Relapse prevention interventions for smoking cessation (Review)

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[Intervention Review]

Relapse prevention interventions for smoking cessation

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ABSTRACT

Background

A number of treatments can help smokers make a successful quit attempt, but many initially successful quitters relapse over time. Several interventions were proposed to help prevent relapse.

Objectives

To assess whether specific interventions for relapse prevention reduce the proportion of recent quitters who return to smoking.

Search strategy

We searched the Cochrane Tobacco Addiction Group trials register in August 2008 for studies mentioning relapse prevention or maintenance in title, abstracts or keywords.

Selection criteria

Randomized or quasi-randomized controlled trials of relapse prevention interventions with a minimum follow up of six months. We included smokers who quit on their own, or were undergoing enforced abstinence, or who were participating in treatment programmes. We included trials that compared relapse prevention interventions to a no intervention control, or that compared a cessation programme with additional relapse prevention components to a cessation programme alone.

Data collection and analysis

Studies were screened and data extracted by one author and checked by a second. Disagreements were resolved by discussion or referral to a third author.

Main results

Fifty-four studies met inclusion criteria, but were heterogeneous in terms of populations and interventions. We considered 36 studies that randomized abstainers separately from studies that randomized participants prior to their quit date.

Looking at studies of behavioural interventions which randomised abstainers, we detected no benefit of brief and 'skills-based' relapse prevention methods for women who had quit smoking due to pregnancy, or for smokers undergoing a period of enforced abstinence during hospitalisation or military training. We also failed to detect significant effects of behavioural interventions in trials in unselected

groups of smokers who had quit on their own or with a formal programme. Amongst trials randomising smokers prior to their quit date and evaluating the effect of additional relapse prevention components we also found no evidence of benefit of behavioural interventions in any subgroup. Overall, providing training in skills thought to be needed for relapse avoidance did not reduce relapse, but most studies did not use experimental designs best suited to the task, and had limited power to detect expected small differences between interventions. For pharmacological interventions, extended treatment with varenicline significantly reduced relapse in one trial (risk ratio 1.18, 95% confidence interval 1.03 to 1.36). Pooling of five studies of extended treatment with bupropion failed to detect a significant effect (risk ratio 1.17; 95% confidence interval 0.99 to 1.39). Two small trials of oral nicotine replacement treatment (NRT) failed to detect an effect but treatment compliance was low and in two other trials of oral NRT randomizing short-term abstainers there was a significant effect of intervention.

Authors' conclusions

At the moment there is insufficient evidence to support the use of any specific behavioural intervention for helping smokers who have successfully quit for a short time to avoid relapse. The verdict is strongest for interventions focusing on identifying and resolving tempting situations, as most studies were concerned with these. There is little research available regarding other behavioural approaches.

Extended treatment with varenicline may prevent relapse. Extended treatment with bupropion is unlikely to have a clinically important effect. Studies of extended treatment with nicotine replacement are needed.

PLAIN LANGUAGE SUMMARY

Do any interventions help smokers who have successfully quit for a short time to avoid relapsing

Some people start smoking again shortly after quitting and are said to have 'relapsed'. Interventions used to help people avoid relapse usually focus on teaching the skills to cope with temptations to smoke. This approach and others have not been shown to be helpful, either for people who quit on their own, or with the help of a cessation treatment, or who quit because they were pregnant or in hospital. Many trials conducted so far have not been of a strong enough design to detect possible small effects. Among drug treatments, extended use of varenicline may help some smokers. Studies of extended use of nicotine replacement treatment are urgently needed.

BACKGROUND

A number of interventions can help people who smoke to quit. These include pharmacological treatments, such as nicotine replacement, some antidepressants and nicotine receptor partial agonists; and behavioural approaches, whether delivered individually or in groups (Hajek 2004; Hughes 2007; Lancaster 2005; Stead 2008; Stead 2005). The interventions increase long-term quit rates compared to control interventions, but there is a steady attrition in overall success rates due to a proportion of initially successful participants returning to smoking over time (relapsing).

Several strategies for relapse prevention have been examined in randomized controlled trials. The most widely studied has been the skills approach where patients learn to identify high-risk situations for relapse, and are provided with cognitive and behavioural strategies to cope with these situations (Marlatt 1985; Marlatt 2008). A smaller number of studies have tested alternative psychological treatments (usually combined with the skills approach). These include imaginary cue exposure, writing tasks, aversive smoking, role-play, social support, and exercise. There is also a separate group of studies that tested the effects of preventing relapse by extending the duration of therapeutic contact. Finally several studies have examined pharmacological treatments for relapse prevention.

There is no clear definition of a relapse prevention intervention as distinct from an extended cessation treatment. This is because, in principle, resumption of smoking at any time after the quit date can count as relapse. In general, relapse prevention is considered to apply to interventions that explicitly seek to reduce relapse rates after an acute treatment phase is successfully completed, or at some time after the quit date of a self-quit attempt. Since the duration of the acute treatment phase varies, there will be variability in the

point at which measurement of a relapse prevention effect begins. This is unavoidable and the approach adopted in this review is to consider as relapse prevention those interventions that are designated by the authors as such, or where there is extended treatment after what would be the normal treatment duration.

Trials of interventions for relapse prevention may randomize people who have already quit, or they may randomize smokers prior to their quit attempt and provide a general smoking cessation intervention to all participants in addition to an extra component provided for those randomized to relapse prevention. The former design has a number of methodological strengths discussed later in this review. We included both types of study in the review.

The aim of reviewing the evidence of efficacy of relapse prevention interventions was to provide information for care providers that may be relevant when deciding how to allocate resources between motivating attempts to stop smoking, supporting smokers who need help during the initial stages of their quit attempt, and providing further support to prevent relapse.

OBJECTIVES

The objective of the review is to assess the extent to which specific interventions for relapse prevention reduce the proportion of recent quitters who return to smoking.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized or quasi-randomized controlled trials with a minimum follow up of six months from quit date.

Types of participants

We considered three types of participants: people who had quit smoking on their own; people who were undergoing enforced abstinence, whether or not they intended to quit permanently; and smokers participating in treatment programmes to assist initial cessation.

Types of interventions

We included interventions identified by study investigators as intended to prevent relapse, compared to either no intervention or to a shorter intervention or to an intervention not oriented towards relapse prevention. We considered behavioural interventions delivered in any format, including group meetings, face-to-face sessions, written or other materials, proactive or reactive telephone support, and pharmacological interventions.

Types of outcome measures

The preferred outcome was prolonged or multiple point prevalence abstinence at follow up of at least six months since randomization. We included trials that only reported point prevalence abstinence (number of participants not smoking at point when assessment is made - abstinent at that time but not necessarily continuously since treatment) at six months or more, with consideration of sensitivity analysis where these had an impact on pooled results. We excluded studies with less than six months follow up.

Search methods for identification of studies

We searched the Cochrane Tobacco Addiction Group register of trials, which includes the results of comprehensive searches of electronic bibliographic databases and conference abstracts. We checked all trials with 'relapse prevention' or 'maintenance' or 'relapse Near prevent*' in title, abstract or keywords for relevance. At the most recent search the trials register included the results of OVID searches of MEDLINE on 6th August 2008, EMBASE and PsycINFO on 20th August 2008 and the Cochrane Library issue 3, 2008.

Data collection and analysis

We included all studies that randomized people already abstaining from smoking. In studies randomizing smokers prior to quitting, almost all behavioural interventions include relapse prevention components. We only included studies that explicitly identified a focus on relapse prevention or maintenance in their titles or abstracts. In addition we included all studies that tested the effect of extended contact by telephone following an initial intervention, whether or not relapse prevention was highlighted. Unless abstainers were randomized, we did not include studies of exercise or studies of aversive smoking, since the interventions used are similar whether described as relapse prevention or not, and are covered in separate Cochrane reviews (Hajek 2004; Ussher 2008). We excluded interventions for hospitalized patients because trials generally do not describe whether participants are already abstinent or not, and interventions typically contain a mixture of cessation and relapse prevention components. All studies of this type are also covered by a separate review (Rigotti 2007)

Methods of the review

One author (LS) identified potentially eligible trials for inclusion, and extracted data. A second author (TL) checked data extraction for included or borderline studies and then together with the third author (PH) agreed study inclusion, and the categorization of studies into subgroups.
We reported the following trial characteristics in the ' Characteristics of included studies' table:

- Country and setting in which study undertaken, including population targeted for recruitment.
- Method of randomization and allocation concealment.
- Demographics of participants, including age, sex, baseline cigarette consumption, and period of prior quitting if relevant.
- Intervention components including number and type of contacts and period of contact.
- Control condition(s).
- Outcome, including length of follow up, definition(s) of cessation used in review and any other measures used.
- Validation of self-reported smoking status, including method used and cut off point for biochemical validation.

Meta-analysis

The primary outcome was the number of quitters at the longest follow up. We used biochemically validated cessation in preference to self report where available. Where given a choice, we included continuous abstinence in preference to point prevalence abstinence. Randomized participants who withdrew, were lost to follow up, or failed to provide samples for validation were usually classified as relapsers or continuing smokers. We noted any exceptions to this in the study details and we estimated whether the choice of denominator was likely to alter the conclusions. If studies reported both strict and more lenient outcomes we extracted both and conducted a sensitivity analysis on the pooled results. Following changes to the Cochrane Tobacco Addiction Group's recommended method of data analysis since this review was last updated, we have changed the way in which we summarize the effects of treatment. We now use the risk ratio rather than the odds ratio for summarizing individual trial outcomes and for estimates of pooled effect. Treatment effects will seem smaller when expressed as risk ratios than when expressed as odds ratios, unless the event rates are very low. For example, if 20 out of 100 participants have quit in the intervention group, and 10 out of 100 in the control group, the risk ratio is 2.0 [(20/100)/(10/100)], whilst the odds ratio is 2.25 [(20/80)/(10/90)]. Whilst there are circumstances in which odds ratios may be preferable, there is a danger that they will be interpreted as if they are risk ratios, making the treatment effect seem larger (Deeks 2002). We estimated a pooled weighted average of risk ratios using a Mantel-Haenszel method, with 95% confidence intervals. If a study reported an odds ratio corrected for clustering or baseline imbalance and we were unable to derive a relative risk we also pooled odds ratios for trials in the same subgroup of a comparison using the inverse variance method to check whether there was an effect on the results.

To investigate heterogeneity we use the I^2 statistic, given by the formula [(Q - df)/Q] x 100%, where Q is the chi-squared statistic and df is its degrees of freedom (Higgins 2003). This describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance). A value greater than 50% may be considered to indicate substantial heterogeneity. In the event of significant statistical or clinical heterogeneity between trials we determined not to report pooled estimates. We planned not to pool results from trials that randomized abstainers with those randomizing smokers, but made one exception to this: see discussion of Killen 2006 in Description of studies section 1.2.3 below. Our predefined subgroups were based on the type and intensity of intervention. We also separated studies in which contact time was matched and those in which the relapse prevention included a longer duration of contact.
Other pre-specified subgroups included trials in spontaneous quitters such as pregnant women, and trials in smokers seeking smoking cessation treatment. We added further subgroup analyses distinguishing between longer (more than four weeks) and shorter intervention durations, in trials randomizing smokers to matched duration interventions, and between more (more than four sessions) and fewer intervention sessions for unmatched intervention and control programmes. We also considered subgroup analyses for 'skills' and social support studies. This replaced our planned subgroup division based on format of intervention (group versus individual) as being more relevant within the available sample of studies.
In the protocol for this review we planned to approach authors for additional data about end of treatment quit rates, and long-term quit rates in early quitters. In view of the heterogeneity of interventions, timing of assessments, and ways of defining abstinence, we decided that additional data, even if suitable and available, would not strengthen the review. We extracted short-term quit rates for trials that did not randomize abstainers, and considered whether any benefit of relapse prevention intervention was apparent at this point, and whether or not it differed from the long-term effect.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.
We identified 54 studies for inclusion, 14 of which were new for the 2009 update. One paper reported two studies that each had multiple arms relevant to different comparisons (Buchkremer

1991 1; Buchkremer 1991 2), and six trials had subgroups or factorial designs that contributed to different sections or subgroups (Curry 1988; Killen 1990; Fortmann 1995; Schmitz 1999; Covey 2007; Croghan 2007). Two (4%) of the studies did not specifically describe the intervention as involving relapse prevention. Two were similar to an included study by the same group (Hall 1987; Klesges 2006) and one randomized abstainers (Hajek 2002). The majority of studies were conducted in the USA.

We describe and analyze separately those studies that randomized people who had already stopped smoking (Section 1) and those that randomized people who were still smoking (Section 2). We made one exception to this scheme in respect of Killen 2006, which we consider along with other extended pharmacotherapy trials in section 1.3.2 below.

Section 1. Studies randomizing abstainers

Thirty-seven studies included people who had already stopped smoking.

We considered separately studies involving unaided abstainers who had stopped smoking where it is prohibited, due to factors such as pregnancy, hospital stay, or military training. Another group of studies concerned ex-smokers recruited from the general population.

We divided studies into those assessing behavioural interventions and those assessing pharmacotherapy. We classified behavioural interventions into intensive and less intensive categories. Intensive interventions involve repeated face-to-face contact usually aimed at teaching clients to identify tempting situations and to apply a range of coping skills and cognitive strategies assumed to be of help in resisting relapse. Less intensive interventions usually attempt to teach these skills via written materials and may also involve one brief face-to-face session and telephone contacts. In the event that any trials used telephone contacts of sufficient frequency and duration to be considered an intensive intervention we would have investigated the sensitivity of our findings to alternative categorization.

1.1 Behavioural interventions in special populations

Seventeen studies focused on populations other than smokers seeking treatment, including pregnant and postpartum women, hospital inpatients, and army recruits. Most used minimal face-to-face contact and relied primarily on written materials and/or phone calls. Studies examining more intensive interventions had very small sample sizes. No study in this group used a pharmacological intervention.

Eight studies among pregnant women (Severson 1997; McBride 1999; Hajek 2001; McBride 2004; Pbert 2004; Morasco 2006; Hannöver 2009; Ruger 2008) and one study in hospital inpatients (Schmitz 1999) included both current smokers and recent ex-smokers, but analyzed the two subgroups separately and so were eligible for inclusion here. Two studies randomized smokers and recent ex-smokers during pregnancy and evaluated the effect of post-pregnancy intervention on women from both groups who did not smoke at delivery (McBride 1999; McBride 2004).

1.1.1 Pregnant and postpartum ex-smokers

Fourteen studies randomized pregnant (Ershoff 1995; Secker-Walker 1995; Lowe 1997; Secker-Walker 1998; McBride 1999; Hajek 2001; McBride 2004; Pbert 2004; Morasco 2006; Ruger 2008) or post-postpartum (Severson 1997; Ratner 2000; Van't Hof 2000; Hannöver 2009) ex-smokers for interventions designed to assist them in remaining abstinent throughout their pregnancy and/or after the delivery.

Six studies evaluated relatively brief interventions comprising an initial face-to-face counselling session supported by written materials given out at the session (Secker-Walker 1995; Lowe 1997; Secker-Walker 1998; Hajek 2001), or over a period of time via repeated mailings (Ershoff 1995), or with the addition of a video (Severson 1997). In each case there was provision for opportunistic support of different intensity at other routine visits. One study provided the initial relapse prevention counselling session and reinforcements at later visits without written pamphlets (Van't Hof 2000). Two studies included no face-to-face contact specific to the intervention but provided a series of phone calls, (McBride 2004) or calls and letters, booklets, and newsletters (McBride 1999). One study used a 90-minute psychotherapy session and additional phone calls (Morasco 2006). Two studies evaluated motivational interviewing (Hannöver 2009; Ruger 2008). One study evaluated a more intensive postpartum intervention that included in addition to the initial session and written materials a series of eight supportive telephone calls (Ratner 2000). One study randomized clinics to implement a provider counselling and office systems intervention (Pbert 2004). We were unable to extract data in a comparable format to pool with the other studies so report it separately

1.1.2 Hospital inpatients

Two studies randomized hospital inpatients suffering from cardiovascular illness who had not smoked from the time of hospital admission. One study evaluated a brief routine one-off intervention supported by written materials (Hajek 2002) and the other compared six weekly sessions of skills-oriented relapse prevention with didactic presentations (Schmitz 1999). A third study randomized patients who had quit during or shortly before hospitalisation to receive three telephone calls after discharge; all patients received counselling in hospital (Hasuo 2004).

1.1.3 Military recruits

Three studies provided interventions to smokers undergoing enforced abstinence during armed forces training. Two randomized

US air force recruits; Klesges 1999 provided a 50-minute session during training, covering the short-term health consequences, costs and social impact of smoking, Klesges 2006 provided two one-hour sessions. Conway 2004 randomized naval recruits; in addition to regular smokers, the intervention targeted former, occasional and experimental smokers. Two interventions were tested; written materials mailed in six instalments after the conclusion of the training, or access to a telephone help line.

1.2 Behavioural interventions in unselected populations

There were ten studies of behavioural interventions in general populations of smokers.

1.2.1 Behavioural interventions for unaided abstainers

Five studies randomized participants recruited from local communities:

- Brandon 2000 & Brandon 2004 recruited volunteers who reported at least one week of abstinence (the average duration of prior abstinence was 16 months in Brandon 2000 and 75 days in Brandon 2004).
- In Fortmann 1995, volunteers recruited with the help of random digit dialling and incentives were randomized following a 24 hour abstinence.
- In Killen 1990, volunteers recruited by advertisements were encouraged over the phone to set a quit date and were randomized if they managed to abstain for 48 hours.
- In Borland 2004 callers to a quitline were recruited into a study a day or two later, and we include only the subgroup who had already quit at this baseline.

All the interventions were relatively low intensity, involving self-help materials or telephone contact:

- Killen 1990 examined effects of an eight-week self-guided relapse prevention programme based on 16 modules. Participants received the basic module at the first session. Following this, another seven modules either selected by the participants or assigned randomly were dispensed via weekly mailings over the next seven weeks. The factorial study also included nicotine chewing gum conditions (covered below).
- Fortmann 1995 evaluated a two-phase self-help relapse prevention programme including 12 weekly progress reports to be mailed by participants to the programme office. The factorial study also included nicotine chewing gum conditions (covered below).
- Brandon 2000 compared effects of a single booklet to a partly pro-active telephone helpline, eight booklet mailings, and a combination of helpline and mailings.
- Borland 2004 compared the provision of tailored advice letters based on telephone assessments to provision of standard materials only.
- Brandon 2004 manipulated contact and content by comparing eight booklet mailing over 12 months, the same booklets at a single mailing, eight supportive letters over 12 months, and a single booklet which we treat as the control in the analysis.

1.2.2 Behavioural interventions for assisted abstainers

Six studies randomized abstaining smokers who had taken part in a formal treatment programme:

- Powell 1981 randomized abstainers at the end of a five-day programme into a four-week support group, a telephone 'buddy' system, or to a no-treatment control.
- Stevens 1989 recruited smokers who had a quit date one week earlier and were smoking no more than one cigarette in the previous four days. Participants were randomized into three weekly skills training group sessions, three weekly discussion group sessions, or to a no-treatment control.
- Razavi 1999 randomized clients abstinent at the end of a three-month treatment with nicotine patch and group support into monthly group meetings focusing on relapse prevention strategies, monthly group meetings run by former smokers offering general support, or to a no-treatment control.
- Smith 2001 randomized participants eight days after quit date, using stratification based on smoking status, so that those who were abstinent during this week were analyzed separately. The two intensive interventions consisted of six 90-minute group sessions spaced over four weeks after the randomization session. They focused either on cessation skills and negative affect (cognitive behavioural treatment) or on fostering intrinsic motivation and resolving patient ambivalence (motivational interviewing). The control group did not receive any intervention after the randomization session.
- Mermelstein 2003 randomized people at the end of a seven-week group behavioural programme to receive either tailored counselling calls or non-specific calls from their counsellor. We only include the subgroup who were abstinent at the end of the group meetings.
- Juliano 2006 was a study of a relapse-sensitive rapid smoking intervention that randomized participants who lapsed in the first 14 days after an intervention including counselling and bupropion.

1.3 Pharmacological interventions

1.3.1 Pharmacological interventions for short-term unaided abstainers

Two studies of nicotine gum randomized participants who had briefly stopped unaided:

- Killen 1990 randomized participants who stopped unaided for 48 hours to nicotine gum on either a fixed or ad lib dosing schedule, with a no gum control.
- Fortmann 1995 randomized participants who stopped smoking unaided for 24 hours into nicotine chewing gum and no medication groups. (Both these factorial studies also included behavioural interventions which are covered above).

1.3.2 Pharmacological interventions for abstainers following cessation pharmacotherapy

Five studies enrolled people to use pharmacotherapy to aid initial cessation before randomizing successful abstainers to a pharmacotherapy for maintenance. We also include in this subgroup a sixth study, Killen 2006, where participants were randomized before starting the quit attempt. The classification of this study is discussed further in the results section. Five studies evaluated effects of extended treatment with bupropion. Three of them also included arms using nicotine replacement therapy (NRT). One study evaluated effects of extended use of varenicline.

- Hays 2001 used bupropion to aid cessation, and participants were randomized if they had been quit for at least one week at the end of seven weeks of treatment. Bupropion or placebo was used for the rest of the year and participants were followed up for a second year.
- Hurt 2003 used nicotine patch to aid cessation, and abstainers were eligible for randomization at the end of eight weeks of patch therapy. Bupropion or placebo was used for six months after randomization and participants were followed up for another six months.
- Killen 2006 used combination therapy of nicotine patch, bupropion and individual relapse prevention counselling for almost three months, then either bupropion or placebo (after tapering of bupropion) for 14 weeks. Follow up was at 12 months from quit date. Since participants were randomized at baseline people who had failed to quit were still eligible for the randomized phase and included in the denominator.
- Covey 2007 used bupropion and nicotine patch combination to aid cessation and randomized abstainers after eight weeks. The double placebo-controlled maintenance phase tested bupropion and nicotine gum in a factorial design. Therapy lasted 16 weeks, and participants were followed up for another six months to assess abstinence 12 months from quit date.
- Croghan 2007 randomized participants to bupropion, nicotine inhaler or combination therapy for three months. In a second phase abstainers using a single therapy were randomized to continue the same therapy or receive a placebo for a further nine months, with post-therapy follow up for a further three months. Abstainers using combination therapy were randomized factorially to bupropion or placebo pill and nicotine inhaler or placebo inhaler.
- Tonstad 2006 used open label varenicline for 12 weeks. Abstainers were randomized to varenicline or placebo for a further 12 weeks, then followed up for six months to assess abstinence 12 months from quit date.

Section 2 Studies randomizing smokers prior to their quit date

There was no study evaluating pharmacotherapy in this category, all studies were assessing behavioural interventions. We included two categories of such studies: those which compared time-matched interventions with and without the relapse prevention elements, and those which looked at the effect of extended patient contact. For studies with more than two groups, we included the most intensive versus the least intensive in the main meta-analysis, and discussed additional differences in the results. We refer to the least intensive intervention as the 'control'.
To evaluate the impact of treatment intensity, we considered separately interventions providing treatment for up to four weeks and interventions providing patient contact for longer than four weeks.

2.1 Intervention and control groups matched for contact time

In ten studies intervention and control conditions were matched for the amount of contact. (Some studies also compared a longer intervention, in which case the relevant arms are also compared in the next category). Eight used a group format for behavioural intervention (Hall 1984; Davis 1986; Curry 1988; Emmons 1988; Buchkremer 1991 1; Buchkremer 1991 2; Becona 1997; Schroter 2006) and two used an individual counselling format (Niaura 1999; Schmitz 1999). Three provided pharmacotherapy to all treatment conditions (Emmons 1988; Buchkremer 1991 1; Buchkremer 1991 2). A factorial design was used to test nicotine gum against no gum (Niaura 1999).
The components used for relapse prevention were varied.

- Hall 1984 was a factorial study. The arms comparing two variants of aversive smoking are combined in this analysis. In six of the 14 sessions the relapse prevention (RP) group received relaxation and relapse prevention skills training and reviewed the cost of smoking and benefits of abstinence, while the control group met for general discussion.
- Davis 1986 compared three six-session treatments, i.e. active skills training, discussion of high-risk situations (not shown in graphs), and a standard programme. There were only 45 participants in the study.
- In one arm of a factorial study Curry 1988 compared two programmes in a self-help format, one using a skills-oriented relapse prevention training permissive to slips, and the other stressing absolute abstinence. The other arm compared these two approaches delivered in a format of eight weekly group sessions, where the absolute abstinence approach also included gradual

reduction and a quit date two weeks later than in the relapse prevention group. The two study arms are treated separately.

- Emmons 1988 compared two programmes with different numbers of sessions across the same period of time, both accompanied by nicotine gum. The relapse prevention programme consisted of eight weekly sessions focused on coping with high-risk situations, cognitive behavioural strategies and role play. The 'Broad Spectrum' behavioural programme consisted of 12 sessions focusing on strategies for dealing with cravings and weight control, with quitting preceded by nicotine fading over three weeks.
- Two trials by Buchkremer and colleagues explored a variety of behavioural components as well as different dosing schedules for the nicotine patch. The programme consisted of nine weekly sessions, with a target quit date after six weeks of gradual reduction. Relapse prevention components including role play were included in one intervention and this was compared to the same length control (Buchkremer 1991 1). In a second study an alternative relapse prevention approach was also used, modifying the programme to reach total abstinence after four weeks, and adding additional behaviour therapy techniques including covert sensitization and thought-stopping. Since the differences were relatively small we combine the two relapse prevention programmes (Buchkremer 1991 2).
- Becona 1997 compared eight-week behavioural treatment programmes with and without a relapse prevention problem-solving component.
- Niaura 1999 tested imaginary cue exposure as an addition to individual cognitive behavioural treatment. All groups had five post-quit sessions, and we have included them in the matched contact control group, although the duration of both control conditions was different. In a factorial design a nicotine gum and no gum condition were compared.
- Schmitz 1999 used a sample of women with cardiac risk and compared six sessions of skills-oriented relapse prevention with six sessions of didactic presentations on cardiac risk and the benefits of quitting.
- Schroter 2006 compared six sessions including components such as role-playing coping responses to high-risk situations and self awareness to a standard behavioural cessation programme that focused on positive changes obtained through abstinence.

2.2 Intervention and control not matched for contact time or duration

Almost all smoking cessation studies which compare more and less intensive treatments include some intervention to prevent relapse. We only included trials that specified relapse prevention as an explicit focus of the intervention in the title or abstract. We did not include studies offering treatment proactively to special populations such as pregnant or hospitalized smokers, because all trials using these groups provide some relapse prevention input within the active treatment arm, and they are covered in separate meta-analyses. Where studies had three or more treatment conditions, the main analyses compare the most and least intensive interventions.

2.2.1 Varying intensity of face-to-face treatment

Seven studies compared longer and shorter programmes. The relative intensity of the common cessation programme and the additional relapse prevention component was variable. We subgrouped studies according to whether the control group received more than four sessions.

- Killen 1984 provided nicotine gum and one-week intensive behavioural treatment which included relapse prevention components plus seven further brief visits, and compared groups with and without two additional group sessions and optional drop-in visits. There was also a group with no gum which was not used in our analysis.
- Brandon 1987 treated a sample of smokers with six sessions over two weeks and compared a group receiving no further treatment with a group receiving four additional relapse prevention sessions. Another arm adding a rapid puffing component is not covered in this review.
- Hall 1987 combined nicotine or placebo gum with either five or 14 sessions, where the more intensive treatment also contained a larger relapse prevention component.
- Buchkremer 1991 1 tested the addition of three booster sessions six months after the basic nine-session programme or programme with relapse prevention components. All groups received nicotine patch.
- Shoptaw 2002 studied smokers treated for heroin dependence and compared nicotine patch combined with 12 weeks of brief visits with the additions of a behavioural programme including relapse prevention and mood management, a contingency management programme where participants were paid for abstinence, and a combination of the latter two.

Two studies had control groups that offered four or fewer sessions

- Hall 1985 combined nicotine gum with either four educational sessions over three weeks, or a behavioural treatment which included relapse prevention components provided in 14 sessions over eight weeks. (A behavioural treatment only group is not included here).
- Lifrak 1997 combined nicotine patch treatment with either three supportive sessions with a nurse over nine weeks, or 16 relapse prevention sessions with a behavioural therapist over 16 weeks.

2.2.2 Extended contact using proactive phone calls

One study (Lando 1996) provided group-based behaviour therapy for eight weeks and compared a group having no further treatment with a group receiving proactive calls 1, 8 and 11 months later. We excluded other studies that tested the use of telephone counselling as an adjunct (add-on) to nicotine replacement therapy, because they did not describe the intervention as relapse prevention, and most of the behavioural support was provided during the period of intended pharmacotherapy, i.e. not extending the overall duration of treatment.

2.2.3 Access to additional web-based support

One study (Japuntich 2006) provided bupropion and brief individual counselling to all participants. The intervention consisted of internet access to the Comprehensive Health Enhancement Support System for Smoking Cessation and Relapse Prevention (CHESS SCRP) for 12 weeks.

Risk of bias in included studies

Sample size

Many trials were small and therefore had limited power to detect realistic differences in quit rates, especially in the group that randomized smokers prior to quit date.

Study design

Studies randomizing successful end-of-treatment quitters provide the most straightforward test of relapse prevention interventions designed for clinical practice (see discussion below). Five studies of pharmacological treatments used this approach, but only two studies of behavioural treatments randomized participants who were abstinent after more than one week of treatment (Razavi 1999; Mermelstein 2003).

Definition of smoking cessation

All studies were required by our inclusion criteria to report smoking status a minimum of six months from the start of the intervention. In the case of studies that randomized smokers prior to quitting, this could have been from the quit date. Some timed follow up from the end of treatment. Five trials (Emmons 1988; Schmitz 1999; Van't Hof 2000; Japuntich 2006; Juliano 2006;) had six months follow up, and all others had a longer follow-up period from the start of intervention.

Some studies did not provide a definition of abstinence (Powell 1981; Becona 1997; Klesges 1999; Hasuo 2004), and most others reported a point prevalence rather than a sustained measure of abstinence.

Validation of self-reported abstinence

Biochemical validation of most or all self-reports of abstinence was reported for most studies. Eleven studies did not attempt any validation (Powell 1981; Severson 1997; Klesges 1999; Van't Hof 2000; Mermelstein 2003; Borland 2004; Conway 2004; Klesges 2006; Schroter 2006; Hannöver 2009; Ruger 2008), but in some other cases samples were not collected from all participants, were not collected at long-term follow up, or were not used to correct self reports. One study noted more deception amongst the intervention group participants than among those in the control condition (Pbert 2004).

Randomization & allocation concealment

All studies stated that allocation was random but few reported the method of sequence generation and allocation in sufficient detail to be certain that risk of bias was minimised. Nine studies used cluster-randomized designs. In the three among military recruits (Klesges 1999; Conway 2004; Klesges 2006) allocation was by training group, and selection bias was unlikely. In a further three allocation was by midwife (Hajek 2001; Pbert 2004) or paediatric practice (Severson 1997), and selection bias in the subsequent enrolment of participants might have been possible. Two of the cluster-randomized trials reported that correlation between outcomes in individuals in the same cluster was small so that reporting individual outcomes was acceptable. These two trials also had high loss to follow up, although there was no evidence of differential loss between arms. One study in pregnant women (Pbert 2004) randomized six clinics but one control clinic withdrew because of poor participant recruitment. Of the remaining five sites, two contributed over 50% of the participants. An appropriate method of analysis was used; due to the small number of clusters there were differences between crude effects and corrected estimates and we did not attempt to incorporate the results into a meta-analysis. One small study ran an intervention and a control group in each of four workplaces. There was no information on recruitment and participant blinding procedures (Schroter 2006).

We give details of individual studies in the tables. In the absence of significant findings in meta-analysis subgroups, or evidence of heterogeneity, we did not attempt to explore any influence of study quality on outcomes.

Effects of interventions

Section 1: Trials in abstainers

1.1 Behavioural interventions in special populations

1.1.1 Pregnant and postpartum ex-smokers

In pooling the results of eight trials of interventions in pregnancy we did not demonstrate a significant benefit at the end of pregnancy (n = 1523, risk ratio [RR] 1.04; 95% confidence interval [CI] 0.98 to 1.11, I^2 = 0%, Analysis 1.1). Twelve studies included follow up during the postpartum period. We also failed to detect any significant benefit among this group of studies, overall or in subgroups according to timing of intervention (n = 3273, RR

1.07; 95% CI 0.98 to 1.18, I^2 = 0%, Analysis 1.2). One further study that we could not include in the meta-analysis did not detect any significant effect of intervention on spontaneous quitters at delivery; the postpartum non smoking rate was higher in the usual care group (Pbert 2004).

1.1.2 Hospital inpatients

There was no evidence of a significant benefit of intervention in hospitalized patients who had not smoked in hospital, based on pooling three studies (Schmitz 1999; Hajek 2002; Hasuo 2004) (n = 667, RR 0.94; 95% CI 0.78 to 1.13, I^2 = 0%, Analysis 2.1)

1.1.3. Military recruits

We did not display results graphically or pool results because denominators were unclear and reported results corrected for clustering. In all three trials the period of enforced abstinence did give rise to a higher quit rate than the spontaneous rate expected in these populations of young smokers, but only Klesges 2006 reported a statistically significant effect. Adjusting for clustering and predictors, the odds ratio for continuous abstinence at one year was 1.23 (95% CI 1.07 to 1.41). The crude abstinence rates were 15.47% versus 13.74% so the absolute effect was small. The earlier study (Klesges 1999) only reported a significant intervention effect in a subgroup of people who had not been planning to remain quit after the end of training. The study in female naval recruits, (Conway 2004) provided the intervention after the end of training and did not detect an effect of either mail or phone intervention; less than 3% of participants called the helpline for counselling.

1.2 Behavioural interventions in unselected populations

1.2.1 Behavioural interventions for unaided abstainers

We found no evidence of a benefit of interventions to prevent relapse in people who had initially quit unaided (Killen 1990; Fortmann 1995; Brandon 2000; Borland 2004; Brandon 2004) (n = 3561, RR 1.08; 95% CI 0.98 to 1.19, I^2 = 1%, Analysis 3.1). All five studies used low intensity self-help interventions, although in one the materials were individually tailored based on information collected via telephone questionnaires and this trial suggested a borderline effect (Borland 2004).

1.2.2 Behavioural interventions for assisted abstainers

We detected no long-term benefit from skills-based interventions to prevent relapse in five studies where abstaining smokers were randomized after they had taken part in a formal treatment programme. (Powell 1981; Stevens 1989; Razavi 1999; Smith 2001; Mermelstein 2003) (n = 1462, RR 1.00; 95% CI 0.87 to 1.15, I^2 = 56%, Analysis 4.1). This meta-analysis compared the most intensive intervention to the least intensive control in the trials with more than two arms. Using different comparison conditions did not change the conclusion.

One small trial (Juliano 2006) offered up to three sessions of rapid smoking to participants who lapsed within 14 days of a cessation intervention. No participants (0/20) were abstinent at six months in intervention group and only one in the control (1/14). There was no evidence of a short-term benefit either. This supports the observation that people who cannot maintain abstinence in the early days of a quit attempt are at particularly high risk of relapse, and does not support the use of rapid smoking as a relapse prevention measure.

1.3 Pharmacological interventions

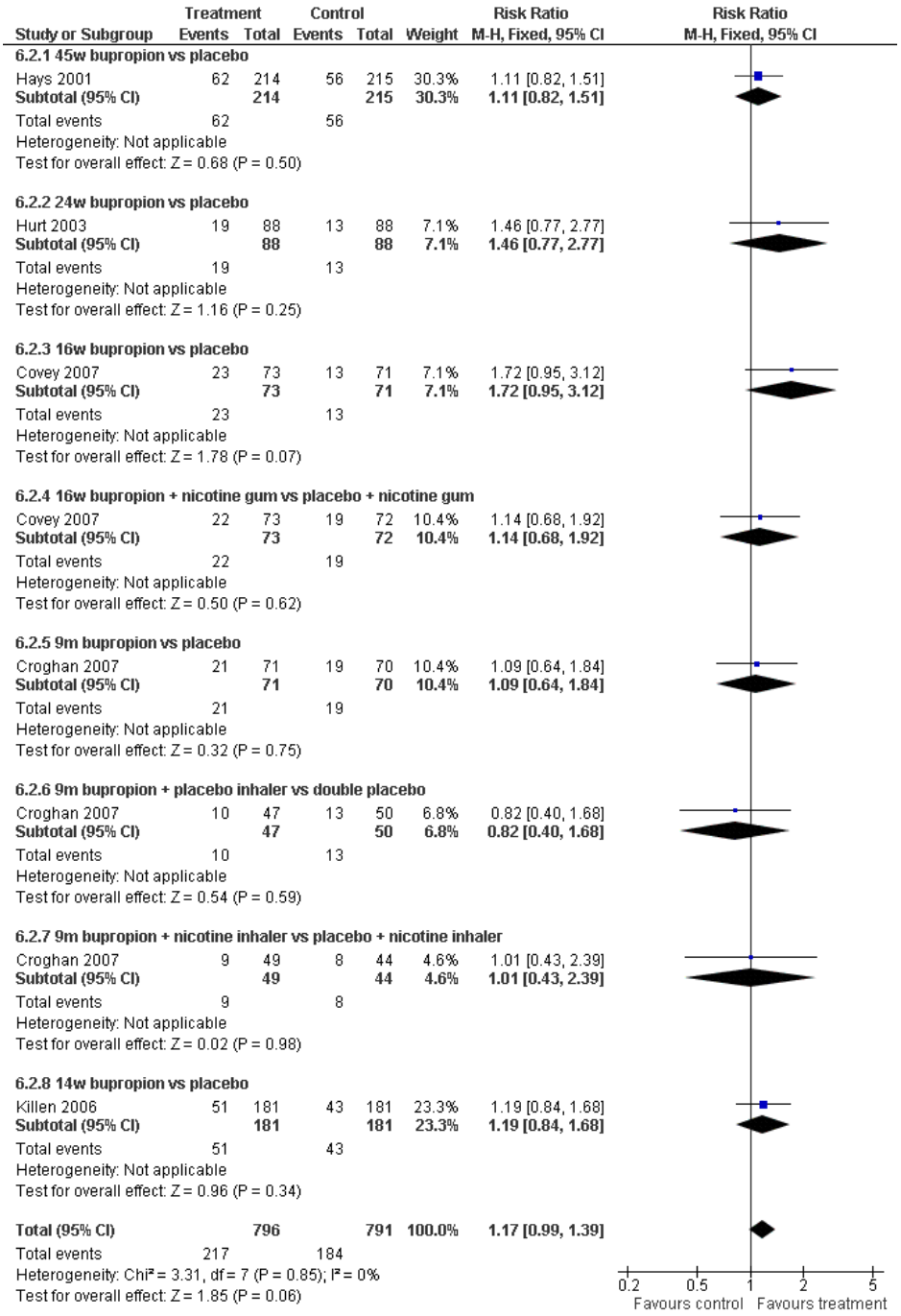
1.3.1 Pharmacological interventions for short-term unaided abstainers

Pooling two large trials of nicotine gum detected a small effect (Killen 1990; Fortmann 1995) (n = 2261, RR 1.24; 95% CI 1.04 to 1.47, I^2 = 56%, Analysis 5.1). In both these studies the period of unassisted abstinence was short and these studies are distinct from the next group in which a more extended period of abstinence was required before the relapse prevention phase was initiated.

1.3.2 Pharmacological interventions for abstainers following cessation therapy

Pooling two studies of NRT (Covey 2007 using gum and Croghan 2007 inhaler, both with factorial designs entered separately) did not detect a significant long-term effect (n=553, RR 1.04, 95% CI 0.77 to 1.40, I^2 = 0%, Analysis 6.1). This contrasts with the two studies covered in the previous section. It is worth noting that the compliance with oral NRT was low and that one study replaced the initial patch treatment with 2mg gum (Covey 2007).
The estimated effect of extended therapy with bupropion based on five studies narrowly misses statistical significance (n=1587, RR 1.17, 95% CI 0.99 to 1.39, I^2 = 0%, Analysis 6.2) Hays 2001; Hurt 2003; Killen 2006; Covey 2007; Croghan 2007). Whilst there was no evidence of statistical heterogeneity there was some clinical heterogeneity in the intervention used for the cessation induction phase, the duration of treatment and the duration of follow up after the end of medication.
Figure 1

Figure 1. Forest plot of comparison: 6 Pharmacotherapy for assisted abstainers, outcome: 6.2 Bupropion versus placebo. Cessation at least 6m after end of therapy, & at least 12m after quit date.



Covey 2007; Croghan 2007 also allow a comparison between combination therapy of bupropion and NRT versus neither. No significant benefit was detected (n= 243, RR 1.18; 95% CI 0.75 to 1.87, Analysis 6.3), and there was some evidence of heterogeneity (I^2 = 66%).

A single study (Tonstad 2006, n=1210) detected a significant benefit of extended varenicline (RR 1.18, 95% CI 1.03 to 1.36, Analysis 6.4).

Section 2: Studies randomizing smokers prior to their quit date

2.1 Intervention and control groups matched for contact time

We found no benefit from the use of specific relapse prevention components in group or individual format interventions, based on 10 trials (n = 872, RR 0.91; 95% CI 0.73 to 1.13, I^2 = 11%, Analysis 7.1). There was no evidence of heterogeneity. As all but one (Niaura 1999) of the studies involved treatment contact for more than four weeks, we did not conduct a subgroup analysis by treatment duration. The majority of trials used a skills training approach so we did not conduct a subgroup analysis by treatment type.

One study with two arms comparing different versions of a self-help programme did not detect a difference in quit rates (Curry 1988, RR 1.52; 95% CI 0.67 to 3.46, Analysis 7.2).

2.2 Intervention and control not matched for contact time or duration

2.2.1 Varying intensity of face to face intervention

We detected no effect of relapse prevention involving extended face-to-face contact in seven trials (Killen 1984; Hall 1985; Brandon 1987; Hall 1987; Buchkremer 1991 1; Lifrak 1997; Shoptaw 2002) (n = 699, RR 1.01; 95% CI 0.80 to 1.27, I^2 = 4%, Analysis 8.1). There was no evidence of differences between subgroups based on number of control group contacts.

2.2.2 Extended contact using proactive telephone calls

One trial (Lando 1996) did not detect a benefit of providing extended contact by telephone after an intensive eight-week group programme (RR 1.07; 95% CI 0.90 to 1.28, Analysis 9.1.1).

2.2.3 Access to additional web-based support

One trial (Japuntich 2006) did not detect a benefit of providing support via the internet as an adjunct to bupropion and brief counselling (RR 1.27, 95% CI 0.70 to 2.31, Analysis 9.1.2). Nor was an effect detected amongst a subgroup of participants who were quit at two-day follow up, a more specific test of relapse prevention. Frequent users were more likely to remain abstinent when controlling for other potential predictors of success.

DISCUSSION

In this review we failed to detect a clinically significant effect of existing behavioural 'relapse prevention' methods for people quitting smoking. However, there are several factors which may temper this disappointing conclusion. The included studies had both methodological and content limitations. Only a small number of studies included in this review had adequate sample sizes to detect the expected effects. Most studies which randomized recent abstainers focused on brief or written interventions rather than on more intensive treatments, and most of the existing studies tested only one particular treatment approach.

This update suggests that there could be a benefit of extended treatment with varenicline for preventing relapse. In a trial of extended varenicline use (Tonstad 2006) 63% of those quit after 12 weeks on varenicline had relapsed by the end of a year, compared to only 56% of those who had a further 12 weeks of therapy. The five studies of bupropion, when combined, narrowly failed to reach significance; none of the five yielded a significant result on their own, and the two comparisons of bupropion plus nicotine replacement therapy (NRT) versus double placebo were also negative. This makes it unlikely that any clinically significant effect was missed.

In discussing the further implications of this review we comment first on the technical aspects and limitations, and attempt to make some methodological recommendations for future work in this area. We then discuss some of the conclusions pertaining to different treatment formats.

Inclusion and exclusion of studies

Identifying criteria for including studies in this review was difficult. We included all studies which randomized abstainers, as these provide the best test of interventions aimed at maintaining abstinence. Studies randomizing smokers prior to quitting presented a challenge. Although such studies may be described as studies of relapse prevention, they usually test primarily smoking cessation interventions, with interventions aimed at preventing relapse added to the treatment programme, but not analyzed separately. One of the problems in considering the inclusion of smoking cessation studies with a specified relapse prevention component was that they were sometimes similar in design to other studies that did not specifically mention relapse prevention in their title or abstract but used virtually identical methods. In our initial analyses we included a wider group of studies (e.g. Goldstein 1989; Zelman 1992; Hall 1994; Hall 1996; Brown 2001), but in the end decided to restrict the analysis of studies randomizing smokers to those that mentioned relapse prevention explicitly. The results of the review are not affected by this decision, as the excluded studies were also small and did not show significant treatment effects either. We also excluded a small number of studies randomizing smokers prior to quitting, that explicitly included relapse prevention or maintenance but concerned smoking cessation interventions that

are already covered by three other Cochrane reviews: exercise (Ussher 2008), aversive smoking (Hajek 2004), and interventions for hospitalized smokers (Rigotti 2007).

The negative results of the individual studies are fairly consistent and it is unlikely that using alternative inclusion criteria would lead to different conclusions, but there are problems in identifying appropriate studies in this difficult area. The possible limitations of the review are that we have failed to identify relevant research, and that we have not pooled studies appropriately. We think it is unlikely that large effects have been missed in the trials so far conducted, but in some cases the studies were too small to detect moderate effects.

The two trial designs according to the timing of randomization

The key methodological feature of the existing attempts to evaluate relapse prevention interventions concerns the time when subjects were randomized, i.e. before or after they stopped smoking.

The main logical argument in favour of randomizing smokers prior to stopping smoking is that much relapse prevention advice could be relevant even in the very first stages of quitting smoking. On the practical side, while it is relatively easy to attract smokers to start an experimental treatment, the samples would be much smaller if only those abstinent at the end of treatment were enrolled. However, combining cessation and relapse prevention reduces the power to detect specific relapse prevention effects. The primary outcome variable is normally the abstinence rate at follow up, and it is difficult to differentiate any effects the intervention may have had on the initial smoking cessation from effects on preventing relapse in smokers who were initially successful. The initial success or failure is likely to be determined by a number of intervention and subject variables other than the relapse prevention component which is usually only a small part of the overall programme. One way to resolve this problem could be to focus the analysis on the initial successes only. However, none of the existing studies used this approach and the published data usually do not include sufficient details to allow survival analysis. Even if relapse rates for initially successful abstainers were available, the relapse prevention effect would be difficult to interpret where comparison groups have different short-term cessation rates.

Randomizing only those smokers who have made a successful quit attempt represents a stronger study design. As cessation interventions are segregated from relapse prevention interventions, the results cannot be skewed by uneven initial cessation rates, any relapse prevention effects are more likely to be detected, and the results are easy to interpret. On the downside, this approach requires more effort to recruit sufficient samples. Of the existing studies of behavioural treatments using this approach, the majority have used spontaneous abstainers such as pregnant women. In fact, of the eligible studies of behavioural methods for relapse prevention, only two studies randomized smokers abstinent at the end of an initial treatment episode (Razavi 1999; Mermelstein 2003), and three randomized smokers abstinent five to eight days after their quit day (Powell 1981; Stevens 1989; Smith 2001).

The difference between the initial smoking cessation and later relapse prevention treatment is much clearer in pharmacotherapy and unsurprisingly, all drug trials but one used this more robust paradigm.

The studies that randomized abstainers varied considerably in the periods of time for which participants had already abstained from smoking, i.e. from 24 hours to 16 months. There seems to be a broad agreement on the conceptual distinction between 'stopping smoking' and 'staying quit' and on the common understanding of the concept of relapse, but there is a lack of accepted operational definitions, although some suggestions have been made (Ossip-Klein 1986). It seems clear that abstinence for a period of time close to inter-cigarette intervals, or overnight abstinence, does not constitute cessation of smoking, and that a return to smoking after several weeks of total abstinence can be classified as a relapse. However, common behaviours such as abstinence for 24 hours, or smoking only a few cigarettes every few days, become more difficult to classify. There is little consensus on what amount of smoking after what type of smoking restraint over what period of time represents a relapse as opposed to the initial failure to stop smoking. Ideally, future relapse prevention studies should follow the example of the existing drug trials and use sufficiently long periods of no smoking and sufficiently strict definitions of the initial abstinence and outcome to avoid areas of contention.

Some methodological recommendations

The ideal study of a relapse prevention intervention aimed at complementing existing treatments for smokers seeking help would randomize smokers who were abstinent continuously and completely for at least four weeks. An appropriate outcome measure would be continuous lapse-free abstinence of at least six months where the intervention was aimed at avoiding lapses, but some lapses would have to be allowed where the intervention aimed at helping patients to cope with lapses should these occur. There is a general agreement that for dependent smokers seeking treatment, becoming an occasional smoker is usually not an option, and that for a long-term success, any lapses would have to cease eventually. It would seem sensible to allow lapses over a limited 'period of grace' (e.g. three or even six months), followed by at least six months of lapse-free abstinence. Most studies in this review were seriously underpowered, using 15 or 20 participants per condition. Future research needs to acknowledge that any effects are likely to be small and that large samples will be needed to avoid Type 2 errors.

Interpreting the review results

The 37 studies randomizing abstainers represent the main interpretable body of data in this field. The results of both special pop-

ulation studies and studies of smokers seeking treatment suggest that behavioural brief interventions and interventions relying on written materials, mailings, and telephone contact are ineffective for relapse prevention. It may be important to notice that more intensive approaches were examined in only a handful of studies, with some being too small to detect any realistic effect. Although intensive interventions in this area need to resolve the likely problems related to intervention costs and patient attendance, there may be scope for further work on such treatments.

Rates of abstinence were very variable across different studies, due to factors that include the population studied, the intensity of any cessation intervention provided, the period for which abstinence had already been maintained, the length of follow up and the definition of cessation. Because of the obvious problems with comparisons of success rates across studies (Hajek 1994), we did not discuss results in terms of the absolute abstinence rates achieved.

With regard to the contents of the behavioural interventions, the negative results concern primarily the traditional skills-based approach which holds a virtual monopoly in this field. It remains a possibility that the original concept is valid, i.e. that patients can benefit from being taught how to identify tempting situations, and that there are effective strategies for coping with such situations that can also be taught. If this is the case, the negative results could have been due to such skills not being taught effectively. If there are any further studies of this approach, they should try to check whether participants acquired and practised the skills taught. However, an alternative possibility has to be considered, i.e. that despite the strong intuitive validity and popularity of the classic relapse prevention procedures, they do not have the desired effect. Future studies may be better advised to focus on alternative approaches not studied extensively or at all so far, such as opportunistic use of nicotine replacement, contingency contracting, social support, cue exposure (only imaginary exposure has been studied so far), interventions aimed at maintaining abstainers' morale and awareness of a danger of feckless slips, etc.

Regarding the pharmacological interventions, while there are good large studies of extended use of bupropion and varenicline, NRT has been studied only in relatively small samples, as an add-on to bupropion trials, and in paradigms likely to generate low treatment compliance which lower the chance of detecting effects of the expected size. Given the good acceptability, safety, and cost profile of NRT, there is a need for trials of extended NRT use in relapse prevention.

AUTHORS' CONCLUSIONS

Implications for practice

The available evidence does not support the use of any specific behavioural component or intervention for helping smokers who have successfully quit for a short time to avoid relapsing to smoking again. The conclusion of a lack of efficacy concerns specifically the traditional treatment focusing on identifying and resolving tempting situations, and minimal interventions using one-off sessions and written materials. There is hardly any evidence available on alternative approaches. Until new positive evidence becomes available, it may be more efficient to focus resources on supporting initial cessation attempts rather than on extended relapse prevention interventions. Regarding pharmacotherapies, extended treatment with varenicline may prevent relapse. Extended treatment with bupropion is unlikely to have a clinically important effect.

Implications for research

There are limitations to the current research, both in the methodology and in treatment approaches tested. Future research, especially in behavioural interventions, should take account of this in designing studies of adequate methodology and sample size, and examining alternatives to attempts to teach skills to cope with risk situations. Studies of extended treatment with nicotine replacement are needed.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Becona 1997

Methods	Setting: Cessation clinic, Spain Recruitment: community volunteers Randomization: method NS Group size: 36-40
Participants	76 smokers, >=10cigs/day (excludes an untreated control group of 40, not randomly selected). 51% F, av. age 34, av. cigs/day 28
Interventions	Both conditions received 8 weekly sessions in groups of 36-40, duration NS, TQD week 4. 2 experienced therapists 1. Standard programme: motivational contract, nicotine fading, stimulus control 2. RP. As 1 + problem solving.
Outcomes	Abstinence at 12m (definition NS) Validation: CO <8ppm during therapy, informants during follow up
Notes	

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomization method not described
Allocation concealment?	Unclear	No information given
Incomplete outcome data addressed? All outcomes	Yes	All randomized participants included in ITT analysis

Borland 2004

Methods	Setting: Quitline, Australia Recruitment: volunteers calling a quitline to request S-H materials
Participants	215 smokers who had quit at time of recruitment (other participants not included in this review) Demographics for all participants: 54% F, approx 47% <30y, av.cigs/day 21 63% had quit in previous week
Interventions	All participants received a quit pack at the time of first contact with the quitline, 1-2 days before recruitment 1. Series of tailored advice letters based on standardized telephone assessment. 2-3 pages, tailored in part by stage of change, timing varied 2. No further intervention

Borland 2004 (*Continued*)

Outcomes	Abstinence at 12m, sustained for 6m Validation: none	
Notes		

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Computer-generated numbers with even numbers allocated to intervention
Allocation concealment?	Yes	ID number generated after agreement to participate
Incomplete outcome data addressed? All outcomes	Yes	Losses to follow-up 23% in each group, all included in ITT analysis

Brandon 1987

Methods	Setting: Cessation clinic, USA Recruitment: community volunteers
Participants	39 abstainers at the end of cessation treatment Sex NS, av.age 31, av.cigs/day 27 Treatment: Groups of 3-7 (probably), Therapists: 3, counterbalanced across treatments
Interventions	All included cessation programme 6x2h over 2w 1. RP 4 x 1.5h sessions, 2,4,8, 12w post-cessation: self monitoring, advice, assignment of exposure and coping exercises 2. No maintenance, one assessment session at 12w
Outcomes	Abstinence at 12m (assume PP) (phone assessment, non-therapist). Validation: CO only during treatment, phoning 2 collaterals - no results given
Notes	A treatment arm that included rapid puffing not included.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomly by treatment group prior to cessation programme, method not described
Allocation concealment?	Unclear	No information given

Brandon 1987 (*Continued*)

Incomplete outcome data addressed? All outcomes	Unclear	8 randomized subjects did not achieve initial cessation and are not included in analysis as their allocation is not given.

Brandon 2000

Methods	Setting: Community, USA Recruitment: advertisements for ex-smokers wanting to avoid relapse
Participants	584 ex-smokers (abstinent >7 days at baseline). Av. age 49, median abstinence 6.5m, mean 16m
Interventions	2x2 factorial design testing mail and phone intervention Mailings condition: 8 Stay Quit booklets mailed at 1,2,3,5,7,9,12m Hotline Condition: Information about Stay Quit hotline. Asked to call to register. Participants were called if they did not register within 2w and at 3m if they had not called. Minimal contact condition received first Stay Quit booklet.
Outcomes	Abstinence at 12m (no smoking in past 7 days) All participants were abstinent at baseline, and relapse rates were low. Validation: CO<10ppm for participants living within 75 miles of laboratory
Notes	No true control Of 804 randomized, results based on 584 who met inclusion criteria and were sent materials. (Until 2009 update, denominator of 446 used. Author provided additional data)

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomization method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	No	Some post-randomizations not included, but equally distributed

Brandon 2004

Methods	Setting: Community, USA Recruitment: advertisements for ex-smokers wanting to avoid relapse
Participants	481 ex-smokers (abstinent >7 days at baseline). 66% F, av.age 52, av.cigs/day 25. Median 75 days of abstinence.

Brandon 2004 (*Continued*)

Interventions	2x2 factorial design testing effects of contact versus content. 1. Repeated mailings. High Contact-High Content. 8 Forever Free booklet mailings at enrolment & 1,2,3,5,7,8,12m 2. Massed mailings. Low Contact-High Content. Same 8 booklets at enrolment. 3. Repeated letters. High Contact-Low Content. Single Forever Free booklet, 7 supportive letters, same schedule as 1. Provided extended contact and social support without skills training. 4. Control: Low Contact-Low Content. Single booklet, no further contact
Outcomes	Abstinence at 24m (no smoking in past 7 days) Validation: CO for 21 local quitters, no misreporting identified
Notes	New for 2009 update No true control. Other 3 arms compared to single booklet condition in main analysis. Of 895 randomized, results based on 431 who met inclusion criteria and returned follow-up questionnaire. Non-responders excluded rather than assumed to have relapsed.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomization method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	85% reached at 24m, no differential drop out

Buchkremer 1991 1

Methods	Setting: Cessation clinic, Germany Recruitment: community volunteers
Participants	256 smokers, no demographic details
Interventions	5 conditions, partly factorial. All received nicotine patch, dose individualized for conditions 1-4, +9 weekly sessions incl reduction, self monitoring, contract management, risk avoidance. TQD after 6w. 1. Additional training in relapse-coping strategies (during cessation phase) 2. Additional 3 booster sessions, 6m after end of main therapy 3. Relapse-coping and boosters 4. Control 5. Control (fixed dose nicotine patch)
Outcomes	Abstinence 12m post EOT (PP). Rates estimated from graphs. Validation: random urine nicotine, 'almost 100% conformity', no correction

Buchkremer 1991 1 (*Continued*)

Notes	3 vs 4 in contact matched comparison, 1+2 vs 4 in extended contact comparison. Inclusion of control group 5 (fixed dose) would marginally increase intervention benefit.	
Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	'randomly assigned to experimental groups after previously being matched for age, sex and cigarette consumption'
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	15/256 (5.9%) dropouts excluded, assignment not given so not included in analysis

Buchkremer 1991 2

Methods	Setting: Cessation clinic, Germany Recruitment: community volunteers	
Participants	185 smokers, no demographic details	
Interventions	4 conditions, partly factorial. All received nicotine patch (dose individualized for conditions 1-3), + 9 weekly sessions incl reduction, self monitoring, contract management, risk avoidance. TQD after 6w. 1. Relapse coping training using role play, TQD at 6w 2. Modified relapse coping. Rapid abstinence, TQD session 4, covert sensitization, thought-stopping 3. Control, individualized patch dose 4. Control, fixed patch dose	
Outcomes	Abstinence 12m post-EOT (PP). Rates estimated from graphs. Validation: random urine, 'almost 100% conformity', no correction	
Notes	1+2 vs 3 in contact matched comparison. Inclusion of control group 4 (fixed dose) would marginally increase intervention benefit.	
Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	'randomly assigned to experimental groups after previously being matched for age, sex and cigarette consumption'
Allocation concealment?	Unclear	No details given

Buchkremer 1991 2 (*Continued*)

Incomplete outcome data addressed? All outcomes	Yes	23/185 (12.4%) dropouts excluded, assignment not given so not included in analysis

Conway 2004

Methods	Setting: Naval training, USA Recruitment: smokers who had enforced abstinence during naval training, unselected, not volunteers
Participants	1682 female navy recruits with a history of smoking (661 reached at follow up). All should have been abstinent for 2m during training av.age 19, no details of cigs/day
Interventions	1. 6 mail contacts over 12m, at 1,2,4,5,7,10m (2 after follow up) 1 page flyers, cognitive behavioural RP; stress management, weight, fitness, tailored for naval women. 2. No intervention control
Outcomes	Abstinence at 12m (30 day) (Edwards 1999 reports 6m outcomes) Validation: none
Notes	Results not displayed graphically since denominators not explicit. No evidence of intervention effect. Impact of clustering was negligible.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Cluster randomization by division (80 people)
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	High loss to follow up

Covey 2007

Methods	Setting: Cessation clinic, USA Recruitment: community volunteers quit after 8w bupropion & nicotine patch
Participants	289 abstainers (excludes 5 withdrawing consent before starting meds) 45% F, av.age 43, av.cigs/day 21 Therapists: Counsellors, 1m training

Covey 2007 (*Continued*)

Interventions	All participants received 8w open-label bupropion & nicotine patch (21mg with weaning) for 7w from TQD. Transition procedures preserved blinding for RP phase but allowed weaning from bupropion. Individual counselling including CBT techniques, 15 minx6 during open label, x4 during RP, x2 during follow up. 1. Bupropion (300mg) & nicotine gum (2mg, use as needed to manage craving) for 16w 2. Bupropion & placebo gum 3. Nicotine gum & placebo pill (150mg bupropion for first week) 4. Double placebo (150mg bupropion for first week)
Outcomes	Abstinence (no relapse to 7 days of smoking) for 12m (10m after randomization, 6m after EOT) (Primary outcome for study was time to relapse) Validation: CO ≤8ppm at each visit
Notes	New for 2009 update Contributes to NRT, bupropion and combination therapy analyses. Quit rate after open-label treatment was 52% so the final quit rate of 30% for combination therapy is equivalent to ~16% of people starting treatment

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Computer-generated randomization, stratified by gender & depression history
Allocation concealment?	Yes	
Incomplete outcome data addressed? All outcomes	Yes	5 randomized participants withdrew before double blind phase. Greater loss to follow up in double placebo, losses included in ITT analysis

Croghan 2007

Methods	Setting: Clinic, USA Recruitment: community volunteers for pharmacotherapy cessation & RP trial Randomization: computer-generated. No explicit statement about allocation concealment
Participants	405 abstainers after 3m pharmacotherapy, 74 from inhaler, 141 bupropion, 190 combination Participant characteristics not presented at start of RP phase
Interventions	In cessation phase participants had been randomized to bupropion (300mg), nicotine inhaler (up to 16 cartridges/day) or combination. Physician advice at entry, brief (<10 min) counselling at monthly study visits (total 12-18 including RP phase) & S-H. Abstainers (7 day PP after 3m therapy) eligible for RP phase. RP intervention randomized single therapy abstainers to continue cessation therapy or

Croghan 2007 (*Continued*)

	placebo for 9m. Combined therapy abstainers randomized to 4 groups: combination, placebo & single therapy, or double placebo
Outcomes	Abstinence at 15m (from TQD, 12m from RP start, 3m from EOT) (PP) Validation: CO ≤8ppm
Notes	New for 2009 update Arms contribute to NRT, bupropion and combination therapy analyses, ignoring differences in cessation induction therapy. Cessation rates at end of induction phase were 14% for inhaler, 26% for bupropion and 34% for combination.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Randomization using a dynamic allocation procedure balancing stratification factors
Allocation concealment?	Yes	Randomization procedure makes prior knowlege of allocation unlikely
Incomplete outcome data addressed? All outcomes	Yes	Losses to follow up post-medication where high and not enumerated by group, but all included in ITT analysis

Curry 1988

Methods	Setting: Cessation clinic, USA Recruitment: community volunteers
Participants	139 smokers, 48 in group arms, 91 in S-H arms Therapists for groups: 2 teams of 2 PhD psychologists. Each team led one group in each programme.
Interventions	Compared 2 approaches, in both a group and a S-H format Groups met 8 x 2h weekly, incl relaxation training, enlisting social support and practising alternative behaviours. S-H intervention provided same components in 8 workbooks. 1. RP: Focused on smoking as learned behaviour. Quit day (for group format) at 3rd session. Additional elements included identifying high risk situations, cognitive restructuring and role playing. 2. 'Absolute Abstinence' (AA) Group. Focused on addictive component of smoking. Quit day (for group format) at 5th session. Additional elements included focused smoking, health education and contingency contract.
Outcomes	Abstinence from m9 to m12 of follow up. Validation: saliva thiocyanate and 2 collateral verifiers.

Curry 1988 (*Continued*)

Notes	Group and S-H arms used in different comparisons within the matched contact time section	
Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomized part by coin toss and part random number table. More assigned to S-H than to group. Friends co-randomized to same programme but not necessarily same format.
Allocation concealment?	No	Not clear that possibility of bias avoided
Incomplete outcome data addressed? All outcomes	Yes	Only 69% began treatment. Losses to follow up included in ITT analysis

Davis 1986

Methods	Setting: Cessation clinic, USA Recruitment: community volunteers Randomization: groups randomized to treatments group size 3 to 8.
Participants	45 smokers who completed treatment Therapists: 9 advanced clinical psychology graduate students with no previous experience. Each conducted one group.
Interventions	All conditions received 6 x 1½-2h weekly meetings based on Pomerleau & Pomerleau broad spectrum cessation package. TQD week 5 1. 'Experimental' condition added active cognitive behavioral skills training focusing on 11 problem situations. 2. 'Enhanced control' added discussion of same problems 3. 'Control' using Pomerleau & Pomerleau alone
Outcomes	Abstinence at 12m (PP) Validation: CO
Notes	1 & 2 treated as RP Condition 2 not displayed. 3/14 quit

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomization method not described

Davis 1986 (*Continued*)

Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	No	5 pretreatment & 6 dropouts during treatment excluded, assignment not specified

Emmons 1988

Methods	Setting: Cessation clinic, USA Recruitment: community volunteers
Participants	49 smokers; 71% F, av. age 41, av. cigs/day 31 (significant difference between groups, 35 vs 27).
Interventions	1. Cessation programme with RP focus. 8 x 1½h weekly, TQD between 3 & 4. prequit self monitoring. Choice of 'cold turkey' or gradual reduction. Relaxation, role play, cognitive coping. 2. Broad spectrum (BS) programme. 12 x 1h over 8w. TQD between 3 & 4. Included nicotine fading.
Outcomes	Abstinence at 6m (PP) (EOT and 3m also reported) Validation: saliva thiocyanate <=85 microg/ml
Notes	Included in contact matched section, although different number of sessions. Inclusion of 4 non-completers would increase apparent benefit of BS.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomization in blocks, method not described
Allocation concealment?	Unclear	No details given. Friends and relatives assigned to same condition, and significant baseline differences between groups; BS smoked more.
Incomplete outcome data addressed? All outcomes	No	Results exclude 4 pretreatment dropouts, 4 non-completers (3RP, 1BS), 1 medical problem

Ershoff 1995

Methods	Setting: HMO health centre, USA Recruitment: pregnant women who had quit smoking since becoming pregnant
Participants	171 pregnant recent quitters, av length of prior abstinence 31 days, 58% had >7 days of total abstinence Av.age 25, av.cigs/day 10
Interventions	1. RP. S-H booklets; 4 on cessation given at baseline visit, 4 RP-oriented mailed at weekly intervals. 2. Control. 1 page tip sheet on behavioural techniques for avoiding relapse. Both groups had a 2 min discussion on smoking & pregnancy with health educator, given 2 page pamphlet, congratulated on quitting
Outcomes	PP (7 day), late in 3rd trimester (also w26 and w34 of pregnancy). Validation: cotinine, at least 1 ≤10ng/ml and none ≥80ng/ml
Notes	11% of women misreported abstinence

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomization method not described
Allocation concealment?	Yes	Allocation prior to patient contact, blind until end of baseline data collection
Incomplete outcome data addressed? All outcomes	Yes	37 (22%) exclusions due to abortion, miscarriage, move from HMO

Fortmann 1995

Methods	Setting: Community, USA Recruitment: smokers identified via a random telephone survey, (volunteers)
Participants	1044 smokers able to quit for 24h; 42% F, av.age 40, av.cigs/day 20
Interventions	Factorial trial of nicotine gum and S-H for RP. All participants also offered an incentive of $100 for quitting for 6m 1. Nicotine gum 2 mg 2. S-H materials 3. Nicotine Gum and S-H materials 4. Monetary incentive only
Outcomes	PP abstinence at 12m Validation: CO<9ppm, salivary cotinine <20ng/ml

Fortmann 1995 (*Continued*)

Notes	1&3 compared to 2&4 to assess effect of nicotine gum 2&3 compared to 1&4 to assess effect of behavioural component	
Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomization method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	94% followed up at 12m, all participants included in ITT analysis

Hajek 2001

Methods	Setting: Antenatal clinics, UK Recruitment: pregnant smokers and recent quitters	
Participants	249 pregnant recent (within 6m) quitters, average abstinence 7w (smokers also in trial, not included for this review) Av age 28, av.cigs/day approx 12	
Interventions	1. Advice from midwife with explanation of CO reading, pamphlet, prompt placed in notes for reinforcement. 2. Usual midwife care	
Outcomes	Abstinence at 12m (prolonged for last 12w of pregnancy and 6m since birth), also at birth Validation: CO <=10ppm	
Notes		
Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Cluster-randomized by midwife
Allocation concealment?	No	Randomized midwives were responsible for recruiting patients, fewer control midwives recruited any, so possible recruitment bias
Incomplete outcome data addressed? All outcomes	Yes	Women who were untraceable or unsuitable for follow up were excluded, other losses included as smokers

Hajek 2002

Methods	Setting: 17 hospitals, UK Recruitment: inpatients with MI or for CABG
Participants	540 smokers or recent quitters (26%) who had not smoked since admission to hospital and motivated to quit
Interventions	1. As control + CO reading, booklet on smoking & cardiac recovery, written quiz, offer to find support 'buddy', commitment, reminder in notes. Implemented by cardiac nurses during routine work, est time 20m. 2. Verbal advice, 'Smoking and your heart' booklet
Outcomes	Abstinence at 12m, sustained (no more than 5 cigs since enrolment & 7day PP) Validation: saliva cotinine <20ng/ml (CO used at 6w follow up and for visits at 12m)
Notes	

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomization method not described
Allocation concealment?	Yes	Serially numbered opaque sealed envelopes
Incomplete outcome data addressed? All outcomes	Yes	26 deaths & 9 moved address excluded from denominator in analysis

Hall 1984

Methods	Setting: Clinic, USA Recruitment: media adverts and referral
Participants	135 smokers; 59% F, av.age approx. 36, av.cigs/day 29 Therapists: 2 psychologists, randomly assigned to groups
Interventions	2 x 2 factorial trial, aversive smoking conditions collapsed. 1. Skills training, 14 x 75 min sessions. 8 sessions over 3w involved 6 secs or 30 secs aversive smoking. 6 sessions over w 1-6 covered relaxation, commitment and cost benefits, and RP skills with role play of risk situations. 2. Discussion control. Same aversive smoking. Other 6 sessions used self-scoring tests and group discussion. Discussion of specific skills discouraged
Outcomes	Abstinence at 12m (PP) Validation: CO<10ppm, plasma thiocyanate< 85ng/mg, and confirmation from significant other.
Notes	Matched for contact time Author tested for therapist and cohort main effects. None significant.

Hall 1984 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomization method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	8 dropouts from grp 1 and 4 from grp 2 before start of RP sessions reincluded in this analysis

Hall 1985

Methods	Setting: Clinic, USA Recruitment: referred by physicians, friends or self
Participants	84 smokers in relevant arms; 53% M, av.age 38, av.cigs/day 30.5 Therapists: 2 psychologists
Interventions	1. Intensive behavioural treatment (incl RP skill training, relaxation, 30 sec aversive smoking of 3 cigs). 14 x 75 min sessions over 8w. 2. Same as 1. + 2 mg nicotine gum available for 6m. 3. Low-contact + nicotine gum. Met 4x in 3w, educational materials, written exercises, group discussion
Outcomes	Abstinence at 52w (assume PP) Validation: CO<10ppm, thiocyanate <85 mg/ml, reports of significant others (biochemical measures failed to confirm self-report in 3 instances)
Notes	2 vs 3, not matched for contact time, controlled for gum. 1 not included in meta-analysis; 10/36 quit.

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomly assigned within time constraints, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	3 dropouts in conditions 1 & 2 are assumed to be included in denominator for reported % abstinent used to derive numbers quit

Hall 1987

Methods	Setting: Clinic, USA Recruitment: community volunteers or referrals
Participants	139 smokers; 53% M, av.age 39, av.cigs/day 30 Therapists: Advanced graduates in clinical psychology or health psychology
Interventions	2 x 2 factorial trial. Nicotine gum/placebo arms collapsed 1. Intensive behavioural treatment incl 6 sec aversive smoking, RP skills training, written exercises. 14 x 75 min sessions (period not stated) 2. 'Low contact' incl written exercises, educational materials, group discussions, quitting techniques. 5 x 60 min.
Outcomes	Abstinence at 52w (assume PP) Validation: thiocyanate <95mm/L (unless marijuana use reported), CO <8ppm, significant other.
Notes	Not matched for contact time No reported interaction between behaviour therapy condition and gum condition so gum/no gum collapsed.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomization method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Unclear	6 dropouts in 1 & 5 in 2 included in ITT analyses

Hannöver 2009

Methods	Setting: Maternity services, Germany Recruitment: Postpartum women in maternity wards
Participants	304 women who had not smoked for 4w at baseline assessment
Interventions	1. Counselling using motivational interviewing. Face-to-face session ~40 days postpartum, telephone boosters 4 & 12w later 2. Usual care from health system, S-H materials on postpartum smoking & partner smoking
Outcomes	Sustained abstinence since birth of baby at 24m (at 6m, 12m, PP also reported) Validation: none
Notes	New for 2009. Trial identified from earlier papers and epub available at time of update. Baseline assessment was conducted a median of 35 days after birth.

Hannöver 2009 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	No	Alternation of screening forms
Allocation concealment?	No	Alternate allocation done at study centre so not known in advance to screener, reducing likelihood of selection bias
Incomplete outcome data addressed? All outcomes	No	Participants who revoked participation before baseline assessment are not included in denominators

Hasuo 2004

Methods	Setting: Hospital, Japan Recruitment: Hospitalised volunteers, recently quit or expecting to quit in hospital. Randomization: computer programme. (No blinding after allocation)
Participants	106 smokers, quit on day of hospital discharge 87% M, av.age 60. 83% quit before admission
Interventions	1. In hospital counselling from public health nurse, 3 x 20 min sessions, + 3 x 5 min calls, 7, 21, 42 days post-discharge. 2. Control: In hospital counselling only
Outcomes	Abstinence at 12m (assume PP) Validation: Urine cotinine
Notes	New for 2009 update

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Randomization by computer stratified by smoking status, FTND & self-efficacy
Allocation concealment?	Yes	Therapists notified of assignment after allocation
Incomplete outcome data addressed? All outcomes	Yes	106 excludes 6 deaths within 12m and 8 who were smoking on day of discharge, includes all other losses

Hays 2001

Methods	Setting: Clinics, USA, 5 sites Recruitment: 784 community volunteers for cessation & RP trial
Participants	429 abstainers (previously >=15 cigs/day) quit after 7w open-label bupropion; 51% F, av.age 46, av.cigs/day 26.
Interventions	All participants first received 7w bupropion, physician advice, S-H materials, and brief individual counselling at follow-up visits to assist cessation 1. Bupropion 300mg/day, 45w 2. Placebo
Outcomes	Continuous abstinence at 2y (1y after EOT) Validation: CO<=10ppm
Notes	Quit rate after open-label phase was 59% so the final quit rate of 29% in the bupropion group is equivalent to 17% of people starting treatment

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Computer-generation randomization
Allocation concealment?	Yes	Code held centrally, investigators blind
Incomplete outcome data addressed? All outcomes	Yes	74% completed study, 2 deaths excluded, all other withdrawals included in ITT analysis

Hurt 2003

Methods	Setting: Clinics, USA, 14 sites Recruitment: 578 community volunteers for cessation & RP trial
Participants	176 abstainers (previously >=15 cigs/day) quit after 8w of nicotine patch; baseline group: 57% F, av. age 42, av. cigs/day 26
Interventions	All participants first received nicotine patch for 8w at a dose or either 22, 33, or 44mg/day, matched to baseline cigs/day. Brief advice to quit & S-H materials but no formal counselling 1. Bupropion 300mg/day for 6m 2. Placebo No additional counselling during maintenance phase
Outcomes	Abstinence at 12m (PP) (6m after EOT). Validation: CO <8ppm
Notes	Quit rate after open-label phase was 31% so the final quit rate of 22% in the bupropion group is equivalent to 7% of people starting treatment

Hurt 2003 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomized by 'dynamic allocation', stratified on sex, cigs/day & years of smoking
Allocation concealment?	Unclear	Not explicit although randomization procedure makes concealment probable

Japuntich 2006

Methods	Setting: Clinic/internet, USA Recruitment: community volunteers
Participants	284 smokers (>=10 cigs/day); 55% F, av. age 41, av. cigs/day 22
Interventions	All participants received bupropion (300mg) for 9w, 3 brief (20 min) individual counselling sessions, 5 clinic visits for assessment, monthly assessment calls. 1. Access to Comprehensive Health Enhancement Support System for Smoking Cessation and Relapse Prevention (CHESS SCRP), for 12w, computer & access provided, daily use recommended, reminders to log on up to 3 a week. 2. No additional support
Outcomes	Abstinence at 6m (PP) Validation: CO $\leq$10ppm
Notes	New for 2009 update. 12m follow-up results not published

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomization method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	20% losses to follow up and intervention participants who didn't get computer included in ITT analysis

Juliano 2006

Methods	Setting: Clinic, USA Recruitment: community volunteers
Participants	34 early lapsers (within 14 days) out of 67 smokers (≥15 cigs/day) enrolling in cessation phase; Initial sample 61% F, av.age 40
Interventions	Most participants received bupropion, all received counselling (prior to quitting, 30 min on quit day) and S-H materials. Participants reported smoking status daily. Lapsers were randomized: 1. Rapid smoking. Puff every 6 secs, 6 trials of up to 3 cigs, 5 min break between. Counselling in 30-45 min break between 3rd & 4th trial. Intention to provide 3 sessions preferably on consecutive days as soon as possible after lapse 2. Usual care - structured interview about lapse via telephone
Outcomes	Abstinence at 6m (PP) Validation: CO ≤6 ppm
Notes	New for 2009 update. Included in behavioural interventions for assisted abstainers but not pooled; both conditions had RP content. 16/20 attended a rapid smoking session, 11 completed 3 sessions

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomization method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	All losses to follow up included in ITT analysis

Killen 1984

Methods	Setting: Clinic, USA Recruitment: community volunteers
Participants	64 smokers (44 in relevant arms); 72% F, av. age 44, av. cigs/day 32 Behaviour therapy provided by 2 psychologists, 1 medical social worker, assigned randomly to treatment conditions, group size 10-12
Interventions	All participated in cessation training (incl cognitive behavioural skills training and an aversive smokeholding procedure), 4 x 1½h sessions over 4 days, in groups of 10-12. 1. Nicotine gum (2mg) for 7w 2. Skills training for RP. 2 sessions in 2w then 4 weekly drop-in sessions. Included identification of high risk situations and coping strategies, homework. 3. Combined 1 and 2

Killen 1984 (*Continued*)

Outcomes	Abstinence for 4w at 10½m after quit date Validation: CO<8ppm (2 people unable to attend assessment, based on self report), Serum thiocyanate measured at 6w only
Notes	3 vs 1 for effect of RP component over NRT alone. 3 vs 2 tests effect of NRT for initial cessation, not included

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomization method not described (married couples allocated to same condition)
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Unclear	Losses to follow up not reported, all participants included

Killen 1990

Methods	Setting: Community, USA (Stanford Stop Smoking Project) Recruitment: media advertisements for volunteers for S-H RP research programme. To be eligible for randomization had to have quit for 48h unaided. (Quit validated by CO<9ppm)
Participants	1218 smokers who had quit for 48h; 52% F, av. age 43, av. cigs/day 25
Interventions	4x3 factorial design crossing gum and S-H conditions: Nicotine gum (2mg) conditions: 1. Ad lib schedule, whenever strong need to smoke 2. Fixed schedule (1 piece/h for at least 12h/day) 3. Placebo gum 4. No gum S-H intervention was based on 16 specially written modules. All participants were given the first 'How to cope with the urge to smoke without smoking' booklet. Then randomized to: - Self selected - chose 7 more to receive in weekly mailings - Random - sent 7 modules at random - No modules - no further contact
Outcomes	Abstinence at 12m (7 day PP) Validation: saliva cotinine<20ng/ml, except for participants who had moved away.
Notes	Quit rates for module/no module conditions provided by authors. Gum conditions collapsed

Killen 1990 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomization method not stated
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Losses to follow up not reported, all participants included except 8 deaths.

Killen 2006

Methods	Setting: Clinic, USA Recruitment: community volunteers
Participants	362 smokers >=10 cigs/day, no current major depression 46% F, av age 45, av cigs/day 20, 25% previous bupropion use
Interventions	All participants received open-label combination pharmacotherapy of bupropion 300 mg for 11w, nicotine patch for 10w. TQD day 7, 30 min individual RP skills training at 6 clinic visits. 1. Bupropion 150 mg for 14w 2. 2w tapering bupropion then placebo. Both arms had 4 further clinic visits during extended therapy
Outcomes	Abstinence at 12m (6m post-EOT)(continuous). PP and 7 day relapse-free outcomes also reported. Validation: CO (10 people not required to provide samples)
Notes	New for 2009 update PP outcomes favour placebo but no outcomes showed significant effects Approximately 52% were quit at the end of baseline therapy

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Pre-assigned random sequence stratified by gender, prior to open-label phase
Allocation concealment?	Yes	Not explicitly concealed but judged probable that it was
Incomplete outcome data addressed? All outcomes	Yes	10% lost to follow up, included in ITT analysis

Klesges 1999

Methods	Setting: Air Force, USA Recruitment: recruits undergoing basic military training (BMT)
Participants	18010 recruits, 29% regular smokers before enforced abstinence during training. 28% F, av.age 20
Interventions	1. Single 50 min intervention during final week of training, 50/group, incl non-smokers. Discussed health effects, costs, social impact, role play. 2. Control: general health video All participants exposed to 6w smoking ban, and shown 2 videos previewing primary intervention
Outcomes	Abstinence at 12m (not defined) Validation: none Relapse amongst baseline ex-smokers and initiation amongst non-smokers also reported.
Notes	Results not displayed graphically since denominators not explicit. No significant overall benefit. ICC small (0.004 for smokers)

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Cluster-randomized by training flight. 75% assigned to intervention
Allocation concealment?	Unclear	Training flights allocation was independent of this trial so potential for bias small
Incomplete outcome data addressed? All outcomes	Yes	96% of available smokers reached

Klesges 2006

Methods	Setting: Air Force, USA Recruitment: recruits undergoing basic military training (BMT)
Participants	Subgroup of ~7525 regular smokers in intervention and ~2639 in control
Interventions	1. 2 1h sessions during w6 of BMT, emphasis on discrepancy between Air Force ideals and smoking. Barriers, role-playing. One sheet of NRT gum available for use at end of training. 2. Same schedule, health-related & first aid videos
Outcomes	Abstinence at 1y (sustained from end of BMT) Validation: none
Notes	

Klesges 2006 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Cluster-randomized by training flight. 75% assigned to intervention
Allocation concealment?	Unclear	Training flights allocation was independent of this trial so potential for bias small
Incomplete outcome data addressed? All outcomes	Unclear	Random subgroup targeted for follow up, 86% reached. People lost to follow up excluded since likely to be missing completely at random

Lando 1996

Methods	Setting: Community, USA Recruitment: community volunteers
Participants	1083 smokers who attended a smoking cessation clinic; 60% F, av.age 45, av. cigs/day 27
Interventions	All participated in 15 session 8w group cessation programme 1. Telephone counselling at 3, 9, 21m. At each point up to 3 calls could be made if requested. 2. Control. No additional contact
Outcomes	Abstinence at 34m (12m after EOT (7 day PP)). Also assessed at 6, 12 & 24m Validation: random half of quitters validated by saliva cotinine <20ng/ml at 12 m. 91% confirmed
Notes	Not pooled with other studies. Analysis 9.1.1

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomization method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	>95% reached at each follow up, all participants included in analysis

Lifrak 1997

Methods	Setting: Substance abuse outpatient facility, USA Recruitment: community volunteers
Participants	69 smokers (≥1 pack/day); 62% F, av. age 39, av. cigs/day 25
Interventions	All received nicotine patch (24 hr, 10w tapered dose) 1. Moderate intensity - 4 meetings with nurse practitioner who reviewed S-H materials and instructed in patch use. 2. High intensity. As 1 plus 16 weekly 45 min cognitive behavioural RP therapy from clinical social worker or psychiatrist
Outcomes	Abstinence at 12m (1w PP) Validation: urine cotinine for some participants, but no corrections made for misreporting.
Notes	High Intensity participants attended median of 8¼ sessions.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomization method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	12 administrative dropouts/exclusions not included, treatment group not specified.

Lowe 1997

Methods	Setting: Prenatal clinic, USA Recruitment: volunteer recent quitters
Participants	78 pregnant women who had quit within previous 3m (9 exclusions and 19 lost to follow up not included) Age/ smoking history not described Therapists: health educator. Reinforcement provided by doctors and nurse trained at workshops
Interventions	1. 10 min counselling with health educator. RP materials at 5th grade reading level, enhance social support with materials, chose 'buddy'. Reinforcement at routine visits by clinic staff. 2. Usual care incl nurse advice
Outcomes	Continued abstinence at end of pregnancy (exact period NS) Validation: saliva thiocyanate
Notes	

Lowe 1997 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomization method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Greater loss to follow up in control so losses to follow up not included in denominators to give conservative RR

McBride 1999

Methods	Setting: Two managed care organizations, USA Recruitment: pregnant smokers and recent quitters
Participants	897 pregnant women (excludes miscarriages), 44% already quit, no minimum consumption. Av.age 28, av.cigs/day: 15 before pregnancy, 5 if still smoking
Interventions	1. Prepartum intervention: Letter tailored to baseline stage of change, health concerns and motivation, S-H book. After 28w follow up sent RP kit. 3 Telephone counselling calls, approx 2w after S-H mailing, and 1 and 2m later. Motivational interviewing approach. Av 8½ min. 2. Pre/postpartum intervention: as 1, plus 3 calls within first 4m postpartum, av 7.7 min. 3 newsletters. 3. Control: S-H booklet only
Outcomes	Abstinence at w28 of pregnancy (analysis 1.1) and 12m postpartum (7 day PP)(analysis 2.1). Also assessed at 8w, 6m postpartum Validation: saliva cotinine requested by mail, <20ng/ml. Only self-reported rates, no difference in confirmation rates
Notes	Abstinence at w28 reported separately for baseline quitters Relapse rate in 28w quitters also reported. 1 vs 2 in analysis 1.2.1 and 1 vs 3 in 1.2.2, control group split to avoid double counting in pooled total. No significant benefit of postpartum intervention.

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomization method not described
Allocation concealment?	Unclear	No details given

Incomplete outcome data addressed? All outcomes	Yes	Nonresponders assumed to have relapsed

McBride 2004

Methods	Setting: Army Medical Centre, USA Recruitment: pregnant smokers & recent quitters with partners
Participants	316 pregnant recent quitters, 267 continuing smokers (excludes miscarriages); av. age 24, av. cigs/day pre-pregnancy 13
Interventions	Both interventions included pre- and postpartum components in addition to usual care 1. Women Only (WO); 3 counselling calls in pregnancy, 3 postpartum, monthly. Motivational interviewing. Late pregnancy relapse prevention kit 2. Partner-assisted (PA); as WO, plus advice on using partner as coach, & 6 calls to partner. Cessation support for smoking partners 3. Usual Care; provider advice and mailed pregnancy-specific S-H
Outcomes	Abstinence at w28 of pregnancy and 12m postpartum (7 day PP). Also assessed at 8w, 6m postpartum Validation: saliva cotinine requested by mail, no difference in return rates, disconfimation rates not given, only self-reported rates reported.
Notes	New for 2009 update End of pregnancy abstinence amongst baseline quitters, combining interventions 1&2 vs control in analysis 1.1. No significant effect of either intervention on end of pregnancy abstinence amongst baseline smokers. 12m postpartum abstinence for those quit at end of pregnancy in analysis 1.2. Abstinence rates not given separately for those quit at randomization, but of end-of-pregnancy quitters came from this category, and the prepartum interventions did not increase cessation.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomization method not stated
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Unclear	Excludes miscarriages, no other information on losses

Mermelstein 2003

Methods	Setting: Cessation clinic, USA Recruitment: community volunteers for cessation programme
Participants	341 quitters at the end of 7w group cessation programme (non-abstinent subgroup not relevant to this review) Demographics for all 771: 66% F, av.age 43, av .cigs/day 23
Interventions	1. Tailored proactive telephone counselling calls from counsellor who provided cessation course. 3 weekly then 3-6 alternate w, 15 min each. 2. Supportive but non-specific proactive counselling calls from counsellor, same schedule.
Outcomes	Abstinence at 15m, 7-day PP Validation: none
Notes	Analysis 4.1 but borderline to pool with other studies since both groups could constitute RP; primarily a test of content. Exclusion does not change finding

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Cluster-randomized by cessation group
Allocation concealment?	Unclear	Unclear whether groups constituted before randomization. Counsellor blind until final session, not blind during RP intervention. Probably low potential for bias
Incomplete outcome data addressed? All outcomes	Yes	96% of entire study provided data at all follow ups

Morasco 2006

Methods	Setting: Prenatal clinic, USA Recruitment: recent quitters
Participants	33 pregnant recent quitters (subgroup of trial); av. age 22, av. cigs/day prior to quit 13
Interventions	All participants received prompted provider advice and S-H. 1. Individual counselling; 90 min psychotherapy session & bimonthly phone calls from mental health counsellors 2. Usual care
Outcomes	Abstinence at end of pregnancy & 6m postpartum (7-day PP) Validation: CO≤8ppm
Notes	New for 2009 update. Baseline smoker results reported separately, not used in this review

Morasco 2006 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomization method not described
Allocation concealment?	Unclear	No details given

Niaura 1999

Methods	Setting: Cessation clinic, USA Recruitment: community volunteers
Participants	120 smokers; 50% F, av. age 44, av. cigs/day 28
Interventions	All participants received single brief individual counselling session 1w before TQD and instructed to use ALA S-H manual 'Freedom from smoking for you and your family', CO measured. All interventions used 5 sessions over 2w post-TQD, led by PhD level therapists 1. Cognitive behavioural with cue exposure (75 min sessions) imagined high risk settings 2. Cognitive behavioural with cue exposure and nicotine gum (90 min) 3. Brief cognitive behavioural. Reviewed progress and reinforced use of S-H manual. (15 min sessions). Control for 1. 4. Cognitive behavioural and nicotine gum (60 min). Control for 2.
Outcomes	Sustained abstinence, 12m and all previous follow ups (1, 3, 6m) Validation: CO<8ppm
Notes	Test of imaginary cue exposure for RP. 1&2 vs 3&4 in analysis 7.1

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomization method not stated
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Unclear	80% completed follow up, no group differences, all included in ITT analysis

Pbert 2004

Methods	Setting: Five community health clinics, USA Recruitment: Low income women receiving prenatal care & participating in Special Supplemental Nutrition Programme
Participants	168 pregnant recent quitters (subgroup of trial); av. age 26, av. cigs/day 15-18 for whole sample
Interventions	System level intervention 1. Training to implement guideline-based 4A's approach for obstetric, paediatric and nutrition programme providers in the Community Health Centres, practice management system for screening and prompts, interclinic communication. 2. No training, usual care from clinic providers
Outcomes	Abstinence at delivery (30 day PP) assessed retrospectively at 1m postpartum assessment, 6m postpartum Validation: Saliva cotinine≤20ppm
Notes	New for 2009 update. Saliva collection was incomplete, and there was lower agreement between self report and cotinine values in intervention group, although difference only significant at final follow up. Not pooled with other studies. Treating non-responders as smokers the OR for not smoking at end of pregnancy was 0.95 (p=0.95)

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	No	Cluster-randomized by clinic, method not stated.
Allocation concealment?	No	Clinics recruited participants after randomization, 1 control clinic dropped out due to poor recruitment, 2 clinics enrolled >50% of participants
Incomplete outcome data addressed? All outcomes	Yes	Higher loss to follow up in intervention (46/81, 57%) than control (37/77, 48%). ITT analysis reported

Powell 1981

Methods	Setting: Clinic, USA Recruitment: community volunteers Therapist: Senior author
Participants	51 quitters (2 treatment dropouts excluded); 57% F, av. age 36, av. cigs/day 29

Powell 1981 (*Continued*)

Interventions	All participants received same cessation programme in a single group. Introductory meeting and 4 consecutive treatment meetings a week later, 1½h. Systematic focus on skill development. Also used a novel aversive smoking exercise conducted at each session. Maintenance/RP conditions: 1. 4w support group (number of meetings not specified) 2. Telephone contact system allowing subjects to phone each other 3. No contact control
Outcomes	Abstinence at 1y, not defined Validation: none
Notes	Arm 2 not shown in graphs, all arms had similar quit rates.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	'Randomly assigned' with deviations for scheduling conflict and in order to separate families and friends.
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	All but one participant contacted at follow up

Ratner 2000

Methods	Setting: Obstetric wards in 5 hospitals, Canada Recruitment: postpartum women
Participants	251 women who had given up smoking for at least 6w prior to delivery; av. age 28, av. cigs/day 10, 74% first child
Interventions	1. Counselling session in hospital + 8 telephone (weekly for 1 m, biweekly for 2 m). Skills training. S-H pamphlets, no-smoking materials. Therapists: trained nurse counsellors 2. Usual care
Outcomes	Continuous abstinence 12m post-delivery Validation: CO<10ppm for participants interviewed in person. Data collectors blind
Notes	

Risk of bias

Item	Authors' judgement	Description

Ratner 2000 (*Continued*)

Adequate sequence generation?	Yes	'Identification numbers randomly assigned to 2 groups, in blocks of 50, via a computer software package.'
Allocation concealment?	Unclear	No details about sequence concealment
Incomplete outcome data addressed? All outcomes	Yes	Denominator excludes 13 not reached at follow up. No differential dropout.

Razavi 1999

Methods	Setting: Workplaces, Belgium Recruitment: employee volunteers
Participants	993 began cessation programme, 349 abstinent at 3m, 344 entered RP phase. 38% F, av. age 39
Interventions	Initial cessation programme of 7 fortnightly visits. Nicotine patch provided if FTQ score >=5. Only quitters abstinent for 1m enrolled in RP 1. 10 monthly sessions incl group discussion and role play led by professional counsellor 2. 10 sessions of group discussion led by former smokers. 3. No RP
Outcomes	Abstinence for 9m from start of RP programme. Validation: CO<10ppm and urine cotinine<=317 ng/ml required. (Rates for CO and self report alone also reported; higher than for doubly validated rates.)
Notes	Interventions 1 and 2 combined in analysis 4.1. Separate quit rates: Intervention 1. 59/135 (44%); Intervention 2. 33/88 (37.5%), difference not statistically significant

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Cluster-randomized by company, using random number and blinded list
Allocation concealment?	Yes	Company allocation blinded and participants recruited prior to randomization
Incomplete outcome data addressed? All outcomes	Yes	Losses to follow up not reported, all randomized participants included in analyses

Ruger 2008

Methods	Setting: Obstetric clinics, USA Recruitment: Pregnant women who smoked or had quit within 3 months of baseline
Participants	57 pregnant recent quitters (subgroup of trial), av. age of whole sample 26
Interventions	1. Motivational interviewing at home visits (average 3). Tailored to Stage of change, S-H materials 2. Usual care
Outcomes	Quit at 6 months postpartum Validation: none
Notes	New for 2009 update

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Method not described
Allocation concealment?	No	No details given, but higher proportion of recent quitters in control (23%) than intervention (15%) suggests possible selection bias
Incomplete outcome data addressed? All outcomes	Unclear	Dropouts not included in reported denominators, included as smokers in meta-analysis

Schmitz 1999

Methods	Setting: Hospital, USA Recruitment: women with or at risk of Coronary Artery Disease (CAD)
Participants	Two separate samples recruited: 1. 53 inpatients with CAD who stopped smoking during hospitalization and wanted to stay quit. 2. 107 women volunteering for cessation treatment who had >1 CAD risk factor Therapists: 2 smoking counsellors and 2 clinical psychology interns
Interventions	1. Coping skills RP, 6 x 1h incl stress management, homework. 2. Health Belief model, 6 x 1h smoking-related health information related to disease state or CAD profile. Focus on benefits of stopping
Outcomes	PP abstinence at 6m Validation: CO<9ppm, urine cotinine<10ng/ml Not all quitters tested, confirmation rates not reported

Schmitz 1999 (*Continued*)

Notes	Inpatient subgroup in quitters section, analysis 2.1, CAD risk group in trials in smokers, matched control section, analysis 7.1. Quit rates were lower in the CAD sample than in the at-risk group

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomization method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Post-randomization dropouts who did not complete baseline and begin treatment were not included in any data.

Schroter 2006

Methods	Setting: Four workplaces, Germany Recruitment: volunteer employees
Participants	79 smokers (>=10 cigs/day); 42% F, av. age 40, av. cigs/day 24
Interventions	Both conditions provided 6 x 90 min sessions over 8w in groups of 8-12 led by qualified providers 1. RP; Skills training, planning and practising coping strategies 2. Standard behavioural cessation course with focus on positive changes obtained through abstinence. Included self-monitoring, environmental cue control, problem-solving skills
Outcomes	Continuous abstinence at 12m, not defined further Validation: none
Notes	New for 2009 update Compares RP to matched standard programme

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Cluster-randomized, 2 groups in each workplace, researchers randomized 1 to each condition, no further details
Allocation concealment?	Unclear	No details given

Incomplete outcome data addressed? All outcomes	Yes	47% attrition reported, but all participants included in analyses

Secker-Walker 1995

Methods	Setting: Private and public prenatal clinics, USA Recruitment: women at 1st prenatal visit
Participants	165 women previously smoking 1+ cigs/day who had quit since start of pregnancy (excludes 10 adverse pregnancy outcomes) Av. age 25
Interventions	1. Individual counselling focusing on pros and cons, problem solving, skills rehearsal. 10-15 min at 1st, 2nd. 3rd prenatal visit, 36w, and 6w postpartum. (93% received postpartum session) 2. Usual care control
Outcomes	Abstinence at 36w pregnancy (analysis 1.1), and at 8-54m postpartum (analysis 1.2). Follow-up point varied. Validation: at 36w, cotinine/creatinine ratio>80 ng/mg, no validation postpartum
Notes	Sensitivity analysis excluding losses to follow up does not alter results.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomization method not stated
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Unclear	No significant differences in loss to follow up at 1y (35%). Numbers randomized used in analyses but restricting to numbers available for follow up does not alter findings

Secker-Walker 1998

Methods	Setting: Prenatal clinic, USA Recruitment: women at 1st prenatal visit
Participants	116 women previously smoking 1+ cigs/day who self reported quitting since start of pregnancy (excludes 9 adverse pregnancy outcomes). 19 of the women showed evidence of smoking at 1st prenatal visit

Secker-Walker 1998 (*Continued*)

Interventions	1. Structured intervention from physician, individual counselling by nurse counsellor, 1st, 2nd, 3rd, 5th , 36w prenatal visits. 2. Usual care from physician, prompted at 1st visit
Outcomes	Sustained abstinence at 36w pregnancy (analysis 1.1), 1y postpartum (analysis 1.2) Validation: CO≤6ppm at 36w, also urine cotinine≤500ng/ml but some missing data
Notes	Process analysis showed counselling to have been received fairly consistently but fell to 66% at 5th visit

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	No significant differences in loss to follow up at 1y (33%). Numbers randomized excl adverse pregnancy outcomes used in denominators

Severson 1997

Methods	Setting: 49 private paediatric practices, USA Recruitment: mothers attending for well baby visits
Participants	1026 ex-smoking mothers (intervention also given to smoking mothers, not relevant to this review) Therapists: paediatricians. 25 intervention practices, 23 control.
Interventions	1. Information pack including a letter from paediatrician on risks of passive smoking, provided by birth hospital, and extended support (counselling plus follow up at 2, 4, & 5m visits) and materials (incl video tape, written materials, signs, magnets, bib) 2. Information pack only
Outcomes	Sustained abstinence at 12m (7 day PP at 6 & 12m) Validation: none
Notes	Study design allowed for clustering in calculating sample size. ICC proved to be low. Use of a corrected odds ratio which did not show a significant benefit did not change conclusions (sensitivity analysis using inverse variance).

Risk of bias

Severson 1997 (*Continued*)

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Cluster-randomized by practice, method not described,
Allocation concealment?	No	Practices randomized before recruitment, and unclear how mothers within practice were recruited so possibility of selection bias
Incomplete outcome data addressed? All outcomes	Yes	Losses to follow up (25%) assumed to have relapsed

Shoptaw 2002

Methods	Setting: Three narcotics treatment centres, USA Recruitment: volunteers on methadone maintenance
Participants	175 smokers (≥10/day); 33% F av. age 43-45, av. cigs/day approx 22
Interventions	All participants received 21mg nicotine patch for 12w. Factorial design crossing contingency management, arms collapsed. 1. Group counselling: 12 x1h weekly sessions, incl mood management. 2. Control: NRT alone
Outcomes	PP abstinence at 12m Validation: CO≤8ppm, urine cotinine<30ng/ml
Notes	

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Randomization using urn technique
Allocation concealment?	Yes	Not described but use of urn technique makes it probable that allocation concealed
Incomplete outcome data addressed? All outcomes	Yes	Number lost to follow up not reported, all missing included as smokers.

Smith 2001

Methods	Setting: Clinic, USA Recruitment: community volunteers
Participants	677 smokers (>10/day) attempted quit for 1w; 57% F, av.age 42; av cigs/day approx 25
Interventions	All participants had attended 3 brief (5-10 min) individual counselling sessions pre-quit, quit day and 8 days post-TQD, + nicotine patches (8w) + NCI booklet 'Clearing The Air'. 1. Cognitive behavioural skills training, x6 from 1w post-TQD, incl managing negative affect, homework, manual. 2. Motivational interviewing, supportive group counselling, x6 from 1w post-TQD. No homework or manual. 3. No further intervention
Outcomes	Abstinence at 12m (7 day PP) Validation: CO<10ppm
Notes	1 vs 3 in analysis 4.1. including 2 does not alter findings; 17.6% quit in 1, 18.8% in 2. No evidence found for hypothesized differences in relative efficacy for smokers at high or low risk of relapse. High-risk smokers expected to do better with motivational intervention.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomized 1w after TQD, stratified by +/- any smoking post-TQD. Method not stated
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Unclear	Number lost to follow up not reported, all missing included as smokers.

Stevens 1989

Methods	Setting: HMO, USA Recruitment: HMO member volunteers
Participants	587 smokers who successfully abstained from smoking for 4 days after a 4-day intensive cessation programme
Interventions	Both group conditions met for 3 x 2h weekly meetings 1. Skills condition. Development and active rehearsal of coping strategies 2. Discussion condition. Social support meetings without rehearsal of strategies 3. No further treatment control

Stevens 1989 (*Continued*)

Outcomes	Abstinence at 1y, no tobacco use in previous 6m Validation: saliva thiocyanate<0.8mg/ml or cotinine<5ng/ml
Notes	Study hypothesis that discussion control would not increase rates, so in main analysis 1 vs 2+3

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Predetermined random number list
Allocation concealment?	Unclear	Not explicit that list concealed although likelihood of selection bias judged to be small
Incomplete outcome data addressed? All outcomes	Yes	Loss to follow up 6.6% overall, non-significantly higher in control. Dropouts included in analysis

Tonstad 2006

Methods	Setting: Cessation clinics in 7 countries. 6 sites in USA Recruitment: smokers of ≥10/day for cessation phase
Participants	1210 adults previously smoking ≥10/day, quit for at least 1w after 12w open-label varenicline
Interventions	1. Varenicline 1mg x 2 daily for 12w with 5 clinic visits 2. Placebo
Outcomes	Sustained abstinence for 9m at 1y Validation: CO≥10ppm
Notes	New for 2009 update. The quit rate after the open label phase was 64%

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Centralised computer-generated randomization
Allocation concealment?	Yes	Based on use of centralised allocation
Incomplete outcome data addressed? All outcomes	Yes	Higher loss to follow up in controls due to relapse

Van't Hof 2000

Methods	Setting: Six hospitals, USA Recruitment: women at time of delivery
Participants	277 women who had quit during pregnancy, cotinine verified as not smoking at recruitment (excludes 10 not followed up for a variety of reasons) Av.age 25, previous cigs/day not reported. 65% were very confident of remaining quit
Interventions	1. 15-30 min of RP counselling from Visiting Nurse after baseline interview. Reinforcement by paediatric care provider at 2w, 2m, 4m well baby clinics, written materials. Chart sticker used to prompt intervention. 2. Usual care, baseline assessment from Visiting Nurse
Outcomes	Abstinence at 6m (assume PP) Validation: none (assessment by phone, no details of blinding of assessor)
Notes	

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	A sensitivity analysis including losses to follow up does not change direction or significance of effect.

RP = relapse prevention; TQD = target quit day;
av = mean average; F = female; M = male; NS = not stated;
min = minutes; m = months; w = weeks; y = years;
FTQ = Fagerström Tolerance Questionnaire; FTND = Fagerström Test for Nicotine Dependence; NRT = nicotine replacement therapy;
S-H = self-help
PP = point prevalence abstinence (abstinent at that time but not necessarily continuously since treatment); EOT = end of treatment;
CO = carbon monoxide; ppm = parts per million;
CBT = cognitive behavioural therapy
HMO = health maintenance organization; ALA = American Lung Association; NCI = National Cancer Institute;
CABG = coronary artery bypass graft; MI = myocardial infarction; MDD = major depressive disorder;
ICC = Intraclass correlation;

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

Alterman 2001	Considered for inclusion because comparison of different intensity interventions. No mention of RP.
Bottausci 1995	Small trial, <10 participants per condition.
Brown 2001	Considered for inclusion because comparison of different intensity interventions. Intervention focus was on use of CBT for treatment of depression. Relapse mentioned only in text.
Carmody 1988	Only 3m follow up reported. No significant differences at this point.
Cinciripini 2000	Not possible to distinguish RP from cessation components.
Copeland 2006	Evaluated a weight management programme for preventing relapse, see separate Cochrane review.
Davis 1995	Short follow up, only 12 participants.
Dooley 1992	Only 3m follow up reported. No significant differences at this point.
Dubren 1977	Only 1m follow up reported.
Dunphy 2000	Only 4-8w follow up after delivery and intervention.
Feeney 2001	Not explicitly described as an RP intervention, and the control condition has low implementation of the basic cessation programme.
Froelicher 2000	Describes a trial in progress, no intervention results.
George 2000	Tested a specialized group therapy intervention for people with schizophrenia compared to a standard programme. Included other components in addition to RP.
Goldstein 1989	Considered for inclusion because comparison of different intensity interventions. No mention of RP
Gruder 1993	Not possible to distinguish between RP and cessation components.
Hall 1994	Considered for inclusion because comparison of different intensity interventions. Primary focus was on CBT for depression as adjunct to cessation intervention. No mention of RP.
Hall 1996	Considered for inclusion because comparison of different intensity interventions. Primary focus was on mood management as adjunct to cessation intervention. No mention of RP.
Hall 1998	Considered for inclusion because comparison of different intensity interventions. No mention of RP.
Klesges 1987	Randomization and analysis by worksite, number of individuals in each treatment condition not given. There was a non-significant difference favouring RP.
Lando 1997	Considered for inclusion because comparison of different intensity interventions. No mention of RP.

(*Continued*)

Macleod 2003	Considered for inclusion because comparison of different intensity interventions. No mention of RP.
Miller 1997	Hospital intervention included RP components but excluded because no information on smoking status of participants, and intervention similar in other respects to other inpatient trials. Also compared 2 intensities of telephone follow up but these were not described as RP.
Reid 1999	Considered for inclusion because comparison of different intensity interventions. No mention of RP.
Solomon 2000	Considered for inclusion because comparison of different intensity interventions. No mention of RP.
Zelman 1992	Considered for inclusion because comparison of different intensity interventions. No mention of RP.

RP = relapse prevention; CBT = cognitive behavioural therapy

DATA AND ANALYSES

Comparison 1. Behavioural interventions for abstinent pregnant/post partum women

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Not smoking at delivery/ last follow up prior to delivery	8	1523	Risk Ratio (M-H, Fixed, 95% CI)	1.04 [0.98, 1.11]
1.1 Self help intervention	1	171	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.91, 1.21]
1.2 Individual counselling	5	641	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.89, 1.15]
1.3 Telephone counselling	2	711	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [0.99, 1.15]
2 Not smoking at longest follow up after delivery	11	3273	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [0.98, 1.18]
2.1 Intervention during pregnancy	5	690	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.82, 1.23]
2.2 Intervention initiated during pregnancy and continued post partum	3	738	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.89, 1.29]
2.3 Intervention initiated after birth	4	1845	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [0.96, 1.25]

Comparison 2. Behavioural interventions for abstinent hospitalised smokers

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cessation at longest follow up	3	667	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.78, 1.13]

Comparison 3. Behavioural interventions for unaided abstainers

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cessation at longest follow up	5	3561	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.98, 1.19]

Comparison 4. Behavioural interventions for assisted abstainers

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cessation at longest follow up	5	1462	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.87, 1.15]

Comparison 5. Pharmacotherapy for unaided abstainers

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cessation 12m after quit date	2	2261	Risk Ratio (M-H, Fixed, 95% CI)	1.24 [1.04, 1.47]
1.1 Nicotine gum vs placebo after brief unassisted abstinence	2	2261	Risk Ratio (M-H, Fixed, 95% CI)	1.24 [1.04, 1.47]

Comparison 6. Pharmacotherapy for assisted abstainers

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Nicotine replacement therapy versus placebo. Cessation 12m+ after quit date	2	553	Risk Ratio (M-H, Fixed, 95% CI)	1.04 [0.77, 1.40]
1.1 16w nicotine gum vs placebo	1	143	Risk Ratio (M-H, Fixed, 95% CI)	1.44 [0.77, 2.69]
1.2 16w nicotine gum +bupropion vs placebo gum +bupropion	1	146	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.59, 1.56]
1.3 9m nicotine inhaler vs placebo	1	168	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.54, 1.72]
1.4 9m nicotine inhaler + bupropion vs placebo inhaler + bupropion	1	96	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.39, 1.93]
2 Bupropion versus placebo. Cessation 12m+ after quit date	5	1587	Risk Ratio (M-H, Fixed, 95% CI)	1.17 [0.99, 1.39]
2.1 45w bupropion vs placebo	1	429	Risk Ratio (M-H, Fixed, 95% CI)	1.11 [0.82, 1.51]
2.2 24w bupropion vs placebo	1	176	Risk Ratio (M-H, Fixed, 95% CI)	1.46 [0.77, 2.77]
2.3 16w bupropion vs placebo	1	144	Risk Ratio (M-H, Fixed, 95% CI)	1.72 [0.95, 3.12]
2.4 16w bupropion + nicotine gum vs placebo + nicotine gum	1	145	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [0.68, 1.92]
2.5 9m bupropion vs placebo	1	141	Risk Ratio (M-H, Fixed, 95% CI)	1.09 [0.64, 1.84]
2.6 9m bupropion + placebo inhaler vs double placebo	1	97	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.40, 1.68]

2.7 9m bupropion + nicotine inhaler vs placebo + nicotine inhaler	1	93	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.43, 2.39]
2.8 14w bupropion vs placebo	1	362	Risk Ratio (M-H, Fixed, 95% CI)	1.19 [0.84, 1.68]
3 Combination NRT & bupropion versus placebo	2	243	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.75, 1.87]
4 Varenicline versus placebo. Cessation 12m+ after quit date	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

Comparison 7. Behavioural interventions for smokers. RP vs. cessation, matched for programme length

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Group or individual format therapy (+/- adjunct pharmacotherapy), cessation at longest follow up	10	872	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.73, 1.13]
2 Self-help format, cessation at longest follow-up	1	91	Risk Ratio (M-H, Fixed, 95% CI)	1.52 [0.67, 3.46]

Comparison 8. Behavioural interventions for smokers. RP vs. cessation, different intensity programmes

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cessation at longest follow up	7	699	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.80, 1.27]
1.1 More than four sessions for control group	5	546	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.70, 1.23]
1.2 Four sessions or less for control group	2	153	Risk Ratio (M-H, Fixed, 95% CI)	1.23 [0.81, 1.86]

Comparison 9. Behavioural interventions for smokers, tests of adjuncts to cessation programmes

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cessation at longest follow up	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Additional proactive telephone contact	1	1083	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [0.90, 1.28]
1.2 Additional web-based support	1	284	Risk Ratio (M-H, Fixed, 95% CI)	1.27 [0.70, 2.31]

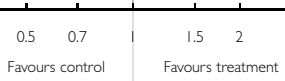
Analysis 1.1. Comparison 1 Behavioural interventions for abstinent pregnant/post partum women, Outcome 1 Not smoking at delivery/ last follow up prior to delivery.

Review: Relapse prevention interventions for smoking cessation

Comparison: 1 Behavioural interventions for abstinent pregnant/post partum women

Outcome: 1 Not smoking at delivery/ last follow up prior to delivery

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Self help intervention					
Ershoff 1995	73/87	67/84		13.3 %	1.05 [0.91, 1.21]
Subtotal (95% CI)	**87**	**84**		**13.3 %**	**1.05 [0.91, 1.21]**
Total events: 73 (Treatment), 67 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.70 (P = 0.48)					
2 Individual counselling					
Hajek 2001	66/114	68/135		12.1 %	1.15 [0.91, 1.45]
Lowe 1997	32/40	29/38		5.8 %	1.05 [0.83, 1.33]
Morasco 2006	10/14	16/19		2.6 %	0.85 [0.58, 1.25]
Secker-Walker 1995	55/85	54/80		10.8 %	0.96 [0.77, 1.19]
Secker-Walker 1998	22/55	29/61		5.4 %	0.84 [0.55, 1.28]
Subtotal (95% CI)	**308**	**333**		**36.8 %**	**1.01 [0.89, 1.15]**
Total events: 185 (Treatment), 196 (Control)					
Heterogeneity: Chi^2 = 3.07, df = 4 (P = 0.55); I^2 =0.0%					
Test for overall effect: Z = 0.17 (P = 0.87)					
3 Telephone counselling					
McBride 1999	224/258	110/137		28.0 %	1.08 [0.98, 1.19]
McBride 2004	173/209	85/107		21.9 %	1.04 [0.93, 1.17]
Subtotal (95% CI)	**467**	**244**		**49.9 %**	**1.06 [0.99, 1.15]**
Total events: 397 (Treatment), 195 (Control)					
Heterogeneity: Chi^2 = 0.24, df = 1 (P = 0.63); I^2 =0.0%					
Test for overall effect: Z = 1.66 (P = 0.098)					
Total (95% CI)	**862**	**661**		**100.0 %**	**1.04 [0.98, 1.11]**
Total events: 655 (Treatment), 458 (Control)					
Heterogeneity: Chi^2 = 3.96, df = 7 (P = 0.78); I^2 =0.0%					
Test for overall effect: Z = 1.34 (P = 0.18)					



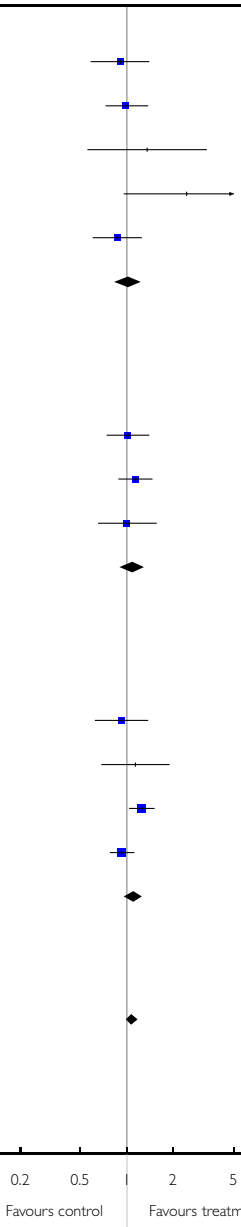
Analysis 1.2. Comparison 1 Behavioural interventions for abstinent pregnant/post partum women, Outcome 2 Not smoking at longest follow up after delivery.

Review: Relapse prevention interventions for smoking cessation

Comparison: 1 Behavioural interventions for abstinent pregnant/post partum women

Outcome: 2 Not smoking at longest follow up after delivery

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Intervention during pregnancy					
Hajek 2001	26/114	34/135		5.9 %	0.91 [0.58, 1.41]
McBride 1999	66/157	33/78		8.4 %	0.99 [0.72, 1.37]
Morasco 2006	6/14	6/19		1.0 %	1.36 [0.55, 3.33]
Ruger 2008	9/24	5/33		0.8 %	2.48 [0.95, 6.45]
Secker-Walker 1998	25/55	32/61		5.8 %	0.87 [0.60, 1.26]
Subtotal (95% CI)	**364**	**326**		**21.9 %**	**1.01 [0.82, 1.23]**
Total events: 132 (Treatment), 110 (Control)					
Heterogeneity: Chi² = 4.65, df = 4 (P = 0.33); I² =14%					
Test for overall effect: Z = 0.06 (P = 0.95)					
2 Intervention initiated during pregnancy and continued post partum					
McBride 1999	63/146	33/78		8.2 %	1.02 [0.74, 1.40]
McBride 2004	105/231	47/118		11.9 %	1.14 [0.88, 1.48]
Secker-Walker 1995	28/85	26/80		5.1 %	1.01 [0.65, 1.57]
Subtotal (95% CI)	**462**	**276**		**25.2 %**	**1.08 [0.89, 1.29]**
Total events: 196 (Treatment), 106 (Control)					
Heterogeneity: Chi² = 0.37, df = 2 (P = 0.83); I² =0.0%					
Test for overall effect: Z = 0.78 (P = 0.44)					
3 Intervention initiated after birth					
Hannver 2009	34/148	39/156		7.3 %	0.92 [0.62, 1.37]
Ratner 2000	25/119	22/119		4.2 %	1.14 [0.68, 1.90]
Severson 1997	200/609	109/417		24.7 %	1.26 [1.03, 1.53]
Van't Hof 2000	78/133	91/144		16.7 %	0.93 [0.77, 1.12]
Subtotal (95% CI)	**1009**	**836**		**52.9 %**	**1.10 [0.96, 1.25]**
Total events: 337 (Treatment), 261 (Control)					
Heterogeneity: Chi² = 5.57, df = 3 (P = 0.13); I² =46%					
Test for overall effect: Z = 1.39 (P = 0.17)					
Total (95% CI)	**1835**	**1438**		**100.0 %**	**1.07 [0.98, 1.18]**
Total events: 665 (Treatment), 477 (Control)					
Heterogeneity: Chi² = 10.90, df = 11 (P = 0.45); I² =0.0%					
Test for overall effect: Z = 1.44 (P = 0.15)					



Analysis 2.1. Comparison 2 Behavioural interventions for abstinent hospitalised smokers, Outcome 1 Cessation at longest follow up.

Review: Relapse prevention interventions for smoking cessation

Comparison: 2 Behavioural interventions for abstinent hospitalised smokers

Outcome: 1 Cessation at longest follow up

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Hajek 2002	94/254	102/251		76.9 %	0.91 [0.73, 1.13]
Hasuo 2004	32/60	25/49		20.6 %	1.05 [0.73, 1.50]
Schmitz 1999	3/29	3/24		2.5 %	0.83 [0.18, 3.73]
Total (95% CI)	**343**	**324**		**100.0 %**	**0.94 [0.78, 1.13]**
Total events: 129 (Treatment), 130 (Control)					
Heterogeneity: Chi^2 = 0.44, df = 2 (P = 0.80); I^2 =0.0%					
Test for overall effect: Z = 0.69 (P = 0.49)					

Analysis 3.1. Comparison 3 Behavioural interventions for unaided abstainers, Outcome 1 Cessation at longest follow up.

Review: Relapse prevention interventions for smoking cessation

Comparison: 3 Behavioural interventions for unaided abstainers

Outcome: 1 Cessation at longest follow up

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Borland 2004	45/139	33/147		7.0 %	1.44 [0.98, 2.12]
Brandon 2000	302/449	91/135		30.6 %	1.00 [0.87, 1.14]
Brandon 2004	187/320	60/111		19.5 %	1.08 [0.89, 1.31]
Fortmann 1995	97/521	97/521		21.2 %	1.00 [0.78, 1.29]
Killen 1990	171/814	74/404		21.6 %	1.15 [0.90, 1.47]
Total (95% CI)	**2243**	**1318**		**100.0 %**	**1.08 [0.98, 1.19]**
Total events: 802 (Treatment), 355 (Control)					
Heterogeneity: Chi^2 = 4.06, df = 4 (P = 0.40); I^2 =1%					
Test for overall effect: Z = 1.50 (P = 0.13)					

Analysis 4.1. Comparison 4 Behavioural interventions for assisted abstainers, Outcome 1 Cessation at longest follow up.

Review: Relapse prevention interventions for smoking cessation

Comparison: 4 Behavioural interventions for assisted abstainers

Outcome: 1 Cessation at longest follow up

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Mermelstein 2003	68/176	75/165		30.9 %	0.85 [0.66, 1.09]
Powell 1981	11/17	11/17		4.4 %	1.00 [0.61, 1.64]
Razavi 1999	59/135	43/121		18.1 %	1.23 [0.90, 1.67]
Smith 2001	40/226	54/223		21.7 %	0.73 [0.51, 1.05]
Stevens 1989	76/184	65/198		25.0 %	1.26 [0.97, 1.64]
Total (95% CI)	**738**	**724**		**100.0 %**	**1.00 [0.87, 1.15]**

Total events: 254 (Treatment), 248 (Control)

Heterogeneity: Chi^2 = 9.12, df = 4 (P = 0.06); I^2 =56%

Test for overall effect: Z = 0.02 (P = 0.98)

Analysis 5.1. Comparison 5 Pharmacotherapy for unaided abstainers, Outcome 1 Cessation 12m after quit date.

Review: Relapse prevention interventions for smoking cessation

Comparison: 5 Pharmacotherapy for unaided abstainers

Outcome: 1 Cessation 12m after quit date

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Nicotine gum vs placebo after brief unassisted abstinence					
Fortmann 1995	110/522	84/522		43.2 %	1.31 [1.01, 1.69]
Killen 1990	129/600	112/617		56.8 %	1.18 [0.94, 1.49]
Total (95% CI)	**1122**	**1139**		**100.0 %**	**1.24 [1.04, 1.47]**
Total events: 239 (Treatment), 196 (Control)					
Heterogeneity: Chi^2 = 0.33, df = 1 (P = 0.57); I^2 =0.0%					
Test for overall effect: Z = 2.47 (P = 0.014)					

Analysis 6.1. Comparison 6 Pharmacotherapy for assisted abstainers, Outcome 1 Nicotine replacement therapy versus placebo. Cessation 12m+ after quit date.

Review: Relapse prevention interventions for smoking cessation

Comparison: 6 Pharmacotherapy for assisted abstainers

Outcome: 1 Nicotine replacement therapy versus placebo. Cessation 12m+ after quit date

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 16w nicotine gum vs placebo					
Covey 2007	19/72	13/71		20.3 %	1.44 [0.77, 2.69]
Subtotal (95% CI)	**72**	**71**		**20.3 %**	**1.44 [0.77, 2.69]**
Total events: 19 (Treatment), 13 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.15 (P = 0.25)					
2 16w nicotine gum +bupropion vs placebo gum +bupropion					
Covey 2007	22/73	23/73		35.6 %	0.96 [0.59, 1.56]
Subtotal (95% CI)	**73**	**73**		**35.6 %**	**0.96 [0.59, 1.56]**
Total events: 22 (Treatment), 23 (Control)					

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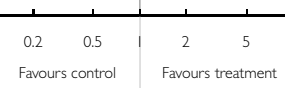
Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Heterogeneity: not applicable					
Test for overall effect: Z = 0.18 (P = 0.86)					
3 9m nicotine inhaler vs placebo					
Croghan 2007	17/81	19/87		28.4 %	0.96 [0.54, 1.72]
Subtotal (95% CI)	**81**	**87**		**28.4 %**	**0.96 [0.54, 1.72]**
Total events: 17 (Treatment), 19 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.13 (P = 0.89)					
4 9m nicotine inhaler + bupropion vs placebo inhaler + bupropion					
Croghan 2007	9/49	10/47		15.8 %	0.86 [0.39, 1.93]
Subtotal (95% CI)	**49**	**47**		**15.8 %**	**0.86 [0.39, 1.93]**
Total events: 9 (Treatment), 10 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.36 (P = 0.72)					
Total (95% CI)	**275**	**278**		**100.0 %**	**1.04 [0.77, 1.40]**
Total events: 67 (Treatment), 65 (Control)					
Heterogeneity: Chi^2 = 1.44, df = 3 (P = 0.70); I^2 =0.0%					
Test for overall effect: Z = 0.27 (P = 0.79)					

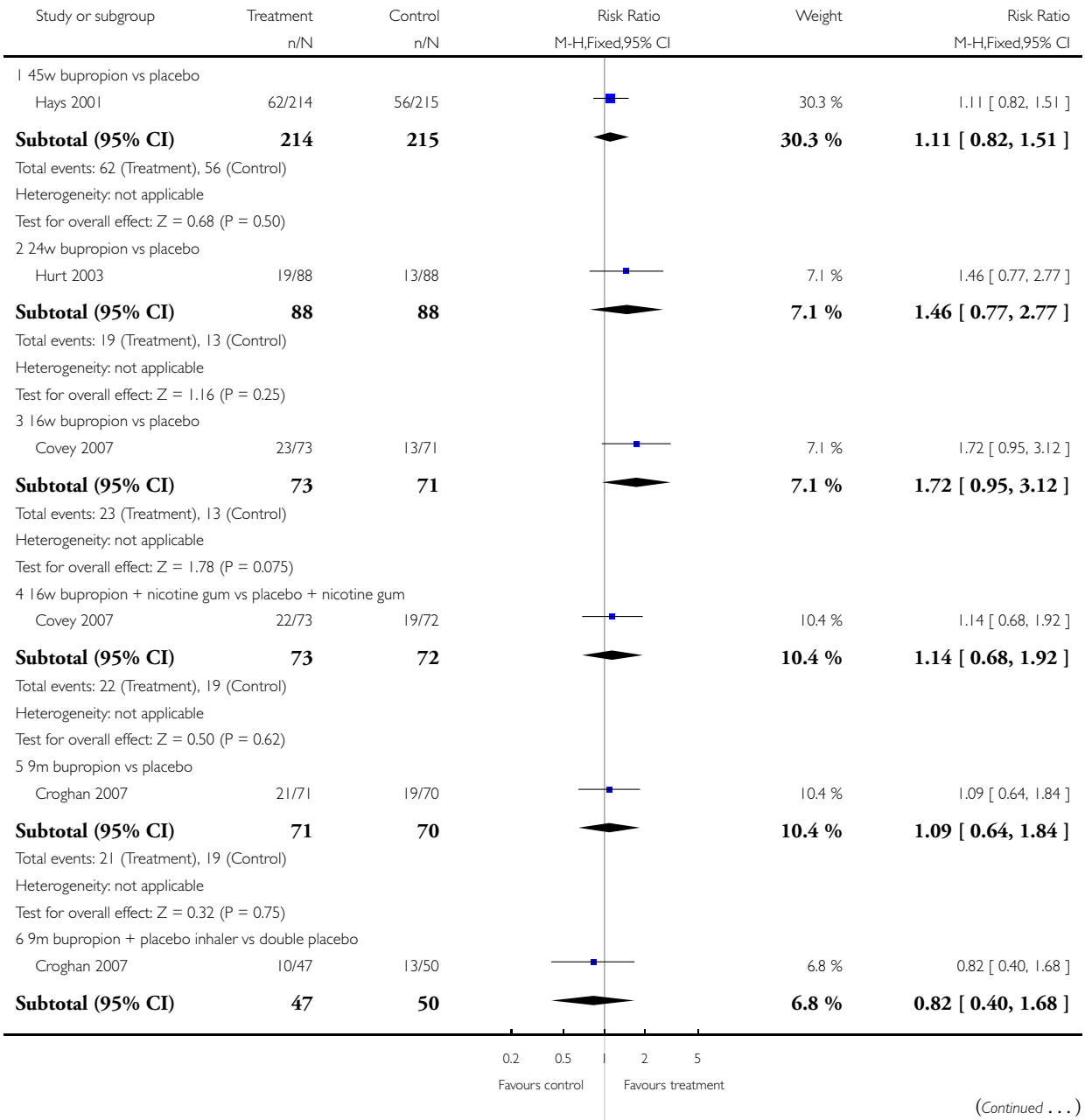


Analysis 6.2. Comparison 6 Pharmacotherapy for assisted abstainers, Outcome 2 Bupropion versus placebo. Cessation 12m+ after quit date.

Review: Relapse prevention interventions for smoking cessation

Comparison: 6 Pharmacotherapy for assisted abstainers

Outcome: 2 Bupropion versus placebo. Cessation 12m+ after quit date



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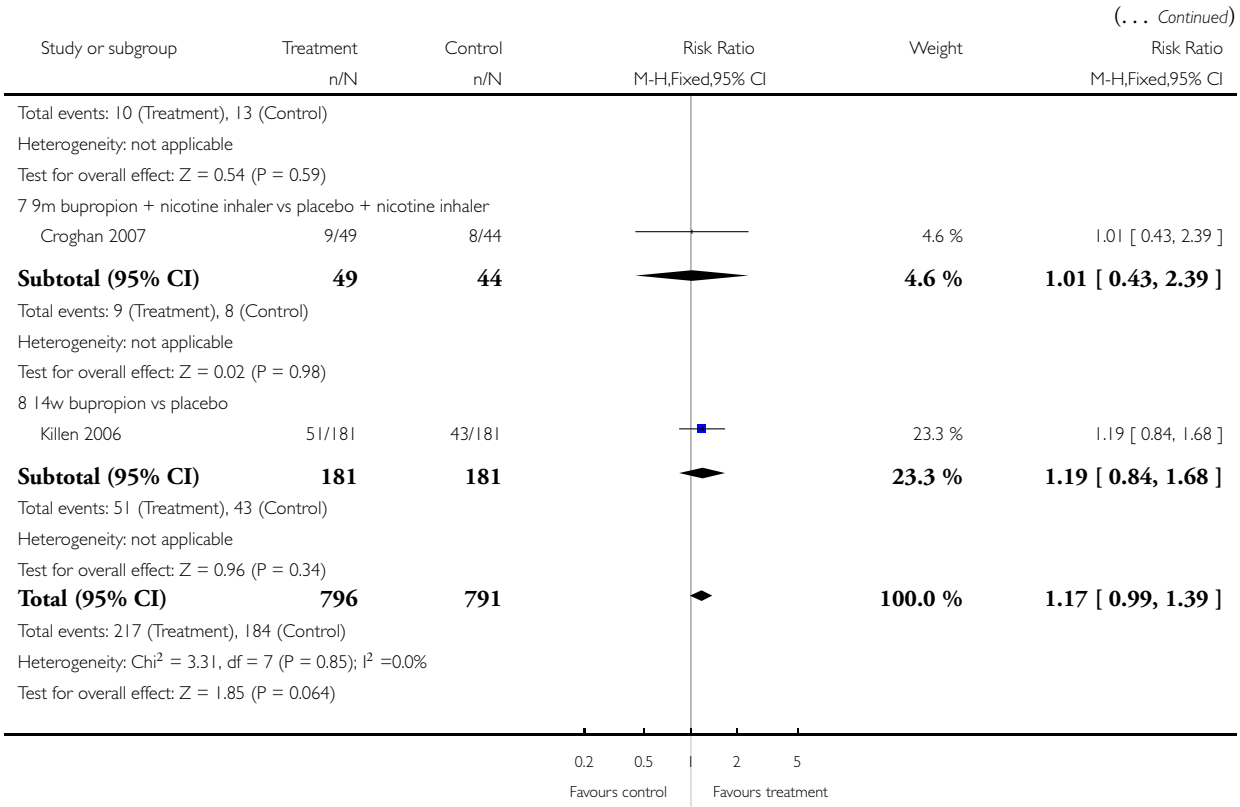
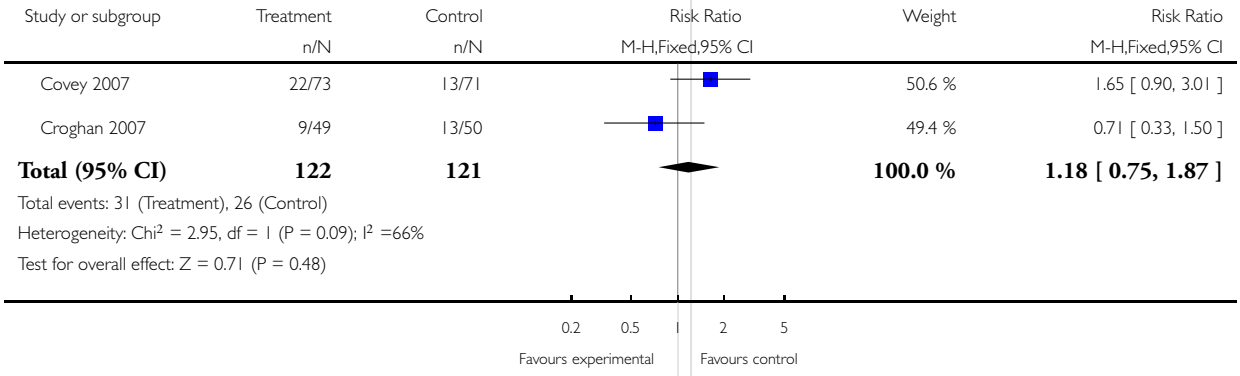


Analysis 6.3. Comparison 6 Pharmacotherapy for assisted abstainers, Outcome 3 Combination NRT & bupropion versus placebo.

Review: Relapse prevention interventions for smoking cessation

Comparison: 6 Pharmacotherapy for assisted abstainers

Outcome: 3 Combination NRT % bupropion versus placebo



Analysis 6.4. Comparison 6 Pharmacotherapy for assisted abstainers, Outcome 4 Varenicline versus placebo. Cessation 12m+ after quit date.

Review: Relapse prevention interventions for smoking cessation

Comparison: 6 Pharmacotherapy for assisted abstainers

Outcome: 4 Varenicline versus placebo. Cessation 12m+ after quit date

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
Tonstad 2006	263/603	224/607		1.18 [1.03, 1.36]

Analysis 7.1. Comparison 7 Behavioural interventions for smokers. RP vs. cessation, matched for programme length, Outcome 1 Group or individual format therapy (+/- adjunct pharmacotherapy), cessation at longest follow up.

Review: Relapse prevention interventions for smoking cessation

Comparison: 7 Behavioural interventions for smokers. RP vs. cessation, matched for programme length

Outcome: 1 Group or individual format therapy (+/- adjunct pharmacotherapy), cessation at longest follow up

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Becona 1997	13/36	12/40		9.9 %	1.20 [0.63, 2.29]
Buchkremer 1991 1	19/43	19/51		15.2 %	1.19 [0.73, 1.94]
Buchkremer 1991 2	29/92	15/32		19.4 %	0.67 [0.42, 1.08]
Curry 1988	6/24	9/24		7.9 %	0.67 [0.28, 1.58]
Davis 1986	2/15	2/16		1.7 %	1.07 [0.17, 6.64]
Emmons 1988	5/23	9/26		7.4 %	0.63 [0.25, 1.60]
Hall 1984	26/65	20/70		16.8 %	1.40 [0.87, 2.25]
Niaura 1999	3/62	8/67		6.7 %	0.41 [0.11, 1.46]

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Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Schmitz 1999	8/60	8/47		7.8 %	0.78 [0.32, 1.93]
Schroter 2006	5/41	8/38		7.2 %	0.58 [0.21, 1.62]
Total (95% CI)	**461**	**411**		**100.0 %**	**0.91 [0.73, 1.13]**
Total events: 116 (Treatment), 110 (Control)					
Heterogeneity: Chi^2 = 10.06, df = 9 (P = 0.35); I^2 =11%					
Test for overall effect: Z = 0.83 (P = 0.41)					

Analysis 7.2. Comparison 7 Behavioural interventions for smokers. RP vs. cessation, matched for programme length, Outcome 2 Self-help format, cessation at longest follow-up.

Review: Relapse prevention interventions for smoking cessation

Comparison: 7 Behavioural interventions for smokers. RP vs. cessation, matched for programme length

Outcome: 2 Self-help format, cessation at longest follow-up

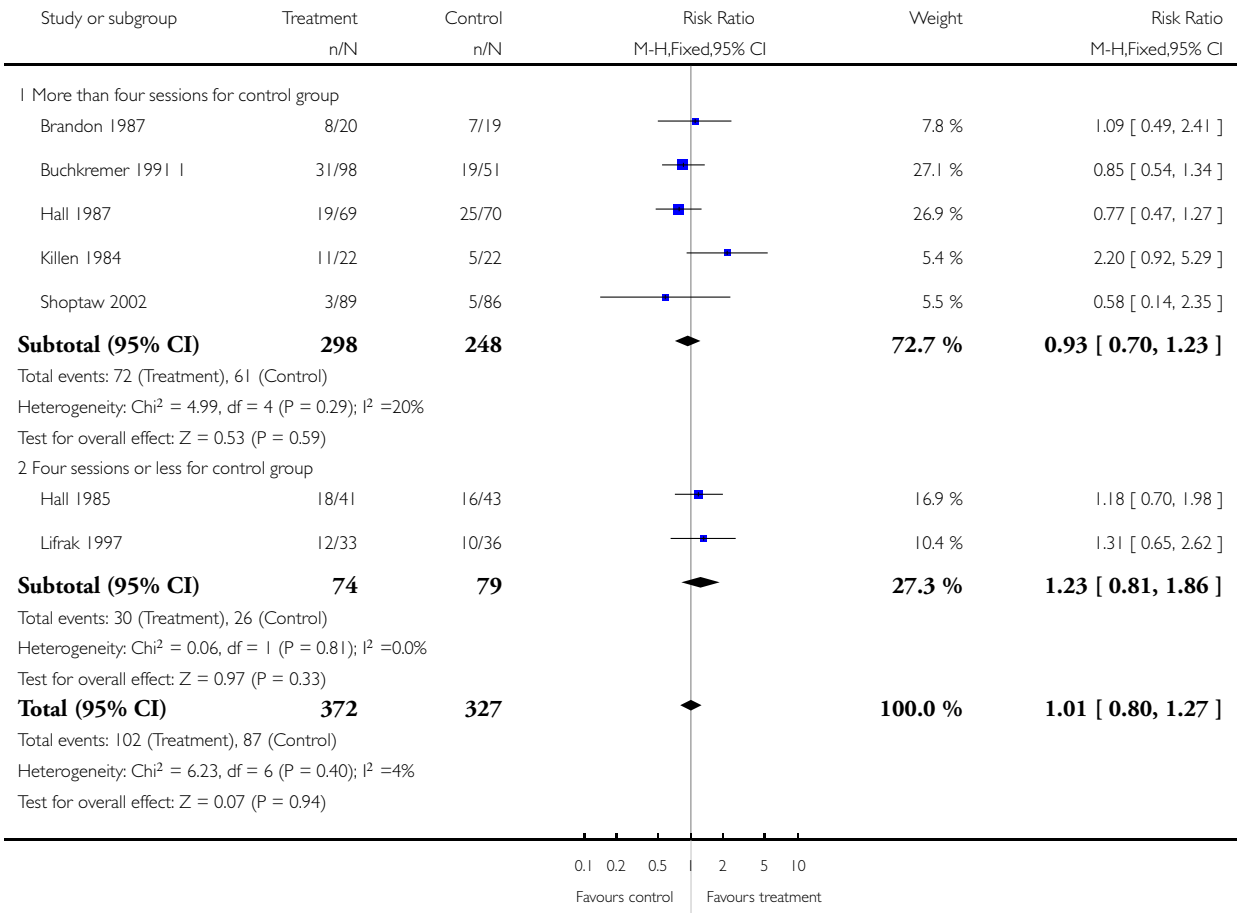
Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Curry 1988	13/50	7/41		100.0 %	1.52 [0.67, 3.46]
Total (95% CI)	**50**	**41**		**100.0 %**	**1.52 [0.67, 3.46]**
Total events: 13 (Treatment), 7 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.00 (P = 0.32)					

Analysis 8.1. Comparison 8 Behavioural interventions for smokers. RP vs. cessation, different intensity programmes, Outcome 1 Cessation at longest follow up.

Review: Relapse prevention interventions for smoking cessation

Comparison: 8 Behavioural interventions for smokers. RP vs. cessation, different intensity programmes

Outcome: 1 Cessation at longest follow up

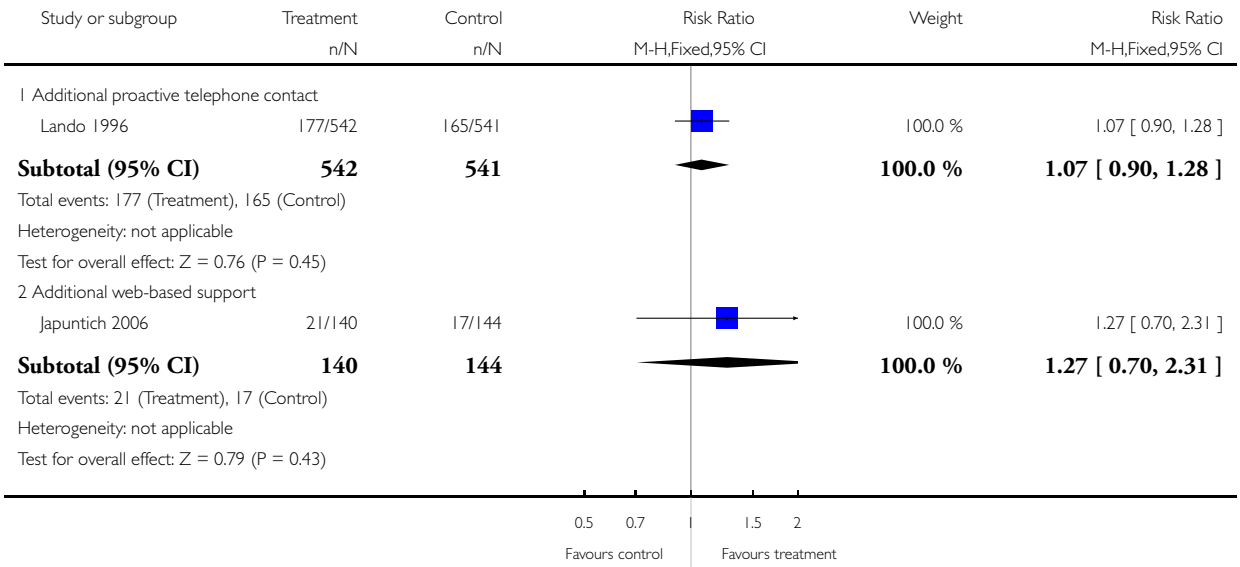


Analysis 9.1. Comparison 9 Behavioural interventions for smokers, tests of adjuncts to cessation programmes, Outcome 1 Cessation at longest follow up.

Review: Relapse prevention interventions for smoking cessation

Comparison: 9 Behavioural interventions for smokers, tests of adjuncts to cessation programmes

Outcome: 1 Cessation at longest follow up



WHAT'S NEW

Last assessed as up-to-date: 18 August 2008.

22 October 2008	New citation required and conclusions have changed	Includes evidence from one trial that extended treatment with varenicline reduces relapse
21 October 2008	New search has been performed	Updated for issue 1, 2009 with 15 new included trials.
20 October 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 1, 2003

Review first published: Issue 1, 2005

CONTRIBUTIONS OF AUTHORS

PH, LS & TL conceived the review and developed the protocol. MJ performed previous work that informed the protocol. LS designed & conducted the searches and screened papers. PH, LS & TL extracted data and agreed on study inclusion and grouping. PH & LS conducted the analyses and jointly wrote the review. MJ & RW provided additional methodological, clinical and policy perspectives.

DECLARATIONS OF INTEREST

One author (PH) was involved in three of the studies included in the review.

SOURCES OF SUPPORT

Internal sources

- University of Oxford, Department of Primary Health Care, UK.
- National School for Health Research School for Primary Care Research, UK.
- Queen Mary's School of Medicine and Dentistry, UK.

External sources

- NHS Research & Development Programme, UK.

INDEX TERMS

Medical Subject Headings (MeSH)

Behavior Therapy; Chewing Gum; Nicotine [therapeutic use]; Nicotinic Agonists; Randomized Controlled Trials as Topic; Recurrence [prevention & control]; Smoking [*prevention & control]; Smoking Cessation [*methods]

MeSH check words

Female; Humans; Male; Pregnancy