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Psychosocial interventions for supporting women to stop smoking in pregnancy

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Abstract

Background—Tobacco smoking in pregnancy remains one of the few preventable factors associated with complications in pregnancy, stillbirth, low birthweight and preterm birth and has serious long-term implications for women and babies. Smoking in pregnancy is decreasing in high-income countries, but is strongly associated with poverty and increasing in low- to middle-income countries.

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

Search methods—In this fifth update, we searched the Cochrane Pregnancy and Childbirth Group's Trials Register (1 March 2013), checked reference lists of retrieved studies and contacted trial authors to locate additional unpublished data.

Selection criteria—Randomised controlled trials, cluster-randomised trials, randomised cross-over trials, and quasi-randomised controlled trials (with allocation by maternal birth date or hospital record number) of psychosocial smoking cessation interventions during pregnancy.

Data collection and analysis—Two review authors independently assessed trials for inclusion and trial quality, and extracted data. Direct comparisons were conducted in RevMan, and subgroup analyses and sensitivity analysis were conducted in SPSS.

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Main results—Eighty-six trials were included in this updated review, with 77 trials (involving over 29,000 women) providing data on smoking abstinence in late pregnancy.

In separate comparisons, counselling interventions demonstrated a significant effect compared with usual care (27 studies; average risk ratio (RR) 1.44, 95% confidence interval (CI) 1.19 to 1.75), and a borderline effect compared with less intensive interventions (16 studies; average RR 1.35, 95% CI 1.00 to 1.82). However, a significant effect was only seen in subsets where counselling was provided in conjunction with other strategies. It was unclear whether any type of counselling strategy is more effective than others (one study; RR 1.15, 95% CI 0.86 to 1.53). In studies comparing counselling and usual care (the largest comparison), it was unclear whether interventions prevented smoking relapse among women who had stopped smoking spontaneously in early pregnancy (eight studies; average RR 1.06, 95% CI 0.93 to 1.21). However, a clear effect was seen in smoking abstinence at zero to five months postpartum (10 studies; average RR 1.76, 95% CI 1.05 to 2.95), a borderline effect at six to 11 months (six studies; average RR 1.33, 95% CI 1.00 to 1.77), and a significant effect at 12 to 17 months (two studies, average RR 2.20, 95% CI 1.23 to 3.96), but not in the longer term. In other comparisons, the effect was not significantly different from the null effect for most secondary outcomes, but sample sizes were small.

Incentive-based interventions had the largest effect size compared with a less intensive intervention (one study; RR 3.64, 95% CI 1.84 to 7.23) and an alternative intervention (one study; RR 4.05, 95% CI 1.48 to 11.11).

Feedback interventions demonstrated a significant effect only when compared with usual care and provided in conjunction with other strategies, such as counselling (two studies; average RR 4.39, 95% CI 1.89 to 10.21), but the effect was unclear when compared with a less intensive intervention (two studies; average RR 1.19, 95% CI 0.45 to 3.12).

The effect of health education was unclear when compared with usual care (three studies; average RR 1.51, 95% CI 0.64 to 3.59) or less intensive interventions (two studies; average RR 1.50, 95% CI 0.97 to 2.31).

Social support interventions appeared effective when provided by peers (five studies; average RR 1.49, 95% CI 1.01 to 2.19), but the effect was unclear in a single trial of support provided by partners.

The effects were mixed where the smoking interventions were provided as part of broader interventions to improve maternal health, rather than targeted smoking cessation interventions.

Subgroup analyses on primary outcome for all studies showed the intensity of interventions and comparisons has increased over time, with higher intensity interventions more likely to have higher intensity comparisons. While there was no significant difference, trials where the comparison group received usual care had the largest pooled effect size (37 studies; average RR 1.34, 95% CI 1.25 to 1.44), with lower effect sizes when the comparison group received less intensive interventions (30 studies; average RR 1.20, 95% CI 1.08 to 1.31), or alternative interventions (two studies; average RR 1.26, 95% CI 0.98 to 1.53). More recent studies included in this update had a lower effect size (20 studies; average RR 1.26, 95% CI 1.00 to 1.59), I^2= 3%, compared to those in the previous version of the review (50 studies; average RR 1.50, 95% CI 1.30 to 1.73). There were similar effect sizes in trials with biochemically validated smoking abstinence (49 studies; average RR 1.43, 95% CI 1.22 to 1.67) and those with self-reported

abstinence (20 studies; average RR 1.48, 95% CI 1.17 to 1.87). There was no significant difference between trials implemented by researchers (efficacy studies), and those implemented by routine pregnancy staff (effectiveness studies), however the effect was unclear in three dissemination trials of counselling interventions where the focus on the intervention was at an organisational level (average RR 0.96, 95% CI 0.37 to 2.50). The pooled effects were similar in interventions provided for women with predominantly low socio-economic status (44 studies; average RR 1.41, 95% CI 1.19 to 1.66), compared to other women (26 studies; average RR 1.47, 95% CI 1.21 to 1.79); though the effect was unclear in interventions among women from ethnic minority groups (five studies; average RR 1.08, 95% CI 0.83 to 1.40) and aboriginal women (two studies; average RR 0.40, 95% CI 0.06 to 2.67). Importantly, pooled results demonstrated that women who received psychosocial interventions had an 18% reduction in preterm births (14 studies; average RR 0.82, 95% CI 0.70 to 0.96), and infants born with low birthweight (14 studies; average RR 0.82, 95% CI 0.71 to 0.94). There did not appear to be any adverse effects from the psychosocial interventions, and three studies measured an improvement in women's psychological wellbeing.

Authors' conclusions—Psychosocial interventions to support women to stop smoking in pregnancy can increase the proportion of women who stop smoking in late pregnancy, and reduce low birthweight and preterm births.

BACKGROUND

Description of the condition

Risks associated with smoking in pregnancy—Tobacco smoking in pregnancy remains one of the few preventable factors associated with complications in pregnancy, such as placental abruption, miscarriage, low birthweight (Kramer 1987), preterm birth (US DHHS 2004; Hammoud 2005; Salihu 2007; Rogers 2009; Vardavas 2010; Baba 2012), stillbirth and neonatal death (Kallen 2001). Tobacco smoking also has serious long-term health implications for women and infants; 5.4 million people per year currently die from tobacco use, and this is expected to rise to eight million per year in the next 30 years (WHO 2008a).

Nicotine and other harmful compounds in cigarettes are developmental toxicants (Rogers 2009), which impact on the brain at critical developmental periods (Dwyer 2008) restricting the supply of oxygen and other essential nutrients, fetal growth (Crawford 2008), development of organs (Morales-Suarez-Varela 2006), including the lungs (Maritz 2008) and neurological development (Herrmann 2008; Blood-Siegfried 2010). Growing evidence suggests these 'developmental origins of disease' have life-long implications (Gluckman 2008).

Young women start smoking for many reasons including: belief it is a rite of passage into adult life, a gesture against authority, trying to appear modern and affluent, or to fit in with social networks (Todd 2001). Tobacco addiction is then caused by nicotine in tobacco which produces a cascade of actions, including release of "pleasure enhancing" dopamine, which strengthens associations of positive feelings with smoking behaviour and appears to be involved in all addictive behaviours (Schmidt 2004). Some suggest the negative feelings of

"nicotine hunger" and unpleasant symptoms associated with nicotine withdrawal (Balfour 2004; Hughes 2007) may be stronger for pregnant women due to the physiological adaptations in pregnancy which accelerate nicotine metabolism (Ebert 2009; Ussher 2012a), however a recent study reported less severe withdrawal symptoms among pregnant women in the first 24 hours of abstinence, compared to non-pregnant women (Ussher 2012b).

Epidemiology of smoking in pregnancy—In high-income countries, such as Australia, Canada, Denmark, New Zealand, Sweden, the United Kingdom (UK) and the United States (US), the prevalence of smoking in pregnancy has declined from between 20% to 35% in the 1980s to between 10% and 20% in the early 2000s (Cnattingius 2004; US DHHS 2004; Giovino 2007; Dixon 2009b; Tong 2009; Al-Sahab 2010; Tappin 2010), with significant declines in the last decade bringing the prevalence of smoking in pregnancy well below 10% by 2010 (Lanting 2012). However, the decline has not been consistent across all sectors of society, with lower rates of decline among women with lower socio-economic status (US DHHS 2004; Pickett 2009; Graham 2010; Johnston 2011b; Lanting 2012). Tobacco smoking in high-income countries is a marker of social disadvantage and has been cited as one of the principal causes of health inequality between rich and poor (Wanless 2004), and understanding these disparities are central to understanding the tobacco epidemic (Graham 2010). In Scotland, 30% of women living in the most deprived areas continued to smoke during pregnancy in 2008, compared to 7% in the least deprived areas (Tappin 2010). Women who continue to smoke in pregnancy are more likely to: have a low income, higher parity, no partner, low levels of social support, limited education; access publicly funded maternity care; and feel criticised by society (Graham 1977; Frost 1994; Graham 1996; Tappin 1996; Wakschlag 2003; US DHHS 2004; Ebert 2007; Schneider 2008; Pickett 2009). The World Health Organization (WHO) report into the *Social Determinants of Health* recognises a paradigm whereby disadvantaged people are more likely to use substances in response to their circumstances (WHO 2008b). There is also a significantly higher prevalence of smoking in pregnancy in several ethnic and aboriginal minority groups (Wiemann 1994; Kaplan 1997; Chan 2001; US DHHS 2004; Wood 2008; Dixon 2009b; Johnston 2011b). In Australia, smoking during pregnancy is three times more prevalent among Aboriginal and Torres Strait Islander women (53%) than among non-Aboriginal women (16%) (Johnston 2011b), and similar disparities are reported between Maori and non-Maori women in New Zealand (Dixon 2009b). These disparities are largely in accord with social and material deprivation. However, in some migrant groups, cultural differences may cut across this social gradient (Troe 2008), which suggests that there are aspects of smoking socialisation not entirely explained by material deprivation. In the United States, the highest rates of pre-pregnancy smoking were reported among Alaskan Native women (55.6%), American Indian women (46.9%), and White women (46.4%), with significantly lower rates (less than 20%) reported among African American, Hispanic and Asian-Pacific women (Tong 2011; Watt 2012). Women who are migrants or refugees to Australia, Canada, New Zealand, Northern Europe, the UK, or the US or who originate from South East Asia also retain a lower prevalence of smoking, despite major social disadvantage (Potter 1996; Small 2000; Bush 2003; Dixon 2009b). However, second-generation migrant women are more likely to smoke during pregnancy than first-generation women (Troe 2008), reflecting movement between stages of 'the tobacco epidemic' (Lopez 1994).

In low- and middle-income countries there is marked variation in prevalence of smoking in pregnancy, which reflects the dynamic nature of the tobacco epidemic in these regions (Richmond 2003; Polanska 2004; Bloch 2008). Smoking rates among pregnant women have been comparatively low (9%) compared to men (50%), due to historical cultural constraints on women's smoking in many low- to middle-income countries (Bloch 2008). However, the prevalence of tobacco smoking among women is increasing and is expected to rise to 20% by 2025, shifting the global tobacco smoking epidemic from high-income countries to low- and middle-income countries (Samet 2001; Richmond 2003). The highest rates of smoking during pregnancy were reported in Latin America (18.3% in Uruguay 2004 to 2005) (Bloch 2008) and Eastern Europe (15% in Romania 2005 to 2006) (Meghea 2010). Low rates were reported in Pakistan (3%) (Bloch 2008), South East Asia (1.3%) (Barraclough 1999; Ostrea 2008), and China (2% in 1999), though increasing rates among female school children are causing concern (Kong 2008). In India and Africa, rates of cigarette smoking were low (1.7% and 6.1% pregnant women reporting smoking cigarettes, respectively), (Steyn 2006; Bloch 2008; Palipudi 2009), while use of smokeless tobacco products was high among Indian (4.9% to 33.5%) (Palipudi 2009; Bloch 2008) and African women (6% to 7.5%) (Steyn 2006; Bloch 2008). The WHO has identified this rise of tobacco use in young females in low-income, high population countries as one of the most ominous developments of the tobacco epidemic (WHO 2008a), jeopardizing efforts to improve maternal and child health (Cnattingius 2004; Bloch 2008). This increase is being driven by aggressive marketing from tobacco companies, who are predicting high profits from sales in low- and middle-income countries (Kaufman 2001), along with increased tobacco production in these regions (FAO 2003), which further entrenches the countries' tobacco dependence. Marketing strategies are specifically targeted at women and weak regulation of tobacco company marketing has been linked to a rapid increase in smoking among women, particularly those who are vulnerable (Kaufman 2001; Gilmore 2004; Graham 2009). A survey of women's knowledge in two African countries suggests women's knowledge of the risks of tobacco products was extremely limited (Chomba 2010), making women more vulnerable to tobacco marketing.

Issues around smoking in pregnancy are complicated by the intersection of gender (Healton 2009), where a woman's role is seen primarily as a 'reproducer', and emphasis is placed on the rights of the unborn fetus (pxii; World Health Organization 2001). There is a risk these arguments may be used to impose authority over women's behaviour, 'blaming' women for their own plight and that of their children, and using guilt or other means to undermine self-confidence; further reducing the control women have in their lives (Greaves 2007a).

In addition to the socio-economic factors associated with continued smoking, there are strong psychological associations, especially with depression and stress (Blalock 2005; Aveyard 2007; Crittenden 2007; Orr 2012), including race-related stress (Heath 2006; Fernander 2010; Nguyen 2012a). Depressed women are up to four times more likely to smoke during pregnancy than non-depressed women (Blalock 2005). Despite these strong associations, there is limited information available about the effects of smoking and interventions in pregnant women with psychological symptoms, as they are often excluded from trials (Blalock 2005). Furthermore, while tobacco control initiatives in high-income countries have been effective in reducing smoking, the stigmatisations of smokers has been

an unintended consequence (Burgess 2009; Wigginton 2012), which is being increasingly recognised by the tobacco control community (Farrimond 2006; Thompson 2007a; Burgess 2009). Anti-smoking campaigns strive to inform, shock or shame people into quitting smoking and rarely take into account low self-esteem, low self-efficacy, poverty, stress and increased caring responsibilities that are common among women who continue to smoke during pregnancy (Gilbert 2005). A systematic review of qualitative experiences of women describes how smoking in pregnancy triggered “intense feelings of personal responsibility and inadequacy” and that women’s responses to social disapproval varied (Flemming 2013). For some, it provided an incentive to attempt to quit, while among others it resulted in increased smoking, either in response to the stress of social pressure or as an act of rebellion against it (Flemming 2013). Some argue that health risk narratives and the associated social stigma produced through anti-smoking campaigns contribute to oppression among marginalised people, and a consequence is that these strategies may inspire resistance and resentment rather than compliance (Bond 2012; Wigginton 2012; Flemming 2013).

Although commercial cigarettes are the most prevalent form of tobacco use worldwide, the use of other forms of tobacco (e.g. smokeless tobacco, cigars and pipes, and waterpipes) are becoming more popular in many parts of the world, especially low- and middle-income countries (England 2010). Of particular concern are increasing efforts by the tobacco industry to commercialise and market smokeless tobacco products to young adults (Lambe 2007). In high-income countries, the use of smokeless tobacco appears to be highly localised among some indigenous groups in Canada and the US, including Lumbee Indian, Navajo, and Alaskan Native communities (Strauss 1997; Spangler 2001; Patten 2009; Kim 2009a; Kim 2010). In India, one-third (33.5%) of all pregnant women reported using smokeless tobacco (Bloch 2008). In the Democratic Republic of Congo, 6% to 41.8% of pregnant women surveyed reported using other forms of tobacco, primarily snuff (Bloch 2008; Chomba 2010). In South Africa 7.5% of pregnant women surveyed reported using snuff (Steyn 2006). In Iran there has been concern over the 8% prevalence of local waterpipe tobacco smoking among pregnant women (Mirahmadizadeh 2008). These tobacco products may be cheaper and viewed as less harmful than cigarettes (England 2010). In some cases use may be a traditional cultural norm or a medicinal aid to reduce nausea in early pregnancy. However, these products can be high in nicotine content and cause nicotine addiction. Use of these products has been associated with increased oral and pancreatic cancer, and cardiovascular disease (England 2010). There is a paucity of research into the effect of these products on pregnancy outcomes and studies into the effects of these products can be challenging as the chemical content of various toxic compounds is variable and often poorly regulated. However, limited evidence suggests smokeless tobacco use is associated with decreased birthweight and preterm birth (Verma 1983; Gupta 2004; Pratinidhi 2010), stillbirth (Gupta 2006; Gupta 2012), maternal anaemia (Subramoney 2008), degenerative placental changes (Ashfaq 2008), and adverse infant neurobehavioural outcomes (Hurt 2005). Smoking more than one waterpipe per day (Tamim 2008) or starting to smoke waterpipes during the first trimester (Mirahmadizadeh 2008) was also associated with an increased risk of having a low birthweight baby.

Exposure to environmental tobacco smoke (ETS) also poses risks to pregnant women and their infants (Yang 2010). Studies suggest the risk may be exacerbated in low-income

countries where exposure to indoor cooking smoke is also common (Kadir 2010). In China, 75.1% of pregnant non-smoking women were regularly exposed to environmental tobacco smoke from their husbands' smoking (Yang 2010). Studies in high-income countries demonstrate that eliminating smoking in the workplace and other public spaces significantly reduces environmental tobacco smoke exposure and improves health outcomes, including preterm births (Cox 2013). One study in Indonesia reported increased collective efficacy when environmental tobacco smoke exposure was addressed through a well-publicised community household smoking ban (Nichter 2010). However, as these measures do not extend to homes (Oncken 2009), some argue domestic environmental tobacco smoke exposure may be increasing as public health policies restrict smoking of partners in public places, and the social position of women may limit their ability to enforce smoke-free policies within their homes (Tong 2009).

A positive theme emerging from this literature is that a higher proportion of women stop smoking during pregnancy than at other times in their lives. Up to 49% of women who smoked before pregnancy 'spontaneously quit' before their first antenatal visit (Quinn 1991; Woodby 1999; Hotham 2008), a quit rate substantially higher than reported in the general population (Ershoff 1999; McBride 2003; Tong 2008). However, these spontaneous quitting rates may be lower among women with lower socio-economic status (Mullen 1999). There are significant psychosocial differences between women who 'spontaneously quit' and women who continue to smoke in late pregnancy. Women who spontaneously quit usually smoke less, are more likely to have stopped smoking before, have a non-smoking partner, have more support and encouragement at home for quitting, are less seriously addicted, and have stronger beliefs about the dangers of smoking (Baric 1976; Ryan 1980; Cinciripini 2000; Passey 2012). Pregnant women are also more likely to use coping strategies to avoid relapse than non-pregnant women (Ortendahl 2007c; Ortendahl 2008a; Ortendahl 2009a), however less than a third of these women remain abstinent after one year postpartum (CDCP 2002; Fang 2004), supporting qualitative evidence that many women see pregnancy as a temporary period of abstinence for the sake of the baby (Stotts 1996; Lawrence 2005a; Flemming 2013). Despite high relapse rates, some studies suggest that the long-term effects of spontaneous quitting in pregnancy are significant (Rattan 2013), and others argue this success is important to recognise to avoid 'pathologising' smoking cessation and eroding confidence in human agency to overcome problems (Chapman 2010).

Given the complexity of the health and social dimensions of smoking in pregnancy there are conflicting perspectives regarding the most appropriate approaches. A dominant theme is that smoking in pregnancy is a lifestyle choice, however, there is concern this can lead to 'victim blaming' (Bond 2005), that individualised, behaviourist approaches are unlikely to adequately address health inequalities alone (Baum 2009), and that drug dependence and addiction is best dealt with in the domain of social policy and public health (Ebert 2009). Nevertheless, some suggest there is a role for individual support which is positive, not punitive (Bond 2012), and others express a concern that framing smoking in pregnancy solely as a social problem may make health professionals reluctant to intervene and offer support (McLellan 2000).

Description of the intervention

This review evaluates the effectiveness of individual psychosocial interventions that aim to motivate and support women to stop smoking in pregnancy, or prevent smoking relapse among women who have spontaneously quit. Psychosocial interventions are defined as non-pharmacological strategies that use cognitive-behavioural, motivational and supportive therapies to help women to quit, including counselling, health education, feedback, financial incentives, and social support from peers and/or partners (see Types of interventions), as well as dissemination trials.

Other smoking cessation intervention reviews—At the time of this update there were 73 other Cochrane reviews assessing the effectiveness of tobacco smoking cessation interventions for all populations (see Appendix 1). These include reviews on the following.

- **Population wide measures** such as: legislative smoking bans, mass media campaigns, organisational interventions (workplace and school-based interventions), healthcare financing systems for increasing use of tobacco dependence treatment, advertising and promotion to reduce tobacco use, preventing tobacco smoking in public places, and impact of advertising on adolescent smoking.
- **Community interventions** including family-based programmes, group behaviour interventions, family and carer interventions for reducing environmental tobacco smoke, school-based programmes, and school policies.
- **Individual psychosocial interventions,** including aversive smoking, acupuncture, hypnotherapy, self-help, exercise, individual behavioural counselling, motivational interviewing, stage-based interventions, competitions and incentives, telephone counselling, mobile phone-based interventions, Internet-based interventions, nursing and physician advice, enhancing partner support, feedback, community pharmacy interventions, training health professionals in smoking cessation, use of electronic records, prevention of weight gain after smoking cessation, improving recruitment into cessation programs, harm reduction, reduction versus abrupt cessation, biomedical risk assessments, electronic cigarettes, incentives to prevent smoking in young people, relapse prevention, and interventions to reduce non-cigarette tobacco use, including waterpipe smoking cessation.
- **Individual pharmacological interventions**, including antidepressants, anxiolytics, nicotine replacement therapy (NRT), clonidine, mecamylamine, nicobrevin, nicotine agonists, opioid agonists, cannabinoid type 1 receptor agonists, silver acetate, lobeline, and nicotine vaccines, increasing adherence to medications for tobacco dependence, behavioural interventions as adjuncts to pharmacotherapies, combined pharmacotherapy and behavioural interventions;and an ‘overview of pharmacological reviews’.
- **Interventions in specific population groups**, including people with: schizophrenia and serious mental illness, depression, substance abuse, cardiovascular and pulmonary disease; pre-operative and hospitalised patients; Indigenous populations and Indigenous youth; and people in dental settings.

- **Other** reviews, assessing effectiveness of interventions to recruit patients into smoking cessation programs, and reduce harm from continued tobacco use.

How the intervention might work

Pregnancy has been described as a 'window of opportunity' for smoking cessation (McBride 2003). Pregnancy increases a woman's perception of risk and personal outcomes, therefore strong affective or emotional responses are more likely to be prompted (Slade 2006; Ortendahl 2008b). It also redefines a woman's self-concept or social role (Ortendahl 2007b), especially when failure to comply with a social role results in social stigmatisation (Ortendahl 2007a; Ortendahl 2008c). Psychosocial interventions involve a range of social and psychological components which aim to increase motivation or affective or emotional responses to support pregnant women to stop smoking and support women to develop coping strategies to avoid relapse (Ortendahl 2007c; Pilling 2010). For example, counselling, feedback and financial incentives are all designed to enhance motivation to quit and move women closer towards the 'action' stage of change. Thirty-seven individual 'behaviour change techniques' or observable components used in interventions in the previous version of this review have been identified (Lorencatto 2012).

Psychosocial interventions to support women to stop smoking in pregnancy increasingly incorporate theoretical frameworks to inform, develop and evaluate strategies designed to influence behaviour (Green 2005b; Glanz 2008; Michie 2008; Bartholomew 2011). Using behaviour change theories in the context of addiction has been identified as a useful way to identify modifiable determinants and/or behaviour change techniques (Webb 2010). There are many theories of behaviour, which provide a summary of constructs, procedures and methods for understanding behaviour, and present hypothesised relationships or causal pathways that influence behaviour (Michie 2012). While some argue there is little apparent consensus about which theories are best to use in designing interventions (Noar 2005), most theories of behaviour change postulate a role for six broad classes of variables (Glanz 2008):

1. attitudes and beliefs about the behaviours or the outcomes of change (used in health education and counselling strategies);
2. beliefs about self-efficacy or perceived ability to enact and/or maintain the target behaviour change (used in counselling strategies such as motivational interviewing or cognitive behaviour therapy);
3. the role of contextual factors, particularly social factors, either directly and/or mediated through people's beliefs (used in social support strategies);
4. previous experience with the behaviour either directly or indirectly through the processes of modelling (modelling can be seen as an element of social influence) (used in social support strategies);
5. priority for action, a person can only pursue a limited number of goals of any one time; and

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6. the notion of a stage-based or systematic step-like progression towards behaviour change, which is incorporated into the assessment stage of many smoking cessation interventions (Prochaska 1992).

Why it is important to do this review

There are many psychosocial interventions that have been evaluated to support women to stop smoking during pregnancy. This review synthesises the evidence from these trials to generate evidence, which is of direct relevance for practitioners, policy-makers, and researchers. Synthesis enables comparison of whether interventions have been shown to be effective in individual studies and whether this effect has been replicated in other settings. Importantly, individual studies are unlikely to have sufficient power to evaluate the effect of interventions on perinatal outcomes or to conduct subgroup analyses to assess if there are differential effects among vulnerable subpopulations with high rates of smoking during pregnancy. Finally, collation of the body of evidence helps to identify any gaps for future research.

This is the fifth update of this Cochrane review, previously entitled '*Interventions to promote smoking cessation during pregnancy*'. The first version was published in 1995 on CD Rom and previously updated in *The Cochrane Library* in 1999, 2004 and 2009. Previous versions of this review have demonstrated the potential for individual interventions during pregnancy to have a modest but significant effect on reducing smoking, preterm births and infants born with low birthweight (Lumley 2009). This evidence has been instrumental in individual psychosocial interventions becoming a part of routine pregnancy care in many high-income countries in the past decade (Flenady 2005; Ministry of Health 2007; Fiore 2008; NICE 2010; Wong 2011). These guidelines generally incorporate a number of interventions, including identifying women who smoke during pregnancy, providing advice about risks, and supporting women to stop smoking.

In this review update, we have 'split' the previous version into two reviews: (1) this review focusing on psychosocial interventions to support women to stop smoking in pregnancy; and (2) a second review specifically focusing on pharmacological interventions to promote smoking cessation in pregnancy (Coleman 2012b). This split was necessary as there are different issues of concern for psychosocial and pharmacological interventions. Psychosocial interventions are now part of routine care in many high-income countries and contemporary issues focus on strategies to increase efficacy, and adaptation of psychosocial interventions to different contexts and settings, sometimes requiring different study designs (e.g. cluster trials of implementation). As many interventions involve multiple strategies or use of components which are tailored to individual women, it is very difficult to assess the independent effect of individual components of psychosocial interventions. As the efficacy and safety of pharmacological treatment (e.g. Nicotine Replacemernt Therapy, Bupropion) during pregnancy (Slotkin 2008) remains uncertain, more rigid study designs (i.e. randomised double-blind placebo-controlled trials) are required to assess the risks and efficacy.

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

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pregnancy in 1999. Women were identified through community networks, and their views emphasised the need to focus attention on potential adverse effects of smoking cessation programmes; in particular, the consequent guilt, anxiety and additional stress experienced by those who continue to smoke, especially through 'high-risk' pregnancies, and the detrimental effect on their relationships with their family and maternity care providers (Oliver 2001).

In this update, we indirectly considered women's views reported in a systematic review of qualitative studies (Flemming 2013), which reinforce the previous contributions, identifying four main themes which have implications for interventions to support women to stop smoking in pregnancy.

1. Smoking is an embedded part of the lives of many women living in disadvantaged circumstances.
2. Women see smoking in pregnancy in terms of the risks it presents to their unborn baby, which can trigger guilt.
3. Quitting was not seen in unambiguously positive terms and was seen to have downsides, disrupting relationships and removing a habit perceived as helping women cope.
4. Partners play an important role in influencing women's smoking behaviour in pregnancy, either as barriers or facilitators to quitting.

We also indirectly considered the views of pregnancy care providers reported in consultation for a Clinical Practice Guideline on Smoking Cessation in pregnancy (Williams 2010) in the UK; and the views of guideline developers requesting evidence for an international guideline on 'Management of Tobacco Use in Pregnancy' (CDCP 2013). Some of the major issues and gaps included:

- whether psychological interventions are effective;
- whether interventions are effective for pregnant teens and other hard-to-reach and vulnerable groups, including ethnic and minority populations;
- whether interventions are effective for women who are mentally unwell or experiencing substance misuse;
- whether interventions are effective in low- and middle-income countries.

In addition to consideration of women's views and feedback from guideline developers, we also considered thesis critiques of the previous version of this review (Gilligan 2008; Vilches 2009), health programme planning models (Green 2005b; Bartholomew 2011), various publications on factors affecting intervention efficacy (Greenhalgh 2004; Hoddinott 2010), descriptions of intervention components (Lorencatto 2012), and the 'critical factors' identified by authors of included studies reported in the results or discussion. As smoking in pregnancy has important impacts on health inequalities, we have introduced a focus on equity in this review, as recommended in the 'PRISM-Equity' guidelines for reporting interventions with a potential impact on equity (Welch 2012). We have synthesised this information into a logic model to identify key variables that may impact on intervention

effectiveness (see Figure 1), to guide analysis and subgroup analyses planning ‘a priori’ (Petticrew 2012).

OBJECTIVES

This review evaluated the effect of psychosocial interventions designed to support women to stop smoking in pregnancy and aimed to address the following questions.

Primary objectives

- To identify whether psychosocial interventions can support women to stop smoking in pregnancy
- To compare the effectiveness of the main psychosocial intervention strategies in supporting women to stop smoking in pregnancy (i.e. counselling, health education, feedback, social support, incentives)

Secondary objectives

- To identify if the intensity of the intervention corresponds to an effect size
- To identify any specific intervention components associated with an effect (e.g. telephone counselling, self-help manuals)
- To identify if psychosocial interventions in pregnancy have an impact on health outcomes for the mother (i.e. caesarean section, breastfeeding) and infant (i.e. mean birthweight, low birthweight, preterm births, very preterm births, perinatal mortality)
- To identify if there are any positive or negative psychological effects reported among women receiving psychosocial interventions in pregnancy
- To identify participants (women and pregnancy care providers) views of the psychosocial interventions in this review
- To identify if psychosocial interventions have an effect on family functioning or other relationships for the mother, including non-accidental injury
- To identify if psychosocial interventions during pregnancy can reduce the proportion of women who start smoking postpartum
- To identify whether any methods for training and implementing psychosocial interventions have an effect on the knowledge, attitudes and behaviour of pregnancy care providers
- To identify whether psychosocial interventions provided for women who have spontaneously quit smoking in early pregnancy, can reduce the proportion of women who start smoking by late pregnancy (relapse)
- To identify whether psychosocial interventions are effective for women in vulnerable subpopulation groups (including women categorised as having low socio-economic status, young women (less than 20 years), ethnic minority and aboriginal women, and women in low- and middle-income countries

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- To identify whether psychosocial interventions, which are shown to be effective when implemented under trial conditions by a dedicated research team (efficacy studies), are still effective when implemented in a routine pregnancy care setting by existing staff (effectiveness studies)
- To identify if psychosocial interventions to support women to stop smoking in pregnancy are cost-effective
- To identify if there are any adverse effects reported as a result of women receiving psychosocial interventions to support them to stop smoking in pregnancy
- To identify whether recently included studies are as effective as studies included in previous versions of this review
- To identify if any of the risk of bias assessments have a significant impact on the effect size of the intervention

METHODS

Criteria for considering studies for this review

Types of studies—All randomised controlled trials, cluster-randomised controlled trials, and randomised cross-over trials of psychosocial interventions where a primary aim of the study was smoking cessation in pregnancy. Quasi-randomised studies were only considered for inclusion if there was a very low risk of interference with the sequence generation (e.g. allocation by odd or even maternal birth date or hospital record number).

Types of participants—

1. Women who are currently smoking or have recently quit smoking and are pregnant, in any care setting.
2. Women who are currently smoking or have recently quit smoking and are seeking a pre-pregnancy consultation.
3. Health professionals in trials of implementation strategies of psychosocial interventions to support pregnant women to stop smoking.

Where possible, we have separated outcomes for women who spontaneously quit smoking when they become pregnant, and women who continue to smoke during pregnancy, as significant differences have been reported previously (Baric 1976; Ryan 1980; Cinciripini 2000; Passey 2012).

Types of interventions—

1. **Counselling** interventions are those which provide motivation to quit, support to increase problem solving and coping skills (Ortendahl 2007c; Ortendahl 2008a; Ortendahl 2009b), and may incorporate ‘transtheoretical’ models of change (Prochaska 1992; Prochaska 2007). This includes interventions such as motivational interviewing, cognitive behaviour therapy, psychotherapy, relaxation, problem solving facilitation, and other strategies. Counselling interventions may be

provided face-to-face, by telephone, via interactive computer programs, or using audiovisual equipment. The duration of counselling may range from brief interventions (less than five minutes) to more intensive interventions, which can last for up to an hour and be repeated over multiple sessions. Counselling may be provided by a range of personnel, including pregnancy care providers, trained counsellors, or others, on-site or by referral to specialist stop smoking services. Interventions that involved provision of videos with personal stories were included as counselling in this review.

2. **Health education** interventions are defined as those where women are provided with information about the risks of smoking and advice to quit, but are not given further support or advice about how to make this change. Interventions where the woman was provided with automated support such as self-help manuals or automated text messaging, but there was no personal interaction at all, were coded as health education in this review.

3. **Feedback** interventions are those where the mother is provided with feedback with information about the fetal health status or measurement of by-products of tobacco smoking to the mother. This includes interventions such as ultrasound monitoring and carbon monoxide or urine cotinine measurements, with results fed back to the mother (does not include where measurements are used for confirming smoking abstinence in the study).

4. **Incentive-based interventions** include those interventions where women receive a financial incentive, contingent on their smoking cessation; these incentives may be gift vouchers. Interventions that provided a ‘chance’ of incentive (e.g. lottery tickets) were not included as ‘incentives’ in this update, but were included in counselling and subgroup analysis of trials incorporating use of lottery tickets will be reported. Gifts and other incentives to promote participation in the study (but were not contingent on smoking cessation), were not coded as incentive-based interventions in this review.

5. **Social support (peer and/or partner)** includes those interventions where the intervention explicitly included provision of support from a peer (including self-nominated peers, ‘lay’ peers trained by project staff, or support from healthcare professionals), or partners, as a strategy to promote smoking cessation.

6. **Other** strategies, which could not be included in the categories listed above, including exercise, and dissemination interventions (where both intervention and control group received the same intervention, but the dissemination strategy differed).

In this review we have categorised interventions according to the ‘main’ strategy used, however many interventions incorporate several components. Therefore, interventions are coded according to whether the strategy was a:

- single intervention - with only one main strategy used;

- multiple intervention - which included several strategies being offered to all women;
- tailored intervention - where additional optional strategies were available for women.

Trials that combined strategies for smoking cessation with other interventions to promote maternal health in pregnancy were considered for the review for smoking cessation and reduction outcomes but not for infant outcome measures such as birthweight, preterm birth, breastfeeding and perinatal mortality, which might be attributable to other components of an intervention package. We have included interventions that offered pharmacological therapies as part of a tailored intervention where there were higher levels of psychosocial support provided to participants in the intervention arm, compared with the control arm. Trials were excluded where the sole aim was to reduce: smokeless tobacco use; environmental tobacco smoke exposure; where the primary population was not pregnant women (e.g. partners, non-pregnant women); or the intervention was not primarily aimed at cessation during pregnancy (e.g. postpartum interventions). Studies were included where smokeless tobacco use, environmental tobacco smoke exposure or partner smoking were targeted in conjunction with interventions addressing the primary aim of supporting pregnant women to stop smoking in pregnancy. We have included dissemination studies, where the primary intervention includes strategies to disseminate smoking cessation interventions in pregnancy care settings (e.g. training, audit and feedback).

Types of comparisons: Any type of comparison group was included and was coded according to the following.

1. ‘ **Usual care**’ or no additional intervention reported.
2. **Less intensive interventions** where the control group received some of the intervention or an approximation of ‘usual care’ consistently provided by the research team.
3. **Alternative interventions**, where the control group received different intervention components than the intervention group, of the same intensity.

Types of settings: Any setting, including residential and community settings, family planning clinics, pre-pregnancy planning clinics or general practitioner clinics, prenatal care clinics and hospitals.

The ‘PROGRESS-Plus’ criteria (Oliver 2008b; Ueffing 2009) were used to categorise interventions which were provided for vulnerable populations, including: social capital; place of residence; occupation; education; socio-economic status; ethnicity; age; or other factors which might impact on vulnerability. These categories are described in more detail in the methods.

Types of outcome measures

Primary outcomes:

1. Smoking abstinence in late pregnancy (point prevalence abstinence):

i. self-reported or biochemically validated;

ii. biochemically validated only.

Secondary outcomes:

1. Continued abstinence in late pregnancy after spontaneous quitting (relapse prevention) in early pregnancy (self-reported or biochemically validated).
2. Smoking abstinence in the postpartum period (self-reported or biochemically validated):
   i. zero to five months;
   ii. six to 11 months;
   iii. 12 to 17 months;
   iv. 18 months or longer.
3. Smoking reduction from the first antenatal visit to late pregnancy:
   i. numbers of women reducing smoking (any definition, > 50% self-reported, or biochemically validated);
   ii. biochemical measures (mean cotinine and thiocynate);
   iii. mean cigarettes per day (self-reported).
4. Perinatal outcomes:
   i. mean birthweight;
   ii. low birthweight (proportion less than 2500 g);
   iii. very low birthweight (less than 1500 g);
   iv. preterm births (proportion less than 37 weeks);
   v. stillbirths;
   vi. neonatal deaths;
   vii. all perinatal deaths.
5. Mode of birth (caesarean section).
6. Breastfeeding initiation and breastfeeding at three and six months after birth.
7. Psychological effects: measures of anxiety, depression and maternal health status in late pregnancy and after birth.
8. Impact on family functioning and other relationships in late pregnancy and postpartum.
9. Participants' views of the interventions, both women's and pregnancy care providers' views.

10. Measures of knowledge, attitudes and behaviour of health professionals (obstetricians, midwives and family physicians) with respect to facilitating smoking cessation in pregnancy.
11. Cost-effectiveness.
12. Adverse effects of smoking cessation programmes.

Search methods for identification of studies

This is the fifth update of this review and the details of previous searches are described in other published versions of this review (Lumley 1995a; Lumley 1995b; Lumley 1995c; Lumley 1995d; Lumley 1999; Lumley 2004; Lumley 2009).

Electronic searches—We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (1 March 2013).

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

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. weekly searches of Embase;
4. handsearches of 30 journals and the proceedings of major conferences;
5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

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

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

Searching other resources—We also checked cited studies while reviewing the trial reports and key reviews. Where necessary, we contacted trial authors to locate additional unpublished data.

We did not apply any language restrictions.

[*In addition, authors conducted a supplementary search for non-randomised studies, for the background and discussion, in MEDLINE, Embase, PsycLIT, and CINAHL (June 2008 to 1 March 2013) using the search strategy detailed in Appendix 2.*]

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Data collection and analysis

Selection of studies—Two review authors independently reviewed the full text of search results from the Cochrane Pregnancy and Childbirth Group and potential trials identified through other sources (CC/SP) to determine if they met the inclusion criteria for this review. Where there was disagreement, advice from co-authors was sought (SO/JC/AO/JT) and consensus reached by discussion.

Data extraction and management—Two review authors independently extracted data from the published reports without blinding as to journal, author, or research group. For each trial the following aspects were reported and coded into EPPI-Reviewer software (Thomas 2010). Independent data extraction was checked and areas of conflicting judgement were resolved by consensus, and where necessary discussion with co-authors. A summary of data collected is outlined in Appendix 3 and a summary reported for individual studies in the Characteristics of included studies table.

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

(1) Sequence generation (checking for possible selection bias): We have described for each included study the methods used to generate the allocation sequence, and have assessed the methods as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non random process, e.g. alternate clinic date; odd or even date of birth; hospital or clinic record number);
- or unclear risk of bias.

Studies where sequence generation was assessed as inadequate and there is a reasonable opportunity to interfere with random allocation (e.g. alternate clinic date) have been excluded in this update of the review. Studies randomised by odd or even date of birth or medical record number have continued to be included in this review as there is limited reasonable opportunity to manipulate the allocation.

(2) Equal baseline characteristics (checking for possible selection bias): To further assess the risk of selection bias, we assessed whether the baseline characteristics were equal in each included study, and have assessed them as:

- low risk of bias (baseline characteristics were assessed and equal in both study arms);
- high risk of bias (where there were significant differences in baseline characteristics, suggesting possible bias in the selection of participants);
- or unclear risk of bias.

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

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (e.g. open random allocation; unsealed or non-opaque envelopes; medical record number; date of birth);
- or unclear risk of bias.

(4) Blinding (checking for possible performance bias) of study participants and intervention providers: We have described for each included study the methods used, if any, to blind study participants and intervention providers from knowledge of which intervention a participant received. However, it is rarely feasible in psychosocial interventions to blind women or the intervention providers to group allocation. We have assessed the methods as:

- low risk of bias;
- high risk of bias;
- or unclear risk of bias.

(5) Blinding (checking for possible performance bias) of outcome assessor: We have described for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received as recommended (West 2005). We have assessed the methods as:

- low risk of bias;
- high risk of bias;
- or unclear risk of bias.

(6) Dealing with incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations, and intention-to-treat analysis): We have described for each included study and for each outcome or class of outcomes the completeness of data including attrition and exclusions from the analysis. We have noted whether attritions and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups. We considered it was reasonable to exclude women from the final analysis who had experienced miscarriage or fetal demise, developed serious medical conditions, moved out of the area, or changed to another provider of care. However, as there are also clear associations between these outcomes and smoking, we have categorised the risk of attrition bias as ‘unclear’. Where possible, we included all other randomised women in the meta-analysis. Where data were

not provided in such a way to enable inclusion of all other randomised participants, we have categorised these studies as high risk of attrition bias. We have assessed the methods as:

- low risk of bias (outcomes for all randomised participants included in analysis);
- high risk of bias (outcomes for all participants not reported, particularly if unequal attrition in both study arms);
- or unclear risk of bias, which includes exclusions for medical conditions or moving.

(7) Reporting all outcomes (checking for possible selective reporting bias): We have described for each included study how the possibility of selective outcome reporting bias was examined by us and what we found. We assessed the methods as:

- low risk of bias (where it is clear that all of the studies' prespecified primary outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the studies' pre-specified outcomes have been reported); one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- or unclear risk of bias.

(8) Reliability of outcome measures used (checking for possible detection bias): The unreliability of self-report as a measure of smoking status in healthcare settings, especially in maternity care (Pettiti 1981), was noted even in the first pregnancy trial (Donovan 1977). While this finding has not always been consistent (Fox 1989; Pickett 2009; Windsor 1985), the majority of other trials show substantial misclassification by self-report, with up to a quarter or a third of women who describe themselves as non-smokers having levels of salivary or urine cotinine (a metabolite of nicotine) incompatible with self-description (Mullen 1991; Petersen 1992; Kendrick 1995; Lillington 1995; Walsh 1997; Moore 2002; Tappin 2005; Parker 2007). A degree of misclassification is not surprising given the social stigma associated with smoking in pregnancy, and there appears to be less misclassification in non-pregnant populations (Patrick 1994). Some studies suggest that measurement of abstinence is reasonably accurate, but that there is greater inconsistency with reporting the amount of cigarettes smoked (Klebanoff 1998; Venditti 2012). Given this potential for bias, biochemical validation of smoking abstinence is now the standard for smoking cessation studies (West 2005; Shipton 2009). Use of cotinine concentration (saliva, urine or plasma) is the most sensitive and specific (saliva less than 15 ng/mL and urine less than 50 ng/mL). However, cotinine does not distinguish between smoking and use of nicotine replacement products, so expired air carbon monoxide is the preferred method for detecting recent smoking (less than 9 ppm) in many studies. Trials measuring cotinine need to ask participants about NRT use (available over the counter), ignore high levels in NRT users, and verify smoking abstinence with carbon monoxide levels (West 2005). However, several studies including use of NRT did use cotinine cut-offs to distinguish between smokers and non-smokers (Hegaard 2007). There may also be differential misclassification between

intervention and control groups, though no investigations have published this effect. We have described for each included study whether the smoking outcome was biochemically validated (including measures used) or assessed by self-report only, and have included data on misclassification by self-report where they have been reported:

- low risk of bias (biochemical validation);
- high risk of bias (no biochemical validation);
- or unclear risk of bias (including partial biochemical validation of a sample of the study population).

(9) Implementation of intervention: There are three main types of potential implementation problems trials (Walsh 2000):

- not all participants in the intervention groups receiving the intervention;
- intervention group participants not receiving all components of the intervention;
- control groups receiving the intervention.

Failure to implement the intervention as planned limits the exposure of women to the intervention, and may negatively impact on the effectiveness of the intervention. Where possible, we included a description of any process evaluation reported. We have assessed the implementation of the intervention as:

- low risk of bias (where process evaluation suggests the majority of participants received the intervention as planned);
- high risk of bias (where process evaluation suggests a significant proportion of women did not receive the intervention as planned);
- or unclear risk of bias (where process evaluation is not reported).

(10) Risk of control group contamination: Exposure of the control group to aspects of the intervention is a common challenge for intervention trials, particularly studies where healthcare providers are required to offer an intervention to some women, and not to others. Some trials use cluster-randomisation in order to reduce the risk of contamination, particularly when healthcare providers are involved in the intervention. The most likely impact is to increase the effect in the control arm, reducing the potential effect size between the intervention and control arms of the study. We have assessed the methods as:

- low risk of bias, where the intervention providers are separate from the control group or strategies are employed to minimise the risk (such as cluster-randomisation);
- high risk of bias, where the same provider is required to administer the intervention to both study arms, or there is specific reporting of suspected contamination in the trial report;
- or unclear risk of bias.

(11) Other bias: We have considered any other potential sources of bias in the study, including whether recruitment was equal in both arms of cluster-randomised trials, and assessed these as:

- low risk of bias;
- high risk of bias;
- or unclear risk of bias.

Measures of treatment effect

Dichotomous data: All data were entered into RevMan 5.2.5 and SPSS 20 for analysis. For dichotomous data, we have presented risk ratios (RR) with 95% confidence intervals. Analysis was conducted on the logged risk ratio, and then converted back to risk ratios for presentation purposes. In this update, smoking cessation outcomes have been converted from an 'odds ratio' for continued smoking, to a 'RR' for quitting, in line with other Cochrane Tobacco Group reviews. Therefore, an average RR > 1 in smoking cessation outcomes are positive in this review. Where less outcome events are desirable (e.g. preterm births, low birthweight infants, mean cigarettes per day), an average RR < 1 is a positive outcome. Analysis tables are labelled accordingly.

For two of the binary outcomes, abstinence in late pregnancy and perinatal deaths, zero cell counts for events in both the treatment and control groups were evident for one study each. The affected studies were Olds 1986 (abstinence in late pregnancy) and Valbo 1996 (perinatal deaths). This is problematic because the formula for calculating relative risk effect sizes requires non-zero cells (i.e., the numerator cannot be zero). Whilst RevMan 5.2.5 automatically corrects for zero events in one group, a manual 'fix' is required when both groups have zero events. The solution as recommended by the Cochrane statistician peer reviewer was to enter the values as zero in the analysis, which means the effect sizes are not estimable and those studies are effectively excluded from those analyses. The affected analyses are Analysis 9.1 for Olds 1986 and Analysis 1.16 and Analysis 11.15 for Valbo 1996. For all three of these affected analyses, the initial set of relevant studies was two; the result is that no pooled effect could be calculated because instead of two effect sizes we only have one effect size for each of these analyses. These instances are clearly marked in the results section.

Continuous data: For continuous data, we used the mean difference (MD) if outcomes were measured in the same way between trials (e.g. birthweight). We used the standardised mean difference (SMD) to combine trials that measured the same outcome, using different methods (e.g. biochemically-validated smoking reduction).

Where standard errors (SE) were reported instead of standard deviations (SD), we used the RevMan calculator to calculate the effect size estimate. In one study, the SD was calculated from the SE. Where no SDs or SEs were reported, we estimated the mean SD from available studies, as recommended in the *Cochrane Handbook 16.1.3.1* (Higgins 2008). The mean birthweight SD was calculated from 13 studies with available SDs (mean SD 578), and

imputed for six studies. The mean cigarettes per day SD was calculated from 14 studies with available SDs (mean SD 6.5), and imputed for five studies.

Unit of analysis issues—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 pregnancy care providers to treat women differentially according to the intervention or usual care protocol, and not to introduce co-interventions in one or other groups (contamination). As women within a cluster are more likely to be similar to one another, and less like the women in another cluster, outcomes from cluster-randomised trials were adjusted for the intra-cluster correlation for the data to be included in this review. Adjusting for the clustering of studies means that cluster trials could be analysed in the same models as individual randomised trials.

Adjustment for cluster randomisation was conducted using a reported intra-cluster correlation (ICC) if available, and if not, a range of ICCs (from 0.003 to 0.20) was assumed and a sensitivity analysis conducted as recommended by (Merlo 2005). The results of the sensitivity analyses showed no substantial difference between the different ICCs (RRs were the same to at least three decimal places across ICC calculations). As such, for studies in which an ICC was not reported, an ICC value of 0.10 was used for the primary analysis and the cluster trials were included by adjusting the SEs (reported ICCs were used where available). The methods used for individual studies are reported in the Characteristics of included studies and Table 2. The adjustment involved reducing the size of each trial to its 'effective sample size' by dividing the sample size by the 'design effect', where the design effect is equal to $1 + (m - 1) \times \text{ICC}$, and m is the average cluster size (see Section *16.3.4* of the *Cochrane Handbook*, Higgins 2008).

Dealing with missing data—Due to the nature of the intervention, there is a high likelihood that women withdrawing from the study or not providing a biochemical sample for analysis, without a 'plausible explanation' (e.g. miscarriage/fetal demise, moving out of the area or changed to another provider of care) are likely to be continuing smokers. Where sufficient information has been reported or has been supplied by the trial authors, we have re-included missing data from each treatment group in the analyses to comply with recommended outcome criteria assessment for smoking cessation trials (West 2005). Only data which were excluded for medical reasons (e.g. miscarriage or preterm birth) or moving from study site were not re-included in this review. We have indicated where an intention-to-treat (ITT) (or available case) analysis was carried out for the smoking cessation outcome in the published report, or adjusted for this review. These assessments and any adjustments are reported in the 'Risk of bias' tables (see incomplete outcome data). Where data could not be re-included, we conducted sensitivity analysis to determine the effect of inclusion of trials assessed as 'high risk' of attrition bias.

Assessment of heterogeneity—We examined levels of heterogeneity in all pooled analyses (Cochran 1954). We used the I^2 statistic to quantify heterogeneity (i.e., inconsistency) among the trials in each analysis (Higgins 2008) and Chi^2 tests to assess the presence of significant variation amongst effect sizes (i.e., whether the observed effects are

significantly different from chance) (Lipsey 2001; Higgins 2008). Forthe Chi^2 tests, in addition to the P value, we report the Q-statistic calculated by the test and the degrees of freedom of the test.

We expected to find a substantial degree of heterogeneity given the breadth of types of interventions, which are broadly categorised as 'psychosocial' and the differences in comparisons. Therefore, we attempted to minimise heterogeneity in this update by reporting separate comparisons for each main intervention strategy (counselling, health education, feedback, incentives, and social support; and whether the intervention was provided as a specific smoking intervention or as part of a broader intervention to improve maternal health) and comparison type (usual care, less intensive intervention, or alternative intervention). Further, we grouped studies within each comparison according to whether the intervention was provided as a single, multiple or tailored intervention.

To indicate considerable statistical heterogeneity, we set a threshold of inconsistency of $I^2 > 75\%$ and a Chi^2 significance level of $P < 0.05$. Where considerable heterogeneity was evident, we did not present pooled results. We further explored heterogeneity by prespecified secondary analysis identified during development of a logic model (see Figure 1 and section on Subgroup analysis and investigation of heterogeneity for a description).

Assessment of reporting biases—Concerns about publication bias have been raised after observations that research evaluations showing beneficial and/or statistically significant findings are more likely to be published than those that have undesirable outcomes or non-significant findings (Higgins 2008). If this phenomenon does occur, then reviews of a biased evidence base will draw biased conclusions. Unfortunately, it is difficult to assess publication bias because there is no way of knowing the extent of what has not been published.

As a result of these concerns, researchers have developed ways of estimating the extent to which there may be some publication bias in the evidence base. Funnel plots (scatter plots in which the effect size from individual studies are plotted against a measure of study precision) are a common method for assessing the possibility of publication bias. Ideally, the spread of effect sizes should be such that there is more scattering of effect sizes at the bottom of the plot, where there is less precision, with a narrowing of the scattering towards the top, where there is greater precision.

Following guidance (Sterne 2001; Higgins 2008), we produced a funnel plot of the RR for the primary outcome on the x-axis, and the SE of the log RR on the y-axis, for each of the main comparisons (Analyses 1 through 10). Only the funnel plots for 'counselling versus usual care' (Analysis 1.1, Figure 2) and 'counselling versus less intensive intervention' (Analysis 2.1, Figure 3) are shown, because the remaining comparisons had too few effect sizes to reliably detect asymmetry in the funnel plot. In the figures, the vertical line indicates the random-effects pooled effect size estimate. In the absence of publication bias, we would expect a roughly symmetrical distribution of effect sizes in the inverted funnel shape. Two review authors examined the plot for publication bias; under the assumption that publication

bias is detectable in these funnel plots, we conclude that it is unlikely that publication bias has biased the findings of this review.

Data synthesis—We used the statistical methods described in the *Cochrane Handbook* (Higgins 2008). We adopted a random-effects approach using method of moments estimators. The comparison analyses and forest plots were generated in RevMan 5.2.5, and meta-regressions and other subgroup analyses (using an analog to the ANOVA) were conducted in SPSS 20.0 using macros developed by Wilson 2005. When examining statistical significance, P values greater than 0.05 were considered non-significant. Where only one study was included in the comparison, the outcomes are not displayed in a separate comparison table and are reported in text only in the results, and data used is displayed in Comparison 11 of 'all outcomes by main intervention strategy' (see Analysis 11.1 for primary outcome and subsequent analyses for secondary outcomes). Effect sizes that were included in the subgroup analyses for the primary outcome (reported in Section 1.2 of the results) were checked for outliers. First, skewness and SE of the skewness were calculated for the primary outcome in SPSS. Skewness was considered to be statistically significant at the 0.05 level when the skewness value divided by its SE was greater than 1.96. Second, given that skewness was detected, we checked for univariate outliers, which were defined as effect sizes greater than two SDs above or below the unweighted mean.

A sensitivity analysis was conducted to test whether Winsorising the outliers (i.e. changing the value of the effect size estimate to the mean ± 2 SDs), which is recommended in Lipsey 2001, affected the pooled effect size estimates. The analyses on the Winsorised datasets were conducted in SPSS, while the unchanged datasets were analysed in RevMan.

There was no substantial difference between pooled effect size estimate for the primary outcome when outliers unchanged (risk ratio (RR) 1.45, 95% confidence interval (CI) 1.27 to 1.64) and pooled effect size estimate with outliers Winsorised (RR 1.44, 95% CI 1.27 to 1.63).

Multivariate outliers of the primary outcome (i.e. abstinence in late pregnancy) were also explored using the predictor variables main intervention strategy (counselling, feedback, incentives, and social support, with health education and the one study with 'other' intervention type as the reference category). As recommended by Tabachnick 2001, the Mahalanobis distance of each study was compared to the Chi^2 critical value of 18.47 (based on $P < .001$ and $df = 4$). The Mahalanobis distance of none of the studies exceeded this value. Therefore, no multivariate outliers were identified for the primary outcome in terms of intervention strategy.

For the comparison analyses (conducted in RevMan and reported in Section 1.1 of the Results), we used the raw (i.e. not Winsorised) effect sizes in the analyses. This is because the subsets of studies are typically too small to reliably detect outliers.

The number needed to treat for benefit (NNTB) (Altman 1998) was calculated to give an approximation of how many women would need to receive the intervention for one of them to avoid an adverse outcome. We used the *Visual Rx* programme (Cates 2008) and based the

computation on the random-effects pooled odds ratio effect size calculated in RevMan 5.2.5. We used the odds ratio rather than the risk ratio as this is invariant to whether the outcome is presented as a beneficial or adverse outcome (Cates 2002).

Subgroup analysis and investigation of heterogeneity—Investigation of heterogeneity is critical in such a large review that includes many different types of interventions and comparisons. It is possible that there are significant differences between subgroups of studies based on characteristics of the interventions, participants, comparisons, study bias etc, as outlined in Figure 1. In the section on Assessment of heterogeneity above, we described how we identified the presence or absence of heterogeneity; in the current section, we describe how we attempted to identify the main sources of variability in the effect size estimates, that is, to attempt to explain inconsistency across studies. We therefore explored how the observed effectiveness differs under different conditions.

Subgroup analyses—Where subgroup analyses were possible for the primary outcome, they were conducted on the whole dataset in SPSS 20 using an adapted ANOVA test. Ideally, the results of the subgroup analyses should produce a non-significant *within-group* heterogeneity statistic (i.e. the P value for Q_W should be > 0.05) to indicate that the effect sizes *within* a group are statistically similar to each other. If the subgroups are significantly different from each other, then the *between-group* heterogeneity statistic will be significant (i.e. the P value for Q_B will be < 0.05). If the between-group heterogeneity statistic Q_B is not statistically significant, then the proposed subgroup variable does not significantly explain differences between the effect sizes.

Two investigations of heterogeneity required meta-regression analyses. These were (1) a model that included two indicators of the difference in intensity of the intervention and control conditions and (2) a model that included both self-help manuals and telephone support as predictors. Meta-regressions were conducted in SPSS 20 using an adapted regression analysis. The overall fit of the regression model is indicated by two statistics: Q_M and Q_R Q_M is the variability associated with the regression model, while Q_R is the random error variability (that which is not accounted for by the model). A significant Q_M suggests that significant variation in the effect size distribution has been explained by the model, and is therefore desired. A significant Q_R, on the other hand, suggests that variability beyond that explained by the model remains, and is thus not ideal (Lipsey 2001).

Subgroup analyses for the primary outcome: We considered both clinical and statistical heterogeneity in the dataset. For the primary outcome, we did not calculate an overall pooled effect size for all intervention types versus all comparison types because clinical heterogeneity makes the overall effect size difficult to interpret. Instead, we focused our analysis of the primary outcome on subgroup analyses, which statistically test the significance of differences between groups, and trends in the pooled effects for different subgroups. The following variables were included in subgroup analyses conducted in SPSS 20 for the primary outcome of smoking abstinence in late pregnancy.

1. Main intervention strategy (counselling, health education, incentives, feedback, social support, or other).

2. Comparison type (usual care, less intensive interventions, or alternative interventions).
3. Biochemically validated versus self-report outcomes.
4. Intensity of the intervention (duration and frequency).
5. Features of the intervention (self-help manuals and telephone support).
6. Socio-economic status of the participants.
7. Newly included studies in this review update.

It is important to note that the subgroup analyses described below do not take into account interactions in the data. For example, the models do not include both intervention type and comparison type in the same model, so we did not test how these factors might interact. Whilst this is a limitation of the analyses presented, we feel that there is still value in determining overall trends across the dataset. Firstly, this allows better comparison with previous versions of the review, for which the review had not separated the studies by comparison. Secondly, it allows us to consider whether what the corpus of studies looks like and whether there are trends across all of the studies. Throughout, we have distinguished between statistical heterogeneity and conceptual (or clinical) heterogeneity, and we hope that these subgroup analyses help to explore these different types of variation more thoroughly. We also note that in future updates of the review, we hope to be able to incorporate the increasingly popular methods of network meta-analysis to better address all of these issues.

Heterogeneity in the secondary outcomes: For most secondary outcomes, we did not calculate an overall pooled effect but instead focused on comparisons within clinically homogeneous subsets. However, for infant outcomes, we calculated overall pooled effect sizes for all intervention types versus all comparison types, for two reasons. Firstly, there was less extreme clinical heterogeneity in terms of intervention strategy in the infant outcomes. Secondly, as a primary objective of this review is to determine whether psychosocial interventions to support women to abstain from smoking in pregnancy have an impact on infant and maternal health outcomes, and large numbers are needed to detect relatively rare events, the pooled infant outcomes are informative. The overall pooled effect size estimates demonstrate the relationship between being randomised to a smoking cessation intervention and birth outcomes only, rather than the effectiveness of any particular intervention strategy.

Due to the small number of studies reporting the secondary outcomes, we were limited in the range of subgroup analyses (i.e. tests for statistical heterogeneity) that we could conduct. As such, comparisons for the secondary outcomes were limited to description of pooled effect sizes for the subgroups, rather than statistical tests of between-group differences.

Descriptions of trends across studies—To gain a greater understanding of key issues that we were not able to synthesise statistically, we present narrative summaries of the intervention effectiveness for dissemination trials; intervention effectiveness by ethnicity of the participants; and other participant characteristic analyses reported by study authors.

Sensitivity analysis—Concerns have been raised about whether clinical trial efficacy will translate to clinical effectiveness when implemented in healthcare practice (Walsh 2000). To determine whether effectiveness studies (defined as those assessing the implementation of an intervention that uses existing service providers) demonstrate a beneficial outcome in the absence of efficacy trials (those provided by dedicated research staff), we conducted a sensitivity analysis with efficacy trials excluded. The pooled effect size estimate, 95% confidence interval, and I^2 value of the effectiveness-only studies was then compared with the overall pooled effect size estimate and its precision and I^2 value.

A number of potentially significant factors were identified during data extraction and coding of the trials (e.g. where 'counselling' was provided by a video-tape rather than in person; where 'counselling' included optional provision of nicotine replacement therapy or incentives etc.). The studies with these characteristics were highlighted and sensitivity analyses conducted for these studies, and the effect that removing them had on the remaining studies in the comparison.

Assessment of risk of bias across studies: Assessment of the risk of bias across studies was conducted through subgroup analyses in SPSS 20 using an adapted ANOVA test. We used subgroup analyses rather than an elimination approach to sensitivity analysis for two reasons. Firstly, the subgroup analysis allows us to test whether high or low risk of bias studies have statistically different pooled effect sizes. Secondly, we included the 'unclear risk of bias' studies as a subgroup in the analyses, which allows us to check for missing data problems. For some of the risk of bias types, many of the studies did not report sufficient information to be able to assess the potential risk of bias. Through the subgroup analysis, we could test whether there was a systematic difference between poorly reported studies and those with assessable risk of bias.

We conducted risk of bias analyses for the following bias types on the **primary outcome.**

- Random sequence generation selection bias.
- Allocation concealment selection bias.
- Incomplete outcome data attrition bias.
- Selective reporting bias.
- Detection bias (biochemical validation of abstinence).
- Blinding of participants and personnel.
- Blinding of outcome assessment.
- Incomplete implementation.
- Equal baseline characteristics in study arms.
- Contamination of control group.
- Other bias.

Due to the small numbers of effect size estimates for the 16 **secondary outcomes** for which we calculated effect size estimates, very few subgroup analyses by risk of bias type were possible. Only four of the outcomes had sufficient data to be analysed in terms of only one or two of the 12 possible risk of bias types. Given this, we did not conduct risk of bias analyses for the secondary outcomes. However, where possible we reported the average RR for studies assessed as having a high and low risk bias.

RESULTS

Description of studies

Results of the search—The original version of this review included a total of **19** studies identified up until 1993 included as separate reports in the Pregnancy and Childbirth CD Rom: behavioural strategies for reducing smoking (n = 9) (Lumley 1995a); counselling for reducing smoking in pregnancy (n = 1) (Lumley 1995b); advice as a strategy for reducing smoking (n = 6) (Lumley 1995c); and feedback as a strategy for reducing smoking (n = 3) (Lumley 1995d).

Following publication of a protocol in 1998, a search was conducted by the Pregnancy and Childbirth Group for the second update of the review published in *The Cochrane Library* in 1999. This update included a total of **44** trials: 37 trials including 16,916 women providing data on smoking cessation and over 800 women in five trials of relapse prevention (Lumley 1999).

The third update in 2004 was based on a search until July 2003 conducted by the Pregnancy and Childbirth Group, the Tobacco Addiction Group Trials Register and a search of MEDLINE, Embase, PsycLIT and AustHealth. A total of **65** trials were included involving over 20,000 women: 48 trials provided data on smoking cessation, six additional cluster trials involving over 7500 women were not included in the meta-analysis (Lumley 2004).

In the fourth update, published in 2009; a search from January 2003 to June 2008 identified 898 reports which were screened, the full text of 35 reports were reviewed and a total of **73** studies, involving over 20,000 women, were included (72 provided outcome data): 56 randomised and quasi-randomised trials and nine cluster-randomised trials provided primary outcome data for this update (Lumley 2009).

In this fifth update of the review, we screened 2030 abstracts (in addition to the search of the Pregnancy and Childbirth Group's Trials Register) and reviewed the full text of 64 reports. We identified 16 new studies meeting the inclusion criteria. As a result of a change in the inclusion criteria we excluded 13 studies from the previous version of the review, including nine quasi-randomised trials, as well as four randomised controlled trials of pharmacological interventions which are now included in a separate review (Coleman 2012b). These are listed in Characteristics of excluded studies. We also included four studies that had been previously excluded (three cluster trials and one abstract report of a trial), as well as nine studies that did not report any outcomes which could be used in meta-analyses, and which are reported in a separate table. We combined two reports of relapse prevention (Ershoff 1995; Secker-Walker 1995) as 'Associated References' to the primary papers reporting

smoking cessation (Ershoff 1989; Secker-Walker 1994), and another paper which did not report any usable outcomes (Solomon 1996) as an 'Associated reference' to the primary report (Secker-Walker 1998). A total of **77** randomised controlled trials, involving over 29,000 women with relevant outcome data, were included in the meta-analysis for this report (primary outcome data for 21,948 women participating in 70 trials and secondary outcome data only for a further 7404 women participating in seven trials). A further nine without outcomes are included but results summarised in Table 1, making a total of **86** studies included in this update. See Figure 4 for summary of search results.

Included studies

Participants: Over 29,000 pregnant women participating in 77 trials with outcomes included in the meta-analysis were assessed as current or recent 'smokers' at recruitment. The criteria used to assess a woman as a 'smoker' varied substantially between trials, and are detailed for each study in the Characteristics of included studies table. There were 1740 women who reported they had 'spontaneously quit' smoking when they became pregnant, and had outcomes reported separately from women who continued to smoke. In one study only one third of the study population smoked commercial cigarettes, while two thirds chewed traditional or commercial smokeless tobacco (Patten 2009).

Participants were generally healthy pregnant adult women over 16 years of age, with 19 trials explicitly excluding women with medical or psychological complications. The majority of trials (n = 47) included women categorised as having low socio-economic status; 43 of these measured the primary outcome. Most trials included women over 16 years of age, with only two trials explicitly targeting young women under 20 years (Albrecht 1998; Albrecht 2006) and one study including women over 15 years of age (Donatelle 2000). Four trials were specifically targeted towards women with 'psychosocial risk factors' (Graham 1992; Belizan 1995; Albrecht 1998; El-Mohandes 2011) and two trials were conducted among women requiring methadone treatment for opioid addiction (Haug 2004; Tuten 2012). Most trials recruited women at the first antenatal clinic visit and during the second trimester of pregnancy, excluding women in the last trimester due to limited time remaining to receive the intervention. However, four trials were explicitly targeted towards women who continued to smoke in late pregnancy ('heavy smokers') (Valbo 1994; Valbo 1996; Stotts 2002; Stotts 2009). Seven studies included mainly women belonging to an ethnic minority population (Graham 1992; Lillington 1995; Gielen 1997; Manfredi 1999; Malchodi 2003; El-Mohandes 2011; Ondersma 2012). Two trials were conducted in aboriginal communities (Creative Spirits 2013) among Aboriginal women in Australia (Eades 2012) and Alaskan Native women the US (Patten 2009), and one trial included more than 40% Maori women in New Zealand (McLeod 2004). Twenty-eight studies explicitly excluded women who were not able to speak English (n = 26), Danish (Hegaard 2003) or Swedish (Hjalmarson 1991). In eight studies access to a telephone or video recorder was required for participation in the study. In two studies, women using nicotine replacement therapy were excluded (Malchodi 2003; Tuten 2012).

Interventions: Of the studies which had outcomes included in the meta-analysis (n = 77/86), the main intervention strategies were categorised as counselling (n = 48), health

education (n = 7), feedback (n = 7), incentives (n = 4), and social support (n = 10). In one study the intervention was classified as 'intensive dissemination' as both arms received the same counselling intervention, with only the dissemination differing (Campbell 2006), and is therefore reported as a separate comparison. In seven studies, the primary aim of the study was to improve maternal health, which included a smoking cessation component of counselling (El-Mohandes 2011); feedback (Reading 1982; LeFevre 1995) and social support (Olds 1986; Belizan 1995; Bullock 1995; Bullock 2009). These studies are reported as separate comparisons and only smoking outcomes are included, as there is potential for other aspects of these interventions to impact on birth outcomes.

One trial was designed exclusively for women who had spontaneously quit smoking (Lowe 1997), and 11 trials included a relapse prevention component for women who had spontaneously quit. Interventions which were provided only during the postpartum period were excluded from this review, though many interventions during pregnancy continued support into the postpartum period and measured postpartum outcomes.

Smoking cessation interventions implemented during pregnancy differ substantially in their intensity, their duration, and the people involved in their implementation. In 31/77 studies the intervention was coded as a single intervention, therefore the 'main intervention strategy' most accurately reflects the type of intervention. However in 33 studies the intervention was coded as 'multiple', where other components of the intervention were offered to all women. In 12 studies the intervention was coded as 'tailored' whereby different intervention components were offered and tailored to women's needs. For example, two trials offered optional nicotine replacement therapy as part of a counselling intervention (Hegaard 2003; Eades 2012), and one trial offered nicotine replacement therapy to both intervention and control participants (Patten 2009). Most counselling studies involved face-to-face contact, using a variety of strategies either alone or in combination (such as motivational interviewing, cognitive behavioural therapy, stages of change). Three trials with the main intervention strategy coded as counselling included a lottery chance for women who reported quitting (Sexton 1984; Walsh 1997; Parker 2007); five included support for peers (Donatelle 2000; Solomon 2000; Hajek 2001; Vilches 2009; Eades 2012) and three included support for partners to quit (Thornton 1997; Vilches 2009; Eades 2012). The duration and frequency of the intervention also varied considerably, as illustrated in Figure 5 and Figure 6.

Thirteen of the counselling interventions involved telephone counselling and in five of these studies all counselling was provided via telephone (Ershoff 1989; Bullock 1995; Solomon 2000; Stotts 2002; Rigotti 2006), and one had only brief additional face-to-face contact (Bullock 2009). Twenty-six studies included self-help manuals as part of the intervention, and in five studies there was a brief introduction to the manuals (less than five minutes) and the intervention was therefore coded as counselling (Ershoff 1989; Messimer 1989; Price 1991; Valbo 1994; Moore 2002), with sensitivity analysis conducted to assess the independent effect of these five studies. In six studies the intervention was provision of a video alone (Secker-Walker 1997; Cinciripini 2000), with a brief intervention (Price 1991) or as part of a counselling intervention (Walsh 1997; Manfredi 1999; Windsor 2011), and these were also coded as counselling as the videos included stories from women. Five

studies included use of computers in the intervention, three of which were part of another main strategy (Lawrence 2003; Vilches 2009; Ondersma 2012); one which included interaction with a pregnancy care provider and was therefore coded as counselling (Tsoh 2010) and another in which the computer-generated messages were the only intervention and was therefore coded as health education (Strecher 2000). In one study the provision of the self-help manual was the only intervention (Hjalmarson 1991), and was therefore coded as health education only as there was no explicit personal component to the interaction. One study provided a mailed audiotape and self-help manual only (Petersen 1992) and one study provided only automated text-messaging (Naughton 2012); these were coded as health education, as there was no clear personal component. Three other studies that reported the intervention consisted of advice to quit only, either in person (Donovan 1977; Lilley 1986) or by post (Burling 1991) were coded as health education.

Five dissemination trials were identified, carried out in Australia (Lowe 2002; Campbell 2006) and the US (Manfredi 1999; Pbert 2004; Windsor 2011), two of which reported only dissemination outcomes (Manfredi 1999; Lowe 2002) and not the primary outcomes of abstinence in late pregnancy, therefore outcomes not able to be included in the meta-analysis are reported in Table 1. In 26 studies the intervention was provided by staff involved in routine pregnancy care (coded as effectiveness studies), and in 43 studies the intervention was provided by dedicated research project staff (coded as efficacy studies), or via automated technology (n = 8), (coded as unclear).

Comparisons: Women in the control arms in 44 of the 77 trials received information about the risks of smoking in pregnancy and were advised to quit as part of ‘usual care’. In 16 of these 44 trials the comparison/control group was described as receiving ‘usual care’ without specifying further what constituted usual practice (at a particular time and in a particular setting) with respect to advice and assistance. In 31 trials the comparison group received some kind of ‘less intensive’ intervention, which included studies where a dedicated research team consistently provided what they considered to be ‘usual care’ for women in the comparison group. In two studies the comparison group received an ‘alternative intervention’, which was categorised as having the same intensity as the intervention group. One was a counselling intervention using cognitive behavioural therapy compared with traditional health education (Cinciripini 2010) and another compared provision of incentives, contingent or not contingent on smoking status (Heil 2008). As expected, the intensity of interventions and controls has increased over time, as indicated by the change in duration (Figure 5) and frequency of contact during the interventions (Figure 6).

Setting: Included trials were conducted between 1976 and 2012 and almost all trials were conducted in high-income countries. This includes the USA (57), Canada (1), the UK (13), Norway (3), Sweden (1), Holland (1), Spain (1), Australia (5), and New Zealand (2). Only two trials have been conducted in middle-income countries: one trial was conducted in four Latin American countries (Argentina, Brazil, Cuba and Mexico) (Belizan 1995), and the other in Poland (Polanska 2004). Neither trial had biochemically validated smoking outcomes. Most trials of interventions to support pregnant women were conducted in public hospitals or community antenatal clinics.

Outcomes reported

Primary outcomes: Sixty randomised controlled trials and 10 cluster-randomised trials reported the primary outcome measure of smoking abstinence in late pregnancy, up to and including the period of hospitalisation for birth (21,948 women), and in 49 trials (including seven cluster-randomised trials), the abstinence was biochemically validated. Nineteen studies reported whether there was a differential effect among women from different ethnic groups, socio-economic status, or other factors such as depression or partner smoking. Nine studies did not report any outcomes which could be included in meta-analysis and a summary table of outcomes for these studies is reported in Table 1.

Secondary outcomes included in meta-analysis: Fourteen trials reported continued abstinence in late pregnancy among women who had quit spontaneously before the intervention, one of which was a trial exclusively for women who had spontaneously quit, so did not also report the primary outcome (Lowe 1997).

Thirty-two trials reported continued abstinence in the postpartum period at zero to five months (n = 26), six to 11 months (n = 13), 12 to 17 months (n = 5) and 18 months and over (n = 2). Two of these trials did not have outcomes in late pregnancy as the assessment was undertaken at home after birth (Strecher 2000; Polanska 2004). Continued abstinence for baseline smokers and spontaneous quitters are combined in this outcome measure for some studies, with abstinence among baseline smokers only reported where available. The details of the outcomes for each study are reported in the Characteristics of included studies table. Thirty-four trials reported various measures of smoking reduction in late pregnancy, including self-reported ‘any reduction’ (n = 7), self-reported reduction greater than 50% (n = 5), and biochemically validated reduction (n = 6). Two trials recorded both self-reported and biochemically validated reduction (Windsor 1985; Tappin 2005); in these cases we have included only the validated data in the analysis. Other reduction measures of reduced smoking included mean biochemical cotinine (n = 6) thiocyanate (n = 1), or mean cigarettes per day (n = 20). Three studies that reported smoking reduction did not include the primary outcomes of smoking abstinence (Donovan 1977; LeFevre 1995; Vilches 2009).

Nineteen trials reported mean birthweight, one of which had not reported any smoking cessation outcomes (Haddow 1991). Fourteen trials reported rates of low birthweight babies (less than 2500 g) and three reported rates of very low birthweight babies (less than 1500 g). Fourteen studies reported rates of preterm births less than 37 weeks’ gestation (n = 14). Other trials reporting perinatal outcomes included: perinatal deaths (n = 4), stillbirths (n = 7), neonatal deaths (n = 4), and neonatal intensive care unit (NICU) admissions (4).

Other perinatal outcome measures reported included fetal growth (Cope 2003; Heil 2008), mean Apgar scores (Tuten 2012), and head circumference (Cope 2003).

Secondary outcomes included in narrative synthesis: Three trials measured mode of birth (Thornton 1997; Cope 2003; Tappin 2005).

Three trials measured breastfeeding initiation and/or duration (Panjari 1999; McLeod 2004 and an associated reference to Heil 2008) (Higgins 2010a).

Nineteen studies reported baseline psychological measures of interventions, three studies reported associations between smoking outcomes and psychological measures, and nine studies reported psychological outcomes.

No studies reported measures of family functioning. However three studies reported perceptions of partner (McBride 2004)) and peer support (Bullock 2009; Hennrikus 2010), and one study provided analysis of social networks (Stotts 2009).

Twenty-six trials addressed issues identified as important to women in a consultation for this review; with two associated references (Berg 2008; Washio 2011) to included studies (Rigotti 2006; Heil 2008), reporting effects of smoking cessation on maternal weight gain.

Seven studies explicitly included the views of women or community in development of the intervention; and 32 trials reported women's views about the content or delivery of the intervention. Three studies reported measures of knowledge, attitudes or practice among pregnancy care providers (Haug 1994; Secker-Walker 1994; Lawrence 2003).

Five studies reported cost-effectiveness measures (Windsor 1985; Ershoff 1989; Dornelas 2006; Parker 2007; Heil 2008).

Two studies reported rates of women who reported an *increase* in smoking (adverse events) (Haug 1994; Tappin 2005).

Excluded studies—Seventy-five studies did not meet the eligibility criteria and were excluded from the review, for the following reasons:

- design not adequately randomised (e.g. cohort studies, pre-post design, quasi-experimental designs);
- primary population was not pregnant women or intervention was not primarily aimed at cessation during pregnancy (e.g. postpartum interventions, intervention for partners, non-pregnant women);
- trial evaluated efficacy of pharmacological treatment with equal psychosocial support in both arms;
- cluster-randomised trials with insufficient information (e.g. number of clusters) provided to enable adjustment for clustering.

See Characteristics of excluded studies for details.

Risk of bias in included studies

Allocation—Sequence generation was described and adequate in 35 trials. In 48 trials the sequence generation was not described or simply described as 'randomised' so it was unclear whether this was adequate or not. Three trials were included which had non-random sequence generation, such as allocation by medical record numbers and birthdate, as it was considered the risk of interference with this sequence is low. There are also many studies where the method of sequence generation was not reported. Quasi-randomised trials where there was a potential for interference, such as clinic attendance day or other quasi-

randomised methods were excluded from this update of the review and the reasons are listed in the Characteristics of excluded studies table.

The method of randomisation was not described in sufficient detail to permit assessment of whether the allocation was concealed at the time of trial entry in 63 studies. In only 12 studies was the allocation adequately concealed and in 11 studies there was clearly no concealment of group allocation.

Equal baseline characteristics: As the sequence generation was not reported in the majority of trials, we assessed whether the baseline characteristics were equal and these were assessed as adequate in 37 studies, unclear (minor differences or not reported) in 33 studies, and inadequate or significant differences in 16 studies. Of the 48 trials with unclear sequence generation, 18 had equal baseline characteristics, seven had unequal baseline characteristics and in 23 there were some minor differences or the baseline characteristics were not reported.

Blinding—Very few trials had any blinding of participants or providers, as this is not practicable in delivering most psychosocial interventions. In 60 studies the participants and providers were clearly aware of group allocation, it was unclear in 15 studies, and in one study they were able to blind participants and/or providers to group allocation.

Blinding of the outcome assessment was rarely reported and was assessed as adequate in 11 studies, unclear in 74 studies, and inadequate in one study.

Incomplete outcome data—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. These women were often excluded from outcome measurement, which means that important outcomes linked in observational studies to smoking exposure were not ascertained. Assessing smoking at 20 to 28 weeks instead of at 36 to 38 weeks would reduce the need to exclude women withparticularly adverse outcomes, since their smoking status in mid-pregnancy would have been ascertained before preterm birth or a perinatal death had occurred. Others moved out of the area or changed to another provider of care. The latter was a common cause of attrition in those trials carried out among populations characterised by severe poverty and the receipt of special needs benefits such as Medicaid, or WIC (food program for women, infants and children) clinics.

In studies where there was longer-term follow-up, attrition was sometimes high; approximately half of the included studies had high levels of missing data (greater than 20%) for some outcomes. All randomised women were included in analysis for the primary outcome (abstinence in late pregnancy) in 25 trials. In 41 trials, some women were excluded from the analysis due to miscarriage or pregnancy loss, or moving, and these were assessed as unclear risk of attrition bias as there are some associations with smoking. In 20 trials, primary outcome data were missing and were unable to be included in this review, and they were assessed as inadequate due to risk of attrition bias. Levels of attrition for each study

and information about any intention-to-treat analysis have been reported in the ‘Risk of bias’ tables .

Selective reporting—It was not clear in many trials the extent of outcome data that were collected and therefore, unclear whether the outcomes were selectively reported in 42 studies. All primary outcomes were adequately reported in 30 studies, and 14 studies were assessed as inadequately reporting primary outcomes.

Other potential sources of bias

Detection bias from misclassification by self-report: Fifty-two trials reported biochemical validation of the primary outcome measure, smoking abstinence. In seven trials there was unclear or partial validation of smoking status. Twenty-seven trials measured smoking status by self-report and are included in this review as ‘high risk’ of bias. Later trials more often relied on a definition of smoking abstinence requiring biochemical validation.

Implementation of intervention: Some studies reported process evaluation demonstrating challenges implementing the intervention and delivering it to all women (Walsh 2000). In 26 studies, process evaluation suggested that the majority of women received the intervention as planned, however 31 studies reported that many women had not received the intervention as planned and in 29 studies it was unclear or not reported.

Smoking cessation interventions implemented during pregnancy differ substantially in their intensity, their duration, and the people involved in their implementation. The timing of the final antenatal assessment of smoking status varied considerably between trials between the second and third trimester. This may have affected the amount of time the participants were exposed to the intervention (if it involved ongoing support), as well as the number of those lost to follow-up and measurement of perinatal outcomes.

Exposure of the control group to the intervention: Another problem with trials in this area can be ‘contamination’ or exposure of the control group to intervention components, particularly if the study is being implemented in a routine care setting. Fifty-eight trials were implemented by dedicated research staff or technology and were assessed as having a low risk of exposing the control group to the intervention. In 12 studies it was unclear, and in 16 studies the authors reported problems with exposure of the control group, or the intervention was provided by routine care providers and the study design was assessed as having a ‘high risk’ of control group exposure.

Other bias: No other risk of bias was suspected in 68 studies. However, in nine studies there were some other risks, such as unequal recruitment to study arms in cluster-randomised trials or financial conflicts of interest, and in nine studies it was unclear if there may be other risks of bias.

Change in ‘usual care’: In many cases the comparison/control group was described as receiving ‘usual care’ without specifying further what constituted usual practice (at a particular time and in a particular setting) with respect to advice and assistance. It can be seen from Figure 5 and Figure 6 that current ‘usual care’ may be a more substantial

intervention than the defined intervention in some of the earliest trials (for example, Baric 1976).

A summary of Risk of bias' assessments in the included trials is set out in Figure 7 and Figure 8.

Effects of interventions

A total of 88 meta-analyses are reported in this review. Meta-analyses were conducted and are presented in data tables for a total of 11 comparisons involving 59 outcomes. Data for comparisons with only one study reporting an outcome are reported in text, but not displayed. In addition, eight non-prespecified meta-analyses conducted in Revman 5.2.5 were reported in text, to assess the effect of factors identified during data extraction and coding (e.g. where 'counselling' involved provision of a videotape only). The results of 21 meta-analyses conducted in SPSS 20 to assess risk of bias and sensitivity analyses are also reported in text and not reported in tables.

1. Primary outcome: Smoking abstinence in late pregnancy

1.1 Comparisons: Main intervention strategy compared with usual care, less intensive intervention, or an alternative intervention, and subgrouped by single, multiple or tailored components: Table 3 presents a cross-tabulation of the main intervention strategies and comparison type, for studies that report the primary outcome. The large number of cells that have very few (i.e., $n \leq 2$) or zero studies means that it is not appropriate to run an interaction analysis with these two variables. Therefore, the synthesis in this section was not achieved through meta-analytic subgroup analyses; rather, the synthesis is a description of trends in the weighted pooled effect size estimate for subsets of studies based on the intervention strategy, the comparison type, and the number of components in the intervention (single component, multiple components, and tailored components). As such, we cannot draw any conclusions about statistical differences between subsets of studies in this section.

1.1.1 Counselling versus usual care: In trials where the main intervention strategy was counselling and the control group received 'usual care', the difference between intervention and control groups was significantly different from zero (27 studies; average risk ratio (average RR) 1.44, 95% confidence interval (CI) 1.19 to 1.75), $I^2 = 55\%$, see Analysis 1.1.

In subsets of studies, the effect size estimate was significantly different from zero where counselling was combined with other strategies (11 studies; average RR 1.59, 95% CI 1.15 to 2.21), $I^2 = 45\%$ or tailored to the needs of individual women (six studies; average RR 1.49, 95% CI 1.01 to 2.20), $I^2 = 75\%$, but the effect was unclear when counselling was provided as a single intervention (10 studies; average RR 1.12, 95% CI 0.89 to 1.42), $I^2 = 11\%$. There was no significant difference in biochemically validated abstinence in late pregnancy in a single study where smoking cessation counselling was provided as part of a broader intervention to improve maternal health (El-Mohandes 2011) and the control group received usual care (RR 1.00, 95% CI 0.72 to 1.40). The analysis for this comparison is not displayed in a table as only one study met the criteria.

1.1.2 Counselling versus less intensive interventions: In trials where the main intervention strategy was counselling and the control group received a less intensive intervention, the effect size had borderline significance (16 studies; average RR 1.35, 95% CI 1.00 to 1.82), I^2 = 74%, see Analysis 2.1. In subsets of studies, the effect size was significantly different from zero for the single trial (Walsh 1997) where counselling was tailored to individual needs (RR 2.39, 95% CI 1.03 to 5.56), and included lottery tickets for women who were abstinent from smoking, but there was no clear difference where counselling was provided alone (n = 5), or in combination with other strategies (n = 10).

1.1.3 Counselling versus alternative intervention: There was no significant effect in the single study (Cinciripini 2010) that compared one counselling strategy (CBT) to an alternative counselling intervention (traditional health education or motivational interviewing) (RR 1.15, 95% CI 0.86 to 1.53). The analysis for this comparison is not displayed in a table as only one study met the criteria.

Other counselling subset analyses (not displayed): In two studies where counselling was provided as part of a tailored intervention that included optional nicotine replacement therapy and was compared with usual care (Eades 2012; Hegaard 2003), the effect was not significantly different from zero (average RR 1.63, 95% CI 0.25 to 10.50), I^2 = 59%.

In two studies where ‘counselling’ involved only provision of a video tape (Secker-Walker 1997; Cinciripini 2000) compared with a less intensive intervention, the effect was unclear as it was not significantly different from zero and there was considerable heterogeneity (average RR 2.31, 95% CI 0.08 to 65.02), I^2 = 78%, and the effect on the subgroup of ‘single’ counselling interventions compared with usual care continued to be borderline non-significant when these two studies were removed from the pooled results (average RR 1.52, 95% CI 0.99 to 2.34). The effect was not significantly different from zero in a single study (Price 1991), which provided brief advice (less than five minutes) in conjunction with provision of a video, compared with usual care (RR 3.94, 95% CI 0.45 to 34.41).

Five studies coded as counselling provided brief advice (less than five minutes) and a self-help manual (Ershoff 1989; Messimer 1989; Price 1991; Valbo 1994; Moore 2002). Four of these studies reported abstinence in late pregnancy and the combined effect was not significantly different from zero (average RR 1.28, 95% CI 0.79 to 2.07), I^2 = 54%.

Four studies coded as counselling included peer and/or partner support as part of a tailored intervention (Solomon 2000 Hajek 2001; Vilches 2009; Eades 2012) compared with usual care, and the combined effect of two studies that reported abstinence in late pregnancy (Hajek 2001; Eades 2012) was not significantly different from zero (average RR 1.09, 95% CI 0.82 to 1.44), I^2 = 0%.

Three studies coded as counselling (tailored) included support for partners to quit smoking (Thornton 1997; Vilches 2009; Eades 2012) compared with usual care, and two studies that reported abstinence in late pregnancy (Thornton 1997; Eades 2012) did not show a combined effect that was significantly different from zero (average RR 1.23, 95% CI 0.66 to 2.31), I^2 = 0%.

Three studies coded as multiple or tailored counselling that included a lottery chance for women who reported abstinence (Sexton 1984; Walsh 1997; Parker 2007) had a combined effect that was significantly different from zero (average RR 1.98, 95% CI 1.61 to 2.42), I^2 = 6%. Two studies that measured self-reported abstinence compared with usual care (Sexton 1984) and a less intensive intervention (Parker 2007) showed a significant effect (average RR 1.69, 95% CI 1.21 to 2.36), and the effect of the single study that reported biochemically validated abstinence (Walsh 1997) was also significantly different from zero (RR 2.39, 95% CI 1.03 to 5.56).

1.1.5 Health education versus usual care: For studies in which the main intervention strategy was health education and the control group received usual care, the pooled effect size estimate was not significantly different from zero (three studies; average RR 1.51, 95% CI 0.64 to 3.59), I^2= 28%, see Analysis 3.1. The effect size estimate was not significant in subsets of trials where health education was provided alone (n = *2*) or in combination with other strategies (n = 1); or when the analysis was restricted to studies with biochemical validation of abstinence, see Analysis 3.2.

1.1.6 Health education versus less intensive interventions: The effect was not significantly different from zero in trials where health education was compared with a less intensive intervention (two studies; average RR 1.50, 95% CI 0.97 to 2.31), I^2 = 0%, and there was little difference whether health education was provided alone (n = 1), or in combination with other strategies (n = 1), see Analysis 4.1.

Other health education subset analyses (not displayed): Two studies coded as health education involved provision of self-help manuals with no additional advice (Hjalmarson 1991) or an audiotape (Petersen 1992) and the combined effect was not significantly different from zero (average RR 1.28, 95% CI 0.79 to 2.07), I^2 = 7%. When these studies were removed from the health education subgroup, the combined effect of the remaining three studies (Lilley 1986; Burling 1991; Naughton 2012) was statistically significantly different from zero (average RR 1.93, 95% CI 1.01 to 3.69), I^2 = 0%.

A single study coded as health education that provided advice via a computer (Strecher 2000), compared with a less intensive intervention reported an effect that was not significantly different from zero in *abstinence at six weeks postpartum* (RR 1.00, 95% CI 0.91 to 1.09).

The effect of a single study coded as health education that provided advice and motivational statements via text compared with a less intensive intervention (Naughton 2012), was not significantly different from zero (RR 1.59, 95% CI 0.68 to 3.73).

1.1.7 Feedback versus usual care: For the two trials where the main intervention was feedback, provided in combination with other strategies, and the control group received usual care (Valbo 1994; Cope 2003), the combined effect size estimate was significantly different from zero (average RR 4.39, 95% CI 1.89 to 10.21), I = 0%, see Analysis 5.1.

The effect of self-reported smoking abstinence in late pregnancy was not significantly different from zero in a single study that provided ultrasound feedback alone (with no smoking cessation advice) as part of a broader intervention to improve maternal health and usual care for the control group (Reading 1982) (RR 2.11, 95% CI 0.98 to 4.52). The analysis for this comparison is not displayed in a table as only one study met the criteria.

1.1.8 Feedback versus less intensive interventions: Two studies assessed the effectiveness of feedback compared with less intensive interventions. The effect size estimates of both studies - one in which feedback was provided alone (Bauman 1983) and one in which feedback was provided in combination with other strategies, for women still smoking in late pregnancy (Stotts 2009), were not significantly different from zero; (average RR 1.19, 95% CI 0.45 to 3.12), I = 49%, see Analysis 6.1.

1.1.9 Incentives versus usual care: There was no significant difference in rates of biochemically validated abstinence in the pooled results of two studies where the main intervention strategy was financial incentives and the control group received usual care (average RR 3.59, 95% CI 0.10 to 130.49). However, there was significant heterogeneity (I^2 = 82%) and interaction between the subgroups (Chi^2 4.03, P = 0.04), so caution is needed considering the combined effect of these trials. The analysis included a trial of incentives (single intervention) (Tuten 2012) (RR 20.72, 95% CI 1.28 to 336.01) and a trial of 'low intensity' incentives (multiple intervention) provided with assistance of a computer program and counselling via a computerised program (Ondersma 2012) (RR 0.90, 95% CI 0.25 to 3.23), see Analysis 7.1.

1.1.10 Incentives versus less intensive or alternative interventions: The effect was significantly different from zero in the single trial where incentives were provided in combination with peer support and the control group received a less intensive intervention (Donatelle 2000) (RR 3.64, 95% CI 1.84 to 7.23). The analysis for this comparison is not displayed in a table as only one study met the criteria.

The effect was also significantly different from zero in the single study where the intervention group received incentives contingent on smoking status (single intervention), and the control group received an equally intensive alternative intervention of incentives which were not contingent on smoking status (Heil 2008) (RR 4.05, 95% CI 1.48 to 11.11). The analysis for this comparison is not displayed in a table as only one study met the criteria.

Another trial of incentives included a second comparison arm of non-contingent incentives (Tuten 2012), which demonstrated a significant effect (RR 18.21, 95% CI 1.33 to 294.43), although this effect size estimate was not included in the meta-analysis (only the comparison with the usual care condition was included in the meta-analyses in this review).

1.1.11 Social support versus less intensive interventions: The combined effect size estimate of six trials where the main intervention strategy included peer or partner (social) support and the control group received a less intensive intervention was not significantly different from zero (average RR 1.29, 95% CI 0.94 to 1.78), I = 18%, see Analysis 8.1. However, the

effect was significantly different from zero in five trials which included peer support (average RR 1.49, 95% CI 1.01 to 2.19), I^2 = 3%, see Analysis 8.2. In the single trial where the intervention involved partner support (McBride 2004), there was no significant effect in self-reported abstinence (RR 1.02, 95% CI 0.70 to 1.50).The analysis for this comparison is not displayed in a table as only one study met the criteria.

1.1.12 Social support as a component of a broader maternal health intervention versus usual care: The effect size was significantly different from zero in one study where tailored peer support was provided as part of a broader intervention to improve maternal health and compared with usual care (RR 1.83, 95% CI 1.22 to 2.73), see Analysis 9.1. A further study in which tailored peer support was provided as part of a broader intervention to improve maternal health and compared with usual care with biochemically validation smoking cessation (Olds 1986) had zero events in both study arms and the effect size estimate was therefore 'not estimable' in Revman 5.2.5. As such, we could not calculate a pooled effect for this comparison.

1.1.13 Social support as a component of a broader maternal health intervention versus less intensive intervention: There was no significant effect in two studies where telephone peer support was provided as part of a broader intervention to improve maternal health, and the control group received a less intensive intervention (average RR 0.80, 95% CI 0.46 to 1.39); see Analysis 10.1 and Analysis 10.2.

1.2 Subgroup analyses: The following subgroup analyses were conducted on the whole dataset using all studies for the primary outcome (smoking abstinence in late pregnancy) (see Analysis 11.1 for list of studies). These analyses were conducted in SPSS using Winsorised data.

1.2.1 Subgroup analysis 1: Main intervention strategy: Three of the main intervention strategy subgroups had pooled effect size estimates that were significantly different from a null effect, indicating that abstinence in late pregnancy was significantly greater in the treatment than in the control group for these strategies: incentives (four studies; average RR 2.95, 95% CI 1.55 to 5.63, I^2 = 15%), feedback (five studies; average RR 2.08, 95% CI 1.23 to 3.50, I^2 = 26%), and counselling (45 studies; RR 1.36, 95% CI 1.17 to 1.57, I^2 = 0%). However, there was no significant difference between treatment and control groups in subgroup analyses of trials where the main intervention strategy was social support (10 studies; average RR 1.29, 95% CI 0.92 to 1.80, I^2 = 0%), or health education (five studies; RR 1.50, 95% CI 0.90 to 2.51, I^2 = 0%). There was not a significant between-group difference (Q_B (4) = 7.70, P = 0.10) and there was within-group homogeneity (as indicated by low I^2 in each subgroup and non-significant Q-statistics for each subgroup; overall Q_W (64) = 57.86, P = 0.69). One study, Campbell 2006, was treated as missing from this analysis as the intervention type category was unclear.

1.2.2 Subgroup analysis 2: Comparison type: We conducted a subgroup analysis to test for differences in the pooled effect size estimate of studies grouped by their comparison type. As there were only two studies with alternative intervention comparators that also reported the primary outcome, we used a pooled estimate of the between-study variance (τ^2)

following the method described in Borenstein 2009. The results suggests that there is no statistically significant difference between effect size estimates grouped by comparison type (Q_B (2) = 1.53, P = 0.47). Studies with comparisons consisting of usual care comparisons had the highest pooled effect size estimate (37 studies; average RR 1.34, 95% CI 1.25 to 1.44), I^2 = 53%, followed by less intensive interventions (30 studies, average RR 1.20, 95% CI 1.08 to 1.31), I^2 = 64%, and the effect size estimate for studies with an alternative intervention comparisons was not statistically different from zero (two studies, average RR 1.26, 95% CI 0.98 to 1.53), I^2 = 82%. Forest plot not shown. It should be noted that studies where the comparison group received only 'usual care' were also more likely to provide a low intensity intervention, as shown in Figure 5 and Figure 6, and discussed below.

1.2.3 Subgroup analysis 3: Biochemically validated versus self-report outcomes: Given concerns about the potential biases (e.g. social desirability bias) of self-report measures of smoking behaviours, we conducted a subgroup analysis comparing biochemically validated smoking abstinence and self-reported abstinence. The results suggest that there is no statistically significant difference between the two groups of effect sizes (Q_B (1) = 0.06, P = 0.80; Q_W (67) = 61.33, P = 0.67), and there was a similar pooled effect size estimate for biochemically validated outcomes (49 studies; average RR 1.43, 95% CI 1.22 to 1.67, I^2 = 0%), compared to self-reported outcomes (20 studies; average RR 1.48, 95% CI 1.17 to 1.87, I^2 = 11%). Although this does not help us to explain the significant heterogeneity in the dataset, it gives us greater confidence in combining self-report with biochemically validated outcomes in further analyses. One study, Thornton 1997, was treated as missing from this analysis as the use of biochemical validation was unclear.

1.2.4 Subgroup analysis 4: Intensity of the intervention: There was no significant difference between effect sizes estimates subgrouped according to the frequency of contact in the intervention (Q_B (5) = 8.88, P = 0.11); see Table 4 for the pooled effect size estimates by group. Moreover, there was no significant difference between effect sizes estimates subgrouped according to the duration of contact in the intervention (Q_B (5) = 5.43, P = 0.37); see Table 5 for the pooled effect size estimates by group.

To explore whether the difference in intensity between conditions was a significant predictor of the outcome, a meta-regression was conducted. The model included two predictor variables: the difference between the intervention and control group frequency of contact categorisations, and the difference between the intervention and control group duration of contact categorisations. The analyses indicated that neither the magnitude of the difference in duration nor frequency of contact significantly predicted the primary outcome (Q_M (2) = 0.17, P = 0.92; Q_R (65) = 63.14, P = 0.54;R^2 = 0.00).

1.2.5 Subgroup analysis 5: Features of the intervention (self-help manuals and telephone support): A meta-regression with two dichotomous predictor variables - the use of self-help manuals and the availability of telephone support - was conducted. Of the studies that reported the primary outcome, 24 studies offered self-help materials to participants and 13 provided telephone support (three of these offered both). The analyses indicated that neither self-help materials (B = −0.14, SE = 0.13) nor telephone support (B = −0.14, SE = 0.15)

significantly predicted the primary outcome (Q_M (2) = 1.83, P = 0.40; Q_R (67) = 63.54, P = 0.60;R^2 = 0.03).

1.2.6 Subgroup analysis 6: Socio-economic status (SES) of the participants: For the primary outcome of abstinence in late pregnancy, there was no significant difference between the two groups of studies with women categorised as 'low' or 'not low' SES (Q_B (1) = 0.11, P = 0.74). The pooled effect size estimate for interventions provided for women categorised as 'low' SES interventions was similar (44 studies; average RR 1.41, 95% CI 1.19 to 1.66, I^2 = 1%), to those provided for women categorised as 'not low' SES (26 studies; average RR 1.47, 95% CI 1.21 to 1.79, I^2 = 0%).

1.2.7 Subgroup analysis 7: Newly included studies in this review update: Of the 70 studies reporting smoking abstinence in late pregnancy outcomes, 50 came from studies in the previous review (Lumley 2009), while 20 were from new studies identified in the updated search. We conducted this subgroup analysis to address concerns that newer trials may have a reduced effect due to the increased information about the risks of smoking in pregnancy in the general population. Although effect sizes from the newly-included studies tended to be lower (20 studies; average RR 1.26, 95% CI 1.00 to 1.59, I^2= 3%), than those from the previous version of the review (50 studies; average RR 1.50, 95% CI 1.30 to 1.73, I^2= 0%), this difference was not statistically significant (Q_B (1) = 1.51, P = 0.22).

1.3 Description of trends in intervention effectiveness: dissemination trials (not displayed): There were five dissemination trials, defined as trials where the intervention was provided at an organisational level and strategies were employed to influence the practice of pregnancy care providers (Manfredi 1999; Lowe 2002; Pbert 2004; Campbell 2006; Windsor 2011). The combined effect of three trials that reported abstinence in late pregnancy (Pbert 2004; Campbell 2006; Windsor 2011) was not significantly different from zero (average RR 0.96, 95% CI 0.37 to 2.50), I^2 = 72%.

1.4 Description of trends in intervention effectiveness: ethnic and aboriginal participants (not displayed): The synthesis in this section was not achieved through meta-analytic subgroup analyses; rather, the synthesis is a description of trends in the weighted pooled effect size estimate for subsets of studies based on ethnicity of the participants. As such, we cannot draw any conclusions about statistical differences between subsets of studies in this section.

The combined effect of five studies (four counselling trials, one incentives trial) among women predominantly from a minority ethnic group (African-American and/or Hispanic) that reported abstinence in late pregnancy was not significantly different from zero (average RR 1.08, 95% CI 0.83 to 1.40), I^2 = 0%. Of those five trials, three were conducted with African-American women (Gielen 1997; El-Mohandes 2011; Ondersma 2012) (average RR 1.01, 95% CI 0.75 to 1.37), I^2 = 0%. The effect size estimate in a single trial among African-American and Hispanic women (Lillington 1995) was not significantly different from zero (RR 1.97, 95% CI 0.70 to 5.50). A single trial of social support developed specifically for Hispanic women in this review (Malchodi 2003) did not demonstrate a significant effect size estimate (RR 1.12, 95% CI 0.61 to 2.06).

The combined effect for the two tailored counselling interventions provided for aboriginal women in Australia (Eades 2012) and Canada (Patten 2009) did not show a significant difference between treatment and control groups in rates of abstinence in late pregnancy (average RR 0.40, 95% CI 0.06 to 2.67), $I^2 = 0\%$.

1.5 Description of participant characteristic analyses reported by study authors: The following is a narrative synthesis of the findings of subgroup analyses reported by primary study authors.

Low socio-economic status (SES): Of seven studies which reported sensitivity analysis by a measure of SES, four reported lower abstinence rates or a negative association with quitting among women with lower SES (Baric 1976; McLeod 2004; Pbert 2004; Rigotti 2006), two reported no significant difference (Ershoff 1989; Tappin 2005), and one study reported 4/5 successful quitters had not graduated from high school (Secker-Walker 1997).

Ethnicity or race: Of nine studies which reported outcomes or sensitivity analysis by ethnic status, one study reported the intervention was less effective among Hispanic and African-American women (Kendrick 1995), one study reported the intervention was less effective among Hispanic compared to African American women (Lillington 1995), three studies reported no difference in outcomes by race or ethnicity (Burling 1991; Strecher 2000; Dornelas 2006), and four studies reported higher quit rates among African-American and/or Hispanic women compared to other women (Petersen 1992; Windsor 1993; Pbert 2004; Parker 2007).

Depression: Two studies that reported outcomes by rates of depression reported a negative association between smoking abstinence and depression (Cinciripini 2000; Rigotti 2006).

Low social support: Three studies that reported measures of social support reported a negative association with low social support (e.g. single mothers) and quitting (Loeb 1983; Thornton 1997; Rigotti 2006).

Partner smoking: Of four studies reporting associations with partner smoking and abstinence in late pregnancy, two reported no significant difference (Rigotti 2006; Stotts 2009) and two reported a negative association (i.e. lower rates of quitting among women whose partners' smoked) (McLeod 2004; Polanska 2004).

1.6 Sensitivity analysis

1.6.1 Efficacy versus effectiveness trials: Given concerns about whether clinical trial efficacy will translate to clinical effectiveness when implemented in healthcare practice (Walsh 2000), we conducted a sensitivity analysis to determine whether effectiveness studies (defined as those assessing the implementation of an intervention that uses existing service providers) demonstrate a beneficial outcome. That is, efficacy trials (those provided by dedicated research staff, n = 43) were excluded from the analysis. The frequencies of key variables for the 26 effectiveness studies (three of which did not report the primary outcome and so were not included in the aforementioned analysis) are presented in Table 6. For the 23 effectiveness trials with primary outcome data, the pooled effect size estimate

significantly favoured the intervention group (average RR 1.42, 95% CI 1.11 to 1.82). This group of studies, however, was substantially heterogeneous (I^2 = 67%; Q (22) = 66.37, P < .001). The pooled effect size estimate for effectiveness studies is very similar to the overall pooled effect size estimate (average RR 1.44, 95% CI 1.27 to 1.63) of the full sample (n = 70), although the effectiveness studies have a wider confidence interval and slightly greater heterogeneity. We can therefore conclude that our overall pooled effect size estimate (n = 70 studies) is not likely to be an over-estimate, although the addition of the efficacy trials introduced greater precision to the estimate.

1.6.2 Assessment of risk of bias across studies

Random sequence generation selection bias: Not calculable due to insufficient numbers of studies with high risk of bias. Twenty-seven studies were classified as low risk of bias, three were high risk of bias, and the remainder were unclear.

Allocation concealment selection bias: Ten studies were classified as low risk of bias, 11 were high risk of bias, and the remainder were unclear. There was no significant between-group heterogeneity (Q_B (2) = 5.22, P = 0.07), although high risk studies had a larger pooled effect size estimate (average RR 2.11, 95% CI 1.48 to 3.00, I^2= 0%) compared to low-risk studies (average RR 1.33, 95% CI 0.99 to 1.79, I^2= 0%), or unclear bias studies (average RR 1.36, 95% CI 1.17 to 1.58, I^2= 1%).

Incomplete outcome data attrition bias: Twenty-two studies were classified as low risk of bias, 13 were high risk of bias, and the remainder were unclear. There was no significant between-group heterogeneity (Q_B (2) = 0.13, P = 0.94). The mean effect size was largest for studies rated as high on this type of bias (average RR 1.47, 95% CI 1.09 to 1.99, I^2= 0%), followed by unclear risk of bias (average RR 1.45, 95% CI 1.22 to 1.73, I^2= 0%), and low risk of bias (average RR 1.39, 95% CI 1.10 to 1.75, I^2= 13%).

Selective reporting bias: Twenty-nine studies were classified as low risk of bias, eight were high risk of bias, and the remainder were unclear. There was no significant between-group heterogeneity (Q_B (2) = 3.56, P = 0.17). The mean effect size was largest for studies rated as low on this type of bias (average RR 1.67, 95% CI 1.34 to 2.06, I^2= 0%), followed by high risk of bias (average RR 1.50, 95% CI 1.09 to 2.08, I^2= 0%), and unclear risk of bias (average RR 1.28, 95% CI 1.08 to 1.52, I^2= 0%).

Detection bias (biochemical validation of smoking abstinence): Forty-nine studies were classified as low risk of bias, 20 were high risk of bias, and one was unclear. There was no significant between-group heterogeneity (Q_B (1) = 0.06, P = 0.80). The mean effect size was similar, but largest, for studies rated as high on this type of bias (average RR 1.48, 95% CI 1.17 to 1.87, I^2= 11%), followed by low risk of bias (average RR 1.43, 95% CI 1.22 to 1.67, I^2= 0%); the one unclear study was treated as missing in this analysis.

Blinding of participants and personnel performance bias: Not calculable due to insufficient numbers of studies with low risk of bias.

Blinding of outcome assessment detection bias: Not calculable due to insufficient numbers of studies with high or low risk of bias.

Other bias (such as unequal recruitment to study arms in cluster trials; potential conflict of interest): Fifty-four studies were classified as low risk of bias, eight were high risk of bias, and the remainder were unclear. There was no significant between-group heterogeneity (Q_B (2) = 1.28, P = 0.53). The mean effect size was largest for studies rated as low on this type of bias (average RR 1.47, 95% CI 1.28 to 1.69, I^2= 0%), followed by high risk of bias (average RR 1.38, 95% CI 0.96 to 1.99, I^2= 0%), and unclear risk of bias (average RR 1.18, 95% CI 0.82 to 1.70, I^2= 0%).

Incomplete implementation: Twenty-two studies were classified as low risk of bias, 27 were high risk of bias, and the remainder were unclear. There was a significant between-group difference for this type of bias (Q_B (2) = 7.07, P = 0.03), though this is due to the difference in studies coded as 'unclear' (average RR 1.87, 95% CI 1.47 to 2.38, I^2= 0%). Low risk of bias studies, assessed as having good implementation, had a similar effect size (average RR 1.33, 95% CI 1.10 to 1.62, I^2= 17%) to high risk of bias studies (average RR 1.27, 95% CI 1.06 to 1.51, I^2= 0%).

Equal baseline characteristics in study arms: Thirty studies were classified as low risk of bias, 15 were high risk of bias, and the remainder were unclear. There was no significant between-group heterogeneity for this type of bias (Q_B (2) = 4.79, P = 0.09). The mean effect size was largest for studies with unclear risk of this type of bias (average RR 1.67, 95% CI 1.33 to 2.10, I^2= 20%), followed by low risk of bias (average RR 1.45, 95% CI 1.21 to 1.74, I^2= 0%), and high risk of bias (average RR 1.13, 95% CI 0.86 to 1.47, I^2= 0%).

Contamination of control group: Forty-nine studies were classified as low risk of bias, 13 were high risk of bias, and the remainder were unclear. There was no significant between-group heterogeneity (Q_B (2) = 2.12, P = 0.35). The mean effect size was largest for studies with unclear risk of this type of bias (average RR 1.50, 95% CI 1.07 to 2.11, I^2= 0%), followed by low risk of bias (average RR 1.48, 95% CI 1.28 to 1.71, I^2= 0%), and high risk of bias (average RR 1.19, 95% CI 0.90 to 1.56, I^2= 29%), which were not significantly different from the null effect.

2. Secondary outcomes

2.1 Relapse prevention: In examining trends in separate comparisons of studies, the effect was not statistically different from zero in eight trials where the intervention was counselling and the control group received usual care (average RR 1.06, 95% CI 0.93 to 1.21; see Analysis 1.3) or four trials comparing counselling with a less intensive intervention (average RR 1.05, 95% CI 0.98 to 1.13; see Analysis 2.3). Single studies comparing health education with usual care (Petersen 1992) and social support with a less intensive intervention (McBride 2004) also did not show a significant difference between intervention and control groups (RR 0.97, 95% CI 0.71 to 1.31 and RR 1.02, 95% CI 0.89 to 1.16, respectively), figures not displayed as comparisons as only single studies.

2.2 Continued abstinence in the postnatal period

2.2.1 Zero to five months: In examining trends in separate comparisons of studies, a significant difference in abstinence at zero to five months was seen between intervention and control groups only in trials where counselling was compared with usual care (10 studies; average RR 1.76, 95% CI 1.05 to 2.95, see Analysis 1.4). However there was considerable heterogeneity between trials (I^2 = 83%) and subgroups (Chi^2 25.05 P < 0.0001), so these results should be considered with caution. Within this comparison, there was a significant effect in single interventions (average RR 1.52, 95% CI 1.13 to 2.05) and multiple interventions (average RR 2.32, 95% CI 1.44 to 3.72), but not in the single tailored intervention (average RR 0.88, 95% CI 0.80 to 0.97). There was also a significant difference in abstinence in a single trial where incentives were compared with an alternative intervention (Heil 2008) (RR 9.73, 95% CI 1.29 to 73.13, analysis not displayed in a table as only one study met the criteria).

However, the difference between intervention and control groups was not statistically significant in trials where: counselling was compared with a less intensive intervention (six studies; average RR 1.17, 95% CI 0.82 to 1.66; see Analysis 2.4); or where social support was compared with a less intensive intervention (two studies; average RR 1.36, 95% CI 0.46 to 4.07; see Analysis 8.3); There was also no clear effect where health education was compared with a less intensive intervention (two studies; average RR 1.29, 95% CI 0.52 to 3.22, see Analysis 4.2), but there is considerable heterogeneity in this comparison (I^2 = 93%, Chi^2 = 25.03, P < 0.0001), so these pooled results should be considered with caution. No significant difference between intervention and control groups was noted in single studies (analyses not displayed in a table as only one study met the criteria) comparing two alternative counselling interventions (Cinciripini 2010) (RR 1.05, 95% CI 0.63 to 1.76); health education versus usual care (Petersen 1992) (RR 1.02, 95% CI 0.75 to 1.38); or counselling as part of a broader intervention to improve maternal health (El-Mohandes 2011) (RR 1.46, 95% CI 0.97 to 2.19); or where social support was provided as part of a broader strategy to improve maternal health (Bullock 2009) (RR 0.96, 95% CI 0.51 to 1.81).

2.2.2 Six to 11 months: In examining trends in separate comparisons of studies, the effect bordered on a significant difference from zero between intervention and control groups in a separate comparison of counselling and usual care (six studies; average RR 1.33, 95% CI 1.00 to 1.77; Analysis 1.5), but not when counselling was compared with a less intensive intervention (three studies; average RR 1.08, 95% CI 0.83 to 1.40, see Analysis 2.5 . Additionally, there was not a significant difference between intervention and control groups when social support was compared with a less intensive intervention (two studies; average RR 1.09, 95% CI 0.83 to 1.42; see Analysis 8.4), or in single studies comparing two alternative counselling interventions (Cinciripini 2010) (RR 0.76, 95% CI 0.33 to 1.73) or contingent and non-contingent incentives (Heil 2008) (RR 3.24, 95% CI 3.24, 95% CI 0.35 to 29.82) (results not displayed as there was only one study in these comparisons).

2.2.3 12 to 17 months: In examining trends in separate comparisons of studies, there was a significant difference between the treatment and control in the two trials comparing counselling versus usual care (average RR 2.20, 95% CI 1.23 to 3.96, see Analysis 1.6), but

not in two trials where counselling was compared with a less intensive intervention (RR 1.25, 95% CI 0.71 to 2.20, see Analysis 2.6); or a single trial (McBride 2004) where a multiple social support intervention was compared with a less intensive intervention (RR 1.22, 95% CI 0.92 to 1.64, analysis not displayed in a table as only one study met the criteria).

2.2.4 18+ months: Two trials of counselling combined with other strategies, and compared with usual care, measured self-reported continued abstinence beyond 17 months postpartum (Secker-Walker 1994; Lawrence 2003). However, no significant difference was reported between intervention and control groups (average RR 1.25, 95% CI 0.57 to 2.73, see Analysis 11.7).

2.3 Smoking reduction: No significant biochemically validated reductions were reported in any comparisons, including a comparison of counselling with usual care (three studies; RR 1.11, 95% CI 0.54 to 2.26, see Analysis 1.8) or counselling with less intensive interventions (two studies; RR 1.35, 95% CI 0.98 to 1.87, see Analysis 2.8). No significant difference in biochemically validated reduction was seen in single study by Tuten 2012 (analyses not displayed in a table as only one study met the criteria) comparing incentives with usual care (RR 7.62, 95% CI 1.92 to 30.25), which also demonstrated a significant difference between intervention and control groups in mean cotinine (standardised mean difference (SMD) −0.87, 95% CI −1.36 to −0.39). El-Mohandes 2011, comparing counselling as part of a broader maternal health strategy similarly did not report a significant difference between intervention and control groups in mean cotinine (SMD 0.11, 95% CI −0.17 to 0.39). The difference was also statistically different from zero for one study (Sexton 1984) measuring mean thiocynate (SMD −0.29, 95% CI −0.44 to −0.15), but not for mean cotinine (SMD −0.05, 95% CI −0.14 to 0.05), see Analysis 1.10.

There was also no statistically significant difference in self-reported reduction in smoking (mean cigarettes per day) seen in comparisons of: counselling and less intensive interventions (two studies; SMD −0.11, 95% CI −0.30 to 0.09, see Analysis 2.9); or health education compared with usual care (two studies, pooled effect not calculated due to considerable heterogeneity I^2 = 76.8%, see Analysis 3.3). No difference in self-reported smoking (mean cigarettes per day) was also seen in several single studies (results not displayed as only one study met criteria), including: Hjalmarson 1991, which compared health education with a less intensive intervention (SMD 0.02, 95% CI −0.15 to 0.18); Tuten 2012 which compared incentives with usual care (SMD −0.23, 95% CI −0.69 to 0.23); LeFevre 1995 which compared feedback as part of a broader maternal health intervention with usual care (SMD 0.23, 95% CI 0.16 to 0.30); or Bullock 1995 which compared social support as part of a broader maternal health intervention with a less intensive intervention (SMD 0.15, 95% CI −0.34 to 0.64). The difference was not significantly different from zero in self-reported reduction (over 50%) in a single study (Hartmann 1996) which compared counselling and usual care (RR 1.59, 95% CI 0.98 to 2.57); or (Solomon 2000) which compared social support with a less intensive intervention (RR 0.96, 95% CI 0.64 to 1.44). Similarly, no difference in self-reported ‘any’ reduction in smoking was seen in a single study (Reading 1982) where feedback as part of a broader maternal intervention was compared with usual care (RR 0.95, 95% CI 0.42 to 2.18).

However, significant differences in self-reported reductions in smoking were seen in separate comparisons of: counselling and usual care for 'any self-reported reduction' (two studies; average RR 1.61, 95% CI 1.06 to 2.43, Analysis 1.9) and mean cigarettes per day (nine studies; SMD −0.25, 95% CI −0.46 to −0.03, Analysis 1.11); counselling and less intensive interventions (two studies; average RR 1.35, 95% CI 1.07 to 1.71, Analysis 2.7); feedback and usual care (two studies; average RR 1.69, 95% CI 1.24 to 2.31, see Analysis 5.2); and social support as part of a broader maternal health intervention with usual care in mean cigarettes per day (SMD −0.28, 95% CI −0.45 to −0.11, see Analysis 9.2). One single study comparing feedback and usual care (Valbo 1994) also reported a significant reduction in mean cigarettes per day (RR −0.63, 95% CI −1.03 to −0.24; results not displayed as only one study in comparison).

2.4 Infant outcomes: As a primary objective of this review is to determine if psychosocial interventions to support women to stop smoking in pregnancy have an impact on infant and maternal health outcomes, and large numbers are needed to detect relatively rare events, the pooled infant outcomes are included in this section of the review. These outcomes demonstrate the relationship between being randomised to a smoking cessation intervention and birth outcomes only, rather than the effectiveness of any particular intervention strategy.

2.4.1 Low birthweight: The pooled results of 14 trials which reported low birthweight (less than 2500 g) demonstrated a significant reduction (average RR 0.82, 95% CI 0.71 to 0.94; see Analysis 11.11). This pooled effect represents the following intervention strategies: eight counselling, two health education, one feedback, two incentives, and one social support. The number needed to treat for benefit (NNTB) in terms of low birthweight is 61, with a 95% CI of 38 to 204. Presented in a different way, nine out of every 100 participants in the control group experienced low birthweight births, compared to seven (95% CI six to eight) out of 100 for the intervention group. In contrast, there was no significant difference in three trials (two counselling and one feedback intervention) which reported infants born very low birthweight (less than 1500 g) (average RR 1.11, 95% CI 0.62 to 2.01, see Analysis 11.12).

In separate comparisons of studies, the effect was no longer significantly different from zero in smaller comparisons of counselling and usual care (six studies; average RR 0.87, 95% CI 0.70 to 1.08, see Analysis 1.12) or less intensive interventions (two studies; average RR 0.58, 95% CI 0.32 to 1.04, see Analysis 2.10), as large sample sizes are required to detect a significant difference in this outcome. There was no significant effect on the proportion of infants born low birthweight (less than 2500 g) in any of the single studies (results not displayed in tables) comparing: health education and usual care (Donovan 1977) (RR 1.10, 95% CI 0.66 to 1.84) or a less intensive intervention (Hjalmarson 1991) (RR 0.60, 95% CI 0.28 to 1.29); feedback and usual care (Haddow 1991) (RR 0.82, 95% CI 0.63 to 1.06); incentives and usual care (Tuten 2012) (RR 0.47, 95% CI 0.20 to 1.11) or an alternative intervention (Heil 2008) (RR 0.43, 95% CI 0.12 to 1.49); or social support and a less intensive intervention (Malchodi 2003) (RR 1.00, 95% CI 0.33 to 2.99). The effect remained non-significant in the three trials reporting very low birthweight infants (less than 1500 g) when separated into comparison of counselling and usual care (Analysis 1.13) and in a single study (Haddow 1991) comparing feedback and usual care (RR 0.90, 95% CI 0.35 to 2,32).

2.4.2 Preterm births: Pooled data from 14 studies reporting preterm births (less than 37 weeks' gestation) showed a statistically significant reduction in preterm births among women receiving psychosocial interventions (average RR 0.82, 95% CI 0.70 to 0.96; see Analysis 11.13), compared to women in the control groups. This pooled effect represents eight counselling, two health education, two feedback, and two incentives intervention strategies. The number needed to treat for benefit in terms of preterm births is 71, with a 95% CI of 42 to 341. Presented in a different way, eight out of every 100 participants in the control group experienced preterm births, compared to seven (95% CI six to eight) out of 100 for the intervention group.

In separate comparisons of studies, the effect was no longer significantly different from zero in comparisons of counselling and usual care (five studies; average RR 0.90, 95% CI 0.64 to 1.27, Analysis 1.14), counselling and less intensive interventions (three studies; average RR 0.82, 95% CI 0.47 to 1.42, Analysis 2.11), or feedback and usual care (two studies; average RR 0.60, 95% CI 0.28 to 1.29, Analysis 5.3), as large sample sizes are required to detect these relatively rare outcomes. Nor was a significant effect seen in comparisons which had only a single study (results not displayed in tables), including: health education and usual care (Donovan 1977) (RR 1.05, 95% CI 0.53 to 2.00) or a less intensive intervention (Hjalmarson 1991) (RR 0.76, 95% CI 0.32 to 1.80); or incentives compared with usual care (Tuten 2012) (RR 0.58, 95% CI 0.20 to 1.66) or an alternative intervention of non-contingent incentives (Heil 2008) (RR 0.38, 95% CI 0.11 to 1.30).

2.4.3 Mean birthweight: Pooled data from 19 studies reporting mean birthweight showed there was a statistically significant increase in mean birthweight of 40.78 g among women receiving the intervention (95% CI 18.45 to 63.10g, see Analysis 11.14), compared to women in the control group. The difference in mean birthweight was statistically significantly different from zero in subgroups of trials using counselling (n = 12) and incentives (n = 2) as the main intervention strategy, but was not significant in subgroups of trials using health education (n = 2), feedback (n = 2), or social support (n = 1) as a main intervention strategy.

In examining trends in separate comparisons of studies, the effect was borderline significant in comparisons of counselling and usual care (nine studies; MD 36.72, 95% CI 0.70 to 72.74, z = 2.00, P = 0.05, see Analysis 1.15), but not for comparisons of counselling and less intensive interventions (three studies; MD 56.02, 95% CI −31.46 to 143.50, see Analysis 2.12), or feedback and usual care (two studies; MD 79.43, 95% CI −53.05 to 211.91, see Analysis 5.4). There was no significant difference in mean birthweight in single studies (results not displayed in separate comparisons, only in comparison 1) comparing: health education and usual care (Donovan 1977) (MD −12.00, 95% CI −102.29 to 78.29) or less intensive interventions (Hjalmarson 1991) (MD 71, 95% CI −26.58 to 168.58); incentives and usual care (Tuten 2012) (MD 162, 95% CI −132.93 to 456.93) or non-contingent (alternative) incentives (Heil 2008) (MD 253, 95% CI-3.67 to 509.67); or social support provided as part of a broader maternal health intervention and a less intensive intervention (Malchodi 2003) (MD 28, 95% CI −152.48 to 208.48).

2.4.4 Perinatal deaths: Pooled data did not show a significant difference between intervention and control groups in perinatal deaths (four studies; average RR 1.13, 95% CI 0.72 to 1.77, see Analysis 11.15; although note that Valbo 1996 had a non-estimable effect), stillbirths (seven studies; average RR 1.22, 95% CI 0.76 to 1.95, see Analysis 11.16), neonatal deaths (four studies; average RR 1.15, 95% CI 0.44 to 3.06, see Analysis 11.17) or neonatal intensive care unit (NICU) admissions (four studies; average RR 0.78, 95% CI 0.59 to 1.04, see Analysis 11.18). These pooled effect size estimates, however, were based on small numbers of studies and had low power to detect clinically important differences. A number of trials also excluded women who had a perinatal death or a preterm birth from the study population.

In separate comparisons of studies, there was no significant effect seen in comparisons of counselling and usual care for: stillbirths (four studies; average RR 1.08, 95% CI 0.51 to 2.30, Analysis 1.17), neonatal deaths (three studies; average RR 2.06, 95% CI 0.61 to 6.92, Analysis 1.18), or NICU admissions (two studies; average RR 0.82, 95% CI 0.52 to 1.29, Analysis 1.19). There was unclear evidence in relation to counselling and usual care for perinatal deaths because the effect size for one of the two studies (Valbo 1996) was not estimable due to zero events in both groups, therefore pooled effect size not calculable (see Analysis 1.16). There was no significant effect observed for feedback and usual care in stillbirths (two studies; average RR 1.28, 95% CI 0.69 to 2.39, Analysis 5.5). There was no difference in single studies (results not displayed in comparison tables, only in comparison 1) comparing: counselling and a less intensive intervention (Ershoff 1989) in stillbirths (RR 1.84, 95% CI 0.17 to 20.04); health education and usual care (Donovan 1977) in perinatal deaths (RR 4.40, 95% CI 0.49 to 39.08); feedback and usual care (Haddow 1991) in perinatal deaths (RR 1.05, 95% CI 0.59 to 1.87) or neonatal deaths (RR 0.40, 95% CI 0.08 to 2.07); incentives and usual care (Tuten 2012) in NICU admissions (RR 0.75, 95% CI 0.45 to 1.25); or incentives and an alternative (non-contingent incentive) intervention (Heil 2008) in NICU admissions (RR 0.76, 95% CI 0.24 to 2.49).

NB. The following sections for outcomes 2.4.5 to 2.12 are narrative descriptions based on the findings reported in the studies, rather than on results of statistical synthesis

2.4.5 Other infant outcomes: Two trials (Cope 2003; Heil 2008) reported significant increases in fetal growth measures including fetal femur length and fetal abdominal circumference, and infant length, but no significant difference in head circumference between control and intervention groups. Two trials reported no significant difference in Apgar scores at one and five minutes post-birth (Cope 2003; Tuten 2012).

2.5 Mode of birth: None of the three trials measuring mode of birth by intervention group (Thornton 1997; Cope 2003; Tappin 2005) reported a significant difference in the rate of operative births by intervention group.

2.6 Breastfeeding: There were mixed results for the effect of interventions on breastfeeding. Two trials that measured breastfeeding initiation (Panjari 1999; McLeod 2004) showed no significant difference in initiation or duration of breastfeeding in control or

intervention arms. One trial of contingency management measured a significant effect on breastfeeding duration (Heil 2008) at both eight weeks and 12 weeks postpartum.

2.7 Psychological effects: Nineteen studies reported baseline psychological measures of interventions, reinforcing the findings from observational studies that there are significant psychological symptoms among many pregnant women who smoke. Up to 75% of pregnant women who smoked had current or previous psychological symptoms (Belizan 1995; Ershoff 1999; Cinciripini 2010; Ondersma 2012) and approximately 20% to 25% of women reported major depression based on CES-D scale assessments (Blalock 2005; Dornelas 2006; Bullock 2009; Cinciripini 2010; El-Mohandes 2011). Four studies identified baseline depression or stress as a 'mediator' or 'predictor' of continued smoking at follow-up (Crittenden 2007; Linares 2009; Stotts 2009; El-Mohandes 2011), suggesting depressive symptoms may be an 'independent contributor to the problem of continued smoking during pregnancy' (Linares 2009). Nine trials reported post-intervention psychological outcome measures and none reported any negative psychological effects. Six trials showed that smoking cessation interventions in pregnancy do not increase stress and psychological symptoms for women (Manfredi 1999; Panjari 1999; Aveyard 2004; Rigotti 2006; Solomon 2006; El-Mohandes 2011). Furthermore, three studies demonstrated that smoking cessation interventions have the potential to improve women's psychological wellbeing and self-esteem (Stotts 2004; Bullock 2009; Cinciripini 2010) and self-efficacy (Stotts 2004).

2.8 Impact on family functioning and other relationships: No studies reported measures of family functioning. Studies reporting analysis of social networks (Stotts 2009), suggest a significant interaction between smoking networks (household and other) or partner smoking (Bullock 2009) and continued smoking of participants in late pregnancy. Two studies reporting perceptions of partner (McBride 2004) and peer support (Hennrikus 2010) had mixed findings. Pregnant women reported less negative partner support through pregnancy, but this increased in the postpartum period (McBride 2004). Women in another study reported an increase in both positive and negative support from a peer including: comments about the woman's lack of willpower, trying to make them feel guilty, expressing anger about smoking and trying to scare women about smoking (Hennrikus 2010).

2.9 Participants views: Twenty-six trials included women's views of the interventions, 12 studies reported providers' views of the interventions and two studies reported measures of knowledge, attitudes or practice among pregnancy care providers.

Women's views: Twenty-nine studies reported that they addressed in the intervention issues identified as concerns by women when consulted for this review (Oliver 2001); including 'coping with stress and emotions', misconceptions about smoking risks, and feelings of guilt. Two studies described using interactive discussions to address issues of concern to individual women (Sexton 1984; Hennrikus 2010).

Three studies reported outcomes related to maternal weight gain. One study (Sexton 1984) reported a slightly higher mean weight gain in the intervention group (12.9 kg) compared to the control group (11.9 kg). Two other studies did not report weight gain by intervention exposure but reported that women with a 'high concern' about weight gain were less likely

to quit smoking during pregnancy or remain abstinent postpartum (Berg 2008), and another reported an increased weight gain of 2.8 kg in women who were abstinent compared to women who continued to smoke (P = 0.04), with an estimated 0.34 kg increase in weight gain for every 10% increase in smoking abstinence (Washio 2011).

Two studies explicitly mentioned consideration of women's views in developing the intervention (Albrecht 1998; Cinciripini 2010), and six studies described the involvement of women or community members in the development of the intervention (Windsor 1985; Belizan 1995; Gielen 1997; Albrecht 2006; Patten 2009; Eades 2012).

Thirty-two studies reported women's views about the content and delivery of the interventions. When asked, most women gave favourable feedback on the intervention and intervention materials (Baric 1976; Ershoff 1989; Belizan 1995; Bullock 1995; Lillington 1995; Secker-Walker 1997; Walsh 1997; Cinciripini 2000; Strecher 2000; Tappin 2000; Hajek 2001; Cope 2003; Tappin 2005; El-Mohandes 2011; Ondersma 2012), particularly audiovisual materials (Windsor 1993; Patten 2009; Ondersma 2012) and telephone support (Bullock 1995; Solomon 2000; Rigotti 2006; Bullock 2009). Women offered personal contact and a manual considered the personal contact the most important element and women appreciated printed materials much less if they were also offered a video, although the video combined with printed materials was no more effective than the printed materials alone (Secker-Walker 1997; Cinciripini 2000). Similarly, women offered motivational interviewing for relapse prevention were more likely to be satisfied than those offered a booklet, although the motivational interviewing was no more effective (Ershoff 1999. Women participating in a study in Ireland (Thornton 1997) reported the importance of providing the intervention in privacy, and suggested that telephone follow-up between visits and a video would have been helpful components in that intervention. Two studies reported that even if they did not like it, women expected to be asked about smoking from their care provider (Walsh 1997; McLeod 2004). Two trials using computer-assisted technology were rated positively (Strecher 2000; Ondersma 2012), but in an earlier trial women expressed concern about entering personal information into a computer (Ershoff 1999).

Despite positive feedback about the content of the intervention, several trials reported difficulty recruiting and retaining women's participation in the intervention (Loeb 1983; Secker-Walker 1994; Cinciripini 2000; Stotts 2004; Patten 2009), and many studies had low participation rates. In a multimodal intervention including counselling and nicotine replacement therapy (NRT), only 87/327 women in the intervention group participated in counselling and only 75 women used NRT (Hegaard 2003).

Offering additional group sessions for smoking cessation was generally a poorly accepted intervention even in otherwise successful trials (Loeb 1983; Windsor 1985), though one study reported groups were well accepted (Sexton 1984). Hypnosis was also a poorly accepted intervention in two studies (Sexton 1984; Valbo 1996). Five studies reported women's negative views of intervention components, including: use of carbon monoxide monitoring and prompt cards (Thornton 1997); some peer support behaviours (Hennrikus 2010), limited perceived efficacy of booklets (Moore 2002), and phone messages (Ershoff 1999).

Providers' views: Ten studies reported providers' views of the intervention. While providers' views about the interventions were generally positive, a recurrent theme was their concern about the time taken by the intervention (Kendrick 1995; Hajek 2001; Moore 2002; Campbell 2006) and the impact on their relationship with women (Hajek 2001; Valbo 1996). Sixty-five per cent of midwives asked to use a carbon monoxide monitor and provide 'stage of change'-based advice considered that this could not be achieved in the time available. This led to less than full implementation and variable motivation to promote smoking cessation counselling among staff in some studies (Kendrick 1995; Moore 2002), but not all (Windsor 2011). One of the reasons given for tailoring messages to 'stages of change' was to address providers' concerns that interventions may alienate women not ready to quit (Hajek 2001). A survey of general practitioners suggested the smoking status of the provider influenced participation in intervention delivery (Haug 1994). Despite these challenges, engagement and involvement of providers was identified as a critical element of implementation (Lowe 1997; McLeod 2004; Campbell 2006) and providers reported that they would like more involvement (Tappin 2000).

2.10 Measures of knowledge attitudes and behaviour of health professionals with respect to facilitating smoking cessation in pregnancy: Two trials reported positive effects of the interventions on midwives' understanding, confidence in delivering the intervention, optimism that the intervention may influence women's smoking behaviour (Lawrence 2003) and obstetric knowledge and practice (Secker-Walker 1992).

2.11 Cost-effectiveness: Four studies reported that the interventions were cost-effective using a variety of measures. Pregnancy-specific, self-help materials were more cost-effective than standard smoking cessation information or self-help materials (Windsor 1985). Specific estimates include: a benefit-cost ratio of 2.8:1 (Ershoff 1990); 1 (non-smoker): $84 (Parker 2007); and an average cost of $56 per person for each smoking cessation intervention, and $299 to produce a non-smoker at the end of pregnancy (Dornelas 2006).

2.12 Adverse effects: Three studies that measured whether women increased their smoking following exposure to the intervention showed mixed results. One trial reported a slightly lower level of cotinine in the intervention group, compared to the control group (Tappin 2005), another reported no difference in self-reported smoking (Hjalmarson 1991), and another reported an increase in smoking among women who did not quit (Haug 1994).

DISCUSSION

Summary of main results

Studies in this review demonstrate that psychosocial interventions can support women to stop smoking in pregnancy. Importantly, the interventions do not appear to have any negative physical or psychological effects, are positively received by most women, and may improve psychological wellbeing. Incentives had the largest effect size, but only when provided intensively. Counselling was effective when provided in conjunction with other strategies or tailored to individual women, but it is unclear whether any types of counselling

are more effective than others. Peer support appeared to be effective, but only when provided as a targeted intervention and not as part of a broader intervention to improve maternal health. It is unclear whether partner-assisted support helps women to quit. Feedback appeared to be effective when combined with other strategies, such as counselling, and compared with usual care, but not less intensive interventions. Health education was not effective in separate comparisons, but the pooled effect was significantly different from zero in subgroup analyses. Among women who received psychosocial interventions there was a significant reduction (18%) in preterm births (less than 37 weeks' gestation), the proportion of babies born low birthweight (18%) (less than 2500 g), and a significant increase in mean birthweight of 41 g. Using data from this review, the NNTB to prevent one infant being born low birthweight is 61 (95% CI 38 to 204); and 71 interventions (95% CI 42 to 341) to prevent one infant being born preterm. These findings provide strong and clear evidence about the risks of smoking during pregnancy, supporting recommendations that it may be an integral part of strategies to reduce preterm births (Green 2005a). Given the benefits of stopping smoking in pregnancy for the woman and her infant, this would seem to be an important intervention, particularly when applied at a population level. However, it remains unclear from dissemination trials whether interventions are effective when implemented into routine pregnancy care.

Among the subgroups of 'main intervention strategies' categorised in this review, the four studies that included use of incentives had the strongest effect. Three trials that compared provision of intensive incentives with usual care (Tuten 2012), incentives and social support compared with a less intensive intervention (Donatelle 2000), and contingent incentives compared with non-contingent incentives (Heil 2008), were significantly different from zero. A three-armed trial, which included a non-contingent arm (Tuten 2012), also showed a significant effect. These non-contingent comparisons provide a 'time-matched' alternative comparison of similar intensity, which helps to identify if it is the 'additional assistance' or incentives which are effective (Mantzari 2012). The effect was also significantly different from zero in the pooled results of three counselling interventions that included lottery tickets (Sexton 1984; Walsh 1997; Parker 2007). These findings are consistent with other reviews of financial incentives in pregnancy (Higgins 2012) and the mechanisms for the effectiveness of incentives for reducing substance abuse more generally has been well documented (Higgins 2008b). However, the results of the incentives trials should be considered with caution as they are based on few trials with a very small number of women (less than 500), all of whom were in the US. Additionally, there was no effect from one trial of 'low intensity' incentives ('CM Lite') combined with an interactive computer-generated counselling program (Ondersma 2012), which relied on women initiating contact with the research team for urine cotinine testing, and provided a maximum of only five verification and 'incentive' interactions, with less than half the women in this arm submitting even one urine test. Interestingly, women in this four-armed trial who received the interactive computer-generated counselling program alone were more likely to quit than women who received the combined incentive and computer-counselling intervention (see Ondersma 2012).

Pooled results of interventions in which counselling was the main intervention strategy showed a significant effect in abstinence in late pregnancy. However, in separate

comparisons, the effect of counselling was only significantly different from zero when combined with other strategies or tailored to individual needs. There was no significant difference seen when one type of counselling (cognitive behavioural therapy (CBT)) was compared with traditional health education (Cinciripini 2010), or when counselling was provided as part of a broader intervention to improve maternal health (El-Mohandes 2011). Group interventions were generally not well accepted in this population of pregnant women, despite being reported as a potentially well accepted intervention in the general population (Bauld 2010). Feedback was effective when combined with other strategies such as counselling, and only when compared with usual care. Findings from this review support recommendations that pregnant women may need more support than just brief advice or health education (Coleman 2004), as it was unclear whether health education alone helped women to quit. However, there was a significant pooled effect among the three trials of health education when two studies were removed providing only self-help materials or an audiotape with no additional personal advice, which is similar to findings in another review (Murthy 2010), and which concluded that apart from brief physician advice, there was limited clarity on the duration of interventions required by other professionals.

Social networks have been suggested as a major cause of relapse (Nguyen 2012b), and a systematic review of qualitative studies identified partners as one of the most important influences on women's smoking and relapse (Flemming 2013). In this review, peer support appeared to be effective when provided as a targeted intervention, and when social support was provided as part of a broader intervention to improve maternal health, but not when [telephone] support was compared with a less intensive intervention. It is unclear from the single trial of partner-assisted support (McBride 2004) that this strategy can help women to stop smoking. Furthermore, counselling interventions that included support for partners to quit also did not show a significant effect, and there were mixed results in the four studies reporting associations between quitting and partner smoking. Mixed results have similarly been reported in a systematic review of five randomised controlled trials (Duckworth 2012), and another review of seven studies reported a non-significant effect (Hemsing 2012), concluding that, "Despite the importance of partner smoking, there are very few effective smoking cessation interventions for pregnant/postpartum women that include or target male partners". This raises questions about arguments that a major reason for the modest effect of smoking interventions is the focus on individual behavioural change rather than acknowledging social factors and focusing on external motivation (Okoli 2010). Additionally, feedback from women demonstrates the support from both partners and peers can sometimes be negative, which raises concerns about the potential risks for vulnerable women in physically or emotionally violent relationships. Evidence from this review suggests that while partner and peer support may be important factors influencing smoking behaviour, eliciting peer and partner support that is positive and can actually support women to stop smoking in pregnancy is a challenge.

The lack of a clear difference in effect seen by increasing intervention intensity challenges the validity of the assumption that ever-increasing the intensity of support will increase quit rates, as has been reported by other commentators (Lando 2001), and supports views that there may be an upper limit of what women accept (Chapman 2012). Newly included studies in this review had lower effect sizes than older studies in the previous version, despite a

general trend towards higher intensity interventions in more recent trials. It may be that women who continue to smoke are not getting ‘more hard core’ but that there are many options already available and additional strategies may not be offering a lot of extra benefit, as risks of smoking during pregnancy, due to health education campaigns, are well known in high-income countries (Campion 1994; Eriksson 1996; Eriksson 1998). One study found relapse within the first two weeks was predictive of continued abstinence, and suggested this indicates that intensive support during the earlier period of nicotine withdrawal may be an important component of interventions (Higgins 2006b).

Studies in this review suggest the effect during pregnancy continues into the postpartum period, up until approximately 18 months postpartum, though the smaller effect size shows many women who did quit during pregnancy relapse postpartum. Some suggest that many pregnant smokers simply suspend their smoking for the duration of pregnancy as opposed to quitting altogether or they commit to ‘temporary abstinence’ for pregnancy (Stotts 1996; Lawrence 2005a; Flemming 2013), but these relapse rates are similar for non-pregnant women (Bombard 2012). Rather than being disappointed by these limited effects, some authors suggest healthcare workers should focus on the positive aspects of these findings and reinforce the positive decisions many women are making when pregnant (Hotham 2008). High post-pregnancy relapse rates have led to some commentators calling for an extension of the period of support for women to stop smoking (Coleman-Cowger 2012). Hjalmarson 1991 reported a high proportion of women abstaining from smoking during their hospital stay for the birth, and suggests this may be an opportunity for intervention to reduce the risk of postpartum relapse. These findings suggest there may be a need for different approaches to promote continued abstinence postpartum, including focusing on the benefits for the mother, without excessive emphasis solely on the benefits for the baby.

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While results are mixed, studies in this review suggest there is a reduction in self-reported smoking but not biochemically validated smoking. Continued nicotine and cigarette exposure may have effects on other outcomes not measured in this review. The level of reduction required to improve health outcomes remains unclear (Secker-Walker 2002a). One study analysing data from Kendrick 1995 suggested that reduction in smoking to fewer than eight cigarettes a day is necessary to avoid reduction in infant birthweight (England 2001), and estimated approximately a mean birthweight which was 200 g higher among women who quit smoking after enrolment, compared to women who continued to smoke during pregnancy. Therefore, extrapolating these data to this review, if all women in the intervention groups stopped smoking and none of those in the control group did, the expected mean birthweight difference would be about 200 g, rather than 41 g. With an absolute difference of six in every 100 women stopping smoking, 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 comparison groups, in line with self-reported changes.

There was no evidence from studies in this review that smoking cessation increases the rate of caesarean section (Thornton 1997; Cope 2003; Tappin 2005), contrary to concerns raised by women about the effects of increased fetal size (Sexton 1984). One observational study modelled increases in birthweight (from 2450 g to 2550 g) in Guatemala and found an

increased risk in caesarean section due to obstruction of eight in every 1000 cases, but this was outweighed by a reduction in caesarean section due to fetal distress of 34 per 1000 cases (Merchant 2001).

Women who smoke are less likely to initiate breastfeeding (Amir 2001a; Amir 2002a; Donath 2004; Einarson 2009; Disantis 2010b), and breastfeed for shorter duration (Sayers 1995; Horta 1997). Therefore, supporting women to initiate and maintain breastfeeding should be considered an important part of any intervention in this population group, and reported as an outcome in intervention studies. Studies in this review had mixed reports of the effect of smoking cessation interventions on breastfeeding (Panjari 1999; McLeod 2004; Higgins 2010b).

Studies in this review (Cinciripini 2000; Rigotti 2006) support a recent qualitative study that concluded “Pregnant women with mental disorders appear more motivated…yet find it more difficult, to stop smoking” (Howard 2013), and other studies that report higher rates of quitting among women with higher self-esteem and self-efficacy (Massey 2013). For these reasons, healthcare workers have reported difficulty addressing smoking with pregnant women (Valbo 1996). Qualitative studies have identified concerns about adverse effects of quitting, or increased guilt over continued smoking, on women’s psychological wellbeing and capacity to cope with adverse circumstances, with follow-on effects to the women’s families (Oliver 2001; Valbo 1996; Flemming 2013). In earlier versions of this review, it has been difficult to assess the effect of interventions on depression, as, despite the strong associations with poor mental health and smoking in pregnancy, women with mental illness were frequently excluded from trials. However, mental wellbeing has been addressed in more recent trials and, contrary to the above concerns, there is no evidence from studies in this review that there are any negative psychological consequences from delivery of individual smoking cessation interventions in pregnancy. Rather, feedback from women from studies in this review was positive with women feeling that “somebody cared” (Bullock 1995). Three studies have shown that provision of psychosocial support can in fact improve women’s psychological wellbeing, which has the potential to have enormous benefits for the mother, the infant, and the whole family (Bullock 1995; Stotts 2004; Cinciripini 2010).

In earlier versions of this review, there appeared to be little evidence of the involvement of pregnant women who smoked or caregivers being involved in the design and evaluation of interventions (Oliver 2001). However, there has been increasing discussion of women’s preferences for cessation support in recent years (Ussher 2004). Studies included in this review suggest women prefer individual personal contact, particularly by telephone, though studies inclusive of telephone support in this review did not appear to be significantly more effective. Rates of satisfaction with interventions delivered by computers or mobile phones were generally positive, but again there was no evidence in this review that the use of these technologies increased the rate of abstinence in late pregnancy. Nevertheless, acceptability of an intervention is an important aspect of population-based interventions.

Some evidence suggests that women in high-income countries are more likely to smoke to control their weight, and that female body image is extensively targeted by tobacco

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marketing campaigns (Pomerleau 2000; CDCP 2002; Levine 2006), although concerns about gaining weight through stopping smoking during pregnancy were not raised by any of the women consulted for this review (Oliver 2001). The systematic review of qualitative studies of women smoking in pregnancy (Flemming 2013) found two studies mentioning weight gain as a factor in considering smoking cessation. Hotham 2002 found that fear of weight gain was a barrier to smoking cessation for some women and Lawson 1994 found some women used smoking to cope with weight gain. Three studies in this update of the review (Sexton 1984; Berg 2008; Washio 2011) address weight gain. Only one study reported a small increase in weight gain among women in the intervention group (Sexton 1984). This concern should be considered in interventions, with interventions available to support women to avoid unwanted weight gain (Farley 2012). It should be noted that weight gain in pregnancy may not necessarily be a negative outcome for many women, particularly women in low- and middle-income countries. The association between smoking and glucose intolerance, a potential mechanism for these effects, remains unclear (Wendland 2008). A Cochrane systematic review of interventions for preventing weight gain after smoking cessation mentioned neither pregnancy nor breastfeeding (Parsons 2009) and therefore cannot be relied upon for evidence relevant to a population where weight may fluctuate for normal physiological reasons and where babies may be sensitive to drug treatments in utero or when breast-feeding.

Public health impact of the interventions

Importantly, psychosocial interventions to support women to stop smoking during pregnancy reduce the population-attributable risk of preterm birth (by 18%) and low birthweight (by 18%), with approximately 71 interventions required to prevent one preterm birth and 61 interventions to prevent one infant being born with low birthweight. As such, smoking cessation is recommended as a key recommendation for reducing the risk of recurrent preterm birth (Chang 2012; Cypher 2012). The number of interventions needed to treat for benefit is extraordinarily low, given the serious clinical consequences of these adverse outcomes. Based on the effectiveness published in the 2004 version of this Cochrane review, if 75% of pregnant women in the US disclosed their smoking status and all received the intervention, then it has been estimated that 31,573 (6%) ‘new quitters’ would be gained and the prevalence of smoking in pregnancy would potentially decrease from 16.4% to 15.6% (Kim 2009b). While these effect size estimates may appear modest, the response to interventions is similar to that of psychosocial interventions to reduce type 2 diabetes mellitus, hypertension and asthma, all of which are conditions that involve a combination of medical illness, personal choice and environmental factors (McLellan 2000). Importantly, the high prevalence of these conditions in the community means that interventions with a modest effect size estimate can have a substantial impact on population health if widely implemented.

Economic costs

Studies in this review report variable cost-effectiveness measures and costs of interventions. Based on a NNTB of one quitter for each 19 interventions, our cost estimates ($US1,064) based on $US56 per interventions is significantly higher than the $US299 reported in Dornelas 2006. However, even with higher estimates, other studies that evaluated the cost-

effectiveness of these interventions clearly show that there is a ‘rapid return on investment’ (Lightwood 1999). Early studies estimated the smoking-attributable maternal costs during pregnancy alone ranged from $US150 million to $US995 million in the early 1990s (Adams 1998), with 2004 estimates of $US122 million or $US279 per smoker (Adams 2011). Estimated birth and first year costs for both mothers and infants attributed to smoking were $1142 to $1358 per smoking woman over a decade ago (Aligne 1997; Miller 2001; Adams 2002). Infant costs are approximately 10 times maternal costs, accounting for 90% of costs in the first year. Low birthweight produces the highest economic burden as it is the most common adverse outcome (Hueston 1994; Miller 2001). A 1% drop in smoking prevalence was estimated to prevent approximately 1300 low birthweight live births and save $US21 million in direct medical costs (Lightwood 1999). Inclusion of smoking attributable and environmental tobacco smoke exposure costs in birth and childhood conditions, pushes estimates into the billions (Aligne 1997), and long-term costs due to chronic disease up to $US57 billion in 1997, in the US alone (Bartlett 1994). An economic evaluation of data provided in the 2009 version of this review estimated the societal benefits from these interventions could be in excess of 500 million pounds sterling per annum in the United Kingdom (Taylor 2009). In contrast with that finding, the quality of diet in pregnancy (in high-income countries) has not been shown to affect the mean birthweight of infants over 32 weeks’ gestation (Rogers 1998). While there is variation in reported costs dependent on conditions included and changing healthcare costs (Ayadi 2006), it is clear that healthcare costs due to smoking in pregnancy are substantial.

Impact on health inequalities

In high-income countries, the reduction in rates of smoking has not been as substantial in women experiencing psychosocial disadvantage, as for the general population. Hence smoking has been identified as a major preventable cause of the health inequalities experienced by women who suffer psychosocial disadvantage, including psychological illness, low educational attainment, young early motherhood, lack of social support, and limited employment (Graham 2006). Some of the reasons may be that disadvantaged women are unable to change the environmental factors that increase the risk of smoking; population-based interventions may have the effect of being judgemental and alienate women; and women are unable to change generational patterns (Graham 2009). Several authors have suggested that women who continue to smoke in late pregnancy would be unlikely to benefit from the usual antenatal interventions, which rely on women’s capacity for self-initiation, self-control and social resources, which they suggest helps to explain why it remains such an intractable problem (Wakschlag 2003; Pickett 2009) and that individual interventions alone are unlikely to impact on inequalities (Baum 2009). However, subgroup analysis of studies included in this review refutes these arguments and suggests that individual interventions provided during pregnancy have similar effectiveness among women with low socio-economic status (SES), as women who are not classified as having low SES, despite several studies reporting a lower effect among participants with lower SES (Baric 1976; McLeod 2004; Pbert 2004; Rigotti 2006). This supports qualitative studies that suggest individual support, which is positive rather than punitive, has an important role (Bond 2012). Therefore, individual psychosocial support should form a part of the tobacco control ‘package’ to reduce smoking during pregnancy, in conjunction with population-based

measures, which have also been shown to have a significant impact on birth outcomes (Adams 2012; Cox 2013) and reducing smoking in disadvantaged populations (Thomas 2008).

The pooled results were not significantly different from zero in eight studies, which were developed predominantly or specifically for ethnic and aboriginal minority women, including African-American women (Gielen 1997; Manfredi 1999; El-Mohandes 2011; Ondersma 2012), African American and Hispanic women (Lillington 1995), Hispanic women (Malchodi 2003), Alaskan Native Women (Patten 2009) and Australian Aboriginal and Torres Strait Islander women (Eades 2012). This is despite primary authors in several studies reporting subgroup analysis of higher quitting rates among African-American and Hispanic women than other women (Petersen 1992; Windsor 1993; Pbert 2004; Parker 2007). These studies tended to involve women more in the development of the intervention and all used several recommended strategies to tailor the intervention (American Legacy Foundation 2012) for initiatives that aim to address the disparities in tobacco use; including hiring culturally competent staff, conducting formative research to identify community needs, piloting and field-testing programs, ‘cultural tailoring’ of smoking cessation resources, and collaborating with key stakeholders and community organisations. Three studies adapted ‘SCRIPT’ materials in the US (see Windsor 2011), which include: ‘asking’ about smoking status; ‘advising’ women to quit; ‘assisting’ women to quit by providing advice on skills and materials such as video’s and self-help materials; and arranging for follow-up by referral at future appointments. Two studies developed audiovisual resources for African American (Ondersma 2012) and Alaskan Indian (Patten 2009) women, and these resources received positive feedback. Despite interventions being reported as feasible and acceptable to communities, there were challenges with implementation and few demonstrated an effect size estimate that was significantly different from zero. Further suggestions included trying to recruit from different settings and including elders to improve recruitment, and recognising the importance of broader social interventions for potentially reaching a larger proportion of pregnant women (Patten 2009). Other reviews of interventions in non-pregnant aboriginal peoples have demonstrated interventions can be effective (Carson 2012), and suggest mobile phone technology may be a feasible intervention strategy (Johnston 2013). Only one study included women using smokeless tobacco products, and identified conflicting beliefs about the effect of these products during pregnancy and the primary change recommended by participants in the study was to provide “more objective” information on the risks of *Iqmik* (smokeless tobacco) use for the infant (Patten 2009).

Most interventions have been developed in high-income countries and there is very limited information about the effectiveness of psychosocial interventions for individual women in low- to middle-income countries (Murthy 2010). The restrictions on tobacco marketing in high-income countries may result in an increase in tobacco marketing companies in low- and middle-income countries. Smoking has the potential to undermine health improvements in low- and middle-income countries and a range of interventions are needed to manage the emerging epidemic (Lopez 1994; Abdullah 2004). However, given the modest effect size estimate of individual interventions, population-based tobacco control strategies are an

urgent priority, as there is now a brief ‘window of opportunity’ to prevent the increase of smoking among women in many low-income countries (Chomba 2010).

Translation of evidence into practice

The first trials of anti-smoking interventions during pregnancy were published more than 30 years ago (Baric 1976; 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). Since then, attempts at widespread implementation of psychosocial interventions to support women to stop smoking in pregnancy have demonstrated many of the challenges of translating ‘evidence into practice’, particularly non-pharmacological evidence (Windsor 1998; Windsor 2000b; Lowe 2002; Moore 2002; NICS 2003; McLeod 2004; Herbert 2005; McDermott 2006; Abatemarco 2007; Manfredi 2011).

Studies in this review can be conveniently categorised within a framework for translation of research into practice (Nutbeam 2006), which suggests progression through several stages from; problem definition (descriptive studies) and formative research for intervention design; intervention efficacy research; to implementation in routine/normal settings (effectiveness research); dissemination across several settings; and institutionalisation (as interventions are provided as part of routine care). Many studies in this review clearly defined the problem and conducted formative research for intervention development (Katz 2008; Gilligan 2009), particularly interventions developed for vulnerable women, including young women (Albrecht 1998; Albrecht 2006). The modest but significant efficacy of psychosocial interventions provided by researchers has been well demonstrated by studies in this review, including counselling interventions.

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. An example in these trials was 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 implemented into routine care (Windsor 2011), used in Baltimore with peer counsellors who received minimal training instead of trained health educators (Gielen 1997), adapted for Alaskan Native women (Patten 2009) and transferred to other countries (Lowe 1998a; Lowe 1998b), the effectiveness was much lower. An analysis of health promotion trials has concluded that where the providers are also the researchers (more likely in single centre studies than multicentre studies), they appear to be better providers for influencing behavioural outcomes and about the same as other providers for other outcome domains (Oliver 2008a). The larger, multicentre trials may therefore be a more accurate representation of implementing policy than smaller, single centre trials. In this review, interventions provided by usual care providers were as effective as interventions provided by researchers, including counselling interventions. However, there was substantial heterogeneity in sensitivity analyses of trials provided by usual care providers in this review, which supports the views that there are many variables to consider when implementing interventions in routine settings (Hoddinott 2010).

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Despite evidence of efficacy and effectiveness, dissemination trials of counselling interventions into pregnancy care settings suggest challenges to translating this efficacy research into routine practice and policy. Data from the five dissemination trials that targeted the intervention at the organisational level, demonstrated significant effects in terms of increased implementation of interventions in routine practice, although challenges were reported and this did not translate into a significant reduction in rates of smoking among women in the intervention arms of these studies. One study that provided clinics with resources and referral options reported an increase in women's recall of receiving interventions (Manfredi 1999). A significantly higher program implementation rate was reported when using an intervention based on Rogers' 'Diffusion of Innovation' theory (43% compared with only 9% implementation in the control group after one year), but there were no data on the impact on smoking outcomes (Lowe 2002). An increased uptake of the intervention by staff was demonstrated using 'active' dissemination compared to a simple mail-out of information (Cooke 2001), but not at levels sufficient to have a significant impact on smoking outcomes in women (Campbell 2006), which was similar to other dissemination trials reporting smoking outcomes (Pbert 2004; Windsor 2011). Another nonrandomised study compared the use of the RE-AIM dissemination model to increase the reach, efficacy, adoption, implementation, maintenance of interventions (Lando 2001) and concluded that multi-faceted approaches using strategies from each intervention were most likely to improve implementation.

There are a number of possible explanations for the limited effect in dissemination trials. Firstly, many of the studies that recruited individual women did not provide information on the number of women who were eligible for inclusion or were approached to take part in trials. The 'participation rate' would have provided useful information about the general 'acceptability' of the intervention, as well as the degree of 'selection bias' in the study population (Sedgwick 2013). Among those studies that did report the proportion approached and recruited from the total 'eligible' population, low participation rates were often reported. Therefore, some of the evidence in this review is from selective samples of the population of women who smoke during pregnancy. Women participating in studies (Mullen 1997) were more likely to be in contemplative and preparation stages of change, be 'recent quitters' and have a lower gestational age, compared to women not participating studies (Ruggiero 2003). The majority of women categorised as 'Black', 'White' and 'Native American' did enrol in the study, while women categorised as 'Hispanic' were less likely (51.6%) to enrol and the majority of Asian women did not enrol (Ruggiero 2003). Dissemination trials and 'cluster trials' that randomise clinics or providers are therefore likely to provide a more accurate estimate of the likely effect in a non-selective population of pregnant women.

Secondly, the implementation of interventions under conditions less stringent than an individually-randomised controlled trial may be reduced, which may limit exposure of the intervention group to the intervention, or components of the interventions (Walsh 2000). Several trials implemented in routine care settings by midwives (Moore 2002; DeVries 2006), doctors (Valbo 1994; Walsh 1997), and routine clinic staff (Kendrick 1995) reported difficulties with implementation. Some of the issues included: variable perceptions of smoking cessation as part of the providers' role (DeVries 2006), stating they were too busy and did not have enough time to complete the intervention (Dunkley 1997; Haines 1998;

Hajek 2001; Valanis 2001b; Leviton 2003), difficulty recruiting providers to the study (Lawrence 2003), providers reporting pessimism about the efficacy of the intervention (Moore 2002), and lack of acceptability of resources (Lowe 1998a; McBride 1999). Several studies reported positive 'facilitators or enabling factors' associated with implementation. Proposed criteria for interventions to be implemented into routine maternity care include: having program materials readily available; feasible provider time commitments; clear training requirements; minimal organisational and administrative barriers (Strand 2003); and program components that are acceptable to providers and women (Haynes 1998; Cabana 1999; Grol 1999; Walsh 2000; Cooke 2001a). Written resources, a written protocol to identify staff responsibilities, and reimbursement have also been suggested as other strategies to improve implementation (Hartmann 2007). A significant increase in both intervention delivery and smoking outcomes was seen in a cluster trial that supported staff with training based on national guidelines, a clinic management system, and establishment of program boards (Pbert 2004). Suggestions to overcome the barriers in a busy clinic setting included increasing the use of referral services and technology to reduce demand on clinicians' time (Moore 2002). Subsequently, use of referral services such as 'quitline' (Williams 2010) and technology-driven interventions have gained popularity in the past five years (Tsoh 2010; Naughton 2012; Ondersma 2012). In the United Kingdom (UK), most services reported use of 'quitline' referral services (Williams 2010). One excluded (non-randomised) study in South Australia (Bowden 2010), describes positive experiences and perceptions of staff in implementing a 'Smoke-free Pregnancy' Project involving brief '5A's' intervention and referrals to 'quitline'. While use of materials such as self-help materials and technological aids did not appear to significantly increase rates of smoking abstinence in this review, they may help to increase the feasibility and reduce the costs of delivering interventions.

A third possible explanation for the limited effect seen in implementation is that trials that involve broader implementation across the system and provision by usual care providers (effectiveness studies), may result in greater exposure of the comparison group to the intervention. While the difference was not significantly different, the pooled effect size was lower among trials that were assessed as having a high risk of contamination in this review. One study illustrated this effect by including a 'historical control' group, in which only 4% stopped smoking, compared to 10% who stopped in the randomised 'concurrent control' and 12% in the intervention group who stopped (Windsor 2011).

Institutionalisation, where interventions are part of routine care, is the final stage of the evidence-practice translation process. Australia, Canada, the UK and the United States (US) have developed guidelines recommending all pregnant women receive interventions to promote smoking cessation in pregnancy (Aveyard 2007; Fiore 2008). However, studies of clinicians practice in Canada, the US and Argentina suggest that while the majority (50% to 100%) 'ask' about smoking status, rates of assistance with effective strategies to support women to stop smoking are very low (11.5% to below 50%) (Floyd 2001; Hartmann 2007; Tong 2008; Mejia 2010; Okoli 2010). Strategies to address the deficiencies identified in these surveys are reported (Chapin 2004) and several studies in this review have trialled strategies to adapt these guidelines and improve implementation into routine settings (Tsoh 2010; Ondersma 2012). A recent survey suggests attitudes may be shifting in the UK about

the provision of advice and support, but not the efficacy of the interventions (Beenstock 2012). A recent survey of women giving birth in Australia suggests there has been a significant increase in the provision of smoking advice and support in routine pregnancy care from 2000 to 2008, though half of smokers still did not receive the full complement of advice and support according to state guidelines, and there was marked variability according to where and from whom women received antenatal care (Perlen 2013).

Strategies to increase disclosure of smoking status—Barriers to implementation have been identified at each step of service provision in relation to support for smoking cessation in pregnancy. This includes detection of women who smoke so they can then be offered a supportive intervention (Tappin 2010). As previously noted, self-reported disclosure of smoking status can be variable. Disclosure is influenced by several factors, including the stigma and guilt associated with smoking in pregnancy, the relationship between the care provider and the way the woman is asked about smoking. In general, it appears that less direct questioning increases disclosure, for example, changing the question format from 'yes' or 'no' to a series of multiple choice questions and asking women to best describe their smoking status (Mullen 1991). There is some evidence from the literature around broader substance use in pregnancy, that asking about substance use of family members (e.g. secondhand smoke exposure) first (Chasnoff 2005; Chasnoff 2007), and leaving sensitive probing personal questions until later in the interview, when a rapport has been established. The rationale is that this provides an opportunity for the woman to gauge the response of the healthcare provider and feel more confident disclosing her smoking status. In the UK, 'opt out' carbon monoxide screening has been proposed to increase disclosure (Tappin 2010; Bauld 2012). Biochemical validation of smoking status is an understandable pre-requisite prior to receipt of contingent incentives, to provide feedback on cotinine levels as a motivational aid; or in the context of a smoking trial. However, the benefits and rationale for not accepting women's disclosure outside these contexts is unclear and was not well received by women in this review (Thornton 1997). Furthermore, there are questions about the accuracy of carbon monoxide monitoring among women with high secondhand smoke exposure (McLaren 2010), and whether there are any adverse effects from routine screening, such as increased domestic violence or effects on mental health.

Adverse effects of interventions

While psychosocial interventions do not pose the same risks to fetal health as pharmacological agents in pregnancy, there are concerns about the potential unintended consequences of these interventions that aim to encourage pregnant women to stop smoking (Burgess 2009). The potential adverse effects identified in this review include: increased smoking; unhelpful peer or partner support; stigmatisation; and nicotine withdrawal.

Despite the number of studies reporting smoking reduction, only three studies reported rates of women who increased smoking by intervention group, and these showed mixed results (Hjalmarson 1991; Haug 1994; Tappin 2005). It would be helpful for studies to measure any increased smoking, particularly in light of recent qualitative evidence that suggests anti-smoking advice may increase resistance to smoking messages for some women (Bond 2012; Flemming 2013).

There has been an increasing focus on the partners and peers of pregnant women, with the additional aim of facilitating cessation by the women themselves (Stanton 2004; Gage 2007). In some cases this reflects cultural and demographic patterns of smoking, where smoking rates are still highest amongst men (Loke 2005; Kazemi 2012); in others, interest in environmental barriers that hinder smoking cessation has led to an understanding of the influence of a woman's social networks on smoking behaviour (McBride 2004). Studies in this review suggest that there are both positive and negative aspects to partner and peer assistance with supporting women to stop smoking in pregnancy (McBride 2004; Hennrikus 2010). This legitimises concerns about the potential adverse effects on relationships and women's position (Greaves 2007a). Therefore, these risks should be taken into consideration when developing interventions involving partners or peers, particularly in subpopulations or regions where protection for women's rights are less than optimal. Pro-active measures to identify women at risk and ensure their safety should be implemented as part of interventions involving peer or partner support (Greaves 2007b).

No studies measured the impact of interventions on stigmatisation of women. However, studies of psychological impact do not suggest there are any negative effects, and individual psychological support may be beneficial (Stotts 2004; Bullock 2009; Cinciripini 2010). Nevertheless, public health professionals must remain ever vigilant when implementing population-based measures, as policies can disrupt highly complex systems and unintended consequences of tobacco policy may differentially impact on vulnerable population groups (Healton 2009). Stigmatisation research suggests that such policies may have unanticipated outcomes for vulnerable mothers, including decreased mental health; increased use of alcohol or cigarettes; avoidance or delay in seeking medical care; and poorer treatment by health professionals (Moore 2009). This stigmatisation may be compounded for some population groups, such as racial minority groups (Bond 2012; Flemming 2013). Few studies reported the effect of nicotine withdrawal, which is a gap given that these withdrawal effects may be more acute during pregnancy (Ussher 2012a; Ussher 2012b).

Overall completeness and applicability of evidence

Most of the included studies were carried out in high-income countries and it is not clear whether the results are applicable in other contexts. Given the rapidly evolving nature of the smoking epidemic in low- to middle-income countries, this is a major gap in the current body of evidence.

Many of the studies that recruited individual women did not provide information on the number of women who were eligible for inclusion or were approached to take part in trials (i.e. the participation rate), which would have provided useful information about the general 'acceptability' of the intervention, as well as the degree of 'selection bias' in the study population (Sedgwick 2013). Among those studies that did report the proportion approached and recruited from the total 'eligible' population, low participation rates were often reported. Therefore, some of the evidence in this review is from selective samples of the population of women who smoke during pregnancy and may affect the applicability of the evidence into routine settings.

The review includes a relatively large number of studies focusing on educational and counselling interventions but relatively few focusing on other approaches, such as the use of incentives and peer support. Furthermore, there are limited data for some outcomes (e.g. some perinatal outcomes, family functioning).

Quality of the evidence

The studies included in the review were of mixed quality and there is a substantial level of heterogeneity amongst the trial results (I^2 often greater than 50%); hence, we would emphasise the need to consider the Risk of bias' tables and urge caution when interpreting the combined effect of the interventions.

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

Agreements and disagreements with other studies or reviews

Agreements and disagreements with the previous review—There have been significant changes in the inclusion criteria for this update, with the 'splitting' of the previous review into pharmacological interventions (Coleman 2012b), and the exclusion of quasi-randomised trials. In this update we have changed the outcome from continued smoking (odds ratio), to quitting (risk ratio) so it is consistent with other Cochrane reviews from the Tobacco Addiction Group, and we have included 'number needed to treat for benefit' analyses, as this is likely to be of greater relevance to service providers. In this update we have also revised all data extraction to ensure that missing data and 'Risk of bias' assessments from all trials have been dealt with consistently across the five updates, so there are some minor amendments to some trial data from previous versions. However, the major findings from this review are similar to the previous review, with minor differences in effect size estimates, namely:

- psychosocial interventions which include counselling, incentives and feedback support women to stop smoking in pregnancy are effective in supporting women to quit, reducing low birthweight infants and preterm births;
- interventions including use of incentives continue to have the largest effect size estimate, but the sample size is very small so these results should be interpreted with caution.

The main differences from the previous review are that a significant effect **was** demonstrated in:·

- continued abstinence in the postpartum period.

A significant effect **was not** demonstrated in:

- a new subcategory of trials providing 'health education' only;

- a new subcategory of trials using social support, although a significant effect was seen in the combined results of trials using targeted peer support, but not in the single trial using partner-assisted support.

Agreements and disagreements with other Cochrane reviews—See Appendix 1 for a full list of other reviews of smoking interventions.

Pharmacological interventions in pregnancy: A review of pharmacological interventions to support women to stop smoking in pregnancy (Coleman 2012b) did not report a significant effect (RR 1.33, 95% CI 0.93 to 1.91) http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD010078/abstract.

Effects of types of interventions for the general population

Relapse prevention: The findings in this review of a significant effect on relapse prevention in the early postpartum period contrast to findings in another Cochrane review of relapse prevention (Hajek 2009). However, relapse prevention interventions for women who had spontaneously quit in this review did not demonstrate a significant effect, which is similar to the findings of Hajek 2009. http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003999.pub3/abstract.

Enhanced partner support: The findings in this review were similar to findings in a review of enhanced partner support in the general population (Park 2012), which did not demonstrate a significant effect (RR 0.99, 95% CI 0.84 to 1.15). See http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD002928.pub3/abstract.

Stages of change: A systematic review of stage-based interventions concluded they are no more effective in general than interventions that do not tailor the intervention according to the stage of change (Riemsma 2003). http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004492.pub4/abstract This is similar to the findings in the previous version of this review.

Individual behavioural support: Our review findings for counselling interventions were similar to those reported by Lancaster 2005a in a review of individual interventions (RR 1.39, 95% CI 1.24 to 1.57), with little difference between intensive support and brief interventions. See http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001292.pub2/abstract.

Self-help materials: Our review findings were different from a review of provision of self-help materials in the general population (Lancaster 2005b) that demonstrated a modest but significant effect (RR 1.21, 95% CI 1.05 to 1.39), particularly when the materials were tailored (RR 1.31, 95% CI 1.20 to 1.42). See http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001118.pub2/abstract.

Competitions and incentives: The findings of our review contrast with findings of a review of incentives among the general population (Cahill 2011a) that showed no significant difference. See http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004307.pub4/

abstract. Given the subgroup analysis in our study is based on a very small number of studies and participants, our results should be viewed with caution.

Effects of interventions among other population groups

Psychosocial interventions among patients with coronary heart disease: The findings of this review are similar to findings of psychosocial interventions among patients with coronary heart disease (Barth 2008), another population with strong motivational factors to stop smoking (odds ratio (OR) 1.66, 95% CI 1.25 to 2.22), with high heterogeneity, and a reduced effect among validated smoking outcomes (OR 1.44, 95% CI 0.99 to 2.11).

Pre-operative interventions: The effect of brief smoking cessation interventions among the patients preparing for surgery was similar to our review (RR 1.41, 95% CI 1.22 to 1.63), although the effect of intensive interventions was significantly higher than in our review. See http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD002294.pub3/abstract.

Hospitalised patients: Our results were similar to those among hospitalised patients (RR 1.37, 95% CI 1.27 to 1.48). See http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001837.pub3/abstract.

Interventions in Indigenous populations: The findings of our review were in contrast to a review of four studies of non-pregnant Indigenous communities (Carson 2012) in New Zealand (2), United States (1) and Australia (1) that reported a modest but significant effect using psychosocial interventions, two of which were supplemented with pharmacological therapy.

AUTHORS' CONCLUSIONS

Implications for practice

Psychosocial interventions can support women to stop smoking in pregnancy, and reduce preterm births and infants born low birthweight. Therefore, psychosocial support to stop smoking should be considered for women who are pregnant, or seeking to become pregnant. Contrary to concerns that women may be upset by offering support to stop smoking, studies in this review suggest women expect and appreciate the support, and interventions are more likely to improve women's psychological wellbeing than worsen it. Qualitative evidence suggests this support should be positive, not punitive (Bond 2012), and is sensitive to potential feelings of guilt and worry, and concerns about the impact of quitting on women's lives and their relationship with significant others (Flemming 2013). Burgess 2009 suggests it may help for healthcare providers to become aware of any of their own biases against mothers who smoke.

Evidence from this review suggests provision of health education and risk advice is not sufficient, and any psychosocial support should include multiple or tailored intervention components that provide help with strategies to quit, positive encouragement and other strategies, such as incentives, feedback or peer support. Partner support does not appear to be effective from the single study in this review, and care is needed when including peer or partner-support components, as some peer and/or partner-support behaviours may be

unhelpful, and may potentially expose vulnerable women to increased risk. Inclusion of support for breastfeeding and prevention of weight gain should also be considered as part of smoking interventions for pregnant women, as obesity has overtaken smoking as a major cause of preterm births in high-income countries (Flenady 2011). Given the high co-morbidity with psychological symptoms and the potential to improve psychological wellbeing, interventions that include psychological support for women with symptoms should be considered. Studies in this review suggest many women resume smoking after pregnancy, so consideration should be given to messages that reinforce the benefits for the mother, rather than solely focusing on benefits for the infant.

There is limited evidence from this review that increasing the intensity of the intervention corresponds to an increased effect size. Therefore, consideration should be given to the quality of the intervention, and providing support that is convenient for women and does not unnecessarily overburden them. Consultation with women and local piloting of programs shown elsewhere to be effective may be a good place to begin to develop strategies suitable for each population. Additionally consultative processes that involve healthcare providers and organisational leaders should be another important consideration for implementation.

Given the clear difficulties which most women still smoking at the first antenatal visit have in stopping smoking, population-wide strategies for smoking control in the whole community are needed to reduce the initiation of smoking by young women: 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 (WHO 2008a). However, these interventions should incorporate strategies to reduce risks identified in this review, including stigmatisation, and negative effects on relationships; avoid singling out mothers and focus more broadly on ‘parents’; avoid depicting mothers who smoke as ‘harming’ their infants, but as women who are important in their own right; and assisting vulnerable women to develop alternative ‘coping’ strategies to deal with living in difficult circumstances (Burgess 2009). Given the strong association between social inequality and continued smoking by pregnant women shown in this review, there is a rationale to support WHO recommendations to reduce social inequalities in the wider community (WHO 2008b).

Implications for research

There is little doubt about ‘whether’ psychosocial interventions are effective in reducing smoking, preterm births or infants born with low birthweight. What is not clear is ‘which’ interventions are effective, ‘how’ these interventions work, ‘who for’ and ‘how’ should these interventions should be implemented, disseminated and institutionalised. As smoking rates have decreased in the general population in high-income countries, it is becoming increasingly recognised that smoking has become more closely correlated with entrenched social disadvantage and psychological co-morbidity (Shoff 2013). Studies are needed that refine interventions to address the specific needs of these subpopulations, without compounding problems of social alienation and low self-efficacy. Given the shifting demographics and burden of diseases from tobacco smoking from high- to low- and middle-income countries, more research is needed to develop strategies which are appropriate for

these settings. In reflecting on whether the objectives of this review have been addressed, the authors feel that further research is needed into:

- the feasibility and effectiveness of interventions in low- and middle-income countries, particularly given the aggressive tobacco marketing in these regions;
- how to implement and disseminate interventions into routine care, and measures of whether they are effective when implemented at a population level;
- the feasibility and effectiveness of the use of incentives to support pregnant women to quit smoking, including evaluation of any adverse effects or negative unforeseen circumstances for pregnant women or the broader community;
- demonstrating effective interventions, including descriptions of how these were developed, to support ethnic and aboriginal women, and young women to stop smoking;
- interventions to support women with mental illness to stop smoking, and whether interventions that improve mental health can also help women to quit smoking;
- developing strategies to ensure that smoking interventions do not have a negative impact on breastfeeding, which would counteract some of the health benefits of quitting smoking for both the mother and her infant;
- whether the timing of the psychosocial support is important, for instance, is more frequent support required in the early stages of quitting and less frequent support required later?

A WHO expert working group (Hunt 2012) recently recommended research in three areas to help reduce smoking during pregnancy:

- social and cultural factors influencing pregnant women’s use of tobacco and exposure to secondhand smoke;
- interventions to promote tobacco cessation and reduce secondhand smoke exposure during pregnancy in high-, low- and middle-income countries;
- describing non-cigarette tobacco use by women and characterising the resulting risks for adverse pregnancy outcomes.

In 2009 the National Institute of Clinical Excellence developed guidance on *Quitting smoking in pregnancy and following childbirth*. Background documents for this guidance (Bauld 2010a; Williams 2010) identified a number of gaps in existing evidence, including:

- whether the way the intervention is delivered influences the effect;
- whether the site or setting influence the effect;
- evidence of effective interventions for vulnerable population groups, including teenage mothers, disabled mothers, women with mental illness, and other women.

Future trials need to include the following elements:

- number of potentially eligible women and number agreeing to participate, as this can help to assess the degree of selection bias in the trial and the potential acceptability and generalisability if implemented at a population level;
- strategies to minimise contamination, as this appears to have an impact on the effect size;
- a description of the intervention in sufficient detail for its replication even if the detail requires a separate paper;
- process data as evidence of implementation;
- women's views of the intervention, particularly if partner or peer support are incorporated;
- biochemical validation of non-smoking status;
- nicotine withdrawal and adverse effects such as increased smoking, or disengagement with services;
- the collection of perinatal outcome data on birthweight, preterm birth and perinatal deaths, particularly for nicotine replacement therapy trials;
- collection of outcome data on breastfeeding, weight gain, operative delivery, maternal psychological wellbeing, and the perceived impact of the intervention on family functioning or other significant relationships;
- subgroup analysis by vulnerabilities (to enable an equity analysis);
- the impact factor or intra-cluster correlation needs to be reported, in order to assess the effect of clustering and include cluster-randomised trials in meta-analysis.

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CHARACTERISTICS OF STUDIES

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

Albrecht 1998

Methods	3-armed randomised-controlled trial (pilot study) evaluated 2 different interventions provided to 'pregnant teens' to reduce smoking in pregnancy and relapse postpartum. The hypothesis was that an intervention including peer support would be more effective than the intervention alone. Study conducted in Pittsburgh, USA. Data collection dates not reported
Participants	**Inclusion criteria:** *12 to 20 years of age*; 4 to 28 weeks' gestation; reported smoking at least 1 cigarette a day; *single marital status*; 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. **Recruitment:** Participants were recruited through local prenatal clinics and public schools. 84 women recruited (not known how many were eligible or approached) and randomised (C = 29, **I1** = 29, **I2** =26). **Baseline characteristics:** Mean cigarettes/day at first visit: C = 6.44; **I1** (TFS) = 5.87; **I2** (TFSB) = 6.81. 63% African-American heritage, 37% European-American heritage **Progress+ coding:** Coded as single (low social capital) and young age (less than 20)
Interventions	**Control:** 30 minutes individual educational session with project nurse including information about the risks of smoking to the mother and the fetus and brochures on smoking and pregnancy. **Intervention 1 (TFS):** Cognitive behavioural group model designed specifically for adolescents based on problem-behaviour theory: eight 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. **Intervention 2 - TFS plus peer support (TFSB):** Utilised all the components of TFS plus 1-to-1 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 **Main intervention strategy:** Social support (multiple intervention) compared to less intensive intervention. TFSB compared with TFS and control in this review as outcomes only reported as combined figures **Intensity rating:** Frequency (C = 2, I = 6); Duration (C = 2, I = 6). Intervention provided by project staff:efficacy study.
Outcomes	Biochemically validated point prevalence abstinence at 4-6 weeks post baseline (late pregnancy*) Reduction in exhaled CO and self-reported mean cigarettes per day are reported as 'reduction' but actual post-intervention measures weren't reported so are not included in this review. Baseline modified Fagerstrom Tolerance questionnaire for adolescents to assess nicotine dependence
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as 'randomly assigned'.
Allocation concealment (selection bias)	Unclear risk	No information.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only 46/84 had complete outcome data (high attrition rate = 45%),UC= 12 (41%), TFS = 13 (46%), TFSB = 13 (50%). No explanation for attrition. ITT analysis not mentioned. All those lost to follow-up were included as continuing smokers in this review
Selective reporting (reporting bias)	High risk	Only smoking outcomes reported and outcomes not reported separately for each of the control arms
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	CO level (>= 8 ppm) in exhaled air used to identify smokers.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Provider and participants unable to be blinded to educational intervention

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	High risk	Process evaluation showed there was a 'significant drop out rate' (45%)
Equal baseline characteristics in study arms	Unclear risk	Baseline smoking characteristics similar, but other baseline characteristics not reported
Contamination of control group	Low risk	Intervention provided by research project staff.

Albrecht 2006

Methods	3-armed randomised controlled trial evaluated the short- and long-term effects of 2 smoking cessation strategies tailored to support pregnant adolescents to attain abstinence in pregnancy and maintain abstinence postpartum The study was conducted in 5 hospital-based and 2 community-based prenatal clinics in Pittsburgh, Pennsylvania, USA. Years of data collection not reported
Participants	**Inclusion criteria:** *'Pregnant teens' aged 14 to 19 years*; 12 to 28 weeks' gestation; able to read, write, and understand English; smoking at least 1 cigarette per day; *single marital status*; having no previous live births; and capable of being reached by telephone **Exclusion criteria:** pregnancy complications (i.e., bleeding or preterm labor) or required confinement to home by their physician **Recruitment:** During prenatal assessment, adolescents self-reporting smoking were invited to participate in study. Those expressing interest signed a consent form to allow the research team to contact them. Expressions of interest also advertised through flyers and brochures 470 screened; 142/224 (63%) eligible women randomised (C = 50; I1: (TFS) = 47; I2: (TFS + B) = 45. **Baseline characteristics:** Number of cigarettes per day before pregnancy: Control 15.75 (10.38); I1: (TFS) 14.08 (7.22); I2: (TFSB) 14.62 (9.72) Fagerstrom dependence score: Control 3.38 (2.05); I1: (TFS) 3.44 (1.79); I2: (TFSB) 3.68 (1.89) **Progress + coding:** Low SES, Low educational attainment, low social capital (single) and young age (< 20 years)
Interventions	**Control:** Usual care that all teens would typically receive from a healthcare provider throughout their pregnancy. Smoking during pregnancy was addressed in the clinic by giving the teens educational materials on this subject during the initial prenatal visit. In this study, this material was explained and distributed to the participants by a research team member during the initial assessment. The meetings lasted 45-60 minutes and occurred at 1 of the antenatal clinics or centrally located community site. During the meeting, addresses and telephone numbers of the control group participants were updated after completion of the assessment. Prior to leaving the meeting, participants were informed of the date and time of their next assessment. Participants also received an attendance incentive (e.g. lipstick, nail polish). If the participant had delivered, the attendance incentive was a baby item **Intervention 1 (TFS):** The TFS intervention consisted of an 8 week group program designed to promote and maintain smoking abstinence based on the Cognitive Behavioral Theory, with modification that incorporated developmental components of Jessor's Problem Behavior Theory, including a peer buddy and a peer co-leader for peer modelling and sanctioning on smoking. Information pertinent to pregnancy and smoking was provided at the beginning of the 8-week program. **Intervention 2 (TFS-B):** The TFS-B group received the same 8-week programming, but participants were required to bring a non-smoking female of a similar age as their buddy to the sessions. The role of the buddy was to reinforce smoking cessation strategies and to provide social support to the participant throughout the study **Main intervention strategy:** Social support (multiple intervention) compared to a less intensive intervention. The control group and TFS-B are compared in this review **Intensity rating:** Frequency (C = 2, I = 6); Duration (C = 3, I = 6). Provided by dedicated project staff: efficacy study.
Outcomes	Biochemically validated point prevalence abstinence 8 weeks (late pregnancy*) and 1 year (6-11 months post partum*) after the intervention
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Consenting adolescents were assigned randomly to 1 of 3 group assignments (TFS, TFS-B, or control) by a computer algorithm with a permutated block design, stratified by entry site
Allocation concealment (selection bias)	Unclear risk	Not reported.

Incomplete outcome data (attrition bias) All outcomes	Low risk	High attrition: C = 60% (i.e. 40% did not complete 1 yr follow-up), TFS = 55%, TFS-B = 53%. Participants included in primary aim analysis pertaining to randomised treatment assignment, regardless of adherence to study treatment (ITT analysis)
Selective reporting (reporting bias)	Low risk	Primary outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemical validation of self-reported smoking status (point prevalence abstinence) using salivary cotinine (> 10 ng). Women reporting less than 1 cigarette per day with salivary cotinine 10-15 ng had salivary nicotine assessment to rule out environmental exposure, and were classified as smokers if that test was > 5 ng
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and providers unlikely to be blinded to this educational intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessor not reported.
Incomplete implementation	High risk	Process evaluation showed poor implementation with almost 50% participants not completing study
Equal baseline characteristics in study arms	Low risk	Baseline characteristics appear equal.
Contamination of control group	Low risk	Intervention provided by research team.

Baric 1976

Methods	A randomised controlled pilot study to evaluate whether medical advice had a effect on smoking cessation in pregnancy Study conducted in Bolton, England. Years of data collection not reported
Participants	**Inclusion criteria:** Pregnant smokers at their first antenatal visit, less than 20 weeks' gestation **Exclusion criteria:** Not reported. **Recruitment:** Women recruited from public antenatal clinic at Bolton and District General Hospital. 510 women screened, 142 eligible, 8 moved house and could not be followed up, and 24 women had spontaneously quit. 110 women randomised: control = 47, intervention = 63 **Baseline characteristics:** 89% heavy smokers and 75% had been smoking for 5 years or more 72% 'working-class' (majority low SES) and 75% had no educational qualifications **Progress+ coding:** Low SES and low educational attainment.
Interventions	**Control:** Usual care, which was advice at the discretion of the doctor. **Intervention:** 1 to 1 counselling ('a short interview') 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 **Main intervention strategy:** Counselling (single intervention) compared with usual care. **Intensity:** Frequency (C = 0, I = 1); Duration: (C = 0, I = 1). Usual care intensity: Frequency = 1, duration = 1. Intervention conducted by existing staff (medical student): effectiveness study
Outcomes	Self-reported abstinence 11 weeks after baseline visit (late pregnancy*) Smoking reduction reported for whole cohort, not by intervention group, therefore not included in this review Discusses participants' views of intervention.
Notes	

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Random sequence generation (selection bias)	Unclear risk	No information provided. Described as “randomly divided”.
Allocation concealment (selection bias)	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	There are some missing data in the tables. It is not clear if there was any overall loss to follow-up or whether missing data relate to specific outcomes only. All randomised women included in this review and those lost to follow-up were included as continuing smokers in this review
Selective reporting (reporting bias)	Unclear risk	No other outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	Smoking outcomes were self-reported by participants during a visit at home. There was no biochemical validation
Blinding of participants and personnel (performance bias) All outcomes	High risk	Educational intervention at first antenatal visit.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	Not reported.
Equal baseline characteristics in study arms	Unclear risk	Not reported.
Contamination of control group	Low risk	Medical student provided intervention (not usual care provider)

Bauman 1983

Methods	Randomised controlled trial of use of exhaled CO feedback for promoting smoking cessation in pregnancy Study conducted in Guildford County, North Carolina, USA over 6 months in 1981
Participants	**Inclusion criteria:** Women currently or recently smoking, attending public clinics **Exclusion criteria:** Not reported. All women attending antenatal care orientation sessions were randomly allocated to experimental or control groups **Recruitment:** 226 women entered prenatal program and 170 (75%) included in analyses. The authors compared those who did not participate and did not find any significant differences. 47% (79/170) were current smokers (C = 43, I = 36) **Baseline characteristics:** 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 **Progress+ coding:** Low SES as all attending public prenatal clinic.
Interventions	**Control:** Women were read a 135 script that described the relationship among cigarette smoking, CO, and the harmful consequences of smoking **Intervention:** Experimental group received same information as control group, and they provided breath specimen in which CO was measured, with feedback of the result **Main intervention strategy:** Feedback (single intervention) compared to a less intensive intervention **Intensity:** Frequency (C = 1, I = 1); Duration (C = 1, I = 1). Implemented by regular health educators: effectiveness study
Outcomes	Biochemically validated abstinence 6 weeks after intervention (late pregnancy*) Exhaled CO (ppm), but no SD reported; unclear if ‘quantity of cigarettes’ is mean cigarettes per day; recency of smoking; depth of inhalation
Notes	Not clear whether this was a group intervention - in which case there was no adjustment for clustering
Risk of bias	
Bias	**Authors’ judgement** **Support for judgement**

Random sequence generation (selection bias)	Low risk	Random number table.
Allocation concealment (selection bias)	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear exactly how many women were randomised to each group, however we assume that those reported as 'current smokers' in table 1 are the baseline numbers, which were all included in this review
Selective reporting (reporting bias)	Unclear risk	None apparent.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemical validation of reported smoking behaviour for those followed up (CO >= 9 ppm in exhaled air)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Intervention was carried out by clinical staff, no participant blinding reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Low risk	All women apparently received the intervention.
Equal baseline characteristics in study arms	Low risk	No difference between experimental and control arms on 12 variables measured
Contamination of control group	Low risk	Implemented by regular health educators at the maternity clinics

Belizan 1995

Methods	Randomised controlled trial of psychosocial support in pregnancy which aimed to improve maternal health, including reducing smoking during pregnancy Conducted in 4 countries in Latin America (Argentina, Brazil, Cuba, and Mexico) from January 1989 to March 1991
Participants	**Inclusion criteria:** *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. **Exclusion criteria:** 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 **Recruitment:** 2,235 women met eligibility criteria and gave consent (I = 1115-though 1110 in table, C = 1120) **Baseline characteristics:** Smokers (I = 23.9%, C = 21.8%), with variation between countries - Argentina (I = 21.9%, C = 20.6%), Brazil (I = 40.7%, C = 33.1%), Cuba (I = 27.4%, C = 28.9%), Mexico (I = 9%, C = 6.8%). Mean cigarettes per day at randomisation: C = 7.9, I = 7.5 **Progress+ coding:** Low SES based on place of residence (low family income 20% in Cuba, 52% in Mexico, 53% in Brazil and 100% in Argentina)
Interventions	**Control:** Routine antenatal care, otherwise unspecified. **Intervention:** 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 utilisation. Additional components were a poster, a booklet, hotline to project office, guided tour of hospital, encouragement of family support and participation. Intervention was provided by specially trained female social workers or obstetric nurses with previous experience of childbirth **Main intervention strategy:** Social support (tailored) compared with usual care. **Intensity:** Frequency (C = 0, I = 6), Duration (C = 0, I = 5). Usual care frequency and duration = 0 (unclear). Intervention provided by study team: efficacy study.
Outcomes	Self-reported point prevalence abstinence at 36 weeks' gestation (late pregnancy*); Mean cigarettes per day.* Multiple perinatal and maternal health outcome data were collected, but not included in this review as other aspects of the intervention may have had an impact Baseline state anxiety score.
Notes	Sample size was planned for the primary trial objective.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Centrally prepared, method not stated.
Allocation concealment (selection bias)	Low risk	Allocation was by opening sealed, opaque envelopes.
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition 202/2230 (9%): 101 in each arm. Unclear what attrition among smokers and no ITT analysis of drop-outs as continuing smokers, so not able to re-include smokers who dropped out in this review
Selective reporting (reporting bias)	Unclear risk	None apparent.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	No biochemical validation of reported smoking behaviour.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Home visitors were aware of group allocation. Social support intervention with home visits
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The evaluation of the interventions was conducted by a team of independent professional interviewers who were not informed of the characteristics of the study
Incomplete implementation	Low risk	Most (83%) of the women randomly assigned to the intervention group received the planned number of home visits, and 90% were visited at least once
Equal baseline characteristics in study arms	Low risk	The distribution of risk factors was similar in the 2 groups and the 2 groups had similar demographic, obstetric, and psychological characteristics at baseline
Contamination of control group	Low risk	The clinic personnel were unaware of the identity of the women in the control group, and no attempts were made to inform them of which women were in the intervention group. Health educators providing intervention were separate from care providers

Bullock 1995

Methods	Randomised controlled trial of telephone support for improving maternal health outcomes, including smoking cessation during pregnancy Study conducted in a metropolitan city in the south island of New Zealand from March to December 1993
Participants	**Inclusion criteria:** Women with telephone access, who were either single or with an unemployed partner, less than 20 weeks' gestation **Exclusion criteria:** None stated. **Recruitment:** Recruited in the outpatient department of a large maternity hospital, or its associated GP practices, or self-referral via an introductory letter, phone call, and full discussion of "Healthy Mothers/Healthy Babies" The eligible population was 221 women of whom 49 were never located, 23 were not interested, 10 refused after explanation, and 8 moved away, did not speak English or had a miscarriage. 131 (59%) participated (103 OPD, 22 from GPs, 6 self-referred) (C = 66, I = 65 randomised). Just over 50% were smokers (C = 35, I = 31). **Baseline characteristics:** Mean cigarettes per day at baseline = 6. 88% European, 10% Maori. 53% single. **Progress+ coding:** Low SES.
Interventions	**Control:** Package of publicly available educational material on healthy behaviours during pregnancy. **Intervention:** Package plus weekly telephone call from trained volunteer with the aim of providing minimal support until 12 weeks after birth; aim "to be a friend and a good listener"; to ask about symptoms; signs; alcohol; drugs; smoking and meals in every call; to encourage attendance at antenatal clinic appointments and to ask about "feeling stressed". Intervention provided by 19 female volunteers, trained for the project with a "case load" of 2 to 6 women each

	Main intervention strategy: Social support (single intervention) compared to a less intensive intervention **Intensity:** Frequency (C = 2, I = 6); Duration (C = 1, I = 4). Intervention provided by project staff: efficacy study.
Outcomes	Self-reported abstinence at 34/40 (late pregnancy*). Mean cigarettes per day*. Anxiety and depression scores at baseline and 34/40. There were other intervention components which might have influenced these outcomes
Notes	No process evaluation is reported. No sample size justification SDs for mean cigarettes per day were not reported, therefore we calculated a mean SD from 14 studies with available mean cigarette SDs (6.5) to include in this review, as recommended by the cochrane handbook

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random assignment to control or intervention in balanced blocks of 50
Allocation concealment (selection bias)	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	High risk	Data being reported were analysed on 122/131 of randomised women (control = 63/66, intervention = 59/65). 1 woman requested to be removed from the study, but there were 8 women who for various reasons had incomplete data. p477 4.5% control 9.2% intervention. Only a proportion were smokers (I = 31, C = 35), and the attrition among these is not reported so we were unable to re-include them in the analysis for this review
Selective reporting (reporting bias)	Unclear risk	None apparent.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	No biochemical validation of reported smoking behaviour.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Caregiver blinded to allocation. Women not blinded to intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	No process evaluation.
Equal baseline characteristics in study arms	Unclear risk	Baseline psychosocial variables (stress; social support; self esteem; depression; anxiety) reported in Table 2. Demographic variables not reported
Contamination of control group	Unclear risk	Care providers blinded to allocation and not involved in intervention delivery

Bullock 2009

Methods	Randomised controlled trial (2 × 2 factorial design) evaluating nurse delivered telephone social support ("Baby BEEP") to improve a range of maternal health outcomes, including smoking during pregnancy. Study conducted in 21 rural Women, Infant and Children Nutritional Supplement (WIC) clinics in a Midwestern state, USA, from January 2002 to July 2006
Participants	**Inclusion criteria:** Women attending rural WIC clinic who reported smoking at least 1 cigarette per day, spoke English, were 18 years or older, and less than 24 weeks' gestation **Exclusion criteria:** Not further specified. **Recruitment:** When a woman attending a WIC clinic reported current smoking, staff explained the availability of a smoking cessation study and asked permission to provide her name and telephone number to the Baby BEEP research team. If the woman agreed, a nurse from the research team was assigned to contact her to arrange a face-to-face visit to explain the study and request written consent 1420 referrals from WIC clinics, 932 eligible, 695 (75%) randomised (C = 171; **I1** (booklets) = 179; **I2** (social support) = 175, **I3** (social support+booklets) = 170. **Baseline characteristics:** > 90% 'ready to quit this pregnancy'.

	Fagerstrom scores: C = 4.8, **I1** (Booklets) = 5.0, **I2** (SS) = 4.9, **I3** (SS+booklets) = 4.7 Mean age: 22 years, 95% white, 63% high school diploma, 70% in relationship Psychosocial assessments indicated participants experienced high levels of perceived stress and depression and low levels of support generally and from partners **Progress+ coding:** Low SES as women recruited from WIC clinics.
Interventions	**Control:** Quit Smoking for Good pamphlet from the American Heart Association and instructed that a member of the research team would call each month to arrange a saliva sample,measure exposure to tobacco smoke and ask some questions for 2more interviews **Intervention (3 arms):** **I1** Serialised Pregnancy-Smoking Cessation Booklets (Booklets):Eight booklets comprised a program called “Stop Smoking! A Special Program for Pregnant Women” adapted to a 7th grade reading level. The first booklet was given to the woman at the recruitment visit without counselling, and the 7 remaining booklets were mailed at weekly intervals **I2** Nurse-Delivered General Social Support (SS): scheduled weekly telephone call and 24-hour access to the nurse for any additional social support needed. The research nurse’s role on the calls was to use empathetic listening skills and provide social, emotional and/or informational support in response to each woman’s individual needs, such as stressors she was facing and ways she could manage her stress responses. The nurses kept logs of all conversations so that they would be able to follow-up on issues of importance on subsequent calls and as a measure of treatment integrity. All participants in these intervention study groups were encouraged to call the nurse any time they felt stressed or the need to talk, and they were also provided with a refrigerator magnet and a business card with their nurse’s first name and a toll-free number. The nurses received 40 h of training for the telephone support intervention. Each research nurse was given information about a variety of community resources available **I3** SS+Booklets: This review included comparisons with the control group and **I3** (SS+Booklets). **Main intervention strategy:** Social support (tailored) compared to a less intensive intervention **Intensity:** Frequency (C = 1, I = 6); Duration (C = 1, I = 4). Intervention provided by project staff: Efficacy study.
Outcomes	Biochemically validated point prevalence abstinence at 28-32 weeks’ gestation* (late pregnancy) and 6 weeks post-delivery (0-5 months postpartum*) Perceived stress scale, prenatal psychosocial profile, mental health index 5; readiness to stop smoking; Fagerstrom Test for Nicotine Dependence. Subgroup analysis for patterns of quitting and associations with partner smoking
Notes	Process evaluation to follow-up phone calls. Low attrition rate suggested as indicator of acceptability

Risk of bias

Bias	**Authors’ judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Assignments were prepared individually for each nurse, were computer generated using SAS
Allocation concealment (selection bias)	Low risk	Opaque, sealed envelope, prepared by the principle investigator that contained the study group assignment
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition: Nine had a spontaneous abortion (C = 2, **I1** = 3, **I2** = 3, **I3** = 1) or non-viable infant (C = 0, **I1** = 4, **I2** = 1, **I3** = 4) and were excluded from the analysis in this review. Those who dropped out and were lost to follow-up for other reasons were included in the final analysis as continuing smokers (C = 7, **I1** = 11, **I2** = 11, **I3** = 7). However, 165 women were lost to lab error in analysing their saliva samples and were not included in analysis. Only 530/695 (76%) randomised participants were included in this analysis C = 126 and **I3** = 124 included in this review.
Selective reporting (reporting bias)	Low risk	All primary outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	165/695 sample lost. Self-reported abstinence in remaining women biochemically validated using salivary cotinine (30 ng/mL or less classified as non-smokers)
Blinding of participants and personnel (performance bias) All outcomes	High risk	The nurses who collected samples when they conducted the follow-up interviews in late pregnancy and 6-weeks postdelivery were aware of the study group assignment
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The laboratory was blind to study group assignment while running the cotinine analyses. The assistants who collected the monthly saliva sample may or may not have been blinded to the study group but the rule was to treat all the women the same way

Incomplete implementation	High risk	Percent of calls completed in each of their caseloads ranged from 58% to 80% (p400)
Equal baseline characteristics in study arms	Low risk	Characteristics appear equal.
Contamination of control group	Low risk	Care-providers not involved in provision of the intervention

Burling 1991

Methods	Randomised controlled trial of CO feedback and brief directive feedback to reduce smoking in pregnancy Study conducted in a large US municipal hospital antenatal clinic, over an 18-month study period (dates not specified)
Participants	**Inclusion criteria:** Pregnant women, currently smoking, at any gestation, attending a clinic for 'uncomplicated pregnancies' **Exclusion criteria:** Very young age (not specified) or "complications" (not specified) **Recruitment:** All attending women were screened for smoking by questionnaire + CO breath measurement (>= 9 ppm) (over 50%were current smokers) and 139 women were randomly assigned (C = 69, I = 70) **Baseline characteristics:** An average of 12.7 cigarettes per day. The population consisted primarily poor and stable 'working class' Caucasian women. (52.4%), Black (44.6%) and Asian (3%) **Progress+ coding:** Low SES.
Interventions	**Control:** Usual care, where a clinic nurse provided health education, including smoking. **Intervention:** A personal letter from the Chief (physician) of the prenatal clinic within 3 days of the visit, mentioning the CO test, discussing the risks of smoking to herself and the fetus and urging her to stop plus the American Cancer Society pamphlet ("Why start life under a cloud?") about the negative effects of smoking and simple guidelines for self-directed smoking cessation **Main intervention strategy:** Health education (single intervention) compared to usual care. CO feedback was provided to both groups so not included as a feedback trial **Intensity:** Frequency (C = 0, I = 1), Duration (C = 0, I = 1). Usual care intensity: Frequency = 1, Duration = 1. Intervention provided by routine clinic staff: Effectiveness study
Outcomes	Biochemically validated point prevalence smoking cessation at 34 weeks' gestation (late pregnancy*)
Notes	Simple intervention so no process evaluation. Clinic-wide implementation so no consent sought.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No information provided.
Allocation concealment (selection bias)	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No consent sought and no loss to followup apparent.
Selective reporting (reporting bias)	Unclear risk	None apparent. Primary outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemical validation of reported behaviour by exhaled CO (>= 9 ppm counted as smoking)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The authors state that clinic staff were unaware of group allocation. Women would not have been blind to educational intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Low risk	All intervention participants provided with letter. No information regarding whether they read it or not

Equal baseline characteristics in study arms	Unclear risk	There were no significant baseline differences between 2 groups in terms of age, ethnicity, term of pregnancy, number of children, number of reported cigarettes smoked, or CO
Contamination of control group	Low risk	Intervention was a letter so unlikely to be sent to control group in error

Byrd 1993

Methods	This randomised controlled study aimed to evaluate the effectiveness of nurse counselling to reduce smoking in pregnancy. The study was conducted in 2 community-based obstetric clinics in Milwaukee (USA). Study dates unclear
Participants	**Inclusion criteria:** Pregnant, 'a current smoker', English speaking, visually able to read 12 point typeset, being able to give free consent, and expecting to reside in Milwaukee following delivery **Exclusion criteria:** Not specified. **Recruitment:** 50% of patients enrolled in third trimester. 57 women randomised, but unclear how many to each group **Baseline characteristics:** Cigarette consumption mean at entry = 8.6 93% participants smoked fewer than 10 cigs per day. 79% Black, 16% had partner, 70% single, 77% unemployed, 32% < grade 12 education, 61% < $10,000 per year No coding as outcomes not able to be included in this review
Interventions	**Control:** A smoking cessation booklet at 6th grade reading level or 11minute videotape. **Intervention:** Booklet or video Nurse counselling based on 4 As recommended by National Cancer Institute. The nurse intervention was a systematic tailored smoking cessation approach that was based on the 4 A (Ask, Advise, Assist, Arrange) approach by the National Cancer Institute Main intervention strategy and intensity not coded as not included in meta-analysis
Outcomes	Self-reported smoking status (20% had CO screening) 1 month after enrolment, in the ninth month of pregnancy, and 1 month postpartum. But not reported by intervention group so unable to include any outcomes in meta-analysis
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method of sequence generation not stated.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Of the 57 participants enrolled in the study, 50 were available for 1 and 9 month followup, and 48 responded to the 1 month postpartum survey. All non-respondents were considered to be smokers at follow-up and considered to have made no quit attempts in the follow-up interval
Selective reporting (reporting bias)	Unclear risk	Outcomes not reported by intervention group, but did not claim results were significant
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	Self-reported smoking status for 80% sample.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personal unlikely to be blinded in educational intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	Not reported.
Equal baseline characteristics in study arms	Unclear risk	Not reported.
Contamination of control group	Low risk	Home visits.

Campbell 2006

Methods	Cluster-randomised controlled trial which aimed to assess 2 methods of disseminating smoking cessation programmes to public antenatal clinics Study conducted in Newcastle, New South Wales, Australia. Data collection dates not reported
Participants	**Inclusion criteria:** Public antenatal clinics with an antenatal clinic and more than 500 births per year (unit of randomisation). Women who attended the clinics and reported to be current smokers were the unit of analysis **Exclusion criteria:** Under 16 years of age, too sick, non-English speaking, illiterate, attendance was first visit **Recruitment:** 23/25 public hospitals agreed to participate 22 clinics randomised (C = 11, I = 11). Assume smoking prevalence identifies eligible smokers (2284 in control clinics and 2821 in intervention clinics). Included in post-dissemination assessment: C = 688, I = 781 **Baseline characteristics:** Smoking details not reported. Proportion more than high school: 22%; Language other than English at home: C = 35%, I = 33% **Progress+ coding:** Low SES as all attending a public pre-natal clinic.
Interventions	The cessation programme "Fresh Start for you and your baby", developed by Windsor, based on CBT, was used. More details are described in Walsh 1997. Coded as a counselling (multi-modal) intervention. **Control:** Simple dissemination of programme to clinics which included mail out of written information on programme benefit and resources **Intervention:** Intensive dissemination of programme which included written information and feedback about programme benefits to managers, provision of programme resources, offers of visits to explain programme and provide training, sample smoking cessation policy, regular contacts to offer support, and computerised feedback on activities **Main intervention strategy:** Intensive dissemination vs less intensive dissemination. **Intensity:** Not coded as same intervention for women in both arms (counselling-tailored). This study is not included in intensity analysis Study provided by existing service providers: effectiveness study
Outcomes	Primary outcomes were the proportion of women whose smoking status was assessed and were provided smoking cessation advice Biochemically validated point prevalence smoking cessation at end of pregnancy* (The proportion of women who had been smokers when they first visited the clinic who had now quit, p99) was a secondary outcome for this study Provider views of interventions discussed.
Notes	No intracluster correlation or impact factor reported, so sensitivity analysis conducted using 4 ICCs and figures adjusting using ICC of 0.1 in outcome tables. See Table 2 for adjustment calculations.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of random allocation not specified, but taken within strata based on clinic size and baseline smoking rates
Allocation concealment (selection bias)	Unclear risk	Not specified.
Incomplete outcome data (attrition bias) All outcomes	High risk	One clinic excluded as did not report final data and some missing data for post-dissemination measures. No ITT of women dropping out of study. Only women completing study measures included in analysis. Unable to re-include in this review
Selective reporting (reporting bias)	Low risk	Smoking status and recall of intervention reported.
Other bias	High risk	There was a shorter recruitment period (1 week instead of 2 weeks) at post-dissemination for the 11 largest clinics (out of the 22 clinics involved), so the sample sizes have been adjusted to account for the shorter recruitment period for those clinics, by increasing the sample size to what they would have expected to have recruited if the period was over 2 weeks instead of 1. We have adjusted for these estimates in this review as outlined in Table 2. Also lower recruitment in control arms compared to intervention arms
Biochemical validation of smoking abstinence (detection bias)	Low risk	Exhaled CO >= 9 ppm.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Educational intervention. Neither women nor providers would have been blind to the intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.

Incomplete implementation	High risk	Process evaluation showed good implementation in intervention group. However time constraints within clinics meant that training sessions could not be repeated. Although training permitted information about the programme to be provided to clinicians and the training videotape modelled smoking cessation skills, the time period was usually inadequate to provide skill development as originally planned. p100
Equal baseline characteristics in study arms	Low risk	Patient population differences on nearly all 14 characteristics were minimal (less than 5%)
Contamination of control group	High risk	Similar proportions of control women received the specific risk information which indicated that midwives had increased the pre-study level of usual care advice

Cinciripini 2000

Methods	Randomised controlled trial evaluating provision of videotaped vignettes for promoting smoking cessation and relapse prevention during pregnancy Study conducted in a community-based university setting, Texas, USA. Data collection dates not reported
Participants	**Inclusion criteria:** Volunteers who were willing to quit within 2 weeks. **Exclusion criteria:** Women smoking < 3 cigarettes per day; < 18 years; > 30 weeks' pregnant; do not have a working video recorder (approximately 12% Americans); depressed **Recruitment:** Through local media, such as newspaper, radio, subscriber letters, community business flyers, waiting room posters 146 women screened and 82 women who met inclusion criteria were randomised (C = 40, I = 42) **Baseline characteristics:** Mean cigarettes/day at first visit: C = 14.5, I = 17.3. **Progress+ coding:** None.
Interventions	**Control:** Received a quit calendar and tip guide. **Intervention:** As for control plus were mailed a video with 6 × 25-30 minute vignettes covering a range of topics and strategies from initial quitting to relapse prevention **Main intervention strategy:** Counselling (single intervention) compared to a less intensive intervention **Intensity:** Frequency (C = 2, I = 2), Duration (C = 1, I = 4). Intervention provided by study staff: efficacy study.
Outcomes	Biochemically validated point prevalence abstinence obtained within 2-3 days of quit date, 4-5 weeks after the quit date (late pregnancy)* and 1 month postpartum (0-5 months postpartum*). Participant evaluation of intervention materials. Associated references report association of quitting and depressive disorders. CES-D scores at baseline only
Notes	Authors say women in this study tend to be heavier smokers than described in previous studies

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not stated.
Allocation concealment (selection bias)	Unclear risk	Not stated.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only 61% of participants completed all assessments. All those with missing data were treated as continuing smokers in this review
Selective reporting (reporting bias)	Low risk	Pre-specified outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	All reports of abstinence were validated by measurement of salivary cotinine
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Video mailed to participants. Not clear if UC givers were aware of group allocation
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.

Incomplete implementation	High risk	Process evaluation showed only 53% of the intervention group viewed 1-3 of the 6 videos. 47% did not view them
Equal baseline characteristics in study arms	Low risk	No significant difference in socioeconomic variables between groups
Contamination of control group	Low risk	Video mailed out to participants only.

Cinciripini 2010

Methods	Randomised controlled trial to evaluate a depression-focused intervention which aims to promote smoking cessation during pregnancy Study conducted in Texas (USA) between January 2005 and January 2008
Participants	**Inclusion criteria:** >= 16 years of age, to be <= 32 weeks pregnant, to have smoked at least a puff or more during the past 7 days, to have a telephone, and to express a willingness to quit smoking during the study (i.e., women with a goal of only reducing cigarette consumption were not eligible) **Exclusion criteria:** Currently participating in psychotherapy or other smoking cessation treatment, had unstable medical conditions that would adversely affect attendance, or demonstrated psychological instability during the screening (e.g., high suicide risk, symptoms of cognitive disorder, or severe intellectual impairment) **Recruitment:** Through newspaper and television advertisements, and physician referrals. 730 women were screened for basic eligibility by telephone. 266/294 (90%) eligible women were randomised (C = 133, I = 133) **Baseline characteristics:** Smoking rate before finding out pregnant (mean cigarettes per day): I = 16.8 (8.7), C = 15.8 (9.1); Current smoking rate (mean cigarettes per day): I = 9.8 (7.1), C = 9.7 (6.7) Fagerstrom Test for Nicotine Dependence score I = 3.2 (2.1), C = 3.5 (2.0) 63% receiving medicaid or county health care, 54% African-American, 10% Hispanic, 33.5% Caucasian; 31.9% had less than high school education. 34.2%had family income < $10,000 75.5% had lifetime major depressive disorder (23.5% current major disorder) **Progress+ coding:** None.
Interventions	Ten individual counselling sessions were scheduled for 60 min. Each session consisted of 15 min of standard behavioural and motivational smoking cessation counselling (common to both groups). Counselling typically involved active efforts to prepare for quitting and maintaining abstinence using self-monitoring of their smoking prior to the quit date, identification of high-risk situations for smoking, and development of coping skills and support before and after the quit date. Therapists used motivational enhancement strategies based on techniques of motivational interviewing if resistant to quitting. The core features included exploration of participant ambivalence, use of open-ended questions, reflective listening, expressed empathy, rolling with resistance, and use of strategies to develop perceived discrepancy between smoking behaviour and important personal goals and values **Control:** The primary goal of the HW treatment was to educate women on ways to decrease stress, to respond to stressful events, and to take care of themselves physically during their pregnancies. The purpose was to provide a time- and attention-matched control for CBASP that was pregnancy relevant but instructional in nature-typical of health-education interventions. Participants chose from a list of discussion topics, including stress, pregnancy symptoms, sleep, exercise, yoga, relaxation training, time management, parenting tips, dealing with anger, negative thoughts and feelings, and postpartum depression. **Intervention:** CBASP was originally developed for the treatment of chronic depression. The primary CBASP treatment strategy is a social problem-solving exercise called Situational Analysis (SA), which is a technique used to create awareness of the contingent relationship between participants' behaviour and outcomes in stressful interpersonal situations. Another CBASP treatment strategy involved increasing participants' awareness of the contingent relationship between their behaviour and interpersonal outcomes within the therapeutic relationship and to apply this learning to relationships within the participants' daily living arenas. The CBASP model assumes that repeated practice of SA within and outside of treatment and increased understanding of participants' interpersonal impact on the therapist lead to acquisition of new perceptual and behavioural skills that improve interpersonal problem resolution. In turn, this is assumed to decrease interpersonal stress and depressive symptoms **Main intervention strategy:** Counselling (single intervention) compared to alternative intervention **Intensity:** Frequency (C = 6, I = 6); Duration (C = 6, I = 6). **Intensity:** Frequency (C = 6, I = 6); Duration (C = 6, I = 6).
Outcomes	Biochemically validated 7-day point prevalence abstinence at end of 10 weeks treatment (late pregnancy*); Smoking cessation 3 & 6 months after treatment, smoking cessation 3 (0-5*) & 6 (6-11*) months postpartum. Continuous and prolonged abstinence also reported Depression (CES-D scores) and probability of cessation 6 months post-treatment
Notes	

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Random sequence generation (selection bias)	Unclear risk	Adaptive randomisation was used to stratify the groups on age, race, history of depression, baseline smoking rate, baseline depressive symptom severity (CES-D >= 16), and longest duration of last depressive episode
Allocation concealment (selection bias)	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition: 3 months: C = 9/133, I = 22/133; 6months C = 42/133, I = 54/133. All analyses were carried out on the intent-to-treat sample, which included 128 participants in the Intervention group and 129 control - excluding only those who experienced a miscarriage during the study (5 participants in Intervention and 4 participants in control)
Selective reporting (reporting bias)	Low risk	All primary outcomes reported
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemical validation of self-reported smoking status (7-day point prevalence only) using expired CO (< 4 ppm) throughout treatment and salivary cotinine (< 15 ng/mL) at follow-up contacts
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and providers unlikely to be blinded to counselling intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Low risk	Process evaluation showed high levels of compliance with counselling standards in both groups. Participants attended an average of 8/10 sessions of approximately 58 mins
Equal baseline characteristics in study arms	Low risk	No significant differences noted.
Contamination of control group	Low risk	There is a potential risk with the same counsellors providing counselling for the intervention and control groups. However global competence ratings for CBASP, HW, and the smoking cessation counselling interventions were measured on a scale ranging from 1 (does not attempt intervention) to 4 (good use of intervention). No differences in competence between the groups were noted, averaging 3.8 (SD across conditions. Statistical agreement of competence ratings between primary and secondary raters was high, with a Cohen's kappa (Landis & Koch, 1977) of .93 (95% CI 0.86 to 1.0)

Cook 1995

Methods	Randomised controlled trial of counselling to support women to stop smoking during pregnancy in the USA. Location and dates of data collection not reported (abstract only available)
Participants	**Inclusion criteria:** Self-reported smokers presenting for prenatal care before 24 weeks' gestation **Exclusion criteria:** Not specified. 150 women randomised. Data for only 43 women (C = 20, I = 23) who had delivered by the time of report are available. 2 women in control group had baseline cotinine levels consistent with abstinence so are not included (C = 18, I = 23) **Baseline characteristics:** Not reported. **Progress+ coding:** None.
Interventions	**Control:** Discussion of smoking risks by a nutritionist and again by a resident physician at initial prenatal visit **Intervention:** Control + regular meetings with a smoking cessation counsellor and physician reinforcement at each visit. The women also received biochemical feedback from urine cotinine **Main intervention strategy:** Counselling (multiple intervention) compared to a less intensive intervention

	Intensity: Frequency (C=1, I=5); Duration (C=1, I=3). Estimates for intervention as little detail provided
Outcomes	Biochemically validated point prevalence abstinence at term or birth (late pregnancy*); >50% reduction in mean cotinine*; and mean birthweight*
Notes	SDs for mean birthweight were not reported, therefore we calculated a mean SD from 13 studies with available birthweight SDs (578) to include in this review, as recommended by the cochrane handbook

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	One woman in the intervention group dropped out of the study and was not included in the original analysis but has been re-included as a continuing smoker in this review, but not included in the mean birthweight analysis
Selective reporting (reporting bias)	High risk	Preliminary results only available. Final results not reported and unable to be accessed
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemical validation by urine cotinine but cut-off levels not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible for participants and personnel to be blinded to counselling intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	Not reported.
Equal baseline characteristics in study arms	Unclear risk	Baseline characteristics not reported (abstract only).
Contamination of control group	High risk	Appears that same physician provided advice to control and intervention women, and not clear if this was not repeated for control group

Cope 2003

Methods	Randomised controlled trial evaluating effectiveness of feedback from a point-of-care cotinine test for supporting women to stop smoking during pregnancy Study conducted in Birmingham, UK. Dates of data collection not reported
Participants	**Inclusion criteria:** 'Current smokers' (> 10 mg/L in preliminary urine cotinine result) **Exclusion criteria:** Not specified. **Recruitment:** Seen at initial antenatal visit and given brief explanation of test and aims of research, and asked to give verbal consent to participate in study. Women then had urine screened for cotinine and completed a questionnaire 745/856 (87%) eligible women agreed to participate and were randomised (C = 447, I = 298 in flow chart and 409 in results text). 280 women were smokers (C = 164, I = 116) **Baseline characteristics:** Average consumption of 11.8 cigarettes per day. Other characteristics not reported **Progress+ coding:** None
Interventions	**Control:** Routine counselling from a doctor or midwife. Urine measured at initial visit but no feedback given to woman **Intervention:** Six-minute urine test completed in their presence. Results given as a number and graphic illustration. A specific quit date within the next 14 days was mutually agreed and the woman was given a printed leaflet containing practical advice on how to reduce their smoking measurement at each visit. A positive friendly attitude of providers - information, feedback, encouragement protocol was repeated whenever the patient returned to the clinic up to and including the 36 week visit, with measurement, questioning about changes in smoking, specific events on the quit date and reinforcement of advice **Main intervention strategy:** Feedback (multiple intervention) compared to usual care. **Intensity:** Frequency (C = 0, I = 5); Duration (C = 0, I = 3). Usual care intensity: F = 1, D = 1

	Intervention provided by study staff: Efficacy study.
Outcomes	Biochemically validated point prevalence smoking cessation at 36 weeks' gestation (late pregnancy*) Proportion with 'some reduction*' (20%-80% urine cotinine). Mean birthweight* and length. Preterm births* reported in attrition and re-included in both numerator and denominator for this outcome Gestation, type of delivery, and Apgar scores collected but results not reported Participants view of interventions reported.
Notes	SDs forv mean birthweight were not reported, therefore we calculated a mean SD from 13 studies with available birthweight SDs (578) to include in this review, as recommended by the cochrane handbook

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quasi-randomised: New referrals to 3 large inner-city hospital antenatal clinics were randomised on the basis of their allocated hospital unit number, even numbers being placed in the case or intervention group, or those who were provided with feedback from the smoking test at point of care. p675
Allocation concealment (selection bias)	High risk	Group allocation could be anticipated.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Only 83/116 women in the control group and 109/164 women in the intervention group completed the study. Those who dropped out for medical reasons: miscarriage (C = 2, I = 3) or premature delivery (C = 6, I = 13), or transferred care (C = 3, I = 5) were excluded (C = 11, I = 21) from smoking outcome analysis. Those who failed to attend appointments, or refused further involvement were re-included as continuing smokers in this review (C = 18, I = 34), leaving a total sample of C = 101, I = 143
Selective reporting (reporting bias)	Low risk	Primary outcomes appear to be reported.
Other bias	High risk	Clear financial conflict of interest declared by author (directorship of company producing feedback tests).
Biochemical validation of smoking abstinence (detection bias)	Low risk	Smoking status biochemically validated with urine cotinine (> 10 mg/L indicates active smoker)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Neither providers nor women were blind to intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	Not reported.
Equal baseline characteristics in study arms	Unclear risk	Not reported.
Contamination of control group	Low risk	Contamination unlikely with provision of specific biochemical test

Donatelle 2000

Methods	Randomised controlled trial of "Significant Other Supporter" (SOS) program, of social support and direct financial rewards to reduce smoking during pregnancy and postpartum Study conducted in Oregon WIC program sites, USA, between June 1996 and June 1997

Participants	**Inclusion criteria:** Women smoking (even a puff in the last 7 days); less than 28 weeks' gestation; over 15 years of age; literate in English **Exclusion criteria:** Not specified. Recruitment: 220/309 (71%) eligible women were randomised (C = 108, I = 112) **Baseline characteristics:** Mean salivary cotinine at baseline: I = 45.4; C = 45.7. Caucasian (I = 90%, C = 88%), household income < $20000 (I = 87%, C = 89%), Single (I = 47%, C = 42%), Mean age (I = 23.5, C = 24.0) **Progress+ coding:** Low SES.
Interventions	**Control:** Verbal and written information on the importance of smoking cessation, a pregnancy specific smoking cessation self-help kit, and monthly telephone calls for self-reports on their smoking status. **Intervention:** As for the control group plus were asked to designate a social supporter (preferably a female non-smoker), and were advised both she and her supporter would receive an incentive: participants were given $50 voucher for each month biochemically confirmed as quit. Supporter received $50 voucher in first month and at 2 months postpartum, and $25 voucher for other months **Main intervention strategy:** Incentives (multiple intervention) compared with a less intensive intervention **Intensity:** Frequency (C = 2, I = 6),Duration (C = 1, I = 3)-estimated duration as limited information available The intervention was delivered by trained program staff or research staff: efficacy study
Outcomes	Biochemically validated point prevalence smoking cessation at 34 weeks' gestation (late pregnancy*) and 2 (0-5*) months postpartum
Notes	Data in outcome tables is inconsistent.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information provided.
Allocation concealment (selection bias)	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	High attrition rates I = 32%; C = 51.5% (reasons not specified), but all drop-outs included as continuing smokers in this analysis
Selective reporting (reporting bias)	Low risk	Main outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Reported quitting validated by salivary cotinine analysis (> 30 ng/mL considered to be smokers). Salivary thiocyanate also used (> 100 ug/mL considered to be smokers)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Neither providers nor women were blinded for this educational intervention with incentives
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	No process evaluation reported.
Equal baseline characteristics in study arms	Unclear risk	Preliminary analysis indicates no significant differences exist between randomised groups on baseline demographic characteristics
Contamination of control group	Low risk	Control group not reported clearly - however intervention given by trained research staff rather than usual care providers so unlikely that there was contamination

Donovan 1977

Methods	Randomised controlled trial of medical advice to stop smoking in pregnancy Study conducted in 3 public maternity units in the UK. Dates of data collection not stated

Participants	**Inclusion criteria:** Pregnant women < 35 years; 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 termination **Exclusion criteria:** Not further specified. **Recruitment:** Consecutive series of patients who contacted 3 maternity units regarding confinement were posted reply-paid questionnaires (including smoking questions), which were used to select eligible participants 588 women provided consent and were randomised. **Baseline characteristics:** Mean cigs/day at beginning of pregnancy (C = 17.6, I = 17.9); mean cigs/day at study entry (C = 15.2, I = 15.2), Mean age (C = 24.2, I = 23.8). Even distribution of social class categories **Progress+ coding:** None.
Interventions	**Control:** ANC usually provided by the hospital, including any anti-smoking advice which may have been given routinely **Intervention:** Individualised medical advice by clinic doctor, (i) tell the woman the facts about smoking in pregnancy; (ii) encourage questions about these facts; (iii) once the woman has agreed to try, discuss how she may best give up; (iv) follow-up the advice at all later contacts. Medical records labelled asking other staff to reinforce advice Details of the intervention are in Donovan 1975. **Main intervention strategy:** Health education (single intervention) compared to usual care **Intensity:** Frequency (C = 0, I = 5); Duration: (C = 0, I = 2)-estimate. Usual care intensity: F = 1, I = 1 Intervention provided by existing service providers: effectiveness study
Outcomes	Self-reported mean cigarettes/day at 4 stages of pregnancy (late pregnancy*); mean birthweight*; low birthweight*; preterm birth* (< 36 weeks); perinatal deaths*. No data on smoking cessation
Notes	Discussion of common problems identified when advising women to stop and on the contextual factors which encourage the continuation of smoking. Major inconsistency in smoking reports pre and post-birth is a problem in this trial Actual standard errors were able to be incorporated into software for this update (previously SD 500 used), so effect size estimates have altered slightly

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Table of random numbers.
Allocation concealment (selection bias)	Unclear risk	Information not provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Twins (C = 2, I = 6) and miscarriages (C = 17, I = 11) not included in analysis. 552 women analysed (C = 289, I = 263). No further attrition reported
Selective reporting (reporting bias)	Unclear risk	Smoking cessation rates not reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	No biochemical validation of reported smoking behaviour.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Notes labelled. Caregivers asked to reinforce information. Educational intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	High risk	Process evaluation of the reinforcement of advice showed little difference between the groups in recall of advice being given
Equal baseline characteristics in study arms	Unclear risk	From table 2 characteristics appear to be equal - but there is no statement or statistic confirming this
Contamination of control group	High risk	Same providers offering intervention and control advice. Process evaluation of the reinforcement of advice showed little difference between the groups in recall of advice being given

Dornelas 2006

Methods	Randomised controlled trial of counselling and telephone support to support women to stop smoking during pregnancy and post-partum Study conducted in Hartford, Connecticut (USA), between January 2001 and December 2002
Participants	**Inclusion criteria:** Pregnant women, over 18 years old, less than 30 weeks' gestation, current smokers (recent quitters included in associated relapse prevention paper (Morasco 2006). **Exclusion criteria:** Recent history of abuse or dependence on alcohol or other non-nicotine substance, major psychiatric illness, no access to a telephone **Recruitment:** Study conducted in the prenatal clinic of a non-profit tertiary care community hospital. Written consent obtained. Unclear how many eligible women participated. 140 women enrolled in study. 33 spontaneously quit (C = 19, I = 14), 107 were randomised but 2 were excluded due to missing data, leaving 105 included in analysis (I = 53, C = 52) **Baseline characteristics:** 70.5% smoked less than 10 cigarettes per day at baseline. Mean 20.8 (12.37) pre-pregnancy 66% Hispanic, 17% Caucasian, 11% African American. 61% unemployed, 54% less than high school education, 60% single, 49% household income < $15000/yr, 52% 1 or more depression items and 19% all 4 items **Progress+ coding:** Low SES and minority ethnic group.
Interventions	**Control:** Usual care according to standard smoking cessation guidelines, with providers offered 2 ×1h training sessions. Research study co-ordinator provided all participants with a booklet, inserted a chart prompt to remind providers to provide personalised quit messages at each visit, and audited charts to ensure the advice was documented **Intervention:** 1 90-minute psychotherapy session provided by masters-prepared mental health therapist trained in smoking cessation. The main goals were to assess readiness to quit, identify potential psychological or social problems that might pose as barriers to quitting, and set a quit date. This was followed by bi-monthly telephone calls from the therapist during pregnancy, and monthly calls after delivery **Main intervention strategy:** Counselling (single intervention) compared to a less intensive intervention **Intensity:** Frequency (C = 5, I = 6), Duration (C = 2, I = 6). Intervention provided by study staff: efficacy study.
Outcomes	Biochemically validated 7-day point prevalence abstinence in late pregnancy* and 6 (6-11) months postpartum* Aggregated results by week of gestation to enter study. An associated study (Morasco 2006) reports abstinence rates for recent quitters (relapse prevention*) Cost-effectiveness of 'cost per quitter'.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No description of methods of randomisation.
Allocation concealment (selection bias)	Unclear risk	No description.
Incomplete outcome data (attrition bias) All outcomes	High risk	2/107 randomised women were excluded from analysis due to missing data and were unable to be re-included in this report as the group allocation is not reported. The remaining dropouts (18% at 6 months postpartum) are included as continuing smokers in this analysis
Selective reporting (reporting bias)	Low risk	All outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemical validation with exhaled CO readings (cut off < 8 ppm but all participants less than 4 ppm)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Educational intervention so blinding not feasible.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	High risk	Process evaluation showed 17/53 did not receive the phone calls as planned
Equal baseline characteristics in study arms	Unclear risk	No significant differences in any of the baseline characteristic between the 2 groups

Contamination of control group	Low risk	Counselling and follow-up sessions provided by psychotherapist not involved in usual care

Dunkley 1997

Methods	Randomised controlled trial of midwifery counselling to support women to stop smoking in pregnancy Study conducted in a large UK maternity service. Data collection dates not specified
Participants	**Inclusion criteria:** Pregnant and booked for maternity care; <18 weeks' gestation; currently smoking 1 or more cigarettes/day Practising midwives regularly attending antenatal clinic. 13 midwives selected for the intervention group and 13 for the control group **Exclusion criteria:** Not specified. **Recruitment:** All women identified as smokers in a busy teaching hospital with 3700 deliveries a year received a letter asking if they would like to participate. 100 women participated (described as 'all 100 women contacted') and were randomised (C = 50, I = 50) **Baseline characteristics:** 'Contemplators' (C = 70%, I = 60%), 'pre-contemplators' (C = 15%, I = 22%), 'ready for action' (C = 15%, I = 18%) No other baseline characteristics reported. **Progress+ coding:** None.
Interventions	**Control:** Usual care. **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 **Main intervention strategy:** Counselling (single intervention) compared to usual care. **Intensity:** Frequency (C = 0, I = 5), duration (C = 0, I = 2)-based on estimated brief contact (< 5min) at a standard number of antenatal visits (8), as very little information about intervention provided. Usual care intensity: F = 0, I = 0 Intervention provided by existing staff: effectiveness study
Outcomes	Self-reported smoking cessation at 37 weeks (late pregnancy)*; and at 4 weeks (0-5 months*) postpartum Reduction in cigarettes/day; "stage of change" at 11 to 18 weeks vs 37 weeks. No biochemical validation of smoking status. Care providers' views discussed
Notes	No process evaluation reported. Abstract data used. States 'after one year' which is assumed to be of year of the study, at 37 weeks' gestation, as reported in figure one. As there were no quitters in the control group, the relapse rates of 4% within 1 month postpartum are assumed to be from the treatment group only

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not stated.
Allocation concealment (selection bias)	Unclear risk	Described as 'randomly allocated'.
Incomplete outcome data (attrition bias) All outcomes	Low risk	94 of 100 randomised women followed up (reasons for attrition not reported). No ITT analysis reported. However, all drop-outs re-included as continuing smokers in this review
Selective reporting (reporting bias)	Unclear risk	All outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	No biochemical validation of reported smoking status.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel unlikely to be blinded to educational intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	Not reported.

Equal baseline characteristics in study arms	Unclear risk	Not reported.
Contamination of control group	Low risk	Midwives randomised so low risk of contamination.

Eades 2012

Methods	Randomised controlled trial which aims to promote smoking cessation and relapse prevention during pregnancy and postpartum The study was conducted in 3 urban community-controlled health services in far north Queensland and Western Australia June 2005 and December 2009
Participants	**Inclusion criteria:** Pregnant Aboriginal or Torres Strait Islander women attending their first antenatal appointment at 1 of the Aboriginal community-controlled health services at or before 20 weeks' gestation; were aged 16 years or older,were self-reported current smokers or recent quitters (quitting when they knew they were pregnant); and were residents of the local area **Exclusion criteria:** Women whose pregnancy was complicated by a mental illness or they were receiving treatment for chemical dependencies other than tobacco or alcohol use **Recruitment:** 1119/1180 women attending the antenatal clinic were assessed for eligibility. 263/379 (69%) eligible women agreed to participate (C = 115, I = 148) **Baseline characteristics:** Median cigarettes per day: C = 10 (4-15), I = 10 (5-15); Spontaneous quitting since pregnancy: C = 8, I = 24 100% Aboriginal and Torres Strait Islander women. Partner (C = 88%, I = 92%) **Progress+ coding:** Low SES and minority ethnic group.
Interventions	**Control:** Usual care consisting of general advice from a GP about quitting smoking, based on existing brief intervention guidelines **Intervention:** Intervention developed after review of the literature and consultation with service providers and community members. At first antenatal visit women received a scripted invitation from the doctor to quit smoking and advised to quit 'cold turkey' and return to the clinic in 3-5 days and at 7-10 days. The woman received an appointment reminder card, fridge magnet, and a letter for other household members requesting their support. Women were asked to bring a partner or support person with them on their second visit. Women still smoking after 7-10 days were offered NRT if no contra-indications. Follow-up visits were conducted by female Aboriginal or Torres Strait Islander health workers and midwives who received training from a behavioural scientist and a GP, a study manual and a 1 page guide with scripted advice **Main intervention strategy:** Counselling (tailored) compared to usual care. Intensity: Frequency (C = 0, I = 4), Duration (C = 0, I = 3). Usual care intensity: F = 1, D = 1 Existing staff delivered intervention: effectiveness study.
Outcomes	Biochemically validated point prevalence smoking abstinence* and relapse prevention* at 36 weeks' gestation (late pregnancy) Post-partum cessation (6 months) not reported due to very high rates of attrition
Notes	Cluster-randomisation by weeks but number of weeks not reported. No analysis for adjustment for clustering reported. Treated as individually randomised controlled trial in this review

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	An Excel computer program was used to randomly allocate weeks to intervention or control for all clinics
Allocation concealment (selection bias)	High risk	Author notes lack of allocation concealment a methodological limitation of the study, which may account for unequal allocation in study arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	High rates of attrition (C = 37/115, I = 50/148) at end of pregnancy (reasons not reported). Very high attrition at 6 months post-partum. ITT analysis. Women lost to follow-up or with missing smoking status were classified as current smokers
Selective reporting (reporting bias)	Unclear risk	6 months postpartum outcomes not reported due to high attrition
Other bias	High risk	Unequal numbers in each group with greater allocation to intervention groups
Biochemical validation of smoking abstinence (detection bias)	Low risk	Self-reported smoking cessation biochemically validated using urinary cotinine (< 250 ng/mL)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Clinic staff made aware of treatment allocation at beginning of each week and unlikely participants were blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessor blinding not reported.
Incomplete implementation	High risk	64% doctors adhered to protocol and a lower proportion of nurses and health workers
Equal baseline characteristics in study arms	High risk	A slightly higher proportion of intervention group were in clinic 1, a slightly lower proportion had a partner, and had recently quit
Contamination of control group	High risk	Same antenatal care providers delivered intervention and control arms. High likelihood of contamination noted in discussion

El-Mohandes 2011

Methods	This randomised controlled trial examines whether an integrated behavioural intervention improves pregnancy outcomes, including smoking cessation The study was conducted in 6 community-based clinical sites serving minority women (African-Americans and Hispanics) in Columbia, USA, from July 2001 to July 2004
Participants	**Inclusion criteria:** Women attending prenatal care in 6 community-based sites who self-identified as belonging to a minority group, being >= 18 years, < 29 weeks pregnant, a DC resident and English speaking. *Had to have 1 risk factor (smoking, ETSE, depression, and IPV).* Only women reporting smoking at baseline are included in this review **Exclusion criteria:** Suicidal women. **Recruitment:** 2913 women approached while waiting for prenatal appointments. 1044/1398 (75%) eligible women provided signed consent to participate in the study (C = 523, I = 521) 302 women reported smoking '1+ puff in the preceding 6 months and 198 reported 'active' smoking at baseline. These 198 'active' smokers at baseline are included in this analysis (C = 92, I = 106) **Baseline characteristics:** 100% African American, 43.7% reliant on social housing, ~80% Medicaid recipients **Progress+ coding:** Minority ethnic group and low SES.
Interventions	**Control:** Not reported-usual care. **Intervention:** The 10-session intervention was delivered during prenatal (eight sessions) and postpartum (2 booster sessions) care visits. 4 prenatal sessions were considered minimal adherence. The session duration was approximately 35 min. The smoking intervention was consistent with the Smoking Cessation or Reduction in Pregnancy Trial (SCRIPT) and the Counseling and Behavioral Interventions Work Group of the United States Preventive Services Task Force recommendations, a 5-step behavioral counselling approach. The intervention was tailored to the woman's stage of change. Women were encouraged to avoid triggers and to use alternative coping and behavioural change strategies. The intervention included content to address both active smoking and ETSE, whether or not they met criteria for ETSE. Women with other risk factors (IPV, depression and drug or alcohol use) also received additional targeted interventions to address those issues **Main intervention strategy:** Counselling (single intervention) compared to usual care. **Intensity:** Frequency (C = 0, I = 5), Duration (C = 0, I = 4). Intervention provided by study staff: efficacy study.
Outcomes	Biochemically validated smoking cessation prior to delivery* (late pregnancy) and at 8-10 weeks (0-5 months*) postpartum. Mean urine cotinine* Outcomes also reported by intervention group for environmental tobacco smoke exposure, depression, intimate partner violence and illicit drug use Detailed pregnancy outcomes reported but not included in this analysis as they were not reported by smoking status at baseline, and these outcomes may be affected by several of the multi-modal interventions aimed at reducing risk factors other than smoking
Notes	Detailed participant satisfaction and intervention acceptability was reported in an associated reference (Katz 2008).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Site- and risk-specific block randomisation to IG or UCG was conducted. A computer generated randomisation scheme considered all possible risk combinations within each of the recruitment sites
Allocation concealment (selection bias)	Low risk	Investigators and field workers were blinded to the block size. Recruitment staff at each site called in the details of the risk profile for a new recruit, and the

		assignment was generated centrally by the data co-ordinating centre
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition: 104/500 (21%) prior to delivery and 116/500 (23%) in the postpartum assessment. Participant data were analysed according to their care group assignment, regardless of whether they received any intervention sessions, using an ITT model
Selective reporting (reporting bias)	Unclear risk	Data on women spontaneously quitting before pregnancy were not reported
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Smoking cessation biochemically validated using salivary cotinine (< 10 ng/mL)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and providers not able to be blinded by dedicated intervention providers minimised risk of contamination of study arms
Blinding of outcome assessment (detection bias) All outcomes	Low risk	4 research teams were allocated to ensure blinding of outcome assessors
Incomplete implementation	High risk	Process evaluation showed 16% women did not attend any sessions, 43% randomised women did not complete first follow-up interview and 31% did not complete 2nd follow-up interview
Equal baseline characteristics in study arms	Low risk	No significant differences noted.
Contamination of control group	Low risk	Persons delivering intervention were separate from care provider team

Ershoff 1989

Methods	Randomised controlled trial of self-help booklets to support women to stop smoking in pregnancy Study conducted in 5 health centres of the same HMO in Los Angeles (USA), from 1985 to 87
Participants	**Inclusion criteria:** English-speaking women attending 1 of 5 health centres for prenatal care, < 18 weeks' gestation; still smoking >= 7 cigarettes a week **Exclusion criteria:** Not specified further. **Recruitment:** 323 who self-reported still smoking >= 7 cigs/week were randomised (C = 158, I = 165). 242 included in final analysis (C = 116, I = 126). 228 women who had spontaneously quit also included (C = 108, I = 110) **Baseline characteristics (smokers):** Prepregnancy smoking: 27.3% 1-10 cigs/day, 14% 11-19 cigs/day, 58.7% 20+ cigs/day. At intake: 71.9% 1-10 cigs/day, 14.9% 11-19 cigs/day, 13.2%20+ cigs/day. Spontaneous quitters: mean pre-pregnancy cigarettes/day = 10.3 Smokers: 64% white, 73% had high school or some college education, 59.9% married **Progress+ coding:** None.
Interventions	**Control:** 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:** 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 1 and list reasons for not smoking; others mailed weekly. Booklets were pregnancy-specific, multi-ethnic, and at a 9th Grade reading level **Main intervention strategy:** Counselling (single intervention) compared to less intensive intervention **Intensity:** Frequency (C = 6, I=6), Duration (C = 4, I = 4). Estimate based on uptake of optional HMO sessions × 5 approximately 20-40 mins Intervention provided by existing health staff: effectiveness study
Outcomes	Biochemically validated abstinence at 34 weeks' gestation (late pregnancy*) Ershoff 1995 reports relapse prevention* among women who had spontaneously quit Ershoff 1990 reports birth outcomes (mean birthweight*; low birthweight*; preterm birth* (< 37 weeks); stillbirths*) and cost outcomes (economic evaluation) Associated reference (Mullen 1991) describes question structure's to improve accurate disclosure of smoking status

Notes	SDs for mean birthweight were not reported, therefore we calculated a mean SD from 13 studies with available birthweight SDs (578) to include in this review, as recommended by the cochrane handbook

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information
Allocation concealment (selection bias)	High risk	The authors state that women had been randomised in advance of their visit. It was not clear how women were recruited to the study or gave consent for participation.The health educator turned over a 'pre-assigned card' to randomise women
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Smokers: Attrition I = 39/165, C = 44/158 not included in analysis. Losses due to termination (C = 11, I = 7); miscarriage (C = 13, I = 12); disenrolment or transfer to another HMO (C = 18, I = 20) Spontaneous quitters: Attrition 22% - Abortion (n = 5), miscarriage (n = 17), disenrolment from HMO or transfer (n = 25) Not re-included in analysis for this review as excluded for medical reasons or moving
Selective reporting (reporting bias)	Unclear risk	None apparent.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemical validation by urinary cotinine levels. For participants reporting no smoking and low exposure to passive smoke urine cotinine had to be less than or equal to 10 ng/mL. For participants reporting a relapse and high exposure to passive smoke some values could be as high as 29 ng/mL though at least 1 sample had to be 10 ng/mL or less
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The authors state that the health educator delivering the intervention was not aware of group allocation, but materials were provided to the experimental group at the clinic visit. Prenatal care providers were blinded to group assignment and no effort was made to modify their usual counselling practices
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Low risk	Process evaluation reports good implementation.
Equal baseline characteristics in study arms	Unclear risk	With the exception of partners smoking status.
Contamination of control group	Unclear risk	Prenatal care providers no involved in intervention so risk of contamination likely to be low

Ershoff 1999

Methods	3-armed randomised controlled trial of interactive computer program and telephone counselling to support women to stop smoking in pregnancy Study conducted in a large group model managed care organisation in Los Angeles, California (USA) with recruitment from November 1996 to June 1997
Participants	**Inclusion criteria:** 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" **Exclusion criteria:** < 18 years of age, > 26 weeks' gestation, do not speak English, or smoked less than 7 cigarettes pre-pregnancy **Recruitment:** Researchers attempted to phone 931 women. 150 could not be contacted, 90 refused to be interviewed, 158 were not eligible and 34 were excluded as they experienced miscarriage (n = 34). 390/458 women (82%) agreed to participate (C = 131, **I1** = 133, **I2** = 126). **Baseline characteristics:** Pre-pregnancy mean cigs per day: C = 17.1 (9.7), **I1** = 17.6 (9.8), **I2** = 16.3 (7.6). Mean cigs per day at intake: C = 6.6(7.3), **I1** = 6.7(6.5), **I2** = 6.3 (6.5). 60% white, approximately 50% college educated, with a mean age of 29.4. Mean cigarette/day at first visit = 6.6 **Progress+ coding:** None.

Interventions	3 interventions, based on stages of change model. **Control:** Received a 32-page self-help booklet "living smoke-free". **Intervention 1 (interactive computer program-IVR):** received the same self-help booklet and had access to a computerised interactive telephone support system, which provided customised messages from a voice model. Participants responded to questions using a touch-tone keypad. **Intervention 2 (motivational interviewing):** received the same self-help booklet and 4-6 × 10-15 minute telephone counselling sessions by nurse educators trained in motivational interviewing. A personalised postcard sent to reinforce verbal communication **Main intervention strategy:** Counselling (single intervention) compared to a less intensive intervention (self-help booklet). Arms 1 and 3 only are compared in this review **Intensity:** Frequency (C = 2, I = 6), Duration (C = 1, I = 3). Intervention provided by study staff: efficacy study.
Outcomes	Biochemically validated smoking cessation at 34 weeks' gestation (late pregnancy*). Mean cigarettes per day* Baseline mental health index and Cohen's perceived stress scale. Number of quit attempts and movement in stages of change.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as "random assignment"
Allocation concealment (selection bias)	Unclear risk	No information.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition 58/390 (14.87) due to abortion (n = 31), disenrolment from health plan (n = 22) and preterm birth less than 32 weeks (n = 5). Lost to follow-up not included as continuing smokers in analysis as attrition due to medical reasons and moving not reincluded in this review, and attrition from each study group not reported separately
Selective reporting (reporting bias)	Unclear risk	Results were difficult to interpret.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemical validation by urinary cotinine levels (< 80 ng/mL)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Authors state that care providers were blind to group allocation. Educational intervention so blinding women not feasible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete implementation	Low risk	Good process evaluation of each of the methods. 79.2% received at least 1 call. Mean 4 calls lasting 12 mins each
Equal baseline characteristics in study arms	Low risk	No significant differences reported.
Contamination of control group	High risk	11% control group received individual smoking cessation counselling as they were classified as high risk patients

Gielen 1997

Methods	Randomised controlled trial of counselling and a self-help guide to support women to stop smoking during pregnancy Study conducted in Baltimore (USA). Study dates not reported
Participants	**Inclusion criteria:** Pregnant women currently smoking (even 1 puff in the past 7 days), either African-American or white **Exclusion criteria:** > 28 weeks' gestation; changing to another prenatal clinic or could not complete baseline interview **Recruitment:** 2,319 women assessed, 32% currently smoking by above definition. 72 were excluded for gestation, ethnicity or changing providers, leaving 662 eligible of whom 510 agreed to participate (77%). 25 quit prior to first visit, 18 did not wish to quit, leaving 467 (C = 235, I = 232) randomised **Baseline characteristics:** Mean cigarettes/day at intake I = 9.7, C = 7.5 (P = 0.01). 85% were on medical assistance. African American: I = 81% C = 89%

	Progress+ coding: Low SES and ethnic minority population.
Interventions	**Control:** Usual clinic and inpatient smoking cessation: A brief discussion with a nurse/health counsellor about the risks of smoking; a recommendation to quit and pamphlets from the area's voluntary agencies. **Intervention:** Peer health counsellors recruited from local communities, received 2 sessions training from PIs who explained content, rationale and how it was to be provided, then observed in practice by PIs with feedback to her. (i) A Pregnant Woman's Guide to Quit Smoking (RA Windsor), 6th Grade level. (ii) 15 minutes 1:1 counselling session with peer health counsellor on how to use the Guide, showing how it is organised to be used daily, and discussing women's thoughts and concerns about quitting, targeting cessation or relapse prevention, as appropriate. (iii) Educational materials for cessation support persons included with the Guide. (iv) Reinforcement at each clinic visit from doctors and nurses, written prescription to stop smoking provided directly from doctor to woman; 2 letters of encouragement (from the doctor and the counsellor) mailed to the woman 1-2 weeks after her first visit **Main intervention strategy:** Counselling (multiple intervention) compared to usual care **Intensity:** Frequency (C = 0, I = 6), Duration (C = 0, I=2). Usual care intensity F = 1, I = 1 Intervention provided by study staff: Efficacy study.
Outcomes	Biochemically validated 7-day point prevalence abstinence in hospital after delivery (late pregnancy*), 6 (6-11*) months postpartum abstinence, and >50%reduction in cotinine* from baseline to late pregnancy interview. Smoking cessation data collected at 3 months but not reported
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. Results show high rate of misclassification by self-report (I = 37%, C = 48%)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No information provided.
Allocation concealment (selection bias)	Unclear risk	Described as "randomly assigned".
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	16.3% attrition due to miscarriage, termination and change of care provider (C = 37, I = 34). 145/391 (37%) remaining women did not provide saliva samples and were treated as smokers in the analysis but those lost to follow-up for other reasons were excluded from the analysis in reports and in this review 6* months postpartum abstinence was collected and only small sample of 6-month data reported (C = 48, I = 46), however all missing data included as continuing smokers in this review
Selective reporting (reporting bias)	High risk	- month postpartum outcomes not reported and minimal follow-up for 6-month postpartum data
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Self-report of 'not even a puff in past 7 days' biochemically validated by salivary cotinine < 30 ng/mL
Blinding of participants and personnel (performance bias) All outcomes	High risk	Educational intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Low risk	Process evaluation showing good implementation.
Equal baseline characteristics in study arms	Unclear risk	Women in control group reported significantly fewer cigarettes per day and more likely to be African-American
Contamination of control group	High risk	Same care providers delivering intervention who were providing care to control group

Graham 1992

Methods	This randomised controlled trial aimed to measure the effectiveness of home-based visiting from trained lay-persons to reduce low birthweight.

	The study was conducted in the prenatal clinic of a university hospital in Cleveland, USA, from March 1987 to September 1989
Participants	**Inclusion criteria:** Living within 5-mile radius of clinic, 17-28 weeks' gestation, 'low' family function rating, at least 1 stressful life event during pregnancy, and additional risk factors such as smoking, low maternal weight-height ratio, aged over 27 years, or history of a previous premature baby **Exclusion criteria:** White patients, difficulty reading English. **Recruitment:** Every person registering at clinic was eligible to be screened. The first 105 screened participants were dropped from the study when it was found that they had difficulty reading the questions. 1326 women screened. 1022 'low risk, 190 'high risk' women - of which 145 were randomised (I = 87, C = 58). 8.5% of low risk and 15% high risk women were smokers **Baseline characteristics:** Smoking characteristics not reported. Predominantly black, poor, inner city population. No progress plus coding as outcomes not able to be included in this review
Interventions	**Control:** Routine care from obstetrical staff in the clinic. **Intervention:** 2 non-professional black women who demonstrated rapport with women served as home-visitors and were trained in childbirth education, community resources, and nutrition during pregnancy. 4 × 1 hour home visits occurred at 4-6 week intervals. The home visitors followed a protocol which included psychosocial support, efforts at stress reduction, information on health risks (especially smoking and drinking), nutrition education, and a small gift **Main intervention strategy:** Not coded as outcomes not included in this review.
Outcomes	Smoking outcomes were not able to be included in this review as it is unclear how many smokers were included in each study arm. Low birthweight was the primary outcome for this study, but was not included in this review, as aspects other than the smoking component of the intervention may have had an effect on birthweight. See Table 1 for summary of outcomes not able to be included in this meta-analysis
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Table of random numbers.
Allocation concealment (selection bias)	Unclear risk	Not stated.
Incomplete outcome data (attrition bias) All outcomes	High risk	24/87 dropped out and unclear if included in analysis. 7 refused intervention, 11 could not be contacted, 5 transferred care, 1 miscarried prior to visit Numbers reported as randomised different in abstract (154) and flow chart (145)
Selective reporting (reporting bias)	Unclear risk	Unclear if selective reporting as smoking cessation was not the primary aim of the intervention
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Unclear risk	Not applicable. Smoking outcomes not reported.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women and home visitors not blinded, as would be expected in an educational intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	High risk	Process evaluation showed only 63/87 women received home visits
Equal baseline characteristics in study arms	Unclear risk	Not reported.
Contamination of control group	Low risk	Home visiting intervention so risk contamination of control group is low

Haddow 1991

Methods	Randomised controlled trial of providing feedback on cotinine to support women to stop smoking in pregnancy and reduce low birthweight Study conducted in physicians offices and clinic sites within Maine (USA) from 1984 to 1987
Participants	**Inclusion criteria:** Pregnant women with a singleton live pregnancy; having maternal serum AFP screening at 15-20 weeks' gestation; who smoked >= 10 cigarettes a day **Exclusion criteria:** Not further specified. **Recruitment:** Physicians approached (no consent from women). 25,628 women completed maternal serum screening form, 97% answered question on smoking and 17% smoked >= 10 cigs/day. 2848 women were randomised (C = 1425, I = 1423) **Baseline characteristics:** Mean cigs/day at baseline: C = 16.3, I = 16.1 Maternal education (mean years): C = 11.8, I = 11.9. **Progress+ coding:** None.
Interventions	**Control:** Standard medical care not otherwise specified. **Intervention:** Report on cotinine generated for her physician with interpretation relating smoking level to birthweight. Physician explained this to the woman and also gave her a copy of the report and a pregnancy-specific booklet about how to quit, using the cotinine information also + repeat measure 1 month later, 2 copies to physician, comparison of 1st and 2nd cotinine, report commenting on the change and its interpretation **Main intervention strategy:** Feedback (multiple intervention) compared to usual care **Intensity:** Frequency (C = 0, I = 3), Duration (C = 0, I = 2). Usual care intensity: F = 0, I = 0 Intervention provided by existing staff: Effectiveness study
Outcomes	No smoking cessation data. Smoking data limited to comparability at first assessment and mean serum cotinine levels, which could not be included as they are disaggregated by low and high study site participation Mean birthweight*; low* and very low* birthweight; preterm birth* (< 37 weeks); stillbirths (> 20 weeks)*; neonatal deaths*; postneonatal deaths
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random numbers.
Allocation concealment (selection bias)	Unclear risk	Information not provided.
Incomplete outcome data (attrition bias) All outcomes	High risk	2700/2848 (94.8%) included in analysis. 3% lost to follow-up and 2% multiple gestations or fetal deaths. Only 695/1343 (48%) women in the intervention groups provided repeat serum cotinine for comparison. No ITT analysis. No smoking outcomes reported and unable to re-include data for mean cotinine and birth outcomes
Selective reporting (reporting bias)	High risk	Results difficult to interpret. Smoking cessation not recorded
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	Serum cotinine measurement at baseline for both the experimental and comparison groups but it was not clear that any follow-up measurements were made for the comparison group
Blinding of participants and personnel (performance bias) All outcomes	High risk	Caregivers aware of group allocation. Experimental group given feedback on serum cotinine levels
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	High risk	Process evaluation showed less than good implementation with differential impact on perinatal outcome by completeness with second blood samples taken for cotinine measurement
Equal baseline characteristics in study arms	Unclear risk	Intervention groups similar at trial entry.
Contamination of control group	Low risk	Intervention not provided by care provider.

Hajek 2001

Methods	Cluster-randomised controlled trial of a brief midwife-delivered intervention to support women to stop smoking in pregnancy Study conducted in nine hospital and community trusts in the UK. Years of data collection not reported
Participants	290 midwives randomised to provide intervention or control care **Inclusion criteria:** Pregnant women currently smoking or stopped within the last 3 months **Exclusion criteria:** Not further specified. **Recruitment:** Women were recruited at first visit (approximately 12 weeks' gestation). Estimated 8700 eligible women. Only 178/290 (61%) midwives (C = 86, I = 92) recruited any women. Financial incentives were paid to boost recruitment. 1287 women provided informed consent **Baseline characteristics:** Current smokers (C = 440, I = 441); Spontaneous quitters (C = 135, I = 114). 189 current smokers were assessed as 'not motivated to stop' therefore received no intervention. Mean cigs/day: Smokers (C = 9.7, I = 10.1), Ex-smokers (C = 10.9, I = 12.6) > 70%married, 26%-27% smokers and 10%-15% ex-smokers had no educational qualifications **Progress+ coding:** None.
Interventions	**Control:** 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 **Main intervention strategy:** Counselling (tailored) compared to usual care. **Intensity:** Frequency (C = 0, I = 5), Duration (C = 0, I = 2). Usual care intensity: F = 1, D = 1 Intervention provided by routine midwives: Effectiveness study
Outcomes	Biochemically validated point prevalence abstinence at birth (late pregnancy*), relapse prevention*, and self-reported continuous abstinence at 6 (6-11) months postpartum among baseline smokers* and spontaneous quitters. Birthweight for smokers and ex-smokers reported, but not by intervention group so not included in this review Participants and midwives views of interventions reviewed.
Notes	Clustering effect not reported, so sensitivity analysis conducted using 4 ICCs and outcome figures adjusted using conservative intracluster correlation of 0.1. See Table 2 for adjustment calculations for cluster trials. Discussion of barriers includes 65% of midwives reporting the intervention could not be undertaken in the time they had available. Sample size justification

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Cluster-randomisation of midwives adequate. Consecutive names on a list of midwives
Allocation concealment (selection bias)	Unclear risk	Midwives randomised.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	167/1287 (12.9%) (C = 83, I = 84) excluded from analysis due to moving away, being untraceable or deemed unsuitable for follow-up (e.g. miscarriage). 1120 in sample. 51/1287 non-responders were included as continuing smokers
Selective reporting (reporting bias)	Unclear risk	Unclear if all outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemical validation by expired CO < 10 ppm.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Midwives aware of allocation group. Educational intervention. Blinding women not feasible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment not reported. Not blinded if performed by midwives
Incomplete implementation	High risk	Process evaluation showed poor implementation in some areas.
Equal baseline characteristics in study arms	High risk	Control group slightly more interested in quitting smoking and less nicotine dependent
Contamination of control group	Low risk	Cluster trial design to minimise risk of contamination.

Hartmann 1996

Methods	Randomised controlled trial of self-help materials and health education to support women to stop smoking in pregnancy Study conducted in a teaching hospital (academic) clinic in North Carolina, USA from August 1991 to January 1993
Participants	**Inclusion criteria:** Pregnant women who smoke. **Exclusion criteria:** > 36 weeks' gestation, psychiatric diagnosis. Recruitment: 842/846 (99%) women attending the clinic completed survey and 793/846 provided a CO breath sample.; 2 were excluded as > 36 weeks' gestation; 1 for psychiatric diagnosis; leaving 266 (32%) eligible smokers (smoked at least once in the prior week). 12 refused, 4 were missed, 2 were not pregnant and 1 was a private patient. 247 women randomised **Baseline characteristics:** Mean cigs/day (C = 14.4, I = 13.5), Want to quit (C = 81%, I = 84%). Smokers in household (C = 75%, I = 78%) White (C = 74%, I = 78%), Single (C = 44%, I = 47%), < 12yrs education (C = 43%, I = 48%) **Progress+ coding:** Low SES.
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:** 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 **Main intervention strategy:** Counselling (multiple intervention) compared to usual care **Intensity:** Frequency (C = 0, I = 6), Duration (C = 0, I = 2). Usual care intensity: F = 1, D = 1 Intervention provided by existing staff: Effectiveness study
Outcomes	Biochemically validated abstinence at last prenatal visit (late pregnancy*). > 50% reduction in self-reported smoking*; Mean cigarettes per day* Cost-effectiveness data reported.
Notes	SDs for mean cigarettes per day were not reported, therefore we calculated a mean SD from 14 studies with available mean cigarette SDs (6.5) to include in this review, as recommended by the cochrane handbook

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random numbers.
Allocation concealment (selection bias)	High risk	State that neither the enrolling nurse nor the patient were aware of allocation, but experimental group notes were flagged
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition 40/247 (16%) (4 miscarriages first trimester, 3 miscarriages second trimester, 3 terminations, 15 moved to alternative care, and 12 lost to follow-up) 207 included in analysis (C = 100, I = 107). Those lost to follow-up not able to be re-included in analysis in this review as numbers not reported by study arm
Selective reporting (reporting bias)	Unclear risk	Not apparent.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Exhaled CO measured at each visit for the experimental group and at 3 visits for the comparison group. < 5 ppm counted as non-smokers
Blinding of participants and personnel (performance bias) All outcomes	High risk	Case notes flagged. States patient not aware of randomisation status
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	No process evaluation reported.
Equal baseline characteristics in study arms	Low risk	No significant differences noted.

Contamination of control group	High risk	Concerns about residents having to treat similar/consecutive patients differently, and self-help manuals accidentally given to some controls. Discussion section reports evidence of contamination with self-help materials being given to controls

Haug 1994

Methods	Cluster-randomised controlled trial of brief GP counselling to support women to stop smoking in pregnancy and prevent relapse postpartum Study conducted in Western Norway from November 1986 to November 1987
Participants	**Inclusion criteria:** No indications of serious social or medical problems, living with a partner, and smoking at least 5 cigarettes per day before pregnancy and still smoking at least 1 cigarette per day at the first checkup **Exclusion criteria:** Not further specified. **Recruitment:** All 398 GPs in western Norway were invited by mail to participate in the study. 187 participating GPs were asked to recruit 4 pregnant and 4 non-pregnant women for the study, at the first checkup in the first trimester. 1/3 pregnant and non-pregnant women ended up in control groups. The GPs who recruited pregnant women for the intervention groups recruited non-pregnant women for the control groups. 2379 pregnant women screened, 674 fulfilled inclusion criteria, 144 refused to participate (21%). 530 pregnant women were randomised (unclear how many each group) **Baseline characteristics:** Mean age starting smoking 27.6, mean cigs per day = 9.5. Mean age 25.9. 18-34 years of age, all living with a partner **Progress+ coding:** None.
Interventions	**Control:** Ordinary control programme during pregnancy and for first year after delivery (usual care) **Intervention:** (i) < 15 mins GP consultation at initial visit about hazards of smoking, how to stop and how to avoid relapse; (ii) information about problems related to 'the smoking fetus'; (iii) delivered with aid of a 5-page 'flip-over'; (iv) 8-page booklet. Women invited to consult their GPs after 1, 6, 12 and 18 months to discuss their smoking habits **Main intervention strategy:** Counselling (multiple intervention) compared with usual care **Intensity:** Frequency (C = 0, I = 3), Duration (C = 0, I = 1). Usual care intensity: F = 0, D = 0 Intervention provided by existing staff (GPs): Effectiveness study
Outcomes	Self-reported abstinence 6 months after study entry (late pregnancy*), biochemically validated at 12 months after study entry (0-5 months postpartum*), self-reported abstinence 15 (6-11 months postpartum*) and 18 months after study entry (12-17 months postpartum*) Sef-reported reduction and increase in smoking. An associated reference (Haug 1992) reports results of a survey of GPs delivering the intervention
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	GPs described as randomly allocated.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	High risk	180/530 dropped out due to spontaneous abortions (24), serious complications (8), moved to another district (31) or for other unknown reasons (117). Only 350/530 (C = 98, I = 252) included in analysis and we were unable to re-include those lost to follow-up for other reasons in this review as they were not reported by group allocation. Further dropouts not explained (C = 97 and I = 244 in outcome tables-re-included in this review as continuing smokers)
Selective reporting (reporting bias)	High risk	Not clear if biochemically validated outcomes reported.
Other bias	High risk	Unequal recruitment to study arms (higher recruitment in intervention arms)
Biochemical validation of smoking abstinence (detection bias)	High risk	Biochemical validation of smoking only at study entry and after 12 months (urinary thiocynate). Unclear if those who had high thiocynate levels were considered smokers. No cut-off levels reported

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible to blind participants and personnel to counselling intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	High risk	59% residents did not document consultation. 1 component dropped
Equal baseline characteristics in study arms	Unclear risk	Not reported.
Contamination of control group	High risk	Same providers asked to provide control and intervention arms for pregnant and non-pregnant women

Haug 2004

Methods	Randomised controlled trial of motivational enhancement therapy to support women to stop smoking in pregnancy Dates of research and location not stated. Assume USA from author affiliations
Participants	**Inclusion criteria:** Opioid-dependent women, <= 26 weeks' gestation, receiving methadone, currently smoking at least 5 cigarettes per day, enrolled in hospital prenatal program. **Exclusion criteria:** Not further specified. **Recruitment:** During first 48 hours of 7-day residential program. 77 women randomised. 14 women excluded from analysis due to miscarriage, abortion, premature delivery and miscalculated gestational age. 63 included in analysis (I = 30, C = 33) **Baseline characteristics:** Mean cigarettes per day 19.9 (SD 11.5). Approximately 50% had lifetime major depressive disorder, 32% were depressed in last month, and 39% had anxiety disorder. 84% African American, 79% single, 97% unemployed. 94% had less than high school education. Not coded for equity analysis as outcomes not able to be included in this review
Interventions	**Control:** Health practitioner advice by trained research staff and printed materials from American Lung Association and American Cancer Society **Intervention:** As control + Motivational Enhancement therapy using 'Project MATCH' manual with modifications for nicotine dependence, provided over 4 sessions by masters level research associates Main strategy and intensity not coded as outcomes unable to be included in meta-analysis
Outcomes	Mean cigarettes per day, mean exhaled CO, mean cotinine, movement in stages of change were collected and authors report that there was no significant difference. However, not actual figures were provided to be able to include these outcomes in meta-analysis in this review
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Just states participants were 'randomly assigned' to 1 of 2 conditions
Allocation concealment (selection bias)	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	High risk	Participant attrition was 14% (n = 9). Final figures not reported so unclear how many included in analysis
Selective reporting (reporting bias)	Unclear risk	Actual smoking rates not reported, despite this being a primary outcome for the study. However, authors did not claim results were significant
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Unclear risk	Cotinine and CO validation measured, but not reported.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Intervention providers and women not blinded as counselling intervention

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated.
Incomplete implementation	Unclear risk	Process evaluation not reported.
Equal baseline characteristics in study arms	Unclear risk	Intervention group had lower mean education levels, were more likely to be Caucasian, and had higher rates of pre-pregnancy cigarettes per day. Other factors equal
Contamination of control group	Low risk	Masters level research associates provided the intervention.

Hegaard 2003

Methods	Quasi-randomised trial of counselling and optional nicotine replacement therapy, to support women to stop smoking in pregnancy Study conducted in a large midwifery centre in the Netherlands, with data collection from 1996 to 1998
Participants	**Inclusion criteria:** All pregnant women attending first prenatal visit. **Exclusion criteria:** Inability to speak Danish, age below 18 years, gestation of more than 22 weeks, verified psychiatric diseases, and alcohol or drug abuse **Recruitment:** 696/905 (77%) eligible women attending first antenatal clinic who smoked agreed to participate in study (informed consent) and were randomised (C = 347, I = 348). 647 included in final analysis (C = 320, I = 327) **Baseline characteristics:** Mean cigs/day = 11, Significant difference in partner smoking (I = 67%, C = 77%, P = 0.03), mean salivary cotinine (C = 141, I = 139) Mean age 29 yrs, > 12 yrs in school (C = 45%, I = 43%), mostly married **Progress+ coding:** None.
Interventions	**Control:** Usual care, which included routine information about the risk of smoking in pregnancy and general advice on smoking cessation or reduction in a standard 30-minute consultation **Intervention:** (i) Extended initial consultation (from 30 to 40 minutes) which included a dialogue about smoking and motivation for cessation (ii) written information about risks of smoking and passive smoking (iii) invitation to join smoking cessation program, based on CBT. The program involved 9 appointments (individually or in a group) over a period of 14 weeks. 3 attendances prepared participants for quitting and 6 were used to maintain cessation and to hand out NRT. CO readings at each visit (iv) NRT offered to all women (2 mg gum or 15 mg patch × 16 h) for 11 weeks (v) encouragement at subsequent 5-6 antenatal visits. **Main intervention strategy:** Counselling (tailored) compared with usual care. **Intensity:** Frequency (C = 0, I = 6), Duration (C = 0, I = 6). Usual care intensity: F = 1, D = 1 Intervention provided by specially trained midwife (study staff): Efficacy study
Outcomes	Biochemically validated smoking cessation at 37 weeks' gestation (late pregnancy*), mean birthweight*, low birthweight*. Preterm births* reported in attrition and re-included in both numerator and denominator for this outcome Regression analysis for passive smoke exposure, years of education reported
Notes	SDs for mean birthweight were not reported, therefore we calculated a mean SD from 13 studies with available birthweight SDs (578) to include in this review, as recommended by the cochrane handbook

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Quasi-randomised by odd or even birth date. Included in review despite inadequate sequence generation as there is a low likelihood of interference with birthdate allocation
Allocation concealment (selection bias)	High risk	Quasi-randomised by odd or even birth date.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition: 10 had miscarriage or stillbirth (C = 5, I = 5); 21 moved out of area (C = 12, I = 9); 17 had a premature delivery (C = 10, I = 7). These were excluded from analysis
Selective reporting (reporting bias)	Low risk	Primary outcomes appear to be reported.
Other bias	Low risk	No other bias detected.

Biochemical validation of smoking abstinence (detection bias)	Low risk	Smoking cessation validated by salivary cotinine <= 30 ng/mL
Blinding of participants and personnel (performance bias) All outcomes	High risk	Providers and participants not able to be blinded to educational intervention and NRT provision not blinded (no placebo)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated.
Incomplete implementation	High risk	Only 87 women (27%) accepted participation: 81 in a group and 6 women accepted an individual smoking cessation program. 71 of 87 participants (82%) participated in 3 or more of a total of 9 meetings in the smoking cessation program. 75 (86%) of 87 women participating in the smoking cessation program were using nicotine substitution in the form of a 15 mg nicotine patch (16 h/day) or 2 mg nicotine chewing gum or a 15 mg nicotine patch (16 h/day) plus 2 mg nicotine chewing gum
Equal baseline characteristics in study arms	Unclear risk	Mostly equal except more women were exposed to passive smoking in the home in the intervention group (77%) than in the control group (67%) (P = 0.03)
Contamination of control group	Unclear risk	The strengths of the study include absence of treatment diffusion as all participants in the intervention group were seen by specially trained midwives as opposed to participants in the control group who were all consulting midwives without such training. The study enjoys a second advantage which is that intervention and control group participants were seen at different week days and hence could not easily share information. The secretaries summoning the pregnant women were continuously reminded about this allocation criterion to avoid treatment diffusion between the intervention and the control group. p814

Heil 2008

Methods	Randomised controlled trial of financial incentives to support women to stop smoking in pregnancy and prevent relapse postpartum Study conducted in Greater Burlington, Vermont (USA) with data collection from 2001 to 2003
Participants	**Inclusion criteria:** Self-reported smoking (even a puff in the last 7 days), gestational age less than 20 weeks, living within study clinic county and not planning to move until at least 6 months postpartum, and speaks English **Exclusion criteria:** Incarceration or previous participation in the study or living with anyone who has previously participated in the study **Recruitment:** Participants were recruited from 1 of 4 large obstetric practices in the Women, Infants and Children (WIC) program. 182 women were eligible for the study, and 82 (45%) agreed to participate. Mean gestation at recruitment (I = 8.9, C = 9.5). 77 included in analysis (C = 40, I = 37) **Baseline characteristics:** Pre-pregnancy cigarettes per day (I = 18.7, C = 18.4), Health insurance (I = 19%, C = 13%). **Progress+ coding:** Low SES as WIC program recipients.
Interventions	**Control** (non-contingent voucher): Participants received voucher independent of smoking status. US$ 15.00 per antenatal visit and US$ 20.00 per postpartum visit, to result in comparable average earnings to the contingent group. Both groups received routine advice from the clinic **Intervention** (contingent voucher): participants chose a quit date, and reported daily to the clinic for CO monitoring for 5 days, then urine cotinine monitoring twice weekly for 7 weeks, weekly for 4 weeks, and then every 2 weeks for the remainder of the pregnancy. Vouchers were given dependent on biochemical validation, beginning at US$ 6.25 and escalated by US$ 1.25 to a maximum of US$ 45.00. Positive test results reset voucher back to original value, but 2 consecutive negative tests restored value to pre-reset value. It is unclear who delivered the intervention **Main intervention strategy:** Incentives (single intervention) compared to alternative intervention Intensity: Frequency (C = 6, I = 6), Duration (C = 6, I = 6). Intervention provided by study staff: efficacy study.
Outcomes	Biochemically validated smoking cessation at >= 28 weeks' gestation (late pregnancy*), 12 weeks (0-5 months*) and 24 weeks' (6-11 months*) postpartum. Reduction in mean cotinine Mean birthweight*, gestational age, fetal growth measures (US), and proportion of NICU admissions*, low birthweight* infants, and preterm births* Nicotine withdrawal symptoms reported in associated reference (Heil 2004).
Notes	Sample size justification. Some discussion of cost implications
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as "randomisation stratified to clinics". Details of randomisation not described
Allocation concealment (selection bias)	Unclear risk	No information.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	5 women withdrew from the study due to fetal demise or termination of pregnancy and were not included in the final analysis (I = 3, C = 2)
Selective reporting (reporting bias)	Low risk	Detailed birth outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemical validation using exhaled CO for 5 days (< 6 ppm) and then urine cotinine (< 80 ng/mL)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and providers not blinded as receiving incentives for participation
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Low risk	Compliance with periodic assessments was relatively high (83%-95%)
Equal baseline characteristics in study arms	Low risk	No significant differences in socio-demographics or smoking characteristics were noted
Contamination of control group	Low risk	Very unlikely - as clear voucher schemes for abstinence and non-abstinence

Hennrikus 2010

Methods	Randomised controlled trial of mobilising peer social networks to support pregnant women to stop smoking The study was conducted in urban Women, Infants and Children (WIC) clinics in Minnesota and an urban university outpatient obstetric clinic in Ohio, USA from 2005 to 2007
Participants	**Inclusion criteria:** Pregnant women in the first or second trimester, a current smoker, and at least 18 years old **Exclusion criteria:** Not further specified. **Recruitment:** Each eligible and consenting participant identified a woman in her social network to act as a supporter. 872 women screened in waiting areas. 82/156 (53%) eligible women and their supporters agreed to participate (C = 28, I = 54) **Baseline characteristics:** Median number of cigarettes smoked per day = 5 (range = 1-25) and 52% smoked their first cigarette within 30 min of waking. 52% of supporters were current smokers and 22% were former smokers. There were no significant differences between study arms 67% from racial minority groups, 65% had high school education or less. Median age = 24 **Progress+ coding:** Low SES as all WIC program recipients.
Interventions	**Control:** 1 in-person counselling session for control and intervention participants designed to increase motivation to quit and provide information about community smoking cessation resources **Intervention:** Peer-supporters in the intervention group had 1 in-person visit and monthly telephone sessions. The primary goal was to develop strategies to help the participant quit smoking by identifying specific activities to support efforts to quit. Women and their supporters were given a pregnancy scrapbook that included pages related to smoking cessation tasks **Main intervention strategy:** Social support (single intervention) compared to a less intensive intervention **Intensity:** Frequency (C = 2, I = 4), Duration (C = 2, I = 5- estimated) Intervention provided by specific staff: Efficacy study.
Outcomes	Biochemically validated smoking status just prior to expected delivery date (late pregnancy*) and 3 (0-5*) months postpartum Women's perceptions of peer support behaviours reported (both positive and negative)
Notes	
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Blocked random allocation sequence
Allocation concealment (selection bias)	High risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition: C = 25%, I = 11% by end of pregnancy. C = 19%, I = 32% by 3 months postpartum. Report ITT analysis for end of pregnancy validated quits. 7 women who had miscarriages were excluded from the analysis. All randomised participants included in the analysis in this review (dropouts included as continuing smokers)
Selective reporting (reporting bias)	Low risk	All primary outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Self-reported smoking status biochemically validated using urinary cotinine (< 100 ng/mL)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible to blind participants and providers to this social support intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors blinded as 'evaluation staff were blinded to group assignment'
Incomplete implementation	High risk	Process evaluation showed over 90% supporters received at least 1 counselling session, but contacts with supporters occurred less frequently than the planned monthly intervals because of difficulty reaching supporters
Equal baseline characteristics in study arms	Unclear risk	Significantly more intervention participants had other children (78% vs. 57%, P = 0.052) and significantly fewer were white (22% vs. 54%, P = 0.016), but other characteristics equal
Contamination of control group	Low risk	Contamination unlikely with this intervention which required researchers to contact intervention group at home

Hiett 2000

Methods	Randomised controlled study of health education and feedback to support women to stop smoking Location and study dates unclear. Assume USA due to author affiliations
Participants	**Inclusion criteria:** Women enrolling for prenatal care. **Exclusion criteria:** Not further specified. **Recruitment:** 49 women randomised (I = 26, C = 23). **Baseline characteristics:** Not reported (abstract only).
Interventions	**Control:** Usual prenatal care. **Intervention:** Education and at least 8 encounters with a program counsellor. Peak flow values and CO levels were obtained at each prenatal visit and shared with intervention group participants only Main intervention strategy and intensity not coded as outcomes not reported
Outcomes	Smoking cessation (biochemically validated) was collected but actual figures not reported so unable to include results in this meta-analysis. Peak flow values reported
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	States 'women were randomised into two groups'.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Data not reported.

Selective reporting (reporting bias)	High risk	Actual figures not reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemical validation of smoking status using urine cotinine and CO (cut-off levels not reported)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel unlikely to be blinded to educational intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	Not reported.
Equal baseline characteristics in study arms	Low risk	Groups similar with maternal age, fagerstrom scores, initial peak flow values and initial urine cotinine levels
Contamination of control group	Unclear risk	Not stated who delivered intervention.

Hjalmarson 1991

Methods	Quasi-randomised trial of a self-help manual to support women to stop smoking in pregnancy Study conducted in public health maternity clinics in Gothenburg, Sweden, with data collection from 1987 to 1988
Participants	**Inclusion criteria:** Pregnant women registered as daily smokers (at least 1 cigarette per day), gestational age less than 12 weeks, and speak Swedish **Exclusion criteria:** Not further specified. **Recruitment:** 13/14 public health clinics participated. Women born days 1-10 of each month were allocated to the control group and women born on days 11-31 were allocated to the intervention group. Unequal group sizes were allocated as it was expected more intervention women would refuse to participate. 723 eligible continuing smokers were randomised (C = 231, I = 492). 417/492 (85%) of the intervention group agreed to participate, and the control group were not asked for consent **Baseline characteristics:** Mean cigs/day 16.8. Mean age 28.4 years. **Progress+ coding:** None.
Interventions	**Control:** Given an information sheet by their doctor with basic facts about smoking and pregnancy, as included in the last pages of the self-help manual **Intervention:** Given a self-help manual on stopping smoking, based on Windsor 1985. The manual was revised and pilot tested. The manual contained 2 phases, a preparatory (one week) and cessation phase. The smoker was given new assignments every day to the quit day and the tasks were based on the principle of behaviour therapy. The cessation period was followed for the first 5 days with new information daily **Main intervention strategy:** Health education (single intervention) compared to less intensive intervention **Intensity:** Frequency (C = 1, I=1), Duration (C = 1, I = 1). Intervention provided by existing staff (obstetrician provided self-help manual): Effectiveness study
Outcomes	Biochemically validated smoking cessation at 30-34 weeks' gestation (late pregnancy*), 8 weeks postpartum (0-5 months), mean birthweight*, preterm births* (< 36 wks), low birthweight babies*, mean cigarettes per day at 30-34 weeks' gestation among baseline smokers*. Mean cigarettes per day at baseline, week 12-14, week 30-34 among all randomised women, 8 weeks after delivery among baseline smokers and all randomised women
Notes	SDs for mean birthweight were not reported, therefore we calculated a mean SD from 13 studies with available birthweight SDs (578) to include in this review, as recommended by the cochrane handbook.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Allocation by birth date is not random sequence. However, this study was included as interference is unlikely with birth dates
Allocation concealment (selection bias)	High risk	Allocation would not be concealed as allocated by birth dates (days 1-10 = control, days 11-31 = intervention)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Loss to follow-up from miscarriage and moving out of district (C = 10% or 23, I = 11% or 46), not included in analysis. However, all other dropouts included as continuing smokers
Selective reporting (reporting bias)	Low risk	All primary outcomes appear to be reported.
Other bias	High risk	Unclear why there are 444 in intervention group and 209 in control group, when report states 10% of 231 were excluded and 11% of 492 were excluded
Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemical validation of smoking status using serum thiocynate (100 ng/mL)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel unlikely to be blinded.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	Manual given to all women who agreed to participate (85% of total assigned to intervention - i.e. 15% refused to participate)
Equal baseline characteristics in study arms	Unclear risk	Only age and mean no of cigarettes reported.
Contamination of control group	Low risk	Unlikely control group would accidentally be given the self-help manual

Hughes 2000

Methods	Randomised controlled trial of stage of change orientated motivational interviewing to support women to stop smoking in pregnancy The study was conducted in infertility and prenatal clinics in 3 hospitals in Ontario (Canada), with data collection from January 1996 to July 1999
Participants	**Inclusion criteria:** Newly referred infertile and pregnant patients who reported smoking more than 3 cigarettes in past 6 months **Exclusion criteria:** Women attending genetic counselling or with habitual abortion or who had previously been evaluated in consultation **Recruitment:** All women attending infertility and prenatal clinics who reported smoking were invited. Unclear how many were eligible. 110 pregnant women randomised (I = 56, C = 54) **Baseline characteristics:** Mean cigs/day = 12.19 (SD 6.81); (I = 13.43 +−7.07, C = 12 +− 6.69
Interventions	**Control:** Standard information that was already provided in the clinics about the impact of smoking on pregnancy **Intervention:** Scripted stage-based information and encouragement to quit at each prenatal visit by physicians, Stage-specific information booklet, optional referral for more in-depth counselling in a smoking cessation clinic **Main intervention strategy:** Counselling (tailored intervention) compared with usual care Intensity not coded as outcomes unable to be included in meta-analysis
Outcomes	Stage of change, biochemically validated cessation at 12 months post follow-up but data for intervention and control groups were combined so outcomes were unable to be included in this review. See Table 1 for description of outcomes. Relative value of intervention components reported.
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomised using computer-generated, blocked schedule, administered through numbered, opaque, sealed envelopes
Allocation concealment (selection bias)	Low risk	Opaque sealed envelopes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No attrition reported and not stated how, if any, dropouts were assessed

Selective reporting (reporting bias)	High risk	Smoking cessation outcomes not reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Unclear risk	Biochemical validation with exhaled CO, but levels used to determine smoking status were not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Providers and women not able to be blinded.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated whether outcome assessors blinded.
Incomplete implementation	Unclear risk	Process evaluation not reported.
Equal baseline characteristics in study arms	Low risk	No significant differences noted.
Contamination of control group	High risk	Same care providers offering intervention and control interventions, therefore high risk of contamination

Kendrick 1995

Methods	Cluster-randomised controlled trial to support women to stop smoking and prevent relapse during pregnancy and postpartum Study conducted in public prenatal and WIC clinics in Maryland, Colorado and Missouri (USA), with data collection from 1987 to 1991
Participants	**Inclusion criteria:** Smoking defined as “even a puff within the last 7 days before the women knew she was pregnant”, who were aggregated into ‘enrolment smokers’ (smoked within 7 days before study enrolment) and ‘recent quitters (smoked before they thought they were pregnant) **Exclusion criteria:** Not further specified. **Recruitment:** 1741/5262, 1936/6087 and 1895/4943 pregnant women screened in Colorado, Missouri and Maryland respectively, with nearly 50% of women in each state smoking. Participation rates ranged from 66% in Maryland to 79% in Missouri **Baseline characteristics:** Mean cigarettes/day at enrolment combined for smokers = 12 cigarettes/day High proportions were young, < 12 years education, white, unmarried and poor. Mean gestation at enrolment = 15.2 - 16.6 weeks **Progress+ coding:** Low SES.
Interventions	**Control:** Usual care not otherwise specified by usual clinic staff. **Intervention:** Based on stages of change, but differed by State, locally adapted with some detailed development. Colorado: 1-5 minutes counselling; assessing smoking status; quitting tips; supportive statements by nurse-clinicians; healthcare providers’ Guide; 8 brochures for pregnant smokers; additional 1 for women postpartum. Maryland: brief clinic-based counselling program + self-help material focusing on the stages of quitting. Missouri: “becoming a life-long smoker” six minutes with clinic patient brochures, flip charts; 1-2 minutes at WIC clinics training staff, chart documentation and forms. All included effects of smoking on the fetus; benefits of quitting; quitting techniques; developing social support; preventing relapse and limiting exposure to environmental tobacco smoke. All materials were at 6th Grade reading level **Main intervention strategy:** Counselling (multiple intervention) compared to usual care **Intensity:** Frequency (C = 0, I = 2), Duration (C = 0, I = 1). Usual care intensity: F = 0, D = 0 Intervention provided by existing staff: Effectiveness study
Outcomes	Biochemically validated point prevalence abstinence at 8 months gestation (late pregnancy*). Smoking outcomes for ‘recent quitters’ (relapse prevention) were not reported. Birthweight and proportion of low birthweight babies are not reported by intervention group so were unable to be included in meta-analysis
Notes	Intracluster correlation of 0.003 reported and used for adjusting outcome figures in analysis. Substantial misclassification of self-report as non-smoking: 28% at enrolment; 35% at 8th month; 49% of self-reported quitters at intervention clinics; 32% of self-reported quitters at control clinics. Process evaluation suggested less difference between I and C clinics than might have been expected. Project staff felt that the use of existing staff to deliver the new interventions and to collect data affected the study negatively especially given the time needed to process questionnaires and urine samples. This led to less than full implementation and variable motivation to promote smoking cessation counselling among staff

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Clinics stratified by size of clinic and also by prior low birthweight programme (Colorado) or % minority clients (Maryland), and randomly assigned to deliver either intervention or continue with standard care. No details of randomisation provided
Allocation concealment (selection bias)	Unclear risk	Cluster-randomised trial.
Incomplete outcome data (attrition bias) All outcomes	High risk	In the 3 states combined, the reasons for loss to follow-up at the eighth month were early termination of pregnancy (7. 6%); enrolment after 32 weeks (6.1%); lost, moved, or unable to locate (27.7%) ; referred to another care provider (2.8%); and refused data collection (1.0%). The total number of enrolment smokers were not reported by intervention groups, and attrition rates were not reported by intervention groups, so we were unable to re-include data for respondents lost to follow-up. Report states loss to follow-up was balanced in experimental and control groups. Varying enrolment and attrition rates in different centres. No ITT analysis
Selective reporting (reporting bias)	Unclear risk	High rates of non-disclosure for smoking outcomes.
Other bias	Unclear risk	Uneven recruitment to study arms in Maryland, which affected the overall allocation (C = 1767, I = 1467)
Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemical validation by urinary cotinine (< 85 ng/mL indicates active smoker)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear whether participants and providers were aware of clinic allocation
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	High risk	Process evaluation reported that implementation was less than ideal
Equal baseline characteristics in study arms	Low risk	Intervention and control sites were similar at enrolment, indicating that stratification and randomisation had been effective (data not shown)
Contamination of control group	Unclear risk	Many patients at control clinics also reported having received (non-SCIP) materials and counselling which indicated that usual care included exposure to smoking cessation messages

Lawrence 2003

Methods	3-armed cluster-randomised trial of self-help manuals and computer-generated advice to support women to stop smoking in pregnancy Study conducted in community midwife clinics in the West Midlands region of the UK, with data collection from July 1998 to March 2001
Participants	**Inclusion criteria:** Head midwife in every trust in region invited to participate and 16/19 agreed to participate. 204 potential midwifery practices identified, and 103 excluded by head midwife as those trusts were already involved in other regions or the practice crossed trust boundaries. Women were eligible if aged 16 years or over and a 'current smoker' at booking **Exclusion criteria:** Women not fluent in English. **Recruitment:** 72/101 practices were randomly sampled (C = 24, **I1** = 24, **I2** = 23). Further practices were later added to each arm due to slow recruitment, particularly in the control arm (C = 17, **I1** = 12, **I2** = 0), leaving active practices (C = 32, **I1** = 30, **I2** = 22). Participating midwives were asked to recruit all eligible women seen in routine antenatal appointments. Initial target of 1440 participants was reduced to 900 due to slow recruitment. Eligible smokers approached: C = 328/965 (34%),**I1** (manuals) = 327/694 (47%), **I2** (computer) = 397/529 (75%). Participation rate: C = 289/328 (88%), **I1** = 305/327 (93%),**I2** = 324/397 (82%). **Baseline characteristics:**Mean cigarettes per day at baseline were similar between groups (reported in 6 smoking categories). Majority (over 60%) smoked 5-20 cigarettes per day and over 50% had a partner who smoked. Median fagerstrom score 3 in all arms 63.6% of participants on < $300/week. **Progress+ coding:** Low SES.
Interventions	**Control:** 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" **Intervention 1 (self-help booklets):** Midwives received 2 and a half days training on theory of transtheoretical model. Participants received a set of 6 stage-based self-help manuals "Pro-Change

	programme for a healthy pregnancy". The midwife assessed each participant's stage of change and pointed the woman to the appropriate manual. No more than 15 minutes was spent on the intervention **Intervention 2 (self-help booklets+computerised advice):**Midwives received the same training as for **I1**, and participants received the same self-help manual and intervention as **I1**. Additionally, the participants used a computer programme, which consisted of questions and auto feedback of what stage they were in and what this meant, and a range of other concepts. It took about 20 minutes for the woman to complete. Printed information of the feedback was sent to the participant within a week of the intervention **Main intervention strategy:** Counselling (multiple intervention) compared with usual care. Intervention 2 were combined and compared with the control arm in this review **Intensity:** Frequency (C = 0, I = 3); Duration (C = 0, I = 3). Usual care intensity: F = 1, D = 1 Intervention provided by existing staff (Midwives providing self-help manuals): effectiveness study
Outcomes	Biochemically validated point prevalence abstinence at 28-30 weeks' gestation (late pregnancy)* (T3) and 10 days post-birth* (T4) (0-5 months postpartum). Effect of midwife training (attitudes, expectations, confidence, concerns and routine practice) was assessed by pre-post training questionnaires Subsequent papers (Lawrence 2005b) measure and describe self-reported smoking cessation at 18 months postpartum, movement in stage of change, partner quitting, social support mobilisation, and the stress of receiving the intervention
Notes	Intracluster correlation of 0.003 reported and used for adjusting outcome data included in this meta-analysis (see Table 2). Sample size calculation given, but unable to recruit sufficient numbers

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	A computerised minimisation programme was used to stratify 72 eligible practices into 3 equal groups from101 available practices
Allocation concealment (selection bias)	High risk	Further practices were added to the sample because of slow recruitment - these were not randomly allocated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Different rates of recruitment and followup in different arms of the trial. 272 (C= 1 04, **I1** = 86, **I2** = 82) women (22.5%) withdrew from the study or were lost to follow-up. Data on smoking status were only available for 67% of women. Where there was no urine sample available women were treated as continuing smokers. All randomised participants were included in the denominator in this analysis, with only those reported as confirmed non-smokers at T4 included as quitters
Selective reporting (reporting bias)	Unclear risk	Not apparent.
Other bias	High risk	Slow recruitment to standard care arm, so additional practices needed to be added
Biochemical validation of smoking abstinence (detection bias)	Low risk	Urinary cotinine analysis (< 1.5 ug/L).
Blinding of participants and personnel (performance bias) All outcomes	High risk	Neither providers nor women blinded to this educational intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete implementation	Low risk	77% T4 questionnaires complete in **I2**.
Equal baseline characteristics in study arms	Low risk	There was little difference at recruitment between the midwives or recruited women in the 3 trial arms
Contamination of control group	Low risk	Cluster design to reduce risk of contamination.

LeFevre 1995

Methods	A randomised controlled trial (RADIUS) of routine ultrasound screening to improve perinatal outcomes, including smoking in pregnancy

	The study was conducted in Missouri, USA, with data collection from November 1987 to May 1991
Participants	**Inclusion criteria:** Last menstrual period known within 1 week, gestational age < 18 weeks, no plans to change providers. All women enrolled in the RADIUS study who reported any smoking in the year before enrolment in the study were evaluated in the subgroup analysis **Exclusion criteria:**Medical or obstetric complications, planning an ultrasound for other reasons, twin pregnancy, not intending to continue pregnancy **Recruitment:** 53,367 pregnant women were screened for entry into RADIUS study; 32, 317 ineligible or excluded; leaving 21,050. 3163 refused (85% participation), 2357 had miscarriage or change of provider; leaving 15,530 randomised (C = 7718, I = 7812), 23. 8% (3,571) of whom were smokers in year before enrolment, and 1901 who were still smoking at enrolment. 3,571 smokers included in this analysis (C = 1803, I = 1768) **Baseline characteristics:** 95% aged 20-35, 95% white, Education: high school or less (C = 30%, I = 29%), some college (C = 29%, I = 30%), college graduation (C = 42%, I = 41%) **Progress+ coding:** None.
Interventions	**Control:** Ultrasounds only if ordered by their physician for medical reasons **Intervention:** Ultrasound at 18-20 and 31-33 weeks, no details about feedback to the mother or others. No specific smoking intervention provided **Main intervention strategy:** Feedback (single intervention) as part of a broader intervention to improve maternal health compared to usual care **Intensity:** Frequency (C = 0, I = 3), Duration (C = 0, I = 2). Usual care intensity: F = 0, D = 0 Intervention provided by study staff: efficacy study.
Outcomes	Mean number of cigarettes per day*. Self-reported smoking cessation recorded on birth certificate, but unable to determine how many smokers in each group so smoking outcomes not included in this review Mean birthweight, preterm births (< 36 weeks), very preterm birth (< 33 weeks), and adverse perinatal outcomes, but were not included in this review as other aspects of the intervention may have impacted on perinatal outcomes
Notes	SDs for mean cigarettes per day were not reported, therefore we calculated a mean SD from 14 studies with available mean cigarette SDs (6.5) to include in this review, as recommended by the cochrane handbook

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Stratified computer randomisation.
Allocation concealment (selection bias)	Unclear risk	Information not provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Small loss to follow-up (approximately 2%). Miscarriage: C = 63, I = 64, records lost or moved: C = 121, I = 131, leaving C = 7534, I = 7617; Available case analysis but smoking cessation was not a primary outcome
Selective reporting (reporting bias)	Low risk	None apparent.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	No biochemical validation.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Smoking status not revealed to sonographer. Intervention not explicitly about smoking cessation
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Low risk	The mean number of sonograms obtained was 2.2 per woman in the ultrasound-screening group
Equal baseline characteristics in study arms	Low risk	Baseline characteristics appear equal.
Contamination of control group	Low risk	The mean number of sonograms obtained was 0.6 per woman in the control group and 55 percent had no sonograms. Only 2% of control group had 2 ultrasounds

Lilley 1986

Methods	A randomised controlled trial of counselling intervention to support women to stop smoking in pregnancy The study was conducted in an antenatal clinic in Newcastle Hospital (UK), from March to May 1982
Participants	**Inclusion criteria:** All pregnant women currently smoking >= 1 cigarette a day at the time of the first antenatal clinic under care of 4 consultant obstetricians **Exclusion criteria:** Women 28 weeks' gestation or more. **Recruitment:** 156 smokers identified in clinics and 5 were excluded as over 28 weeks' gestation. 151 randomised (C = 74, I = 77) **Baseline characteristics:** Mean cigarettes per day before pregnancy: C = 18.3, I = 18. 1. Mean cigs per day at booking: C = 14.4, I = 15.1. Mean age: C = 25 years, I = 22.7 years. Partner unemployment: C = 53%, I = 57% **Progress + coding:** Low SES as study in 'deprived area' and high partner unemployment
Interventions	**Control:** Usual antenatal care with possible exposure to a concurrent television series (6 × 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) four weeks later there was a pre-planned 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. **Main intervention strategy:** Health education (multiple intervention) compared to usual care **Intensity:** Frequency: (C = 0, I = 4), Duration (C = 0, I = 2) Estimate. Usual care intensity: F = 1. D = 1 Intervention provided by existing staff (resident): Effectiveness study
Outcomes	Self-reported smoking cessation 9-16 weeks after booking visit (late pregnancy*). Mean cigarettes per day* (the SD used in the analysis in this review was calculated from a P value of 0.05 given in the paper)
Notes	Short interval between intervention and assessment.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as balanced "simple random allocation" in blocks.
Allocation concealment (selection bias)	Unclear risk	Information not provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Small loss to follow-up, some missing data but balanced across groups. Attrition 6/151 (4%, C = 3, I = 3): not pregnant (C = 1), 1 guilt over previous stillbirth (I = 1), and miscarriages or medical complications (C = 2, I = 2). 145 included in analysis (C = 73, I = 72)
Selective reporting (reporting bias)	Low risk	None apparent.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	No biochemical validation of self-reported smoking cessation
Blinding of participants and personnel (performance bias) All outcomes	High risk	Neither women nor providers blinded to this educational intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	High risk	A home visit at 4 weeks was made to the remaining 76 test patients. 31 (41%) were found at home; 29 were given further antismoking advice; 45 (59%) were out and a letter of encouragement was left
Equal baseline characteristics in study arms	Unclear risk	Mean age of test mothers 22.7, controls 25. Report notes other variables were equal, but figures are not reported
Contamination of control group	Low risk	Main component home visit.

Lillington 1995

Methods	Cluster-randomised controlled trial of 'Time for a Change' behavioural intervention to support low income African American and Hispanic women to stop smoking and prevent relapse in pregnancy and prevent relapse postpartum Study conducted in 4Women, Infant, and Children (WIC) clinics in south and central Los Angeles (USA) from October 1990 to December 1992
Participants	**Inclusion criteria:** 4 clinic sites identified from similar neighbourhoods and pairmatched based on ethnic mix. Pregnant women at least 18 years of age who had smoked in the previous year **Exclusion criteria:** Not further specified. **Recruitment:** Clinics randomly assigned. All pregnant women were asked about smoking and participants in intervention sites were asked for informed consent. 8019 women screened (419 current smokers and 692 ex-smokers). 768/1102 (69%) current (410) or ex-smokers (692) entered the study. 18% refused (198), 12% (132) ineligible due to young age, early delivery or referral to a different clinic **Baseline characteristics:** Smoking: Current 40.5% (I = 51%, C = 36.5%); ex-smoker 59.5% (I = 49%, C = 63.5%) Mean age 26.8 (I = 27.3, C = 26.6). African American 53%, Hispanic 42.6% **Progress+ coding:** Low SES in this review as WIC clinic recipients, and ethnic minority population
Interventions	**Control:** Usual care, including printed information about the risks of smoking during pregnancy and a group quit-smoking message as part of the initial WIC visit **Intervention:** (i) Assessment of smoking motivation and intention to quit. (ii) Bilingual health educators (Spanish and English) with bachelors degrees provided 15 minutes individual counselling that included risk information and quit messages or reinforcement. (iii) Self help guide 'Time for a change' with an explanation of how to use it and behavioural counselling.(iv) Explanation of how to win prizes by completing activity sheets (v) booster postcard 1 month after study entry **Main intervention strategy:** Counselling (multiple intervention) compared with usual care **Intensity:** Frequency: (C = 0, I = 4), Duration (C = 0, I = 2). Usual care intensity: F = 1, D = 1 Intervention provided by dedicated study staff: efficacy study
Outcomes	Self-reported smoking cessation and relapse prevention at 9 months gestation (late pregnancy*), and 6 weeks postpartum (0-5 months postpartum*) Differential quite rates reported by African-American and Hispanic ethnic status Participants views of intervention.
Notes	Adjustment for clustering not reported. Adjustment in this review as per Table 2.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	4 participating clinics were identified from similar neighbourhoods and pair-matched based on ethnic mix. 2 clinics were 'randomly assigned' as control sites, and 2 clinics were assigned as intervention sites
Allocation concealment (selection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	High risk	28% attrition (213/768), C = 28%, I = 25%(not stated how many from each arm, so not able to be re-included in this review). Drop-outs due to inability to contact, miscarriage or discontinuance with the WIC program. 555 included in analysis (C = 400, I = 155)
Selective reporting (reporting bias)	Low risk	Primary outcomes appear to be reported.
Other bias	High risk	Unequal recruitment to each study arm.
Biochemical validation of smoking abstinence (detection bias)	High risk	Self-reported abstinence only. Only able to obtain biochemical validation with salivary cotinine (cut-off 20 ng/mL) on 111/254 women who reported they were not smoking. High misclassification. Self-reported rates used in this review
Blinding of participants and personnel (performance bias) All outcomes	High risk	Providers and women not able to be blinded due to educational nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	Only 12/155 women returned and completed 12 worksheets.
Equal baseline characteristics in study arms	High risk	Intervention group had a significantly higher proportion of smokers at baseline (51% vs 36%) and

		a significantly lower proportion of participants in the third trimester for the initial WIC visit (27% vs 36%)
Contamination of control group	Low risk	Cluster trial at service level with minimal contact with control organisations

Loeb 1983

Methods	Randomised controlled trial of interventions (individual and group), based on the 'MRFIT' trial, to support women to stop smoking during pregnancy Study conducted in 1 of 2 hospitals in the Kaiser Permanente HMO of Oregon (USA), with women recruited between July 1979 and September 1980
Participants	**Inclusion criteria:** Pregnant women who answered 'yes' to a questionnaire about whether they now smoked **Exclusion criteria:** Not further specified. **Recruitment:** 3856 pregnant women screened in first antenatal visit: 963 self-reported current smokers (25%) were randomised (C = 486, I = 477). All women in intervention group were invited to participate in study but high refusal rates (37%). After some changes to recruitment strategy refusal rate dropped to 30.6% **Baseline characteristics:** Partner smoking: 74.1%. Mean age 23.3 years. 66.2% married. 21% smokers in receipt of public assistance but only 7% of non-smokers **Progress+ coding:** None.
Interventions	**Control:** Usual care: normal medical care for the duration of their pregnancy **Intervention:** (i) letter of invitation, 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 × 1.5 hour group sessions, once a week; (v) subsequent optional support groups, individual sessions and phone calls **Main intervention strategy:** Counselling (tailored intervention) compared with usual care **Intensity:** Frequency (C = 0, I = 6), Duration (C = 0, I = 6). Usual care intensity: F = 0, D = 0 Intervention provided by dedicated project staff: efficacy study
Outcomes	Self-reported smoking cessation in late pregnancy*. Biochemically validated with cord blood thiocyanate in a subsample (C = 24, I = 29)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details of randomisation.
Allocation concealment (selection bias)	Unclear risk	Described as "randomly assigned".
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition rates high at all stages of this study. Approximately 45% lost to follow-up. I = 271/477 (56.8%) completed last questionnaire, with 'similar numbers in control group' (C = 276/486). However. all dropouts included as continuing smokers in this review
Selective reporting (reporting bias)	Unclear risk	Birth outcomes reported by smoking status, not intervention group
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	Biochemical validation with urine thiocynate at delivery on a small subsample (C = 24, I = 29)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and providers not blinded to allocation.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	High risk	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
Equal baseline characteristics in study arms	Unclear risk	Differences between intervention and control group not reported
Contamination of control group	Low risk	Usual care providers not delivering intervention.

Lowe 1997

Methods	A randomised controlled trial of brief counselling to support women who had recently quit smoking to prevent relapse during pregnancy and postpartum The study was conducted alongside a concurrent trial (Windsor 1993) to support women to stop smoking during pregnancy, relapse prevention among women who had stopped smoking since the beginning of pregnancy, in 4 public maternity clinics in Birmingham, Alabama (USA) from 1987 to 1989
Participants	**Inclusion criteria:** Pregnant women reporting as having quit within 3 months of first prenatal visit **Exclusion criteria:** Not further specified. **Recruitment:** 106/115 women who were invited agreed to participate (92%) and were randomised (C = 54, I = 52) **Baseline characteristics:** All recent quitters within 3 months of first visit. No other baseline characteristics reported, though report states there was no significant differences in age, race, gestation, or smoking history between intervention and control, or those lost to follow-up **Progress+ coding:** None.
Interventions	**Control:** Usual prenatal care, including nurses' advice to all women not to smoke. **Intervention:** i) 10-minute counselling by health educator using smoking relapse prevention materials on effects of smoking; benefits of maintaining cessation; possible problems; smoking triggers; solutions to smoking cues; strategies for staying quit, contract, and flip chart (5th grade reading material) ii) "stay quit buddy" encouragement, non-smoking gifts and pamphlets, iii) clinic reinforcement by prenatal staff through reminder form in the notes and to confirm abstinence, praise, encourage continuing cessation **Main intervention strategy:** Counselling (multiple intervention) compared to usual care **Intensity:** Frequency (C = 0, I = 5), Duration (C = 0, I = 2). Usual care intensity: F = 1, D = 1 Intervention provided by dedicated project staff: Efficacy study
Outcomes	Biochemically validated relapse in late pregnancy*.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as "randomly assigned".
Allocation concealment (selection bias)	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	3 had a miscarriage, 4 moved and 2 had babies for adoption, leaving C = 2/54, I = 7/52 included in analysis. Smoking status reported on 80% (C = 38, I = 40), but ITT analysis for main outcome, so those subsequently lost to follow-up treated as continuing smokers
Selective reporting (reporting bias)	Unclear risk	Unclear what data were collected. Only smoking outcomes reported
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemical validation of non-smoking or reporting smoking less than or equal to 7 cigarettes since quitting with salivary thiocyanate analysis (cut-off levels not stated)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Notes flagged. Providers and women not blinded to allocation
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Low risk	Process evaluation showed good implementation.

Equal baseline characteristics in study arms	Low risk	Figures not reported but author states there was no difference
Contamination of control group	High risk	Issues of possible 'contamination' in clinics with individual randomisation discussed

Lowe 2002

Methods	Cluster-randomised trial to evaluate *dissemination* of a behavioUrally-based program to support women to stop smoking in pregnancy Study conducted in Queensland (Australia). Data collection dates not stated
Participants	**Inclusion criteria:** Public hospitals which provided antenatal and delivery care for 10 or more patients a year, had less than 50% Aboriginal and Torres Strait Islander population, and did not currently provide any antenatal smoking cessation care **Exclusion criteria:** Not further specified. **Recruitment:** Hospitals were matched on number of births, location of population centre (rural/metropolitan), and whether they had a specific antenatal clinic 80 (92% public hospitals) hospitals eligible. 10 omitted as they stopped providing antenatal care. 70 hospitals (35 pairs) included **Baseline characteristics:** Characteristics of individuals not reported. No outcomes included in study so not coded.
Interventions	**Control:** Received 'awareness' phase of intervention based in Rogers' Diffusion of Innovation theory. Flyers were distributed to all hospitals **Intervention:** Control +'Persuasion' phase, which included an educational workshop and presentation. 'Implementation phase' where each hospital conducted the recommended program **Main intervention strategy:** Intensive dissemination vs less intensive intervention. No outcomes to include in analysis **Intensity:** NA
Outcomes	Self-reported implementation of program at each hospital. Success was defined as the routine offer of an evidence-based smoking cessation program to at least 80% of the pregnant clients who smoke
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Report states hospitals were randomised into intervention and control groups, within matched pairs
Allocation concealment (selection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	High risk	Complete follow-up could not be obtained primarily due to the inability to contact either the medical superintendent or the director of nursing after a minimum of 3 attempts High attrition (37% hospitals), though those not responding were included in analysis as 'not implemented'
Selective reporting (reporting bias)	Unclear risk	Smoking cessation rates not reported, but not included as an aim of this dissemination study
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Unclear risk	Smoking status not assessed in this dissemination study.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear whether control hospitals were blinded.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated.
Incomplete implementation	High risk	37% reported as 'not implemented'.
Equal baseline characteristics in study arms	Low risk	Matching of the hospitals was successful as there were no differences in number of births, rurality, and

		whether they had a specialised antenatal service at baseline
Contamination of control group	Low risk	Cluster design likely to minimise risk of contamination.

Malchodi 2003

Methods	Randomised controlled trial of peer counselling to support women to stop smoking in pregnancy Study conducted in a large urban clinic in Hartford Hospital (USA), with recruitment from January 1998 to February 2000
Participants	**Inclusion criteria:** Pregnant women who smoke at least 1 cigarette per day in week before learning of pregnancy, less than 20 weeks' gestation, literate in English or Spanish, 18 years of age or older, and intending to carry to term **Exclusion criteria:** Women using smokeless tobacco or nicotine replacement products, or who reported current substance abuse or dependence **Recruitment:** All pregnant women screened at first prenatal visit and invited if met criteria. Informed consent obtained. Participation rate not reported, but states high smoking prevalence in pregnancy (29%) and hospital had over 4000 deliveries per year, and only 142 women recruited to study (C = 75, I = 67) **Baseline characteristics:** Mean cigarettes/day at baseline significantly higher in intervention group: C = 11.2 (SD 8.4); I = 13.3 (SD 13.3). Baseline CO C = 7.25 (SD 8.4), I = 5.12 (SD 5.01). Short term Fagerstrom score: C = 3.8 (2.87), I = 4.2 (2.44) Mean age C = 26, I = 26. Approximately 40% 12 years education or above. > 85% single. 63% Black, 12%-13% Hispanic, 23%-24% white. 'Low-income, uninsured women'. **Progress+ coding:** Low SES, ethnic minority, single population.
Interventions	**Control:** Usual care, which included the program of "Ask, Advise, Arrange and Assist", based on cognitive behaviour, described by Windsor 2000a, and provision of self-help materials, and smoking cessation counselling as per protocol as each visit **Intervention:** As for the control group + peer counselling from lay community health outreach workers (telephone or home visits). Peer counsellors received 2 × 3 hours of training **Main intervention strategy:** Social support (single intervention) compared to less intensive intervention **Intensity:** Frequency (C = 5, I = 6), Duration (C = 2, I = 5). Intervention provided by dedicated project staff: Efficacy study
Outcomes	Biochemically validated smoking abstinence*, and reduction (cigarettes/day) at 36 weeks' gestation (late pregnancy). Mean exhaled CO Mean birthweight* and proportion of babies* born low birthweight were provided by the study authors (unpublished data)
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated list.
Allocation concealment (selection bias)	Unclear risk	Information not provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	High attrition rates (C = 27/75 or 36%, I = 29/67 or 43%). ITT analyses for whole sample and for those remaining at follow-up
Selective reporting (reporting bias)	Unclear risk	Birth outcomes only reported by smoking status not intervention group
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Urinary cotinine levels at baseline and at 36 weeks' gestation (200ng/mL cut-off). Exhaled CO at each prenatal visit (< 8 ppm)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	States that caregivers were masked but women may have discussed but educational/counselling support intervention that women may have discussed with caregivers
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.

Incomplete implementation	Unclear risk	Process evaluation suggests reasonable implementation (median 6 contacts for those who remained in study), but high attrition limits exposure to intervention
Equal baseline characteristics in study arms	High risk	The peer counselling group had a greater proportion of heavier smokers at baseline
Contamination of control group	High risk	Discussion notes that quit rate in control group higher than expected and that 'usual care' in this trial may be more comprehensive. Which is likely as prompts etc were provided as part of trial participation to remind providers to offer support as per guidelines. Providers were also given training about the guidelines from trial staff

Manfredi 1999

Methods	Cluster-randomised controlled dissemination trial of "It's Time" program, in 33 prenatal, family planning and paediatric clinics Study was conducted in Chicago (USA) between November 1994 and July 1996
Participants	**Inclusion criteria:** 33 prenatal, family-planning and well-child clusters at 12 public health clinics were included. Services were matched into pairs on type of public health clinic (health department, neighbourhood health centre, university clinic), location (urban/rural), and racial mix. 10 months baseline measures were taken. The intervention was randomly assigned to 6 intervention and 6 control public health clinics **Exclusion criteria:** Not further specified. **Recruitment:** 1495 smokers identified (21% of women screened). 77% (1112) women in intervention group and 85%(1045) women in the control group agreed to participate. 63% (516) women in intervention group and 61% (548) women in control group completed the follow-up assessments (T2) **Baseline characteristics:** Mean cigarettes per day: C = 10.96, I = 12.01, Black C = 68.3%, I = 81.2%, > high school ed C = 39.2%, I = 38.9% Not coded as no outcomes included in review.
Interventions	**Control:** Not stated. **Intervention:** (i) Provider focused: Charts flagged with 'smoker' sticker, charts prepared with booklets and agreement form, documentation; (ii) Patient focused: motivational video played in waiting room, posters, brief provider advice, booklet, agreement form, letters reminding women of advice, 15-minute motivational interview **Main intervention strategy:** Counselling (multiple intervention) vs usual care. Intensity not coded as no outcomes able to be included in this review
Outcomes	Dissemination and smoking cessation outcomes reported, but not able to include in this review as we were unable to separate pregnant women from women attending family planning and paediatric clinics
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Just states 'randomly allocated'.
Allocation concealment (selection bias)	Unclear risk	Not stated.
Incomplete outcome data (attrition bias) All outcomes	High risk	37%-39% attrition (due mostly to lack of working telephones) and not clear how accounted for in analysis. Conducted analysis which suggests those lost to attrition did not differ significantly in race, cigarettes, stage of readiness, motivation, or confidence
Selective reporting (reporting bias)	Unclear risk	Actual outcomes for each service not reported so difficult to assess
Other bias	Low risk	No other bias detected
Biochemical validation of smoking abstinence (detection bias)	High risk	Self-reported smoking status, not biochemically validated.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women and provider not able to be blinded.

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	Not reported, despite being a dissemination trial.
Equal baseline characteristics in study arms	Unclear risk	Smokers in intervention clinics slightly older and more likely to be African-American
Contamination of control group	Low risk	Low risk of contamination as cluster trial.

Mayer 1990

Methods	3-armed randomised controlled trial comparing 2 smoking cessation interventions to support women to stop smoking in pregnancy Study conducted in WIC clinics in Grand Rapids, Michigan (USA), from 1985 to 86
Participants	**Inclusion criteria:** Pregnant women currently smoking (>= 1 cigarette/day). **Exclusion criteria:** Not further specified. **Recruitment:** 271/641 attending the clinics (42%) identified as smokers. 219/271 (81%) agreed to participate and were randomised (C = 77, **I1** = 70, **I2** = 72). **Baseline characteristics:** Mean cigarettes/day prior to pregnancy I = 19.9, C = 20.3. 75% white. 76.5% on medicaid. **Progress+ coding:** Low SES as WIC recipients.
Interventions	**Control:** Usual care which included printed information about the risks of smoking in pregnancy. Intervention 1 (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 2 (multi-component): 20-minute 1:1 counselling including risk information ("Because I Love My Baby" Am Lung Assoc, flip chart and brochure to take away), and behavioural change manual adapted from Windsor 1985 and the Am Lung Assoc "Freedom from Smoking" focusing on contracting and self-monitoring (CBT) **Main intervention strategy:** Counselling (multiple intervention) compared to usual care. Intervention 2 compared with control in this review **Intensity:** Frequency (C = 0, I = 2), Duration (C = 0, I= 2). Usual care intensity: F = 1, D= 1 Unclear whether intervention provided by existing staff or dedicated project workers
Outcomes	Self-reported smoking cessation at 9 months gestation (late pregnancy*) and approximately 4.7 weeks after birth (0-5 months postpartum*)
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Described as "randomly assigned".
Allocation concealment (selection bias)	Unclear risk	Not stated.
Incomplete outcome data (attrition bias) All outcomes	Low risk	15% attrition (33/219) at follow-up. All those lost to follow-up were treated as continuing smokers in this review
Selective reporting (reporting bias)	Low risk	Not apparent.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	Biochemically validated with salivary thiocyanate in approximately a third of participants (n = 66), but no adjustment for misclassification
Blinding of participants and personnel (performance bias) All outcomes	High risk	Caregivers not blinded to this educational intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated.
Incomplete implementation	Unclear risk	No process evaluation.
Equal baseline characteristics in study arms	Unclear risk	Differences between study participants and refusals on variables available from the WIC record were

		relatively minor for important variables as were study group differences
Contamination of control group	Low risk	Health educator, not usual care provider, offering intervention

McBride 1999

Methods	3-armed randomised control trial of an intervention to support women to stop smoking and prevent relapse in pregnancy and postpartum The study was conducted at the Group Health Cooperative of Puget Sound (Seattle, USA) (HMO), and Park-Nicollet of Minnesota (USA), a multispecialty group practice. Years of data collection not stated
Participants	**Inclusion criteria:** 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 **Exclusion criteria:** Unable to speak English. **Recruitment:** Women booked for a first prenatal visit were offered, by letter, study participation and unless they opted out were given a baseline telephone interview to assess smoking status. 9152 approached, 714 ineligible because of miscarriage, pregnancy termination, inability to speak English; 697 (8%) refused; 262 could not be reached by telephone after repeated attempts. 7479 (82%) completed survey. 1007/7479 (13%) were current smokers or recent quitters and were randomised: 897 participated (457 from Seattle, 440 from Minnesota), C = 297, **I1** = 294, **I2** = 306. Current smoker at baseline = 56% (C = 165, **I1** = 176, **I2** = 160). **Baseline characteristics:** Mean cigarettes/day before pregnancy = 14.9; Current mean cigarettes/day = 4.8. Mean age 27.7 years; Household income >= 30000 $US 67%; College graduates 17%; 88% white **Progress+ coding:** None.
Interventions	There were 3 stages of change based interventions, all delivered by mail or telephone without involving prenatal care providers. **Control:** 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. **Intervention 1:** 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. **Intervention 2:** The pre-post group received as for group 2 + an additional 3 counselling calls in the first 4 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 **Main intervention strategy:** Counselling (multiple intervention) compared to less intensive intervention. Intervention 1 and 2 were only reported as combined outcomes in late pregnancy, and included in this review. Postpartum outcomes are reported by intervention group and combines smokers at baseline and spontaneous quitters **Intensity:** Frequency (C = 2, I = 6); Duration (C = 1, I = 3). Intervention provided by dedicated project staff: Efficacy study
Outcomes	Self-reported 7-day point prevalence abstinence at 28 weeks’ gestation (late pregnancy*), with sample biochemically validated. (combined I1&I2); Relapse prevention in late pregnancy (spontaneous quitters*); Abstinence at 8 weeks (0-5 months*); 6 months* (6-11 months); and 12 months (12-17 months) postpartum (combined baseline smokers and spontaneous quitters). Response rates were 92% at 28 weeks; 91% at 8 weeks’ postpartum; 89% at 6 months postpartum; 87% at 12 months postpartum A subsequent paper reports partner abstinence.
Notes	Process evaluation describes participation in specific intervention components, including relapse prevention

Risk of bias

Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described. They were stratified by baseline smoking status
Allocation concealment (selection bias)	Unclear risk	No information provided.

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	110/1007 (11%) attrition. 88 miscarried and 22 were sent wrong intervention material and were excluded from analysis. 897 women included in final analysis. For self-reported smoking status non-respondents were treated as continuing smokers
Selective reporting (reporting bias)	Unclear risk	Smoking outcomes only reported and only combined outcomes for abstinence at 28 weeks' gestation
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	Salivary cotinine analysis. Salivary cotinine requested from all who reported abstaining for 7 days (< 20 ng/mL as cut-off). 64%-78% returned saliva samples and as there were no differences, outcomes reported are based on self-reported status
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible to blind providers and women to counselling intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	All samples were analysed for cotinine at the American Health Foundation laboratory. The computer-assisted telephone surveys were implemented by trained interviewers who had no role in intervention activities
Incomplete implementation	Low risk	Over 90% in the intervention group recalled receiving the self-help booklet, relapse prevention kit, counselling calls and newsletters
Equal baseline characteristics in study arms	Unclear risk	There were some baseline differences reported in text.
Contamination of control group	Low risk	The intervention was delivered via mail and telephone without involving prenatal health care providers

McBride 2004

Methods	3-armed randomised controlled trial of counselling and social support interventions to support women to stop smoking during pregnancy and prevent relapse post-partum The study was conducted in Womack Army Medical Centre at Fort Bragg in Feyettville, North Carolina (USA) from 1996 to 2001
Participants	**Inclusion criteria:** <= 20 weeks pregnant, >= 18 years of age, current smokers or recent quitters (i.e., were smokers in the 30 days prior to pregnancy but not smoking at intake), living with an intimate partner, and willing to have the partner contacted for participation in the study **Exclusion criteria:** Not further specified. **Recruitment:** 6156 woman screened at first prenatal clinic appointments were sent introductory letters with a toll-free number to call to decline contact. 997 pregnant smokers or recent quitters underwent further screening and 625 eligible women were randomised **Baseline characteristics:** Active smokers (C = 91, **I1** = 87, **I2** = 89). Recent quitters (C = 107, **I1** = 105, **I2** = 104). Current mean cigarettes per day 6 (SD 5). 52% had a partner who smoked Mean age 24 years; Household income >= 20000 $US 44%; >high school 52%; 96% married; 77% white **Progress+ coding:** none.
Interventions	**Control:** 'Usual care' where women received provider advice to quit smoking at the first prenatal visit and were mailed the American Cancer Society's self-help guide, "Make Yours a Fresh Start Family," written at the fifth-grade reading level and designed for pregnant women **Intervention 1 (woman only):** Control plus late pregnancy relapse-prevention kit (a booklet and gift items) and 6 counselling calls (3 in pregnancy and 3 in postpartum) initiated by a health advisor, who used a standardised protocol based on motivational interviewing techniques. All intervention contacts were completed by 4 months postpartum. Prenatal calls were timed to occur in each trimester and emphasised using self-help materials to take stage-appropriate steps towards cessation or to develop skills for remaining abstinent. Postpartum calls were timed to occur at monthly intervals and emphasised skills for remaining abstinent in the transition from pregnancy to parenting **Intervention 2 (partner-assisted group):** Woman only intervention plus a PA adjunct, in which the smoker described how her partner could be a coach to build and maintain the confidence she needed to quit smoking. An "It Takes Two" booklet and companion video were developed to guide couples in discussing support behaviours related to the woman's smoking. Partners received 6 separate calls (3 in pregnancy and 3 postpartum) from the woman's health advisor. These calls were made separately to the 2 individuals (pregnant woman and partner) and guided by a motivational interviewing protocol similar to that used for counselling the women. The second and fourth calls to the couple focused on developing a written agreement regarding helpful partner support

	behaviours. Partners who smoked were given self-help cessation guides, free nicotine patches if needed, and stage-appropriate counselling **Main intervention strategy:** Social support (multiple intervention) compared to a less intensive intervention. Intervention 2 compared to control in this review **Intensity:** Frequency (C = 2, I = 6); Duration (C = 1, I = 5). Estimate as duration of calls not reported Intervention provided by dedicated project staff: efficacy study
Outcomes	Self-reported point prevalence abstinence at 28 weeks pregnancy (late pregnancy*), relapse prevention at 28 weeks pregnancy (late pregnancy*), continued abstinence of combined spontaneous quitters and smokers at 2 (0-5*), 6 (6-11*) and 12 (12-17) months postpartum Partner cessation and perceived support were reported.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Reported as 'stratified by smoking status, partners smoking status and partners willingness to be involved and randomised to one of 3 conditions'
Allocation concealment (selection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	42 (7%) women who miscarried were excluded resulting in a sample of 583 (C = 198, **I1** = 192, **I2** = 193). An ITT approach was used, in which all randomised women (other than those who had miscarried)were included in the final analysis as continuing smokers. Drop out rates did not differ significantly across groups
Selective reporting (reporting bias)	Low risk	All primary outcomes appear to be reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	Self-reported smoking status only.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible to blind participants to social support intervention, requiring partner consent
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	High risk	Partner participation decreased steadily throughout the trial
Equal baseline characteristics in study arms	Low risk	Baseline characteristics appear equal.
Contamination of control group	Low risk	Care providers not providing intervention.

McLeod 2004

Methods	4-armed cluster-randomised trial (2×2) to support women to stop smoking in pregnancy and breastfeed postpartum Study conducted in the lower North Island, New Zealand, with recruitment from June 1999 to September 2000
Participants	**Inclusion criteria:** The midwifery team was the unit of randomisation, which were stratified by locality and randomised into 1 of 4 groups. All midwives in selected localities in the lower north island were invited to take part. Midwives asked all pregnant women who had smoked at the time they conceived to take part in the study **Exclusion criteria:** Not further specified. **Recruitment:** 93/121 (77%) midwives invited (from 62 midwifery teams), agreed to participate, and were randomised into 1 of 4 study arms (C = 23,**I1** = 22,**I2** = 22, **I3** = 26). 61 midwives recruited women to the study (76%). 46/349 (13%) women approached declined to take part in the study, 6 were ineligible, and 297 were recruited (C=60, I1=60, I2=69, I3=108) **Baseline characteristics:** Partner smoking (C = 50%, **I1** = 47%, **I2** = 62%, **I3** = 49%).

	Mean age: C = 24.9, **I1** = 26.1, **I2** = 27.3, **I3** = 25.1. Maori: C = 42%. **I1** = 36%. **I2** = 20%, **I3** = 27%. Over 50% in receipt of community services card. **Progress+ coding:** Low SES.
Interventions	Intervention developed with provider input and detailed discussion of provider views included **Control:** 'Usual' maternity care from a midwife, which ranged from asking about smoking, giving advice to quit and to providing more detailed smoking-cessation advice **Intervention 1 (smoking education):** Midwife training to implement education and support for smoking cessation and reduction **Intervention 2 (breastfeeding):** Midwife training and support to implement education and support for breastfeeding for women who smoked **Intervention 3 (combined):** Midwife training to implement smoking education and breastfeeding programmes Smoking education included motivational interviewing provided by a midwife (who was allocated an extra funded visit and given 4 hours training with a counsellor), flip-chart, video-tape **Main intervention strategy:** Counselling (single intervention) compared to usual care. Groups 1 and 3 compared to groups 2 and 4 in this review **Intensity:** Frequency (C = 0, I = 2), Duration (C = 0, I = 2). Usual care intensity: F = 1, D = 1 Intervention provided by existing staff (midwives): Effectiveness study
Outcomes	Biochemically validated smoking cessation at 28 and 36 weeks' gestation* (late pregnancy), and 6 weeks and 4 months postpartum* (0-5 months postpartum). Smoking reduction outcomes of self-reported 'cut down a little' or 'cut down significantly' are not included in this review as outcomes unclear Breastfeeding outcomes also reported.
Notes	Design effect for clustering reported, so outcome figures used

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random sequence generation using excel for each stratum.
Allocation concealment (selection bias)	Low risk	Group allocation by external statistician.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Missing data for most outcomes, 28% attrition for 4 month postnatal follow-up. Only women who moved from the area were excluded from analysis in this review
Selective reporting (reporting bias)	Unclear risk	Smoking status only reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	Serum cotinine samples provided by 108 women. 17/19 self-reported non-smokers had cotinine levels consistent with non-smoking, but outcomes not adjusted for misclassification. 15 ng/mL cut-off level
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible to blind midwives to allocation group. Women were not aware of midwife group allocation
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	There were problems with some midwives not recruiting any women to the study, but the degree of implementation among those women recruited is not reported
Equal baseline characteristics in study arms	High risk	When compared with control group, women in the smoking group were older and less likely to be Maori. Also the number of women recruited to the combined group was much larger than the other groups, which suggests potential issues with recruitment
Contamination of control group	Unclear risk	Cluster-study design to avoid contamination.

Messimer 1989

Methods	Cluster-randomised controlled trial to test the effectiveness of the ALA smoking in pregnancy intervention to support women to stop smoking in pregnancy Study conducted in 11 private obstetric practices in Michigan and Upper Wisconsin (USA), with recruitment from August 1985 to June 1986
Participants	**Inclusion criteria:** 24 physicians in 11 private practices participated in the study (12 family physicians and 12 obstetricians). Study practices randomised into 'roughly equal groups'. Women smoking at first antenatal appointment, less than 28 weeks' gestation were recruited to study **Exclusion criteria:** Not further specified. **Recruitment:** All women attending those clinics invited to participate. After giving informed consent, each woman was assigned a code number and had a questionnaire pack placed in her chart. 639 women screened (5 refusals), 206 smokers (32%), 69/209 had quit since becoming pregnant and 137 continuing smokers were included in the study (C = 70, I = 67) **Baseline characteristics:** Pre-pregnancy mean cigs per day = 20; current mean cigarettes per day = 11 98% white, 70% married, majority (80%) completed high school **Progress+ coding:** None.
Interventions	**Control:** 3 counselling sessions with physician on risks, ashtrays removed from waiting rooms and staff asked not to smoke in front of patients **Intervention:** Control plus (i) use of ALA materials (because you love your baby flip chart; because you love your baby packets, because you love your baby poster) (ii) encouragement to send off for materials (freedom from smoking manual), (iii) slide tape presentation at each women's first obstetrics visit **Main intervention strategy:** Counselling (multiple intervention) compared to less intensive intervention **Intensity:** Frequency (C = 3, I = 5), Duration (C = 1, I = 2). Intervention provided by existing staff (physicians): Effectiveness study
Outcomes	Self-reported smoking abstinence at 32-36 weeks' gestation (late pregnancy*) and first postpartum visit (timing not specified but assumed is standard 6 weeks pp visit), 0-5 months pp*
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Stratified by size - and then assigned by coin toss.
Allocation concealment (selection bias)	High risk	Allocation not concealed with coin toss randomisation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition: 7 miscarriages (C = 4, I = 3), 2 therapeutic abortions (C = 0, I = 2), 11 moved (C = 6, I = 5) and 8 had an incomplete dataset (C = 4, I = 4). Those with incomplete dataset were re-included as continuing smokers in this review (C = 60, I = 57)
Selective reporting (reporting bias)	Low risk	Primary outcomes appear to be reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	No biochemical validation of smoking status (self-report only)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible to blind providers and women to educational intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Low risk	Exact rates not reported - but 'only minor deviations' suggests very high implementation
Equal baseline characteristics in study arms	Unclear risk	Not reported.
Contamination of control group	Low risk	Cluster-randomised by clinic - so unlikely to have ALA materials

Morre 1998

Methods	Randomised controlled trial of nurse telephone support, which aimed to reduce infants born low birthweight and preterm, and included advice on smoking Study conducted in a community public clinic in the USA. Location and dates of data collection unclear
Participants	**Inclusion criteria:** Women with a preterm labour risk score of at least 7 on the Wake Forest University School of Medicine risk assessment tool; English-speaking; access to telephone; 22-32 weeks' gestation **Exclusion criteria:** Not further specified. **Recruitment:** 1850/3127 (59.2%) eligible women contacted. 1554 (84%) agreed to participate and were randomised (C = 779, I = 775) **Baseline characteristics:** 21.2% (n = 253) identified themselves as smokers. Black = 1113, White or other = 320. **Progress+ coding:** Not coded for this review as outcomes unable to be included
Interventions	**Control:** Booklet about preventing preterm labour, available in regular clinic. $10 gift certificate for completing questionnaire at 34 weeks' gestation **Intervention:** As control + instruction about signs of preterm labour, nurse telephone call schedule. 3 telephone calls per week which addressed: assessment of health status (including cigarette use); recommendations; and discussion of additional issues important to mother. $25 gift certificate at 37 weeks or after the birth of their baby if they returned their assessment and remained in contact with the nurse by telephone **Main intervention strategy:** Counselling (single intervention) compared to usual care. **Intensity:** Not coded as outcomes not able to be included.
Outcomes	Low birthweight and preterm births. Outcomes not included in study as unclear what proportion of outcomes were related to smokers. Furthermore, other aspects of the intervention (other than smoking cessation) may have impacted on perinatal outcomes so not included in this review
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random assignment by biostatistician using computer randomisation table
Allocation concealment (selection bias)	Low risk	Opaque sealed envelopes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	7.8% attrition due to moving or multiple pregnancies, leaving 1433 included in birth outcome analysis. I = 718, C = 715
Selective reporting (reporting bias)	Unclear risk	Smoking rates not reported, though not the primary aim of study
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	Self-reported smoking, but not reported as an outcome in this study
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women and providers not able to be blinded to counselling intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessor blinded.
Incomplete implementation	Low risk	Process evaluation not reported.
Equal baseline characteristics in study arms	Low risk	No significant differences between groups.
Contamination of control group	Unclear risk	Telephone intervention so unlikely calls were made to wrong women

Moore 2002

Methods	Cluster-randomised trial of self-help booklets to support women to stop smoking and prevent relapse in pregnancy Study conducted in 3 NHS hospital trusts in England (UK), with recruitment from May 1998 to July 2000
Participants	**Inclusion criteria:** Midwives were the unit of randomisation. Women attending first visit; >= 16 years; < 17 weeks' gestation; literate in English were eligible. 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" **Exclusion criteria:** Not further specified. **Recruitment:** All 128 community midwives in 3 trusts agreed to participate and were randomly allocated to 6 strata (C = 64, I = 64). Three midwives went on maternity leave and did not recruit any women (C = 64, I = 61). 8,586 women screened and 1527/1803 (85%) eligible women consented to participate (C = 803, I = 724) **Baseline characteristics:** Current smokers: C = 97, I = 97; Current but reduced since pregnancy: C = 464, I = 445 (All current smokers C = 561, I = 542); Recent quitters: C = 242, I = 182. Mean cigarettes per day before pregnancy: C = 15.1, I = 16. Mean cigarettes per day at baseline C = 5.5, I = 6.4 Maternal age: C = 26.7, I = 27.2. Left full time education by 16 years: C = 63.6%, I = 61%. **Progress+ coding:** Low SES.
Interventions	**Control:** Midwives continued to give routine advice according to usual practice. **Intervention:** Midwives 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 **Main intervention strategy:** Counselling (single intervention) compared to usual care. **Intensity:** Frequency: (C = 0, I = 4), Duration (C = 0, I = 1). Usual care intensity: F = 1, D = 1 Intervention provided by existing staff: Effectiveness study
Outcomes	7-day point prevalence abstinence at 26 weeks' gestation (late pregnancy*), with 94% validated by urine cotinine (80 ng/mL). Self-reported mean cigarettes per day in late pregnancy*. Relapse prevention for recent quitters not reported separately so outcomes for smokers and recent quitters are combined in this analysis. Stillbirths or neonatal deaths (not included as unable to separate), and preterm births (< 27 weeks) not included as rates < 36-37 weeks not reported. Reported as 'attrition'
Notes	Reported intracluster correlation of 0.031 used to adjust outcome data for inclusion in outcome tables. Sample size justification

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Stratified random allocation by computer-generated random numbers. 118 midwives stratified according to workload and randomly allocated to provide intervention or control care
Allocation concealment (selection bias)	Unclear risk	No information.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	92/1527 (6%) excluded from analysis due to miscarriage or termination (C = 36, I = 40), stillbirth or neonatal death (C = 9, I = 6)-not included as unable to separate, preterm birth (C = 1). Those lost to further follow-up (C = 50, I = 68) were included as continuing smokers in this review, leaving 1435 (C = 757, I = 678)
Selective reporting (reporting bias)	High risk	Outcomes not reported separately for baseline smokers and spontaneous quitters
Other bias	Unclear risk	Some unequal recruitment in each arm
Biochemical validation of smoking abstinence (detection bias)	Low risk	Urinary cotinine levels analysed (cut-off 60 ng/mL and 100 ng/mL)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Midwives randomised. Educational intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessment blinding not reported. However, follow-up rates were high in both groups, and all data coding and cleaning was undertaken blind to treatment allocation
Incomplete implementation	High risk	Detailed qualitative and quantitative process analysis of participants' and midwives' views of the intervention, which suggested poor implementation in some areas
Equal baseline characteristics in study arms	High risk	There were some differences between the 2 treatment groups at baseline, most notably in the numbers of women who had stopped smoking before the booking appointment and in the quantity of cigarettes consumed before the pregnancy and at the time of booking

Contamination of control group	High risk	Some concerns about contamination of control group reported.

Naughton 2012

Methods	Pilot randomised controlled trial to evaluate the feasibility, acceptability and potential effectiveness of tailored leaflets and SMS text messaging self-help intervention (MiQuit) to support women to stop smoking in pregnancy Study conducted in 7 National Health Service Trusts in the south east, east and north east of England (UK), with recruitment between December 2008 and October 2009
Participants	**Inclusion criteria:** Pregnant women less than 21 weeks' gestation, 16 years of age and over, smoked >= 7 cigarettes per week, owned or had regular use of a mobile phone, and could understand written English **Exclusion criteria:** Not further specified. **Recruitment:** 625 women were referred by midwives to the study and 207/512 (40%) eligible women agreed to participate and were randomised to the study (C = 105, I = 102) **Baseline characteristics:** Cigarettes per day before pregnancy and at enrolment reported by 6 categories and equal in both arms. Majority (over 60%) 11-20 cigs/day before pregnancy and approx 50% 4-10 cigarettes/day at enrolment Median age 26-27 years; 16% did not complete high school; 100% white **Progress+ coding:** None.
Interventions	**Control:** Participants received a non-tailored self-help leaflet, which matched the tailored leaflet in format and style, and the same assessment texts as MiQuit participants but no intervention texts **Intervention:** Participants receive MiQuit tailored self-help leaflet by post. Thereafter automated tailored text message component of intervention is initiated. 80 texts sent out over 11 weeks. MiQuit participants could also request instant response supportive texts at any time of the day **Main intervention strategy:** Health education (multiple intervention) compared to less intensive intervention **Intensity:** Frequency: (C = 2, I = 5), Duration: (C = 1, I = 1). Technological intervention: Unclear whether efficacy or effectiveness study
Outcomes	Biochemically validated 7-day point prevalence at 3-month follow-up (late pregnancy)*, self-reported 4-week point prevalence, initiation and frequency of quit attempts and 7-day point prevalence at 3 and 7 weeks after enrolment; Self-efficacy (5-point scale), acceptability measures
Notes	Process evaluation showed 98% intervention and 89% control participants received the leaflet and 87% intervention participants reported reading text messages at least once

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Generation of the randomisation tables and allocation of participants were implemented in a computer programme and managed by SS who had no contact with participants or involvement in data collection or entry
Allocation concealment (selection bias)	Low risk	'The allocation sequence was concealed from other members of the research team, midwives, and participants' (p570)
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Drop-outs due to miscarriage or stillbirth were excluded from the analysis (I = 6, C = 3). Reported as combined figure. 11% further attrition for other reasons (I = 10, C = 13), were included in analysis as continuing smokers (C = 96, I = 102)
Selective reporting (reporting bias)	Low risk	All primary outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemical validation of self-reported smoking cessation with salivary cotinine (< 13 ng/mL)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women unlikely to be blinded to educational intervention.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	'FN undertook data collection and was blinded to group allocation until all data had been collected.' (p570)
Incomplete implementation	Low risk	90% MiQuit participants reported reading all the leaflet at least once
Equal baseline characteristics in study arms	Low risk	There were not differences between trial arms on baseline variables except that more participants in the control arm had

		smoked in a previous pregnancy (difference adjusted for in analyses)
Contamination of control group	Low risk	Technological intervention so low risk of contamination between study arms

Olds 1986

Methods	4-armed randomised controlled trial which aimed to improve the uptake of prenatal care and pregnancy outcomes (especially low birthweight), and included advice about smoking Study conducted in a semi-rural county of New York State (USA), with recruitment between April 1978 and September 1980
Participants	**Inclusion criteria:** Pregnant women with no prior live births + any of the following: < 19 years; single; low socio-economic status, and any other women with no prior live births who wished to participate in the program **Exclusion criteria:** > 25 weeks' gestation (though some were enrolled at 25-29 weeks) **Recruitment:** 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 women were interviewed and 400 enrolled (80%). Families were stratified by marital status, race, and 7 geographic regions (C = 90, **I1** = 94, **I2** = 100, **I3** = 116). 141 smokers (C = 64, I = 77). **Baseline characteristics:** Mean cigarettes per day at intake: C = 6.94, I = 7.65. 47% < 19 years old, 62% single, 61% low SES (15% had none of these factors). Non-Whites (46) excluded because too few; serious maternal or fetal conditions (20) excluded **Progress+ coding:** Low SES.
Interventions	**Control:** Health and developmental screening of the baby at 12 and 24 months; **Intervention 1:** Control + free transport to pregnancy and well-child visits (control); **Intervention 2:** 1+ nurse home visits during pregnancy (intervention); **Intervention 3:** 2+ 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 (partners, family and friends) and linkage of parents to community services, including nutritional care, prenatal providers and other services **Main intervention strategy:** Social support (tailored intervention) compared to usual care. Intervention 2&3 (nurse-visiting arms) compared to control and intervention 1 arms (no nurse visiting) in this review. **Intensity:** Freqency (C = 0, I = 6), Duration (C = 0, I = 4). Usual care intensity: F = 0, D=0 Intervention provided by dedicated study team: Efficacy study
Outcomes	Cotinine levels taken in a subsample (n = 116), but no women reported smoking cessation at 32 weeks' gestation (late pregnancy)*. Mean cigarettes per day at 32 weeks (late pregnancy*). No mean cotinine levels reported for inclusion. Self-reported reduction in cigarettes, but not reported as a mean for inclusion in this review. Birth outcomes were not included as aspects of the intervention, other than smoking cessation, may potentially improve birth outcomes
Notes	SDs for mean cigarettes per day were not reported, therefore we calculated a mean SD from 14 studies with available mean cigarette SDs (6.5) to include in this review, as recommended by the cochrane handbook

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No information provided.
Allocation concealment (selection bias)	Unclear risk	Not specified.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	6.5% attrition (C = 12, I = 14) due to moving or miscarriage. However outcomes for 307/400 women only reported. Outcomes for all smokers at intake reported
Selective reporting (reporting bias)	Low risk	Detailed range of outcomes reported.
Other bias	Unclear risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Serum cotinine analysis on subsample of 116. No self-reported cessation to validate

Blinding of participants and personnel (performance bias) All outcomes	High risk	Home visitation programme. Blinding of participants and personnel not viable
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The interviewers and medical record reviewers hired by the research project did not know to which treatment the women had been assigned
Incomplete implementation	Unclear risk	Not reported.
Equal baseline characteristics in study arms	High risk	Women assigned a nurse had less social support.
Contamination of control group	Low risk	Home visits.

Olds 2002

Methods	3-armed randomised controlled trial of home visiting during pregnancy by paraprofessionals and nurses to improve maternal and child health, and included advice about smoking The study was conducted in 21 prenatal clinics in Denver (USA) from March 1994 to June 1995
Participants	**Inclusion criteria:** Pregnant women with no previous live births and either qualified for Medicaid or had no private medical insurance **Exclusion criteria:** Not further specified. **Recruitment:** By written invite, and were not required to respond. 735/1135 eligible women participated in the study, 70 of whom were smokers (C = 25, **I1** = 21, **I2** = 24). **Baseline characteristics:** Not reported among smoking subgroup.
Interventions	**Control:** Developmental screening and referral services for children at 6, 12, 15, 21 and 24 months old **Intervention 1 (Paraprofessional):** Screening and referral plus paraprofessional home visiting for first 2 years of infants life. Aimed to improve maternal and fetal health, improve health and development of child, and enhance parents personal development **Intervention 2 (Nurse):** Screening and referral plus nurse home visiting for first 2 years of infants life. Aimed to improve maternal and fetal health, improve health and development of child, and enhance parents personal development **Main intervention strategy:** Social support. Not coded or compared in this review as outcomes unable to be included
Outcomes	Outcomes not able to be included in meta-analysis, as only mean reduction in cotinine reported. See Table 1 for outcome summary.
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated random sequence.
Allocation concealment (selection bias)	Unclear risk	Allocation conducted in separate data centre.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear whether all randomised smokers were included in cotinine analysis
Selective reporting (reporting bias)	High risk	Smoking cessation rates not reported, but are not a primary outcome of this study
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Unclear risk	Unclear whether all randomised women included in cotinine analysis
Blinding of participants and personnel (performance bias) All outcomes	High risk	Providers and women not able to be blinded as social support intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors blinded to allocation. Study team unaware of allocation, unless the participant told them
Incomplete implementation	Low risk	Paraprofessionals completed an average of 6.3 visits and nurses an average of 6.5 visits

Equal baseline characteristics in study arms	Unclear risk	Baseline characteristics of smokers not reported. But treatment groups similar with 'few exceptions'
Contamination of control group	Low risk	Home visits.

Ondersma 2012

Methods	4-armed (2× 2 factorial design) randomised controlled trial of a computer-delivered brief intervention (CD-5As) and incentives to support women to stop smoking in pregnancy The study was conducted in 4 prenatal care clinics in Detroit, MI (USA) with recruitment from July 2008 to November 2009, and final evaluation completed by January 2010
Participants	**Inclusion criteria:** Pregnant women aged 18 years or older, being no further than 27 weeks' gestation, and reporting smoking in the past week **Exclusion criteria:** Unable to understand spoken English. **Recruitment:** 1317 women were screened while in the clinic waiting area. 110/114 (96%) eligible women provided consent and were randomised (C = 26, **I1**: CD-5As only = 26, **I2**: CM-Lite only = 28, **I3** = CM-Lite+CD 5As = 30). **Baseline characteristics:** Average cigarettes per day in week prior to recruitment: mean = 8 (SD 8.2). 70% lived with a smoker. 52.8% had a fagerstrom score >= 4 (nicotine dependence) Mean age 27.9 (6.4); 90% Black. K6 emotional distress 14.9. **Progress+ coding:** Low SES and ethnic minority.
Interventions	**Control:** Usual Care from prenatal care from care-providers without influence from the research team **Intervention 1 CD-5As only:** Computer delivered brief intervention designed to be consistent with '5As national guidelines (USA)' (Ask, Advise, Assess, Assist, Arrange) and-for those who are unwilling to set a quit goal-the 5Rs (with steps involving the highlighting of Relevance, Risks, Rewards, Roadblocks, and Repetition). The 'Advice' included a 5 minute video featuring a male Black Obstetrician and 3 testimonials from women of varying race, which was direct but designed to be positive and frame the benefits of quitting rather than the risks of smoking **Intervention 2 CM-Lite (incentives) only:** This modified version of 'contingency management' was designed for use with non-treatment-seeking persons in a health care setting with the presumption of (a) at least occasional repeat office visits and (b) limited ability of medical staff to monitor participants or participate in training. Thus, no proactive tracking was provided in CM-Lite: It was designed to be patient initiated, with staff checking eligibility if and when a patient asks to have their smoking status verified rather than relying on staff to check the eligibility of every incoming patient. CM-Lite calls for testing at prenatal care visits only and unlimited incentivisation attempts, but only up to a maximum of 5 episodes of reinforcement (in the form of retail gift cards worth $50), only at prenatal clinic visits, each at least a week apart. CM-Lite was delivered with the help of a website which facilitated the process of verifying eligibility of participants, provided step-by-step guidance in how to conduct a valid test for urinary cotinine, recorded the results of testing, and provided a record of all incentive attempts and their outcome **Intervention 3 CD-5As + CM-Lite combined.** **Main intervention strategy:** Incentives (tailored intervention) compared to usual care. Intervention 2 compared with control in this review **Intensity:** Frequency (C = 0, I = 5), Duration (C = 0, I = 1). Usual care intensity unclear: F = 0, D = 0 Technological intervention: unclear whether delivered by existing staff (Effectiveness study) or dedicated project staff (efficacy study)
Outcomes	Biochemically validated 7-day point prevalence at 10-week follow-up (late pregnancy*) with CO and urinary cotinine. Secondary help-seeking (Quitline), self-reported sustained abstinence in the past 30 days, Fagerstrom Test for nicotine dependence; K6 measure of overall emotional distress; Acceptability (satisfaction-related measures)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer randomisation of all participants into either CD-5As or time control conditions and after participants completed all computer-delivered content-research assistants used a predetermined list of computer-generated random numbers to further randomise half of all participants into the CM condition
Allocation concealment (selection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition 16/110 (14.5%) lost to follow-up. All analyses were on an intent-to-treat basis that analysed participants as allocated to condition without respect to completion of treatment elements. Only 2 women

		who withdrew due to miscarriage (one in combined arm and 1 in usual care arm) were excluded from the analysis in this review
Selective reporting (reporting bias)	Low risk	All primary outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Self-reported 7-day abstinence biochemically validated with expired CO (< 4 ppm) and urinary cotinine (< 100 ng/mL)*
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Each intervention involved the same level of interaction with the computer and took the same approximate amount of time, thus keeping research assistants blind to computer-delivered intervention condition. Not feasible to blind participants
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is not stated whether outcome assessors were blinded.
Incomplete implementation	Unclear risk	Process evaluation showed all participants assigned to CD-5As condition completed the items and evaluations and gave high satisfaction ratings. Of the participants assigned to CM-Lite only 37.9% initiated testing of at least 1 urine sample (mean 3. 7, SD 1.9)
Equal baseline characteristics in study arms	Low risk	There were no significant differences between conditions on any of the baseline characteristics examined, although 1 variable (minority vs. non-minority race) was below P = .10 and so was controlled for in subsequent analyses
Contamination of control group	Low risk	The risk of contamination between study arms is low as interventions are all provided via technology

Panjari 1999

Methods	Randomised controlled trial of counselling interventions to support women to stop smoking in pregnancy Study conducted in a public antenatal clinic in Melbourne, Victoria, Australia. Data collected from April 1994 to June 1996
Participants	**Inclusion criteria:** 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 **Recruitment:** 9193 women screened, 1942 (21%) current smokers and 625 (7%) spontaneous quitters (not included in study but described in Panjari 1997). 1013/1942 smokers (52%) agreed to participate (929 refused or not eligible) and were randomised (C = 537, I = 476). **Baseline characteristics:** Mean cigarettes per day = 21 before pregnancy and 11 at time of first antenatal visit. 74% had a smoking partner Mean age 26 years. **Progress+ coding:** Low SES as authors note mostly low income women.
Interventions	**Control:** Usual care, which included advice at the discretion of the caregiver, and 0 pamphlet “Smoking & Pregnancy” distributed during a group pregnancy information session **Intervention:** As for the control group plus 4 counselling sessions by a midwife specifically trained and employed to provide smoking cessation counselling, using CBT. Sessions included video presentation, interactive discussion and strong verbal messages. These were followed up with a 5 to 10 minute personalised counselling session **Main intervention strategy:** Counselling (single intervention) compared to usual care. **Intensity:** Frequency (C = 0, I = 3), Duration (C = 0, I = 3). Usual care intensity: F = 1, D=1 Intervention provided by dedicated project staff: efficacy study
Outcomes	Self-reported smoking cessation biochemically validated with urine cotinine at 36 weeks’ gestation (late pregnancy*), 6 weeks postpartum (0-5 months)*, and 6 months (6-11 months*) postpartum*. Preterm births*, mean birthweight*, proportion LBW* (< 2500 g) Reduction in mean cigarettes/day* and mean urinary cotinine levels* Breastfeeding at 6 weeks and 6 months postpartum. General health assessment at first visit and 36 weeks General health questionnaire (including stress and depression measurement) at baseline and end of pregnancy
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information.
Allocation concealment (selection bias)	Unclear risk	Described as "randomly allocated".
Incomplete outcome data (attrition bias) All outcomes	Low risk	28% attrition (381/1013). 72/1013 (C = 35, I = 37) were excluded as they were over 20 weeks' gestation, had a twin pregnancy or were transferred to the chemical dependency clinic. 209/1013 (C=109, I=100) excluded due to transfer to another hospital, miscarriage, termination of pregnancy and withdrawal from the study. The numbers of those who withdrew from the study were not reported separately in this group, therefore all were re-included as continuing smokers in this review (but were not included in mean outcome data)
Selective reporting (reporting bias)	Low risk	A detailed list of birth outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Urinary cotinine levels measured at baseline and in late pregnancy (< 115/ng/mL)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Educational intervention delivered by clinic midwife.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	High risk	Process evaluation showed 71% women in the intervention group received the full intervention
Equal baseline characteristics in study arms	Low risk	There were no statistically significant differences between women allocated to the intervention and the control groups in terms of socio-demographic variables and smoking patterns
Contamination of control group	Low risk	Intervention provided by a research mid-wife, not usual care provider

Parker 2007

Methods	3-armed randomised controlled trial aimed to evaluate the feasibility, cost and effectiveness of a telephone counselling intervention to support women to stop smoking in pregnancy Study conducted at 22 urban prenatal care clinics in Rhode Island (Connecticut) and Massachusetts (USA). Study period not reported
Participants	**Inclusion criteria:** Pregnant women who had smoked at least 1 puff of a cigarette within the past 30 days, no more than 26 weeks pregnant, had access to a telephone where she could be reached, and speak English or Spanish **Exclusion criteria:** Not further specified. **Recruitment:** 8526 pregnant women were assessed at their first or second visit. 1065/1582 eligible women (67%) agreed to participate and were randomly assigned to 3 conditions (C (self-help materials)=378; **I1** (Self-help materials+quit and win contest) = 329; **I2** (self-help materials + quit and win contest + motivational interviewing counselling calls = 358) **Baseline characteristics:** Strateifed by participation in calls: Mean cigarettes per day at baseline: 7.9 (6.3) to 8.7 (5.8). Baseline cotinine: 869 to 1239 mg/mL Majority white, 40% <= 11 years education. **Progress+ coding:** Low SES as 80% Medicaid recipients.

Interventions	**Control:** Participants received self-help materials, which included a quit kit (A Smoker's Guide to Quit Smoking) and a video (Commit to Quit), which had been shown to be effective in significantly reducing exposure or assisting pregnant women to quit smoking (SCRIPT trials) **Intervention 1:** Received the quit kit and were enrolled in a "Quit and Win" (Q&W) monetary incentive lottery program. Eligibility for the prize (US$100) was restricted to smokers who reported abstinence for at least 30 days and had their report confirmed by urinary cotinine. **Intervention 2:** Received the quit kit, the Q&W program, and up to 3 Motivational Interviewing telephone calls This review compares the control group and Intervention 2. **Main intervention strategy:** Counselling (multiple intervention) compared to a less intensive intervention **Intensity:** Frequency (C = 1, I = 4), Duration (C = 1, I = 3). Intervention provided by dedicated project staff: Efficacy study
Outcomes	Self-reported smoking cessation biochemically validated with urinary cotinine (< 80 ng/mL) at 32 weeks' gestation (late pregnancy)*, 6 weeks and 6 months postpartum (outcomes not reported). Cost-effectiveness analysis
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition: C = 101/378 (27%), I = 118/358 (33%) by 6 months postpartum (reasons not reported). All randomised women included in analysis
Selective reporting (reporting bias)	High risk	Smoking cessation at 6 weeks and 6 months postpartum not reported
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	Biochemical validation of self-reported smoking status using urinary cotinine (<80ng/mL). Conference report states only 219 women with biochemically confirmed smoking status were included in report. But pg 1045 states "Samples were obtained from 114 women during the first prenatal visit, from 113 during the third trimester, and 23 during the 6 month postpartum visit. We were unable to contact the remainder of the women, and therefore did not have samples to confirm their self-reported smoking status"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible for participants and personnel to be blinded to educational intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	High risk	Process evaluation showed researchers were unable to reach 14%, 86% received 1 call, 60% 2 calls and 46% 3 calls
Equal baseline characteristics in study arms	Low risk	The absence of significant differences for multiple salient predictors and other weaker predictors of smoking behaviour change strongly suggested that the call groups were comparable at baseline
Contamination of control group	Low risk	Specific counsellors providing intervention so low risk of contamination

Patten 2009

Methods	Randomised controlled pilot study of a targeted intervention to support pregnant Alaskan Native women to stop smoking in pregnancy Study conducted in the Y-K Delta region in Western Alaska (USA), with recruitment from 2007 to 2008
Participants	**Inclusion criteria:** Pregnant Alaskan women ≥ 18 years, ≤ 24 weeks' gestation, self-reported smoking or Iqmik/ST use in the last 7 days, planning to quit in the next 30 days, access to a telephone and VCR/DVD player, and willing to participate in all study procedures **Exclusion criteria:** Planning an abortion, current (past 3 months) participation in pharmacological or behavioural tobacco treatment, and another woman from her household had enrolled

	Recruitment: 293 women expressed an interest in the study and were referred to study coordinator. 81 did not attend screening appointment, 114 reported not smoking and 4 were ineligible. 35/94 (37%) of the remaining eligible women agreed to participate and were randomised (C = 18, I = 17) **Baseline smoking characteristics:** Current tobacco use (in past 7 days): Iqmik C = 44% (8), I = 47% (8); Commercial chew C = 22% (4), I = 18% (3); Cigarette smoking C = 33% (6), I = 35% (6). Spouse/partner uses tobacco: C = 78% (14), I = 54% (7). Smoking ban in the home C =89% (16), I= 88% (14). Chewing ban in the home C = 12% (2) , I = 19% (3) Baseline characteristics not reported. **Progress+ coding:** Low SES, ethnic minority population.
Interventions	**Control:** Participants in the control arm received an intervention consistent with the 5-component treatment (5A's) recommended for pregnant smokers by the Clinical Practice Guideline: Ask, Advise, Assess, Assist, and Arrange. At the first visit, participants in this condition received a brief (5-min) face-to-face intervention based on the 5A's and 4 pregnancy and culturally specific brochures. The counsellor encouraged and assisted the participant to set a quit date. Participants requesting NRT or another medication from the counsellor were referred to the YKDRH clinical cessation program and enrolment in this program was tracked as part of this study **Intervention:** At the first visit women in the intervention group received: (i) a self-help guide adapted from the SCRIPT trials (Windsor 1999) and from culturally appropriate brochures developed and used by the YKDRH clinical cessation program (ii) 15-25 minutes of face-to-face counselling based on the 5A's (iii) a video which was produced that included stories of Alaska Native women who stopped using tobacco during pregnancy. Focus groups suggested that story-telling was a potentially acceptable intervention component. The counsellor then discussed the video with the woman (iv) A further 4 × 10-15 minute proactive interactive sessions were provided by telephone, based on a counsellor manual which was developed based on completed evaluation research, at Weeks 1, 2, 4, and 6. These sessions provided opportunities for the counsellor to teach additional cessation skills and reinforce self-efficacy. The woman was encouraged to set a quit date at each contact, if she had not quit **Main intervention strategies:** Counselling (multiple intervention) compared to a less intensive intervention **Intensity:** Frequency (C = 2, I = 6), Duration (C = 2, I = 3). Intervention provided by dedicated study staff: Efficacy study
Outcomes	Biochemically validated tobacco use in (salivary cotinine< 20n g/mL) 60 days post randomisation (late pregnancy*). Acceptability to women
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	35 participants were stratified by primary type of tobacco used (Iqmik, commercial ST, or cigarettes) and randomly assigned
Allocation concealment (selection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition: C = 1/18 (6%), I = 5/17 (29%). 1 miscarriage in each study arm excluded from this analysis. All other drop outs counted as continuing smokers
Selective reporting (reporting bias)	Low risk	All primary outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Self-reported tobacco use status biochemically validated using salivary cotinine (< 20 ng/mL). Some women were using NRT
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible to blind participants and personnel to counselling intervention
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not reported.
Incomplete implementation	Low risk	Process evaluation showed good treatment compliance and acceptability of intervention
Equal baseline characteristics in study arms	High risk	Level of education and spouse/partner smoking unequal.
Contamination of control group	High risk	Assessments and interventions provided by the same individual in each community

Pbert 2004

Methods	Cluster-randomised controlled trial of implementation of the "Quit Together" program which aims to support women to stop smoking and prevent relapse in pregnancy Study conducted WIC clinics in Massachusetts (USA) of implementation, with data collection from May 1997 to November 2000
Participants	Unit of randomisation was 6 community health centres with on-site WIC programs, prenatal services and paediatric services, and patients of diverse race and ethnicity. 1 control site was dropped due to low recruitment **Inclusion criteria:** Pregnant women, English or Spanish speaking, less than 32 weeks' gestation, current smoker or spontaneous quitter, planning to remain in area for 6 months after delivery **Exclusion criteria:** Not further specified. **Recruitment:** 7853 women screened. 609/693 (88%) eligible smokers and ex-smokers consented, completed baseline interviews and were randomised (C = 300, I = 309) **Baseline characteristics:** Current smokers (C =72.3%, I = 70.2%), spontaneous quitters (C = 27.7%, I = 29.8%). Mean cigarettes per day before pregnancy: C = 18.43, I = 14. 89 Mean age 26 years. White (C = 78.6%, I = 22.8%), Black (C = 1.8%, I = 39%), Hispanic (C = 4.7%, I = 27.6%). Unmarried: C = 60.8%, I = 68.8%. Medicaid C = 63.1%, I = 65.5%. < High school C = 62.2%, I = 46.7% **Progress+ coding:** Low SES as high proportion of WIC recipients.
Interventions	**Control:** Usual care condition, in which no training or intervention occurred **Intervention:** The dissemination intervention consisted of: (i) provider training based on national clinical practice guidelines (ii) an office practice management system for routine screening and follow-up reminders, and (iii) establishment of program boards. The intervention to women was based on motivational interviewing and the "4A's" from the 'SCRIPT trial' conducted by Windsor 2000b. **Main intervention strategy:** Counselling (single intervention and intensive dissemination) compared to usual care **Intensity:** Frequency (C = 0, I = 2), Duration (C = 0, I = 1). Usual care intensity: F = 0, D=0 Intervention provided by existing staff: Effectiveness study
Outcomes	Biochemically validated smoking cessation and relapse prevention at 1 month postpartum combined (late pregnancy*), and 3 (0-5*) and 6 (6-11*) months postpartum. 6-month figures not reported in text but estimated from Figure 3 to be I = 11%, C = 4% Mean cigarettes/day* estimated from figure 4. Associated references describe detailed organisational change and implementation processes for the clinic setting, subanalysis of a range of outcomes by socio-economic status; and clinical knowledge of nicotine dependence (Bonollo 2002).
Notes	No estimates of clustering effect reported, so sensitivity analysis conducted and intracluster correlation of 0.10 used to adjust data for inclusion in outcome tables (see table 2 for adjustment details) SDs for mean cigarettes per day were not reported, therefore we calculated a mean SD from 14 studies with available mean cigarette SDs (6.5) to include in this review, as recommended by the cochrane handbook

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No information provided.
Allocation concealment (selection bias)	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	High risk	34/609 (6%) had a miscarriage and 12/609 (2%) transferred to another health service. 13 women excluded for other reasons (unexplained), but they are not reported by intervention group to be re-included and the figures reported in the flow chart are combined with drop-outs for other reasons. Also high loss to follow-up. 550/609 women included in this analysis
Selective reporting (reporting bias)	Unclear risk	Trial part of a nutritional program, but only smoking outcomes in this report
Other bias	Unclear risk	One control site dropped due to low recruitment. Otherwise recruitment to study arms appears balanced
Biochemical validation of smoking abstinence (detection bias)	Low risk	A woman was considered to be a smoker if she reported smoking in 30 days prior to 1 month postpartum interview. Salivary cotinine was analysed for women reporting abstinence in 7 days prior to the interview (<= 20 ng/mL)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Sites aware of allocation status.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.

Incomplete implementation	Unclear risk	Process evaluation not reported.
Equal baseline characteristics in study arms	Unclear risk	While no differences between SI and UC were statistically significant, some were large (e.g., race/ethnicity, education). This reflects the variability in size and race/ethnicity distributions among CHCs, the unit of randomisation
Contamination of control group	Low risk	Cluster design to avoid contamination.

Petersen 1992

Methods	3-armed randomised controlled trial of self-help materials and counselling to support women to stop smoking and prevent relapse during pregnancy and postpartum Study conducted at a large Boston HMO (USA), with recruitment from March 1986 to September 1988
Participants	**Inclusion criteria:** English-speaking literate women enrolling in prenatal care; who reported themselves as currently occasional or regular smokers or who had quit smoking in the previous 3 months **Exclusion criteria:** < 18 years of age; > 24 weeks' gestation. **Recruitment:** 1442 women screened during early pregnancy class. 317 current smokers and recent quitters were identified. Participants from 3 centres were randomised to control and first intervention (**I1**) arms, and participants from a fourth arm were not randomly allocated and are not included in analysis ion this review. 93/317 attrition, leaving 224 included (C = 78, **I1** = 71, **I2** (not randomised) = 75). **Baseline characteristics:** Baseline smokers : 142 (C = 47, **I1** = 43, **I2** = 52) and baseline spontaneous quitters: 104 (C = 36, **I1** = 34, **I2** = 34) analysed at 6 months gestation. Majority 17-28 years, No participants less than high school, less than $US 20000/yr (C = 18.7%, **I1** = 20%, **I2** = 32.3%). Over 80% married and majority white. **Progress+ coding:** None.
Interventions	**Control:** Routine obstetric care, including a mailed list of community-based smoking cessation resources other pregnancy-related health education materials. Brief repeated counselling by obstetricians and midwives for both groups as part of routine care. **Intervention 1:** Pregnancy-specific self-help manual (Am Lung Assoc and Harvard Community Health Plan (HMO)) and audiotape on safe aerobic exercise and pregnancy-related relaxation, mailed with other health-related education. Smoking component emphasised behavioural strategies for quitting, issues and concerns specific to pregnant women, non-smoking as part of a continuum of care in pregnancy; included a maintenance section for the postpartum period **Intervention 2:** As for I1 plus training for obstetrician and nurse practitioner to provide training, and support letters from physician **Main intervention strategy:** Health education (single intervention) compared to usual care. Intervention 1 and control compared in this review as the **I2** group was not randomised. **Intensity:** Frequency (C = 0, I = 2), Duration (C = 0, I = 1). Usual care intensity: F = 3, D=2 Intervention provided by dedicated project staff: Efficacy study
Outcomes	Smoking cessation for smokers and spontaneous quitters at 6 months gestation (late pregnancy* and 8 weeks postpartum (0-5 months*) Description of costs.
Notes	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)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Table of random numbers. Allocation to intervention arm 2 was not randomised but offered to all eligible enrollees at 1 clinic: therefore data from this intervention arm are not included in the review
Allocation concealment (selection bias)	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	High risk	93/317 (29%) were excluded from analyses due to miscarriage, therapeutic abortion, moving, or left the Harvard Health Plan, leaving 217 included. However, 246 (C = 83, **I1** = 77, **I2** = 86) 'baseline smokers and spontaneous quitters' included in analysis at 6 months gestation and 219 included in 8 weeks postpartum. It is not clear which randomised women are included in analysis
Selective reporting (reporting bias)	Unclear risk	None apparent but results were not simple to interpret.
Other bias	Low risk	No other bias detected.

Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemical validation in 50% women. Those refusing urine test were coded as smoking
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	State that caregivers were blind as materials to the intervention group were mailed. Not feasible to blind women
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Low risk	All women received materials for intervention 1 used in this review. Some implementation problems noted with the counselling arm (**I2**), but that was not included in this review.
Equal baseline characteristics in study arms	High risk	Differences in educational attainment.
Contamination of control group	Low risk	Unlikely with mail out of materials.

Polanska 2004

Methods	Cluster-randomised trial of intervention to support women to stop smoking and prevent relapse in pregnancy and postpartum Study conducted in the Lodz district, Poland, with data collection from December 2000 to December 2001
Participants	Unit of randomisation was maternity units, selected from 33 in district and stratified by size. Control = 1 small, 2 medium, 2 big; Intervention = 2 small, 4 medium, 4 big (as higher refusal expected in intervention arms **Inclusion criteria:** Current smokers or women who quit 1 month before the visit **Exclusion criteria:** Not further specified. **Recruitment:** 15/33 maternity units were allocated to intervention (10) or control (5) groups All pregnant women screened. 194/194 (100%) eligible women in control group and 216/275 (78.5%) eligible women in the intervention group agreed to participate **Baseline characteristics:** Current smokers: C = 156, I = 158. Spontaneous quitters: C = 38, I = 58. Cigarettes per day: < 5 (C = 8.8%, I = 10.3%), 5-50 (C = 54.7%, I = 46%), > 10 (C = 36.5%, I = 43.7%). Fagerstrom score 0-6 (C = 98.9%, I = 92.3%) Mean age: C = 25.9, I = 25.5; < 12 years education: C = 76.2%, I = 74.3%; Unmarried: C = 39.2%, I = 52.5% **Progress+ coding:** Low SES population as described by author.
Interventions	**Control:** Received standard written information about health risks of smoking **Intervention:** Received 4-9 midwife home visits, based on a booklet translated from English (Ottawa) to Polish and adapted to Polish conditions: “How to talk about smoking with high risk pregnant smokers” **Main intervention strategy:** Counselling (single intervention) compared to usual care. **Intensity:** Frequency (C = 0, I = 6), Duration (C = 0, I = 4). Usual care intensity: F = 1, D=1 Intervention provided by midwives, which appear to be existing staff, though this is not explicitly reported: coded as effectiveness study
Outcomes	Self-reported smoking cessation ‘shortly after delivery at home’ (0-5 months postpartum*) Relapse prevention rates* in text (p274). Mean birthweight* calculated by combined smokers and quitters in Table 6 An associated reference (Polanska 2005) reports relapse after 12 months* (12-17 months postpartum). All randomised from women from original study included as denominator and those not included in the follow-up analysis assumed to have relapsed in this review. Spontaneous quitters and smokers combined from Table 2 to calculate self-reported abstinence at 12 months
Notes	No estimates of clustering effect reported, so sensitivity analysis conducted and intra-cluster correlation of 0.10 used to adjust data for inclusion in outcome tables as shown in Table 2.

Risk of bias

Bias	**Authors’ judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Notes random allocation, but no description of how this occurred. Only 15/33 eligible clinics allocated
Allocation concealment (selection bias)	Unclear risk	Not specified.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition: Miscarriages: Smokers: I = 9/158 and C= 12/156. Spontaneous quitters: I = 2/58 and C= 1/38. Not included in analysis

		Those lost to follow-up: Smokers: (C = 6, I = 6) and Spontaneous quitters (C = 0, I = 2) are included in analysis of smoking outcomes
Selective reporting (reporting bias)	Unclear risk	Birthweight and relapse prevention outcomes difficult to interpret and unable to be included
Other bias	Unclear risk	Twice as many sites were allocated to the intervention arms as the control arms as it was assumed more women would refuse to participate in intervention activities. However recruitment to study arms was equal
Biochemical validation of smoking abstinence (detection bias)	High risk	Self-reported smoking status only.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel not blinded to this educational intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	No. of visits received not reported.
Equal baseline characteristics in study arms	High risk	Intervention group more likely to be married, have fewer children, and have a higher smoking addiction
Contamination of control group	Unclear risk	Cluster-design to minimise risk of contamination.

Price 1991

Methods	3-armed randomised controlled trial of 2 brief interventions to support women to stop smoking in pregnancy Study conducted in an inner urban setting, Toledo, Ohio (USA), with recruitment from December 1987 to March 1989
Participants	**Inclusion criteria:** Not specified. **Exclusion criteria:** > 28 weeks' gestation. **Recruitment:** All 1,164 patients screened, 486 current smokers (42%). 293 refused or were ineligible (40% participation). 193 smokers randomised to study (C = 71, **I1** = 52, **I2** = 70). **Baseline characteristics:** Baseline smoking not reported. Mean age=22.6 (5.6), ranging from 15-43 years. 58% single, 70% white, 87% had not graduated from high school. Author describes population as "Typically low income, single and poor" **Progress+ coding:** Low SES.
Interventions	**Control:** Usual care not specified or assessed but "usual for physicians to address this issue with participants at least 1 prenatal visit". **Intervention 1:** American Lung Association self-help booklet (with brief overview and explanation) emphasising behaviour modification skills, relation techniques and the support of significant others, and were given an opportunity to ask questions of the health educator. Progress reviewed with health educator at the second visit **Intervention 2:** 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. 1 month later they viewed a second 4 min video and the health educator was available to answer questions **Main intervention strategy:** Counselling (single intervention) compared to usual care. The control and intervention 2 (video-tape) are compared in this review **Intensity:** Frequency (C = 0, I = 3), Duration (C = 0, I = 2). Usual care intensity: F = 1, D=1 Intervention provided by dedicated project staff: Efficacy study
Outcomes	Biochemically validated smoking cessation 'two or three weeks prior to delivery' (late pregnancy*). Smoking reduction* and mean cigarettes/day*
Notes	Program was developed with input from a questionnaire (based on Health Belief Model) and open-ended questions about the advantages and disadvantages of smoking when pregnant from local population. 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

Bias	**Authors' judgement**	**Support for judgement**

Random sequence generation (selection bias)	Unclear risk	Not reported.
Allocation concealment (selection bias)	High risk	Tossed die (allocation could therefore be changed). Method resulted in 3 unequal groups, so randomisation to only 2 groups for some of the study period, which was the control and intervention 2 (videotape) group, compared in this review
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition 44% (C = 46, **I1** = 13, **I2** = 25) . Reasons for attrition not reported. However all drop-outs treated as continuing smokers in this review
Selective reporting (reporting bias)	Low risk	Primary outcomes appear to be reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Smoking cessation was biochemically validated using exhaled CO (<= 7 ppm cut-off)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible to blind participants and personnel to counselling intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	High risk	44% did not receive intervention.
Equal baseline characteristics in study arms	Unclear risk	Not reported.
Contamination of control group	Low risk	Specific educators providing intervention (pregnancy care providers not involved)

Reading 1982

Methods	Randomised controlled trial of ultrasound feedback on health beliefs and behaviours to improve maternal health, including smoking Study conducted in London, England (UK). Recruitment dates not specified
Participants	**Inclusion criteria:** Caucasian origin, aged between 18 and 32 years, married or within a stable relationship, attending King's College Hospital antenatal booking clinics **Exclusion criteria:** Women with a previous history of miscarriage, extended infertility investigations, or meet criteria for risk of congenital malformations **Recruitment:** Women 'briefly informed that the study involved a continuing evaluation of aspects of obstetric care and that they would be seen on occasions throughout the pregnancy'. 6 women refused. 194 women recruited (see associated reference (Reading 1982), and were randomised to 3 arms: control (delayed ultrasound) = 55; **I1** (low feedback) = 62; and **I2** (high feedback = 67). The control arm was added during the course of recruitment and is not included in this review. 129 women included, 65 (50%) smokers at baseline (**I1** = 26/62, **I 2**= 39/67). **Baseline characteristics:** Smoking characteristics not reported. Selective inclusion criteria: Pregnant women at 10-14 weeks' gestation; 18 to 32 years; 85% had planned pregnancy, at low risk of complications; 86% nulliparous **Progress+ coding:** None.
Interventions	**Control:** Women were assessed in the clinic following a delay interval **Intervention 1 (low feedback):** Routine ultrasound at 16 weeks' gestation in which women were unable to view the monitor screen, did not receive specific visual or verbal feedback, and they received a global evaluation of the form "all is well". **Intervention 2 (high feedback):** Women were shown the monitor screen and provided with standardized visual and verbal feedback as to fetal size, shape, and movement. No clear smoking cessation component **Main intervention strategy:** Feedback (single intervention) compared to usual care. Intervention 1 (low feedback) compared to Intervention 2 (high feedback) in this review. Control group details only reported in associated reference, so no smoking outcomes available **Intensity:** Frequency (C = 0, I=1), Duration (C = 0, I = 1). Usual care intensity: F = 0, D = 0 Unclear whether dedicated project staff delivered the intervention or not
Outcomes	Self-reported smoking cessation at 16 weeks' gestation (late pregnancy*), without biochemical validation. Self-reported reduction in smoking*
Notes	Cites evidence for the reliability of self-report.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as "assigned at random".
Allocation concealment (selection bias)	Unclear risk	No information.
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition: 3/129 (2%) from low feedback group in smoking outcomes. But considerable amounts of missing data for some variables. Those lost to follow-up not included in ITT analysis, and unclear whether they were smokers at baseline so not re-included
Selective reporting (reporting bias)	Unclear risk	Data collected not specified.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	No biochemical validation of quitting.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Intervention with verbal feedback, so not feasible to blind women. State that those providing care were not involved in the study
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	3/62 low feedback group did not attend next visit at 16 weeks
Equal baseline characteristics in study arms	Low risk	Data in Tables 1 and 2 seem similar.
Contamination of control group	High risk	Assuming same ultrasonographer providing intervention for control and intervention groups

Rigotti 2006

Methods	Randomised controlled trial of a telephone counselling intervention to support women to stop smoking and prevent relapse during pregnancy and postpartum Study conducted in a network-managed care organisation and a group of 65 community based prenatal care practices Massachusetts, New England (USA), with recruitment from September 2001 to July 2004
Participants	**Inclusion criteria:** Pregnant smokers (at least 1 cigarette in the past 7 days), at least 18 years of age, 26 weeks or less gestation, willing to consider altering smoking during pregnancy, reachable by telephone, English speaking and expected to live in New England for the next year **Exclusion criteria:** Not further specified. **Recruitment:** Smokers initially identified on 'Obstetric Risk Assessment' form, yielded low recruitment so 65/140 obstetric or family practices agreed to refer patients and 35 sent in 1 or more referral forms. 1444 pregnant smokers were referred to the study and 665 assessed as eligible. 442/446 (66%) agreed to participate and were randomised (C = 222, I = 220) **Baseline characteristics:** Mean cigarettes per day before pregnancy: C = 20.8, I = 20.9; Current mean cigarettes per day: C = 10, I = 10.4; Partner smoking: C = 62%, I = 71% Mean age: C = 28.1, I = 28.9; Mean years education: C = 13, I = 13.1; White: C = 87%, I = 88%; Private health insurance: C = 70%, I = 75%. Depression in last month: C = 1. 3%, I = 1.3% **Progress+ coding:** None.
Interventions	**Control:** In addition to usual care, the control group were mailed a validated pregnancy-tailored smoking cessation booklet, and their prenatal care providers were sent the ACOG smoking cessation practice guideline, with a reminder to address smoking at the participant's visits. The enrolment call concluded with a trained counsellor providing brief smoking counselling (less than 5 minutes). Smokers who requested further assistance were referred to the Massachusetts telephone quitline **Intervention:** The intervention group received as for the control group, plus a series of telephone calls accompanied by additional mailed written materials. Each participant had a dedicated counsellor who offered up to 90 minutes of counselling during pregnancy and up to 15 minutes over the 2 months postpartum. The trained counsellor tailored the call to the participant's needs, consistent with the 5-step smoking cessation guideline, and drew on social learning theory and the transtheoretical model of change, the health belief model, and the principles of motivational interviewing

	Main intervention strategy: Counselling (multiple intervention) compared to a less intensive intervention **Intensity:** Frequency (C = 2, I = 4), Duration (C = 1, I = 3). Intervention provided by dedicated project staff: Efficacy study
Outcomes	Biochemically validated 7-day point prevalence abstinence at 28 weeks to term (late pregnancy*), and 3 (0-5) months postpartum*. Also measured reduction in smoking (proportion >50% reduction in cigarettes per day*), sustained abstinence at both time-points, and number of quit attempts Self-efficacy and social support at baseline and follow-up. Concerns about weight gain reported in an associated reference (Berg 2008). Women's satisfaction with the intervention.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated.
Allocation concealment (selection bias)	Low risk	Stated that recruiters were not aware of group allocation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition: 21/442 (5%) were excluded from the analysis due to miscarriage (C = 10/220, I = 11/222). 113 women did not have final assessment due to refusal (22%), baby born before assessment or lost to follow-up, but were included in the final analysis (ITT analysis) and in this review (C = 209, I = 212). Missing data (up to 30%) for outcomes measured in the postnatal period
Selective reporting (reporting bias)	High risk	Not clear if all outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Salivary cotinine (<= 20ng/mL cut-off) confirmation in 66%, and those refusing to provide a sample were included as continuing smokers
Blinding of participants and personnel (performance bias) All outcomes	High risk	All providers and women sent smoking cessation practice guideline
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Low risk	Mean number of calls received was 5.
Equal baseline characteristics in study arms	High risk	Both groups were similar, though the intervention group had a significantly higher proportion of women who had made a quit attempt this pregnancy and had social support to quit from partner and significant differences in parity, gestation, and partner smoking
Contamination of control group	Low risk	Trained counsellors delivering intervention not usual care givers

Secker-Walker 1994

Methods	Randomised controlled trial of counselling to support women to stop smoking in pregnancy and postpartum Study conducted at the University of Vermont, Burlington (USA), with recruitment from May 1984 to June 1987
Participants	**Inclusion criteria:** Pregnant women less than 25 weeks' gestation, smoking at least 1 cigarette a day **Exclusion criteria:** Not further specified. **Recruitment:** Women receiving prenatal care from obstetricians and nurse-midwives, or residents through Maternal, Infant & Child clinic for under-insured or non-insured women, were randomly assigned (23% Medicaid in study). 775/808 (96%) smokers invited agreed to participate. 175/775 women spontaneously quit before their first visit and were randomised into a separate study of relapse prevention (C = 86, I = 89) (Secker-Walker 1995). 600 smokers randomised (C = 300, I = 300).

	Baseline characteristics: Mean cigarettes per day pre-pregnancy C = 25.1, I = 24.4. Mean cigarettes per day at first prenatal visit: C = 12.4, I = 14.1 Mean age: 24 years; Less than high school: C = 30.7%, I = 28.2%; Medicaid recipient C = 23.2%, I = 25.3% (50% private insurance) **Progress+ coding:** Low SES due to high rates of women who hadn't completed high school
Interventions	**Control:** 'Usual advice about smoking provided by obstetrician or midwife'. **Intervention:** Counselling from a trained health educator who: 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 agreeing to quit and formulating a plan, women were provided with skills rehearsal and a pregnancy-specific booklet. Follow-up at second antenatal clinic, 36 weeks and 6-week check (where infant health and parental role modelling was discussed) and re-encouraged to quit. Health educators given selected readings, discussion, rehearsal with psychologist + health educator (both former smokers) about smoking and smoking cessation counselling techniques + American Lung Association training group for class leaders + 4-week pilot The relapse prevention component was individualised but carried out within a defined protocol. Counselling about preventing relapse and a booklet. Follow-up at second antenatal clinic, 36 weeks and 6-week check (where infant health and parental role modelling was discussed) **Main intervention strategy:** Counselling (multiple intervention) compared to usual care **Intensity:** Frequency (C = 0, I = 3), Duration (C = 0, I = 3). Usual care intensity: F = 1, D = 1 Intervention provided by dedicated project staff: Efficacy study
Outcomes	Smoking cessation at 36 weeks' gestation (75% biochemically validated with cotinine) (late pregnancy*), Long-term quitting measured at 8-15 months' pp (6-11 months pp*) , 16-24 pp (18 months postpartum), and 25-54 pp (self-reported) Relapse prevention* reported in associated reference (Secker-Walker 1995). Mean birthweight*, low birthweight*, other smoking-related complications (PPROM, placental abruption and placenta praevia) Reduction in mean cotinine/creatinine ratio at 36 weeks' gestation
Notes	Sample size calculated for 10% increase (from 10% to 20%) in quitting. No adjustment for misclassification. Recall of advice about smoking. Separate paper (Secker-Walker 1992) evaluates training program for residents.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Described as "randomly assigned".
Allocation concealment (selection bias)	Unclear risk	Not stated. Unclear when randomisation took place.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Smokers: Attrition 39/600 (6.5%) due to miscarriage (27), fetal deaths (7), infant deaths (5), 48 transferred care (C = 24, I = 24), and were excluded from analysis, leaving C = 258, I = 255 Further losses were: 41 dropped out of study (C = 4, I = 37), and 59 were lost to follow-up (C = 28, I = 31), but were re-included in this review as continuing smokers, but are not included in mean birthweight and other birth outcomes analyses. Significant difference in pregnancy dropout rates for I (13% drop-out rate) and C (1.4% drop-out rate). Those lost to followup smoked more Voluntary drop-outs treated as continuing smokers for some analyses Spontaneous quitters: attrition 8/175 (5%) due to miscarriage (5), abortion (1), fetal demise (1), and infant death (1) and lost records (2) were excluded from analysis, leaving C = 80, I = 85. Further attrition: transferred care (15)-not reported by study arm, dropped out of study (9), lost to follow- up (8), re-included in baseline as continuing smokers in this review Differential withdrawal in I and C groups a concern; good information collected on drop-outs being different
Selective reporting (reporting bias)	Unclear risk	Data collected not specified. Only smoking outcomes reported
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Urinary cotinine/creatinine ratio levels measured at 36 weeks (< 80 ng/mg)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Educational intervention in antenatal clinics.

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Low risk	All but 9 intervention women not lost to follow-up received all 3 counselling sessions before 36 weeks, and 89% received the postpartum 1
Equal baseline characteristics in study arms	High risk	Mostly similar but women in intervention group tended to smoke more cigarettes at time of their first visit
Contamination of control group	Low risk	A separate health educator provided intervention.

Secker-Walker 1997

Methods	Randomised controlled trial of a videotape to support women to stop smoking in pregnancy Study conducted in the offices of 'University Associates in Obstyetrics and Gynecology', in Burlington, Vermont (USA), with recruitment from November 1992 to April 1993
Participants	**Inclusion criteria:** Pregnant women smoking 'an average of one or more cigarettes per day' **Exclusion criteria:** Not further specified. **Recruitment:** Women recruited through University prenatal clinics where obstetricians and nurse-midwives provide private prenatal care, and residents provide prenatal care for under-insured women. 60/67 (89%) smokers who were invited agreed to participate and were randomly assigned (C = 30, I = 30) **Baseline characteristics:** Mean cigarettes per day before pregnancy = 22.6. Mean age: 23 years; 30% married; 33% had less than high school education; 98% white **Progress+ coding:** Low SES in this review as participants recruited from a state-supported clinic for underinsured women
Interventions	**Control:** Advice from an obstetrician or nurse-midwife (as per prompt sheet) and a booklet on quitting. The protocol for this advice has been described in Secker-Walker 1992. **Intervention:** As for control plus a 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 **Main intervention strategy:** Counselling (single intervention) compared to a less intensive intervention **Intensity:** Frequency (C = 1, I = 2), Duration (C = 1, I = 2). Unclear if technological intervention provided by existing staff or dedicated project staff
Outcomes	Smoking cessation in late pregnancy* (36/40), biochemically validated with exhaled CO measurements Process evaluation included perceptions of the videotape contents
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Described as "randomly assigned".
Allocation concealment (selection bias)	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	4/60 (7%) women, all in the intervention had a miscarriage and 7 (C = 2, I = 5) moved to another care-provider, and were excluded from the analysis 3 (C = 1, I = 2) lost to follow-up but were re-included in this review, leaving C = 28, I = 21. Loss to follow-up not balanced, greater loss from the intervention group
Selective reporting (reporting bias)	Unclear risk	Not apparent.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Exhaled CO (<8 ppm) used to validate self-reported smoking cessation

Blinding of participants and personnel (performance bias) All outcomes	High risk	Educational intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	High risk	53% viewed the videotape. 17% had no VCR, and 10% reported having no time
Equal baseline characteristics in study arms	High risk	Mean exhaled CO level was significantly lower in intervention group
Contamination of control group	Low risk	Video tape unlikely to be provided to women in control group

Secker-Walker 1998

Methods	Randomised controlled trial of a counselling intervention to support women to stop smoking in pregnancy and prevent relapse postpartum The study was conducted in offices of the 'University Associates in Obstetrics and Gynecology' in Vermont (USA), with recruitment from October 1988 to October 1992
Participants	**Inclusion criteria:** Woman who reported smoking 1 or more cigarettes per day at onset of pregnancy **Exclusion criteria:** Not further specified. **Recruitment:** Women recruited through the state-supported (Maternal and Infant Care) prenatal clinic for underserved women or attending the Adolescent clinic for women 12 to 18 years. 524/544 (96%) women who were invited agreed to participate and were randomised. 399 current smokers (C = 202, I = 197); 125 spontaneous quitters (C = 63, I = 62) (separate paper). **Baseline characteristics:** *Smokers:* Mean cigarettes per day before pregnancy C = 25.1, I = 26.1; mean cigarettes per day at first prenatal visit: C = 11.8, I = 13.4. Another smoker in the household (C = 82.6%, I = 78.5%) Mean age: 23 years, < high school (C = 41%, I = 48%), 27% married; medicaid recipients (C = 73.1%, I = 71.9%); Adolescent clinic (C = 13.5%, I = 11.9%) *Spontaneous quitters:* Mean cigarettes per day before pregnancy (C = 14.1, I = 13.5). Other smokers in household (C = 64%, I = 70%) Mean age: C = 21.9, I = 20.9; < high school (C = 27%, I = 36%); 29% married; Medicaid recipients (C = 68.1%, I = 65.1%); adolescent clinic (C = 14.9%, I = 11.4%) **Progress+ coding:** Low SES.
Interventions	**Control:** Physician acknowledged women's smoking, gave a rationale for quitting, strong recommendation to quit and provided smoking cessation booklet designed for pregnant women. 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. **Intervention:** A structured smoking cessation protocol provided by physicians trained in its use (Secker-Walker 1992) at 1st, 2nd, 3rd and 5th visits: acknowledging the woman's smoking, her exhaled CO level, any progress towards quitting, rationale for and 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, 3rd, 5th and 7th visit included praise for those who had quit with referral to counsellor for help in staying quit. 36 week visits included a briefer protocol followed with referral for those who wanted to change, praise for success and referral to a nurse counsellor if smoking **Main intervention strategy:** Counselling (multiple intervention) compared to less intensive intervention **Intensity:** Frequency (C = 1, I = 5), Duration (C = 1, I = 3). Intervention provided by existing staff, with referral to a counsellor: Effectiveness study
Outcomes	Biochemically validated 7-day point prevalence abstinence at 36 weeks' gestation (late pregnancy *) and 1 year postpartum*. Mean cigarettes per day at 36 weeks' gestation* and 12 months postpartum. Mean birthweight*. Low birthweight* Relapse prevention at 36 weeks' gestation (late pregnancy*) and 12 months postpartum reported in associated reference (Secker-Walker 1998b) Preterm births* are reported in attrition and are re-included in both numerator and denominator for this outcome
Notes	Methods included a detailed process evaluation of participants' views and recall of provider advice. Sample size justification Separate paper reports relationship between exhaled CO and birthweight (Secker-Walker 1997b)

Risk of bias

Bias	Authors' judgement	Support for judgement

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Random sequence generation (selection bias)	Unclear risk	Described as “randomly assigned”.
Allocation concealment (selection bias)	Unclear risk	No details provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	High attrition. More than 25% lost to follow-up in pregnancy and more than 30% lost to longer-term follow-up *Smokers:* 109/399 (27% attrition) 24 (6%) women with miscarriage (14), fetal demise (5) and infant deaths (5) were excluded from analysis and are not reported by group allocation. Report states 376 women remain included (instead of 375) (C = 191, I = 185) 68 women transferred care (C = 34, I = 34) , 17 delivered before 36 weeks (C = 8, I = 9) and were not included in 36-week analysis 12 women withdrew from study (C = 5, I = 7) and 3 lost to follow-up (C = 3), and were re-included as continuing smokers in this review, but are not included in mean cigarettes per day or perinatal outcomes. 114 (I) and 110 (UC) were contacted 1 year after birth, including 16 (I) and 18 (UC) lost to follow-up during pregnancy. Women with adverse outcomes were not included in the analysis *Spontaneous quitters:* 33/125 (26%) attrition. Women with miscarriage (5), abortion (1), infant death (1), pregnancy loss (1), moving to another clinic or moving (22; C = 13, I = 9), delivering before 36 weeks (I = 2). All excluded from analysis leaving C = 48, I = 44
Selective reporting (reporting bias)	Unclear risk	Only smoking outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Self-reported cessation with biochemical validation by exhaled CO (<6 ppm) or urinary cotinine (<500 ng/mL)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Intervention by clinic staff. Notes flagged.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Low risk	Methods included a detailed process evaluation of participants’ views and recall of provider advice and suggests ‘to a large extent the intervention was implemented as planned’
Equal baseline characteristics in study arms	Unclear risk	No significant differences except for larger proportion of women in intervention group had not made a quit attempt in the past
Contamination of control group	Unclear risk	No women in cessation group received cessation counselling beyond the physician advice. Though the same physician provided advice so unclear if this was influenced by the intervention

Sexton 1984

Methods	Randomised controlled trial of a multifaceted intervention to support women to stop smoking in pregnancy Study conducted in a large university hospital obstetric clinic in Baltimore (USA) with enrolment over a 2.5 year period (dates not specified)
Participants	**Inclusion criteria:** Pregnant women who were smoking >= 10 cigarettes/day immediately prior to pregnancy, <18 weeks’ gestation **Exclusion criteria:** Not further specified. **Recruitment:** Eligible women sought by a variety of methods but majority were attending 1 of 52 private obstetricians or a hospital antenatal clinic. Obstetric staff sought permission for study staff to contact women. 935 women recruited (participation rate unclear) (C = 472, I = 463). 157/935 had spontaneously quit (C = 17% or 80, I = 16% or 74, which only add up to 154). Smoking rates among spontaneous quitters not reported separately so all randomised women included in analyses **Baseline characteristics:** Mean cigarettes per day pre-pregnancy: C = 20.7, I = 20.9; mean cigarettes per day at randomisation: C = 11.7, I = 10.7

	Mean age 24.9 years, Mean education 12.3 years, Black C = 41.3%, I = 40.3% **Progress+ coding:** None.
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 and health risks of smoking was mailed every 2 weeks with "homework" linked to telephone calls; group sessions were also available. There was a monthly lottery and in the last year of the study a monthly newsletter. Hypnosis was offered by discontinued as poorly accepted **Main intervention strategy:** Counselling (tailored) compared to usual care. **Intensity:** Frequency (C = 0, I = 6), Duration (C = 0, I = 6). Usual care intensity: F = 0, I = 0 Intervention provided by dedicated study staff: Efficacy study
Outcomes	Self-reported smoking at eight months gestation (late pregnancy*) Mean cigarettes per day* at 8 months gestation and mean thiocyanate* Mean birthweight*; low birthweight*; very low birthweight*, perinatal deaths*, neonatal deaths*, stillbirths* % Apgar scores <7 at 1 minute and 5 minutes; length and head circumference
Notes	Change of criteria for enrolment after the first 185 as 35% of these had smoked < 10/day and 71% of that group had quit spontaneously with little relapse. Detailed account of the intervention is in Nowicki 1984.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not stated.
Allocation concealment (selection bias)	Unclear risk	No information.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition: 56/935 (6%), 35 miscarriages (C = 17/572, I = 18/463), 1 fetal death (C = 1), 20 stillbirths (C = 11, I = 9) excluded from analysis, leaving C = 443, I = 436. Women lost to follow-up included as continuing smokers in this review. Missing data for mean outcomes not included
Selective reporting (reporting bias)	High risk	Extensive range of outcomes reported. Outcomes not reported separately for spontaneous quitters
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	Self-reported smoking outcomes were not validated by salivary thiocyanate, despite it being collected. Mean thiocyanate for each group reported only
Blinding of participants and personnel (performance bias) All outcomes	High risk	Educational intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	Group sessions in the intervention were not readily accepted
Equal baseline characteristics in study arms	Low risk	Groups 'similar' at time of randomisation.
Contamination of control group	Low risk	Specific personnel employed to deliver intervention - not usual carers

Solomon 2000

Methods	Randomised controlled trial of telephone peer support to help women stop smoking in pregnancy Study conducted in a large obstetric practice in Burlington, Vermont (USA), with recruitment from 1996 to 1997
Participants	**Inclusion criteria:** Women reporting smoking at least 1 cigarette in the past week at their first antenatal visit **Exclusion criteria:** Not further specified.

	Recruitment: 151/186 (81%) women approached agreed to participate and were randomised (C = 74, I = 77) **Baseline characteristics:** Mean cigarettes/day before pregnancy: C = 20.2, I = 22.6; Mean cigarettes per day at first visit: C = 9.8, I = 10.5. Mean exhaled CO: C = 11.3, I = 11.3. Mean other smokers in household: C = 1.5, I = 1.3 Mean age C = 23.7, I = 23.1; Mean years education: C = 11.5, I = 11.7; White: C = 96%, I = 94.8%. Medicaid recipient: C = 74.6%, C = 77.5% **Progress+ coding:** Low SES.
Interventions	**Control:** Received brief smoking cessation advice (including encouraging a quit date) from a midwife or obstetrician at each of the 3 prenatal visits and stage appropriate printed materials. Midwives and obstetricians were provided with a 45 minute training session and protocol prompt sheets were placed in charts at first prenatal visits **Intervention:** Received the same as the control group, plus any women in the experimental visit who reported they possibly, probably or definitely intended to quit smoking were offered telephone peer support by the obstetrician/midwife. The telephone peer support was provided by a female ex-smoker, who received 8 hours of training. The support person called the participant within several days of referral to provide support, encouragement and reinforcement of positive changes in smoking behaviour. Ongoing calls typically occurred on a weekly basis, but more frequently around a quit date. On average calls lasted 10 minutes **Main intervention strategy:** Social support (tailored intervention) compared to a less intensive intervention **Intensity:** Frequency: (C = 3, I = 6), Duration (C = 1, I = 4). Unclear whether intervention provided by dedicated or existing staff
Outcomes	Biochemically validated 7-day point prevalence abstinence at 28-34/40 gestation (late pregnancy*) Proportion of smoking reduction by more than 50%* was reported for a proportion (135 women) but unclear how many had dropped out of intervention and control groups. As report states 'no significant difference' in dropouts by intervention group (total n = 16) we have imputed 8 for each arm and calculated the number of reductions from a proportion of the remaining sample Movement in stages of change also reported for this group.
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	States participants were randomised into either experimental or control condition
Allocation concealment (selection bias)	Unclear risk	No information.
Incomplete outcome data (attrition bias) All outcomes	Low risk	16/151 (11%) attrition at follow-up. Unclear how many from each arm, so outcomes (> 50% reduction and SOC movement) reported as a proportion of those remaining were not able to be included. All randomised women were included in the primary outcome of smoking cessation, with those lost to follow-up treated as continuing smokers
Selective reporting (reporting bias)	Unclear risk	Only smoking outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Urinary cotinine assessment at 28-34 weeks used to confirm smoking status (cut-off <80 ng/mL)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible to blind participants and personnel to allocation. Medical charts flagged and referral for social support required by care providers
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	High risk	Process evaluation showed 53% received the peer intervention. 9 (12%) had low intentions of quitting smoking during pregnancy and were never offered the peer support, 9 (12%) had no home telephone and were not referred, and 15 (19%) refused the offering, leaving 44 (57%) who were referred for peer support. Data from log sheets completed by the telephone support person revealed that 3 women referred were never reached; therefore, only 53% of the women in the experimental condition received the peer support intervention

Equal baseline characteristics in study arms	Low risk	Baseline comparisons of women in the experimental and control conditions revealed no significant differences in demographics, pregnancy history, or smoking information
Contamination of control group	Low risk	Unlikely telephone counselling would have been provided to control group in error

Stotts 2002

Methods	Randomised controlled trial of intensive late pregnancy intervention to support 'resistant' smokers to stop smoking in pregnancy Study conducted in 3 large multispecialty clinics in Houstan and Dallas metropolitan areas, Texas (USA). Enrolment over a 17-month period, dates not specified
Participants	**Inclusion criteria:** Women were screened for eligibility into 2 concurrent studies: Pregnant women who smoked more than 5 cigarettes per week prior to pregnancy, fluent in English, over 18 years, less than 20 weeks' gestation at first prenatal visit. Women who continue to smoke at 28 weeks' gestation, after having counselling and 8 self-help booklets earlier in pregnancy care, and had telephone access, were eligible for this study **Exclusion criteria:** Women who had quit smoking at 28 weeks (continuous abstinence for 28 days),were enrolled in a large trial to prevent postpartum relapse (Project PANDA) **Recruitment:** 6956 (99%) women completed intake screening. 1255 current and recent smokers received brief intervention in early pregnancy as described by Ershoff 1989. 522/1255 (42%) had transferred care, had fetal demise or abortion, were over 34 weeks' gestation, or could not be reached. All 269/733 (37%)who reported continuing to smoke at 28 weeks and were randomised to this study, as data collection and implementation were adopted as routine procedures, and required no formal written consent (C = 135, I = 134) **Baseline characteristics:** > 61 cigarettes/week before pregnancy: I = 57.9%, C = 43%; Partner smoking: C = 62.5%, I = 69.6% Mean age: C = 28.1, I = 28.6; Married: C = 71.1%, I = 65.7%, White: C = 76.3%, I = 81.3%. < high school: C = 11%, I = 9% **Progress+ coding:** None.
Interventions	**Control:** All women smoking at intake (< 20 weeks), were provided with MI counselling (3-5 mins) and a series of 8 motivational self-help books (first given in person and 7 mailed weekly thereafter), based on "stage of change" program as described by Ershoff 1989. **Intervention:** The high intensity intervention group (and their partners) then received: (i) a 20-30 min MI telephone counselling call (conducted by trained counsellors and nurse health educators), (ii) a personalised, stages of change based feedback letter, (iii) a final MI-based telephone call conducted 4-5 days after the feedback letter was sent The MI counselling calls were adapted from the Motivational Enhancement Therapy developed for Project MATCH (Miller 1992). **Main intervention strategy:** Counselling (multiple intervention) compared to less intensive intervention **Intensity:** Frequency: (C = 6, I = 6), Duration: (C = 1, I = 3). Intervention provided by dedicated project staff: efficacy study
Outcomes	Biochemically validated smoking cessation at 34 weeks' gestation (late pregnancy*) Self-reported smoking cessation at 6 weeks, 3 months* and 6 months* postpartum Movement in "stages of change". Breastfeeding rates and general health behaviours obtained but not reported Discussion of provider views.
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated random number list.
Allocation concealment (selection bias)	Unclear risk	No details provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	35% attrition for cotinine testing: 175/269 provided cotinine subsample (C = 82, I = 84). 39% attrition for 6 weeks postpartum follow-up All women lost to follow-up for cotinine validated smoking status at 36/40 were included in this review as continuing smokers. Analysis includes all randomised women
Selective reporting (reporting bias)	Unclear risk	Only smoking outcomes reported.
Other bias	Low risk	No other bias detected.

Biochemical validation of smoking abstinence (detection bias)	Low risk	Urinary cotinine analysis (cut-off 80 ng/mL) for a subset of the sample at 34 weeks' gestation, but women without cotinine validation were included as continuing smokers. Postpartum outcomes self-reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel likely to have been aware of group allocation, though no formal consent requested
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Described as "single blind" (cotinine analysis performed blind)
Incomplete implementation	High risk	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
Equal baseline characteristics in study arms	High risk	Group differences were found on number of cigarettes smoked per week at baseline, but no differences in demographic variables
Contamination of control group	Low risk	Specific counsellors delivered the intervention.

Stotts 2004

Methods	Randomised controlled trial (pilot study) of motivational interviewing intervention to support women to stop smoking in pregnancy Study conducted in a university-based, public obstetric/gynaecology clinic (USA). Exact location and recruitment dates not reported
Participants	**Inclusion criteria:** Pregnant women who reported smoking in the past 7 days who were at least 16 years of age, fluent in English, less than 28 weeks' gestation **Exclusion criteria:** Not further specified. **Recruitment:** Women attending a university-based, public obstetric/gynaecology clinic. Unclear how many women were approached or eligible, though author communication reports challenges with recruitment. 54 women randomised (C = 28, I = 21, from author communication) **Baseline characteristics:** Not reported but discussion describes women as 'socio-economically disadvantaged pregnant smokers' **Progress+coding:** Low SES.
Interventions	**Control:** Usual care, which in this university-based prenatal clinic included physicians or nurses acknowledging a pregnant woman's reported smoking and recommending that she quit **Intervention:** MI intervention over the course of 8 weeks: (i) 1 face-to-face MI session; (ii) 3 MI-based telephone counselling calls; and (iii) 1 personalised feedback letter providing assessment results. MI incorporated specific counselling strategies, including personalized and objective feedback, to create a supportive, non-confrontational environment through which clients can resolve ambivalence and initiate change **Main intervention strategy:** Counselling (multiple intervention) compared to usual care **Intensity:** Frequency: (C = 0, I = 4), Duration (C = 0, I = 2). Usual care intensity F = 1, I = 1 2 masters-level counsellors delivered the intervention: Efficacy study
Outcomes	Biochemically validated smoking cessation at post-treatment assessment (late pregnancy*) Stages of change, processes of change, self-efficacy, decisional balance, and depression scores also reported
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	States women 'were randomized' into an intervention or usual care condition
Allocation concealment (selection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Outcomes reported as percentages. 5 women excluded from the analysis (as per author communication) for which there was no data (C = 2, I = 3), so abstinent percentages are based on C = 5/28 and I = 3/ 21. These women were included as continuing smokers in this review

Selective reporting (reporting bias)	Unclear risk	Primary outcomes reported, author communication states low recruitment so focused on other outcomes in this pilot study
Other bias	Unclear risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemically validated smoking cessation with salivary cotinine (cut-off > 20 ng/mL)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible to blind participants and personnel to counselling intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	Not reported.
Equal baseline characteristics in study arms	Low risk	Not reported but author states " Initial comparisons of socio-demographic and smoking history variables revealed no differences between the MI and UC groups"
Contamination of control group	Low risk	Unlikely as intervention delivered by specific counsellors.

Stotts 2009

Methods	3-armed randomised controlled trial of personalised feedback during ultrasound and counselling to support women to stop smoking in pregnancy The study was conducted in Women, Infant and Child (WIC) clinics in Houston and Harris County Area, University of Texas Houston Medical School obstetric clinics and the local community (USA). Recruitment years not reported
Participants	**Inclusion criteria:** Pregnant women reporting having smoked a cigarette in the past 7 days; age 16 years and older; English speaking, and gestational age between 16 and 26 weeks (to recruit later-pregnancy continuing smokers who have had the most difficulty stopping smoking for the pregnancy) **Exclusion criteria:** Not further specified. **Recruitment:** Via routine prenatal screening and widely distributed advertisements. 4, 258 women were screened. 360/725 (49.6%) of eligible women agreed to participate and were randomly assigned to 3 conditions: C (BP) = 120, **I1** (BP + US) = 120, **I2** (MI + US) = 120. **Baseline characteristics:** Mean number of cigarettes per day: C = 11.72 (8.73), **I1** = 11.78 (9.47), **I2** = 11.03 (8.14). Partner smoking: C = 68 (68), **I1** = 82 (79.6), **I2** = 76 (72.4). Baseline cotinine: C = 117, **I1** = 116, **I2** = 131. Mean gestational age: C = 23.63, **I2** = 22.48, **I2** = 21.12; Mean age: 24.65, **I1** = 25.45, **I2** = 25.21; Mean years education: C = 11.40, **I1** = 11.37, **I 2**= 11.63; White: C = 65. 22%, **I1**= 57.02%, **I2** = 49.57% (remainder African-American and Hispanic); Income <$US15,000/yr: C = 49.58%, **I1** = 55.85%, **I2** = 56.67%. **Progress+ coding:** Low SES.
Interventions	**Control (BP)**: Best Practice or "BP" counselling based on the Agency for Healthcare Research Quality practice guidelines for identifying patients who smoke and intervening for smoking cessation (5A's and 5R's). Nurses trained and instructed to keep counselling to 10-15 minutes. Participants were also given American Cancer Society literature on prenatal smoking cessation and the toll-free number for the quit smoking hotline **Intervention 1: BP+ Ultrasound feedback** sessions lasting approximately 30 minutes . In addition to providing routine ultrasound results, the ultrasound session was designed to provide information regarding the effect of cigarette smoke on the fetus using a motivational style. The sonographers received 2 hours of training and a laminated prompt card. Smoking risk messages were incorporated into discussion **Intervention 2: BP+US+ Motivational Interviewing** consisting of 1 45- to 50-min, face-to-face, individual counselling session conducted immediately after the ultrasound; 1 personalised feedback letter mailed 1 week later; and 1 follow-up counselling session conducted via telephone 2 weeks subsequent to the initial session, provided by master's level counsellors. Elements of the transtheoretical model were included and smoking in the household and social networks were also addressed **Main intervention strategy:** Feedback (multiple intervention) compared to a less intensive intervention **Intensity:** Frequency: (C = 2, I = 4), Duration: (C = 1, I = 3). Intervention provided by dedicated study staff: Efficacy study
Outcomes	Biochemically validated smoking cessation at 8 months gestation (late pregnancy*) 'Predictors of abstinence' including: Stages of change, depression (Beck's Depression Inventory), baseline smoking, ethnicity, and social networks reported

Notes	Concerns about potential distress with the ultrasounds intervention were considered in a pilot study of 30 women (Groff 2005) indicated no significant increase in anxiety post-ultrasound

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A block randomisation method, using blocks of 6 (2 per condition), was used to generate 360 slots, 120 per intervention group
Allocation concealment (selection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition:16/360 (4.4%), C = 6, **I1** = 5, **I2** = 5 (reasons not reported). Analyses were conducted using an ITT approach with all randomised participants included in the baseline and those lost to follow-up treated as continued smoking
Selective reporting (reporting bias)	Low risk	Primary outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Self-reported smoking status biochemically validated using salivary cotinine (< 20 ng/mL)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible to blind participants and personnel to counselling intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessor blinding not reported.
Incomplete implementation	Unclear risk	Procecss evaluation not reported.
Equal baseline characteristics in study arms	Low risk	Treatment group differences only for gestational age at baseline
Contamination of control group	Low risk	Low risk of contamination as counselling provided by specialist counsellors, not accessible to the control group

Strecher 2000

Methods	Randomised controlled trial of computer generated messages to support women to stop smoking in pregnancy Study conducted in 2 university hospitals in North Carolina and Michigan (USA), with recruitment from December 1996 to December 1997
Participants	**Inclusion criteria:** Women who have "smoked 100 cigarettes in their lifetime and still smoking" or "had quit since becoming pregnant" **Exclusion criteria:** Not further specified. **Recruitment:** Unclear how many women screened during first prenatal visit. using a self-administered computer screening program. 173 women randomised (C = 85, I = 88) **Baseline characteristics:** Mean cigarettes per day before pregnancy: C = 18.7, I = 20.3; current mean cigarettes per day: C = 11.8, I = 12.9; Mean cotinine: C = 2597, I = 2701; Mean smokers in household: C = 1.1, I = 1.0 Mean age: C = 26.6, I = 25.5; Mean education: C = 12.5, I = 12.5; White: C = 81.2%, I = 87.4% **Progress+ coding:** None.
Interventions	**Control:** Received "a pregnant woman's guide to quit smoking" at the first visit **Intervention:** Entered personal data into a hand-held computer at antenatal visits, which subsequently generated personalised tailored messages, which were posted to the woman **Main intervention strategy:** Health education (single intervention) compared to less intensive intervention **Intensity:** Frequency (C = I, I = 6), Duration (C = 1, I = 2). Unclear if intervention provided by dedicated project or existing staff as technological intervention
Outcomes	Biochemically validated smoking cessation at 6 weeks postpartum* (0-5 months pp) Biochemically validated cessation at 24/40 gestation ('mid-term') and self-reported cessation 3 months postpartum but outcomes not reported Mean cigarettes per day and cotinine concentrations collected and reported as 'not significant' but actual figures not reported

	Participant evaluation of using hand-held computers and reactions to computerised materials
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

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	By computer algorithm.
Allocation concealment (selection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias) All outcomes	High risk	Outcome data (C = 87, I = 104) are inconsistent with figures reported as randomised in methods and baseline data table (C = 85, I = 88). If comparing outcome data using ITT and excluding those 'lost to follow-up' it appears that more than 30% of the control group (30/87) were lost to follow-up. In this review we have used the ITT data (C = 87, I = 104) as the denominator
Selective reporting (reporting bias)	High risk	Results are conflicting and actual figures for pregnancy (24/40) are not reported, nor are figures for mean cigarettes per day or cotinine concentrations
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Urinary cotinine analysis at 24 weeks' gestation and at 6 weeks postpartum (cut-off < 80ng/mL)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel not blinded to intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	Process evaluation not reported.
Equal baseline characteristics in study arms	Low risk	Baseline comparisons revealed no significant differences in age, race, education, number of cigarettes smoked before pregnancy, and baseline stage of change
Contamination of control group	Low risk	Technological intervention so contamination unlikely.

Tappin 2000

Methods	Randomised controlled trial (pilot study) of home based motivational interviewing to support women to stop smoking in pregnancy Study conducted in a Glasgow Hospital, Scotland (UK), with recruitment from March to May 1997
Participants	**Inclusion criteria:** Women who identified as smokers on a questionnaire at antenatal clinic booking **Exclusion criteria:** Not further specified. 133/393 (34%) women screened identified as smokers and 100/133 (75%) agreed to participate and were randomised (C =5 0, I = 50) **Baseline characteristics:** Mean cigarettes per day pre-pregnancy C = 18.1, I = 19.6; current mean cigarettes per day C = 13.2, I = 14.8; partner smoking: C = 82%, I = 90%; Mean cotinine C = 126 ng/mL, I = 136 ng/mL Mean age: C = 25.9, I = 26.6; 76% 'severely deprived' participants **Progress+ coding:** Low SES.
Interventions	**Control:** Received usual advice from their prenatal providers, which should include information about smoking **Intervention:** Received 2-5 motivational interviewing sessions (mean 2.6 hours), based on stages of change, in the clients' home conducted by a midwife with 3 weeks training in smoking cessation counselling **Main intervention strategy:** Counselling (single intervention) compared to usual care. **Intensity:** Frequency: (C = 0, I = 4), Duration (C = 0, I = 4). Usual care intensity: F = 1, D = 1 Intervention provided by dedicated study staff: Efficacy study
Outcomes	Biochemically validated smoking cessation at >=27/40 (late pregnancy*) Mean birthweight*, preterm births*, stillbirths*. Ranking interviews measured movement around the 'cycle of change'

	Detailed evaluation of participant and midwifery views of interventions
Notes	SDs for mean birthweight were not reported, therefore we calculated a mean SD from 13 studies with available birthweight SDs (578) to include in this review, as recommended by the cochrane handbook

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random numbers stratified by deprivation.
Allocation concealment (selection bias)	Low risk	Group allocation by telephone.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition (2%). Some missing data for cotinine validation. Smoking outcome results reported for all of those randomised, and those with missing data counted as continuing smokers in this review
Selective reporting (reporting bias)	Low risk	Detailed outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Serum cotinine levels measured.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible to blind participants and personnel to counselling intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	Good process evaluation of implementation quality according to rating tool, showed 79% of women in the intervention group received at least 2 counselling sessions
Equal baseline characteristics in study arms	Low risk	No apparent difference.
Contamination of control group	Low risk	Specific counsellors provided intervention at home so contamination unlikely. Less than 20% of the control group recalled being given smoking information at the time of booking

Tappin 2005

Methods	Randomised controlled trial of home-based counselling to support women to stop smoking in pregnancy Study conducted in 2 hospitals in Glasgow, Scotland (UK), with recruitment from March 2001 to May 2003
Participants	**Inclusion criteria:** Women reporting smoking at prenatal booking visit and less than or equal to 24 weeks' gestation **Exclusion criteria:** Not further specified. **Recruitment:** 762/1684 (45%) eligible women agreed to participate (C = 411, I = 351) **Baseline characteristics:** Current mean cigarettes per day: C = 11.3, I = 11.7; At least 1 other smoker in house: C = 66%, I = 65% Mean age: C = 26.9, I = 26.5; Most deprived social category (6-7): C = 73%, I = 69% **Progress+ coding:** Low SES.
Interventions	**Control:** Midwives provided standard health promotion including information on smoking in pregnancy from a book given to all women in pregnancy in Scotland **Intervention:** Women also were offered 2-5 additional home visits of about 30 minutes duration from the same study midwife **Main intervention strategy:** Counselling (single intervention) compared to usual care. **Intensity:** Frequency: (C = 0, I = 4), Duration (C = 0, I = 4). Usual care intensity: F = 1, D = 1 Intervention provided by dedicated study staff: Efficacy study
Outcomes	Biochemically validated and self-reported quitting soon after the routine 36 week antenatal visit (late pregnancy*), reduction (mean cotinine*, self-reported*, and biochemically validated, which was at least half baseline measurement*), and increased smoking, mean birthweight*, preterm delivery*, very low birthweight*, low birthweight*, neonatal death*, stillbirths*, and admission to NICU*

	Data collected on other adverse events including antenatal admissions, miscarriage, termination of pregnancy, and assisted delivery Discussion of participant and provider views of intervention and thorough process evaluation showed good implementation
Notes	Sample size calculated by recruitment to achieve sufficient power not able to be achieved

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Stratified central randomisation.
Allocation concealment (selection bias)	Low risk	Group allocation provided by central administrator.
Incomplete outcome data (attrition bias) All outcomes	Low risk	29/762 (4%) women lost to follow-up: fetal loss = 6 (C = 2, I = 4) were excluded from this analysis; no late interview or cotinine = 10 (C = 5, I = 5), Not traceable 12 (C = 7, I = 5). Some missing data for cotinine validation All randomised participants (except fetal losses) included in smoking outcomes, and those with missing data counted as continuing smokers
Selective reporting (reporting bias)	Low risk	Detailed outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Serum cotinine (cut-off <13.7 ng/mL) or salivary cotinine (cut-off < 14.2 ng/mL) used to validate self-reported abstinence
Blinding of participants and personnel (performance bias) All outcomes	High risk	Midwife intervention, with caregivers not blinded.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	'A second administrator, blind to the random allocation, established a primary outcome'
Incomplete implementation	High risk	26% of women did not have any home visits.
Equal baseline characteristics in study arms	Low risk	No apparent major difference noted.
Contamination of control group	Low risk	Research midwives provided the intervention.

Thornton 1997

Methods	Randomised controlled trial of counselling intervention to support women to stop smoking and prevent relapse in pregnancy Study conducted in a large public antenatal clinic, in Rotunda Ireland, with recruitment during 3 months in 1995
Participants	**Inclusion criteria:** Women who 'currently smoke' or had spontaneously quit since becoming pregnant **Exclusion criteria:** Non-viable pregnancy identified at first visit or intending to deliver at another hospital **Recruitment:** 967/524 (54%) women attending the public clinic were smokers. 418/518 (81%) eligible women agreed to participate and were randomised (C = 209, I = 209) **Baseline characteristics:** Current smoker: C = 192, I = 203; Spontaneous quitter: C = 17, I = 6; 34% smoked more than 20 cigarettes per day currently; Partner smoking: C = 74%, I = 69.9% < 21 years age C = 17%, I = 24%; Mean gestation at first visit I = 15.5, C = 15.3; Not living with partner C = 39.2%, I = 42.6%; age finished education C = 16.1, I = 16.0; Lower social class C = 71.5%, I = 70.9% **Progress+ coding:** Low SES.
Interventions	**Control:** Routine prenatal advice on a range of health issues, from midwives and obstetricians **Intervention:** As for the control group + (i) structured 1 to 1 counselling by a trained facilitator (based on stages of change theory); (ii) partners invited to be involved in the program; (iii) an information pack (developed in collaboration with a focus group of women), which included a self-help booklet; (iv) and invited to join a stop smoking support group. A CO monitor was available for the intervention group, to quantify smoking habit and act as a motivational tool **Main intervention strategy:** Counselling (tailored) compared to usual care.

	Intensity: Frequency: (C = 0, I = 5); Duration (C = 0, I = 2). Usual care intensity: F = 1, D = 1 Intervention provided by dedicated study staff: Efficacy study
Outcomes	Biochemically validated smoking cessation* and relapse prevention* at delivery (late pregnancy) and 3 months postpartum among baseline smokers* and spontaneous quitter. Mean cigarettes per day at delivery*, reduction in daily cigarettes since first visit, quit attempts, comparisons of quitters and non quitters at various stages. Infant outcomes at birth (singleton births): mean birthweight*, proportion LBW(2500 g)*, preterm births*, stillbirths*, neonatal deaths*, NICU admissions*, delivery type, mean gestation Infant outcomes at 3 months postpartum: neonatal deaths, attendance at GP; attendance or admission to hospital
Notes	Detailed process analysis and participant feedback of program implementation

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Random number tables with restricted randomisation in groups of 10
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	31/418 (7%) attrition at delivery (I = 13/209 or 6.2%, C 18/209 or = 8.6%). Miscarriage (7), delivered elsewhere (3), moved overseas (2), changed care provider (7) or never returned to Rotunda hospital after first visit (12), and were excluded from this analysis All other women lost to follow-up counted as continuing smokers in this review
Selective reporting (reporting bias)	Low risk	All outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Unclear risk	Exhaled CO measurement on 145/209 women on postnatal ward (cut-off < 4 ppm). Presume smoking outcomes reported are those biochemically validated although this is not explicitly stated
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible to blind participants and study personnel to counselling intervention. Intervention provided by trained facilitator, with staff unaware of allocation
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	High risk	Detailed process evaluation describes how women rarely initiated contact at subsequent visits and the groups sessions were poorly attended
Equal baseline characteristics in study arms	High risk	Intervention group were less likely to have spontaneously quit, or be employed
Contamination of control group	Low risk	Research facilitator provided intervention.

Tsoh 2010

Methods	Randomised controlled trial of a computer-delivered brief intervention 'Video Doctor' to support women to stop smoking in pregnancy Study conducted as part of 'Health in Pregnancy' study in 5 community prenatal clinics in San Francisco Bay Area (USA), with recruitment from 2006 to December 2007
Participants	**Inclusion criteria:** Pregnant women 'smoking in the past 30 days' who were English-speaking, 18 years or older, and less than 26 weeks pregnant **Exclusion criteria:** Not further specified. **Recruitment:** 1208 women were screened for eligibility in the prenatal clinic waiting rooms and 114 refused (91% participation in screening). 42/410 (10%) eligible women identified as smokers on a risk assessment using a laptop computer via a low-literacy computerised interview with audio voiceover, and were randomised (C = 19, I = 23) **Baseline characteristics:** Current mean cigarettes per day I = 6.8, C = 6.7. Mean age C = 26.8, I = 27.5; White C = 31.6%, I = 17.4% (remaining Hispanic, Back or 'other'); Less than high school C = 21.1%, I = 26.1%; Married C = 26.3%, I = 47. 8%

	Progress+ coding: None.
Interventions	**Control:** Received the clinic's usual care and did not interact with the 'Video Doctor' program. All participants received a gift card ($30-$50) for completing assessments Intervention: Participants received tailored advice from 'Video Doctor', a multimedia interactive intervention delivered on a laptop computer via a secure Internet connection. An actor-portrayed Video Doctor delivered interactive risk-reduction messages designed to simulate an ideal discussion with a prenatal health care provider who provided non-judgmental counselling following several key principles of motivational interviewing. At the conclusion of each intervention session, the program automatically printed 2 documents: (a) a cueing sheet for providers, which offered a summary of the patient's risk profile and suggested risk-reduction counselling statements; and (b) an educational worksheet for participants with questions for self-reflection, harm reduction tips, and local resources. The cueing sheet was placed in the patient's medical record for the provider's use during the prenatal appointment **Main intervention strategy:** Counselling (multiple intervention) compared to usual care **Intensity:** Frequency (C = 0, I = 3), Duration (C = 0, I = 2). Usual care intensity: F = 0, D = 0 Technological intervention which prompted usual care providers: Effectiveness study
Outcomes	Self-reported 30-day abstinence after 1 month and 2 months (late pregnancy*). Mean reduction in cigarettes smoked per day and days smoked
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Women reporting risks were stratified by risk combination and randomly assigned by the computer to intervention or usual care groups
Allocation concealment (selection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition: I = 5/23 (22%), C = 5/19 (26%) at 1-month follow-up and I = 9/23 (39%) , C = 13/19 (32%) at 2-month follow-up (reasons not reported) All randomised participants included in analysis and women lost to follow-up treated as continuing smokers in this review
Selective reporting (reporting bias)	Low risk	Primary outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	Self-reported smoking cessation outcomes only - no biochemical validation of smoking status
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible to blind participants and personnel as intervention includes counselling component
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessor not reported.
Incomplete implementation	Low risk	Only 3 women in the usual care group did not recall receiving provider advice
Equal baseline characteristics in study arms	Low risk	Similar baseline characteristics.
Contamination of control group	Unclear risk	Some risk of contamination between study arms as same provider delivering counselling to intervention and control groups. Process evaluation showed 77.8% intervention group received 2 provider advice sessions, compared to 21.4% control group

Tuten 2012

Methods	3-armed randomised controlled trial of contingent incentives to support women to stop smoking in pregnancy Study conducted in the Center for Addiction and Pregnancy Treatment, at the Johns Hopkins Bayview Medical Center, Baltimore (USA), with recruitment from May 2005 to January 2009

Participants	**Inclusion criteria:** Requiring methadone during pregnancy, nicotine dependent or smoking 10 or more cigarettes daily, aged 18 years or older, <= 30 weeks' gestation, and capable of providing informed consent **Exclusion criteria:** Nicotine replacement therapy. **Recruitment:** 1072/1181 women screened smoked (90.7%). 125/1072 were eligible, and 102/125 (82%) agreed to participate, and were randomised to 3 conditions (C = 32, **I1** (non-contingent incentives) = 28, **I2** (contingent incentives) = 42). **Baseline characteristics:** Current mean cigarettes per day = 18.0. Mean age 30.8 years; 65% Caucasian; 11.1 mean years education; 85.3% currently single. 94.7% unemployed **Progress+ coding:** Low SES.
Interventions	**Control:** As part of usual care, inpatients at the centre are provided with specific information about the adverse effects associated with cigarette smoking for the mother and the infant. In addition, patients are provided with educational materials about risks of smoking during pregnancy. During follow-up obstetric appointments, patients are asked routinely about their cigarette smoking and commended on efforts to abstain. TAU participants were informed that they would be compensated for providing urine and breath samples, but that they would not earn incentives as part of their study participation **Intervention 1 (non-contingent incentives):** Participants were informed that they had the chance to earn vouchers, but whether they earned a voucher and the amount they earned was determined by an already generated schedule and thus was not linked to their own cigarette smoking. NCBI participants were required to leave CO and urine samples to receive any voucher earnings generated by the 'yoked' schedule, for 12 weeks or until delivery **Intervention 2 (contingent incentives):** Incentives contingent upon cigarette smoking reduction or abstinence for a period of 12 weeks or until delivery. Smoking targets were minimal during the initial weeks of intervention, and increased gradually to ensure adequate learning and reinforcement. Incentives could be earned for each sample left on Monday, Wednesday and Friday (3 samples per week) if the following reduction and abstinence targets were met: week 1: any reduction; weeks 2-4: 10% reduction; weeks 5-7: 25% reduction; weeks 8-9: 50% reduction; week 10-11: 75% reduction; and week 12 until delivery: abstinence (CO < 4 ppm.). Participants had the opportunity to earn a $7.50 voucher for the first smoking reduction target, and the value of the voucher increased by $1/day for each consecutive target met throughout the 12-week incentive period to amaximum of $41.50. If a contingent participant failed to meet the tobacco use reduction target during the 12-week incentive period, she earned $0 for that sample and the incentive schedule was reset to the original voucher value of $7.50. If the participant again met the target reduction on 5 consecutive occasions, she earned vouchers at the previously attained level **Main intervention strategy:** Incentives (single intervention) compared to usual care. Contingent incentives compared to usual care in this review **Intensity:** Frequency: (C = 0, I = 6), Duration (C = 0, I = 5). Usual care intensity: F = 3, D = 2 Intervention provided by dedicated project staff: Efficacy study
Outcomes	Biochemically validated point prevalence abstinence after 12 weeks of intervention (late pregnancy*); 75% cotinine reduction (> 50% reduction*); mean cotinine*; mean cigarettes per day 1 and three months post intervention* and 6 weeks postpartum Mean birthweight*, preterm births*, low birthweight*, NICU admissions* Spontaneous abortion, length of hospital stay, mean gestational age at delivery, mean 1-and 5-minute Apgars, urine toxicology and treatment for NAS Comparisons with non-contingent incentives (arm 2) are also reported
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	States patients were 'randomly assigned' to 1 of 3 conditions
Allocation concealment (selection bias)	Unclear risk	Not stated.
Incomplete outcome data (attrition bias) All outcomes	High risk	33% attrition (34/102) for pregnancy and birth outcomes and no explanation as to reasons for missing data. Unclear whether all women randomised were included in the outcome assessment, as percentage results only are reported. Assume all persons not meeting 'nonsmoking targets' (p1872) are counted as continuing smokers
Selective reporting (reporting bias)	Low risk	Primary outcomes appear to be reported, except smoking outcomes postpartum
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	CO sampling to evaluate changes during in-patient treatment phase and urine cotinine (cut-off 200 ng/mL)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible to blind participants and personnel to incentives intervention
Blinding of outcome assessment (detection bias)	Unclear risk	Not stated if outcome assessment was blinded.

All outcomes		
Incomplete implementation	Low risk	This was a well accepted intervention with high rates of participation among all 3 conditions
Equal baseline characteristics in study arms	Low risk	The conditions did not differ significantly on demographic, pre-treatment or baseline cigarette smoking measures
Contamination of control group	Low risk	Unlikely given the design of the study.

Valbo 1994

Methods	Randomised controlled trial of ultrasound feedback and cognitive-behavioural modification, to support women to stop smoking in pregnancy Study conducted in the National University Hospital, Oslo, Norway (Europe), with recruitment from June 1990 to October 1991
Participants	**Inclusion criteria:** Pregnant women attending antenatal clinic for 18 weeks for ultrasound, and still smoking 10 cigarettes per day or more (heavy smokers) **Exclusion criteria:** Not further specified. **Recruitment:** Not stated how many women approached or eligible (1800 births/year, study over 15 months). 112 women randomised (C = 56, I = 56) **Baseline characteristics:** Mean cigarettes per day at 18 weeks' gestation: C = 14.8, I = 12.5. Smoking partner: C = 80%, I = 74% Mean age: C = 28.4, I = 20.2. **Progress+ coding:** None.
Interventions	**Control:** Routine 18-week ultrasound and information on the negative effects of smoking and encouragement to quit, reinforced by a pamphlet, provided at the time of the ultrasound examination. **Intervention:** At the time of the 18 week ultrasound scan, offered the Windsor self-help manual (translated into Norwegian) describing a 10-day program which includes relapse prevention. During ultrasound (by midwife and obstetrician) women were given information about the negative effects of smoking. 2 weeks later women were sent an encouraging reminder and an appointment for an additional 32-week scan by an obstetrician, in which women were further encouraged to quit. A second reminder was sent 2 weeks later **Main intervention strategy:** Feedback (multiple intervention) compared to usual care. **Intensity:** Frequency (C = 0, I = 3), Duration (C = 0, I = 2). Usual care intensity: F = 1, D = 1 Intervention provided by existing staff: Effectiveness study
Outcomes	Self-reported abstinence at delivery (late pregnancy*); self-reported reduction in smoking at birth* mean cigarettes per day at birth*. Stillbirths* reported in attrition and re-included in both numerator and denominator for this outcome
Notes	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

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Described as "consecutively randomised".
Allocation concealment (selection bias)	High risk	Women consecutively randomised into 2 groups.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition: one stillbirth in intervention arm excluded from analysis. 7 women who did not return questionnaires (C = 6, I = 1)were not included in the study report but have been re-included as continuing smokers in this review (C = 56, I = 55)
Selective reporting (reporting bias)	Unclear risk	Only smoking outcomes reported.
Other bias	Unclear risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	No biochemical validation.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible to blind participants and providers to educational intervention and ultrasound. Although it is unclear if consent was sought so participants may have been blind

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Low risk	No process evaluation reported but assume most women received manual and ultrasounds
Equal baseline characteristics in study arms	Unclear risk	Intervention group had significantly higher daily smoking on entry
Contamination of control group	High risk	Usual care providers offering intervention and control components

Valbo 1996

Methods	Randomised controlled trial of hypnosis to support women to stop smoking during pregnancy Study conducted in Buskerud Central Hospital in Oslo, Norway (Europe), with recruitment from January 1992 to June 1993
Participants	**Inclusion criteria:** Women still smoking at 18 week ultrasound visit. **Exclusion criteria:** Not further specified. **Recruitment:** Expected numbers of pregnant smokers were 630. 158 (25%) agreed to participate and were randomised (78, I = 80) **Baseline characteristics:** Mean cigarettes/day prior to pregnancy I = 15.6, C = 15.0; Mean cigarettes per day at 18 weeks' gestation C = 9.7, I = 11.3; Partner smoking C = 73%, I = 71% Mean age C = 26.5, I = 27.9. **Progress+ coding:** None.
Interventions	**Control:** "Routine pregnancy health care". **Intervention:** Anaesthesiologist provided 2 × 45 minute sessions at 2 week interval of a protocol-based script (Handbook of the American Society of Clinical Hypnosis); the tape played after hypnosis was established emphasised the unpleasant effects of smoking, affirmed her wish to quit, encouraged her will and capacity to quit, and instructed her in meeting cravings with relaxation techniques and self-hypnosis, explained during the session. Second visit tape was different with more weight on her capacity and taking control. Both tapes avoided "moralizing about her responsibility for pregnancy outcome" **Main intervention strategy:** Counselling (single intervention) compared to usual care. **Intensity:** Frequency (C = 0, I = 4); Duration (C = 0, I = 3). Usual care intensity: F = 0, D = 0 Intervention provided by dedicated study staff: Efficacy study
Outcomes	Self-reported abstinence at birth (late pregnancy*), mean cigarettes per day at birth*, Self-reported reduction in smoking* (The SD used in the analysis in this review was calculated from a P value = 0.2 given in the paper) and increase at end of pregnancy, Perinatal deaths*.
Notes	Process evaluation did not rate the intervention highly: mean score of 2.05/7

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	The numbers from 1 to 100 were set up in random order, and by drawing lot, the women willing to participate were randomised into the intervention or control group
Allocation concealment (selection bias)	Unclear risk	Women allocated to groups by drawing lots (it was not clear when this took place)
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Of 80 allocated to intervention 13 did not receive an appointment in time, and 15 did not attend, and were excluded from the analysis
Selective reporting (reporting bias)	Unclear risk	Only smoking outcomes reported.
Other bias	Unclear risk	Not other bias' detected.
Biochemical validation of smoking abstinence (detection bias)	High risk	No biochemical validation.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Psychological intervention, authors state that usual caregivers were not aware of group allocation

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	High risk	28/80 women randomised did not receive the intervention
Equal baseline characteristics in study arms	High risk	Significantly more smokers in intervention group at entry.
Contamination of control group	Low risk	Dedicated hypnotist provided intervention.

Vilches 2009

Methods	4-armed cluster-randomised controlled trial of counselling interventions to support women to stop smoking in pregnancy Study conducted in primary health care clinics in Malaga, southern Spain, with data collection from 2001-2003
Participants	**Inclusion criteria:** 12/23 community clinics selected to balance neighbourhood SES (low, medium, and high). Women included if less than 15 weeks' gestation and smoked at least 1 cigarette since knowing they were pregnant **Exclusion criteria:** not further specified. **Recruitment:** 12 clinics 'randomly selected', stratified by SES status of neighbourhood. 3 randomly allocated to each study arm, based on SES status (3 levels, low, medium, high: so 1 level each study arm). Clinics balanced across study arms Women identified in 1999 in a preconceptual program (2,932 women screened in 23 clinics-38% were smokers). 719 eligible smokers from the 12 clinics were invited, of whom 455 agreed to participate (63% participation). 132 women spontaneously quit smoking after baseline and 27 had a spontaneous abortion; both were excluded from the study. 296 women were randomised (C = 54, **I1** = 71, **I2** = 47, **I3** = 124). **Baseline characteristics:** Mean cigarettes per day before becoming pregnant 20.6 (9. 58); Fagerstrom score: 4.78 (SD 5.38) 97.7% married. Education: 4% did not complete junior high school, 45% completed junior level only (9 years), 33% 12 years school, 17% university level. SES: 4.8% high, 24.6% medium/high, 53.4% medium/low, 17.1% low SES **Progress+ coding:** None.
Interventions	**Control:** Usual care. All 3 interventions were based on CBT, adapted to pregnant women taking into account factors important to women for smoking and quitting, but differ in intensity (frequency and duration). **Intervention 1 (low intensity):** 1 session 30 minutes by midwives who were trained in smoking cessation psychosocial education, provided with audiovisual materials and gave women a pamphlet. Delivered in 2nd trimester, usually before week 24. Included smokers and those who had spontaneously quit. Able to invite companions or people involved in pregnancy to session. Session covered basic smoking risks and benefits of quitting, motivational therapy and CBT for self-control to quit smoking, self-monitoring, developing alternative behaviours, stimulus control, setting a quit date and how to obtain social support. **Intervention 2 (medium intensity): I1**+ additional 3 group sessions × 90 mins over 4 weeks in 3rd trimester (weekly and then after 15 days) in clinic. Provided by midwife with additional training. Reviewed homework, introduced topic of day, set objectives and activity to complete before the following week. Recommended that by second week they abstain from tobacco. Only pregnant women invited to groups (6-10 women in each group), no partners. Audiovisual materials and self help guide to support sessions. **Intervention 3 (high intensity): I1**+5 × 90 mins weekly group sessions in 3rd trimester provided by clinical psychologist. Midwife present in sessions. Reviewed homework, set objectives and goals etc (similar to **I2**), counselled to quit smoking on 4th week of program. Used audiovisual equipment. CO monitoring and feedback provided in 2nd session with motivational interviewing. Included relapse prevention. Companions not included in group sessions **Main intervention strategy:** Counselling (multiple intervention) compared to usual care. Intervention 3 (high intensity) and control (usual care) compared in this review **Intensity:** Frequency (C = 0, I = 6); Duration (C = 0, I = 5). Usual care intensity: F = 0, D = 0 Intervention provided by dedicated study staff: Efficacy study
Outcomes	Self-reported mean cigarettes per day in late pregnancy*; Mean exhaled CO; Mean birthweight* Biochemically validated point prevalence abstinence rates not reported. Breastfeeding rates at 8 weeks postpartum reported
Notes	Report in Spanish.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Clinics described as 'randomly assigned'.

Allocation concealment (selection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	High risk	455 consented and 132 excluded as they spontaneously quit smoking, and further 27 excluded due to spontaneous abortion. Substantial attrition in this study (92% in I3): 296 randomised, 204 started intervention and 142 completed intervention and used in the analysis. Not able to be re-included as mean outcomes only reported (e.g. mean cigs/day, mean CO). Randomised : C = 54, **I1** = 71,**I2** = 47, **I3** = 124. Started intervention: C = 54,**I1** = 71, **I2** = 12, **I3** = 67 Completed intervention and analysed: C = 54, **I1** = 71, **I2** = 8, **I3** = 9.
Selective reporting (reporting bias)	High risk	Biochemically validated smoking cessation rates, proportion of preterm births, and stages of change outcomes stated as primary and secondary outcomes and not reported
Other bias	High risk	Tried to balance women across study arms and clinics (40 per arm per clinic) but were unable to achieve this
Biochemical validation of smoking abstinence (detection bias)	Unclear risk	Exhaled CO validation measured but biochemically confirmed smoking cessation rates not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	States clinics were not aware of allocation.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors blinded.
Incomplete implementation	Unclear risk	Only 8% completed the high and medium intensity interventions (group sessions)
Equal baseline characteristics in study arms	Unclear risk	Baseline characteristics not reported by individual study arm
Contamination of control group	Unclear risk	Cluster-randomised trial design minimises risk of contamination

Walsh 1997

Methods	Randomised controlled trial of a counselling intervention to support women to stop smoking in pregnancy Study conducted in a public hospital antenatal clinic in Newcastle, Australia, with screening from January 1990 to May 1991
Participants	**Inclusion criteria:** Pregnant women attending their first antenatal clinic appointment who answered yes to ‘Are you a smoker?”, were less than 26 weeks’ gestation, ill or psychologically unwell **Exclusion criteria:** Not further specified. **Recruitment:** 1,909 pregnant women were screened by midwives, 725 smokers (38%). 293/538 (54%) eligible women agreed to participate and were randomised (C = 145, I = 148) **Baseline characteristics:** Not reported. **Progress+ coding:** None
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 (CBT):** (i) 2-3 minute standardised risk information from Doctor. (ii) 14 minute video on risk information rebuttal of barriers to quitting, cessation tips and 10-minute standardised information (iii) Counselling from midwife after the video, using a flip chart, with negotiation of a quit date whenever possible (iv) Self-help manual on risks, barriers and cessation plus 4 packets of confectionary gum (v) Lottery chance (4 prizes) for biochemically validated abstainers at the next visit (vi) Social support from accompanying adult (partner/friend/other) via support tip sheet, contract and form letter, chart, reminder sticker in the medical record, form-letter and sticker from 1st visit Midwife mailed within 10 days + 2nd visit and 34 to 36 week visit 5 minute counselling from Midwife and 1-2 minute risk advice from Doctor. Women still smoking at 34-36 weeks were advised to attend an external cessation course **Main intervention strategy:** Counselling (tailored) compared to a less intensive intervention

	Intensity: Frequency (C = 2, I = 3); Duration (C = 1, I = 2). Intervention provided by existing staff: Effectiveness study
Outcomes	Biochemically validated point prevalence abstinence at 34 weeks' gestation (late pregnancy*) and 6-12 weeks' postpartum*. Preterm births* are reported in attrition and re-included in both numerator and denominator for this outcome Program costs and time commitments. Discussion of provider views and implementation issues in associated reference (Walsh 2000).
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated.
Allocation concealment (selection bias)	Low risk	Described as "precoded questionnaires in manila envelopes".
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition 14% due to: Leaving clinic (C = 7, I = 7), miscarriage or termination (C = 10, I = 10), and preterm birth (C = 3, I = 4), leaving 252 included in analysis (C = 125, I = 127) 25% lost to follow-up and further missing data for some variables including cotinine validation, however those with missing data were treated as continuing smokers in the analysis
Selective reporting (reporting bias)	Unclear risk	Only smoking outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Urinary cotinine was measured and revealed discrepancy with self-reported smoking status. biochemically validated with salivary cotinine (I = 86%, C = 78%) Cotinine data inconsistent with self-report were 52% in controls and 12% in the intervention group
Blinding of participants and personnel (performance bias) All outcomes	High risk	Educational intervention by usual care providers and notes flagged
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	High risk	Midwives involved in recruitment to the trial had variable 'success' in consent rates (9%-76%). Overall participation was quite low (54%)
Equal baseline characteristics in study arms	Low risk	Report states baseline characteristics were equal on 12 variables tested
Contamination of control group	Unclear risk	Same care providers for both groups.

Windsor 1985

Methods	3-armed randomised trial controlled trial (SCRIPT trial I) of interventions to support women to stop smoking in pregnancy Study conducted in public health clinics in Birmingham, Alabama (USA), from October 1983 to September 1984
Participants	**Inclusion criteria:** Pregnant women presenting for their first prenatal visit who reported smoking at least 1 cigarette in the last 7 days **Exclusion criteria:** >= 32 weeks' gestation. **Recruitment:** 460/1838 (25%) pregnant women screened were current smokers. 368/460 (80%) agreed to participate. Unclear exactly how many randomised to each group as attrition not reported by study arm **Baseline characteristics:** No baseline data on cigarettes/day. Mean age: 23.6; Black: 57%; Mean years education 11.5. **Progress+ coding:** Low SES as attending public clinics.

Interventions	**Control:** Smoking cessation advice routinely given at prenatal visits: 2-3 minutes within a group prenatal education session at the 1st visit, when maternity clinic staff recommend quitting. **Intervention 1:**10 minute standardised counselling session from a health educator (B Comm H Ed) + ALA "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. **Intervention 2:** as for **I1** except that the manual was "A pregnant woman's self-help guide to quit smoking" (instead of the ALA manual) **Main intervention strategy:** Counselling (multiple intervention) compared to usual care. Control and Intervention 2 compared in this review **Intensity:** Frequency: (C = 0, I = 1); Duration: (C = 0, I = 1). Usual care intensity: F = 1, D = 1 Intervention provided by dedicated study staff (health educators): Efficacy study
Outcomes	Biochemically validated point prevalence abstinence at mid-pregnancy, and during last month of pregnancy or within 48 hours of birth (late pregnancy*); and number of women who self-reported reduction in smoking in late pregnancy*
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated.
Allocation concealment (selection bias)	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition 29/338 (9%) due to: leaving system or moved (9), miscarriage or termination (10), and 10 who went to poorly attended group discussions (this intervention abandoned), leaving 309 included in analysis (C = 104, **I1** = 103, **I2** = 102). All other women lost to follow-up were treated as continuing smokers
Selective reporting (reporting bias)	Unclear risk	Only smoking outcomes reported.
Other bias	Low risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemical validation of self-reported smoking cessation using salivary thiocynate <100 ug/mL
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Educational intervention by health educators in antenatal clinics. Participants unlikely to be blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Unclear risk	"Multiple attempts were made to bring pregnant smokers together for a peer-led, focused group discussion: not feasible in this setting". Pre-trial assessment showed no nurses (n = 80) had smoking cessation training and less than 20% felt confident to advise women on how to stop
Equal baseline characteristics in study arms	Low risk	Characteristics in study arms appear equal.
Contamination of control group	Low risk	Administered by trained health educators, not involved in pregnancy care

Windsor 1993

Methods	Randomised controlled trial (SCRIPT trial II) of a cognitive behaviour therapy intervention to support women to stop smoking in pregnancy Study conducted in 4 public maternity clinics of the Jefferson County Health Department in Birmingham, Alabama (USA), with recruitment from September 1987 to November 1989
Participants	**Inclusion criteria:** Pregnant women who self-reported smoking during the first prenatal visit 'at least one puff of one cigarette in the last 7 days' **Exclusion criteria:** >= 32 weeks' gestation, did not stay for visit or did not return, prisoners, or had difficulty reading the baseline questionnaire

	Recruitment: 1171/4352 (27%) of women screened at first prenatal visit were current smokers and 210 (3%) spontaneous quitters (who were included in a separate trial: Lowe 1997). 994/1061 (94%) eligible women agreed to participate and were randomised (C = 501, I = 493) **Baseline characteristics:** Mean cotinine 114 ng/mL. 45% had low cotinine levels (< 99 ng/mL) Mean age = 24.6 years; Mean education = 12.4 years; Black = 52% **Progress+ coding:** Low SES in this review as attending public maternity clinic
Interventions	**Control:** 2-minute talk on smoking 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: (i) 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 (ii) Clinic reinforcement (chart sticker) + letter from Doctor within 7 days (iii) Social support in form of a 'buddy' letter, contract and buddy tip sheet + monthly newsletter with testimonials, cessation tips and additional information on risks **Main intervention strategy:** Counselling (multiple intervention) compared to a less intensive intervention **Intensity:** Frequency (C = 1, I = 4), Duration: (C = 1, I = 3). Intervention provided by dedicated project staff: Efficacy study
Outcomes	Biochemically validated point prevalence abstinence at 4-8 weeks after first visit (midpoint), 32 weeks' gestation (late pregnancy*). "Significant" reduction* if cotinine at least 50% value of baseline cotinine* Cost estimates. Separate trial reports data on spontaneous quitters (Lowe 1997).
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition 180/994 (18%) due withdrawal from the service, miscarriage or abortion (C = 87, I = 93) were not included in analysis, leaving C = 414, I = 400 Further 15% lost to follow-up survey or cotinine analysis included as continuing smokers in this review
Selective reporting (reporting bias)	Unclear risk	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
Other bias	Unclear risk	No other bias detected.
Biochemical validation of smoking abstinence (detection bias)	Low risk	Biochemical validation of smoking status using salivary cotinine (cut-off >= 30 ng/mL)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Notes flagged. Educational intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Low risk	Process evaluation showed 100% implementation of counselling and social support, and 88% for re-inforecement at subsequent visits
Equal baseline characteristics in study arms	Low risk	NS difference in baseline cotinine.
Contamination of control group	Low risk	Trained counsellor, not pregnancy care provider, delivered the intervention

Windsor 2011

Methods	Randomised controlled trial (SCRIPT Trial III) of counselling intervention provided by routine care staff (effectiveness study) to support women to stop smoking in pregnancy Study conducted in 16 /67 counties providing Medicaid care in Birmingham, Alabama (USA). Counties matched by number of smokers and percentage Black and White women, and 1 county per dyad (n=8) randomly selected to participate in study. There were 10 prenatal care clinics and 28 regular staff members in the 8 counties selected. Recruitment dates not reported, but study conducted over 5 years
Participants	**Inclusion criteria:** Pregnant women who reported ≥1 cigarette ('even one puff') in the last 7 days, or had a cotinine level ≥20 ng/mL **Exclusion criteria:** Not further specified. **Recruitment:** 6,514 women were screened at first antenatal visit and 1340/1736 (77%) eligible smokers agreed to participate. 1 trial site dropped out leaving 1,093 who were randomised (C=546, I=547) **Baseline characteristics:** Cigarettes per day: C= 9.8 (&10.3 among drop-outs), I=10. 4 (&12.0 among dropouts); Lives with smoker: C=69.8 (&75.3% among dropouts), I=73.7 (&66% among dropouts). Mean cotinine: C=163, I=181 Mean age: 22 years; Black C=15.7%, I=15.4%. **Progress+ coding:** Low SES as Medicaid clinics.
Interventions	Staff orientation and assessment, and 3 hours SCRIPT training for staff in intervention sites **Control:** All participants received 4 elements of the "5A's" best practice guidelines (Ask-Advise-Remind) **Intervention:** Participants received (Assist) Procedures 4 through 8: (i) A 14 minute 'Commit to Quit Smoking During and After Pregnancy' video (ii) A 'Pregnant Woman's Guide to Quit Smoking' written at 6th grade reading level and includes a 10 day self-help guide for cessation (Windsor 1985), and (iii) A ≤10-minute counselling session (MI) **Main intervention strategy:** Counselling (multiple intervention) compared to a less intensive intervention **Intensity:** Frequency (C=2, I=2), Duration (C=1, I=2). Intervention provided by existing staff: Effectiveness study
Outcomes	Biochemically validated point prevalence abstinence in late pregnancy* (>60 days after first visit, and <90 days postpartum) Number with a "significant reduction" in cotinine* (>50ng/mL at baseline and <50% at follow up, quitters not included as significant reducers) An additional 'historical' control group also provides comparison pre and post intervention
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as 'randomly selected' counties. Then "Smokers were randomly assigned at each clinic to an experimental group or control group after screening, consent, and baseline assessment"
Allocation concealment (selection bias)	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition: C=97/546 (17%) and I=95/547 (17%). Reasons for drop-out not reported. An intent-to-treat policy was used in the computation of impact rates and all dropouts included as continuing smokers in this review
Selective reporting (reporting bias)	Unclear risk	Unclear if there was 1 or 2 assessments (i. e. 1 assessment *between* >60 days after first visit and <90 days post partum; or 2 'assessments performed >60 days after first visit, *and* <90 days postpartum'). Only 1 assessment reported.
Other bias	High risk	Figures in Table 1 (baseline, C=546, I=547) conflict with the outcome denominator in Table 2, which is reported to include those lost to followup (C=549, I=544). Figures reported in Table 1 used for denominator and Table 2 for numerator in this report
Biochemical validation of smoking abstinence (detection bias)	High risk	72% self-reported quitters validated with biochemical verification (salivary cotinine <20ng/mL). 10% non-disclosure of smoking detected
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel not blinded to counselling intervention

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete implementation	Low risk	Process evaluation showed reasonable implementation (over 80%)
Equal baseline characteristics in study arms	Unclear risk	Equal on all variables apart from mean cotinine (ng/mL)
Contamination of control group	High risk	Process evaluation suggests there was significant contamination of the randomised control group with regular clinic staff providing the intervention to both study arms

AFP: alpha fetoprotein

ALA: American lung association

AN: antenatal

BP: blood pressure

C: control group

CBT: cognitive behavioural therapy

CI: Confidence interval

CO: carbon monoxide

GP: general practitioner

HMO: Health Maintenance Organisation

I: intervention group

ICC: Intracluster correlation co-efficient

ITT:intention to treat

LBW: low birthweight

MI: motivational interviewing

min: minutes

MRFIT: randomised trial of health promotion carried out in the US

NICU: neonatal intensive care unit

NNTB: number needed to benefit

NRT: nicotine replacement therapy

OPD: out-patient department

Pls: principal investigators

ppm: parts per million

PPROM: preterm, prelabour rupture of the membranes

SD: Standard deviation

SES: socioeconomic status

SHO: senior house officer

TFS: teen fresh start

TFSB: teen fresh start + peer support

UC: usual care

UK: United Kingdom

US: ultrasound

USA: United States

vs: versus

WIC: Food program for Women, Infants and Children in the US

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

Study	Reason for exclusion
Albrecht 2011	Program description only, not a randomised controlled study.
Andrews 2007	Women included were not-pregnant, plus quasi-randomised study design
Berlin 2008	Double-blind study of nicotine replacement therapy.
Boshier 2003	Cohort study, not a randomised study design.
Bowden 2010	Cohort study only, no control or comparison group.
Brandon 2012	Part of the intervention is provided during pregnancy but primary aim of the study is to prevent relapse after pregnancy and post-partum outcomes only reported
Britton 2006	Quasi-experimental design. Control and experimental convenience samples collected consecutively
Chan 2005	Controlled observational study of Bupropion for smoking cessation in pregnancy
Coleman 2007	Randomised controlled trial of pharmacological intervention with equal psychosocial support in both arms
Culp 2007	Controlled trial/evaluation of “The Community-Based Family Resource and Support” (CBFRS) Program. Control group not randomised
DeVries 2006	Quasi-cluster-randomised study with inadequate sequence generation (40 practices selected with matched controls)
Disantis 2010	Non-randomised postpartum intervention to promote smoking cessation and breastfeeding
Dixon 2009	Longitudinal cohort study only.
Edwards 2009	Evaluation of ‘SMART moms’ project, which has no control group
El-Mohandes 2013	Randomised-controlled trial of pharmacological interventions (nicotine replacement therapy) with equal psychosocial support in both study arms
Emmons 2000	Controlled trial/evaluation of the “Healthy Baby Second Hand Smoke Study” uses historical controls. Good documentation of implementation problems
Ershoff 1983	The intervention took place in 1 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
Everett-Murphy 2010	Evaluation of smoking cessation counselling using a historical control group only (pre-post study design, not randomised and no contemporary control group)
Ferguson 2012	Pregnant women excluded from this study (non-pregnant study population)
Ferreira-Borges 2005	Pre-test post-test control group design (not randomised).
Fish 2011	Intervention aimed at partners of pregnant women only. Pregnant women not included in the intervention
French 2007	Controlled clinical trial of postpartum relapse prevention. Excluded as not a trial during pregnancy, and not randomised
Gadomski 2011	Evaluation of ‘The BABY and ME-Tobacco Free’ program for relapse prevention postpartum. Quasi-experimental design with non-randomised control group (matched randomly selected controls)
Gebauer 1998	Study of effect of one 15-minute counselling session and a follow-up telephone call, performed 1994-95, using historical controls from 1993-1994
Gillies 1987	In this controlled clinical trial the intervention was carried out in 1 hospital with another hospital in the same city acting as a control, after a prior descriptive study which showed the similarity between the 2 in terms of social and demographic factors including smoking. There was no randomisation and recruitment differed substantially across the 2 sites. Data for smoking reduction and smoking cessation are combined in the paper with no separate data on cessation and no adjustment for clustering
Grange 2005	Cohort study design.
Hahn 2005	Controlled trial with a volunteer sample of non-pregnant contest registrants, compared with a randomly selected group of smokers not exposed to the campaign/contest. Context registrants not randomised and there is evidence of differences between groups
Hannover 2008	Counselling intervention aimed at relapse prevention postpartum only. Screened for participation during birth admission
Herbert 2011	Intervention to reduce ‘Environmental Tobacco Smoke’ exposure aimed at postpartum relapse prevention only
Higgins 2004	Pilot study with 37/53 participants consecutively assigned (not randomised)

Hotham 2006	Randomised controlled trial of pharmacotherapy (nicotine replacement therapy) with equal psychosocial support in both study arms
Hymowitz 2006	Postpartum trial only which measures paediatrician implementation of smoking cessation and relapse prevention interventions
Jaakola 2001	Controlled study, not randomised, of effects of a population-based smoking cessation programand its impact on smoking in pregnancy. Controls were matched on inclusion criteria from another district
Johnston 2011	Cohort smoking data from a randomised controlled trial of maternal vaccines
Kaper 2006	Non-pregnant population.
Kapur 2001	Randomised controlled trial of pharmacotherapy with equal psychosocial support in both study arms
Karatay 2010	Evaluation of a motivational interviewing intervention with no control group
Kazemi 2012	Intervention aimed at partners of pregnant women only to reduce passive tobacco smoke exposure for pregnant women in Iran
Kientz 2005	Unable to determine number allocated to each trial arm and unclear what happened if unequal flip of coin
Koren 2009	Randomised controlled trial of pharmacotherapy with equal psychosocial support in both study arms
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 4 months after birth. There was no adjustment for cluster-randomisation in the analysis of the study findings
Lee 2008	Intervention aimed at partners of pregnant women only to reduce passive tobacco smoke exposure for pregnant women in China
Loke 2005	Intervention aimed at smoking cessation in men (partners of pregnant women)
Lowe 1998a	Quasi-randomised study with inadequate sequence generation (allocation by alternate clinic weeks)
Lowe 1998b	Quasi-randomised study with inadequate sequence generation (allocation by alternate clinic weeks)
MacArthur 1987	Quasi-randomised study with inadequate sequence generation (allocation by date of clinic visit)
Mauriello 2011	Formative research only for a non-randomised intervention with no control group
Miller 2003	A pilot study of a pharmacological intervention (Bupropion).
Mullen 1997	Study designed to promote postpartum smoking cessation (not antepartum or part of a trial conducted in pregnancy)
Murray 2008	Intervention to promote smoking cessation among a general (not specifically pregnant) primary care population
O'Connor 1992	Quasi-randomised study with inadequate sequence generation (alternate allocation according to day of week)
Oncken 2008	Randomised controlled trial of pharmacotherapy (nicotine replacement therapy) with equal psychosocial support in both arms
Peden 2008	Quasi-randomised study with sequential allocation to study arms
Phillips 2012	Intervention aimed at post-partumrelapse prevention only. Mother's were recruited during infant's admission to NICU
Polanska 2011	Observational cohort study only with no comparison group.
Pollak 2007	Randomised controlled trial of pharmacotherapy (nicotine replacement therapy) and equal psychosocial support in both arms
Power 1989	The intervention in this trial was unusual in that the focus was on anticipated benefits of smoking cessation to women themselves (not on harm to the fetus and infant), and on alternative coping strategies, with a designated midwife-facilitator to answer queries and provide friendly advice and encouragement. The intervention was carried out in 1 hospital with another being a comparison setting, after a prior study which showed the similarity between the 2 in social and demographic factors including smoking rates. There was no randomisation. Recruitment differed significantly across the 2 hospitals. Data for smoking cessation and smoking reduction are combined with no separate data on cessation and no adjustment for clustering
Ratner 1999	Postpartum intervention only. No interventions in pregnancy.
Reitzel 2010	Intervention aimed at postpartum relapse prevention only.
Rush 1992	Quasi-experimental study with inadequate sequence generation (group allocation by alternate weeks)
Scott 2000	This controlled clinical trial of the impact of using interactive software to promote smoking cessation, was excluded as it used historical controls
Shakespeare 1990	Not a smoking in pregnancy intervention.

Stanton 2004	Intervention aimed at partner's of pregnant women only. Aim was to maximise potential of life-changing period for men too. Did not include pregnant women
Suplee 2004	Randomised trial of relapse prevention counselling in the postpartum period only (not pregnancy)
Sutton 2007	Intervention of tailored smoking cessation letters, self-help materials and counselling for the general population (not specifically pregnant women)
Valanis 2001	This prospective controlled clinical trial design to test the effect of a low intensity intervention, used historical controls
Valbo 1991	Quasi-experimental study with inadequate sequence generation (3 months consecutive recruitment for each arm)
Wadland 2007	General study population (not pregnant). Implementation trial to change provider behaviour and increase referrals to quitline. Estimated smoking cessation outcome data only
Wiggins 2004	Cluster-randomised controlled trial comparing 2 postnatal interventions to improve maternal health
Wilkinson 2010	Quasi-experimental design with a non-randomised controlled pre-post test study design
Windsor 2000a	Quasi-experimental study with inadequate sequence generation (80% control group not randomly assigned)
Winickoff 2010	Intervention aimed at postpartum relapse prevention only with women recruited during birth admission
Wisborg 1998	This randomised study of the effect of midwifery training on smoking cessation intervention implementation and pregnancy outcomes, was excluded due to concerns about allocation concealment (clinic day allocation)
Wisborg 2000	Randomised controlled trial of a pharmacological intervention (nicotine replacement therapy) and equal psychosocial support in both study arms
Yilmaz 2006	Postnatal intervention in pediatric setting.

HMO: Health Maintenance Organisation

NICU: neonatal intensive care unit

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

Althabe 2012

Trial name or title	Not stated.
Methods	Cluster-randomised controlled trial.
Participants	Pregnant women attending antenatal care in Argentina and Uruguay
Interventions	A multifaceted intervention to implement the "5A's" strategy
Outcomes	Provision of smoking advice and smoking abstinence.
Starting date	Not stated.
Contact information	F. Althabe: Department of Mother and Child Health Research, Institute for Clinical Effectiveness and Health Policy (IECS), Buenos Aires, Argentina
Notes	

Blasco Oliete 2004

Trial name or title	Not stated.
Methods	Randomised clinical trial.
Participants	Pregnant women smoking at least 1 cigarette each day attending 4 clinics in Madrid, Spain
Interventions	Brief counselling (3 to 5 minutes) on smoking cessation compared with a group intervention over 3 half-hour sessions

Outcomes	Not clear.
Starting date	Not clear.
Contact information	meliton65@eresmas.com No response from authors to written request for further trial information on 18/7/2012
Notes	Original article in Spanish. Study report (2004) describes the study design. No papers including results have yet been identified

Everett 2008

Trial name or title	Not stated.
Methods	Ongoing study of intervention to promote smoking cessation among men and women during pregnancy
Participants	Pregnant women and their partners.
Interventions	Not clear.
Outcomes	Not clear.
Starting date	Not clear.
Contact information	everettk@health.missouri.edu Minimal study information provided in response to email request sent 18/7/2012
Notes	

Lasater 2007

Trial name or title	Reducing ETS exposure of pregnant women and newborns.
Methods	Randomised 2-arm study in 6 prenatal clinics designed to develop and evaluate the efficacy of 5 tailored DVDs in reducing exposure to ETS among low-income pregnant/postpartum women
Participants	Pregnant women who attend first prenatal visit by 16 weeks' gestation who are exposed to tobacco smoke daily. **Exclusion criteria:** women expecting complications or multiple births
Interventions	Provision of tailored DVDs to take home.
Outcomes	Salivary cotinine concentration of mother and baby.
Starting date	Feb 2006
Contact information	Thomas M Lasater, Brown University, Rhode Island. email: thomas_lasater@brown.edu
Notes	

Loukopoulou 2011

Trial name or title	M-SCOPE
Methods	Randomised controlled trial which aims to test whether offering Greek pregnant smokers a high intensity intervention increases smoking cessation during pregnancy, when compared to a low intensity intervention
Participants	Pregnant women smoking more than 5 cigarettes per week recruited in the second trimester of pregnancy
Interventions	The control group will receive 5 mins of brief advice and a leaflet, while the intervention group will receive 30 minutes of counselling by a trained health professional (based on 5A's) and a self-help manual
Outcomes	Biochemically validated smoking cessation at end of pregnancy and 6 months postpartum, infant birthweight, gestational age and other health-related complications in pregnancy

Starting date	November 2009 to June 2012.
Contact information	vardavas@hsph.harvard.edu
Notes	Preliminary results reported in an abstract published in 'Chest' were provided in response to written request for further trial information sent on 18/7/2012. However these outcomes were not reported in sufficient detail to be included in this review

Lynagh 2012

Trial name or title	An RCT protocol of varying financial incentive amounts for smoking cessation among pregnant women
Methods	RCT (pilot).
Participants	90 consenting pregnant women.
Interventions	2 intervention arms will be assessed: (1) a $AUD20 incremental personal financial incentive; and (2) a $AUD40 incremental personal financial incentive. Women from both intervention groups will have an opportunity to receive a PFI at 8 study intervention sessions contingent upon smoking abstinence
Outcomes	(i) consent rates; (ii) loss to follow-up rates of study participants and (iii) participant compliance with saliva and hair cotinine analyses for biochemical validation of smoking status. Womens perceptions of the intervention will also be ascertained by 6 interview questions
Starting date	Not clear.
Contact information	marita.lynagh@newcastle.edu.au
Notes	Australian New Zealand Clinical Trials Registry (ANZCTR) number: ACTRN12612000399897

Mejdoubi 2011

Trial name or title	Nurse Family Partnership in Dutch preventive health care.
Methods	Randomised controlled trial.
Participants	High risk pregnant women. The VoorZorg program target's women that definitely need support: most have 4 or more risk factors such as poverty, (sexual) violence in the past or present relationship, no support of a network and alcohol- or drug abuse
Interventions	VoorZorg: The primary aim is to reduce child abuse and other goals are to improve health outcomes in pregnancy. It is based on Bandura's Self-Efficacy Theory; Brofenbrenner's ecological model, and Bowlby's Attachment theory. Similar to intervention by Olds 1984 in the USA. Voorzorg consists of approximately 10 nurse home visits during pregnancy, 20 during the first year of the child's life and 20 during the second year of the child's life. The duration for each visit in 1.5 hours and nurses use manuals. Incentives provided for participation in study
Outcomes	Smoking cessation.
Starting date	Not stated.
Contact information	crijnen@xs4all.nl No response to written request for further information sent to trial authors on 18/7/2012
Notes	

Robling 2012

Trial name or title	Building Blocks - a trial of home visits for first time mothers
Methods	Individually randomised controlled trial.
Participants	First time pregnancy: 1. Women aged 19 years or under (at recruitment/consent) 2. Lives within the catchment area covered by the local family nurse partnership (FNP) team

	3. First pregnancy confirmed by health services (including those expecting multiple birth) unless previous pregnancy ended in miscarriage, stillbirth or termination 4. Recruited no later than 24 weeks. 5. Gillick competent to provide adequate informed consent to research participation including competence in English at conversational level or higher
Interventions	This trial will assess the effectiveness of the FNP in England compared with existing universal services
Outcomes	Primary: 1. Changes in prenatal tobacco use (maternal measure), measured at baseline and 34 - 36 weeks' gestation interviews 2. Birthweight (child measure), measured at birth (collected afterwards) 3. Emergency attendances/admissions within 2 years of birth, measured at all timepoints 4. Proportion of women with a second pregnancy within 2 years of first birth, measured at all timepoints Secondary: 1. Intention to breastfeed 2. Prenatal attachment 3. Injuries and ingestions 4. Breast feeding (initiation and duration) 5. Language development 6. Education 7. Employment 8. Income/benefits 9. Home (tenure) 10. Health status 11. Self-efficacy 12. Social support 13. Paternal involvement
Starting date	Not clear.
Contact information	**Dr Mike Robling:** Associate Director South East Wales Trials Unit Department of Primary Care and Public Health 7th Floor Neuadd Meirionnydd Cardiff University Heath Park http://www.cardiff.ac.uk/medic/subsites/buildingblocks/index.html
Notes	ISRCTN23019866

Ruger 2008

Trial name or title	Not stated.
Methods	Randomised controlled trial.
Participants	302 low-income pregnant women less than 28 weeks pregnant, English or Spanish-speaking, and who were not receiving inpatient drug treatment were recruited from multiple obstetric sites in the Boston metropolitan area (USA). Current smokers or women smoking in the past 3 months (recent quitters) were included
Interventions	Motivational interviewing interventions to promote smoking cessation and reduce environmental tobacco smoke exposure provided during 3 home visits, with feedback provided about the household nicotine levels
Outcomes	Smoking cessation at end of pregnancy and relapse prevention; infant health outcomes; life-years and quality of life; primary cost data and economic analysis
Starting date	1997-2000
Contact information	jennifer.ruger@yale.edu
Notes	Written request for further trial information sent 18/7/2012, but advised that results were not yet available

Tappin 2012

Trial name or title	Cessation in Pregnancy Incentives Trial (CPIT).
Methods	Individually randomised controlled trial.
Participants	600 pregnant smokers identified at maternity booking who, when contacted by specialist cessation services, agree to having their details passed to the NHS Smokefree Pregnancy Study Helpline to discuss the trial

Interventions	Standard care plus the additional offer of financial voucher incentives to engage with specialist cessation services and/or to quit smoking during pregnancy £50 for attending a face-to-face appointment with their NSPS adviser and setting a quit date; £50 if quit 4 weeks after their quit date corroborated by a carbon monoxide breath test result less than 10 ppm collected by a research nurse; £100 if quit after 12 weeks corroborated by a carbon monoxide breath test collected by a research nurse; £200 if they self-report quit for at least 2 months when contacted for primary outcome assessment by the Helpline at 34 to 38 weeks' gestation
Outcomes	Self-reported smoking in late pregnancy verified by cotinine measurement
Starting date	Recruitment started in December 2011. On 9 June 2012, 199 of 600 were enrolled in the 12 month trial
Contact information	David Tappin: david.tappin@glasgow.ac.uk Paediatric Epidemiology and Community Health Unit, Section of Child Health, Division of Developmental Medicine, Glasgow University, Yorkhill Campus, Glasgow G3 8SJ, Scotland, U.K
Notes	Current Controlled Trials ISRCTN87508788

Ussher 2012

Trial name or title	Physical activity as an aid to smoking cessation during pregnancy (LEAP) trial
Methods	Individually randomised controlled trial.
Participants	Pregnant women who smoke at least 1 cigarette a day (and at least 5 cigarettes a day before pregnancy), and are between 10 and 24 weeks pregnant
Interventions	Supervised exercise on a treadmill plus physical activity consultations
Outcomes	Self-reported and biochemically validated continuous abstinence from smoking between a specified quit date and the end of pregnancy
Starting date	The LEAP trial began recruiting patients in April 2009, and recruitment will close in November 2012 Data collection for the primary outcome is due to be completed in July 2013. As of October 2nd 2012, 768 women were recruited
Contact information	Michael Ussher: mussher@sgul.ac.uk Division of Population Health Sciences and Education, St George's University of London, Cranmer Terrace, London SW17 ORE, UK
Notes	ISRCTN48600346

Zhu 2004

Trial name or title	Telephone intervention (California Smokers' Helpline) or pregnant smokers
Methods	Randomised trial.
Participants	Pregnant smokers who called the helpline for services.
Interventions	Control group received a self-help quit kit of written materials, including the American Cancer Society booklet for pregnant smokers. Intervention group received the quit kit plus up to 7 counselling calls
Outcomes	Self-reported smoking cessation in third trimester.
Starting date	
Contact information	Shu-Hong Zhu 2004, University of California. szhu@ucsd.edu
Notes	Author emailed 2008, advised that results would not be available until publication. No response to written request for further trial information on 18/7/2012

ETS: environmental tobacco smoke

Europe PMC Funders Author Manuscripts

DATA AND ANALYSES

Comparison 1

Smoking cessation interventions: counselling vs usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Abstinence in late pregnancy	27	11979	Risk Ratio (M-H, Random, 95% CI)	1.44 [1.19, 1.75]
1.1 Single interventions	10	3753	Risk Ratio (M-H, Random, 95% CI)	1.12 [0.89, 1.42]
1.2 Multiple interventions	11	4407	Risk Ratio (M-H, Random, 95% CI)	1.59 [1.15, 2.21]
1.3 Tailored interventions	6	3819	Risk Ratio (M-H, Random, 95% CI)	1.49 [1.01, 2.20]
2 Abstinence in late pregnancy: biochemically validated only	18	9250	Risk Ratio (M-H, Random, 95% CI)	1.25 [1.03, 1.50]
2.1 Single interventions	7	3413	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.85, 1.25]
2.2 Multiple interventions	7	3860	Risk Ratio (M-H, Random, 95% CI)	1.39 [0.94, 2.04]
2.3 Tailored interventions	4	1977	Risk Ratio (M-H, Random, 95% CI)	1.42 [0.84, 2.41]
3 Continued abstinence (relapse prevention) in late pregnancy for spontaneous quitters	8	688	Risk Ratio (M-H, Random, 95% CI)	1.06 [0.93, 1.21]
3.1 Single interventions	2	100	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.93, 1.07]
3.2 Multiple interventions	3	297	Risk Ratio (M-H, Random, 95% CI)	1.08 [0.93, 1.26]
3.3 Tailored interventions	3	291	Risk Ratio (M-H, Random, 95% CI)	1.19 [0.97, 1.46]
4 Abstinence at 0 to 5 months postpartum	10		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
4.1 Single interventions	5	1164	Risk Ratio (M-H, Random, 95% CI)	1.52 [1.13, 2.05]
4.2 Multiple interventions	4	1097	Risk Ratio (M-H, Random, 95% CI)	2.32 [1.44, 3.72]
4.3 Tailored interventions	1	367	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.80, 0.97]
5 Abstinence at 6 to 11 months postpartum	6	2458	Risk Ratio (M-H, Random, 95% CI)	1.33 [1.00, 1.77]
5.1 Single interventions	2	776	Risk Ratio (M-H, Random, 95% CI)	1.34 [0.93, 1.92]
5.2 Multiple interventions	3	1055	Risk Ratio (M-H, Random, 95% CI)	1.47 [0.86, 2.52]
5.3 Tailored interventions	1	627	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.40, 2.46]
6 Abstinence at 12 to 17 months postpartum	2	431	Risk Ratio (M-H, Random, 95% CI)	2.20 [1.23, 3.96]
6.1 Single interventions	1	109	Risk Ratio (M-H, Random, 95% CI)	2.55 [1.05, 6.21]
6.2 Multiple interventions	1	322	Risk Ratio (M-H, Random, 95% CI)	1.97 [0.91,4.29]
7 Abstinence at 18+ months postpartum	2	934	Risk Ratio (M-H, Random, 95% CI)	1.25 [0.57, 2.73]
7.1 Multiple interventions	2	934	Risk Ratio (M-H, Random, 95% CI)	1.25 [0.57, 2.73]
8 Reduction in late pregnancy: biochemically validated	3	1311	Risk Ratio (M-H, Random, 95% CI)	1.11 [0.54, 2.26]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8.1 Single interventions	1	657	Risk Ratio (M-H, Random, 95% CI)	0.63 [0.34, 1.20]
8.2 Multiple interventions	2	555	Risk Ratio (M-H, Random, 95% CI)	1.50 [0.71, 3.20]
9 Reduction in late pregnancy: self reported (various definitions)	2	323	Risk Ratio (M-H, Random, 95% CI)	1.61 [1.06, 2.43]
9.1 Single interventions	2	323	Risk Ratio (M-H, Random, 95% CI)	1.61 [1.06, 2.43]
10 Biochemical measures in late pregnancy: mean cotinine	3	1742	Std. Mean Difference (IV, Random, 95% CI)	−0.05 [−0.14, 0.05]
10.1 Single interventions	2	1328	Std. Mean Difference (IV, Random, 95% CI)	−0.06 [−0.17, 0.05]
10.2 Multiple interventions	1	414	Std. Mean Difference (IV, Random, 95% CI)	−0.01 [−0.21, 0.18]
11 Mean cigarettes per day in late pregnancy	9	3368	Std. Mean Difference (IV, Random, 95% CI)	−0.25 [−0.46, −0.03]
11.1 Single interventions	5	1928	Std. Mean Difference (IV, Random, 95% CI)	−0.06 [−0.30, 0.18]
11.2 Multiple interventions	2	270	Std. Mean Difference (IV, Random, 95% CI)	−0.60 [−1.02, −0.18]
11.3 Tailored interventions	2	1170	Std. Mean Difference (IV, Random, 95% CI)	−0.43 [−0.83, −0.03]
12 Low birthweight infants (< 2500 g)	6	3836	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.70, 1.08]
12.1 Single interventions	2	1460	Risk Ratio (M-H, Random, 95% CI)	0.79 [0.56, 1.11]
12.2 Multiple interventions	1	414	Risk Ratio (M-H, Random, 95% CI)	1.08 [0.45, 2.61]
12.3 Tailored interventions	3	1962	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.66, 1.32]
13 Very low birthweight infants (< 1500 g)	2	1666	Risk Ratio (M-H, Random, 95% CI)	1.27 [0.60, 2.71]
13.1 Single interventions	1	731	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.32, 2.59]
13.2 Tailored interventions	1	539	Risk Ratio (M-H, Random, 95% CI)	1.83 [0.62, 5.43]
14 Preterm births	5	2653	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.64, 1.27]
14.1 Single interventions	3	1571	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.60, 1.17]
14.2 Tailored interventions	2	1082	Risk Ratio (M-H, Random, 95% CI)	1.13 [0.46, 2.80]
15 Mean birthweight	9	4846	Mean Difference (IV, Random, 95% CI)	36.72 [0.70, 72.74]
15.1 Single interventions	4	1880	Mean Difference (IV, Random, 95% CI)	45.65 [−10.17, 101.48]
15.2 Multiple interventions	2	624	Mean Difference (IV, Random, 95% CI)	84.65 [−95.37, 264.67]
15.3 Tailored interventions	3	2342	Mean Difference (IV, Random, 95% CI)	23.25 [−52.12, 98.62]
16 Perinatal deaths	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
16.1 Single interventions	1	130	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
16.2 Tailored interventions	1	539	Risk Ratio (M-H, Random, 95% CI)	1.10 [0.52, 2.31]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
17 Stillbirths	4	2212	Risk Ratio (M-H, Random, 95% CI)	1.08 [0.51, 2.30]
17.1 Single interventions	2	859	Risk Ratio (M-H, Random, 95% CI)	2.58 [0.38, 17.48]
17.2 Tailored interventions	2	1353	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.41, 2.10]
18 Neonatal deaths	3	2095	Risk Ratio (M-H, Random, 95% CI)	2.06 [0.61, 6.92]
18.1 Single interventions	1	762	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.07, 18.65]
18.2 Tailored interventions	2	1333	Risk Ratio (M-H, Random, 95% CI)	2.35 [0.61, 9.07]
19 NICU admissions	2	1140	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.52, 1.29]
19.1 Single interventions	1	762	Risk Ratio (M-H, Random, 95% CI)	0.71 [0.47, 1.07]
19.2 Tailored interventions	1	378	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.55, 2.46]

Comparison 2

Smoking cessation interventions: counselling vs less intensive intervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Abstinence in late pregnancy	16	5247	Risk Ratio (M-H, Random, 95% CI)	1.35 [1.00, 1.82]
1.1 Single interventions	5	735	Risk Ratio (M-H, Random, 95% CI)	1.51 [0.90, 2.54]
1.2 Multiple interventions	10	4260	Risk Ratio (M-H, Random, 95% CI)	1.23 [0.84, 1.78]
1.3 Tailored interventions	1	252	Risk Ratio (M-H, Random, 95% CI)	2.39 [1.03, 5.56]
2 Abstinence in late pregnancy: biochemically validated only	12	2858	Risk Ratio (M-H, Random, 95% CI)	1.46 [1.15, 1.85]
2.1 Single interventions	5	735	Risk Ratio (M-H, Random, 95% CI)	1.51 [0.90, 2.54]
2.2 Multiple interventions	6	1871	Risk Ratio (M-H, Random, 95% CI)	1.38 [1.05, 1.80]
2.3 Tailored interventions	1	252	Risk Ratio (M-H, Random, 95% CI)	2.39 [1.03, 5.56]
3 Continued abstinence (relapse prevention) in late pregnancy (spontaneous quitters)	4	692	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.98, 1.13]
3.1 Single interventions	2	204	Risk Ratio (M-H, Random, 95% CI)	1.02 [0.88, 1.18]
3.2 Multiple interventions	2	488	Risk Ratio (M-H, Random, 95% CI)	1.06 [0.96, 1.17]
3.3 Tailored interventions	0	0	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
4 Abstinence at 0 to 5 months postpartum	6	1980	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.82, 1.66]
4.1 Single interventions	1	82	Risk Ratio (M-H, Random, 95% CI)	0.63 [0.11, 3.60]
4.2 Multiple interventions	4	1646	Risk Ratio (M-H, Random, 95% CI)	1.19 [0.99, 1.43]
4.3 Tailored interventions	1	252	Risk Ratio (M-H, Random, 95% CI)	12.80 [1.70, 96.35]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5 Abstinence at 6 to 11 months postpartum	3	1271	Risk Ratio (M-H, Random, 95% CI)	1.08 [0.83, 1.40]
5.1 Single interventions	1	105	Risk Ratio (M-H, Random, 95% CI)	2.45 [0.50, 12.08]
5.2 Multiple interventions	2	1166	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.80, 1.38]
6 Abstinence at 12 to 17 months postpartum	2	1188	Risk Ratio (M-H, Random, 95% CI)	1.25 [0.71, 2.20]
6.1 Multiple interventions	2	1188	Risk Ratio (M-H, Random, 95% CI)	1.25 [0.71, 2.20]
7 Reduction in late pregnancy: self-reported > 50%	2	1235	Risk Ratio (M-H, Random, 95% CI)	1.35 [1.07, 1.71]
7.1 Multiple interventions	2	1235	Risk Ratio (M-H, Random, 95% CI)	1.35 [1.07, 1.71]
8 Reduction in late pregnancy: biochemically validated	2	758	Risk Ratio (M-H, Random, 95% CI)	1.35 [0.98, 1.87]
8.1 Multiple interventions	2	857	Risk Ratio (M-H, Random, 95% CI)	1.35 [0.98, 1.87]
9 Mean cigarettes per day in late pregnancy	2	397	Std. Mean Difference (IV, Random, 95% CI)	−0.11 [−0.30, 0.09]
9.1 Single interventions	1	121	Std. Mean Difference (IV, Random, 95% CI)	0.01 [−0.34, 0.37]
9.2 Multiple interventions	1	276	Std. Mean Difference (IV, Random, 95% CI)	−0.16 [−0.40, 0.08]
10 Low birthweight infants (< 2500 g)	2	305	Risk Ratio (M-H, Random, 95% CI)	0.58 [0.32, 1.04]
10.1 Single interventions	1	227	Risk Ratio (M-H, Random, 95% CI)	0.55 [0.25, 1.21]
10.2 Multiple interventions	1	276	Risk Ratio (M-H, Random, 95% CI)	0.61 [0.25, 1.50]
11 Preterm births	3	794	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.47, 1.42]
11.1 Single interventions	1	227	Risk Ratio (M-H, Random, 95% CI)	0.55 [0.25, 1.21]
11.2 Multiple interventions	1	308	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.46, 2.95]
11.3 Tailored interventions	1	952	Risk Ratio (M-H, Random, 95% CI)	1.30 [0.30, 5.71]
12 Mean birthweight	3	546	Mean Difference (IV, Random, 95% CI)	56.02 [−31.46, 143.50]
12.1 Single interventions	1	227	Mean Difference (IV, Random, 95% CI)	57.00 [−93.50, 207.50]
12.2 Multiple interventions	2	319	Mean Difference (IV, Random, 95% CI)	76.01 [−88.59, 240.61]

Comparison 3

Smoking cessation interventions: health education vs usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Abstinence in late pregnancy	3	374	Risk Ratio (M-H, Random, 95% CI)	1.51 [0.64, 3.59]
1.1 Single interventions	2	229	Risk Ratio (M-H, Random, 95% CI)	1.29 [0.49, 3.42]
1.2 Multiple interventions	1	145	Risk Ratio (M-H, Random, 95% CI)	4.06 [0.46, 35.41]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Abstinence in late pregnancy: biochemically validated only	2	229	Risk Ratio (M-H, Random, 95% CI)	1.29 [0.49, 3.42]
2.1 Single interventions	2	229	Risk Ratio (M-H, Random, 95% CI)	1.29 [0.49, 3.42]
3 Mean cigarettes per day in late pregnancy	2		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
3.1 Single interventions	1	552	Std. Mean Difference (IV, Random, 95% CI)	−0.72 [−0.89, −0.55]
3.2 Multiple interventions	1	135	Std. Mean Difference (IV, Random, 95% CI)	−0.32 [−0.66, 0.02]

Comparison 4

Smoking cessation interventions: health education vs less intensive intervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Abstinence in late pregnancy: biochemically validated	2	851	Risk Ratio (M-H, Random, 95% CI)	1.50 [0.97, 2.31]
1.1 Single interventions	1	653	Risk Ratio (M-H, Random, 95% CI)	1.46 [0.88, 2.43]
1.2 Multiple interventions	1	198	Risk Ratio (M-H, Random, 95% CI)	1.59 [0.68, 3.73]
2 Abstinence at 0 to 5 months postpartum	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.1 Single interventions	2	844	Risk Ratio (M-H, Random, 95% CI)	1.29 [0.52, 3.22]

Comparison 5

Smoking cessation interventions: feedback vs usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Abstinence in late pregnancy	2	355	Risk Ratio (M-H, Random, 95% CI)	4.39 [1.89, 10.21]
1.1 Multiple interventions	2	355	Risk Ratio (M-H, Random, 95% CI)	4.39 [1.89, 10.21]
2 Reduction in late pregnancy: various definitions	2	355	Risk Ratio (M-H, Random, 95% CI)	1.69 [1.24, 2.31]
2.1 Multiple interventions	2	355	Risk Ratio (M-H, Random, 95% CI)	1.69 [1.24, 2.31]
3 Preterm births	2	3111	Risk Ratio (M-H, Random, 95% CI)	0.60 [0.28, 1.29]
3.1 Multiple interventions	2	3111	Risk Ratio (M-H, Random, 95% CI)	0.60 [0.28, 1.29]
4 Mean birthweight	2	3006	Mean Difference (IV, Random, 95% CI)	79.43 [−53.05, 211.91]
4.1 Multiple interventions	2	3006	Mean Difference (IV, Random, 95% CI)	79.43 [−53.05, 211.91]
5 Stillbirths	2	2960	Risk Ratio (M-H, Random, 95% CI)	1.28 [0.69, 2.39]
5.1 Multiple interventions	2	2960	Risk Ratio (M-H, Random, 95% CI)	1.28 [0.69, 2.39]

Comparison 6

Smoking cessation interventions: feedback vs less intensive intervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Abstinence in late pregnancy: biochemically validated	2	319	Risk Ratio (M-H, Random, 95% CI)	1.19 [0.45, 3.12]
1.1 Single interventions	1	79	Risk Ratio (M-H, Random, 95% CI)	0.60 [0.16, 2.22]
1.2 Multiple interventions	1	240	Risk Ratio (M-H, Random, 95% CI)	1.69 [0.89, 3.20]

Comparison 7

Smoking cessation interventions: incentives vs usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Abstinence in late pregnancy: biochemically validated	2	129	Risk Ratio (M-H, Random, 95% CI)	3.59 [0.10, 130.49]
1.1 Single interventions	1	74	Risk Ratio (M-H, Random, 95% CI)	20.72 [1.28, 336.01]
1.2 Tailored interventions	1	55	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.25, 3.23]

Comparison 8

Smoking cessation interventions: social support vs less intensive intervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Abstinence in late pregnancy (peer and partner support)	6	734	Risk Ratio (M-H, Random, 95% CI)	1.29 [0.94, 1.78]
1.1 Single interventions	2	224	Risk Ratio (M-H, Random, 95% CI)	1.35 [0.57, 3.18]
1.2 Multiple interventions	3	359	Risk Ratio (M-H, Random, 95% CI)	1.48 [0.74, 2.95]
1.3 Tailored interventions	1	151	Risk Ratio (M-H, Random, 95% CI)	1.22 [0.59, 2.52]
2 Abstinence in late pregnancy: biochemically validated (peer support only)	5	554	Risk Ratio (M-H, Random, 95% CI)	1.49 [1.01, 2.19]
2.1 Single interventions	2	224	Risk Ratio (M-H, Random, 95% CI)	1.35 [0.57, 3.18]
2.2 Multiple interventions	2	179	Risk Ratio (M-H, Random, 95% CI)	2.26 [1.15, 4.46]
2.3 Tailored interventions	1	151	Risk Ratio (M-H, Random, 95% CI)	1.22 [0.59, 2.52]
3 Abstinence at 0 to 5 months postpartum	2	473	Risk Ratio (M-H, Random, 95% CI)	1.36 [0.46, 4.07]
3.1 Single interventions	1	82	Risk Ratio (M-H, Random, 95% CI)	5.8 [0.33, 101.27]
3.2 Multiple interventions	1	391	Risk Ratio (M-H, Random, 95% CI)	1.11 [0.87, 1.41]
4 Abstinence at 6 to 11 months postpartum	2	486	Risk Ratio (M-H, Random, 95% CI)	1.09 [0.83, 1.42]
4.1 Multiple interventions	2	486	Risk Ratio (M-H, Random, 95% CI)	1.09 [0.83, 1.42]

Comparison 9

Maternal health intervention with smoking cessation component: social support (tailored) vs usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Abstinence in late pregnancy	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 Self-reported	1	492	Risk Ratio (M-H, Random, 95% CI)	1.83 [1.22, 2.73]
1.2 Biochemically validated	1	141	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
2 Self-reported mean cigarettes per day in late pregnancy	2	542	Std. Mean Difference (IV, Random, 95% CI)	−0.28 [−0.45, −0.11]
2.1 Self-reported	1	401	Std. Mean Difference (IV, Random, 95% CI)	−0.24 [−0.43, −0.04]
2.2 Biochemically validated	1	141	Std. Mean Difference (IV, Random, 95% CI)	−0.40 [−0.73, −0.06]

Comparison 10

Maternal health intervention with smoking cessation component: social support vs less intensive intervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Abstinence in late pregnancy	2	316	Risk Ratio (M-H, Random, 95% CI)	0.80 [0.46, 1.39]
1.1 Single interventions	1	66	Risk Ratio (M-H, Random, 95% CI)	0.45 [0.09, 2.16]
1.2 Tailored interventions	1	250	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.48, 1.57]
2 Abstinence in late pregnancy: biochemically validated	1	250	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.48, 1.57]
2.1 Tailored interventions	1	250	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.48, 1.57]

Comparison 11

Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Abstinence in late pregnancy: self-reported and biochemically validated (non-winsorised)	70	21948	Risk Ratio (M-H, Random, 95% CI)	1.45 [1.27, 1.64]
1.1 Counselling	45	17681	Risk Ratio (M-H, Random, 95% CI)	1.37 [1.17, 1.59]
1.2 Health education	5	1225	Risk Ratio (M-H, Random, 95% CI)	1.47 [1.02, 2.13]
1.3 Feedback	5	739	Risk Ratio (M-H, Random, 95% CI)	2.09 [1.17, 3.72]
1.4 Incentives	4	426	Risk Ratio (M-H, Random, 95% CI)	3.09 [1.34, 7.15]
1.5 Social support	10	1683	Risk Ratio (M-H, Random, 95% CI)	1.29 [0.97, 1.73]

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Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.6 Other	1	194	Risk Ratio (M-H, Random, 95% CI)	1.63 [0.62, 4.32]
2 Abstinence in late pregnancy: biochemically validated only (non-winsorised)	49		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.1 Counselling	30	11924	Risk Ratio (M-H, Random, 95% CI)	1.27 [1.11, 1.47]
2.2 Health education	4	1080	Risk Ratio (M-H, Random, 95% CI)	1.43 [0.98, 2.08]
2.3 Feedback	3	365	Risk Ratio (M-H, Random, 95% CI)	1.70 [0.71, 4.08]
2.4 Incentives	4	426	Risk Ratio (M-H, Random, 95% CI)	3.09 [1.34, 7.15]
2.5 Social support	7	549	Risk Ratio (M-H, Random, 95% CI)	1.31 [0.90, 1.91]
2.6 Other	1	194	Risk Ratio (M-H, Random, 95% CI)	1.63 [0.62, 4.32]
3 Continued abstinence (Relapse prevention) in late pregnancy for spontaneous quitters	14		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
3.1 Counselling	12		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
3.2 Health education	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
3.3 Social support	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
4 Abstinence at 0 to 5 months postpartum	26		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
4.1 Counselling	18		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
4.2 Health education	3		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
4.3 Incentives	2		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
4.4 Social support	3		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
5 Abstinence at 6 to 11 months postpartum	13		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
5.1 Counselling	10		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
5.2 Incentives	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
5.3 Social support	2		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
6 Abstinence at 12 to 17 months postpartum	5		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
6.1 Counselling	4		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
6.2 Social support	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
7 Abstinence at 18+ months postpartum	2		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
7.1 Counselling	2		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
8 Smoking reduction: numbers of women reducing smoking in late pregnancy	15		Risk Ratio (M-H, Random, 95% CI)	Totals not selected

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Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8.1 Self-reported some reduction in smoking (various definitions)	5		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
8.2 Self-reported > 50% reduction in smoking	4		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
8.3 Biochemically validated reduction	6		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
9 Smoking reduction: biochemical measures in late pregnancy	6		Std. Mean Difference (IV, Random, 95% CI)	Totals not selected
9.1 Mean cotinine levels	5		Std. Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
9.2 Mean thiocynate level	1		Std. Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
10 Smoking reduction: self-reported mean cigarettes per day measured in late pregnancy or at delivery	20		Std. Mean Difference (IV, Random, 95% CI)	Totals not selected
10.1 Counselling	11		Std. Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
10.2 Health education	3		Std. Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
10.3 Feedback	2		Std. Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
10.4 Incentives	1		Std. Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
10.5 Social support	3		Std. Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
11 Low birthweight (under 2500 g)	14	8562	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.71, 0.94]
11.1 Counselling	8	4339	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.68, 1.01]
11.2 Health education	2	1172	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.49, 1.55]
11.3 Feedback	1	2848	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.63, 1.06]
11.4 Incentives	2	124	Risk Ratio (M-H, Random, 95% CI)	0.45 [0.22, 0.93]
11.5 Social support	1	79	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.33, 2.99]
12 Very low birthweight (under 1500 g)	3	4366	Risk Ratio (M-H, Random, 95% CI)	1.11 [0.62, 2.01]
12.1 Counselling	2	1666	Risk Ratio (M-H, Random, 95% CI)	1.27 [0.60, 2.71]
12.2 Feedback	1	2700	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.35, 2.32]
13 Preterm birth (under 37 weeks)	14	7852	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.70, 0.96]
13.1 Counselling	8	3447	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.71, 1.20]
13.2 Health education	2	1170	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.55, 1.56]
13.3 Feedback	2	3111	Risk Ratio (M-H, Random, 95% CI)	0.60 [0.28, 1.29]
13.4 Incentives	2	124	Risk Ratio (M-H, Random, 95% CI)	0.49 [0.22, 1.08]
14 Mean birthweight	19	9859	Mean Difference (IV, Random, 95% CI)	40.78 [18.45, 63.10]

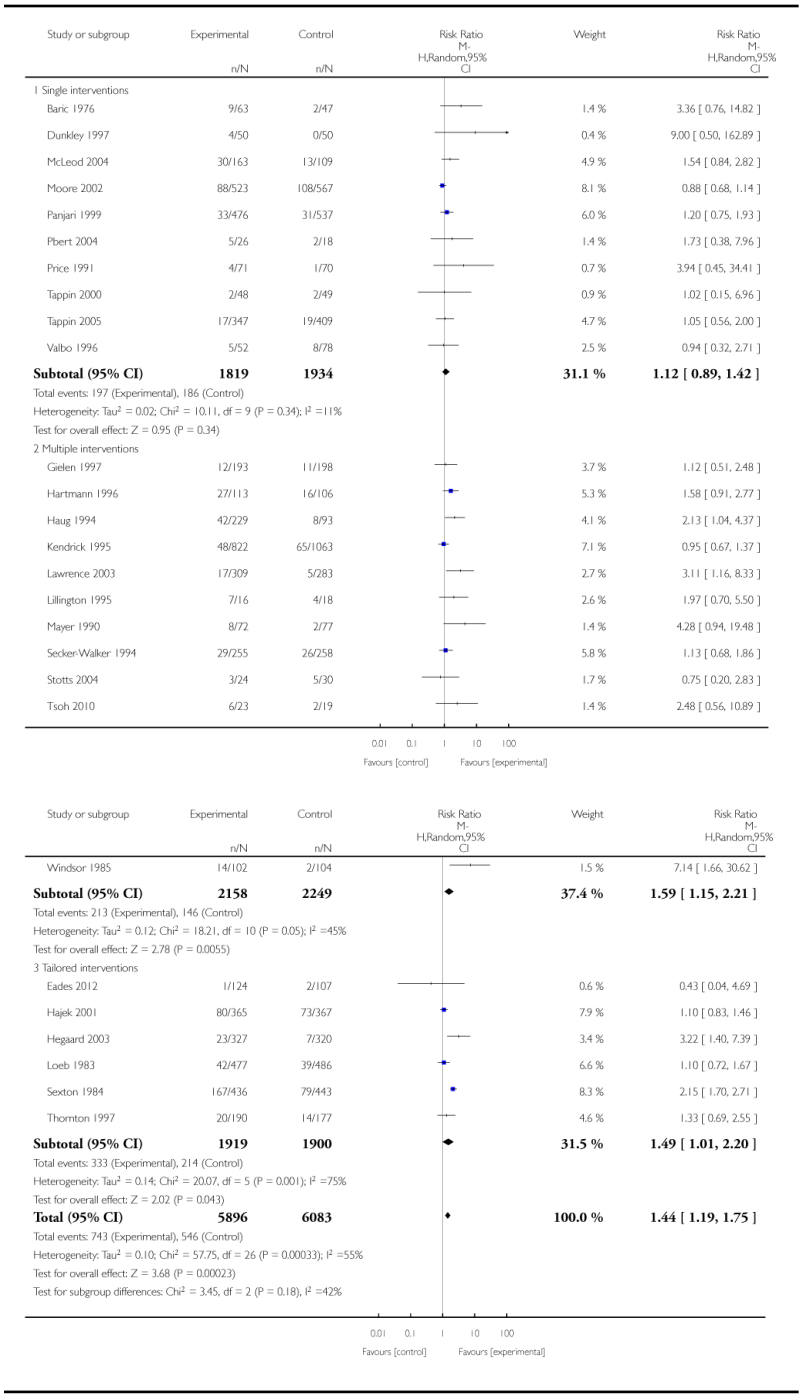
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
14.1 Counselling	12	5392	Mean Difference (IV, Random, 95% CI)	39.93 [9.12, 70.74]
14.2 Health education	2	1172	Mean Difference (IV, Random, 95% CI)	27.35 [−53.88, 108.58]
14.3 Feedback	2	3006	Mean Difference (IV, Random, 95% CI)	79.43 [−53.05, 211.91]
14.4 Incentives	2	147	Mean Difference (IV, Random, 95% CI)	213.78 [20.16, 407.40]
14.5 Social support	1	142	Mean Difference (IV, Random, 95% CI)	28.0 [−152.48, 208.48]
15 Perinatal deaths	4	4465	Risk Ratio (M-H, Random, 95% CI)	1.13 [0.72, 1.77]
15.1 Counselling	2	1065	Risk Ratio (M-H, Random, 95% CI)	1.10 [0.52, 2.31]
15.2 Health education	1	552	Risk Ratio (M-H, Random, 95% CI)	4.40 [0.49, 39.08]
15.3 Feedback	1	2848	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.59, 1.87]
16 Stillbirths	7	5414	Risk Ratio (M-H, Random, 95% CI)	1.22 [0.76, 1.95]
16.1 Counselling	5	2454	Risk Ratio (M-H, Random, 95% CI)	1.14 [0.55, 2.33]
16.2 Feedback	2	2960	Risk Ratio (M-H, Random, 95% CI)	1.28 [0.69, 2.39]
17 Neonatal deaths	4	4905	Risk Ratio (M-H, Random, 95% CI)	1.15 [0.44, 3.06]
17.1 Counselling	3	2095	Risk Ratio (M-H, Random, 95% CI)	2.06 [0.61, 6.92]
17.2 Feedback	1	2810	Risk Ratio (M-H, Random, 95% CI)	0.40 [0.08, 2.07]
18 NICU admissions	4	1264	Risk Ratio (M-H, Random, 95% CI)	0.78 [0.59, 1.04]
18.1 Counselling	2	1140	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.52, 1.29]
18.2 Incentives	2	124	Risk Ratio (M-H, Random, 95% CI)	0.76 [0.47, 1.21]

Analysis 1.1. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 1 Abstinence in late pregnancy

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Outcome: 1 Abstinence in late pregnancy



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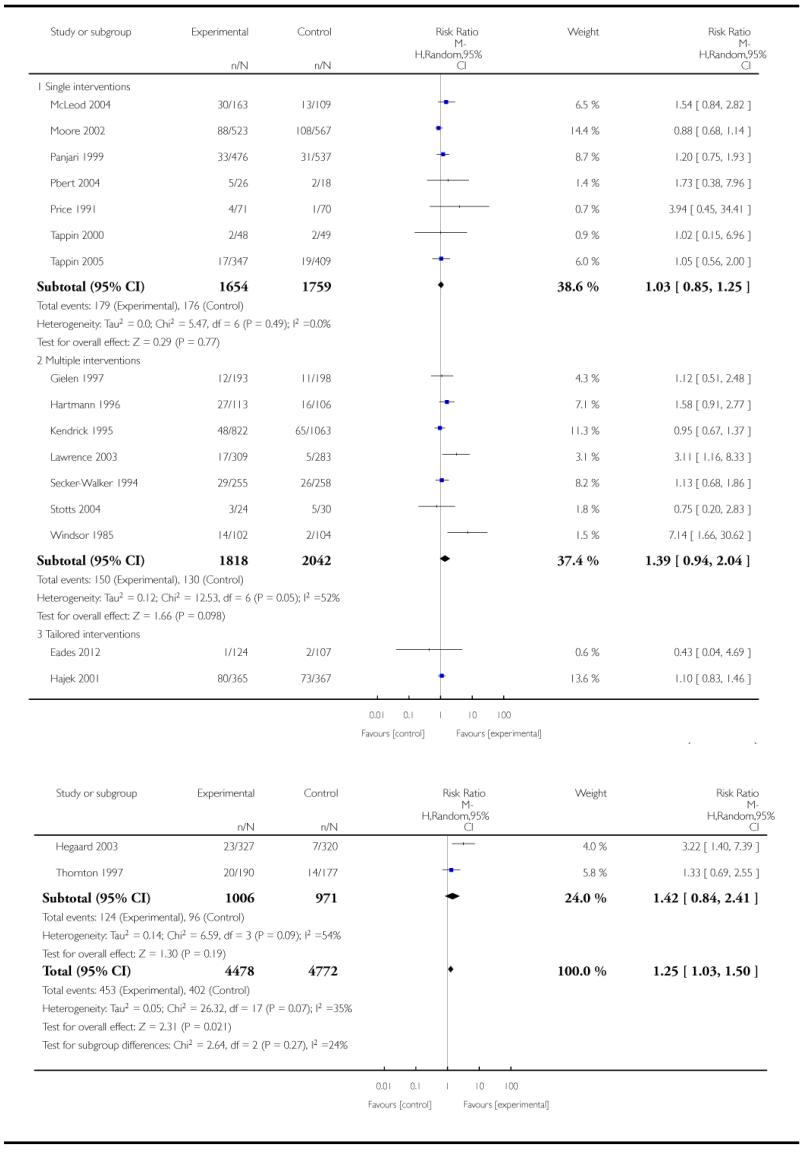
Analysis 1.2. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 2 Abstinence in late pregnancy: biochemically validated only

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Outcome: 2 Abstinence in late pregnancy: biochemically validated only

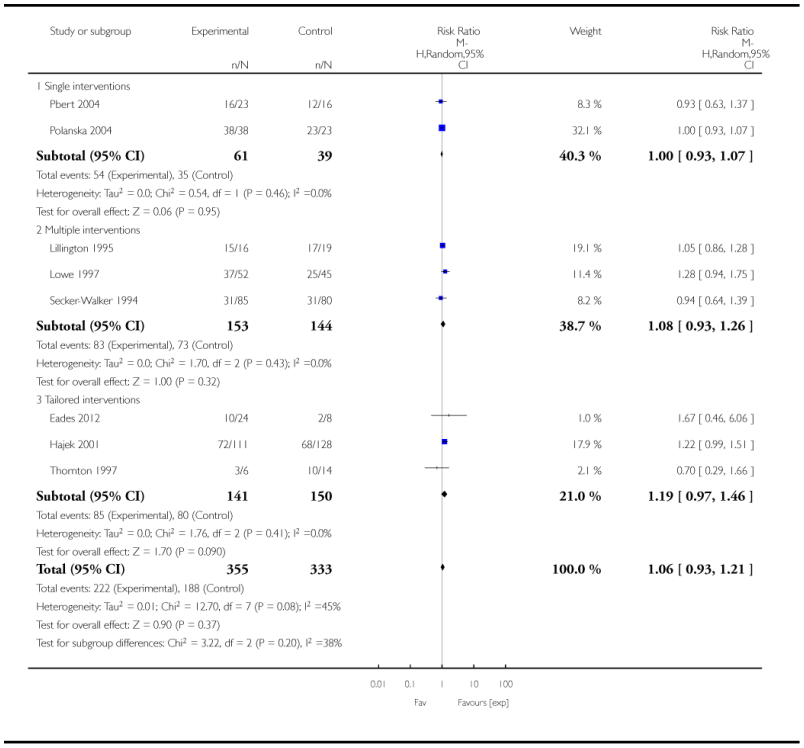


Analysis 1.3. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 3 Continued abstinence (relapse prevention) in late pregnancy for spontaneous quitters

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Outcome: 3 Continued abstinence (relapse prevention) in late pregnancy for spontaneous quitters

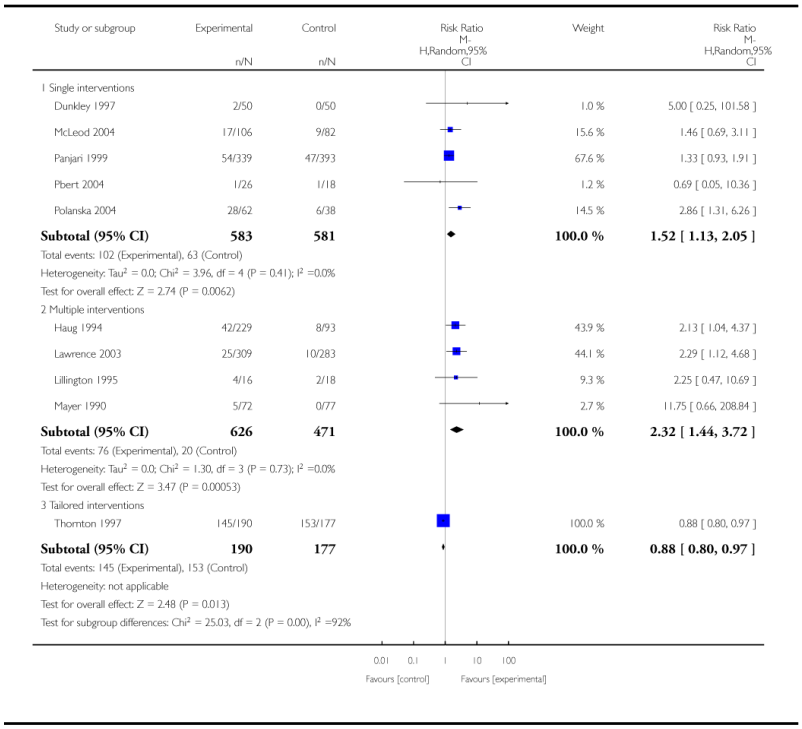


Analysis 1.4. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 4 Abstinence at 0 to 5 months postpartum

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Outcome: 4 Abstinence at 0 to 5 months postpartum



Analysis 1.5. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 5 Abstinence at 6 to 11 months postpartum

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Outcome: 5 Abstinence at 6 to 11 months postpartum

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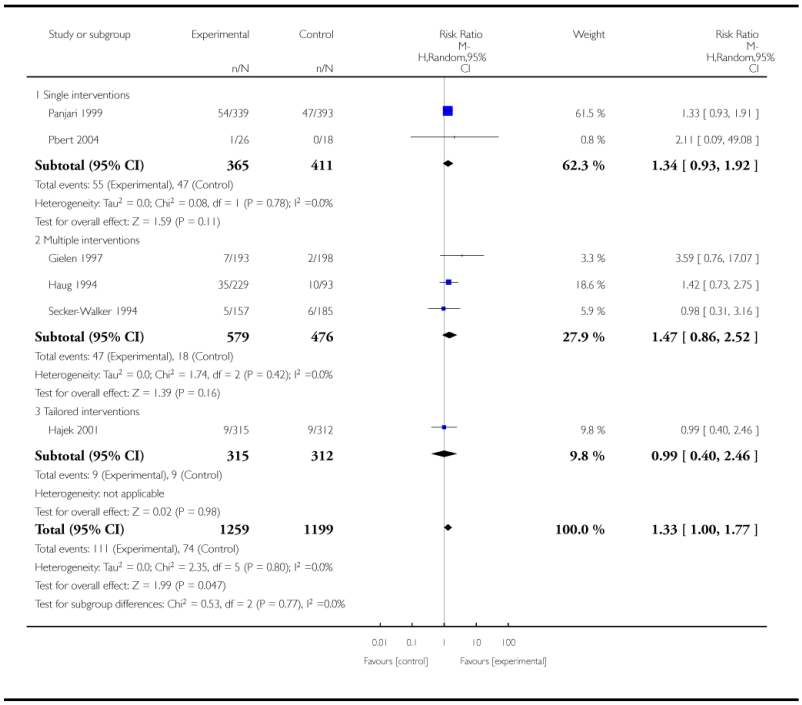

Analysis 1.6. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 6 Abstinence at 12 to 17 months postpartum

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Outcome: 6 Abstinence at 12 to 17 months postpartum

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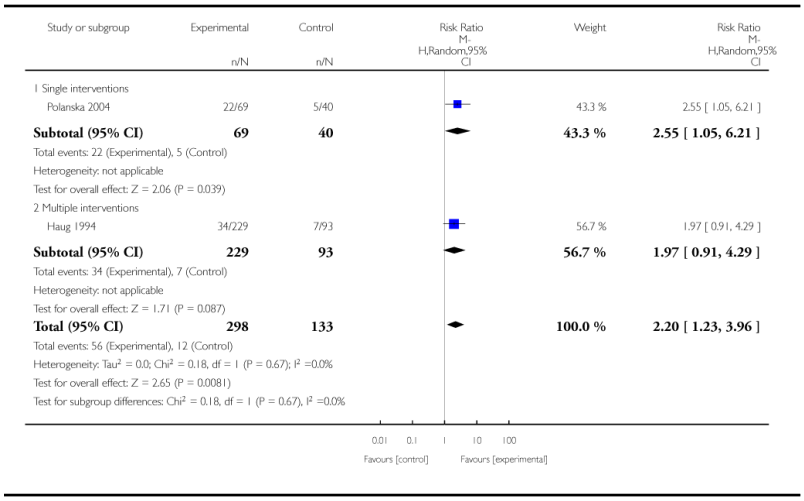
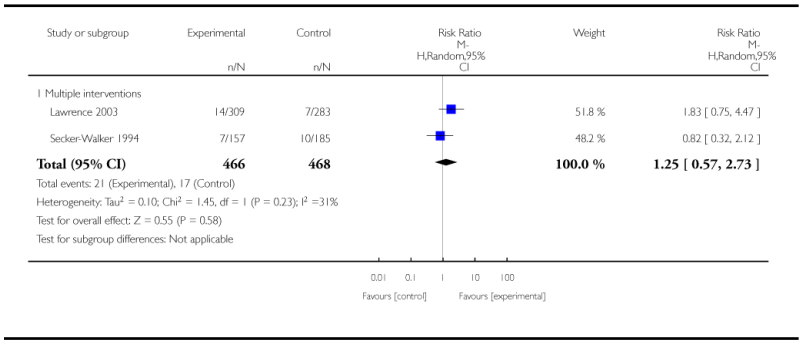


Analysis 1.7. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 7 Abstinence at 18+ months postpartum

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Outcome: 7 Abstinence at 18+ months postpartum



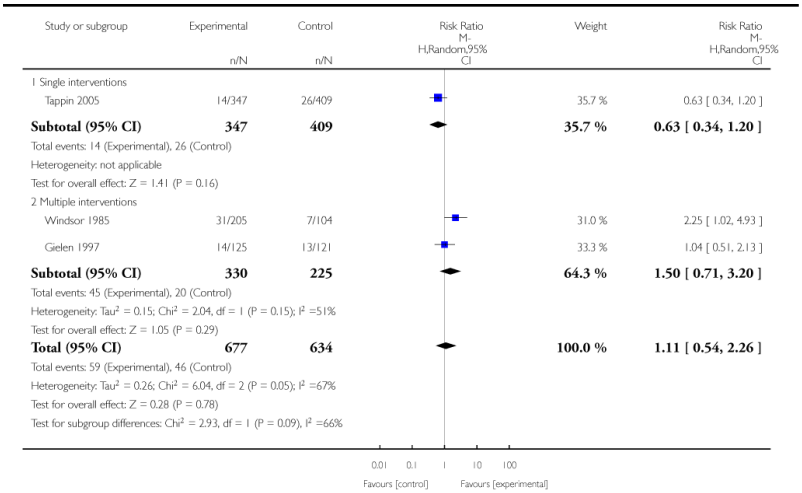
Analysis 1.8. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 8 Reduction in late pregnancy: biochemically validated

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Europe PMC Funders Author Manuscripts

Outcome: 8 Reduction in late pregnancy: biochemically validated

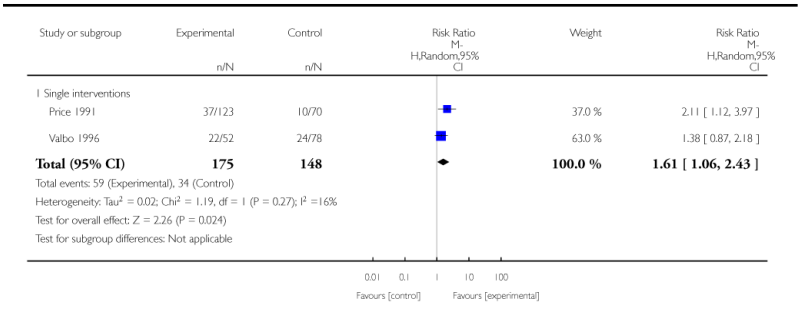


Analysis 1.9. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 9 Reduction in late pregnancy: self reported (various definitions)

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Outcome: 9 Reduction in late pregnancy: self reported (various definitions)

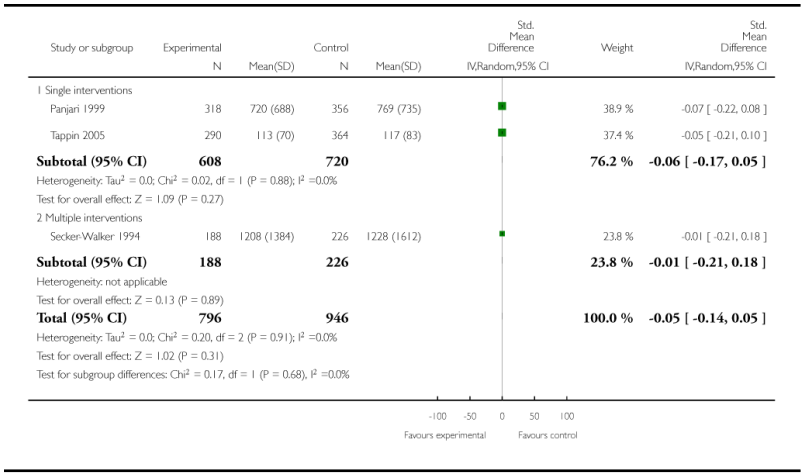


Analysis 1.10. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 10 Biochemical measures in late pregnancy: mean cotinine

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Outcome: 10 Biochemical measures in late pregnancy: mean cotinine



Analysis 1.11. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 11 Mean cigarettes per day in late pregnancy

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Outcome: 11 Mean cigarettes per day in late pregnancy

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Analysis 1.12. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 12 Low birthweight infants (< 2500 g)

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Outcome: 12 Low birthweight infants (< 2500 g)

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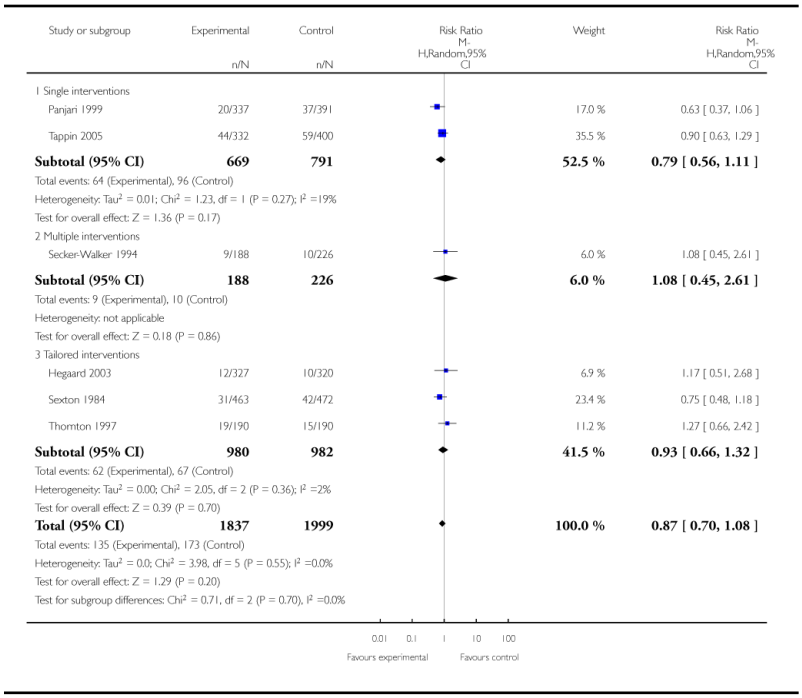
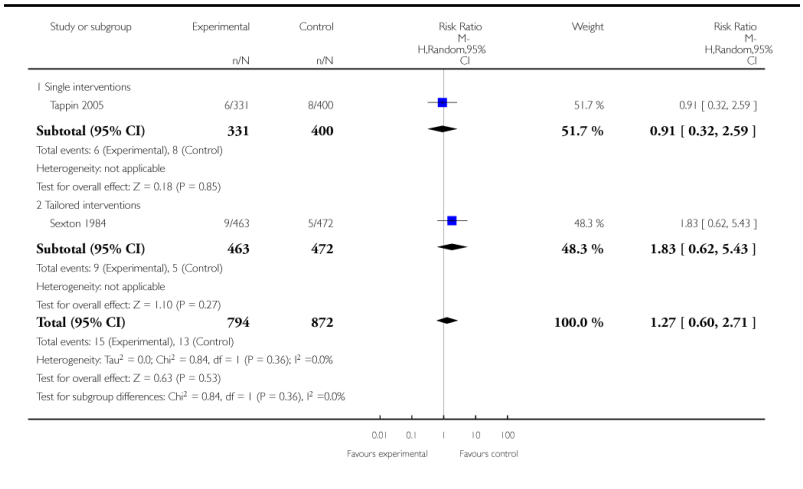


Analysis 1.13. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 13 Very low birthweight infants (< 1500 g)

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Outcome: 13 Very low birthweight infants (< 1500 g)



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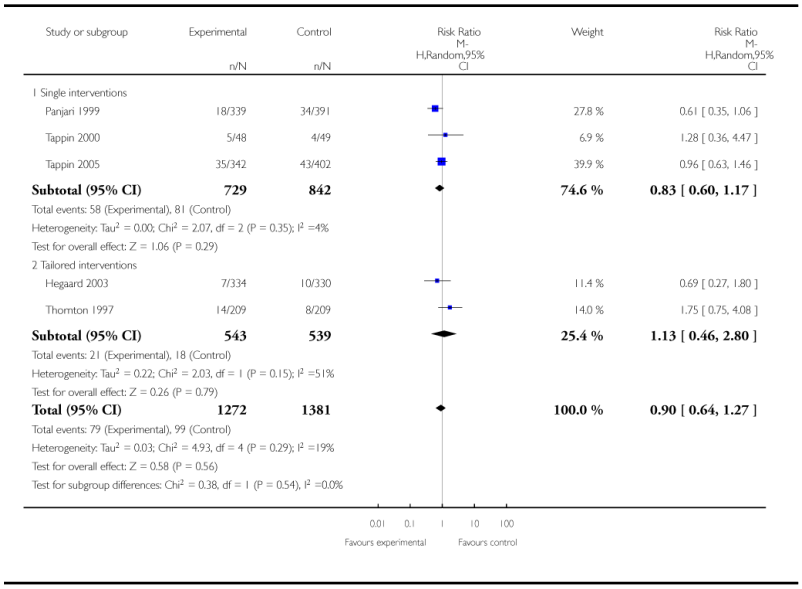
Analysis 1.14. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 14 Preterm births

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Outcome: 14 Preterm births



Analysis 1.15. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 15 Mean birthweight

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Outcome: 15 Mean birthweight

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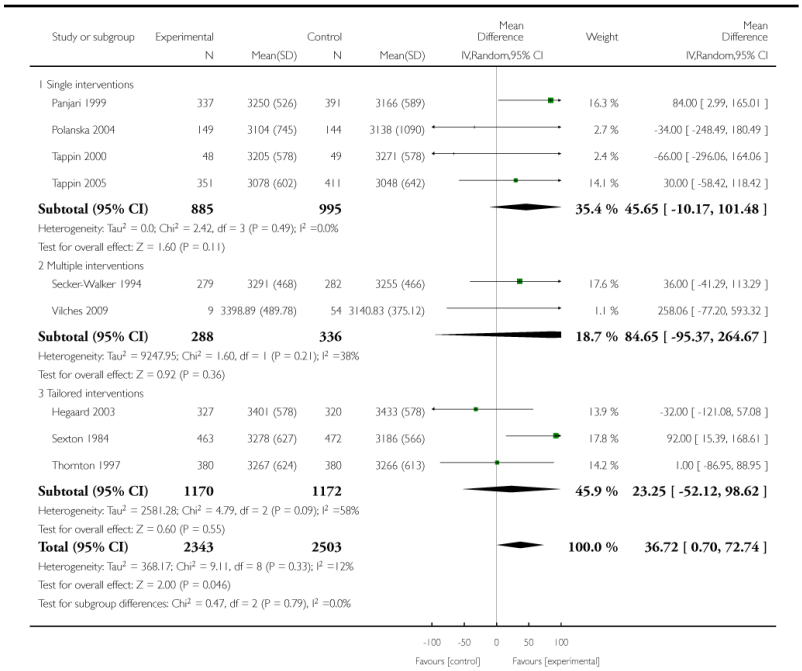
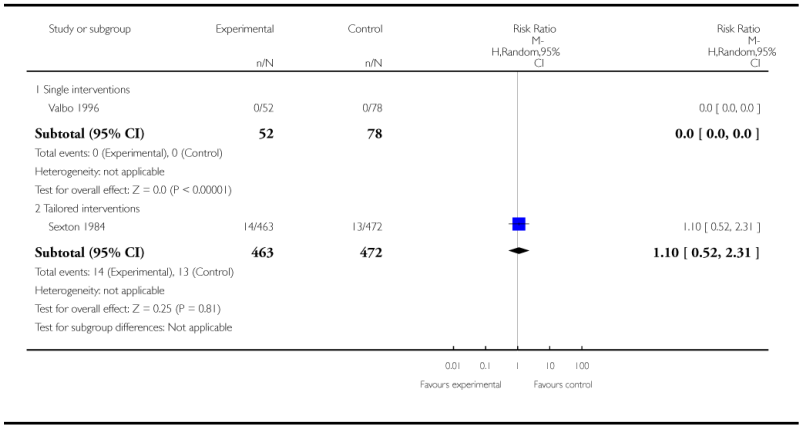


Analysis 1.16. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 16 Perinatal deaths

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Outcome: 16 Perinatal deaths



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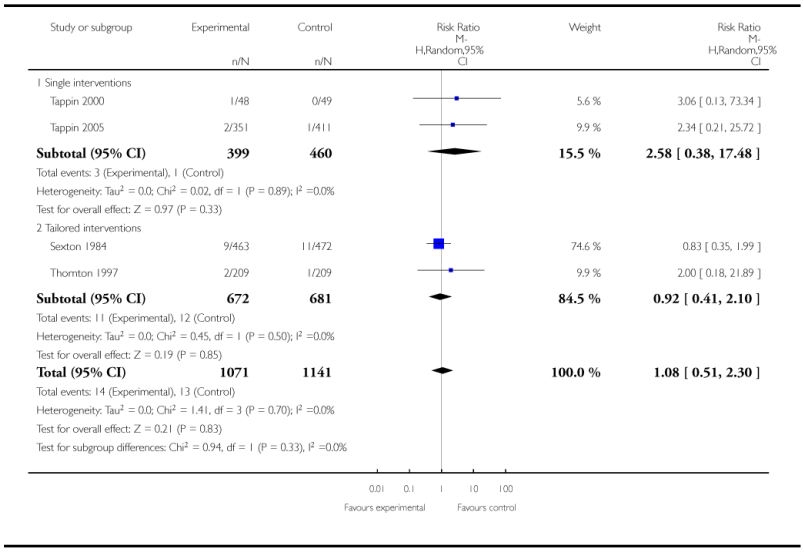
Analysis 1.17. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 17 Stillbirths

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Outcome: 17 Stillbirths

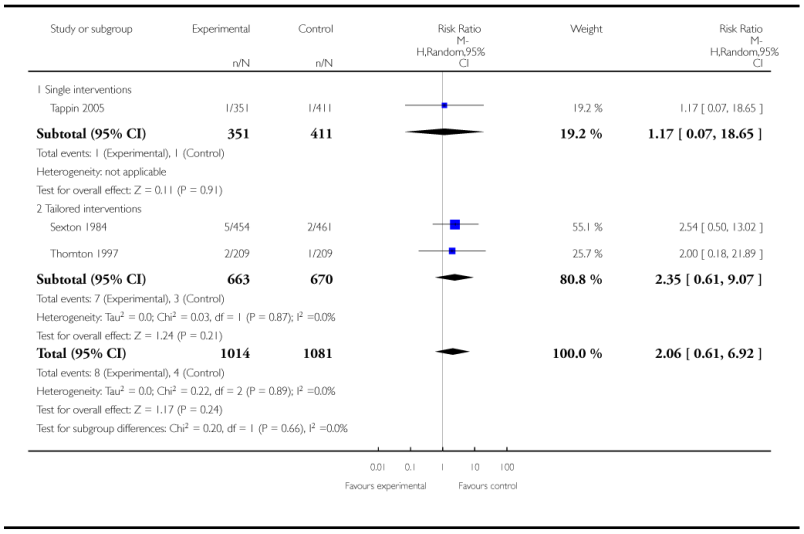


Analysis 1.18. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 18 Neonatal deaths

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Outcome: 18 Neonatal deaths

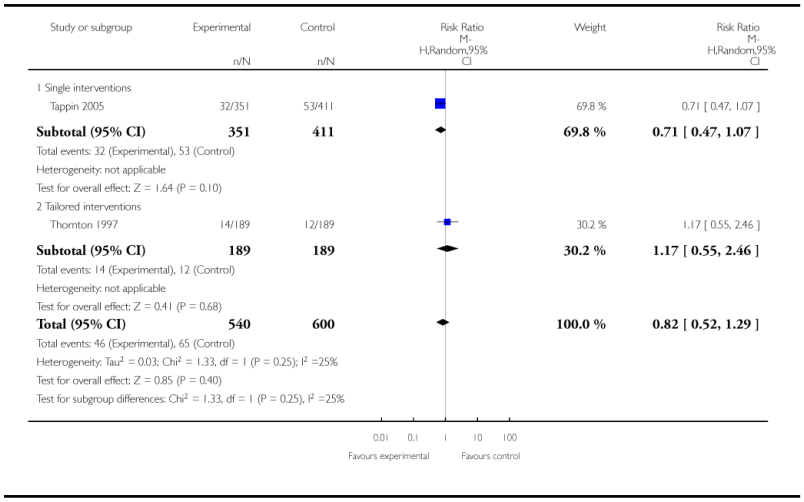


Analysis 1.19. Comparison 1 Smoking cessation interventions: counselling vs usual care, Outcome 19 NICU admissions

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 1 Smoking cessation interventions: counselling vs usual care

Outcome: 19 NICU admissions



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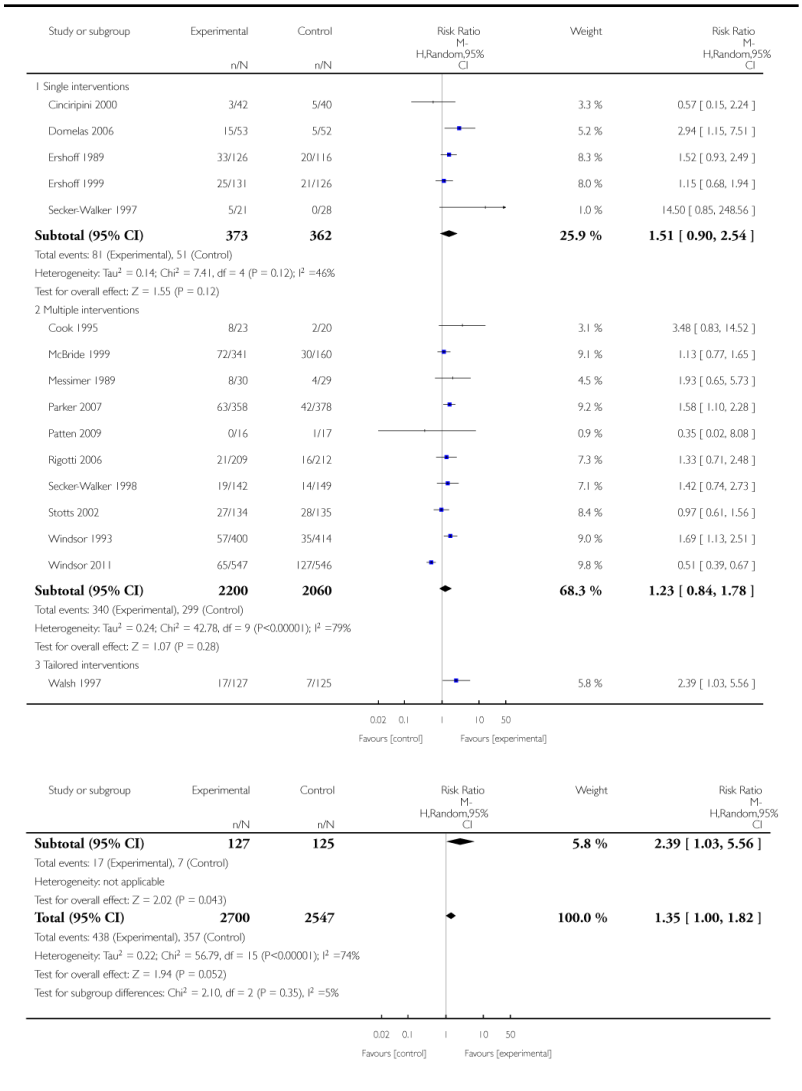
Analysis 2.1. Comparison 2 Smoking cessation interventions: counselling vs less intensive intervention, Outcome 1 Abstinence in late pregnancy

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 2 Smoking cessation interventions: counselling vs less intensive intervention

Outcome: 1 Abstinence in late pregnancy

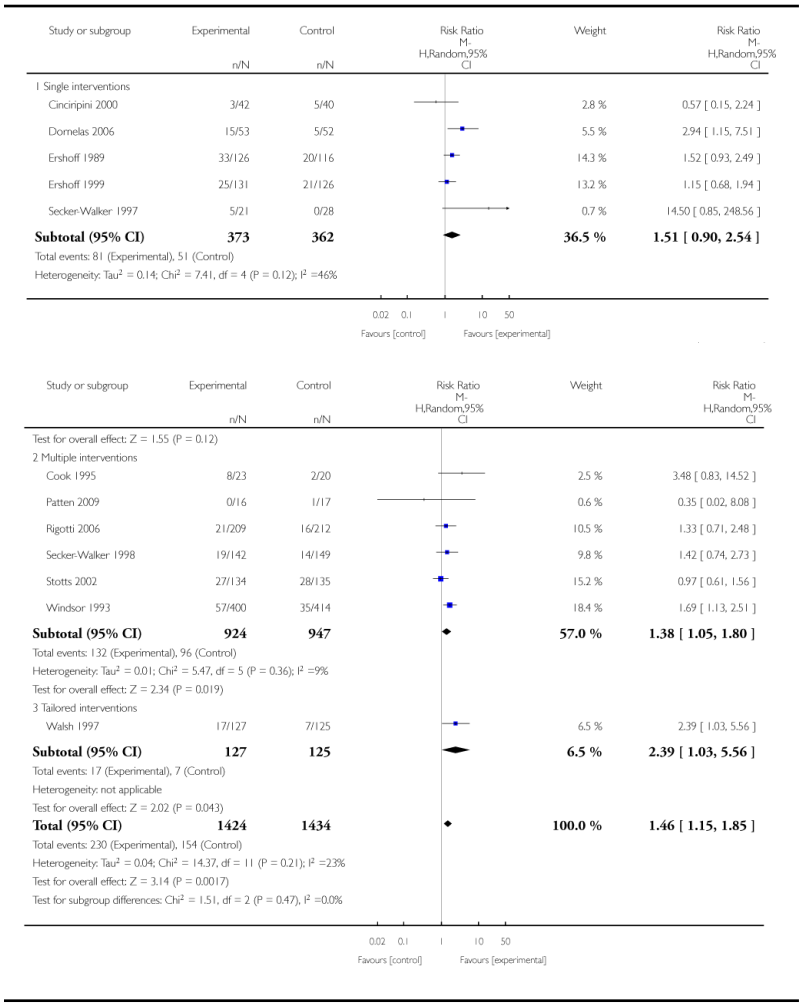


Analysis 2.2. Comparison 2 Smoking cessation interventions: counselling vs less intensive intervention, Outcome 2 Abstinence in late pregnancy: biochemically validated only

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 2 Smoking cessation interventions: counselling vs less intensive intervention

Outcome: 2 Abstinence in late pregnancy: biochemically validated only

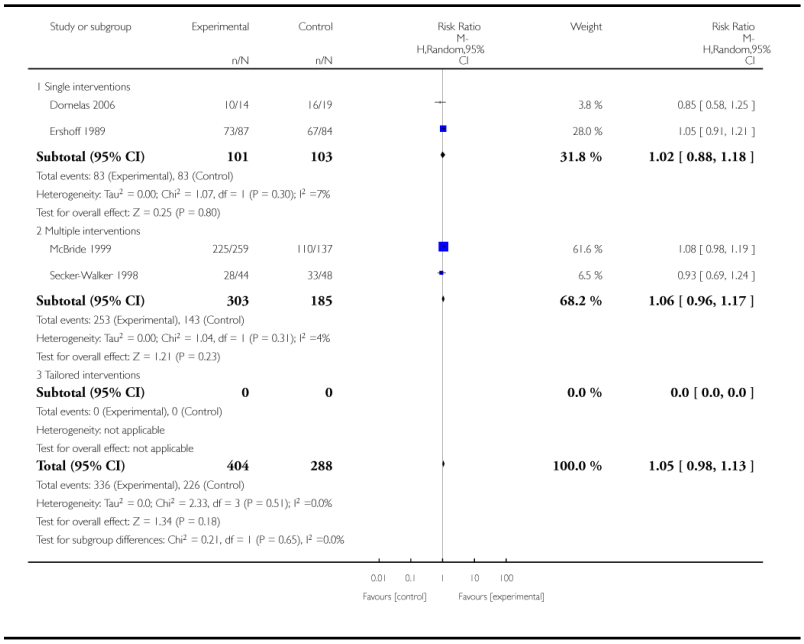


Analysis 2.3. Comparison 2 Smoking cessation interventions: counselling vs less intensive intervention, Outcome 3 Continued abstinence (relapse prevention) in late pregnancy (spontaneous quitters)

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 2 Smoking cessation interventions: counselling vs less intensive intervention

Outcome: 3 Continued abstinence (relapse prevention) in late pregnancy (spontaneous quitters)



Analysis 2.4. Comparison 2 Smoking cessation interventions: counselling vs less intensive intervention, Outcome 4 Abstinence at 0 to 5 months postpartum

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 2 Smoking cessation interventions: counselling vs less intensive intervention

Outcome: 4 Abstinence at 0 to 5 months postpartum

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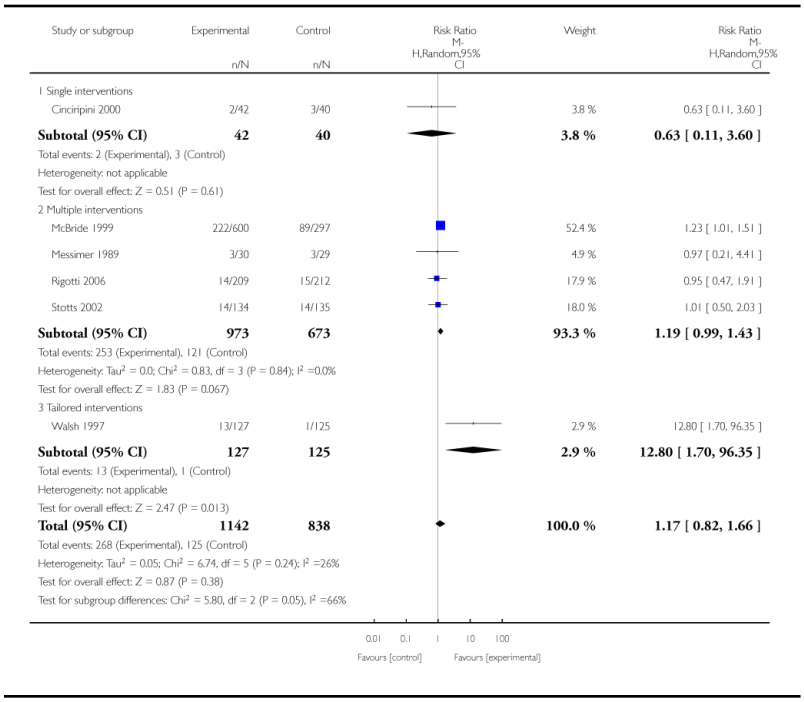

Analysis 2.5. Comparison 2 Smoking cessation interventions: counselling vs less intensive intervention, Outcome 5 Abstinence at 6 to 11 months postpartum

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 2 Smoking cessation interventions: counselling vs less intensive intervention

Outcome: 5 Abstinence at 6 to 11 months postpartum

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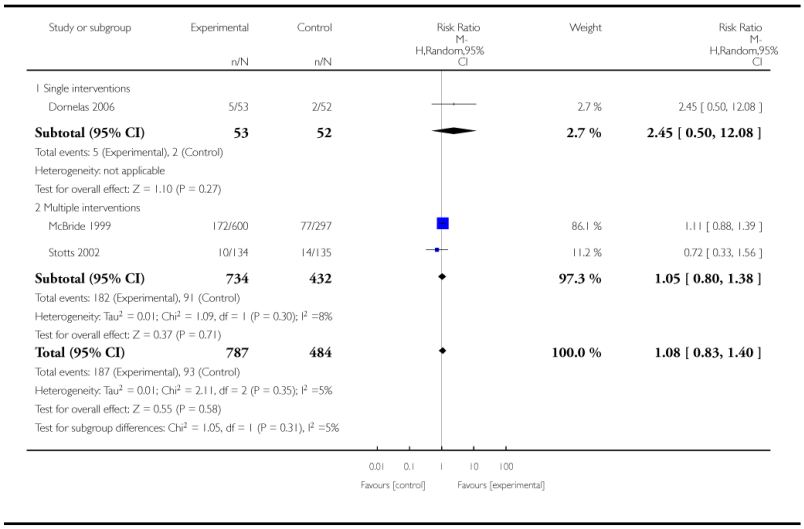
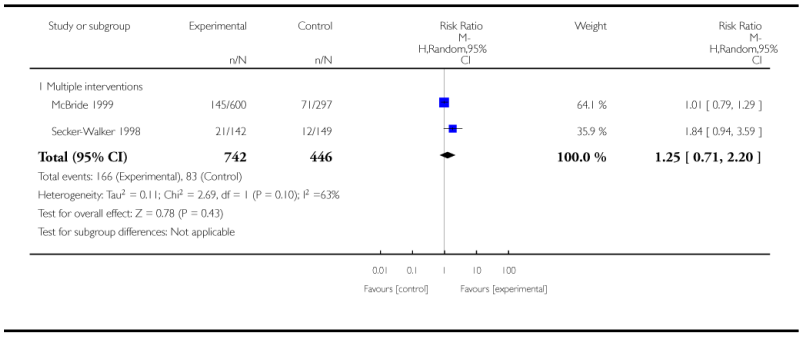


Analysis 2.6. Comparison 2 Smoking cessation interventions: counselling vs less intensive intervention, Outcome 6 Abstinence at 12 to 17 months postpartum

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 2 Smoking cessation interventions: counselling vs less intensive intervention

Outcome: 6 Abstinence at 12 to 17 months postpartum



Analysis 2.7. Comparison 2 Smoking cessation interventions: counselling vs less intensive intervention, Outcome 7 Reduction in late pregnancy: self-reported > 50%

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

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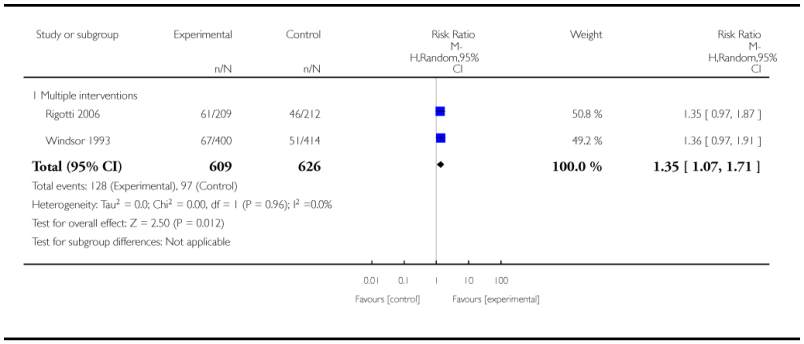
Comparison: 2 Smoking cessation interventions: counselling vs less intensive intervention

Outcome: 7 Reduction in late pregnancy: self-reported > 50%

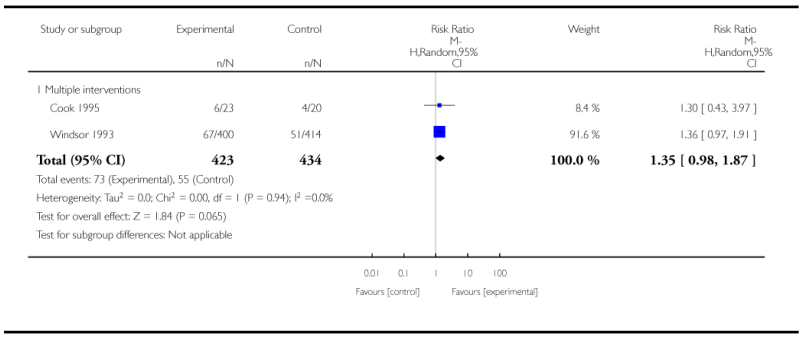


Analysis 2.8. Comparison 2 Smoking cessation interventions: counselling vs less intensive intervention, Outcome 8 Reduction in late pregnancy: biochemically validated

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 2 Smoking cessation interventions: counselling vs less intensive intervention

Outcome: 8 Reduction in late pregnancy: biochemically validated

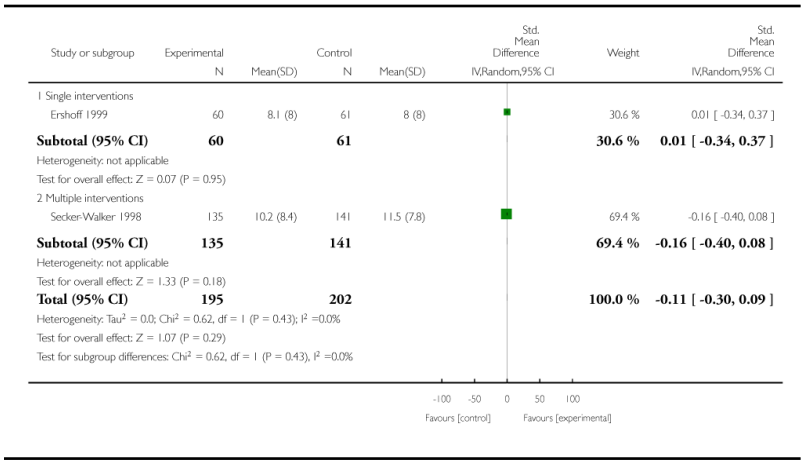


Analysis 2.9. Comparison 2 Smoking cessation interventions: counselling vs less intensive intervention, Outcome 9 Mean cigarettes per day in late pregnancy

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 2 Smoking cessation interventions: counselling vs less intensive intervention

Outcome: 9 Mean cigarettes per day in late pregnancy

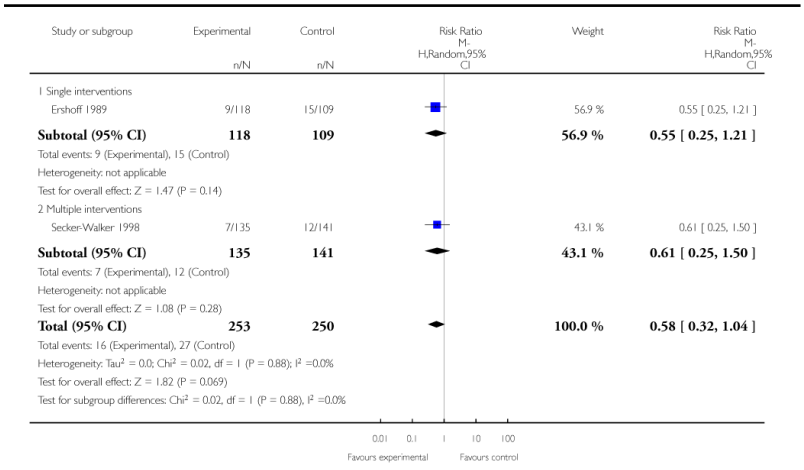


Analysis 2.10. Comparison 2 Smoking cessation interventions: counselling vs less intensive intervention, Outcome 10 Low birthweight infants (< 2500 g)

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 2 Smoking cessation interventions: counselling vs less intensive intervention

Outcome: 10 Low birthweight infants (< 2500 g)



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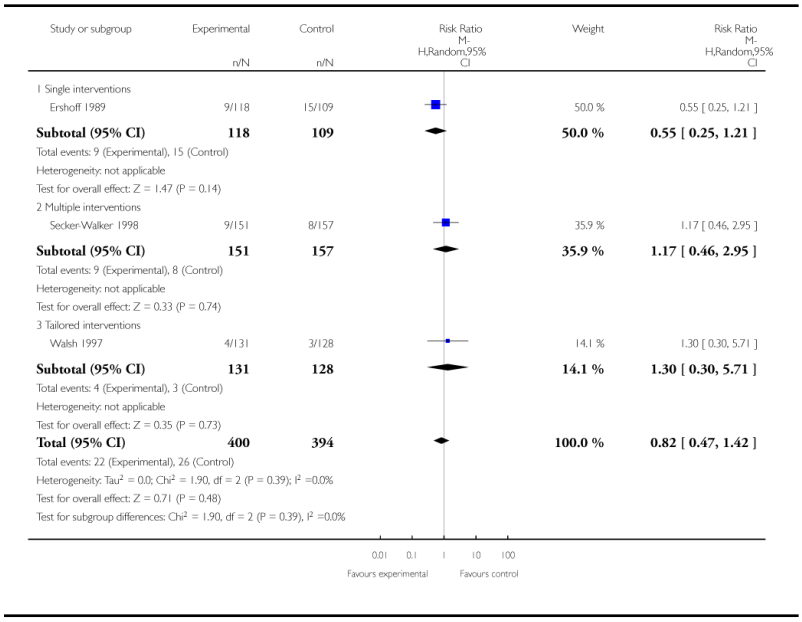
Analysis 2.11. Comparison 2 Smoking cessation interventions: counselling vs less intensive intervention, Outcome 11 Preterm births

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 2 Smoking cessation interventions: counselling vs less intensive intervention

Outcome: 11 Preterm births



Analysis 2.12. Comparison 2 Smoking cessation interventions: counselling vs less intensive intervention, Outcome 12 Mean birthweight

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 2 Smoking cessation interventions: counselling vs less intensive intervention

Outcome: 12 Mean birthweight

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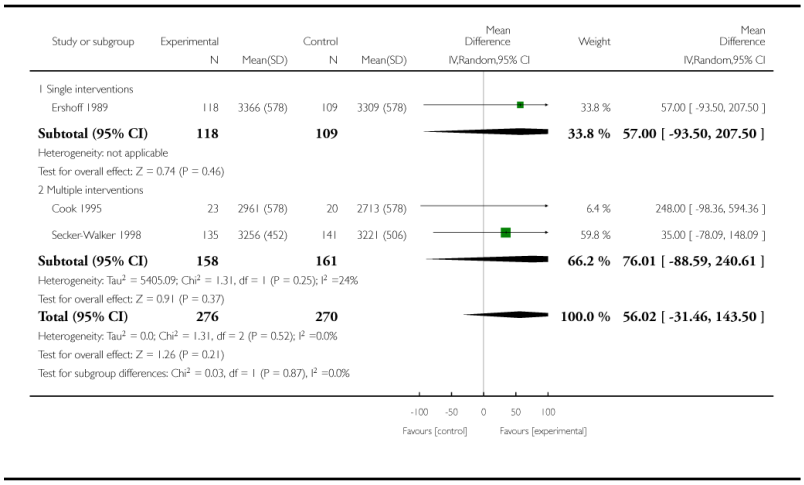
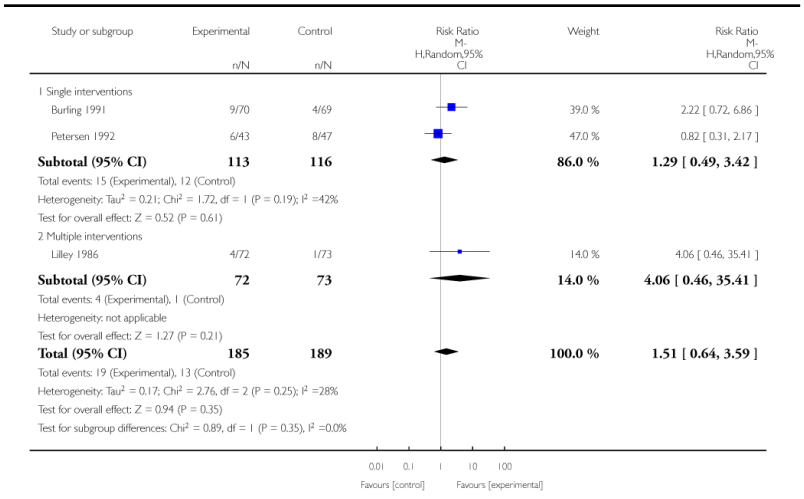


Analysis 3.1. Comparison 3 Smoking cessation interventions: health education vs usual care, Outcome 1 Abstinence in late pregnancy

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 3 Smoking cessation interventions: health education vs usual care

Outcome: 1 Abstinence in late pregnancy



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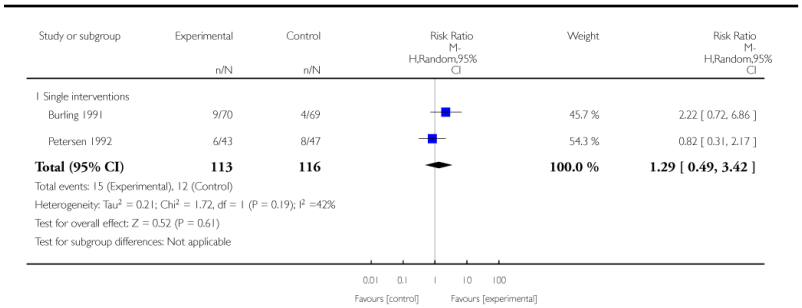
Analysis 3.2. Comparison 3 Smoking cessation interventions: health education vs usual care, Outcome 2 Abstinence in late pregnancy: biochemically validated only

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 3 Smoking cessation interventions: health education vs usual care

Outcome: 2 Abstinence in late pregnancy: biochemically validated only

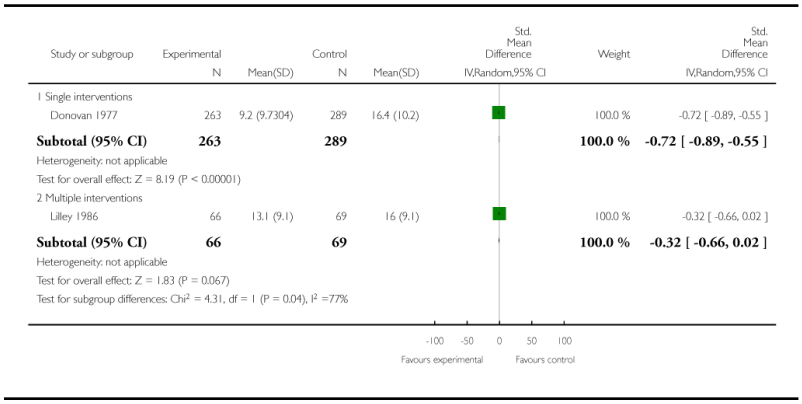


Analysis 3.3. Comparison 3 Smoking cessation interventions: health education vs usual care, Outcome 3 Mean cigarettes per day in late pregnancy

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 3 Smoking cessation interventions: health education vs usual care

Outcome: 3 Mean cigarettes per day in late pregnancy

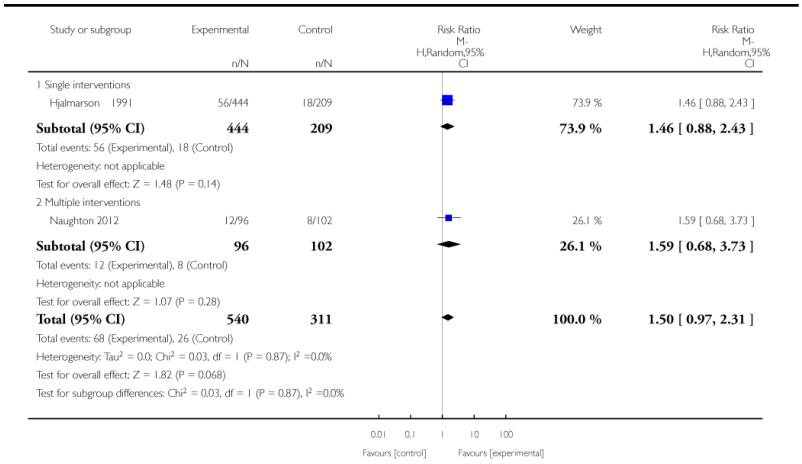


Analysis 4.1. Comparison 4 Smoking cessation interventions: health education vs less intensive intervention, Outcome 1 Abstinence in late pregnancy: biochemically validated

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 4 Smoking cessation interventions: health education vs less intensive intervention

Outcome: 1 Abstinence in late pregnancy: biochemically validated

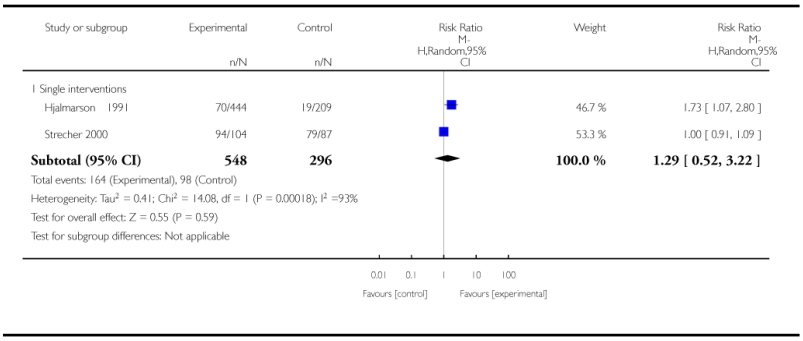


Analysis 4.2. Comparison 4 Smoking cessation interventions: health education vs less intensive intervention, Outcome 2 Abstinence at 0 to 5 months postpartum

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 4 Smoking cessation interventions: health education vs less intensive intervention

Outcome: 2 Abstinence at 0 to 5 months postpartum

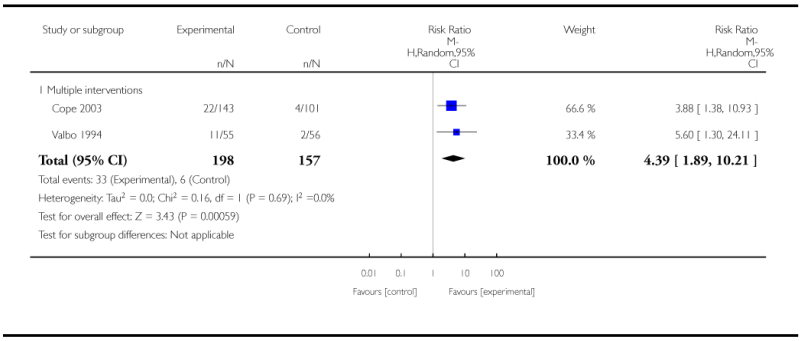


Analysis 5.1. Comparison 5 Smoking cessation interventions: feedback vs usual care, Outcome 1 Abstinence in late pregnancy

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 5 Smoking cessation interventions: feedback vs usual care

Outcome: 1 Abstinence in late pregnancy



Analysis 5.2. Comparison 5 Smoking cessation interventions: feedback vs usual care, Outcome 2 Reduction in late pregnancy: various definitions

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 5 Smoking cessation interventions: feedback vs usual care

Outcome: 2 Reduction in late pregnancy: various definitions

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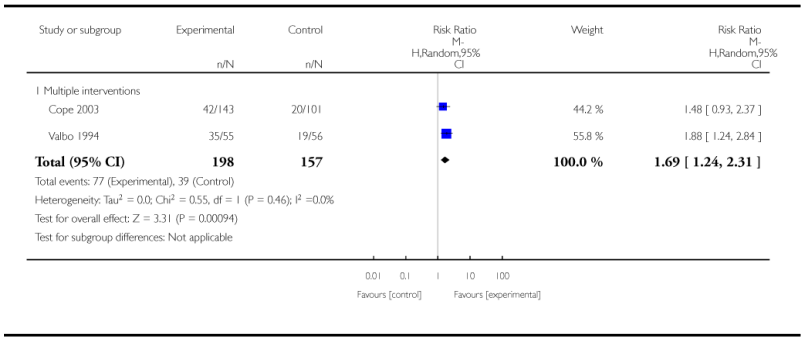
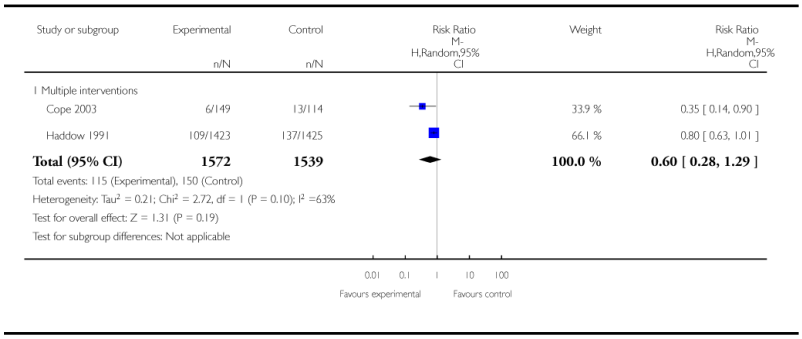


Analysis 5.3. Comparison 5 Smoking cessation interventions: feedback vs usual care, Outcome 3 Preterm births

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 5 Smoking cessation interventions: feedback vs usual care

Outcome: 3 Preterm births



Analysis 5.4. Comparison 5 Smoking cessation interventions: feedback vs usual care, Outcome 4 Mean birthweight

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 5 Smoking cessation interventions: feedback vs usual care

Outcome: 4 Mean birthweight

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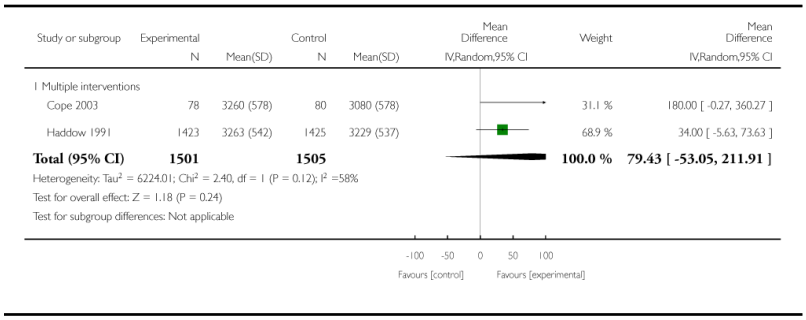
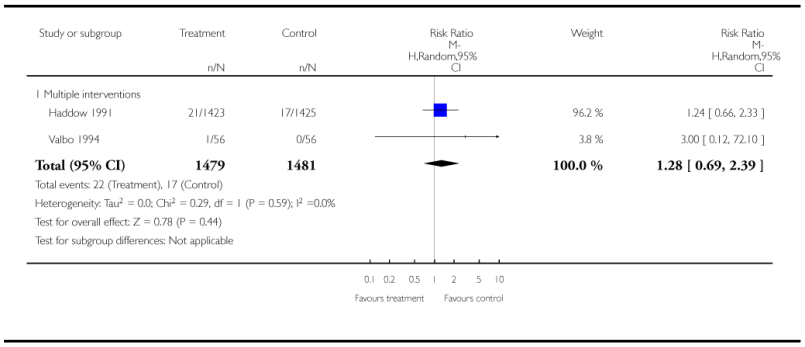


Analysis 5.5. Comparison 5 Smoking cessation interventions: feedback vs usual care, Outcome 5 Stillbirths

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 5 Smoking cessation interventions: feedback vs usual care

Outcome: 5 Stillbirths



Analysis 6.1. Comparison 6 Smoking cessation interventions: feedback vs less intensive intervention, Outcome 1 Abstinence in late pregnancy: biochemically validated

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 6 Smoking cessation interventions: feedback vs less intensive intervention

Outcome: 1 Abstinence in late pregnancy: biochemically validated

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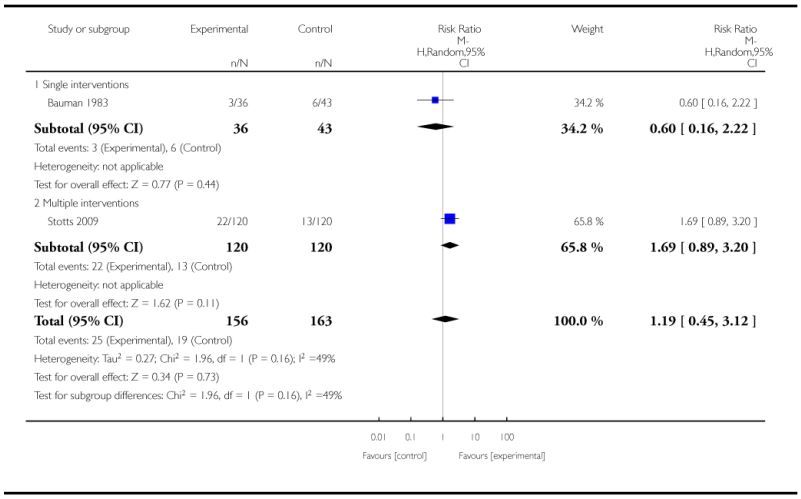
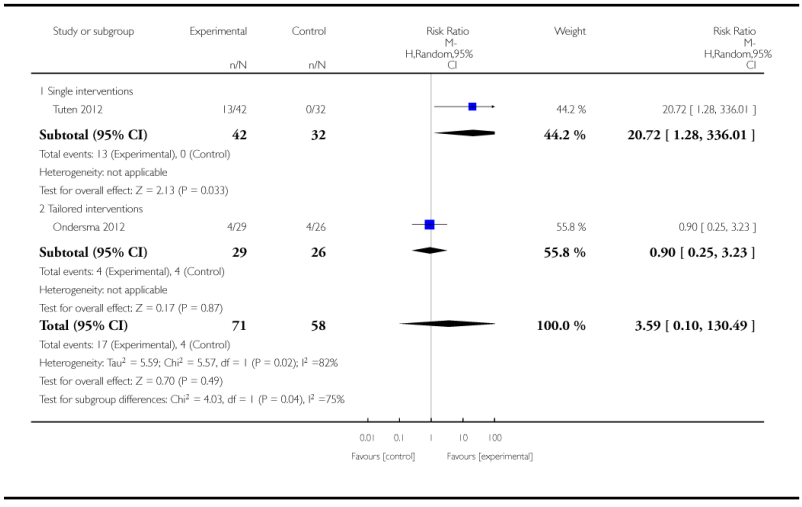


Analysis 7.1. Comparison 7 Smoking cessation interventions: incentives vs usual care, Outcome 1 Abstinence in late pregnancy:biochemically validated

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 7 Smoking cessation interventions: incentives vs usual care

Outcome: 1 Abstinence in late pregnancy:biochemically validated



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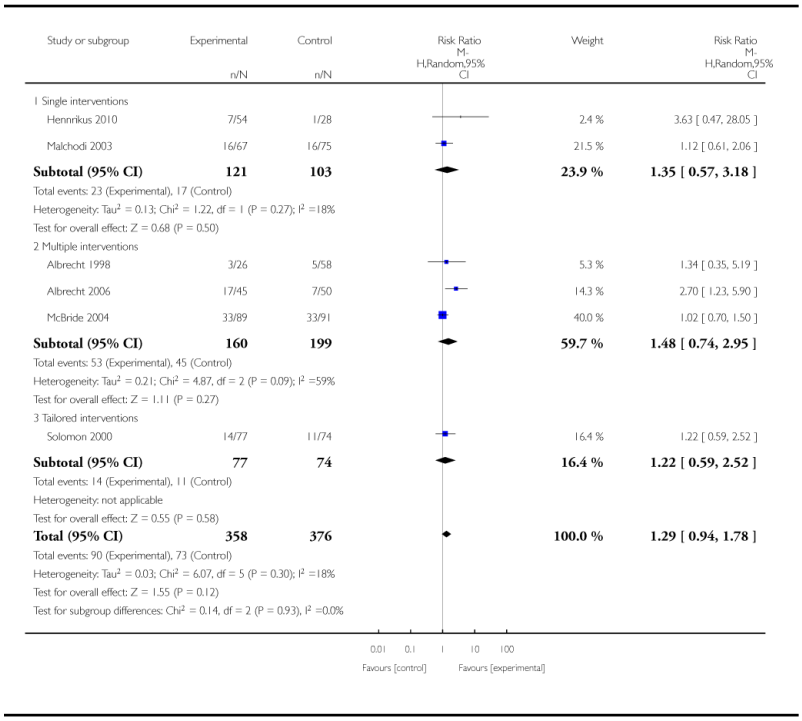
Analysis 8.1. Comparison 8 Smoking cessation interventions: social support vs less intensive intervention, Outcome 1 Abstinence in late pregnancy (peer and partner support)

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 8 Smoking cessation interventions: social support vs less intensive intervention

Outcome: 1 Abstinence in late pregnancy (peer and partner support)

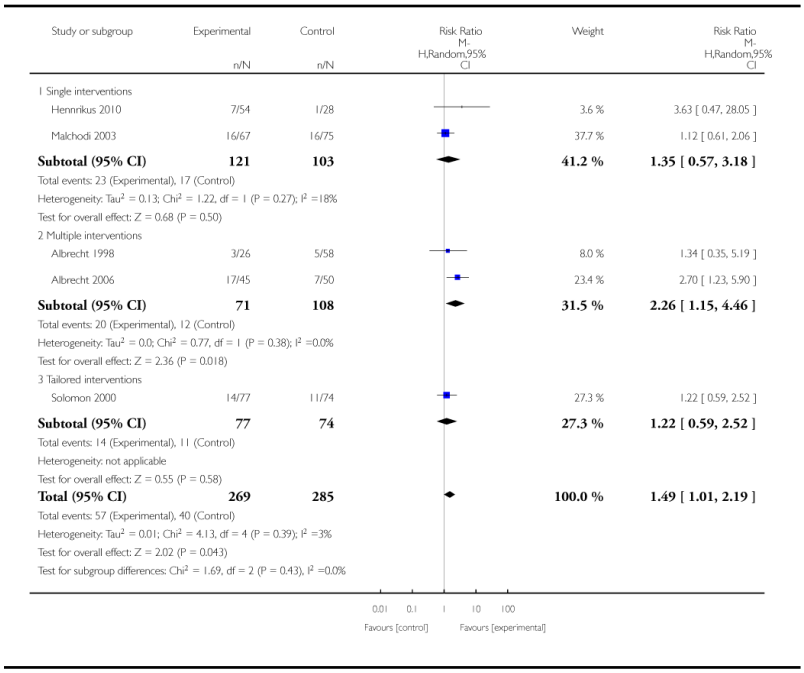


Analysis 8.2. Comparison 8 Smoking cessation interventions: social support vs less intensive intervention, Outcome 2 Abstinence in late pregnancy: biochemically validated (peer support only)

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 8 Smoking cessation interventions: social support vs less intensive intervention

Outcome: 2 Abstinence in late pregnancy: biochemically validated (peer support only)



Analysis 8.3. Comparison 8 Smoking cessation interventions: social support vs less intensive intervention, Outcome 3 Abstinence at 0 to 5 months postpartum

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 8 Smoking cessation interventions: social support vs less intensive intervention

Outcome: 3 Abstinence at 0 to 5 months postpartum

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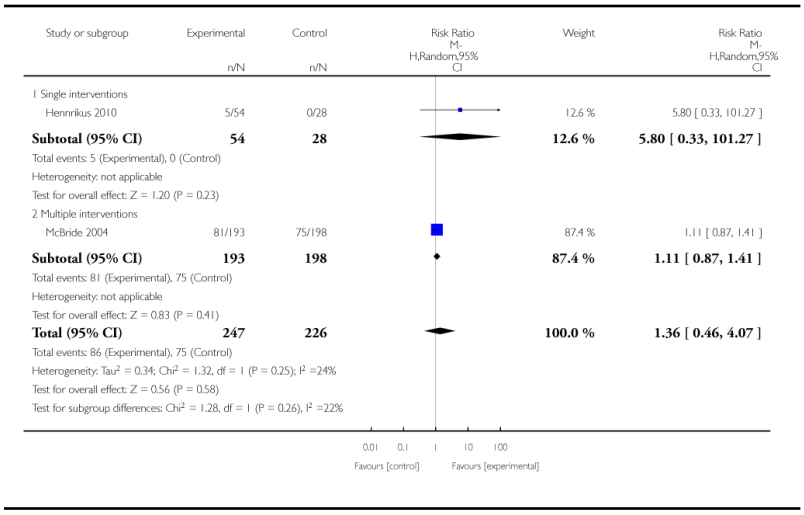
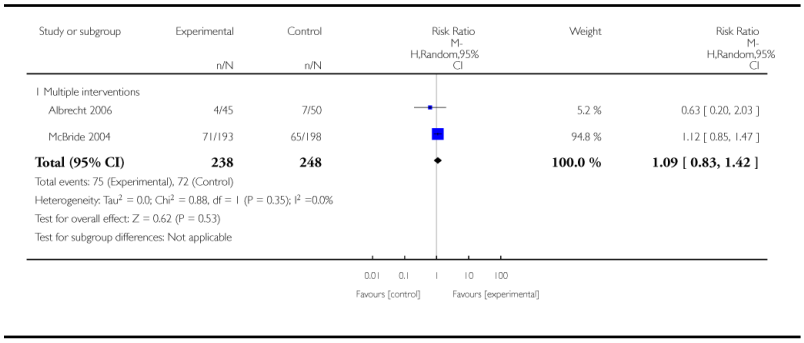


Analysis 8.4. Comparison 8 Smoking cessation interventions: social support vs less intensive intervention, Outcome 4 Abstinence at 6 to 11 months postpartum

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 8 Smoking cessation interventions: social support vs less intensive intervention

Outcome: 4 Abstinence at 6 to 11 months postpartum



Analysis 9.1. Comparison 9 Maternal health intervention with smoking cessation component: social support (tailored) vs usual care, Outcome 1 Abstinence in late pregnancy

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

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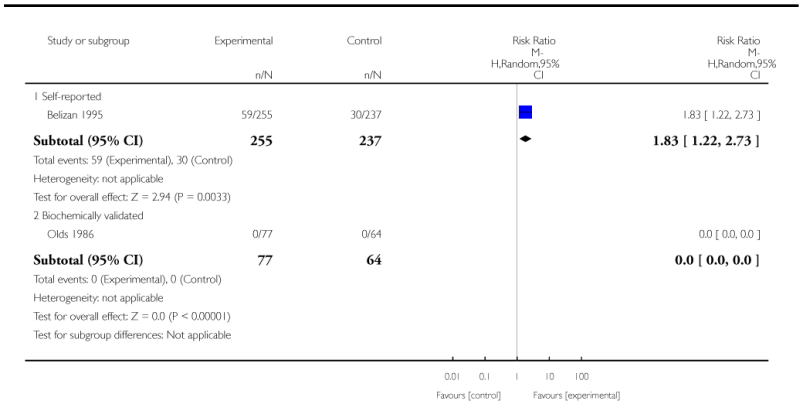
Comparison: 9 Maternal health intervention with smoking cessation component: social support (tailored) vs usual care

Outcome: 1 Abstinence in late pregnancy

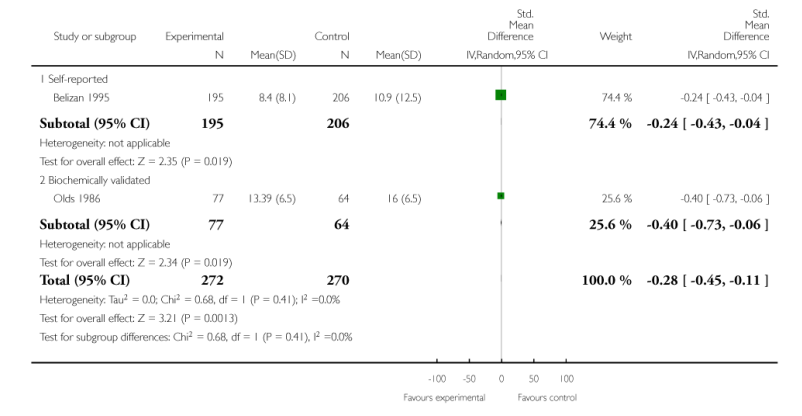


Analysis 9.2. Comparison 9 Maternal health intervention with smoking cessation component: social support (tailored) vs usual care, Outcome 2 Self-reported mean cigarettes per day in late pregnancy

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 9 Maternal health intervention with smoking cessation component: social support (tailored) vs usual care

Outcome: 2 Self-reported mean cigarettes per day in late pregnancy



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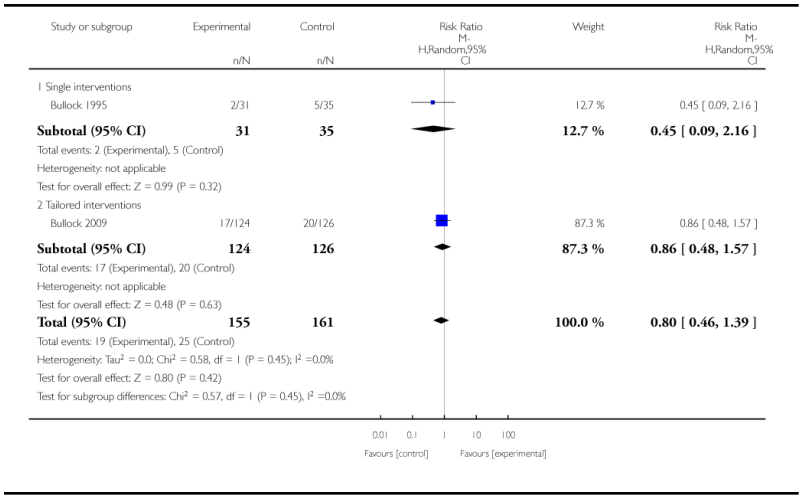
Analysis 10.1. Comparison 10 Maternal health intervention with smoking cessation component: social support vs less intensive intervention, Outcome 1 Abstinence in late pregnancy

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 10 Maternal health intervention with smoking cessation component: social support vs less intensive intervention

Outcome: 1 Abstinence in late pregnancy

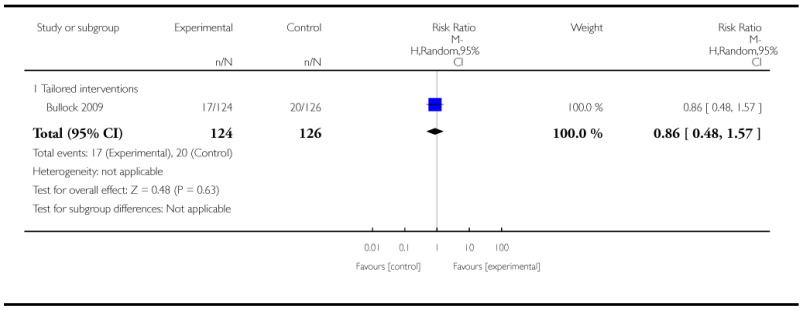


Analysis 10.2. Comparison 10 Maternal health intervention with smoking cessation component: social support vs less intensive intervention, Outcome 2 Abstinence in late pregnancy: biochemically validated

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 10 Maternal health intervention with smoking cessation component: social support vs less intensive intervention

Outcome: 2 Abstinence in late pregnancy: biochemically validated



Analysis 11.1. Comparison 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy, Outcome 1 Abstinence in late pregnancy: self-reported and biochemically validated (non-winsorised)

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

Outcome: 1 Abstinence in late pregnancy: self-reported and biochemically validated (non-winsorised)

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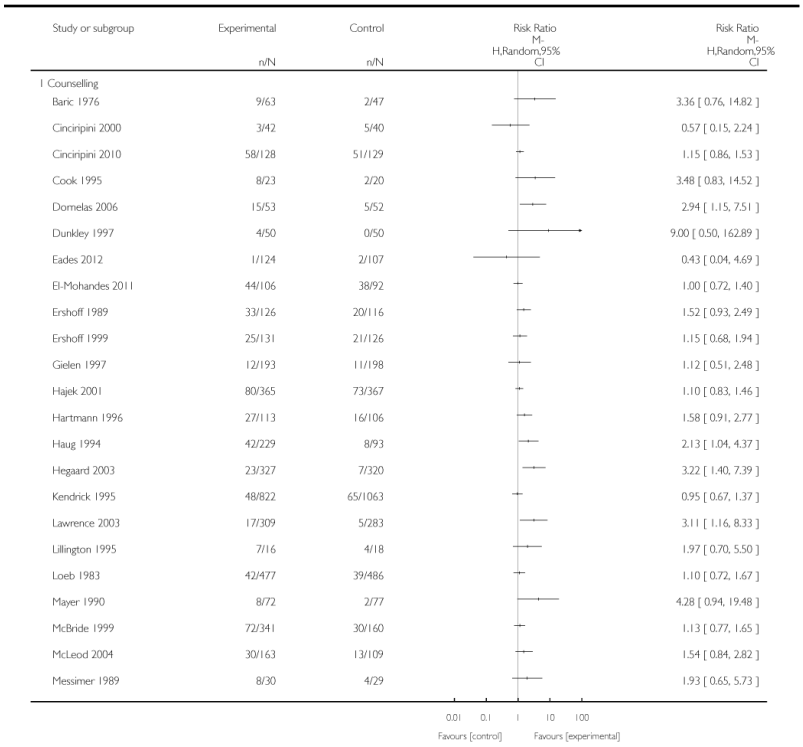

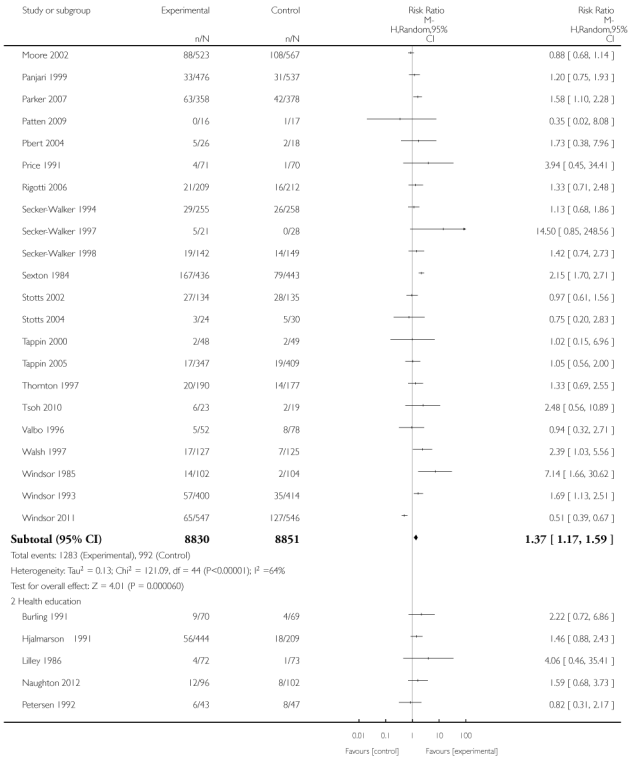

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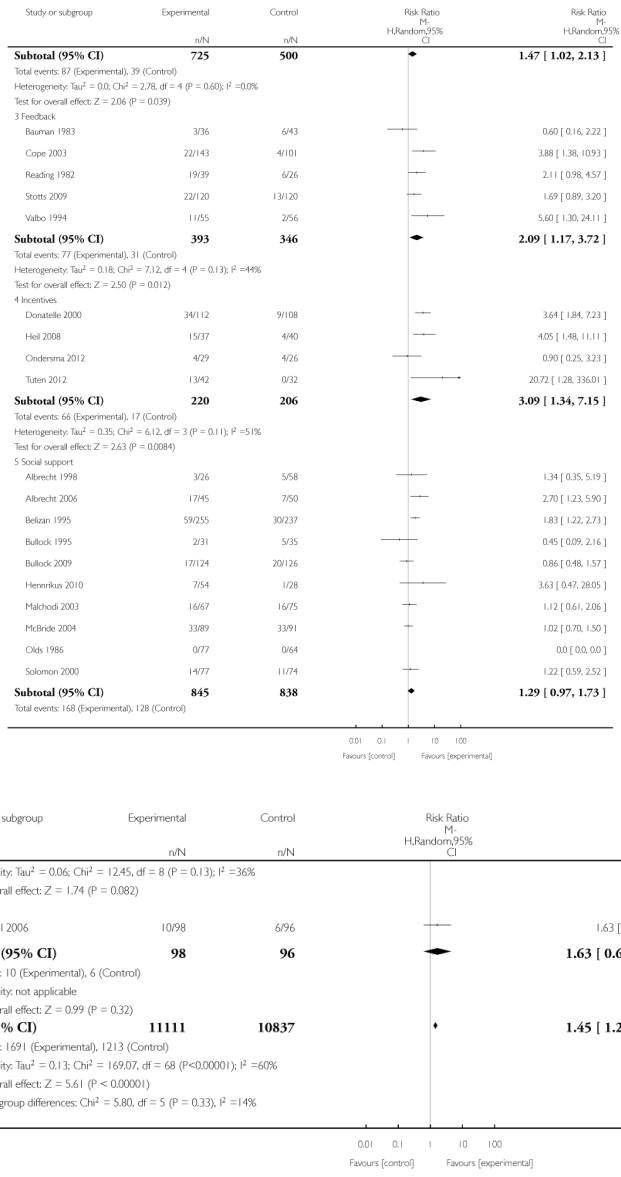

Analysis 11.2. Comparison 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy, Outcome 2 Abstinence in late pregnancy: biochemically validated only (nonwinsorised)

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

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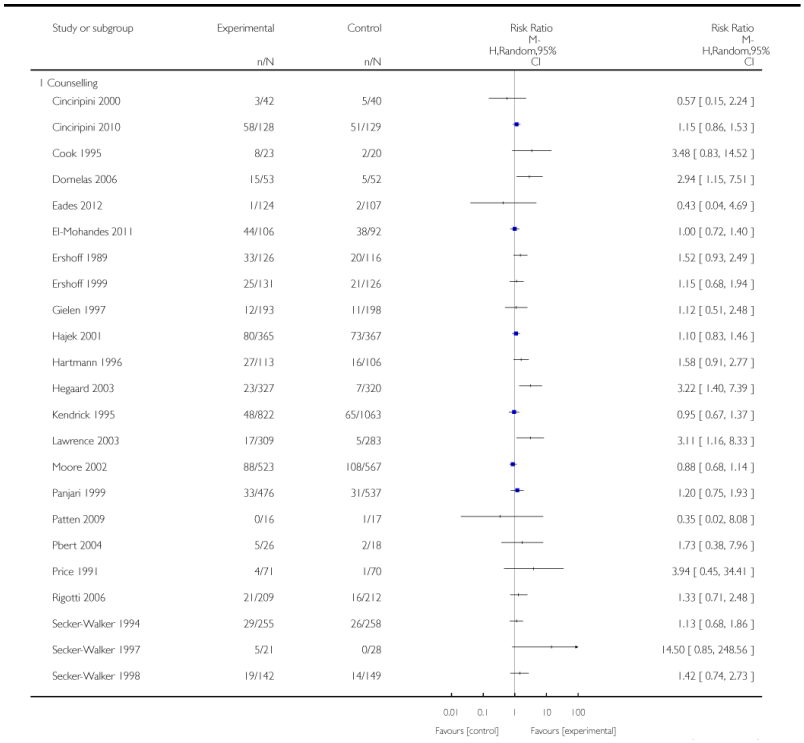
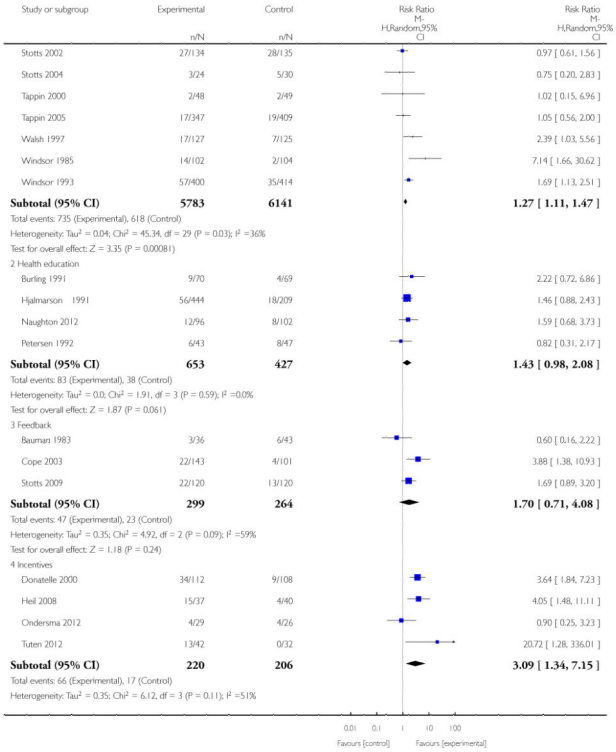
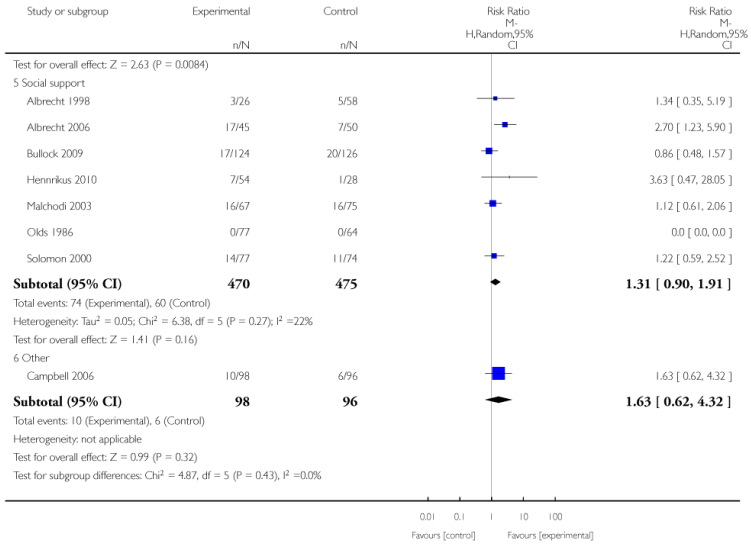
Outcome: 2 Abstinence in late pregnancy: biochemically validated only (non-winsorised)







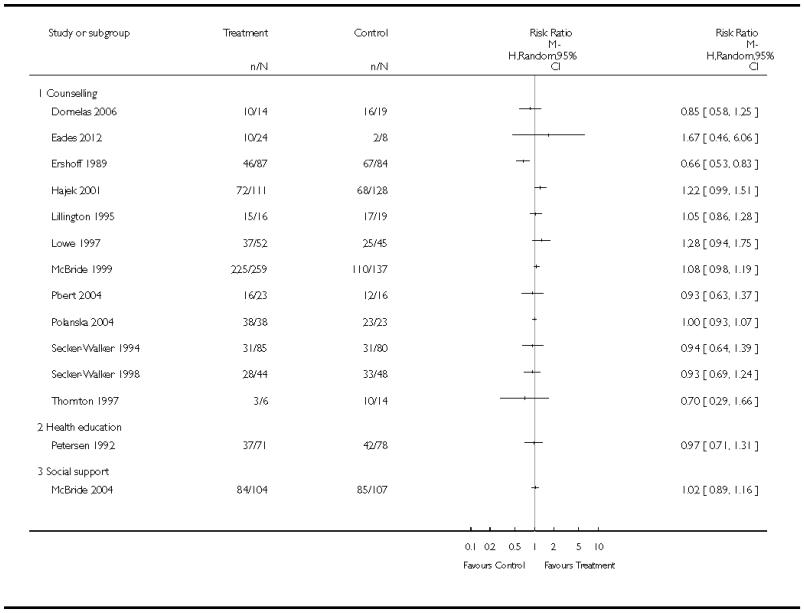
Analysis 11.3. Comparison 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy,

Outcome 3 Continued abstinence (Relapse prevention) in late pregnancy for spontaneous quitters.

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

Outcome: 3 Continued abstinence (Relapse prevention) in late pregnancy for spontaneous quitters

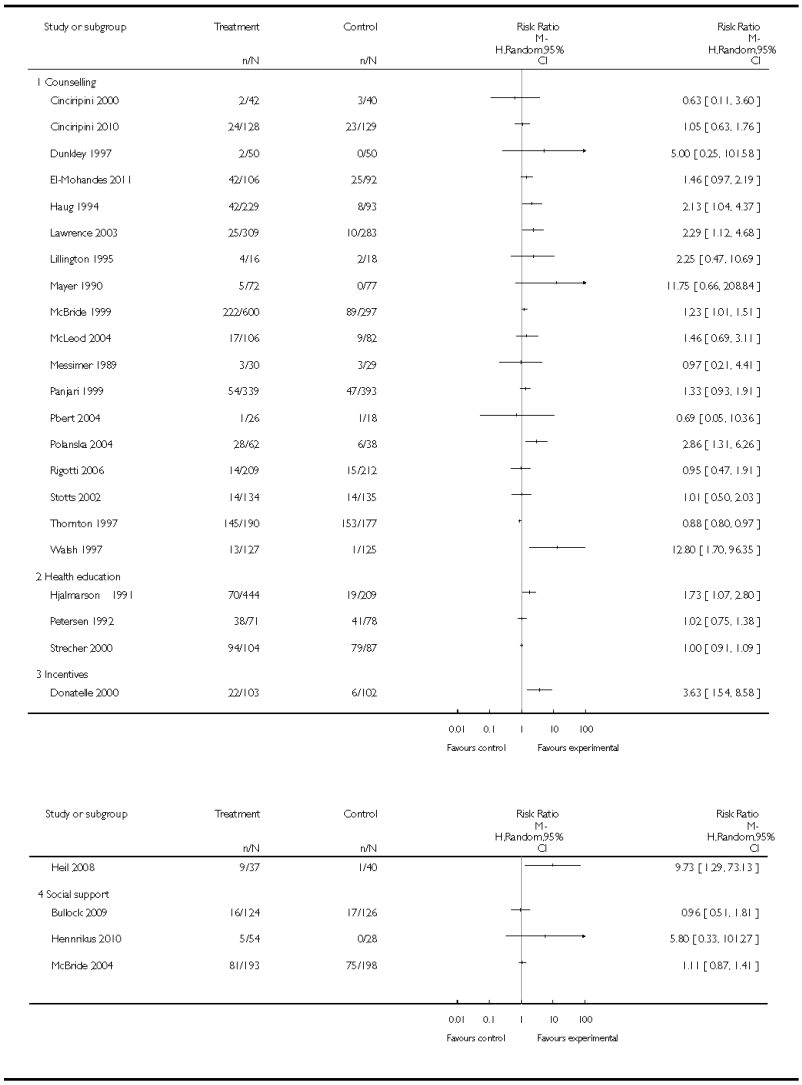


Analysis 11.4. Comparison 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy, Outcome 4 Abstinence at 0 to 5 months postpartum.

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

Outcome: 4 Abstinence at 0 to 5 months postpartum



Analysis 11.5. Comparison 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy, Outcome 5 Abstinence at 6 to 11 months postpartum.

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

Outcome: 5 Abstinence at 6 to 11 months postpartum

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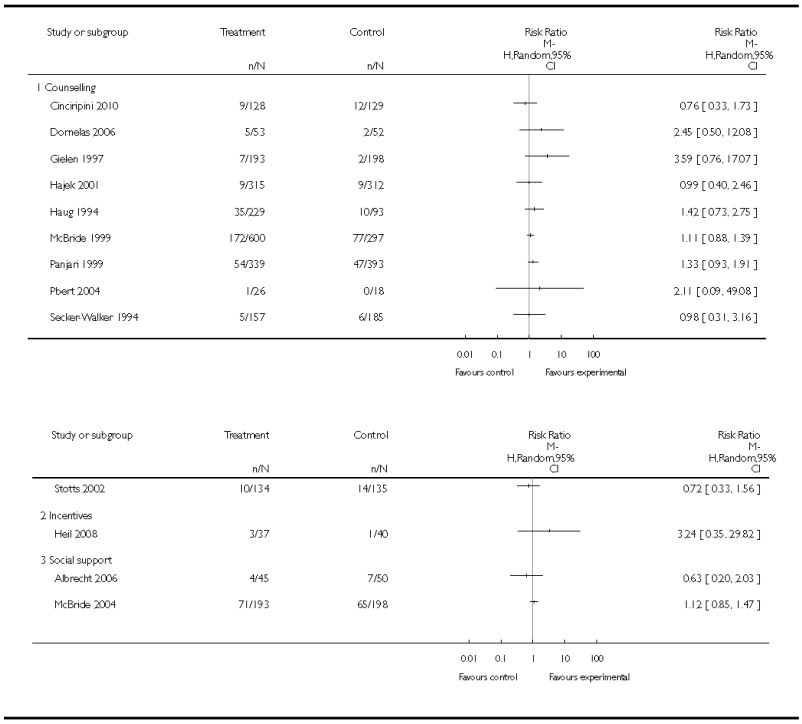
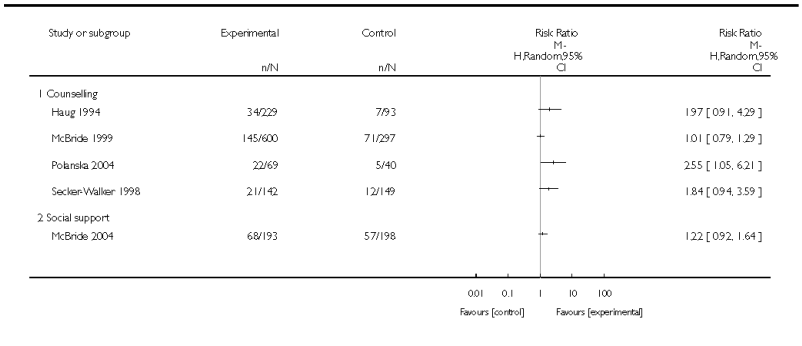


Analysis 11.6. Comparison 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy, Outcome 6 Abstinence at 12 to 17 months postpartum.

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

Outcome: 6 Abstinence at 12 to 17 months postpartum



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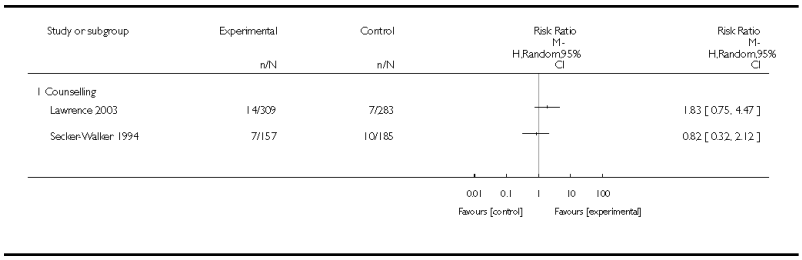
Analysis 11.7. Comparison 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy, Outcome 7 Abstinence at 18+ months postpartum.

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

Outcome: 7 Abstinence at 18+ months postpartum

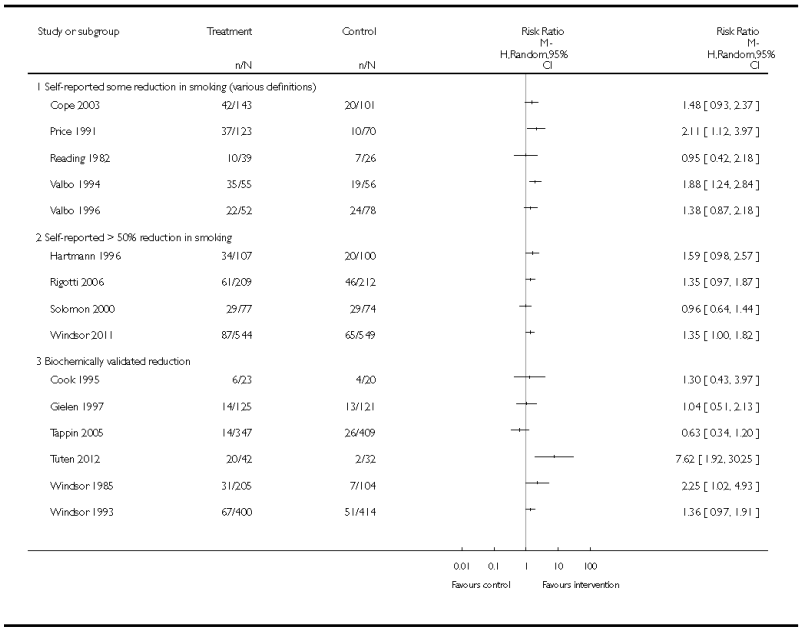


Analysis 11.8. Comparison 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy, Outcome 8 Smoking reduction: numbers of women reducing smoking in late pregnancy.

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

Outcome: 8 Smoking reduction: numbers of women reducing smoking in late pregnancy

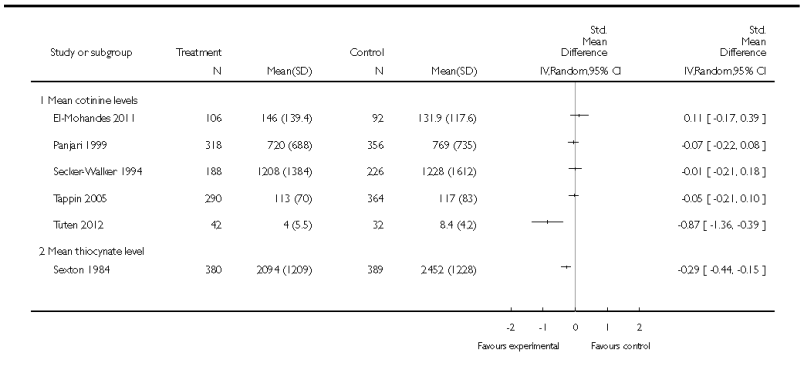


Analysis 11.9. Comparison 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy, Outcome 9 Smoking reduction: biochemical measures in late pregnancy.

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

Outcome: 9 Smoking reduction: biochemical measures in late pregnancy



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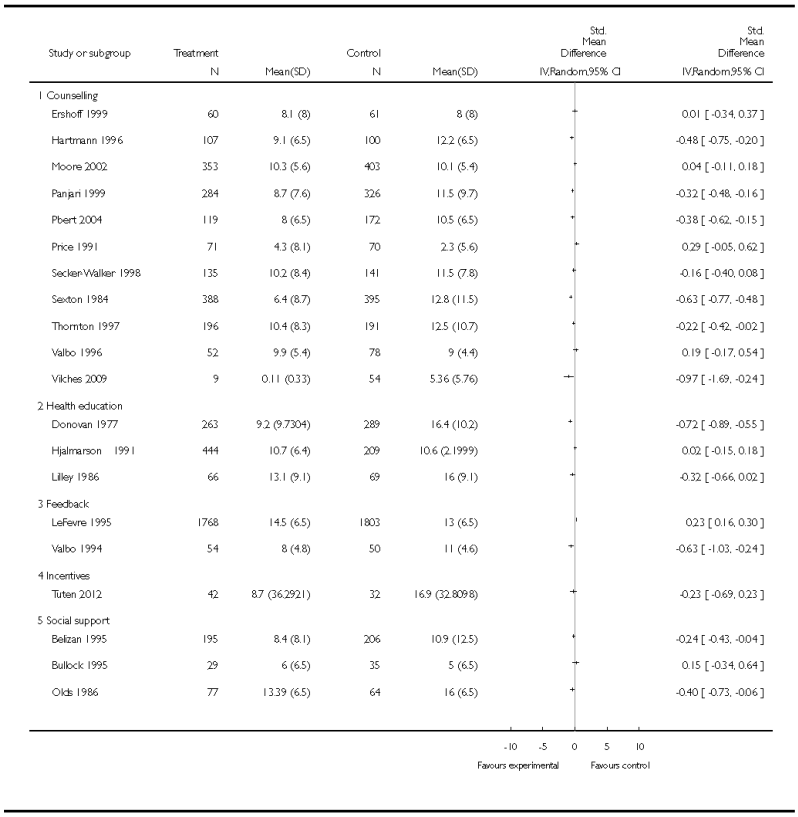
Analysis 11.10. Comparison 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy, Outcome 10 Smoking reduction: self-reported mean cigarettes per day measured in late pregnancy or at delivery.

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

Outcome: 10 Smoking reduction: self-reported mean cigarettes per day measured in late pregnancy or at delivery

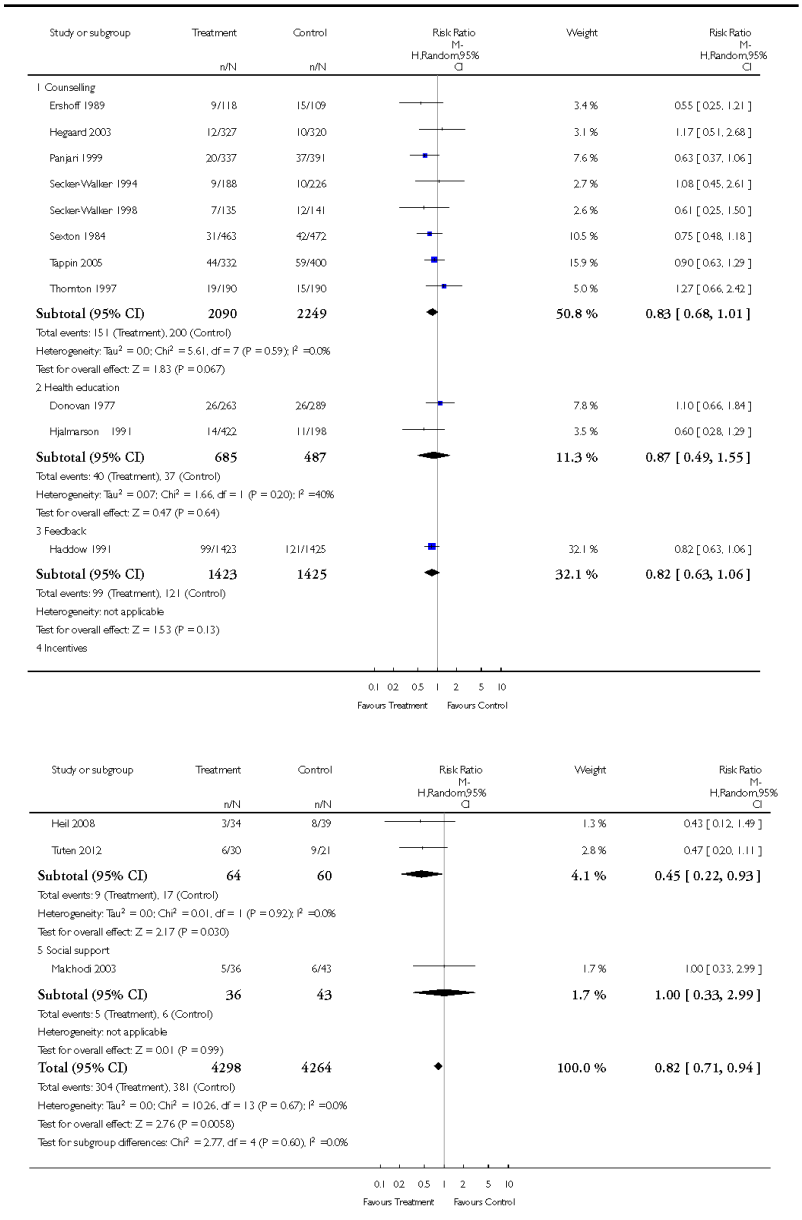


Analysis 11.11. Comparison 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy, Outcome 11 Low birthweight (under 2500 g).

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

Outcome: 11 Low birthweight (under 2500 g)



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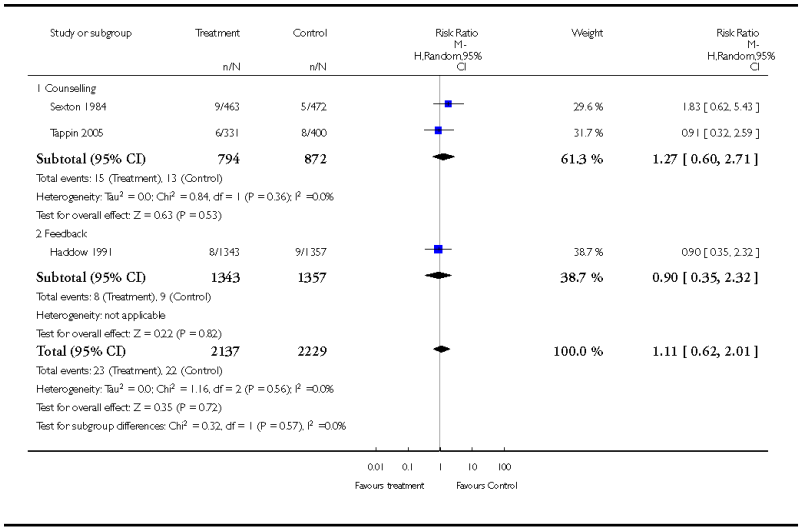
Analysis 11.12. Comparison 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy, Outcome 12 Very low birthweight (under 1500 g).

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

Outcome: 12 Very low birthweight (under 1500 g)

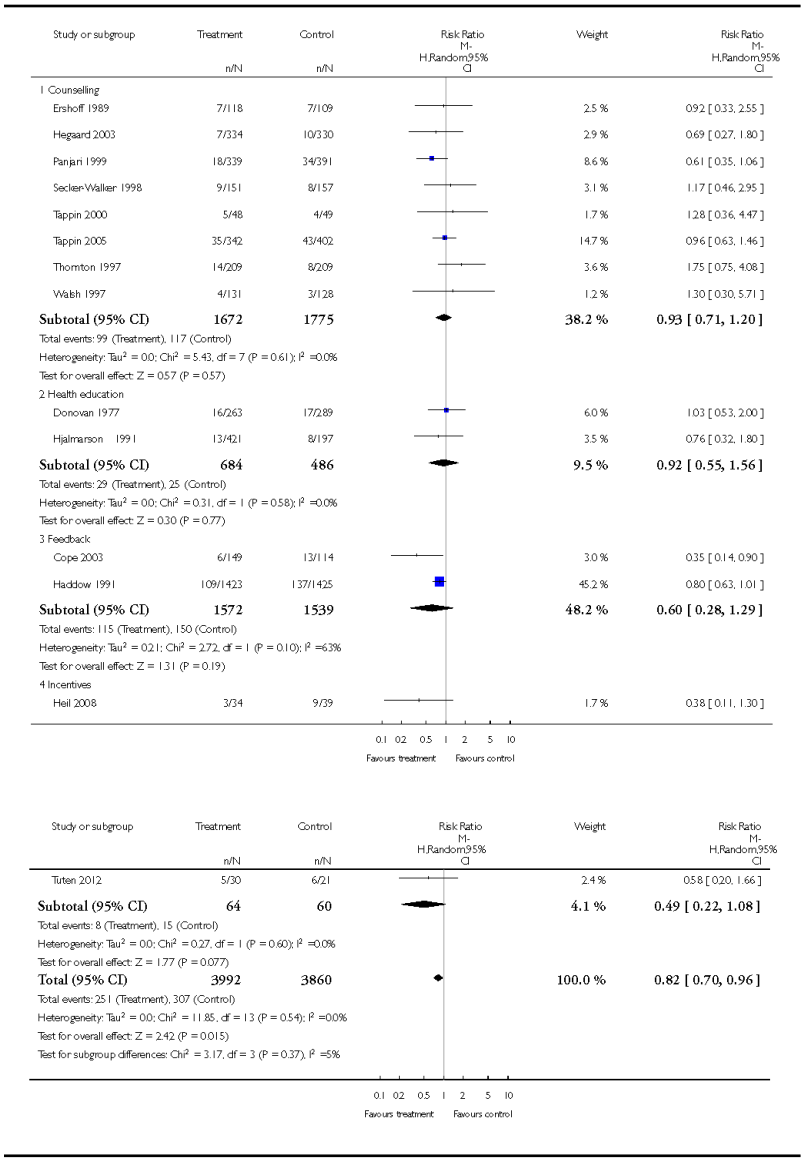


Analysis 11.13. Comparison 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy, Outcome 13 Preterm birth (under 37 weeks).

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

Outcome: 13 Preterm birth (under 37 weeks)



Analysis 11.14. Comparison 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy, Outcome 14 Mean birthweight.

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

Outcome: 14 Mean birthweight

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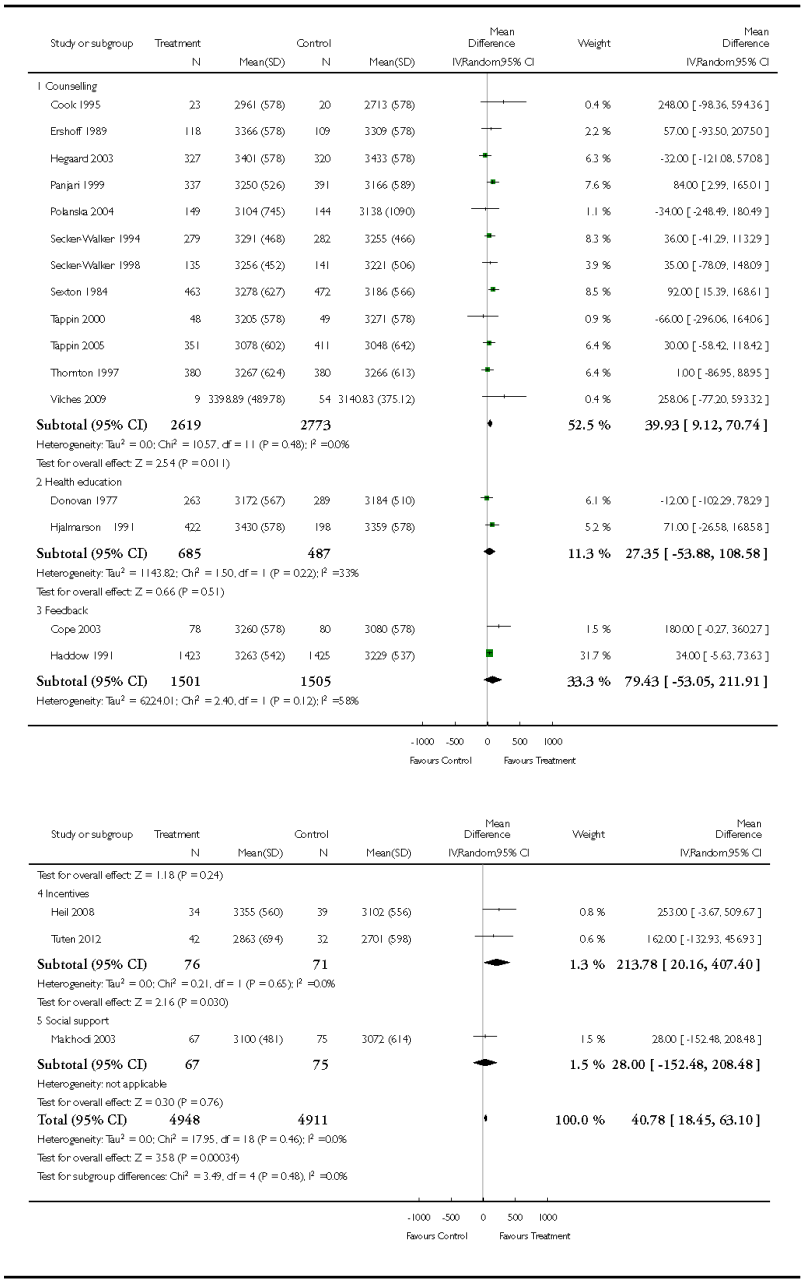

Analysis 11.15. Comparison 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy, Outcome 15 Perinatal deaths.

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

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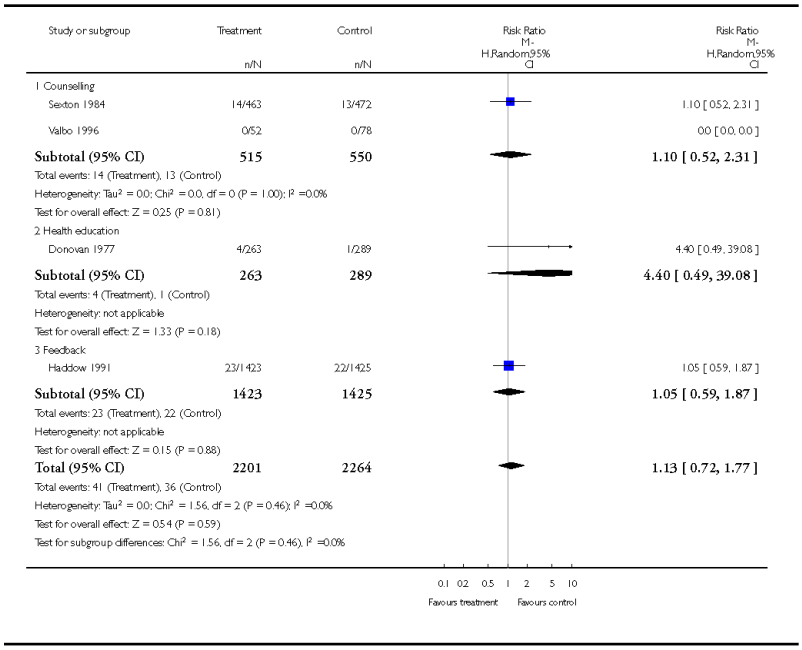
Comparison: 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

Outcome: 15 Perinatal deaths



Analysis 11.16. Comparison 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy, Outcome 16 Stillbirths.

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

Outcome: 16 Stillbirths

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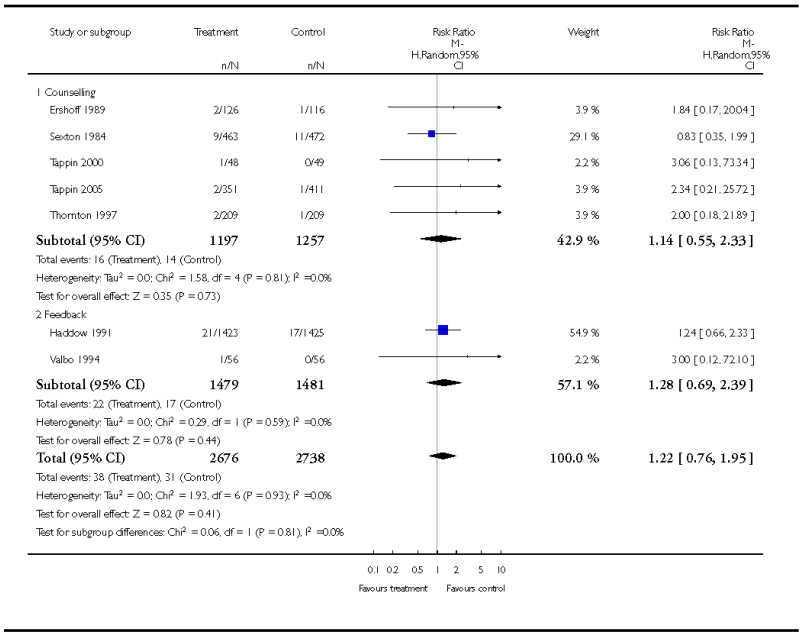

Analysis 11.17. Comparison 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy, Outcome 17 Neonatal deaths.

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

Outcome: 17 Neonatal deaths

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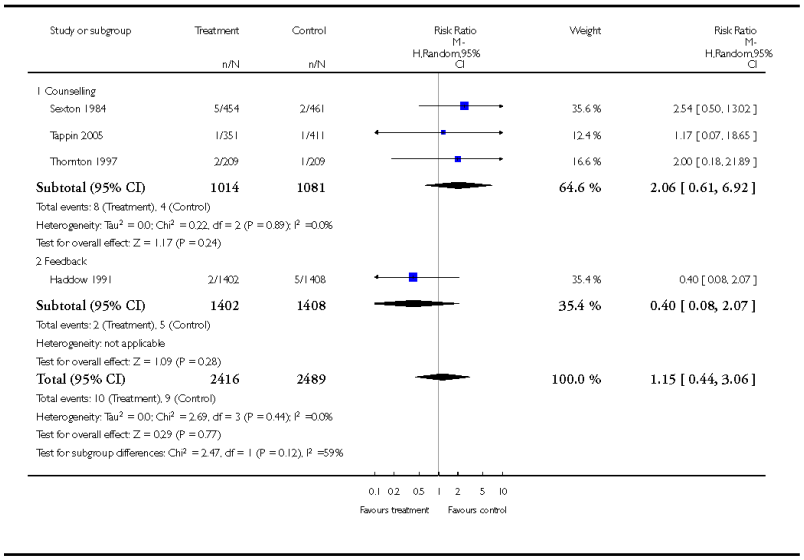

Analysis 11.18. Comparison 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy, Outcome 18 NICU admissions.

Review: Psychosocial interventions for supporting women to stop smoking in pregnancy

Comparison: 11 Interventions for smoking cessation in pregnancy versus control: subgrouped by main intervention strategy

Outcome: 18 NICU admissions

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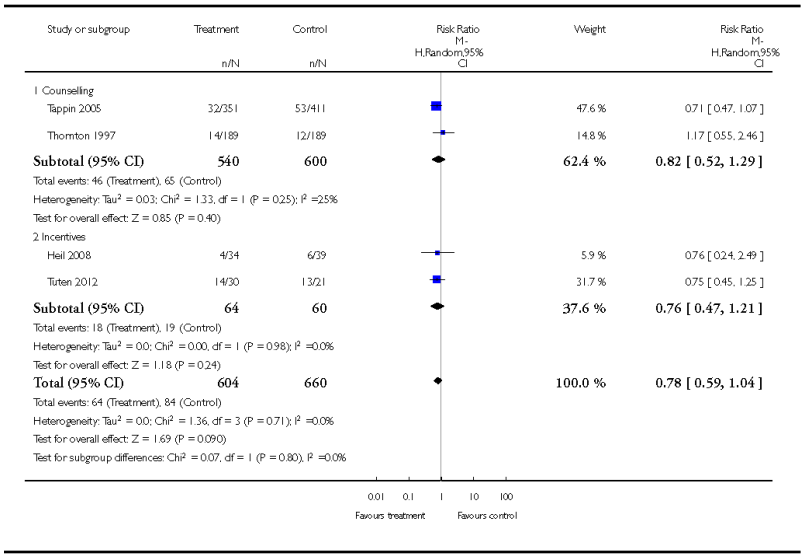

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* . Indicates the major publication for the study

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PLAIN LANGUAGE SUMMARY

Psychosocial interventions for supporting women to stop smoking in pregnancy

Smoking during pregnancy increases the risk of the mother having complications during pregnancy and the baby being born with low birthweight and preterm (before 37 weeks). Tobacco smoking during pregnancy is relatively common, although the trend is towards it becoming less frequent in high-income countries and more frequent in low- to middle-income countries.

The review showed that psychosocial interventions to support women to stop smoking increased the proportion of women who stopped smoking in late pregnancy and reduced the number of low birthweight and preterm births. There did not appear to be any adverse effects from the psychosocial interventions, and three studies measured an improvement in women's psychological wellbeing.

The review includes 86 randomised controlled trials, with data from seventy-seven trials (involving over 29,000 women). Nearly all studies were in high-income countries. The intervention that supported the most women to stop smoking in pregnancy appeared to be providing incentives. However, these results are based on only four trials with a small number of women (all in the US), and they only seemed to help women stop smoking when provided intensively (three trials). Counselling also appeared to be effective in supporting women to quit, but only when combined with other strategies (27 trials). The effectiveness of counselling was less clear when women in the control group received a less intensive smoking intervention (16 trials). Feedback also appeared to help women quit, but only when compared with usual care and combined with other strategies (two studies). It was unclear whether health education alone helped women quit, but the numbers of women involved in these trials were comparatively small. The evidence for social support was mixed; for instance, targeted peer support appeared to help women quit (five trials) but in one trial partner support did not. Women also reported that peer and partner support could be both helpful and unhelpful.

Increasing the frequency and duration of the intervention did not appear to increase the effectiveness. Interventions appeared to be as effective for women who were poor, as those who were not; but there is insufficient evidence that the interventions were effective for ethnic (five trials) and aboriginal women (two trials). Trials where the interventions became part of routine pregnancy care did not appear to help more women to quit, which suggests there are challenges to translating this evidence into practice.

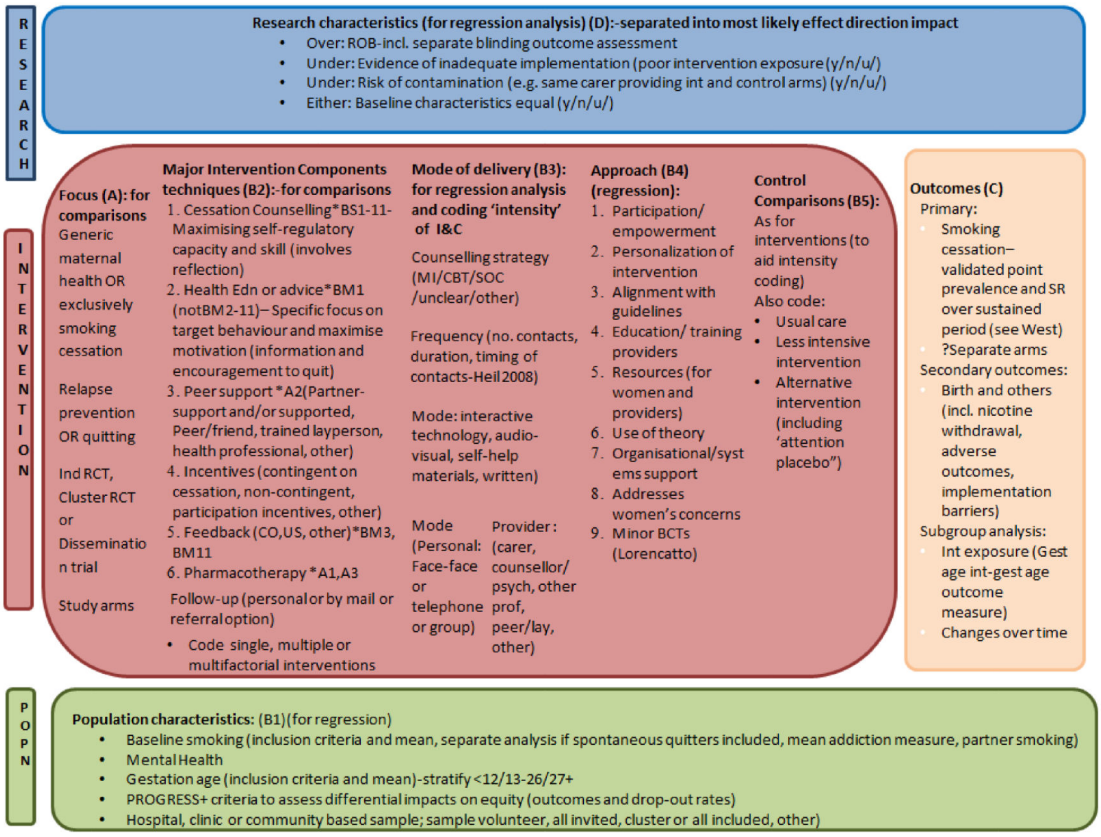

Figure 1. Logic model for systematic review analysis of potential factors impacting on efficacy of interventions for supporting women to stop smoking in pregnancy.

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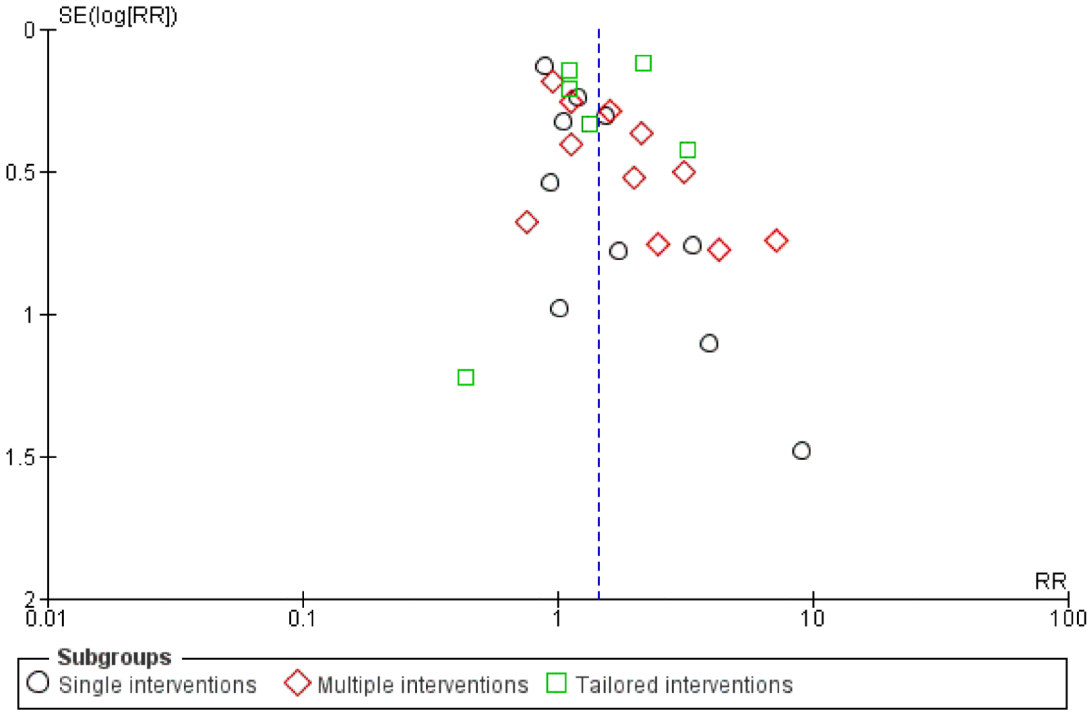

Figure 2. Funnel plot of comparison: 1 Smoking cessation interventions: counselling vs usual care, outcome: 1.1 Abstinence in late pregnancy.

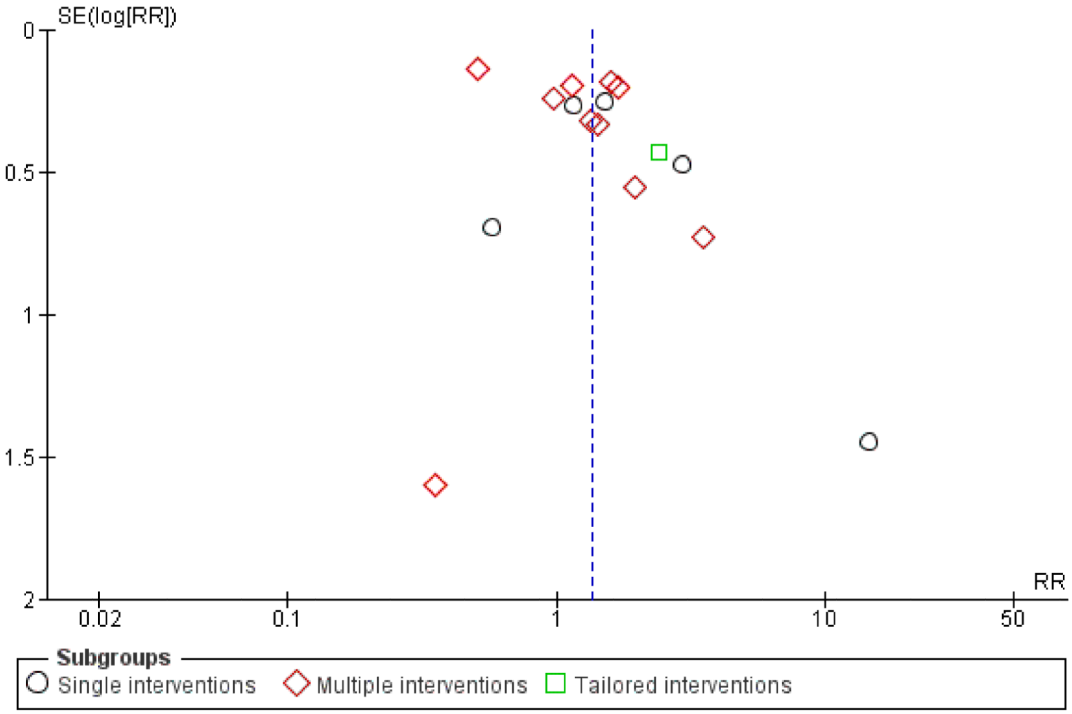

Figure 3. Funnel plot of comparison: 2 Smoking cessation interventions: counselling vs less intensive intervention, outcome: 2.1 Abstinence in late pregnancy.

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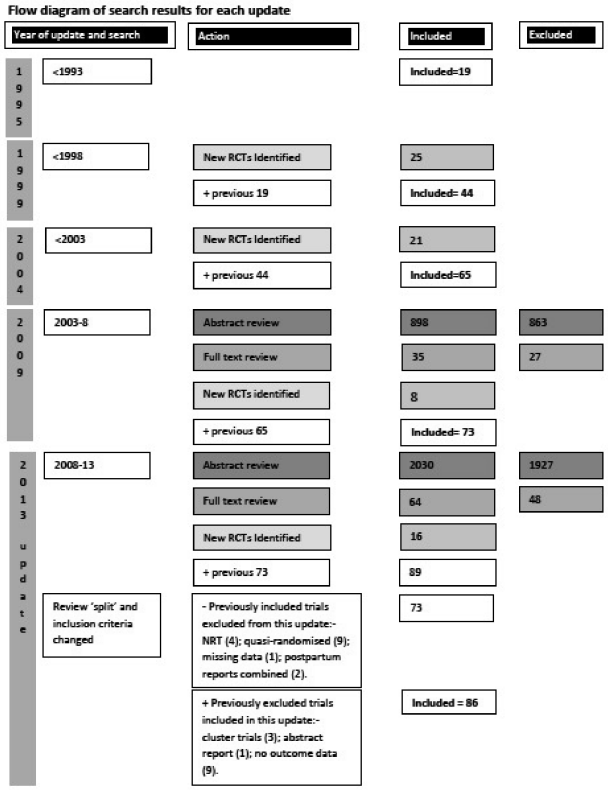

Figure 4. Search flow chart.

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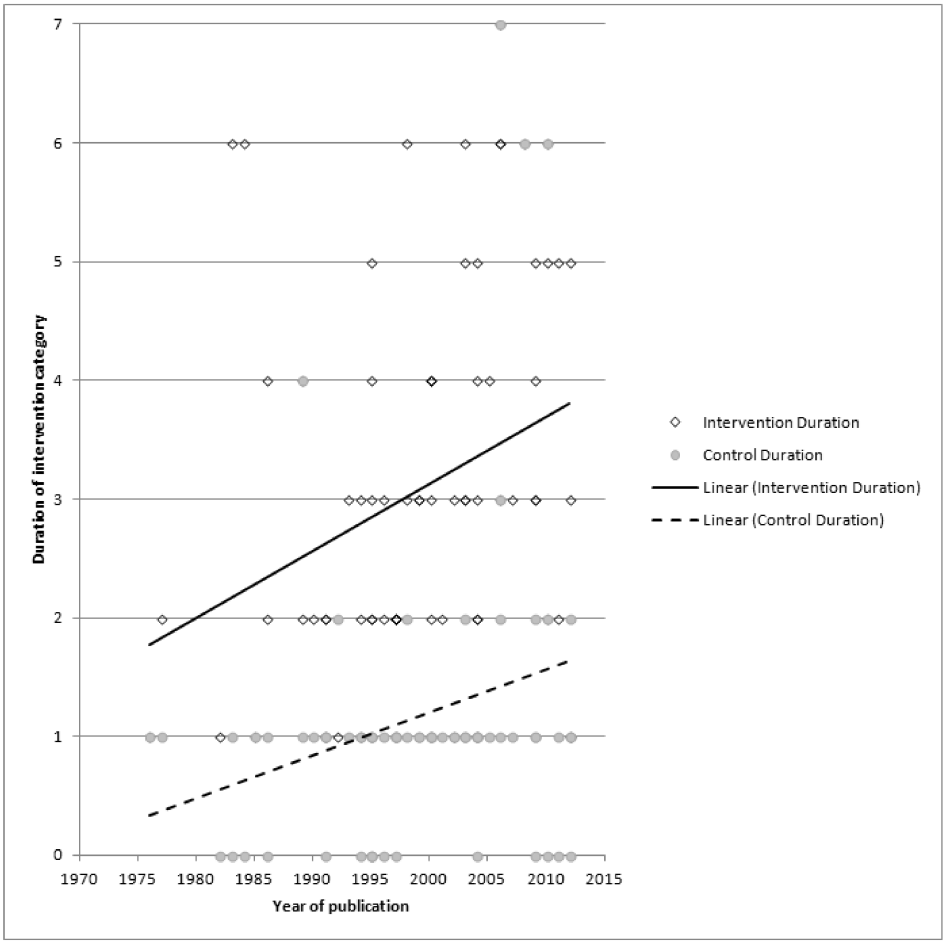

Figure 5. Duration of contact for each condition by publication year.

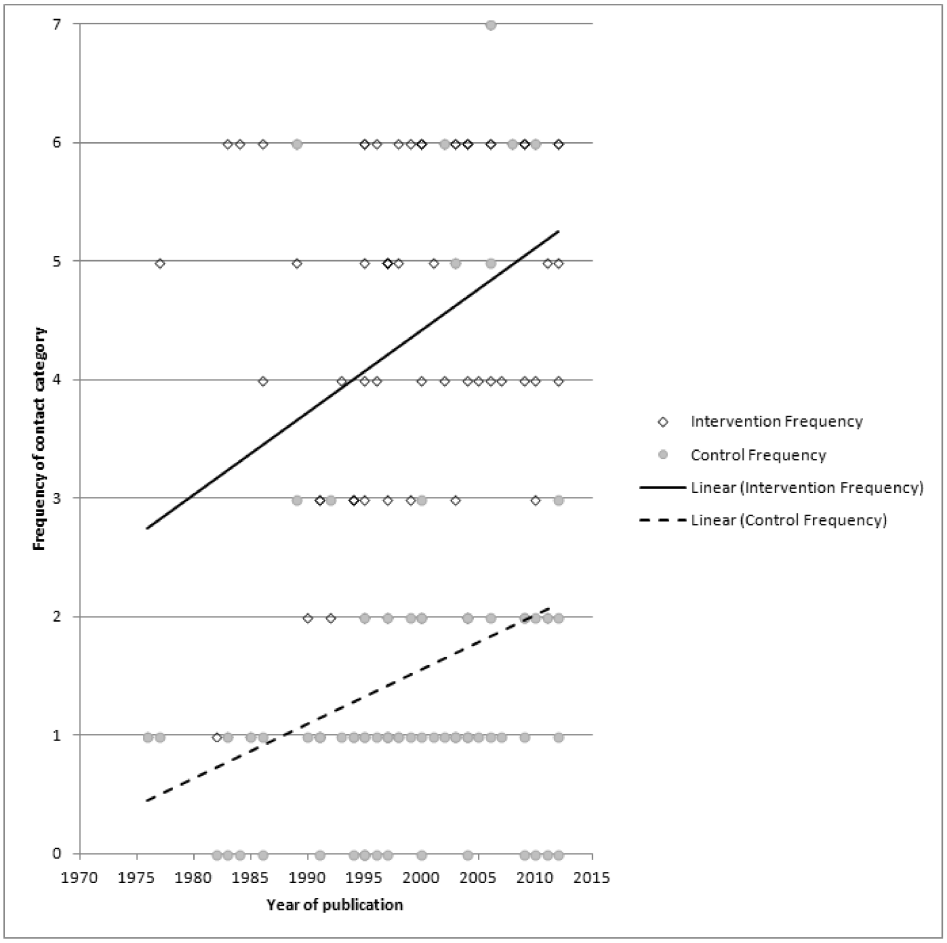

Figure 6. Frequency of contact for each condition by publication year.

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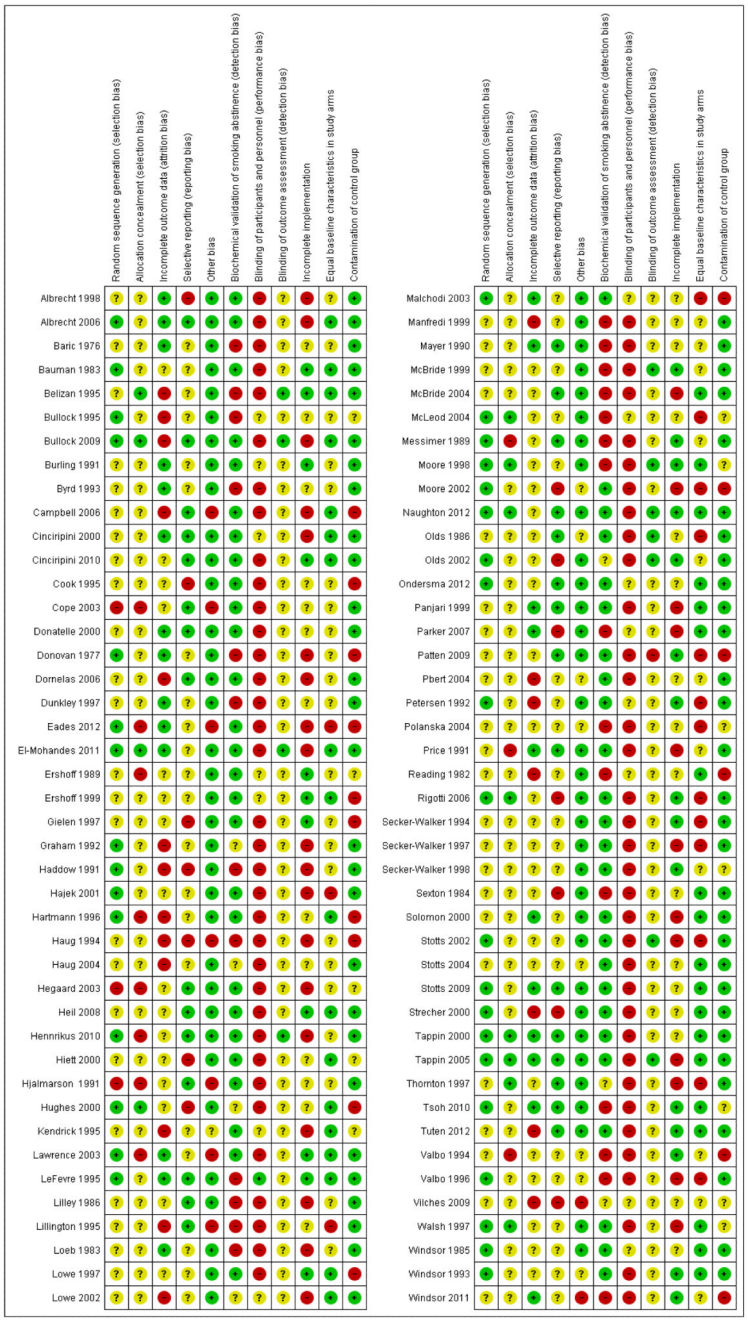

Figure 7. 'Risk of bias' summary: review authors' judgments about each risk of bias item for each included study.

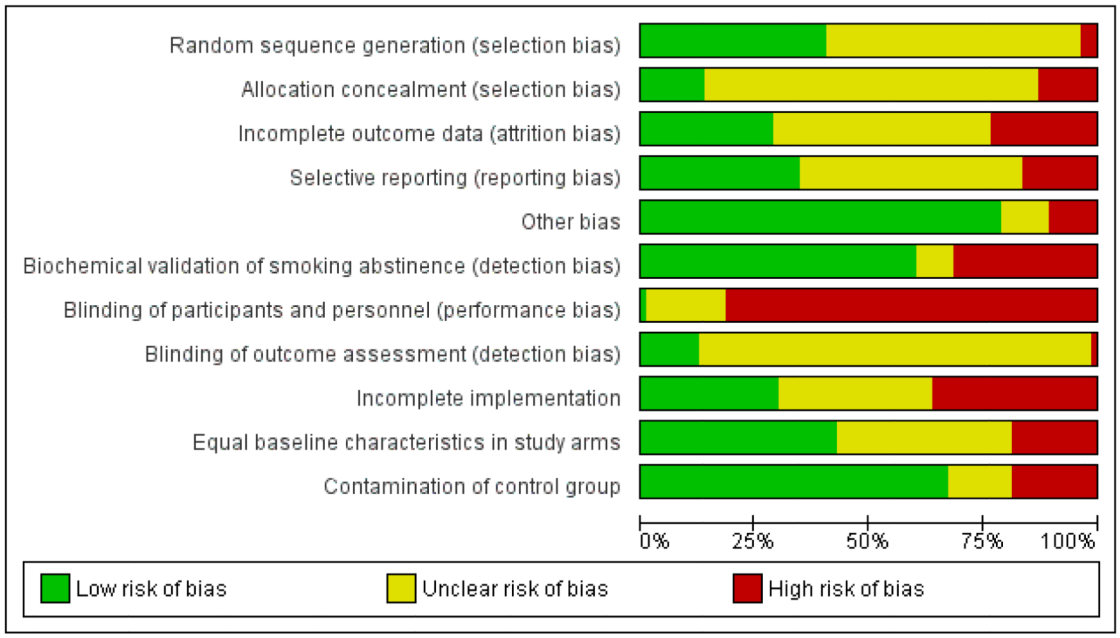

Figure 8. 'Risk of bias' graph: review authors' judgments about each risk of bias item presented as percentages across all included studies.

Table 1

Primary outcomes from studies which met inclusion criteria, however outcomes were not able to be included in metaanalysis

Study ID	Main findings	Rationale for not including outcomes in meta-analysis
Byrd 1993	There was no statistically significant difference in smoking status among those who received either type ofmedia or nurse counselling	Results could not be included as smoking cessation rates were not reported by intervention group
Graham 1992	There was no decrease in the rate of low birthweight for women who received the intervention	Smoking outcomes were not reported. Birthweight outcomes were not included in this review, as aspects other than the smoking component of the intervention may have had an effect on birthweight, and it is unclear how many smokers were in each group, or what proportion quit
Haug 2004	There was no significant difference in smoking between the intervention (motivational enhancement therapy) and control groups on self-reported cigarettes per day, mean carbon monoxide or mean cotinine	Study reports actual outcome data for movement in stages of change only. Outcome data for smoking cessation, cigarettes per day, carbon monoxide and cotinine levels are not reported
Hiett 2000	Significantly more women were able to quit smoking when enrolled in the intervention	Actual cessation rates not reported (poster abstract only available)
Hughes 2000	There was no difference between intervention and control groups in mean delta stage of change or 12-month rate of maintained cessation in pregnant women (-0.62 vs -0.65)	Data from intervention and control Outcomes were combined for intervention and control groups in pregnant women. Unable to extract numbers
Lowe 2002	At 1 month, 65% of behaviourally-based intervention hospitals agreed to provide materials about smoking cessation, compared to 3% control hospitals. After 1 year, 43%intervention hospitals still providedmaterials, compared to 9% of control hospitals. McNemar's Chi2 indicates a statistically meaningful difference between the proportion of intervention hospitals implementing the program and the proportion of control hospitals implementing the program (2 1 = 12, P = 0.0005)	Implementation data only included. No smoking cessation data provided
Manfredi 1999	Compared to controls, smokers attending family planning, prenatal and well-child clinics, exposed to the intervention were more likely to have quit (14.5% vs 7. 7%)	It was not possible to separate out which data was related to pregnantwomen, as opposed towomen recruited from family planning and well child clinics. Further, it was not clear at what stage in pregnancy women were recruited and what the post-partum time points were
Moore 1998	There was no significant difference in LBWwere 10.9% in the intervention group and 14.0% in controls (RR = 0.75, 95% CI 0.55 to 1.03). Preterm births rates were 9.7 in the intervention group and 11.0 in the controls (RR = 0.87, 95% CI 0.62 to 1.22)	Smoking outcomes were not reported. Birthweight and pretermbirth outcomes were not included in this review, as aspects other than the smoking component of the intervention may have had an effect on birthweight and preterm births
Olds 2002	Significant reduction in mean cotinine among women who smoked at baseline. Mean reduction of 12.32 ng/mL in the control group, compared to asmean reduction of 259.00 ng/mL in nurse-home visiting group	Study reports the mean cotinine reduction only, not mean cotinine levels or smoking cessation rates. It is also unclear how many randomised women were included in this analysis

CI: confidence interval

LBW: low birthweight

RR: risk ratio

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Table 2

Cluster-randomised trial adjustment details

ICC	Trial ID	Timing	Timing code	Outcome description	Outcome code	Mean cluster size		No. of clusters		Sample size		Ceased smoking %		Continued smoking %		Ceased smoking n		Continued smoking n		ICC		Between cluster var	IF(int)	IF(comp)	Effective sample size, denominator		Effective sample size, continue			Effective sample size, ceased			
						mi	mc	ci	cc	ni	nc	i%	c%	i%	c%	i	c	i	c	ri	rc	s^2c			ni	nc	i	c	OR	i	c	OR	RR
0.003																																		
	Campbell 2006	2nd or subsequent visit	0		1	71.0	62.5	11	11	781	688	10.5	6.4	89.5	93.6	82	44	699	644	0.003	0.003		1.21	1.18	645	581	578	544	0.583	68	37	1.72	1.641
	Hajek 2001	Birth	0		1	5.9	6.7	92	86	545	575	22.0	20.0	78.0	80.0	120	115	425.1	460	0.003	0.003		1.01	1.017	537.1	565.4	419	452.3	0.886	118	113	1.13	1.1
	Haug 1994		0		1	2	2	125	62	252	98	18.25	8.16	81.75	91.84	46	8	206	90	0.003	0.003		1.00	1.00	251	98	205	90	0.398	46	8	2.51	2.237
	Kendrick 1995	36/40 gest	0		1	27.8	36.8	32	32	888	1177	5.9	6.1	94.1	93.9	52	72	835.6	1105	0.003	0.003		1.08	1.11	822	1063	774	998	1.036	48	65	0.97	0.967
	Lawrence 2003	30 wk gest	0		1	17	8	23	41	324	289	5.6	1.73	94.44	98.27	18	5	306	284	0.003	0.003		1.05	1.02	309	283	292	278	0.299	17	5	3.34	3.211
	Lillington 1995	late preg	0		1	39.5	73.0	2	2	79	146	43.04	24.66	56.96	75.34	34	36	45	110	0.003	0.003		1.12	1.22	71	120	40	90	0.433	30	30	2.31	1.745
	McLeod 2004	36/40 gest	0		1	6.273	4.615	11	13	69	60	20.3	13.3	79.71	86.67	14	8	55	52				1.096	1.100	63	55	50	47	0.604	13	7	1.65	
	McLeod 2004	36/40 gest	0		1	9	7.5	12	8	108	60	17.6	10.0	82.41	90	19	6	89	54				1.075	1.100	100	55	83	49	0.52	18	5	1.92	
	McLeod 2004	36/40 gest	0		1	7.696	5.714	23	21	177	120	18.6	11.7	81.36	88.33	33	14	144	106				*	1.10	163	109	133	96	0.577	30	13	1.73	
	Messimer 1989	32-36 weeks' gest	0		1	10.91	10.36	5.5	5.5	60	57	25.0	14.0	75	85.96	15	8	45	49	0.003	0.003		1.03	1.03	58	55	44	48	0.49	15	8	2.04	1.781
	Moore 2002	24-28/40 gest	0		1	10.59	11.83	64	64	678	757	16.7	19.0	83.33	80.98	113	144	565	613	0.031	0.031		1.30	1.34	523	567	435	459	1.175	87	108	0.85	0.876
	Pbert 2004	36/40 gest	0		1	63.67	100.5	3	2	191	201	20.0	11.0	80.0	89.0	38	22	152.8	178.9	0.003	0.003		1.19	1.30	161	155	129	138	0.493	32	17	2.03	1.822
0.05																																		
	Campbell 2006	2nd or subsequent visit	0		1	71.0	62.5	11	11	781	688	10.5	6.4	89.5	93.6	82	44	699	644	0.050	0.050		4.50	4.08	174	169	155	158	0.583	18	11	1.72	1.641
	Hajek 2001	Birth	0		1	5.9	6.7	92	86	545	575	22.0	20.0	78.0	80.0	120	115	425.1	460	0.050	0.050		1.25	1.284	437.3	447.7	341	358.2	0.886	96	90	1.13	1.1
	Haug 1994		0		1	2	2	125	62	252	98	18.25	8.16	81.75	91.84	46	8	206	90	0.050	0.050		1.05	1.03	240	95	196	87	0.398	44	8	2.51	2.237
	Kendrick 1995	36/40 gest	0		1	27.8	36.8	32	32	888	1177	5.9	6.1	94.1	93.9	52	72	835.6	1105	0.003	0.003		1.08	1.11	822	1063	774	998	1.036	48	65	0.97	0.967
	Lawrence 2003	30 wk gest	0		1	17	8	23	41	324	289	5.6	1.73	94.44	98.27	18	5	306	284	0.003	0.003		1.05	1.02	309	283	292	278	0.299	17	5	3.34	3.211
	Lillington 1995	late preg	0		1	39.5	73.0	2	2	79	146	43.04	24.66	56.96	75.34	34	36	45	110	0.050	0.050		2.93	4.60	27	32	15	24	0.433	12	8	2.31	1.745
	McLeod 2004	36/40 gest	0		1	6.273	4.615	11	13	69	60	20.3	13.3	79.71	86.67	14	8	55	52				1.096	1.100	63	55	50	47	0.604	13	7	1.65	
	McLeod 2004	36/40 gest	0		1	9	7.5	12	8	108	60	17.6	10.0	82.41	90	19	6	89	54				1.075	1.100	100	55	83	49	0.52	18	5	1.92	
	McLeod 2004	36/40 gest	0		1	7.696	5.714	23	21	177	120	18.6	11.7	81.36	88.33	33	14	144	106				*	1.10	163	109	133	96	0.577	30	13	1.73	
	Messimer 1989	32-36 weeks' gest	0		1	10.91	10.36	5.5	5.5	60	57	25.0	14.0	75	85.96	15	8	45	49	0.050	0.050		1.50	1.47	40	39	30	33	0.49	10	5	2.04	1.781
	Moore 2002	24-28/40 gest	0		1	11	12	64	64	678	757	16.7	19.0	83.33	80.98	113	144	565	613	0.031	0.031		1.30	1.34	523	567	435	459	1.175	87	108	0.85	0.876
		36/40 gest	0		1	64	101	3	2	191	201	20.0	11.0	80.0	89.0	38	22	152.8	178.9	0.050	0.050		4.13	5.98	46	34	37	30	0.493	9	4	2.03	1.822
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	Hajek 2001	Birth	0		1	6	7	92	86	545	575	22.0	20.0	78.0	80.0	120	115	425.1	460	0.100	0.100		1.49	1.569	365.2	366.6	285	293.3	0.886	80	73	1.13	1.1
	Haug 1994		0		1	2	2	125	62	252	98	18.25	8.16	81.75	91.84	46	8	206	90	0.100	0.100		1.10	1.06	229	93	187	85	0.398	42	8	2.51	2.237
	Kendrick 1995	36/40 gest	0		1	28	37	32	32	888	1177	5.9	6.1	94.1	93.9	52	72	835.6	1105	0.003	0.003		1.08	1.11	822	1063	774	998	1.036	48	65	0.97	0.967
	Lawrence 2003	30 wk gest	0		1	17	8	23	41	324	289	5.6	1.73	94.44	98.27	18	5	306	284	0.003	0.003		1.05	1.02	309	283	292	278	0.299	17	5	3.34	3.211
	Lillington 1995	late preg	0		1	39.5	73.0	2	2	79	146	43.04	24.66	56.96	75.34	34	36	45	110	0.100	0.100		4.85	8.20	16	18	9	13	0.433	7	4	2.31	1.745
	McLeod 2004	36/40 gest	0		1	6.273	4.615	11	13	69	60	20.3	13.3	79.71	86.67	14	8	55	52				1.096	1.100	63	55	50	47	0.604	13	7	1.65	
	McLeod 2004	36/40 gest	0		1	9	7.5	12	8	108	60	17.6	10.0	82.41	90	19	6	89	54				1.075	1.100	100	55	83	49	0.52	18	5	1.92	

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ICC	Trial ID	Timing	Timing code	Outcome description	Outcome code	Mean cluster size		No. of clusters		Sample size		Ceased smoking %		Continued smoking %		Ceased smoking n		Continued smoking n		ICC		Between cluster var	IF(int)	IF(comp)	Effective sample size, denominator		Effective sample size, continue			Effective sample size, ceased			
						mi	mc	ci	cc	ni	nc	i%	c%	i%	c%	i	c	i	c	ri	rc	s^2c			ni	nc	i	c	OR	i	c	OR	RR
	McLeod 2004	36/40 gest	0		1	7.696	5.714	23	21	177	120	18.6	11.7	81.36	88.33	33	14	144	106				*	1.10	163	109	133	96	0.577	30	13	1.73	
	Messimer 1989	32-36 weeks' gest	0		1	10.91	10.36	5.5	5.5	60	57	25.0	14.0	75	85.96	15	8	45	49	0.100	0.100		1.99	1.94	30	29	23	25	0.49	8	4	2.04	1.781
	Moore 2002	24-28/40 gest	0		1	11	12	64	64	678	757	16.7	19.0	83.33	80.98	113	144	565	613	0.031	0.031		1.30	1.34	523	567	435	459	1.175	87	108	0.85	0.876
	Pbert 2004	36/40 gest	0		1	64	101	3	2	191	201	20.0	11.0	80.0	89.0	38	22	152.8	178.9	0.100	0.100		7.27	10.95	26	18	21	16	0.493	5	2	2.03	1.822
0.2																																		
	Campbell 2006	2nd or subsequent visit	0		1	71	63	11	11	781	688	10.5	6.4	89.5	93.6	82	44	699	644	0.200	0.200		15.00	13.31	52	52	47	48	0.583	5	3	1.72	1.641
	Hajek 2001	Birth	0		1	6	7	92	86	545	575	22.0	20.0	78.0	80.0	120	115	425.1	460	0.200	0.200		1.98	2.137	275	269	214	215	0.886	60	54	1.13	1.1
	Haug 1994		0		1	2	2	125	62	252	98	18.25	8.16	81.75	91.84	46	8	206	90	0.200	0.200		1.20	1.12	210	88	172	81	0.398	38	7	2.51	2.237
	Kendrick 1995	36/40 gest	0		1	28	37	32	32	888	1177	5.9	6.1	94.1	93.9	52	72	835.6	1105	0.003	0.003		1.08	1.11	822	1063	774	998	1.036	48	65	0.97	0.967
	Lawrence 2003	30 wk gest	0		1	17	8	23	41	324	289	5.6	1.73	94.44	98.27	18	5	306	284	0.003	0.003		1.05	1.02	309	283	292	278	0.299	17	5	3.34	3.211
	Lillington 1995	late preg	0		1	39.5	73.0	2	2	79	146	43.04	24.66	56.96	75.34	34	36	45	110	0.200	0.200		8.70	15.40	9	9	5	7	0.433	4	2	2.31	1.745
	McLeod 2004	36/40 gest	0		1	6.273	4.615	11	13	69	60	20.3	13.3	79.71	86.67	14	8	55	52				1.096	1.100	63	55	50	47	0.604	13	7	1.65	
	McLeod 2004	36/40 gest	0		1	9	7.5	12	8	108	60	17.6	10.0	82.41	90	19	6	89	54				1.075	1.100	100	55	83	49	0.52	18	5	1.92	
	McLeod 2004	36/40 gest	0		1	7.696	5.714	23	21	177	120	18.6	11.7	81.36	88.33	33	14	144	106				*	1.10	163	109	133	96	0.577	30	13	1.73	
	Messimer 1989	32-36 weeks' gest	0		1	10.91	10.36	5.5	5.5	60	57	25.0	14.0	75	85.96	15	8	45	49	0.200	0.200		2.98	2.87	20	20	15	17	0.49	5	3	2.04	1.781
	Moore 2002	24-28/40 gest	0		1	11	12	64	64	678	757	16.7	19.0	83.33	80.98	113	144	565	613	0.031	0.031		1.30	1.34	523	567	435	459	1.175	87	108	0.85	0.876
	Pbert 2004	36/40 gest	0		1	64	101	3	2	191	201	20.0	11.0	80.0	89.0	38	22	152.8	178.9	0.200	0.200		13.53	20.90	14	10	11	9	0.493	3	1	2.03	1.822
Key:	Outcome					Data given		Sensitivity analysis				From formula in Merlo											* wt'd ave of IF in 2 intv arms										
	ADDITIONAL OUTCOMES found 21/11/08																																	
	Eades 2012	late preg	0	continued smoking for spontaneous quitters in late pregnancy	2																				24	8	14	6					
	Hajek 2001	late preg	0		2	1.2	1.6	92	86	114	135	22.0	20.0	64.9	53.3	40	63	74	72	0.003	0.003		1.00	1.002	113.9	134.8	74	71.88	1.619	40	63	0.62	0.752
	Lillington 1995	late preg	0		2	38	127.0	2	2	76	254	5.263	10.63	94.74	89.37	4	27	72	227	0.003	0.003		1.11	1.38	68	184	65	165	2.141	4	20	0.47	0.495
	Pbert 2004	late preg	0		2	27	39	3	2	81	77	70.4	77.9	29.6	22.1	57	60	24	17	0.003	0.003		1.08	1.11	75	69	22	15	1.486	53	54	0.67	0.903
	Polanska 2004	late preg	0		2	5.6	7.4	10	5	56	37	100	100	0	0	56	37	0	0	0.003	0.003		1.01	1.02	55	36	0	0	#####	55	36	#DIV/0!	1
	Haug 1994	0-5 mo pp	1	maintained cessation at 0-5 mo pp	1	2	2	125	62	252	98	18.25	8.16	81.75	91.84	46	8	206	90	0.003	0.003		1.00	1.00	251	98	205	90	0.398	46	8	2.51	2.237
	Lawrence 2003	10 days pp	1	10 days pp	1	17	8	23	41	324	289	8.0	3.5	92.0	96.5	26	10	298	279	0.003	0.003		1.05	1.02	309	283	284	273	0.411	25	10	2.43	
	Lillington 1995	0-5 mo pp	1	maintained cessation at 0-5 mo pp	1	39.5	73.0	2	2	79	146	25.32	11.64	74.68	88.36	20	17	59	129	0.003	0.003		1.12	1.22	71	120	53	106	0.389	18	14	2.57	2.174
	McLeod 2004	4/12pp	1		1	8	6	23	21	177	120	15.8	10.8	84.2	89.2	28	13	149	107	0.003	0.003		1.02	1.01	174	118	146	106	0.647	27	13	1.55	
	Messimer 1989	0-5 mo pp	1		1	10.91	10.36	5.5	5.5	60	57	8.3	10.5	91.67	89.47	5	6	55	51	0.003	0.003		1.03	1.03	58	55	53	50	1.294	5	6	0.77	0.792
	Pbert 2004	0-5 mo pp	1		1	64	101	3	2	191	201	4.2	3.0	95.8	97.0	8	6	183	195	0.003	0.003		1.19	1.30	161	155	154	150	0.704	7	5	1.42	1.403
	Polanska 2004	0-5 mo pp	1		1	14.9	28.8	10	5	149	144	44.3	16.7	55.7	83.3	66	24	82.99	120	0.003	0.003		1.04	1.08	143	133	80	111	0.252	63	22	3.97	2.653
	Hajek 2001	6 mo pp	2	maintained cessation at 6-11 mo pp	1	4.7	5.1	92	86	431	440	22.0	20.0	97.0	97.0	13	13	418	427	0.003	0.003		1.01	1.012	426.3	434.6	413	421.8	0.979	13	13	1.02	1.021
	Haug 1994	6-11 mo pp	2		1	2	2	125	62	252	98	18.25	8.16	84.52	88.78	39	11	213	87	0.003	0.003		1.00	1.00	251	98	212	87	0.691	39	11	1.45	1.379
	Pbert 2004	6-11 mo pp	2		1	64	101	3	2	191	201	4.7	2.5	95.3	97.5	9	5	182	196	0.003	0.003		1.19	1.30	161	155	153	151	0.516	8	4	1.94	1.894
	Haug 1994	12-17 mo pp	3	maintained cessation at 12-17 mo pp	1	2	2	125	62	252	98	18.25	8.16	85.32	92.86	37	7	215	91	0.003	0.003		1.00	1.00	251	98	214	91	0.447	37	7	2.24	2.056
	Polanska 2004	12-17 mo pp	3		1	20.5	36.2	10	5	205	181	31.7	12.7	68.29	87.29	65	23	140	158	0.003	0.003		1.06	1.11	194	164	132	143	0.314	61	21	3.19	2.495
	Lawrence 2003	18 mo pp	4	18 mo pp	1	17	8	23	41	324	289	4.6	2.4	95.4	97.6	15	7	309	282	0.003	0.003		1.05	1.02	309	283	295	276	0.511	14	7	1.96	
0.05																																		

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ICC	Trial ID	Timing	Timing code	Outcome description	Outcome code	Mean cluster size		No. of clusters		Sample size		Ceased smoking %		Continued smoking %		Ceased smoking n		Continued smoking n		ICC		Between cluster var	IF(int)	IF(comp)	Effective sample size, denominator		Effective sample size, continue			Effective sample size, ceased			
						mi	mc	ci	cc	ni	nc	i%	c%	i%	c%	i	c	i	c	ri	rc	s^2c			ni	nc	i	c	OR	i	c	OR	RR
	Eades 2012	late preg	0	continued smoking for spontaneous quitters in late pregnancy	2																				24	8	14	6					
	Hajek 2001	late preg	0		2	1.2	1.6	92	86	114	135	22.0	20.0	64.9	53.3	40	63	74	72	0.050	0.050		1.01	1.028	112.7	131.3	73	70.01	1.619	40	61	0.62	0.752
	Lillington 1995	late preg	0		2	38	127.0	2	2	76	254	5.263	10.63	94.74	89.37	4	27	72	227	0.050	0.050		2.85	7.30	27	35	25	31	2.141	1	4	0.47	0.495
	Pbert 2004	late preg	0		2	27	39	3	2	81	77	70.4	77.9	29.6	22.1	57	60	24	17	0.050	0.050		2.30	2.88	35	27	10	6	1.486	25	21	0.67	0.903
	Polanska 2004	late preg	0		2	5.6	7.4	10	5	56	37	100	100	0	0	56	37	0	0	0.050	0.050		1.23	1.32	46	28	0	0	#####	46	28	#DIV/0!	1
	Haug 1994	0-5 mo pp	1	maintained cessation at 0-5 mo pp	1	2	2	125	62	252	98	18.25	8.16	81.75	91.84	46	8	206	90	0.050	0.050		1.05	1.03	240	95	196	87	0.398	44	8	2.51	2.237
	Lawrence 2003	10 days pp	1	10 days pp	1	17	8	23	41	324	289	8.0	3.5	92.0	96.5	26	10	298	279	0.003	0.003		1.05	1.02	309	283	284	273	0.411	25	10	2.43	
	Lillington 1995	0-5 mo pp	1	maintained cessation at 0-5 mo pp	1	39.5	73.0	2	2	79	146	25.32	11.64	74.68	88.36	20	17	59	129	0.050	0.050		2.93	4.60	27	32	20	28	0.389	7	4	2.57	2.174
	McLeod 2004	4/12pp	1		1	8	6	23	21	177	120	15.8	10.8	84.2	89.2	28	13	149	107	0.050	0.050		1.33	1.24	133	97	112	87	0.647	21	11	1.55	
	Messimer 1989	0-5 mo pp	1		1	10.91	10.36	5.5	5.5	60	57	8.3	10.5	91.67	89.47	5	6	55	51	0.050	0.050		1.50	1.47	40	39	37	35	1.294	3	4	0.77	0.792
	Pbert 2004	0-5 mo pp	1		1	64	101	3	2	191	201	4.2	3.0	95.8	97.0	8	6	183	195	0.050	0.050		4.13	5.98	46	34	44	33	0.704	2	1	1.42	1.403
	Polanska 2004	0-5 mo pp	1		1	15	29	10	5	149	144	44.3	16.7	55.7	83.3	66	24	82.99	120	0.050	0.050		1.70	2.39	88	60	49	50	0.252	39	10	3.97	2.653
	Hajek 2001	6 mo pp	2	maintained cessation at 6-11 mo pp	1	4.7	5.1	92	86	431	440	22.0	20.0	97.0	97.0	13	13	418	427	0.050	0.050		1.18	1.206	363.9	364.9	353	354.1	0.979	11	11	1.02	1.021
	Haug 1994	6-11 mo pp	2		1	2	2	125	62	252	98	18.25	8.16	84.52	88.78	39	11	213	87	0.050	0.050		1.05	1.03	240	95	203	85	0.691	37	11	1.45	1.379
	Pbert 2004	6-11 mo pp	2		1	64	101	3	2	191	201	4.7	2.5	95.3	97.5	9	5	182	196	0.050	0.050		4.13	5.98	46	34	44	33	0.516	2	1	1.94	1.894
	Haug 1994	12-17 mo pp	3	maintained cessation at 12-17 mo pp	1	2	2	125	62	252	98	18.25	8.16	85.32	92.86	37	7	215	91	0.050	0.050		1.05	1.03	240	95	205	88	0.447	35	7	2.24	2.056
	Polanska 2004	12-17 mo pp	3		1	20.5	36.2	10	5	205	181	31.7	12.7	68.29	87.29	65	23	140	158	0.050	0.050		1.98	2.76	104	66	71	57	0.314	33	8	3.19	2.495
	Lawrence 2003	18 mo pp	4	18 mo pp	1	17	8	23	41	324	289	4.6	2.4	95.4	97.6	15	7	309	282	0.003	0.003		1.05	1.02	309	283	295	276	0.511	14	7	1.96	
0.1																																	
	Eades 2012	late preg	0	continued smoking for spontaneous quitters in late pregnancy	2																				24	8	14	6					
	Hajek 2001	late preg	0		2	1.2	1.6	92	86	114	135	22.0	20.0	64.9	53.3	40	63	74	72	0.100	0.100		1.02	1.057	111.3	127.7	72	68.12	1.619	39	60	0.62	0.752
	Lillington 1995	late preg	0		2	38	127.0	2	2	76	254	5.263	10.63	94.74	89.37	4	27	72	227	0.100	0.100		4.70	13.60	16	19	15	17	2.141	1	2	0.47	0.495
	Pbert 2004	late preg	0		2	27	39	3	2	81	77	70.4	77.9	29.6	22.1	57	60	24	17	0.100	0.100		3.60	4.75	23	16	7	4	1.486	16	13	0.67	0.903
	Polanska 2004	late preg	0		2	5.6	7.4	10	5	56	37	100	100	0	0	56	37	0	0	0.100	0.100		1.46	1.64	38	23	0	0	#####	38	23	#DIV/0!	1
	Haug 1994	0-5 mo pp	1	maintained cessation at 0-5 mo pp	1	2	2	125	62	252	98	18.25	8.16	81.75	91.84	46	8	206	90	0.100	0.100		1.10	1.06	229	93	187	85	0.398	42	8	2.51	2.237
	Lawrence 2003	10 days pp	1	10 days pp	1	17	8	23	41	324	289	8.0	3.5	92.0	96.5	26	10	298	279	0.003	0.003		1.05	1.02	309	283	284	273	0.411	25	10	2.43	
	Lillington 1995	0-5 mo pp	1	maintained cessation at 0-5 mo pp	1	39.5	73.0	2	2	79	146	25.32	11.64	74.68	88.36	20	17	59	129	0.100	0.100		4.85	8.20	16	18	12	16	0.389	4	2	2.57	2.174
	McLeod 2004	4/12pp	1		1	8	6	23	21	177	120	15.8	10.8	84.2	89.2	28	13	149	107	0.100	0.100		1.67	1.47	106	82	89	73	0.647	17	9	1.55	
	Messimer 1989	0-5 mo pp	1		1	10.91	10.36	5.5	5.5	60	57	8.3	10.5	91.67	89.47	5	6	55	51	0.100	0.100		1.99	1.94	30	29	28	26	1.294	3	3	0.77	0.792
	Pbert 2004	0-5 mo pp	1		1	64	101	3	2	191	201	4.2	3.0	95.8	97.0	8	6	183	195	0.100	0.100		7.27	10.95	26	18	25	18	0.704	1	1	1.42	1.403
	Polanska 2004	0-5 mo pp	1		1	15	29	10	5	149	144	44.3	16.7	55.7	83.3	66	24	82.99	120	0.100	0.100		2.39	3.78	62	38	35	32	0.252	28	6	3.97	2.653
	Hajek 2001	6 mo pp	2	maintained cessation at 6-11 mo pp	1	4.7	5.1	92	86	431	440	22.0	20.0	97.0	97.0	13	13	418	427	0.100	0.100		1.37	1.412	314.9	311.7	305	302.5	0.979	9	9	1.02	1.021
	Haug 1994	6-11 mo pp	2		1	2	2	125	62	252	98	18.25	8.16	84.52	88.78	39	11	213	87	0.100	0.100		1.10	1.06	229	93	194	82	0.691	35	10	1.45	1.379
	Pbert 2004	6-11 mo pp	2		1	64	101	3	2	191	201	4.7	2.5	95.3	97.5	9	5	182	196	0.100	0.100		7.27	10.95	26	18	25	18	0.516	1	0	1.94	1.894
	Haug 1994	12-17 mo pp	3	maintained cessation at 12-17 mo pp	1	2	2	125	62	252	98	18.25	8.16	85.32	92.86	37	7	215	91	0.100	0.100		1.10	1.06	229	93	195	86	0.447	34	7	2.24	2.056
	Polanska 2004	12-17 mo pp	3		1	20.5	36.2	10	5	205	181	31.7	12.7	68.29	87.29	65	23	140	158	0.100	0.100		2.95	4.52	69	40	47	35	0.314	22	5	3.19	2.495
	Lawrence 2003	18 mo pp	4	18 mo pp	1	17	8	23	41	324	289	4.6	2.4	95.4	97.6	15	7	309	282	0.003	0.003		1.05	1.02	309	283	295	276	0.511	14	7	1.96	
0.2																																	
	Eades 2012	late preg	0	continued smoking for spontaneous quitters in late pregnancy	2																				24	8	14	6					

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ICC	Trial ID	Timing	Timing code	Outcome description	Outcome code	Mean cluster size		No. of clusters		Sample size		Ceased smoking %		Continued smoking %		Ceased smoking n		Continued smoking n		ICC		Between cluster var	IF(int)	IF(comp)	Effective sample size, denominator		Effective sample size, continue			Effective sample size, ceased			
						mi	mc	ci	cc	ni	nc	i%	c%	i%	c%	i	c	i	c	ri	rc	s^2c			ni	nc	i	c	OR	i	c	OR	RR
	Hajek 2001	late preg	0		2	1.2	1.6	92	86	114	135	22.0	20.0	64.9	53.3	40	63	74	72	0.200	0.200		1.05	1.114	108.8	121.2	71	64.63	1.619	38	57	0.62	0.752
	Lillington 1995	late preg	0		2	38	127.0	2	2	76	254	5.263	10.63	94.74	89.37	4	27	72	227	0.200	0.200		8.40	26.20	9	10	9	9	2.141	0	1	0.47	0.495
	Pbert 2004	late preg	0		2	27	39	3	2	81	77	70.4	77.9	29.6	22.1	57	60	24	17	0.200	0.200		6.20	8.50	13	9	4	2	1.486	9	7	0.67	0.903
	Polanska 2004	late preg	0		2	5.6	7.4	10	5	56	37	100	100	0	0	56	37	0	0	0.200	0.200		1.92	2.28	29	16	0	0	#####	29	16	#DIV/0!	1
	Haug 1994	0-5 mo pp	1	maintained cessation at 0-5 mo pp	1	2	2	125	62	252	98	18.25	8.16	81.75	91.84	46	8	206	90	0.200	0.200		1.20	1.12	210	88	172	81	0.398	38	7	2.51	2.237
	Lawrence 2003	10 days pp	1	10 days pp	1	17	8	23	41	324	289	8.0	3.5	92.0	96.5	26	10	298	279	0.003	0.003		1.05	1.02	309	283	284	273	0.411	25	10	2.43	
	Lillington 1995	0-5 mo pp	1	maintained cessation at 0-5 mo pp	1	39.5	73.0	2	2	79	146	25.32	11.64	74.68	88.36	20	17	59	129	0.200	0.200		8.70	15.40	9	9	7	8	0.389	2	1	2.57	2.174
	McLeod 2004	4/12pp	1		1	8	6	23	21	177	120	15.8	10.8	84.2	89.2	28	13	149	107	0.200	0.200		2.34	1.94	76	62	64	55	0.647	12	7	1.55	
	Messimer 1989	0-5 mo pp	1		1	10.91	10.36	5.5	5.5	60	57	8.3	10.5	91.67	89.47	5	6	55	51	0.200	0.200		2.98	2.87	20	20	18	18	1.294	2	2	0.77	0.792
	Pbert 2004	0-5 mo pp	1		1	64	101	3	2	191	201	4.2	3.0	95.8	97.0	8	6	183	195	0.200	0.200		13.53	20.90	14	10	14	9	0.704	1	0	1.42	1.403
	Polanska 2004	0-5 mo pp	1		1	15	29	10	5	149	144	44.3	16.7	55.7	83.3	66	24	82.99	120	0.200	0.200		3.78	6.56	39	22	22	18	0.252	17	4	3.97	2.653
	Hajek 2001	6 mo pp	2	maintained cessation at 6-11 mo pp	1	4.7	5.1	92	86	431	440	22.0	20.0	97.0	97.0	13	13	418	427	0.200	0.200		1.74	1.823	248.1	241.3	241	234.2	0.979	7	7	1.02	1.021
	Haug 1994	6-11 mo pp	2		1	2	2	125	62	252	98	18.25	8.16	84.52	88.78	39	11	213	87	0.200	0.200		1.20	1.12	210	88	178	78	0.691	33	10	1.45	1.379
	Pbert 2004	6-11 mo pp	2		1	64	101	3	2	191	201	4.7	2.5	95.3	97.5	9	5	182	196	0.200	0.200		13.53	20.90	14	10	13	9	0.516	1	0	1.94	1.894
	Haug 1994	12-17 mo pp	3	maintained cessation at 12-17 mo pp	1	2	2	125	62	252	98	18.25	8.16	85.32	92.86	37	7	215	91	0.200	0.200		1.20	1.12	210	88	179	82	0.447	31	6	2.24	2.056
	Polanska 2004	12-17 mo pp	3		1	20.5	36.2	10	5	205	181	31.7	12.7	68.29	87.29	65	23	140	158	0.200	0.200		4.90	8.04	42	23	29	20	0.314	13	3	3.19	2.495
	Lawrence 2003	18 mo pp	4	18 mo pp	1	17	8	23	41	324	289	4.6	2.4	95.4	97.6	15	7	309	282	0.003	0.003		1.05	1.02	309	283	295	276	0.511	14	7	1.96	
Key:	Outcome					Data given		Sensitivity analysis				From formula in Merlo																					

Timing codes:
0. Late pregnancy
1. 0-5 mo pp
2. 6-11 mo pp
3. 12-17 mo pp
4. 18 mo pp
Outcome codes:
1. abstinence
2. relapse prevention for spontaneous quitters