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# Re-starting smoking in the postpartum period after receiving a smoking cessation intervention: a systematic review

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## ABSTRACT

**Aims** In pregnant smoking cessation trial participants, to estimate (1) among women abstinent at the end of pregnancy, the proportion who re-start smoking at time-points afterwards (primary analysis) and (2) among all trial participants, the proportion smoking at the end of pregnancy and at selected time-points during the postpartum period (secondary analysis). **Methods** Trials identified from two Cochrane reviews plus searches of Medline and EMBASE. Twenty-seven trials were included. The included trials were randomized or quasi-randomized trials of within-pregnancy cessation interventions given to smokers who reported abstinence both at end of pregnancy and at one or more defined time-points after birth. Outcomes were validated biochemically and self-reported continuous abstinence from smoking and 7-day point prevalence abstinence. The primary random-effects meta-analysis used longitudinal data to estimate mean pooled proportions of re-starting smoking; a secondary analysis used cross-sectional data to estimate the mean proportions smoking at different postpartum time-points. Subgroup analyses were performed on biochemically validated abstinence. **Results** The pooled mean proportion re-starting at 6 months postpartum was 43% [95% confidence interval (CI) = 16–72%,  $I^2 = 96.7%$ ] (11 trials, 571 abstinent women). The pooled mean proportion smoking at the end of pregnancy was 87% (95% CI = 84–90%,  $I^2 = 93.2%$ ) and 94% (95% CI = 92–96%,  $I^2 = 88%$ ) at 6 months postpartum (23 trials, 9262 trial participants). Findings were similar when using biochemically validated abstinence. **Conclusions** In clinical trials of smoking cessation interventions during pregnancy only 13% are abstinent at term. Of these, 43% re-start by 6 months postpartum.

**Keywords** Meta-analysis, postpartum period, pregnancy, randomized controlled trial, re-starting smoking, smoking, smoking cessation, smoking cessation interventions, systematic review, tobacco.

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## INTRODUCTION

Tobacco smoking during pregnancy remains a major global public health issue [1]; a conservative estimate for the annual economic burden in the United Kingdom is £23.5 million [2] and in the United States \$110 million [3]. Although in developed countries the prevalence of smoking is declining and is currently approximately 10–27% [4–8], rates are higher and rising in developing countries [9,10]. Most women quit spontaneously upon finding out that they are pregnant, with approximately 38–62% achieving abstinence [5,6,11–13]. Unfortunately, many re-start smoking after childbirth and in so

doing increase their risks of smoking-related morbidities, as well as their offspring's risks of passive smoking-associated morbidities [14–16] and becoming smokers themselves. [17].

Cessation interventions can be both effective and cost-effective at supporting pregnant smokers' quit attempts [18–21], and significant money and effort is spent on helping pregnant women to stop, with both developing and developed countries investing in cessation support [22–24]. For example, approximately 21 780 pregnant smokers in the United Kingdom (15% of pregnant smokers and 3% of all maternities) accessed National Health Service (NHS) Stop Smoking

Services in the financial year 2012–13, 47% of whom achieved cessation by 4 weeks after a quit date, at a cost of £235 per quitter and total costs of £5 118 300 [25,26]. Unfortunately, high rates of re-starting smoking after childbirth may mean that this expenditure has fewer beneficial health effects than it could; knowing how many pregnant smokers who, in supported quit attempts, stop smoking during pregnancy but then re-start smoking afterwards would help to quantify this. Data from cohort studies of pregnant smokers who are spontaneous quitters and not documented as having received cessation support show that 46–76% of women who stop smoking in pregnancy re-start smoking during the months after birth [12,27–30]. However, women who receive smoking cessation support in pregnancy, such as those who use UK NHS Stop Smoking Services, may be different from spontaneous quitters; for example, they may be more nicotine-dependent and hence find it harder to quit [12,31]. Therefore, we cannot assume that rates of re-starting smoking after childbirth among pregnant smokers who seek and obtain support will be the same as those among unsupported, ‘spontaneous’ quitters. Hence, in this paper, we use longitudinal, prolonged abstinence data from smoking cessation trials which enrolled pregnant smokers to describe the rates and timing of pregnant smokers’ return to smoking after childbirth. We contextualize rates of return to smoking by synthesizing, in analyses, point prevalence smoking status data collected across studies at different postpartum time-points and summarizing the proportions of women smoking at each.

## METHODS

### Rationale for inclusion of studies

It was anticipated that robust data on smoking behaviour during and after pregnancy would be reported by trials identified for inclusion from two recent Cochrane systematic reviews which investigated behavioural [18] and pharmacological smoking cessation interventions used during pregnancy [19]. Searches were updated, being run until 4 March 2015; search strategy details can be found in Supporting information, file 1. For ongoing trials, attempts were made to contact the principal investigators to obtain available results.

### Participants

Pregnant smokers in any care setting who could be considered to have motivation to stop smoking were included. Women who consented to join smoking cessation trials were assumed to be motivated to quit (see ‘Study design’).

### Interventions

Any intervention(s) aimed to encourage smoking cessation during pregnancy. Control group participants could receive placebo, another cessation intervention or no intervention.

### Outcomes

Biochemically validated continuous abstinence from end of pregnancy to at least one postpartum follow-up point or biochemically validated 7-day point prevalence abstinence reported at both the end of pregnancy and at least one postpartum follow-up point. For all outcomes, self-reported data were accepted if validation was not conducted.

### Study design

We aimed to include trials which enrolled participants who, similar to pregnant smokers who seek out and receive smoking cessation support, could be considered motivated to try to stop smoking. Hence, we included trials with individual-level randomization or quasi-randomization (e.g. by days of the week or on alternate days), because participants who consented to join a cessation-orientated study could be considered to have some motivation to quit. Cluster trials were included only if participants, despite being randomized within clusters, also consented individually to join the study and hence could be considered to have motivation for cessation.

### Exclusion criteria

Studies were excluded if: (1) intervention(s) were delivered to women who were not smoking; (2) data were presented in a format that could not be analysed and further information was not forthcoming from authors; (3) they enrolled smokers and ‘recent quitters’ but did not report outcomes separately; and (4) they did not have fixed postpartum follow-up time-points.

### Data extraction

Abstracts for identified articles were screened by two reviewers and those deemed relevant were retrieved in full; two reviewers extracted data and performed quality assessments independently, discussing any discrepancies until agreement was secured. A summary of the data extracted is shown in Table 1.

### Quality assessment

Quality assessment was conducted by two reviewers using the Cochrane ‘Risk of bias’ tool developed by Higgins *et al.* [32], with two modifications. Under the heading ‘Attrition bias’, we noted whether the statistical analysis had been conducted on an intention-to-treat basis such that

**Table 1** Summary of data extraction from included studies.

Category	Data extracted
Background characteristics of trial	Author(s) Year published Year(s) of conducting trial Setting, including geographical location Trial design Description of subjects, including were women expecting to quit if reported Unit of randomization
Details of control and experimental interventions	Who is receiving the intervention? What/who is involved in delivering the intervention? What is the intensity of the intervention?
Statistical analysis	All randomized participants included in final analysis? Which randomized participants were excluded from the analysis? How were patients lost to follow-up treated (e.g. were they assumed to be smoking)?
Biochemical validation	Was biochemical validation conducted during pregnancy, stating time-points? Was biochemical validation conducted after pregnancy, stating time-points? Biochemical validation cut-off point? Was biochemical validation conducted on all abstinent smokers or on a sample?
General trial results	Number of women eligible to recruit Number recruited/randomized Number lost to follow-up
Smoking behaviour	Self-reported point prevalence/prolonged abstinence at reported time-points (both within and after pregnancy) Biochemically validated point prevalence/prolonged abstinence at reported time-points (both within and after pregnancy)

participants lost to follow-up were considered to be smoking [33]. Under 'Other bias', it was recorded whether biochemical validation of abstinence had been undertaken, the method used and upon which participants this was conducted.

### Data synthesis

To minimize potential heterogeneity, as far as possible only data collected at similar time-points were synthesized. To achieve this, we tabulated follow-up time-points reported across all trials and identified those used by the greatest number of studies as time-points for data pooling. Study data were allocated to review time-points which were closest to the time that study data collection had actually occurred. Where abstinence was reported as occurring within a period, the soonest time after childbirth was used to represent the time that cessation occurred in analyses (e.g. a 6-month time-point was used for cessation reported as occurring between 6 and 12 months after childbirth).

For our primary analysis we used individual women's longitudinally collected 'continuous abstinence' data to investigate the rates of re-starting smoking in those women who reported abstinence at the end of pregnancy. Specifically, we pooled the proportions of women who re-started smoking at different postpartum follow-up points. The proportion who re-started smoking was defined as:

*Proportion re-start smoking* =

$$\frac{\text{Number re-started smoking at postpartum follow up}}{\text{Number abstinent at the end of pregnancy}}$$

Studies which reported only point prevalence cessation data were not used in this primary analysis, because point prevalence data reflect a short period of abstinence. Using this outcome, individuals can oscillate repeatedly between abstinence to smoking, hence one cannot guarantee that women reporting abstinence at postpartum follow-up would be the same women as those reporting abstinence at the end of pregnancy.

To contextualize the rates of re-starting smoking calculated using longitudinal data we summarize, in a secondary, cross-sectional analysis, participants' smoking rates after childbirth by pooling the proportions of women smoking in individual trials, with proportions defined as:

$$\text{Proportion smoking} = \frac{\text{Number smoking at follow up}}{\text{Total number of trial participants}}$$

For both primary and secondary analyses, we undertook subgroup analyses restricted to those studies for which biochemically validated abstinence were available.

As heterogeneity was anticipated, pooled mean proportions and 95% confidence intervals (CIs) were generated

using a random-effects (DerSimonian & Laird) meta-analysis, with statistical heterogeneity between trials quantified using the  $I^2$  statistic. All analyses were conducted using Stata version 14. [34]

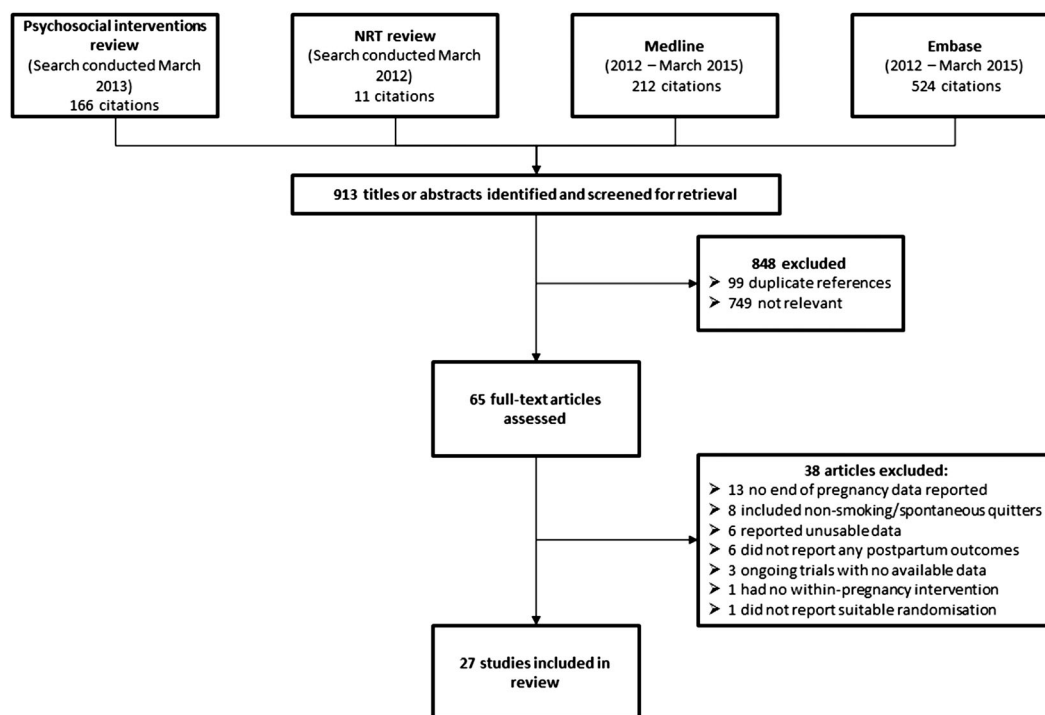
## RESULTS

Searches identified 913 possible studies, and 65 studies were assessed by reading full texts with 27 being included in the review (see Fig. 1). We contacted ongoing trials investigators in August 2014 and March 2015, but no new studies were identified; we were unable to make contact for two trials [35,36], and no results were available for another [37]. Four studies reported continuous abstinence only [38–41], seven reported both continuous and point-prevalence abstinence [42–48] and 16 reported point-prevalence abstinence only [49–64]. The primary meta-analysis contained 571 women from 11 studies [38–48], while the secondary meta-analysis included 9262 women from 23 studies [42–64]. A summary of the characteristics of included studies can be found in Supporting information, file 2.

Twenty studies were randomized controlled trials (RCTs) with individual randomization [38,40–43,46–54,59–64], five were cluster-randomized [39,45,55–57] and two were quasi-randomized [44,58]. Of the cluster-randomized studies, all required participants to give consent to join the study, therefore no cluster RCTs were excluded from the review on the basis of not consenting women to join.

Control groups received information booklets in 15 studies [39,44–53,55,61,64]; counselling (eight studies) [41,42,46,47,54,57,59,64]; placebo patches (three studies) [42,59,64]; one used non-contingent vouchers (rewards given to participants for attending the clinic) [53]; and one did not report what the control intervention was [62]. Three studies used ‘usual care’ as a control, but did not define this [56,60,63], while one study reported using ‘usual care’ as provided by the UK NHS [40]. The control group received no intervention in one study [38]. Fourteen studies reported using a single technique for the control intervention [43–46,48–50,52,54,56–58,60,63].

For the intervention groups, 17 studies reported using information booklets [39,43–45,47–53,55,57,58,60,63,64], 20 reported using counselling [38,39,41–43,46–49,51,52,54,55,57–61,63,64], four used nicotine replacement therapy (NRT) [42,46,59,64], three used social support interventions [39,49,54], two used motivational interviewing (MVI) techniques [56,62] and two used financial incentives [40,50]. The following interventional approaches were employed in one study each: ‘stages of change’ [45], contingent vouchers (smoker rewarded for meeting certain criteria) [53], letters of support [62] and physical activity [41]. Only four studies used a single technique [38,44,56,61], with most trials utilizing combinations of intervention strategies. Nine studies reported the continuation of the cessation intervention into the postpartum period [41,43,47,50,51,53,59,60,62].



**Figure 1** Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram



**Risk of bias assessment**

The quality of included studies was generally judged to be poor, and quality assessments of these can be found in Supporting information, file 3. An intention-to-treat analysis was not conducted in 19 studies [38,39,43,44,47–53,55–58,60–63]; in others, participants were not included in analyses for reasons such as miscarriage, premature birth, loss to follow-up, lost samples, moved hospitals/areas, withdrawal of participation or being delivered interventions to which they had not been randomized. Eighteen studies used biochemical validation, with salivary cotinine (five studies) [41,43,47,49,55], urinary cotinine (six studies) [40,48,53,54,58,61], carbon monoxide (seven studies) [39–42,51,59,61], salivary thiocyanate (one study) [50] or blood thiocyanate (one study) [44].

**Publication bias**

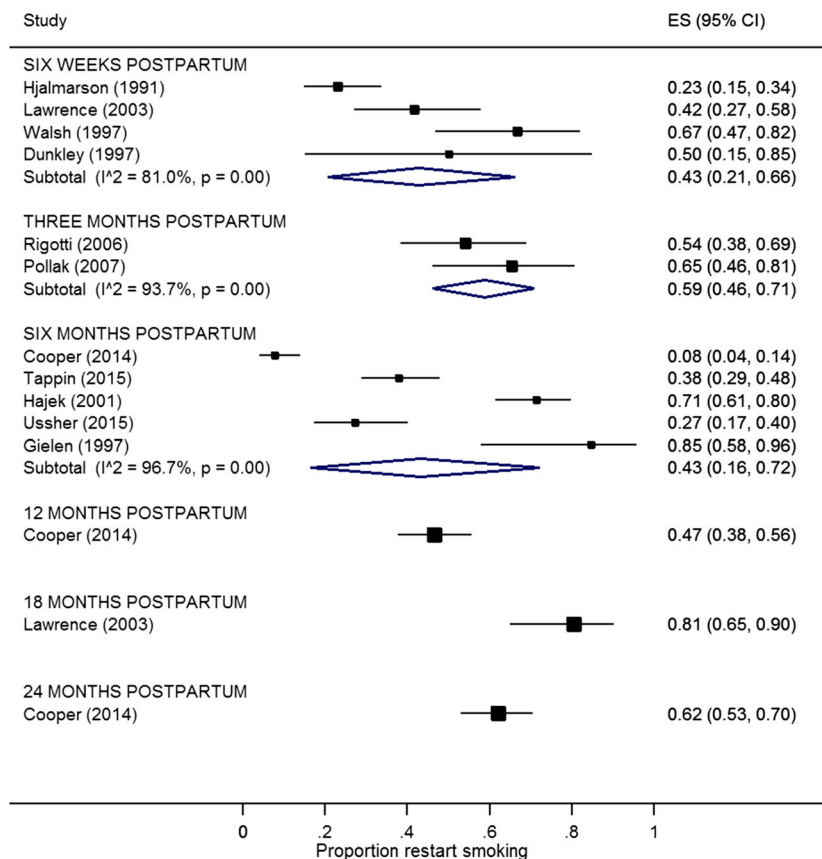
Where possible, for all time-points at which data were pooled, funnel plots were examined for evidence of bias; however, only the end of pregnancy included all studies and thus seemed the most pertinent. This plot suggested that small studies with negative effect sizes were less likely to be included in the review (see Supporting information, file 4), so there is potential publication bias.

**Selection of time-points**

Included studies reported abstinence at 4–8 weeks post-randomization (i.e. during pregnancy), at the end of pregnancy and at the following time-points postpartum: 10 days [45], 4 weeks [38], 6 weeks [48,49,52,55–58,62], 8 weeks [44,50], 3 months [46,47,53,54,62–64], 4 months [56], 6 months [39–43,51–53,59,62], 8 months [60], 12 months [42,64,65], 18 months [45] and 24 months [42]. Follow-up data from studies were aggregated as follows: 4–8 weeks post-randomization; end of pregnancy (as defined in individual studies) and for postnatal time-points: 6 weeks (data from 10 days and 4, 6 and 8 weeks after childbirth), 3 months (data from 3 and 4 months), 6 months (6 and 8 months), 12 months, 18 months and 24 months postpartum.

**Primary analysis: proportion re-starting smoking**

Figure 2 demonstrates the primary meta-analysis using data from the 11 studies which provided continuous abstinence data. The pooled mean estimate of the proportion of women re-starting smoking by 6 months postpartum is 43% (95% CI = 16–72%,  $I^2 = 96.7\%$ ). Only six studies were included in the subgroup analysis [39,43–45,47,48], with biochemically validated continuous abstinence data



**Figure 2** Forest plot of the proportion of women re-starting smoking using continuous abstinence, with studies ordered by weighting (highest weighting first)

available up to 6 months postpartum. A similar pattern of re-starting smoking was observed in the subgroup analysis; again, most women who re-started smoking had done so within the first 6 months after childbirth. The only difference between the primary and subgroup analyses was that estimates for the proportions re-starting smoking were generally higher in studies using validated data; from studies using biochemically validated data; for example, the pooled mean proportion of women re-starting smoking at 6 months postpartum was 74% (95% CI = 64–82%) in the subgroup analysis (see Supporting information, file 5).

### Secondary analysis: proportion smoking

Figure 3 illustrates the meta-analysis of the proportion smoking at different time-points among all trial participants using point-prevalence of smoking data from the 23 studies which provided this. At the end of pregnancy, the pooled mean estimate of the proportion smoking was 87% (95% CI = 84–90%,  $I^2 = 93.2\%$ ), and at 6 months postpartum the pooled mean estimate of the proportion smoking was 94% (95% CI = 92–96%,  $I^2 = 88.0\%$ ). Seventeen studies reported biochemically validated point prevalence abstinence [42–64], but again data were available only up to 6 months postpartum. There appeared to be a similar pattern of smoking in the subgroup analysis (i.e. of trials providing validated outcome data) compared to the secondary analysis (see Supporting information, file 6). Estimates of the proportion smoking were higher in the subgroup analyses at the end of pregnancy, 3 months and 6 months postpartum. At the end of pregnancy, the pooled mean proportion of trial participants reporting smoking was 89% (95% CI = 86–91%,  $I^2 = 91.2\%$ ), while the pooled mean proportion was 96% (95% CI = 92–99%,  $I^2 = 70.7\%$ ) at 6 months postpartum.

## DISCUSSION

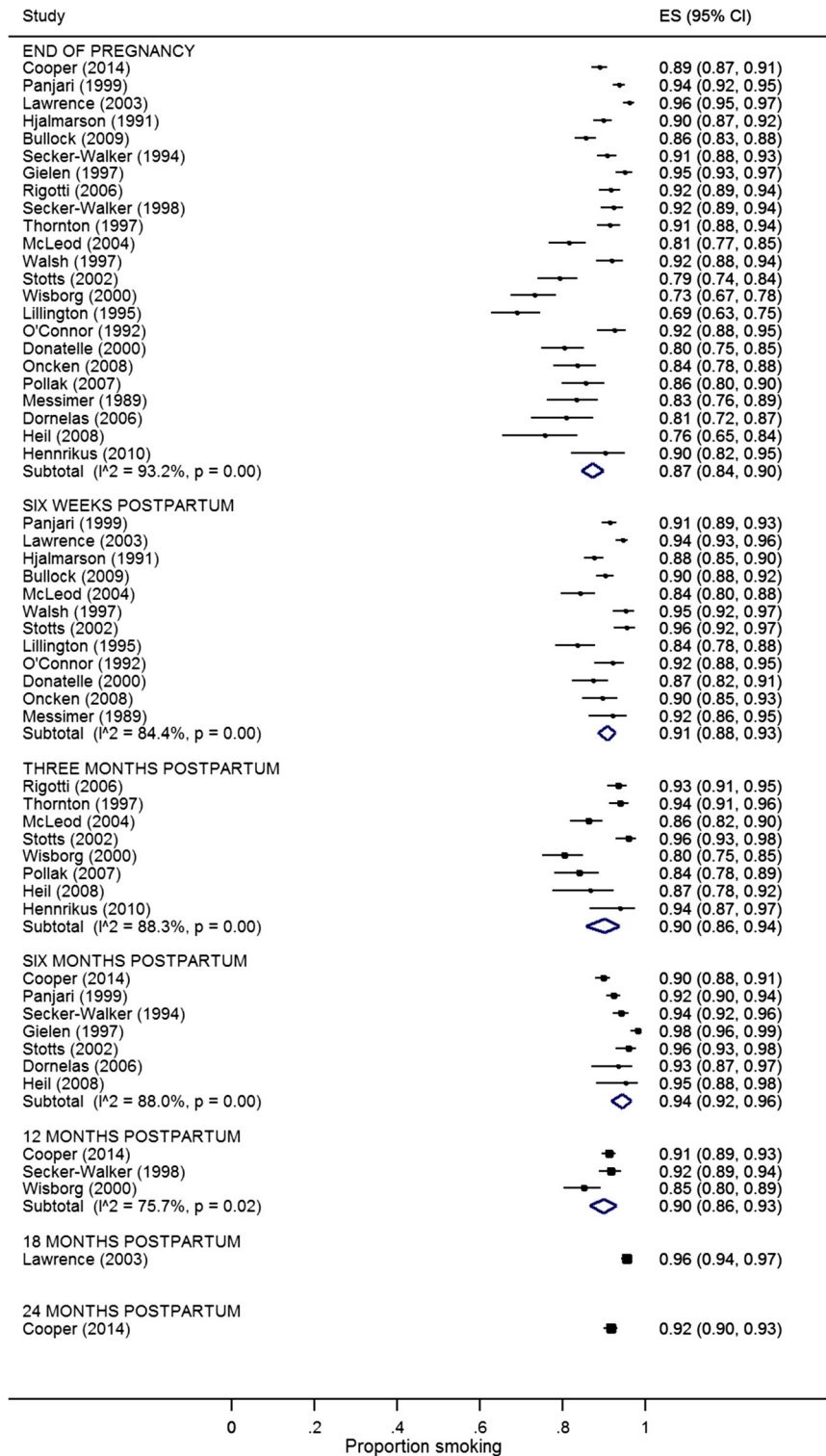
We believe this is the first study to investigate systematically the rates of re-starting smoking after childbirth and we found that in smoking cessation trials, among the minority of women abstinent at the end of pregnancy, a mean estimate of 43% had re-started smoking by 6 months postpartum. Furthermore, there appeared to be little re-starting of smoking after this point. A secondary analysis estimated that, across trials, the mean proportion smoking at the end of pregnancy was 87%, rising to 94% 6 months later, which suggests that the majority of smoking cessation trials' participants continue to smoke both throughout pregnancy and after childbirth.

A strength of this work is its novelty and systematic approach which has provided, for the first time, quantification of rates of re-starting smoking after pregnancy. Additionally, as trial data are likely to be collected at a

consistently higher standard than cohort study or routinely collected data and are more likely to be biochemically verified, the review probably uses the highest quality data available. It includes sufficient trials (11) and participants (571) to estimate the proportion of women who re-start smoking after childbirth, and also much more data (23 trials, and 9262 participants) which could be used to locate this finding in the context of smoking rates recorded in other trials that did not report continuous abstinence.

A weakness is the high level of heterogeneity present in meta-analyses. We attempted to minimize heterogeneity by aggregating data collected only at similar time-points after pregnancy and by including only those smoking cessation trials which women consented to join, and so which included only women motivated to stop smoking. Despite these measures, the  $I^2$  statistic for analyses was high and heterogeneity is likely to have arisen from variety in interventions delivered and in study populations. Although the presence of heterogeneity means that pooled proportions obtained from meta-analyses should be viewed with caution, study findings represent the first effort to synthesize data on postpartum smoking using the best available data.

Relatively few studies reported longitudinal continuous abstinence data, and this restricted the volume of data available to estimate re-start rates. The more frequently used outcome was 7 days' abstinence from smoking, but this outcome could not be used in the primary analysis because individuals reporting abstinence in the postpartum would not necessarily be the same women as those reporting abstinence at the end of pregnancy. Instead, we reported a cross-sectional analysis of smoking rates estimated from point prevalence smoking rates to give context to re-start rates estimated using longitudinal data. However, in an analysis of non-pregnant smokers and quitters, prolonged and point prevalence measures of smoking abstinence after quitting recorded at the same time-points were correlated closely; the ratio of prolonged to point prevalence abstinence was 0.74 (95% CI = 0.70–0.79) [66]. Our review suggests similarly that using either self-reported prolonged or point prevalence abstinence measures to estimate rates of re-starting smoking can give similar findings. Using longitudinal data, we found that a mean 43% of women had re-started smoking by 6 months postpartum. Using the estimated mean proportions of smoking at the end of pregnancy (87%) and 6 months postpartum (94%), it can be assumed that 13% of women are abstinent at delivery but only 6% remain so at 6 months, hence the proportion re-starting is estimated crudely from cross-sectional point prevalence data as  $(7/13 \times 100)$  or 54%. The similarity in re-start rates obtained using either longitudinal or cross-sectional data suggests that change in smoking status in the postpartum



**Figure 3** Forest plot of the proportion of women smoking among all trial participants based on 7-day point prevalence abstinence, with studies ordered by weighting (highest weighting first)

is generally in one direction, from not smoking to smoking. If many women re-started and stopped smoking repeatedly after childbirth, one would expect different findings to arise from estimates of re-starting smoking made using these different outcome measures.

As this review includes only trials in which pregnant smokers showed motivation to stop smoking by consenting to join a smoking cessation study, findings are likely to be generalizable to those pregnant smokers who seek support from health-care providers with cessation attempts.



Unfortunately, most of these women do not manage to stop smoking in pregnancy, and nearly half of those who do re-start smoking within 6 months of childbirth. Additionally, although there is no similar review which investigates rates of re-starting smoking among women who stop smoking in pregnancy without receiving support ('spontaneous quitters'), comparison with individual studies suggests that rates may be broadly similar. We estimated that mean proportions of women re-starting at 6, 12 and 24 months postpartum were 43, 47 and 62%, respectively, whereas individual observational studies of 'spontaneous quitters' provide estimates of proportions re-starting of 30–76% [67–77], 32–59% [29,30,71,72] and 59% [27] at these time-points.

## CONCLUSIONS

Most pregnant smokers do not achieve abstinence from smoking while they are pregnant, and among those that do, most will re-start smoking within 6 months of childbirth. This would suggest that despite large amounts of health-care expenditure on smoking cessation, few women and their offspring gain the maximum benefits of cessation.

## Declaration of interests

We have read and understood the *Addiction* policy on declaration of interests and declare the following interests: T.C. reports personal fees from Pierre Fabre Laboratories, France, outside the submitted work; M.J., S.L., S.P. and S.W. have nothing to declare.

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### Supporting information

Additional supporting information may be found in the online version of this article at the publisher's web-site.

**Supplementary File 1** Electronic search strategies for Medline and Embase.

**Supplementary File 2** Characteristics of included studies table.

**Supplementary File 3** Authors' individual assessment of bias for each included study.

**Supplementary File 4** Deeks funnel plot for publication bias.

**Supplementary File 5** Sub-group analysis of the proportion of women restarting smoking using biochemically validated continuous abstinence only.

**Supplementary File 6** Sub-group analysis of the proportion of women smoking using biochemically validated 7-day point prevalence abstinence.