Individual behavioural counselling for smoking cessation (Review)

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TABLE OF CONTENTS

[Intervention Review]

Individual behavioural counselling for smoking cessation

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ABSTRACT

Background

Individual counselling from a smoking cessation specialist may help smokers to make a successful attempt to stop smoking.

Objectives

The objective of the review is to determine the effects of individual counselling.

Search strategy

We searched the Cochrane Tobacco Addiction Group Specialized Register for studies with counsel* in any field. Date of the most recent search: May 2008.

Selection criteria

Randomized or quasi-randomized trials with at least one treatment arm consisting of face-to-face individual counselling from a healthcare worker not involved in routine clinical care. The outcome was smoking cessation at follow up at least six months after the start of counselling.

Data collection and analysis

Both authors extracted data. The intervention and population, method of randomization and completeness of follow up were recorded.

Main results

We identified 30 trials with over 7000 participants. Twenty-two trials compared individual counselling to a minimal behavioural intervention. Individual counselling was more effective than control. The relative risk (RR) for smoking cessation at long-term follow up was 1.39, 95% confidence interval (CI) 1.24 to 1.57. In a subgroup of four trials where all participants received nicotine replacement therapy the point estimate of effect for counselling was smaller but just reached significance (RR 1.27; 95% CI 1.02 to 1.59). We failed to detect a greater effect of intensive counselling compared to brief counselling (5 trials, RR 0.96, 95% CI 0.74 to 1.25). None of the three other trials that compared different counselling models of similar intensity detected significant differences.

Authors' conclusions

Individually delivered smoking cessation counselling can assist smokers to quit.

PLAIN LANGUAGE SUMMARY

Does individually delivered counselling help people to stop smoking

Individual counselling is commonly used to help people who are trying to quit smoking. The review looked at trials of counselling by a trained therapist providing one or more face-to-face sessions, separate from medical care. All the trials involved sessions of more than 10 minutes, with most also including further telephone contact for support. The review found that individual counselling could help smokers quit, but there was not enough evidence about whether more intensive counselling was better.

BACKGROUND

Psychological interventions to aid smoking cessation include self-help materials, brief therapist-delivered interventions such as advice from a physician or nurse, intensive counselling delivered on an individual basis or in a group, and combinations of these approaches. Previous reviews have shown a small, but consistent, effect of brief, therapist-delivered interventions (Stead 2008a). The effect of self-help interventions is less clear (Lancaster 2005). More intensive intervention in a group setting increases quit rates (Stead 2005).

In this review, we assess the effectiveness of more intensive counselling delivered by a smoking cessation counsellor to a patient on a one-to-one basis. One problem in assessing the value of individual counselling is that of confounding with other interventions. For example, counselling delivered by a physician in the context of a clinical encounter may have different effects from that provided by a non-clinical counsellor. One approach to this problem is to employ statistical modelling (logistic regression) to control for possible confounders, an approach used by the US Public Health Service in preparing clinical practice guidelines (AHCPR 1996; Fiore 2000; Fiore 2008). An alternative approach is to review only unconfounded interventions. This is the approach we have adopted in the Cochrane Tobacco Addiction Review Group. In this review, we therefore specifically exclude counselling provided by doctors or nurses during the routine clinical care of the patient, and focus on smoking cessation counselling delivered by specialist counsellors. We define counselling broadly, based only on a minimum time spent in contact with the smoker, not according to the use of any specific behavioural approach.

OBJECTIVES

The review addresses the following hypotheses:

1. Individual counselling is more effective than no treatment or brief advice in promoting smoking cessation.

2. Individual counselling is more effective than self-help materials in promoting smoking cessation.

3. A more intensive counselling intervention is more effective than a less intensive intervention.

Studies comparing different counselling approaches are also included here if they are not covered by other Cochrane reviews of specific interventions. Comparisons between individual counselling and behavioural therapy conducted in groups are now covered in the Cochrane review of group behavioural therapy (Stead 2005)

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, where at least one treatment arm consisted of an unconfounded intervention from a counsellor.

Types of participants

Any smokers, except pregnant women (smoking cessation interventions in pregnancy are addressed by a separate review, Lumley 2004). Trials recruiting only children and adolescents are also excluded.

Types of interventions

We defined individual counselling as a face-to-face encounter between a smoking patient and a counsellor trained in assisting smoking cessation. This review specifically excludes studies of counselling delivered by doctors and nurses as part of clinical care, which are covered in separate reviews (Rice 2008; Stead 2008a). It also excludes interventions which address multiple risk factors in addition to smoking, and interventions where counselling was confounded with provision of pharmacotherapy. Studies that evaluated the effect of counselling as an addition to pharmacotherapy are included.

Types of outcome measures

The outcome was smoking cessation at the longest follow up reported. We used sustained abstinence, or multiple point prevalence, where available. We included studies using self report with or without biochemically validated cessation, and performed sensitivity analyses to determine whether the estimates differed significantly in studies without verification.

Search methods for identification of studies

We searched the Tobacco Addiction Group Specialized Register for studies with counsel* in title, abstract or keyword fields. We also checked previous reviews and meta-analyses for relevant studies, including all studies in the previous US guidelines (AHCPR 1996; Fiore 2000). Date of most recent search May 2008.

Data collection and analysis

Both authors extracted data. The principal outcome was cessation rates. The information extracted included descriptive information (the population and intervention studied), method of randomization and allocation concealment, completeness of follow up, and whether self-reported cessation was validated. Participants lost to follow up were assumed to be continuing smokers.

We summarized individual study results as a risk ratio, calculated as: (number of quitters in intervention group/ number randomized to intervention group) / (number of quitters in control group/ number randomized to control group). Where appropriate we performed meta-analysis using a Mantel-Haenszel fixed-effect method to estimate a pooled risk ratio with 95% confidence intervals (Greenland 1985). Earlier versions of this review reported effects as odds ratios, and pooled using the Peto method (Yusuf 1985). The Tobacco Addiction group now recommends the use of risk ratios as being easier to interpret. The amount of statistical heterogeneity between trials was estimated using the I^2 statistic (Higgins 2003). Values over 50% can be regarded as moderate heterogeneity, and values over 75% as high.

In order to include any cluster-randomized study that reported an odds ratio adjusted for clustering, we also conducted a secondary meta-analysis using the generic inverse variance method for pooling the odds ratios from studies.

We made the following comparisons:

- Individual counselling versus no treatment, brief advice or self-help materials
- More intensive versus less intensive individual counselling
- Comparisons between counselling methods matched for contact time

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

There are 30 studies included in this review, with over 7000 participants. In a small number of cases difficulties in applying the inclusion criteria were resolved by discussion. In two cases we were uncertain whether the providers were acting as specialist counsellors or were providing interventions as part of usual care in other healthcare roles. We included Aveyard 2007 and Wiggers 2006 after discussion about this aspect of their designs. We included one study that had only five months follow up (Kim 2005).

Twenty-two studies compared individual counselling to a minimal level of behavioural intervention. Five studies compared different intensities of counselling and three compared different counselling approaches which were similar in intensity of contact.

Studies with minimal contact controls

In these 22 studies the minimal intervention offered to the control comparison group ranged from usual care to up to 10 minutes of advice, with or without the provision of self-help materials. All the interventions classified as individual counselling involved more than 10 minutes of face-to-face contact. Ten used a single face-to-face session (Windsor 1988; Weissfeld 1991; Stevens 1993; Rigotti 1997 Simon 1997; Dornelas 2000; Glasgow 2000; Molyneux 2003; Hennrikus 2005; Kim 2005). The counselling in Kim 2005 was particularly brief at only 11 minutes on average. All of these included further telephone contact except Molyneux 2003 and the low intensity condition tested by Weissfeld and colleagues.

Within this group of studies, nicotine replacement therapy (NRT) was systematically provided to all participants in three trials. Fiore 2004 compared individual counselling and nicotine patch to two less intensive conditions; nicotine patch with or without a single telephone counselling session and tailored materials. Simon 2003 compared nicotine patch and an in-hospital session plus five telephone counselling calls to nicotine patch and a single 10 minute

in-hospital session. Jorenby 1995 used two different doses of nicotine patch (collapsed in the analysis) crossed with three levels of behavioural support (minimal, individual or group) in a factorial design. The individual counselling group was compared with a minimal support condition that was given a self-help pamphlet by a physician and thereafter had weekly assessments but no further counselling. Aveyard 2007 provided nicotine patch to all participants. A fourth trial provided nicotine patches to participants ready to quit in either group (Wiggers 2006). In one trial (Simon 1997) smokers randomized to receive counselling were given a prescription for nicotine gum if there were no contraindications. Although 65% in the counselling condition used gum compared to 17% of the control group, its use was not significantly associated with quitting.

In the control interventions, provision of written materials was generally confounded with brief advice. No trials directly addressed whether providing counselling in addition to a structured self-help programme increased efficacy. Therefore in the meta-analysis we have not distinguished between brief advice, usual care or provision of self-help materials as the control intervention with which counselling is compared.

Studies of counselling intensity

We considered separately five studies that compared intensive counselling to less intensive intervention which still involved more than 10 minutes of face-to-face contact.

- Weissfeld 1991, compared two intensities of counselling with a control; both intensities are combined versus control in the first analysis but compared in this analysis.
- Lifrak 1997 compared two intensities of counselling as an adjunct to nicotine patch therapy. The lower intensity one was a four session advice and education intervention from a nurse practitioner who reviewed self-help materials and monitored patch use. The higher intensity intervention added 16 weekly sessions of cognitive behavioural relapse prevention therapy.
- Alterman 2001 used similar interventions to Lifrak 1997 but added a lower intensity control of a single 30-minute session with a nurse practitioner.
- Tonnesen 2006 compared seven visits and five phone calls with a contact time of 4½ hours to four visits and six calls taking 2½ hours. This trial had a factorial design also comparing a nicotine sublingual tablet and placebo; we entered the arms with and without NRT in separate subgroups.
- Aveyard 2007 compared seven weekly contacts with four contacts for people receiving cessation support with nicotine patches.

Studies of counselling methods

Three studies compared different counselling approaches that had similar contact times

- Schmitz 1999 involved six one-hour sessions. One intervention used a coping skills relapse prevention model. It was compared with a health belief model that focused on smoking-related health information, the relationship with coronary disease and the benefits of quitting.
- Ahluwalia 2006 provided three face-to-face visits and three phone contacts extending over six weeks, and 2 mg nicotine gum for eight weeks. One intervention used motivational interviewing and the other a health education focus.
- McCarthy 2008 provided eight 10-minute counselling sessions during assessment visits in a trial that also compared bupropion to placebo. The counselling was consistent with US practice guidelines. The control focused on medication use and adherence, and general support and encouragement.

Study populations

Thirteen of the 30 studies recruited medical or surgical hospital inpatients (Pederson 1991; Ockene 1992; Stevens 1993; Rigotti 1997; Simon 1997; Dornelas 2000; Molyneux 2003; Simon 2003; Hennrikus 2005; Pedersen 2005), or outpatients (Weissfeld 1991; Kim 2005; Tonnesen 2006). One recruited some inpatients (Schmitz 1999). Three other studies recruited drug- and alcohol-dependent veterans attending residential rehabilitation (Bobo 1998; Burling 1991; Burling 2001). Other studies recruited smokers in primary care clinics (Fiore 2004; Aveyard 2007), primary care and local community (Aleixandre 1998), local community and university (Alterman 2001), communities and worksites (Nakamura 2004), at a periodic healthcare examination (Bronson 1989), at a Planned Parenthood clinic (Glasgow 2000), employees volunteering for a company smoking cessation programme (Windsor 1988) and community volunteers (Jorenby 1995; Lifrak 1997; Ahluwalia 2006; McCarthy 2008),. Lack of interest in quitting was not an explicit exclusion criterion in any study, but the level of motivation to quit smoking was sometimes difficult to assess. One trial enrolled all smokers admitted to hospital (Stevens 1993), whilst one enrolled 90% of smokers approached (Rigotti 1997). In one large study in primary care 68% of smokers agreed to participate and 52% met inclusion criteria and were recruited (Fiore 2004). In other studies a larger proportion of eligible smokers may have declined randomization because of lack of interest in quitting.

Two studies recruited only women: Schmitz 1999 recruited 53 women hospitalised with coronary artery disease (CAD) and 107 volunteers with CAD risk factors. Glasgow 2000 recruited 1154 women attending Planned Parenthood clinics, who were not selected for motivation to quit. Weissfeld 1991 recruited only men, Simon 2003 and Nakamura 2004 recruited predominantly men.

Intervention components

The counselling interventions typically included the following components: review of a participant's smoking history and mo-

tivation to quit, help in the identification of high-risk situations, and the generation of problem-solving strategies to deal with such situations. Counsellors may also have provided non-specific support and encouragement. Some studies provided additional components such as written materials, video or audiotapes. The main components used in each study are shown in the Characteristics of included studies table.

Intervention providers

The therapists who provided the counselling were generally described as smoking cessation counsellors. Their professional backgrounds included social work, psychology, psychiatry, health education and nursing. In one study, the therapist for some of the sessions was a nurse practitioner (Alterman 2001), and in two others the therapists were research doctors or nurses trained in counselling (Molyneux 2003; Hennrikus 2005). In Aveyard 2007 all the support was from primary care nurses who were not full-time counsellors. We included this study because the nurses were trained to provide counselling support as part of the National Health Service Stop Smoking Services and were not offering it as part of usual care. In Tonnesen 2006 the counselling was provided by nurses employed in a lung clinic and in Wiggers 2006 it was provided by nurse practitioners in a cardiology outpatient clinic.

Excluded studies

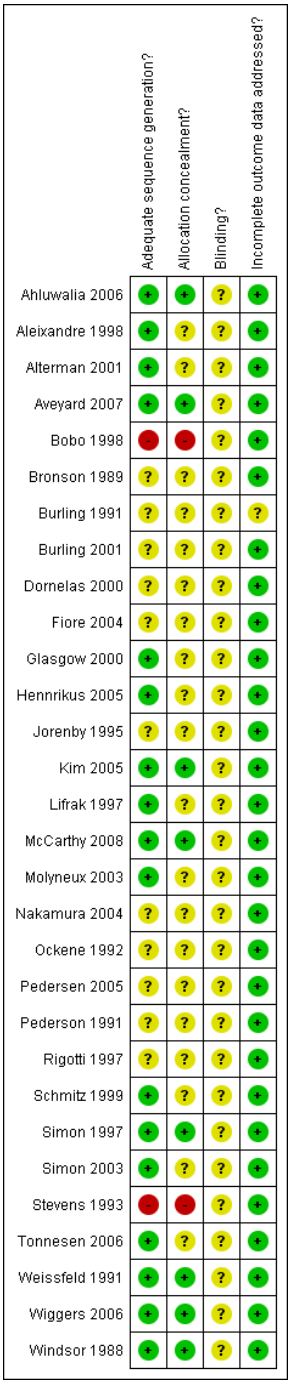
We excluded one study that provided motivational interviewing as part of an intervention to reduce passive smoke exposure in households with young children (Emmons 2001). Cessation was a secondary outcome and there was no significant difference in quit rates, which were not reported separately by group. A sensitivity analysis of including this study assuming equal quit rates did not alter the review results.

Other studies which were identified as potentially relevant but did not meet the full inclusion criteria are listed with their reasons for exclusion in the table of excluded studies.

Risk of bias in included studies

We evaluated four domains of study quality; randomization sequence generation; sequence concealment, blinding during treatment and follow up; and incomplete outcome data. A summary is displayed in Figure 1.

Figure 1. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.



Seventeen studies reported the method for generating the randomization sequence in sufficient detail to be classified as having a low risk of bias, but only eight also described a method of allocation likely to ensure that the assignment was concealed until after allocation (Simon 1997; Weissfeld 1991, Windsor 1988; Kim 2005; Ahluwalia 2006; Wiggers 2006; Aveyard 2007; McCarthy 2008;). In other trials neither the method of randomization nor allocation concealment was described. One of the included studies has been described as a randomized trial (Meenan 1998). The primary report (Stevens 1993) makes it clear that the intervention was delivered to one of two hospitals, alternating on a monthly basis for 14 months. This design was used to avoid control patients hearing the intervention given to others in shared rooms. All eligible smokers in the intervention hospital were regarded as participants whether or not the intervention was delivered, thus avoiding selection bias, and the intervention was not provided by hospital staff. There were no significant differences between intervention and usual care groups at baseline; there were however a larger number of patients in the usual care group. As it seems unlikely that there would have been a high risk of systematic bias from this design, we included the study and performed sensitivity analysis.

One study (Bobo 1998) used cluster randomization of 12 residential centres, and reported the outcome as an odds ratio adjusted for the effect of clustering. We include this in a secondary analysis using the outcomes from the other trials expressed as odds ratios and pooled using the inverse variance method.

There was little information about blinding. Whilst the therapists delivering counselling could not have been blind, in some cases other care providers were noted to be unaware of intervention status. It was unclear what information participants were given, but almost all trials included an active control group that received some information about stopping smoking.

Biochemical validation of self-reported non-smoking was attempted for all those categorized as quitters in 19 studies (Windsor 1988; Weissfeld 1991; Ockene 1992; Jorenby 1995; Rigotti 1997; Glasgow 2000; Alterman 2001; Burling 2001; Molyneux 2003; Simon 2003; Fiore 2004; Nakamura 2004; Hennrikus 2005; Kim 2005; Ahluwalia 2006; Tonnesen 2006; Wiggers 2006; Aveyard 2007; McCarthy 2008). One study tested for cotinine but did not report validated rates (Bobo 1998). In two studies, only a sample of respondents was tested (Pederson 1991; Schmitz 1999). Self report was confirmed by a significant other for all quitters in one study (Dornelas 2000) and for six of 29 quitters in a second (Simon 1997). Quit rates were based on self report alone in five studies (Bronson 1989; Stevens 1993; Lifrak 1997; Aleixandre 1998; Pedersen 2005). One study had no self-reported long-term quitters (Burling 1991). One study using saliva cotinine reported relatively high and differential levels of refusal to provide samples and samples that failed to confirm abstinence (Hennrikus 2005).

Most studies reported the number of participants who dropped out or were lost to follow up, and included these people as smokers in intent to treat analyses (ITT). In most cases the percentage lost was small and similar across groups. One study (Fiore 2004) excluded randomized participants who failed to collect their free supply of nicotine patches, and as a consequence also did not receive any additional behavioural components to which they were allocated. The proportions excluded were similar in all the intervention groups, so we have used the denominators as given.

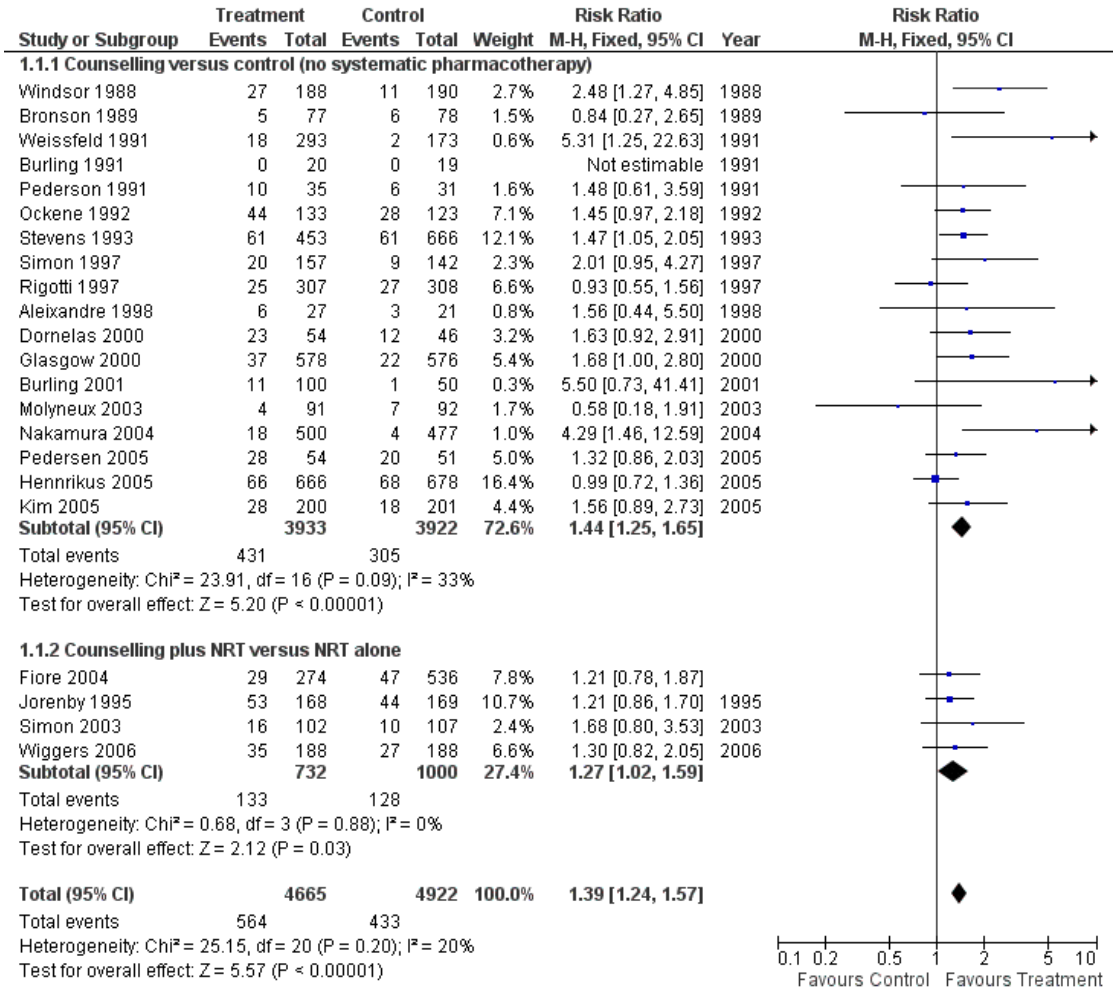
Effects of interventions

Counselling versus minimal contact control

We estimated a pooled effect size based on 22 studies of counselling, including one (Burling 1991) where there were no quitters and which therefore did not contribute to the meta-analysis. The relative risk (RR) was 1.39; 95% confidence interval (CI) 1.24 to 1.57 (analysis 1.1), with no evidence of significant heterogeneity (I^2=20%).

Figure 2

Figure 2. Forest plot of comparison: 1 Individual counselling compared to minimal contact control, outcome: 1.1 Smoking cessation at longest follow-up.



The estimate remained almost the same if the trial without individual randomization (Stevens 1993) was excluded. Incorporating the results from a cluster-randomized trial that provided the outcome as a corrected odds ratio (Bobo 1998) did not substantially alter the effect (data not shown). Sensitivity analysis including only the 15 trials in this group that had complete biochemical validation of self-reported cessation did not alter the results. Sensitivity analysis including only the studies rated adequate for allocation concealment gave a larger estimated effect. The subgroup of four studies where counselling was tested as an adjunct to nicotine replacement therapy had a smaller estimated effect which just reached significance (RR 1.27; 95% CI 1.02 to 1.59; comparison 1.1.2) but the confidence intervals of the subgroups with and without NRT overlapped.

More intensive versus less intensive counselling

In an analysis combining five studies, there was no evidence of benefit from more intensive compared to brief counselling and the point estimate was close to 1, although the confidence intervals are wide and do not exclude the possibility of a small but potentially clinically useful dose-response effect (RR 0.96; 95% CI 0.74 to 1.24; analysis 2.1). There was no evidence of more effect in the absence of NRT, but only the participants in Weissfeld 1991 and the placebo arms of Tonnesen 2006 did not have pharmacotherapy. With the inclusion of two additional studies in this update, the point estimate is lower and the significance is no longer sensitive to the way in which the three intervention arms in one study

(Alterman 2001; analysis 2.2) are handled. Comparing the high intensity to the medium intensity interventions, which match most closely the two arms of the Lifrak 1997 study does produce a significant treatment effect but this no longer leads to a significant pooled effect because of the contribution of the large Aveyard 2007 study where a slightly more intensive planned intervention had a lower quit rate. This pragmatic study differs in some respects in that the difference in counselling intensity was modest, consisting of one additional visit and two supportive phone calls, not all of which were delivered.

Comparisons between counselling approaches

None of the three trials detected significant differences between different types of counselling, where number of contacts and general intensity were similar. Schmitz 1999, comparing a relapse prevention approach with a health belief model, showed no significant difference, but with wide confidence intervals (RR 0.94; 95% CI 0.45 to 1.98; analysis 3.1.1). Ahluwalia 2006 compared a motivational interviewing to a health education approach and the point estimate favoured the latter (RR 0.51; 95% confidence interval 0.34 to 0.76; analysis 3.1.2). Participants were making quit attempts and using nicotine gum or placebo and therefore the motivational aspect may have been less relevant. McCarthy 2008 was also a pharmacotherapy trial with a factorial design and the specific behavioural components did not increase quitting over instructions about medication and general support (RR 0.93; 95% CI 0.62 to 1.39; analysis 3.1.3). There was no evidence of an interaction between medication and counselling in either of the factorial trials.

DISCUSSION

There is consistent evidence that individual counselling increases the likelihood of cessation compared to less intensive support. Almost half the trials recruited people in hospital settings, but there was no evidence of heterogeneity of results in different settings.

These results are consistent with the US Public Health Service practice guideline (Fiore 2008). The guideline supports the use of intensive counselling. The guideline evidence in this area is based on meta-analyses conducted for the previous update of the guideline (Fiore 2000) and includes indirect comparisons. These included an analysis of 58 trials where treatment conditions differed in format (self help, individual counselling with person-to-person contact, pro-active telephone counselling or group counselling) and estimated an odds ratio (OR) for successful cessation with individual counselling compared to no intervention of 1.7 (95% confidence interval (CI) 1.4 to 2.0) (Fiore 2008 Table 6.13). Individual counselling in their categorization would have also included counselling from a physician. When they separately analyse the effect of different providers of care the estimates suggest that non-physician clinicians (a category including psychologists, social workers and counsellors) are similarly effective compared to a no-provider reference group (OR 1.7, 95% CI 1.3 to 2.1) as physicians (OR 2.2, 95% CI 1.5 to 3.2) (Fiore 2008 Table 6.11).

In our review there was no evidence of significant heterogeneity between relative quit rates in the different trials. Absolute quit rates varied across studies but this is likely to be related to the motivation of the smokers to attempt to quit and the way in which cessation was defined. Cessation rates were generally higher in trials where nicotine replacement therapy (NRT) was also used (Alterman 2001; Jorenby 1995; Lifrak 1997 ; Simon 2003), although there were exceptions (Ahluwalia 2006 ; Aveyard 2007). Rates were also higher amongst patients with cardiovascular disease (Ockene 1992 ; Dornelas 2000 ; Pedersen 2005) . Quit rates tended to be lower in studies recruiting hospitalised patients unselected for their readiness to quit (Rigotti 1997 ; Stevens 1993; Molyneux 2003). All these features of a trial are likely to affect absolute quit rates, confounding a possible effect of the exact content of the intervention.

The following description of the intervention used in the Coronary Artery Smoking Intervention Study (CASIS) (Ockene 1992) is broadly typical of the interventions used: "The telephone and individual counseling sessions were based on a behavioral multicomponent approach in which counselors used a series of open-ended questions to assess motivation for cessation, areas of concern regarding smoking cessation, anticipated problems and possible solutions. Cognitive and behavioral self-management strategies, presented in the self help materials, were discussed and reinforced". Although we cannot exclude the possibility that small differences in components, and in the therapists' training or skills, have an effect on the outcome, it is not possible to detect such differences in the meta-analysis.

Most of the counselling interventions in this review included repeated contact, but differed according to whether face-to-face or telephone contact was used after an initial meeting. There are too few trials to draw conclusions from indirect comparisons about the relative efficacy of the various contact strategies. Again, the homogeneity of the results suggests that the way in which contact is maintained may not be important. A separate Cochrane review of telephone counselling suggests that telephone support aids quitting (Stead 2006).

The five trials that directly compared different intensities of individual support did not detect evidence of a dose-response effect. There was variation between the studies in absolute quit rates; 6% in both treatments groups in a Veterans Medical Centre (Weissfeld 1991), compared to 36% versus 28% (Lifrak 1997) and from 11% to 33% (Alterman 2001). In most of these studies the counselling was provided in addition to NRT. Although the relative difference is small, an absolute increase in long-term quit rates in the order of six percentage points, as seen in Lifrak 1997, would be a clinically

useful benefit if this size of effect was shown to be robust in other studies. In some of the trials in this comparison the difference between the counselling protocols may be too small to affect long-term quitting. The intended difference may also be eroded if the more intensive support cannot be consistently delivered.

There is now a marginally significant benefit of counselling versus control when provided in addition to NRT. The point estimate was smaller than for trials that did not use pharmacotherapy and it is possible that the relative additional benefit is smaller when the quit rates in the control group are already increased by the use of an effective pharmacotherapy. It is also possible that there is no true difference between this subgroup of trials and the others and that the smaller estimated effect is a chance finding. We did not prespecify a subgroup analysis based on use of pharmacotherapy, and it does not contribute to heterogeneity between the results. Average quit rates in both intervention and controls in this subgroup were higher than in the intervention and controls not receiving pharmacotherapy, and the absolute difference in quit rates was similar in the two subgroups. As already noted though, direct comparison of quit rates requires caution because of multiple differences between trials.

AUTHORS' CONCLUSIONS

Implications for practice

Counselling interventions given outside routine clinical care, by smoking cessation counsellors including health educators and psychologists, assist smokers to quit.

Implications for research

Individual counselling is an established treatment for smoking cessation. Identifying the most effective and cost-effective intensity and duration of treatment for different populations of smokers is still an area for research. However differences in relative effect are likely to be small, especially when counselling is used alongside pharmacotherapy. Small trials are unlikely to provide clear evidence of long-term efficacy.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Ahluwalia 2006

Methods	Setting: Community health centre, USA Recruitment: community volunteers interested in quitting
Participants	755 African American light smokers (<= 10 cpd) 67% female, av. age 45, av. cpd 8 Therapists: trained counsellors
Interventions	Factorial trial, 2mg nicotine gum/placebo arms collapsed for this review 1. Counselling using Motivational Interviewing (MI) approach. 3 in-person visits at randomization, wk1, wk8, and phone contact at wk3, wk6, wk16, S-H materials. 2. Counselling using Health education (HE) approach. Same schedule & materials as 1.
Outcomes	PP abstinence at 6m (7 day PP) Validation: cotinine <=20 ng/ml
Notes	New for 2008. Not in main analysis; compares two counselling styles. No significant effect of gum, no evidence of interaction.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Centrally generated blocked scheme, block size 36
Allocation concealment?	Yes	Sealed envelopes opened sequentially
Blinding? All outcomes	Unclear	Staff & participants blind to pharmacotherapy but not to type of counselling
Incomplete outcome data addressed? All outcomes	Yes	118 (15.6%) lost to follow-up included in ITT analysis. HE participants less likely to be lost. Alternative assumptions about losses did not alter conclusions. Low level of cotinine validation.

Aleixandre 1998

Methods	Setting: Primary care clinic, Spain Recruitment: clinic & community volunteers
Participants	48 smokers (excludes 6 dropouts) 65% female, av. age 36, av. cpd 24-27 Therapist: unclear, primary care clinic staff
Interventions	1. 'Advanced', 4 x30 min over 4 wks, video, cognitive therapy, social influences, relapse prevention 2. 'Minimal' 3 min advice immediately after randomization
Outcomes	Abstinence at 12m Validation: no biochemical validation
Notes	

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Stratified on cigarette consumption & age, block size 4.
Allocation concealment?	Unclear	No details given
Blinding? All outcomes	Unclear	Staff not blind, unclear for participants
Incomplete outcome data addressed? All outcomes	Yes	6 post-randomization dropouts excluded from ITT analyses. Their inclusion would marginally increase effect size.

Alterman 2001

Methods	Setting: cessation clinic, USA Recruitment: community volunteers
Participants	240 smokers of > 1 pack/day 45-54% female, av. age 40, av. cpd 27 Therapists: Nurse practitioners (NP) and trained counsellors
Interventions	All interventions included 8 wks nicotine patch (21 mg with weaning) 1. Low intensity. Single session with NP. 2. Moderate intensity. as 1 plus additional 3 sessions at wks 3,6,9 with NP. 3. High intensity. As 2. + 12 sessions cognitive behavioural therapy with trained therapist within 15 wks.
Outcomes	Abstinence at 1 yr Validation: urine cotinine < 50ng/ml, CO <= 9ppm

Alterman 2001 (*Continued*)

Notes	3 vs 2+1 in intensive versus minimal intervention, but sensitivity analysis. Quit rates significantly lower in 2 than 1 or 3	

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	'Urn technique'
Allocation concealment?	Unclear	No details given. Allocation took place after baseline session common to all conditions
Blinding? All outcomes	Unclear	Staff not blind, unclear for participants
Incomplete outcome data addressed? All outcomes	Yes	30 (12.5%) lost to follow up included in ITT analysis

Aveyard 2007

Methods	Setting: 26 general practices (primary care clinics), UK Recruitment: 92% volunteers in response to mailings
Participants	925 smokers 51% female, av. age 43, 50% smoked 11-20 cpd Therapists: Practice nurses trained to provide cessation support & manage NRT
Interventions	Both interventions included 8 wks 16mg nicotine patch 1. Basic support; 1 visit (20-40 mins) before quit attempt, phone call on TQD, visits/ phone calls at 7-14 days & at 21-28 days (10-20 mins) 2. Weekly support; as 1. plus additional call at 10 days & visits at 14 & 21 days
Outcomes	Abstinence at 12m (sustained at 1, 4, 12, 26 wks) Validation: CO <10ppm at treatment visits, saliva cotinine <15ng/ml at follow ups
Notes	New for 2008 update. Not in main analysis; compares higher and lower intensity counselling. Therapists were not full time specialist counsellors.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Random number generator
Allocation concealment?	Yes	Numbered sealed envelopes

Blinding? All outcomes	Unclear	Staff making follow-up calls were blind
Incomplete outcome data addressed? All outcomes	Yes	288 (31%) lost to follow up, similar across groups, included in ITT analysis

Bobo 1998

Methods	Setting: 12 residential centres for alcohol/drug treatment, USA Recruitment: inpatient volunteers
Participants	(50 participants in each of 12 sites) 67% male, av. age 33 50% smoked >1 pack/day Therapists: centre staff for 1st session, trained counsellors for telephone sessions
Interventions	1. 4 x10-15min sessions. 1st during inpatient stay. 3 by telephone, 8, 12, 16 wks post-discharge. 2. No intervention
Outcomes	Abstinence at 12m post discharge (7 day PP) Validation: saliva cotinine, but validated quit rates not reported (A primary outcome for the study was alcohol abstinence)
Notes	Cluster-randomized, so individual data not used in primary meta-analysis. Entered into a secondary analysis using inverse variance method, using adjusted OR 1.02 (CI 0.50 to 2.49)

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	No	Matched pairs of centres allocated by coin toss, 2 centres declined participation after allocation
Allocation concealment?	No	Cluster randomized with participant recruitment (by research team) after centre allocation so potential for selection bias
Blinding? All outcomes	Unclear	Staff not blind, unclear for participants
Incomplete outcome data addressed? All outcomes	Yes	22% lost to follow up. Including them as smokers made little difference to estimates

Bronson 1989

Methods	Setting: internal medicine practice, USA Recruitment: attenders for periodic health examinations
Participants	155 smokers 38%m , av. age 42, av. cpd 25 Therapist: smoking cessation counsellor
Interventions	1. Two 20 min counselling sessions during a periodic health examination (benefits of quitting, assessment of motivation, quit plan, high risk/problem solving) 2. Control (completed smoking behaviour questionnaire) Physicians carrying out health examinations were blind to group assignment and would have given similar advice to all participants.
Outcomes	Abstinence at 18m (sustained from 6-18m) Validation: no biochemical validation at 18m, limited sample for saliva cotinine at 6m
Notes	18m data reported in Secker-Walker 1990

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Blinding? All outcomes	Unclear	Physicians blind, counsellor not blind, participants probably blind,
Incomplete outcome data addressed? All outcomes	Yes	20 (13%) not contacted at 6 & 18m, included in ITT analysis.

Burling 1991

Methods	Setting: Inpatient substance abuse treatment centre, USA Recruitment: inpatient volunteers
Participants	39 male veteran inpatients Therapist: paraprofessional counsellor (Social Work Master's candidate)
Interventions	1. Smoking cessation programme; daily 15 min counselling session and computer-guided nicotine fading with contingency contract 2. Wait list control.
Outcomes	Abstinence 6m after discharge Validation - none - no self-reported quitters at 6m
Notes	

Burling 1991 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Blinding? All outcomes	Unclear	Staff not blind, participants unclear
Incomplete outcome data addressed? All outcomes	Unclear	Loss to follow up not reported

Burling 2001

Methods	Setting: Inpatient Veterans rehabilitation centre, USA Recruitment: inpatient volunteers
Participants	150 veteran drug- & alcohol-dependent smokers. 95%m, av. age 40, av. cpd 17 Therapists: Masters/Doctoral level counsellors
Interventions	All participants were receiving standard substance abuse treatment, smoking banned in building. 1. Multicomponent. 9 wk programme; 7 wk daily counselling, 2 wk biweekly. Target quit wk 5. Nicotine fading, contingency contracting, relapse prevention, coping skills practice. Nicotine patch (14 mg) 4 wks. 2. As 1, but skills generalized to drug & alcohol relapse prevention. 3. Usual care. Other programmes & NRT available
Outcomes	Abstinence at 12m (sustained at 1, 3, 6m follow ups) Continuous abstinence rates taken from graph & abstract. PP rates also reported Validation: CO & cotinine
Notes	1+2 vs 3 Using PP rates would give lower estimate of treatment effect. No significant difference between 1 &2, but favoured 1.

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

Burling 2001 (*Continued*)

Blinding? All outcomes	Unclear	Staff not blind, participants unclear
Incomplete outcome data addressed? All outcomes	Yes	12 (8%) lost to follow up included in ITT analysis

Dornelas 2000

Methods	Setting: Hospital inpatients, USA Recruitment: Acute MI patients (not selected for motivation to quit)
Participants	100 MI patients (98% smoked in previous wk) 23% female, aged 27-83, av cpd 29 Therapist: Psychologist
Interventions	1. 8 x20 min sessions, 1st during hospitalisation, 7 by phone (<1, 4, 8, 12, 20 & 26 wks post-discharge). Stage of change model, motivational interviewing, relapse prevention. 2. Minimal care. Recommended to watch online patient education video, referral to local resources.
Outcomes	Sustained abstinence at 1 yr (no smoking since discharge) Validation: household member confirmation for 70%. 1 discrepancy found
Notes	

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	'drawing random numbers from an envelope'
Allocation concealment?	Unclear	No details given
Blinding? All outcomes	Unclear	No information on blinding
Incomplete outcome data addressed? All outcomes	Yes	20 (20%) lost to follow up included in ITT analysis

Fiore 2004

Methods	Setting: Primary care patients, 16 clinics, USA Recruitment: Clinic attenders willing to accept treatment

Fiore 2004 (*Continued*)

Participants	961 smokers of >=10 cpd. (A further 908 were allowed to select treatment. Demographic details based on 1869) 58% female, av. age 40, av. cpd 22 Therapists: Trained cessation counsellors
Interventions	(Self-selected group of factorial trial not included in meta-analysis) 1. Nicotine patch, 22mg, 8 wks incl tapering. 2. As 1 plus Committed Quitters programme, single telephone session and tailored S-H. 3. As 2 plus individual counselling, 4 x 15-25 min sessions, pre-quit, ~TQD, next 2 wks
Outcomes	Continuous abstinence at 1 yr (no relapse lasting 7 days), also PP. Validation: CO, cut-off not specified. 2 discordant
Notes	3 versus 1&2 used in meta-analysis. More conservative than 3 versus 2.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Blinding? All outcomes	Unclear	No information on blinding
Incomplete outcome data addressed? All outcomes	Yes	Denominators in meta-analysis based on numbers who collected patches (85%, similar across arms).

Glasgow 2000

Methods	Setting: 4 Planned Parenthood clinics, USA Recruitment: Clinic attenders, unselected for motivation
Participants	1154 female smokers Av. age 24, av. cpd 12 Therapists: 4 hours training
Interventions	Both groups received 20 sec provider advice. 1. Video (9 min) targeted at young women. 12-15 min counselling session, personalized strategies, stage-targeted S-H materials. Offered telephone support call 2. Generic S-H materials
Outcomes	Abstinence at 6m (for 30 days) Validation: saliva cotinine <= 10ng/ml

Glasgow 2000 (*Continued*)

Notes	26% did not want telephone component, 31% of remainder not reached.	
Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Randomized, block size 4, fixed schedule
Allocation concealment?	Unclear	No details given
Blinding? All outcomes	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	10% loss to follow up included in ITT analysis

Hennrikus 2005

Methods	Setting: 4 hospitals, USA Recruitment: Newly admitted inpatients invited to participate, not selected by motivation
Participants	2095 current smokers 53% female, av. age 47, cpd NS, 15-20% precontemplators Therapists: research nurses with 12 hours training
Interventions	1. Control: modified usual care: smoking cessation booklet in hospital (not used in meta-analysis). 2. Brief advice (A): as control, plus labels in records to prompt advice from nurses and physicians. 3. Brief advice and counselling (A+C): As 2. plus 1 bedside (or phone) session using motivational interviewing and relapse prevention approaches and 3 to 6 calls (2-3 days, 1 wk, 2-3 wk, 1m, 6m)
Outcomes	Abstinence at 12m (7-day PP). Validation: saliva cotinine<15 ng/ml
Notes	New for 2008. Brief advice & counselling compared to Brief advice. Including Usual Care in control as well would marginally increase relative effect but not change conclusion of no effect.

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	'randomly ordered within blocks of 30 assignments'

Hennrikus 2005 (*Continued*)

Allocation concealment?	Unclear	Allocation by research assistant, concealment not described
Blinding? All outcomes	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	78 (3.7%) excluded from ITT analysis due to death or too ill for follow up. 426 (20%) lost to follow up included in ITT analysis; higher loss in treatment than control.

Jorenby 1995

Methods	Setting: clinical research centres, USA (2 sites) Recruitment: community volunteers
Participants	504 smokers >= 15 cpd av. age 44, av. cpd 26-29 Therapists: Trained smoking cessation counsellors
Interventions	Factorial trial; compared 22 mg/day vs 44 mg/day nicotine patch and 3 types of adjuvant treatment. All participants had 8 weekly assessments by research staff 1. Minimal - S-H materials from physician at screening visit for trial entry, instructed not to smoke whilst wearing patch. No further contact with counsellors. 2. Individual - S-H at screening visit + motivational message. Met nurse counsellor x3 after TQD. Counsellor helped generate problem-solving strategies and provided praise and encouragement. 3. Group - S-H + motivational message. 8x 1hr weekly group sessions. Skills training, problem-solving skills.
Outcomes	7 day PP abstinence at 26 wks Validation; CO < 10ppm.
Notes	No significant difference in dose-related outcome and no dose-counselling interaction at 26 wks reported, so patch arm collapsed in analysis. 2 vs 1, counselling vs NRT alone, Comparison with group counselling covered in Cochrane group therapy review.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomized, method not stated
Allocation concealment?	Unclear	'In a double blind manner' for NRT, but not specified for counselling

Jorenby 1995 (*Continued*)

Blinding? All outcomes	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	16.3% lost to follow up included in ITT analysis, no difference across conditions

Kim 2005

Methods	Setting: Outpatient clinic, South Korea Recruitment: outpatients, not selected on motivation
Participants	401 daily smokers, 65% willing to quit within 1m 92% m, av. age 52 Therapists: Retired nurses trained in cessation
Interventions	Test of 5As approach. All participants had first been Asked about smoking status & Advised to quit by physicians and told to go to onsite counsellors, who Assessed willingness to quit, and enrolled & randomized patients. 1. Intervention: Counsellors provided Assist and Arrange components to participants willing to quit within 1m; set quit date, provided Self-help materials, supplied cigarette substitute (~11 min average). Culturally specific for Koreans. Other participants given 4Rs. Follow-up calls at 1 wk & m (~7min). 2. Control: Counsellors told participants to quit without further assistance.
Outcomes	Abstinence at 5m Validation: CO<=7ppm
Notes	New for 2008 Marginal to include because 5m follow up and counselling was very brief

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Random list with block size of 6 and 12 allocation strata
Allocation concealment?	Yes	Assignments in sealed opaque envelopes
Blinding? All outcomes	Unclear	Outcome assessors were unaware of participants' group
Incomplete outcome data addressed? All outcomes	Yes	7 lost to follow up included in ITT analysis

Lifrak 1997

Methods	Setting: substance abuse outpatient facility, USA Recruitment: community volunteers
Participants	69 smokers av. age 39, av. cpd 25 Therapists: nurse practitioner for 1. and 2, clinical social worker or psychiatrist experienced in addiction treatment for 2.
Interventions	Both interventions included use of nicotine patch (24 hr, 10 wks tapered dose) 1. Moderate intensity - 4 meetings with nurse who reviewed S-H materials and instructed in patch use. 2. High intensity. As 1 plus 16 weekly 45 min cognitive behavioural relapse-prevention therapy
Outcomes	Abstinence at 12m, 1 wk PP Validation: urine cotinine for some participants, but no corrections made for misreporting.
Notes	Both interventions regarded as counselling, used in comparison of intensity.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Block randomization (block size 10)
Allocation concealment?	Unclear	No details given
Blinding? All outcomes	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	12 administrative drop-outs/exclusions not included, treatment group not specified. All others included.

McCarthy 2008

Methods	Setting: clinic, USA Recruitment: community volunteers
Participants	463 smokers 50% female, av. age 36-41 across arms, av.cpd 22 Therapists: trained college-aged or bachelor's level staff, supervised by experienced counsellor
Interventions	Factorial trial. Bupropion/placebo pharmacotherapy arms collapsed. 1. Counselling; 8 x10min session, 2 prequit, TQD, 5 over 4 wks 2. Psychoeducation about medication, support & encouragement. Same no. of sessions,

McCarthy 2008 (*Continued*)

	80mins less contact time	
Outcomes	7 day PP abstinence at 12m Validation: CO ≤10ppm	
Notes	New for 2008	
Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Random number table
Allocation concealment?	Yes	Staff who screened and enrolled participants were unaware of the experimental condition to be assigned
Blinding? All outcomes	Unclear	Staff and participants blind to medication but not counselling
Incomplete outcome data addressed? All outcomes	Yes	171 (37%) failed to attend quit date visit or lost to follow up, included in ITT analysis

Molyneux 2003

Methods	Setting: hospital, UK Recruitment: hospital inpatients	
Participants	274 smokers (183 in relevant arms) admitted to medical and surgical wards, smoked in last 28 days 60% m, av age 60, median cpd 17, 81% had previous quit attempt Therapists: research doctor or nurse trained in cessation counselling	
Interventions	1. Usual Care, no smoking advice 2. Brief (20 min) bedside counselling + advice leaflet + advice on NRT 3. As 2 plus choice of NRT product (not relevant to this review)	
Outcomes	Continuous abstinence at 12m Validation: CO < 10ppm	
Notes		
Risk of bias		
Item	**Authors' judgement**	**Description**

Molyneux 2003 (*Continued*)

Adequate sequence generation?	Yes	'List generated for each centre allocating equally in random permuted blocks of nine.'
Allocation concealment?	Unclear	No details given
Blinding? All outcomes	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	72 (39%) lost to follow up included in ITT analysis

Nakamura 2004

Methods	Setting: communities & worksites, Japan Recruitment: Smokers with hypertension and/or hypercholesterolemia having health check-ups
Participants	977 smokers 98% m, av. age 45, av. cpd 25, ~20% in preparation/ contemplation Therapists: mostly public health nurses
Interventions	Intervention: Stage-base counselling, 1 x40 min, 4 x20-30 min at 1,2,4,6m. + Phone call if TQD set Control: Matched contact intervention for hypertension (161) or hypercholesterolemia (318)
Outcomes	Abstinence at 6m, sustained 4 point prevalence at 1,2,4,6m Validation: CO≤8ppm
Notes	New for 2008. Recruited a largely unmotivated population

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Method not stated
Allocation concealment?	Unclear	No information given
Blinding? All outcomes	Unclear	No information given
Incomplete outcome data addressed? All outcomes	Yes	54 (5.5%) lost to follow up included in ITT analysis

Ockene 1992

Methods	Setting: cardiac catheterization labs at 3 hospitals, USA Recruitment: inpatient smokers or recent quitters with coronary artery stenosis, following arteriography
Participants	267 smokers (256 surviving at 12m follow up) av. age 53, av. cpd 25 Therapists: Masters level health educators
Interventions	1. Minimal intervention - 10 min advice and review of an information sheet 2. Inpatient counselling session, 30 min, outpatient visits and telephone calls. Opportunity to attend group programme
Outcomes	Abstinence at 12m (sustained for 6m) Validation: saliva cotinine < 20ng/ml
Notes	Average length of contact for intervention was 1.22 hr (20min to > 5hr)

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Method not stated
Allocation concealment?	Unclear	No details given
Blinding? All outcomes	Unclear	Physicians unaware of intervention condition, therapists blinded, participants unclear
Incomplete outcome data addressed? All outcomes	Yes	No mention of losses to follow up and all survivors included in denominators.

Pedersen 2005

Methods	Setting: hospital, Denmark Recruitment: Inpatients with cardiac disease
Participants	105 smokers 36% female, ~70% aged >50 Therapists: counsellors
Interventions	1. Usual care control: in hospital advice to quit + information about NRT + NRT available. 2. Intervention: As 1. plus 5 x30 min post discharge contacts
Outcomes	Abstinence at 12 months (point prevalence) Validation: none

Pedersen 2005 (*Continued*)

Notes	New for 2008	
Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	Sealed envelopes, but not stated to be numbered
Blinding? All outcomes	Unclear	No information
Incomplete outcome data addressed? All outcomes	Yes	10 (9.5%) lost to follow up, included in ITT analysis

Pederson 1991

Methods	Setting: Chest unit, USA Recruitment: Inpatients with COPD	
Participants	74 cigarette smokers av. age 53, 75% smoked 20+ cpd Therapist: Non-specialist trained in counselling	
Interventions	1. Advice to quit 2. Individual counselling; between 3 & 8 15-20 min sessions on alternate days during hospitalisations. S-H manual, support & encouragement.	
Outcomes	Abstinence at 6m Sample validated by COHb	
Notes		
Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Method not described
Allocation concealment?	Unclear	No details given
Blinding? All outcomes	Unclear	Physicians blinded, therapist not blinded, participants unclear

Pederson 1991 (*Continued*)

Incomplete outcome data addressed? All outcomes	Yes	8 lost to follow up were reincluded in ITT analysis by reviewers. 8 deaths excluded

Rigotti 1997

Methods	Setting: hospital, USA Recruitment: Inpatients in medical or surgical services, smoking > 1 cig in month before admission
Participants	615 smokers or recent quitters (excluding 35 deaths). 37% of intervention and 32% of controls had a current smoking-related health problem. Therapist: research assistant supervised by a nurse
Interventions	1. Usual care 2. Single bedside counselling session (motivational interviewing, cognitive behavioural and relapse prevention techniques), av 15 min, S-H materials, chart prompts, 1-3 telephone calls post-discharge
Outcomes	Abstinence at 6m (PP, sustained abstinence reported based on self report) Validation: saliva cotinine for people living in Mass (85% of quitters)
Notes	Use of validated PP rather than sustained abstinence gives more conservative treatment effect

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Each day's list of eligible smokers put in random order and patients recruited consecutively in this order. Randomized by research assistant
Allocation concealment?	Unclear	No details given
Blinding? All outcomes	Unclear	Outcome was assessed by blinded interviewer.
Incomplete outcome data addressed? All outcomes	Yes	73 (22.4%) lost to follow up included in ITT analysis, no evidence of differential loss. 35 (5.4%) deaths excluded.

Schmitz 1999

Methods	Setting: hospital, USA Recruitment: women with or at risk of Coronary Artery disease (CAD)
Participants	Two separate samples recruited: 53 inpatients with CAD who stopped smoking during hospitalisation and wanted to stay quit. 107 women volunteering for cessation treatment who had > 1 CAD risk factor Therapists: 2 smoking counsellors + 2 clinical psychology interns
Interventions	1. Coping skills, relapse prevention, 6 x1 hr including stress management, homework. 2. Health Belief model, 6 x1 hr. smoking-related health information about disease state or CAD profile. Focus on benefits of stopping
Outcomes	Abstinence at 6m (PP) Validation: CO < 9ppm, urine cotinine < 10ng/ml Not all quitters tested, confirmation rates not reported
Notes	Post-randomization drop-outs who did not complete baseline and begin treatment were not included in any data. Quit rates were lower in the CAD sample than in the at-risk group

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	'Randomly assigned', stratified on smoking rate and myocardial infarction status
Allocation concealment?	Unclear	No details given
Blinding? All outcomes	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Pretreatment drop outs were excluded, all others included in ITT analysis

Simon 1997

Methods	Setting: Veterans Administration hospital, USA Recruitment: smokers undergoing non-cardiac surgery
Participants	299 smokers (smoked within 2 wks of admission) (excl 25 deaths) 98% m, av. age 54, av. cpd 20 Therapist: public health educator
Interventions	1. Multicomponent: single counselling session (30-60 min) prior to discharge (based on social learning theory and stages of change). Video, prescription for nicotine gum if no contraindications. 5 follow-up counselling calls over 3m

Simon 1997 (*Continued*)

	2. Brief counselling (10 min) and S-H materials.
Outcomes	Abstinence at 12m Validation: serum or saliva cotinine < 15ng/ml. 6 self reports confirmed only by 'significant other'.
Notes	65% of Group 1 and 17% of Group 2 reported using NRT, but use of NRT was not significantly associated with quitting in either group

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	'Random list of assignments'
Allocation concealment?	Yes	'Sealed opaque envelopes opened on formal enrollment'
Blinding? All outcomes	Unclear	Therapists could not have been blind. No information on patients
Incomplete outcome data addressed? All outcomes	Yes	25 (8%) lost to follow up included in ITT analysis, 25 (8%) died, excluded from denominator

Simon 2003

Methods	Setting: Veterans Affairs hospital, USA Recruitment: hospitalised smokers in contemplation or preparation stage of change
Participants	209 smokers, >= 20 cigs in total in week before hospitalisation, excludes 14 deaths during follow up 97% m, av. age 55, av cpd 23 Therapists: trained nurse or public health educator
Interventions	1. Intensive counselling: single counselling session (30-60 min) prior to discharge (based on social learning theory and stages of change), 5 telephone counselling calls < 30 min, 1 & 3 wks, monthly for 3m + S-H. Recycling encouraged. Nicotine patches begun in hospital, dose based on pre-hospitalisation smoking rates. 2m supply at discharge. 2. Nicotine patches as 1. ~10 min session on risks & benefits, S-H.
Outcomes	Abstinence at 12m (7 day PP) Validation: saliva cotinine < 15ng/ml
Notes	

Risk of bias

Simon 2003 (*Continued*)

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	'Randomly assigned using computerized algorithm'
Allocation concealment?	Unclear	No details provided
Blinding? All outcomes	Unclear	No details provided; there was an active control
Incomplete outcome data addressed? All outcomes	Yes	7 (3%) lost to follow up included in ITT analysis, 14 (6%) died & excluded from denominator

Stevens 1993

Methods	Setting: 2 Health Maintenance Organization hospitals, USA Recruitment: All hospitalised smokers or recent ex-smokers with stay > 36hrs
Participants	1119 smokers or recent quitters (5%) av. age 44, av. cpd 20 Therapists: Masters level cessation counsellors
Interventions	1. 20 min counselling session, 12 min video, quit kit, choice of S-H materials, 1-2 follow-up telephone calls, access to hotline, bimonthly newsletter mailings. 2. Usual care
Outcomes	Abstinence at 12m (2 PP, 3 & 12m) Validation: due to low success in obtaining samples for cotinine analysis, data are based on self report only.
Notes	A sensitivity analysis on the effect of exclusion of this non-random study is reported.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	No	Not random, intervention alternated between hospitals on a monthly basis in order to avoid contamination
Allocation concealment?	No	Intervention or control status of hospital known when patients recruited
Blinding? All outcomes	Unclear	Patients in control arm were not identified to hospital staff, and were probably unaware of study design. Telephone assessments were by blinded assessors

Incomplete outcome data addressed? All outcomes	Yes	6% loss to follow up, no difference by group, included in ITT analysis

Tonnesen 2006

Methods	Setting: 7 chest clinics, Denmark Recruitment: outpatient attender
Participants	370 smokers of >1 cpd with COPD 52% female, av. age 61, av. cpd 20 Therapists: 20 nurses with cessation experience, trained to support medication use and provide standardised counselling
Interventions	Factorial trial. Nicotine sublingual tablet and placebo arms collapsed in meta-analysis 1. High support: 7 x 20-30min clinic visits (0, 2, 4, 8, 12 wks, 6m, 12m) & 5 x 10min phone calls (1, 6, 10 wks , 4½m. 9m), total contact time 4½ hrs. 2. Low support: 4 clinic visits (0, 2 wks, 6m, 12m) & 6 phone calls (1, 4, 6, 9, 12 wks, 9m), total time 2½ hrs
Outcomes	Sustained abstinence at 12m (validated at all visits from wk 2, PP also reported) Validation: CO<10ppm
Notes	New for 2008 update. Compares higher and lower intensity counselling. Therapists were not full time specialist counsellors.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Block randomization list at each centre
Allocation concealment?	Unclear	Allocation process not described
Blinding? All outcomes	Unclear	Described as double blind, but unclear that this applied to behavioural components
Incomplete outcome data addressed? All outcomes	Yes	82 (22%) lost to follow up, included in ITT analysis

Weissfeld 1991

Methods	Setting: Veterans Administration outpatient clinics, USA Recruitment: veterans attending walk-in and general medicine clinics invited to attend quit smoking programme Randomization: Two stages; initially in 1:2 to control or intervention, then 1:1 to high or low intensity occurred after delivery of low intensity session.
Participants	466 male smokers av. age 55 years, av. cpd 26 Therapists: smoking cessation counsellors
Interventions	1. Control - pamphlet on hazards of smoking 2. Low Intensity counselling - single session 20-30 min and S-H booklet 3. High intensity counselling - same initial session, with sustained contact of 3m. One further face-to-face session, telephone calls and mailings, behavioural S-H manual. Prescription and sample of nicotine gum and instructions for use.
Outcomes	Abstinence for 1m at 6m (9m for high intensity group, 6m after last contact) Validation: nicotine metabolites in urine
Notes	Using validated quit rates there was no difference between 2 and 3, although self-reported quitting was greater in 3. Main analysis uses 2&3 vs 1 with sensitivity analysis of 2 vs 1. Comparison of intensity uses 3 vs 2 39% of group 3 used nicotine gum vs 8% and 7% in 2 and 1

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Random number table
Allocation concealment?	Yes	Consecutively numbered envelopes containing treatment assignment.
Blinding? All outcomes	Unclear	Therapists not blind, unclear whether participants were
Incomplete outcome data addressed? All outcomes	Yes	34 (7.3%) died or lost to follow up included in ITT analysis. More lost in high intensity group.

Wiggers 2006

Methods	Setting: Cardiovascular outpatient department, Netherlands Recruitment: patients attending regular consultation; consenting patients referred to nurse practitioner.
Participants	385 smokers (8 deaths excluded from outcomes) 37% female, av. age 59, av.cpd 21 Therapist: nurse practitioner
Interventions	In both groups, patients planning to quit received 8 wks nicotine patch with instruction from nurse. 1. 'Minimal Intervention Strategy for cardiology patients (C-MIS). 15-30 mins at baseline, 1 phone call at 2 wks, additional session on request. Assessment of dependency & motivation, barriers; TQD set for motivated patients 2. Usual care without motivational counselling.
Outcomes	Abstinence for 7 days at 12m Validation: Urine or saliva nicotine/cotinine/thiocyanate. Self-reported smokers also tested; validated rates include smokers with negative biochemical results, so self-reported non-smoking used in MA
Notes	New for 2008. Included on grounds that participants were referred to nurse practitioner for counselling; not part of usual care.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	'A computerized balanced randomization programme taking prognostic factors (e.g. clinic attendance, age and gender) into account.'
Allocation concealment?	Yes	'While patients completed their baseline questionnaire (and signed a written informed consent) nurses randomly assigned ...'
Blinding? All outcomes	Unclear	'Patients were not informed about the behavioural intervention [before enrollment] in order to avoid a Hawthorne effect'. Follow up was blind to allocation.
Incomplete outcome data addressed? All outcomes	Yes	One withdrawal due to cognitive problems and 8 deaths during follow up not included in analyses. At 12m 45 not reached by mail or phone, included in ITT. More unmarried patients lost.

Windsor 1988

Methods	Setting: University worksite, USA Recruitment: Employees volunteering for a quit smoking programme
Participants	378 smokers av. age 37, av. cpd 23-27 Therapist: health educator
Interventions	All groups received a 10 min session of brief advice 1. + S-H manuals 2. + S-H and another session of counselling (20-30 min) with skills training, buddy selection and a contract. 3. as 1. with monetary rewards for cessation 4. as 2. with monetary rewards for cessation
Outcomes	Abstinence at 1 yr (sustained at 6 wks, 6m, 1yr, no more than 2 cigs in period) Validation: saliva thiocyanate < 100μg/ml at all follow ups.
Notes	There was no apparent effect of monetary incentives so this arm is collapsed. 4&2 vs 3& 1. Number of quitters estimated from graphs

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Computer-generated assignment
Allocation concealment?	Yes	Sealed numbered envelopes opened after informed consent & baseline questionnaire
Blinding? All outcomes	Unclear	Therapists could not be blind, unlikely that participants were
Incomplete outcome data addressed? All outcomes	Yes	37 lost to f-up, included in ITT analysis

av - average (mean)
CI - confidence interval
CO - carbon monoxide
COHb - carboxyhaemoglobin
COPD - chronic obstructive pulmonary disease
cpd - cigarettes per day
m - month
MA - meta-analysis
MI - myocardial infarction
min - minute
NRT - Nicotine Replacement Therapy
OR - odds ratio
PP - point prevalence (abstinent at defined period)

ppm - parts per million
S-H - Self help materials
TQD - Target Quit Date
wk - week
yr - year

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

Study	Reason for exclusion
Alonso-Pérez 2007	Allocation to behavioural treatment was by clinic attended; each of 3 primary care clinics provided different treatment.
Bolman 2002	Intervention provided by a nurse as part of usual care, included in Cochrane review of nursing interventions (Rice 2008).
Borrelli 2005	Intervention provided by a nurse during normal duties, included in Cochrane review of nursing interventions (Rice 2008).
Camarelles 2002	Compares Individual to group counselling, see Cochrane review of group based interventions (Stead 2005).
Canga 2000	Intervention provided by a nurse, included in Cochrane review of nursing interventions (Rice 2008).
Colby 1998	Short follow up (three months).
Emmons 2001	Data not available for intervention and control groups separately. No significant difference reported. Cessation was a secondary outcome in this trial using motivational interviewing to reduce passive smoke exposure. Participants were not selected by motivation to quit.
Froelicher 2004	Intervention provided by a nurse; included in Cochrane review of nursing interventions (Rice 2008)
Gifford 2004	Trial of an acceptance & commitment-based treatment intervention that included multiple group sessions in addition to individual counselling. Comparator was nicotine patch therapy.
Hilberink 2005	Intervention provided by physicians & nurses in usual care setting, not specialist counselling.
Hyman 2007	Multiple risk factor intervention.
Kadowaki 2000	Intervention was multicomponent and included advice/counselling from a physician, nurse and a group programme. Follow up only 5 months.
Lando 1992	There was no face-to-face contact with counsellors. Contact was by pro-active telephone calls.
Lopez 2007	Multiple risk factor intervention enrolling smokers and nonsmokers.
Malchodi 2003	Intervention specifically for pregnant women, see Cochrane review of smoking cessation interventions in pregnancy (Lumley 2004)

(*Continued*)

Marks 2002	Intervention was provided in a self-help format.
Mildestvedt 2007	Multiple risk lifestyle intervention.
Mooney 2007	Short follow up (6 wks). Study added a pharmacotherapy compliance enhancing component to individual counselling using CBT.
Niaura 1999	All participants received individual counselling; Included in Cochrane NRT review (Stead 2008b).
Okuyemi 2006	Intervention combined group and individual counselling with pharmacotherapy.
Rabkin 1984	The health education arm of the trial included a group meeting with didactic lecture, film and discussion, followed by a single individual session with a therapist. We decided that this did not meet the criteria for individual counselling.
Rodriguez 2003	Intervention combined the systematic use of NRT with counselling; covered in Cochrane review of worksite interventions (Cahill 2008)
Sanz-Pozo 2006	Intervention provided by nurses in a primary care clinic, included in Cochrane review of nursing interventions (Rice 2008)
Schnoll 2005	Short follow up (three months). Compared 2 counselling approaches, no difference detected.
Schwartz 1967	Success was defined as reduction in smoking of over 85%, not complete abstinence.
Sherman 2007	Primary outcome was not cessation; assessed rates of receiving counselling, referral and treatment.
Soria 2006	Motivational interviewing intervention by primary care physician during routine care
Stein 2006	Test of motivational interviewing; not all partipants attempted to quit
Stevens 2000	Intervention providers were respiratory therapists not counsellors. Included in Cochrane review of interventions in hospital inpatients, (Rigotti 2007).
Williams 2006	Study targeted multiple risk factors.
Woodruff 2002	Short follow up (three months).

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

Niaura 2004

Trial name or title	Positive Paths
Methods	RCT
Participants	HIV+ smokers
Interventions	Brief intervention modeled on PHS guidelines versus a more intensive motivational counselling intervention, with both interventions providing 8 weeks of NRT to those setting a quit date.
Outcomes	Smoking cessation
Starting date	Completed
Contact information	Ray Niaura
Notes	NCT00551720

DATA AND ANALYSES

Comparison 1. Individual counselling compared to minimal contact control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Smoking cessation at longest follow-up	22	9587	Risk Ratio (M-H, Fixed, 95% CI)	1.39 [1.24, 1.57]
1.1 Counselling versus control (no systematic pharmacotherapy)	18	7855	Risk Ratio (M-H, Fixed, 95% CI)	1.44 [1.25, 1.65]
1.2 Counselling plus NRT versus NRT alone	4	1732	Risk Ratio (M-H, Fixed, 95% CI)	1.27 [1.02, 1.59]

Comparison 2. More intensive versus less intensive counselling

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Smoking cessation at longest follow-up	5	1897	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.74, 1.25]
1.1 No pharmacotherapy	2	478	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.53, 2.22]
1.2 Adjunct to pharmacotherapy	4	1419	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.71, 1.25]
2 Sensitivity analyses for Alterman 2001 in intensive versus brief counselling comparison	5		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 Using Alterman high versus low	5	1817	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [0.81, 1.37]
2.2 Using Alterman high versus moderate	5	1817	Risk Ratio (M-H, Fixed, 95% CI)	1.20 [0.91, 1.58]

Comparison 3. Comparisons between counselling approaches of similar intensity

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Smoking cessation at longest follow-up	3		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Relapse Prevention versus Health Belief model	1	160	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.45, 1.98]
1.2 Motivational Interviewing versus Health Education	1	755	Risk Ratio (M-H, Fixed, 95% CI)	0.51 [0.34, 0.76]

1.3 Counselling versus equal sessions of psychoeducation	1	463	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.62, 1.39]

Analysis 1.1. Comparison 1 Individual counselling compared to minimal contact control, Outcome 1 Smoking cessation at longest follow-up.

Review: Individual behavioural counselling for smoking cessation

Comparison: 1 Individual counselling compared to minimal contact control

Outcome: 1 Smoking cessation at longest follow-up

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 Counselling versus control (no systematic pharmacotherapy)				
Windsor 1988	27/188	11/190		2.48 [1.27, 4.85]
Bronson 1989	5/77	6/78		0.84 [0.27, 2.65]
Weissfeld 1991	18/293	2/173		5.31 [1.25, 22.63]
Burling 1991	0/20	0/19		0.0 [0.0, 0.0]
Pederson 1991	10/35	6/31		1.48 [0.61, 3.59]
Ockene 1992	44/133	28/123		1.45 [0.97, 2.18]
Stevens 1993	61/453	61/666		1.47 [1.05, 2.05]
Simon 1997	20/157	9/142		2.01 [0.95, 4.27]
Rigotti 1997	25/307	27/308		0.93 [0.55, 1.56]
Aleixandre 1998	6/27	3/21		1.56 [0.44, 5.50]
Dornelas 2000	23/54	12/46		1.63 [0.92, 2.91]
Glasgow 2000	37/578	22/576		1.68 [1.00, 2.80]
Burling 2001	11/100	1/50		5.50 [0.73, 41.41]
Molyneux 2003	4/91	7/92		0.58 [0.18, 1.91]
Nakamura 2004	18/500	4/477		4.29 [1.46, 12.59]
Pedersen 2005	28/54	20/51		1.32 [0.86, 2.03]
Hennrikus 2005	66/666	68/678		0.99 [0.72, 1.36]
Kim 2005	28/200	18/201		1.56 [0.89, 2.73]
Subtotal (95% CI)	**3933**	**3922**		**1.44 [1.25, 1.65]**
Total events: 431 (Treatment), 305 (Control)				
Heterogeneity: Chi^2 = 23.91, df = 16 (P = 0.09); I^2 =33%				
Test for overall effect: Z = 5.20 (P < 0.00001)				

(*Continued . . .*)

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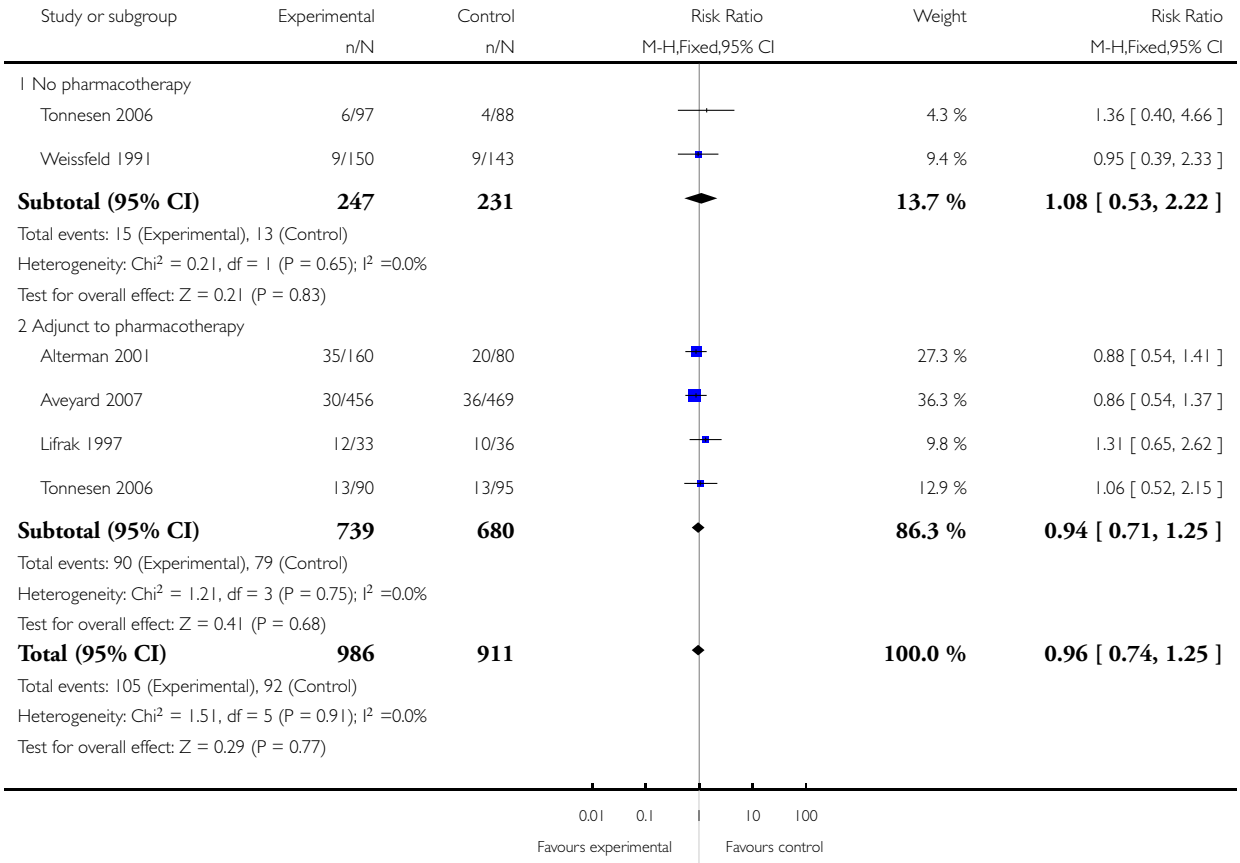
Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
2 Counselling plus NRT versus NRT alone				
Fiore 2004	29/274	47/536		1.21 [0.78, 1.87]
Jorenby 1995	53/168	44/169		1.21 [0.86, 1.70]
Simon 2003	16/102	10/107		1.68 [0.80, 3.53]
Wiggers 2006	35/188	27/188		1.30 [0.82, 2.05]
Subtotal (95% CI)	**732**	**1000**		**1.27 [1.02, 1.59]**
Total events: 133 (Treatment), 128 (Control)				
Heterogeneity: Chi^2 = 0.68, df = 3 (P = 0.88); I^2 =0.0%				
Test for overall effect: Z = 2.12 (P = 0.034)				
Total (95% CI)	**4665**	**4922**		**1.39 [1.24, 1.57]**
Total events: 564 (Treatment), 433 (Control)				
Heterogeneity: Chi^2 = 25.15, df = 20 (P = 0.20); I^2 =20%				
Test for overall effect: Z = 5.57 (P < 0.00001)				

Analysis 2.1. Comparison 2 More intensive versus less intensive counselling, Outcome 1 Smoking cessation at longest follow-up.

Review: Individual behavioural counselling for smoking cessation

Comparison: 2 More intensive versus less intensive counselling

Outcome: 1 Smoking cessation at longest follow-up

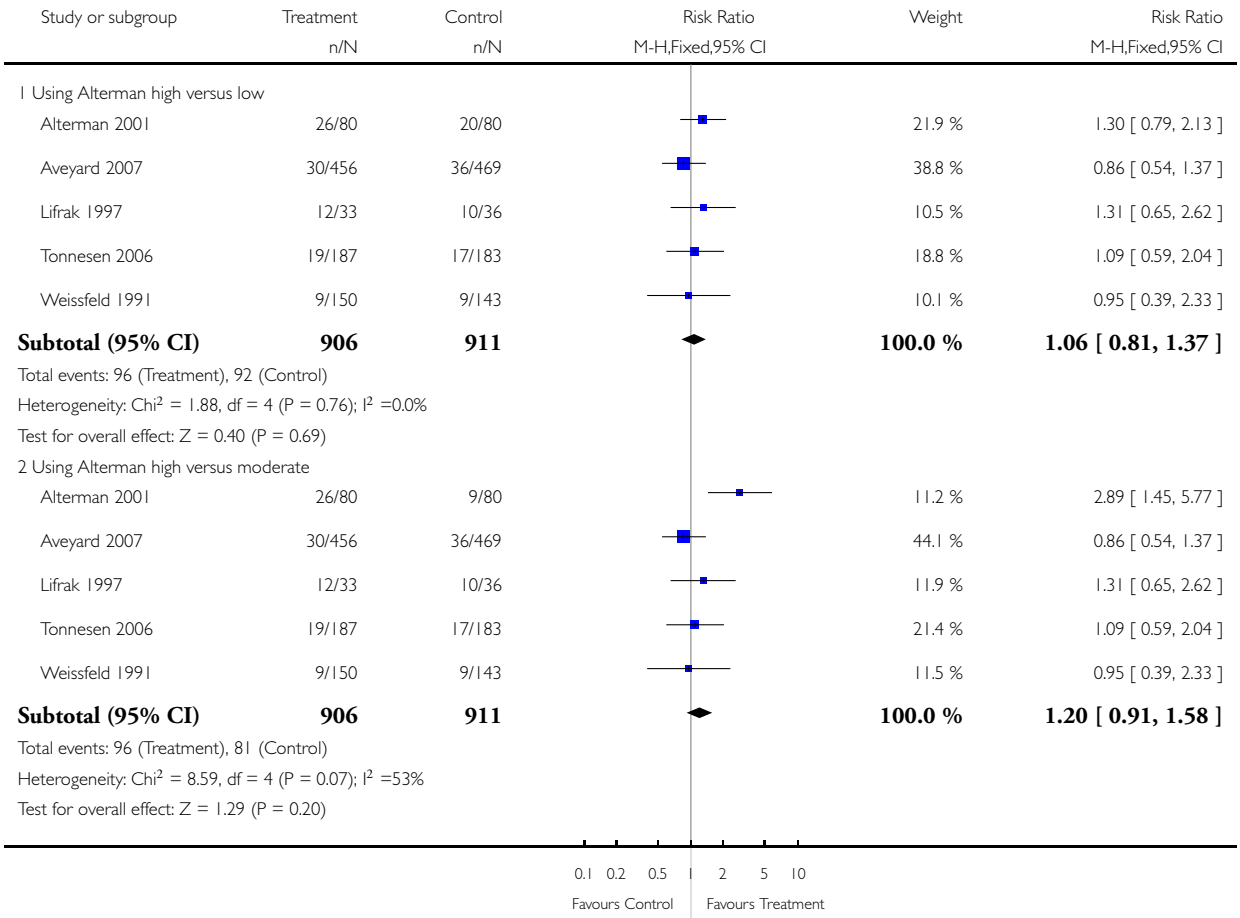


Analysis 2.2. Comparison 2 More intensive versus less intensive counselling, Outcome 2 Sensitivity analyses for Alterman 2001 in intensive versus brief counselling comparison.

Review: Individual behavioural counselling for smoking cessation

Comparison: 2 More intensive versus less intensive counselling

Outcome: 2 Sensitivity analyses for Alterman 2001 in intensive versus brief counselling comparison

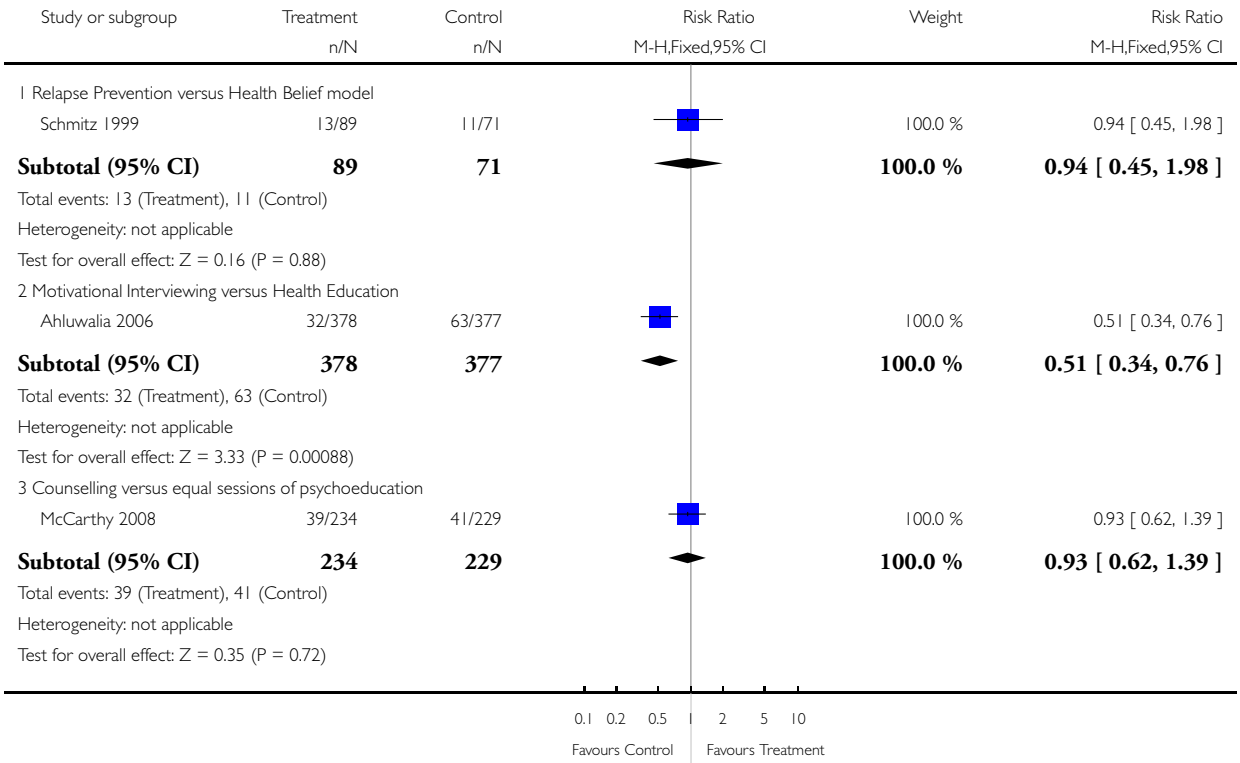


Analysis 3.1. Comparison 3 Comparisons between counselling approaches of similar intensity, Outcome 1 Smoking cessation at longest follow-up.

Review: Individual behavioural counselling for smoking cessation

Comparison: 3 Comparisons between counselling approaches of similar intensity

Outcome: 1 Smoking cessation at longest follow-up



WHAT'S NEW

Last assessed as up-to-date: 14 July 2008.

Date	Event	Description
16 July 2008	New search has been performed	Updated for 2008 issue 4 with nine new studies. No changes to conclusions
21 May 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 4, 1998

Review first published: Issue 2, 1999

Date	Event	Description
8 February 2005	New citation required but conclusions have not changed	Updated for 2005 Issue 2 with three new studies. No changes to conclusions.
7 April 2002	New citation required but conclusions have not changed	Updated for 2002 Issue 3 with six new studies. No changes to conclusions.

CONTRIBUTIONS OF AUTHORS

TL and LS jointly conceived the review, developed the protocol, extracted data, wrote the text and are guarantors. LS conducted the searches and preliminary screening of studies.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- Oxford University Department of Primary Health Care, UK.
- National Institute for Health Research School for Primary Care Research, UK.

External sources

- NHS Research and Development Programme, UK.

INDEX TERMS

Medical Subject Headings (MeSH)

*Behavior Therapy; *Counseling; Psychotherapy, Group; Randomized Controlled Trials as Topic; Smoking [*prevention & control]; Smoking Cessation [*methods]

MeSH check words

Humans