or not they smoked. There was no intervention to promote smoking cessation</td>
</tr>
<tr>
<td>Mullen 1997</td>
<td>Study designed to promote postpartum smoking cessation (not antepartum)</td>
</tr>
<tr>
<td>Olds 1994</td>
<td>Outcome data on child development in this paper have been excluded because the multicomponent interventions being compared might have had effects on child development other than by a change in maternal smoking</td>
</tr>
<tr>
<td>Olds 2002</td>
<td>This 3 armed randomised controlled trial of home visiting by paraprofessionals and nurses was excluded as it did not contain any quitting data, only urine cotinine measurements</td>
</tr>
<tr>
<td>Oncken 2006</td>
<td>No control group without intervention of nicotine gum.</td>
</tr>
</tbody>
</table>
Continued

<table>
<thead>
<tr>
<th>Author</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power 1989</td>
<td>The intervention in this trial was unusual in that the focus was on anticipated benefits of smoking cessation to women themselves (not on harm to the fetus and infant), and on alternative coping strategies, with a designated midwife-facilitator to answer queries and provide friendly advice and encouragement. The intervention was carried out in 1 hospital with another being a comparison setting, after a prior study which showed the similarity between the 2 in social and demographic factors including smoking rates. There was no randomisation. Recruitment differed significantly across the 2 hospitals. Data for smoking cessation and smoking reduction are combined with no separate data on cessation and no adjustment for clustering.</td>
</tr>
<tr>
<td>Ratner 1999</td>
<td>Postpartum intervention only. No interventions in pregnancy.</td>
</tr>
<tr>
<td>Scott 2000</td>
<td>This controlled clinical trial of the impact of using interactive software to promote smoking cessation, was excluded as it used historical controls.</td>
</tr>
<tr>
<td>Shakespeare 1990</td>
<td>Data on smoking reduction and smoking cessation are combined with no separate data on smoking cessation</td>
</tr>
<tr>
<td>Stanton 2004</td>
<td>Intervention aimed at men (partners of pregnant women).</td>
</tr>
<tr>
<td>Stotts 2003</td>
<td>Brief conference abstract reporting on a study looking at stages of change. No separate results were reported for women in the intervention and control groups.</td>
</tr>
<tr>
<td>Stotts 2004</td>
<td>Published data does not specify numbers in each of the control and intervention group, to enable extraction of outcome data figures presented as a percentage.</td>
</tr>
<tr>
<td>Suplee 2004</td>
<td>Randomised trial of relapse prevention counselling in the postpartum period only (not pregnancy)</td>
</tr>
<tr>
<td>Thyrian 2006</td>
<td>Randomised trial of postpartum intervention only (not prenatal)</td>
</tr>
<tr>
<td>Valanis 2001</td>
<td>This prospective controlled clinical trial design to test the effect of a low intensity intervention, used historical controls.</td>
</tr>
<tr>
<td>Wadland 2007</td>
<td>Implementation trial to change provider behaviour and increase referrals to quitline. Estimated smoking cessation outcome data only</td>
</tr>
<tr>
<td>Wiggins 2004</td>
<td>Smoking cessation outcome data not included. Not specifically a smoking cessation trial</td>
</tr>
<tr>
<td>Wisborg 1998</td>
<td>This randomised study of the effect of midwifery training on smoking cessation intervention implementation and pregnancy outcomes, was excluded due to concerns about allocation concealment (clinic day allocation)</td>
</tr>
<tr>
<td>Yilmaz 2006</td>
<td>Postnatal intervention in pediatric setting.</td>
</tr>
</tbody>
</table>

HMO: Health Maintenance Organisation
WIC: Food program for Women, Infants and Children in the US
**Characteristics of studies awaiting assessment**  
*ordered by study ID*

**Blasco Oliete 2004**

<table>
<thead>
<tr>
<th>Methods</th>
<th>Randomised clinical trial.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Pregnant women smoking at least 1 cigarette each day attending 4 clinics in Madrid, Spain</td>
</tr>
<tr>
<td>Interventions</td>
<td>Brief counselling (3 to 5 minutes) on smoking cessation compared with a group intervention over 3 half hour sessions</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Not clear.</td>
</tr>
<tr>
<td>Notes</td>
<td>Original article in Spanish.</td>
</tr>
<tr>
<td></td>
<td>Study report (2004) describes the study design. No papers including results have yet been identified</td>
</tr>
</tbody>
</table>

**Characteristics of ongoing studies**  
*ordered by study ID*

**Coleman 2007**

<table>
<thead>
<tr>
<th>Trial name or title</th>
<th>UK Trial of nicotine replacement therapy (NRT) in pregnancy - “SNAP”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Double-blind, randomised, placebo-controlled trial in 5 east midland hospitals</td>
</tr>
<tr>
<td>Participants</td>
<td>Pregnant, nicotine-addicted women are recruited as they attend for antenatal ultrasound scans (12-24 weeks' gestation). Women report smoking at least 10 cigarettes before pregnancy and still smoke at least 5 cigarettes daily. Min exhaled Co of 8 ppm</td>
</tr>
<tr>
<td></td>
<td>Exclusion criteria: severe cardiovascular disease, unstable angina, cardiac arrhythmias, recent cerebrovascular accident or TIA, chronic generalised skin disorders or known sensitivity to skin patches, chemical dependence/alcohol addiction problems, major fetal anomalies, or unable to give informed consent</td>
</tr>
<tr>
<td>Interventions</td>
<td>Participants receive 8 weeks of treatment with either nicotine or placebo 16 hour transdermal patches, accompanied by intensive behavioural support delivered by a research midwife, and follow up behavioural support from NHS stop smoking services (for both intervention and control women)</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Biochemically validated smoking cessation immediately before childbirth</td>
</tr>
<tr>
<td></td>
<td>Also: cost per smoker; validated smoking status at 1/12 post quit date, self-reported smoking status at 6/12 and 24/12 after birth, fetal loss, fetal and maternal morbidity</td>
</tr>
<tr>
<td>Starting date</td>
<td>1 February 2006</td>
</tr>
<tr>
<td>Contact information</td>
<td>Dr Tim Coleman, School of Community Services, University Hospital Nottingham. <a href="mailto:tim.coleman@nottingham.ac.uk">tim.coleman@nottingham.ac.uk</a></td>
</tr>
<tr>
<td>Notes</td>
<td>End date 31 January 2012</td>
</tr>
</tbody>
</table>
### El-Khorazaty 2007

<table>
<thead>
<tr>
<th>Trial name or title</th>
<th>Project DC-HOPE (NICH-DC Initiative) in Columbia, USA.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Randomised controlled trial in 6 urban prenatal care clinics. Research staff were grouped into four teams, with separation of recruits, intervention providers and assessors. Block randomisation (site and risk-specific) to intervention and control group</td>
</tr>
<tr>
<td>Participants</td>
<td>Pregnant women eligible if Washington residents, African American or Latino, at least 18 years of age, at 28 weeks' gestation or less, and English speaking</td>
</tr>
<tr>
<td>Interventions</td>
<td>Multimodal integrated counselling and educational intervention which aims to reduce smoking and environmental tobacco exposure. Intervention provided by a trained counsellor after the routine antenatal visit and at 2 postpartum sessions. Individualised counselling targeting areas of risk identified using an &quot;audio-computer-assisted self-interview&quot;</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Cotinine validated cessation at end of pregnancy (end of pregnancy and 8-10 weeks' postpartum), depression, violence, prematurity, birthweight</td>
</tr>
<tr>
<td>Contact information</td>
<td>Nabil El-Khorazaty <a href="mailto:nek@rti.org">nek@rti.org</a></td>
</tr>
<tr>
<td>Notes</td>
<td>Author contacted 2008 - need to await publication of results</td>
</tr>
</tbody>
</table>

### Groff 2005

<table>
<thead>
<tr>
<th>Trial name or title</th>
<th>Ultrasound and motivational enhancement for prenatal smoking cessation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Randomised clinical trial to test efficacy of motivational enhancement therapy and feedback</td>
</tr>
<tr>
<td>Participants</td>
<td>Pregnant women delivering at 2 UT-Houston teaching hospitals, 15-28 weeks' gestation and over 16 years of age</td>
</tr>
<tr>
<td>Interventions</td>
<td>Participants randomised to 1 of 3 groups (best practice counselling; BP counselling + ultrasound; BP ultrasound + motivational enhancement counselling</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Cotinine validated cessation at 34 weeks' gestation and 6 weeks' postpartum</td>
</tr>
<tr>
<td>Starting date</td>
<td>2001</td>
</tr>
<tr>
<td>Contact information</td>
<td>Janet Y Groff (Principal Investigator). University of Texas Medical School, Texas, 77030</td>
</tr>
<tr>
<td>Notes</td>
<td>National Center for Research Resources reports the study has been completed. No response to letter to investigator sent in 2008</td>
</tr>
</tbody>
</table>
### Lasater 2007

**Trial name or title**  
Reducing ETS exposure of pregnant women and newborns.

**Methods**  
Randomised 2-arm study in 6 prenatal clinics designed to develop and evaluate the efficacy of five tailored DVDs in reducing exposure to ETS among low-income pregnant/postpartum women.

**Participants**  
Pregnant women who attend first prenatal visit by 16 weeks' gestation who are exposed to tobacco smoke daily. Exclusion criteria: women expecting complications or multiple births.

**Interventions**  
Provision of tailored DVDs to take home.

**Outcomes**  
Salivary cotinine concentration of mother and baby.

**Starting date**  
Feb 2006

**Contact information**  
Thomas M Lasater, Brown University, Rhode Island.  
email: thomas_lasater@brown.edu

**Notes**  

### Lopez 2005

**Trial name or title**  
Relapse prevention self-help intervention (“Forever Free” booklets) for pregnant and postpartum exsmokers

**Methods**  
Randomised clinical trial.

**Participants**  
Pregnant women, 18 years or older, able to read and speak English, 4-8 months pregnant, smoked at least 10 cigarettes per day for at least 1 year prior to pregnancy, quit smoking because of pregnancy and have reported no tobacco use in the previous 7 days.

**Interventions**  
Intervention is provision of mailed “Forever free for baby and me” booklets. The control group receive existing materials from the National Cancer Institute and the American Cancer Society.

**Outcomes**  
7 day point prevalence abstinence at end of pregnancy.

**Starting date**  
5/1/2004

**Contact information**  
thomas.brandon@moffitt.org Tobacco Research and Intervention Program

**Notes**  
No response from author in 2008.

### Miller 2003

**Trial name or title**  
Bupropion SR for smoking cessation in pregnancy.

**Methods**  
Randomised, double-blind, placebo-controlled clinical trial.

**Participants**  
Pregnant smokers >13 weeks' gestation meeting specific criteria.
### Miller 2003

**Trial name or title**
Interventions for promoting smoking cessation during pregnancy (Review)

**Methods**
8 week intervention of conventional behavioural smoking cessation intervention, combined with either placebo (control) or SR bupropion (intervention)

**Outcomes**
Point prevalence abstinence and reduction. Intention to treat analysis conducted, but outcome for ITT abstinence not reported in abstract

**Starting date**

**Contact information**
Hugh Miller 2003, University of Arizona, Tucson, AZ

**Notes**
No response to letter to first author of abstract sent in 2008

### Patten 2006

**Trial name or title**
Tobacco cessation treatment for Pregnant Alaska Natives.

**Methods**
Randomised 2 group clinical trial.

**Participants**
Pregnant women 18 years and above, Alaskan native, less than 24 weeks' pregnant, self-reported use of tobacco in past 7 days, planning to quit, have access to a telephone, access to a television and VCR

**Interventions**
Control group (n = 30) receive standard counselling and self-help written materials. Intervention group receive standard counselling, plus 10-15 mins of culturally tailored counselling and a culturally tailored video

**Outcomes**
Self-reported cessation at 36 weeks' gestation.

**Starting date**

**Contact information**
Christi Patten, Principal Investigator, Mayo clinic, Rochester, Minnesota, USA

**Notes**

### Zhu 2004

**Trial name or title**
Telephone intervention (California Smokers' Helpline) or pregnant smokers

**Methods**
Randomised trial.

**Participants**
Pregnant smokers who called the helpline for services.

**Interventions**
Control group received a self-help quit kit of written materials, including the American Cancer Society booklet for pregnant smokers. Intervention group received the quit kit plus up to 7 counselling calls

**Outcomes**
Self-reported smoking cessation in third trimester.
Zhu 2004  *(Continued)*

<table>
<thead>
<tr>
<th>Starting date</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact information</td>
<td>Shu-Hong <em>Zhu 2004</em>, University of California. <a href="mailto:szhu@ucsd.edu">szhu@ucsd.edu</a></td>
</tr>
<tr>
<td>Notes</td>
<td>Author emailed 2008, advised that results would not be available until publication</td>
</tr>
</tbody>
</table>
## DATA AND ANALYSES

### Comparison 1. Interventions for smoking cessation in pregnancy versus control

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Continued smoking in late pregnancy</td>
<td>65</td>
<td>21258</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.94 [0.93, 0.96]</td>
</tr>
<tr>
<td>1.1 Individually randomised trials</td>
<td>56</td>
<td>15915</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.94 [0.92, 0.96]</td>
</tr>
<tr>
<td>1.2 Cluster-randomised trials</td>
<td>9</td>
<td>5343</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.97 [0.94, 1.00]</td>
</tr>
<tr>
<td>2 Continued smoking in pregnancy subgrouped by risk of bias</td>
<td>64</td>
<td>21117</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.94 [0.93, 0.96]</td>
</tr>
<tr>
<td>2.1 Low risk of bias (biochem val + ITT + ad. rand.)</td>
<td>14</td>
<td>5691</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.97 [0.94, 0.99]</td>
</tr>
<tr>
<td>2.2 Moderate risk of bias (biochem val only)</td>
<td>35</td>
<td>11638</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.94 [0.92, 0.97]</td>
</tr>
<tr>
<td>2.3 High risk of bias (no biochem validation)</td>
<td>15</td>
<td>3788</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.91 [0.87, 0.95]</td>
</tr>
<tr>
<td>3 Continued smoking in late pregnancy by intensity of intervention</td>
<td>65</td>
<td>21258</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.94 [0.93, 0.96]</td>
</tr>
<tr>
<td>3.1 High intensity</td>
<td>44</td>
<td>14453</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.94 [0.92, 0.96]</td>
</tr>
<tr>
<td>3.2 Medium intensity</td>
<td>18</td>
<td>5670</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.95 [0.92, 0.98]</td>
</tr>
<tr>
<td>3.3 Low intensity</td>
<td>3</td>
<td>1135</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.95 [0.83, 1.09]</td>
</tr>
<tr>
<td>4 Continued smoking in late pregnancy subgrouped by main intervention strategy</td>
<td>65</td>
<td>21257</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.94 [0.93, 0.96]</td>
</tr>
<tr>
<td>4.1 Cognitive behaviour strategies</td>
<td>30</td>
<td>9570</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.95 [0.93, 0.97]</td>
</tr>
<tr>
<td>4.2 Stages of change</td>
<td>11</td>
<td>5073</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.99 [0.97, 1.00]</td>
</tr>
<tr>
<td>4.3 Feedback</td>
<td>4</td>
<td>572</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.92 [0.84, 1.02]</td>
</tr>
<tr>
<td>4.4 Rewards</td>
<td>4</td>
<td>1285</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.76 [0.71, 0.81]</td>
</tr>
<tr>
<td>4.5 Pharmacotherapy (NRT, Bupropion etc) nicotine replacement therapy</td>
<td>5</td>
<td>1147</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.95 [0.92, 0.98]</td>
</tr>
<tr>
<td>4.6 Other</td>
<td>11</td>
<td>3610</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.96 [0.93, 0.98]</td>
</tr>
<tr>
<td>5 Continued smoking (relapse) for spontaneous quitters in late pregnancy</td>
<td>8</td>
<td>1064</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.91 [0.75, 1.10]</td>
</tr>
<tr>
<td>6 Mean birthweight</td>
<td>21</td>
<td>15119</td>
<td>Mean Difference (IV, Random, 95% CI)</td>
<td>39.26 [15.77, 62.74]</td>
</tr>
<tr>
<td>7 Mean birthweight subgrouped by main intervention strategy</td>
<td>21</td>
<td>15119</td>
<td>Mean Difference (IV, Random, 95% CI)</td>
<td>39.26 [15.77, 62.74]</td>
</tr>
<tr>
<td>7.1 Cognitive behavioural therapy</td>
<td>9</td>
<td>3809</td>
<td>Mean Difference (IV, Random, 95% CI)</td>
<td>47.01 [12.22, 81.80]</td>
</tr>
<tr>
<td>7.2 Stages of change</td>
<td>2</td>
<td>1312</td>
<td>Mean Difference (IV, Random, 95% CI)</td>
<td>-5.84 [-66.40, 54.72]</td>
</tr>
<tr>
<td>Section</td>
<td>Trials</td>
<td>N</td>
<td>Summary Effect Size (SMD, Random, 95% CI)</td>
<td></td>
</tr>
<tr>
<td>---------</td>
<td>--------</td>
<td>---</td>
<td>-----------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>7.3 Feedback</strong></td>
<td>3</td>
<td>6611</td>
<td>Mean Difference (IV, Random, 95% CI) 47.80 [−14.67, 110.28]</td>
<td></td>
</tr>
<tr>
<td><strong>7.4 Rewards</strong></td>
<td>2</td>
<td>1008</td>
<td>Mean Difference (IV, Random, 95% CI) 123.98 [−1.92, 249.89]</td>
<td></td>
</tr>
<tr>
<td><strong>7.5 Pharmacotherapy</strong></td>
<td>3</td>
<td>1078</td>
<td>Mean Difference (IV, Random, 95% CI) 34.40 [−125.77, 194.58]</td>
<td></td>
</tr>
<tr>
<td><strong>7.6 Other</strong></td>
<td>2</td>
<td>1301</td>
<td>Mean Difference (IV, Random, 95% CI) 36.27 [−18.71, 91.25]</td>
<td></td>
</tr>
<tr>
<td><strong>8 Low birthweight (under 2500 g)</strong></td>
<td>16</td>
<td>9916</td>
<td>Risk Ratio (M-H, Random, 95% CI) 0.83 [0.73, 0.95]</td>
<td></td>
</tr>
<tr>
<td><strong>9 Very low birthweight (under 1500 g)</strong></td>
<td>4</td>
<td>5496</td>
<td>Risk Ratio (M-H, Random, 95% CI) 1.13 [0.72, 1.77]</td>
<td></td>
</tr>
<tr>
<td><strong>10 Perinatal deaths</strong></td>
<td>3</td>
<td>4335</td>
<td>Risk Ratio (M-H, Random, 95% CI) 1.10 [0.69, 1.76]</td>
<td></td>
</tr>
<tr>
<td><strong>11 Preterm birth (under 37 or under 36 weeks)</strong></td>
<td>14</td>
<td>11930</td>
<td>Risk Ratio (M-H, Random, 95% CI) 1.17 [0.34, 4.01]</td>
<td></td>
</tr>
<tr>
<td><strong>12 Stillbirths</strong></td>
<td>6</td>
<td>4706</td>
<td>Risk Ratio (M-H, Random, 95% CI) 0.85 [0.61, 1.18]</td>
<td></td>
</tr>
<tr>
<td><strong>13 Neonatal deaths</strong></td>
<td>3</td>
<td>4143</td>
<td>Risk Ratio (M-H, Random, 95% CI) 1.17 [0.72, 1.77]</td>
<td></td>
</tr>
<tr>
<td><strong>14 NICU admissions</strong></td>
<td>4</td>
<td>1394</td>
<td>Risk Ratio (M-H, Random, 95% CI) 1.13 [0.72, 1.77]</td>
<td></td>
</tr>
<tr>
<td><strong>15 Smoking reduction: numbers of women reducing smoking in late pregnancy</strong></td>
<td>13</td>
<td></td>
<td>Subtotals only</td>
<td></td>
</tr>
<tr>
<td>15.1 Self-reported some reduction in smoking (various definitions)</td>
<td>5</td>
<td>1487</td>
<td>Risk Ratio (M-H, Random, 95% CI) 1.52 [1.29, 1.78]</td>
<td></td>
</tr>
<tr>
<td>15.2 Self-reported &gt; 50% reduction in smoking</td>
<td>3</td>
<td>779</td>
<td>Risk Ratio (M-H, Random, 95% CI) 1.23 [0.91, 1.67]</td>
<td></td>
</tr>
<tr>
<td>15.3 Biochemically validated reduction</td>
<td>5</td>
<td>1549</td>
<td>Risk Ratio (M-H, Random, 95% CI) 1.27 [0.84, 1.91]</td>
<td></td>
</tr>
<tr>
<td><strong>16 Smoking reduction: biochemical measures in late pregnancy</strong></td>
<td>4</td>
<td>2511</td>
<td>Std. Mean Difference (IV, Random, 95% CI) -0.11 [-0.24, 0.02]</td>
<td></td>
</tr>
<tr>
<td>16.1 Mean cotinine levels</td>
<td>3</td>
<td>1742</td>
<td>Std. Mean Difference (IV, Random, 95% CI) -0.05 [-0.14, 0.05]</td>
<td></td>
</tr>
<tr>
<td>16.2 Mean thiocynate level</td>
<td>1</td>
<td>769</td>
<td>Std. Mean Difference (IV, Random, 95% CI) -0.29 [-0.44, -0.15]</td>
<td></td>
</tr>
<tr>
<td><strong>17 Smoking reduction: self-reported mean cigarettes per day measured in late pregnancy or at delivery</strong></td>
<td>9</td>
<td>3372</td>
<td>Mean Difference (IV, Random, 95% CI) -0.67 [-1.49, 0.16]</td>
<td></td>
</tr>
<tr>
<td><strong>18 Maintained smoking cessation at 1-5 months postpartum</strong></td>
<td>20</td>
<td>6097</td>
<td>Risk Ratio (M-H, Random, 95% CI) 1.65 [1.22, 2.24]</td>
<td></td>
</tr>
<tr>
<td>18.1 Individually randomised trials</td>
<td>15</td>
<td>4726</td>
<td>Risk Ratio (M-H, Random, 95% CI) 1.43 [1.08, 1.91]</td>
<td></td>
</tr>
<tr>
<td>18.2 Cluster-randomised trials</td>
<td>5</td>
<td>1371</td>
<td>Risk Ratio (M-H, Random, 95% CI) 2.08 [0.78, 5.56]</td>
<td></td>
</tr>
<tr>
<td><strong>19 Maintained smoking cessation at 6 to 12 months postpartum</strong></td>
<td>8</td>
<td>2624</td>
<td>Risk Ratio (M-H, Random, 95% CI) 1.39 [0.82, 2.38]</td>
<td></td>
</tr>
<tr>
<td>19.1 Individually randomised trials</td>
<td>8</td>
<td>2624</td>
<td>Risk Ratio (M-H, Random, 95% CI) 1.39 [0.82, 2.38]</td>
<td></td>
</tr>
<tr>
<td>19.2 Cluster-randomised trials</td>
<td>0</td>
<td>0</td>
<td>Risk Ratio (M-H, Random, 95% CI) Not estimable</td>
<td></td>
</tr>
</tbody>
</table>
### WHAT'S NEW

Last assessed as up-to-date: 3 December 2008.

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>17 November 2008</td>
<td>New citation required but conclusions have not changed</td>
<td>Two new authors have joined the review team for this substantive update, which includes the addition of risk of bias assessments for all trials; additional outcomes tables for smoking reduction, continued cessation in the postnatal period, neonatal intensive care unit admissions, psychological impacts of smoking, views of participants and providers; inclusion of additional data from previously included cluster-randomised trials; and risk of bias sensitivity analysis</td>
</tr>
<tr>
<td>17 November 2008</td>
<td>New search has been performed</td>
<td>Search updated: 7 new randomised controlled trials (Cope 2003; Dornelas 2006; Heil 2008; Higgins 2004; Hotham 2005; Pollak 2007; Rigotti 2006) and 4 cluster randomised controlled trials (Campbell 2006; McLeod 2004; Pbert 2004; Polanska 2004) included. Mullen 1991 and Hughes 2000 previously included have now been excluded.</td>
</tr>
</tbody>
</table>

### HISTORY


<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>3 November 2008</td>
<td>Amended</td>
<td>Converted to new review format.</td>
</tr>
<tr>
<td>31 July 2003</td>
<td>New search has been performed</td>
<td>We have updated the Background and Results sections (comment on the differences between the interventions when trials are grouped by intervention). Twenty new trials reporting smoking cessation were included with five additional cluster-randomised trials. Nine additional trials were excluded. Six trials provided new data on fetal and perinatal outcomes. The overall conclusions about the effectiveness of smoking cessation interventions did not change. New analyses grouping interventions by strategies showed that the pooled cognitive-behavioural interventions were effective, nicotine replacement therapy was borderline, and trials using 'stages of change' approaches or feedback were not effective. The two trials using a com-</td>
</tr>
</tbody>
</table>

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*Interventions for promoting smoking cessation during pregnancy (Review)*

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Combination of rewards and social support were significantly more effective than other strategies. The increased information on perinatal outcomes strengthened the findings of a reduction in preterm birth and low birthweight. One trial reported method of delivery and one reported breastfeeding; neither showed an effect of the intervention.

CONTRIBUTIONS OF AUTHORS

Original review (1999)
Judith Lumley (JL) and Sandy Oliver (SO) conceived and designed the original review, and together with Elizabeth Waters (EW) and Laura Oakley (LO) completed data extraction and wrote the original review. JL carried out the analyses. EW was unable to contribute after 2002.
All contributed to the final text.

Update (2004)
JL coordinated the review update, extracted data, conducted the analyses and interpretation of data and wrote the review.
Catherine Chamberlain (CC) searched and screened search results, retrieved papers, extracted data, wrote to authors for additional information and entered data.
SO and LO provided general advice and contributed to the final text.

Update (2009)
JL screened retrieved papers against eligibility criteria, provided general advice on the review and contributed to the final text.
CC coordinated and secured funding for the review, undertook searches, retrieved papers, extracted data, wrote to authors for additional information, entered and analysed data, and wrote the review.
Therese Dowswell (TD) completed risk of bias assessments for trials included prior to the 2009 update and revised data abstraction records into an electronic format. TD revised the risk of bias assessments for RevMan 5 format, extracted, entered and analysed data on reduction and postpartum outcomes, and provided general advice and a methodological perspective on the review.
SO and LO extracted and analysed data on participant and provider views, provided general advice and contributed to the text of the review.
Lyn Watson (LW) provided expert statistical advice on including cluster trials, extracted data for cluster trials and adjusted the data.

DECLARATIONS OF INTEREST
Mother and Child Health Research (LaTrobe University), formerly Centre for the Study of Mothers’ and Children’s Health (Judith Lumley) receives a funding contribution from the Victorian Health Promotion Foundation, which has a statutory responsibility for reducing tobacco use in the State of Victoria.
** SOURCES OF SUPPORT **

**Internal sources**

- La Trobe University 1996 to date, Australia.
- 3centres Collaboration, funded by the Victorian Department of Human Services, Australia.

Financial support for 2008 update

**External sources**

- NHS Central R & D Programme, Department of Health 1995-1996, UK.
- Victorian Health Promotion Foundation, Australia.
- Department of Health, UK funding for EPI-Centre, London University, UK.
- Public Health Branch Victorian Department of Human Services, Australia.
- Commonwealth Department of Health and Ageing, Australia.

Financial support for 2008 update

**INDEX TERMS**

**Medical Subject Headings (MeSH)**

*Pregnancy; Infant, Low Birth Weight; Infant, Newborn; Obstetric Labor, Premature [prevention & control]; Patient Education as Topic; Pregnancy Outcome; Randomized Controlled Trials as Topic; Smoking Cessation [*methods]*

**MeSH check words**

Female; Humans