DOI: 10.1111/j.1471-0528.2011.03065.x
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Systematic review

# The effect of smoking cessation counselling in pregnant women: a meta-analysis of randomised controlled trials

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*Accepted 26 May 2011. Published Online 22 August 2011.*

**Background** Pregnant smokers are often prescribed counselling as part of multicomponent cessation interventions. However, the isolated effect of counselling in this population remains unclear, and individual randomised controlled trials (RCTs) are inconclusive.

**Objective** To conduct a meta-analysis of RCTs examining counselling in pregnant smokers.

**Search strategy** We searched the CDC Tobacco Information and Prevention, Cochrane Library, EMBASE, Medline and PsycINFO databases for RCTs evaluating smoking cessation counselling.

**Selection criteria** We included RCTs conducted in pregnant women in which the effect of counselling could be isolated and those that reported biochemically validated abstinence at 6 or 12 months after the target quit date.

**Data collection and analysis** Overall estimates were derived using random effects meta-analysis models.

**Main results** Our search identified eight RCTs ($n$ = 3290 women), all of which examined abstinence at 6 months. The proportion of women that remained abstinent at the end of follow up was modest, ranging from 4 to 24% among those randomised to counselling and from 2 to 21% among control women. The absolute difference in abstinence reached a maximum of only 4%. Summary estimates are inconclusive because of wide confidence intervals, albeit with little evidence to suggest that counselling is efficacious at promoting abstinence (odds ratio 1.08, 95% confidence interval 0.84–1.40). There was no evidence to suggest that efficacy differed by counselling type.

**Conclusions** Available data from RCTs examining the isolated effect of smoking cessation counselling in pregnant women are limited but sufficient to rule out large treatment effects. Future RCTs should examine pharmacological therapies in this population.

**Keywords** Counselling, meta-analysis, pregnancy, smoking cessation.

*Please cite this paper as:* Filion K, Abenhaim H, Mottillo S, Joseph L, Gervais A, O'Loughlin J, Paradis G, Pihl R, Pilote L, Rinfret S, Tremblay M, Eisenberg M. The effect of smoking cessation counselling in pregnant women: a meta-analysis of randomised controlled trials. BJOG 2011;118:1422–1428.

## Introduction

The effects of cigarette smoking during pregnancy on obstetrical and neonatal outcomes are substantial and include an increased risk of early and late pregnancy loss, intrauterine growth restriction, placental abruption and prematurity.[1–4] With increased public awareness of these risks and the benefits of smoking cessation, the prevalence of smoking during pregnancy has decreased.[5–7] Nevertheless, a substantial proportion of pregnant women continue to smoke. An estimated 13.8% of US women smoked during pregnancy in 2005.[7] Uncertainty regarding the safety

of pharmacological smoking cessation interventions in pregnant women has led to most interventions focusing on behavioural approaches such as counselling. The US Department of Health and Human Services' *Treating Tobacco Use and Dependence Clinical Practice Guideline* recommends the use of psychosocial interventions (including counselling) for pregnant women who smoke.[8,9] However, this recommendation is based on their meta-analysis of randomiased controlled trials (RCTs) that included counselling as part of multicomponent interventions and, with scarce resources, there is a need to examine the individual components of such interventions to maximise their cost-effectiveness.[10] RCTs that attempted to isolate the effect of counselling on smoking abstinence in pregnant women were of limited sample size resulting in imprecise estimates of its efficacy. We therefore conducted a meta-analysis of RCTs that examined the effect of smoking cessation counselling, including minimal clinical intervention, individual counselling, group counselling and telephone counselling, among pregnant women to estimate its efficacy in this population.

## Methods

This meta-analysis was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[11]

### Data sources

The methods used in this meta-analysis are similar to those of a previous meta-analysis.[12] Briefly, we systematically searched the CDC Tobacco Information and Prevention Library, Cochrane Library, EMBASE, Medline and PsycINFO databases from inception to June 2010 to identify all trials examining the efficacy of smoking cessation counselling among pregnant smokers. The following keywords were used: cognitive therapy, counselling, behavioural therapy, dentist, general practitioner, group counselling, group therapy, individual counselling, nurse, physician and telephone counselling. We also searched the references of published RCTs, relevant reviews and previous meta-analyses to identify additional RCTs not found in our electronic search.

### Study selection

The RCTs were included if: (i) the study population comprised pregnant smokers; (ii) they investigated the efficacy of smoking cessation counselling, including minimal clinical intervention, individual counselling, group counselling or telephone counselling; (iii) biochemically validated point prevalence or continuous smoking abstinence at 6 or 12 months follow up were reported; and (iv) they were published in English. Minimal clinical intervention was defined as brief advice to 'stop smoking' delivered in <20 minutes by a physician or nurse not trained in smoking cessation, during a single routine consultation.[13] Individual counselling consisted of one or more face-to-face encounters of 15 minutes or more between a smoker and a trained smoking cessation counsellor not involved in the smoker's routine clinical care. Group counselling consisted of at least two counselling meetings in which at least two smokers were present. Finally, telephone counselling consisted of telephone calls to help in smoking cessation. These telephone calls could be proactive (i.e. initiated by the counsellor) or reactive (i.e. initiated by the smoker).

Trials were excluded if they randomised physicians, therapists, or centres rather than women because of the clustered nature of these data. We also excluded RCTs that examined self-help or educational interventions other than counselling (e.g. reading educational pamphlets, watching a video) as these interventions were judged to be inherently different from counselling. In addition, we excluded RCTs that did not include a usual care control group. For RCTs of minimal clinical intervention, usual care was defined as no intervention or self-help material only and for RCTs of individual, group or telephone counselling, usual care consisted of minimal clinical intervention with or without self-help material. Finally, we excluded RCTs that included multicomponent interventions (including two or more types of counselling) or that had co-interventions if the co-intervention was not used in both treatment groups.

### Data extraction

Data extraction was carried out by two independent reviewers. For each RCT, reviewers extracted information on study design, country where the RCT was conducted, demographic and clinical characteristics of the study populations, counselling session duration and type of counselling, duration of treatment, duration of follow up, fetal gestational age at follow up and smoking abstinence outcomes. Disagreements were resolved by consensus or, when necessary, by a third reviewer.

### Outcome classification

We extracted the 'most rigorous criterion' of abstinence reported for each RCT.[14] The most rigorous criterion was defined as the most conservative outcome of smoking abstinence reported for any given RCT. Starting from the most conservative outcome, the criteria of abstinence reported were (i) continuous abstinence at 12 months, (ii) continuous abstinence at 6 months, (iii) point prevalence at 12 months, and (iv) point prevalence at 6 months. We defined continuous abstinence conservatively as no smoking from the initial target quit date until the end of follow up. We defined point prevalence abstinence as no smoking during a given time period (usually 7 days) immediately before follow up. Both continuous abstinence

and point prevalence measures were biochemically validated using biological measures such as expired carbon monoxide level or salivary cotinine. Abstinence data were extracted according to an intention-to-treat analysis. However, we excluded women who withdrew before follow up from the analysis ($n = 232$). Women who withdrew typically did so because of pregnancy loss, though a small number did so because they moved before follow up. In addition, randomised women who were 'lost-to-follow-up' were considered to have returned to smoking.

### Statistical analyses

Overall estimates were derived across all RCTs using a meta-analytic random effects model, with treatment effects summarised using odds ratios (OR) with corresponding 95% confidence intervals (95% CI). This model included a parameter for the between-study variability in ORs, which could arise from differences in study population, trial methodology, interventions used and setting. Between-study heterogeneity was estimated using the $I^2$ statistic. In addition, we stratified by type of counselling and, in sensitivity analyses, we excluded RCTs that reported postpartum smoking abstinence. All analyses were conducted using MIX 1.7.[15,16]

## Results

### Literature search

Our literature search identified 515 potentially relevant RCTs (Figure 1). These include 62 RCTs that reported 6- or 12-month biochemically validated smoking abstinence outcomes, eight of which were conducted in pregnant women. These eight RCTs were included in the present meta-analysis.

### Study characteristics

The eight RCTs[17–24] randomised a total of 3290 women (Table 1). Four were multicentre RCTs. The majority of RCTs were conducted in the USA; two were conducted in the UK. Most RCTs examined pregnant women from the general population, with one restricted to pregnant women of low socio-economic status and one restricted to pregnant Hispanic women. The sample sizes of individual RCTs ranged from 100 to 762 women. Six RCTs examined the efficacy of individual, face-to-face counselling, and two RCTs investigated that of telephone counselling. The number of counselling sessions ranged from three to nine, and the total duration of counselling varied from 180 to 600 minutes. Only one RCT reported treatment duration.[19] All RCTs reported abstinence at 6 months of follow up (Table 2), and follow up ranged from 28 weeks of gestation to 6 weeks postpartum.

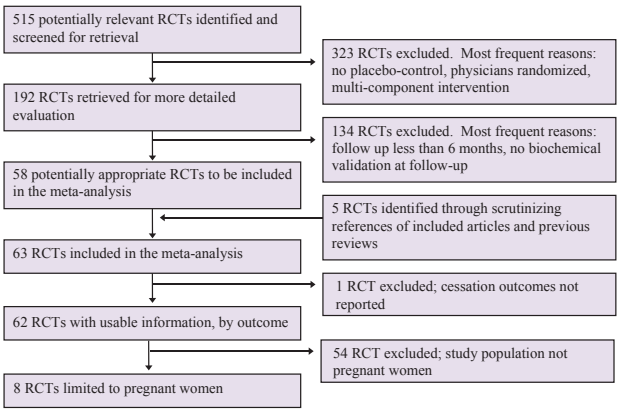


**Figure 1.** Flow diagram describing systematic literature search.

### Smoking cessation

The proportion of pregnant women who remained abstinent at the end of follow up was modest, ranging from 4 to 24% among those randomised to counselling and from 2 to 21% among those randomised to control (Table 2). The absolute difference in smoking abstinence between the intervention and control groups at the end of follow up was 4% or less in all RCTs. When data were analysed across all RCTs, the effect of smoking cessation counselling among pregnant women was inconclusive because of the wide 95% CI (OR 1.08, 95% CI 0.84–1.40; $I^2$ 0%) (Figure 2), although large treatment effects were ruled out. Similar results were obtained when analyses were restricted to individual counselling (OR 1.12, 95% CI 0.81–1.56; $I^2$ 0%) and telephone counselling (OR 1.03, 95% CI 0.68–1.55; $I^2$ 0%).

In a sensitivity analysis, we excluded RCTs that assessed smoking abstinence during the postpartum period. The results of this analysis were consistent with those of our primary analysis (OR 1.17, 95% CI 0.87–1.57; $I^2$ 0%).

## Discussion

Our study was designed to estimate the efficacy of smoking cessation counselling among pregnant women. We found that few RCTs, all of limited size, have isolated the effect of counselling on biochemically validated smoking abstinence in this population of women. Consequently, our summary estimates are inconclusive because of the wide 95% CIs. However, our meta-analysis has ruled out large treatment effects and suggests that there is little evidence to indicate that counselling in isolation is efficacious for smoking cessation in pregnant women. Large, multicentre RCTs would be required to conclusively address this issue but, with large effects ruled out, such RCTs would probably not represent an optimal use of scarce resources. Future RCTs should therefore examine alternative smoking cessation interventions, including pharmacotherapies.

**Table 1.** Baseline characteristics of RCTs investigating counselling in pregnant smokers

| Study | Sample size | Population | Design | Country | Mean CPD | Treatment characteristics | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | Type of counselling | No. of sessions | Mean total session duration (minutes) |
| Tappin[20] | 762 | Pregnant women | MC | UK | 28 | Individual | 6 | 180 |
| Secker-Walker[18] | 561 | Pregnant women | SC | USA | 25 | Individual | 3 | NR |
| Rigotti[23] | 421 | Pregnant women | MC | USA | 21 | Telephone | NR | NR |
| Secker-Walker[19] | 399 | Pregnant women | SC | USA | 25 | Individual | 5 | NR |
| Bullock[24]* | 349 | Pregnant women of low SE status | MC | USA | NR | Telephone | NR | NR |
| Bullock[24]** | 346 | Pregnant women of low SE status | MC | USA | NR | Telephone | NR | NR |
| Ruger[22] | 210 | Pregnant women | MC | USA | NR | Individual | 3 | NR |
| Malchodi[17] | 142 | Pregnant Hispanic women | SC | USA | 12 | Individual | 8 | 360 |
| Tappin[21] | 100 | Pregnant women | SC | UK | 19 | Individual | 9 | 600 |

CPD, cigarettes per day; MC, multicentre; NR, not reported; SC, single centre; SE, socio-economic.
*Social support plus self-help booklets.
**Social support alone.

**Table 2.** Smoking cessation outcomes in RCTs investigating counselling in pregnant smokers

| Study | Type of counselling | Sample size* | Most rigorous outcome reported | | | Smoking abstinence (%) | |
|---|---|---|---|---|---|---|---|
| | | | Follow-up (months) | Gestational age of fetus at follow up (weeks) | Abstinence classification | Active | Control |
| Tappin[20] | Individual | 743 | 6 | 37 | Point prevalence | 5 | 5 |
| Secker-Walker[18] | Individual | 513 | 6 | 36 | Point prevalence | 11 | 10 |
| Rigotti[23] | Telephone | 421 | 6 | 28** | Point prevalence | 10 | 8 |
| Secker-Walker[19] | Individual | 399 | 6 | 36 | Continuous abstinence | 6 | 2 |
| Bullock[24]*** | Telephone | 270 | 6 | 6**** | Point prevalence | 12 | 14 |
| Bullock[24]***** | Telephone | 260 | 6 | 6**** | Point prevalence | 11 | 13 |
| Ruger[22] | Individual | 210 | 6 | 28** | Point prevalence | 7 | 8 |
| Malchodi[17] | Individual | 142 | 6 | 36 | Point prevalence | 24 | 21 |
| Tappin[21] | Individual | 100 | 6 | 36 | Point prevalence | 4 | 8 |

*The number of women included here may differ from the number included in Table 1 because of the exclusion of women who withdrew from the study (e.g. loss of pregnancy, moving). Women lost-to-follow-up were considered to have returned to smoking.
**Gestational age ranged from 28 weeks to term.
***Social support plus self-help booklets.
****Six weeks postpartum.
*****Social support alone.

In 2005, the American College of Obstetrics and Gynecology recommended that pregnant women who are light to moderate smokers undergo a short counselling session with pregnancy-specific educational materials.[25] More recently, the 2008 Update of the *Treating Tobacco Use and Dependence Clinical Practice Guidelines* recommended the use of psychosocial interventions (including counselling) based on a meta-analysis of eight RCTs of pregnant women.[9] In this meta-analysis, the authors found that such interventions increased abstinence from 7.6 to 13.3% (OR 1.8, 95% CI 1.4–2.3). Many of these RCTs evaluated the use of multicomponent interventions (e.g. interventions that included counselling and educational material not provided to the control group, psychosocial programmes that

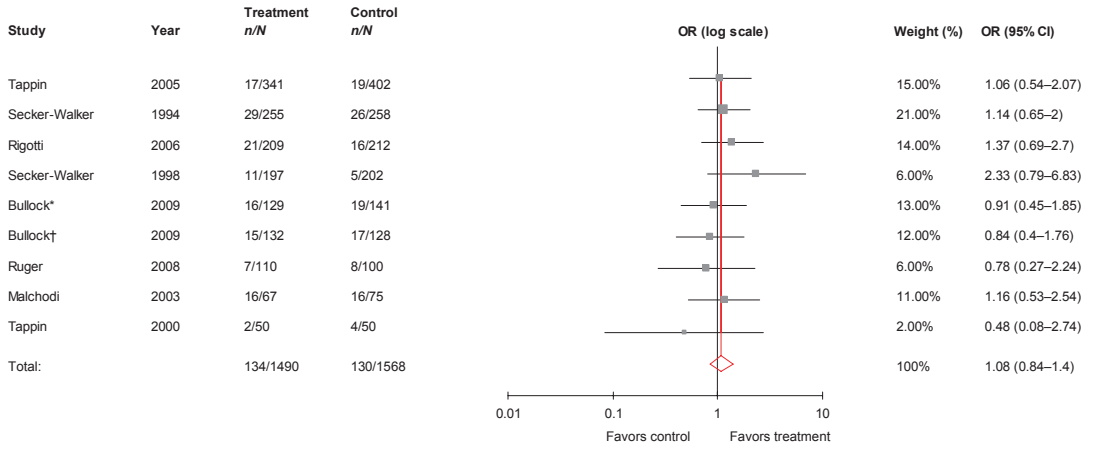


**Figure 2.** Forest plot describing the isolated effect of counselling on the odds of smoking abstinence among pregnant smokers. Smoking abstinence was defined using the most rigorous criteria reported in individual trials, and data were pooled using a random-effects model. *Social support plus self-help booklets. †Social support alone.

combined at least two types of counselling); such trials were excluded from the present study because its objective was to estimate the isolated effect of counselling. We also included two subsequently published trials (with three treatment arms) that showed no treatment benefit.

Even at the upper limit of our estimated treatment effects, counselling appears to be less efficacious in pregnant women than in the general population[12] and less efficacious than pharmacotherapies in the general population.[26] The reason for the lower efficacy in pregnant women remains unclear. Many women quit smoking spontaneously upon learning that they are pregnant; these women are typically lighter smokers before pregnancy than those who continue to smoke.[27] Consequently, those who use counselling probably have higher nicotine dependence levels. In addition, pregnant women concerned with postcessation weight gain are less likely to quit.[28] Concerns about weight gain also affect motivation to remain abstinent during the postpartum period.[29] Finally, a recent systematic review of qualitative studies found that pregnant women have negative perceptions of cessation services provided by health professionals.[30]

Available data suggest that the use of nicotine replacement therapies (NRTs) is less harmful than continued smoking.[9,31,32] However, NRTs remain contraindicated during pregnancy in most countries. One exception to this is the UK, where the cautious use of NRTs is recommended in pregnant women following a detailed discussion of the risks and benefits with their healthcare provider.[33] Given the known harms of smoking while pregnant, the use of NRTs when counselling is not successful may represent an attractive strategy to achieve and maintain abstinence.[34,35] However, completed trials to date have provided conflicting safety data regarding NRT use during pregnancy. In an RCT by Pollak et al.,[36] a two-fold increase in the incidence of serious adverse events among those randomised to NRT resulted in the early termination of enrolment. In another RCT, Oncken et al.[37] found that randomisation to NRT resulted in increased birthweight and duration of gestation. These conflicting results highlight the need for additional RCTs examining the efficacy and safety of NRTs in pregnant women. In addition to large RCTs that are adequately powered to assess safety, surveillance of obstetric and neonatal outcomes via registries is required because of the rare but serious nature of many adverse outcomes.

The safety concerns regarding the use of pharmacotherapies in pregnant women highlight some of the potential benefits of introducing smoking cessation interventions in the preconception period. In 2005, 21.5% of pregnant women participating in the population-based Pregnancy Risk Assessment Monitoring System (PRAMS) smoked before pregnancy.[7] In women who plan their pregnancies, preconception intervention with drugs (usually more effective than behavioural therapies[12,26]) is safe. Despite the potential benefits of preconception interventions, a 2001/2 survey of Canadian obstetrician–gynaecologists and family physicians found that less than half discussed the risks of smoking during pregnancy with women of childbearing age who were not pregnant.[38]

The use of smoking cessation interventions in pregnant women has been examined in previous systematic reviews and meta-analyses.[9,39–42] However, many of these previous reports had important limitations such as the inclusion of quasi-experimental designs,[42] outdated literature searches[40–42] and the inclusion of studies that did not biochemically validate smoking abstinence.[39,40,42] The inclusion of RCTs that did not biochemically validate abstinence is particularly problematic because women not only under-report

smoking relapses but this under-reporting occurs differentially between treatment groups.[43] We found that counselling resulted in smaller benefits than reported in previous meta-analyses, although our estimates have slightly wider CIs. These differences are probably a result of our stricter inclusion criteria.

Our study does have some potential limitations. First, inclusion was restricted to published RCTs. Consequently, our meta-analysis may be affected by publication bias, a limitation inherent to almost all meta-analyses. Second, heterogeneity was present among types of counselling examined and study designs; data were therefore analysed using a random-effects model, which accounts for both within-study and between-study variability, and type-specific secondary analyses were conducted. As a result of the limited number of included RCTs, our type-specific analyses lacked sufficient precision to provide meaningful estimates. The small number of RCTs also prevented a formal analysis of sources of heterogeneity via meta-regression and resulted in overall treatment estimates that are accompanied by wider 95% CIs than desired. Our estimates do, however, rule out large treatment effects (i.e. OR > 1.4), such as those reported for counselling or pharmacological interventions in the general population.[12,26] Third, we decided *a priori* to use the most rigorous reported measure of smoking abstinence,[14] which emphasises 12-month rather than 6-month outcomes. Some may argue that for pregnant women, the 6-month outcomes may be more relevant because they typically take place during pregnancy rather than the postpartum period. However, no included RCTs reported 12-month outcomes. Hence, despite our *a priori* prioritisation, all presented data are for 6 months of follow up. Fourth, biochemical validation is often unable to detect smoking over the entire follow-up period. There may therefore be some misclassification of smoking status in the RCT that reported continuous abstinence. Finally, women who participate in RCTs may be different from those seen in everyday practice, and the generalisability of these data remains unclear. Nonetheless, they represent the best available evidence regarding the isolated effect of smoking cessation counselling among pregnant women.

## Conclusions

Available data from RCTs examining smoking cessation counselling in pregnant women are limited and inconclusive because of wide 95% CIs that include both a marginally important decrease in smoking abstinence and a clinically important increase in abstinence among those randomised to counselling. However, our meta-analysis suggests that there is little evidence to indicate that counselling in isolation is efficacious in this population of women. Available data indicate that the proportion of women who remain abstinent is low, highlighting the need to also examine the efficacy of other types of interventions in this population. This includes RCTs evaluating the safety and efficacy of pharmacological interventions as well as those investigating the use of combination therapies that include both pharmacological and counselling components.

### Disclosure of interest

The authors have no relationships to disclose.

### Contribution to authorship

KBF and HA drafted the manuscript, and KBF revised the manuscript. SM performed the literature search, extracted data and conducted the statistical analyses. All authors contributed to study design, interpretation of results, and critically reviewed the manuscript.

### Details of ethics approval

This study involved published data and so did not require ethics approval.

### Funding

This work was supported by the Canadian Institutes of Health Research (CIHR grant number 81257). KBF is supported, in part, by postdoctoral fellowships from the Heart and Stroke Foundation of Canada and the Fonds de la Recherche en Santé du Québec (FRSQ). SM was supported, in part, by a Canadian Cardiovascular Outcomes Research Team (CCORT) summer studentship funded through a CIHR Team Grant in Cardiovascular Outcomes Research. LJ, LP and MJE are Chercheurs-Nationaux of the FRSQ. JO is the Canada Research Chair in the Early Determinants of Adult Chronic Disease. GP holds a CIHR Chair in Applied Public Health Research. SR is a Junior Physician-Scientist of the FRSQ. ■

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