Smoking cessation in Secondary Care

Review 2 (Component 1)

Smoking cessation interventions in acute and maternity services: Review of effectiveness

Report to National Institute for Health and Clinical Excellence

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Katie Myers, Hayden McRobbie and Peter Hajek

November 2021: NICE guidelines PH45 (June 2013) and PH48 (November 2013) have been updated and replaced by NG209. The recommendations labelled [2013] or [2013, amended 2021] in the updated guideline were based on these evidence reviews. See www.nice.org.uk/guidance/NG209 for all the current recommendations and evidence reviews.

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GLOSSARY

Abstinence	Throughout this review we refer to abstinence from smoking as abstinence. Rates of abstinence are also presented. See point prevalence abstinence, continuous abstinence, sustained abstinence and CO-validated abstinence.
Biochemically validated	Self-reported abstinence rates are often validated, or confirmed, by biochemical tests. These tests include measurement of CO in expired breath and cotinine in saliva, blood, and urine.
Bupropion	Bupropion or Zyban ™ is an atypical antidepressant that is also effective in helping people to stop smoking. In the UK it is only licensed as a smoking cessation aid
CO-validated abstinence	Measurement of carbon monoxide in expired breath is commonly used to validate self-reported abstinence. A cut-off of 10 ppm is routinely used, so if someone reports they have not smoked and have a CO reading of less than 10ppm then they would be considered to be a CO-validated abstainer.
Continuous abstinence	This measures continuous abstinence from smoking, either not a single puff or a small number of slips allowed (e.g. less than 5 cigarettes in total), from a pre-determined time point (e.g. Quit Date) to all follow-up points. Continuous abstinence rates are typically lower than point prevalemce abstinence rates, but more likely to give a more accurate assessment of the effect of an intervention.
Nicotine replacement therapy	Nicotine replacement therapy is a licensed medicinal product to aid smoking cessation, smoking reduction and temporary abstinence. There are seven different formats: patch, gum, lozenge, sublingual tablet, nasal spray, mouth spray and inhalator.
Point prevalence abstinence	This measures abstinence from smoking at a particular time. 7-day point prevalence (i.e. not smoking at all over the past 7 days) is a commonly used measure.
Varenicline	Varenicline or Champix ™ is a nicotine analogue that was developed specifically to help people stop smoking. It acts primarily to reduce the severity of tobacco withdrawal symptoms thus making quitting easier.

LIST OF ABBREVIATIONS

CABG/S	Coronary Artery Bypass Graft/Surgery
CAD	Coronary Artery Disease
CBT	Cognitive Behavioural Therapy
CCU	Coronary Care Unit
CHD	Coronary Heart Disease
CHF	Congestive Heart Failure
CI	Confidence Interval
CO	Carbon Monoxide
COHb	Carboxyhaemoglobin
COPD	Chronic Obstructive Pulmonary Disease
CVD	Cardiovascular Disease
EDD	Estimated date of delivery
FTND	Fagerstrom Test for Nicotine Dependence
FU	Follow-up
HV	Health Visitor
ICU	Intensive Care Unit
ITT	Intention to treat
MI	Myocardial Infarction
MW	Midwife
NRT	Nicotine Replacement Therapy
OR	Odds Ratio
PP	Point Prevalence
PVD	Peripheral Vascular Disease
RCT	Randomised Controlled Trial
RR	Relative Risk
SC	Smoking cessation
SOC	Stage of Change

TQD	Target Quit Date
TTM	Transtheoretical Model

Executive Summary

INTRODUCTION

Each year thousands of UK smokers are admitted to acute care for treatment of smoking related diseases. Hospitalisation provides a good opportunity to stop smoking. Such patients are often highly motivated to quit, UK hospitals are smoke-free environments with no cues for smoking, and the hospital admission brings smokers into contact with healthcare professionals who can advise on giving up smoking and offer evidence-based treatment.

Pregnancy is another opportune moment for stopping smoking. Most women in the UK know that smoking in pregnancy is discouraged and many are aware of some of the risks it can pose to their unborn child. Midwives and other primary care workers provide encouragement and advice and most stop-smoking services offer specialist help.

This documents reviews the available evidence concerning efficacy of different types of smoking cessation interventions with hospital patients and their relatives and with pregnant women and their partners to help guide relevant clinical recommendations.

RESEARCH QUESTIONS

This review aims to answer the following two questions posed by NICE:

Question 1: How effective are smoking cessation interventions in helping people from the populations of interest?

Question 2: How effective are interventions for temporary abstinence in helping people from the populations of interest?

STRUCTURE OF THE REVIEW

The review is divided into two chapters that address the two populations of interest: (1) users of acute secondary care services and staff and visitors of these services, and (2) users of maternity services and their partners.

METHODOLOGY

TYPES OF STUDIES CONSIDERED IN THIS REVIEW

We included all randomised controlled trials of smoking cessation interventions with the populations of interest as well as trials with patients' relatives and with staff.

CATEGORISING INTERVENTIONS BY INTENSITY

A number of different types of behavioural interventions have been proposed to help smokers quit. They can be categorised according to their theoretical underpinning, use of treatment aids such as booklets, videos and biological feedback, background of the person delivering the intervention, etc. We used the approach of the Cochrane review of

interventions with hospital patients (Rigotti et al. 2007 [Systematic review, ++]) and categorised the interventions according to the length of time over which support was provided. Length of support is generally related to the cost of the intervention and also to its efficacy. Such approach seems practical for informing clinical recommendations.

The studies have been categorised into the following levels of intensity:

Intensity 1: Single contact with or without take-away written and other materials, no follow-up support.

Intensity 2: One or more contacts with or without take-away written and other materials up to but not beyond the target quit date (TQD)

Intensity 3: Any contact plus follow-up for up to but not beyond 4 weeks after TQD

Intensity 4: Any contact plus telephone/correspondence/e-mail etc. based follow-up for > 1 month

Intensity 5: Any contact plus follow-up for > 1 month including at least one face-to-face contact

We also considered whether the interventions work when they are and when they are not accompanied by pharmacological treatments.

Issues not covered in this review

We excluded trials with psychiatric patients and did not consider evidence relating to the health benefits of stopping smoking.

Outcomes and data extraction

For trials concerning secondary care, the principal outcome measure was abstinence from smoking at least six months after the start of the intervention. For trials concerning users of maternity services, the principal outcome measure was abstinence from smoking at the longest follow-up period up to and including delivery; and separately abstinence from smoking at the longest follow-up after delivery.

We extracted the most conservative measure of quitting at the longest follow up. Participants lost to follow up were counted as continuing smokers.

Evaluation of trial quality

Each of the included studies was rated ++, + or - to indicate its quality, as follows.

++	Self-reported abstinence was verified biochemically, sustained or continuous abstinence reported, no other risks of bias
+	Self-reported abstinence was verified biochemically, only point prevalence abstinence reported, no major risks of bias
–	Self-reported abstinence not validated and/or other major risks of bias (e.g. incomplete randomization, unclear N, unclear calculation of success rates)

DATA ANALYSIS

Where it was appropriate to pool studies, data were entered into RevMan 5. We pooled data using Mantel-Haenszel fixed-effect method, with 95% confidence intervals. To investigate statistical heterogeneity we used the I^2 statistic. Where there was substantial heterogeneity between studies we explored possible reasons for this using subgroup analyses. We express results as odds ratios (intervention odds/control odds) for achieving abstinence from smoking together with the 95% confidence interval for this estimate.

EVIDENCE STATEMENTS

Scoring the strength of evidence was based on the quality of the individual studies, the number of studies included in the meta-analysis, and the results of the meta-analysis.

The strength of evidence was classified as:

- No evidence
- Weak evidence: None of the included studies score [+] for quality and/or the result of the meta-analysis is only marginally significant
- Moderate evidence: One or more studies score [+] or [++] for quality and the result of the meta-analysis is significant, but most studies are of low quality and/or less than 3 studies are included and/or the results of the meta-analysis are heterogeneous
- Strong evidence: One or more studies score [+] and [++] for quality, the result of the meta-analysis is significant and homogenous, and there are more than two studies included in the meta-analysis

SEARCH METHODOLOGY

We systematically searched reviews and trials published between 1990 and December 2011 in the English language, but we also included literature published in early 2012 while we were working on the review. The searchable databases included ASSIA, MEDLINE, Cochrane Central Register of Controlled Trials, CINAHL and PsychINFO (a full list of the databases searched is included in the review protocol in Appendix 1). Several websites were also searched for relevant data these included NHS Centre for Smoking Cessation and Treatment, Action on Smoking and Health (ASH), Treat tobacco.net and WHO Tobacco Free Initiative (a full list of websites searched is included in Appendix 1). A systematic search of the grey literature was not undertaken but hand searching of bibliographies of systematic reviews that met the inclusion criteria was carried out to ensure that relevant data was included in this review. The search terms included for this review are also in the review protocol in Appendix 1).

SEARCH RESULTS

Searches of the databases returned 29,083 records. A total of 284 papers were identified for full text retrieval. A flow diagram illustrating the screening procedure is included in figure 1. Studies excluded are listed in the appendix 2, along with a brief reason for exclusion.

Chapter 1: Smoking Cessation Interventions in Acute Care Services

We found 75 trials evaluating smoking cessation interventions delivered in acute care settings that had follow-up periods of at least 6 months. The chapter is divided into five sections.

SECTION 1: EFFICACY OF INTERVENTIONS DELIVERED TO NON-SURGERY PATIENTS

SUBSECTION 1: INTERVENTION INTENSITY

We analysed first all available studies, and followed this by an analysis of only those which validated self-reported abstinence biochemically and were least vulnerable to bias.

Analysis of all available studies:

Intensity 1:
Three studies (Brandt et al 1997 [RCT +]; Hennrikus, et al 2005 [RCT +]; Papadakis et al 2011 [RCT +]) reported on the effects of one-off brief interventions (Intensity 1 and 2) with no follow-up. The results were homogenous and show no additional effect of such interventions compared to usual care (OR=1.26; 95% CI:0.89-1.78).

Intensity 2:
The results from six studies (Chouinard et al 2005 [RCT ++]; Hajek et al 2002 [RCT ++]; Molyneux et al 2003 [RCT ++]; Nagle et al 2005 [RCT +]; Pederson et al 1991 [RCT +]; Pelletier et al 1998 [RCT -]) which reported slightly more intensive interventions in hospital (a longer counselling session or two and booklets) with no further follow up were similar, showing no effect of such interventions (OR=1.04; 95%CI: 0.83-1.31). The results were again homogenous.

Intensity 3: Ten studies (Kim et al 2005 [RCT +]; Miller et al 1997 [RCT +]; Neuner et al 2009 [RCT -]; Ortigosa et al 2000 [RCT +]; Rigotti et al 1994 [RCT ++]; Rigotti et al 1997 [RCT +]; Schiebel et al 2007 [RCT -]; Stevens et al 1993 [RCT -]; Stevens et al 2000 [RCT -]; Wiggers et al 2006 [RCT +]) provided telephone support post-discharge for up to 4 weeks. This generated a marginally significant effect overall (OR=1.17; 95% CI: 1.01-1.36), but there was no effect when only studies which validated self-reported abstinence were included (see below). The studies were homogenous.

Intensity 4: There were 26 trials (British Thoracic Society B 1990 [RCT ++]; Chouinard et al 2005 [RCT ++]; De Busk et al 1994 [RCT ++]; Dornelas et al 2000 [RCT +]; Feeney et al 2001 [RCT ++]; Froelicher et al 2004 [RCT +]; Hasuo et al 2004 [RCT +]; Haug et al 2011 [RCT -]; Hennrikus et al 2005 [RCT +]; Horn et al 2008 [RCT -]; Lacasse et al 2008 [RCT -]; Li et al 2008 [RCT -]; Metz et al 2007 [RCT -]; Miller et al 1997 [RCT +]; Mosca et al 2010 [RCT +]; Quist-Paulsen et al 2003 [RCT +]; Reid et al 2003 [RCT +]; Reid et al 2007 [RCT -]; Rosal et al 1992 [RCT ++]; Simon et al 2003 [RCT +]; Sivarajan et al 2004 [RCT -]; Smith et al 2009 [RCT -]; Smith et al 2011 [RCT +]; Taylor et al 1990 [RCT +]; Taylor et al 1996 [RCT +]; Wakefield et al 2004 [RCT ++]) that included telephone follow-ups for over 4 weeks. Such interventions were

effective (OR=1.54; 95%CI: 1.39-1.70). The studies were heterogeneous, with two outliers (Feeney et al 2001, [RCT ++]; Taylor et al 1996, [RCT +]). Removing them reduced the heterogeneity (p=0.24) with the result remaining significant (OR=1.48, 1.33-1.64).

Intensity 5: Ten studies (Bolman et al 2002 [RCT -]; Borglykke et al 2008 [RCT +]; British Thoracic Society A 1990 [RCT ++]; Carlsson et al 1997 [RCT -]; Hennrikus et al 2010 [RCT +]; Hilleman et al 2004 [RCT ++]; Lewis et al 2009 [RCT +]; Mohiuddin et al 2007 [RCT ++]; Pedersen et al 2005 [RCT -]; Vial et al 2002 [RCT-]) included at least one post-discharge face-to-face contact. They differed widely in the number of sessions and the nature of support provided. There were also substantial differences in the nature of the control interventions.. There was an overall significant effect (OR=1.66; 95%CI: 1.38-2.00), but the studies were heterogeneous. Removing the outliers, which provided intensive face-to-face treatment over extended periods of time (Hilleman et al. 2004, [RCT ++]; Mohiuddin et al 2007, [RCT ++]) reduced heterogeneity (p=0.19). The overall effect was reduced as well but it remained significant (OR=1.45, 1.19-1.76).

The analysis of studies which validated self-reported abstinence replicated the finding that only interventions of Intensity 4 and 5 which provide support to smokers over a period longer than 4 weeks showed efficacy.

PART 2: ROLE OF MEDICATION

Some of the interventions examined above included medications and some did not. The finding of differential effectiveness of interventions of different intensity could have been confounded by more intensive interventions being more likely to include pharmacotherapy.

We divided studies of each intensity into those that included medications (mostly NRT, sometimes with options including also bupropion and varenicline) and those that did not.

Intensity 1 – behavioural support only: Two studies (Brandt et al 1997 [RCT +]; Hennrikus, et al 2005 [RCT +]) included behavioural support only and this showed no effect on abstinence (OR=1.24; 95%CI: 0.87-1.76).

Intensity 1 – behavioural support plus medications: One study (; Papadakis et al 2011 [RCT +]) included medications. At this level of support, such interventions were not effective (OR=2.00; 95%CI: 0.30-13.26).

Intensity 2 – behavioural support only: Three studies (Hajek et al 2002 [RCT ++]; Pederson et al 1991 [RCT +]; Pelletier et al 1998 [RCT -]) included behavioural support only and pooled data show that this was not effective (OR=1.07; 95%CI: 0.79-1.45).

Intensity 2 – behavioural support plus medications: Three studies (Chouinard et al 2005 [RCT ++]; Molyneux et al 2003 [RCT ++]; Nagle et al 2005 [RCT +]) included medications. The interventions were not effective (OR=1.01; 95%CI: 0.71-1.42).

Intensity 3 – behavioural support only: Seven studies (Kim et al 2005 [RCT +]; Miller et al 1997 [RCT +]; Ortigosa et al 2000 [RCT +]; Rigotti et al 1994 [RCT +]; Schiebel et al 2007 [RCT -]; Stevens et al 1993 [RCT -]; Stevens et al 2000 [RCT -]) included behavioural support only and pooled data show that this was not effective (OR=1.17; 95%CI: 0.98-1.40).

Intensity 3 – behavioural support plus medications: Three studies (Neuner et al 2009 [RCT -]; Rigotti et al 1997 [RCT +]; Wiggers et al 2006 [RCT +]) included medications. At this level of support, such interventions were not effective (OR=1.19; 95%CI: 0.91-1.55).

Intensity 4 – behavioural support only: Eighteen studies (British Thoracic Society B 1990 [RCT ++]; Dornelas et al 2000 [RCT +]; Feeney et al 2001 [RCT ++]; Froelicher et al 2004 [RCT +]; Hasuo et al 2004 [RCT +]; Haug et al 2011 [RCT -]; Hennrikus et al 2005 [RCT +]; Horn et al 2008 [RCT -]; Li et al 2008 [RCT -]; Metz et al 2007 [RCT -]; Miller et al 1997 [RCT +]; Mosca et al 2010 [RCT +]; Rosal et al 1992 [RCT ++]; Sivarajan et al 2004 [RCT -]; Smith et al 2009 [RCT - ; Smith et al 2011 [RCT +]; Taylor et al 1996 [RCT +]; Wakefield et al 2004 [RCT ++])) included behavioural support only and pooled data show this level of support was effective (OR=1.51; 95%CI: 1.35-1.69).

Intensity 4 – behavioural support plus medications: Eight studies (Chouinard et al 2005b [RCT ++]; De Busk et al 1994 [RCT ++]; Lacasse et al 2008 [RCT -]; ; Quist-Paulsen et al 2003 [RCT +]; Reid et al 2003 [RCT +]; Reid et al 2007 [RCT -]; Simon et al 2003 [RCT +]; Taylor et al 1990 [RCT +]) included medications. At this level of support, such interventions were effective (OR=1.66; 95%CI: 1.33-2.08).

Intensity 5 – behavioural support only: Three studies (Bolman et al 2002 [RCT +]; British Thoracic Society A 1990 [RCT ++]; Carlsson et al 1997 [RCT -]) included behavioural support only and pooled data showed borderline efficacy (OR=1.28; 95%CI: 1.01-2.63).

Intensity 5 – behavioural support plus medications: Eight studies (Borglykke et al 2008 [RCT +]; Hennrikus et al 2010 [RCT +]; Hilleman et al 2004 [RCT ++]; Lewis et al 2009 [RCT +]; Mohiuddin et al 2007 [RCT ++]; Pedersen et al 2005 [RCT -]; Tonnesen et al 2006 [RCT ++]; Vial et al 2002 [RCT -]) included medications. At this level of support, such interventions were effective (OR=2.26; 95%CI: 1.71-2.98).

Low intensity interventions were ineffective with or without medications. Interventions of Intensity 4 and 5 showed uncertain or modest efficacy without medications and good efficacy when medications were included. The analysis of studies which validated self-reported abstinence replicated these findings.

SUBSECTION 2: PATIENT GROUPS

There is little reason to expect that stop-smoking interventions targeting dependent smokers motivated to quit will differ in efficacy depending on smokers' physical illness. However, we analysed separately the interventions for the main groups of hospital patients.

A. Patients with cardiovascular disease

The results are the same as for all patient groups together, showing lack of efficacy for low intensity interventions, and significant effects of more intensive interventions.

Intensity 1: There were no such studies

Intensity 2: Pooled results from 3 studies (Chouinard et al 2005 [RCT ++]; Hajek et al 2002 [RCT ++]; Pelletier et al 1998 [RCT -]) showed no effect of this intensity (OR=1.11; 95%CI: 0.82-1.51).

Intensity 3: Pooled results from 4 studies (Miller et al 1997 [RCT +]; Ortigosa et al 2000 [RCT +]; Rigotti et al 1997 [RCT +]; Wiggers et al 2006 [RCT +]) showed no effect of this intensity (OR=1.12; 95%CI: 0.83-1.52).

Intensity 4: Pooled results from 16 studies (Chouinard et al 2005 [RCT ++]; De Busk et al 1994 [RCT ++]; Dornelas et al 2000 [RCT +]; Feeney et al 2001 [RCT ++]; Froelicher et al 2004 [RCT +]; Lacasse et al 2008 [RCT -]; Li et al 2008 [RCT -]; Miller et al 1997 [RCT +]; Mosca et al

2010 [RCT +]; Quist-Paulsen et al 2003 [RCT +]; Reid et al 2003 [RCT +]; Reid et al 2007 [RCT -]; Rosal et al 1992 [RCT ++]; Sivarajan et al 2004 [RCT -]; Smith et al 2009 [RCT -]; Taylor et al 1990 [RCT +]) showed that this level of intensity is effective in patients with CVD (OR=1.54; 95%CI: 1.34-1.76).

Intensity 5: Pooled results from 6 studies (Bolman et al 2002 [RCT -]; Carlsson et al 1997 [RCT -]; Hennrikus et al 2010 [RCT +]; Hilleman et al 2004 [RCT ++]; Mohiuddin et al 2007 [RCT ++]; Pedersen et al 2005 [RCT -]) showed that this level of intensity is effective in patients with CVD (OR=1.81; 95%CI: 1.42-2.32).

B. Patients with respiratory disease

The results are similar to those from other patient groups, showing lack of efficacy for low intensity interventions, and better effects of more intensive interventions, although in this group of studies, only interventions with post-discharge face-to-face contact achieved a significant effect.

Intensity 1: There was only one study offering this intensity of treatment (Brandt et al 1997 [RCT +]) that showed no significant effect (OR=2.83; 95%CI: 0.77-10.47).

Intensity 2: Similarly one study offering this intensity of treatment (Pederson et al 1991 [RCT +]) showed no significant effect (OR=1.22; 95%CI: 0.55-2.70).

Intensity 3: No studies were available

Intensity 4: Pooled results from one study (British Thoracic Society B 1990 [RCT ++]) showed no effect of this intensity in patients with respiratory illness (OR=1.78; 95%CI: 1.16-2.74).

Intensity 5: Pooled results from 3 studies (Borglykke et al 2008 [RCT +]; British Thoracic Society A 1990 [RCT ++]; Tonnesen et al 2006 [RCT ++]; showed that this level of intensity is effective in patients with respiratory illness (OR=1.50; 95%CI: 1.11-2.02).

C. Patients with cancer

There was only one study focusing on cancer patients. This was Intensity 4 with no medications and showed no intervention effect (Wakefield et al 2004, [RCT ++]).

D. Unselected/other hospital patients

The results are similar as for all patient groups together, showing lack of efficacy for low intensity interventions, and significant effects of Intensity 4 interventions, though the results of the three Intensity 5 interventions did not reach significance.

Intensity 1: Pooled results from 2 studies (Hennrikus, et al 2005 [RCT +]; Papadakis et al 2011 [RCT +]) showed no effect (OR=1.18; 95%CI: 0.83-1.70).

Intensity 2: Results from two studies (Molyneux et al 2003 [RCT ++]; Nagle et al 2005 [RCT +]) showed no effect (OR=0.90; 95%CI: 0.62-1.30).

Intensity 3: Pooled results from 7 studies (Kim et al 2005 [RCT +]; Miller et al 1997 [RCT +]; Neuner et al 2009 [RCT -]; Rigotti et al 1997 [RCT +]; Schiebel et al 2007 [RCT -]; Stevens et al

1993 [RCT -]; Stevens et al 2000 [RCT -]) showed a modest improvement in abstinence rates (OR=1.19; 95%CI: 1.02-1.40).

Intensity 4: Pooled results from 10 studies (Feeney et al 2001 [RCT ++]; Hasuo et al 2004 [RCT +]; Haug et al 2011 [RCT -]; Hennrikus et al 2005 [RCT +]; Horn et al 2008 [RCT -]; Metz et al 2007 [RCT -]; Miller et al 1997 [RCT +]; Simon et al 2003 [RCT +]; Smith et al 2011 [RCT +]; Taylor et al 1996 [RCT +]) showed a positive effect (OR=1.60; 95%CI: 1.38-1.84).

Intensity 5: Pooled results from 2 studies (Lewis et al 2009 [RCT +]; Vial et al 2002 [RCT-]) failed to show a significant effect (OR=1.43; 95%CI: 0.85-2.42).

D. Patients receiving intervention after hospital discharge

Three trials evaluated interventions delivered after hospital discharge. Briefer interventions without medications lacked efficacy (Schofield et al 1999 [RCT +] Intensity 1. One study of an intensity 4 intervention involving extended contact and NRT had a positive result (Caruthers et al 2005 [RCT +]) whilst another showed no effect (Hanssen et al 2008 [RCT -]). Pooling data from the intensity 4 interventions shows a lack of effect (OR=1.62, 95%CI: 0.87-3.03).

CONCLUSIONS

The overall picture emerges showing that brief interventions (Intensity 1 and 2) with users of acute care are not effective, even if they include medications. Interventions providing support for over 4 weeks have modest or uncertain effects if they do not include medications, but they have significant effects when medications are included.

SECTION 2: EFFICACY OF INTERVENTIONS DELIVERED TO SURGICAL PATIENTS

Seven trials evaluated interventions initiated prior to surgery. With one exception (Croghan et al 2005, [RCT +]), all trials included NRT.

Intensity 1: No studies were available

Intensity 2: Two trials (Croghan et al 2005 [RCT +]; Martucci et al 2010 [RCT +]) found mixed effects but the pooled result reached statistical significance (OR=1.97; 95% CI:1.04-3.75).

Intensity 3: One study (Thomsen et al 2010 [RCT +]) showed no effect (OR=1.42; 95%CI: 0.43-4.74).

Intensity 4: Two studies (Ratner et al 2004 [RCT +]; Simon et al. 1997 [RCT +]) showed no effect (OR=1.37; 95% CI:0.83-2.27).

Intensity 5: Two studies (Lindstom et al 2008 [RCT ++]; Moller et al 2002 [RCT ++]) showed a significant effect (OR=3.99; 95%CI: 1.83-8.70).

One trial (Rodriguez et al 2007 [RCT -]) evaluated effects of one session of stop-smoking messages delivered under deep sedation, but failed to show an effect of this type of intervention (OR=0.82; 95%CI: 0.30-2.25).

CONCLUSIONS

Brief interventions (Intensity 1 and 2) initiated prior to surgery lack efficacy even if accompanied by NRT. Extended support accompanied by medication is effective. Stop-smoking messages delivered under sedation are not effective.

SECTION 3: EFFICACY OF PHARMACOLOGICAL INTERVENTIONS WITH HOSPITAL PATIENTS

In this section, we covered trials that evaluated medications by comparing study arms which differed in whether or not they received active medication, but which received the same intensity of behavioural support.

Six trials (Campbell et al 1991 [RCT ++]; Campbell et al 1996 [RCT ++]; Hand et al 2002 [RCT ++]; Lewis et al 1998 [RCT +]; Tonnesen et al 2000 [RCT ++]; Tonnesen et al 2006 [RCT ++]) compared NRT accompanied by behavioural support (intensity 4 or 5 in all studies) with the same support delivered with placebo or with no medication. NRT was effective (OR=1.52; 95%CI: 1.07-2.17).

One trial (Tonnesen et al 2000 [RCT ++]) compared patch and inhaler alone with the two medications combined. The results showed that single NRTs were as effective as their combination (OR=0.50; 95% CI: 0.16-1.53).

Two trials (Rigotti et al 2006 [RCT ++]; Simon et al 2009 [RCT +]) compared bupropion and placebo. Both trials relied on telephone calls and neither offered any post-quit face-to-face support. The trials did not show the intervention effective (OR=1.17; 95%CI:0.67-2.07).

One small placebo controlled trial (Steinberg et al 2011 [RCT +]) evaluated varenicline accompanied by brief counselling session/sessions (it is not clear if there was one or more, but it was attended by 16 participants only). The trial did not find the treatment effective (OR=0.64; 95%CI: 0.22-1.80).

CONCLUSIONS

NRT accompanied by behavioural support is effective. A combination of patches and inhaler was not more effective than each medication on its own. Bupropion and varenicline provided without on-going face-to-face support lack efficacy.

SECTION 4: EFFICACY OF INTERVENTIONS WITH PATIENTS' RELATIVES

Three trials of intervention of Intensity 1 and 2 evaluated interventions with parents of children hospitalised on paediatric wards (Chan et al 2005, [RCT -]; Mahabee-Gittens et al

2008, [RCT -]; Ralston et al 2008, [RCT -]). The interventions overall lacked efficacy despite this group studies having shorter follow-ups (OR=2.85; 95%CI 0.92-8.81).

Conclusions

Brief interventions (Intensity 1 and 2) with parents of hospitalised children lack efficacy.

Section 5: Efficacy of interventions with hospital staff

We found only one study (Dalsgaro et al 2004 [RCT ++] evaluating an intervention with hospital employees. The trial showed bupropion with regular face-to-face support to be an effective treatment for hospital employees (OR=2.84; 95%CI: 1.28-6.30).

Conclusions

Bupropion accompanied by intensive support is an effective treatment for hospital employees.

Narrative summary

Intervention intensity

A range of interventions aimed at helping smokers in acute care settings stop smoking has been proposed. Advice by doctors and nurses during a hospital visit, possibly repeated and reinforced during the hospital stay (if applicable) and accompanied by leaflets, is by far the simplest and least expensive option which could be provided routinely on a large scale. Unfortunately, there is no evidence that such interventions work. Smokers in acute care have usually received strong encouragements to stop smoking on a number of previous occasions and the fact that they continue to smoke despite high motivation to stop suggests a high level of dependence and a need for more intensive treatment.

The next level of intervention, which is still requiring modest resources is to reinforce the in-hospital intervention by telephone calls over the first few weeks after discharge. This too was not shown effective.

For interventions with acute care patients to be effective, an extended support and stop smoking medication provided for over 4 weeks seem necessary. Face-to-face support may provide better results than support provided over telephone. Importantly, support alone without medications has only uncertain effects but it has good efficacy when provided together with smoking cessation medications.

Patient groups

There is no a-priori reason to expect that smokers with different diagnoses would react differently to different interventions. We nevertheless analysed the main patient categories including patients with cardiovascular disease, respiratory disease, patients undergoing surgery, patients receiving intervention only after discharge, and general patient samples separately. The results broadly confirm the main findings. Only Intensity 5 interventions (over 4 weeks of face to face support) accompanied by medications were effective with patients undergoing surgery.

PHARMACOTHERAPY

NRT accompanied by extended multi-session support lasting over 4 weeks is effective in the acute services setting. A few small trials evaluated bupropion and varenicline accompanied by minimal support and did not find such treatments effective. NRT is known to be ineffective without support and follow-up and this is probably true for other stop-smoking medications as well.

PATIENT RELATIVES

Brief interventions (Intensity 1 and 2) with parents of hospitalised children did not show efficacy.

HOSPITAL STAFF

Bupropion with face-to-face support of over 4 weeks is an effective treatment for hospital staff.

IMPACT OF BACKGROUND OF STAFF DELIVERING THE INTERVENTIONS

We were unable to ascertain whether the background of the person providing the interventions affect outcomes, but given that extended support provided by staff other than doctors is effective, encouraging doctors to provide on-going telephone or face-to-face counselling sessions to smokers would not seem an economical approach. The professional background of stop-smoking advisors is likely to be of limited importance. The key ingredients of efficacy seem to be the length of support and inclusion of medications.

EVIDENCE STATEMENTS

Statements 1.1 to 1.5 concern non-surgical patients

ES 1.1: There is strong evidence from trials that validated self-reported abstinence rates that interventions with no follow-up (Intensity 1 and 2) are ineffective.

Two studies of level 1 intensity (Brandt et al 1997 [RCT +]; Papadakis et al 2011 [RCT +]), and five of level 2 intensity support (Chouinard et al 2005 [RCT ++]; Hajek et al 2002 [RCT ++]; Molyneux et al 2003 [RCT ++]; Nagle et al 2005 [RCT +]; Pederson et al 1991 [RCT +]) showed no effect. Pooled data from these studies confirm lack of effect: Intensity 1 OR=2.52 (95%CI: 0.86-7.40); Intensity 2 OR=0.96 (95%CI: 0.89-1.38)

ES 1.2: There is strong evidence from trials that validated self-reported abstinence rates that interventions delivered with telephone follow-ups for up to 4 weeks (Intensity 3) are not effective.

Six studies (Kim et al 2005 [RCT +]; Miller et al 1997 [RCT +]; Ortigosa et al 2000 [RCT +]; Rigotti et al 1994 [RCT ++]; Rigotti et al 1997 [RCT +]; Wiggers et al 2006 [RCT +]) showed no effect. Pooling these data give an odds ratio of 1.11 (95% CI: 0.89-1.38).

ES 1.3: There is strong evidence from trials that validated self-reported abstinence rates that interventions accompanied by on-going behavioural support for over 4 weeks in combination with smoking cessation medications are effective.

Of the eleven studies examining the efficacy of level 4 intensity interventions plus medication compared to usual care six showed a significant benefit (British Thoracic Society [RCT ++]; De Busk et al 1994 [RCT ++]; Feeney et al 2001 [RCT ++]; Miller et al 1997 [RCT +]; Quist-Paulsen et al 2003 [RCT +]; Taylor et al 1990 [RCT +]) and five did not (Chouinard et al 2005 [RCT ++]; Mosca et al 2010 [RCT +]; Rosal et al [RCT ++]; Smith et al 2011 [RCT +]; Wakefield et al 2004 [RCT ++]). When these studies are pooled there is evidence of a beneficial effect of this level of intervention (OR=1.65; 95%CI: 1.42-1.91). There were five studies examining level 5 intensity interventions with medication. Four showed a significantly positive effect (Borglykke et al 2008 [RCT +]; Hennrikus et al 2010 [RCT +]; Hilleman et al 2004 [RCT ++]; Mohiuddin et al 2007 [RCT ++]), and three did not (British Thoracic Society 1990 [RCT ++]; Lewis et al 2009 [RCT++]; Tonnesen et al 2006 [RCT ++]). When these studies are pooled there is evidence of a beneficial effect of this level of intervention (OR=1.87; 95%CI: 1.48-2.36).

ES 1.4: There is strong evidence that interventions with limited follow-up (Intensity 1-3) are not effective across non-surgical patient groups.

All interventions of intensity levels 1-3 were ineffective for patients with **cardiovascular disease** (Chouinard et al 2005 [RCT ++]; Hajek et al 2002 [RCT ++]; Pelletier et al 1998 [RCT -]; Miller et al 1997 [RCT +]; Ortigosa et al 2000 [RCT +]; Rigotti et al 1994 [RCT +]; Wiggers et al 2006 [RCT +]), **respiratory disease** (Brandt et al 1997 [RCT +]; Pederson et al 1991 [RCT +]), and **other groups of hospital patients** (Hennrikus, et al 2005 [RCT +]; Papadakis et al 2011 [RCT +]; Kim et al 2005 [RCT +]; Miller et al 1997 [RCT +]; Molyneux et al 2003 [RCT ++]; Nagle et al 2005 [RCT +]; Neuner et al 2009 [RCT -]; Rigotti et al 1997 [RCT +]; Schiebel et al 2007 [RCT -]; Steven et al 1997 [RCT]; Stevens et al 2000 [RCT -]).

ES 1.5: There is strong evidence that interventions with medications and follow-up of over 4 weeks are effective across non-surgical patient groups.

For patients with **cardiovascular disease** 8 trials of interventions for intensity 4-5 showed a positive effect (De Busk et al 1994 [RCT ++]; Feeney et al 2001 [RCT ++]; Hennrikus et al 2010 [RCT +]; Hilleman et al 2004 [RCT ++]; Mohiuddin et al 2007 [RCT ++] Quist-Paulsen et al 2003 [RCT +]; Smith et al 2011 [RCT +]; Taylor et al 1990 [RCT +]) and 14 did not (Bolman et al 2002 [RCT -]; Carlsson et al 1997 [RCT -]; Rosal 1992 [RCT ++]; Chouinard et al 2005 [RCT ++]; Dornelas et al 2000 [RCT +]; Froelicher et al 2004 [RCT +]; Lacasse et al 2008 [RCT -]; Li et al 2008 [RCT -]; Miller et al 1997 [RCT +]; Mosca et al 2010 [RCT +]; Pedersen et al 2005 [RCT -]; Reid et al 2003 [RCT +]; Reid et al 2007 [RCT -]; Sivarajan et al 2004 [RCT -]). When these studies are pooled there is evidence of a beneficial effect of this level of intervention. Intensity 4 OR=1.54 (95%CI: 1.34-1.76); Intensity 5 OR=1.81 (95%CI: 1.42-2.32).

For patients with **respiratory disease** 2 trials of interventions for intensity 4-5 showed a positive effect (British Thoracic Society B 1990 [RCT ++]; Borglykke et al 2008 [RCT +]) and 2 showed no effect (British Thoracic Society A 1990 [RCT ++]; Tonnesen et al 2006 [RCT ++]). There was only one study of intensity 4 intervention (British Thoracic Society B 1990 [RCT ++]) that showed benefit (OR=1.78; 95% CI:1.16-2.74). Pooling the intensity 5 intervention studies also showed a beneficial effect (OR=1.50 95%CI: 1.11-2.02).

For **other non-surgical groups of hospital patients** 5 trials of interventions for intensity 4-5 showed a positive effect (Feeney et al 2001 [RCT ++]; Haug et al 2011 [RCT -]; Metz et al 2007 [RCT -]; Miller et al 1997 [RCT +]; Taylor et al 1996 [RCT +]) and 7 did not (Hasuo et al 2004 [RCT +]; Hennrikus et al 2005 [RCT +]; Horn et al 2008 [RCT -]; Lewis et al 2009 [RCT +]; Simon et al 2003 [RCT +]; Smith et al 2011 [RCT +]; Vial et al 2002 [RCT-]). Pooling the intensity 4 intervention studies also showed a beneficial effect (OR=1.60 95%CI: 1.38-1.84). However pooling the two Intensity 5 studies (Lewis et al 2009 [RCT +]; Vial et al 2002 [RCT-]) showed no significant effect (OR=1.43; 95%CI: 0.85-2.42).

ES 1.6: There is mixed evidence concerning the efficacy of brief interventions in patients undergoing surgery.

Only one (Martucci et al 2010 [RCT +]) of three studies (Croghan et al 2005 [RCT +]; Martucci et al 2010 [RCT +]; Thomsen et al 2010 [RCT +]) investigating the efficacy of level 2-3 pre-operative smoking cessation interventions was positive. Pooling data from the intensity 2 studies (Croghan et al 2005 [RCT +]; Martucci et al 2010 [RCT +]) showed a borderline benefit of this level of intervention (OR=1.97; 95%CI: 1.04-3.75). The one study of intensity 3 interventions (Thomsen et al 2010 [RCT +]) showed no effect (OR=1.42; 95%CI: 0.42-4.74).

ES 1.7: There is moderate evidence that in patients undergoing surgery smoking cessation interventions relying mostly on telephone contact (intensity 4) are not effective.

Two trials (Ratner et al 2004 [RCT +]; Simon et al 1997 [RCT -]) showed no effect of this level of intervention. Pooled data gives an odds ratio of 1.37 (95%CI: 0.83-3.27).

ES 1.8: There is strong evidence that in patients undergoing surgery intensive interventions (intensity 5) alongside nicotine replacement therapy are effective.

Two trials (Lindstrom et al 2008 [RCT ++]; Moller et al 2002 [RCT ++]) show a positive effect. Pooled data gives an odds ratio of 3.99 (95%CI: 1.83-8.70).

ES 1.9: There is weak evidence that stop smoking messages delivered under deep sedation are not effective.

One trial (Rodriguez et al 2007 [RCT -]) showed no effect (OR=0.82; 95%CI: 0.30-2.25)

ES 1.10: There is strong evidence that nicotine replacement treatment accompanied by extended support is effective in general hospital patients.

Only one (Tonnesen et al 2006 [RCT ++]) of the six trials (Campbell et al 1991 [RCT ++]; Campbell et al 1996 [RCT ++]; Hand et al 2002 [RCT ++]; Lewis et al 1998 [RCT +]; Tonnesen et al 2000 [RCT ++]; Tonnesen et al 2006 [RCT ++]) examining the efficacy of NRT showed a positive effect. However pooling these data showed a benefit of NRT (OR=1.52; 95% CI: 1.07-2.17).

ES 1.11: There is moderate evidence that bupropion and varenicline provided without face-to-face support are ineffective in acute care non-surgical patients

Bupropion: two trials showed no effect (Rigotti et al 2006 [RCT ++]; Simon et al 2009 [RCT +]). Varenicline: one trial showed no effect Steinberg et al 2011 [RCT +]). The odds ratios (95% CI) for bupropion and varenicline are 1.17 (0.67-2.87) and 0.64 (0.22-1.80) respectively.

ES 1.12: There is weak evidence that low intensity interventions with smoking parents of hospitalised children lack efficacy.

Three trials (Chan et al 2005, [RCT -]; Mahabee-Gittens et al 2008, [RCT -]; Ralston et al 2008 [RCT -]) have all negative results. Pooling these data show no significant effect of such interventions (OR=2.85; 95%CI: 0.92-8.81). There were no studies investigating the efficacy of bupropion or varenicline combined with face-to-face support in acute care patients

ES 1.13: There is moderate evidence that treatment of hospital staff with bupropion combined with regular face-to-face support is effective.

One high quality trial (Dalsgaro et al 2004 [RCT ++]) found a positive effect.

Chapter 2: Smoking Cessation Interventions with Users of Maternity Services

We found 81 trials evaluating smoking cessation interventions with users of maternity services.

We were struck by the low quality of many of these studies, especially older ones. In many studies the denominators used to calculate success rates kept changing, key methodological details were not provided, validation results were not taken into account in calculating outcomes, comparison groups were clustered post-hoc, and papers convey a sense of a strenuous effort to come up with positive results.

The chapter is divided into five sections.

SECTION 1: EFFICACY OF BEHAVIOURAL INTERVENTIONS DELIVERED DURING PREGNANCY

PART 1: INTERVENTION INTENSITY

For each intensity of support, the results are presented separately for outcomes up to delivery, and outcomes post-delivery (usually from several months up to one year post-partum). We presented the results of all the studies first, and followed this with a meta-analysis including only trials which validated self-reported abstinence biochemically.

Intensity 1

Up to delivery: We found 17 studies that examined the effect of level 1 intensity interventions delivered during pregnancy on cessation rates up to delivery (Baric et al 1976 [RCT -]; Bauman et al 1983 [RCT -]; Dunkely et al 1997 [RCT -]; Hajek et al 2001 A [RCT ++]; Hjalmarson et al 1991 [RCT +]; Kendrick et al 1995 [RCT +]; Lowe et al 1998 A [RCT +]; Lowe et al 1998 B [RCT +]; MacArthur et al 1987 [RCT -]; Mayer et al 1990 [RCT -]; Moore et al 2002 [RCT +]; Petersen et al 1992 [RCT -]; Reading et al 1992 [RCT -]; Secker-Walker et al; 1997 [RCT +]; Windsor et al 1985 [RCT +]; Windsor et al 2000 [RCT +]; Windsor et al 1985 B [RCT +]. This type of intervention was not effective in increasing abstinence rates (OR=1.12; 95%CI:0.96-1.31).

Post partum: We found four studies that examined the efficacy of level 1 intensity intervenations on post-partum abstinence rates (Hajek et al 2001 [RCT ++]; Hjalmarson et al 1991 [RCT +]; Petersen et al 1992 [RCT -]; Strecher et al 2000 [RCT -]). The intervention had no effect on smoking cessation rates post-partum (OR=1.27; 95%CI: 0.91-1.78).

Conclusion: One-off interventions accompanied by written and other materials lack efficacy.

Intensity 2

Up to delivery: We found 2 studies that examined the effect of level 2 intensity interventions delivered during pregnancy on cessation rates in late pregnancy (Burling et al

1991 [RCT -]; Pbert et al 2004 [RCT -]). Pooling data from these studies showed a significant effect on abstinence rates (OR=2.08; 95%CI: 1.25-3.49), however given the low quality of these studies, the result should be interpreted with caution.

Post partum: Data from one study (Pbert et al 2004 [RCT -]) that examined the efficacy of level 2 intensity intervenations on post-partum abstinence rates showed a significant effect (OR=2.82; 1.21-6.57].

Conclusion: Two low quality studies evaluating intensity 2 interventions found an effect.

Intensity 3

Up to delivery: We pooled data from three studies (O'Connor et al 1992 [RCT +]; Tsoh et al 2010 [RCT -]; Valbo et al 1996 [RCT -]) that examined the effect of level 3 intensity smoking cessation interventions delivered during pregnancy on cessation rates in late pregnancy. The meta-analysis shows a benefit of such interventions (OR=1.48; 95% CI: 0.75-2.93).

Post partum: Two studies (O'Connor et al 1992 [RCT +]; Polanska et al 2004 [RCT -]) examined the efficacy of level 3 intensity intervenations on post-partum abstinence rates and pooled data showed a significant effect (OR=3.66; 95%CI: 2.28-5.87).

Conclusion: Four studies evaluating interventions that followed smokers up for up to 4 weeks found the interventions effective up to delivery. One study (O'Connor et al 1992 [RCT +]) with post-delivery follow-up found no long-term effect.

Intensity 4

Up to delivery: We found 13 studies (Bullock et al 1995 [RCT -]; Cinciripini et al 2000 [RCT +]; Dornelas et al 2006 [RCT +]; Ershoff et al 1989 [RCT ++]; Ershoff et al 1999 [RCT +]; Lilley et al 1986 [RCT -]; McBride et al 1999 [RCT -]; McLeod et al 2004 [RCT +]; Patten et al 2010 [RCT +]; Rigotti et al 2006 [RCT +]; Sexton et al 1984 [RCT +]; Solomon et al 2000 [RCT +]; Walsh et al 1997 [RCT +]) that examined the effect of level 4 intensity interventions delivered during pregnancy on cessation rates in late pregnancy. Pooling these data showed a significant effect of this type of intervention (OR=1.70; 95%CI: 1.43-2.01)

Post partum: Eight of the studies (Bullock et al 2009 [RCT +]; Cinciripini et al 2000 [RCT +]; Dornelas et al 2006 [RCT +]; McBride et al 1999 [RCT -]; McLeod et al 2004 [RCT +]; Rigotti et al 2006 [RCT +]; Stotts et al 2002 [RCT -]; Walsh et al 1997 [RCT +]) examined the effect of level 4 intensity intervenations on post-partum abstinence rates. The meta-analysis showed no effect of this level on intervention (OR=1.16; 95%CI: 0.87-1.55).

Conclusion: Intensity 4 interventions were effective up to delivery, but not after.

Intensity 5

Up to delivery: We found 17 studies that examined the effect of level 5 intensity interventions delivered during pregnancy on cessation rates in late pregnancy (Albrecht et al 1998 [RCT -]; Belizan et al 1995 [RCT -]; Cope et al 2003 [RCT -]; De Vries et al 2006 [RCT -]; Gielen et al 1997 [RCT +]; Hartman et al 1996 [RCT +]; Hegaard et al 2003 [RCT +]; Lawrence

et al 2003 [RCT +]; Loeb et al 1983 [RCT +]; Malchodi et al 2003 [RCT +]; Panjari et al 1999 [RCT +]; Secker-Walker et al 1994 [RCT -]; Tappin et al 2000 [RCT +]; Tappin et al 2005 [RCT +]; Thornton et al 1997 [RCT +]; Valbo et al 1994 [RCT -]; Windsor et al 1993 [RCT+]). Pooling data from these studies revealed a significant effect of this level of intervention (OR=1.51; 95% CI: 1.28-1.78).

Post partum: Pooling data from the four studies that examined the efficacy of level 5 intensity intervenations on post-partum abstinence rates (De Vries et al 2006 [RCT -]; Lawrence et al 2003 [RCT +]; Thornton et al 1997 [RCT +]; Valbo et al 1991 [RCT -]) showed no effect (OR=1.28; 95%CI: 0.90-1.81).

Conclusion: Intensity 5 interventions were also effective up to delivery, but not after.

Results of studies that validated self-reported abstinence

Intensity 1 – Validated

Up to delivery: Nine studies of level 1 intensity interventions delivered during pregnancy reported biochemically validated abstinence rates in late pregnancy (Hajek et al 2001 [RCT ++]; Hjalmarson et al 1991 [RCT +]; Kendrick et al 1995 [RCT +]; Lowe et al 1998 A [RCT +]; Lowe et al 1998 B [RCT +]; Moore et al 2002 [RCT +]; Secker-Walker et al; 1997 [RCT +]; Windsor et al 1985 [RCT +]; Windsor et al 1985 B [RCT +]). Pooling data showed no effect of this type of intervention on abstinence rates (OR=1.01; 95%CI:0.85-1.19).

Post partum: Pooling data from the three studies (Hajek et al 2001 [RCT ++]; Hjalmarson et al 1991 [RCT +]; Strecher et al 2000 [RCT -]) that examined the efficacy of level 1 intensity interventions on post-partum biochemically validated abstinence rates showed no effect (OR=1.46; 95%CI: 0.98-2.17).

Intensity 2 – Validated

There were no studies of this kind.

Intensity 3 – Validated

Up to delivery and Post partum: Only one study of level 3 intensity interventions delivered during pregnancy reported biochemically validated abstinence rates in late pregnancy and post-partum (O'Connor et al 1992 [RCT +]). This study showed no effect at either time point (End of pregnancy OR=2.42; 95%CI: 0.82-7.12; Post-partum OR =2.65; 95%CI: 0.91-7.71).

Intensity 4 – Validated

Up to delivery: Eight studies of intensity 4 interventions delivered during pregnancy reported biochemically validated abstinence rates in late pregnancy (Cinciripini et al 2000 [RCT +]; Dornelas et al 2006 [RCT +]; Ershoff et al 1989 [RCT ++]; Ershoff et al 1999 [RCT +]; Patten et al 2010 [RCT +]; +]; Rigotti et al 2006 [RCT +]; Solomon et al 2000 [RCT +]; Walsh et al 1997 [RCT +]). Only three of these studies showed a significant effect on their own, but

pooling the data showed that this type of intervention increased abstinence rates (OR=1.72; 95%CI:1.27-2.33).

Post partum: Pooling data from the six studies (Bullock et al 2009 [RCT +]; Cinciripini et al 2000 [RCT +]; Dornelas et al 2006 [RCT +]; Rigotti et al 2006 [RCT +]; Stotts et al 2002 [RCT -]; Walsh et al 1997 [RCT +]) that examined the efficacy of level 4 intensity interventions on post-partum biochemically validated abstinence rates did not show a significant effect (OR=1.27; 95%CI: 0.88-1.85).

Intensity 5 - Validated

Up to delivery: 12 studies of level 5 intensity interventions delivered during pregnancy reported biochemically validated abstinence rates in late pregnancy (Albrecht et al 1998 [RCT -]; Gielen et al 1997 [RCT +]; Hartman et al 1996 [RCT +]; Hegaard et al 2003 [RCT+]; Lawrence et al 2003 [RCT +]; Loeb et al 1983 [RCT +]; Malchodi et al 2003 [RCT +]; Panjari et al 1999 [RCT +]; Tappin et al 2000 [RCT +]; Tappin et al 2005 [RCT +]; Thornton et al 1997 [RCT +]; Windsor et al 1993 [RCT+]). Although only two of these studies showed a significant effect of the intervention on their own, pooling all the data showed a small but significant effect of this type of intervention on abstinence rates (OR=1.34; 95%CI:1.11-1.63).

Post partum: Two studies (Lawrence et al 2003 [RCT +], Thornton et al 1997 [RCT +]) examined the efficacy of level 5 intensity intervention on post-partum. They showed no significant effect (OR=0.93; 95%CI: 0.62-1.38), but note that this study showed no effect up to delivery either.

Background of advisors delivering the interventions

We compared validated studies evaluating interventions delivered by midwives and those delivered by advisors other than midwives.

There were four studies of intensity 1 interventions, three (Hajek et al 2001 [RCT ++]; Lowe et al 1998 A [RCT +]; Secker-Walker et al; 1997 [RCT +]) utilising midwives, and one (Windsor et al 1985 [RCT +]) using non-midwives. The one study using non-midwives showed an effect (OR=8.11, 95%CI: 1.79-36.68), the midwife delivered interventions did not (OR=1.02, 95%CI: 0.63-1.66).

There were nine studies of intensity 4 interventions, two utilising midwives (Solomon et al 2000 [RCT +]; Walsh et al 1997 [RCT +]), and seven that used non-midwives (Bullock et al 2009 [RCT +]; Cinciripini et al 2000 [RCT +]; Dornelas et al 2006 [RCT +]; Ershoff et al 1989 [RCT ++]; Patten et al 2010 [RCT +]; Rigotti et al 2006 [RCT +]; Stotts et al 2002 [RCT -]). Both showed a significant effect of this type of intervention (midwives OR=2.49, 95%CI: 1.19-5.24; non-midwives 1.40 95%CI: 1.02-1.92).

There were thirteen studies of intensity 5 interventions, six utilising midwives (Hegaard et al 2003 [RCT+]; Lawrence et al [RCT +]; Panjari et al 1999 [RCT +]; Tappin et al 2000 [RCT +]; Tappin et al 2005 [RCT +]; Thornton et al 1997 [RCT +]) and seven that used non-midwives Gielen et al 1997 [RCT +]; Hartman et al 1996 [RCT +]; Loeb et al 1983 [RCT +]; Lowe et al 1997 [RCT +]; Malchodi et al 2003 [RCT +]; Pollack 2007 et al, [RCT ++]; Windsor et al 1993 [RCT+]). Both showed a significant effect of this type of intervention (midwives OR=1.33, 95%CI: 1.00-1.77; non-midwives 1.47 95%CI: 1.15-1.88).

The professional background of advisors delivering the intervention had no effect on outcome.

Conclusions

In studies that validated self-reported abstinence, brief one-off interventions (Intensity 1) were not effective. The only study of Intensity 3 interventions (O'Connor 1992, [RCT +]) did not detect a significant effect. Intensity 4 and 5 interventions showed efficacy during pregnancy and up to delivery. The effects did not extend into post-natal period. The professional background of advisors delivering the intervention had no effect on outcome.

SECTION 1A: EFFECTS OF INCENTIVES

There were 4 studies examining the effects of incentives contingent on abstinence (Donatelle et al 2000 [RCT ++]; Heil et al 2008 [RCT ++]; Higgins et al 2004 [RCT +]; Higgins et al 2010 [RCT +]. All validated self-reported abstinence biochemically. Pooling these data showed a significant effect both up to delivery (OR=5.77; 95%CI: 3.34-9.98) and post-partum (OR=5.86; 95%CI: 2.74-12.52).

Three of the studies followed up the participants after the incentives were discontinued (Heil et al 2008 [RCT ++]; Higgins et al 2004 [RCT +]; Higgins et al 2010 [RCT +]). Pooling data from these studies confirmed an ongoing benefit of incentives (OR=10.29; 95%CI: 2.75-38.51)

Conclusions

Provisions of incentives contingent on abstinence was effective in increasing cessation rates both pre-delivery and post-partum, and the effect was maintained even after the incentives were discontinued.

SECTION 1B: EFFICACY OF INTERVENTIONS TARGETING PARTNERS

We found only one study of a stop-smoking intervention targeting partners of pregnant women (De Vries 2006, [RCT -]). The study write-up does not allow data extraction, but the authors report that the intervention had no effect. Three other studies involved partners. Lilley et al. 1986 [RCT -] used leaflets directed at both the woman and her partner. Lowe et al. 1998 [RCT +] used an intervention which included a no-smoking contract between the woman and her partner. McBride et al. 2004 [RCT +] included partners as coaches and also provided support for partners who smoke. The studies do not allow data extraction on the partner component, but all three had overall negative results.

SECTION 2: EFFICACY OF INTERVENTIONS DELIVERED POST-PARTUM

Three trials studied interventions provided to women after delivery (Winickoff et al 2010 [RCT +]; Hannover et al 2009 [RCT -]; Wall et al 1995 [RCT -]). None of the trials validated

self-reported abstinence and only the highest intensity intervention (intensity 5) studied by Wall et al (1995) showed an effect.

SECTION 3: EFFICACY OF PHARMACOTHERAPIES

Nicotine replacement therapy is the only drug treatment that has been evaluated for use in pregnancy so far. All the trials validated self-reported abstinence biochemically at some time points at least. Four trials used patches (Coleman et al 2012, [RCT ++]; Hotham et al 2006 [RCT ++]; Kapur et al 2001, [RCT +]; Wisborg et al 2000, [RCT ++]), one used gum (Oncken et al 1998, [RCT +]) and one used a choice between patch, gum or lozenge (Pollack 2007 et al, [RCT ++]). The results were negative across the levels of support.

Nicotine replacement treatment did not show efficacy across the levels of support.

SECTION 4: EFFICACY OF INTERVENTIONS TO PREVENT RELAPSE

We found 14 studies (Ershoff et al 1995 [RCT +]; Hajek et al [RCT ++]; Hannover et al 2009 [RCT -]; Johnson et al 2000 [RCT +]; Lowe et al 1997 [RCT +]; McBride et al 1999 [RCT -]; McBride et al 2004 [RCT +]; Morasco et al 2006 [RCT +]; Pbert et al 2004 [RCT -]; Ratner et al 2000 [RCT -]; Reitzel et al 2010 [RCT ++];Ruger et al 2008 [RCT -]; Secker-Walker et al 1995 [RCT +]; Secker-Walker et al 1998 [RCT ++]; Severson et al 1997 [RCT -]; Van't Hof et al 2000 [RCT-]) focused on women who stopped smoking, with the aim of helping them to prevent relapse during and after pregnancy.

Regardless of how the studies were grouped (time of intervention, intensity of intervention, validation of abstinence) the interventions showed no effect.

NARRATIVE SUMMARY

INTERVENTION INTENSITY

As with acute care smokers, a range of interventions aimed at users of maternity services has been proposed. Advice by midwives accompanied by leaflets is by far the simplest and least expensive option that could be provided routinely on a large scale. It has been evaluated in 20 randomised trials and pooling them together shows that such one-off interventions have little effect.

Pregnant smokers are likely to have received strong encouragements to stop smoking from their friends, families, and health care providers. Those who continue to smoke despite such advice may need more intensive help.

Interventions of Intensity 2 and 3 were evaluated in only a small number of trials. The results suggest that these are likely to have only limited, if any, effects. Interventions of Intensity 4 and 5 however show efficacy, although the effects are not maintained after delivery.

It is worth noting that unlike in studies of acute care interventions, there was no observable trend in favour of face-to-face contact compared to telephone support. This could be in part

at least due to difficulties reported in some studies in getting pregnant women to attend face-to-face sessions.

The only Intensity 1 trial with a positive result used non-midwifery advisors. The efficacy of interventions of Intensity 4 and Intensity 5 was similar regardless of the professional background of the person delivering the intervention. These results correspond with the results of a survey of UK services for pregnant smokers (Taylor and Hajek, 2001). Some services employed midwives to deliver specialist stop-smoking interventions while others employed advisors with different backgrounds. Advisor background had no effect on 4-week success rates.

The current practice within NHS is for pregnant smokers to receive multisession support and medication from stop smoking specialists employed by local stop smoking services. The key finding of this review supports this practice.

Interventions using incentives contingent on abstinence

There is evidence that progressive reinforcement schedules using incentives contingent on abstinence are effective. It should be noted that the existing studies used carefully designed schedules where continuing abstinence was frequently checked and the rewards were progressive, with temporary lapses resetting the rewards to lower levels. This differs from some of the uncontrolled experiments conducted currently within the NHS. Implementing such interventions in routine care would be demanding. The staff would need to strictly adhere to schedules and frequent contacts from the above studies, and measures would need to be in place to try to limit a range of problems inherent in this approach.

Efficacy of pharmacotherapy

Nicotine replacement therapy in pregnancy is considered much safer than smoking (see Review 1) but only a few studies have evaluated its use in pregnancy and several of them were aborted due to concerns, which were in all cases shown unwarranted. As with other populations, NRT did not work when accompanied by minimal behaviour support. However, in this group, it did not show efficacy even when accompanied by more intensive support. Only a few studies with relatively small samples are available, the results go in the 'right' direction and it is possible that another large trial with the same trend would tip the pooled results over the significance line. It is also possible that NRT accompanied by home visits as provided by the UK services may be effective, but additional trials are needed to determine this (see Research Gaps below).

Interventions with partners

We did not find any positive results of such interventions, but they were not extensively evaluated. Recruiting pregnant women is generally difficult, and large studies recruiting women plus smoking partners may not be practicable.

Interventions to prevent relapse

Interventions to prevent relapse in women who stopped smoking recently show no effect, regardless of their timing (during pregnancy, at delivery, or post-partum).

Evidence Statements

ES: 2.1: There is strong evidence from trials that validated self-reported abstinence rates that low intensity (intensity 1-3) smoking cessation interventions in pregnancy (i.e. those

that have minimal contact and follow-up for < 1 month following a target quit date) have no effect on abstinence rates in late pregnancy.

Only one study (Windsor et al 1985 [RCT +]) found an effect of a low intensity intervention (Intensity 1) whilst ten showed no effect (Hajek et al 2001 [RCT ++]; Hjalmarson et al 1991 [RCT +]; Kendrick et al 1995 [RCT +]; Lowe et al 1998 A [RCT +]; Lowe et al 1998 B [RCT +]; Moore et al 2002 [RCT +]; O'Connor et al 1992 [RCT +]; Secker-Walker et al; 1997 [RCT +]; Windsor et al 1985 [RCT +]; Windsor et al 1985 B [RCT +]). Pooling data from these studies showed no significant effect. Intensity 1 OR=1.01 (95%CI: 0.85-1.19); Intensity 3 OR=2.42 (95%CI: 0.82-7.12).

ES 2.2: There is moderate evidence from trials that validated self-reported abstinence rates that low intensity (intensity 1-3) smoking cessation interventions in pregnancy have no effect on abstinence rates post-partum.

Three studies (Hajek et al 2001 [RCT ++]; (O'Connor et al 1992 [RCT +]; Strecher et al 2000 [RCT -]) showed no effect and one (Hjalmarson et al 1991 [RCT +]) showed a modest benefit. Pooling data from these studies showed no significant effect. Intensity 1 OR=1.46 (95%CI: 0.98-2.17); Intensity 3 OR=2.65 (95%CI: 0.91-7.71).

ES 2.3: There is strong evidence from trials that validated self-reported abstinence rates that higher intensity (intensity 4-5) smoking cessation interventions in pregnancy (i.e. those that provide follow-up for > 1 month after a target quit date, either by telephone, written or electronic correspondence or face-to-face contact) increase abstinence rates in late pregnancy.

Six studies (Dornelas et al 2006 [RCT +]; Ershoff et al 1989 [RCT ++]; Walsh et al 1997 [RCT +]; Hartman et al 1996 [RCT +]; Hegaard et al 2003 [RCT+] Windsor et al 1993 [RCT+]) demonstrated efficacy of such interventions (Intensity 4-5), whilst 14 showed no effect (Albrecht et al 1998 [RCT -]; Cinciripini et al 2000 [RCT +]; Ershoff et al 1999 [RCT +]; Gielen et al 1997 [RCT +];; Lawrence et al [RCT +]; Loeb et al 1983 [RCT +]; Malchodi et al 2003 [RCT +]; Panjari et al 1999 [RCT +]; Patten et al 2010 [RCT +]; Rigotti et al 2006 [RCT +]; Solomon et al 2000 [RCT +]; Tappin et al 2000 [RCT +]; Tappin et al 2005 [RCT +]; Thornton et al 1997 [RCT +]). Pooling data from these studies showed a significant effect. Intensity 4 OR=1.72 (95%CI: 1.27-2.33); Intensity 5 OR=1.34 (95%CI: 1.11-1.63).

ES 2.4: There is strong evidence from trials that validated self-reported abstinence rates that high intensity (intensity 4-5) smoking cessation interventions in pregnancy do not increase abstinence rates post-partum.

One RCT (Walsh et al 1997 [RCT +]) showed that this type of intervention retained its beneficial effect on abstinence rates into the post-partum period, however this finding was not replicated by others (Bullock et al 2009 [RCT +]; Cinciripini et al 2000 [RCT +]; Dornelas et al 2006 [RCT +]; Lawrence et al [RCT +]; Rigotti et al 2006 [RCT +]; Stotts et al 2002 [RCT -]; Thornton et al 1997 [RCT +]). Pooling data from these studies showed no significant effect. Intensity 4 OR=1.27 (95%CI: 0.88-1.85); Intensity 5 OR=0.93 (95%CI: 0.62-1.38).

ES 2.5: There is no evidence that interventions delivered by midwives are more effective than interventions delivered by other providers such as counsellors and health advisors.

Only one Intensity 1 trial had a positive result and this trial used a non-midwifery intervention (Windsor et al 1985 [RCT +]). The efficacy of interventions of Intensity 4 (Bullock et al 2009 [RCT +]; Cinciripini et al 2000 [RCT +]; Dornelas et al 2006 [RCT +]; Ershoff et al 1989 [RCT ++]; Patten et al 2010 [RCT +]; Rigotti et al 2006 [RCT +]; Stotts et al 2002 [RCT -]; Solomon et al 2000 [RCT +]; Walsh et al 1997 [RCT +]) and Intensity 5 (Gielen et al 1997 [RCT +]; Hartman et al 1996 [RCT +]; Loeb et al 1983 [RCT +]; Lowe et al 1997 [RCT +]; Malchodi et al 2003 [RCT +]; Pollak et al 2007 [RCT +]; Hegaard et al 2003 [RCT +]; Lawrence et al 2003 [RCT +]; Panjari et al 1999 [RCT +]; Tappin et al 2000 [RCT +]; Tappin et al 2005 [RCT +]; Thornton et al 1997 [RCT +]) were similar regardless of the professional background of the person delivering the intervention.

ES 2.6: There is strong evidence that the provision of financial incentives (vouchers redeemable for retail items for up to >$1,000) contingent on abstinence is effective in increasing cessation rates in late pregnancy, post-partum, and after the incentives are discontinued.

All four studies identified that examined this type of intervention demonstrated efficacy at time points up to delivery (Donatelle et al 2000 [RCT ++]; Heil et al 2008 [RCT ++]; Higgins et al 2004 [RCT +]; Higgins et al 2010 [RCT +])

Three studies demonstrated efficacy post-partum (Donatelle et al 2000 [RCT ++]; Higgins et al 2004 [RCT +]; Higgins et al 2010 [RCT +]), whilst one did not (Heil et al 2008 [RCT ++]). Pooled results show efficacy (OR=5.86; 2.74-12.52)

Two studies demonstrated efficacy post-discontinuation (Higgins et al 2004 [RCT +]; Higgins et al 2010 [RCT +]), whilst one did not (Heil et al 2008 [RCT ++]). Pooled results show efficacy (OR=10.29; 95%CI: 2.75-38.51).

ES 2.7: There is weak evidence that smoking cessation interventions targeting partners of pregnant women are ineffective.

One study (De Vries et al 2006, [RCT-) found no effect of such intervention with partners but did see a significant effect on women smokers. The three others (Lilley et al. 1986 [RCT -]; Lowe et al. 1998 [RCT +]; McBride et a. 2004 [RCT +]), which included a partner component had overall negative results as well in terms of women or partner smoking.

ES 2.8: There is weak evidence that low intensity interventions delivered to women post-partum are not effective and high intensity interventions are effective.

One study (Winickoff et al 2010 [RCT +]) showed no effect of Intensity 1 intervention. One study of Intensity 4 intervention (Hannover et al 2009 [RCT -]) showed no effect, whilst another of intensity 5 (Wall et al 1996 [RCT -]) demonstrated efficacy.

ES 2.9: There is strong evidence from trials that validated self-reported abstinence rates that nicotine replacement therapy, when used in standard doses, is ineffective in helping pregnant women quit smoking during pregnancy.

Of the six studies, four examined the use of patches (Coleman et al 2012, [RCT ++]; Hotham et al 2006 [RCT ++]; Kapur et al 2001, [RCT +]; Wisborg et al 2000, [RCT ++]), one of gum (Oncken et al 1998, [RCT +]) and one of a choice between patch, gum or lozenge (Pollak 2007 et al, [RCT ++]). None demonstrated a significant benefit over placebo across levels of support. Pooling interventions of different intensity provided negative results as well: Intensity 3 OR=1.27 (95%CI: 0.82-1.96); Intensity 4 OR=8.20 (95%CI: 0.40-169.90); Intensity 5 OR=1.48 (95%CI: 0.96-2.28).

ES 2.10: There is strong evidence from trials that validated self-reported abstinence rates that nicotine replacement therapy, when used in standard doses, has no effect on abstinence rates post-partum.

Three trials (Oncken et al 1998, [RCT +]; Pollack 2007 et al, [RCT ++]; Wisborg et al 2000, [RCT ++]) failed to demonstrate long-term efficacy of NRT. Pooling data from these studies showed no significant effect. Intensity 5 OR=1.08 (95%CI: 0.65-1.79).

ES 2.11: There is strong evidence from trials that validated self-reported abstinence rates that interventions aimed to prevent relapse in women who stopped smoking during pregnancy are ineffective regardless of their timing.

All 9 studies that focused on relapse prevention during and after pregnancy failed to show any beneficial effect (Ershoff et al 1995 [RCT +]; Hajek et al [RCT ++]; Johnson et al 2000 [RCT +]; Lowe et al 1997 [RCT +]; McBride et al 2004 [RCT +]; Morasco et al 2006 [RCT +]; Reitzel et al 2010 [RCT ++]; Secker-Walker et al 1995 [RCT +]; Secker-Walker et al 1998 [RCT ++]). Pooling these data confirm a lack of effect (OR=1.15; 95%CI: 0.94-1.43)

APPLICABILITY STATEMENT AND RESEARCH GAPS

The NHS practice currently involves referral of pregnant women who smoke to specialist smoking cessation treatment that typically consists of multi-session behavioural support for at least 4-weeks following a target quit date supplemented by the use of NRT and usually also by home visits. This is more intensive than any of the interventions evaluated so far. Women are referred by midwives and the intervention is provided by specialist pregnancy advisors employed for this purpose. The service is expensive because only a relatively small number of pregnant smokers attend treatment and the success rates are lower than in the mainstream service, but it is felt that if pregnant smokers were referred to mainstream service instead, the proportion of women taking up the referral and the results would be even lower. In this sense, the current UK practice have overtaken research results

We identified four areas where more research is needed.

1. The reviewed evidence suggests that lower intensity interventions are effective and that NRT is not effective in this population. The UK advisors however provide a more intensive support than that examined in any of the studies reviewed. It is possible that NRT accompanied by this level of support is more effective than other options, but it is also possible that more economical interventions with a wider reach would provide the same or better results. Some of the minimal support studies reviewed above reported very high success rates (mostly studies with low quality rating), but overall the quit rates tended to be under 10%, and lower in studies which followed the women post-partum. A trial is needed comparing the current UK practice of intensive specialist support, home visits and medication with an Intensity 3 or 4 intervention which could be delivered routinely by midwives.

2. There is good evidence that incentives contingent on abstinence facilitate smoking cessation. It should be noted though that the procedure shown effective required frequent visits, progressive reinforcement, and re-setting the rewards after lapses. The NHS is currently experimenting with incentives schemes, but these are typically provided in a much looser way and their efficacy is not formally evaluated. There are potential problems with the approach as discussed in Myers at al (2009), but it may hold a promise. A randomised evaluation of its implementation in routine care would help to assess its practicality, cost, and likely impact.

3. Regarding the lack of efficacy of relapse prevention interventions, in this area, an additional problem is that pregnant women who stopped smoking are unlikely to use medications or attend treatment sessions. Opportunistic encouragements and written materials which until recently were the only practicable options are known to lack efficacy. Currently however, electronic media provide a new alternative. A relapse prevention intervention based on text messaging has been shown practicable and it currently awaits a formal evaluation. If proven effective in general population (where such evaluation would be much easier to implement than in pregnant smokers), the next step would be to evaluate such approach formally with users of maternity services as well.

4. Regarding stop smoking medications, two approaches await evaluation. A. Pregnant women metabolise nicotine about twice as fast as non-pregnant smokers. It is possible that NRT dosing which follows the standard labelling leads to under-dosing in pregnancy and that higher dosing may achieve better results. B. Varenicline has been shown effective with several hard to reach groups. It has no known teratogenic effects. Given the lack of evidence that NRT helps in pregnancy and the high priority of smoking cessation in pregnancy, studies are needed to determine safety and efficacy of varenicline in this group.

INTRODUCTION

Each year thousands of smokers are admitted to secondary care in the United Kingdom (UK) for treatment of smoking related diseases. Hospitalisation provides a unique opportunity for people to stop smoking. Smokers who are admitted to hospital are often highly motivated to quit and the hospital setting provides a potentially supportive environment to do so. Hospitals are smokefree environments and admission brings smkokers into direct contact with healthcare professionals who can advise on giving up smoking and offer evidence-based treatment.

Pregnancy is another opportune moment for stopping smoking. Most women in the UK know that smoking in pregnancy is discouraged and many are aware of some of the risks it can pose to their unborn child. Midwives and other primary care workers provide encouragement and advice and most stop-smoking services offer specialist help.

There exists extensive literature on interventions in these settings, which can contribute to guidelines on how best to support such smokers. The literature can be divided into trials which evaluate specific stop smoking interventions, and papers which concern barriers and facilitators to implementing specific treatments and overall smoke-free and tobacco control provision in acute services and within maternity care pathways.

This review concerns the efficacy of smoking cessation interventions with hospital patients and their relatives and with pregnant women and their partners. Review 3 addresses the barriers and facilitators and practical circumstances of delivering smoking cessation help to these groups.

AIM

The aim of this review is to examine the efficacy of smoking cessation interventions delivered in acute services (including patients, visitors, and staff) and to users of maternity services who smoke and their partners.

RESEARCH QUESTIONS

This review aims to answer the following two questions posed by NICE:

Question 1: How effective are smoking cessation interventions in helping people from the populations of interest?

Question 2: How effective are interventions for temporary abstinence in helping people from the populations of interest?

STRUCTURE OF THE REVIEW

The review is divided into two chapters that address the two populations of interest: (1) users of acute secondary care services and staff and visitors of these services, and (2) users of maternity services and their partners.

Chapter 1 concerns users of acute secondary care services and staff and visitors of these services and is divided into five sections.

Section 1 covers the efficacy of interventions delivered to non-surgical patients. This section concerns trials comparing interventions of different intensity with minimal support or usual care;

Section 2 covers the efficacy of interventions delivered to patients undergoing surgery;

Section 3 covers the efficacy of pharmacotherapies to aid smoking cessation in acute secondary care service users. This section concerns trials where comparison groups differed in the provision of medications but not in the level of behavioural support;

Section 4 covers the efficacy of interventions delivered to hospital employees;

Section 5 covers the efficacy of interventions delivered to parents of hospitalised children

Chapter 2 concerns the efficacy of interventions delivered to users of maternity services and their partners. It is divided into four sections.

Section 1 covers the efficacy of interventions delivered to pregnant women. This section concerns trials comparing interventions of different intensity with minimal support or usual care. Two separate subsections cover studies examining the efficacy of interventions based on incentives; and studies examining the efficacy of interventions targeting partners of pregnant women;

Section 2 covers the efficacy of interventions delivered post-partum;

Section 3 covers the efficacy of pharmacotherapies to aid smoking cessation in users of maternity services. This section concerns trials where study arms received the same intensity of behavioural support, but differed in receiving or not receiving active pharmacotherapy;

Section 4 covers efficacy of interventions to prevent relapse.

In both Chapters, each section includes meta-analyses and narrative summaries. An interpretative evaluation and evidence statements are at the end of the Chapters.

METHODOLOGY

TYPES OF STUDIES CONSIDERED IN THIS REVIEW

We included all randomised controlled trials with the populations of interest as well as trials with patients' relatives and with staff.

TYPES OF INTERVENTIONS CONSIDERED IN THIS REVIEW

In the Chapter concerning acute secondary care services, we included any intervention that was initiated during hospitalisation and that aimed to assist clients in stopping or reducing smoking or in remaining abstinent. We also included studies where interventions started before and after hospitalisation, e.g. those commenced during pre-operative assessment or initiated after discharge, where such practice could be initiated by the secondary care teams. Studies of smoking interventions delivered as part of broader rehabilitation programmes were included if it was possible to extract data on the outcome of the smoking cessation component. We also included interventions that were delivered to staff and visitors of acute services. In the Chapter concerning pregnancy, any intervention that was initiated during are after pregnancy and that aimed to assist users of maternity services in stopping or reducing smoking or in remaining abstinent was included.

CATEGORISING INTERVENTIONS BY INTENSITY

A number of different types of behavioural interventions have been proposed to help smokers quit. They can be categorised according to their theoretical underpinning, use of treatment aids such as booklets, videos and biological feedback, background of the person delivering the intervention, etc. The Cochrane review of interventions with hospital patients (Rigotti et al. 2007 [Systematic review, ++]) categorised the interventions according to the length of time over which support was provided. Length of support is generally related to the cost of the intervention and also to its efficacy. Such approach seems practical for informing clinical recommendations and we used it throughout this review.

The studies have been categorised by the length of time over which support was provided, and whether extended contact was face-to-face or not, into the following levels of intensity:

Intensity 1: Single contact with or without take-away written and other materials, no follow-up support.

Intensity 2: One or more contacts with or without take-away written and other materials up to but not beyond the target quit date (TQD)

Intensity 3: Any contact plus follow-up for up to but not beyond 4 weeks after TQD

Intensity 4: Any contact plus telephone/correspondence/e-mail etc. follow-up for > 1 month

Intensity 5: Any contact plus follow-up for > 1 month including at least one face-to-face contact

For the purposes of evidence statements, the term brief intervention will be used as a term to reflect both intensity 1 & 2 interventions. Intensive support will be used as a term for intensity 3-5 interventions.

We also considered whether the interventions work when they are and when they are not accompanied by pharmacological treatments.

Issues not covered in this review

We excluded trials of interventions delivered entirely outside the secondary care and maternity care settings, and trials with psychiatric patients. This review did not consider evidence relating to the health benefits of stopping smoking. Interventions with health care professionals aimed at identifying smokers and referring them to treatment were initially scheduled as a part of this review. However, the consideration of such trials fits more closely into the forthcoming review of treatment barriers and facilitators.

Outcomes and data extraction

For trials concerning secondary care, the principal outcome measure was abstinence from smoking at least six months after the start of the intervention. For trials concerning users of maternity services, the principal outcome measure was abstinence from smoking at the longest follow-up period up to and including delivery; and separately abstinence from smoking at the longest follow-up after delivery.

Regarding data extraction, we followed the approach used in the Cochrane reports and extracted data indicating the most conservative measure of quitting at the longest follow up. Biochemically validated quit rate was preferred to self-reported abstinence, continuous or sustained abstinence was preferred to point prevalence abstinence, and abstinence at later time-points was preferred to abstinence at shorter time points. Participants lost to follow up were counted as continuing smokers.

Evaluation of trial quality

In smoking cessation studies where study arms differ in patient contact, one of the main potential sources of bias is lack of validation of self-reported abstinence. This is because participants who receive more attention and resources can feel under greater pressure to report benefit. Another factor which has a potential to bias smoking cessation studies is the use of short-term 7-day 'point prevalence' abstinence reported long after the intervention finished, as opposed to sustained abstinence that traces the effects of the initial intervention. Not using ITT is the third major potential source of bias as patients failing in their quit attempt are more likely to drop out than those who are successful. We were able to largely remove this bias as most studies reported the original sample sizes and so we were able to re-calculate ITT results where needed. We also assessed randomization procedures and allocation concealment, but these features can be expected to have only limited impact on trials of smoking cessation interventions where there exist no strong predictors of outcome.

Each of the included studies was rated ++, + or - to indicate its quality. The quality of the included reviews was assessed using criteria outlined in NICE guidance. The quality of included trials was assessed as follows.

Table 1: Quality assessment ratings

++	Self-reported abstinence was verified biochemically, sustained or continuous abstinence reported, no other risks of bias
+	Self-reported abstinence was verified biochemically, only point prevalence abstinence reported, no major risks of bias
–	Self-reported abstinence not validated and/or other major risks of bias (e.g. incomplete randomization, unclear N, unclear calculation of success rates)

We rated the quality of reviews as ++ for systematic reviews showing awareness of key methodological features of stop-smoking studies, + for reviews which were less systematic and/or did not take into account the key quality aspects of included studies, and – for reviews which were selective and/or posed methodological problems.

DATA ANALYSIS

Where it was appropriate to pool studies, data were entered into RevMan 5. We pooled data using Mantel-Haenszel fixed-effect method, with 95% confidence intervals. To investigate statistical heterogeneity we used the I^2 statistic. Where there was substantial heterogeneity between studies we explored possible reasons for this using subgroup analyses. We express results as odds ratios (intervention odds/control odds) for achieving abstinence from smoking together with the 95% confidence interval for this estimate.

EVIDENCE STATEMENTS

Evidence statements used in this review contain a descriptor, strength, and direction of the evidence.

Scoring the strength of evidence was based on the quality of the individual studies, the number of studies included in the meta-analysis, and the results of the meta-analysis.

The strength of evidence was classified as:

- No evidence
- Weak evidence: None of the included studies score [+] for quality and/or the result of the meta-analysis is only marginally significant
- Moderate evidence: One or more studies score [+] or [++] for quality and the result of the meta-analysis is significant, but most studies are of low quality and/or less than 3 studies are included and/or the results of the meta-analysis are heterogeneous
- Strong evidence: One or more studies score [+] and [++] for quality, the result of the meta-analysis is significant and homogenous, and there are more than two studies included in the meta-analysis

APPLICABILITY STATEMENTS

The degree of applicability of the main conclusions to the UK setting is assessed in the narrative summary at the end of each Chapter.

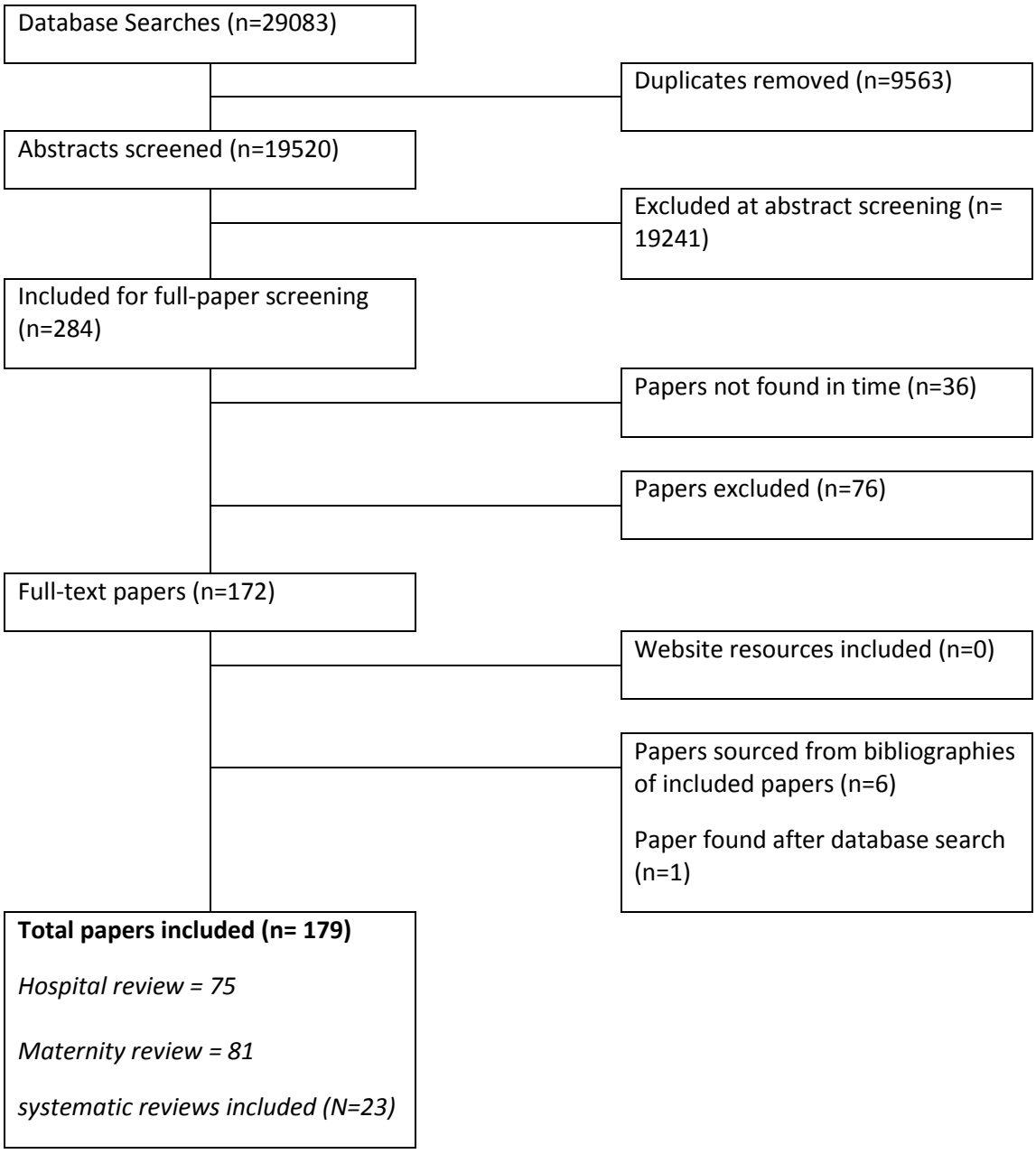
SEARCH METHODOLOGY

We systematically searched reviews and trials published between 1990 and December 2011 in the English language, but we also included literature published in early 2012 while we were working on the review. The searchable databases included ASSIA, MEDLINE, Cochrane Central Register of Controlled Trials, CINAHL and PsychINFO (a full list of the databases searched is included in the review protocol in Appendix 1). Several websites were also searched for relevant data these included NHS Centre for Smoking Cessation and Treatment, Action on Smoking and Health (ASH), Treat tobacco.net and WHO Tobacco Free Initiative (a full list of websites searched is included in Appendix 1). A systematic search of the grey literature was not undertaken but hand searching of bibliographies of systematic reviews that met the inclusion criteria was carried out to ensure that relevant data was included in this review. The search terms included for this review are also in the review protocol in Appendix 1).

SEARCH RESULTS

Searches of the databases returned 29,083 records. After duplicates were removed a total of 19,520 titles and abstracts were screened. Full papers were also obtained where there was no abstract and the relevance could not be assessed by the title alone. One member of the project team screened all titles and abstracts and a second member of the team re-screened 30% to check accuracy. Of the total number of abstracts 267 (1.4%) required review from a third member of the project team as to whether they should be included in the review. A total of 284 papers were identified for full text retrieval. A flow diagram illustrating the screening procedure is included in figure 1 below. Studies excluded at the full-paper screening stage are listed in the appendix 2, along with a brief reason for exclusion.

Figure 1: Flow diagram for papers



CHAPTER ONE

SMOKING CESSATION INTERVENTIONS IN ACUTE SERVICES

INTRODUCTION

Hospitalised smokers are often aware that their illness is related to their smoking. This is the case particularly for smokers with cardiovascular disease, respiratory illness and certain cancers. Being admitted to hospital with a smoking-related problem is likely to increase motivation to quit. The hospital stay also brings smokers into contact with health professionals who can provide further encouragement and help. Apart from routine encouragement and advice by doctors and nurses, many Specialist Stop Smoking Services in the UK employ staff who can provide specialist help and initiate stop-smoking interventions at bedside. In addition to this, UK hospitals are now smoke-free which means that smokers undergo a period of abstinence from smoking, without being exposed to the usual environmental cues and prompts to smoke. Such smokers are also often frightened and focused on their health problem, and so generally cope with tobacco abstinence during their hospital stay well, especially where hospitals provide nicotine replacement to those who need it. All these factors can be expected to encourage smoking cessation and to facilitate engagement in stop-smoking treatment in those who need help.

A large number of studies evaluated a range of stop-smoking interventions trying to use this window of opportunity and they are reviewed in this chapter. It is worth noting at this stage, that there are some problems in generalising the results of the majority of these studies to the UK setting. The NHS is now far ahead of the care for smokers available in most other countries, in that stop smoking medications are provided free of charge and there is also free access to specialist multi session face-to-face counselling. Most of the existing trials were conducted in environments and with methods, which were much less favourable to successful smoking cessation than the current UK routine practice. Nevertheless, the existing literature is extensive and it does provide some useful pointers.

Our brief was to review RCTs evaluating smoking cessation interventions and interventions aimed at facilitating temporary abstinence. We identified a relatively large number of studies seeking to determine the efficacy of smoking cessation interventions delivered to users of acute services, but we did not identify any studies evaluating interventions aimed at facilitating temporary abstinence.

STRUCTURE OF THE CHAPTER

We found 75 studies evaluating smoking cessation interventions with users of acute services which had follow-up periods of at least 6 months. The studies are summarised in Table 2.

Table 2: Summary of studies included in Chapter 1

	Summary
Bolman et al 2002 Netherlands	*Participants:* 789 inpatients recruited from cardiac wards across 11 hospitals *Intervention:* Advice from a cardiologist and 15-30 min nurse counselling on ward. Advice again in the outpatient clinic at 4-6 weeks post discharge. (Intensity 5) *Control procedure:* Usual care *Outcomes:* 12 month sustained abstinence *Validation:* None *Quality:* - *Notes:* Data from 25 deaths, 38 refusals, and 64 people with missing baseline data were excluded from analysis.
Borglykke et al 2008 Denmark	*Participants:* 223 patients hospitalised with COPD *Interventions:* Standard information offered in hospital and group counselling over 5 weeks, NRT offered (Intensity 5) *Control procedure:* Standard information only *Outcomes:* PP at 12m *Validation:* Blood COHb *Quality:* + *Notes:* Blood samples assessed in 84% of patients
Brandt 1997, Denmark	*Participants:* 56 hospitalised COPD patients *Interventions:* Smokers informed they have an illness called 'smokers lung' (Intensity 1) *Control procedure:* Smokers informed they have an illness called chronic bronchitis *Outcomes:* 12 months (not specified) *Validation:* CO *Quality:* +
British Thoracic Society A 1990, UK	*Participants:* 1462 chest outpatients *Interventions:* advice + target quit day discussed, 5 letters and 2 HV contacts (Intensity 5) *Control procedure:* Advice only *Outcomes:* 9 month continuous abstinence

	Validation: Blood COHb *Quality:* ++
British Thoracic Society B 1990, UK	*Participants:* 1392 chest outpatients *Interventions:* (1) advice only; (2) advice + agreement to quit; (3) advice + 6 letters; and (4) advice + agreement + letters *Outcomes:* 6 month continuous abstinence *Validation:* Blood COHb *Quality:* ++ Notes: We merged 1+2 (one-off intervention, Control) and 3+4 (extended contact; Intensity 4) for analysis
Campbell et al 1991, UK	*Participants:* 212 in-patients with smoking-related diseases *Intervention:* Physician advice plus a single session of inpatient counselling and nicotine gum for 3 months. Followed up at 2, 3, 5 weeks, 3 months, and 6 months by counsellor (Intensity 4) *Control procedure:* Same as intervention but with placebo gum *Outcomes:* 12 month sustained abstinence *Validation:* CO *Quality:* ++
Campbell et al 1996, UK	*Participants:* 62 Inpatients with respiratory or cardiovascular disease *Intervention:* Physician advice plus a single session of inpatient counselling and nicotine patch for 3 months. Outpatient follow-up by counsellor at 2, 4, 8, and 12 weeks (Intensity 4) *Control procedure:* Same as intervention but with placebo patch *Outcomes:* 12 months sustained abstinence *Validation:* CO *Quality:* ++
Carlsson 1997, Sweden	*Participants:* 168 MI patients, intervention after discharge *Interventions:* CVD prevention programme with exercise, diet and stop-smoking advice (Intensity 5) *Control procedure:* Usual care via GP *Outcomes:* Abstinence from smoking at 1 year (not defined) *Validation:* none *Quality:* -
Caruthers 2005, USA	*Participants:* 80 smokers after discharge from hospital

	Interventions: 8 phone calls, some used medications (Intensity 4) *Control procedure:* Usual care *Outcomes:* 6 month PP *Validation:* CO validated *Quality:* + *Notes:* Unpublished PhD thesis. Controls for baseline differences not clear.
Chan et al 2005, Hong Kong	*Participants:* 80 smoking parents of sick children brought to hospital *Interventions:* Motivational interviewing and telephone reminders 1 week after intervention (Intensity 3) *Control procedure:* Healthy diet counselling *Outcomes:* 1 month PP *Validation:* None *Quality:* - Note: Intervention with parents of patients
Chouinard et al 2005, Canada	*Participants:* 168 inpatients with CVD or PVD *Interventions:* (a) Single session of inpatient nurse counselling plus pharmacotherapy (nicotine patches, gum and bupropion). (Intensity 2); (b) Same as intervention (a), but with 6 follow-up telephone calls over 2 months post discharge (Intensity 4) *Control procedure:* Cessation advice *Outcomes:* 6 month sustained abstinence *Validation:* Urine cotinine or CO *Quality:* ++ *Notes:* 23% used pharmacotherapy.
Croghan et al 2005, USA	*Participants:* 30 smokers undergoing surgical resection of lung or oesophageal cancers *Intervention:* Advice from surgeons and study nurses and a single session of inpatient counselling (Intensity 2) *Control procedure:* Physician advice only *Outcomes:* 6 months 7-day PP *Validation:* CO or saliva tobacco alkaloid *Quality:* +
Dalsgaro et al 2004, Denmark	*Participants:* 336 hospital employees *Interventions:* 5 counselling sessions, 2 phone calls over 6 months, and 7 weeks Bupropion. (Intensity 5)

	Control procedure: Identical support + 7 weeks placebo *Outcomes:* 6 month continuous abstinence *Validation:* CO validated *Quality:* ++ Notes: Hospital employees, not patients
De Busk et al 1994, USA	*Participants:* 252 inpatients with acute MI *Intervention:* Physician advice plus single session of counselling and NRT. Self help materials and relaxation tapes were also provided. Follow-up at 48hrs, 1 weeks and then monthly for 6-months via telephone (Intensity 4) *Control procedure:* Advice only *Outcomes:* 12 months sustained abstinence *Validation:* CO and plasma cotinine. *Quality:* ++ *Notes:* NRT was provided to only the 'highly-addicted' patients. Intervention post-discharge.
Dornelas et al 2000, USA	*Participants:* 100 smokers Inpatients with acute MI. *Intervention:* Single inpatient counselling session followed by telephone calls at weeks 1, 4, 8, 12, 16, 20, and 26 (Intensity 4) *Control procedure:* Advice only *Outcomes:* 12 month PP *Validation:* Significant other *Quality:* - Note: Validation available for only 70% of cases
Feeney et al 2001, Australia,	*Participants:* 198 inpatients with acute MI *Intervention:* Physician advice to quit plus single session of nurse counselling. Outpatient telephone follow up at 1,2,3,4 weeks and 2,3,6,12 months (Intensity 4) *Control procedure:* Same as above but no proactive follow-up contact *Outcomes:* 12 month sustained abstinence *Validation:* Urinary cotinine *Quality:* ++
Froelicher et al 2004 USA	*Participants:* 277 inpatients with CVD or PVD from across 10 hospitals *Intervention:* Physician advice plus single session of nurse counselling. Then outpatient telephone follow-up at 2,7,21,28,90 days (Intensity 4)

	Control procedure: Physician advice + booklet *Outcomes:* 12 months 7-day PP *Validation:* Saliva cotinine OR verification by significant other *Quality:* +
Hajek et al 2002, UK	*Participants:* 540 inpatients with acute MI. *Intervention:* Nurse advice and single session of inpatient counselling with self-help materials (Intensity 2) *Control procedure:* Brief intervention (Intensity 1 and 2) and booklet *Outcomes:* 12 months continuous abstinence *Validation:* CO and salivary cotinine. *Quality:* ++
Hand et al 2002, UK	*Participants:* 245 hospital in-patients and outpatients with smoking related diseases *Interventions:* Advice and support + 3 weeks use of nicotine patch and nicotine inhalator (Intensity 5) *Control procedure:* Advice and support only *Outcomes:* 1 year continuous abstinence *Validation:* CO validated *Quality:* ++
Hanssen et al 2009, Norway	*Participants:* 288 MI patients *Interventions:* pro-active telephone follow-up included smoking cessation advice (8 calls in 6 months + access to reactive line) (Intensity 4) *Control procedure:* No intervention *Outcomes:* 18 month (not defined if PP or continuous abstinence) *Validation:* None *Quality:* - *Notes:* 7 died in each group. Intervention was provided post-discharge
Hasuo et al 2004, Japan	*Participants:* 120 inpatients with any diagnosis *Intervention:* 3 sessions of inpatient nurse counselling and then telephone follow up at 7, 21, 42 days (Intensity 4) *Control procedure:* Same as above, but no follow-up calls (intensity 2) *Outcomes:* 12 months – not defined *Validation:* urinary cotinine (not clear if results are self-report or cotinine validated) *Quality:* -

Haug et al 2011, Germany	*Participants:* 477 patients in a rehabilitation centre (following acute medical illnesses) *Interventions:* Internet based smoking cessation intervention + 6 post discharge email invites to log on (Intensity 4) *Control procedure:* Baseline smoking assessment only *Outcomes:* 6 month PP *Validation:* None *Quality:* -
Hennrikus et al 2005, USA	*Participants:* 2095 inpatients (all diagnoses) from across 4 hospitals *Interventions:* (1) Physician advice and smoking cessation booklet with an additional booklet mailed after discharge (Intensity 1); (2) Physician advice plus single session of inpatient nurse counselling followed by 3-6 telephone calls over 6 months (Intensity 4) *Control procedure:* Smoking cessation booklet in hospital *Outcomes:* 12 month 7-day PP *Validation:* Saliva cotinine *Quality:* + *Notes:* 43% of counselling sessions in intervention 2 were conducted after discharge by telephone rather than at bedside
Hennrikus et al 2010, USA	*Participants:* 124 outpatients with peripheral arterial disease *Interventions:* minimum of 6 counselling sessions over 5 months + pharmacotherapy (a choice of NRT, bupropion or varenicline) (Intensity 5) *Control procedure:* Brief intervention (Intensity 1 and 2) and information about smoking cessation services *Outcomes:* 6 month PP *Validation:* CO validated or salivary cotinine *Quality:* +
Hilleman et al 2004, USA	*Participants:* 39 smokers who had recently undergone CABG *Interventions:* referred immediately to smoking cessation service for 8 week course + NRT (Intensity 5) *Control procedure:* Called monthly and if reported smoking then referred onto 8 week course *Outcomes:* 12 month continuous abstinence *Validation:* CO validated *Quality:* ++
Horn et al 2008, USA	*Participants:* 75 teenage smokers *Interventions:* In-hospital counselling, audio workbook, personalised postcard sent after

	discharge and 3 FU calls (1, 3 and 6 months) (Intensity 4) *Control procedure:* Basic advice *Outcomes:* 6 month – asked, "did you smoke in the last month?" *Validation:* None *Quality:* -
Kim 2005, South Korea	*Participants:* 401 general outpatients *Interventions:* Nurse advice, stage matching, setting TQD, booklets, mailed reminders, phone calls at 1 week and 1 month (Intensity 3) *Control procedure:* Usual care *Outcomes:* Abstinence from smoking at 5 months ('since the last quit attempt') *Validation:* CO *Quality:* +
Lacasse et al 2008, Canada	*Participants:* 196 patients on cardio-pulmonary wards *Interventions:* Psychological support and NRT + up to 4 phone calls within 6 weeks post discharge (Intensity 4) *Control procedure:* Usual care *Outcomes:* 1 year PP *Validation:* Urine cotinine, but not taken into account *Quality:* -
Lewis 2009, UK	*Participants:* 450 hospitalised smoker *Interventions:* (1) counselling + 4 weekly out-patients appointments and information about stop smoking services (Intensity 4); (2) as above but given an appointment at the stop smoking service (Intensity 5). Patients were recommended to use NRT or bupropion. *Control procedure:* brief intervention (Intensity 1 and 2) *Outcomes:* 1 year PP *Validation:* CO validated *Quality:* +
Lewis et al 1998, USA	*Participants:* 185 inpatients with any diagnosis except certain cardiac conditions *Interventions:* (1) Physician advice, a single session of counselling, nicotine patch for 6 weeks and self-help materials. Follow-up telephone calls at 1,3,6 weeks and 6 months. [Intensity 4]; (2) As above but with placebo patch (Intensity 4) *Control procedure:* Advice only *Outcomes:* 6 month PP

	Validation: CO *Quality:* +
Li et al 2008 USA	*Participants:* 277 female smokers hospitalized with CVD *Interventions:* Inpatient counselling + 5 follow up phone calls over 3 months (Intensity 4) *Control procedure:* Usual care *Outcomes:* 30 month PP *Validation:* None *Quality:* -
Lindström et al 2008, Sweden	*Participants:* 117 smokers undergoing elective surgery *Interventions:* Weekly sessions, face-to-face or by telephone and NRT, 4 week pre and post surgery (Intensity 5) *Control procedure:* Usual care *Outcomes:* Abstinence from 3 weeks pre to 4 weeks post surgery *Validation:* CO validation *Quality:* ++
Mahabee-Gittens et al 2008, USA	*Participants:* 365 smoking parents of paediatric patients admitted to the emergency department. *Interventions:* Brief intervention + fax referral to a quitline (Intensity 1) *Control procedure:* Usual care *Outcomes:* 3 month PP *Validation:* None *Quality:* - *Notes:* Parents of patients
Martucci et al 2010 Italy	*Participants:* 233 smokers undergoing bronchoscopy *Interventions:* 15 minutes advice before and after surgery. Pharmacotherapy suggested but only prescribed on demand (Intensity 2) *Control procedure:* Usual care *Outcomes:* 12 month PP *Validation:* CO validation *Quality:* +
Metz et al 2007, Germany	*Participants:* 307 smokers at a rehabilitation centre for acute and chronic disorders *Interventions:* CBT or Motivational Treatment in hospital + 5 telephone booster sessions

	(Intensity 4) *Control procedure:* CBT or Motivational Treatment in hospital + usual care *Outcomes:* 12 month PP *Validation:* None *Quality:* -
Miller et al 1997, USA	*Participants:* 1942 general hospital inpatients *Interventions:* (1) Physician advice, single inpatient counselling session and self help materials. Telephone follow-up at 48 hours, 1, 3, and 12 weeks (Intensity 4); (2) As above by only one follow-up call (at 48 hours) (Intensity 3). *Control procedure:* Advice only *Outcomes:* 12 month sustained abstinence *Validation:* Plasma cotinine or family member corroboration *Quality:* +
Mohiuddin et al 2007, USA	*Participants:* 209 in-patients with acute coronary syndrome or decompensated CHF *Intervention:* Single session of inpatient counselling, self-help booklet, and NRT and/or bupropion. Outpatient follow-up consisted of weekly group meetings for up to 3m. (Intensity 5) *Control procedure:* Same as intervention but without any follow up (Intensity 2) *Outcomes:* 12 months sustained abstinence *Validation:* CO *Quality:* ++ *Notes:* NRT or bupropion offered on individualized basis to both groups
Moller et al 2002, Denmark	*Participants:* 120 smokers undergoing surgery *Intervention:* Weekly counselling initiated 6-8 week pre-operatively with NRT (type not specified). Abstinence or reduction option. (Intensity 5) *Control procedure:* Usual care *Outcomes:* 12 month sustained abstinence *Validation:* CO validation *Quality:* ++
Molyneux et al 2003, UK	*Participants:* 274 medical and surgical inpatients *Interventions:* (1) brief counselling plus a self-help booklet, no NRT and no follow up (Intensity 2); (2) brief counselling plus a self-help booklet and an offer of 6-week supply of NRT. No follow up (Intensity 2) *Control procedure:* Usual care

	Outcomes: 12 months sustained *Validation:* CO *Quality:* ++ *Notes:* NRT offered= gum, patch, inhalator, lozenge, nasal spray; 96% used NRT
Mosca et al 2010, USA	*Participants:* 304 admitted to hospital with CHD *Interventions:* Counselling during hospital + 3 FU calls (2, 4, 12 weeks) and a final visit/call at 6 weeks post discharge (Intensity 4) *Control procedure:* Usual care *Outcomes:* 6 month (not defined) *Validation:* CO validated *Quality:* +
Nagle et al 2005, Australia	*Participants:* 1422 inpatients (all diagnoses, but those in ICU were excluded) *Intervention:* Two sessions of inpatient nurse counselling plus a booklet and offer of NRT in hospital and for 5 days post-discharge. There was no follow-up (Intensity 2) *Control procedure:* Physician advice and booklet *Outcomes:* 12 months 7-day PP *Validation:* Saliva cotinine *Quality:* +
Neuner et al 2009, Germany	*Participants:* 1044 smokers at an emergency department *Interventions:* in-hospital counselling + telephone booster sessions (nicotine gum given to those who set a TQD) (Intensity 3) *Control procedure:* Usual care *Outcomes:* 12 month PP *Validation:* None *Quality:* -
Ortigosa *et al* 2000, Spain	*Participants:* 90 Inpatients with acute MI *Intervention:* Physician advice with telephone follow up at 2,3 and 4 weeks (Intensity 3) *Control procedure:* Usual care *Outcomes:* 12 month PP *Validation:* CO *Quality:* +
Papadakis et al 2011,	*Participants:* 28 patients at stroke prevention clinic *Interventions:* Breif counselling from a nurse specialist plus 4 weeks supply of free

Canada	smoking cessation medication (a choice of NRT, bupropion or varenicline) + a prescription for further supply (Intensity 1) *Control procedure:* Prescription only *Outcomes:* 6 month PP *Validation:* CO validated *Quality:* +
Pedersen *et al* 2005, Denmark	*Participants:* 105 inpatients with CHD *Intervention:* Advice to quit plus information about NRT (NRT was available). Patients attended 5 outpatient visits post discharge (Intensity 5) *Control procedure:* As above, but without follow-up *Outcomes:* 12 month PP *Validation:* None *Quality:* -
Pederson *et al* 1991, USA	*Participants:* 74 inpatients with COPD. *Intervention:* Physician advice (prior to admission), followed by 3-9 sessions of inpatient counselling and self help materials, but no outpatient follow-up (Intensity 2) *Control procedure:* Advice only *Outcomes:* 6 month PP *Validation:* Serum COHb *Quality:* + *Notes:* Only a subset validated
Pelletier *et al* 1998, Canada	*Participants:* 504 inpatients with acute MI. *Intervention:* Physician advice and self-help materials (Intensity 2) *Control procedure:* Usual care *Outcomes:* 12 months PP *Validation:* None *Quality:* - *Note:* Not fully randomised
Quist-Paulsen *et al* 2003, Norway	*Participants:* 240 inpatients admitted to a cardiac ward *Intervention:* 1-2 sessions of inpatient nurse counselling and advice on using NRT. Telephone follow up at 2,7 and 21 days and 3 and 5 months, with a clinic visit with a cardiac nurse at 6 weeks (Intensity 4) *Control procedure:* Advice to quit and self-help booklet

	Outcomes: 12 months PP *Validation:* Urine cotinine *Quality:* + *Notes:* Nicotine gum or patch encouraged for patients with strong urges to smoke in hospital
Ralston *et al* 2008, USA	*Participants:* 42 smoking caregivers of children admitted to hospital for respiratory illness *Interventions:* Counselling >30 minutes and offered NRT (Intensity 2) *Control procedure:* Brief counselling *Outcomes:* 6 month (not defined) *Validation:* None *Quality:* -
Ratner et al 2004, Canada	*Participants:* 237 patients awaiting surgery *Interventions:* Face-to-face counselling 1-3 weeks pre surgery and written materials, nicotine gum and smoking cessation hotline number. Post surgery counselling in hospital and via telephone (Intensity 4) *Control procedure:* Usual care *Outcomes:* Abstinence at 12 month (no definition provided) *Validation:* CO validation or urine cotinine *Quality:* +
Reid et al 2003 Canada	*Participants:* 254 inpatients admitted with CVD *Intervention:* A single session of brief nurse counselling followed by telephone call at 4 weeks. If patients were smoking at this time they were offered 3 counselling sessions (weeks 4, 8 and 12) and nicotine patch for 8 weeks (Intensity 4) *Control procedure:* Same as above, but without outpatient follow-up. *Outcomes:* 12 month 7-day PP *Validation:* CO validation in a random sample of 25 self-reported abstainers *Quality:* +
Reid et al 2007 Canada	*Participants:* 99 hospitalised smokers with CAD *Interventions:* Counselling in hospital and offer of NRT + interactive voice response follow up (contact patients at 3,14 and 30 days post discharge) (Intensity 4) *Control procedure:* Counselling in hospital and offer of NRT + usual care *Outcomes:* 12 month PP *Validation:* None

	Quality: -
Rigotti *et al* 1997 USA	*Participants:* 615 inpatients in medical or surgical services. *Intervention:* Physician advice and a single session of inpatient counselling plus self-help materials. Telephone follow-up was provided weekly for 3 weeks post discharge. (Intensity 3) *Control procedure:* Usual care *Outcomes:* 6 month PP *Validation:* Salivary cotinine. *Quality:* +
Rigotti *et al* 1994 USA	*Participants:* 87 inpatients scheduled for CABG surgery *Intervention:* 3 inpatient counselling sessions, plus self-help material, followed by one telephone call 1 week post discharge (Intensity 3) *Control procedure:* Advice only *Outcomes:* 12 month sustained abstinence *Validation:* Salivary cotinine. *Quality:* ++
Rigotti *et al* 2006 USA	*Participants:* 254 inpatients with CVD or PVD from across 5 hospitals *Intervention:* Bupropion 150 mg b.d. for 12 weeks plus a single session of nurse counselling in hospital. Patients were also given a self-help booklet and received 5 follow up phone calls at 2,7,21 days, and 2 and 3 months (Intensity 4) *Control procedure:* Same as above but with placebo *Outcomes:* 12 months continuous abstinence *Validation:* Saliva cotinine *Quality:* ++
Rodriguez et al 2007 *USA*	*Participants:* 111 smokers undergoing deep sedation (for incision and drainage of abscess, or orthopaedic reduction or relocation) *Interventions:* 30 minutes of music played during sedation + scripted smoking-cessation message (Intensity NA) *Control procedure:* Music only *Outcomes:* 2 week sustained abstinence *Validation:* Self report *Quality:* - *Notes:* Study was stopped due to lack of effect
Rosal et al 1992,	*Participants:* 267 inpatients (smokers or recent quitters) with coronary artery stenosis.

USA	*Intervention:* 2 sessions of inpatient counselling, plus self help materials and relaxation tapes. Telephone follow up at 1, 3 weeks and 3 months if quit, or 2 and 4 months if did not quit (Intensity 4) *Control procedure:* Advice only *Outcomes:* 12 months sustained abstinence *Validation:* CO *Quality:* ++
Schiebel et al 2007 USA	*Participants:* 39 smokers at an emergency department *Interventions:* Advice to quit + proactive quitline intervention (baseline session + 4 FU calls around TQD) (Intensity 3) *Control procedure:* Advice to quit + self help manual *Outcomes:* 6 month PP *Validation:* None *Quality:* -
Schofield et al 1999, Australia	*Participants:* 4158 hospitalised smokers *Interventions:* Personalised letter urging them to quit from physician, sent 1-2 weeks post discharge (Intensity 1) *Control procedure:* Usual care *Outcomes:* 12 month PP *Validation:* Urine cotinine or CO validated *Quality:* +
Simon *et al* 2003, USA	*Participants:* 223 inpatients (all diagnoses) *Intervention:* A single session of nurse or health educator counselling and booklet, plus nicotine patch treatment for 8 weeks. Telephone follow-up conducted at 1 and 3 weeks and 1, 2, and 3 months (Intensity 4) *Control procedure:* A single session of nurse or health educator counselling and booklet, plus nicotine patch treatment for 8 weeks but no telephone contact *Outcomes:* 12 months 7-day PP *Validation:* Saliva cotinine OR report by spouse *Quality:* +
Simon et al 2009, USA	*Participants:* 85 smokers admitted to hospital for at least 24 hours *Interventions:* counselling and 5 FU calls +7 weeks Bupropion (Intensity 4) *Control procedure:* counselling and 5 FU calls + 7 weeks placebo

	Outcomes: 6 month PP *Validation:* Salivary cotinine *Quality:* +
Simon et al 1997, USA	*Participants:* 229 smokers undergoing non-cardiac surgery *Intervention:* Inpatient counselling (30-60 mins), self-help materials, video and nicotine gum (3mg) if no contraindications. Telephone FU 5 times in 1-3 weeks post discharge, 2m and 3m (Intensity 4) *Control procedure:* Advice only *Outcomes:* 12 month PP *Validation:* CO or corroboration by significant other *Quality:* -
Sivarajan et al 2004, USA	*Participants:* 277 women hospitalized with CVD *Interventions:* Counselling at bedside, tapes and booklets + 5 FU calls (Intensity 4) *Control procedure:* Usual care *Outcomes:* 30 month PP *Validation:* None *Quality:* -
Smith et al 2009, Canada	*Participants:* 276 patients admitted with MI or for a CABG *Interventions:* Counselling, take home materials + 7 FU calls over 2 months post discharge (Intensity 4) *Control procedure:* Advice from doctor/nurse + 2 pamphlets *Outcomes:* 12 month PP *Validation:* None *Quality:* -
Smith et al 2011, Canada	*Participants:* 643 inpatients *Interventions:* In-hospital education + multiple FU calls (up to 60 days post discharge) (Intensity 4) *Control procedure:* Brief in-hospital advice + pamphlets *Outcomes:* 12 month PP *Validation:* Salivary cotinine *Quality:* +
Steinberg et al 2011, USA	*Participants:* 79 hospitalised smokers *Interventions:* Brief behavioural support (5-10 mins) + varenicline. Data collection visits

	at 4, 12 and 24 weeks (Intensity 5) *Control procedure:* Support + placebo *Outcomes:* abstinent at all time points 4, 12, 24 weeks PP *Validation:* CO validated *Quality:* +
Stevens *et al* 1993, USA	*Participants:* 1119 general hospital inpatients admitted for >36 hours *Intervention:* Single session of inpatient counselling supplemented by self-help materials. 1-2 telephone contacts were provided in the first 3 weeks of discharge (Intensity 3) *Control procedure:* Usual care *Outcomes:* 12 month sustained abstinence *Validation:* None *Quality:* -
Stevens *et al* 2000, USA	*Participants:* 1173 general hospital inpatients admitted for >36 hours *Intervention:* Single session of counselling supplemented by self-help materials, video. Follow up consisted of 1 telephone call at 1-week post discharge (Intensity 3) *Control procedure:* Usual care *Outcomes:* 12 month sustained abstinence *Validation:* None *Quality:* -
Taylor *et al* 1990, USA	*Participants:* 173 inpatients with acute MI. *Intervention:* A single session of inpatient counselling supplemented by self-help materials and relaxation tapes. Nicotine gum was available. 6-7 telephone follow-up calls were undertaken over 4 months post discharge (Intensity 4) *Control procedure:* Usual care *Outcomes:* 12 month sustained abstinence *Validation:* Serum thiocyanate and CO *Quality:* +
Taylor et al 1996, USA	*Participants:* 328 hospitalised smokers *Interventions:* 1 hour in-hospital counselling session + 4 FU calls after discharge (Intensity 4) *Control procedure:* Brief intervention (Intensity 1 and 2) *Outcomes:* 1 year PP *Validation:* plasma cotinine or family confirmation

	Quality: +
Thomsen et al 2010, Denmark	*Participants:* 130 female smokers undergoing breast cancer surgery *Interventions:* Single smoking cessation counselling session and NRT, 3-7 days pre surgery (Intensity 3) *Control procedure:* Usual care *Outcomes:* 12 month continuous *Validation:* None *Quality:* +
Tonnesen et al 2000, Denmark	*Participants:* 446 smokers referred to a lung clinic *Interventions:* 1) 15mg patch 2) nicotine inhaler 3) 15mg patch + inhaler for 3 months (Intensity 4) *Control procedure:* 5mg patch "placebo" for 3 months *Outcomes:* 12 month continuous abstinence *Validation:* Salivary cotinine *Quality:* ++
Tonnesen et al 2006, Denmark	*Participants:* 370 COPD patients *Interventions:* 12 week course of nicotine sublingual tablets with low (4 visits + 6 phone calls) or high (7 visits + 5 phone calls) intensity support (Intensity 5 for both) *Control procedure:* 12 week course of placebo sublingual tablets with low (4 visits + 6 phone calls) or high (7 visits + 5 phone calls) intensity support *Outcomes:* 1 year continuous abstinence *Validation:* CO validated *Quality:* ++
Vial *et al* 2002, Australia	*Participants:* 102 inpatients from medical and surgical wards *Interventions:* (1) Pharmacist consultation about NRT use, supplemented by a booklet and up to 16 weeks of subsidized nicotine patches that could be obtained at weekly visits to the hospital pharmacist; (2) As above, but patches were obtained from a community pharmacists (Intensity 5) *Control procedure:* advice to quit plus a booklet *Outcomes:* 12 month sustained abstinence *Validation:* CO test 'whenever possible' *Quality:* -
Wakefield et al 2004, Australia	*Participants:* 137 cancer patients *Interventions:* Motivational intervention and a FU call (Intensity 4)

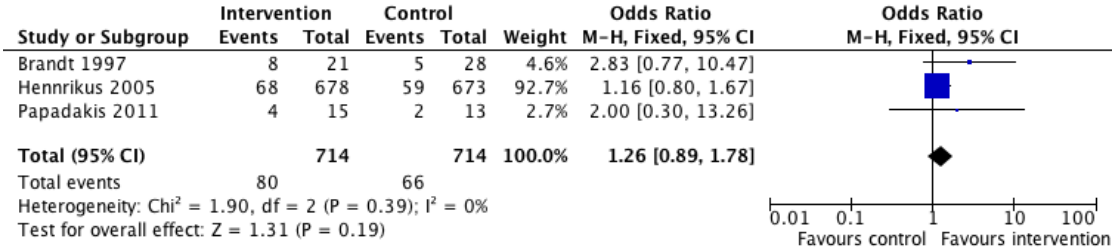
	Control procedure: Usual care *Outcomes:* 6 month continuous abstinence *Validation:* Urine cotinine or CO validated *Quality:* ++
Wiggers et al 2006, Netherlands	*Participants:* 385 smokers at outpatient departments (vascular surgery, cardiology and vascular medicine) *Interventions:* counselling, 8 weeks nicotine patches + a FU call (Intensity 3) *Control procedure:* Usual care *Outcomes:* 12 month PP *Validation:* Urine or Salivary cotinine *Quality:* +

SECTION 1: EFFICACY OF INTERVENTIONS DELIVERED TO NON-SURGERY PATIENTS

PART 1: INTERVENTION INTENSITY

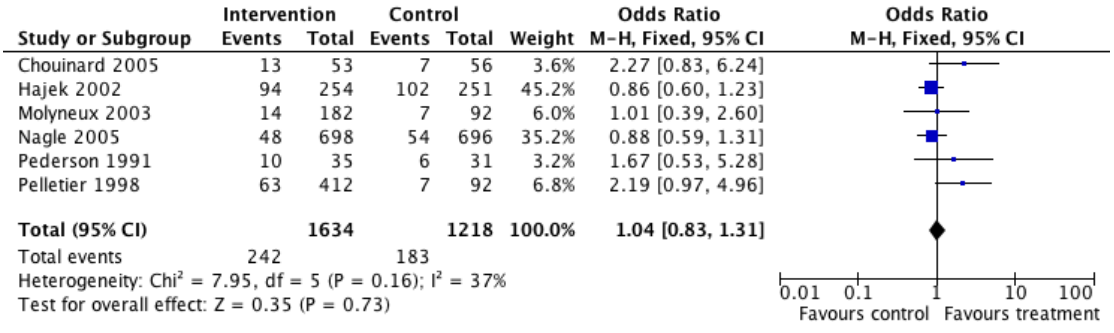
Below we analyse all studies where more intensive support was compared with less intensive or no support. Drug trials where both study arms received the same intensity of behavioural support are analysed in Section 3.

Intensity 1 (Single contact in hospital lasting up to 15 minutes, no follow-up support)



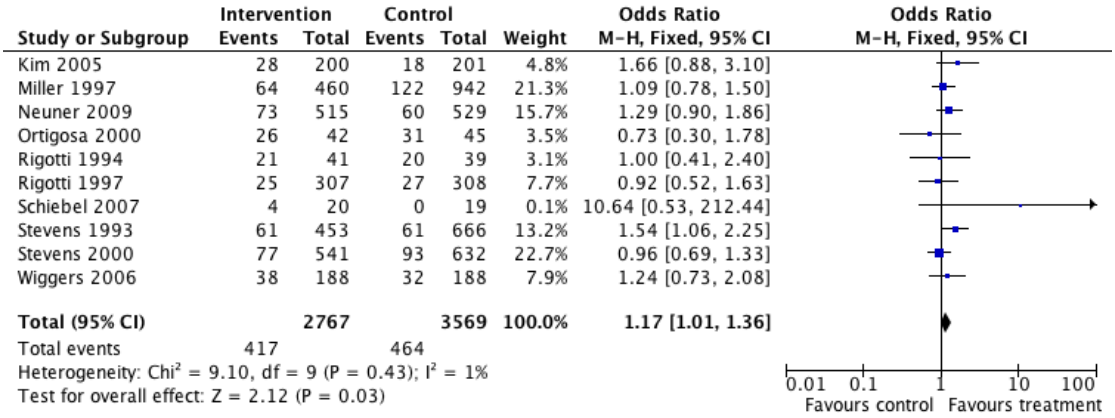
Three studies reported on the effects of one-off brief interventions (Intensity 1 and 2) with no follow-up. The results were homogenous and show no additional effect of such interventions compared to usual care.

Intensity 2 (One or more contacts in hospital lasting in total > 15 minutes, no follow-up support)



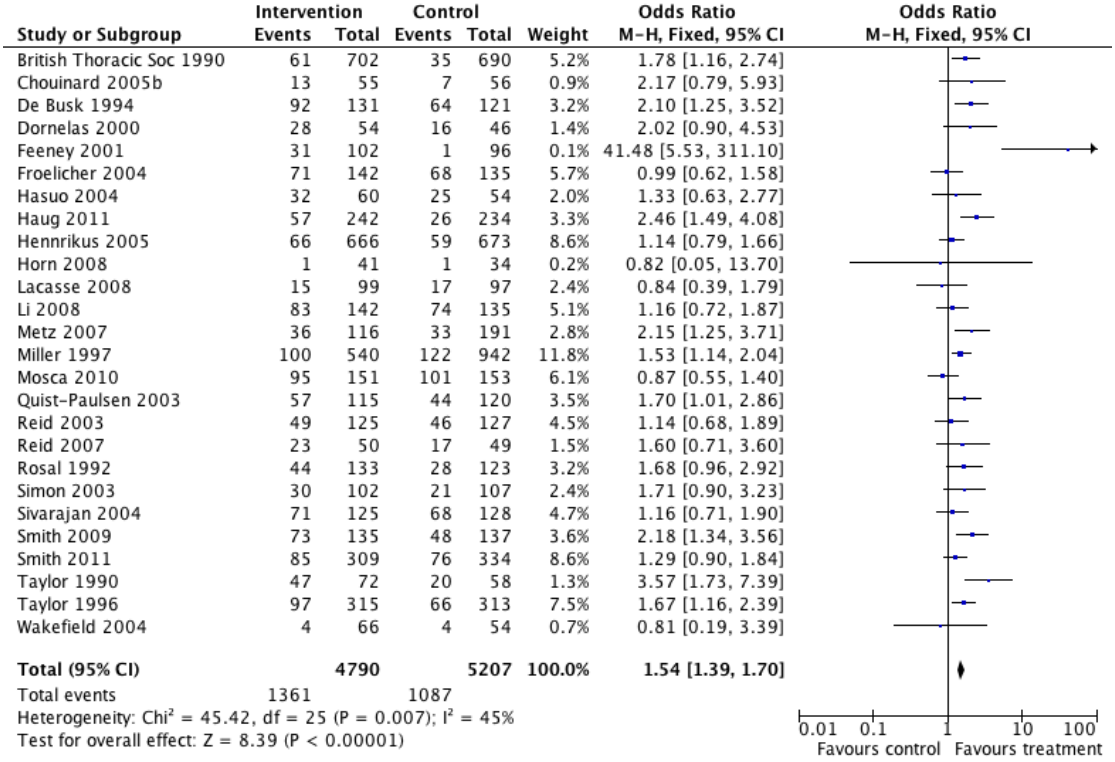
The results from six studies which reported slightly more intensive interventions in hospital (a longer counselling session or two and booklets) with no further follow up were similar, showing no effect of such interventions. The results were again homogenous.

Intensity 3 (Any hospital contact plus follow-up <=1 month)



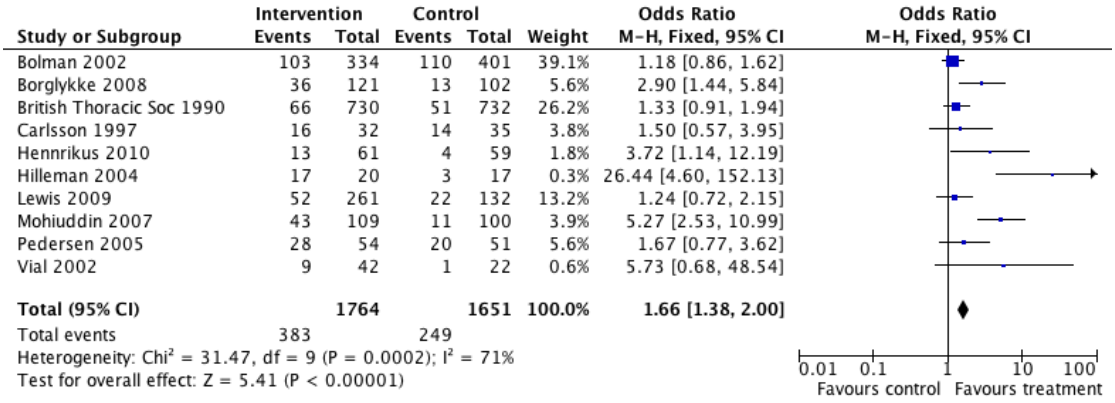
Ten studies provided telephone support post-discharge for up to 4 weeks. This also did not generate a significant effect overall. The studies are homogenous. Only one study (Stevens et al 1993, [RCT -]) yielded a significant result. If there is an effect, it is likely to be small.

Intensity 4



The largest number of trials (26) included telephone follow-ups for over 4 weeks. Such interventions are effective. The studies were heterogeneous, with two outliers (Feeney et al 2001, [RCT ++]; Taylor et al 1996, [RCT +]). Removing them reduced the heterogeneity (p=0.06) with the result remaining significant (OR=1.48, 1.33-1.64).

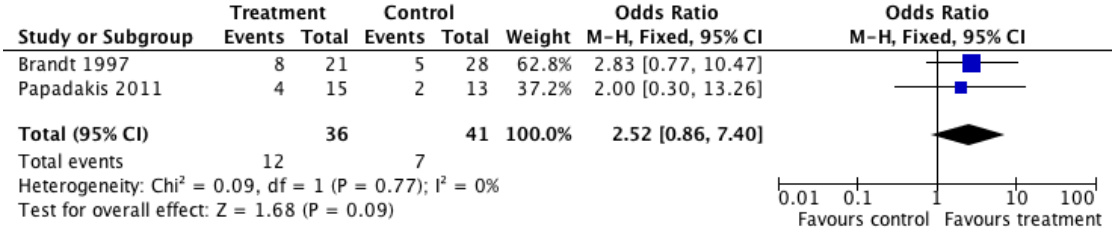
Intensity 5 (Any hospital contact plus follow-up >1 month including at least one face-to-face session)



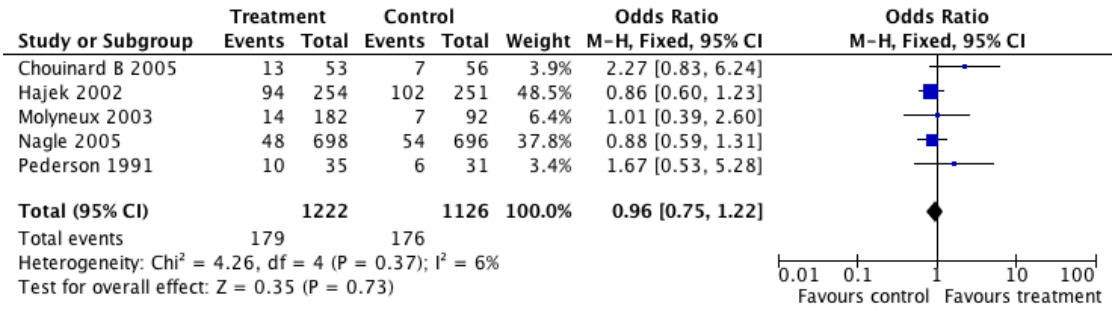
Ten studies included at least one post-discharge face-to-face contact. They differed widely in the number of sessions and the nature of support provided. There were also substantial differences in the nature of the control interventions, which ranged from minimal to Intensity 5. There was an overall significant effect, but the studies were heterogeneous. Removing the two outliers, which both provided intensive face-to-face treatment over extended periods of time (Hilleman et al 2004, [RCT ++]; Mohiuddin et al 2007, [RCT ++]) reduced heterogeneity (p=0.19). The overall effect was reduced as well but it remained significant (OR=1.45, 1.19-1.76).

We next re-ran the five analyses including only studies which validated self-reported abstinence.

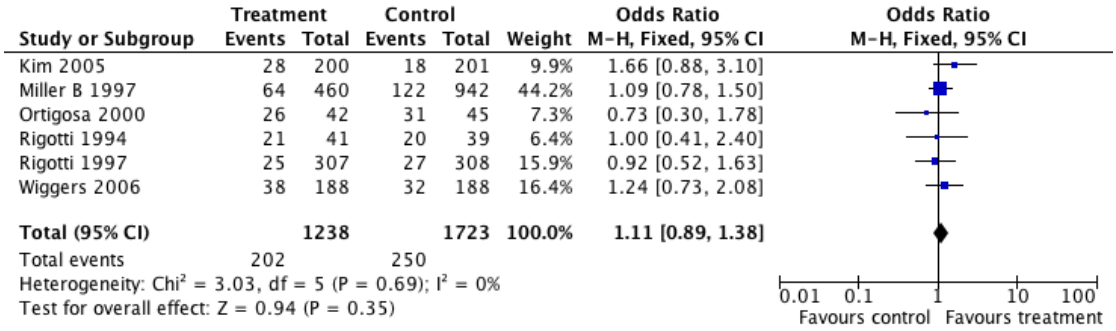
Validated studies of intensity 1



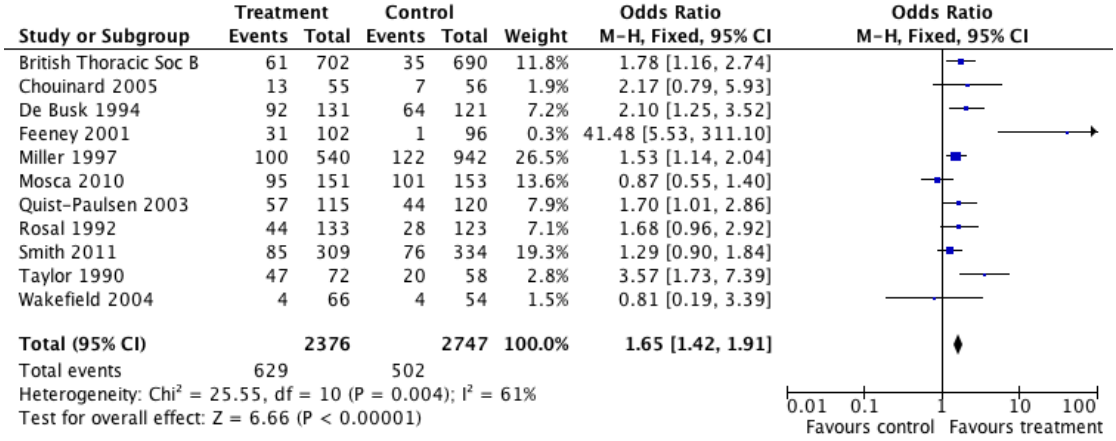
Validated studies of intensity 2



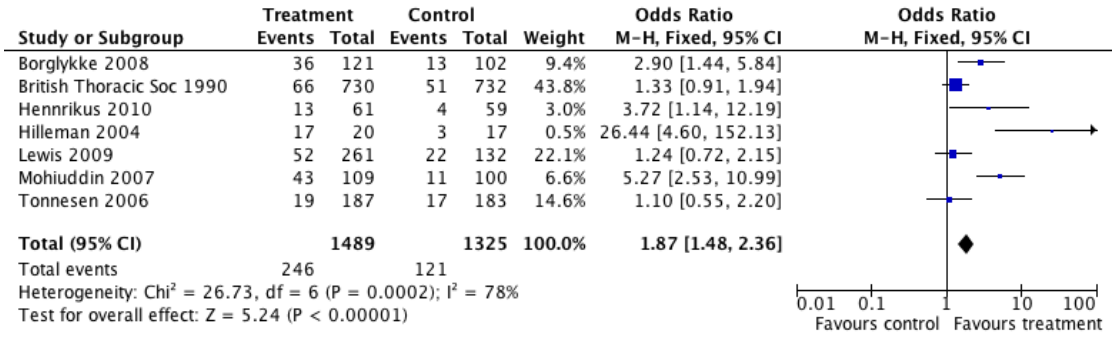
Validated studies of intensity 3



Validated studies of intensity 4



Validated studies of intensity 5

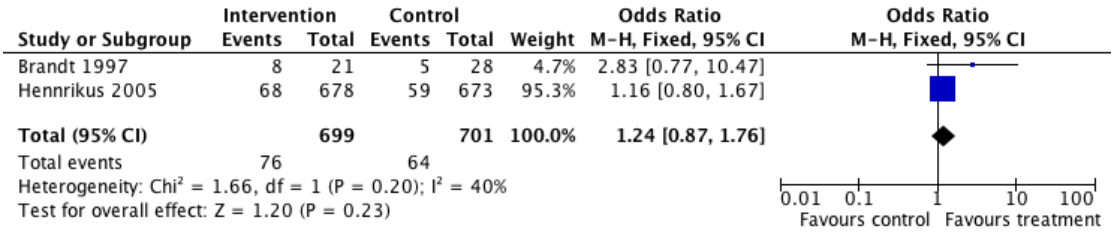


The results remain unaltered, showing a lack of efficacy for low intensity interventions, and significant effects of interventions providing follow-up support for the duration longer than four-weeks. They thus agree with the finding by Rigotti et al. (2007 [Systematic Review ++]).

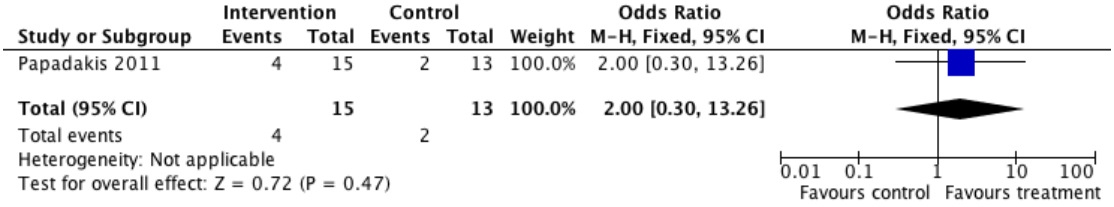
The next key question, not addressed in the previous meta-analyses, concerns the role of stop smoking medications. Some of the interventions examined in these studies included medications and some did not. The analyses presented above do not clarify whether significant effects can be achieved without medications, and whether the finding of differential effectiveness of interventions of different intensity is confounded by more intensive interventions being more likely to include pharmacotherapy. Clarifying this issue has obvious implications for recommended practice and for intervention costs.

We divided studies of each intensity into those which included medications and those that did not. The relevant meta-analyses are presented below. Medication was mostly NRT.

Intensity 1 – behavioural support only



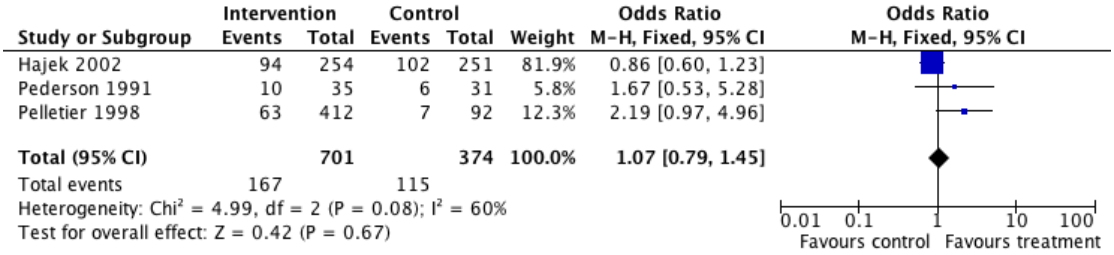
Intensity 1 – behavioural support plus medications



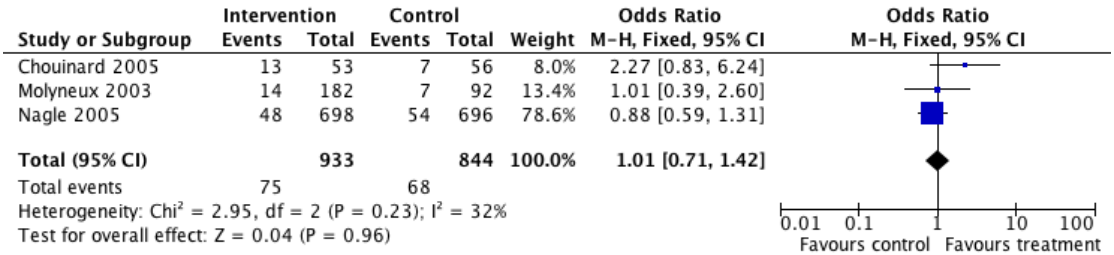
The study allowed a choice of NRT, bupropion or varenicline.

Intensity 1 interventions are ineffective with or without medications.

Intensity 2 – behavioural support only



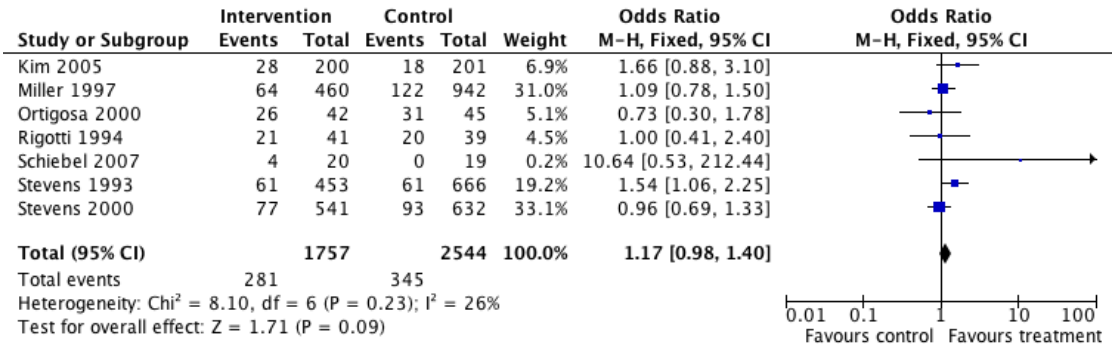
Intensity 2 – behavioural support plus medications



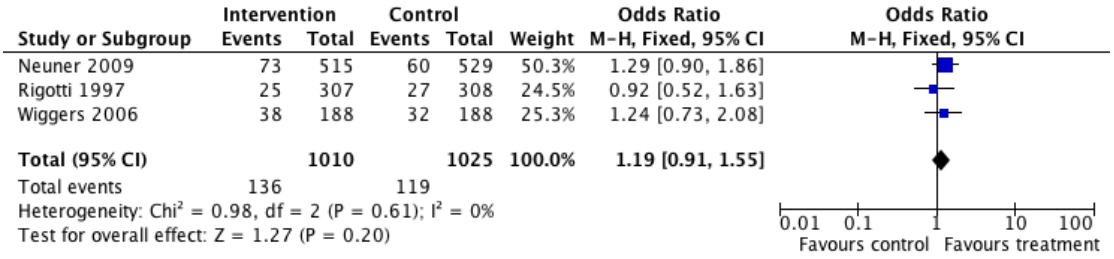
All studies used NRT.

Intensity 2 interventions are ineffective with or without medications.

Intensity 3 – behavioural support only



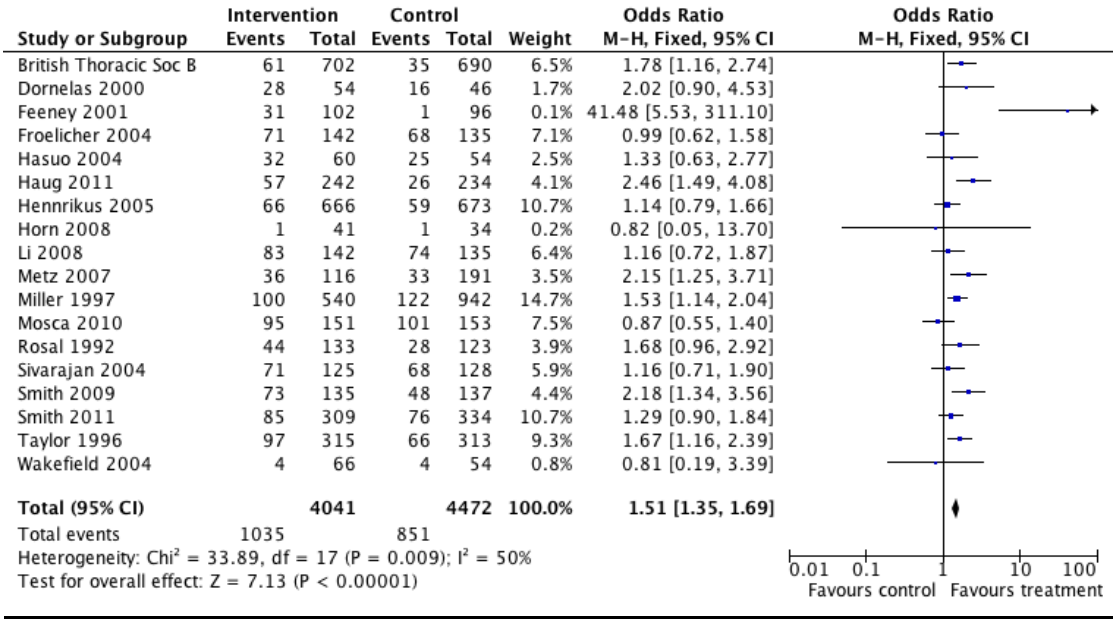
Intensity 3 – behavioural support plus medications



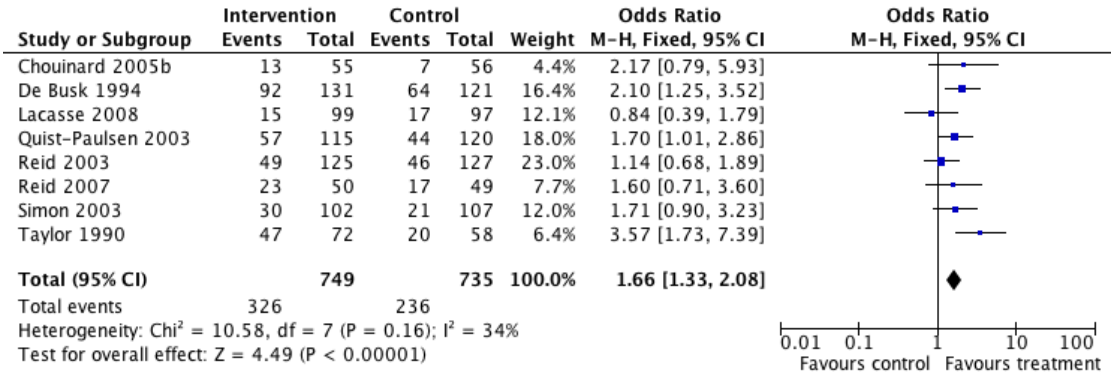
All three studies used NRT.

Intensity 3 interventions are ineffective with or without medications. The results are homogenous.

Intensity 4 – behavioural support only



Intensity 4 – behavioural support plus medications

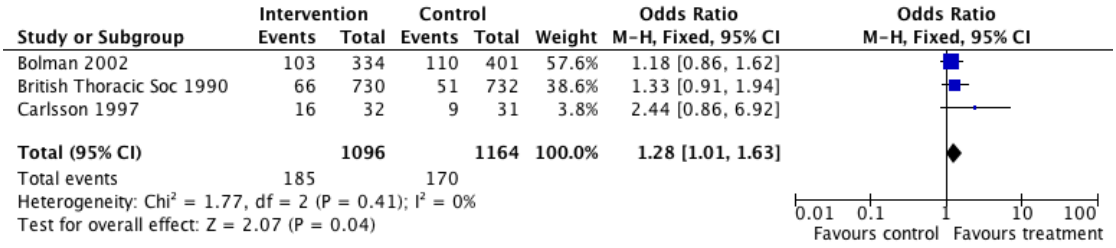


All studies used NRT. Chouinard et al 2005 [RCT ++] included bupropion as well.

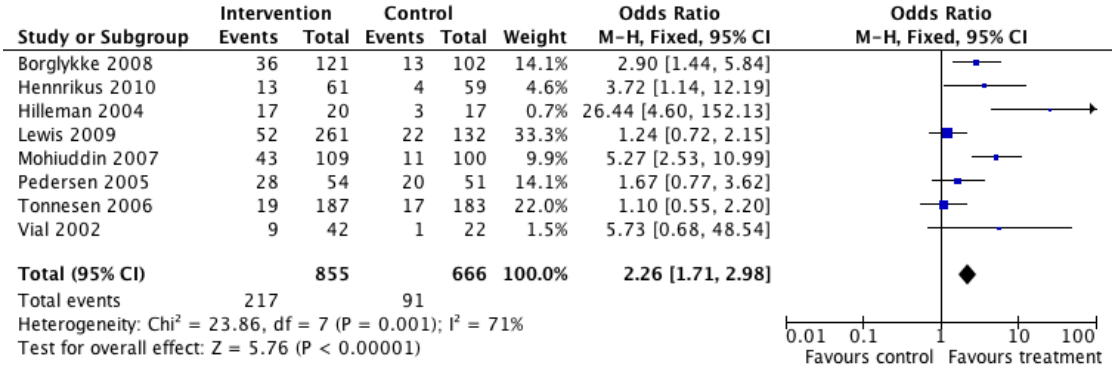
The results of the pooled behaviour support only studies were heterogenous. Removing the outlier (Feeny et al. 2001 [RCT ++]) reduces heterogeneity (p=0.10) with the result remaining significant (OR=1.43, 1.26-1.61).

Intensity 4 interventions are effective without medications and their efficacy further increases when medications are added.

Intensity 5 – behavioural support only



Intensity 5 – behavioural support plus medications

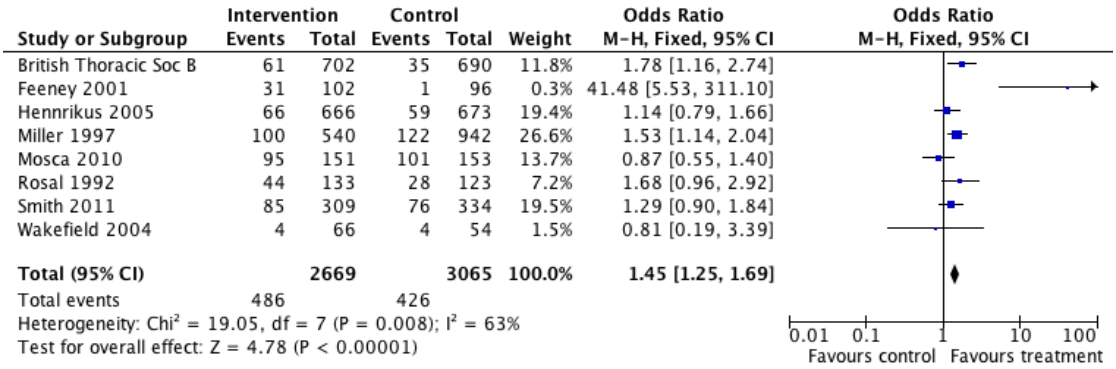


All studies used NRT, Mohiuddin et al 2007 [RCT ++] included bupropion as well and Hennrikus et al 2010 [RCT +] provided a choice of NRT, bupropion or varenicline.

Intensity 5 interventions without medications showed borderline effects, but with medications included, such interventions have good efficacy.

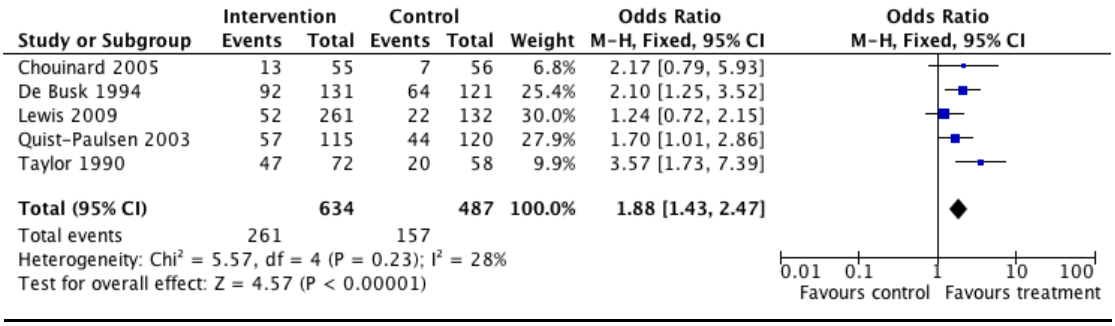
We next re-ran intensity 4 & 5 analyses including only studies which validated self-reported abstinence.

Intensity 4 – behavioural support only – validated

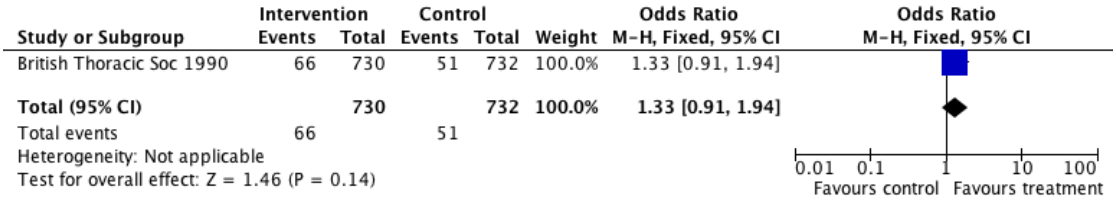


The results of the pooled validated behaviour support only studies were heterogenous. Removing the outlier (Feeny et al. 2001 [RCT ++]) reduces heterogeneity (p=0.28) with the result remaining significant (OR=1.35, 1.15-1.57).

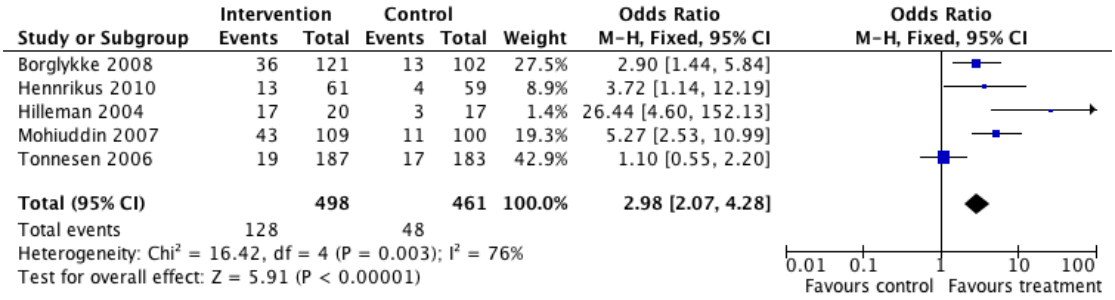
Intensity 4 –behavioural support plus medications – validated



Intensity 5 – behavioural support only – validated



Intensity 5 – behavioural support plus medications – validated



The results of the pooled validated behaviour support plus medications studies were heterogenous. Removing the outlier (Tonnesen et al. 2006 [RCT ++]) reduces heterogeneity (p=0.13) with the result remaining significant (OR=4.39, 2.81-6.84).

The analyses including validated studies only show good efficacy of intensive interventions accompanied by medications, especially when support is provided face-to-face.

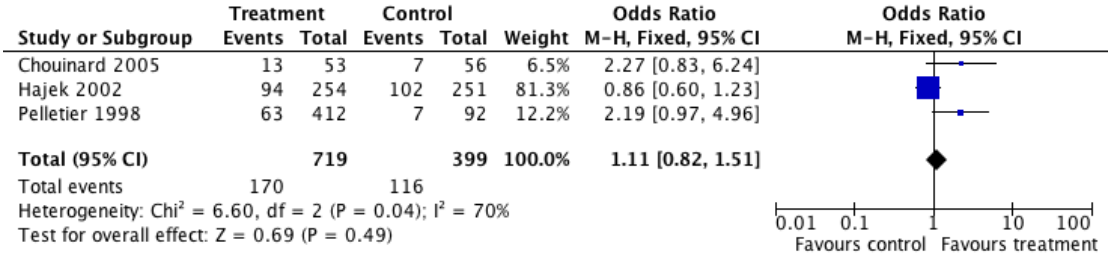
PART 2: PATIENT GROUPS

There is little reason to expect that stop-smoking interventions targeting dependent smokers motivated to quit will differ in efficacy depending on smokers' physical illness. However, we analysed separately the interventions for the main groups of hospital patients.

A. PATIENTS WITH CARDIOVASCULAR DISEASE

Intensity 1: There were no such studies

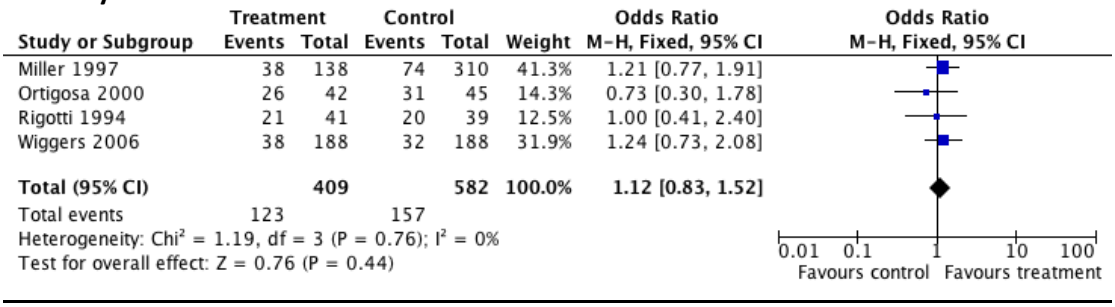
Intensity 2:



Study or Subgroup	Treatment Events	Treatment Total	Control Events	Control Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Chouinard 2005	13	53	7	56	6.5%	2.27 [0.83, 6.24]
Hajek 2002	94	254	102	251	81.3%	0.86 [0.60, 1.23]
Pelletier 1998	63	412	7	92	12.2%	2.19 [0.97, 4.96]
Total (95% CI)		**719**		**399**	**100.0%**	**1.11 [0.82, 1.51]**
Total events	170		116			

Heterogeneity: $Chi^2 = 6.60$, df = 2 (P = 0.04); $I^2 = 70\%$
Test for overall effect: Z = 0.69 (P = 0.49)

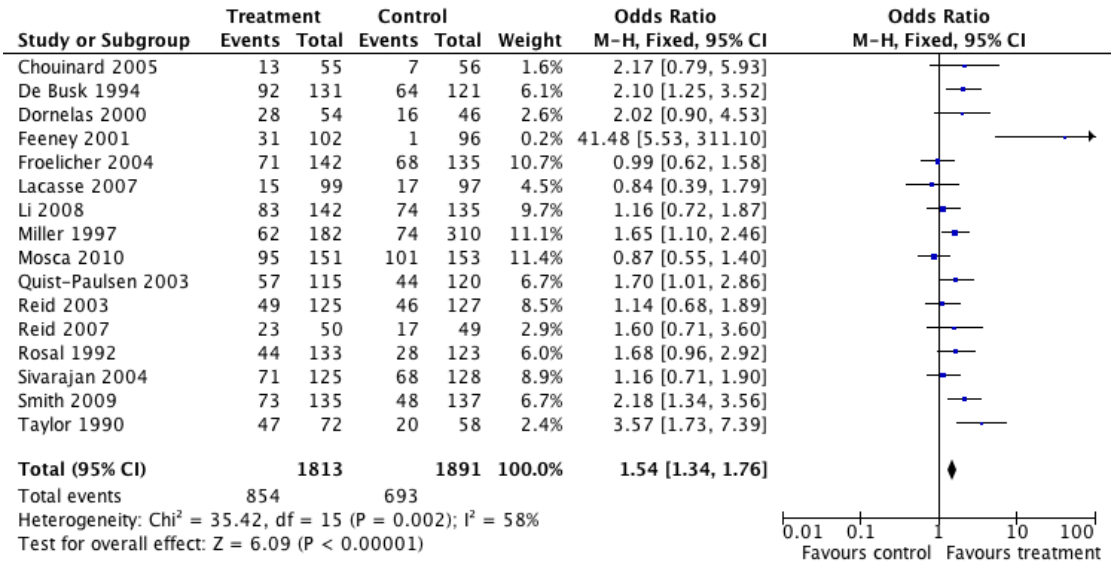
Intensity 3:



Study or Subgroup	Treatment Events	Treatment Total	Control Events	Control Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Miller 1997	38	138	74	310	41.3%	1.21 [0.77, 1.91]
Ortigosa 2000	26	42	31	45	14.3%	0.73 [0.30, 1.78]
Rigotti 1994	21	41	20	39	12.5%	1.00 [0.41, 2.40]
Wiggers 2006	38	188	32	188	31.9%	1.24 [0.73, 2.08]
Total (95% CI)		**409**		**582**	**100.0%**	**1.12 [0.83, 1.52]**
Total events	123		157			

Heterogeneity: $Chi^2 = 1.19$, df = 3 (P = 0.76); $I^2 = 0\%$
Test for overall effect: Z = 0.76 (P = 0.44)

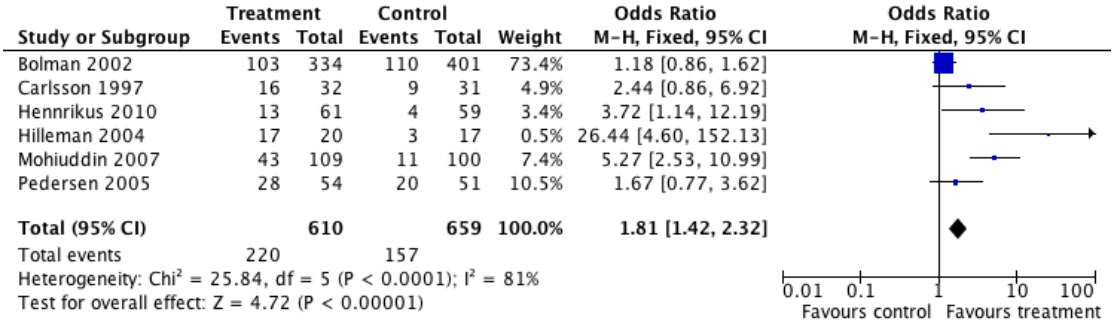
Intensity 4



Study or Subgroup	Treatment Events	Treatment Total	Control Events	Control Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Chouinard 2005	13	55	7	56	1.6%	2.17 [0.79, 5.93]
De Busk 1994	92	131	64	121	6.1%	2.10 [1.25, 3.52]
Dornelas 2000	28	54	16	46	2.6%	2.02 [0.90, 4.53]
Feeney 2001	31	102	1	96	0.2%	41.48 [5.53, 311.10]
Froelicher 2004	71	142	68	135	10.7%	0.99 [0.62, 1.58]
Lacasse 2007	15	99	17	97	4.5%	0.84 [0.39, 1.79]
Li 2008	83	142	74	135	9.7%	1.16 [0.72, 1.87]
Miller 1997	62	182	74	310	11.1%	1.65 [1.10, 2.46]
Mosca 2010	95	151	101	153	11.4%	0.87 [0.55, 1.40]
Quist-Paulsen 2003	57	115	44	120	6.7%	1.70 [1.01, 2.86]
Reid 2003	49	125	46	127	8.5%	1.14 [0.68, 1.89]
Reid 2007	23	50	17	49	2.9%	1.60 [0.71, 3.60]
Rosal 1992	44	133	28	123	6.0%	1.68 [0.96, 2.92]
Sivarajan 2004	71	125	68	128	8.9%	1.16 [0.71, 1.90]
Smith 2009	73	135	48	137	6.7%	2.18 [1.34, 3.56]
Taylor 1990	47	72	20	58	2.4%	3.57 [1.73, 7.39]
Total (95% CI)		**1813**		**1891**	**100.0%**	**1.54 [1.34, 1.76]**
Total events	854		693			

Heterogeneity: $Chi^2 = 35.42$, df = 15 (P = 0.002); $I^2 = 58\%$
Test for overall effect: Z = 6.09 (P < 0.00001)

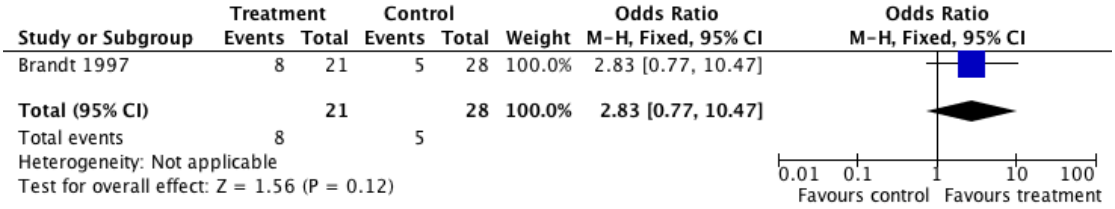
Intensity 5



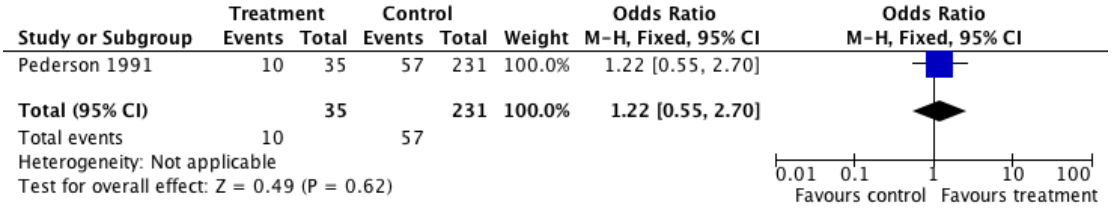
The results are the same as for all patient groups together, showing lack of efficacy for low intensity interventions, and significant effects of interventions providing support over periods longer than four weeks.

B. Patients with respiratory disease

Intensity 1

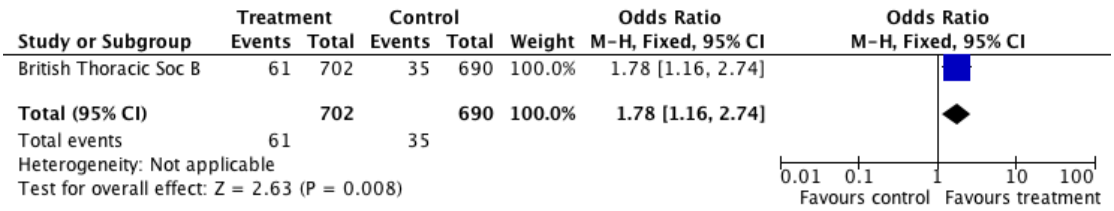


Intensity 2

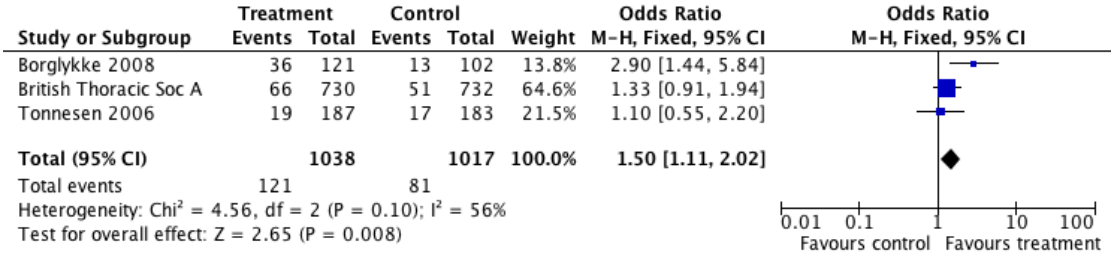


Intensity 3: No studies were available

Intensity 4



Intensity 5



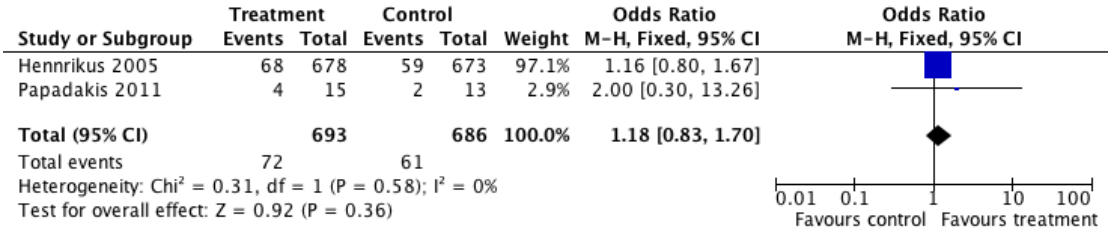
The results are similar to those from other patient groups, showing lack of efficacy for low intensity interventions, and better effects of more intensive interventions, although in this group of studies, only interventions with extended face-to-face support achieved a significant effect.

C. Patients with cancer

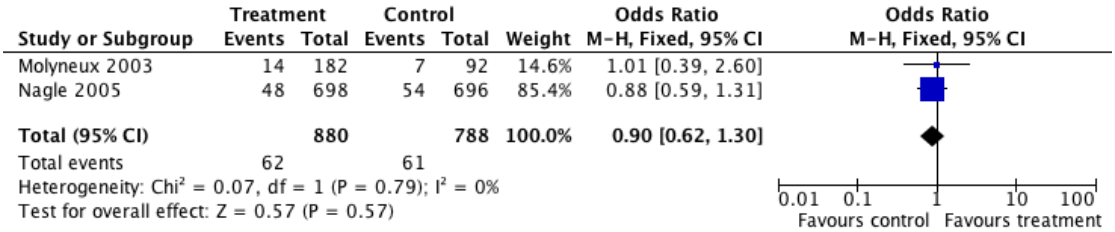
There was only one study focusing on cancer patients. This was Intensity 4 with no medications and showed no intervention effect (Wakefield et al 2004, [RCT ++]).

D. Unselected/other hospital patients

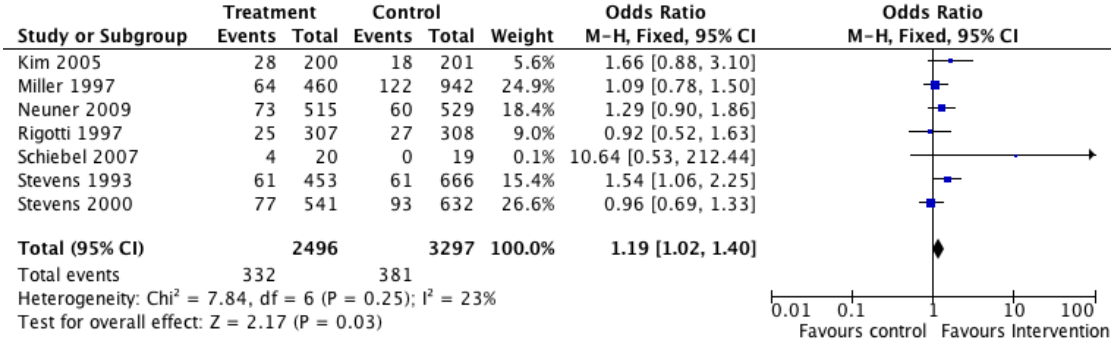
Intensity 1



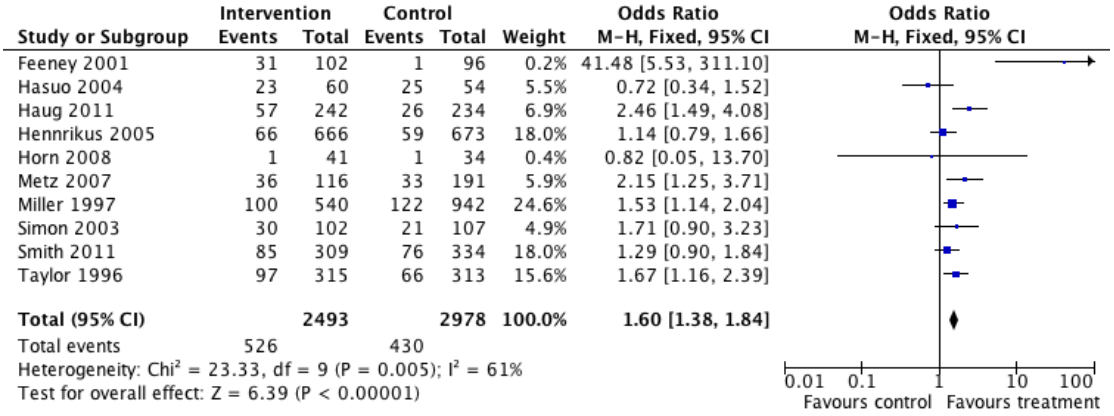
Intensity 2



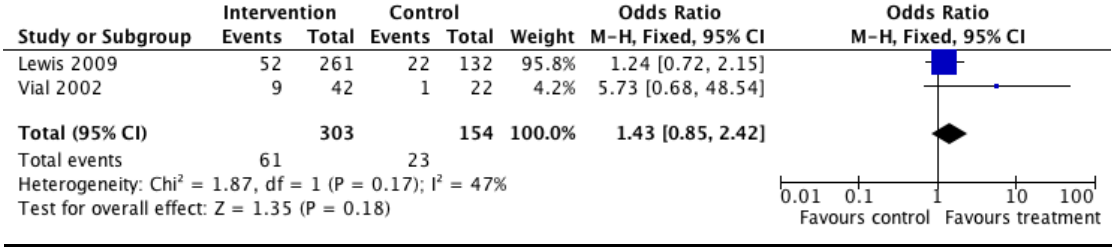
Intensity 3



Intensity 4



Intensity 5

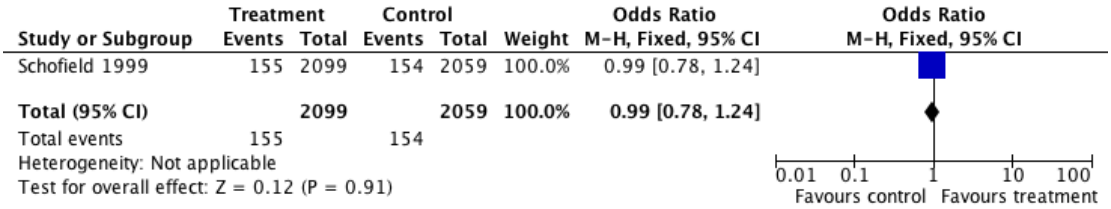


The results show lack of efficacy for low intensity interventions and significant effects of Intensity 4 interventions, though the results of the three Intensity 5 interventions did not reach significance (Lewis et al 2009 [RCT +]; Pedersen et al 2005 [RCT -]; Vial et al 2002 [RCT -]).

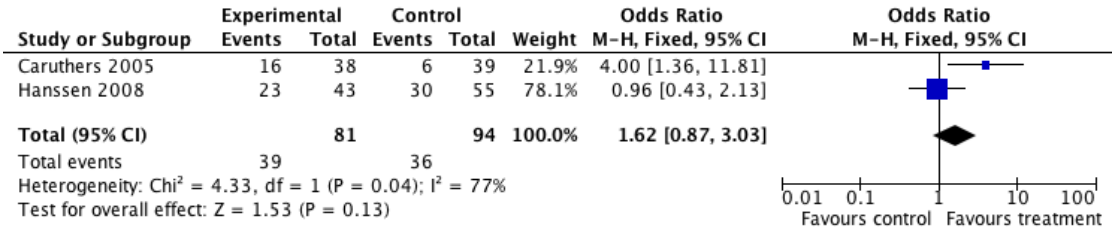
D. Patients receiving intervention after hospital discharge

Three trials evaluated interventions delivered after hospital discharge (i.e. patients did not receive any intervention whilst in hospital). We are including them because they target hospital patients and hospitals could in theory refer patients to such programmes. One trial (Carruthers et al 2005 [RCT +]) included NRT.

Intensity 1



Intensity 4



Only one study evaluating the efficacy of extended support accompanied by NRT showed a significant effect.

CONCLUSIONS

The overall picture emerges showing that brief interventions (Intensity 1 and 2) with users of acute care are not effective, even if they include medications. Regarding interventions providing support for over 4 weeks, interventions with face-to-face support seem to achieve better results than interventions relying on phone calls, but without the addition of medications, any effects are modest. The inclusion of medications strongly enhances efficacy of these treatment.

Note on the impact of professional background of staff delivering stop-smoking interventions

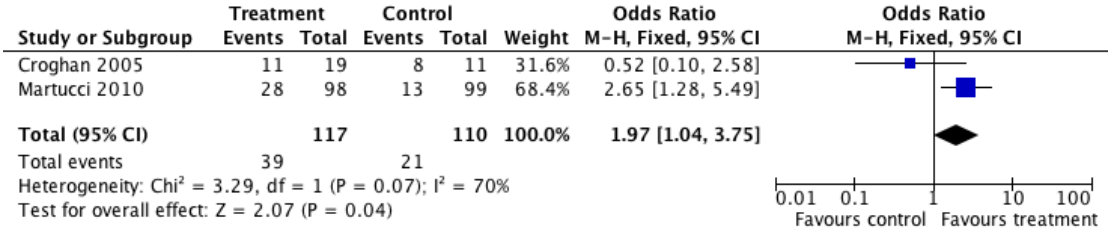
We were unable to assess systematically any effects of the background of the person providing the advice. Brief intervention (Intensity 1 and 2) was provided mostly by doctors, while on-going interventions by telephone calls and face-to-face contacts were provided by trained stop-smoking advisors. It is unlikely that brief intervention (Intensity 1 and 2) by staff other than doctors would be effective. Given that extended support provided by staff other than doctors is effective, encouraging doctors to provide on-going telephone or face-to-face counselling sessions to smokers would not seem an economical use of their time. The professional background of stop-smoking advisors is likely to have limited relevance. The key ingredients of efficacy seem to be the length of support and inclusion of medications

SECTION 2: EFFICACY OF INTERVENTIONS DELIVERED TO SURGERY PATIENTS

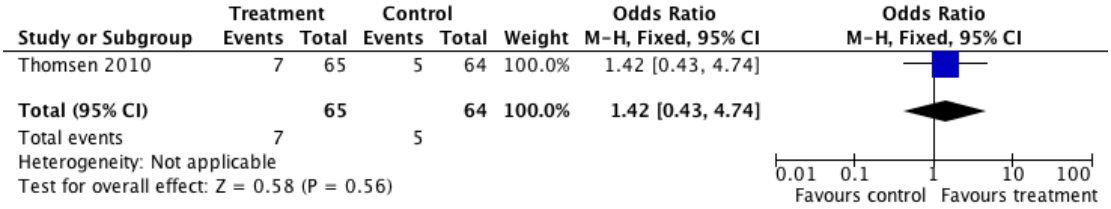
Six trials evaluated interventions initiated prior to surgery. With one exception (Croghan et al 2005 [RCT +]), all trials included NRT.

Intensity 1: There were no such trials

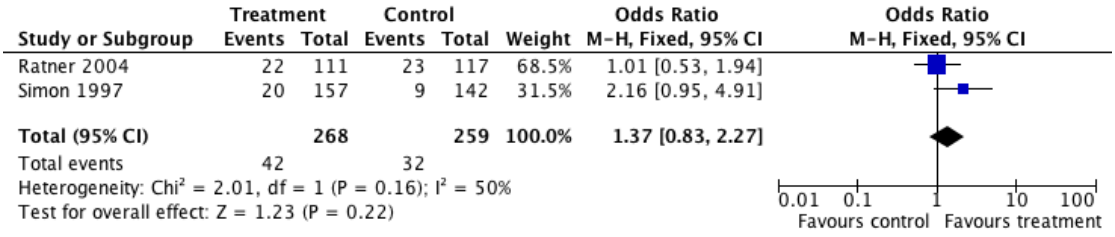
Intensity 2



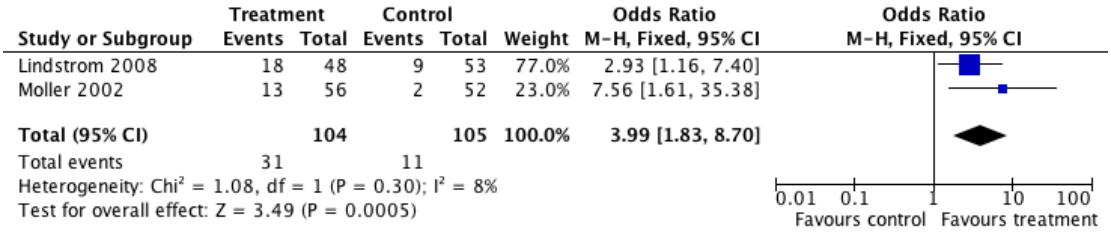
Intensity 3



Intensity 4



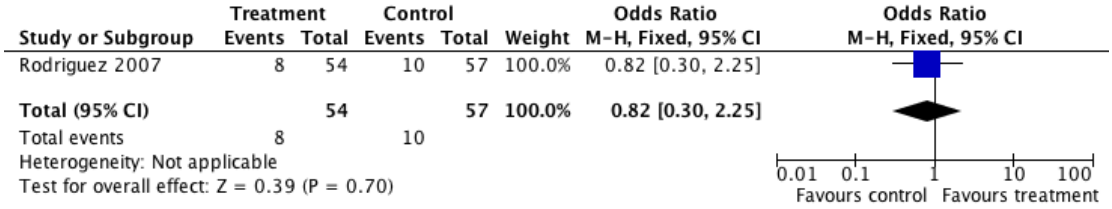
Intensity 5



Of the two studies examining level 2 intensity interventions, one was positive and one was negative. As the larger study was positive, the pooled results reach statistical significance.

Both studies of Intensity 5 interventions provided face-to-face contact and NRT. Both showed good efficacy.

One trial (Rodriquez et al 2007 [RCT -]) evaluated effects of one session of stop-smoking messages delivered under deep sedation.



The intervention had no effect.

CONCLUSIONS

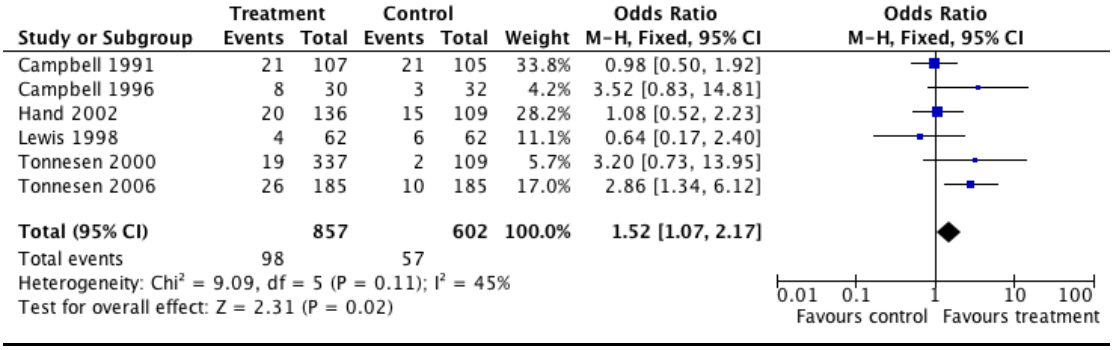
Brief interventions (Intensity 1 and 2) initiated prior to surgery lack efficacy even if accompanied by NRT. Face-to-face support lasting for over 4 weeks accompanied by NRT is effective.

Stop-smoking messages delivered under sedation are not effective.

SECTION 3: EFFICACY OF PHARMACOLOGICAL INTERVENTIONS WITH HOSPITAL PATIENTS

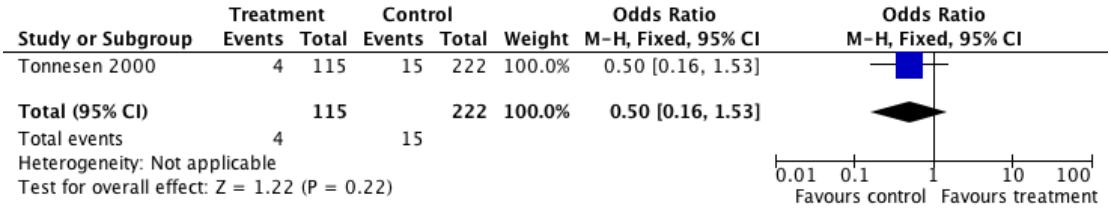
In this section, we cover trials which evaluated medications by comparing study arms with the same intensity of behavioural support which only differed in whether they received active medications or not.

Six trials compared NRT treatment accompanied by behavioural support with the same support delivered with placebo or with no medication. The intensity of behavioural support was 4 or 5 in all trials.



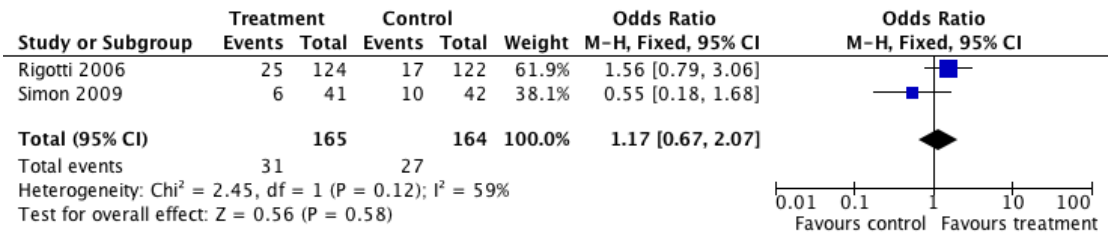
In this group of studies, NRT was effective.

One trial compared patch and inhaler alone with the two medications combined.



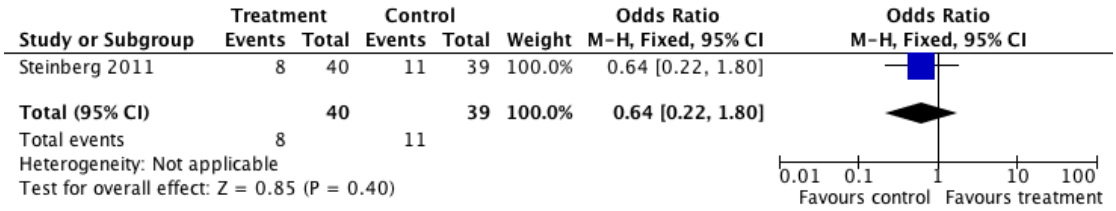
Single NRTs were as effective as their combination.

Two trials compared bupropion and placebo. Both trials relied on telephone calls and neither offered any post-quit face-to-face support.



The trials did not show the intervention effective.

One small placebo controlled trial evaluated varenicline accompanied by brief counselling session/sessions (it is not clear if there was one or more, but it was attended by 16 participants only).



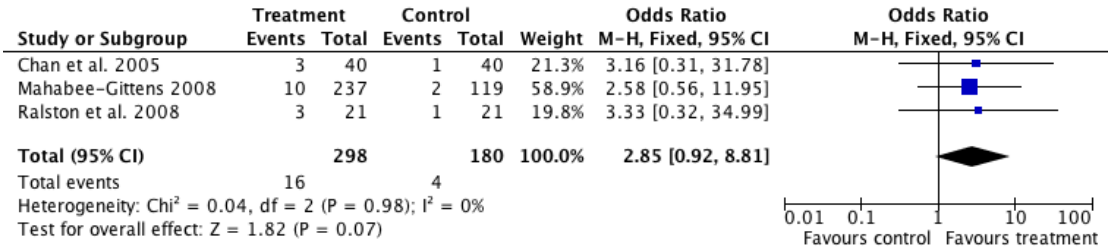
The trial did not find the treatment effective.

CONCLUSIONS

NRT accompanied by behavioural support extended over four weeks is effective. A combination of patches and inhaler was not more effective than each medication on its own. Bupropion and varenicline provided without on-going face-to-face support lack efficacy.

SECTION 4: EFFICACY OF INTERVENTIONS WITH PATIENTS' RELATIVES

Three trials evaluated interventions with parents of children hospitalised on paediatric wards. Two used one-off advice with a phone reminder (Chan et al 2005 [RCT -]) or fax referral to Quitline (Mahabee-Gittens et al 2008 [RCT -]) and one used >30 minutes of counselling and access to NRT for some participants (Ralston et al 2008 [RCT -], Intensity 2). This group of studies had shorter follow-ups (Chan one month, Mahabee-Gittens 3 months, Ralston 6 months).



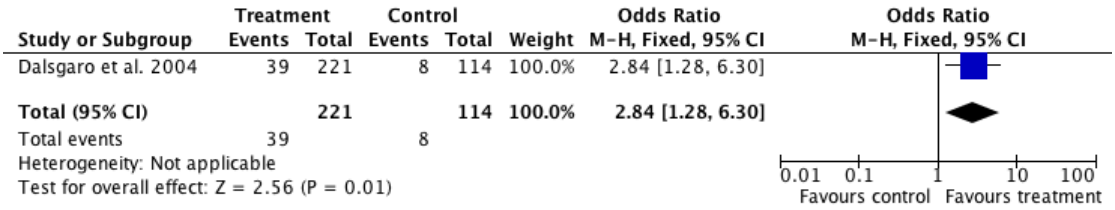
The interventions overall lacked efficacy despite a short follow-up. This is relevant because intervention effects often dissipate over time.

CONCLUSIONS

Brief interventions (Intensity 1 and 2) with parents of hospitalised children lack efficacy.

SECTION 5: EFFICACY OF INTERVENTIONS WITH HOSPITAL STAFF

We found only one study evaluating an intervention with hospital employees. It was a high-quality placebo controlled trial of bupropion with Intensity 5 support.



The trial showed bupropion with regular face-to-face support to be an effective treatment for hospital employees.

CONCLUSIONS

Bupropion accompanied by intensive support is an effective treatment for hospital employees.

SYSTEMATIC REVIEWS

We found two relevant Cochrane reviews. We discussed Rigotti et al. (2007 [systematic review, ++]) review earlier. Our conclusions in the areas covered by Rigotti et al. are similar. The same applies to the review by Thomsen et al. (2010 [systematic review, ++]) concerning surgery patients, also discussed above.

We identified 11 other reviews, listed below. We rated their quality as ++ for systematic reviews showing awareness of key methodological features of stop-smoking studies, + for reviews which were less systematic and/or did not take into account the key quality aspects of included studies, and – for reviews which were selective and/or posed methodological problems. All relevant and eligible studies included in these reviews are also included in our review.

Author	Aim	Number of studies	Findings	Quality
Aziz 2008	Effectiveness of smoking cessation intervention in hospitalised patients with cardiovascular disease	11	Significantly higher abstinence rates in patients receiving intervention in hospital continued post discharge for at least 3 months alongside NRT compared to usual care	+
Barth 2009	Effectiveness of behavioural interventions, telephone support and self-help interventions in people with coronary heart disease (CHD)	16	Positive effects of interventions on abstinence after 6 to 12 months	+
Mistiaen 2008	Effectiveness of follow – up telephone calls in the first month after discharge (not smoking specific)	33	Inconclusive evidence about the effectiveness of telephone FU	++
Munafo 2001	Effectiveness of interventions for hospitalised patients	15	High intensity behavioral support of at least 1 month of follow up contact is effective	++
Nayan 2011	Smoking cessation interventions and rates of smoking in cancer patients	8	No significant difference between interventions and usual care	++
Rice 2008	Effectiveness of nurse-delivered smoking cessation intervention	42	Slightly increased rate of quitting	++
Rice 2009	Effectiveness of nurse-delivered smoking cessation intervention – updated from Rice 2008	34	Interventions of high and low intensity provided by a nurse generated an increased rate of quitting	++
Rigotti 2008	Effectiveness of hospital interventions initiated during hospital stay	33	Counselling initiated during hospitalization with follow up of at least 1 month increased long term smoking cessation	++
Van der Meer 2009	Effectiveness of smoking cessation interventions in people with COPD	5	Interventions including medications were effective	++

Wagena 2004	Effectiveness of behavioural interventions for people with COPD	5	Intensive behavioral support + NRT increased abstinence rates. Bupropion did not increase abstinence rates.	++
Wiggers 2003	Effectiveness of smoking cessation interventions in cardiovascular patients	12	No evidence of effectiveness for pharmacotherapy, self help materials, group, individual or telephone counseling. Limited evidence for doctor or nurse delivered advice	+

NARRATIVE SUMMARY

INTERVENTION INTENSITY

A range of interventions aimed at helping smokers in acute care settings stop smoking has been proposed. Advice by doctors and nurses during a hospital visit, possibly repeated and reinforced during the hospital stay (if applicable) and accompanied by leaflets, is by far the simplest and least expensive option which could be provided routinely on a large scale. Unfortunately, there is no evidence that such interventions work. Smokers in acute care have usually received strong encouragements to stop smoking on a number of previous occasions and the fact that they continue to smoke despite high motivation to stop suggests a high level of dependence and a need for more intensive treatment.

The next level of intervention which is still requiring modest resources is to reinforce the in-hospital intervention by telephone calls over the first few weeks after discharge. This too was not shown effective.

For interventions with acute care patients to be effective, an extended support and stop smoking medication provided for over 4 weeks seem necessary. Face-to-face support may provide better results than support provided over telephone. Importantly, support alone without medications has only uncertain effects but it has good efficacy when provided together with smoking cessation medications.

PATIENT GROUPS

There is no a-priori reason to expect that smokers with different diagnoses would react differently to different interventions. We nevertheless analysed the main patient categories including patients with cardiovascular disease, respiratory disease, and general patient samples separately. The results broadly confirm the main findings. Only Intensity 5 interventions (extended face to face support) accompanied by medications were effective with patients undergoing surgery.

PHARMACOTHERAPY

NRT accompanied by extended multi-session support lasting over 4 weeks is effective in the acute services setting. A few small trials evaluated bupropion and varenicline accompanied by minimal support and did not find such treatments effective. NRT is known to be ineffective without support and follow-up and this is probably true for other stop-smoking medications as well.

PATIENT RELATIVES

Brief interventions (Intensity 1 and 2) with parents of hospitalised children did not show efficacy.

HOSPITAL STAFF

Bupropion with regular face-to-face support is an effective treatment for hospital staff.

IMPACT OF BACKGROUND OF STAFF DELIVERING THE INTERVENTIONS

We were unable to ascertain whether the background of the person providing the interventions affect outcomes, but given that extended support provided by staff other than doctors is effective, encouraging doctors to provide on-going telephone or face-to-face counselling sessions to smokers would not seem an economical approach. The professional background of stop-smoking advisors is likely to be of limited importance. The key ingredients of efficacy seem to be the length of support and inclusion of medications.

EVIDENCE STATEMENTS

Statements 1.1 to 1.5 concern non-surgical patients

ES 1.1: There is strong evidence from trials that validated self-reported abstinence rates that interventions with no follow-up (Intensity 1 and 2) are ineffective.

Two studies of level 1 intensity (Brandt et al 1997 [RCT +]; Papadakis et al 2011 [RCT +]), and five of level 2 intensity support (Chouinard et al 2005 [RCT ++]; Hajek et al 2002 [RCT ++]; Molyneux et al 2003 [RCT ++]; Nagle et al 2005 [RCT +]; Pederson et al 1991 [RCT +]) showed no effect. Pooled data from these studies confirm lack of effect: Intensity 1 OR=2.52 (95%CI: 0.86-7.40); Intensity 2 OR=0.96 (95%CI: 0.89-1.38)

ES 1.2: There is strong evidence from trials that validated self-reported abstinence rates that interventions delivered with telephone follow-ups for up to 4 weeks (Intensity 3) are not effective.

Six studies (Kim et al 2005 [RCT +]; Miller et al 1997 [RCT +]; Ortigosa et al 2000 [RCT +]; Rigotti et al 1994 [RCT ++]; Rigotti et al 1997 [RCT +]; Wiggers et al 2006 [RCT +]) showed no effect. Pooling these data give an odds ratio of 1.11 (95% CI: 0.89-1.38).

ES 1.3: There is strong evidence from trials that validated self-reported abstinence rates that interventions accompanied by on-going behavioural support for over 4 weeks in combination with smoking cessation medications are effective.

Of the eleven studies examining the efficacy of level 4 intensity interventions plus medication compared to usual care six showed a significant benefit (British Thoracic Society [RCT ++]; De Busk et al 1994 [RCT ++]; Feeney et al 2001 [RCT ++]; Miller et al 1997 [RCT +]; Quist-Paulsen et al 2003 [RCT +]; Taylor et al 1990 [RCT +]) and five did not (Chouinard et al 2005 [RCT ++]; Mosca et al 2010 [RCT +]; Rosal et al [RCT ++]; Smith et al 2011 [RCT +]; Wakefield et al 2004 [RCT ++]). When these studies are pooled there is evidence of a beneficial effect of this level of intervention (OR=1.65; 95%CI: 1.42-1.91). There were five studies examining level 5 intensity interventions with medication. Four showed a significantly positive effect (Borglykke et al 2008 [RCT +]; Hennrikus et al 2010 [RCT +];

Hilleman et al 2004 [RCT ++]; Mohiuddin et al 2007 [RCT ++]), and three did not (British Thoracic Society 1990 [RCT ++]; Lewis et al 2009 [RCT++]; Tonnesen et al 2006 [RCT ++]). When these studies are pooled there is evidence of a beneficial effect of this level of intervention (OR=1.87; 95%CI: 1.48-2.36).

ES 1.4: There is strong evidence that interventions with limited follow-up (Intensity 1-3) are not effective across non-surgical patient groups.

All interventions of intensity levels 1-3 were ineffective for patients with **cardiovascular disease** (Chouinard et al 2005 [RCT ++]; Hajek et al 2002 [RCT ++]; Pelletier et al 1998 [RCT -]; Miller et al 1997 [RCT +]; Ortigosa et al 2000 [RCT +]; Rigotti et al 1994 [RCT +]; Wiggers et al 2006 [RCT +]), **respiratory disease** (Brandt et al 1997 [RCT +]; Pederson et al 1991 [RCT +]), and **other groups of hospital patients** (Hennrikus, et al 2005 [RCT +]; Papadakis et al 2011 [RCT +]; Kim et al 2005 [RCT +]; Miller et al 1997 [RCT +]; Molyneux et al 2003 [RCT ++]; Nagle et al 2005 [RCT +]; Neuner et al 2009 [RCT -]; Rigotti et al 1997 [RCT +]; Schiebel et al 2007 [RCT -]; Steven et al 1997 [RCT]; Stevens et al 2000 [RCT -]).

ES 1.5: There is strong evidence that interventions with medications and follow-up of over 4 weeks are effective across non-surgical patient groups.

For patients with **cardiovascular disease** 8 trials of interventions for intensity 4-5 showed a positive effect (De Busk et al 1994 [RCT ++]; Feeney et al 2001 [RCT ++]; Hennrikus et al 2010 [RCT +]; Hilleman et al 2004 [RCT ++]; Mohiuddin et al 2007 [RCT ++] Quist-Paulsen et al 2003 [RCT +]; Smith et al 2011 [RCT +]; Taylor et al 1990 [RCT +]) and 14 did not (Bolman et al 2002 [RCT -]; Carlsson et al 1997 [RCT -]; Rosal 1992 [RCT ++]; Chouinard et al 2005 [RCT ++]; Dornelas et al 2000 [RCT +]; Froelicher et al 2004 [RCT +]; Lacasse et al 2008 [RCT -]; Li et al 2008 [RCT -]; Miller et al 1997 [RCT +]; Mosca et al 2010 [RCT +]; Pedersen et al 2005 [RCT -]; Reid et al 2003 [RCT +]; Reid et al 2007 [RCT -]; Sivarajan et al 2004 [RCT -]). When these studies are pooled there is evidence of a beneficial effect of this level of intervention. Intensity 4 OR=1.54 (95%CI: 1.34-1.76); Intensity 5 OR=1.81 (95%CI: 1.42-2.32).

For patients with **respiratory disease** 2 trials of interventions for intensity 4-5 showed a positive effect (British Thoracic Society B 1990 [RCT ++]; Borglykke et al 2008 [RCT +]) and 2 showed no effect (British Thoracic Society A 1990 [RCT ++]; Tonnesen et al 2006 [RCT ++]). There was only one study of intensity 4 intervention (British Thoracic Society B 1990 [RCT ++]) that showed benefit (OR=1.78; 95% CI:1.16-2.74). Pooling the intensity 5 intervention studies also showed a beneficial effect (OR=1.50 95%CI: 1.11-2.02).

For **other non-surgical groups of hospital patients** 5 trials of interventions for intensity 4-5 showed a positive effect (Feeney et al 2001 [RCT ++]; Haug et al 2011 [RCT -]; Metz et al 2007 [RCT -]; Miller et al 1997 [RCT +]; Taylor et al 1996 [RCT +]) and 7 did not (Hasuo et al 2004 [RCT +]; Hennrikus et al 2005 [RCT +]; Horn et al 2008 [RCT -]; Lewis et al 2009 [RCT +]; Simon et al 2003 [RCT +]; Smith et al 2011 [RCT +]; Vial et al 2002 [RCT-]). Pooling the intensity 4 intervention studies also showed a beneficial effect (OR=1.60 95%CI: 1.38-1.84). However pooling the two Intensity 5 studies (Lewis et al 2009 [RCT +]; Vial et al 2002 [RCT-]) showed no significant effect (OR=1.43; 95%CI: 0.85-2.42).

ES 1.6: There is mixed evidence concerning the efficacy of brief interventions in patients

undergoing surgery.

Only one (Martucci et al 2010 [RCT +]) of three studies (Croghan et al 2005 [RCT +]; Martucci et al 2010 [RCT +]; Thomsen et al 2010 [RCT +]) investigating the efficacy of level 2-3 pre-operative smoking cessation interventions was positive. Pooling data from the intensity 2 studies (Croghan et al 2005 [RCT +]; Martucci et al 2010 [RCT +]) showed a borderline benefit of this level of intervention (OR=1.97; 95%CI: 1.04-3.75). The one study of intensity 3 interventions (Thomsen et al 2010 [RCT +]) showed no effect (OR=1.42; 95%CI: 0.42-4.74).

ES 1.7: There is moderate evidence that in patients undergoing surgery smoking cessation interventions relying mostly on telephone contact (intensity 4) are not effective.

Two trials (Ratner et al 2004 [RCT +]; Simon et al 1997 [RCT -]) showed no effect of this level of intervention. Pooled data gives an odds ratio of 1.37 (95%CI: 0.83-3.27).

ES 1.8: There is strong evidence that in patients undergoing surgery intensive interventions (intensity 5) alongside nicotine replacement therapy are effective.

Two trials (Lindstrom et al 2008 [RCT ++]; Moller et al 2002 [RCT ++]) show a positive effect. Pooled data gives an odds ratio of 3.99 (95%CI: 1.83-8.70).

ES 1.9: There is weak evidence that stop smoking messages delivered under deep sedation are not effective.

One trial (Rodriguez et al 2007 [RCT -]) showed no effect (OR=0.82; 95%CI: 0.30-2.25)

ES 1.10: There is strong evidence that nicotine replacement treatment accompanied by extended support is effective in general hospital patients.

Only one (Tonnesen et al 2006 [RCT ++]) of the six trials (Campbell et al 1991 [RCT ++]; Campbell et al 1996 [RCT ++]; Hand et al 2002 [RCT ++]; Lewis et al 1998 [RCT +]; Tonnesen et al 2000 [RCT ++]; Tonnesen et al 2006 [RCT ++]) examining the efficacy of NRT showed a positive effect. However pooling these data showed a benefit of NRT (OR=1.52; 95% CI: 1.07-2.17).

ES 1.11: There is moderate evidence that bupropion and varenicline provided without face-to-face support are ineffective in acute care non-surgical patients

Bupropion: two trials showed no effect (Rigotti et al 2006 [RCT ++]; Simon et al 2009 [RCT +]). Varenicline: one trial showed no effect Steinberg et al 2011 [RCT +]). The odds ratios (95% CI) for bupropion and varenicline are 1.17 (0.67-2.87) and 0.64 (0.22-1.80) respectively.

ES 1.12: There is weak evidence that low intensity interventions with smoking parents of hospitalised children lack efficacy.

Three trials (Chan et al 2005, [RCT -]; Mahabee-Gittens et al 2008, [RCT -]; Ralston et al 2008 [RCT -]) have all negative results. Pooling these data show no significant effect of such interventions (OR=2.85; 95%CI: 0.92-8.81). There were no studies investigating the efficacy of bupropion or varenicline combined with face-to-face support in acute care patients

ES 1.13: There is moderate evidence that treatment of hospital staff with bupropion combined with regular face-to-face support is effective.

One high quality trial (Dalsgaro et al 2004 [RCT ++]) found a positive effect.

APPLICABILITY STATEMENTS

The NHS practice currently involves interventions at bed-side accompanied by medications and/or referrals to specialist stop-smoking service for treatment after discharge which combines extended face-to-face support with smoking cessation medications. The reviewed evidence confirms that this is likely to be the optimal approach. The high cost of such approach is mitigated by the fact that the NHS provides centrally funded stop-smoking serviceswhich are proactively recruiting smokers and have ample capacity to accept such referrals and to treat them without further costs and without any delays.

CHAPTER TWO: Smoking Cessation Interventions with Users of Maternity Services

INTRODUCTION

Most pregnant smokers in the UK are aware that smoking is unhealthy for their unborn child and many are receptive to stop-smoking encouragement and advice. However, there are several negative prognostic factors present as well, such as young age and living with smokers. Given the potentially serious negative health consequences of smoking for the mother and the child, a provision of help to pregnant smokers is considered an important priority.

A question arises as to what form should such provision take. The options range from one-off brief routine interventions through written materials and phone calls to intensive face-to-face treatments accompanied by medications. Such options differ in the likelihood of success, reach, attractiveness to smoker, and cost.

Due to the importance and emotional appeal of the topic, large investments have been made in the clinical practice but also in research in this area. More randomised trials have examined stop-smoking interventions with pregnant women than with any other single group. Their results can inform the best practice in this field.

This chapter reviews the existing experimental literature. As with the studies from acute care, caution is needed in generalising the results of many of the studies to the UK setting. The NHS actively promotes free specialist multi session face-to-face stop-smoking treatments accompanied by nicotine replacement medications, and it employs specialist staff to provide it. Most of the existing trials were conducted in environments and with methods that were much less favourable to successful smoking cessation than the current UK routine practice.

Our brief was to review RCTs evaluating smoking cessation interventions and interventions aimed at facilitating temporary abstinence. We identified a large number of studies seeking to determine the efficacy of smoking cessation interventions delivered to users of maternity services. We did not identify any studies of interventions aimed at facilitating temporary abstinence. Although changes in cigarette consumption in women who failed to stop smoking are sometimes reported, there is a general consensus that such outcomes have limited value. Given the large volume of material to review, tight time limits, and questionable value of such information, we did not attempt to systematically review the impact of stop-smoking interventions on cigarette consumption. The review focuses on stopping smoking as the key indicator of efficacy.

STRUCTURE OF THE CHAPTER

We found 81 studies evaluating smoking cessation interventions with users of maternity services that had follow-up periods of at least 6 months. The studies are summarised in e.g. the contents of leaflets).

Were were unable to retrieve three relevant studies on time (Secker-Walker et al 1994 [RCT -]; Thornton et al 1997 [RCT +]; Valbo et al 1994 [RCT -]. For these studies, we used data extraction from the Cochrane review. This is noted in the table summarising the included studies.

Table 3. They cover four different topics, which are addressed in the five separate sections.

- Section 1: Efficacy of behavioural interventions delivered during pregnancy. This section concerns trials where study arms differed in the intensity of behavioural support.
- Section 1A: Efficacy of interventions based on incentives
- Section 1B: Efficacy of interventions targeting partners
- Section 2: Efficacy of behavioural interventions delivered post-partum
- Section 3: Efficacy of pharmacotherapies delivered during and/or after pregnancy. This section concerns trials where study arms received the same intensity of behavioural support, but differed in receiving or not receiving active pharmacotherapy.
- Section 4: Efficacy of interventions to prevent relapse

An interpretative summary of findings is provided at the end of each section, and narrative summary and evidence statements are at the end of the Chapter.

Note on data extraction and the quality of relevant studies

In this field, full ITT analysis was rarely provided. Most studies excluded women with miscarriage, those who left their current health service provider, and usually also at least some of the women not available for follow-up. As these different categories were usually merged, we only had an option to go along with the reported sample, or include the full original sample. We opted for including the full sample.

We were struck by the low quality of many of these studies, especially older ones. The denominators used to calculate success rates kept changing, key methodological details were not provided, validation results were not taken into account in calculating outcomes, comparison groups were clustered post-hoc, and many papers convey a sense of a strenuous effort to come up with positive results. The Cochrane review of this literature (Lumley et al. 2009 [Systematic Review +]) is also of a lower standard than other Cochrane reviews, with limited attention paid to methodological considerations specific to smoking cessation research and categorisation of studies in a way that is not useful for practical considerations (e.g. the contents of leaflets).

Were were unable to retrieve three relevant studies on time (Secker-Walker et al 1994 [RCT -]; Thornton et al 1997 [RCT +]; Valbo et al 1994 [RCT -]. For these studies, we used data extraction from the Cochrane review. This is noted in the table summarising the included studies.

TABLE 3: SUMMARY OF STUDIES INCLUDED IN CHAPTER 2

Albrecht et al 1998, US	*Participants:* 84 teenage smokers *Interventions:* 8 didactic group sessions (TFS) or same with one-to-one non-smoking peer buddy (TFSB) (Intensity 5) *Control procedure:* Usual care (30 minute individual session with nurse). TFS program adapted by one developed by American Cancer Society. *Outcomes:* 4-6 weeks post intervention *Validation:* CO *Quality:* - Note: Study poorly reported, focus on cigs/day, results massaged. 5 quitters in TFS and UC groups combined (so estimate 2 and 3, though it is possible the actual figures not reported because all 5 were in UC). Unclear who carried out intervention.
Baric et al 1976, UK	*Participants:* 110 smokers, recruited at first antenatal visit (<20 weeks gestation) (I: n=63, C: n=47) Interventions: one-to-one counselling from senior medical student. Strong encouragement to quit, or reduce to <5 cigs/day (Intensity 1) *Control procedure*: Usual care (advice at discretion of the doctor) *Outcomes:* 11 weeks after baseline visit *Validation*: none *Quality:* -
Bauman et al 1983 USA	*Participants:* 170 pregnant women, 79 current smokers, in 1st or 2nd trimester *Interventions:* CO breath test plus anti-smoking advice delivered by the regular health educators at ante-natal clinics (Intensity 1) *Control procedure: Anti-smoking advice only* *Outcomes:* Self reported abstinence 6 weeks after intervention/advice *Validation:* none *Quality:* -
Belizan et al 1995, Latin America (4 countries)	*Participants:* 532 smokers *Interventions:* 4-6 home visits at 22, 26, 30 and 34 weeks gestation attended by social worker or nurse and support person, booklets, 'antismoking program'. Specially trained

	female social workers or obstetrics nurses delivered the intervention (intensity 5) *Control procedure:* Usual care provided by physicians and nurses *Outcomes:* 14 weeks post start of intervention (36 weeks of gestation) *Validation:* none *Quality:* - Note: Smoking one of a range of health behaviour interventions, no quit rates reported, figures below derived from a table in the paper
Bullock et al 1995, New Zealand	*Participants:* 131 women (50% smokers) with telephone access, single or with unemployed partner *Intervention:* Introduction pack plus weekly telephone call to provide support by trained volunteer until 12 weeks postpartum. (Intensity 4) *Control procedure:* Introduction pack and publicly available educational material *Outcomes:* 34/40 weeks of gestation *Validation:* none *Quality:* -
Bullock et al 2009, USA	*Participants:* 695 smokers *Interventions:* 1) Booklets alone; 2) Social support alone (weekly calls and a beep to provide 24-7 contact with nurse if needed); 3) Social support + booklet (Intensity 4) *Control procedure:* Usual care (pamphlet) *Outcomes:* 6 week post partum, PP *Validation:* Salivary cotinine *Quality:* +
Burling et al 1991, US	*Participants:* 139 smokers *Interventions:* Educational program by clinic nurse, personal letter from Chief of the Prenatal Clinic recommending quitting, CO feedback and 'Why Start Life Under a Cloud' booklet . Clinic nurse provided advice regarding health behaviours (including smoking). (Intensity 2) *Control procedure:* Usual care by nurse *Outcomes:* 34 weeks of gestation (not clear how long after intervention), not clear how smoking status established *Validation:* unclear (CO was measured by no mention of use to validate self-reports) *Quality:* - Note: Poorly reported, only % with little info on how calculated.
Cinciripini et al 2000, US	*Participants:* 82 smokers

	Interventions: Usual care with physician, mailed materials (Quit Calendar and Tip Guide) and 6 videos (Intensity 4) *Control procedure:* Usual care with physician and mailed materials only *Outcomes:* 4-5 post TQD and 1M post-partum, not clear how asked *Validation:* salivary cotinine at both time points *Quality:* + *Note:* Intervention to get staff involved had no effect on staff behaviour. Badly reported, figures do not tally.
Coleman et al 2012, UK	*Participants:* 1,050 smokers *Interventions:* 4 weeks nicotine patch 15mg/16 hours (plus another 4 weeks if abstinent one month after quit date) plus midwife counselling at baseline and 3 FU telephone calls (QD, 3 days post quit and at 4 weeks). 'Research midwife' specified, trained to provide behavioural support according to national standards (Intensity 3) *Control procedure:* As above but placebo patch *Outcomes:* Sustained abstinence, but allowing <5 cigs on up to 5 occasions *Validation:* CO or salivary cotinine *Quality:* ++
Cope et al 2003, UK	*Participants:* 280 smokers *Interventions:* Feedback on urine cotinine test, leaflet, quit-date set, procedure repeated at each visit up to delivery (number of visits not given) with reinforcement of advice. Counselling about smoking in pregnancy from hospital midwife and obstetrician as part of usual care (Intensity 5) *Control procedure:* Routine counselling from doctor or midwife *Outcomes:* 36 weeks; not clear how asked *Validation:* not matched to self-report so classified as none (colourimetry) *Quality:* - Note: 'Validated' N larger than self-reported, and write-up unclear. It was also unclear who carried out intervention.
De Vries et al 2006, Netherlands	*Participants:* 328 smokers *Interventions:* Video, self-help guide, booklet on effects of remaining smoke free post-delivery, booklet for partners (see note below), monthly sessions with MWs providing brief health counselling (who discussed smoking at 3 and 8 months gestation). MW trained based on work with MIS protocol, dedicated 10mins of consultation to smoking cessation (Intensity 5) *Control procedure:* Usual care from MW *Outcomes:* 6 weeks post intervention (PP) and 6 weeks post-partum (PP at both time points)

	Validation: Only 7 urine samples available post-partum, not taken into account *Quality:* - Note: Cluster randomised, no Ns given. Partner intervention is reported as having no effect, but no figures, % or Ns are provided.
Donatelle et al 2000, US	*Participants:* 309 smokers *Interventions:* Advice (delivered by WIC program or research staff) and self-help kit, designated supporter, monthly incentives for validated abstinence to both ($50 for first and last quit month and $25 for additional quit months), monthly phone calls for 10 months including 2M post-partum (intervention delivered by trained program or research staff) (Intensity 5). *Control procedure:* As above but no designated support. Brief intervention (Intensity 1 and 2) delivered by trained WIC program or SOS program research staff. *Outcomes:* 7-day PP at 8M gestation and 2M post-partum *Validation:* Salivary thiocyanate at all time points *Quality:* +
Dornelas et al 2006, US	*Participants:* 105 smokers *Interventions:* 1.5 hour counselling session and bi-monthly phone follow-up during pregnancy and monthly phone FU for 6 months post-delivery, conducted by a masters prepared mental health counsellor (Intensity 4) *Control procedure:* Usual care (standard cessation advice from a HCP) *Outcomes:* 7-day PP at delivery and 6M post-partum *Validation:* CO at all time points *Quality:* +
Dunkley et al. 1997, US	*Participants:* 100 smokers *Interventions:* Intervention midwives were trained to assess stage of change and provided a behavioural intervention (few details on intervention reported) (Intensity 1) *Control procedures:* Usual care Outcomes: 11-18 w and 37 w Validation: none Quality: - Notes: Includes care providers' views, include in review 3
Ershoff et al 1989, US	*Participants:* 242 smokers *Interventions:* Advice from health educator, leaflet and first of 8 booklets, others mailed weekly. (Intensity 4) *Control procedure:* Advice and leaflet only from health educator

	Outcomes: Continuous abstinence from week 20 to delivery *Validation:* Urinary cotinine *Quality:* ++
Ershoff et al 1995, US	*Participants:* 171 recent quitters *Interventions:* Advice from health educator, leaflet and 4 booklets with remaining 4 mailed at weekly intervals (Intensity 3) Intervention given during pregnancy *Control procedure:* 1 page tip sheet and behavioural technique for avoiding relapse *Outcomes:* 7-day PP during 3rd trimester *Validation:* Cotinine *Quality:* +
Ershoff et al 1999, US	*Participants:* 390 smokers *Interventions:* Booklet and 4-6 weekly proactive MI counselling sessions over phone with nurse (Intensity 4) *Control procedure:* 1) Tailored booklet; 2) Booklet plus access to automated phone messages, both by prenatal care providers (Intensity 1-2) *Outcomes:* 7–day PP at 34 weeks *Validation:* Urinary cotinine *Quality:* + Note: Very few phone messages were accessed, control procedure merged
Gielen et al 1997, US	*Participants:* 391 smokers *Interventions:* Booklet, 2 letters of encouragement mailed 1-2 weeks after first visit, baseline session with peer advisor, advice at each pre-natal visit from RNs and MDs (Intensity 5) *Control procedure:* Usual care from nurse *Outcomes:* 7-day PP at third trimester *Validation:* Salivary cotinine *Quality:* + Note: Documents high misreport rate, salivary failures 7 (37%) in I and 10 (48%) in C.
Hajek et al 2001 A, UK	*Participants:* 871 smokers *Interventions:* Baseline session with MW, tailored booklet ('How to stop smoking for good' or 'How to stay off smoking for good'), CO feedback plus invitation to pair with another pregnant smoker (Intensity 1) *Control procedure:* Usual care from MW *Outcomes:* 3M continuous abstinence at delivery and continuous abstinence 6M post-

	delivery *Validation:* CO *Quality:* ++ Note: Cluster randomised
58 et al 2001 B, UK	*Participants:* 249 recent ex-smokers *Interventions:* Baseline session with MW, tailored booklet ('How to stop smoking for good' or 'How to stay off smoking for good'), CO feedback plus invitation to pair with another pregnant smoker. (Intensity 1) *Control procedure:* Usual care from MW *Outcomes:* 3M continuous abstinence at delivery and continuous abstinence 6M post-delivery *Validation:* CO *Quality:* ++ Note: Cluster randomised; MWs had difficulty recruiting pregnant women
Hannover et al 2009 A, Germany	*Participants:* 338 smokers *Interventions:* Counselling in mothers home by trained counsellor + FU calls (4 and 12 weeks). Four counsellors were trained and supervised by a member of the Motivational Interviewing Network of Trainers. (Intensity 4) *Control procedure:* Usual care and self help material for each parent. *Outcomes:* 24 month sustained abstinence *Validation:* None *Quality:* -
Hannover et al 2009 B, Germany	*Participants:* 304 ex- smokers, post-partum women who were abstinent for 4 weeks at baseline *Interventions:* as above. *Control procedure:* as above *Outcomes:* 24 month sustained abstinence since birth of baby *Validation:* None *Quality:* -
Hartman et al 1996, US	*Participants:* 207 smokers *Interventions:* Advice and goals by doctors at each ante-natal visit, letter of support from physician and monthly postcards, CO feedback, volunteer counsellors (Intensity 5) *Control procedure:* Standard care by doctor *Outcomes:* Abstinence (unspecified) at end of pre-natal care

	Validation: CO *Quality:* +
Hegaard et al 2003, Denmark	*Participants:* 647 smokers *Interventions:* MW counselling at prenatal visit, CO, offer of a smoking cessation program of 9 one-to-one or group sessions over 14 weeks chaired by MW plus offer of NRT (Intensity 5) *Control procedure:* Usual care by MW *Outcomes:* Abstinence at 37 weeks (not clear if PP or cont) *Validation:* salivary cotinine *Quality:* + *Note:* Over 50% misreport rate - self-reported 14.4% (N=47) vs. 5% (16); validated 7% vs. 2.2%
Heil et al 2008, US	*Participants:* 82 smokers *Interventions:* Incentives contingent on abstinence (up to $1,180) for up to 24w post-partum, incremental, re-set after lapses. Visits daily for days 1-5, 2nd week twice weekly visit, week 3-7 once a week, biweekly until delivery (Intensity 5) *Control procedure:* Incentives to attend ($15 per visit antepartum and $20 per visit postpartum), non-contingent on abstinence *Outcomes:* Sustained abstinence at 28w or above; 7-day PP at 12 w and 24 w post partum. *Validation:* Urine cotinine *Quality:* + *Note:* Cluster randomised, cont. abstinence data collected but not reported for post-partum period. Unclear who provided the intervention (paper states 'clinic staff')
Higgins et al 2004, US *(pilot study for Heil et al. 2008)*	*Participants:* 53 smokers *Interventions:* As in Heil (Intensity 5) *Control procedure:* Incentives to attend ($11.50 per visit antepartum and $20 per visit postpartum), non-contingent on abstinence. *Outcomes:* As in Heil, but PP only *Validation:* As in Heil *Quality:* - *Note:* Only partially randomised, the rest assigned 'as consecutive admissions' – not explained. Unclear who provided the intervention, possibly study staff in obstetric clinic.
Higgins et al 2010, USA	*Participants:* 166 smokers *Interventions:* Abstinent contingent vouchers ($35) – visits daily for 5 days, twice weekly in week 2 (for 7 weeks), then weekly for 4 weeks, every other week until delivery.

	Postpartum visit once weekly for the first 4 weeks then every other week to 12 weeks (Intensity 5) *Control procedure:* As above + non-contingent vouchers ($35) *Outcomes:* end of pregnancy and 24 weeks post-partum, PP *Validation:* CO validated and urinary cotinine *Quality:* + Notes: Unclear who provided intervention
Hjalmarson et al 1991, Sweden	*Participants:* 653 smokers *Interventions:* Self-help manual delivered by obstetrician (Intensity 1) *Control procedure:* Usual care (information sheet from doctor) *Outcomes:* Continuous abstinence end-of-pregnancy and 8w post-partum *Validation:* Blood thiocyanate at all time points *Quality:* +
Hotham et al 2006, Australia	*Participants:* 40 smokers *Interventions:* 5 min counselling, quit brochure, set QD, 2 min supportive counselling given at all antenatal visits + Nicotine patches . Researchers officers were midwives who had undergone training with Quitline Staff (Intensity 4) *Control procedure:* As above but no offer of free NRT *Outcomes:* last antenatal visit *Validation:* CO and salivary cotinine *Quality:* ++ *Note:* No data provided for post partum outcomes
Johnson 2000, Canada	*Participants:* 254 ex-smokers *Interventions:* RP counselling in-hospital, self help materials, 8 telephone calls by the nurse who initiated counselling in-hospital (Intensity 4) *Control procedure:* Usual care *Outcomes:* 6 months post partum (not clear if PP or cont) *Validation:* CO validated *Quality:* +
Kapur et al 2001, Canada	*Participants:* 30 smokers *Interventions:* Nicotine patch (daily, 18-hour patch 15mg for 8 weeks, 10mg for next 2 weeks and 5mg for last 2 weeks), 4 counselling sessions at baseline, 1, 4 and 8 weeks provided by the Motherisk Program plus weekly telephone contact with researcher

	(Intensity 5) *Control procedure:* Placebo gum, same support *Outcomes:* Abstinence in 2nd Trimester (not clear if PP or cont) *Validation:* Serum thiocyanate *Quality:* + *Note:* Study stopped when rapid foetal movement occurred 3h after stopping smoking in a woman on placebo.
Kendrick et al 1995, USA	*Participants:* 5572 smokers *Interventions:* Different "models" and focus in each state but all used counselling + written materials (Colorado intervention: 5-minute counselling sessions by the nurse, 8 brochures for pregnant smokers and 1 brochure for postpartum women; Maryland intervention: brief counselling with self-help materials; Missouri intervention: written materials plus emphasis on being a lifetime ex-smoker) (Intensity 1) *Control procedure:* Usual care *Outcomes:* Questionnaire at 8 month of pregnancy at 6-12 week post-partum visit (data for this not included). Not clear if PP or continuous. *Validation:* Urine cotinine *Quality:* - Note: Cluster randomised (prenatal clinics across 3 states). ITT cannot be calculated as total Ns for intervention and control were not reported. Unclear who provided intervention
Lawrence et al 2003, UK	*Participants:* 918 smokers *Interventions:* a) 6 TTM based self help manuals) b) TTM self help manual and support from MW + sessions with an interactive computer programme giving tailored SC advice (both conditions delivered by MW and had 3 face to face sessions to discuss manual) (Intensity 5) *Control procedure:* Standard care delivered by MW *Outcomes:* 28-30 week and 10 day postpartum continuous abstinence *Validation:* Urine cotinine *Quality:* + Note: Cluster randomised
Lilley et al 1986, UK	*Participants:* 151 smokers *Interventions:* Individual counselling from doctor and leaflets directed at patient and partner, FU at 4 weeks at home, letter reinforcing advice to stop smoking 2 weeks after first visit (Intensity 4) *Control procedure:* Usual care *Outcomes:* 6 weeks after intervention (not clear if PP or cont)

	Validation: None *Quality:* -
Loeb et al 1983, US	*Participants:* 963 smokers *Interventions:* Letter of invitation, group meeting with short information session by physician, individual session with trained smoking counsellor, 6 weekly group sessions and follow up groups and calls (Intensity 5) *Control procedure:* Usual care *Outcomes:* Late pregnancy (not clear if PP or cont) *Validation:* Cord blood thiocyanate Quality: +
Lowe et al 1998, a Australia	*Participants:* 217 smokers *Interventions:* 1 session with MW and self-help manual, signed contract to stop smoking between participant and partner and between participant and quit-smoking friend (Intensity 1) *Control procedure:* Manual alone *Outcomes:* 20 week antenatal visit, PP *Validation:* Urinary cotinine *Quality:* +
Lowe et al 1998, b Australia	*Participants:* 108 smokers *Interventions:* 1 session with MW and self-help manual (Intensity 1) *Control procedure:* Usual care *Outcomes:* 20 week antenatal visit, PP *Validation:* Urinary cotinine *Quality:* + Note: Cluster randomised
Lowe et al 1997, Australia	*Participants:* 78 pregnant ex-smokers *Interventions:* 10 minute counselling with health educator, RP materials, materials to enhance social support, chose “buddy”. Reinforcement at routine visits by clinic staff (Intensity 5) *Control procedure:* Usual care including nurse advice *Outcomes:* Continued abstinence at end of pregnancy *Validation:* Saliva thiocyanate *Quality:* - (analysis does not include LTF as greater in control group)

Macarthur et al 1987, UK	*Participants:* 982 smokers *Interventions:* Health education from obstetrician about smoking at clinic visit plus leaflet (or delivered by MW if overlooked by obstetrician) (Intensity 1) *Control procedure:* Usual care (routine advice) *Outcomes:* At delivery smoking status noted *Validation:* urinary cotinine obtained for some of the women but later abandoned *Quality:* -
Malchodi et al 2003, US	*Participants:* 142 pregnant smokers *Interventions:* usual care + peer-led smoking cessation programme from the clinic HCPs and smoking cessation counselling from lay community health outreach workers (8 face to face contacts) (Intensity 5) *Control procedure:* Usual care by doctors and nurses which included regular advice at each prenatal visit *Outcomes:* 36 week gestation *Validation:* CO and urinary cotinine, not clear if cont or PP *Quality:* +
Mayer et al 1990, USA	*Participants:* 219 smokers *Interventions:* A: 1 session (20 mins) and booklets on behavioural strategies plus contract with quit date; B: 1 session (10 mins) and booklets on risk to baby (both by health educator) (Intensity 1) *Control procedure:* Usual care (written materials plus clinic attendance) *Outcomes:* Abstinence at last month of pregnancy (not clear if PP or cont) *Validation:* No (partial, results not taken into account) *Quality:* - Note: Poorly reported study. Interventions did not differ but better than UC
McBride et al 1999, USA	*Participants:* 897 (mixed smokers and recent quitters) *Interventions:* 1) Booklet plus pre-partum intervention: self-help booklet, mailed an RP kit, 3 pre-partum calls and a personalised letter; 2) Same plus 3 counselling calls within the first 4 months post-partum and newsletters at 2, 6 and 12 weeks post-partum (both Intensity 4) *Control procedure:* Self-help booklet only *Outcomes:* 7-day PP at 28 weeks of pregnancy and 12 months postpartum (longest F-U) *Validation:* Saliva samples (not consistent, outcomes based on self-reports) *Quality:* -

McBride et al b 1999, US	*Participants:* 438 ex-smokers at 28W of pregnancy (mixture of smokers and ex-smokers at baseline, all received intervention, see McBride et al 1999a) *Interventions:* 3 counselling calls within the first 4 months post-partum and newsletters at 2, 6 and 12 weeks post-partum (Intensity 4) *Control procedure:* Prenatal intervention or prenatal routine care – nothing post partum, so merged *Outcomes:* 7-day PP 12 months postpartum *Validation:* Inconsistent and not taken into account *Quality:* -
McBride et al 2004, US	*Participants:* 316 ex-smokers *Interventions: 1)* 3 counselling calls in pregnancy; 3 postpartum, monthly. Motivational Interviewing. Late pregnancy RP kit. 2) Partner assisted – as 1 plus advice to use partner as coach + 6 calls to partner + cessation support for smoking partners (Intensity 4) *Control procedure:* Usual care (provider advice and mailed pregnancy specific S-H) *Outcomes*: 7-day PP at 28 weeks and 12 month postpartum *Validation:* Saliva cotinine Quality: + Notes: Combined interventions 1 and 2 versus control for analysis. Unclear who provided intervention
McLeod et al 2004, New Zealand	*Participants:* 297 smokers at time of conception *Interventions:* 1) Smoking Education Group: education and support for cessation and reduction by MW; 2) Breast-feeding Group: education and support for breast feeding women who smoked by MW; 3) Combined Group: MW implemented smoking education and breast-feeding programmes (Intensity 4) *Control procedure:* Usual care by MW *Outcomes:* 36 weeks gestation and 4 months post partum (not clear if PP or cont) *Validation:* Serum cotinine (not clear if all data is validated or takes into account positive results) *Quality:* + Note: Cluster randomised
Moore et al 2002, UK	*Participants:* 1527 smokers *Interventions:* Usual care plus first of 5 booklets provided by MW, remaining 4 mailed to women (Intensity 1) *Control procedure:* Usual care only by MW *Outcomes:* 7-day PP at smoking status at the end of the 2nd trimester, PP *Validation:* Urinary cotinine

	Quality: + Note: Cluster randomised
Morasco et al, 2006	*Participants:* 33 ex-smokers *Interventions:* individual counselling, 90 minutes psychotherapy session and bimonthly phone calls from mental health counsellors (Intensity 4) Intervention given during pregnancy. *Control procedure:* Usual care *Outcomes:* 7-day PP at end of pregnancy and 6 month post partum *Validation:* CO validation *Quality*: +
O'Connor et al 1992, Canada	*Participants:* 224 smokers *Interventions:* Usual care plus a 20 minute one-to-one session with a public health nurse and a telephone FU (Intensity 3) *Control procedure:* Usual care (included brief intervention (Intensity 1 and 2) from MW + 2 hour group session by research nurse plus 1 follow up session) *Outcomes:* 7-day PP at 36 weeks gestation and 6 weeks postpartum, PP *Validation:* Urinary cotinine *Quality:* +
Oncken et al 2008, US	*Participants:* 194 smokers *Interventions:* Individual counselling and 6 week treatment with nicotine gum (Intensity 5) *Control procedure:* Same support with placebo gum *Outcomes:* 7-day post-partum at 32-34 weeks of gestation and 6-12 weeks postpartum *Validation:* Urinary cotinine and CO validated at both time points *Quality:* +
Panjari et al 1999, Australia	*Participants:* 732 smokers *Interventions:* Usual care plus 4 counselling sessions with same MW (first session 25 mins included video, subsequent sessions brief between 5-10 mins) up to 28w, booklets (Intensity 5) *Control procedure:* Usual care *Outcomes:* Abstinence at 34-36 weeks (not clear if PP or cont) *Validation:* Urinary cotinine *Quality:* + Note: N kept changing in the report, N randomised and evaluable used for data

	extraction.
Patten et al 2010, USA	*Participants:* 35 smokers *Interventions:* counselling at baseline based on the 5A's, video + FU calls at 1, 2, 4 and 6 weeks by a female counsellor (Intensity 4) *Control procedure:* Brief intervention (Intensity 1 and 2) based on the 5A's by a female counsellor and 4 pregnancy brochures *Outcomes:* ≥ 60 days post randomisation (not clear if PP or cont) *Validation:* Salivary cotinine *Quality:* + Note: $25 gift certificate after each assessment
Pbert et al 2004 A, USA	*Participants:* 392 smokers *Interventions:* Aimed at staff – to provide 4A support and booklets, elicit commitment to quit (Intensity 2) *Control procedure:* usual care (no training) *Outcomes:* 7-day PP pre-delivery (mixed with 1-M post-deliver 30-days) and 6M post-partum 7-day PP *Validation:* Salivary cotinine, but inconsistent *Quality:* - Note: Cluster randomised. Unclear who provided intervention
Pbert et al 2004 B, US	*Participants:* 158 ex-smokers *Interventions:* Aimed at staff – to provide 4A support and booklets, elicit commitment to maintain abstinence (Intensity 1) *Control procedure:* usual care (no training) *Outcomes:* 7-day PP pre-delivery (mixed with 1-M post-deliver 30-days) and 6M post-partum *Validation:* Salivary cotinine at pre-delivery, not used consistently *Quality:* - *Note:* Same paper as above. Results strange, no effect 6M after intervention, but another 6M later there was an effect
Petersen et al 1992 US	*Participants:* 1,439 current and recent smokers (quit in previous 3 months) *Intervention:* Pregnancy-specific self-help manual, audiotape on safe aerobic exercise. (Intensity 1) *Control procedure*: Routine obstetric care, mailed list of community-based smoking cessation resources and pregnancy-related materials *Outcomes:* Mid pregnancy and 6 month postpartum (not clear if PP or cont)

	Validation: Validation inconsistent Quality: -
Polanska et al 2004, USA	*Participants:* smokers or recently quit (within the month) *Interventions:* 4 home visits by MW (with offer of extending to further 5 visits if not successfully abstinent on fourth visit) plus written materials and final visit post-delivery. (Intensity 3) *Control procedure:* Standard written materials about the health risks of smoking on the foetus plus MW home visit post-delivery *Outcomes:* Smoking status shortly after delivery (not clear it PP or cont) *Validation:* None *Quality:* - Note: Cluster randomised, data difficult to extract
Pollak et al 2007, USA	*Participants:* 181 smokers *Interventions:* CBT provided by support specialists (five face-to-face visits and one via telephone 48 hours after quit date) plus quit kit plus NRT (patch, lozenge or gum) (Intensity 5) *Control procedure:* Same support but no NRT *Outcomes*: 7-day PP at 7 weeks post randomisation and 3 months postpartum *Validation:* salivary cotinine at all time points (paid $10 for each sample) *Quality:* +
Ratner et al, 2000	*Participants:* 251 post partum ex-smokers *Intervention:* Counselling session in hospital by trained nurse counsellors + 8 telephone (weekly for 1 month and biweekly for 2 months) (Intensity 4) *Control procedures:* Usual care *Outcomes*: Continuous abstinence at 12 months post partum *Validation*: CO validation only for those interviewed in person *Quality:* -
Reading et al 1982, UK	*Participants:* 129 smokers *Interventions:* Real-time ultrasound high feedback (mothers could see image) (Intensity 1) (unclear who carried out intervention) *Control procedure:* low feedback *Outcomes:* asked at 16 week ultrasound appointment if any health behaviours have changed since the last visit *Validation:* None

	Quality: - Note: No baseline details given on smoking status
Reitzel 2010, US	*Participants:* 251 ex-smokers *Interventions:* 3 clinic visits (30-33 weeks pregnant, week 8 and 26 postpartum) and given incentives ($40) at each visit, self help materials, 5-10 mins of RP counselling and either a) 6 telephone calls or b) all of the above plus 2 in-person counselling sessions (Intensity 5). Research personnel with Tobacco Treatment Specialist (TTS) training provided the brief intervention (Intensity 1 and 2) (usual care). Master's or doctoral-level couselors received MI, TTS and MAPS/MAPS+ protocol training *Control procedure:* Usual care *Outcomes:* Continuous abstinence at 26 weeks post partum *Validation:* CO validated *Quality:* ++
Rigotti et al 2006, US	*Participants:* 442 smokers *Interventions:* Proactive telephone counselling (delivered by a trained counsellor) during pregnancy and over 2-months post-partum (mean of 5 calls totalling 68 minutes) + targeted self-help materials (Intensity 4) *Control procedure:* One brief counselling call by trained counsellor+ self-help material *Outcomes:* Self-reported abstinence (7-day pp) at the end of pregnancy and 3-months post partum. Sustained abstinence (abstinent at end of pregnancy and 3-months) *Validation:* Salivary cotinine *Quality:* + Note: Authors excluded 21 women from analyses because they miscarried
Ruger et al, 2008	*Participants:* 57 ex-smokers *Interventions:* Motivational Interviewing at home visits (average 3) with self-help materials (Intensity 5) Intervention given during pregnancy *Control procedure:* Usual care *Outcomes:* 6 months postpartum *Validation:* none *Quality:* - Note: Timing of home visits and who provided intervention is not clear
Secker-Walker et al 1994, US	*Participants:* 600 smokers *Interventions:* Session with a trained health educator. Follow-up at 2nd antenatal clinic, 36 week and 6 week post-partum (Intensity 5) *Control procedures:* Usual care

	Outcomes: 36 weeks' gestation (not clear if PP or cont) *Validation*: Cotinine validated in only a subsample Quality: - Notes: Lumley data extraction used as paper could not be accessed.
Secker-Walker et al 1995, US	*Participants:* 175 ex-smokers *Intervention:* Individual counselling with health educator. Follow-up at 2nd prenatal visit, 36w and 6w postpartum plus booklet (intensity 5) *Control procedures:* Usual care *Outcomes:* 36 week pregnancy and 6w postpartum (not clear if PP or cont) *Validation:* Cotinine only at 36w pregnancy *Quality:* +
Secker-Walker et al 1997, US	*Participants:* 60 smokers *Interventions:* Brief intervention from obstetrician/MW and tip-sheet plus a video-tape showing the experience of 4 female smokers going through the quitting process (n=30) (Intensity 1) *Control procedure:* Brief intervention (Intensity 1 and 2) from an obstetrician/MW and tip-sheet only (n=30) *Outcomes:* Self-reported smoking status at 36 weeks (not clear if PP or cont) *Validation:* CO *Quality:* +
Secker-Walker et al 1998, US	*Participants:* 116 ex-smokers *Interventions:* Structured intervention from physician, individual counselling from nurse at 1st, 2nd, 3rd, 5th and 36w prenatal visits (Intensity 5) *Control procedure:* Brief intervention (Intensity 1 and 2) from physician *Outcomes:* Sustained abstinence from the 2nd prenatal visit to 36w of pregnancy and 1 year postpartum *Validation:* CO and urine cotinine at 36w *Quality:* ++
Severson et al (1997)	*Participants*: 1026 mothers who were ex-smokers *Intervention:* Information pack including a letter from paediatrician and extended support (counselling plus FU at 2, 4 and 5m visits by paediatricians) and materials (Intensity 5) *Control procedures*: Information pack only *Outcomes:* Sustained abstinence at 12 months (PP at 6 and 12month)

	Validation: None *Quality*: -
Sexton et al 1984, US	*Participants:* 935 smokers recruited from 52 obstetric providers *Interventions:* At least one face-to-face visit with a trained advisor (one had experience in pregnancy counselling one with experience in smoking intervention) + monthly phone calls and mail contacts (included homework assignments) (Intensity 4) *Control procedure:* Usual care (not specified) *Outcomes:* 8th month of pregnancy (not clear if PP or cont) *Validation:* None *Quality:* -
Solomon et al (2000), US	*Participants:* 171 smokers recruited from a large obstetric practice *Interventions:* Brief cessation advice from an obstetrician/midwife + written materials, plus telephone support delivered by an ex-smoker on a weekly basis (n=77) (Intensity 4) *Control procedure:* Brief cessation advice from an obstetrician/MW + written materials at first 3 prenatal visits (n=74) *Outcomes:* 7 day PP at week 34 *Validation:* Urinary cotinine *Quality:* + Note: Only 53% of women in the intervention group actually received the calls. Those who did receive calls had 13 on average.
Stotts et al (2002), US	*Participants:* 269 women smoking in week 28 of pregnancy. *Interventions:* Stage of Change-based personalized feedback letter and two sessions of MI delivered via telephone by trained counsellors and Nurse-educators within weeks 28-30 of pregnancy (Intensity 4) *Control procedure:* Usual care *Outcomes:* 34 weeks post partum (not clear if PP or cont) *Validation:* Urinary cotinine at week 34, not with all self-reported abstainers *Quality:* - Note: Mixed non-smokers and light smokers in outcome measures. Urine samples only available for 175 women
Strecher et al (2000), US	*Participants:* 173 smokers recruited from two obstetric clinics *Interventions:* Series of tailored computer generated messages based on answers to questionnaires, sent through the mail (one after each prenatal visit) (n=88) (Intensity 1) *Control procedure:* Self-help guide to quitting smoking (n=85) *Outcomes:* 24 weeks gestation and 12 weeks post partum (not clear if PP or cont)

	Validation: urinary cotinine *Quality:* - Note: There appear to be a number of errors in this paper, the numbers do not tally. Unsure who provided intervention.
Tappin et al (2000), UK	*Participants:* 100 smokers *Interventions:* MI (2-5 sessions, time over which these occurred is not stated) delivered at women's homes by a MW (Intensity 5) *Control procedure:* Usual care *Outcomes:* late pregnancy (not clear if PP or cont) *Validation:* Serum cotinine *Quality:* +
Tappin et al (2005), UK	*Participants:* 762 smokers *Interventions:* MI (2-5 sessions of 30 minutes) delivered at women's homes by a MW (n=351) (Intensity 5) *Control procedure:* Usual care (advice from MW plus booklet providing information on smoking in pregnancy n=411) *Outcomes:* Quitting defined as self report plus cotinine concentrations of < 13.7 ng/ml serum or < 14.2 ng/ml saliva at 36 weeks (not clear if PP or cont) *Validation:* Plasma or salivary cotinine *Quality:* +
Thornton et al 1997, UK	*Participants:* 418 pregnant women currently smoked or had recently quit *Intervention*: Routine advice from MW and obstetricians plus one-to-one counselling by a trained facilitator, invited to join a stop smoking support group, partner invited, CO monitoring (Intensity 5) *Control procedure*: Routine prenatal advice *Outcomes*: At delivery and 3 months postpartum (not clear if PP or cont) *Validation*: CO *Quality*: + *Notes*: Lumley data extraction used as paper could not be accessed. Timing of intervention is not clear.
Tsoh et al 2010, US	*Participants:* 42 smokers *Interventions:* 15 minute Video Doctor program (designed to simulate discussion with a prenatal HCP) + provider cueing sheet and educational worksheet for participant (Intensity 3) *Control procedure:* Usual care

	Outcomes: 30 day abstinence at 2 month FU *Validation:* None *Quality:* - Note: All participants received gift cards at baseline, 1 and 2 months FU ($30, £40 & $50)
Valbo et al 1991, Norway	*Participants:* 200 smokers *Interventions:* (I1) Smoking cessation group of 6 x 2hr sessions over 5 weeks delivered by a Clinical Psychologist (n=50) (Intensity 5); (I2) Information delivered from a doctor during a 1-hour session (Intensity 1); (I3) Pamphlet on risks of smoking and advice to quit (n=50) (Intensity 5) *Control procedure:* No advice (n=50) *Outcomes:* 7-day PP at 12 months post partum *Validation:* None *Quality:* -
Valbo et al 1994, Norway	*Participants:* 112 pregnant smokers *Interventions:* Self-help manual for 10-day program. 2 week reminder, 32 week scan + reinforcement by obstetrician or MW (Intensity 5) *Control procedure:* Information and encouragement to quit plus pamphlet by obstetrician or MW *Outcomes:* Late pregnancy (not clear if PP or cont) *Validation:* None *Quality:* - *Notes*: Lumley data extraction used as paper could not be accessed.
Valbo et al 1996, Norway	*Participants:* 158 smokers *Interventions:* Two hypnosis sessions (45 minutes each) over 2 weeks delivered by anaesthesiologist (n=52) (Intensity 3) *Control procedure:* Routine care (n=78) *Outcomes:* Continuous abstinence from 'quit day' at delivery. *Validation:* None *Quality:* - Note: 80 women were randomised to the intervention, but only 52 participated (13 did not get an appointment in time and 15 did not attend).
Van't Hof et al 2000, US	*Participants:* 287 mothers identified as non-smokers at time of delivery *Interventions:* nurse counselling (15-30mins) at 2 week, 2 and 4 month well baby clinic visits (Intensity 5)

	Control procedure: Usual care from paediatric provider *Outcomes:* 7-day PP at 6 months *Validation:* None *Quality:* -
Wall et al 1995, US	*Participants:* 2901 mothers who reported smoking in the month prior to getting pregnant *Interventions:* leaflet packs and personalised letter from paediatrician + group counselling by paediatrician at well baby visits at 2 weeks, 2, 4 and 6 months (4 in total) + watching a videotape (Intensity 5) *Control procedure:* leaflet packs + personalised letter from paediatrician only *Outcomes:* 7-day PP at 6 months *Validation:* None *Quality:* -
Walsh et al 1997, Australia	*Participants:* 253 smokers *Interventions:* Advice from a doctor; information video; 10 minutes MW counselling, self-help manual, then 3 follow-up MW visits and brief risk advice from doctor, enrolment in lottery for confirmed abstainers at second visit and invitation for adult to attend program with patient (Intensity 4) *Control procedure:* Brief intervention (Intensity 1 and 2) from a doctor and midwife plus anti-smoking materials *Outcomes:* 34th week of gestation and 6-12 weeks post-partum (not clear if PP or cont) *Validation:* Urinary cotinine *Quality:* + Note: Ns unclear
Windsor et al 1985, US	*Participants:* 309 smokers *Interventions:* (1) 10 minute skills counselling session (delivered by health educators) + generic self-help guide + booklet (n=103) (Intensity 1); (2) 10 minute skills counselling session + pregnancy specific self-help guide +booklet (Intensity 1) *Control procedure:* Usual care (2-3 minutes within a group prenatal education session at 1st visit) *Outcomes:* 7-day PP at mid and end of pregnancy *Validation:* Salivary thiocyanate *Quality:* + Note: Unclear if Ns reported are at mid-pregnancy, end of pregnancy or both
Windsor et al 1993, US	*Participants:* 994 smokers *Interventions:* Brief nurse advice to quit, an initial 15 min counselling session (delivered

	by a health counsellor) + self-help material (2 pamphlets), two follow-up visits (timing not specified), one of which included the provision of social support methods (a buddy letter, a buddy contract, and a buddy tip sheet) + quarterly newsletter with quitter testimonials (Intensity 5) *Control procedure:* Brief nurse advice to quit and self-help material *Outcomes:* Mid-pregnancy (4-8 weeks after 1st visit) and after 32 weeks gestation (not clear if PP or cont) *Validation:* Salivary cotinine *Quality:* + Note: Only one follow-up visit was given to women who enrolled late in pregnancy.
Windsor et al 2000, UK	*Participants:* 265 smokers *Interventions:* Video + guide to quitting smoking and a < 5 min counselling session . Patient education methods delivered by trained regular staff members (Intensity 1) *Control procedure:* Risk education and advised to stop smoking *Outcomes:* The first pre-natal visit after consent (not clear if PP or cont) *Validation:* Salivary cotinine (not clear if used in calculating success rate) *Quality:* -
Winickoff et al 2010, US	*Participants:* 101 parents (mix baseline ex-smokers and smokers, and mothers and fathers) *Interventions:* In-hospital counselling by trained study staff + quitline referral + letter to the newborn's paediatrician, parents primary care provider and mothers obstetrician recommending strategies to facilitate cessation (Intensity 1) *Control procedure:* Usual care *Outcomes*: 7-day PP at 3 months post-partum, PP *Validation:* Saliva swab (for cotinine analysis) mailed to participants *Quality:* + Note: $50 given as an incentive to return saliva swabs. For review 3 paper reports that hospital retained the question about fathers smoking status after the study finished because staff found it useful.
Wisborg et al 2000, Denmark	*Participants:* 250 smokers *Interventions:* Nicotine (15mg/16hr for 8 weeks, 10mg/16hr for 3 weeks) + 4 prenatal clinic visits (or telephone contact if did not attend clinic) with MW delivered counselling + pamphlet (Intensity 5) *Control procedure:* Same support, placebo patches *Outcomes:* Continuous abstinence 4-weeks prior to delivery and one year post partum *Validation:* Salivary cotinine at 4th visit *Quality:* ++

SECTION 1: EFFICACY OF BEHAVIOURAL INTERVENTIONS DELIVERED DURING PREGNANCY

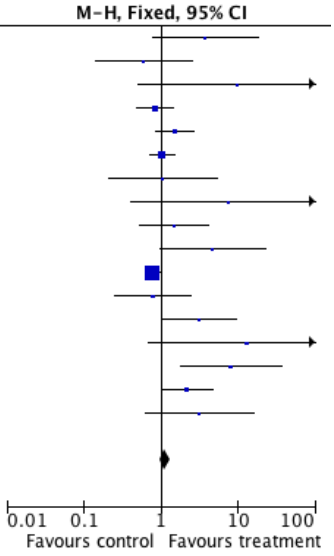
PART 1: INTERVENTION INTENSITY

Below we analyse all studies where more intensive behavioural support was compared with less intensive or no support. Drug trials where both study arms received the same intensity of behavioural support are analysed in Section 3. For each intensity of support, the results are presented separately for outcomes up to delivery, and outcomes post-delivery (usually from several months up to one year post-partum). We present the results of all the studies first, and follow this with a meta-analysis including only trials which validated self-reported abstinence biochemically. We also analysed separately studies in which interventions were delivered by midwives and those where the advisors had non-midwifery background.

Intensity 1 – Up to delivery

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Baric 1976	9	63	2	47	0.6%	3.75 [0.77, 18.25]
Bauman 1983	3	39	6	49	1.6%	0.60 [0.14, 2.56]
Dunkely 1997	4	50	0	50	0.2%	9.77 [0.51, 186.52]
Hajek a 2001	26	431	31	440	9.5%	0.85 [0.49, 1.45]
Hjalmarson 1991	56	492	18	231	7.2%	1.52 [0.87, 2.65]
Kendrick 1995	54	888	69	1177	18.4%	1.04 [0.72, 1.50]
Lowe a 1998	3	106	3	111	0.9%	1.05 [0.21, 5.31]
Lowe b 1998	4	59	0	47	0.2%	7.70 [0.40, 146.77]
Macarthur 1987	9	493	6	489	2.0%	1.50 [0.53, 4.24]
Mayer 1990	8	72	2	77	0.6%	4.69 [0.96, 22.87]
Moore 2002	156	724	207	803	50.9%	0.79 [0.62, 1.00]
Petersen 1992	6	43	8	47	2.2%	0.79 [0.25, 2.50]
Reading 1982	19	39	6	26	1.2%	3.17 [1.05, 9.58]
Secker-Walker 1997	5	30	0	30	0.1%	13.16 [0.69, 249.48]
Windsor 1985	14	102	2	104	0.6%	8.11 [1.79, 36.68]
Windsor 2000	24	139	11	126	3.2%	2.18 [1.02, 4.66]
Windsor b 1985	6	103	2	104	0.6%	3.15 [0.62, 16.01]
Total (95% CI)		**3873**		**3958**	**100.0%**	**1.12 [0.96, 1.31]**
Total events	406		373			

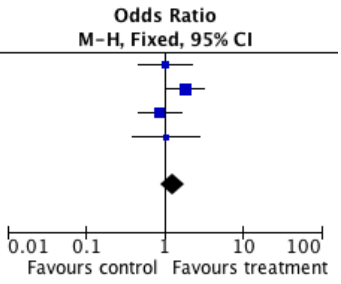
Heterogeneity: $Chi^2 = 38.29$, df = 16 (P = 0.001); $I^2 = 58\%$
Test for overall effect: Z = 1.43 (P = 0.15)



Intensity 1 – Post partum

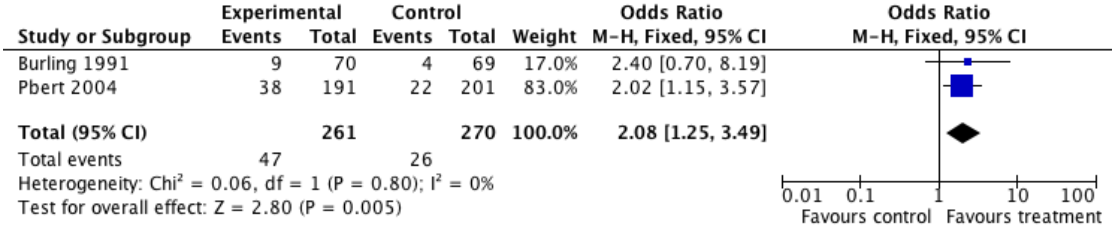
Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Hajek a 2001	13	431	13	440	20.0%	1.02 [0.47, 2.23]
Hjalmarson 1991	70	492	19	231	35.6%	1.85 [1.09, 3.15]
Petersen 1992	35	71	41	78	31.8%	0.88 [0.46, 1.67]
Strecher 2000	10	104	8	87	12.6%	1.05 [0.40, 2.79]
Total (95% CI)		**1098**		**836**	**100.0%**	**1.27 [0.91, 1.78]**
Total events	128		81			

Heterogeneity: $Chi^2 = 3.63$, df = 3 (P = 0.30); $I^2 = 17\%$
Test for overall effect: Z = 1.42 (P = 0.15)

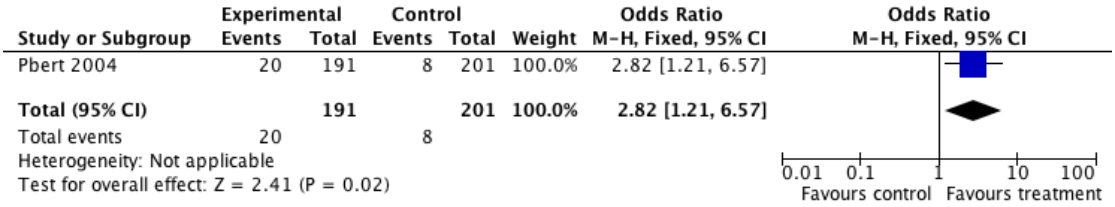


One-off interventions accompanied by written and other materials lack efficacy.

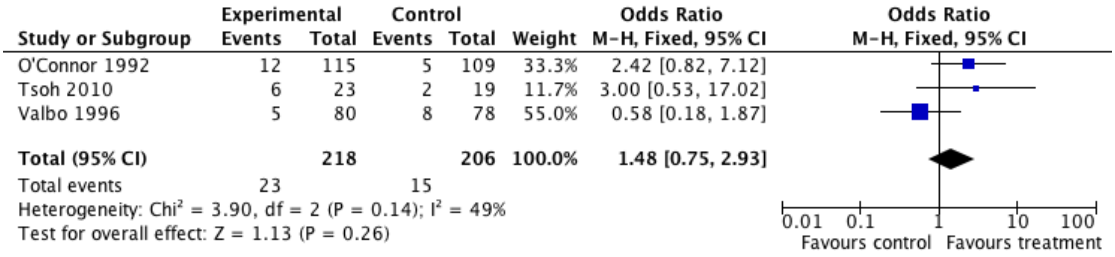
Intensity 2 – Up to delivery



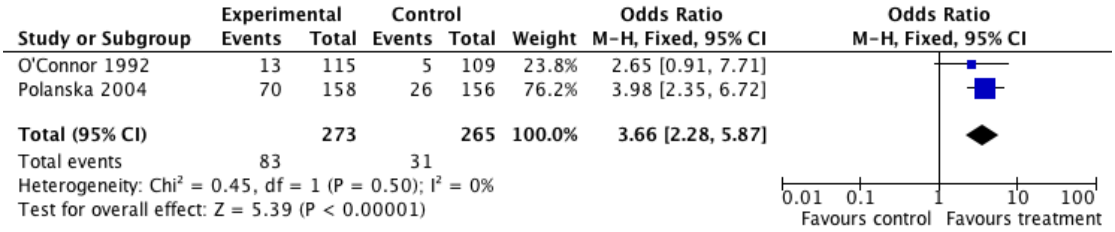
Intensity 2 – Post partum



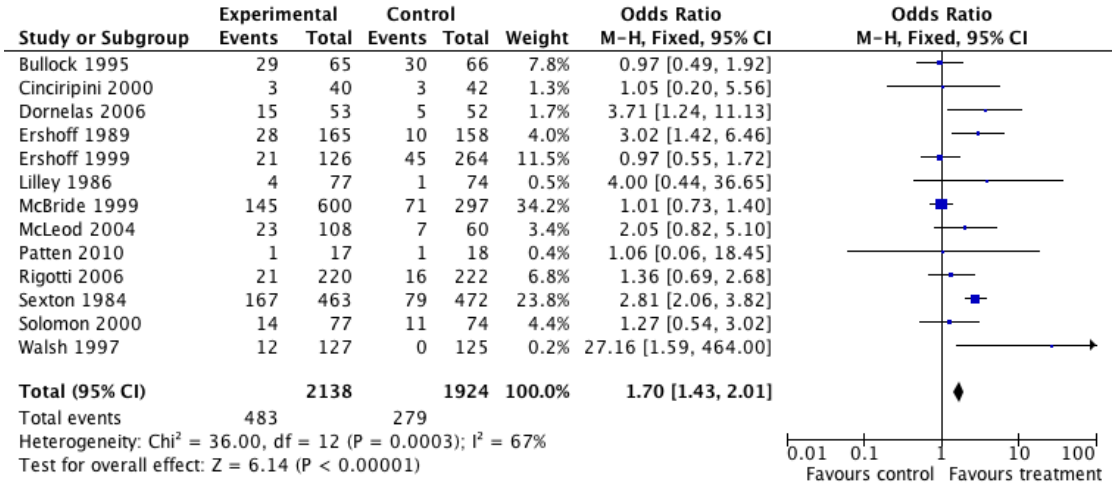
Intensity 3 – Up to delivery



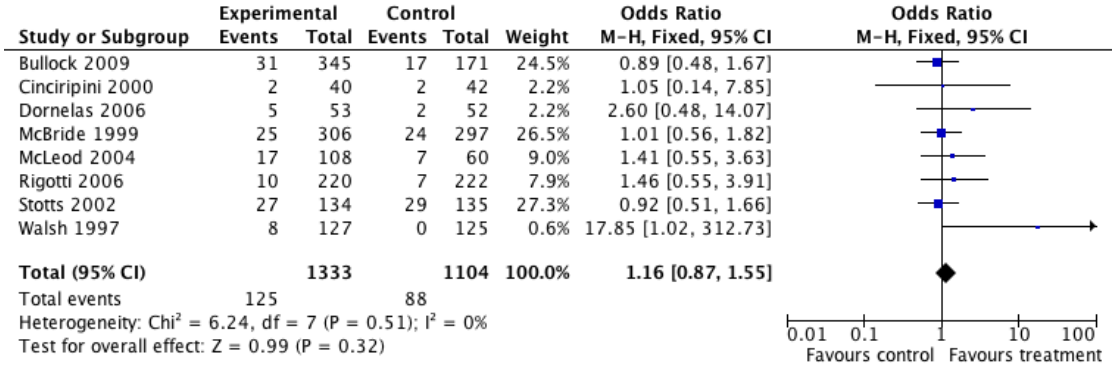
Intensity 3 – Post partum



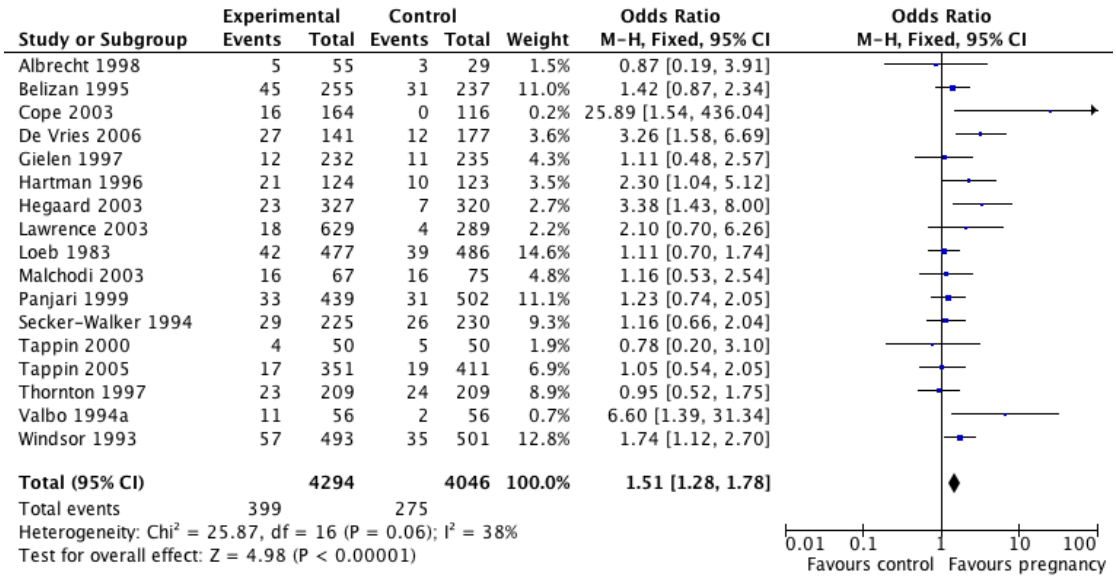
Intensity 4 – Up to delivery



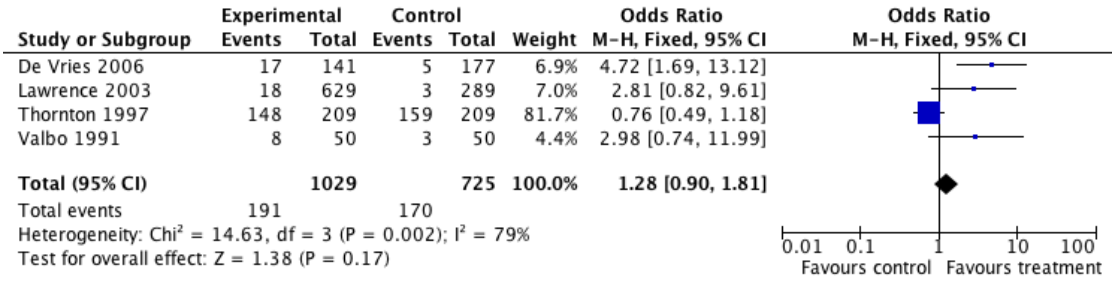
Intensity 4 – Post partum



Intensity 5 - Up to delivery



Intensity 5 – Post partum

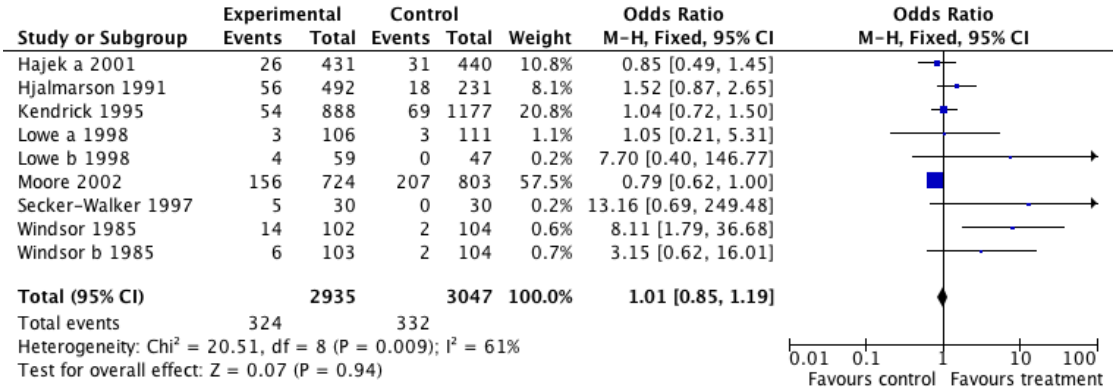


When all studies are included, apart from Intensity 1 (one-off interventions accompanied by written materials or videos), all intensities of intervention had a significant impact up to delivery. With the exception of Intensity 2 where a single study (Pbert et al 2004 [RCT -]) reported a significant result, no pooled results showed efficacy post-partum.

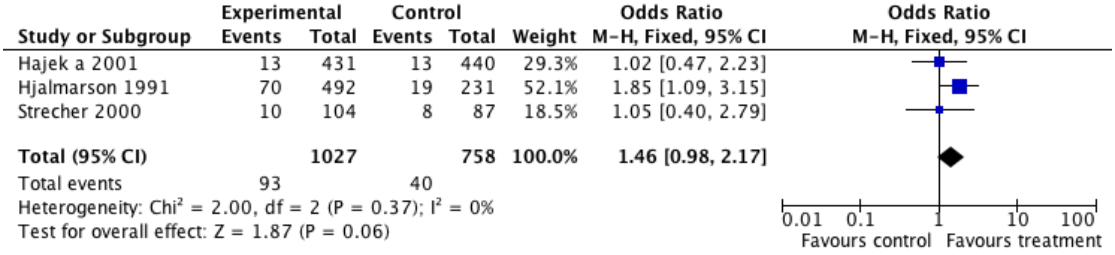
Results of studies that validated self-reported abstinence

Below are analyses including only studies that validated self-reported abstinence biochemically.

Intensity 1 – Validated – Up to delivery



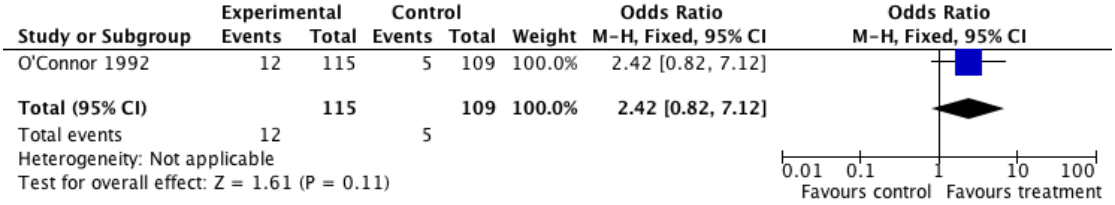
Intensity 1 – Validated – Post partum



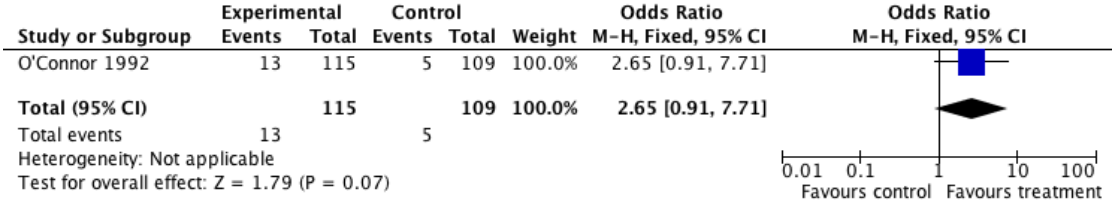
Intensity 2 - Validated

There were no studies of this kind.

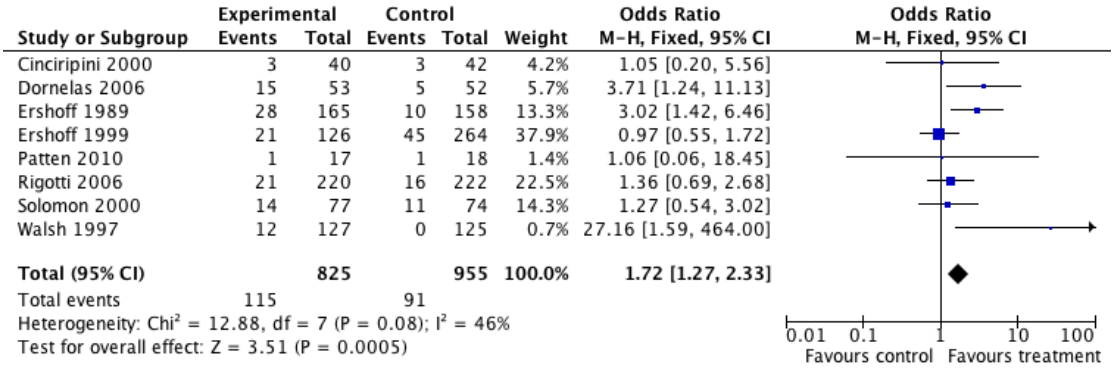
Intensity 3 – Validated – Up to delivery



Intensity 3 – Validated – Post partum



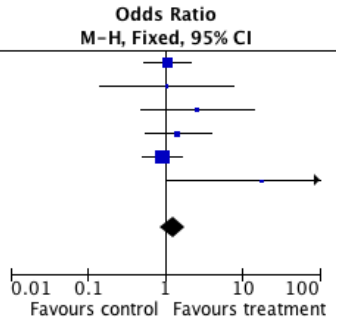
Intensity 4 – Validated – Up to delivery



Intensity 4 – Validated – Post partum

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Bullock 2009	19	179	17	171	31.5%	1.08 [0.54, 2.15]
Cinciripini 2000	2	40	2	42	3.8%	1.05 [0.14, 7.85]
Dornelas 2006	5	53	2	52	3.7%	2.60 [0.48, 14.07]
Rigotti 2006	10	220	7	222	13.5%	1.46 [0.55, 3.91]
Stotts 2002	27	134	29	135	46.7%	0.92 [0.51, 1.66]
Walsh 1997	8	127	0	125	1.0%	17.85 [1.02, 312.73]
Total (95% CI)		**753**		**747**	**100.0%**	**1.27 [0.88, 1.85]**
Total events	71		57			

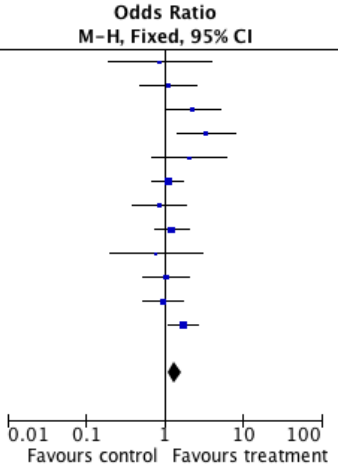
Heterogeneity: $Chi^2 = 5.44$, df = 5 (P = 0.36); $I^2 = 8\%$
Test for overall effect: Z = 1.26 (P = 0.21)



Intensity 5 - Validated – Up to delivery

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Albrecht 1998	5	55	3	29	2.0%	0.87 [0.19, 3.91]
Gielen 1997	12	232	11	235	5.7%	1.11 [0.48, 2.57]
Hartman 1996	21	124	10	123	4.6%	2.30 [1.04, 5.12]
Hegaard 2003	23	327	7	320	3.6%	3.38 [1.43, 8.00]
Lawrence 2003	18	629	4	289	2.9%	2.10 [0.70, 6.26]
Loeb 1983	42	477	39	486	19.3%	1.11 [0.70, 1.74]
Malchodi 2003	16	75	16	67	7.3%	0.86 [0.39, 1.90]
Panjari 1999	33	439	31	502	14.6%	1.23 [0.74, 2.05]
Tappin 2000	4	50	5	50	2.5%	0.78 [0.20, 3.10]
Tappin 2005	17	351	19	411	9.1%	1.05 [0.54, 2.05]
Thornton 1997	23	209	24	209	11.7%	0.95 [0.52, 1.75]
Windsor 1993	57	493	35	501	16.8%	1.74 [1.12, 2.70]
Total (95% CI)		**3461**		**3222**	**100.0%**	**1.34 [1.11, 1.63]**
Total events	271		204			

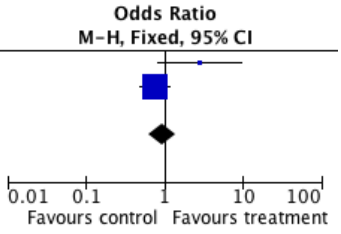
Heterogeneity: $Chi^2 = 13.01$, df = 11 (P = 0.29); $I^2 = 15\%$
Test for overall effect: Z = 3.03 (P = 0.002)



Intensity 5 - Validated– Post partum

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Lawrence 2003	18	629	3	289	7.9%	2.81 [0.82, 9.61]
Thornton 1997	148	209	159	209	92.1%	0.76 [0.49, 1.18]
Total (95% CI)		**838**		**498**	**100.0%**	**0.93 [0.62, 1.38]**
Total events	166		162			

Heterogeneity: $Chi^2 = 3.88$, df = 1 (P = 0.05); $I^2 = 74\%$
Test for overall effect: Z = 0.38 (P = 0.70)

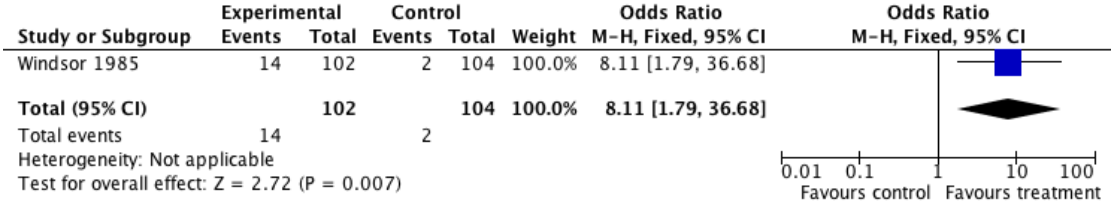


In studies that validated self-reported abstinence, brief one-off interventions (Intensity 1) and intervention with follow-up of up to 4 weeks (Intensity 3) were not effective during pregnancy or post-delivery. Interventions of Intensity 4 and Intensity 5, which provided support for longer than four weeks were effective during pregnancy but not post-partum.

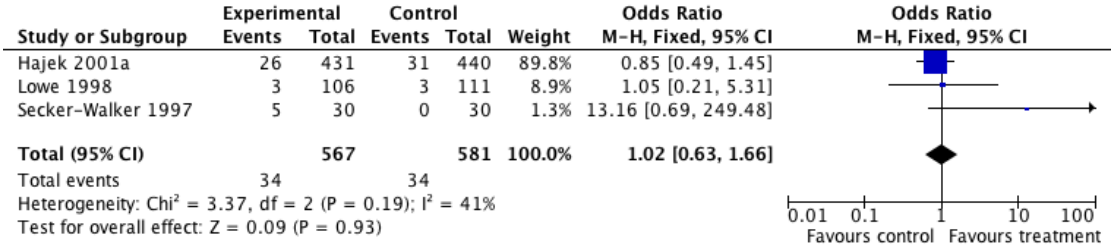
Background of advisors delivering the interventions

We compared validated studies evaluating interventions delivered by midwives and those delivered by advisors other than midwives.

Non-midwife - Intensity 1

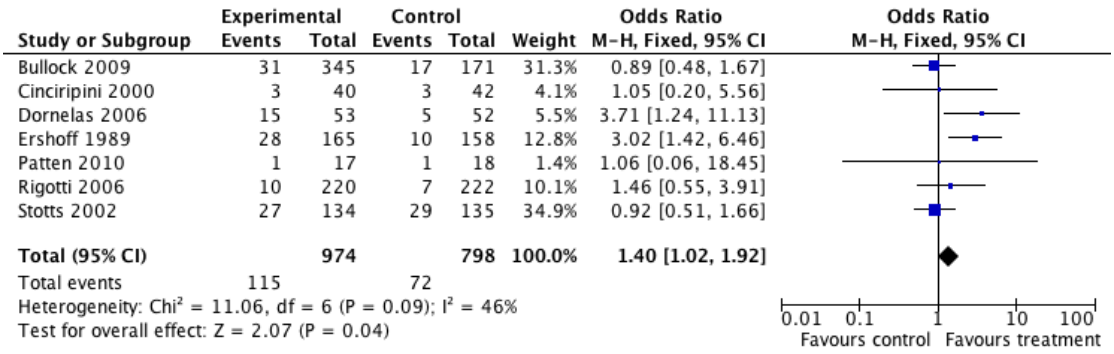


Midwife– Intensity 1

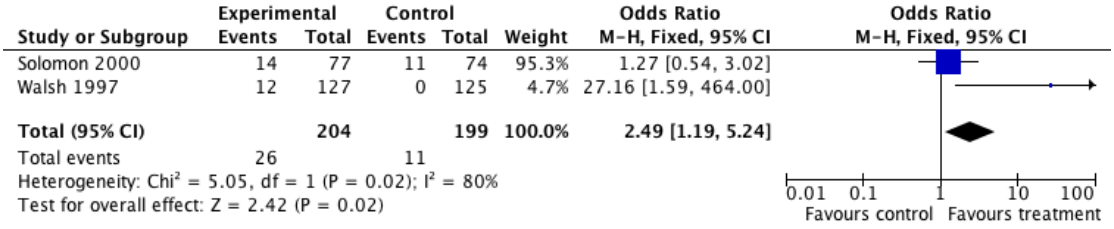


There were no eligible validated trials of Intensity 2 and no eligible MW interventions of Intensity 3

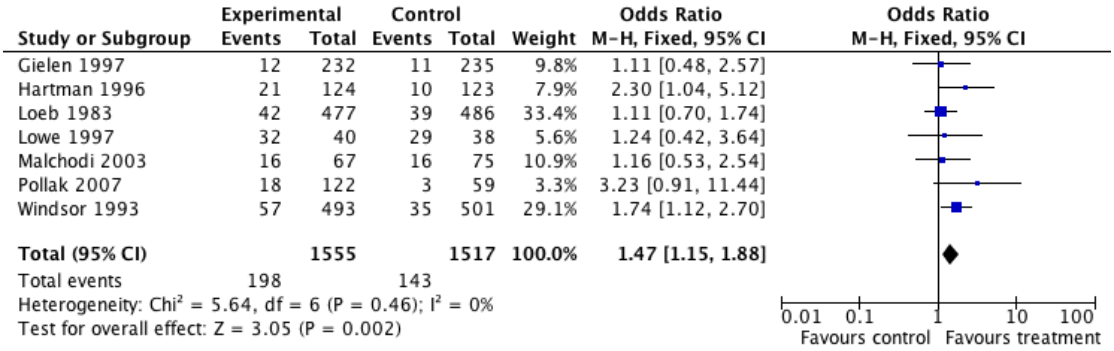
Non-midwife - Intensity 4



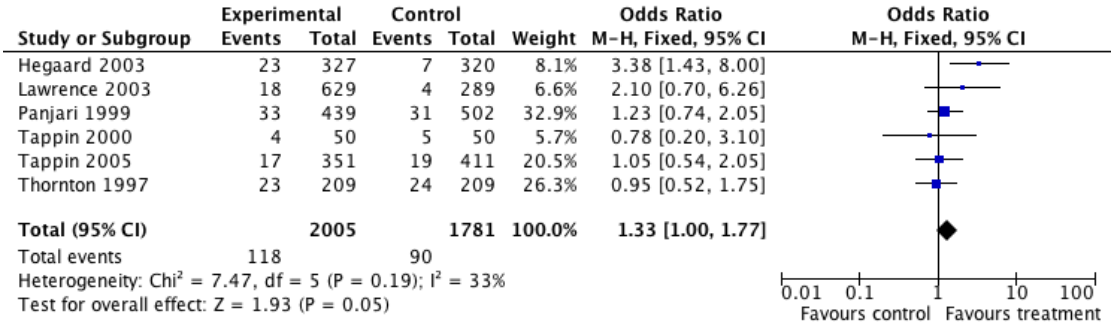
Midwife – Intensity 4



Non-midwife - Intensity 5



Midwife - Intensity 5



Intensity 1 interventions are ineffective and Intensity 4 and 5 interventions are effective regardless of the background of the advisors.

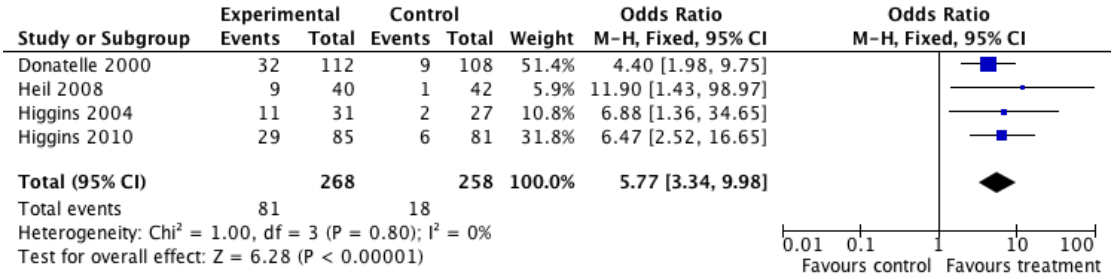
SECTION 1A: EFFECTS OF INCENTIVES

We analysed separately studies evaluating the effects of incentives as the presumed active ingredient in such interventions is different from the presumed active ingredient of other behavioural interventions.

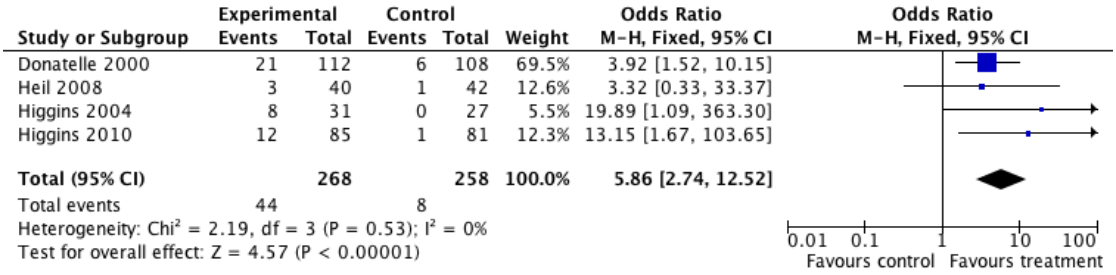
There were 4 US studies examining the effects of incentives contingent on abstinence. All validated self-reported abstinence biochemically. The interventions used incremental reinforcement schedules where women attended frequent check-ups with biochemical validation, and received increasing rewards that were re-set following lapses back to smoking. In three of the studies, the total rewards a woman could accumulate exceeded $1,000.

We extracted data concerning effects during pregnancy, post-delivery, and also at least one month after the incentive scheme was discontinued.

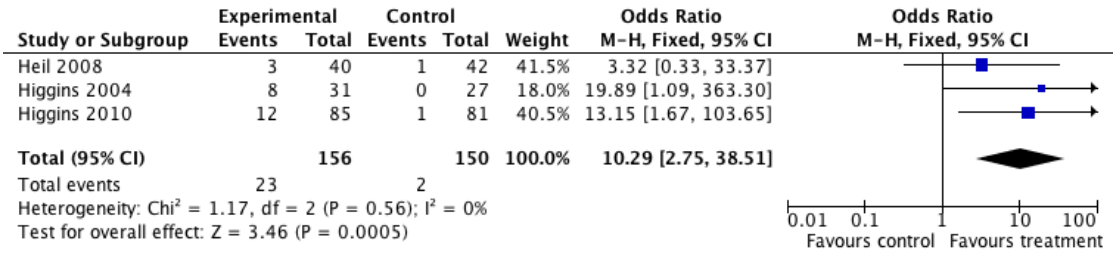
Effects of incentives - up to delivery



Effects of incentives - post-partum



Effects of incentives - after the scheme was discontinued



The provision of incentives contingent on abstinence was effective in increasing cessation rates both pre-delivery and post-partum, and the effect was maintained after the incentives were discontinued.

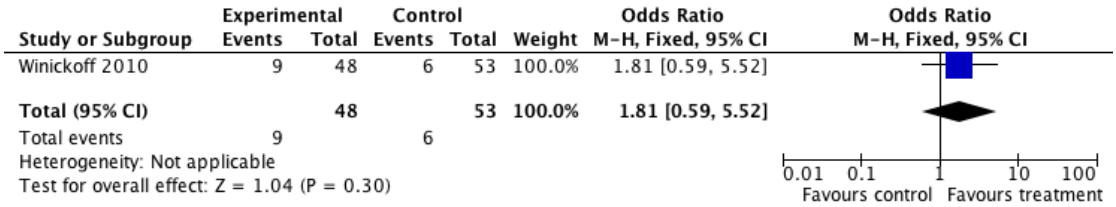
SECTION 1B: EFFICACY OF INTERVENTIONS TARGETING PARTNERS

We found only one study of stop-smoking intervention targeting partners of pregnant women (De Vries et al. 2006, [RCT -]). The study write-up does not allow data extraction, but the authors report that the intervention had no effect. Three other studies involved partners. Lilley et al. 1986 [RCT -] used leaflets directed at both the woman and her partner. Lowe et al. 1998 [RCT +] used an intervention which included a no-smoking contract between the woman and her partner. McBride et al. 2004 [RCT +] included partners as coaches and also provided support for partners who smoke. The studies do not allow data extraction on the partner component, but all three had overall negative results.

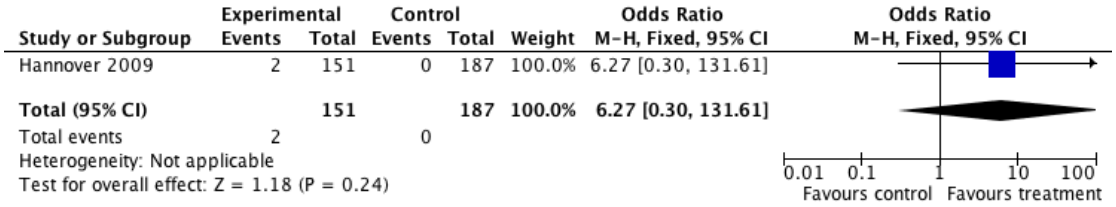
SECTION 2: EFFICACY OF INTERVENTIONS DELIVERED POST-PARTUM

Three trials studied interventions initiated after delivery. None of the trials validated self-reported abstinence.

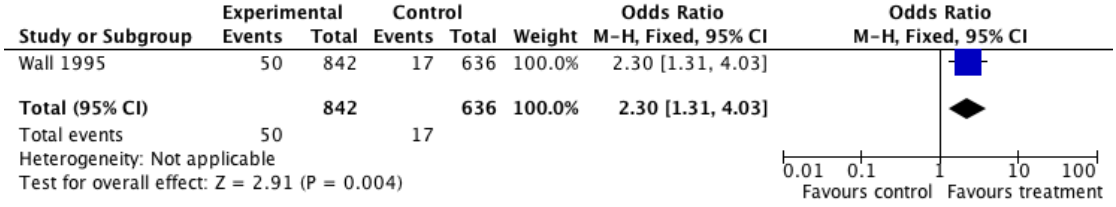
Intensity 1



Intensity 4



Intensity 5

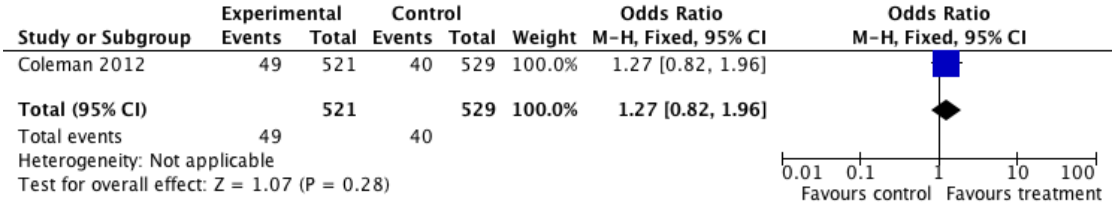


Only the Intensity 5 trial (Wall 1995, [RCT -]) showed a significant intervention effect.

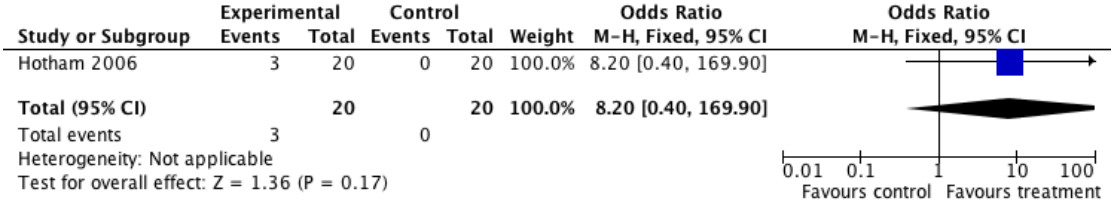
SECTION 3: EFFICACY OF PHARMACOTHERAPIES

Nicotine replacement therapy is the only treatment that has been evaluated for use in pregnancy so far. All the trials validated self-reported abstinence biochemically, though one (Wisborg et al 2000, [RCT ++]) which validated self-reported abstinence at earlier FU points did not do so at 1-year. Four trials used patches (Coleman et al 2012, [RCT ++]; Hotham et al 2006 [RCT ++]; Kapur et al 2001, [RCT +]; Wisborg et al 2000, [RCT ++]), one used gum (Oncken et al 1998, [RCT +]) and one used a choice between patch, gum or lozenge (Pollack 2007 et al, [RCT ++]).

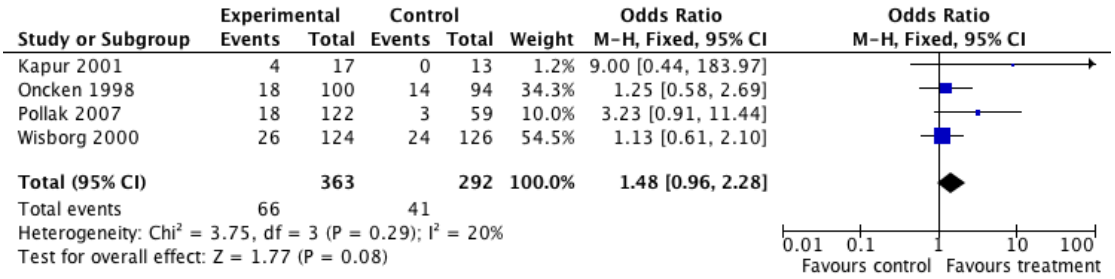
Intensity 3 – NRT effects during pregnancy



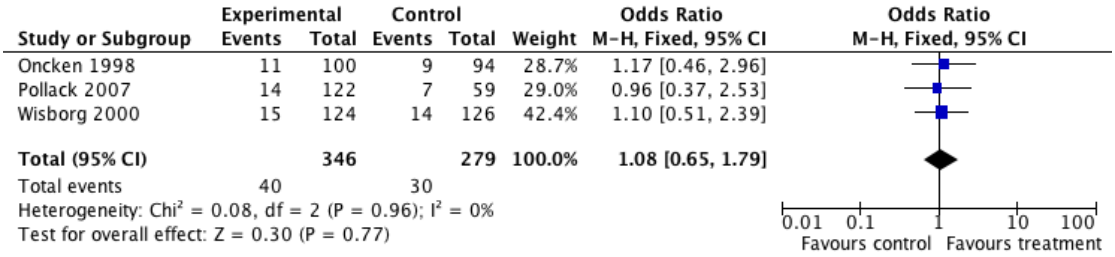
Intensity 4 – NRT effects during pregnancy



Intensity 5 - NRT effects during pregnancy



Intensity 5 – NRT effects post-partum



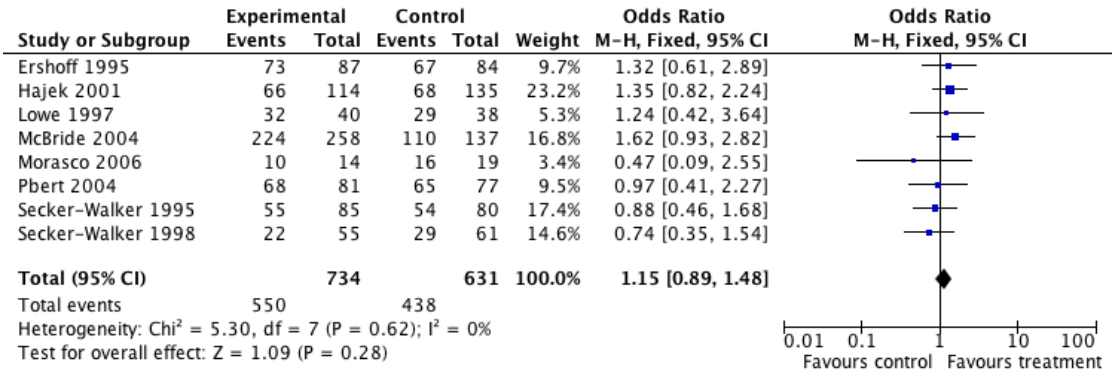
Nicotine replacement treatment did not show efficacy across the levels of support.

SECTION 4: EFFICACY OF INTERVENTIONS TO PREVENT RELAPSE

Fourteen studies focused on women who stopped smoking, with the aim of helping them to prevent relapse during and after pregnancy. We first pooled the studies according to the timing of the intervention and then analysed only studies which validated self-reported abstinence. Finally, we looked separately at interventions of different intensity.

Intervention delivered during pregnancy

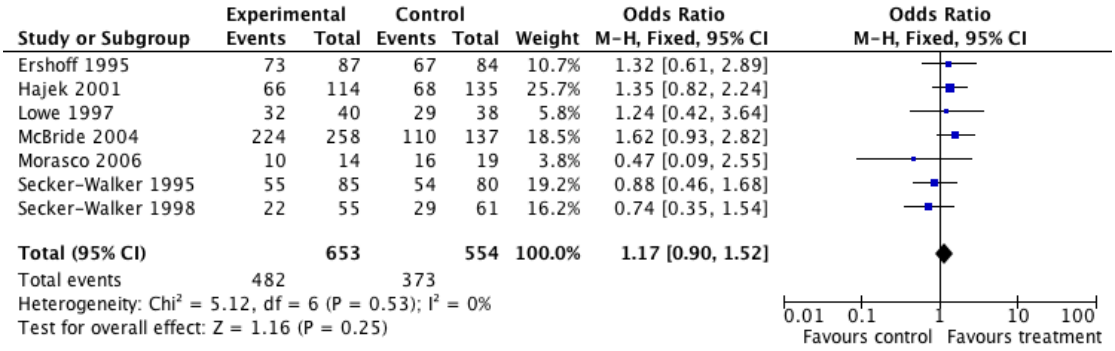
Intervention delivered during pregnancy, effects up to delivery



Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Ershoff 1995	73	87	67	84	9.7%	1.32 [0.61, 2.89]
Hajek 2001	66	114	68	135	23.2%	1.35 [0.82, 2.24]
Lowe 1997	32	40	29	38	5.3%	1.24 [0.42, 3.64]
McBride 2004	224	258	110	137	16.8%	1.62 [0.93, 2.82]
Morasco 2006	10	14	16	19	3.4%	0.47 [0.09, 2.55]
Pbert 2004	68	81	65	77	9.5%	0.97 [0.41, 2.27]
Secker-Walker 1995	55	85	54	80	17.4%	0.88 [0.46, 1.68]
Secker-Walker 1998	22	55	29	61	14.6%	0.74 [0.35, 1.54]
Total (95% CI)		**734**		**631**	**100.0%**	**1.15 [0.89, 1.48]**
Total events	550		438			

Heterogeneity: Chi² = 5.30, df = 7 (P = 0.62); I² = 0%
Test for overall effect: Z = 1.09 (P = 0.28)

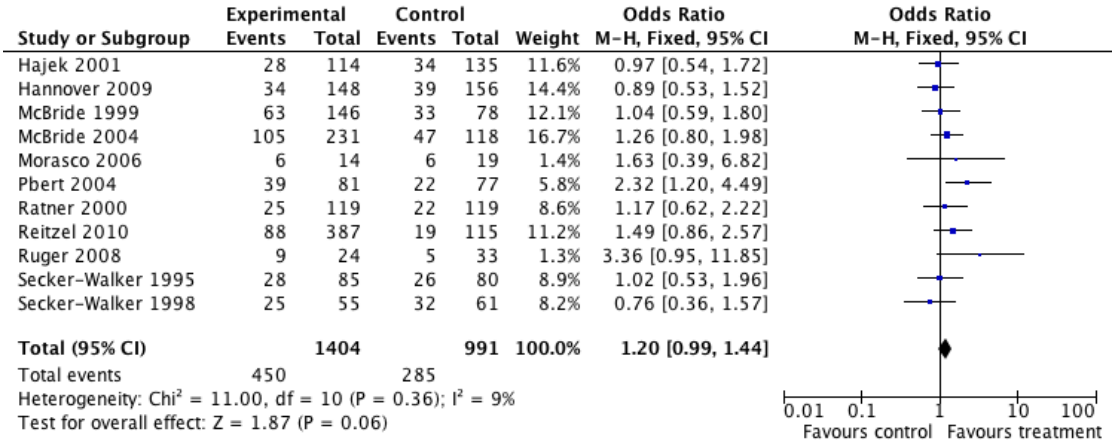
Intervention delivered during pregnancy, effects up to delivery - Validated only



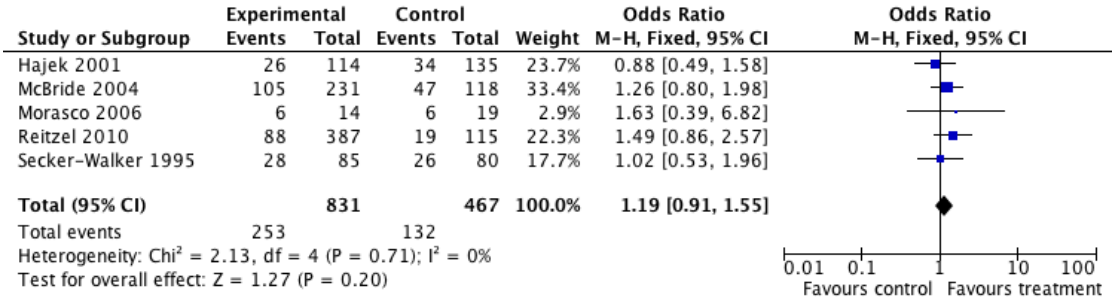
Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Ershoff 1995	73	87	67	84	10.7%	1.32 [0.61, 2.89]
Hajek 2001	66	114	68	135	25.7%	1.35 [0.82, 2.24]
Lowe 1997	32	40	29	38	5.8%	1.24 [0.42, 3.64]
McBride 2004	224	258	110	137	18.5%	1.62 [0.93, 2.82]
Morasco 2006	10	14	16	19	3.8%	0.47 [0.09, 2.55]
Secker-Walker 1995	55	85	54	80	19.2%	0.88 [0.46, 1.68]
Secker-Walker 1998	22	55	29	61	16.2%	0.74 [0.35, 1.54]
Total (95% CI)		**653**		**554**	**100.0%**	**1.17 [0.90, 1.52]**
Total events	482		373			

Heterogeneity: Chi² = 5.12, df = 6 (P = 0.53); I² = 0%
Test for overall effect: Z = 1.16 (P = 0.25)

Intervention delivered during pregnancy, effects post-partum

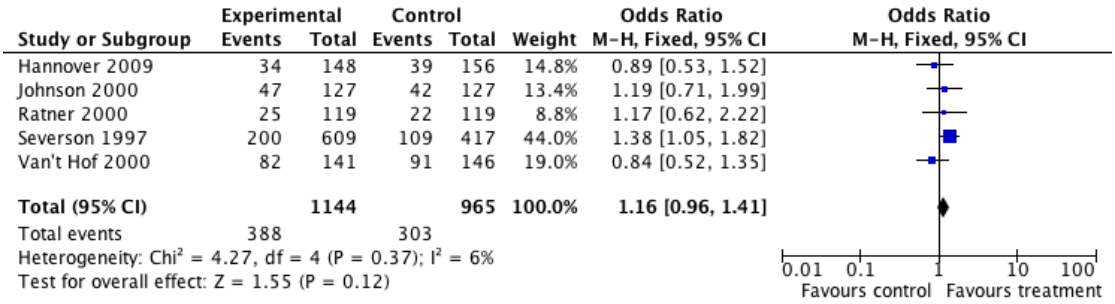


Intervention delivered during pregnancy, effects post-partum – Validated only

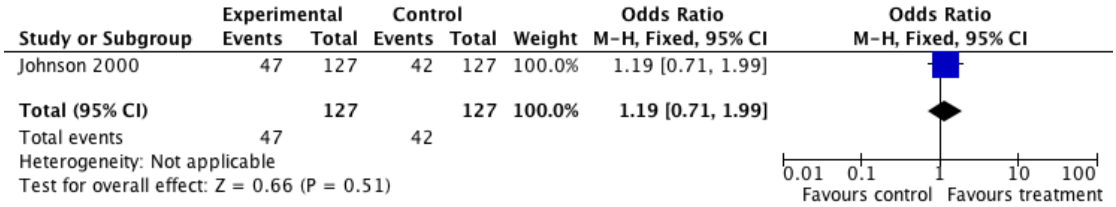


Intervention delivered post delivery

Interventions delivered post delivery, effects post-partum

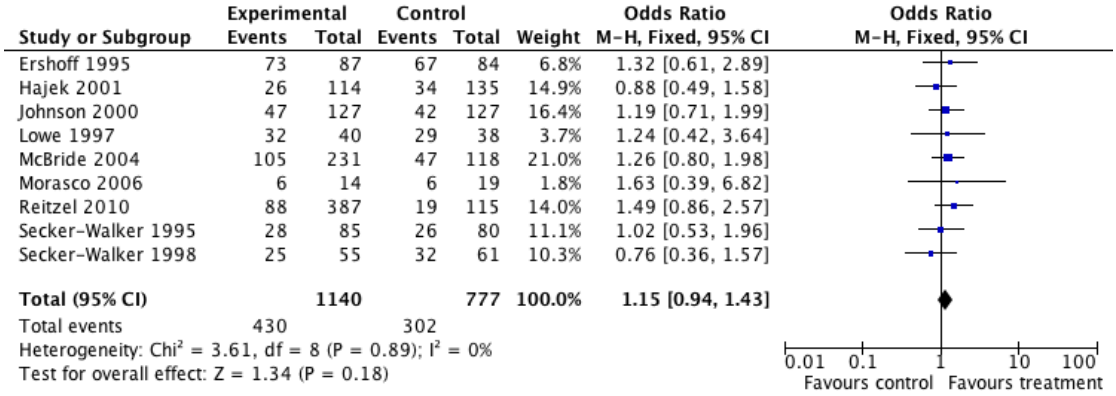


Interventions delivered post delivery, effects post-partum – Validated only

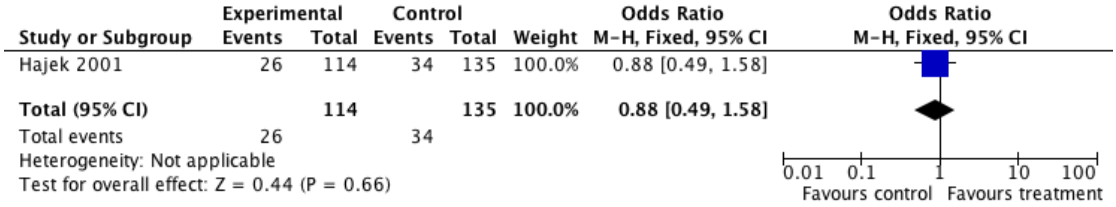


We repeated these analyses using validated studies only.

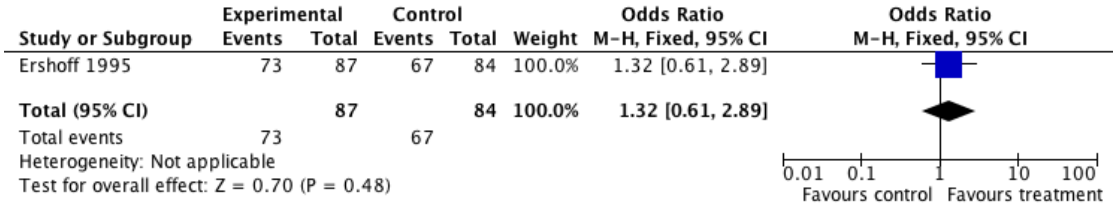
All validated studies



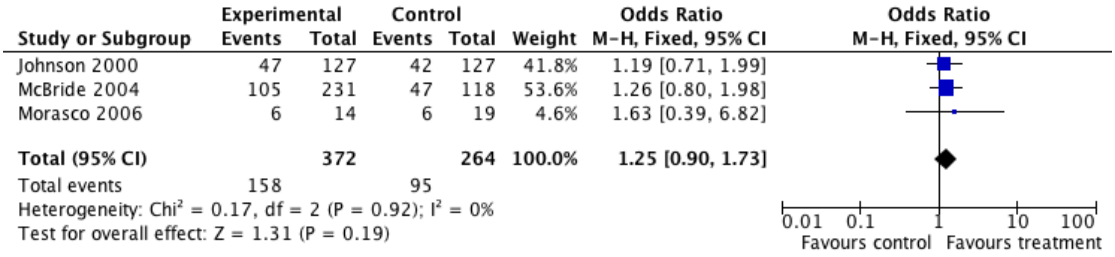
Validated studies of Intensity 1



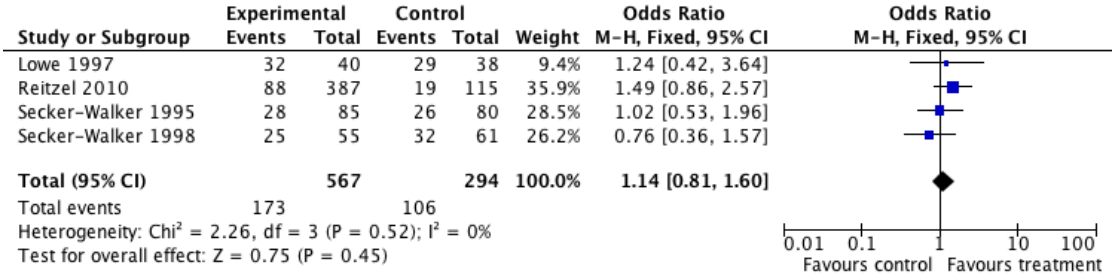
Validated studies of Intensity 3



Validated studies of Intensity 4



Validated studies of Intensity 5



Relapse prevention interventions with users of maternity service lack efficacy.

SYSTEMATIC REVIEWS:

We found two relevant Cochrane reviews. Lumley et al. (2009 [systematic review, +]) covers interventions with pregnant women and Hajek et al. (2009 [systematic review, ++]) covers relapse prevention interventions and includes a section on interventions with pregnant women. We also found one relevant report commissioned by NICE (Myers et al. 2009 [systematic review, ++]) on relapse preventions in pregnancy.

We identified 7 other reviews, listed below. All relevant and eligible studies included in these reviews are also included in our review.

Author	**Summary**
Dolan-Mullen et al 1994 Meta analysis	Review and meta-analysis of 10 randomised trials of prenatal smoking cessation interventions. Found a positive effect. *Quality: +*
Kelley et al. 2001 Meta analysis	Review of 36 studies assessing the effectiveness of prenatal interventions. Pooled 36 studies and concluded that interventions should employ further follow-up. *Quality: ++*
Melvin et al 2000 Review	General review of smoking cessation interventions during pregnancy quoting a meta-analysis by Mullen (1999) that pooled data from 16 trials and found a significant effect.

	Quality: -
Mullen 1999	Paper on order
Naughton et al 2008 Meta-analysis	Review and meta-analysis. Meta-analysis of 15 randomised and quasi-randomised controlled trials of self-help intervention in pregnancy, found a significant effect. *Quality: +*
Windsor et al 1998 Review	Review of 23 randomised and quasi-randomised trials of smoking cessation interventions in pregnant women, reports a significant effect. Quality: +
Lumley et al 2000(Walsh & Redman, 1993) Systematic Review	Cochrane review of the efficacy of smoking cessation interventions in pregnancy. 45 RCTs, pooled data from 34, showed a significant effect. Quality +
Walsh & Redman 1993 Review	Review of 20 trials of interventions to help pregnant women stop smoking, not pooled. Quality +

All the reviews above report positive results. The reviews were generally less strict in data extraction and in outcome definitions than our review and they report larger effects, especially for brief interventions (Intensity 1 and 2), but overall their conclusions generally tally with our findings.

NARRATIVE SUMMARY

INTERVENTION INTENSITY

As with hospital patients, a range of interventions aimed at users of maternity services has been proposed. Advice by midwives accompanied by leaflets is by far the simplest and least expensive option that could be provided routinely on a large scale. It has been evaluated in 20 randomised trials and pooling them together shows that such one-off interventions have little effect.

Pregnant smokers are likely to have received strong encouragements to stop smoking from their friends, families, and health care providers. Those who continue to smoke despite such advice may need more substantial assistance.

Interventions of Intensity 2 and 3 were evaluated in only a small number of trials. The results suggest that these are likely to have only limited, if any, effects. Interventions of Intensity 4 and 5 however show efficacy, although the effects are not maintained after delivery.

It is worth noting that unlike in studies of acute care interventions, there was no observable trend in favour of face-to-face contact compared to telephone support. This could be in part at least due to difficulties reported in some studies in getting pregnant women to attend face-to-face sessions.

The only Intensity 1 trial with a positive result used non-midwifery advisors. The efficacy of interventions of Intensity 4 and Intensity 5 was similar regardless of the professional background of the person delivering the intervention. These results correspond with the results of a survey of UK services for pregnant smokers (Taylor and Hajek, 2001). Some services employed midwives to deliver specialist stop-smoking interventions while others employed advisors with different backgrounds. Advisor background had no effect on 4-week success rates.

The current practice within NHS is for pregnant smokers to receive multisession support and medication from stop smoking specialists employed by local stop smoking services. The key finding of this review supports this practice.

Interventions using incentives contingent on abstinence

There is evidence that progressive reinforcement schedules using financial incentives contingent on abstinence are effective. It is possible that the frequent visits for verification of abstinence and collection of rewards provide an extra level of support, which contributes to the intervention effect. It should be noted that the existing studies used carefully designed schedules where continuing abstinence was frequently checked and the rewards were progressive, with temporary lapses resetting the rewards to lower levels. This differs from some of the uncontrolled experiments conducted currently within the NHS. Implementing such interventions in routine care would be demanding. The staff would need to strictly adhere to schedules and frequent contacts from the above studies, and measures would need to be in place to try to limit a range of problems inherent in this approach.

Efficacy of pharmacotherapy

Nicotine replacement therapy in pregnancy is considered much safer than smoking (see Review 1) but only a few studies have evaluated its use in pregnancy and several of them were aborted due to concerns, which were in all cases shown unwarranted. As with other populations, NRT did not work when accompanied by minimal behaviour support. However, in this group, it did not show efficacy even when accompanied by more intensive support. Only a few studies with relatively small samples are available, the results go in the 'right' direction and it is possible that another large trial with the same trend would tip the pooled results over the significance line. It is also possible that NRT accompanied by home visits as provided by the UK services may be effective, but additional trials are needed to determine this (see Research Gaps below).

Interventions to prevent relapse

Interventions to prevent relapse in women who stopped smoking recently show no effect, regardless of their timing (during pregnancy, at delivery, or post-partum). This tallies with the general lack of efficacy of existing relapse prevention interventions.

Evidence Statements

ES: 2.1: There is strong evidence from trials that validated self-reported abstinence rates that low intensity (intensity 1-3) smoking cessation interventions in pregnancy (i.e. those that have minimal contact and follow-up for < 1 month following a target quit date) have no effect on abstinence rates in late pregnancy.

Only one study (Windsor et al 1985 [RCT +]) found an effect of a low intensity intervention (Intensity 1) whilst ten showed no effect (Hajek et al 2001 [RCT ++]; Hjalmarson et al 1991 [RCT +]; Kendrick et al 1995 [RCT +]; Lowe et al 1998 A [RCT +]; Lowe et al 1998 B [RCT +];

Moore et al 2002 [RCT +]; O'Connor et al 1992 [RCT +]; Secker-Walker et al; 1997 [RCT +]; Windsor et al 1985 [RCT +]; Windsor et al 1985 B [RCT +]). Pooling data from these studies showed no significant effect. Intensity 1 OR=1.01 (95%CI: 0.85-1.19); Intensity 3 OR=2.42 (95%CI: 0.82-7.12).

ES 2.2: There is moderate evidence from trials that validated self-reported abstinence rates that low intensity (intensity 1-3) smoking cessation interventions in pregnancy have no effect on abstinence rates post-partum.

Three studies (Hajek et al 2001 [RCT ++]; (O'Connor et al 1992 [RCT +]; Strecher et al 2000 [RCT -]) showed no effect and one (Hjalmarson et al 1991 [RCT +]) showed a modest benefit. Pooling data from these studies showed no significant effect. Intensity 1 OR=1.46 (95%CI: 0.98-2.17); Intensity 3 OR=2.65 (95%CI: 0.91-7.71).

ES 2.3: There is strong evidence from trials that validated self-reported abstinence rates that higher intensity (intensity 4-5) smoking cessation interventions in pregnancy (i.e. those that provide follow-up for > 1 month after a target quit date, either by telephone, written or electronic correspondence or face-to-face contact) increase abstinence rates in late pregnancy.

Six studies (Dornelas et al 2006 [RCT +]; Ershoff et al 1989 [RCT ++]; Walsh et al 1997 [RCT +]; Hartman et al 1996 [RCT +]; Hegaard et al 2003 [RCT+] Windsor et al 1993 [RCT+]) demonstrated efficacy of such interventions (Intensity 4-5), whilst 14 showed no effect (Albrecht et al 1998 [RCT -]; Cinciripini et al 2000 [RCT +]; Ershoff et al 1999 [RCT +]; Gielen et al 1997 [RCT +];; Lawrence et al [RCT +]; Loeb et al 1983 [RCT +]; Malchodi et al 2003 [RCT +]; Panjari et al 1999 [RCT +]; Patten et al 2010 [RCT +]; Rigotti et al 2006 [RCT +]; Solomon et al 2000 [RCT +]; Tappin et al 2000 [RCT +]; Tappin et al 2005 [RCT +]; Thornton et al 1997 [RCT +]). Pooling data from these studies showed a significant effect. Intensity 4 OR=1.72 (95%CI: 1.27-2.33); Intensity 5 OR=1.34 (95%CI: 1.11-1.63).

ES 2.4: There is strong evidence from trials that validated self-reported abstinence rates that high intensity (intensity 4-5) smoking cessation interventions in pregnancy do not increase abstinence rates post-partum.

One RCT (Walsh et al 1997 [RCT +]) showed that this type of intervention retained its beneficial effect on abstinence rates into the post-partum period, however this finding was not replicated by others (Bullock et al 2009 [RCT +]; Cinciripini et al 2000 [RCT +]; Dornelas et al 2006 [RCT +]; Lawrence et al [RCT +]; Rigotti et al 2006 [RCT +]; Stotts et al 2002 [RCT -]; Thornton et al 1997 [RCT +]). Pooling data from these studies showed no significant effect. Intensity 4 OR=1.27 (95%CI: 0.88-1.85); Intensity 5 OR=0.93 (95%CI: 0.62-1.38).

ES 2.5: There is no evidence that interventions delivered by midwives are more effective than interventions delivered by other providers such as counsellors and health advisors.

Only one Intensity 1 trial had a positive result and this trial used a non-midwifery intervention (Windsor et al 1985 [RCT +]). The efficacy of interventions of Intensity 4 (Bullock et al 2009 [RCT +]; Cinciripini et al 2000 [RCT +]; Dornelas et al 2006 [RCT +]; Ershoff

et al 1989 [RCT ++]; Patten et al 2010 [RCT +]; Rigotti et al 2006 [RCT +]; Stotts et al 2002 [RCT -]; Solomon et al 2000 [RCT +]; Walsh et al 1997 [RCT +]) and Intensity 5 (Gielen et al 1997 [RCT +]; Hartman et al 1996 [RCT +]; Loeb et al 1983 [RCT +]; Lowe et al 1997 [RCT +]; Malchodi et al 2003 [RCT +]; Pollak et al 2007 [RCT +]; Hegaard et al 2003 [RCT +]; Lawrence et al 2003 [RCT +]; Panjari et al 1999 [RCT +]; Tappin et al 2000 [RCT +]; Tappin et al 2005 [RCT +]; Thornton et al 1997 [RCT +]) were similar regardless of the professional background of the person delivering the intervention.

ES 2.6: There is strong evidence that the provision of financial incentives (vouchers redeemable for retail items for up to >$1,000) contingent on abstinence is effective in increasing cessation rates in late pregnancy, post-partum, and after the incentives are discontinued.

All four studies identified that examined this type of intervention demonstrated efficacy at time points up to delivery (Donatelle et al 2000 [RCT ++]; Heil et al 2008 [RCT ++]; Higgins et al 2004 [RCT +]; Higgins et al 2010 [RCT +])

Three studies demonstrated efficacy post-partum (Donatelle et al 2000 [RCT ++]; Higgins et al 2004 [RCT +]; Higgins et al 2010 [RCT +]), whilst one did not (Heil et al 2008 [RCT ++]). Pooled results show efficacy (OR=5.86; 2.74-12.52)

Two studies demonstrated efficacy post-discontinuation (Higgins et al 2004 [RCT +]; Higgins et al 2010 [RCT +]), whilst one did not (Heil et al 2008 [RCT ++]). Pooled results show efficacy (OR=10.29; 95%CI: 2.75-38.51).

ES 2.7: There is weak evidence that smoking cessation interventions targeting partners of pregnant women are ineffective.

One study (De Vries et al 2006, [RCT-) found no effect of such intervention with partners but did see a significant effect on women smokers. The three others (Lilley et al. 1986 [RCT -]; Lowe et al. 1998 [RCT +]; McBride et a. 2004 [RCT +]), which included a partner component had overall negative results as well in terms of women or partner smoking.

ES 2.8: There is weak evidence that low intensity interventions delivered to women post-partum are not effective and high intensity interventions are effective.

One study (Winickoff et al 2010 [RCT +]) showed no effect of Intensity 1 intervention. One study of Intensity 4 intervention (Hannover et al 2009 [RCT -]) showed no effect, whilst another of intensity 5 (Wall et al 1996 [RCT -]) demonstrated efficacy.

ES 2.9: There is strong evidence from trials that validated self-reported abstinence rates that nicotine replacement therapy, when used in standard doses, is ineffective in helping pregnant women quit smoking during pregnancy.

Of the six studies, four examined the use of patches (Coleman et al 2012, [RCT ++]; Hotham et al 2006 [RCT ++]; Kapur et al 2001, [RCT +]; Wisborg et al 2000, [RCT ++]), one of gum (Oncken et al 1998, [RCT +]) and one of a choice between patch, gum or lozenge (Pollak 2007

et al, [RCT ++]). None demonstrated a significant benefit over placebo across levels of support. Pooling interventions of different intensity provided negative results as well: Intensity 3 OR=1.27 (95%CI: 0.82-1.96); Intensity 4 OR=8.20 (95%CI: 0.40-169.90); Intensity 5 OR=1.48 (95%CI: 0.96-2.28).

ES 2.10: There is strong evidence from trials that validated self-reported abstinence rates that nicotine replacement therapy, when used in standard doses, has no effect on abstinence rates post-partum.

Three trials (Oncken et al 1998, [RCT +]; Pollack 2007 et al, [RCT ++]; Wisborg et al 2000, [RCT ++]) failed to demonstrate long-term efficacy of NRT. Pooling data from these studies showed no significant effect. Intensity 5 OR=1.08 (95%CI: 0.65-1.79).

ES 2.11: There is strong evidence from trials that validated self-reported abstinence rates that interventions aimed to prevent relapse in women who stopped smoking during pregnancy are ineffective regardless of their timing.

All 9 studies that focused on relapse prevention during and after pregnancy failed to show any beneficial effect (Ershoff et al 1995 [RCT +]; Hajek et al [RCT ++]; Johnson et al 2000 [RCT +]; Lowe et al 1997 [RCT +]; McBride et al 2004 [RCT +]; Morasco et al 2006 [RCT +]; Reitzel et al 2010 [RCT ++]; Secker-Walker et al 1995 [RCT +]; Secker-Walker et al 1998 [RCT ++]). Pooling these data confirm a lack of effect (OR=1.15; 95%CI: 0.94-1.43)

APPLICABILITY STATEMENT AND RESEARCH GAPS

The NHS practice currently involves referral of pregnant women who smoke to specialist smoking cessation treatment that typically consists of multi-session behavioural support for at least 4-weeks following a target quit date supplemented by the use of NRT and usually also by home visits. This is more intensive and sophisticated than any of the interventions evaluated so far. Women are referred by midwives and the intervention is provided by specialist pregnancy advisors employed for this purpose. The service is expensive because only a relatively small number of pregnant smokers attend treatment and the success rates are lower than in the mainstream service, but it is felt that if pregnant smokers were referred to mainstream service instead, the proportion of women taking up the referral would be even lower. In this sense, the current UK practice have overtaken research results

We identified four areas where more research is needed.

1. The reviewed evidence suggests that lower intensity interventions are effective and that NRT is not effective in this population. The UK advisors however provide a more intensive support than that examined in any of the studies reviewed. It is possible that NRT accompanied by this level of support is more effective than other options, but it is also possible that more economical interventions with a wider reach would provide the same or better results. Some of the minimal support studies reviewed above reported very high success rates (mostly studies with low quality rating), but overall the quit rates tended to be under 10%, and lower in studies which followed the women post-partum. A trial is needed comparing the current UK practice of intensive specialist support, home visits and

medication with an Intensity 3 or 4 intervention which could be delivered routinely by midwives.

2. There is good evidence that incentives contingent on abstinence facilitate smoking cessation. It should be noted though that the procedure shown effective required frequent visits, progressive reinforcement, and re-setting the rewards after lapses. The NHS is currently experimenting with incentives schemes, but these are typically provided in a much looser way and their efficacy is not formally evaluated. There are potential problems with the approach as discussed in Myers at al (2009), but it may hold a promise. A randomised evaluation of its implementation in routine care would help to assess its practicality, cost, and likely impact.

3. Regarding the lack of efficacy of relapse prevention interventions, in this area, an additional problem is that pregnant women who stopped smoking are unlikely to use medications or attend treatment sessions. Opportunistic encouragements and written materials which until recently were the only practicable options are known to lack efficacy. Currently however, electronic media provide a new alternative. A relapse prevention intervention based on text messaging has been shown practicable and it currently awaits a formal evaluation. If proven effective in general population (where such evaluation would be much easier to implement than in pregnant smokers), the next step would be to evaluate such approach formally with users of maternity services as well.

4. Regarding stop smoking medications, two approaches await evaluation. A. Pregnant women metabolise nicotine about twice as fast as non-pregnant smokers. It is possible that NRT dosing which follows the standard labelling leads to under-dosing in pregnancy and that higher dosing may achieve better results. B. Varenicline has been shown effective with several hard to reach groups. It has no known teratogenic effects. Given the lack of evidence that NRT helps in pregnancy and the high priority of smoking cessation in pregnancy, studies are needed to determine safety and efficacy of varenicline in this group.

References

REFERENCES FOR INCLUDED PAPERS IN CHAPTER 1

British Thoracic Society (1990). "Smoking cessation in patients: two further studies by the British Thoracic Society. Research Committee of the British Thoracic Society." Thorax **45**(11): 835-840.

Bolman, C., H. De, et al. (2002). "Evaluation of a nurse-managed minimal-contact smoking cessation intervention of cardiac inpatients." Health Education Research **17**(1).

Borglykke, A., C. Pisinger, et al. (2008) "The effectiveness of smoking cessation groups offered to hospitalised patients with symptoms of exacerbations of chronic obstructive pulmonary disease (COPD)." The clinical respiratory journal, 158-165.

Brandt, C. J. (1997). "Effect of diagnosis of "smoker's lung"." The Lancet **349**: 253.

Campbell, E., G. Villagra, et al. (1991). "Teaching and promoting smoking cessation counseling in primary care residencies: Description of a method." Teaching and Learning in Medicine **3**(1): 20-27.

Campbell, I. A., R. J. Prescott, et al. (1996). "Transdermal nicotine plus support in patients attending hospital with smoking-related diseases: a placebo-controlled study." Respiratory Medicine **90**(1): 47-51.

Carlsson, R., G. Lindberg, et al. (1997) "Influence of coronary nursing management follow up on lifestyle after acute myocardial infarction." Heart (British Cardiac Society), 256-259.

Caruthers, D. D. (2005). "Enhancing tobacco abstinence following hospitalization." NaN.

Chan, S. S., T. H. Lam, et al. (2005) "A randomized controlled trial of an individualized motivational intervention on smoking cessation for parents of sick children: a pilot study." Applied nursing research : ANR, 178-181.

Chouinard, M.C. and S. Robichaud-Ekstrand (2005). "The effectiveness of a nursing inpatient smoking cessation program in individuals with cardiovascular disease." Nursing Research **54**(4): 243-254.

Croghan, G. A. (2005). "Smoking cessation intervention and post-operative outcomes in esophageal and luncg cancer patients." Society for research on nicotine and tobacco 11th annual meeting **139**.

Dalsgaro, O. J., N.C. G. Hansen, et al. (2004). "A multicenter, randomized, double-blind, placebo-controlled, 6-month trial of bupropion hydrochloride sustained-release tablets as an aid to smoking cessation in hospital employees." Nicotine & Tobacco Research **6**(1): 55-61.

DeBusk, R. F., N. H. Miller, et al. (1994). "A case-management system for coronary risk factor modification after acute myocardial infarction." Annals Of Internal Medicine **120**(9): 721-729.

Dornelas, E. A., R. A. Sampson, et al. (2000). "A randomized controlled trial of smoking cessation counseling after myocardial infarction." Preventive Medicine **30**(4): 261-268.

Feeney, G. F., A. McPherson, et al. (2001). "Randomized controlled trial of two cigarette quit programmes in coronary care patients after acute myocardial infarction." Internal Medicine Journal **31**(8): 470-475.

Froelicher, E. S. S., N. H. Miller, et al. (2004). "High rates of sustained smoking cessation in women hospitalized with cardiovascular disease - The Women's Initiative for Nonsmoking (WINS)." Circulation **109**(5): 587-593.

Hajek, P., T. Z. Taylor, et al. (2002). "Brief intervention during hospital admission to help patients to give up smoking after myocardial infarction and bypass surgery: randomised controlled trial." BMJ (Clinical Research Ed.) **324**(7329): 87-89.

Hand, S., S. Edwards, et al. (2002). "Controlled trial of three weeks nicotine replacement treatment in hospital patients also given advice and support." Thorax **57**(8): 715-718.

Hanssen, T. A., J. E. Nordrehaug, et al. (2009). "Does a telephone follow-up intervention for patients discharged with acute myocardial infarction have long-term effects on health-related quality of life? A randomised controlled trial." Journal Of Clinical Nursing **18**(9): 1334-1345.

Hasuo, S., H. Tanaka, et al. (2004). "[Efficacy of a smoking relapse prevention program by postdischarge telephone contacts: a randomized trial]." [Nihon Koçsh Eisei Zasshi] Japanese Journal Of Public Health **51**(6): 403-412.

Haug, S., C. Meyer, et al. (2011). "Efficacy of an internet program for smoking cessation during and after inpatient rehabilitation treatment: a quasi-randomized controlled trial." Addictive Behaviors **36**(12): 1369-1372.

Hennrikus, D., A. M. Joseph, et al. (2010). "Effectiveness of a smoking cessation program for peripheral artery disease patients: a randomized controlled trial." Journal Of The American College Of Cardiology **56**(25): 2105-2112.

Hennrikus, D. J., H. A. Lando, et al. (2005). "The TEAM project: the effectiveness of smoking cessation intervention with hospital patients." Preventive Medicine **40**(3): 249-258.

Hilleman, D. E., S. M. Mohiuddin, et al. (2004). "Comparison of conservative and aggressive smoking cessation treatment strategies following coronary artery bypass graft surgery." Chest **125**(2): 435-438.

Horn, K., G. Dino, et al. (2008). "Feasibility of a smoking cessation intervention for teens in the emergency department: reach, implementation fidelity, and acceptability." American Journal Of Critical Care: An Official Publication, American Association Of Critical-Care Nurses **17**(3): 205-216.

Kim, H. S. (2005). "[Prospective study on the relating factors to the stages of change in smoking cessation and barriers in coronary artery disease patients]." Taehan Kanho Hakhoe Chi **35**(1): 27-36.

Lacasse, Y., R. Lamontagne, et al. (2008) "Randomized trial of a smoking cessation intervention in hospitalized patients." Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 1215-1221.

Lewis, K. E., L. Durgan, et al. (2009). "Can smokers switch from a hospital-based to a community-based stop smoking service? an open-label, randomized trial comparing three referral schemes." Nicotine & Tobacco Research: Official Journal Of The Society For Research On Nicotine And Tobacco **11**(6): 756-764.

Lewis, S. F., T. M. Piasecki, et al. (1998). "Transdermal nicotine replacement for hospitalized patients: a randomized clinical trial." Preventive Medicine **27**(2): 296-303.

Li, W. W. and E. S. Froelicher (2008) "Predictors of smoking relapse in women with cardiovascular disease in a 30-month study: extended analysis." Heart & lung : the journal of critical care, 455-465.

Lindstrom, D., O. Sadr Azodi, et al. (2008). "Effects of a perioperative smoking cessation intervention on postoperative complications: a randomized trial." Annals Of Surgery **248**(5): 739-745.

Moller, A. M., N. Villebro, et al. (2002) "Effect of preoperative smoking intervention on postoperative complications: a randomised clinical trial." Lancet, 114-117.

Mahabee-Gittens, M. E., J. S. Gordon, et al. (2008). "A smoking cessation intervention plus proactive quitline referral in the pediatric emergency." Nicotine and Tobacco Research **10**(12): 1745-1751.

Martucci, P., P. Sestini, et al. (2010). "Smoking cessation in patients requiring bronchoscopy: the Bronchoscopy AntiSmoking Study (BASIS)." Respiratory Medicine **104**(1): 61-66.

Metz, K., S. Flˆter, et al. (2007) "Telephone booster sessions for optimizing smoking cessation for patients in rehabilitation centers." Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 853-863.

Miller, N. H., P. M. Smith, et al. (1997). "Smoking cessation in hospitalized patients. Results of a randomized trial." Archives Of Internal Medicine **157**(4): 409-415.

Mohiuddin, S. M., A. N. Mooss, et al. (2007). "Intensive smoking cessation intervention reduces mortality in high-risk smokers with cardiovascular disease." Chest **131**(2): 446-452.

Molyneux, A., S. Lewis, et al. (2003). "Clinical trial comparing nicotine replacement therapy (NRT) plus brief counselling, brief counselling alone, and minimal intervention on smoking cessation in hospital inpatients." Thorax **58**(6): 484-488.

Mosca, L., A. H. Christian, et al. (2010). "A randomized clinical trial of secondary prevention among women hospitalized with coronary heart disease." Journal Of Women's Health (2002) **19**(2): 195-202.

Nagle, A. L., M. J. Hensley, et al. (2005). "A randomised controlled trial to evaluate the efficacy of a nurse-provided intervention for hospitalised smokers." Australian And New Zealand Journal Of Public Health **29**(3): 285-291.

Neuner, B., E. Weiss-Gerlach, et al. (2009). "Emergency department-initiated tobacco control: a randomised controlled trial in an inner city university hospital." Tobacco Control **18**(4): 283-293.

Ortigosa, A., F. J. Ochoa Gomez, et al. (2000). "[Efficacy of an intervention in smoking cessation in patients with myocardial infarction]." Medicina Clonica **114**(6): 209-210.

Papadakis, S., D. Aitken, et al. (2011). "A randomised controlled pilot study of standardised counselling and cost-free pharmacotherapy for smoking cessation among stroke and TIA patients." BMJ Open **1**(2).

Pedersen, L., S. Johansen, et al. (2005). "[Smoking cessation among patients with acute heart disease. A randomised intervention project]." Ugeskrift For Laeger **167**(33): 3044-3047.

Pedersen, L. L. (1991). "The effects of counselling on smoking cessation among patients hospitalised with chronic obstructive pulmonary disease: a randomised clinical trial." International journal of the addiction **26**(1): 107-119.

Pelletier, J. G. and J. T. Moisan (1998). "[Smoking cessation for hospitalized patients: a quasi-experimental study in Quebec]." Canadian Journal Of Public Health. Revue Canadienne De Sant√ © Publique **89**(4): 264-269.

Quist-Paulsen, P. and F. Gallefoss (2003). "Randomised controlled trial of smoking cessation intervention after admission for coronary heart disease." BMJ (Clinical Research Ed.) **327**(7426): 1254-1257.

Ralston, S. and M. Roohi (2008) "A randomized, controlled trial of smoking cessation counseling provided during child hospitalization for respiratory illness." Pediatric pulmonology, 561-566.

Ratner, P. A., J. L. Johnson, et al. (2004). "Efficacy of a smoking-cessation intervention for elective-surgical patients." Research In Nursing & Health **27**(3): 148-161.

Reid, R., A. Pipe, et al. (2003). "Stepped care approach to smoking cessation in patients hospitalized for coronary artery disease." Journal Of Cardiopulmonary Rehabilitation **23**(3): 176-182.

Reid, R. D., A. L. Pipe, et al. (2007). "Interactive voice response telephony to promote smoking cessation in patients with heart disease: a pilot study." Patient Education And Counseling **66**(3): 319-326.

Rigotti, N., R. Munafo' Marcus, et al. (2007) "Interventions for smoking cessation in hospitalised patients." Cochrane Database of Systematic Reviews DOI: 10.1002/14651858.CD001837.pub2.

Rigotti, N. A., J. H. Arnsten, et al. (1997). "Efficacy of a smoking cessation program for hospital patients." Archives Of Internal Medicine **157**(22): 2653-2660.

Rigotti, N. A., K. M. McKool, et al. (1994). "Predictors of smoking cessation after coronary artery bypass graft surgery. Results of a randomized trial with 5-year follow-up." Annals Of Internal Medicine **120**(4): 287-293.

Rigotti, N. A., A. N. Thorndike, et al. (2006). "Bupropion for smokers hospitalized with acute cardiovascular disease." The American Journal Of Medicine **119**(12): 1080-1087.

Rodriguez, R. M., O. Taylor, et al. (2007). "A Prospective, Randomized Trial in the Emergency Department of Suggestive Audio-Therapy under Deep Sedation for Smoking Cessation." The Western Journal Of Emergency Medicine **8**(3): 79-83.

Rosal, M. C. (1998). "Coronary Artery Smoking Intervention Study (CASIS): 5-year Follow-up." Health Psychology **17**(5): 476-478.

Schiebel, N. E. E. and J. O. Ebbert (2007). "Quitline referral vs. self-help manual for tobacco use cessation in the Emergency Department: a feasibility study." BMC Emergency Medicine **7**: 15-15.

Schofield, P. E., D. J. Hill, et al. (1999). "The effectiveness of a directly mailed smoking cessation intervention to Australian discharged hospital patients." Preventive Medicine **29**(6 Pt 1): 527-534.

Simon, J. A., T. P. Carmody, et al. (2003). "Intensive smoking cessation counseling versus minimal counseling among hospitalized smokers treated with transdermal nicotine replacement: a randomized trial." The American Journal Of Medicine **114**(7): 555-562.

Simon, J. A., C. Duncan, et al. (2009). "Sustained-release bupropion for hospital-based smoking cessation: a randomized trial." Nicotine & Tobacco Research: Official Journal Of The Society For Research On Nicotine And Tobacco **11**(6): 663-669.

Simon, J. A., S. N. Solkowitz, et al. (1997). "Smoking cessation after surgery. A randomized trial." Archives Of Internal Medicine **157**(12): 1371-1376.

Sivarajan Froelicher, E. S., N. H. Miller, et al. (2004). "High rates of sustained smoking cessation in women hospitalized with cardiovascular disease: the Women's Initiative for Nonsmoking (WINS)." Circulation **109**(5): 587-593.

Smith, P. M. and E. Burgess (2009). "Smoking cessation initiated during hospital stay for patients with coronary artery disease: a randomized controlled trial." CMAJ: Canadian Medical Association Journal, Journal De L'association Medicale Canadienne **180**(13): 1297-1303.

Smith, P. M., L. Corso, et al. (2011). "Nurse case-managed tobacco cessation interventions for general hospital patients: results of a randomized clinical trial." The Canadian Journal Of Nursing Research, Revue Canadienne De Recherche En Sciences Infirmi√ ®res **43**(1): 98-117.

Steinberg, M. B., J. Randall, et al. (2011). "Tobacco dependence treatment for hospitalized smokers: a randomized, controlled, pilot trial using varenicline." Addictive Behaviors **36**(12): 1127-1132.

Stevens, V. J., R. E. Glasgow, et al. (1993). "A smoking-cessation intervention for hospital patients." Medical Care **31**(1): 65-72.

Stevens, V. J., R. E. Glasgow, et al. (2000). "Implementation and effectiveness of a brief smoking-cessation intervention for hospital patients." Medical Care **38**(5): 451-459.

Tonnesen, P., K. Mikkelsen, et al. (2006) "Nurse-conducted smoking cessation in patients with COPD using nicotine sublingual tablets and behavioral support." Chest, 334-342.

Tonnesen, P. and K. L. Mikkelsen (2000) "Smoking cessation with four nicotine replacement regimes in a lung clinic." The European respiratory journal : official journal of the European Society for Clinical Respiratory Physiology, 717-722.

Taylor, C. B., N. Houston-Miller, et al. (1990). "Smoking cessation after acute myocardial infarction: effects of a nurse-managed intervention." Annals Of Internal Medicine **113**(2): 118-123.

Taylor, C. B., N. H. Miller, et al. (1996). "A nurse-managed smoking cessation program for hospitalized smokers." American Journal Of Public Health **86**(11): 1557-1560.

Thomsen, T., H. Tonnesen, et al. (2010). "Brief smoking cessation intervention in relation to breast cancer surgery: A randomized controlled trial." Nicotine & Tobacco Research **12**(11): 1118-1124.

Thomsen, T., N. Villebro, et al. (2010) "Interventions for preoperative smoking cessation." Cochrane Database of Systematic Reviews DOI: 10.1002/14651858.CD002294.pub3.

Vial, R. J., T. E. Jones, et al. (2002). "Smoking cessation program using nicotine patches linking hospital to the community." Journal of Pharmacy Practice and Research **32**(1): 57-62.

Wakefield, M., I. Olver, et al. (2004). "Motivational interviewing as a smoking cessation intervention for patients with cancer: randomized controlled trial." Nursing Research **53**(6): 396-405.

Wiggers, L. C., E. M. Smets, et al. (2006) "The effect of a minimal intervention strategy in addition to nicotine replacement therapy to support smoking cessation in cardiovascular outpatients: a randomized clinical trial." European journal of cardiovascular prevention and rehabilitation : official journal of the European Society of Cardiology, Working Groups on Epidemiology & Prevention and Cardiac Rehabilitation and Exercise Physiology, 931-937.

REFERENCES FOR EXCLUDED PAPERS IN CHAPTER 1

(2007). "Inpatient smoking-cessation programs get the job done." AARC Times **31**(10): 192-193.

(2008). "Treating patients who use tobacco." Critical Care Nurse **28**(5): 10-11.

(2009). "Stop smoking hospitals pilots." Nursing Times **105**(24): 2-3.

(2010). "Thoracic surgeons can help patients stop smoking with a brief smoking cessation program." AHRQ Research Activities(360): 14-15.

(2011). "Motivate patients to stop smoking." Healthcare Benchmarks And Quality Improvement **18**(1): 6-7.

Allen, B., Jr., L. L. Pederson, et al. (1998). "Effectiveness of physicians-in-training counseling for smoking cessation in African Americans." Journal Of The National Medical Association **90**(10): 597-604.

An, L. C., J. H. Bluhm, et al. (2008). "A randomized trial of a pay-for-performance program targeting clinician referral to a state tobacco quitline." Archives Of Internal Medicine **168**(18): 1993-1999.

Bernstein, S. L., P. Bijur, et al. (2011). "A randomized trial of a multicomponent cessation strategy for emergency department smokers." Academic Emergency Medicine: Official Journal Of The Society For Academic Emergency Medicine **18**(6): 575-583.

Canga, N., J. De Irala, et al. (2000). "Intervention study for smoking cessation in diabetic patients: a randomized controlled trial in both clinical and primary care settings." Diabetes Care **23**(10): 1455-1460.

Carson, K. V., M. P. Brinn, et al. (2010) "Varenicline tartrate and counselling versus counselling alone in a randomised controlled trial for inpatient smoking cessation: 3 month interim results [abstract]." Respirology, A30.

Choo, Y. M., K. C. Ong, et al. (2004) "Effectiveness of a smoking cessation program among hospitalized patients in Singapore." Chest, 713s.

Dalton, J. A., I. Swenson, et al. (1991). "Counseling hospitalized patients to quit smoking--study of an educational intervention." Journal Of Continuing Education In Nursing **22**(5): 209-212.

Fonteyn, M. E. (2004). "A nurse led smoking cessation intervention increased cessation rates after hospital admission for coronary heart disease." Evidence-Based Nursing **7**(2): 46-46.

Gies, C. E., D. Buchman, et al. (2008). "Effect of an inpatient nurse-directed smoking cessation program." Western Journal Of Nursing Research **30**(1): 6-19.

Gritz, E. R., C. R. Carr, et al. (1991). "A smoking cessation intervention for head and neck cancer patients: trial design, patient accrual, and characteristics." Cancer Epidemiology, Biomarkers & Prevention: A Publication Of The American Association For Cancer Research, Cosponsored By The American Society Of Preventive Oncology **1**(1): 67-73.

Hanssen, T. A., J. E. Nordrehaug, et al. (2007). "Improving outcomes after myocardial infarction: a randomized controlled trial evaluating effects of a telephone follow-up intervention." European Journal Of Cardiovascular Prevention And Rehabilitation: Official Journal Of The European Society Of Cardiology, Working Groups On Epidemiology & Prevention And Cardiac Rehabilitation And Exercise Physiology **14**(3): 429-437.

Holmes-Rovner, M., M. Stommel, et al. (2008). "Does outpatient telephone coaching add to hospital quality improvement following hospitalization for acute coronary syndrome?" Journal Of General Internal Medicine **23**(9): 1464-1470.

Jha, A. K. (2005). "In-hospital smoking cessation counseling after myocardial infarction." Journal of Clinical Outcomes Management **12**(5): 240-241.

Joseph, A. M., S. M. Norman, et al. (1996) "The safety of transdermal nicotine as an aid to smoking cessation in patients with cardiac disease." The New England journal of medicine, 1792-1798.

Lacasse, Y., R. Lamontagne, et al. (2005) "Randomized trial of a smoking cessation intervention in patients hospitalized in a cardio-respiratory institute." Chest, 204s.

Lisspers, J., O. Sundin, et al. (1999). "Behavioral effects of a comprehensive, multifactorial program for lifestyle change after percutaneous transluminal coronary angioplasty: A prospective, randomized, controlled study." Journal of Psychosomatic Research **46**(2): 143-154.

Mackay, M., A. Graham, et al. (2010). "12-MONTH EVALUATION OF A SMOKING CESSATION INTERVENTION FOR HOSPITALIZED CARDIAC PATIENTS." Canadian Journal of Cardiology **26**: 166D-166D.

Maud-Christine, C. V. and S. Robichaud-Ekstrand (2005). "The effectiveness of a nursing inpatient smoking cessation program in individuals woith cardiovscular disease." Nursing Research **54**(4): 243-254.

Mohjuddin, S. M., A. N. Mooss, et al. (2006) "Intensive multicomponent smoking cessation intervention decreases mortality in hospitalized high-risk cardiac smokers." Journal of the American College of Cardiology, 375a.

Moller, A. M., T. Pedersen, et al. (2003). "Effect of smoking on early complications after elective orthopaedic surgery." Journal of Bone & Joint Surgery, British Volume **85B**(2): 178-182.

Murray, E. W. (2002). "A preoperative smoking intervention decreased postoperative complications in elective knee or hip replacement." Evidence Based Nursing **5**(3): 84-85.

Park, E. R., S. Japuntich, et al. (2011). "A smoking cessation intervention for thoracic surgery and oncology clinics: a pilot trial." Journal Of Thoracic Oncology: Official Publication Of The International Association For The Study Of Lung Cancer **6**(6): 1059-1065.

Peterson, W. (2004). "A nurse managed smoking cessation and relapse prevention programme did not reduce smoking rates at 12 months beyond rates achieved by usual care in women with cardiovascular disease." Evidence Based Nursing **7**(3): 83-84.

Reid, R. D., D. A. Aitken, et al. (2011). "Randomized trial of an automated telephone follow-up system for smoking cessation in smokers with CHD." Canadian Journal of Cardiology **27**(5 SUPPL. 1).

Richman, P. B., S. Dinowitz, et al. (2000). "The emergency department as a potential site for smoking cessation intervention: a randomized, controlled trial." Academic Emergency Medicine: Official Journal Of The Society For Academic Emergency Medicine **7**(4): 348-353.

Stainislaw, A. E. and M. E. Wewers (1994). "A SMOKING CESSATION INTERVENTION WITH HOSPITALIZED SURGICAL CANCER-PATIENTS - A PILOT-STUDY." Cancer Nursing **17**(2): 81-86.

Tan, S. T., K. Rajpal, et al. (2011). "Smoking cessation in patients undergoing treatment for head and neck cancer." The New Zealand Medical Journal **124**(1328): 130-131.

Thorndike, A. N., S. Regan, et al. (2008). "Depressive symptoms and smoking cessation after hospitalization for cardiovascular disease." Archives Of Internal Medicine **168**(2): 186-191.

Uzuner, O., I. Goldstein, et al. (2008). "Identifying patient smoking status from medical discharge records." Journal of the American Medical Informatics Association **15**(1): 14-25.

van Elderen-van Kemenade, T., S. Maes, et al. (1994). "Effects of a health education programme with telephone follow-up during cardiac rehabilitation." The British Journal Of Clinical Psychology / The British Psychological Society **33 (Pt 3)**: 367-378.

Vander Weg, M. W., R. C. Klesges, et al. (2008) "Trial design: blood pressure control and weight gain prevention in prehypertensive and hypertensive smokers: the treatment and prevention study." Contemporary clinical trials, 281-292.

Volpp, K. G., A. Gurmankin Levy, et al. (2006). "A randomized controlled trial of financial incentives for smoking cessation." Cancer Epidemiology, Biomarkers & Prevention: A Publication Of The American Association For Cancer Research, Cosponsored By The American Society Of Preventive Oncology **15**(1): 12-18.

Wolfenden, L., J. Wiggers, et al. (2008). "Pilot of a preoperative smoking cessation intervention incorporating post-discharge support from a Quitline." Health Promotion Journal Of Australia: Official Journal Of Australian Association Of Health Promotion Professionals **19**(2): 158-160.

Wolfenden, L., J. Wiggers, et al. (2005). "Increasing smoking cessation care in a preoperative clinic: a randomized controlled trial." Preventive Medicine **41**(1): 284-290.

Wong, K. W., K. Y. Wong, et al. (2005). "Effects of nurse-initiated telephone follow-up on self-efficacy among patients with chronic obstructive pulmonary disease." Journal of Advanced Nursing **49**(2): 210-222.

REFERENCES FOR INCLUDED PAPERS IN CHAPTER 2

Albrecht, S., L. Payne, et al. (1998). "A preliminary study of the use of peer support in smoking cessation programs for pregnant adolescents." Journal Of The American Academy Of Nurse Practitioners **10**(3): 119-125.

Baric, L. (1976). "A study of health education aspects of smoking in pregnancy." International Journal of Health Education **19**(2): 1-17.

Bauman KE, K. G., Dent CW, Bryan ES. (1983). "The influence of observing carbon monoxide level on cigarette smoking by public prenatal patients. ." American Journal of Public Health **73**: 1089-1091.

Belizan, J. M. (1995). "Impact of health education during pregnancy on behavior and utilization of health resources." American Journal of Obstetrics and Gynecology **173**: 894-899.

Bullock, L., K. D. Everett, et al. (2009). "Baby BEEP: A randomized controlled trial of nurses' individualized social support for poor rural pregnant smokers." Maternal And Child Health Journal **13**(3): 395-406.

Bullock LF, H. A., Duff GB, Wells JE. (1995). "Telephone support for pregnant women: outcome in late pregnancy." New Zealand Medical Journal **108**: 476-478.

Burling, A., E. Bigelow, et al. (1991). "Smoking during pregnancy: Reduction via objective assessment and directive advice." Behavior Therapy **22**(1): 31-40.

Cinciripini, Pm, et al. (2000) "An evaluation of videotaped vignettes for smoking cessation and relapse prevention during pregnancy: the very important pregnant smokers (VIPS) program." Tobacco Control, 61-63.

Coleman, T., S. Cooper, et al. (2012). "A randomized trial of nicotine-replacement therapy patches in pregnancy." The New England Journal Of Medicine **366**(9): 808-818.

Cope, G. F., P. Nayyar, et al. (2003). "Feedback from a point-of-care test for nicotine intake to reduce smoking during pregnancy." Annals Of Clinical Biochemistry **40**(Pt 6): 674-679.

de Vries, H., M. Bakker, et al. (2006). "The effects of smoking cessation counseling by midwives on Dutch pregnant women and their partners." Patient Education And Counseling **63**(1-2): 177-187.

Donatelle, R. J., S. L. Prows, et al. (2000). "Randomised controlled trial using social support and financial incentives for high risk pregnant smokers: significant other supporter (SOS) program." Tobacco Control **9 Suppl 3**: III67-III69.

Dornelas, A. (2008). "Addictions to cocaine, alcohol, or cigarettes." Psychotherapy with cardiac patients: Behavioral cardiology in practice.: 157-172.

Dornelas, E. A., J. Magnavita, et al. (2006). "Efficacy and cost-effectiveness of a clinic-based counseling intervention tested in an ethnically diverse sample of pregnant smokers." Patient Education And Counseling **64**(1-3): 342-349.

Dunkley, J. (1997). "Training midwives to help pregnant women stop smoking." Nursing Times **93**(5): 64-66.

Ershoff, D. H., V. P. Quinn, et al. (1999). "The Kaiser Permanente prenatal smoking-cessation trial: when more isn't better, what is enough?" American Journal Of Preventive Medicine **17**(3): 161-168.

Ershoff, D. H., V. P. Quinn, et al. (1995). "Relapse prevention among women who stop smoking early in pregnancy: a randomized clinical trial of a self-help intervention." American Journal Of Preventive Medicine **11**(3): 178-184.

Ershoff DH, Q. V., Mullen PD. (1989). "A randomized trial of a serialized self-help smoking cessation program for pregnant women in an HMO." American Journal of Public Health **79**(2): 182-187.

Gielen, A. C., R. Windsor, et al. (1997) "Evaluation of a smoking cessation intervention for pregnant women in an urban prenatal clinic." Health education research, 247-254.

Hajek, P., R. West, et al. (2001). "Randomized controlled trial of a midwife-delivered brief smoking cessation intervention in pregnancy." Addiction (Abingdon, England) **96**(3): 485-494.

Hannover, W., J. R. Thyrian, et al. (2008) "Smoking during pregnancy and postpartum: Smoking rates and intention to quit smoking or resume after pregnancy." Journal of Womens Health, 631-640.

Hartmann, K. E., J. M. Thorp, Jr., et al. (1996). "A randomized controlled trial of smoking cessation intervention in pregnancy in an academic clinic." Obstetrics And Gynecology **87**(4): 621-626.

Hegaard, H. K., H. Kjaergaard, et al. (2003) "Multimodal intervention raises smoking cessation rate during pregnancy." Acta obstetricia et gynecologica Scandinavica, 813-819.

Heil, S. H., S. T. Higgins, et al. (2008). "Effects of voucher-based incentives on abstinence from cigarette smoking and fetal growth among pregnant women." Addiction (Abingdon, England) **103**(6): 1009-1018.

Higgins, S. T., I. M. Bernstein, et al. (2010). "Effects of smoking cessation with voucher-based contingency management on birth outcomes." Addiction (Abingdon, England) **105**(11): 2023-2030.

Higgins, S. T., S. H. Heil, et al. (2004). "A pilot study on voucher-based incentives to promote abstinence from cigarette smoking during pregnancy and postpartum." Nicotine & Tobacco Research: Official Journal Of The Society For Research On Nicotine And Tobacco **6**(6): 1015-1020.

Hjalmarson, A. I., L. Hahn, et al. (1991). "Stopping smoking in pregnancy: effect of a self-help manual in controlled trial." British Journal Of Obstetrics And Gynaecology **98**(3): 260-264.

Hotham, E. D., A. L. Gilbert, et al. (2006). "A randomised-controlled pilot study using nicotine patches with pregnant women." Addictive Behaviors **31**(4): 641-648.

Johnson, J. L., P. A. Ratner, et al. (2000). "Preventing smoking relapse in postpartum women." Nursing Research **49**(1): 44-52.

Kapur, B., R. Hackman, et al. (2001). "Randomized, double-blind, placebo-controlled trial of nicotine replacement therapy in pregnancy." Current Therapeutic Research - Clinical and Experimental **62**(4): 274-278.

Kendrick, J. S., S. C. Zahniser, et al. (1995). "Integrating smoking cessation into routine public prenatal care: the Smoking Cessation in Pregnancy project." American Journal Of Public Health **85**(2): 217-222.

Lawrence, T., P. Aveyard, et al. (2003). "A cluster randomised controlled trial of smoking cessation in pregnant women comparing interventions based on the transtheoretical (stages of change) model to standard care." Tobacco Control **12**(2): 168-177.

Lilley J, F. D. (1986). "A randomised controlled trial of individual counselling of smokers in pregnancy." Public Health **100**: 309-315.

Loeb BK, W. G., Bailey J. (1983). "Smoking intervention in pregnancy. Proceedings of the Fifth World Conference on Smoking and Health." Winnipeg, Canada. Ottawa: Canadian Council on Smoking and Health: 389-395.

Lowe, J. B. and M. Wakefield (1998). "Smoking and pregnancy: time to implement evidence-based solutions." Australian And New Zealand Journal Of Public Health **22**(5): 523-524.

Lowe, J. B., R. Windsor, et al. (1997). "Smoking relapse prevention methods for pregnant women: a formative evaluation." American Journal Of Health Promotion: AJHP **11**(4): 244-246.

MacArthur C, K. E., Newton JR. (1987). "Effect of anti- smoking health education on infant size at birth: a randomized controlled trial." British Journal of Obstetrics and Gynaecology **94**: 295-300.

Malchodi, C. S., C. Oncken, et al. (2003). "The effects of peer counseling on smoking cessation and reduction." Obstetrics And Gynecology **101**(3): 504-510.

Mayer, J. P., B. Hawkins, et al. (1990). "A randomized evaluation of smoking cessation interventions for pregnant women at a WIC clinic." American Journal Of Public Health **80**(1): 76-78.

McBride, C. M., D. H. Baucom, et al. (2004). "Prenatal and postpartum smoking abstinence a partner-assisted approach." American Journal Of Preventive Medicine **27**(3): 232-238.

McBride, C. M., S. J. Curry, et al. (1999). "Prevention of relapse in women who quit smoking during pregnancy." American Journal Of Public Health **89**(5): 706-711.

McLeod, D., S. Pullon, et al. (2004). "Can support and education for smoking cessation and reduction be provided effectively by midwives within primary maternity care?" Midwifery **20**(1): 37-50.

Moore, L., R. Campbell, et al. (2002). "Self help smoking cessation in pregnancy: cluster randomised controlled trial." BMJ (Clinical Research Ed.) **325**(7377): 1383-1383.

Morasco, B. J., E. A. Dornelas, et al. (2006). "Spontaneous smoking cessation during pregnancy among ethnic minority women: a preliminary investigation." Addictive Behaviors **31**(2): 203-210.

O'Connor, A. M., B. L. Davies, et al. (1992). "Effectiveness of a pregnancy smoking cessation program." Journal Of Obstetric, Gynecologic, And Neonatal Nursing: JOGNN / NAACOG **21**(5): 385-392.

Oncken, C., E. Dornelas, et al. (2008). "Nicotine gum for pregnant smokers: a randomized controlled trial." Obstetrics And Gynecology **112**(4): 859-867.

Panjari, M., R. Bell, et al. (1999). "A randomized controlled trial of a smoking cessation intervention during pregnancy." The Australian & New Zealand Journal Of Obstetrics & Gynaecology **39**(3): 312-317.

Patten, C. A., R. A. Windsor, et al. (2010). "Feasibility of a tobacco cessation intervention for pregnant Alaska Native women." Nicotine & Tobacco Research: Official Journal Of The Society For Research On Nicotine And Tobacco **12**(2): 79-87.

Pbert, L., J. K. Ockene, et al. (2004) "A community health center smoking-cessation intervention for pregnant and postpartum women." American journal of preventive medicine, 377-385.

Petersen, L., J. Handel, et al. (1992). "Smoking reduction during pregnancy by a program of self-help and clinical support." Obstetrics And Gynecology **79**(6): 924-930.

Polanska K, H. W., Sobala W, Lowe JB. (2004). "Efficacy and Effectiveness of the smoking cessation program for pregnant women." International Journal of Occupational Medicine and Environmental Health **17**(3): 369-377.

Pollak, K. I., C. A. Oncken, et al. (2007) "Nicotine replacement and behavioral therapy for smoking cessation in pregnancy." American journal of preventive medicine, 297-305.

Reading AE, S. C., Cox DNB, Campbell S. (1982). "Health beliefs and health care behaviour in pregnancy." Psychological Medicine **12**: 379-383.

Reitzel, L. R., J. I. Vidrine, et al. (2010). "Preventing postpartum smoking relapse among diverse low-income women: a randomized clinical trial." Nicotine & Tobacco Research: Official Journal Of The Society For Research On Nicotine And Tobacco **12**(4): 326-335.

Rigotti, N. A., E. R. Park, et al. (2006). "Efficacy of telephone counseling for pregnant smokers: a randomized controlled trial." Obstetrics And Gynecology **108**(1): 83-92.

Secker-Walker, R. H., L. J. Solomon, et al. (1994). "Individualized smoking cessation counseling during prenatal and early postnatal care." American Journal Of Obstetrics And Gynecology **171**(5): 1347-1355.

Secker-Walker, R. H., L. J. Solomon, et al. (1995). "Smoking relapse prevention counseling during prenatal and early postnatal care." American Journal Of Preventive Medicine **11**(2): 86-93.

Secker-Walker, R. H., L. J. Solomon, et al. (1998). "Reducing smoking during pregnancy and postpartum: physician's advice supported by individual counseling." Preventive Medicine **27**(3): 422-430.

Secker-Walker, R. H., L. J. Solomon, et al. (1997). "Modeling smoking cessation: exploring the use of a videotape to help pregnant women quit smoking." Women & Health **25**(1): 23-35.

Severson, H. H., J. A. Andrews, et al. (1997). "Reducing maternal smoking and relapse: long-term evaluation of a pediatric intervention." Preventive Medicine **26**(1): 120-130.

Sexton M, H. J. (1984). "A clinical trial of change in maternal smoking and its effect on birth weight." JAMA **251**: 911-915.

Solomon, L. J., R. H. Secker-Walker, et al. (2000). "Proactive telephone peer support to help pregnant women stop smoking." Tobacco Control **9 Suppl 3**: III72-III74.

Stotts, A. L., C. C. Diclemente, et al. (2002). "One-to-one: a motivational intervention for resistant pregnant smokers." Addictive Behaviors **27**(2): 275-292.

Strecher, V. J., K. R. Bishop, et al. (2000). "Quit for keeps: tailored smoking cessation guides for pregnancy and beyond." Tobacco Control **9 Suppl 3**: III78-III79.

Tappin, D. M., M. A. Lumsden, et al. (2005). "Randomised controlled trial of home based motivational interviewing by midwives to help pregnant smokers quit or cut down." BMJ (Clinical Research Ed.) **331**(7513): 373-377.

Tappin, D. M., M. A. Lumsden, et al. (2000). "The effect of home-based motivational interviewing on the smoking behaviour of pregnant women: a pilot randomized controlled efficacy study." Ambulatory Child Health **6**: 34-36.

Thornton, L. (1997). "Smoking and pregnancy: feasibility and effectiveness of a smoking intervention programme among pregnant women [thesis]." Dublin: Dept of Public Health.

Tsoh, J. Y., M. A. Kohn, et al. (2010). "Promoting smoking cessation in pregnancy with Video Doctor plus provider cueing: a randomized trial." Acta Obstetricia Et Gynecologica Scandinavica **89**(4): 515-523.

Valbo, A. and P. Schioldborg (1994). "Smoking cessation in pregnancy: The effect of self-help manuals." Journal of Maternal-Fetal Investigation **4**(3): 167-170.

Valbo A, S. P. (1991). "Smoking cessation in pregnancy: mode of intervention and effect. ." Acta Obstetricia et Gynecologica Scandinavica **70**(309-13).

Valbo, A., D. S. Thelle, et al. (1996). "Smoking cessation in pregnancy: A multicomponent intervention study." Journal of Maternal-Fetal Investigation **6**(1): 3-8.

Van't Hof, S. M., M. A. Wall, et al. (2000) "Randomised controlled trial of a postpartum relapse prevention intervention." Tobacco control, Iii64-66.

Wall, M. A., H. H. Severson, et al. (1995). "Pediatric office-based smoking intervention: impact on maternal smoking and relapse." Pediatrics **96**(4 Pt 1): 622-628.

Walsh, R. A., S. Redman, et al. (1997). "A smoking cessation program at a public antenatal clinic." American Journal Of Public Health **87**(7): 1201-1204.

Windsor, R. A. (2000). "Counselling smokers in Medicaid maternity care: the SCRIPT project." Tobacco Control **9 Suppl 1**: I62-I62.

Windsor, R. A., C. Q. Li, et al. (1993). "The dissemination of smoking cessation methods for pregnant women: achieving the year 2000 objectives." American Journal Of Public Health **83**(2): 173-178.

Windsor RA, S. D., Samuelsson C, Bartlett EE, Manzella B, Reese Y, et al. (1985). "The effectiveness of smoking cessation methods for smokers in public health maternity clinics: a randomized trial." American Journal of Public Health **75**: 1389-1392.

Winickoff, J. P., E. A. Healey, et al. (2010). "Using the postpartum hospital stay to address mothers' and fathers' smoking: the NEWS study." Pediatrics **125**(3): 518-525.

Wisborg, K., T. B. Henriksen, et al. (2000). "Nicotine patches for pregnant smokers: a randomized controlled study." Obstetrics And Gynecology **96**(6): 967-971.

REFERENCES FOR EXCLUDED PAPERS IN CHAPTER 2

(1997). "Smoking cessation program focuses on pregnant women." Healthcare Demand & Disease Management **3**(11): 169-173.

Albrecht, S. A., D. Caruthers, et al. (2006). "A randomized controlled trial of a smoking cessation intervention for pregnant adolescents." Nursing Research **55**(6): 402-410.

Atkinson, E., L. Hotham, et al. (2003) "Nicotine replacement therapy as an adjunct to smoking cessation counselling in pregnancy - a randomised study to evaluate efficacy in an antenatal clinic setting." Australian and New Zealand Journal of Obstetrics and Gynaecology, 175-187.

Bauman KE, K. G., Dent CW, Bryan ES. (1983). "The influence of observing carbon monoxide level on cigarette smoking by public prenatal patients. ." American Journal of Public Health **73**: 1089-1091.

Byrd, J. C. and C. D. Meade (1993). "Smoking cessation among pregnant women in an urban setting." Wisconsin Medical Journal **92**(11): 609-612.

Campbell, E., R. A. Walsh, et al. (2006). "A group randomised trial of two methods for disseminating a smoking cessation programme to public antenatal clinics: effects on patient outcomes." Tobacco Control **15**(2): 97-102.

Chen-Louie, T. (1993). "[Commentary on] Health education for pregnant smokers: its behavioral impact and cost benefit. Windsor RA, Lowe JB, Perkins LL et al. AM J PUBLIC HEALTH 1993;83(2):201-6." AWHONN's Women's Health Nursing Scan **7**(4): 12-13.

de Weerd, S., C. M. Thomas, et al. (2001). "Maternal smoking cessation intervention: targeting women and their partners before pregnancy." American Journal Of Public Health **91**(11): 1733-1734.

Donovan, J. W. (1996) "Randomised controlled trial of anti-smoking advice in pregnancy: 20 years on." Journal of Epidemiology and Community Health, 237-238.

Donovan, J. W. (1996). "Randomised controlled trial of anti-smoking advice in pregnancy. 1977." Journal Of Epidemiology And Community Health **50**(3): 232-236.

Edwards, N. and N. Sims-Jones (1998). "Smoking and smoking relapse during pregnancy and postpartum: results of a qualitative study." Birth (Berkeley, Calif.) **25**(2): 94-100.

El-Mohandes, A., M. El-Khorazaty, et al. (2011). "Smoking Cessation and Relapse Among Pregnant African-American Smokers in Washington, DC." Maternal & Child Health Journal **15**: 96-106.

Gadomski, A., L. Adams, et al. (2011). "Effectiveness of a combined prenatal and postpartum smoking cessation program." Maternal And Child Health Journal **15**(2): 188-197.

Groner, J. A., K. Ahijevych, et al. (2000). "The impact of a brief intervention on maternal smoking behavior." Pediatrics **105**(1 Pt 3): 267-271.

Haddow, J. E., G. J. Knight, et al. (1991). "Cotinine-assisted intervention in pregnancy to reduce smoking and low birthweight delivery." British Journal Of Obstetrics And Gynaecology **98**(9): 859-865.

Health Technology, A. (2010) "A pragmatic randomized controlled trial of physical activity as an aid to smoking cessation during pregnancy (Project record)." Health Technology Assessment.

Hennrikus, D., P. Pirie, et al. (2010). "Increasing support for smoking cessation during pregnancy and postpartum: results of a randomized controlled pilot study." Preventive Medicine **50**(3): 134-137.

Hughes, E. G., D. A. Lamont, et al. (2000). "Randomized trial of a "stage-of-change" oriented smoking cessation intervention in infertile and pregnant women." Fertility And Sterility **74**(3): 498-503.

Jehn, L., N. Lokker, et al. (2003). "First Breath prenatal smoking cessation pilot study: preliminary findings." WMJ: Official Publication Of The State Medical Society Of Wisconsin **102**(3): 29-34.

Kendzor, D. E., M. S. Businelle, et al. (2010). "Breast feeding is associated with postpartum smoking abstinence among women who quit smoking due to pregnancy." Nicotine & Tobacco Research: Official Journal Of The Society For Research On Nicotine And Tobacco **12**(10): 983-988.

Lemola, S. and A. Grob (2008). "Smoking cessation during pregnancy and relapse after childbirth: the impact of the grandmother's smoking status." Maternal And Child Health Journal **12**(4): 525-533.

Lillington, L., J. Royce, et al. (1995). "Evaluation of a smoking cessation program for pregnant minority women." Cancer Practice **3**(3): 157-163.

Lowe, J. B., K. P. Balanda, et al. (2002). "Dissemination of an efficacious antenatal smoking cessation program in public hospitals in Australia: a randomised controlled trial." Health Education & Behavior **29**(5): 608-620.

Pollak, K. I., C. M. McBride, et al. (2001). "Women's perceived and partners' reported support for smoking cessation during pregnancy." Annals Of Behavioral Medicine: A Publication Of The Society Of Behavioral Medicine **23**(3): 208-214.

Roske, K., W. Hannover, et al. (2009). "Smoking Cessation Counselling for Pregnant and Postpartum Women among Midwives, Gynaecologists and Paediatricians in Germany." International Journal of Environmental Research and Public Health **6**(1): 96-107.

Ruggiero, L., C. A. Redding, et al. (1997). "A stage-matched smoking cessation program for pregnant smokers." American Journal of Health Promotion **12**(1): 31-34.

Sheahan, S. L. and S. M. Wilson (1997). "Smoking cessation for pregnant women and their partners: a pilot study." Journal Of The American Academy Of Nurse Practitioners **9**(7): 323-326.

Stanton, W. R., J. B. Lowe, et al. (2004). "Randomised control trial of a smoking cessation intervention directed at men whose partners are pregnant." Preventive Medicine **38**(1): 6-9.

Valanis, B., E. Lichtenstein, et al. (2001). "Maternal smoking cessation and relapse prevention during health care visits." American Journal Of Preventive Medicine **20**(1): 1-8.

Windsor, R. A. (2000). "Counselling smokers in Medicaid maternity care: the SCRIPT project." Tobacco Control **9 Suppl 1**: I62-I62.

Yilmaz, G., C. Karacan, et al. (2006) "Brief intervention on maternal smoking: a randomized controlled trial." Child: care, health and development, 73-79.

ADDITIONAL REFERENCES

Dolan-Mullen, P., G. Ramirez, et al. (1994). "A meta-analysis of randomized trials of prenatal smoking cessation interventions." American Journal Of Obstetrics And Gynecology **171**(5): 1328-1334.

Hajek, P., L. F. Stead, et al. (2005). "Relapse prevention interventions for smoking cessation." Cochrane Database Of Systematic Reviews (Online)(1): CD003999.

Kelley, K., R. Bond, et al. (2001). "Effective approaches to persuading pregnant women to quit smoking: a meta-analysis of intervention evaluation studies." British Journal Of Health Psychology **6**(Pt 3): 207-228.

Lumley, J., C. Chamberlain, et al. (2009). "Interventions for promoting smoking cessation during pregnancy." Cochrane Database Of Systematic Reviews (Online)(3): CD001055.

Lumley, J., S. Oliver, et al. (2000). "Interventions for promoting smoking cessation during pregnancy." Cochrane Database Of Systematic Reviews (Online)(2): CD001055.

Melvin, C. L., P. Dolan-Mullen, et al. (2000). "Recommended cessation counselling for pregnant women who smoke: a review of the evidence." Tobacco Control **9 Suppl 3**: III80-III84.

Mullen, P. D., I. Pollak, et al. (1999). "Success attributions for stopping smoking during pregnancy, self-efficacy, and postpartum maintenance." Psychology of Addictive Behaviors **13**(3): 198-206.

Myers (2009). "Rapid review of interventions to prevent relapse in pregnant ex-smokers. Report to National Institute for Health and Clinical Excellence." NICE.

Naughton, F., A. T. Prevost, et al. (2008). "Self-help smoking cessation interventions in pregnancy: a systematic review and meta-analysis." Addiction (Abingdon, England) **103**(4): 566-579.

Taylor, T. H., P. (2001). "Smoking cessation services for pregnant women. Survey of English health Authorities." Report to Health Development Agency and Department of Health.

Windsor, R. A., N. R. Boyd, et al. (1998). "A meta-evaluation of smoking cessation intervention research among pregnant women: improving the science and art." Health Education Research **13**(3): 419-438.

Appendices

APPENDIX 1: REVIEW PROTOCOL FOR REVIEWS 2 & 3

Overview of project

The National Institute for Health and Clinical Excellence (NICE) has been asked by the Department of Health to develop two separate pieces of complementary guidance on:

- 'Smoking cessation in secondary care: acute and maternity services'
- 'Smoking cessation in secondary care: mental health services'.

The guidance will address smokefree policies and smoking cessation and make recommendations on approaches to help secondary care commissioners, professionals and managers (including patients and service users and their family or carers, visitors and staff) in hospitals and other acute, maternity or mental healthcare settings (including emergency care, planned specialist medical care or surgery, and maternity care provided in hospitals, outpatient clinics, community outreach and rural units, as well as intensive services in psychiatric units and secure hospitals).

There are five components of work associated with the guidance development:

1. Smoking cessation in acute and obstetric services: one review of effectiveness and one review of barriers and facilitators (reviews 2 & 3).
2. Smoking cessation in mental health services: one review of effectiveness and one review of barriers and facilitators (reviews 4 & 5).
3. Smokefree strategies and interventions in secondary care settings: one review of effectiveness and one review of barriers and facilitators (reviews 6 & 7).
4. An economic analysis (cost effectiveness review and economic model)
5. Review of effects of nicotine in secondary care (review 1)

The CPHE has commissioned the National Centre for Smoking Cessation and Training (NCSCT) to deliver four of these components (1,2,3 and 5).

This review protocol sets out the process for Component One - Smoking cessation in acute and maternity services: one review of effectiveness (review 2) and one review of barriers and facilitators (review 3).

The aim of these reviews is to answer key questions as set out in the final scope document for the guidance on 'Smoking cessation in secondary care: acute and maternity services'.

The Review Team

This review will be led by Miss Katie Myers. She has led a NICE review of Relapse Prevention Interventions in Pregnancy[1] and was the lead author on the Pre-operative Smoking Cessation

systematic review[2]. Ms Myers has experience in searching literature for systematic reviews and project management. Professor Hajek will lead on the writing of the review. He has a long history of working with NICE and extensive experience in systematic reviews[1-6]. Dr McRobbie will assist the Project Team with literature screening and quality appraisal. He has led on a NICE systematic review (see McRobbie et al 2006[3]) and is an author of two Cochrane Systematic Reviews[7 8] and another recent systematic review[2]. Dr McRobbie was also a lead author of the literature review for the New Zealand Smoking Cessation Guidelines[9].

Mr Nigel Chee will provide expert project management support to the Project Team given the tight timeframes for this Component. He is an experienced manager with experience in managing large and complex health research, strategy, policy and implementation projects. He is also a co-author of the Clinical Guidelines for Weight Management in New Zealand Adults and the Clinical Guidelines for Weight Management in New Zealand Children[10]. He will primarily focus on driving the process for the project to ensure timelines are met and will also manage the relationships between the key stakeholders (including the Project Team, Independent Information Specialist, collaborators, NCSCTC CIC and NICE).

Independent Information Specialist

In addition to the skills and experience of the Project Team an independent information specialist (Ms Claire Stansfield) from the Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre) will provide advice on the search strategy and the approach to undertaking the literature search. Ms. Stansfield has extensive expertise in methods for identifying research for systematic reviews, is familiar with the syntax requirements of the databases used in NICE systematic reviews, and is a member of the Cochrane Collaboration's Information Retrieval Methods Group.

Collaborators

This review will also involve several other collaborators (listed below) who are leading components 2 and 3. The rationale for involving these wider collaborators is that we believe there are significant overlaps between the four components. Although each component "stands alone", we believe that working as a broader collective team will enable synergies across the work to be completed. The wider team is multi-disciplinary consisting of health and clinical psychologists, clinicians, research nurses, epidemiologists and medical statisticians and covers a wide range of specialist technical expertise including mental health care, secondary care and tobacco control research.

- Professor Ann McNeill (University of Nottingham);
- Dr Jo Leonardi-Bee (University of Nottingham);
- Dr Rachael Murray (University of Nottingham);
- Dr Elena Ratschen (University of Nottingham);
- Professor Sarah Lewis (University of Nottingham);
- Ms Kathryn Angus (University of Stirling); and
- Mr Douglas Eadie (University of Stirling).

The review process

This review will involve the following steps, which are described further within this protocol.

1) Searching and retrieval of relevant evidence/studies as outlined in the search protocol and strategy (see Appendix 1)
2) Selecting relevant evidence/studies using appropriate title/abstract screening checklists (see Appendix 2). Titles/abstracts will be screened independently by two reviewers.
3) Retrieval of full papers assessed to be potentially relevant following title/abstract screening.
4) Full papers will be screened independently by two reviewers and quality assessed using the NICE quality appraisal checklists (see Appendices 4-6).
5) Data will be extracted from each paper and entered into data extraction tables (see Appendices 7 & 8).
6) Data will be collated and presented in evidence tables, narrative summaries, summary tables, graphical presentation, and meta-analysis where appropriate. Sensitivity analyses related to inequality measures will be carried out, where possible.
7) Evidence statements and applicability statements will be formulated.

Project deliverables

Review 2

At the completion of this process the review team will:

1 Submit a **1st draft of the review** to the NICE Team by 16 March 2012
2 Undertake any amendments to the draft following NICE comments and provide a revised draft (**2nd draft**) by 9 April 2012
3 Present the review findings to the PDG meeting on 25 April 2012
4 Undertake any amendments to the reviews following comment from the PDG and summit a **3rd draft by** 8 May 2012
5 Provision of written contributions and technical support during and after the completion of the reviews, as required during the development of the public health programme guidance. This will include:
   - Supporting the NICE Team in responding to any stakeholder comments on the reviews during the consultation on the evidence and draft guidance (consultation is currently planned for April to July 2013).
   - Attendance at PDG meetings as required (dates for these meetings are outlined in Annex 2).
6 Submit the **final review** following public consultation, by 31 July 2013

Review 3

At the completion of this process the review team will:

7 Submit a **1st draft of the review** to the NICE Team by 4 May 2012
8 Undertake any amendments to the draft following NICE comments and provide a revised draft (**2nd draft**) by 28 May 2012
9 Present the review findings to the PDG meeting on 13 June 2012
10 Undertake any amendments to the reviews following comment from the PDG and summit a **3rd draft by** 25 June 2012

11 Provision of written contributions and technical support during and after the completion of the reviews, as required during the development of the public health programme guidance. This will include:
   - Supporting the NICE Team in responding to any stakeholder comments on the reviews during the consultation on the evidence and draft guidance (consultation is currently planned for April to July 2013).
   - Attendance at PDG meetings as required (dates for these meetings are outlined in Annex 2).
12 Submit the **final review** following public consultation, by 31 July 2013

Background

Hospitalisation provides a unique opportunity for people to stop smoking. Smokers who are admitted to hospital are often highly motivated to quit and the hospital setting provides a potentially supportive environment to do so. Hospitals are smokefree environments and admission brings people into direct contact with healthcare professionals who can advise on giving up smoking and offer evidence-based treatment.

Smoking cessation counselling delivered in an acute hospital setting, combined with follow-up support on discharge, seems to increase smoking cessation rates[11]. There are also data from systematic reviews to show that intensive smoking cessation interventions provided to pregnant women who smoke and delivered to people awaiting surgery can be effective in increasing long-term cessation rates.[1](Lumley et al., 2009; Moller & Villebro, 2009) However, this opportunity is often missed. Abstaining from smoking often results in a tobacco withdrawal syndrome (TWS) that comprises of a number of changes such as mood alterations, physical symptoms and signs, as well as biochemical and physiological changes.[1](Hughes, 2007) Not all smokers who are hospitalised will experience TWS but for those who do these symptoms can be managed. Current pharmacotherapies for smoking cessation, in particular fast acting nicotine replacement therapy (NRT) products, can be effective in alleviating tobacco withdrawal symptoms[1(West & Shiffman, 2001)] and could be offered to assist patients to abstain during their hospital stay.

There seems to be a number of barriers to providing help to smokers in secondary care. For instance there is a widespread concern that stopping smoking shortly before surgery may have negative effects on surgery outcomes, hospital electronic records are often inflexible and make recording of patient smoking status difficult, staff do not see addressing smoking as a part of their core duties,. There is a need to systematically review not just the efficacy of stop smoking interventions, which are usually evaluated in a somewhat rarified research setting but also the barriers and facilitators of stop smoking activities in acute and maternity settings. There is a scope to systematically increase referrals and access to smoking cessation services across both acute and maternity hospital settings, which such a review could facilitate.

Aim

The review aims to address the research questions set out below.

Scope

Groups that will be covered

The review will include evidence from smokers of all ages who use acute and maternity services, including those who are in the process of being referred to hospital and those who have recently been discharged. The review will all also capture:

- People who live in the same household as someone who is using acute and maternity services, such as partners, parents and other family members and carers
- visitors to acute and maternity care settings
- staff working in acute or maternity care settings, in particular, those who have direct contact with people using the services (this includes support staff, volunteers, those working for agencies or as locums and people employed by contractors)

This review will not consider the following populations:

- users of primary care services;
- users of mental health services; and
- staff working in, and visitors to, secondary care mental health settings.

Activities / interventions that will be covered

This review will address the effectiveness and barriers and facilitators of smoking cessation interventions in acute and maternity services. This will include:

- Interventions that help the populations of interest stop smoking
- Interventions that help populations of interest temporarily abstain

Activities / interventions that will not be covered

This review will not consider evidence relating to cut down to quit programmes in acute and maternity care settings. It will also not consider evidence relating to interventions aimed at staff to improve identification and referral of smokers.

These reviews will not consider evidence relating to smoking cessation and temporary abstinence interventions in users of primary care services, mental health services and staff working in, and visitors to, secondary care mental health services.

PICO table to summarise the review scope

Population
The review will include evidence from smokers of all ages who use acute and maternity services, including those who are in the process of being referred to hospital and those who have recently been discharged. The review will all also capture any literature on: • People who live in the same household as someone who is using acute and maternity services, such as partners, parents and other family members and carers • visitors to acute and maternity care settings • staff working in acute or maternity care settings, in particular, those who have direct

contact with people using the services (this includes support staff, volunteers, those working for agencies or as locums and people employed by contractors)

Intervention/Activity

This review will address the effectiveness and barriers and facilitators of smoking cessation interventions in acute and maternity services. This will include

- Interventions that help people stop smoking
- Interventions that help people temporarily abstain

Comparison

Data comparing pharmacological interventions with placebo or control procedures including no intervention, usual practice, or which compares two or more intervention types.

Data comparing behavioural interventions including face-to-face, self-help, telephone and internet interventions with control procedures

Data comparing other treatments (e.g. alternative medicine) with control procedures

The above comparisons will cover all studies concerning smoking cessation and temporary abstinence.

Data providing information on barriers and facilitators to smoking cessation in hospital and maternity service settings

Outcomes

Review 2

The following factors and outcomes will be considered in review 2:

- the effectiveness of smoking cessation interventions in acute and maternity service settings
- the effectiveness of temporary abstinence interventions in acute and maternity service settings

The key outcomes will include Russell Standard abstinence rates (continuous validated long-term abstinence rates based on ITT analysis). Where such strict outcomes are not available, other measures of outcome will be taken into account (e.g. point-prevalence short term un-validated abstinence rates). Other outcomes will include use and uptake of stop-smoking services and medications, and adverse events.

Review 3

The following factors and outcomes will be considered in review 3:

- How can community, primary, acute and maternity care providers collaborate more effectively to provide joined up services for smoking cessation in terms of post-discharge care, sharing information on patients smoking status, advice and help

provided, treatment outcomes, and in using referral pathways to specialist treatment?
- What barriers and facilitators affect the delivery of effective interventions identified in review 2 from multiple perspectives?

Research questions

This review will attempt to answer the following six questions:

Question 1: How effective are smoking cessation interventions in helping people from the populations of interest?

Question 2: How effective are interventions for temporary abstinence in helping people from the populations of interest?

Question 3: How effective are the current approaches used by maternity care services to identify and refer smokers to stop-smoking services?

Question 4: How effective are the current approaches used by maternity care services to provide smokers with smoking cessation information, advice and support?

Question 5: How can community, primary, acute and maternity care providers collaborate more effectively to provide joined up services for smoking cessation?

Question 6: What barriers and facilitators affect the delivery of effective interventions?

Literature search protocol

Aims

The aim of the literature search is to identify evidence on the effectiveness and barriers and facilitators of smoking cessation interventions in acute and maternity services in the population of interest (see section 4.1 for further details).

Search approach

Review 2

This review will use a systematic approach to identify literature of the highest quality available that provides information on:

a) the effectiveness of smoking cessation interventions in acute and maternity service settings

b) the effectiveness of temporary abstinence interventions in acute and maternity service settings

c) the effectiveness of current approaches used by maternity care services to identify and refer people to stop-smoking services, for example provided by public or private providers

d) the effectiveness of current approaches used by maternity care services to identify and provide smoking cessation information, advice and support, for example by a nurse or physician

e) the effective approaches to encourage maternity care professionals to record smoking status and refer to stop-smoking services

The review will also focus on literature that provides information on:

- how the effectiveness of interventions vary between different service users (including their family or people they live with), visitors and people that work in acute and maternity services and if they are more effective in combination
- deliverer, setting, timing, frequency duration and severity of dependence has on the impact and effectiveness of the intervention
- adverse events reported from smoking cessation and temporary abstinence interventions

Review 3

This review will use a systematic approach to identify literature that provides information on:

1. How can community, primary, acute and maternity care providers collaborate more effectively to provide joined up services for smoking cessation, cessation in terms of sharing information on patient smoking status, advice and help provided, treatment outcomes, and in using referral pathways to specialist treatment?

2. What barriers and facilitators affect the delivery of effective interventions, for example the interventions identified in review 2?

The review will also focus on literature that provides information on:

- the views (knowledge, attitude, beliefs) of different population groups and service providers
- deliverer, setting, timing, frequency duration and severity of dependence has on the acceptability of the intervention
- adverse events reported from smoking cessation and temporary abstinence interventions

These reviews will not consider evidence relating to smoking cessation and temporary abstinence interventions in users of primary care services, mental health services and staff working in, and visitors to, secondary care mental health services. If a study concerns both primary and secondary care, evidence relevant to the search questions would be included.

Search questions

1: How effective are smoking cessation interventions in helping people from the populations of interest?

2: How effective are interventions for temporary abstinence in helping people from the populations of interest?

3: How effective are the current approaches used by maternity care services to identify and refer smokers to stop-smoking services?

4: How effective are the current approaches used by maternity care services to provide smokers with smoking cessation information, advice and support?

5: What are the barriers and facilitators to Joined up working / collaboration within or across settings, for example between primary and secondary care?

6: What barriers and facilitators affect the delivery of effective interventions?

Developing the search strategy

The main search strategy has been developed to capture the following:

(1) Review population and setting

The following search terms will be used

Patient admission/; hospitalization/; outpatients/ inpatients/; child, hospitalized/; adolescent, hospitalized/; Pregnant women/; patients/; patient#; (pregnant NS teens; teenager#; adolescent#; women; mothers); inpatient#, outpatient#; “out patients” inhospital; (day N2 patient#); ill patients; acutely ill; primip*; primigravid*; (patient# N2 surgery; operation; discharge#; readmission#; postdischarge#; emergency; emergencies; refer; refers; referral; referring; admit; admittance#; admitting; admission#; readmittance; readmitting; readmission#; postoperable; postoperative; admit; admits); maternity; maternal health; obstetrics; prenatal care; (“prenantal; antenatal; perinatal; obstetric; maternal AND service; services; clinic; clinics; health; healthcare”); hospitalised; hospitalized; secondary care; acute care; secondary health service; secondary health services; acute health service; acute health services; acute setting; acute settings; acute service; acute services; (acute; general; stay; staying W2 ward; wards); (accident; emergency; surgical; surgery; acute W unit; department); hospitals; hospital; (patient# N2 “post discharge”; maternal health services/; obstetric and gynecology department, hospital/; obstetrics/; hospitals+/; hospital units/; outpatient clinics, hospital/; emergency service, hospital; emergency medical services/; hospital staff/personnel/ W1 worker#; surgeon#; gyne#cologist#; obstetrician#; midwiv#; midwife; doctor#; nurse#; physician#; clinician#; pharmacist#; health W1 worker#; consultant#; medical W1 specialist#; medical W1 officer#

(2) Tobacco use

Tobacco use cessation/; Tobacco use disorder/; Tobacco, smokeless/; Smoking cessation/; Smoking/; Tobacco/; Tobacco; cigar*; "hand-roll"; handroll*; "hand-rolls"; "hand-rolled"; bidi; bidis; beedi; beedis; rolie; rolies; paan; gutkha; snuff; betel; cigar; cigars

(3) Smoking cessation

quit*; abstain*; abstinence; reduction; restrict*; reduce; cessation; (smoking; smoker#; tobacco; cigarette; cigarettes N2 quit; quitting; quitted; abstain; abstinence; reduction; reduces; reduce; abstaining); (tobacco; smoking; ADJ control); smoking services; smoking service; anti smoking; anti tobacco; temporary abstinence; (quit, abstain, abstinence, reduction, reduce, abstaining, ADJ2 tobacco, smoking, cigarette); (smoking, tobacco, cigarette#, smoker# N2 prevent; prevention; preventing; prevents; restrict#; restrict; restriction; restricted; restricts; restricting).

(4) Collaborative working

The following terms will be used to capture relevant literature on collaborative and joined up working in acute and maternity settings:

partnership# ; "team work" ; "teamwork"; teamworking; "team working"; cooperation; (cooperative W1 behavio#r); "integration"; "integrative approach"; "integrative approaches"; collaborat*; interagenc*; multiagenc*; "inter-institutional"; "inter-institutionally"; "inter-professional"; "inter-departmental"; "inter-departmentally"; interinstitutional*; interprofessional; interdepartmental*; "interprofessional relations"; "interprofessional relationships"; (multidisciplin*); "cross discipline"; "cross disciplinary"; (interagency); linkage#; "cross-discipline"; "cross-disciplinary".

Search strategy

The search strategy for Medline is shown in Appendix 1.

A systematic search of the grey literature will not be undertaken but hand searching of bibliographies of systematic reviews the meet the inclusion criteria will be carried out to ensure that relevant data are included in this review.

To supplement the search for evidence NICE may issue a call for evidence from registered stakeholders. Relevant evidence will be included in this review

Equality and Diversity

The search strategy will be inclusive and aims to capture a broad range of evidence across all ethnic and disadvantaged groups.

Electronic resources

Databases

The following list includes the electronic databases that will be searched

- AMED (Allied and Complementary Medicine)
- ASSIA (Applied Social Science Index and Abstracts)
- British Nursing Index
- CINAHL (Cumulative Index of Nursing and Allied Health Literature)
- Cochrane Central Register of Controlled Trials
- Cochrane Database of Systematic Reviews
- Database of Abstracts of Reviews of Effectiveness (DARE; 'other reviews' and Health Technology Assesment (HTA) database in CRD database)

- Current Contents
- EMBASE
- EPPI Centre TRoPHI
- HMIC (or King's Fund catalogue and DH data)
- Medline
- UK Clinical Research Network Portfolio Database
- PsycINFO
- Sociological Abstracts
- Social Policy and Practice
- Web of Knowledge (Science and Social Science Citation Indexes)
- CDC Smoking & Health Resource Library database
- Specialist (public health) systematic review registers
    - EPPI Centre DoPHER
    - Health Evidence ca

Websites

A minimum of 10 Internet sites will be searched from the following:

- Smoke free http://smokefree.nhs.uk
- NHS Centre for Smoking Cessation and Training http://www.ncsct.co.uk/,
- Action on Smoking and Health (ASH) http://www.ash.org.uk
- Treat tobacco.net http://www.treatobacco.net/en/index.php
- Society for Research on Nicotine and Tobacco http://www.srnt.org
- International Union against Cancer http://www.uicc.org
- WHO Tobacco Free Initiative (TIF) http://www.who.int/tobacco/en
- International Tobacco Control Policy Evaluation Project http://www.itcproject.org
- Tobacco Harm Reduction http://www.tobaccoharmreduction.org/index.htm
- Current controlled trials www.controlled-trials.com
- Association for the treatment of tobacco use and dependence (ATTUD) www.attud.org
- National Institute on drug abuse- the science of drug abuse and addiction http://www.nida.nih.gov/nidahome.html
- NICE
- Public health observatories
- Scottish Government
- Welsh Assembly Government
- NHS Evidence
- Joseph Rowntree Foundation
- The Centre for Tobacco Control Research (University of Stirling)
- UK Centre for Tobacco Control Studies
- Tobacco Control Research Group (University of Bath)
- http://www.controlled–trials.com

Restrictions

The following inclusion and exclusion criteria will be applied to the searches.

Inclusion Criteria

The following will be included:

Review 2:

- Systematic reviews
- Controlled studies published from 1990 to the most recent available at the time of the search

Review 3:

- All relevant experimental, observational and qualitative studies
- Descriptive reports

Exclusion Criteria

The following will be excluded:

- Animal studies
- Studies that do not primarily address the review questions; and
- Studies not published in English

Gathering the evidence.

The search strategy will be translated for use, and then run on each of the various databases and websites.

Documenting the search process

At the completing of searching each database the following steps will be undertaken:

1. Results from the database searches will be downloaded into 'Endnote'. Items which cannot be downloaded into bibliographic software will be recorded in a Word document
2. A word document containing the search strategies for each resource searched will be created. Each strategy will include audit information, as shown in appendix 2.
3. A final de-duplicated 'Reference manager database'.

Reference details for any studies which may be of relevance to the contractors who will be undertaking, component 2 (Mental Health reviews), component 3 (smokefree reviews) component 4 (Cost effectiveness review and economic analysis) or component 5 (nicotine review) will be recorded in EndNote and provided to the NICE Team to pass these files onto the relevant contractors.

Reviewing the evidence

Reviewing of the scientific evidence will involve the following five steps:

1) Select the relevant evidence.
2) Assess its quality.
3) Extract, synthesise and present it.
4) Derive evidence statements.
5) Assess its applicability.

Studies will be selected on the basis of relevance to the scope of this review and consideration will given to:

- Relevance to the PICO table described above
- The hierarchy of evidence
- Availability of evidence – if high quality evidence is not available then we will use the best available evidence.

Selecting the relevant evidence

Title/ abstract screening

All titles and abstracts obtained from the search will be independently screened by members of our Project Team; using a screening checklist (a sample screening checklist is outlined in Appendix 3). Where there is disagreement the full paper will be obtained and resolved by discussion. .

The following studies will be considered:

- Quantitative studies (both experimental and observational studies);
- Qualitative studies;
- Systematic reviews; and
- Information that addresses the review questions.

Full-paper screening

Full papers will be obtained for those abstracts that meet the criteria for inclusion and will be independently screened for inclusion by members of the project team. Any disagreement will be resolved via discussion. The composite inter-rater reliability scores will be reported and the selection process will be summarised in a flow diagram. Each study excluded at the full-paper screening stage will be listed in the appendix of the review, along with the reason for its exclusion.

Assessment of study quality

The internal and external validity of studies will be assessed using quality appraisal checklists provided in appendix 4.

Each paper will be graded using the rating scale summarised below. Quality of this process will be assessed by appraising 10% of papers by a second appraiser to check accuracy. Any disagreement will be resolved by a third appraiser. The composite inter-rater reliability scores will be reported. This approach was utilised in previous NICE systematic reviews completed by members of this review team.(McRobbie, Hajek, Bullen, & Feigen, 2006; Myers, West, & Hajek, 2009)

Internal validity

The review team will use the checklists to ascertain if potential sources of bias have been minimised and to determine if its conclusions are open to any degree of doubt. Each study should be rated ('++', '+' or '-') to indicate its quality, where:

- ++ All or most of the checklist criteria have been fulfilled; where they have not been fulfilled the conclusions are very unlikely to alter.
- \+ Some of the checklist criteria have been fulfilled, where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter.
- – Few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter.

The reasons for the quality rating will be documented in the appraisal checklist.

External validity

The external validity of studies will be assessed by determining the extent to which the findings for the study population are generalisable to the whole 'source population'. A rating of EV++, EV+, or EV- will be applied to indicate the degree of quality.

Data extraction and synthesis

Data extraction

A narrative summary and evidence table will be completed for each selected study. Data will be extracted into the evidence tables and will document data regarding the: population; intervention (e.g. use of nicotine replacement products); and outcomes. The template that will be used for the evidence table is shown in Appendix 6, and is based on the recommendations of the NICE CPHE Methods Manual.[16] For quantitative studies exact p-values (whether or not significant) and confidence Intervals, where available, will be reported. Separate evidence tables will be produced to summarise the evidence related to each review question.

For qualitative data, analysis of the themes will be presented in the evidence tables along with a brief narrative of the paper – See Appendix 7.

Data synthesis

Findings from the review will be grouped into sections that will answer each review question. Subsections will be created to summarise data related to particular sub-topics. Evidence statements will be provided for each subsection.

Where data allows, meta-analyses will be undertaken.

Qualitative data will be themed and summarised. The main topics are likely to concern setting up systems for identification and referral of pregnant smokers, setting up systems for

treatment in both pregnancy and secondary care, and issues concerning follow-up/post discharge care.

Meta-analyses

Meta-analyses will be conducted using RevMan software. A fixed effect model will be used, except in situations where there is statistical heterogeneity where a random effects model will be used. Forest plots will be presented for all meta-analyses.

Narrative summaries

The key findings of evidence will be summarised in concise narrative summaries that relate to particular sub-topics.

Evidence statments

The proposed evidence statements to be used in this evidence review will follow NICE recommendations. Statements will contain a descriptor, strength, and direction (positive or negative) of the evidence. Quality ratings of studies will be used to formulate the strength. The overall strength will be summarised using the following:

- No evidence
- Weak evidence
- Moderate evidence
- Strong evidence

Evidence statements will also be developed from qualitative data. These will summarise the quality, context and key findings, and state the degree of concurrence between studies.

Applicability statements

The degree of applicability of the evidence, summarised in each evidence statement in this review, to the UK setting will be assessed. For each study included the reviewers will assess characteristics of the population, setting, intervention and outcomes studied. An applicability statement, showing the applicability of the evidence to the UK setting will be formulated and presented after each evidence statement using the following terms:

- directly applicable
- partially applicable
- not applicable.

Issues related to Inequalities

Any issues related to inequalities that appear in the literature will be flagged and summarised in a separate section of the final report.

References

Hughes, J. R. (2007). Effects of abstinence from tobacco: valid symptoms and time course. *Nicotine Tob Res, 9*(3), 315-327.

Lumley, J., Chamberlain, C., Dowswell, T., Oliver, S., Oakley, L., & Watson, L. (2009). Interventions for promoting smoking cessation during pregnancy. *Cochrane Database Syst Rev*(3), CD001055.

McRobbie, H., Hajek, P., Bullen, C., & Feigen, V. (2006). Rapid review of non-NHS treatments for smoking cessation Retrieved 6 Oct 2011 http://www.nice.org.uk/nicemedia/pdf/SmokingCessationNon-NHSFullReview.pdf

Moller, A., & Villebro, N. (2009). Interventions for preoperative smoking cessation. *Cochrane Database Syst Rev*(3).

Myers, K., West, O., & Hajek, P. (2009). A rapid review of interventions to prevent relapse in pregnant ex-smokers: A report to the National Institute for Health and Clinical Excellence. London.

Pollak, I., & Mullen, P. D. (1997). An exploration of the effects of partner smoking, type of social support, and stress on postpartum smoking in married women who stopped smoking during pregnancy. *Psychology of Addictive Behaviors, 11*(3), 182-189.

Walsh, R., & Redman, S. (1993). Smoking cessation in pregnancy: Do effective programmes exist? *Health Promotion International, 8*(2), 111-127.

West, R., & Shiffman, S. (2001). Effect of oral nicotine dosing forms on cigarette withdrawal symptoms and craving: a systematic review. *Psychopharmacology (Berl), 155*(2), 115-122.

Search strategy for Medline

Smoking cessation in acute and maternity services: one review of effectiveness and one review of barriers and facilitators

Platform: EBSCO

Search conducted by C. Stansfield on 4 January 2011

Results: 6634

#	Query	Results
S1	MH ("TOBACCO USE CESSATION+")	18854
S2	(MH "Smoking Cessation")	16197
S3	(MH "Smoking/PC")	13139
S4	TI ("hand-roll" OR handroll* OR "hand-rolls" OR "hand-rolled" OR bidi OR bidis OR beedi OR beedis OR rolie OR rolies OR paan OR gutkha OR snuff OR betel OR cigar OR cigars)	1331
S5	AB ("hand-roll" OR handroll* OR "hand-rolls" OR "hand-rolled" OR bidi OR bidis OR beedi OR beedis OR rolie OR rolies OR paan OR gutkha OR snuff OR betel OR cigar OR cigars)	2629
S6	TI (quit* OR abstain* OR abstinence OR reduction OR restrict* OR reduce OR cessation)	119903
S7	AB (quit* OR abstain* OR abstinence OR reduction OR restrict* OR reduce OR cessation)	1167034
S8	TI ((stop N2 smoking) OR (stopping N2 smoking) OR (stopped N2 smoking) OR (stoppage N2 smoking))	526
S9	TI ((stop N2 cigarette) OR (stopping N2 cigarette) OR (stopped N2 cigarette) OR (stoppage N2 cigarette))	6
S10	AB ((stop N2 cigarette) OR (stopping N2 cigarette) OR (stopped N2 cigarette) OR (stoppage N2 cigarette))	63
S11	TI ((stop N2 cigarettes) OR (stopping N2 cigarettes) OR (stopped N2 cigarettes) OR (stoppage N2 cigarettes))	4
S12	AB ((stop N2 cigarettes) OR (stopping N2 cigarettes) OR (stopped N2 cigarettes) OR (stoppage N2 cigarettes))	39
S13	AB ((stop N2 tobacco) OR (stopping N2 tobacco) OR (stopped N2 tobacco) OR (stoppage N2 tobacco))	106
S14	TI ((stop N2 tobacco) OR (stopping N2 tobacco) OR (stopped N2 tobacco) OR (stoppage N2 tobacco))	28
S15	TI ((smoking N3 services) OR (smoking N3 service) OR (anti N1 smoking) OR (anti N1 tobacco))	531
S16	AB ((smoking N3 services) OR (smoking N3 service) OR (anti N1 smoking)	1348

	OR (anti N1 tobacco))	
S17	AB ((smoking N2 prevent) OR (smoking N2 prevention) OR (smoking N2 preventing) OR (smoking N2 prevents) OR (tobacco N2 prevent) OR (tobacco N2 prevention) OR (tobacco N2 preventing) OR (tobacco N2 prevents) OR (cigarette# N2 prevent) OR (cigarette# N2 prevention) OR (cigarette# N2 preventing) OR (cigarette# N2 prevents) OR (smoker# N2 restrict#) OR (smoker# N2 restriction) OR (smoker# N2 restricted) OR (cigarette# N2 restrict) OR (cigarette# N2 restricted) OR (cigarette# N2 restricts) OR (cigarette# N2 restricting) OR (cigarette# N2 restriction) OR (tobacco N2 restrict) OR (tobacco N2 restricted) OR (tobacco N2 restricts) OR (tobacco N2 restricting) OR (tobacco N2 restriction) OR (smoking N2 restrict) OR (smoking N2 restricted) OR (smoking N2 restricts) OR (smoking N2 restricting) OR (smoking N2 restriction)) OR TI ((smoking N2 prevent) OR (smoking N2 prevention) OR (smoking N2 preventing) OR (smoking N2 prevents) OR (tobacco N2 prevent) OR (tobacco N2 prevention) OR (tobacco N2 preventing) OR (tobacco N2 prevents) OR (cigarette# N2 prevent) OR (cigarette# N2 prevention) OR (cigarette# N2 preventing) OR (cigarette# N2 prevents) OR (smoker# N2 restrict#) OR (smoker# N2 restriction) OR (smoker# N2 restricted) OR (cigarette# N2 restrict) OR (cigarette# N2 restricted) OR (cigarette# N2 restricts) OR (cigarette# N2 restricting) OR (cigarette# N2 restriction) OR (tobacco N2 restrict) OR (tobacco N2 restricted) OR (tobacco N2 restricts) OR (tobacco N2 restricting) OR (tobacco N2 restriction) OR (smoking N2 restrict) OR (smoking N2 restricted) OR (smoking N2 restricts) OR (smoking N2 restricting) OR (smoking N2 restriction))	3480
S18	AB (temporary abstinence) OR TI (temporary abstinence)	34
S19	TI ((tobacco N2 quit) OR (tobacco N2 quitting) OR (tobacco N2 quitted) OR (tobacco N2 abstain) OR (tobacco N2 abstinence) OR (tobacco N2 reduction) OR (tobacco N2 reduces) OR (tobacco N2 reduce) OR (tobacco N2 abstaining))	269
S20	AB ((tobacco N2 quit) OR (tobacco N2 quitting) OR (tobacco N2 quitted) OR (tobacco N2 abstain) OR (tobacco N2 abstinence) OR (tobacco N2 reduction) OR (tobacco N2 reduces) OR (tobacco N2 reduce) OR (tobacco N2 abstaining))	1157
S21	TI ((smoking N2 quit) OR (smoking N2 quitting) OR (smoking N2 quitted) OR (smoking N2 abstain) OR (smoking N2 abstinence) OR (smoking N2 reduction) OR (smoking N2 reduces) OR (smoking N2 reduce) OR (smoking N2 abstaining))	1154
S22	AB ((smoking N2 quit) OR (smoking N2 quitting) OR (smoking N2 quitted) OR (smoking N2 abstain) OR (smoking N2 abstinence) OR (smoking N2 reduction) OR (smoking N2 reduces) OR (smoking N2 reduce) OR (smoking N2 abstaining))	6788
S23	TI ((cigarette N2 quit) OR (cigarette N2 quitting) OR (cigarette N2 quitted) OR (cigarette N2 abstain) OR (cigarette N2 abstinence) OR (cigarette N2 reduction) OR (cigarette N2 reduces) OR (cigarette N2 reduce) OR (cigarette N2 abstaining))	154
S24	AB ((cigarette N2 quit) OR (cigarette N2 quitting) OR (cigarette N2 quitted) OR (cigarette N2 abstain) OR (cigarette N2 abstinence) OR (cigarette N2 reduction) OR (cigarette N2 reduces) OR (cigarette N2 reduce) OR (cigarette N2 abstaining))	586

S25	TI ((cigarettes N2 quit) OR (cigarettes N2 quitting) OR (cigarettes N2 quitted) OR (cigarettes N2 abstain) OR (cigarettes N2 abstinence) OR (cigarettes N2 reduction) OR (cigarettes N2 reduces) OR (cigarettes N2 reduce) OR (cigarettes N2 abstaining))	30
S26	AB ((cigarettes N2 quit) OR (cigarettes N2 quitting) OR (cigarettes N2 quitted) OR (cigarettes N2 abstain) OR (cigarettes N2 abstinence) OR (cigarettes N2 reduction) OR (cigarettes N2 reduces) OR (cigarettes N2 reduce) OR (cigarettes N2 abstaining))	282
S27	TI ((smoking N2 cessation) OR (tobacco N2 cessation) OR (cigarettes N2 cessation) OR (cigarette N2 cessation))	6240
S28	AB ((smoking N2 cessation) OR (tobacco N2 cessation) OR (cigarettes N2 cessation) OR (cigarette N2 cessation))	12419
S29	TI ((smoker# N2 quit) OR (smoker# N2 quitting) OR (smoker# N2 quitted) OR (smoker# N2 abstain) OR (smoker# N2 abstaining) OR (smoker# N2 abstinence) OR (smoker# N2 reduction) OR (smoker# N2 reduce#) OR (smoker# N2 abstaining))	231
S30	AB ((smoker# N2 quit) OR (smoker# N2 quitting) OR (smoker# N2 quitted) OR (smoker# N2 abstain) OR (smoker# N2 abstaining) OR (smoker# N2 abstinence) OR (smoker# N2 reduction) OR (smoker# N2 reduce#) OR (smoker# N2 abstaining))	2118
S31	(S4 OR S5) AND (S6 OR S7)	530
S32	S1 or S2 or S3 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26 or S27 or S28 or S29 or S30 or S31	36889
S33	(MH "Patient Admission")	16145
S34	(MH "Hospitalization+")	133618
S35	(MH "Outpatients")	6928
S36	(MH "Inpatients")	10026
S37	(MH "Child, Hospitalized")	5455
S38	(MH "Adolescent, Hospitalized")	376
S39	(MH "Pregnant Women")	4529
S40	(MH "Patients")	14318
S41	TI (patient#)	1076780
S42	TI ((pregnant N3 teens) OR (pregnant N3 teenage#) OR (pregnant N3 teenager#) OR (pregnant N3 adolescent#) OR (pregnant N3 women) OR (pregnant N3 mothers))	13792
S43	AB ((pregnant N3 teens) OR (pregnant N3 teenage#) OR (pregnant N3 teenager#) OR (pregnant N3 adolescent#) OR (pregnant N3 women) OR (pregnant N3 mothers))	45618
S44	TI (inpatient# OR outpatient# OR "out patient" OR "out patients" OR "inhospital" OR (day N2 patient#) OR "ill patients" OR "acutely ill" OR primip* OR primigravid*)	40738
S45	AB (inpatient# OR outpatient# OR "out patient" OR "out patients" OR "inhospital" OR (day N2 patient#) OR "ill patients" OR "acutely ill" OR primip* OR primigravid*)	169326

S46	TI ((patient# N2 surgery) OR (patient# N2 operation) OR (patient# N2 discharge#) OR (patient# N2 readmission#) OR (patient# N2 postdischarge#) OR (patient# N2 emergency) OR (patient# N2 emergencies))	14963
S47	AB ((patient# N2 surgery) OR (patient# N2 operation) OR (patient# N2 discharge#) OR (patient# N2 readmission#) OR (patient# N2 postdischarge#) OR (patient# N2 emergency) OR (patient# N2 emergencies))	119288
S48	TI ((patient# N2 referral#) OR (patient# N2 referring) OR (patient# N2 admittance#) OR (patient# N2 admitting) OR (patient# N2 admission#) OR (patient# N2 readmittance) OR (patient# N2 readmitting) OR (patient# N2 readmission#) OR (patient# N2 postoperable) OR (patient# N2 postoperative) OR (patient# N2 refer) OR (patient# N2 refers) OR (patient# N2 admit) OR (patient# N2 admits))	4715
S49	AB ((patient# N2 referral#) OR (patient# N2 referring) OR (patient# N2 admittance#) OR (patient# N2 admitting) OR (patient# N2 admission#) OR (patient# N2 readmittance) OR (patient# N2 readmitting) OR (patient# N2 readmission#) OR (patient# N2 postoperable) OR (patient# N2 postoperative) OR (patient# N2 refer) OR (patient# N2 refers) OR (patient# N2 admit) OR (patient# N2 admits))	46690
S50	TI (maternity OR "maternal health" OR obstetrics OR "prenatal care" OR "prenatal services" OR "antenatal care" OR "antenatal services" OR "obstetric care" OR "obstetric services" OR "perinatal care" OR "prenatal clinic" OR "prenatal clinics" OR "prenatal health" OR "prenatal service" OR "antenatal clinic" OR "antenatal clinics" OR "antenatal service" OR "antenatal health" OR "obstetric clinic" OR "obstetric clinics" OR "obstetric service" OR "obstetric health" OR "perinatal clinic" OR "perinatal clinics" OR "perinatal service" OR "perinatal services" OR "perinatal health" OR pregnancy OR "maternity healthcare" OR "obstetric healthcare" OR "prenatal healthcare" OR "antenatal healthcare" OR "perinatal healthcare" OR "maternal care" OR "maternal service" OR "maternal services" OR hospitalised OR hospitalized OR "secondary care" OR "acute care" OR "secondary health service" OR "secondary health services" OR "acute health service" OR "acute health services" OR "acute setting" OR "acute settings" OR "acute service" OR "acute services")	157954
S51	AB (maternity OR "maternal health" OR obstetrics OR "prenatal care" OR "prenatal services" OR "antenatal care" OR "antenatal services" OR "obstetric care" OR "obstetric services" OR "perinatal care" OR "prenatal clinic" OR "prenatal clinics" OR "prenatal health" OR "prenatal service" OR "antenatal clinic" OR "antenatal clinics" OR "antenatal service" OR "antenatel health" OR "obstetric clinic" OR "obstetric clinics" OR "obstetric service" OR "obstetric health" OR "perinatal clinic" OR "perinatal clinics" OR "perinatal service" OR "perinatal services" OR "perinatal health" OR pregnancy OR "maternity healthcare" OR "obstetric healthcare" OR "prenatal healthcare" OR "antenatal healthcare" OR "perinatal healthcare" OR "maternal care" OR "maternal service" OR "maternal services" OR hospitalised OR hospitalized OR "secondary care" OR "acute care" OR "secondary health service" OR "secondary health services" OR "acute health service" OR "acute health services" OR "acute setting" OR "acute settings" OR "acute service" OR "acute services")	255290
S52	TI ((acute W2 ward) OR (acute W2 wards) OR (general W2 ward) OR (general W2 wards) OR (stay W2 ward) OR (staying W2 ward) OR (stay W2 wards) OR (staying W2 wards))	677

S53	AB ((acute W2 ward) OR (acute W2 wards) OR (general W2 ward) OR (general W2 wards) OR (stay W2 ward) OR (staying W2 ward) OR (stay W2 wards) OR (staying W2 wards))	2962
S54	TI ((accident W3 unit) OR (accident W3 department) OR (emergency W1 unit) OR (emergency W1 department) OR (surgical W1 ward) OR (patient# N2 surgery) OR (surgery W2 unit) OR (surgery W2 department) OR (acute W2 unit) OR (acute W2 department))	23092
S55	AB ((accident W3 unit) OR (accident W3 department) OR (emergency W1 unit) OR (emergency W1 department) OR (patient# N2 surgery) OR (surgical W1 ward#) OR (surgery W2 unit) OR (surgery W2 department) OR (acute W2 unit) OR (acute W2 department))	108278
S56	TI (hospitals OR hospital OR (patient# N2 "post discharge"))	181415
S57	AB (hospitals OR hospital OR (patient# N2 "post discharge"))	493665
S58	(MH "Maternal Health Services+")	28351
S59	(MH "Obstetrics and Gynecology Department, Hospital")	2214
S60	(MH "Obstetrics")	14150
S61	(MH "Hospitals+")	180568
S62	(MH "Hospital Units+")	66597
S63	(MH "Outpatient Clinics, Hospital+")	14543
S64	(MH "Emergency Service, Hospital+")	40071
S65	(MH "Emergency Medical Services")	27584
S66	TI (("hospital staff") OR ("hospital personnel") OR (hospital W1 worker#) OR surgeon# OR gyne#cologist# OR obstetrician# OR midwiv* OR midwife)	25287
S67	AB (("hospital staff") OR ("hospital personnel") OR (hospital W1 worker#) OR surgeon# OR gyne#cologist# OR obstetrician# OR midwiv* OR midwife)	103541
S68	TI (hospital) OR AB (hospital)	533136
S69	TI (doctor# OR nurse# OR physician# OR clinician# OR pharmacist# OR health W1 worker# OR consultant# OR (medical W1 specialist#) OR (medical W1 officer#))	191646
S70	AB (doctor# OR nurse# OR physician# OR clinician# OR pharmacist# OR health W1 worker# OR consultant# OR (medical W1 specialist#) OR (medical W1 officer#))	412247
S71	S69 or S70	543647
S72	(S68 and S71)	67181
S73	AB (partnership# or "team work" or "teamwork" OR teamworking OR "team working" or cooperation or (cooperative W1 behavio#r) or "integration" or "integrative approach" OR "integrative approaches" or collaborat* or interagenc* or multiagenc* or "inter-institutional" or "inter-institutionally" or "inter-professional" or "inter-departmental" or "inter-departmentally" or interinstitutional* or interprofessional or interdepartmental* or "interprofessional relations" or "interprofessional relationships" or (multidisciplin*) or "cross discipline" OR "cross disciplinary" or (interagency) OR linkage# OR "cross-discipline" OR "cross-disciplinary")	261508
S74	TI (partnership# or "team work" or "teamwork" OR teamworking OR "team	71666

	working" or cooperation or (cooperative W1 behavio#r) or "integration" or "integrative approach" OR "integrative approaches" or collaborat* or interagenc* or multiagenc* or "inter-institutional" or "inter-institutionally" or "inter-professional" or "inter-departmental" or "inter-departmentally" or interinstitutional* or interprofessional or interdepartmental* or "interprofessional relations" or "interprofessional relationships" or (multidisciplin*) or "cross discipline" OR "cross disciplinary" or (interagency) OR linkage# OR "cross-discipline" OR "cross-disciplinary")	
S75	(S33 or S34 or S35 or S36 or S37 or S38 or S39 or S40 or S41 or S42 or S43 or S44 or S45 or S46 or S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53 or S54 or S55 or S56 or S57 or S58 or S59 or S60 or S61 or S62 or S63 or S64 or S65 or S66 or S67 or S68 or S72 or S73 or S74)	2614599
S76	S75 AND S32	7304
S77	MH ("Humans") AND MH ("Animals")	1253188
S78	MH ("Animals")	4777882
S79	S78 NOT S77	3524694
S80	S76 NOT S79	6634

Notes:

= wildcard of 1 or 0 characters

* = truncation

N2 = words within 2 places of each other in any order

W2 = words within 2 places of each other in the order written in the text

Appendix 2: Audit information that will accompany each database and website search

Database name	
Search date	
Database host *(name of host or environment in which the database was searched)*	
Coverage dates	
Name of searcher	
Search strategy checked by	
Number of records retrieved	
Name of EndNote library	
Number of records loaded into EndNote library	
Reference numbers of records in EndNote library *(range of unique reference numbers assigned to the records by EndNote)*	
Number of records after deduplication in EndNote library	

Appendix 3: Title/Abstract Screening Checklist

Review 2

1	Does the paper report a controlled trial of a smoking cessation intervention in acute and maternity services, or a controlled trial of interventions to encourage staff to identify pregnant smokers and provide advice or referral?	Yes – get full text	No – exclude

Where the assessor is unsure about a paper then the abstract will be discussed among all reviewers and a final decision made.

Review 3

1	Does the paper report on smoking cessation in acute and maternity services?	Yes – go to next question	No – exclude
2	Does the paper provide information on barriers, facilitators or joined-up working?	Yes – get full text	No – exclude

Where the assessor is unsure about a paper then the abstract will be discussed among all reviewers and a final decision made.

Appendix 4: Quality appraisal checklist for quantitative studies

Study identification:		
Study design:		
Assessed by:		
Section 1: Population		
• Representative sample? (selection biases e.g. low proportion agreed to participate, highly selected subgroups)	☐ ++ ☐ + ☐ - ☐ NR ☐ NA	Comments:
Section 2: Methods		
Randomisation • Individual/cluster corrected for/unclear? • Could the researcher influence the allocation?	☐ ++ ☐ + ☐ - ☐ NR ☐ NA	
Intervention delivery • Intervention delivered to most patients in the intervention arm? • Contamination between study arms?	☐ ++ ☐ + ☐ - ☐ NR ☐ NA	
Generalizability to UK • Setting and intervention relevant for UK practice?	☐ ++ ☐ + ☐ - ☐ NR ☐ NA	
Section 3: Outcomes		
• Abstinence validated and validation results taken into account in outcome calculations? • Reports continuous abstinence or only point prevalence abstinence? • Participants lost to follow-up included as smoking?	☐ ++ ☐ + ☐ - ☐ NR ☐ NA	
• Length of follow-up: under 1M=-, 1-5M=+, 6M or more=++	☐ ++ ☐ + ☐ - ☐ NR ☐ NA	
	☐	
Overall assessment **++=good sample and design, Russell Standard outcomes**	☐ ++ ☐ + ☐ - ☐ NR ☐ NA	

Appendix 5: Review screening form

Study identification	
Checklist completed by**:**	
In a well-conducted systematic review:	
Is the literature search sufficiently rigorous to identify all the relevant studies?	Yes No Unclear
Overall Quality	Comments

Appendix 6: Data extraction form/Evidence Table for Quantitative studies

Study details	Population	Intervention	Outcomes	Results	Notes
Authors	Study population	Method of allocation	ITT?	Abstinence rates	Limitations
Year		Intervention	Validated?		
Citation			Continuous or PP?		
		Control/comparison			
Study design		Sample size	Follow-up periods		
Quality score		Baseline differences not controlled for?			
External validity					

Appendix 7: Data extraction form/Evidence Table for Qualitative papers

Study details	Population		Notes
Authors			
Year			
Citation		Key themes relevant to this review:	

APPENDIX 2 – PAPERS UNAVAILABLE FOR THE HOSPITAL SECTION (N=19)

(1994) "Nicotine replacement therapy for patients with coronary artery disease. Working Group for the Study of Transdermal Nicotine in Patients with Coronary artery disease."
(2010) "How one facility helps patients stop smoking."
(2011) "How one facility helps patients stop smoking."
Anders (2011)
Bock (2008)
Eisenberg (2011)
Glavas (2003)
Grandi (2011)
Kapur (2004)
Meysman (2010)
Murphy (1994)
Nett (1992)
Rigotti (1996)
Spencer (2004)
Strayer (2004)
Todd (1998)
Weissfeld (1991)
Wewers (1992)
Wewers (1993)

APPENDIX 3 – PAPERS EXCLUDED FROM THE HOSPITAL SECTION (N=41)

(2007). "Inpatient smoking-cessation programs get the job done."	Article not relevant
(2008). "Treating patients who use tobacco."	Article not relevant
(2009). "Stop smoking hospitals pilots."	Newspaper article
(2010). "Thoracic surgeons can help patients stop smoking with a brief smoking cessation program."	Link to another paper - Kozower 2010
(2011). "Motivate patients to stop smoking."	Not RCT
Allen (1998)	Excluded by Rigotti
An (2008)	Not RCT
Bernstein (2011)	Only 3 month FU
Canga (2000)	Not included as not in right setting
Carson (2010)	Conference paper preliminary data only
Choo (2004)	Only 1 month FU data available
Dalton (1991)	Psychiatric setting
Fonteyn (2004)	Commentary on Quist-Paulsen 2003, exclude
Gies (2008)	Not RCT
Gritz (1991)	Describes trial and SS but no results
Hanssen (2007)	2008 paper includes longest time FU - 18 months
Holmes-Rovner(2008)	Cannot extract data
Jha (2005)	Review of Taylor
Joseph (1996)	Study methods - get full paper
Lacasse (2005)	Conference report on Lacasse 2007 study
Lisspers (1999)	Cannot extract data
Moller (2003)	Different question but related to Moller 2002
Mackay (2010)	Poster - not RCT
Maud-Christine (2005)	Chouinard paper - already included in Rigotti
Mohjuddin (2006)	Summary of Mohiuddin (2007)

Murray (2002)	Commentary on 2002 paper
Park (2011)	Non-randomised
Peterson (2004)	Not relevant setting
Reid (2011)	Conference report
Richman (2000)	3 month FU only
Stainislaw (1994)	Only 5 week FU
Tan (2011)	Not RCT
1994) "Nicotine replacement therapy for patients with coronary artery disease. Working Group for the Study of Transdermal Nicotine in Patients with Coronary artery disease."	Not acute services setting
Thorndike (2008)	Secondary analysis of Rigotti paper
Uzuner (2008)	Review 3
van Elderen-van Kemenade (1994)	No detail on number of baseline smokers
Vander Weg (2008)	Not relevant setting
Volpp (2006)	Not relevant setting
Wolfenden (2005)	No data - include in review 3
Wolfenden (2008)	Less than 12 month follow up, results not clear
Wong (2005)	No data/focus on smoking cessation

APPENDIX 4 – PAPERS UNABLE TO GET FOR THE MATERNITY SECTION (N=17)

Alves (2011)
Chan (2008)
Health Technology (2006) Double-blind, randomised, placebo-controlled trial of nicotine replacement therapy (NRT) in pregnancy
Mullen (1999)
Smith (2006)
Stenchever (2003)
Valbo (1994)
Valbo (1996)
Windsor (2011)
Wisborg (1997)
King (1992)
Olds et al 1986
Price et al 1991
Rush et al 1992
Langford et al 1983
Gilles et al 1990
Messimer et al 1989

APPENDIX 5 – PAPERS EXCLUDED FROM THE MATERNITY SECTION (N=35)

(1997). "Smoking cessation program focuses on pregnant women."	Summary of McBride
Albrecht (2006)	Excluded from Lumley
Atkinson et al. (2003)	Abstract with no details
Bauman (1983)	Included in Lumley but data extraction could not be done
Byrd (1993)	No Ns for between groups
Campbell (2006)	Included in Lumley but not a trial of stop smoking interventions. Ns also difficult to extract
Chen-Louie (1993)	Commentary
Donovan (1996)	Commentary
Groner et al. (2000)	Focus on mothers (older children) and ETS
Health Technology (2010) A pragmatic randomized controlled trial of physical activity as an aid to smoking cessation during pregnancy	Project HTA grant
Hennrikus (2010)	No data on baseline or postpartum smoking rates
Hughes (2000)	Excluded from Lumley
Jehn (2003)	Not RCT
Lillington (1995)	Excluded from Lumley
Lowe (2002)	Excluded from Lumley
Röske (2009)	Equation modelling for Hannover - no data
Ruggiero (1997)	Not RCT

Sheahan (1997)	No data - use in review 3
Stanton (2004)	Excluded from Lumley
Yilmaz (2006)	Excluded from Lumley
Donovan (1996)	No cessation data
Haddow (1991)	No cessation data
Shakespeare (1990)	No cessation data
Lillington (1995)	Not RCT
Gebour (1998)	Not RCT
Windsor 2000	Brief report
Valanis et al 2001	Not RCT
Weerd et al 2001	letter commenting on Pollack et al 2001. Weerd et al cite a cohort study that they had completed. Since it was not a RCT it cannot be included.
Pollak et al 2001	letter commenting on Pollak (Pollak & Mullen, 1997) et al 2001.
Gulmezoglu et al 1997	Use systematic reviews to extract data
Ershoff et al 1990	This can be excluded as it reports only the economic evaluation of the 1989 trial.
El-Mohandes et al 2011	Unable to extract data
Gadomski et al 2011	Quasi randomised
Kendzor 2010	Not relevant analysis

Lemola et al 2008	No intervention included
Edwards et al 998	More relevant to review 3