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# **A systematic review of smoking cessation and relapse prevention interventions in parents of babies admitted to a neonatal unit (after delivery)**

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## **Citation**

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## **Review question(s)**

This review will undertake a quantitative systematic review of smoking cessation and relapse prevention in the parents and household members of babies admitted to a neonatal unit after delivery.

The aim will be met by exploring the question:

How effective have smoking cessation and relapse prevention interventions been in parents and household members of babies admitted to a neonatal unit after birth?

## **Searches**

The following databases will be searched:

- MEDLINE
- EMBASE
- Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library)
- PsycINFO
- Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- Web of Science.

We will search from inception to the present day. We will screen the reference lists of all included studies and of systematic reviews identified by our electronic searches. We will also contact study authors for further information when necessary. We will only include fully published studies published in English.

The search strategy will consist of two components. First, studies will be identified that have involved neonates in some way. This search will be broad to ensure that any interventions that have targeted the parents and household members of this population are included. The search will not seek to identify studies focussed on parents. Instead those not focussed on the parents or household members will be screened out at the abstract or full paper review stage. Second, studies will be identified where a smoking intervention has been tested. Again, this search will be broad in order to include both smoking relapse and smoking cessation interventions.

## **Types of study to be included**

We will include all prospective studies that have used an intervention and its evaluation, compared to some form of control group, or control period. This will include RCTs, non- randomised controlled trials, and before and after trials.

## **Condition or domain being studied**

Smoking, Smoking cessation, Smoking relapse prevention

## **Participants/ population**

The parent/s or adult household members of newborns (full or preterm) admitted to a neonatal unit in any country, of any age who:

- 1) Is a current smoker OR
- 2) Was a smoker at any time within the one year period prior to the baby's birth.

## **Intervention(s), exposure(s)**

We will include all eligible studies that investigate the effectiveness of smoking cessation or relapse prevention interventions in this population. The intervention must have commenced during their admission on the neonatal unit or their admission onto the neonatal unit has made them eligible for the intervention.

## **Comparator(s)/ control**

1. Usual care
2. No intervention
3. Another type of smoking cessation/relapse prevention intervention

## **Context**

Smoking during pregnancy can cause serious pregnancy-related health problems. These include complications during labour, an increased risk of miscarriage, premature birth, still birth, low birth-weight, perinatal asphyxiation and sudden unexpected death in infancy. Smoking has been identified as a major risk factor contributing to low birthweight infants. Babies born to women who smoke, weigh on average 200g less than babies born to non-smokers. Smokers had a 40% higher risk of preterm birth compared with non-smokers. Smoking in pregnancy increases infant mortality by about 40% and more than a quarter of the risk of sudden unexpected death in infancy is attributable to smoking. Furthermore, infants of parents who smoke are more likely to suffer from serious respiratory infections (such as bronchitis and pneumonia), asthma and problems of the ear, nose and throat (including glue ear). Exposure to smoke in the womb has also been associated with psychological problems in childhood such as Attention Deficit Hyperactivity Disorder (ADHD).

Costs related to infant outcomes from maternal smoking (including increased risk of preterm delivery, low birth weight, Sudden Infant Death Syndrome, perinatal mortality, asthma, otitis media, and upper and lower respiratory infections) are estimated to cost the NHS between £12 million and £23.5 million per year.

Up to 45% of pregnant smokers are known to spontaneously give up smoking during pregnancy, but in 2005, almost four in ten mothers in England (38%) lived in a household where at least one person smoked during their pregnancy. In most cases the person who smoked was the mother's partner. However, only a minority of these partners, gave up after the woman gave birth with 15% not smoking when the baby was aged 4–10 weeks rising to almost a quarter (24%) quitting by the time their baby was 8–10 months. In addition, women with partners who smoke find it harder to quit and are more likely to relapse if they do manage to quit. Rates of smoking in pregnancy also differ across age groups, with mothers aged 20 or under being six times more likely than those aged 35 and over to have smoked throughout pregnancy (35% and 6% respectively). Equally, pregnant women are more likely to smoke if they are less educated (based on educational qualification e.g. completed GCSEs), live in rented accommodation or are single.

In 2015-16, 10.6% of mothers (66,010) were recorded as smokers at the time of delivery in the UK, which has improved from 11.4% in 2014-15 (70,981)(13). However, it should be noted that the geographical distribution by Clinical Commissioning Group (CCG) of women smoking at the time of delivery shows regional differences. Rates varied from 1.5% in NHS Central London (Westminster) to 26.0% in NHS Blackpool.

Continued abstinence from smoking following pregnancy (postpartum) has health benefits for the mother and the child, as it reduces a child's exposure to second hand smoke (SHS). However, postpartum relapse rates amongst mothers are high. It is estimated that by 12 months postpartum, 80%-90% of women who quit smoking during pregnancy will have relapsed. Relapse rates are also disproportionately spread, with women from lower socioeconomic groups being at higher risk of smoking relapse following pregnancy.

Adams et al, 2002 suggested that smokers are likely to be over-represented in the mothers of infants requiring NICU admission, with the relative risk of admission to NICU for these neonates being increased by at least 20% compared to mothers who do not smoke. In a later paper, they found no significant relationship of maternal smoking to the odds of admission to NICU but found a positive effect of exposure to prenatal smoke and the length of stay for admitted infants. Aside from obstetric complications, there is clearly a complex overlay of other factors that may result in pre-term birth, such as maternal age, previous pre-term delivery, maternal stress, ethnicity as well as possibly alcohol and smoking.

Our review concentrates on smoking cessation and relapse prevention interventions in the parents or household members of babies admitted to a neonatal unit (after delivery), as 1) this could be a population in which there is a higher percentage of parental smokers; 2) preterm and premature babies are more prone to respiratory disease than are full term neonates so are more vulnerable to the effects of second-hand smoke 3) long hospital stays give parents prolonged contact with healthcare professionals which could offer a good opportunity for intervention. The underlying aim of this review is to synthesise quantitative evidence of smoking cessation and relapse prevention interventions in the parents or household members of babies (pre-term or full term) admitted to a neonatal unit after birth and draw conclusions as to how best to develop interventions in this vulnerable group.

As a precursor to registering this review, searches of PROSPERO and PubMed databases of protocols for registered systematic reviews were undertaken (08/2016), with no similar ongoing review being identified.

## **Outcome(s)**

### **Primary outcomes**

Based on Russell Standard:

- 1) Cessation outcome: Parents or household members that stopped smoking or abstained from smoking (defined as having smoked no more than 5 cigarettes in total during this time period) after the intervention, either biochemically verified or self-reported.
- 2) Relapse outcome: Parents or household members who had stopped smoking that did not relapse after the intervention at 12 months (52 week quit rate) follow-up, either biochemically verified or self-reported. If data is available at 6 months, this will also be collected.

Note: where studies do not use the Russell Standard outcomes, we will collect their closest equivalent cessation/relapse outcomes to the standards described (noting any issues with their outcome measure).

### **Secondary outcomes**

If sufficient data are available for the intervention group and control, at 6 and 12 month (or available) follow-ups:

- number of respiratory infections during infancy
- re-admissions to hospital during infancy
- Breastfeeding rates
- Smoking bans in the car and home

## **Data extraction, (selection and coding)**

The outputs of the searches will be imported using EndNote reference management software (Alfasoft, Luton, UK), and duplicate records will be removed. Two reviewers will review all identified records (titles and abstracts) from the databases search and assess eligibility, according to the pre-specified criteria. If there is any uncertainty at this stage, the article will remain included until the full text is reviewed. The screening process will identify records to be reviewed through the full-text article. The full texts of studies which potentially meet our inclusion criteria will be retrieved and reviewed independently by two authors. Study authors will be contacted if information is missing or unclear. Any disagreements will be resolved by discussion between the two authors with a third adjudicating if required (RH). Two reviewers will verify the final list of included studies. A PRISMA flow chart of the study selection procedure will be prepared.

Data extracted will include: study title; authors; year of publication; journal/source; study design (e.g. RCT, non-randomised controlled trial); aims/objectives; participant characteristics; sample size; methodology; type of smoking cessation intervention; means and standard deviations for intervention and control groups for primary and secondary outcomes; use of intention-to-treat (ITT) analysis; summarised findings; and summarised conclusions. Data extraction will be conducted by one reviewer and checked by a second reviewer. Any disagreement will be resolved by discussion or involvement of a third reviewer.

### **Risk of bias (quality) assessment**

RCTs and non-randomised studies will be assessed using the Cochrane handbook for systematic reviews of interventions(20, 21) and CRD Guidance(22).

Review authors will pilot the risk of bias assessments prior to use. Disagreements will be resolved by discussion and a third reviewer (RH) consulted if necessary.

Study authors will be contacted for additional information or clarification of study methods if required.

### **Strategy for data synthesis**

Where possible, data assessing treatment effect will be pooled in a statistical meta-analysis. 10% of results will be independently checked for data entry errors. Odds ratios (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed using the standard Chi-squared test. A Forrest plot and funnel plot (by size of study) will be attempted for RCTs, if possible.

If outcomes are too heterogeneous, and meta-analysis is not appropriate, then a narrative review will be undertaken. A summary of effectiveness of each intervention type (pharmacological, psychological and combination) will be included. Sensitivity analyses regarding the quality of the study will be undertaken, including some measure of length and intensity of the intervention. Both fixed and random effects meta-analysis may be used if appropriate.

### **Analysis of subgroups or subsets**

- Pharmacological interventions
- Psychological interventions
- Combination
- Other ( e.g. acupuncture)

If possible, subgroup analyses by participant characteristics

### **Dissemination plans**

Review findings will be presented at an academic conference (e.g. the Society for the Study of Addiction annual symposium) and the final manuscript reporting the review will be submitted for publication in a peer-reviewed academic journal.

### **Contact details for further information**

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### **Organisational affiliation of the review**

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**Anticipated completion date**

02 January 2017

**Funding sources/sponsors**

None.

**Conflicts of interest**

None known

**Language**

English

**Country**

England

**Subject index terms status**

Subject indexing assigned by CRD

**Subject index terms**

Hospitalization; Humans; Parents; Secondary Prevention; Smoking; Smoking Cessation

**Stage of review**

Ongoing

**Date of registration in PROSPERO**

13 October 2016

**Date of publication of this revision**

13 October 2016

**Stage of review at time of this submission**

Preliminary searches

**Started**

Yes

**Completed**

No

Piloting of the study selection process

Yes

No

Formal screening of search results against eligibility criteria

No

No

Data extraction

No

No

Risk of bias (quality) assessment

No

No

Data analysis

No

No