Interventions for promoting smoking cessation during pregnancy (Review)

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[Intervention Review]

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 We contacted trial authors to locate additional unpublished data.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.

Description of the condition

BACKGROUND

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).

Tobaccco 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 (Wanless 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 Europe, North America or Australia who originate from South East Asia retain a lower prevalence of smoking, despite major social disadvantage (Bush 2003; Potter 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 Organizaton have 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; Tsoi 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. There are also other reviews assessing effectiveness of interventions in specific population groups (people with schizophrenia (protocol only), depression (protocol only), cardiovascular and pulmonary disease, and hospitalised patients), *see* Appendix 1.

OBJECTIVES

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?

METHODS

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 Merlo 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 I^2 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

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.

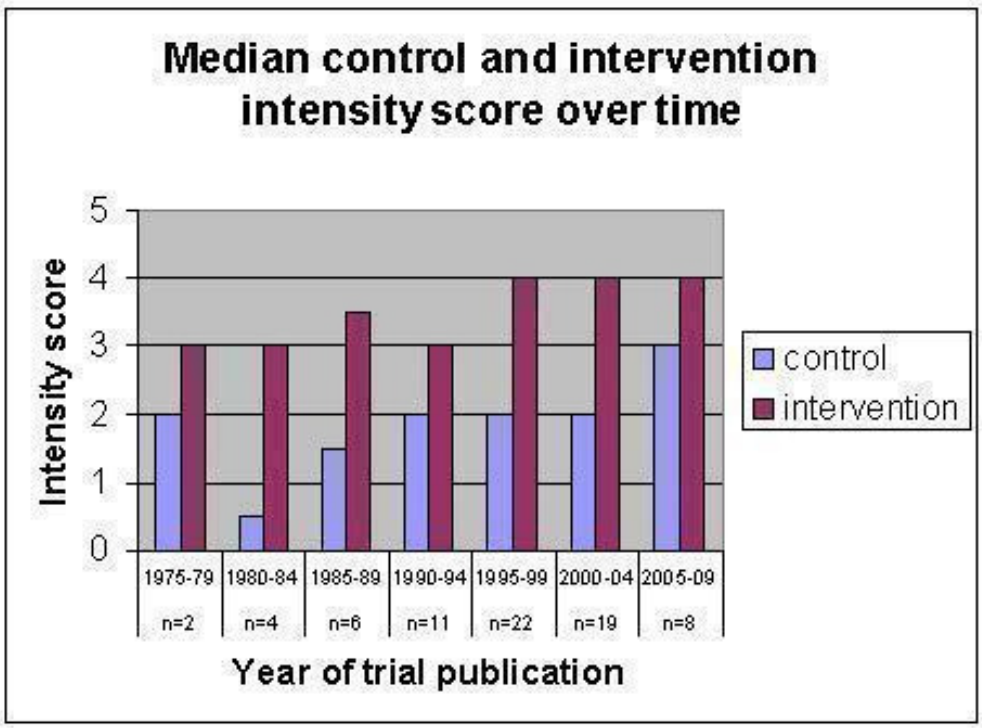
Participants

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 subpopulations.

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).

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.

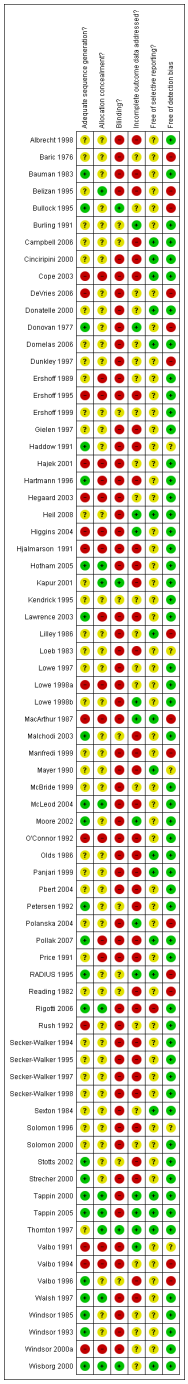
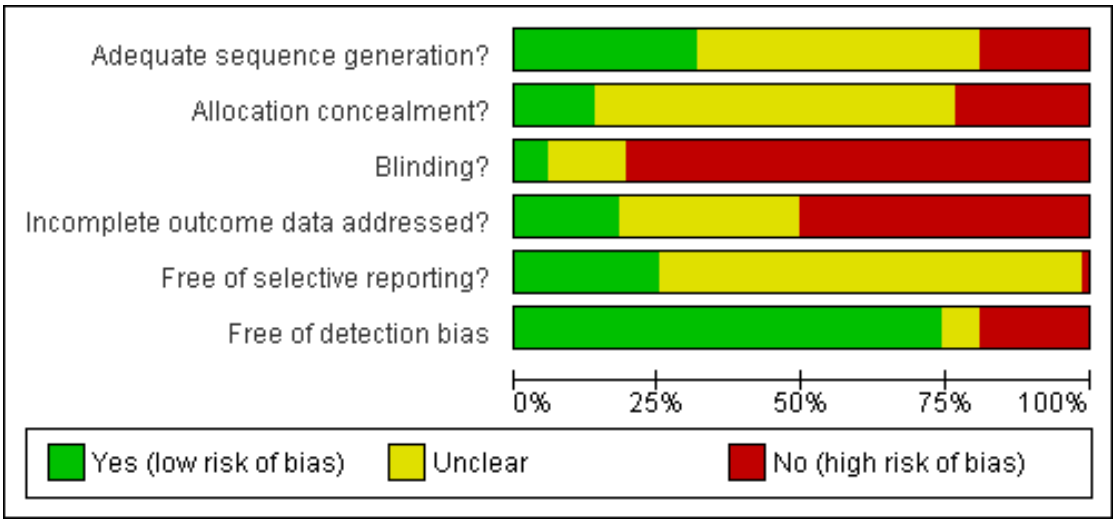


Figure 3. Risk of bias graph: review authors' judgments about each risk of bias item presented as percentages across all included studies.



Effects of interventions

1. 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 to1.00 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 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 (I^2 = 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-

velopment 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 iniation 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' activites (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 no 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 subjectively 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 midwives 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 confirm 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.

Crittenden, 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 (I^2 > 55%). Subgroup analyses of trials at low risk of bias had the largest effect on reducing the heterogeneity, but some heterogeneity remained (I^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 birthweight difference 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 women's lifecourse. 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

1977). The first trial to demonstrate the reversibility of the birthweight 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 A's", 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 women'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 multicentre 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 time (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) suspended 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; Ussher 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-contemplation, 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.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Described as randomly assigned.

Albrecht 1998 (*Continued*)

Allocation concealment?	Unclear	No information.
Blinding? Women and clinical staff	No	Provider and participants unable to be blinded to educational intervention
Incomplete outcome data addressed? All outcomes	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
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 (*Continued*)

Allocation concealment?	Unclear	No information provided.
Blinding? Women and clinical staff	No	Educational intervention at first antenatal visit.
Incomplete outcome data addressed? All outcomes	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
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

Item	**Authors' judgement**	**Description**

Bauman 1983 (*Continued*)

Adequate sequence generation?	Yes	Random number table.
Allocation concealment?	Unclear	No information provided.
Blinding? Women and clinical staff	No	Intervention was carried out by UC staff, no participant blinding
Incomplete outcome data addressed? All outcomes	No	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
Free of selective reporting?	Unclear	None apparent.
Free of detection bias?	Yes	Biochemical validation of reported smoking behaviour for those followed up

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

Belizan 1995 (*Continued*)

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

Risk of bias

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

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*)

	of 2 to 6 women each. Theoretical basis: social support. Intensity rating: I = 4, C = 1
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

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Computer-generated random assignment to control or intervention in balanced blocks of 50
Allocation concealment?	Unclear	No information provided.
Blinding? Women and clinical staff	Yes	Caregiver blinded to allocation. Women not blinded to intervention
Incomplete outcome data addressed? All outcomes	Unclear	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
Free of selective reporting?	Unclear	None apparent.
Free of detection bias?	No	No biochemical validation of reported smoking behaviour.

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*)

	lines for self-directed smoking cessation. Theoretical basis: feedback. Intensity rating: I = 3, C = 2
Outcomes	CO measurements (biochemical validation) and smoking data were collected at all subsequent visits
Notes	Simple intervention so no process evaluation. Clinic-wide implementation so no consent sought.

Risk of bias

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

Campbell 2006

Methods	Cluster-randomised trial in Newcastle, New South Wales, Australia
Participants	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
Interventions	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)

Campbell 2006 (*Continued*)

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

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Method of random allocation not specified, but taken within strata based on clinic size and baseline smoking rates
Allocation concealment?	Unclear	Not specified.
Blinding? Women and clinical staff	Unclear	Educational intervention. Neither women nor providers would have been blind to the intervention
Incomplete outcome data addressed? All outcomes	No	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
Free of selective reporting?	Yes	Smoking status and recall of intervention reported.
Free of detection bias?	Yes	Exhaled carbon monoxide >= 9.

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*)

	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
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

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

Cope 2003

Methods	Randomised controlled trial in 3 large inner city hospital antenatal clinics, Birmingham, UK
Participants	"Current smokers" (> 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

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

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	No	Sequence generation based on odd or even hospital numbers.
Allocation concealment?	No	Group allocation could be anticipated.
Blinding? Women and clinical staff	No	Neither providers nor women were blind to the intervention.
Incomplete outcome data addressed? All outcomes	No	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)

Cope 2003 (*Continued*)

Free of selective reporting?	Yes	
Free of detection bias?	Yes	Smoking status validated with urine cotinine. >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

DeVries 2006

Methods	Cluster-randomised trial in Maastricht, The Netherlands. Feb-December 1996
Participants	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
Interventions	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
Outcomes	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
Notes	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

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	No	The first 40 practices (118 midwives) were selected, from 4 provinces, which were then matched (by location and level of urban-

DeVries 2006 (*Continued*)

		isation) into 2 pairs. All midwives in a province were allocated to either intervention or control care
Allocation concealment?	Unclear	Not reported.
Blinding? Women and clinical staff	No	Neither providers nor women were blinded for this counselling intervention
Incomplete outcome data addressed? All outcomes	Unclear	Not clear, figures are not consistent, as well as loss to follow up there are missing data for some variables When all drop-outs included as smokers 7-day abstinence I = 19% of 141 and C = 7% of 177, included in this analysis
Free of selective reporting?	Unclear	None apparent.
Free of detection bias?	No	Biochemical validation for a small sub-sample only.

Donatelle 2000

Methods	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
Participants	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).
Interventions	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
Outcomes	Smoking cessation biochemically validated with salivary cotinine at 34 weeks' gestation and 2 months postpartum
Notes	Data in outcome tables is inconsistent.

Donatelle 2000 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	No information provided.
Allocation concealment?	Unclear	No information provided.
Blinding? Women and clinical staff	No	Neither providers nor women were blinded for this educational intervention with incentives
Incomplete outcome data addressed? All outcomes	Unclear	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
Free of selective reporting?	Yes	Main outcomes reported.
Free of detection bias?	Yes	Reported quitting validated by salivary cotinine analysis.

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 >= 5 cigarettes/day and had been smoking >= 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

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

Dornelas 2006

Methods	Randomised controlled trial conducted in Hartford, Connecticut, USA, between January 2001 and December 2002
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.

Dornelas 2006 (*Continued*)

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

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

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

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*)

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	No information
Allocation concealment?	No	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
Blinding? Women and clinical staff	No	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
Incomplete outcome data addressed? All outcomes	Unclear	Attrition I = 39/165, C = 44/158 not included in analysis (due to miscarriage, abortion or dis-enrolment from the HMO)
Free of selective reporting?	Unclear	None apparent.
Free of detection bias?	Yes	Biochemical validation by urinary cotinine levels.

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

Item	Authors' judgement	Description

Ershoff 1995 (*Continued*)

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	

Ershoff 1999 (*Continued*)

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Described as "random assignment"
Allocation concealment?	Unclear	No information.
Blinding? Women and clinical staff	Unclear	Authors state that care providers were blind to group allocation. Educational intervention so blinding women not feasible
Incomplete outcome data addressed? All outcomes	Unclear	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
Free of selective reporting?	Unclear	Results were difficult to interpret.
Free of detection bias?	Yes	Biochemical validation by urinary cotinine levels.

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*)

	the doctor and the counsellor) mailed to the woman 1-2 weeks after her first visit Theoretical basis: social learning theory. Intensity rating: I = 4, C = 2
Outcomes	Smoking cessation in third trimester, validated by salivary cotinine. Proportion cotinine reduction > 50%
Notes	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%)

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	No information provided.
Allocation concealment?	Unclear	Described as "randomly assigned".
Blinding? Women and clinical staff	No	Educational intervention.
Incomplete outcome data addressed? All outcomes	No	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)
Free of selective reporting?	Unclear	None apparent.
Free of detection bias?	Yes	Biochemical validation by salivary cotinine.

Haddow 1991

Methods	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
Participants	Pregnant women with a singleton live pregnancy; having maternal serum AFP screening at 15-20 weeks' gestation; who smoked >= 10 cigarettes a day. 25,628 screened, 97% answered question on smoking, about 3,000 met smoking criteria (17%). 1423 inter-

Haddow 1991 (*Continued*)

	vention and 1425 control with 41 + 39 lost to follow up
Interventions	Control: standard medical care not otherwise specified. Intervention: report on cotinine generated for her physician with interpretation relating smoking level to birthweight. Physician explained this to the woman and also gave her a copy of the report and a pregnancy-specific booklet about how to quit, using the cotinine information also + repeat measure 1 month later, 2 copies to physician, comparison of 1st and 2nd cotinine, report commenting on the change and its interpretation. Theoretical basis: feedback. Intensity rating: I = 3, C = 1
Outcomes	No smoking cessation data. Smoking data limited to comparability at first assessment and serum cotinine levels; mean birthweight; low and very low birthweight; preterm birth (< 37 weeks); fetal deaths; neonatal deaths; postneonatal deaths. 695/1343 women provided repeat serum cotinine for comparison
Notes	Physician consent only sought. Process evaluation showed less than good implementation with differential impact on perinatal outcome by completeness with second blood samples taken for cotinine measurement

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Computer-generated random numbers.
Allocation concealment?	Unclear	Information not provided.
Blinding? Women and clinical staff	No	Caregivers aware of group allocation. Experimental group given feedback on serum cotinine levels
Incomplete outcome data addressed? All outcomes	No	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
Free of selective reporting?	Unclear	Results difficult to interpret. Smoking cessation not recorded
Free of detection bias?	Unclear	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

Hajek 2001

Methods	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
Participants	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
Interventions	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
Outcomes	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.
Notes	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

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	No	Consecutive names on a list of midwives.
Allocation concealment?	No	Midwives randomised.
Blinding? Women and clinical staff	No	Midwives aware of allocation group. Educational intervention. Blinding women not feasible
Incomplete outcome data addressed? All outcomes	Unclear	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
Free of selective reporting?	Unclear	Clustering effect not reported, so sensitivity analysis conducted using four ICCs and outcome figures adjusted using conservative intracluster correlation of 0.1

Hajek 2001 (*Continued*)

Free of detection bias?	Yes	Biochemical validation by expired CO.

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

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Computer-generated random numbers.
Allocation concealment?	No	State that neither the enrolling nurse nor the patient were aware of allocation, but experimental group notes were flagged

Hartmann 1996 (*Continued*)

Blinding? Women and clinical staff	No	Case notes flagged. States patient not aware of randomisation status
Incomplete outcome data addressed? All outcomes	No	Attrition 16%. Drop-outs not reported by intervention group so not able to be included in analysis
Free of selective reporting?	Unclear	Not apparent.
Free of detection bias?	Yes	Expired CO measured at each visit for the experimental group and at 3 visits for the comparison group

Hegaard 2003

Methods	Trial of multimodel 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

Item	Authors' judgement	Description
Adequate sequence generation?	No	Quasi-randomised, allocation of even/uneven birth dates to designated clinic days
Allocation concealment?	No	Possible for those recruiting to anticipate allocation. Educational intervention by usual caregiver
Blinding? Women and clinical staff	No	Educational intervention by usual caregiver, so not blinded.
Incomplete outcome data addressed? All outcomes	Unclear	Uneven randomisation. Approximately 10% lost to follow up and missing data 16-19% at later data collection points. Women lost to follow up were excluded from the analysis but those remaining in part of the study with missing data were treated as continuing smokers
Free of selective reporting?	Unclear	Birthweight and low birthweight data provided. No other adverse outcomes reported
Free of detection bias?	Yes	Salivary cotinine measured to verify reported abstinence.

Heil 2008

Methods	Randomised controlled trial in Greater Burlington, Vermont, USA. 2001-2003
Participants	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)

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

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Described as "randomisation stratified to clinics". Details of randomisation not described
Allocation concealment?	Unclear	No information.
Blinding? Women and clinical staff	No	Participants and providers not blinded as receiving incentives for participation
Incomplete outcome data addressed? All outcomes	Yes	Small loss to follow up due to pregnancy termination or fetal death. Available case analysis
Free of selective reporting?	Yes	Detailed birth outcomes reported.
Free of detection bias?	Yes	Exhaled CO for 5 days (< 6 ppm) and then urine cotinine (< 80 ng/ml)

Higgins 2004

Methods	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

Item	Authors' judgement	Description
Adequate sequence generation?	No	37/53 were consecutively assigned (quasi-randomised) as part of pilot study, and 16/53 were randomised
Allocation concealment?	No	Group allocation could be anticipated.
Blinding? Women and clinical staff	No	Unable to blind participants or providers in this trial.
Incomplete outcome data addressed? All outcomes	Yes	Very low loss to follow up (10% at end of pregnancy). Those lost to follow up were counted as continuing smokers

Higgins 2004 (*Continued*)

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)

Hjalmarson 1991

Methods	Quasi-randomised (allocation by birth date) trial of smoking cessation intervention based on RA Windsor self-help manual in 13/14 public health maternity clinics in Gothenburg, Sweden 1987-1988
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	Same data published by Svanberg 1992. No process evaluation.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	No	By birthday. Uneven groups.
Allocation concealment?	No	Possible to predict allocation.
Blinding? Women and clinical staff	No	Neither provider nor women blinded to this educational intervention

Hjalmarson 1991 (*Continued*)

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

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Computer-generated sequence.
Allocation concealment?	Yes	Described as "sealed envelope system". Unclear whether envelopes opaque

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

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

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Described as "randomised".
Allocation concealment?	Yes	Placebo controlled trial.
Blinding? Women and clinical staff	Yes	Placebo controlled trial. Described as double-blind. Placebo provided but most of the

Kapur 2001 (*Continued*)

		women in the placebo group did not complete the programme
Incomplete outcome data addressed? All outcomes	No	Biochemical validation data was missing for approximately a third of the sample. Not clear if there was ITT analysis
Free of selective reporting?	Unclear	No birth outcomes reported.
Free of detection bias?	Yes	Biochemical validation by serum thiocyanate and salivary cotinine, but missing data for these outcomes

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;

Kendrick 1995 (*Continued*)

	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

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	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
Allocation concealment?	Unclear	Cluster-randomised trial.
Blinding? Women and clinical staff	Unclear	Unclear whether participants and providers were aware of clinic allocation
Incomplete outcome data addressed? All outcomes	Unclear	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
Free of selective reporting?	Unclear	High rates of non-disclosure for smoking outcomes.
Free of detection bias?	Yes	Biochemical validation by urinary cotinine.

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

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

Lawrence 2003 (*Continued*)

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.

Risk of bias

Lilley 1986 (*Continued*)

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

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 sae, 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; 25.2% dropped out; 38% did not participate; 18% could not be contacted
Risk of bias	

Loeb 1983 (*Continued*)

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	No details of randomisation.
Allocation concealment?	Unclear	Described as "randomly assigned".
Blinding? Women and clinical staff	No	
Incomplete outcome data addressed? All outcomes	No	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
Free of selective reporting?	Unclear	Birth outcomes reported by smoking status, not intervention group
Free of detection bias?	Unclear	Biochemical validation at delivery on a small sub-sample.

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*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Described as "randomly assigned".
Allocation concealment?	Unclear	No information provided.
Blinding? Women and clinical staff	No	Notes flagged.
Incomplete outcome data addressed? All outcomes	Unclear	Approximately 20% attrition. Intention to treat analysis for main outcome, those lost to follow up treated as continuing smokers
Free of selective reporting?	Unclear	Unclear what data were collected. Only smoking outcomes reported
Free of detection bias?	Yes	Salivary thiocyanate analysis.

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*)

	the midwifery caution against smoking; (I): the midwife provided the booklet without any additional discussion or counselling Intensity rating I = 4, C = 2.
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

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

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
Outcomes	Smoking behaviour/reduction (self-report) and smoking cessation at 20 weeks, biochemically validated
Notes	Process evaluation of materials was positive, though staff identified a range of barriers to implementing smoking cessation counselling

Risk of bias

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

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	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. Control: routine advice, not specified further. Intensity rating: I = 2, C = 0 (not clear).
Outcomes	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). Report includes observational data (according to smoking behaviour) smoking status not biochemically validated
Notes	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.

Risk of bias

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

Malchodi 2003

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

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Computer-generated list.
Allocation concealment?	Unclear	Information not provided.
Blinding? Women and clinical staff	Unclear	State that caregivers were masked but educational/counselling support intervention that women may have discussed with caregivers
Incomplete outcome data addressed? All outcomes	No	High attrition rates (I = 43%, C = 36%) . ITT analyses for whole sample and for those remaining at follow up
Free of selective reporting?	Unclear	Birth outcomes only reported by smoking status not intervention group
Free of detection bias?	Yes	Urinary cotinine levels at baseline and at 36 weeks' gestation. Exhaled CO at each prenatal visit

Manfredi 1999

Methods	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
Participants	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
Interventions	Control group received smoking cessation advice and available brochures, dependant 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)
Outcomes	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
Notes	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

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Cluster randomisation. Described as "randomly assigned".
Allocation concealment?	Unclear	Matched pairs of clinics with one allocated to experimental condition
Blinding? Women and clinical staff	No	Educational intervention.
Incomplete outcome data addressed? All outcomes	No	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

Free of selective reporting?	Unclear	Data not adjusted for clustering.
Free of detection bias?	No	No biochemical validation.

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.

Risk of bias

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

Mayer 1990 (*Continued*)

Free of detection bias?	Unclear	Saliva samples from a sub-sample of the participants.

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

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

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.

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
Notes	Refusal rate approximately 20%. Design effect for clustering reported, so outcome figures used

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Random sequence generation using excel for each stratum.
Allocation concealment?	Yes	Group allocation by external statistician.
Blinding? Women and clinical staff	No	Not possible to blind midwives to allocation group. Women were not aware of midwife group allocation
Incomplete outcome data addressed? All outcomes	No	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
Free of selective reporting?	Unclear	Smoking status only reported.
Free of detection bias?	Yes	Cotinine serum assay.

Moore 2002

Methods	Cluster-randomised trial of provision of self-help in 3 UK NHS hospital trusts, 1998-2000
Participants	128 community midwives in 3 trusts were randomly allocated to 6 strata. Inclusion criteria: women attending first visit; > 16 years; < 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
Interventions	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).

Moore 2002 (*Continued*)

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

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Stratified random allocation by computer-generated random numbers. 118 midwives stratified according to workload and randomly allocated to provide intervention or control care
Allocation concealment?	Unclear	No information.
Blinding? Women and clinical staff	No	Midwives randomised. Educational intervention.
Incomplete outcome data addressed? All outcomes	Yes	Some attrition: 8%. Drop-outs included in denominator for ITT analysis
Free of selective reporting?	Unclear	No adjustment for clustering.
Free of detection bias?	Yes	Urinary cotinine levels analysed.

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

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	No	Alternate according to the day of the week.
Allocation concealment?	No	Nurse delivering the intervention attended on alternate days. Authors state the appointments were made by a person who was unaware of the intervention days
Blinding? Women and clinical staff	No	Educational intervention by designated nurse.
Incomplete outcome data addressed? All outcomes	No	Full data available for 76%.
Free of selective reporting?	Unclear	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
Free of detection bias?	Yes	Reported smoking validated by urinary cotinine levels.

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

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	No information provided.
Allocation concealment?	Unclear	Not specified.
Blinding? Women and clinical staff	No	Home visitation programme.
Incomplete outcome data addressed? All outcomes	No	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

Free of selective reporting?	Yes	Detailed range of outcomes reported.
Free of detection bias?	Yes	Serum cotinine analysis on sub-sample of 116/354.

Panjari 1999

Methods	Randomised controlled trial of personalised smoking cessation interventions in a low socioeconomic population in Melbourne, Victoria, Australia. Data collected from April 1994-June 1996
Participants	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: > 20 weeks' gestation; twin pregnancy; 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
Interventions	Control group received UC, which included advice at the discretion of the caregiver, a group counselling session, and a pamphlet "Smoking & 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
Outcomes	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 (< 2500 g) Reduction in mean cigarettes/day and cotinine levels. General health questionnaire (including stress and depression measurement) at baseline and end of pregnancy
Notes	Process evaluation showed 71% women in the intervention group received the full intervention

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	No information.
Allocation concealment?	Unclear	Described as "randomly allocated".
Blinding? Women and clinical staff	No	Educational intervention delivered by clinic midwife.

Incomplete outcome data addressed? All outcomes	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

Pbert 2004

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 "4A's" 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 intracluster correlation of 0.10 used to adjust data for inclusion in outcome tables

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	No information provided.
Allocation concealment?	Unclear	No information provided.
Blinding? Women and clinical staff	No	Sites aware of allocation status.
Incomplete outcome data addressed? All outcomes	No	One clinic dropped out due to poor recruitment.

Pbert 2004 (*Continued*)

Free of selective reporting?	Unclear	Trial part of a nutritional program, but only smoking outcomes in this report. ITT not conducted in trial report, but all dropouts included as continuing smokers in this review
Free of detection bias?	Yes	Cotinine assay.

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

Item	**Authors' judgement**	**Description**

Petersen 1992 (*Continued*)

Adequate sequence generation?	Yes	Table of random numbers. Allocation to intervention arm 2 was not randomised but offered to all eligible enrollees at one clinic: data from this intervention arm are not included in the review
Allocation concealment?	Unclear	No information provided.
Blinding? Women and clinical staff	Unclear	State that caregivers were blind as materials to the intervention group were mailed. Not feasible to blind women
Incomplete outcome data addressed? All outcomes	No	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
Free of selective reporting?	Unclear	None apparent but results were not simple to interpret.
Free of detection bias?	Yes	Urinary cotinine validation performed on a 50% sub-sample of those that reported not smoking

Polanska 2004

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

Risk of bias

Item	Authors' judgement	Description

Polanska 2004 (*Continued*)

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

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	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

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Computerised-random number generation.
Allocation concealment?	No	Described as "open label randomised trial".
Blinding? Women and clinical staff	No	Caregivers and women not blinded.
Incomplete outcome data addressed? All outcomes	No	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
Free of selective reporting?	Yes	All adverse outcomes reported.
Free of detection bias?	Yes	Salivary cotinine

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

	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

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Not reported.
Allocation concealment?	No	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
Blinding? Women and clinical staff	No	Educational intervention in antenatal clinics.
Incomplete outcome data addressed? All outcomes	No	Relatively low participation and high attrition (57% dropout) from enrolment to completion. Differential drop-out rate in the three study groups. No ITT
Free of selective reporting?	Unclear	Low participation and high attrition.
Free of detection bias?	Yes	Biochemical validation by exhaled CO.

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,

RADIUS 1995 (*Continued*)

	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: I = 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

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Stratified computer randomisation.
Allocation concealment?	Unclear	Information not provided.
Blinding? Women and clinical staff	Unclear	Smoking status not revealed to sonographer. Intervention not explicitly about smoking cessation
Incomplete outcome data addressed? All outcomes	Yes	Small loss to follow up (approximately 2%) . Available case analysis but smoking cessation was not a primary outcome
Free of selective reporting?	Yes	None apparent.
Free of detection bias?	No	No biochemical validation.

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

Reading 1982 (*Continued*)

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. Cites evidence for the reliability of self-report (Pettiti 1981).

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Described as "assigned at random".
Allocation concealment?	Unclear	No information.
Blinding? Women and clinical staff	Unclear	Intervention with verbal feedback, so not feasible to blind women. State that those providing care were not involved in the study
Incomplete outcome data addressed? All outcomes	No	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
Free of selective reporting?	Unclear	Data collected not specified.
Free of detection bias?	No	No biochemical validation.

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 miscarraige. 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

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Computer generated.
Allocation concealment?	Yes	Stated that recruiters were not aware of group allocation.
Blinding? Women and clinical staff	No	All providers and women sent smoking cessation practice guideline
Incomplete outcome data addressed? All outcomes	No	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

Free of selective reporting?	No	
Free of detection bias?	Yes	Salivary cotinine confirmation in 66%.

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

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	No	Alternation (group allocation on alternate weeks).
Allocation concealment?	Unclear	Not specified.
Blinding? Women and clinical staff	No	Caregivers not blinded to counselling intervention.

Incomplete outcome data addressed? All outcomes	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.

Secker-Walker 1994 (*Continued*)

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

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Described as "randomly assigned".
Allocation concealment?	Unclear	Not stated. Unclear when randomisation took place.
Blinding? Women and clinical staff	No	Educational intervention in antenatal clinics.
Incomplete outcome data addressed? All outcomes	No	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
Free of selective reporting?	Unclear	Data collected not specified. Only smoking outcomes reported
Free of detection bias?	Yes	Urinary cotinine levels measured at 36 weeks.

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

Secker-Walker 1995 (*Continued*)

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

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Described as 'randomly assigned'.
Allocation concealment?	Unclear	Not stated. Unclear when randomisation took place.
Blinding? Women and clinical staff	No	Educational intervention in antenatal clinics.
Incomplete outcome data addressed? All outcomes	No	Data included on approx 65% of participants who had biochemical validation of smoking status. Voluntary drop-outs treated as continuing smokers for some analyses
Free of selective reporting?	Unclear	Only smoking outcomes reported.
Free of detection bias?	Yes	Urinary cotinine levels measured at 36 weeks.

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

Secker-Walker 1997 (*Continued*)

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

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Described as "randomly assigned".
Allocation concealment?	Unclear	No information provided.
Blinding? Women and clinical staff	No	Educational intervention.
Incomplete outcome data addressed? All outcomes	No	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
Free of selective reporting?	Unclear	Not apparent.
Free of detection bias?	Yes	Exhaled CO measured at 36 weeks' gestation.

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

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Described as "randomly assigned".
Allocation concealment?	Unclear	No details provided.
Blinding? Women and clinical staff	No	Intervention by clinic staff. Notes flagged.

Secker-Walker 1998 (*Continued*)

Incomplete outcome data addressed? All outcomes	No	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
Free of selective reporting?	Unclear	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
Free of detection bias?	Yes	Validation by exhaled CO and urinary cotinine levels.

Sexton 1984

Methods	A randomised trial of an intervention to increase birthweight by changing maternal smoking, carried out in Baltimore, USA. Enrolled during a 2.5 year period (dates not specified)
Participants	Pregnant women who were smoking >= 10 cigarettes/day immediately prior to pregnancy (71% of whom were spontaneous quitters), < 18 weeks' gestation, attending 52 private physicians and the hospital antenatal clinic. Heterogeneous population, including large inner-city and suburban. 89% of those eligible were recruited n = 935, 463 (I), 472 (C) . Mean cigarettes/day pre-pregnancy I = 20.9, C = 20.7
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. Miscarriage; 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*)

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

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? Women and clinical staff	No	Caregivers not blinded to this educational intervention.
Incomplete outcome data addressed? All outcomes	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

Risk of bias

Solomon 2000 (*Continued*)

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

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

	of change". Breastfeeding rates and general health behaviours obtained but not reported
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

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Computer-generated random number list.
Allocation concealment?	Unclear	No details provided.
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

Strecher 2000 (*Continued*)

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

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	By computer algorithm.
Allocation concealment?	Unclear	Not described.
Blinding? Women and clinical staff	No	Caregivers not blinded to intervention.
Incomplete outcome data addressed? All outcomes	No	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
Free of selective reporting?	Unclear	Results are conflicting.
Free of detection bias?	Yes	Urinary cotinine analysis at 24 weeks' gestation and at 6 weeks' postpartum

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*)

Outcomes	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%
Notes	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

Risk of bias

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

Tappin 2005

Methods	Randomised controlled trial of home-based motivational interviewing by midwives. Trial conducted in Glasgow, Scotland, from March 2001 to May 2003
Participants	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.
Interventions	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

Tappin 2005 (*Continued*)

	Theoretical basis: motivational interviewing and CBT
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

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

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

Thornton 1997 (*Continued*)

	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

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

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).
Outcomes	Smoking cessation and reduction assessed immediately after the intervention, biochemically validated but not reported
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

Risk of bias

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

Valbo 1994

Methods	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
Participants	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
Interventions	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
Outcomes	Smoking cessation and reduction in late pregnancy. No biochemical validation
Notes	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

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	No	Described as "consecutively randomised".
Allocation concealment?	No	Women consecutively randomised into 2 groups.
Blinding? Women and clinical staff	No	Educational intervention and ultrasound.
Incomplete outcome data addressed? All outcomes	Unclear	Attrition approximately 10%. All drop-outs included in analysis as continuing smokers
Free of selective reporting?	Unclear	Only smoking outcomes reported.
Free of detection bias?	No	No biochemical validation and difference in smoking rates between groups at baseline

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

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

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

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Computer generated.

Walsh 1997 (*Continued*)

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

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

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Computer generated.
Allocation concealment?	Unclear	Not reported.
Blinding? Women and clinical staff	No	Notes flagged. Educational intervention.
Incomplete outcome data addressed? All outcomes	Unclear	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
Free of selective reporting?	Unclear	Only smoking outcomes reported.
Free of detection bias?	Yes	Saliva samples analysed.

Windsor 2000a

Methods	Evaluation trial of behavioural impact of new patient education methods ("SCRIPT") , provided by trained Medicaid maternity care staff members, in Alabama, USA, 1997-2001, from 17 eligible counties at 22 urban prenatal care clinics
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-

Windsor 2000a (*Continued*)

	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

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

Wisborg 2000

Methods	Double-blind, placebo controlled trial of nicotine replacement therapy (patches) in pregnant women in a Danish obstetric hospital

Wisborg 2000 (*Continued*)

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

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

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
Pls: 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]*

Study	Reason for exclusion
Albrecht 2006	Outcome data not reported in format to include in meta-analysis. No reply from authors to request for numerical outcome data
Boshier 2003	Cohort study, not a randomised study design.
Britton 2006	Quasi-experimental design. Control and experimental convenience samples collected consecutively
Byrd 1993	There are no data provided by trial allocation.
Chan 2005	Controlled observational study of Bupropion for smoking cessation in pregnancy
Cook 1995	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 Louiseville, USA. No further results published and no response to letter to author in 2008 requesting final data
Cope 2001	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

(*Continued*)

Culp 2007	Controlled trial/evaluation of "The Community-Based Family Resource and Support" (CBFRS) Program. Control group not randomised
Emmons 2000	Controlled trial/evaluation of the "Healthy Baby Second Hand Smoke Study" uses historical controls. Good documentation of implementation problems
Ershoff 1983	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
Ferreira-Borges 2005	Pre-test post-test control group design (not randomised).
French 2007	Controlled clinical trial of postpartum relapse prevention. Excluded as not a trial during pregnancy, and not randomised
Gebauer 1998	Study of effect of one 15 minute counselling session and a follow-up telephone call, performed 1994-95, using historical controls from 1993-1994
Gillies 1987	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
Graham 1992	Although the multicomponent intervention included a smoking change component there are no smoking data in the paper
Grange 2005	Cohort study design.
Hahn 2005	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
Haug 1994	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
Haug 2004	Actual outcome smoking cessation figures are not reported. No reply from author to written request for outcome data
Heil 2003	Non-pregnant population.
Hiett 2000	Insufficient recruitment data in abstract to include in meta-analysis. No reply to letter sent to author for andditional information in 2008
Hughes 2000	Insufficient outcome data reported for meta-analysis
Hymowitz 2006	Postpartum trial only which measures paediatrician implementation of smoking cessation and relapse prevention interventions

(*Continued*)

Jaakola 2001	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
Kaper 2006	Non-pregnant population.
Kientz 2006	Pretest post test control group design (not randomised).
Langford 1983	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
Lillington 1995	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
Loke 2005	Intervention aimed at smoking cessation in men (husbands of pregnant women)
Lowe 2002	Data are available on uptake of programs at a hospital level but not at present on smoking cessation effectiveness or perinatal outcomes
Messimer 1989	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
Moore 1998	Not specifically a smoking cessation trial. Data does not include the proportion of smokers which continue to smoke after the intervention
Mullen 1990	Data are provided on those who stopped smoking only, not data by trial allocation
Mullen 1991	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
Mullen 1997	Study designed to promote postpartum smoking cessation (not antepartum)
Olds 1994	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
Olds 2002	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
Oncken 2006	No control group without intervention of nicotine gum.

(*Continued*)

Power 1989	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
Ratner 1999	Postpartum intervention only. No interventions in pregnancy.
Scott 2000	This controlled clinical trial of the impact of using interactive software to promote smoking cessation, was excluded as it used historical controls
Shakespeare 1990	Data on smoking reduction and smoking cessation are combined with no separate data on smoking cessation
Stanton 2004	Intervention aimed at men (partners of pregnant women).
Stotts 2003	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
Stotts 2004	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
Suplee 2004	Randomised trial of relapse prevention counselling in the postpartum period only (not pregnancy)
Thyrian 2006	Randomised trial of postpartum intervention only (not prenatal)
Valanis 2001	This prospective controlled clinical trial design to test the effect of a low intensity intervention, used historical controls
Wadland 2007	Implementation trial to change provider behaviour and increase referrals to quitline. Estimated smoking cessation outcome data only
Wiggins 2004	Smoking cessation outcome data not included. Not specifically a smoking cessation trial
Wisborg 1998	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)
Yilmaz 2006	Postnatal intervention in pediatric setting.

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

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

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

Coleman 2007

Trial name or title	UK Trial of nicotine replacement therapy (NRT) in pregnancy - "SNAP"
Methods	Double-blind, randomised, placebo-controlled trial in 5 east midland hospitals
Participants	Pregnant, nicotine-addicted women are recruited as they attend for antenatal ultrasound scans (12-24 weeks' gestation). Women report smoking at lest 10 cigarettes before pregnancy and still smoke at least 5 cigarettes daily. Min exhaled Co of 8 ppm 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
Interventions	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)
Outcomes	Biochemically validated smoking cessation immediately before childbirth 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
Starting date	1 February 2006
Contact information	Dr Tim Coleman, School of Community Services, University Hospital Nottingham. tim.coleman@nottingham.ac.uk
Notes	End date 31 January 2012

El-Khorazaty 2007

Trial name or title	Project DC-HOPE (NICH-DC Initiative) in Columbia, USA.
Methods	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
Participants	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
Interventions	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 "audio-computer-assisted self-interview"
Outcomes	Cotinine validated cessation at end of pregnancy (end of pregnancy and 8-10 weeks' postpartum), depression, violence, prematurity, birthweight
Starting date	Recruitment 2001-2003. Follow up completed 2004.
Contact information	Nabil El-Khorazaty nek@rti.org
Notes	Author contacted 2008 - need to await publication of results

Groff 2005

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

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 (*Continued*)

Interventions	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	Nov 2006. Expected completion Nov 2007.
Contact information	Christi Patten, Principal Investigator, Mayo clinic, Rochester, Minnesota, USA contact: hughes.christine@mayo.edu
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*)

Starting date	
Contact information	Shu-Hong Zhu 2004, University of California. szhu@ucsd.edu
Notes	Author emailed 2008, advised that results would not be available until publication

DATA AND ANALYSES

Comparison 1. Interventions for smoking cessation in pregnancy versus control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Continued smoking in late pregnancy	65	21258	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.93, 0.96]
1.1 Individually randomised trials	56	15915	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.92, 0.96]
1.2 Cluster-randomised trials	9	5343	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.94, 1.00]
2 Continued smoking in pregnancy subgrouped by risk of bias	64	21117	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.93, 0.96]
2.1 Low risk of bias (biochem val + ITT +ad. rand.)	14	5691	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.94, 0.99]
2.2 Moderate risk of bias (biochem val only)	35	11638	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.92, 0.97]
2.3 High risk of bias (no biochem validation)	15	3788	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.87, 0.95]
3 Continued smoking in late pregnancy by intensity of intervention	65	21258	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.93, 0.96]
3.1 High intensity	44	14453	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.92, 0.96]
3.2 Medium intensity	18	5670	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.92, 0.98]
3.3 Low intensity	3	1135	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.83, 1.09]
4 Continued smoking in late pregnancy subgrouped by main intervention strategy	65	21257	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.93, 0.96]
4.1 Cognitive behaviour strategies	30	9570	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.93, 0.97]
4.2 Stages of change	11	5073	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.97, 1.00]
4.3 Feedback	4	572	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.84, 1.02]
4.4 Rewards	4	1285	Risk Ratio (M-H, Random, 95% CI)	0.76 [0.71, 0.81]
4.5 Pharmacotherapy (NRT, Bupropion etc) nicotine replacement therapy	5	1147	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.92, 0.98]
4.6 Other	11	3610	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.93, 0.98]
5 Continued smoking (relapse) for spontaneous quitters in late pregnancy	8	1064	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.75, 1.10]
6 Mean birthweight	21	15119	Mean Difference (IV, Random, 95% CI)	39.26 [15.77, 62.74]
7 Mean birthweight subgrouped by main intervention strategy	21	15119	Mean Difference (IV, Random, 95% CI)	39.26 [15.77, 62.74]
7.1 Cognitive behavioural therapy	9	3809	Mean Difference (IV, Random, 95% CI)	47.01 [12.22, 81.80]
7.2 Stages of change	2	1312	Mean Difference (IV, Random, 95% CI)	-5.84 [-66.40, 54.72]

7.3 Feedback	3	6611	Mean Difference (IV, Random, 95% CI)	47.80 [-14.67, 110.28]
7.4 Rewards	2	1008	Mean Difference (IV, Random, 95% CI)	123.98 [-1.92, 249.89]
7.5 Pharmacotherapy	3	1078	Mean Difference (IV, Random, 95% CI)	34.40 [-125.77, 194.58]
7.6 Other	2	1301	Mean Difference (IV, Random, 95% CI)	36.27 [-18.71, 91.25]
8 Low birthweight (under 2500 g)	16	9916	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.73, 0.95]
9 Very low birthweight (under 1500 g)	4	5496	Risk Ratio (M-H, Random, 95% CI)	1.16 [0.69, 1.96]
10 Perinatal deaths	3	4335	Risk Ratio (M-H, Random, 95% CI)	1.13 [0.72, 1.77]
11 Preterm birth (under 37 or under 36 weeks)	14	11930	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.74, 0.98]
12 Stillbirths	6	4706	Risk Ratio (M-H, Random, 95% CI)	1.10 [0.69, 1.76]
13 Neonatal deaths	3	4143	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.34, 4.01]
14 NICU admissions	4	1394	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.61, 1.18]
15 Smoking reduction: numbers of women reducing smoking in late pregnancy	13		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
15.1 Self-reported some reduction in smoking (various definitions)	5	1487	Risk Ratio (M-H, Random, 95% CI)	1.52 [1.29, 1.78]
15.2 Self-reported > 50% reduction in smoking	3	779	Risk Ratio (M-H, Random, 95% CI)	1.23 [0.91, 1.67]
15.3 Biochemically validated reduction	5	1549	Risk Ratio (M-H, Random, 95% CI)	1.27 [0.84, 1.91]
16 Smoking reduction: biochemical measures in late pregnancy	4	2511	Std. Mean Difference (IV, Random, 95% CI)	-0.11 [-0.24, 0.02]
16.1 Mean cotinine levels	3	1742	Std. Mean Difference (IV, Random, 95% CI)	-0.05 [-0.14, 0.05]
16.2 Mean thiocynate level	1	769	Std. Mean Difference (IV, Random, 95% CI)	-0.29 [-0.44, -0.15]
17 Smoking reduction: self-reported mean cigarettes per day measured in late pregnancy or at delivery	9	3372	Mean Difference (IV, Random, 95% CI)	-0.67 [-1.49, 0.16]
18 Maintained smoking cessation at 1-5 months postpartum	20	6097	Risk Ratio (M-H, Random, 95% CI)	1.65 [1.22, 2.24]
18.1 Individually randomised trials	15	4726	Risk Ratio (M-H, Random, 95% CI)	1.43 [1.08, 1.91]
18.2 Cluster-randomised trials	5	1371	Risk Ratio (M-H, Random, 95% CI)	2.08 [0.78, 5.56]
19 Maintained smoking cessation at 6 to 12 months postpartum	8	2624	Risk Ratio (M-H, Random, 95% CI)	1.39 [0.82, 2.38]
19.1 Individually randomised trials	8	2624	Risk Ratio (M-H, Random, 95% CI)	1.39 [0.82, 2.38]
19.2 Cluster-randomised trials	0	0	Risk Ratio (M-H, Random, 95% CI)	Not estimable

Analysis 1.1. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 1 Continued smoking in late pregnancy.

Review: Interventions for promoting smoking cessation during pregnancy

Comparison: 1 Interventions for smoking cessation in pregnancy versus control

Outcome: 1 Continued smoking in late pregnancy

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Individually randomised trials					
Albrecht 1998	23/26	53/58		0.8 %	0.97 [0.83, 1.14]
Baric 1976	54/63	45/47		1.3 %	0.90 [0.80, 1.01]
Bauman 1983	36/39	43/49		1.0 %	1.05 [0.92, 1.21]
Belizan 1995	196/255	207/237		1.8 %	0.88 [0.81, 0.96]
Bullock 1995	36/65	36/66		0.3 %	1.02 [0.74, 1.38]
Burling 1991	61/70	65/69		1.4 %	0.93 [0.83, 1.03]
Cinciripini 2000	39/42	35/40		1.0 %	1.06 [0.92, 1.23]
Cope 2003	142/164	112/116		2.1 %	0.90 [0.84, 0.96]
Donatelle 2000	78/112	99/108		1.0 %	0.76 [0.66, 0.87]
Dornelas 2006	38/53	47/52		0.6 %	0.79 [0.66, 0.96]
Dunkley 1997	46/50	50/50		1.7 %	0.92 [0.84, 1.01]
Ershoff 1989	93/126	96/116		1.1 %	0.89 [0.78, 1.02]
Ershoff 1999	106/131	105/126		1.3 %	0.97 [0.87, 1.09]
Gielen 1997	181/193	187/198		2.5 %	0.99 [0.94, 1.04]
Hartmann 1996	86/113	90/106		1.1 %	0.90 [0.79, 1.02]
Hegaard 2003	304/327	313/320		2.9 %	0.95 [0.92, 0.98]
Heil 2008	22/37	36/40		0.3 %	0.66 [0.50, 0.88]
Higgins 2004	19/30	21/23		0.3 %	0.69 [0.51, 0.94]
Hjalmarson 1991	398/444	198/209		2.7 %	0.95 [0.90, 0.99]
Hotham 2005	17/20	20/20		0.6 %	0.85 [0.70, 1.05]
Kapur 2001	13/17	13/13		0.3 %	0.78 [0.58, 1.03]
Lilley 1986	68/72	72/73		2.3 %	0.96 [0.90, 1.02]
Loeb 1983	435/477	447/486		2.8 %	0.99 [0.95, 1.03]

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Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Lowe 1998a	108/111	113/116		2.7 %	1.00 [0.96, 1.04]
Lowe 1998b	40/44	34/34		1.4 %	0.91 [0.82, 1.01]
MacArthur 1987	449/493	464/489		2.9 %	0.96 [0.93, 0.99]
Malchodi 2003	51/67	59/75		0.7 %	0.97 [0.81, 1.16]
Mayer 1990	64/72	75/77		1.7 %	0.91 [0.83, 1.00]
McBride 1999	269/341	130/160		1.6 %	0.97 [0.89, 1.06]
O'Connor 1992	78/90	79/84		1.6 %	0.92 [0.84, 1.02]
Olds 1986	77/77	64/64			Not estimable
Panjari 1999	443/476	506/537		2.9 %	0.99 [0.96, 1.02]
Petersen 1992	37/43	39/47		0.7 %	1.04 [0.87, 1.24]
Pollak 2007	105/122	58/59		1.9 %	0.88 [0.81, 0.95]
Price 1991	67/71	69/70		2.2 %	0.96 [0.90, 1.02]
Reading 1982	20/39	20/26		0.2 %	0.67 [0.46, 0.97]
Rigotti 2006	188/209	196/212		2.3 %	0.97 [0.92, 1.03]
Rush 1992	153/175	131/144		2.0 %	0.96 [0.89, 1.04]
Secker-Walker 1994	196/225	204/230		2.1 %	0.98 [0.92, 1.05]
Secker-Walker 1997	21/26	30/30		0.6 %	0.81 [0.67, 0.98]
Secker-Walker 1998	116/135	130/144		1.7 %	0.95 [0.87, 1.04]
Sexton 1984	296/463	393/472		1.9 %	0.77 [0.71, 0.83]
Solomon 2000	63/77	63/74		1.0 %	0.96 [0.83, 1.11]
Stotts 2002	91/134	89/135		0.8 %	1.03 [0.87, 1.22]
Strecher 2000	94/104	79/87		1.7 %	1.00 [0.91, 1.09]
Tappin 2000	46/48	47/49		1.8 %	1.00 [0.92, 1.09]
Tappin 2005	334/351	392/411		2.9 %	1.00 [0.97, 1.03]
Thornton 1997	186/209	185/209		2.1 %	1.01 [0.94, 1.08]
Valbo 1991	31/50	47/50		0.5 %	0.66 [0.53, 0.83]
Valbo 1994	45/56	54/56		1.0 %	0.83 [0.73, 0.96]
Valbo 1996	47/52	70/78		1.3 %	1.01 [0.90, 1.13]
Walsh 1997	110/127	118/125		1.9 %	0.92 [0.85, 0.99]
Windsor 1985	88/102	102/104		1.8 %	0.88 [0.81, 0.95]
Windsor 1993	343/400	379/414		2.6 %	0.94 [0.89, 0.98]

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Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Windsor 2000a	115/139	116/127		1.6 %	0.91 [0.83, 0.99]
Wisborg 2000	103/124	108/126		1.4 %	0.97 [0.87, 1.08]
Subtotal (95% CI)	**8178**	**7737**		**84.5 %**	**0.94 [0.92, 0.96]**
Total events: 6965 (Treatment), 7033 (Control)					
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 150.92$, df = 54 (P<0.00001); $I^2 = 64\%$					
Test for overall effect: Z = 6.73 (P < 0.00001)					
2 Cluster-randomised trials					
Campbell 2006	87/98	90/96		1.7 %	0.95 [0.87, 1.03]
DeVries 2006	47/58	68/73		1.0 %	0.87 [0.76, 1.00]
Hajek 2001	285/365	293/367		2.0 %	0.98 [0.91, 1.05]
Kendrick 1995	774/822	998/1063		3.1 %	1.00 [0.98, 1.03]
Lawrence 2003	572/611	274/284		3.0 %	0.97 [0.94, 1.00]
McLeod 2004	133/163	96/109		1.5 %	0.93 [0.84, 1.02]
Moore 2002	435/523	459/567		2.4 %	1.03 [0.97, 1.09]
Pbert 2004	21/26	16/18		0.4 %	0.91 [0.71, 1.17]
Polanska 2004	35/62	32/38		0.4 %	0.67 [0.52, 0.87]
Subtotal (95% CI)	**2728**	**2615**		**15.5 %**	**0.97 [0.94, 1.00]**
Total events: 2389 (Treatment), 2326 (Control)					
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 19.91$, df = 8 (P = 0.01); $I^2 = 60\%$					
Test for overall effect: Z = 1.78 (P = 0.075)					
Total (95% CI)	**10906**	**10352**		**100.0 %**	**0.94 [0.93, 0.96]**
Total events: 9354 (Treatment), 9359 (Control)					
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 180.06$, df = 63 (P<0.00001); $I^2 = 65\%$					
Test for overall effect: Z = 7.02 (P < 0.00001)					

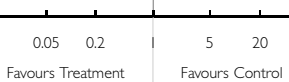
Analysis 1.2. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 2 Continued smoking in pregnancy subgrouped by risk of bias.

Review: Interventions for promoting smoking cessation during pregnancy

Comparison: 1 Interventions for smoking cessation in pregnancy versus control

Outcome: 2 Continued smoking in pregnancy subgrouped by risk of bias

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Low risk of bias (biochem val + ITT +ad. rand.)					
Hotham 2005	17/20	20/20		0.6 %	0.85 [0.70, 1.05]
Lawrence 2003	572/611	274/284		3.0 %	0.97 [0.94, 1.00]
Malchodi 2003	51/67	59/75		0.7 %	0.97 [0.81, 1.16]
McLeod 2004	133/163	96/109		1.5 %	0.93 [0.84, 1.02]
Moore 2002	435/523	459/567		2.4 %	1.03 [0.97, 1.09]
Pollak 2007	99/122	52/59		1.1 %	0.92 [0.81, 1.05]
Rigotti 2006	188/209	196/212		2.3 %	0.97 [0.92, 1.03]
Stotts 2002	91/134	89/135		0.8 %	1.03 [0.87, 1.22]
Tappin 2000	46/48	47/49		1.8 %	1.00 [0.92, 1.09]
Tappin 2005	334/351	392/411		3.0 %	1.00 [0.97, 1.03]
Walsh 1997	110/127	118/125		1.9 %	0.92 [0.85, 0.99]
Windsor 1985	88/102	102/104		1.8 %	0.88 [0.81, 0.95]
Windsor 1993	343/400	379/414		2.6 %	0.94 [0.89, 0.98]
Wisborg 2000	103/124	108/126		1.4 %	0.97 [0.87, 1.08]
Subtotal (95% CI)	**3001**	**2690**		**25.0 %**	**0.97 [0.94, 0.99]**
Total events: 2610 (Treatment), 2391 (Control)					
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 20.29$, df = 13 (P = 0.09); $I^2 = 36\%$					
Test for overall effect: Z = 2.96 (P = 0.0031)					
2 Moderate risk of bias (biochem val only)					
Albrecht 1998	23/26	53/58		0.8 %	0.97 [0.83, 1.14]
Bauman 1983	36/39	43/49		1.0 %	1.05 [0.92, 1.21]
Burling 1991	61/70	65/69		1.4 %	0.93 [0.83, 1.03]
Campbell 2006	87/98	90/96		1.7 %	0.95 [0.87, 1.03]
Cinciripini 2000	39/42	35/40		1.0 %	1.06 [0.92, 1.23]
Cope 2003	142/164	112/116		2.1 %	0.90 [0.84, 0.96]



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Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Donatelle 2000	78/112	99/108		1.0 %	0.76 [0.66, 0.87]
Dornelas 2006	38/53	47/52		0.6 %	0.79 [0.66, 0.96]
Ershoff 1989	93/126	96/116		1.1 %	0.89 [0.78, 1.02]
Ershoff 1999	106/131	105/126		1.3 %	0.97 [0.87, 1.09]
Gielen 1997	181/193	187/198		2.6 %	0.99 [0.94, 1.04]
Hajek 2001	285/365	293/367		2.0 %	0.98 [0.91, 1.05]
Hartmann 1996	86/113	90/106		1.1 %	0.90 [0.79, 1.02]
Hegaard 2003	304/327	313/320		2.9 %	0.95 [0.92, 0.98]
Heil 2008	22/37	36/40		0.3 %	0.66 [0.50, 0.88]
Higgins 2004	19/30	21/23		0.3 %	0.69 [0.51, 0.94]
Hjalmarson 1991	398/444	198/209		2.7 %	0.95 [0.90, 0.99]
Kapur 2001	13/17	13/13		0.3 %	0.78 [0.58, 1.03]
Kendrick 1995	774/822	998/1063		3.2 %	1.00 [0.98, 1.03]
Lowe 1998a	108/111	113/116		2.7 %	1.00 [0.96, 1.04]
McBride 1999	269/341	130/160		1.6 %	0.97 [0.89, 1.06]
O'Connor 1992	78/90	79/84		1.6 %	0.92 [0.84, 1.02]
Panjari 1999	443/476	506/537		3.0 %	0.99 [0.96, 1.02]
Pbert 2004	21/26	16/18		0.4 %	0.91 [0.71, 1.17]
Petersen 1992	37/43	39/47		0.7 %	1.04 [0.87, 1.24]
Price 1991	67/71	69/70		2.3 %	0.96 [0.90, 1.02]
Rush 1992	153/175	131/144		2.0 %	0.96 [0.89, 1.04]
Secker-Walker 1994	196/225	204/230		2.1 %	0.98 [0.92, 1.05]
Secker-Walker 1997	21/26	30/30		0.6 %	0.81 [0.67, 0.98]
Secker-Walker 1998	116/135	130/144		1.8 %	0.95 [0.87, 1.04]
Sexton 1984	296/463	393/472		1.9 %	0.77 [0.71, 0.83]
Solomon 2000	63/77	63/74		1.0 %	0.96 [0.83, 1.11]
Strecher 2000	94/104	79/87		1.7 %	1.00 [0.91, 1.09]
Thornton 1997	186/209	185/209		2.1 %	1.01 [0.94, 1.08]
Windsor 2000a	115/139	116/127		1.6 %	0.91 [0.83, 0.99]
Subtotal (95% CI)	**5920**	**5718**		**54.5 %**	**0.94 [0.92, 0.97]**
Total events: 5048 (Treatment), 5177 (Control)					
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 114.51$, df = 34 ($P<0.00001$); $I^2 = 70\%$					

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Favours Treatment Favours Control

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Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Test for overall effect: Z = 4.65 (P < 0.00001)					
3 High risk of bias (no biochem validation)					
Baric 1976	54/63	45/47		1.3 %	0.90 [0.80, 1.01]
Belizan 1995	196/255	207/237		1.8 %	0.88 [0.81, 0.96]
Bullock 1995	36/65	36/66		0.3 %	1.02 [0.74, 1.38]
DeVries 2006	47/58	68/73		1.0 %	0.87 [0.76, 1.00]
Dunkley 1997	46/50	50/50		1.7 %	0.92 [0.84, 1.01]
Lilley 1986	68/72	72/73		2.3 %	0.96 [0.90, 1.02]
Loeb 1983	435/477	447/486		2.8 %	0.99 [0.95, 1.03]
Lowe 1998b	40/44	34/34		1.4 %	0.91 [0.82, 1.01]
MacArthur 1987	449/493	464/489		2.9 %	0.96 [0.93, 0.99]
Mayer 1990	64/72	75/77		1.7 %	0.91 [0.83, 1.00]
Polanska 2004	35/62	32/38		0.4 %	0.67 [0.52, 0.87]
Reading 1982	20/39	20/26		0.2 %	0.67 [0.46, 0.97]
Valbo 1991	31/50	47/50		0.5 %	0.66 [0.53, 0.83]
Valbo 1994	45/56	54/56		1.0 %	0.83 [0.73, 0.96]
Valbo 1996	47/52	70/78		1.3 %	1.01 [0.90, 1.13]
Subtotal (95% CI)	**1908**	**1880**		**20.5 %**	**0.91 [0.87, 0.95]**
Total events: 1613 (Treatment), 1721 (Control)					
Heterogeneity: Tau^2 = 0.00; Chi^2 = 41.22, df = 14 (P = 0.00016); I^2 =66%					
Test for overall effect: Z = 4.30 (P = 0.000017)					
Total (95% CI)	**10829**	**10288**		**100.0 %**	**0.94 [0.93, 0.96]**
Total events: 9271 (Treatment), 9289 (Control)					
Heterogeneity: Tau^2 = 0.00; Chi^2 = 175.52, df = 63 (P<0.00001); I^2 =64%					
Test for overall effect: Z = 6.90 (P < 0.00001)					

Analysis 1.3. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 3 Continued smoking in late pregnancy by intensity of intervention.

Review: Interventions for promoting smoking cessation during pregnancy

Comparison: 1 Interventions for smoking cessation in pregnancy versus control

Outcome: 3 Continued smoking in late pregnancy by intensity of intervention

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 High intensity					
Albrecht 1998	23/26	53/58		0.8 %	0.97 [0.83, 1.14]
Belizan 1995	196/255	207/237		1.8 %	0.88 [0.81, 0.96]
Bullock 1995	36/65	36/66		0.3 %	1.02 [0.74, 1.38]
Campbell 2006	87/98	90/96		1.7 %	0.95 [0.87, 1.03]
Cope 2003	142/164	112/116		2.1 %	0.90 [0.84, 0.96]
Donatelle 2000	78/112	99/108		1.0 %	0.76 [0.66, 0.87]
Dornelas 2006	38/53	47/52		0.6 %	0.79 [0.66, 0.96]
Ershoff 1999	106/131	105/126		1.3 %	0.97 [0.87, 1.09]
Gielen 1997	181/193	187/198		2.6 %	0.99 [0.94, 1.04]
Hajek 2001	285/365	293/367		2.0 %	0.98 [0.91, 1.05]
Hartmann 1996	86/113	90/106		1.1 %	0.90 [0.79, 1.02]
Hegaard 2003	304/327	313/320		2.9 %	0.95 [0.92, 0.98]
Heil 2008	22/37	36/40		0.3 %	0.66 [0.50, 0.88]
Higgins 2004	19/30	21/23		0.3 %	0.69 [0.51, 0.94]
Hotham 2005	17/20	20/20		0.6 %	0.85 [0.70, 1.05]
Kapur 2001	13/17	13/13		0.3 %	0.78 [0.58, 1.03]
Lawrence 2003	572/611	274/284		3.0 %	0.97 [0.94, 1.00]
Lilley 1986	68/72	72/73		2.3 %	0.96 [0.90, 1.02]
Loeb 1983	435/477	447/486		2.8 %	0.99 [0.95, 1.03]
Malchodi 2003	51/67	59/75		0.7 %	0.97 [0.81, 1.16]
McBride 1999	269/341	130/160		1.6 %	0.97 [0.89, 1.06]
McLeod 2004	133/163	96/109		1.5 %	0.93 [0.84, 1.02]
O'Connor 1992	78/90	79/84		1.6 %	0.92 [0.84, 1.02]

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Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Olds 1986	77/77	64/64			Not estimable
Panjari 1999	443/476	506/537		3.0 %	0.99 [0.96, 1.02]
Pbert 2004	21/26	16/18		0.4 %	0.91 [0.71, 1.17]
Polanska 2004	35/62	32/38		0.4 %	0.67 [0.52, 0.87]
Pollak 2007	99/122	52/59		1.1 %	0.92 [0.81, 1.05]
Rigotti 2006	188/209	196/212		2.3 %	0.97 [0.92, 1.03]
Rush 1992	153/175	131/144		2.0 %	0.96 [0.89, 1.04]
Secker-Walker 1994	196/225	204/230		2.1 %	0.98 [0.92, 1.05]
Secker-Walker 1998	116/135	130/144		1.8 %	0.95 [0.87, 1.04]
Sexton 1984	296/463	393/472		1.9 %	0.77 [0.71, 0.83]
Solomon 2000	63/77	63/74		1.0 %	0.96 [0.83, 1.11]
Stotts 2002	91/134	89/135		0.8 %	1.03 [0.87, 1.22]
Tappin 2000	46/48	47/49		1.8 %	1.00 [0.92, 1.09]
Tappin 2005	334/351	392/411		3.0 %	1.00 [0.97, 1.03]
Thornton 1997	186/209	185/209		2.1 %	1.01 [0.94, 1.08]
Valbo 1994	45/56	54/56		1.0 %	0.83 [0.73, 0.96]
Valbo 1996	47/52	70/78		1.3 %	1.01 [0.90, 1.13]
Walsh 1997	110/127	118/125		1.9 %	0.92 [0.85, 0.99]
Windsor 1993	343/400	379/414		2.6 %	0.94 [0.89, 0.98]
Windsor 2000a	115/139	116/127		1.6 %	0.91 [0.83, 0.99]
Wisborg 2000	103/124	108/126		1.4 %	0.97 [0.87, 1.08]
Subtotal (95% CI)	**7514**	**6939**		**66.8 %**	**0.94 [0.92, 0.96]**
Total events: 6346 (Treatment), 6224 (Control)					
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 118.47$, df = 42 ($P<0.00001$); $I^2 = 65\%$					
Test for overall effect: $Z = 5.83$ ($P < 0.00001$)					
2 Medium intensity					
Baric 1976	54/63	45/47		1.3 %	0.90 [0.80, 1.01]
Burling 1991	61/70	65/69		1.4 %	0.93 [0.83, 1.03]
Cinciripini 2000	39/42	35/40		1.0 %	1.06 [0.92, 1.23]
DeVries 2006	47/58	68/73		1.0 %	0.87 [0.76, 1.00]
Dunkley 1997	46/50	50/50		1.7 %	0.92 [0.84, 1.01]
Ershoff 1989	93/126	96/116		1.1 %	0.89 [0.78, 1.02]

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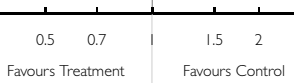
Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Hjalmarson 1991	398/444	198/209		2.7 %	0.95 [0.90, 0.99]
Kendrick 1995	774/822	998/1063		3.2 %	1.00 [0.98, 1.03]
Lowe 1998a	108/111	113/116		2.7 %	1.00 [0.96, 1.04]
Lowe 1998b	40/44	34/34		1.4 %	0.91 [0.82, 1.01]
Mayer 1990	64/72	75/77		1.7 %	0.91 [0.83, 1.00]
Moore 2002	435/523	459/567		2.4 %	1.03 [0.97, 1.09]
Petersen 1992	37/43	39/47		0.7 %	1.04 [0.87, 1.24]
Price 1991	67/71	69/70		2.3 %	0.96 [0.90, 1.02]
Secker-Walker 1997	21/26	30/30		0.6 %	0.81 [0.67, 0.98]
Strecher 2000	94/104	79/87		1.7 %	1.00 [0.91, 1.09]
Valbo 1991	31/50	47/50		0.5 %	0.66 [0.53, 0.83]
Windsor 1985	88/102	102/104		1.8 %	0.88 [0.81, 0.95]
Subtotal (95% CI)	**2821**	**2849**		**29.0 %**	**0.95 [0.92, 0.98]**
Total events: 2497 (Treatment), 2602 (Control)					
Heterogeneity: Tau^2 = 0.00; Chi^2 = 48.26, df = 17 (P = 0.00008); I^2 =65%					
Test for overall effect: Z = 3.44 (P = 0.00058)					
3 Low intensity					
Bauman 1983	36/39	43/49		1.0 %	1.05 [0.92, 1.21]
MacArthur 1987	449/493	464/489		2.9 %	0.96 [0.93, 0.99]
Reading 1982	20/39	20/26		0.2 %	0.67 [0.46, 0.97]
Subtotal (95% CI)	**571**	**564**		**4.1 %**	**0.95 [0.83, 1.09]**
Total events: 505 (Treatment), 527 (Control)					
Heterogeneity: Tau^2 = 0.01; Chi^2 = 5.67, df = 2 (P = 0.06); I^2 =65%					
Test for overall effect: Z = 0.69 (P = 0.49)					
Total (95% CI)	**10906**	**10352**		**100.0 %**	**0.94 [0.93, 0.96]**
Total events: 9348 (Treatment), 9353 (Control)					
Heterogeneity: Tau^2 = 0.00; Chi^2 = 175.52, df = 63 (P<0.00001); I^2 =64%					
Test for overall effect: Z = 6.90 (P < 0.00001)					



Analysis 1.4. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 4 Continued smoking in late pregnancy subgrouped by main intervention strategy.

Review: Interventions for promoting smoking cessation during pregnancy

Comparison: 1 Interventions for smoking cessation in pregnancy versus control

Outcome: 4 Continued smoking in late pregnancy subgrouped by main intervention strategy

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Cognitive behaviour strategies					
Albrecht 1998	23/26	53/58		0.8 %	0.97 [0.83, 1.14]
Campbell 2006	87/98	90/96		1.7 %	0.95 [0.87, 1.03]
Cinciripini 2000	39/42	35/40		0.9 %	1.06 [0.92, 1.23]
Dornelas 2006	38/53	47/52		0.6 %	0.79 [0.66, 0.96]
Ershoff 1989	93/126	96/116		1.1 %	0.89 [0.78, 1.02]
Gielen 1997	181/193	187/198		2.6 %	0.99 [0.94, 1.04]
Hartmann 1996	89/113	90/106		1.2 %	0.93 [0.82, 1.05]
Hjalmarson 1991	398/444	198/209		2.7 %	0.95 [0.90, 0.99]
Lowe 1998a	108/111	113/116		2.7 %	1.00 [0.96, 1.04]
Lowe 1998b	40/44	34/34		1.4 %	0.91 [0.82, 1.01]
Malchodi 2003	51/67	59/75		0.7 %	0.97 [0.81, 1.16]
Mayer 1990	64/72	75/77		1.7 %	0.91 [0.83, 1.00]
McBride 1999	269/341	130/160		1.6 %	0.97 [0.89, 1.06]
McLeod 2004	133/163	96/109		1.5 %	0.93 [0.84, 1.02]
Moore 2002	435/523	459/567		2.4 %	1.03 [0.97, 1.09]
O'Connor 1992	78/90	79/84		1.6 %	0.92 [0.84, 1.02]
Panjari 1999	443/476	506/537		3.0 %	0.99 [0.96, 1.02]
Petersen 1992	37/43	39/47		0.7 %	1.04 [0.87, 1.24]
Polanska 2004	35/62	32/38		0.4 %	0.67 [0.52, 0.87]
Rigotti 2006	188/209	196/212		2.3 %	0.97 [0.92, 1.03]
Secker-Walker 1994	196/225	204/230		2.1 %	0.98 [0.92, 1.05]
Secker-Walker 1998	116/135	130/144		1.7 %	0.95 [0.87, 1.04]
Tappin 2000	46/48	47/49		1.8 %	1.00 [0.92, 1.09]

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Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Tappin 2005	334/351	392/411		3.0 %	1.00 [0.97, 1.03]
Valbo 1991	31/50	47/50		0.5 %	0.66 [0.53, 0.83]
Valbo 1994	45/56	54/56		1.0 %	0.83 [0.73, 0.96]
Walsh 1997	110/127	118/125		1.9 %	0.92 [0.85, 0.99]
Windsor 1985	88/102	102/104		1.8 %	0.88 [0.81, 0.95]
Windsor 1993	343/400	379/414		2.6 %	0.94 [0.89, 0.98]
Windsor 2000a	115/139	116/127		1.6 %	0.91 [0.83, 0.99]
Subtotal (95% CI)	**4929**	**4641**		**49.8 %**	**0.95 [0.93, 0.97]**
Total events: 4253 (Treatment), 4203 (Control)					
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 63.90$, df = 29 (P = 0.00020); $I^2 = 55\%$					
Test for overall effect: Z = 4.51 (P < 0.00001)					
2 Stages of change					
DeVries 2006	47/58	68/73		1.0 %	0.87 [0.76, 1.00]
Dunkley 1997	46/50	50/50		1.7 %	0.92 [0.84, 1.01]
Ershoff 1999	106/131	105/126		1.3 %	0.97 [0.87, 1.09]
Hajek 2001	285/365	293/367		2.0 %	0.98 [0.91, 1.05]
Kendrick 1995	774/822	998/1063		3.2 %	1.00 [0.98, 1.03]
Lawrence 2003	572/611	274/284		3.0 %	0.97 [0.94, 1.00]
Pbert 2004	21/26	16/18		0.4 %	0.91 [0.71, 1.17]
Solomon 2000	63/77	63/74		1.0 %	0.96 [0.83, 1.11]
Stotts 2002	91/134	89/135		0.8 %	1.03 [0.87, 1.22]
Strecher 2000	94/104	79/87		1.7 %	1.00 [0.91, 1.09]
Thornton 1997	186/209	185/209		2.1 %	1.01 [0.94, 1.08]
Subtotal (95% CI)	**2587**	**2486**		**18.1 %**	**0.99 [0.97, 1.00]**
Total events: 2285 (Treatment), 2220 (Control)					
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 9.81$, df = 10 (P = 0.46); $I^2 = 0.0\%$					
Test for overall effect: Z = 1.66 (P = 0.097)					
3 Feedback					
Bauman 1983	36/39	43/49		1.0 %	1.05 [0.92, 1.21]
Burling 1991	61/70	65/69		1.4 %	0.93 [0.83, 1.03]
Cope 2003	142/164	112/116		2.1 %	0.90 [0.84, 0.96]
Reading 1982	20/39	20/26		0.2 %	0.67 [0.46, 0.97]
Subtotal (95% CI)	**312**	**260**		**4.7 %**	**0.92 [0.84, 1.02]**
Total events: 259 (Treatment), 240 (Control)					
Heterogeneity: $Tau^2 = 0.01$; $Chi^2 = 7.35$, df = 3 (P = 0.06); $I^2 = 59\%$					

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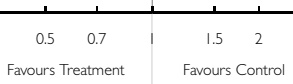
Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Test for overall effect: Z = 1.54 (P = 0.12)					
4 Rewards					
Donatelle 2000	78/112	99/108		1.0 %	0.76 [0.66, 0.87]
Heil 2008	22/37	36/40		0.3 %	0.66 [0.50, 0.88]
Higgins 2004	19/30	21/23		0.3 %	0.69 [0.51, 0.94]
Sexton 1984	296/463	393/472		1.9 %	0.77 [0.71, 0.83]
Subtotal (95% CI)	**642**	**643**		**3.5 %**	**0.76 [0.71, 0.81]**
Total events: 415 (Treatment), 549 (Control)					
Heterogeneity: Tau^2 = 0.0; Chi^2 = 1.32, df = 3 (P = 0.72); I^2 =0.0%					
Test for overall effect: Z = 8.42 (P < 0.00001)					
5 Pharmacotherapy (NRT, Bupropion etc) nicotine replacement therapy					
Hegaard 2003	304/327	313/320		3.0 %	0.95 [0.92, 0.98]
Hotham 2005	17/20	19/19		0.6 %	0.85 [0.70, 1.05]
Kapur 2001	13/17	13/13		0.3 %	0.78 [0.58, 1.03]
Pollak 2007	99/122	52/59		1.1 %	0.92 [0.81, 1.05]
Wisborg 2000	103/124	108/126		1.4 %	0.97 [0.87, 1.08]
Subtotal (95% CI)	**610**	**537**		**6.3 %**	**0.95 [0.92, 0.98]**
Total events: 536 (Treatment), 505 (Control)					
Heterogeneity: Tau^2 = 0.0; Chi^2 = 3.28, df = 4 (P = 0.51); I^2 =0.0%					
Test for overall effect: Z = 3.55 (P = 0.00039)					
6 Other					
Baric 1976	54/63	45/47		1.2 %	0.90 [0.80, 1.01]
Belizan 1995	196/255	207/237		1.8 %	0.88 [0.81, 0.96]
Bullock 1995	36/65	36/66		0.3 %	1.02 [0.74, 1.38]
Lilley 1986	68/72	72/73		2.3 %	0.96 [0.90, 1.02]
Loeb 1983	435/477	447/486		2.9 %	0.99 [0.95, 1.03]
MacArthur 1987	449/493	464/489		2.9 %	0.96 [0.93, 0.99]
Olds 1986	77/77	64/64			Not estimable
Price 1991	67/71	69/70		2.3 %	0.96 [0.90, 1.02]
Rush 1992	153/175	131/144		2.0 %	0.96 [0.89, 1.04]
Secker-Walker 1997	21/26	30/30		0.6 %	0.81 [0.67, 0.98]
Valbo 1996	47/52	70/78		1.3 %	1.01 [0.90, 1.13]
Subtotal (95% CI)	**1826**	**1784**		**17.5 %**	**0.96 [0.93, 0.98]**
Total events: 1603 (Treatment), 1635 (Control)					
Heterogeneity: Tau^2 = 0.00; Chi^2 = 12.29, df = 9 (P = 0.20); I^2 =27%					



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Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Test for overall effect: Z = 3.34 (P = 0.00084)					
Total (95% CI)	**10906**	**10351**		**100.0 %**	**0.94 [0.93, 0.96]**
Total events: 9351 (Treatment), 9352 (Control)					
Heterogeneity: Tau² = 0.00; Chi² = 174.29, df = 63 (P<0.00001); I² =64%					
Test for overall effect: Z = 6.87 (P < 0.00001)					

Analysis 1.5. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 5 Continued smoking (relapse) for spontaneous quitters in late pregnancy.

Review: Interventions for promoting smoking cessation during pregnancy

Comparison: 1 Interventions for smoking cessation in pregnancy versus control

Outcome: 5 Continued smoking (relapse) for spontaneous quitters in late pregnancy

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Dornelas 2006	4/14	3/19		2.2 %	1.81 [0.48, 6.83]
Ershoff 1995	14/87	17/84		9.4 %	0.80 [0.42, 1.51]
Lowe 1997	15/52	20/45		13.3 %	0.65 [0.38, 1.11]
McBride 1999	34/259	27/137		18.1 %	0.67 [0.42, 1.06]
Pbert 2004	7/23	4/16		3.5 %	1.22 [0.43, 3.48]
Petersen 1992	34/71	36/78		33.1 %	1.04 [0.74, 1.46]
Secker-Walker 1995	13/44	12/43		8.8 %	1.06 [0.55, 2.05]
Secker-Walker 1998	16/44	15/48		11.7 %	1.16 [0.66, 2.06]
Total (95% CI)	**594**	**470**		**100.0 %**	**0.91 [0.75, 1.10]**
Total events: 137 (Treatment), 134 (Control)					
Heterogeneity: Tau² = 0.0; Chi² = 6.28, df = 7 (P = 0.51); I² =0.0%					
Test for overall effect: Z = 0.98 (P = 0.33)					

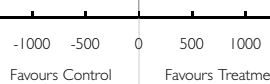
Analysis 1.6. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 6 Mean birthweight.

Review: Interventions for promoting smoking cessation during pregnancy

Comparison: 1 Interventions for smoking cessation in pregnancy versus control

Outcome: 6 Mean birthweight

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
Heil 2008	34	3355 (560)	39	3102 (556)		0.8 %	253.00 [-3.67, 509.67]
Polanska 2004	149	3104 (745)	144	3138 (1090)		1.1 %	-34.00 [-248.49, 180.49]
Pollak 2007	122	3061 (661)	59	3132 (688)		1.2 %	-71.00 [-282.13, 140.13]
Tappin 2000	48	3205 (500)	49	3271 (500)		1.3 %	-66.00 [-265.01, 133.01]
Malchodi 2003	67	3100 (481)	75	3072 (614)		1.5 %	28.00 [-152.48, 208.48]
Ershoff 1989	118	3366 (500)	109	3309 (500)		2.8 %	57.00 [-73.19, 187.19]
Wisborg 2000	124	3457 (500)	126	3271 (500)		3.0 %	186.00 [62.04, 309.96]
Rush 1992	175	3163 (606)	144	3119 (443)		3.4 %	44.00 [-71.31, 159.31]
Cope 2003	109	3260 (430)	83	3080 (380)		3.4 %	180.00 [65.11, 294.89]
Secker-Walker 1998	135	3256 (452)	141	3221 (506)		3.5 %	35.00 [-78.09, 148.09]
Tappin 2005	351	3078 (602)	411	3048 (642)		5.1 %	30.00 [-58.42, 118.42]
Thornton 1997	380	3267 (624)	380	3266 (613)		5.1 %	1.00 [-86.95, 88.95]
Donovan 1977	263	3172 (500)	289	3184 (500)		5.5 %	-12.00 [-95.51, 71.51]
Panjari 1999	337	3250 (526)	391	3166 (589)		5.7 %	84.00 [2.99, 165.01]
Hjalmarson 1991	492	3430 (500)	231	3359 (500)		6.0 %	71.00 [-7.16, 149.16]
Secker-Walker 1994	279	3291 (468)	282	3255 (466)		6.1 %	36.00 [-41.29, 113.29]
Hegaard 2003	327	3401 (500)	320	3433 (500)		6.1 %	-32.00 [-109.06, 45.06]
Sexton 1984	463	3278 (627)	472	3186 (566)		6.2 %	92.00 [15.39, 168.61]
MacArthur 1987	493	3164 (500)	489	3130 (500)		7.9 %	34.00 [-28.55, 96.55]
Haddow 1991	1423	3263 (542)	1425	3229 (537)		11.8 %	34.00 [-5.63, 73.63]



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Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
RADIUS 1995	1768	3352 (528)	1803	3349 (544)		12.7 %	3.00 [-32.16, 38.16]
Total (95% CI)	**7657**		**7462**			**100.0 %**	**39.26 [15.77, 62.74]**

Heterogeneity: Tau^2 = 804.85; Chi^2 = 29.27, df = 20 (P = 0.08); I^2 =32%

Test for overall effect: Z = 3.28 (P = 0.0011)

Analysis 1.7. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 7 Mean birthweight subgrouped by main intervention strategy.

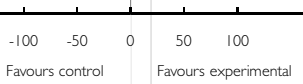
Review: Interventions for promoting smoking cessation during pregnancy

Comparison: 1 Interventions for smoking cessation in pregnancy versus control

Outcome: 7 Mean birthweight subgrouped by main intervention strategy

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Cognitive behavioural therapy							
Ershoff 1989	118	3366 (500)	109	3309 (500)		2.8 %	57.00 [-73.19, 187.19]
Hjalmarson 1991	492	3430 (500)	231	3359 (500)		6.0 %	71.00 [-7.16, 149.16]
Malchodi 2003	67	3100 (481)	75	3072 (614)		1.5 %	28.00 [-152.48, 208.48]
Panjari 1999	337	3250 (526)	391	3166 (589)		5.7 %	84.00 [2.99, 165.01]
Polanska 2004	149	3104 (745)	144	3138 (1090)		1.1 %	-34.00 [-248.49, 180.49]
Secker-Walker 1994	135	3256 (452)	141	3221 (506)		3.5 %	35.00 [-78.09, 148.09]
Secker-Walker 1998	279	3291 (468)	282	3255 (466)		6.1 %	36.00 [-41.29, 113.29]
Tappin 2000	48	3205 (500)	49	3271 (500)		1.3 %	-66.00 [-265.01, 133.01]
Tappin 2005	351	3078 (602)	411	3048 (642)		5.1 %	30.00 [-58.42, 118.42]
Subtotal (95% CI)	**1976**		**1833**			**33.0 %**	**47.01 [12.22, 81.80]**

Heterogeneity: Tau^2 = 0.0; Chi^2 = 3.28, df = 8 (P = 0.92); I^2 =0.0%



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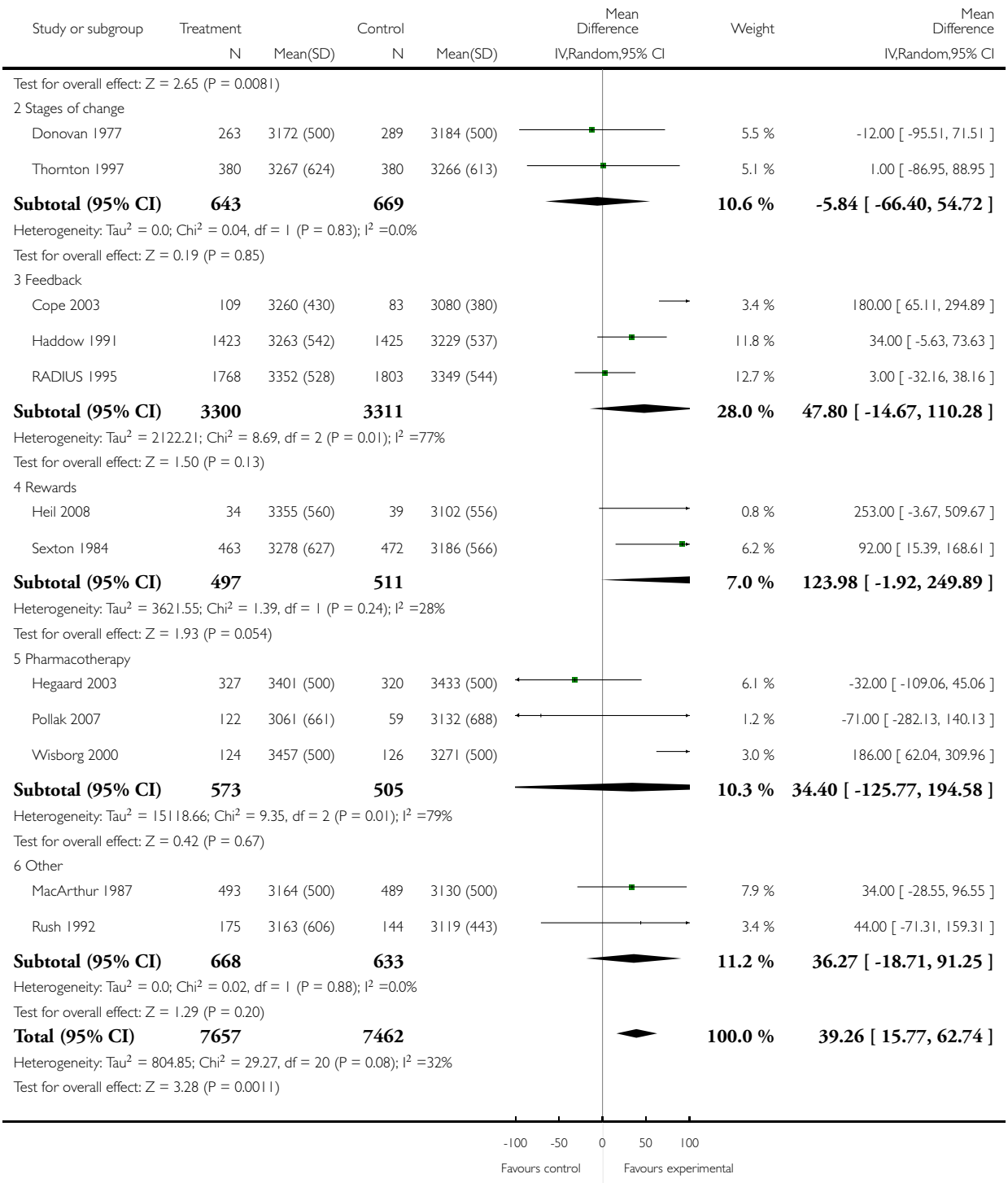


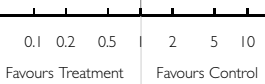
Analysis 1.8. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 8 Low birthweight (under 2500 g).

Review: Interventions for promoting smoking cessation during pregnancy

Comparison: 1 Interventions for smoking cessation in pregnancy versus control

Outcome: 8 Low birthweight (under 2500 g)

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Donovan 1977	26/263	26/289		6.8 %	1.10 [0.66, 1.84]
Ershoff 1989	9/118	15/109		3.0 %	0.55 [0.25, 1.21]
Haddow 1991	99/1423	121/1425		28.1 %	0.82 [0.63, 1.06]
Hegaard 2003	12/327	10/320		2.7 %	1.17 [0.51, 2.68]
Heil 2008	3/34	8/39		1.2 %	0.43 [0.12, 1.49]
Hjalmarson 1991	14/422	11/198		3.1 %	0.60 [0.28, 1.29]
MacArthur 1987	40/493	47/489		11.3 %	0.84 [0.56, 1.26]
Malchodi 2003	5/36	6/43		1.5 %	1.00 [0.33, 2.99]
Panjari 1999	20/337	37/391		6.7 %	0.63 [0.37, 1.06]
Pollak 2007	17/122	5/59		2.0 %	1.64 [0.64, 4.24]
Secker-Walker 1994	9/188	10/226		2.4 %	1.08 [0.45, 2.61]
Secker-Walker 1998	7/135	12/141		2.3 %	0.61 [0.25, 1.50]
Sexton 1984	31/463	42/472		9.2 %	0.75 [0.48, 1.18]
Tappin 2005	44/332	59/400		14.0 %	0.90 [0.63, 1.29]
Thornton 1997	19/190	15/190		4.4 %	1.27 [0.66, 2.42]
Wisborg 2000	4/120	11/122		1.5 %	0.37 [0.12, 1.13]
Total (95% CI)	**5003**	**4913**		**100.0 %**	**0.83 [0.73, 0.95]**
Total events: 359 (Treatment), 435 (Control)					
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 12.65$, df = 15 (P = 0.63); $I^2 = 0.0\%$					
Test for overall effect: Z = 2.66 (P = 0.0079)					



Analysis 1.9. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 9 Very low birthweight (under 1500 g).

Review: Interventions for promoting smoking cessation during pregnancy

Comparison: 1 Interventions for smoking cessation in pregnancy versus control

Outcome: 9 Very low birthweight (under 1500 g)

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Hjalmarson 1991	8/1423	9/1425		30.5 %	0.89 [0.34, 2.30]
MacArthur 1987	7/493	5/489		21.1 %	1.39 [0.44, 4.35]
Sexton 1984	9/463	5/472		23.3 %	1.83 [0.62, 5.43]
Tappin 2005	6/331	8/400		25.0 %	0.91 [0.32, 2.59]
Total (95% CI)	**2710**	**2786**		**100.0 %**	**1.16 [0.69, 1.96]**

Total events: 30 (Treatment), 27 (Control)

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 1.29$, df = 3 (P = 0.73); $I^2 = 0.0\%$

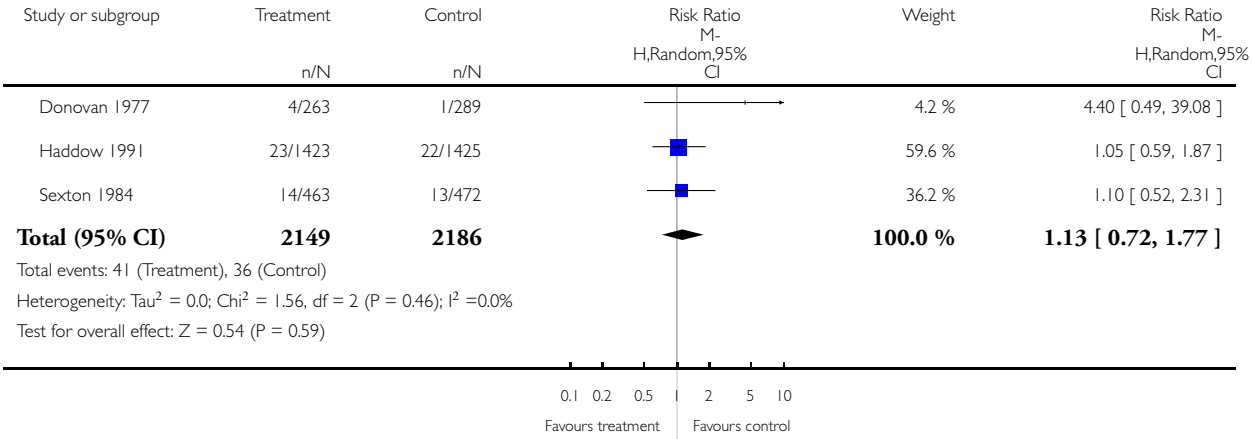
Test for overall effect: Z = 0.56 (P = 0.57)

Analysis 1.10. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 10 Perinatal deaths.

Review: Interventions for promoting smoking cessation during pregnancy

Comparison: 1 Interventions for smoking cessation in pregnancy versus control

Outcome: 10 Perinatal deaths



Analysis 1.11. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 11 Preterm birth (under 37 or under 36 weeks).

Review: Interventions for promoting smoking cessation during pregnancy

Comparison: 1 Interventions for smoking cessation in pregnancy versus control

Outcome: 11 Preterm birth (under 37 or under 36 weeks)

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Donovan 1977	16/263	17/289		4.5 %	1.03 [0.53, 2.00]
Ershoff 1989	7/118	7/109		1.9 %	0.92 [0.33, 2.55]
Haddow 1991	109/1423	137/1425		33.7 %	0.80 [0.63, 1.01]
Hegaard 2003	7/327	10/320		2.1 %	0.69 [0.26, 1.78]
Heil 2008	3/34	9/39		1.3 %	0.38 [0.11, 1.30]
Hjalmarson 1991	13/421	8/197		2.6 %	0.76 [0.32, 1.80]
MacArthur 1987	32/493	37/489		9.4 %	0.86 [0.54, 1.35]
Panjari 1999	18/339	34/391		6.4 %	0.61 [0.35, 1.06]
Pollak 2007	24/122	9/59		4.0 %	1.29 [0.64, 2.60]
RADIUS 1995	57/1768	67/1803		16.2 %	0.87 [0.61, 1.23]
Tappin 2000	5/48	4/49		1.2 %	1.28 [0.36, 4.47]
Tappin 2005	35/342	43/402		10.9 %	0.96 [0.63, 1.46]
Thornton 1997	14/209	8/209		2.7 %	1.75 [0.75, 4.08]
Wisborg 2000	10/120	12/122		3.0 %	0.85 [0.38, 1.89]
Total (95% CI)	**6027**	**5903**		**100.0 %**	**0.86 [0.74, 0.98]**

Total events: 350 (Treatment), 402 (Control)

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 8.78$, df = 13 (P = 0.79); $I^2 = 0.0\%$

Test for overall effect: Z = 2.17 (P = 0.030)

Analysis 1.12. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 12 Stillbirths.

Review: Interventions for promoting smoking cessation during pregnancy

Comparison: 1 Interventions for smoking cessation in pregnancy versus control

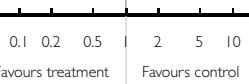
Outcome: 12 Stillbirths

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Ershoff 1995	2/118	1/109		3.9 %	1.85 [0.17, 20.09]
Haddow 1991	21/1423	17/1425		54.9 %	1.24 [0.66, 2.33]
Pollak 2007	2/122	2/59		5.9 %	0.48 [0.07, 3.35]
Sexton 1984	9/463	11/472		29.2 %	0.83 [0.35, 1.99]
Tappin 2000	1/48	0/49		2.2 %	3.06 [0.13, 73.34]
Thornton 1997	2/209	1/209		3.9 %	2.00 [0.18, 21.89]
Total (95% CI)	**2383**	**2323**		**100.0 %**	**1.10 [0.69, 1.76]**

Total events: 37 (Treatment), 32 (Control)

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 2.03$, df = 5 (P = 0.84); $I^2 = 0.0\%$

Test for overall effect: Z = 0.40 (P = 0.69)



Analysis 1.13. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 13 Neonatal deaths.

Review: Interventions for promoting smoking cessation during pregnancy

Comparison: 1 Interventions for smoking cessation in pregnancy versus control

Outcome: 13 Neonatal deaths

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Haddow 1991	2/1402	5/1408		39.0 %	0.40 [0.08, 2.07]
Sexton 1984	5/454	2/461		39.1 %	2.54 [0.50, 13.02]
Thornton 1997	2/209	1/209		21.8 %	2.00 [0.18, 21.89]
Total (95% CI)	**2065**	**2078**		**100.0 %**	**1.17 [0.34, 4.01]**

Total events: 9 (Treatment), 8 (Control)

Heterogeneity: $Tau^2 = 0.31$; $Chi^2 = 2.69$, df = 2 (P = 0.26); $I^2 = 26\%$

Test for overall effect: Z = 0.26 (P = 0.80)

Analysis 1.14. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 14 NICU admissions.

Review: Interventions for promoting smoking cessation during pregnancy

Comparison: 1 Interventions for smoking cessation in pregnancy versus control

Outcome: 14 NICU admissions

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Heil 2008	4/34	6/39		7.8 %	0.76 [0.24, 2.49]
Pollak 2007	13/122	4/59		9.4 %	1.57 [0.54, 4.61]
Tappin 2005	32/351	53/411		63.1 %	0.71 [0.47, 1.07]
Thornton 1997	14/189	12/189		19.6 %	1.17 [0.55, 2.46]
Total (95% CI)	**696**	**698**		**100.0 %**	**0.85 [0.61, 1.18]**

Total events: 63 (Treatment), 75 (Control)

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 2.74$, df = 3 (P = 0.43); $I^2 = 0.0\%$

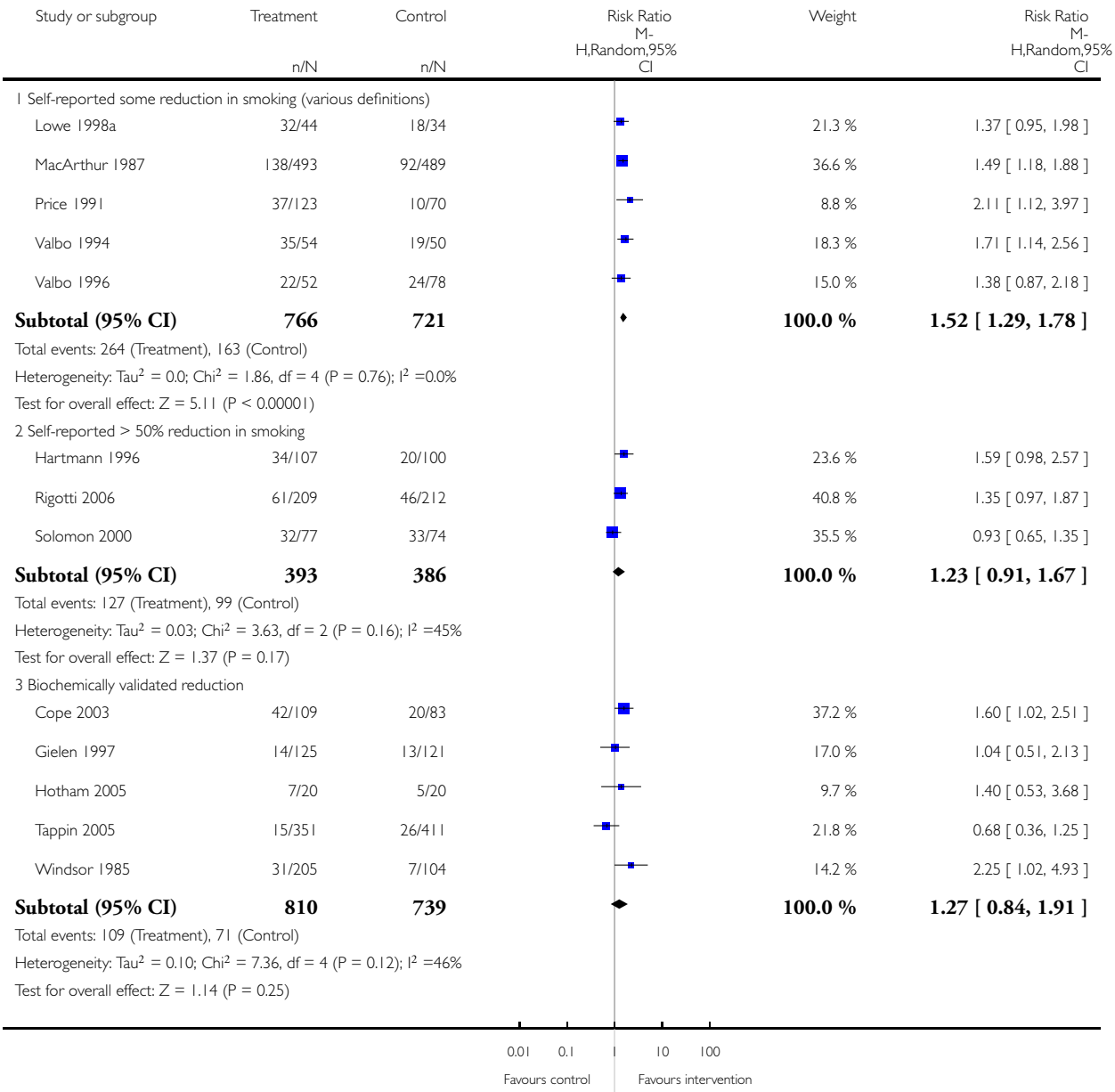
Test for overall effect: Z = 0.99 (P = 0.32)

Analysis 1.15. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 15 Smoking reduction: numbers of women reducing smoking in late pregnancy.

Review: Interventions for promoting smoking cessation during pregnancy

Comparison: 1 Interventions for smoking cessation in pregnancy versus control

Outcome: 15 Smoking reduction: numbers of women reducing smoking in late pregnancy



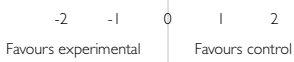
Analysis 1.16. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 16 Smoking reduction: biochemical measures in late pregnancy.

Review: Interventions for promoting smoking cessation during pregnancy

Comparison: 1 Interventions for smoking cessation in pregnancy versus control

Outcome: 16 Smoking reduction: biochemical measures in late pregnancy

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
1 Mean cotinine levels							
Panjari 1999	318	720 (688)	356	769 (735)		26.0 %	-0.07 [-0.22, 0.08]
Secker-Walker 1994	188	1208 (1384)	226	1228 (1612)		21.3 %	-0.01 [-0.21, 0.18]
Tappin 2005	290	113 (70)	364	117 (83)		25.6 %	-0.05 [-0.21, 0.10]
Subtotal (95% CI)	**796**		**946**			**72.9 %**	**-0.05 [-0.14, 0.05]**
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.20$, df = 2 (P = 0.91); $I^2 = 0.0\%$							
Test for overall effect: Z = 1.02 (P = 0.31)							
2 Mean thiocynate level							
Sexton 1984	380	2094 (1209)	389	2452 (1228)		27.1 %	-0.29 [-0.44, -0.15]
Subtotal (95% CI)	**380**		**389**			**27.1 %**	**-0.29 [-0.44, -0.15]**
Heterogeneity: not applicable							
Test for overall effect: Z = 4.05 (P = 0.000052)							
Total (95% CI)	**1176**		**1335**			**100.0 %**	**-0.11 [-0.24, 0.02]**
Heterogeneity: $Tau^2 = 0.01$; $Chi^2 = 8.08$, df = 3 (P = 0.04); $I^2 = 63\%$							
Test for overall effect: Z = 1.71 (P = 0.088)							



Analysis 1.17. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 17 Smoking reduction: self-reported mean cigarettes per day measured in late pregnancy or at delivery.

Review: Interventions for promoting smoking cessation during pregnancy

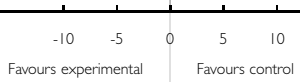
Comparison: 1 Interventions for smoking cessation in pregnancy versus control

Outcome: 17 Smoking reduction: self-reported mean cigarettes per day measured in late pregnancy or at delivery

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
Ershoff 1999	60	8.1 (8)	61	8 (8)		5.8 %	0.10 [-2.75, 2.95]
Hjalmarson 1991	444	9.3 (6.4)	209	9.6 (2.95)		16.6 %	-0.30 [-1.02, 0.42]
Lilley 1986	66	13.1 (9.1)	69	16 (9.1)		5.2 %	-2.90 [-5.97, 0.17]
Moore 2002	353	10.3 (5.6)	403	10.1 (5.4)		16.1 %	0.20 [-0.59, 0.99]
Panjari 1999	284	8.7 (7.6)	326	11.5 (9.7)		12.4 %	-2.80 [-4.17, -1.43]
Price 1991	71	4.3 (8.1)	70	2.3 (5.6)		7.7 %	2.00 [-0.30, 4.30]
Rush 1992	175	10.5 (7.7)	144	11.9 (7.8)		10.4 %	-1.40 [-3.11, 0.31]
Thornton 1997	196	10.4 (8.3)	191	12.5 (10.7)		9.4 %	-2.10 [-4.01, -0.19]
Wisborg 2000	124	7.2 (2.93)	126	7 (2.93)		16.5 %	0.20 [-0.53, 0.93]
Total (95% CI)	**1773**		**1599**			**100.0 %**	**-0.67 [-1.49, 0.16]**

Heterogeneity: $Tau^2 = 0.93$; $Chi^2 = 27.73$, df = 8 (P = 0.00053); $I^2 = 71\%$

Test for overall effect: Z = 1.59 (P = 0.11)



Analysis 1.18. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 18 Maintained smoking cessation at 1-5 months postpartum.

Review: Interventions for promoting smoking cessation during pregnancy

Comparison: 1 Interventions for smoking cessation in pregnancy versus control

Outcome: 18 Maintained smoking cessation at 1-5 months postpartum

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Individually randomised trials					
Cinciripini 2000	2/42	3/40		2.2 %	0.63 [0.11, 3.60]
Donatelle 2000	22/103	6/102		4.8 %	3.63 [1.54, 8.58]
Heil 2008	9/37	1/40		1.8 %	9.73 [1.29, 73.13]
Higgins 2004	10/30	0/23		1.0 %	16.26 [1.00, 263.78]
Hjalmarson 1991	70/444	19/209		6.5 %	1.73 [1.07, 2.80]
McBride 1999	16/600	6/297		4.5 %	1.32 [0.52, 3.34]
O'Connor 1992	13/94	5/96		4.3 %	2.66 [0.99, 7.16]
Panjari 1999	54/339	47/393		7.0 %	1.33 [0.93, 1.91]
Petersen 1992	38/71	41/78		7.2 %	1.02 [0.75, 1.38]
Pollak 2007	24/122	8/59		5.3 %	1.45 [0.69, 3.03]
Rigotti 2006	14/209	15/212		5.5 %	0.95 [0.47, 1.91]
Stotts 2002	14/84	14/82		5.6 %	0.98 [0.50, 1.92]
Thornton 1997	148/209	159/209		7.7 %	0.93 [0.83, 1.04]
Walsh 1997	13/127	1/125		1.8 %	12.80 [1.70, 96.35]
Wisborg 2000	21/124	18/126		6.1 %	1.19 [0.66, 2.11]
Subtotal (95% CI)	**2635**	**2091**		**71.4 %**	**1.43 [1.08, 1.91]**
Total events: 468 (Treatment), 343 (Control)					
Heterogeneity: Tau^2 = 0.16; Chi^2 = 50.04, df = 14 (P<0.00001); I^2 =72%					
Test for overall effect: Z = 2.46 (P = 0.014)					
2 Cluster-randomised trials					
DeVries 2006	14/65	10/84		5.3 %	1.81 [0.86, 3.81]
Lawrence 2003	135/611	10/284		5.9 %	6.27 [3.35, 11.74]
McLeod 2004	17/106	9/82		5.3 %	1.46 [0.69, 3.11]
Pbert 2004	16/23	13/16		7.0 %	0.86 [0.60, 1.23]
Polanska 2004	28/62	6/38		5.1 %	2.86 [1.31, 6.26]

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Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Subtotal (95% CI)	**867**	**504**		**28.6 %**	**2.08 [0.78, 5.56]**
Total events: 210 (Treatment), 48 (Control)					
Heterogeneity: Tau^2 = 1.14; Chi^2 = 50.68, df = 4 (P<0.00001); I^2 =92%					
Test for overall effect: Z = 1.46 (P = 0.15)					
Total (95% CI)	**3502**	**2595**		**100.0 %**	**1.65 [1.22, 2.24]**
Total events: 678 (Treatment), 391 (Control)					
Heterogeneity: Tau^2 = 0.31; Chi^2 = 114.65, df = 19 (P<0.00001); I^2 =83%					
Test for overall effect: Z = 3.22 (P = 0.0013)					

Analysis 1.19. Comparison 1 Interventions for smoking cessation in pregnancy versus control, Outcome 19 Maintained smoking cessation at 6 to 12 months postpartum.

Review: Interventions for promoting smoking cessation during pregnancy

Comparison: 1 Interventions for smoking cessation in pregnancy versus control

Outcome: 19 Maintained smoking cessation at 6 to 12 months postpartum

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Individually randomised trials					
Dornelas 2006	5/53	2/52		8.3 %	2.45 [0.50, 12.08]
Heil 2008	3/37	1/40		4.9 %	3.24 [0.35, 29.82]
Higgins 2004	8/30	0/23		3.3 %	13.16 [0.80, 216.85]
McBride 1999	13/600	8/297		17.4 %	0.80 [0.34, 1.92]
Panjari 1999	54/339	47/393		28.1 %	1.33 [0.93, 1.91]
Secker-Walker 1994	5/157	6/185		12.7 %	0.98 [0.31, 3.16]
Stotts 2002	10/84	14/82		19.7 %	0.70 [0.33, 1.48]
Walsh 1997	13/127	1/125		5.7 %	12.80 [1.70, 96.35]

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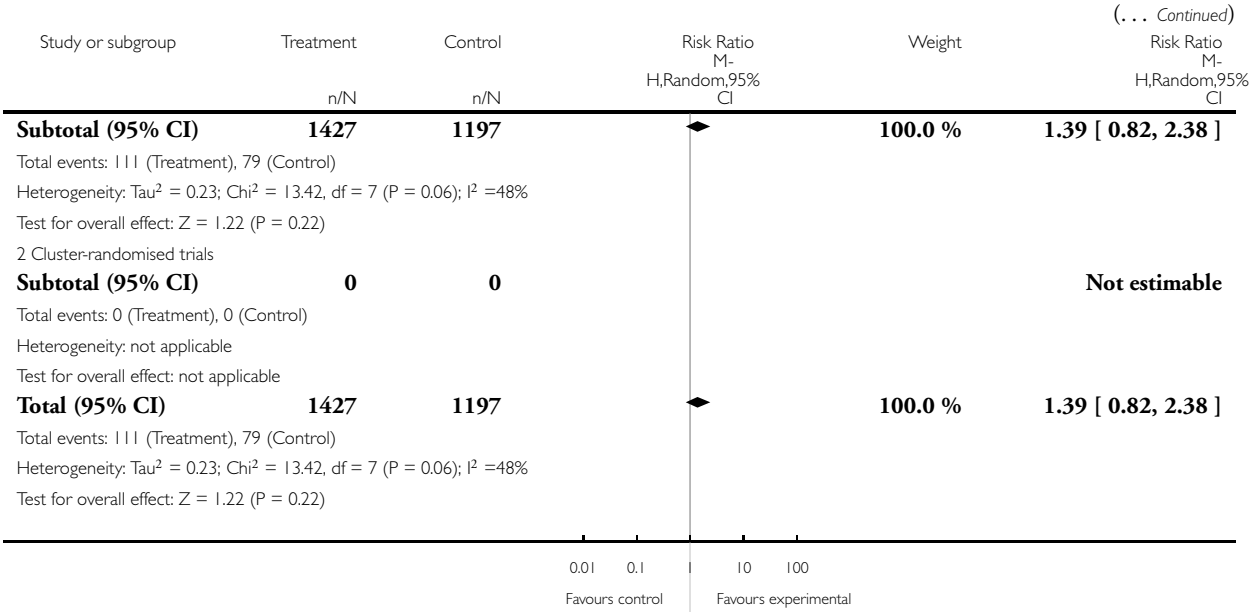

APPENDICES

Appendix 1. Reviews of interventions for smoking cessation in a general population

Population-wide measures

Healthcare financing systems for increasing the use of tobacco dependence treatment (Kaper 2005)
Interventions for preventing tobacco sales to minors (Stead 2005b)
Interventions for preventing tobacco smoking in public places (Serra 2008)
Smoking bans for reducing smoking prevalence and tobacco consumption (Callinan 2006)
Mass media interventions for preventing smoking in young people (Sowden 1998)
Mass media interventions for smoking cessation in adults (Bala 2008)

Organisational interventions

School-based programmes for preventing smoking (Thomas 2006)
Workplace interventions for smoking cessation (Cahill 2008d)

Community interventions

Community interventions for preventing smoking in young people (Sowden 2003)
Community interventions for reducing smoking among adults (Secker-Walker 2002b)
Community pharmacy personnel interventions for smoking cessation (Sinclair 2004)
Family and carer smoking control programmes for reducing children's exposure to environmental tobacco smoke (Priest 2008)
Family-based programmes for preventing smoking by children and adolescents (Thomas 2007)
Group behaviour therapy programmes for smoking cessation (Stead 2005a)

Individual strategies

Acupuncture and related interventions for smoking cessation (White 2006)

Aversive smoking for smoking cessation (Hajek 2001)
Biomedical risk assessment as an aid for smoking cessation (Bize 2005)
Competitions and incentives for smoking cessation (Cahill 2008a)
Enhancing partner support to improve smoking cessation (Park 2004)
Exercise interventions for smoking cessation (Ussher 2008)
Hypnotherapy for smoking cessation (Abbot 1998)
Individual behavioural counselling for smoking cessation (Lancaster 2005a)
Internet-based interventions for smoking cessation (Koshy 2008)
Interventions for preventing weight gain after smoking cessation (Parsons 2009)
Interventions for smokeless tobacco use cessation (Ebbert 2007)
Interventions for waterpipe smoking cessation (Maziak 2007)
Mobile phone-based interventions for smoking cessation (Whittaker 2007)
Motivational interviewing for smoking cessation (Lai 2008)
Nursing interventions for smoking cessation (Rice 2008)
Physician advice for smoking cessation (Stead 2008b)
Quit and Win contests for smoking cessation (Cahill 2008c)
Self-help interventions for smoking cessation (Lancaster 2005b)
Stage-based interventions for smoking cessation (Cahill 2007b)
Telephone counselling for smoking cessation (Stead 2006c)
Training health professionals in smoking cessation (Lancaster 2000)

Pharmacotherapies

Antidepressants for smoking cessation (Hughes 2007a)
Anxiolytics for smoking cessation (Hughes 2000)
Cannabinoid type 1 receptor antagonists (rimonabant) for smoking cessation (Cahill 2007a)
Clonidine for smoking cessation (Gourlay 2004)
Lobeline for smoking cessation (Stead 1997)
Mecamylamine (a nicotine antagonist) for smoking cessation (Lancaster 1998)
Nicobrevin for smoking cessation (Stead 2006b)
Nicotine receptor partial agonists for smoking cessation (Cahill 2008b)
Nicotine replacement therapy for smoking cessation (Stead 2008a)
Nicotine vaccines for smoking cessation (Hatsukami 2008)
Opioid antagonists for smoking cessation (David 2006)
Silver acetate for smoking cessation (Lancaster 1997)

Relapse prevention

Relapse prevention interventions for smoking cessation (Hajek 2009)

Specific population group interventions

Interventions for preoperative smoking cessation (Møller 2005)
Interventions for smoking cessation and reduction in individuals with schizophrenia (Tsoi 2008)
Interventions for smoking cessation in hospitalised patients (Rigotti 2007)
Interventions for tobacco cessation in the dental setting (Carr 2006)
Smoking cessation interventions for smokers with current or past depression (van der Meer 2006)
Tobacco cessation interventions for young people (Grimshaw 2006)

Appendix 2. Search strategy for EMBASE, PsycLIT and CINAHL

A qualified librarian searched these databases using the Cochrane search strategy and free text terms “pregnancy” or “antenatal” or prenatal“ and ”smoking“ or ”tobacco“ (January 2003 to June 2008).

WHAT'S NEW

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

Date	Event	Description
17 November 2008	New citation required but conclusions have not changed	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
17 November 2008	New search has been performed	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.

HISTORY

Protocol first published: Issue 2, 1998

Review first published: Issue 3, 1998

Date	Event	Description
3 November 2008	Amended	Converted to new review format.
31 July 2003	New search has been performed	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.

(*Continued*)

		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 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