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

Smoking remains one of the few potentially preventable factors associated with low birthweight, preterm birth and perinatal death.

Objectives

To assess the effects of smoking cessation programs implemented during pregnancy on the health of the fetus, infant, mother, and family.

Search strategy

We searched the Cochrane Pregnancy and Childbirth Group trials register and the Cochrane Tobacco Addiction Group trials register (July 2003), MEDLINE (January 2002 to July 2003), EMBASE (January 2002 to July 2003), PsychLIT (January 2002 to July 2003), CINAHL (January 2002 to July 2003), and AUSTHEALTH (January 2002 to 2003). We contacted trial authors to locate additional unpublished data. We handsearched references of identified trials and recent obstetric journals.

Selection criteria

Randomised and quasi-randomised trials of smoking cessation programs implemented during pregnancy.

Data collection and analysis

Four reviewers assessed trial quality and extracted data independently.

Main results

This review included 64 trials. Fifty-one randomised controlled trials (20,931 women) and six cluster-randomised trials (over 7500 women) provided data on smoking cessation and/or perinatal outcomes. Despite substantial variation in the intensity of the intervention and the extent of reminders and reinforcement through pregnancy, there was an increase in the median intensity of both 'usual care' and interventions over time.

There was a significant reduction in smoking in the intervention groups of the 48 trials included: (relative risk (RR) 0.94, 95% confidence interval (CI) 0.93 to 0.95), an absolute difference of six in 100 women continuing to smoke. The 36 trials with validated

smoking cessation had a similar reduction (RR 0.94, 95% CI 0.92 to 0.95). Smoking cessation interventions reduced low birthweight (RR 0.81, 95% CI 0.70 to 0.94) and preterm birth (RR 0.84, 95% CI 0.72 to 0.98), and there was a 33 g (95% CI 11 g to 55 g) increase in mean birthweight. There were no statistically significant differences in very low birthweight, stillbirths, perinatal or neonatal mortality but these analyses had very limited power. One intervention strategy, rewards plus social support (two trials), resulted in a significantly greater smoking reduction than other strategies (RR 0.77, 95% CI 0.72 to 0.82). Five trials of smoking relapse prevention (over 800 women) showed no statistically significant reduction in relapse.

Authors' conclusions

Smoking cessation programs in pregnancy reduce the proportion of women who continue to smoke, and reduce low birthweight and preterm birth. The pooled trials have inadequate power to detect reductions in perinatal mortality or very low birthweight.

PLAIN LANGUAGE SUMMARY

Interventions for promoting smoking cessation during pregnancy

Strategies can help support women to stop cigarette smoking in pregnancy so babies have better health.

Cigarette smoking in pregnancy is common, particularly where there is low income and social disadvantage. Smoking in pregnancy increases the risk of babies having low birthweight and being born too early. Babies often struggle to cope with life outside the womb and can suffer ill health later in life. Many mothers find it hard to stop, or to reduce, smoking during pregnancy even knowing the benefits this may have, because smoking can help them cope with stress. There are effective strategies to help and support women to stop smoking that lead to fewer premature babies and better birthweights for babies.

BACKGROUND

Cigarette smoking during pregnancy is common. Prevalence studies in the 1990s show that between one in five and one in three pregnant women in developed countries report smoking (for example, Campion 1994; Cnattingius 1997; Dodds 1995; Husten 1996; Stewart 1995; Tappin 1997; Wiemann 1994). Evidence on trends in smoking prevalence in pregnancy are inconsistent, though Norway, Sweden and Canada have identified declines through the late 1980s (Cnattingius 1997; Eriksson 1996; Stewart 1995). In Australia, smoking prevalence has decreased from 23% in 1998 to 19.5% in 2001 (AIHW 2002). In the US, the 2000 Surgeon-General's Report on Women and Smoking showed a decline from 34% in 1965 to 22 to 23% in the late 1990s but no change from 1998 to 2000. Estimates of smoking in pregnancy in the US differ by State as well as by maternal age and education. In 2000-2001 the proportion of pregnant women smoking in Alabama was 16.9% among women under 20, but 9.3% among women 35 and over. In Maine the equivalent proportions were 34.6% and 10.5% (MMWR 2004).

There are marked social differences between women who smoke and those who do not, with continued smoking and high daily consumption showing a strong association with social disadvantage, high parity, being without a partner, low income, or (in the USA) receiving Medicaid-funded maternity care (Frost 1994; Graham 1977; Graham 1994; Graham 1996; Tappin 1996). The high prevalence of smoking in several indigenous peoples is in accord with their social and material deprivation (for example, Chan 2001; Hunt 2003; Kaplan 1997; Wiemann 1994) but, in other groups, cultural differences may cut across this social gradient. Women who are migrants or refugees to Northern Europe, North America or Australia from South East Asia retain a lower prevalence of smoking, despite major social disadvantage (for example, Potter 1996; Small 2000); in the US, African American and Hispanic women have a lower prevalence of smoking in pregnancy than other women in more recent studies (Andreski 1995; Wiemann 1994) though the 1998 Surgeon-General's Report showed an upswing in smoking by young women from these communities (CDCP 1998).

In addition to the social factors associated with continued smoking, there are common psychosocial associations, especially depression, job strain/workload, exposure to intimate partner violence and low levels of practical support (Borelli 1996; Dejin-Karlsson 1996; McNutt 2002; Wergeland 1996). Fear of weight gain is another factor in continued smoking, with women being more

likely to smoke to control their weight, and female body image being extensively targeted by tobacco marketing campaigns (CDCP 2002).

A higher proportion of women stop smoking during pregnancy than at other times in their lives. Up to 40% of women in the US who smoke before pregnancy stop before their first antenatal visit (Quinn 1991; Woodby 1999), a rate substantially higher that reported in the general population (Ershoff 1999; McBride 2003). 'Spontaneous quitters' usually smoke less, are more likely to have stopped smoking before, or to have a non-smoking partner, or to have more support and encouragement at home for quitting, or to have stronger beliefs about the dangers of smoking (Baric 1976; 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.

Smoking remains one of the few potentially preventable factors associated with low birthweight (less than 2,500 g), very preterm birth (less than 32 weeks) and perinatal death (Kramer 1987). It is this that makes it an important public health issue in pregnancy. In contrast with that finding, the quality of diet in pregnancy (in developed countries) has not been shown to affect the mean birthweight of infants over 32 weeks' gestation (Rogers 1998).

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. There is little evidence from either human or animal studies that this association is due to physiological effects of smoking on breastfeeding (Amir 2001; Amir 2002).

The first trials of anti-smoking interventions during pregnancy were published more than 20 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). Population-based campaigns to encourage smoking reduction and smoking cessation during pregnancy are widespread (Campion 1994; Eriksson 1996). There appears to be some adoption of systematic intervention programs during antenatal care (Lowe 2002; Windsor 2000b) but there are still widespread problems with implementation (Lumley 2002).

The interventions used in smoking cessation programs have been criticised for taking little account of relevant health promotion theory and knowledge (Solomon 1996; Stotts 1996), for inadequate implementation and little or no process evaluation (Windsor 1998). Evidence about the unreliability of self-report as a measure of smoking status in healthcare settings, especially in maternity care, noted even in the first pregnancy trial (Donovan 1977), though not found by others in the 1980s (Fox 1989), is very strong in more recent trials (Kendrick 1995; Petersen 1992; Walsh 1997). This finding means that trials which do not validate smoking status, are likely to have substantial measurement errors and thus reduced power to identify true effects.

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). A recent 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). Preliminary consultation with health promotion specialists has also 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 circumstances, with flow-on effects to the well-being of other family members as possible adverse effects of smoking cessation interventions (Oliver 1997).

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. 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.

Adams 1998, and Melvin 2000 estimate smoking costs of maternal conditions attributed to smoking in pregnancy (preterm prelabour rupture of membranes (PPROM), ectopic pregnancy, placenta praevia, placental abruption, spontaneous abortion) with a protective effect against pre-eclampsia modelled as well, at a total of $135 to $167 million per annum in the US, based on 1993 US healthcare cost and dollar estimates, of smoking in pregnancy. Birth and first year costs for both mothers and infants attributed to smoking are $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).

OBJECTIVES

The primary objective was to identify whether continued smoking during pregnancy can be reduced by information about the risks of continued smoking, advice to quit, more intensive advice or individual counselling, group counselling, feedback on pathophysiological effects of smoking on the mother or fetus, the provision of nicotine replacement therapy, more detailed information/pictures of the fetus, the supplementation of information and advice with self-help manuals/videos or computer aided messages on strategies for quitting, rewards or incentives, peer support or additional social support.

Other objectives

(1) To compare the effectiveness of information and advice alone with more intensive interventions during pregnancy.

(2) To identify whether smoking reduction* and smoking cessation interventions increase mean birthweight, and reduce low birthweight.

(3) To identify whether smoking reduction* and smoking cessation interventions reduce preterm birth and very preterm birth.

(4) To identify whether smoking reduction* and cessation interventions reduce perinatal mortality.

(5) To identify whether smoking reduction* and cessation interventions increase operative delivery.

(6) To identify whether smoking reduction* and cessation interventions increase breastfeeding initiation and the duration of breastfeeding.

(7) To identify whether smoking reduction* and cessation interventions increase anxiety or depression, or have a negative effect on measures of maternal health or coping skills.

(8) To identify participants' views of the intervention(s).

(9) To identify whether smoking reduction* and cessation interventions have negative effects on family functioning, including non-accidental injury.

(10) To identify whether smoking reduction* and cessation intervention increase the proportion of women who do not start smoking again after the end of pregnancy.

(11) To compare methods for training health professionals (general practitioners, midwives, obstetricians) in the provision of effective smoking cessation programs.

*As smoking reduction cannot be reliably identified at present these outcomes are not reported.

This review does not address smoking cessation trials outside pregnancy: *see* the reviews by Lancaster 1997; Silagy 1997; Silagy 2002. Trials which combine strategies for smoking cessation with other interventions in pregnancy are considered for the review 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.

METHODS

Criteria for considering studies for this review

Types of studies

All studies with randomised or quasi-randomised allocation will be considered.

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) Information about the harmful effects of smoking on the fetus and infant, the mother herself or other family members (verbal, written or both).
(2) Advice by a health professional to 'stop smoking'.
(3) Supplementation of advice by reinforcement at subsequent antenatal visits.
(4) Supplementation of advice by group counselling.
(5) Supplementation of advice by the provision of peer support.
(6) Supplementation of advice by recording smoking status, or measuring by-products of smoking at other antenatal visits.
(7) Supplementation of advice by feedback of the effects of smoking on the fetus (fetal movements, fetal breathing, fetal heart rate).
(8) Supplementation of advice by positive information about the fetus and fetal development (for example, describing the ultrasound in detail).
(9) Individualised advice and support for smoking cessation based on 'stages of change'.
(10) Provision of pregnancy-specific self-help manual on strategies for quitting. Provision of the following as an adjunct to information and advice:

- nicotine replacement therapy;
- telephone follow up with reinforcement of advice and strategies for quitting;
- rewards and incentives.

(11) Strategies to change the attitudes, knowledge and behaviour of healthcare providers with respect to smoking cessation.

Types of outcome measures

(1) Smoking cessation 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) Method of delivery.
(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.
(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.
* As smoking reduction cannot be reliably identified at present this outcome is not reported.

Search methods for identification of studies

We searched the Cochrane Pregnancy and Childbirth Group trials register (July 2003).
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. monthly searches of MEDLINE;
3. handsearches of 30 journals and the proceedings of major conferences;
4. weekly current awareness search of a further 37 journals.
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 'Search strategies for identification of studies' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.
Trials identified through the searching activities described above are given a code (or codes) depending on the topic. The codes are linked to review topics. The Trials Search Co-ordinator searches the register for each review using these codes rather than keywords.
In addition, we searched the Cochrane Tobacco Addiction Group's trials register (July 2003). We also searched MEDLINE on OVID (January 2002 to July 2003) using the following search strategy:
1 exp pregnancy
2 exp smoking
3 exp "tobacco use cessation" or "smoking cessation"
4 exp health promotion
5 exp preventive medicine or health education
6 exp prenatal care
7 exp prenatal exposure delayed effects
8 1 or 6 or 7
9 2 or 3
10 4 or 5
11 8 and 9 and 10
12 Limit to yr=2002-2003
13 Exp harm reduction
14 12 and 13
We adapted the search strategy to search, EMBASE (January 2002 to July 2003), PsychLIT (January 2002 to July 2003), CINAHL (January 2002 to July 2003), and AUSTHEALTH (January 2002 to 2003). Personal contact with authors was used to locate additional unpublished data. References of identified trials and recent obstetric journals were handsearched up to September 2003. These include: *American Journal of Obstetrics and Gynecology; Obstetrics & Gynaecology; BJOG: an international journal of obstetrics and gynaecology; Acta Obstetrica et Gynecologica Scandivica; Tobacco Control; BMJ* and *The Lancet*.

Data collection and analysis

Data extraction
Two reviewers independently extracted data from the published reports without blinding as to journal, author, or research group. For each trial the following aspects were documented:
(1) country of origin;
(2) study population;
(3) inclusion and exclusion criteria;
(4) participation rate of eligible study population;
(5) timing within pregnancy of recruitment and outcome measurement;
(6) the nature of the intervention(s);
(7) process evaluation of the intervention(s);
(8) withdrawals;
(9) details of the study design (including method of allocation, individual or cluster randomisation, blinding, methods of outcome assessment, validation of smoking status);
(10) outcome measures.
We sought additional information from individual investigators.
Quality assessment
We used a flexible approach to assess the methodological quality of the included studies as recommended in the Cochrane Reviewers' Handbook 4.1.6 (p45) (Clarke 2002).
The quality criteria in this review address:

(1) selection bias: allocation concealment and randomisation described as inadequate (high risk of bias) if using alternation, record numbers, date of birth, weeks or open list numbers;
(2) performance bias: usual caregiver not blinded to allocation (inevitable where the usual caregiver implemented the intervention);
(3) detection bias: low risk of bias if biochemically validated;
(4) sample size justification;
(5) attrition bias: not relevant as all dropouts were counted as continuing smokers in this review.
All studies were then coded independently by two reviewers (C Chamberlain, J Lumley):
(1) low risk of bias = all criteria met (1 to 4);
(2) moderate risk of bias = two or more criteria met (1 to 4);
(3) high risk of bias = two or more criteria not met (1 to 4).
All studies with a low to moderate risk of bias were categorised as high quality.
The intensity of the intervention was also assessed independently by two reviewers (C Chamberlain, J Lumley), and was categorised as follows:
(1) 0 = if undefined except as 'usual care', or limited to advice not to smoke;
(2) 1 = provision of written information on smoking (posters/pamphlets);
(3) 2 = personal advice to quit and written information;
(4) 3 = strategies for quitting (written or personal), personal advice and written information, and/or written follow up;
(5) 4 = personal follow up (telephone calls, counselling, peer support) and strategies to quit, personal advice to quit and written information.
All studies categorised as four were defined as high intensity; studies categorised as three were defined as medium intensity, studies categorised as less than three were defined as low intensity.
Biochemical validation measures that defined active rather than passive exposure to cigarette smoke (Melvin 2000) were:
(1) urinary cotinine more than 80 ng/ml;
(2) salivary cotinine more than 0.30 ng/ml;
(3) expired carbon monoxide more than nine parts per million.
Other biochemical measures such as serum thiocyanate were also included in biochemical validation of self reported smoking status.
Data analysis:
(1) We used the statistical methods described by Yusuf (Yusuf 1985).
(2) In all pooled analyses, we tested for heterogeneity (Cochran 1954).
(3) Secondary analyses looked at outcomes separately for trials with and without biochemically validated smoking cessation, trials with a high intensity intervention and those with high quality scores for the design and implementation of the intervention.
(4) Given the likelihood of publication bias (non-publication of small trials showing little or no effect) the point estimates were plotted against the sample size.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.
See table of 'Characteristics of included studies'.

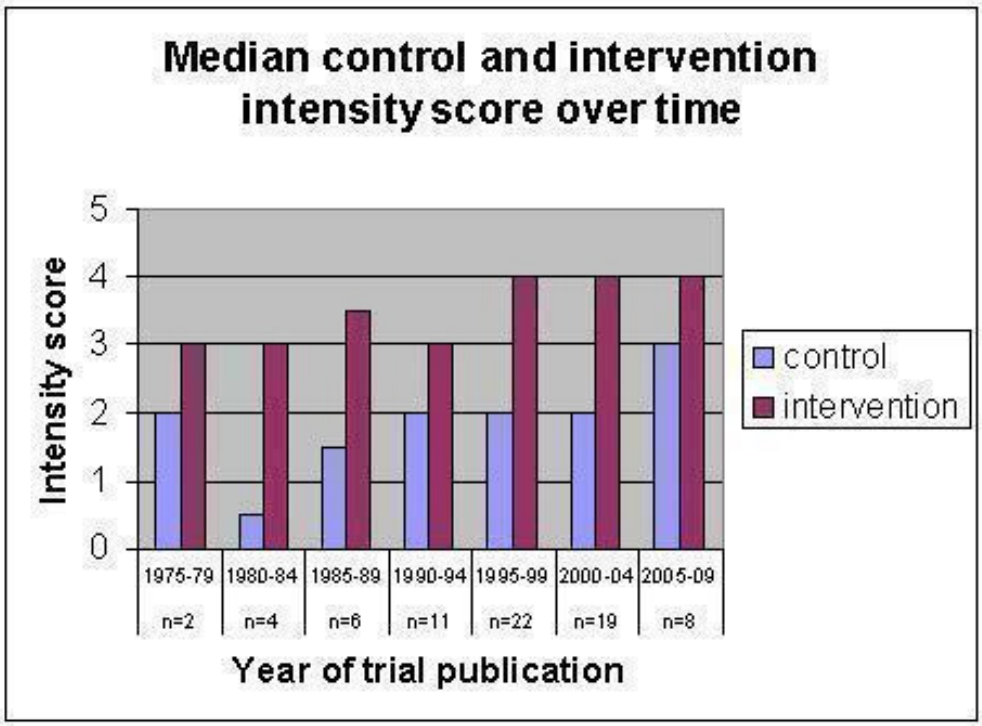
Risk of bias in included studies

See table of 'Characteristics of included studies' and 'Characteristics of excluded studies'.

Effects of interventions

Interventions commonly included in these programs were: the provision of information on the risks of smoking to the fetus and infant and the benefits of quitting; recommendations to quit and setting a quit date; feedback about the fetus; feedback about harmful levels of cotinine or carbon monoxide; teaching cognitive-behavioural strategies for quitting smoking; advice tailored to 'stages of change'; provision of rewards, social or peer support; and nicotine replacement therapy. There was substantial variation in the intensity of the intervention and the extent of reminders and reinforcement through pregnancy. There has been an increase in the median intensity of both 'usual care' and interventions over time (*see* Figure 1).

Figure 1. Median intensity score over time



A total of 64 trials, conducted between 1975 and 2003 and comprising over 20,000 women, were identified and included in the review. Six additional studies provided data on over 7500 women in cluster-randomised trials. Participants were healthy pregnant women and the usual setting was a hospital or community antenatal clinic. The principal outcome measure was continued smoking in late pregnancy. Sixteen trials provided some information on fetal outcomes: mean birthweight, low birthweight, preterm birth and perinatal mortality. One trial reported method of delivery (Thornton 1997) with no differences in the proportions of women having an operative delivery; there were no differences in quitting in this trial. One trial reported breastfeeding proportions in women who could be followed up six weeks after birth (intervention + control = 625) as 47% versus 46%, and as 22% versus 23% in the 559 (intervention + control) followed up at six months after birth (Panjari 1999).

Three studies reported baseline psychological well-being though two of them did not report findings post-intervention (Cinciripini 2000; Ershoff 1999). The third, Panjari 1999, found no change in the proportion of women with scores on the General Health Questionnaire in late pregnancy showing probable anxiety and or depression compared with baseline and no differences in the proportions of women in intervention and control groups with late pregnancy probable anxiety and or depression, but the prevalence of these common mental health problems was high (20%) in both arms on both occasions. No studies have measured the well-being of other family members.

Seven trials measured participants' views of interventions (Bakker 2001; Hajek 2001; Moore 2002; Secker-Walker 1998; Strecher 2000; Tappin 2000; Thornton 1997), and there have been eight recent trials which have analysed health professional training, knowledge, attitudes and/or practice to provide valuable information on implementation barriers (Bakker 2001; Cooke 2001; Hajek 2001; Moore 2002; Secker-Walker 1992; Stotts 2000; Tappin 2000; Windsor 2000b).

One trial showed that simple change in question format (from yes or no to multiple options including "I used to smoke", and "I have cut down"), will increase smoking disclosure (Mullen 1991).

Pooled data from 48 trials revealed a significant reduction in continued smoking in late pregnancy in the intervention groups (pooled relative risk (RR) 0.94, 95% confidence interval (CI) 0.93

to 0.95). This equates to an absolute difference in the proportion continuing to smoke of 6%. There was significant heterogeneity among these trials. The findings were similar when analyses were restricted to the 36 trials with biochemically validated smoking cessation (pooled RR 0.94, 95% CI 0.92 to 0.95) and an absolute difference in continued smoking of 6%. There were no statistically significant differences between these findings and those in the 25 trials of high intensity (pooled RR 0.92, 95% CI 0.91 to 0.94) with an absolute difference in continued smoking of 8%, nor in the 25 trials with a high quality score (pooled RR 0.95, 95% CI 0.94 to 0.97) which had an absolute difference in continued smoking of 5%, or the 17 trials with validated smoking cessation, a high intensity intervention, and a high quality score (pooled RR 0.95, 95% CI 0.93 to 0.97) which had an absolute difference in continued smoking of 5%. All these groups showed significant heterogeneity.

When trials were grouped by intervention strategies the cognitive behavioural group, which was the largest, showed a similar pooled effect to that of the whole group (RR 0.95, 95% CI 0.92 to 0.97) from the pooled data from all trials. The seven trials using "stages of change" theory were not effective (pooled RR 0.98, 95% CI 0.94 to 1.01, nor were the three trials using feedback (pooled RR 0.92, 95% CI 0.77 to 1.11). The three trials of nicotine replacement therapy were bordeline (pooled RR 0.94, 95% CI 0.89 to 1.00). Only one group of the trials (those including a social support and a reward component) showed a significantly larger effect (pooled RR 0.77, 95% CI 0.72 to 0.82). Their results were consistent but comprised only two trials.

The subset of 16 trials with information on perinatal outcomes revealed a reduction in low birthweight (pooled RR 0.81, 95% CI 0.70 to 0.94), a reduction in preterm birth (pooled RR 0.84, 95% CI 0.72 to 0.98), and an increase in mean birthweight of 33 g (95% CI 11 g to 55 g). There was no heterogeneity in the low birthweight or preterm birth findings but heterogeneity was marked for the mean birthweight differences. There were no differences in very low birthweight, stillbirths, neonatal deaths 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 = 9842). 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 development at nine to 10 years (MacArthur 1987). Neither height nor weight, nor intelligence quotient (IQ) or a screening test for "soft" neurological signs identified any differences between the intervention and control groups (insufficient data for tabulation).

The six cluster-randomised trials cannot be included in RevMan tables but are in an additional Table 1. The two smaller trials found a reduction in smoking with the intervention but neither included smoking validation. The other four were trials which involved dissemination of interventions into routine care, three of them using the primary care midwife to implement the intervention (Hajek 2001; Lawrence 2003; Moore 2002), the fourth (Kendrick 1995) carried out in WIC (food program for women, infants and children) clinics.

Five trials (more than 800 women) among the 64 included a specific intervention for smoking relapse prevention among women who had stopped smoking by the first antenatal visit. In these, the pooled odds ratio for smoking in late pregnancy did not reach statistical significance (RR 0.80, 95% CI 0.63 to 1.03).

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 state 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 recent systematic review of smoking cessation 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).

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).

DISCUSSION

Assessing trial quality

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. The concealment of allocation at the time of outcome assessment was not often specified but this criterion was replaced in later trials by a definition of smoking cessation requiring biochemical validation.

Assessing the quality of the intervention

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). As these trials are among the largest published trials it shows that it may be inappropriate, when interventions are complex, for trial size to be taken as a surrogate measure of trial quality.

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).

In many cases the comparison/control group was described as receiving 'usual care' without specifying further the current practice at the time in that setting with respect to advice and assistance. In recent trials (for example, Lowe 1998a; Secker-Walker 1994; Walsh 1997) care is specified in detail, and 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).

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 need to be adjusted for intra-cluster correlation and inter-cluster heterogeneity. Lack of adjustment for clustering was a major reason for excluding trials from this review. Four of the six cluster-randomised trials which are included (Bakker 2001; Hajek 2001; Lawrence 2003; Moore 2002) implemented the intervention with the midwives who were the primary care-providers of women in the trials. There is evidence from the text of these articles that the midwives had reservations about implementing smoking cessation strategies within antenatal care. In a fifth trial (Kendrick 1995) it is clear that the clinic staff, caring for extremely disadvantaged women, felt overwhelmed by the study requirements, and it is not surprising that four of the five trials were not successful in increasing smoking cessation. The exception (Bakker 2001) did not have biochemically validated smoking cessation so that its true effectiveness remains uncertain.

Dissemination trials

Although four trials discussed under cluster randomisation were in many senses dissemination trials, this paragraph discusses trials designed to have an impact on policy and practice at the level of a large organisation. Two trials were identified, both being carried out in Australia (Cooke 2001; Lowe 2002). Data are available from them on uptake of programs at a hospital level but not at present on smoking cessation effectiveness or perinatal outcomes. In trials which evaluated dissemination of smoking cessation programs into routine pregnancy care, 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). Cooke (Cooke 2001) and Windsor (Windsor 2000b) found improved implementation with an intensive method of program dissemination.

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.

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 36/38 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.

Smoking reduction and misclassification of smoking by self-report

One of the two earliest trials (Donovan 1977) demonstrated marked differences in self-reports of smoking collected from the same women in early pregnancy and after birth. However, other trials in the 1980s concluded from the comparison of self-report with biochemical or biophysical measures of smoking that self-report was reliable (Fox 1989). The findings in later studies are completely different: all show substantial misclassification on self-report with up to a quarter or a third of women describing themselves as non-smokers having levels of salivary or urinary cotinine (biomarker) incompatible with that self-description (Kendrick 1995; Lowe 1998a; Walsh 1997).

As the biochemical measures have a relatively poor correlation with the number of cigarettes smoked it is not possible to use, for

example, cotinine levels to assess smoking reduction. A very high proportion of pregnant women describe themselves as having "cut down" but given the problems of self-report described in the previous paragraph 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.

Windsor 1993 has proposed using a halving of the cotinine level at 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 2002) 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)

Fetal and infant health outcomes

The close to 20% 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 30 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. Future trials need to take more seriously the inclusion of perinatal mortality as an outcome measure.

Nicotine replacement therapy (NRT) during pregnancy

NRT in this review does not appear to have a significant advantage over other types of interventions. Only one study (Hegaard 2003) evaluated the effect of NRT as part of a multi-modal approach to smoking cessation in pregnancy, with a RR of 0.95 (95% CI 0.92 to 0.98). One concern about its use in pregnancy is the possibility of adverse effects of nicotine on the fetus, through alterations in uterine, placental or blood flow or directly on the brain. 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.

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). 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. All NRT trials in pregnancy to date are of nicotine patches (continuous use formulations). 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.

No trials of the antidepressant bupropion to increase smoking cessation in pregnancy have been reported (Oncken 2003).

New developments

One expanding area in the literature on smoking cessation interventions during pregnancy is descriptive work on the barriers to implementation in hospital and clinic settings (for example, Aquilino 2003; McLeod 2003; Walsh 1995) of interventions already shown to be effective.

Another is the publication of interventions to increase smoking cessation among the partners of pregnant women, with the additional aim of facilitating cessation by the women themselves (Stanton 2004).

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. In order to avoid 'victim-blaming', or the perception of 'victim-blaming', attention needs to be given to the consumer concerns mentioned in 'Implications for research' and to the existing evidence on barriers to implementation in antenatal care. 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.

Interventions involving additional group sessions during pregnancy have been reported as being poorly attended in most settings, though accepted in two trials in Scandinavia.

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 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.

Given the strong association between social inequality and continued smoking by pregnant women, and bearing in mind the contribution of smoking to the global burden of disease in developed market economies, midwives, general practitioners and obstetricians need to support strategies in the wider community to reduce social inequalities.

Implications for research

Future trials need to include the following elements:

- 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 description of the intervention in sufficient detail for its replication even if the detail requires a separate paper.

- A relapse prevention component for those who have stopped smoking before the first antenatal visit.

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

- Biochemical validation of non-smoking status.

- The collection of outcome data on birthweight, preterm birth and perinatal deaths.

- Collection of outcome data on breastfeeding, operative delivery, maternal psychological well-being, and the perceived impact of the intervention on family functioning.

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. Until subgroup analyses are reported in trials this important question cannot be answered.

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.

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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 usual care 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. No details of randomisation or whether usual care providers were blinded to allocation. of bias.
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	Usual Care (UC) 30 minutes individual educational session with project nurse including information about the risks of smoking to the mother and the fetus + brochures on smoking and pregnancy. Teen Fresh Start (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. Teen Fresh Start + 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. High intensity intervention
Outcomes	Smoking cessation at 4-6 weeks post baseline, validated by exhaled CO. Only 46/84 had outcome data (high attrition rate = 45%), UC = 12 (41%), TFS = 13 (46%), TFSB = 13 (50%). 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
Allocation concealment?	Unclear	B - Unclear

Bakker 2001

Methods	Cluster-randomised trial measuring (i) the short-term effects of routine prenatal care provider (midwife) smoking cessation counselling and provision of smoking cessation materials. All midwives in a province were allocated to either intervention or control care. Only 24.2% of chairs of midwifery agreed to approach midwives in their region to participate. The first 40 practices (118 midwives) were selected, from 4 provinces, which were then matched (by location and level of urbanisation) into 2 pairs. (ii)measuring the longer-term effects
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 gest 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 + a folder about smoking cessation in pregnancy, (Both trials i and ii) Intervention group received routine care + a minimum of 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; midwife booklet and post-delivery booklet. Information was based on the stages of change model
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. Attrition 12.8%, not different in I and C arms, detailed process evaluation, including views of participants and midwives Attrition rate 12.8%, with NS difference in attrition between experimental and control groups. (ii) Self-reported quit attempts at 6 weeks and 6 months postpartum; attrition 9.1% (I), 7.9% (C) 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. Good process evaluation documented poor implementation in some aspects. A separate detailed paper published on process evaluation issues. (ii) Only 16.7% of women received the post-delivery booklet. No validation of longer-term self-reported smoking

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

Baric 1976

Methods	A randomised pilot study of the effect of medical advice on smoking cessation in pregnancy, in two public antenatal clinics in Bolton and District General Hospital, England. No sample size or randomisation details
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

Baric 1976 (*Continued*)

Interventions	Control group received usual care, which was advice at the discretion of the doctor. Intervention group received 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 = 3
Outcomes	Smoking cessation assessed by self report in a home interview 11 weeks after baseline visit. No biochemical validation of smoking status
Notes	

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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. Allocation by a computer-generated random number table to experimental or control group. No randomisation details or 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
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 + 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.
Outcomes	Smoking cessation 6 weeks after intervention confirmed by subsequent CO <= 9 ppm in breath specimen. Outcome measurement for 170/226 women. Attrition rate 24.8%, and allocation not reported
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*)

Allocation concealment?	Unclear	B - Unclear

Belizan 1995

Methods	Randomised trial of psychosocial support in pregnancy in 4 hospitals in Latin America (Argentina, Brazil, Cuba, Mexico). January 1989 - March 1991. Randomisation in balanced blocks of 20, prepared centrally, provided in sealed, opaque envelopes opened after the baseline interview had been completed. Providers unaware of the allocation of women to either arm of the trial
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. High intensity intervention involving 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, hot line 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
Outcomes	Self reported smoking cessation, no biochemical validation. Multiple perinatal and maternal health outcome data were collected. As there are many paths other than smoking reduction/cessation by which these outcomes might have been modified by the intervention, only smoking cessation has been abstracted in this review
Notes	Sample size was planned for the primary trial objective. Process evaluation showing good implementation is reported.

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Yes	A - Adequate

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. Computer-generated random assignment to control or intervention in balanced blocks of 50. Caregiver blinded to allocation. No sample size justification. No sample size justification
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 + 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" of 2 to 6 women each
Outcomes	Both perinatal and maternal health outcomes were assessed but as there were other intervention components which might have influenced these outcomes only smoking cessation data were abstracted for this review. No biochemical validation of smoking status. 9 women (of 131) were lost to follow up by late pregnancy, counted as still smoking. Attrition = 7%
Notes	No process evaluation is reported.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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. No description of randomisation. Caregivers blinded to allocation
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)
Interventions	Control group (usual care): clinic nurse provided health education, including smoking. Intervention: usual care + 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 + American Cancer Society pamphlet ("Why start life under a cloud?") about the negative effects of smoking and simple guidelines for self-directed smoking cessation

Burling 1991 (*Continued*)

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
Allocation concealment?	Unclear	B - Unclear

Cinciripini 2000

Methods	Trial of provision of videotaped vignettes for promoting smoking cessation and relapse prevention in a community-based university setting, Texas, US. No details of randomisation, caregiver blinded
Participants	Volunteers who were willing to quit within two 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 VCR (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 minutes vignettes covering a range of topics and strategies from initial quitting to relapse prevention
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. Baseline CES-D depression scale. Participant evaluation of intervention materials. Attrition rate 39%.
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
Allocation concealment?	Unclear	B - Unclear

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-June 1997. No randomisation details. Quality score = moderate-risk of bias
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 + were asked to designate a social supporter (preferably a female non-smoker), and were advised both she and her supporter would receive an incentive: participant = $50 voucher/month biochemically confirmed as quit. Supporter = $50 voucher in first month and at 2 months postpartum, and $25 voucher for other months. High intensity
Outcomes	Smoking cessation biochemically validated with salivary cotinine at 34 weeks gestation and 2 months postpartum. Attrition rate I = 32%; C = 51.5%
Notes	Data in outcome tables is inconsistent.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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. Randomisation details unclear. Caregivers not blinded (asked to reinforce information). Quality score = high-risk of bias
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
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 (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
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. No biochemical validation of smoking status.

Donovan 1977 (*Continued*)

Notes	Details of the intervention are in Donovan et al 1975 [see Donovan 1977]. 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
Allocation concealment?	Unclear	B - Unclear

Dunkley 1997

Methods	Trial of midwifery counselling around the "stages of change" model", in a large UK maternity. No details of randomisation and caregivers aware of allocation. Quality score = high-risk of bias
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
Outcomes	Smoking cessation; cigarettes/day; "stage of change" at 11 to 18 weeks vs 37 weeks. No biochemical validation of smoking status
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. UK.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Ershoff 1989

Methods	Prospective randomised controlled trial in 5 health centres of the same HMO in Los Angeles, 1985 - 87. Educator turned over a pre-assigned card after a brief smoking related interview to determine allocation
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); disenrollment 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
Outcomes	Smoking cessation validated with urine cotinine; birthweight; low birthweight; preterm birth (< 37 weeks) ; stillbirths. Attrition I = 51%, C = 49%
Notes	Process evaluation showed good implementation.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

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"
Outcomes	Smoking data validated with urine cotinine only collected, 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*)

Allocation concealment?	No	C - Inadequate

Ershoff 1999

Methods	Trial of three alternative methods of smoking cessation interventions, in a large group model managed care organization in California, US. No details of randomisation. Caregivers blinded to allocation
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
Outcomes	Smoking cessation in the third trimester "not even a puff in the last 7 days", biochemically validated with urine cotinine. Baseline mental health index and Cohen's perceived stress scale. Number of quit attempts and movement in stages of change.
Notes	Data from group one and group three only compared in outcome tables. Good process evaluation of each of the methods

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - Unclear

Gielen 1997

Methods	Randomised trial of a smoking cessation and relapse prevention intervention in an urban, prenatal clinic in Baltimore, US. Nov 1996 - June 1997. No details of randomisation and caregivers not blinded to allocation
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 Johns 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,

Gielen 1997 (*Continued*)

	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 about the risks of smoking; a recommendation to quit and pamphlets from the areas'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 the doctor and the counsellor) mailed to the woman 1-2 weeks after her first visit
Outcomes	Smoking cessation in third trimester, validated by salivary cotinine. Attrition I = 35.2%, C = 35.3%.
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

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Haddow 1991

Methods	Randomised trial in physicians offices and clinic sites within Maine, 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. Random allocation through computer-generated number on maternal serum screening request form. Caregiver not blinded
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 intervention 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 gave her also a copy of the report and a pregnancy-

Haddow 1991 (*Continued*)

	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
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
Allocation concealment?	No	C - Inadequate

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. Sample size justification
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 usual care 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
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 views of interventions reviewed. Attrition rate 7%.
Notes	Data not adjusted for clustering, so they were not included in outcome tables. 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

Risk of bias

Hajek 2001 (*Continued*)

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Hartmann 1996

Methods	Trial of medical smoking cessation counselling and peer support, in a teaching hospital (academic) clinic in North Carolina 1991-1993. Randomised by computer-generated random number table and charts "flagged" to identify those in the intervention group
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
Outcomes	Smoking cessation biochemically validated by exhaled CO at each visit. Attrition rate 16%
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
Allocation concealment?	No	C - Inadequate

Hegaard 2003

Methods	Trial of multimodel intervention to promote smoking cessation in pregnancy in a large midwifery centre in the Netherlands, 1996 - 1998. Quasi-randomised, allocation of even/uneven birth dates to designated clinic days. Usual caregivers provided intervention, so not blinded to allocation. Sample size justification
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 & 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 monoxide levels taken at each visit, the first 3 weeks prepared women for quitting, with 6 attendance to maintain cessation and provide an NRT regime tailored to Fagerstrom nicotine dependence assessments
Outcomes	Self reported smoking cessation at 37 weeks gestation, biochemically validated in 51% participants. Mean birthweight; low birthweight (< 2500 g); preterm births (< 37 weeks)
Notes	

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

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 + 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

Hjalmarson 1991 (*Continued*)

Outcomes	Smoking cessation data; biochemically validated (blood thiocyanate < 100 ng/ml) at first and second antenatal visit and in late pregnancy, and postpartum; mean birthweight; low birthweight; preterm birth (< 36 weeks)
Notes	Same data published by Svanberg 1992. No process evaluation.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Hughes 2000

Methods	Trial of tailored, scripted "stage-of-change" intervention and fact booklet, for infertile and pregnant women, in 3 university teaching hospitals in Ontario, Canada. Randomisation of consenting participants using a computer-generated, blocked schedule, administered through numbered opaque envelopes. Care-givers not blinded to allocation
Participants	Pregnant women smoking 3 or more cigarettes per day in the past 6 months. Mean gest at enrolment I = 18.91, C = 20.55. 110 recruited. Mean number of cigarettes/day I = 13.43, C = 12
Interventions	Control group completed a questionnaire and self identified current smoking "stage of change" and received standard information about the negative effects of smoking in pregnancy, reinforced with whatever literature was available and CO measurements. The intervention group received the same as the control group + (i) scripted advice prompted by sets of cards, which are tailored to each stage; (ii) stage specific information booklets; (iii) referral for more in depth counselling
Outcomes	Self reported smoking levels, validated by exhaled CO, and movement in the stages of change measured at enrolment, 6 and 12 months. Number of quit attempts; triggers for resuming smoking.
Notes	Data from both infertile and pregnant women combined, so not included in tables. Process evaluation provided and only 5/56 accepted referral to a smoking cessation clinic. Concern selective intervention by the same provider may have influenced "routine" advice to the control group

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

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 one 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
Outcomes	Smoking cessation during second trimester, biochemically validated with serum and salivary cotinine levels
Notes	Study ceased after only 30 women recruited due to severe withdrawal symptoms in the 30th recruit (allocated to placebo)

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Kendrick 1995

Methods	Cluster randomised trial of smoking cessation in public prenatal and WIC clinics in Maryland, Colorado and Missouri, USA, 1987-89. 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
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 gest at enrolment = 15.2 - 16.6 weeks. Mean cigarettes/day at enrolment combined for smokers = 12 cigarettes/day
Interventions	Control: usual care not otherwise specified. 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; health care 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

Kendrick 1995 (*Continued*)

	support; preventing relapse and limiting exposure to environmental tobacco smoke. All materials were at 6th Grade reading level
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	Substantial misclassification of self report as non-smoking: 28% at enrollment; 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
Allocation concealment?	Unclear	B - Unclear

Lawrence 2003

Methods	Cluster-randomised trial of two different interventions, in community midwife clinics in the West Midlands region of the UK. A computerised minimisation programme was used to allocate 72 eligible practices into 3 equal groups from 101 available practices. Caregivers not blinded (implementing intervention). 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
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
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 two 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 participants 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 on the occasions, which consisted of questions to stage the woman with 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

Lawrence 2003 (*Continued*)

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

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

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. Simple randomisation in balanced blocks of 8. Unclear whether caregivers masked
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 + 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.
Outcomes	Smoking status and smoking/day assessed 6 weeks later. Not biochemically validated
Notes	Short interval between intervention and assessment.

Risk of bias

Item	Authors' judgement	Description

Lilley 1986 (*Continued*)

Allocation concealment?	No	C - Inadequate

Loeb 1983

Methods	Trial of anti-smoking interventions (individual and group) based on the MRFIT trial, carried out in Oregon where 95% of pregnant women attending one of the two hospitals were enrolled in the Kaiser Permanente HMO, 1979-1980. No details of randomisation or whether caregivers masked to allocation
Participants	, questionnaire response rate 25%. 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	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
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

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - Unclear

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. No details of randomisation and caregivers not masked.
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 + flip chart (5th Grade reading material + 'stay quit buddy' encouragement = non-smoking gifts and pamphlets) + clinic reinforcement by prenatal staff

Lowe 1997 (*Continued*)

	through reminder form in the notes + staff training to confirm abstinence, praise, encourage continuing cessation
Outcomes	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

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Lowe 1998a

Methods	Quasi-randomised study using alternate allocation within antenatal clinic of a large metropolitan public hospital in Brisbane 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 complications of pregnancy 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 + a 15 minutes 1:1 motivational counselling session provided by the midwife, focussing 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 the midwifery caution against smoking; (I): the midwife provided the booklet without any additional discussion or counselling
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.

Lowe 1998a (*Continued*)

	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
Allocation concealment?	No	C - Inadequate

Lowe 1998b

Methods	See Lowe 1998a for setting as this trial followed immediately after the first one. Quasi-randomised trial with alternate weeks allocated to control and intervention
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. Two 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
Outcomes	Smoking behaviour 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
Allocation concealment?	Unclear	D - Not used

MacArthur 1987

Methods	Quasi-randomised trial with alternation of 4 week blocks to intervention or control 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 nine
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

MacArthur 1987 (*Continued*)

	(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.
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
Allocation concealment?	No	C - Inadequate

Malchodi 2003

Methods	Trial of effects of peer counselling on smoking cessation and reduction in a large urban clinic. Hartford Hospital, US, Jan 1998-Feb 2000. Computer-generated random allocation, with usual care providers masked to allocation
Participants	Low income, uninsured women, who smoke "at least one 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
Outcomes	Smoking cessation and reduction 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 birth weight correlated with cigarettes/day in late pregnancy. Attrition rate I = 43%, C = 36%

Notes	

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Manfredi 2000

Methods	Cluster randomised trial of a smoking cessation program in 10 public clinics in Chicago, US, 1994-6. Randomisation to study group within matched pairs of clinics
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 Millers brief motivational interviewing approach
Outcomes	Self reported smoking cessation, not biochemically validated. Movement in stages of change. Attrition rate I = 38%, C = 41%
Notes	Data not included in outcome tables due to inconsistent data reporting (baseline and control groups combined) and data not adjusted for clustering. Good process analysis provides outcomes by exposure to intervention

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Mayer 1990

Methods	Trial comparing three smoking cessation interventions in WIC clinics in Grand Rapids, Michigan, USA, 1985-86. Not details of randomisation or whether caregivers masked to allocation
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

Mayer 1990 (*Continued*)

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 + brochure to take away), and behavioural change manual adapted from RA Windsor and the Am Lung Assoc "Freedom from Smoking" focussing on contracting and self monitoring (cognitive behaviour therapy)
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
Allocation concealment?	Unclear	B - Unclear

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. No details of randomisation. Caregivers masked to allocation
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 reaches 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 stage 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. & 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
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)
Notes	Process evaluation describes participation in specific intervention components, including relapse prevention

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Moore 2002

Methods	Cluster randomised trial of provision of self help in 3 UK NHS hospital trusts, 1998-2000. 118 midwives stratified according to workload and randomly allocated to provide intervention or control care. Computer-generated randomisation, caregivers not masked to allocation. Sample size justification
Participants	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 usual care + 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
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. Attrition rate 8%.
Notes	Data not included in outcome tables as it was not adjusted for clustering. Good 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

Risk of bias

Item	Authors' judgement	Description

Allocation concealment?	No	C - Inadequate

Mullen 1991

Methods	Randomised, factorial design to identify the best way of encouraging the disclosure of smoking in pregnant women, in a HMO, Texas, 1988-1990. No randomisation details
Participants	Pregnant women enrolled in an HMO; >= 18 years; able to speak and read English; free of mental or sensory handicap; mental retardation or mental illness. 1078/1206 recruited. 121 refused others were < 18 or non-English speaking
Interventions	The 4 options compared were: (1) Format (i) a single yes/no question vs (ii) a multiple choice. (2) Channel (iii) oral vs (iv) written forms of the two questions. Oral vs written forms of the two questions
Outcomes	Proportion of women smokers who disclosed smoking, biochemically validated with urine cotinine cutoff >= 50 ng/ml. No smoking cessation data
Notes	Those who refused urine testing were classified as "smoking disclosed". Misclassification of self-report as non-smoking was low in this study (3%)

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - Unclear

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. No details of randomisation and unclear whether caregivers masked
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 + pamphlet inviting women to a 2 hour cessation class in the evenings where the Windsor self help manual would be taught/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
Outcomes	Smoking cessation biochemically validated by urine cotinine.

O'Connor 1992 (*Continued*)

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
Allocation concealment?	Unclear	D - Not used

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. No details of randomisation and unclear whether caregivers were masked to allocation
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. High intensity intervention.
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
Allocation concealment?	Yes	A - Adequate

Panjari 1999

Methods	Trial of personalised smoking cessation interventions in a low socioeconomic population in Australia. No details of randomisation methods or whether caregivers were masked to allocation
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 nonparticipants refusing to enter the study
Interventions	Control group received usual care, 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 + 4 counselling sessions by a midwife specifically trained and employed to provide smoking cessation counselling, using cognitive behaviour therapy. 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
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 birth weight, proportion LBW (< 2500 g). Attrition rate = 15%
Notes	Process evaluation showed 71% women in the intervention group received the full intervention

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Petersen 1992

Methods	A randomised trial comparing the impact on smoking cessation of two different packages of material mailed to current smokers and recent quitters at a large Boston HMO, USA, 1986-1988. Randomisation using table of random numbers for one intervention. Clinic staff were not aware of the allocation. Allocation to intervention 2 was not randomised but offered to all eligible enrollees at one clinic: data on this intervention is not included in the review
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	Usual care: 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 + 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

Petersen 1992 (*Continued*)

	a maintenance section for the postpartum period. Intervention based on cognitive behaviour therapy
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
Allocation concealment?	Yes	A - Adequate

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 usual care in an inner urban setting, Toledo, Ohio, USA, 1987-89. Randomisation by dice, which did not work well (no allocation to usual care some of the time). Unclear whether allocation masked to caregivers
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. Relatively low participation and 57% dropout from enrolment to completion
Interventions	Control: usual care not specified or assessed but "usual for physicians to address this issue with participants at least one 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
Outcomes	Smoking reduction 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

Price 1991 (*Continued*)

Allocation concealment?	No	C - Inadequate

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 promoted maternal smoking cessation during pregnancy. Randomisation by microcomputer based sequencing. Not clear whether caregivers were blinded to allocation
Participants	53,367 pregnant women; -32,317 ineligible or excluded; leaving 21,050 -3,163 refused; -2,357 had miscarriage or change of provider; leaving 15,530 (7,812 intervention + 7,718 controls). subsequently - 64 + 63 miscarriage, -131+121 records lost or women moved, leaving 7,617 + 7,534; 1,768 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 one week, gest 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
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**
Allocation concealment?	Unclear	B - Unclear

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. No details of randomisation or whether caregivers blinded to allocation
Participants	Pregnant women at 10 - 14 weeks gestation; 18 to 32 years; stable relationship; Caucasian; 85% had planned pregnancy, at low risk of complications; 86% nulliparous. Exclusions: prior miscarriage or extended infertility investigations
Interventions	Control: no/low feedback. Intervention: high feedback about the fetus, with the fetus visible
Outcomes	Self reported smoking cessation at 16 weeks gestation, without biochemical validation

Reading 1982 (*Continued*)

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).

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

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. Caregivers not masked to allocation
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
Outcomes	Smoking cessation, biochemically validated with exhaled CO and serum thiocyanate. Mean birthweight in subgroup smoking >= 5 cigarettes at booking
Notes	Detailed account of the intervention in King and Eiser 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
Allocation concealment?	No	C - Inadequate

Secker-Walker 1992

Methods	Evaluation of a program to train obstetric and family practice residents to give smoking advice during antenatal care, using pre- and post- training evaluation of their skills with a simulated patient, and exit interviews with women participating in a randomised trial of individualised smoking cessation counselling. 1988-1990, Vermont, USA
Participants	All residents providing (supervised) prenatal care, at the University of Vermont
Interventions	Description of training and copies of 4 papers on smoking cessation advice + small group training by physician and psychologist during 1 hour workshop. Workshop: review of the project; description of advice and rationale for each step; use of protocol prompt sheet; video of advice being offered by GP and Obstetrician; role play with corrective feedback; basic care description; (individual training for residents unable to attend) + 30 minute refresher session with counsellor before the rotation + counsellor discussed actual progress and adherence
Outcomes	Scores on video/simulated patient (blinded assessment, systematic scoring) significantly increased with no change in the time required to provide the advice; exit interviews showed good adherence to the protocol by 96/99 (intervention) and 66/67 (control) interviewees, as did women's proposed actions post-intervention, also in exit interviews
Notes	Useful for dissemination trials of smoking cessation in hospitals

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

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 usual care, at the University of Vermont, USA, 1984-1987. No details of randomisation and it is unclear whether caregivers were masked to allocation
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 gest 13/40), smoking at least 1 cigarette a day, no exclusions mentioned. 808 interviewed, 33 refused, 175 sp 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: usual care, 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

Secker-Walker 1994 (*Continued*)

	former smokers) about smoking and smoking cessation counselling techniques + Am Lung Association training group for class leaders + 4 week pilot
Outcomes	Smoking cessation at 36 weeks gestation, 75% biochemically validated with cotinine. Mean birthweight, low birthweight, other smoking-related complications (pPROM, placental abruption and placenta praevia)
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.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Secker-Walker 1995

Methods	Trial of relapse prevention counselling for spontaneous quitters, Vermont USA.. See Secker-Walker 1994 for methodology details
Participants	Those from Secker-Walker 1994 who had stopped smoking spontaneously before their first prenatal clinic visit (n = 175, 89 (I) and 86 (C) among whom there were 5 miscarriages, 1 termination, 1 fetal death and 1 infant death leaving 85 (I) and 80 (C). Further losses were 15 transferred to other care, 9 dropped out and 8 lost to follow up
Interventions	Control: usual care by own provider. Intervention: see Secker-Walker 1994 for training of health educators and cessation planning; in this group dealt with concerns about staying away from smoking, her perceptions of the advantages and disadvantages of maintaining cessation, problem-solving and skills practice, + booklet; 39 weeks and postpartum visits focused on infant risks and benefits
Outcomes	Smoking cessation, biochemically validated). Mean birthweight, low birthweight, preterm birth.
Notes	Exclusion of fetal and infant deaths. Biochemically validated smoking cessation showed substantial misclassification at 36 weeks in this study, more so than for the continuing smokers

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Secker-Walker 1997

Methods	Trial comparing the added effectiveness for smoking cessation during pregnancy of a free videotape using peer role models, Vermont, USA, 1992-1993. No details of randomisation. Caregivers not masked to allocation
Participants	Women in a state supported clinic for underinsured women, currently smoking at least 1 cigarette/day, 7/67 refused leaving 30 (I) + 30 (C), 4 had miscarriage leaving 26 + 30, 3 lost to follow-up and 7 moved to another care-provider leaving 17 + 27 seen at 36 weeks. Mean cigarettes per day pre-pregnancy = 22.6
Interventions	Control: advice from obstetrician or nurse-midwife + tip sheet on quitting. Intervention: as above + 29 minute videotape of 4 women going through the process of quitting during pregnancy; talking about feelings; coping with weight gain; getting support, which could be borrowed and taken home. Based on social learning theory
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
Allocation concealment?	Unclear	B - Unclear

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 usual care (UC), Vermont, USA, 1988-92. Sample size justification. The study included a relapse prevention component, reported separately. No details of randomisation. Caregivers could not be masked to allocation
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.

Secker-Walker 1998 (*Continued*)

	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 et al, 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 + 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
Outcomes	Smoking cessation maintained in late pregnancy (36/40) and 1 year postpartum, biochemically validated with exhaled CO and urine cotinine. Mean birthweight Low birthweight
Notes	Methods included a detailed process evaluation.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Sexton 1984

Methods	A randomised trial of an intervention to increase birthweight by changing maternal smoking, carried out in Baltimore, USA. No details of randomisation and it is unclear whether usual caregivers were masked to allocation
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: usual care, 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 + 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
Outcomes	Smoking in late pregnancy, 97% biochemically validated with salivary thiocynate. Miscarriage; fetal deaths; mean birthweight; low birthweight; very low birthweight; % Apgar scores < 7 at 1 minute and 5 minutes; length and head circumference

Notes	Change of criteria for enrollment 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 et al 1984. Group sessions in the intervention were not readily accepted

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Solomon 1996

Methods	A trial of a smoking cessation intervention on women's 'stages of change' (precontemplation, contemplation, preparation and action) was assessed. No details of randomisation process
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 + cessation pamphlet designed for pregnant women. Intervention: as control + quit date or date to cut down set + 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
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 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
Allocation concealment?	Unclear	B - Unclear

Solomon 2000

Methods	Trial of proactive telephone peer support in a large obstetric practice in Vermont, US, 1996-7. No description of randomisation procedure. Caregivers not able to be masked to allocation
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 + offered telephone peer support (from a female ex-smoker, who received 8 hours of training) for women with moderate or high intentions of quitting. who called the participant within several days to provide support for positive changes in smoking behaviour
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%. Attrition = 16 (10.6%)
Notes	Process evaluation showed 53% received the peer intervention

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Stotts 2000

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, US. Random allocation determined by a computer generated list. Unclear whether caregivers masked to allocation
Participants	Women who continue to smoke at 28 week gestation, after having counselling and 8 self help booklets earlier in pregnancy care. Inclusion criteria were women fluent in English, over 18 yrs, 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 et al. 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

Stotts 2000 (*Continued*)

Outcomes	Self reported smoking cessation at 34 weeks gestation, validated by an anonymous urine cotinine sub-sample. Postpartum follow up (6w, 3m, 6m) 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

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Strecher 2000

Methods	Trial of personalised, computer generated, smoking cessation messages, in 2 university hospitals in North Carolina & Michigan, USA, Dec 1996-97. Randomisation by computer algorithm. Unclear whether caregivers masked to allocation
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
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 - assumption was ITFV were smokers. Participant evaluation of using hand-held computers and reactions to computerised materials

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Tappin 2000

Methods	Pilot study of home based motivational interviewing for smoking cessation in a Glasgow Hospital, Scotland, March-May 1997. Consenting women stratified and randomly allocated to 2 equal groups using blinded telephone allocation. Unclear whether caregivers masked to
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
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 Millers 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
Allocation concealment?	Yes	A - Adequate

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. Randomisation by random number tables, allocation concealed by opaque sealed envelopes and restricted in groups of ten. Intervention provided by trained facilitator, with staff unaware of allocation
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. Participation rate = 81% (n = 418). Intervention group were less likely to have spontaneously quit, or be employed. Mean gest at first visit I = 15.5, C = 15.3. Number of daily cigarettes at intake: 1-9 I = 61, C = 54; 10-19 I = 74, C = 73; 20+ I = 68, C = 65
Interventions	The control group completed a questionnaire at first visit, followed by routine prenatal advice on a range of health issues, from midwives and obstetricians. The intervention group received as for the control group + structured one to one counselling by a trained facilitator (based on stages of change theory); partners invited to be involved in the program; an information pack; and invited to join a stop smoking support group. A carbon monoxide monitor was available for the intervention group, to quantify smoking habit and act as a motivational tool. High intensity intervention
Outcomes	Smoking cessation at delivery, 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

Thornton 1997 (*Continued*)

	(2500 g), preterm births, NNICU admissions, infant outcomes at 3 months. Attrition at delivery: I = 6.2%, C = 8.6%.
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
Allocation concealment?	Yes	A - Adequate

Valbo 1991

Methods	Quasi-randomised trial of smoking cessation interventions (allocation to 1 of 4 arms, 3 intervention and 1 control, by date of enrollment 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. Caregivers not masked to allocation.
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 + 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
Outcomes	Smoking cessation assessed immediately after the intervention, biochemically validated but not reported. intervention arms
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

Valbo 1991 (*Continued*)

Allocation concealment?	No	C - Inadequate

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 1990-1991. No details of randomisation and caregivers not masked to allocation
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 + 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 + encouragement and appointment for 32 week scan + reinforcement at the 32 weeks scan + 2 weeks later a further letter. Both intervention and control information were provided by obstetrician or midwife
Outcomes	Smoking cessation 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**
Allocation concealment?	No	C - Inadequate

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. Randomised by random number tables, with usual caregivers masked to allocation
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 recipe (Handbook of the American Society of Clinical Hypnosis); the tape played after hypnosis was

Valbo 1996 (*Continued*)

	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"
Outcomes	Self reported smoking cessation, reduction 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**
Allocation concealment?	Yes	A - Adequate

Walsh 1997

Methods	Trial of a structured, cognitive-behavioural, smoking cessation program for pregnant women delivered by usual care providers in a public hospital antenatal clinic in Newcastle, Australia, 1990-1991. Randomised after consent by precoded questionnaires in opaque envelopes, with a computer generated sequence
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 cognitive behaviour therapy: (i) 2-3 minute standardised risk information from Doctor + 14 minute video on risk information rebuttal of barriers to quitting, cessation tips + 10 minute standardised information and counselling from Midwife after the video, using a flip chart, with negotiation of a quit date whenever possible + self-help manual on risks, barriers and cessation + 4 packets of confectionary gum + lottery chance (4 prizes) for biochemically validated abstainers at the next visit + social support from accompanying adult (partner/friend/other) vis support tip sheet, contract and form letter + chart reminder vis sticker in the medical record + form-letter + 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
Outcomes	Smoking status at mid and late pregnancy and postpartum, biochemically validated with salivary cotinine (I = 86%, C = 78%)
Notes	Midwives involved in recruitment to the trial had variable 'success'. Overall participation was quite low (54%).

Walsh 1997 (*Continued*)

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

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

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. No details of randomisation. Usual caregivers masked to allocation. Sample size justification
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)
Outcomes	Smoking cessation or reduction, biochemically validated by salivary thiocynate, 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". All those lost to follow up were considered smokers. 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

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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. Randomisation by a computer-generated system. Caregivers not masked to allocation
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
Outcomes	Smoking cessation at 32 weeks gestation, biochemically validated with salivary thiocyanate
Notes	Separate paper on spontaneous quitters (Lowe et al, 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
Allocation concealment?	Yes	A - Adequate

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. 17 eligible counties (> 50 pregnant smokers per year) stratified (% black: white pop; % pregnant smokers) into 8 clusters and 50% randomly selected (no details). Usual caregivers not able to be masked to allocation
Participants	Women screened at first visit (9 - 12 weeks gestation) for self-reported smoking, validated by salivary cotinine. 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), 80% phase 2 group (n = 139) formed intervention group. Both groups smoked approximately 10 cigarettes/d at baseline
Interventions	Nurses, social workers and WIC administrators received orientation sessions. Partnerships were developed for program implementation. Control group patients had self report smoking status ("Ask", and a saliva sample, and counselling ("advise"). Intervention (based on cognitive behaviour therapy) group were

Windsor 2000a (*Continued*)

	provided with 2 further components "assist and arrange", which included a motivational video to take home to show partners, "A pregnant woman's guide to quit smoking", and < 5 min counselling session
Outcomes	Self reported smoking status at 60 days after first visit, validated by salivary cotinine. Significant (> 50%) reduction in baseline cotinine (harm reduction measures). No quit attempts. Attrition rate 13% (n = 34) , counted as smokers
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

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Wisborg 2000

Methods	Double-blind, placebo controlled trial of nicotine replacement therapy (patches) in pregnant women in a Danish obstetric hospital. Women consenting to participate were randomly assigned in blocks of 6, to nicotine or placebo patches. The investigation team were blinded to allocation
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
Outcomes	Self reported abstinence of at least 7 days at 2nd, 3rd, and 4th prenatal visits, validated by salivary cotinine measurement. 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. Compliance lower for placebo group, who may have guessed allocation. Limited details on 3 months and 1 year follow up

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

AFP: alpha fetoprotein

BP: blood pressure
CO: carbon monoxide
GP: general practitioner
HMO: Health Maintenance Organisation
LBW: low birth weight
min: minutes
MRFIT: randomised trial of health promotion carried out in the US
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
Byrd 1993	There are no data provided by trial allocation.
Cooke 2001	Data are available on uptake of programs at a hospital level but not at present on smoking cessation effectiveness or perinatal outcomes
Emmons 2000	Quasi-experimental evaluation study 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
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 quasi-randomised study the intervention was carried out in one hospital with another hospital in the same city acting as a control, after a prior descriptive study which showed the similarity between the two in terms of social and demographic factors including smoking. There was no randomisation and recruitment differed substantially across the two 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
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

(*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
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
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
Mullen 1990	Data are provided on those who stopped smoking only, not data by trial allocation
Mullen 1997	Data are provided on those who stopped smoking only, not data by trial allocation
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
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 one hospital with another being a comparison setting, after a prior study which showed the similarity between the two in social and demographic factors including smoking rates. There was no randomisation. Recruitment differed significantly across the two hospitals. Data for smoking cessation and smoking reduction are combined with no separate data on cessation and no adjustment for clustering
Scott 2000	This quasi-experimental study 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
Valanis 2001	This prospective quasi-experimental study design to test the effect of a low intensity intervention, used historical controls
Wisborg 1998	This quasi-randomised (clinic day allocation) study of the effect of midwifery training on smoking cessation intervention implementation and pregnancy outcomes, was excluded due to concerns about allocation concealment

HMO: Health Maintenance Organisation
WIC: Food program for Women, Infants and Children in the US

DATA AND ANALYSES

Comparison 1. All trials

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Continued smoking in late pregnancy	47	13882	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.92, 0.96]
2 Mean birthweight	16	13618	Mean Difference (IV, Random, 95% CI)	33.03 [11.32, 54.74]
3 Low birthweight (under 2500 g)	13	8930	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.70, 0.95]
4 Very low birthweight (under 1500 g)	3	4765	Risk Ratio (M-H, Random, 95% CI)	1.26 [0.69, 2.32]
5 Preterm birth (under 37 or under 36 weeks)	11	10932	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.72, 0.98]
7 Stillbirths	5	4525	Risk Ratio (M-H, Random, 95% CI)	1.16 [0.71, 1.88]
8 Neonatal deaths	3	4143	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.34, 4.01]
9 Perinatal deaths	3	4335	Risk Ratio (M-H, Random, 95% CI)	1.13 [0.72, 1.77]

Comparison 2. Trials with biochemically validated smoking cessation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Continued smoking in late pregnancy	35	10362	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.92, 0.97]

Comparison 3. Interventions with high quality scores

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Continued smoking in late pregnancy	25	7819	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.93, 0.97]

Comparison 4. Interventions of high intensity with high quality scores and biochemically validated smoking cessation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Continued smoking in late pregnancy	17	5252	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.94, 0.98]

Comparison 5. Trials subgrouped by intervention intensity

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Continued smoking in late pregnancy	48	13884	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.92, 0.96]
1.1 High intensity	35	10503	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.92, 0.97]
1.2 Medium intensity	10	2246	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.91, 0.97]
1.3 Low intensity	3	1135	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.83, 1.09]

Comparison 6. Trials subgrouped by intervention strategy

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Continued smoking in late pregnancy	46	13603	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.92, 0.96]
1.1 Cognitive behaviour strategies	20	6155	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.92, 0.97]
1.2 Stages of Change	7	1465	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.95, 1.02]
1.3 Feedback	3	292	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.77, 1.11]
1.4 Rewards	2	1155	Risk Ratio (M-H, Random, 95% CI)	0.77 [0.72, 0.82]
1.5 Nicotine Replacement Therapy	3	927	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.92, 0.98]
1.6 Other	11	3609	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.93, 0.98]

Comparison 7. Trials to prevent smoking relapse in women who stopped smoking in early pregnancy

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Smoking in late pregnancy	5	843	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.63, 1.04]

ADDITIONAL TABLES

Table 1. Randomised cluster trials: summary of effect

Trial ID	Outcome measurement	Adjustment	Effect	95% CI
Kendrick 1995	Biochemically validated smoking cessation at 8 months of pregnancy	Odds ratio adjusted	1.0	0.69-1.6
Manfredi 1999	Self reported smoking cessation at 5-8 weeks post birth	Odds ratio Z-score adjusted	0.67	0.38-1.15 p = 0.006
Bakker 2000b	Self reported smoking cessation at 6 weeks post birth	Odds ratio adjusted	0.42	0.18-0.97
Hajek 2001	Biochemically validated smoking cessation at birth	Odds ratio	0.86	0.48-1.57
Moore 2002	Biochemically validated smoking cessation at 6-7 months of pregnancy	Odds ratio adjusted	0.89	0.48-1.57
Lawrence 2003	Biochemically validated smoking cessation at 10 days post birth	Odds ratio adjusted	0.58	0.26-1.33

WHAT'S NEW

Last assessed as up-to-date: 30 June 2004.

Date	Event	Description
16 February 2009	Amended	Author contact details edited

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 (Bakker 2001; Cinciripini 2000; Donatelle 2000; Ershoff 1999; Hajek 2001; Hegaard 2003; Hughes 2000; Kapur 2001; Lawrence 2003; Malchodi 2003; Manfredi 2000; Moore 2002; Panjari 1999; Solomon 2000; Stotts 2000; Strecher 2000; Tappin 2000; Thornton 1997; Windsor 2000a; Wisborg 2000). Nine additional trials were excluded. Six trials provided new data on fetal and perinatal outcomes The overall conclusions about the effectiveness of smoking cessation interventions did not change. New analyses grouping interventions by strategies showed that the pooled cognitive-behavioural interventions were effective, nicotine replacement therapy was borderline, and trials using 'stages of change' approaches or feedback were not effective. The two trials using a 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

Judith Lumley (JL) and Sandy Oliver (SO) co-wrote the original review protocol, and the initial review. JL, SO and Elizabeth Waters (EW) abstracted the trial data; JL carried out the analyses. All contributed to the final text.

Laura Oakley (LO) contributed to data abstraction and to the text of the review in the subsequent updates. EW was unable to contribute after 2002.

Catherine Chamberlain (CC) carried out the searches for the current update. She also abstracted trials' data, as did SO, LO and JL. JL and CC drafted the text with input from SO and LO; CC entered the data and carried out the analyses, with input from JL.

DECLARATIONS OF INTEREST

Mother and Child Health Research, 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.

External sources

- NHS Central R & D Programme, Department of Health 1995-1996, UK.
- Victorian Health Promotion Foundation, Australia.
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- Public Health Branch Victorian Department of Human Services, Australia.

INDEX TERMS

Medical Subject Headings (MeSH)

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; Pregnancy