Cochrane Library

Cochrane Database of Systematic Reviews

Individual behavioural counselling for smoking cessation (Review)

Lancaster T, Stead LF

Lancaster T, Stead LF.
Individual behavioural counselling for smoking cessation.
Cochrane Database of Systematic Reviews 2017, Issue 3. Art. No.: CD001292.
DOI: 10.1002/14651858.CD001292.pub3.

www.cochranelibrary.com

WILEY

TABLE OF CONTENTS

[Intervention Review]

Individual behavioural counselling for smoking cessation

Tim Lancaster[1], Lindsay F Stead[2]

[1]GKT School of Medical Education, King's College London, London, UK. [2]Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, UK

Contact address: Tim Lancaster, GKT School of Medical Education, King's College London, London, UK. tim.lancaster@kcl.ac.uk.

Editorial group: Cochrane Tobacco Addiction Group.
Publication status and date: Edited (no change to conclusions), published in Issue 3, 2018.

Citation: Lancaster T, Stead LF. Individual behavioural counselling for smoking cessation. *Cochrane Database of Systematic Reviews* 2017, Issue 3. Art. No.: CD001292. DOI: 10.1002/14651858.CD001292.pub3.

ABSTRACT

Background

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

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.

Search methods

We searched the Cochrane Tobacco Addiction Group Specialized Register for studies with counsel* in any field in May 2016.

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 in duplicate. We recorded characteristics of the intervention and the target population, method of randomization and completeness of follow-up. We used the most rigorous definition of abstinence in each trial, and biochemically-validated rates where available. In analysis, we assumed that participants lost to follow-up continued to smoke. We expressed effects as a risk ratio (RR) for cessation. Where possible, we performed meta-analysis using a fixed-effect (Mantel-Haenszel) model. We assessed the quality of evidence within each study using the Cochrane 'Risk of bias' tool and the GRADE approach.

Main results

We identified 49 trials with around 19,000 participants. Thirty-three trials compared individual counselling to a minimal behavioural intervention. There was high-quality evidence that individual counselling was more effective than a minimal contact control (brief advice, usual care, or provision of self-help materials) when pharmacotherapy was not offered to any participants (RR 1.57, 95% confidence interval (CI) 1.40 to 1.77; 27 studies, 11,100 participants; I^2 = 50%). There was moderate-quality evidence (downgraded due to imprecision) of a benefit of counselling when all participants received pharmacotherapy (nicotine replacement therapy) (RR 1.24, 95% CI 1.01 to 1.51; 6 studies, 2662 participants; I^2 = 0%). There was moderate-quality evidence (downgraded due to imprecision) for a small benefit of more

intensive counselling compared to brief counselling (RR 1.29, 95% CI 1.09 to 1.53; 11 studies, 2920 participants; I^2 = 48%). None of the five other trials that compared different counselling models of similar intensity detected significant differences.

Authors' conclusions

There is high-quality evidence that individually-delivered smoking cessation counselling can assist smokers to quit. There is moderate-quality evidence of a smaller relative benefit when counselling is used in addition to pharmacotherapy, and of more intensive counselling compared to a brief counselling intervention.

PLAIN LANGUAGE SUMMARY

Does individually-delivered counselling help people to stop smoking?

Background

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. The outcome was being a non smoker at least six months later.

Study characteristics

We searched for trials in May 2016 and identified 49 trials Inlcuding around 19,000 participants. All the trials involved one or more face-to-face counselling sessions lasting at least 10 minutes, but most were much longer. Many also included further telephone contact for additional support. Thirty-three of the trials compared individual counselling to a control group that only had minimal support, which could be usual care, brief advice about stopping smoking, or written materials. Of these, 27 did not offer any medication such as nicotine replacement therapy (NRT), which also helps people stop. Six of the 33 provided NRT or other medication to everyone in the trial. Twelve studies compared more intensive to less intensive counselling, and five compared different types of counselling.

Results and quality of evidence

Combining the results of the studies showed that having individual counselling could increase the chance of quitting by between 40% and 80%, compared to minimal support. This means that if seven out of 100 smokers managed to quit for at least six months using the sort of brief support given to the control groups, then between 10 and 12 in 100 would be expected to be successful after having counselling. We judged the quality of this evidence to be high. If everyone also had NRT or other medication, and 11 in 100 could quit in the control group, between 11 and 16 in 100 would be expected to be successful with the addition of counselling. We assessed this evidence as being of moderate quality, because the size of benefit was less certain. Having more intensive counselling support, for example more sessions, probably helps more, but the additional benefit is likely to be small, and again was of moderate quality because the size of benefit was uncertain. The few studies that compared different types of counselling did not show any differences between them.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Individual counselling compared to minimal contact control for smoking cessation

Patient or population: People who smoke
Setting: Healthcare and community settings
Intervention: Individual counselling from a smoking cessation counsellor including at least one face-to-face session lasting 10 minutes or more
Comparison: Minimal-contact control (usual care, brief advice or self-help materials)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Numbers quit in control condition	Numbers quit after individual counselling				
Smoking cessation at longest follow-up - 6 months or more *No systematic pharmacotherapy*	Study population 7 per 100	11 per 100 (10 to 12)	RR 1.57 (1.40 to 1.77)	11,100 (27 RCTs)	⊕⊕⊕⊕ HIGH	Limiting to studies at low risk of bias on all assessed domains marginally increases estimate of effect
Smoking cessation at longest follow-up - 6 months or more *Pharmacotherapy offered to all participants*	Study population 11 per 100	13 per 100 (11 to 16)	RR 1.24 (1.01 to 1.51)	2662 (6 RCTs)	⊕⊕⊕⊖ MODERATE [1]	Higher control group quit rate reflecting use of pharmacotherapy

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1]Downgraded due to wide confidence intervals.

Summary of findings 2. More intensive compared to less intensive counselling for smoking cessation

More intensive compared to less intensive counselling for smoking cessation

Patient or population: People who smoke
Setting: Healthcare and community settings
Intervention: More intensive individual counselling (± pharmacotherapy)
Comparison: Individual counselling (± pharmacotherapy)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Numbers quit with less intensive counselling	Numbers quit with more intensive counselling				
Smoking cessation at longest follow-up	Without pharmacotherapy		RR 1.29 (1.09 to 1.53)	2920 (11 RCTs)	⊕⊕⊕⊕ HIGH	Effect estimates for subgroups of studies with and without pharmacotherapy for all participants overlapped, so the overall pooled estimate is used with alternative control group estimates from subgroups
	9 per 100 [1]	12 per 100 (10 to 14)				
	With pharmacotherapy					
	14 per 100 [2]	18 per 100 (15 to 21)				

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio;

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1]Based on average in studies without pharmacotherapy.
[2]Based on average in studies with pharmacotherapy.

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 2013a). The effect of self-help interventions is less clear (Hartmann-Boyce 2014). More intensive intervention in a group setting increases quit rates (Stead 2017).

In this review, we assess the effectiveness of more intensive counselling delivered by a smoking cessation counsellor to a person 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. We therefore specifically exclude from this review 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.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized or quasi-randomized controlled trials (RCTs) with a minimum follow-up of six months, where at least one treatment arm consisted of an unconfounded intervention from a counsellor. Studies in which the treatment arm combined counselling and pharmacotherapy, and the control condition had neither, are covered in a separate review (Stead 2016).

Types of participants

Any smokers, except pregnant women (smoking cessation interventions in pregnancy are addressed by a separate review, Chamberlain 2013). We also exclude trials recruiting only children and adolescents.

Types of interventions

We defined individual counselling as a face-to-face encounter between a smoker 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 2013; Stead 2013a). It also excludes studies of interventions that combined counselling with provision of pharmacotherapy, compared to brief support (Stead 2016), studies of motivational interviewing (Lindson-Hawley 2015) and interventions which address multiple risk factors in addition to smoking. We include studies that evaluate the effect of counselling as an addition to pharmacotherapy.

We include studies comparing different counselling approaches if they are not covered by other Cochrane Reviews of specific interventions. Comparisons between individual counselling and behavioural therapy conducted in groups are covered in the Cochrane Review of group behavioural therapy (Stead 2017).

Types of outcome measures

The outcome was smoking cessation at the longest reported follow-up. We used sustained abstinence where available, or multiple point prevalence. 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 Cochrane Tobacco Addiction Group Specialized Register for studies with counsel* in title, abstract or keyword fields. At the time of the search the Register included the results of searches of the Cochrane Central Register of Controlled trials (CENTRAL), issue 4, 2016; MEDLINE (via OVID) to update 20160513; EMBASE (via OVID) to week 201621; PsycINFO (via OVID) to update 20160516. See the Tobacco Addiction Group Module in the Cochrane Library for full search strategies and list of other resources searched. We also checked previous reviews and meta-analyses for relevant studies, including all studies in the previous US guidelines (AHCPR 1996; Fiore 2000; Fiore 2008). The most recent search was conducted in May 2016.

Data collection and analysis

One author (LS, who is also the Cochrane Information Specialist for the Tobacco Addiction Group) prescreened results of the searches. Both authors checked reports of studies of potentially relevant interventions.

Both authors extracted data independently.

Information extracted included descriptive details on the setting of the study, the population, and details of intervention(s) and control conditions, including number and duration of planned sessions.

Assessment of risk of bias in included studies

We assessed risk of selection, detection and attrition bias, based on the reported methods of randomization and allocation concealment (selection bias), use of biochemical validation of self-reported abstinence (detection bias) and numbers lost to follow-up (attrition bias).

Measures of treatment effect & data synthesis

We summarized individual study results as a risk ratio (RR), calculated as: (number of quitters in intervention group/number randomized to intervention group) / (number of quitters in control group/number randomized to control group). We assumed that participants lost to follow-up continued to smoke and included them as such in denominators. Where appropriate we performed meta-analysis using a Mantel-Haenszel fixed-effect method to estimate a pooled risk ratio with a 95% confidence interval (CI) (Greenland 1985). We estimated the amount of statistical heterogeneity between trials using the I^2 statistic (Higgins 2003). Values over 50% can be regarded as moderate heterogeneity, and values over 75% as high.

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

We include 49 studies in this updated review, with around 19,000 participants. Thirty-three studies (11 new for this update) contribute to the primary analysis comparing individual counselling to a minimal contact behavioural intervention. Eleven studies (six new) compared different intensities of counselling and five (two new) compared different counselling approaches which were similar in intensity of contact.

In a few cases we resolved difficulties in applying the inclusion criteria by discussion. In two cases (Wiggers 2006; Aveyard 2007) 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 both after discussion about this aspect of their designs. We included one study that had only five months follow-up (Kim 2005).

Study populations

Nineteen of the 49 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; Brunner 2012), or outpatients (Weissfeld 1991; Kim 2005; Tonnesen 2006; Hennrikus 2010; Chan 2012; Ramon 2013; Thankappan 2013; Chen 2014). One recruited some inpatients (Schmitz 1999). Four other studies recruited drug- and alcohol-dependent veterans attending residential rehabilitation (Bobo 1998; Burling 1991; Burling 2001; Mueller 2012). One study recruited new mothers in maternity wards (Hannover 2009); we considered the subgroup of trial participants who were smoking at this point. Other studies recruited smokers in primary care clinics (Fiore 2004; Aveyard 2007; Marley 2014; Ramos 2010), dental clinics (Nohlert 2009), 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), participants in a lung cancer screening study (Marshall 2016), and community volunteers (Jorenby 1995; Lifrak 1997; Ahluwalia 2006; Killen 2008; McCarthy 2008, Wu 2009; Garvey 2012; Kim 2015). 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 the 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.

Special populations included Australian Aboriginal people (Marley 2014), homeless people (Okuyemi 2013), people under community corrections supervision (Cropsey 2015) and people with schizophrenia (Williams 2010). Two studies recruited Asian minority populations in the US; Kim 2015 (Koreans) and Wu 2009 (Chinese), and one recruited African Americans (Ahluwalia 2006).

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

Thirty studies were conducted in the USA, three in Spain (Aleixandre 1998; Ramos 2010; Ramon 2013), three in Denmark (Pedersen 2005; Tonnesen 2006; Brunner 2012), two in the UK (Molyneux 2003; Aveyard 2007), two in Australia (Marley 2014; Marshall 2016), and one each in Germany (Hannover 2009), Switzerland (Mueller 2012), Sweden (Nohlert 2009), Netherlands (Wiggers 2006), Hong Kong (Chan 2012), China (Chen 2014), Japan (Nakamura 2004), Korea (Kim 2005), and India (Thankappan 2013).

Intervention components

The counselling interventions typically included the following components: review of a participant's smoking history and motivation 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 tables.

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.

Studies with minimal contact controls

In the 33 studies with a minimal contact control the treatments offered to the control comparison group ranged from usual care to up to 15 minutes of advice, with or without the provision of self-help materials. To be classified as individual counselling the trials had to involve at least one session with face-to-face contact lasting more than 10 minutes, although the duration was typically much longer. The face-to-face counselling in Kim 2005 was the shortest, at only 11 minutes on average. Three tested a single face-to-face session without further support by telephone (Weissfeld 1991 (low-intensity arm); Molyneux 2003; Marshall 2016). Nine others offered a single face-to-face session with further support by telephone (Windsor 1988; Weissfeld 1991 (high-intensity arm); Stevens 1993; Rigotti 1997; Simon 1997; Dornelas 2000; Glasgow 2000; Hennrikus 2005; Kim 2005). All the other studies planned multiple sessions of face-to-face support, and sometimes also telephone contacts.

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. Provision of written materials was generally accompanied by brief advice; no trials directly addressed the effect of providing counselling as an addition to a structured self-help programme. One trial offered 15 minutes of counselling on a healthy diet to controls (Chan 2012), and one offered autogenic training, a relaxation-based programme not shown to aid cessation (Mueller 2012).

Within this group of studies, pharmacotherapy was systematically provided to participants in all trial arms in six trials. Nicotine patch was provided to all participants in Jorenby 1995; Simon 2003; Fiore 2004; Okuyemi 2013. Cropsey 2015 provided bupropion to all participants. Wiggers 2006 provided nicotine patches to participants ready to quit in either trial arm. Since the use of pharmacotherapy might change the relative effect of additional counselling, we include these studies in a subgroup analysis. 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.

Studies of counselling intensity

Eleven studies compared intensive counselling to less intensive interventions that also met our definition of counselling by involving more than 10 minutes of face-to-face contact. We considered these studies separately from those using a minimal-contact control. Eight of these studies provided pharmacotherapy to all participants and we included subgroups for studies with and without pharmacotherapy. Tonnesen 2006 contributed to both subgroups.

- 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.
- Killen 2008 provided six counselling session and combined NRT and bupropion, and compared different schedules of extended contact.
- Nohlert 2009 compared eight 40-minute sessions over four months with a single 30-minute session introducing a self-help programme.
- Wu 2009 compared four 60-minute culturally-tailored counselling sessions to four 60-minute health education sessions covering general health, nutrition, exercise and tobacco. All sessions were in Chinese, and all participants were offered nicotine patch.
- Williams 2010 compared 24 weekly 45-minute counselling sessions to nine 20-minute sessions that focused on medication management. All participants were given nicotine patches.
- Brunner 2012 provided a 30-minute counselling session and offer of nicotine patch during a hospital stay and tested the effect of an additional five outpatient sessions including free samples of NRT; we included this in the non-pharmacotherapy subgroup, as it was not provided as standard to all participants.
- Kim 2015 compared eight weekly 40-minute sessions of culturally-tailored counselling to eight 10-minute sessions focusing on medication management. All participants received nicotine patches.

Studies of counselling methods or timing

Five studies compared different counselling approaches that had similar contact times. We considered these separately from the groups above.

- 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.
- Garvey 2012 compared two different schedules of 14 counselling sessions, either front-loaded with six sessions in the first two weeks after quit date, or just two in that period. All participants received nicotine patches.

- Ramon 2013 directly compared delivery of counselling either entirely face-to-face or with a combination of face-to-face and telephone to a control group where all contact after the pre-quit session was by telephone.

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 including this study assuming equal quit rates did not alter the review results.

We list 48 other studies identified as potentially relevant but which did not meet the full inclusion criteria, with their reasons for exclusion in the table Characteristics of excluded studies. We note where studies were included in other Cochrane Reviews.

Risk of bias in included studies

We assessed the risks of selection bias, detection bias and attrition bias.

Twenty-seven studies reported the method for generating the randomization sequence in sufficient detail to be classified as having a low risk of bias, but only 14 also described a method of allocation likely to ensure that the assignment was concealed until after allocation, and thus being at low risk of selection bias (Simon 1997; Weissfeld 1991; Windsor 1988; Kim 2005; Ahluwalia 2006; Wiggers 2006; Aveyard 2007; Killen 2008; McCarthy 2008; Williams 2010; Chan 2012; Ramon 2013; Marley 2014; Marshall 2016). In most other trials, neither the method of randomization nor the use of allocation concealment was described. We judged five trials to be at high risk of selection bias, due to the method of randomization or concealment, or both (Stevens 1993; Bobo 1998; Dornelas 2000; Hannover 2009; Brunner 2012).

We judged the risk of detection bias to be low if self-reported abstinence was confirmed biochemically. Eight studies were at high risk of bias because no validation was attempted and trial arms had different amounts of contact with study staff, making differential misreporting of abstinence more likely (Bronson 1989; Stevens 1993; Aleixandre 1998; Pedersen 2005; Nohlert 2009; Thankappan 2013; Kim 2005; Ahluwalia 2006). We rated three studies as unclear; one study tested for cotinine but did not report validated rates (Bobo 1998), and in two others validation was incomplete and results were based on self-report (Pederson 1991; Marshall 2016).

We judged the risk of attrition bias to be low if loss to follow-up was reported by group, was no greater than 50% and not substantially different between groups. Most studies reported the number of participants who dropped out or were lost to follow-up, and included these people as smokers in analysis denominators. We judged most studies to be at low risk of bias, because the percentage lost was small and similar across conditions. We classified two studies as being at high risk (Ramos 2010; Mueller 2012), and one as unclear (Burling 1991). 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.

Overall we classified 11 of the 49 included studies (22%) as being at low risk of bias on all the domains we considered. A summary is displayed in Figure 1.

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

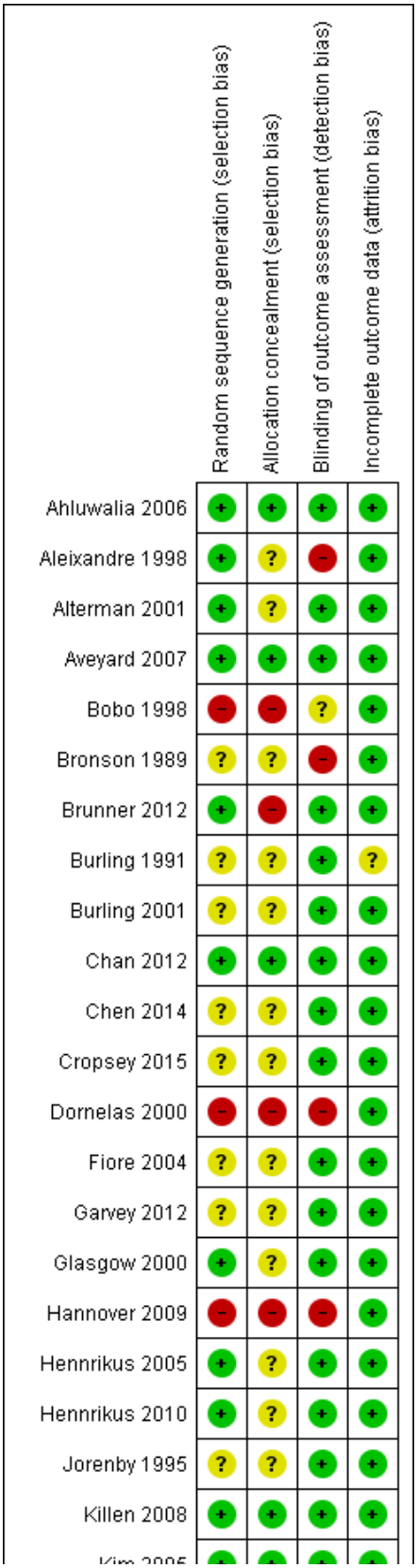
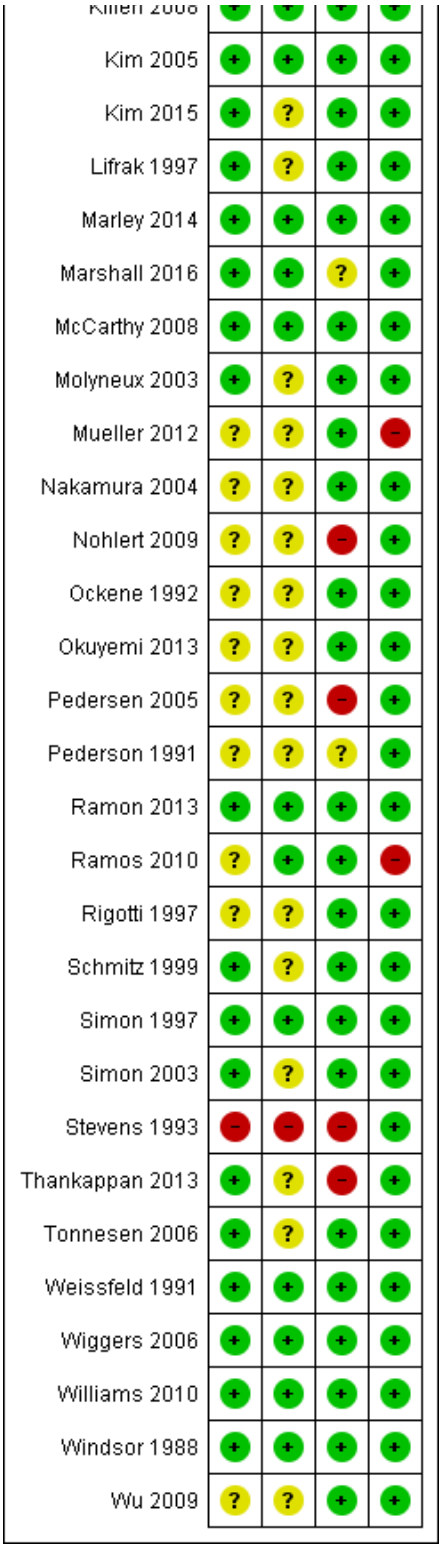


Figure 1. (Continued)



We did not formally assess the risk of performance bias. There was little information about blinding of participants or staff during treatment. Whilst the therapists delivering counselling could not have been blinded, 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. Because of this, we do not consider that the risk of bias from this aspect of design for this group of studies is high.

Effects of interventions

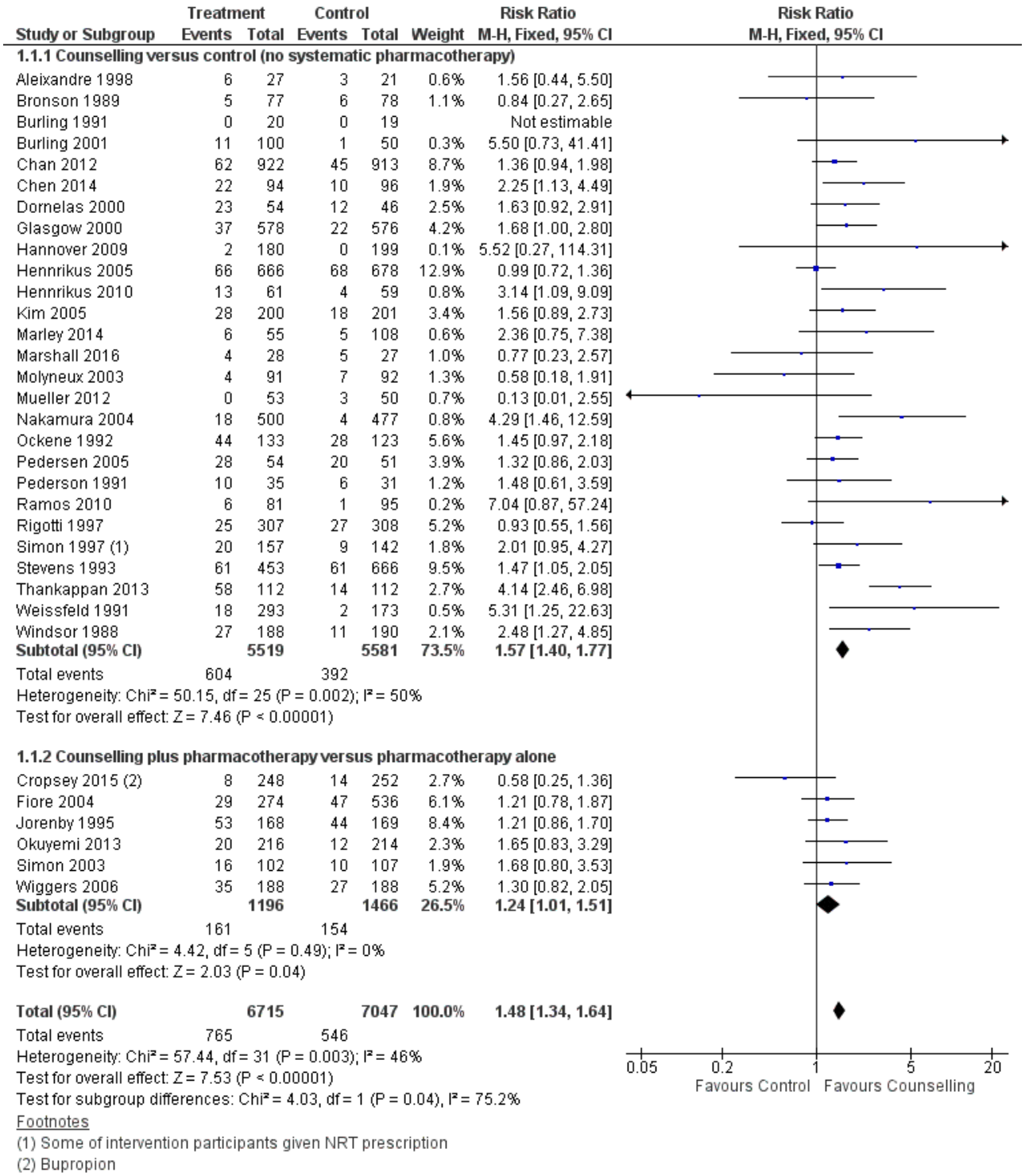
See: **Summary of findings for the main comparison** Individual counselling compared to minimal contact control for smoking cessation; **Summary of findings 2** More intensive compared to less intensive counselling for smoking cessation

Counselling versus minimal contact control

We estimated a pooled effect size based on 33 studies of counselling, including one (Burling 1991) where there were no quitters and which therefore did not contribute to the meta-analysis. The risk ratio (RR) was 1.48 (95% confidence interval (CI) 1.34 to 1.64, n = 13,762; Analysis 1.1), with some evidence of heterogeneity (I^2 = 46%). Restricting the analysis to seven studies at low risk of bias on all domains (Windsor 1988; Weissfeld 1991; Simon 1997; Kim 2005; Wiggers 2006; Chan 2012; Marley 2014) did not alter the conclusions; the point estimate increased slightly (RR 1.65, 95% CI 1.32 to 2.06). The estimate was higher in the subgroup of 27 studies where pharmacotherapy was not provided (RR 1.57, 95% CI 1.40 to 1.77; n = 11,100; I^2 = 50%) than in the six testing the additional effect of counselling when participants had access to pharmacotherapy (RR 1.24, 95% CI 1.01 to 1.51; n = 2662; I^2 = 0%) and a test for subgroup difference detected a difference between subgroups with and without pharmacotherapy. We base the estimates of absolute effect in Summary of findings for the main comparison on the subgroup estimates.

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.



More intensive versus less intensive counselling

Eight of the studies compared different levels of counselling as adjuncts to pharmacotherapy, and four did not offer medication (Tonnesen 2006 contributes different arms to each subgroup). The estimates in the two subgroups overlapped. Pooling all 11 studies, there was evidence of a small benefit from more intensive compared to brief counselling (RR 1.29, 95% CI 1.09 to 1.53; n = 2920; I^2 = 48%; Analysis 2.1), a change from the previous version of the review in which pooling five studies did not detect evidence of benefit. The moderate heterogeneity was attributable to two new studies with large effects. The control groups in these were

distinct, with Wu 2009 offering general health education and Kim 2015 focusing on medication management. A sensitivity analysis excluding these two studies no longer detected evidence of a dose response to counselling intensity. Limiting the analysis to four studies at low risk of bias also failed to suggest evidence of benefit.

Comparisons between counselling approaches

We did not pool these clinically heterogeneous five studies. Only one of them detected a significant difference between different types of counselling, where number of contacts and general intensity were similar. Schmitz 1999, comparing a relapse prevention approach to a health belief model, showed no significant difference, but with wide confidence intervals (RR 0.94, 95% CI 0.45 to 1.98; n = 160; 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% CI 0.34 to 0.76; n = 755; 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; n = 463; analysis 3.1.3). There was no evidence of an interaction between medication and counselling in either of the factorial trials. Garvey 2012 did not show that front-loading the schedule of sessions was associated with greater quit success, but CIs did not exclude no effect (RR 1.81, 95% CI 0.79 to 4.15; n = 242; analysis 3.1.4). Ramon 2013 did not detect a difference between face-to-face and telephone counselling (RR 1.39, 95% CI 0.89 to 2.19; n = 301; analysis 3.1.5), or combined contact (face-to-face plus telephone) versus telephone only (RR 1.44, 95% CI 0.92 to 2.25; n = 299), but confidence intervals were again wide.

DISCUSSION

There is consistent evidence that individual counselling increases the likelihood of cessation compared to less intensive support. Individual counselling, used independently of pharmacotherapy, was estimated to increase cessation by 40% to 80% after at least six months, based on pooling 27 trials with over 11,000 participants. Assuming a control group quit rate of 7% from a brief intervention, the provision of counselling would be expected to result in 10% to 12% quit, an absolute increase of 3% to 5%. We rated the quality of this evidence as high, using the GRADE approach (Summary of findings for the main comparison). This estimate was based on using counselling without any pharmacotherapy. The six trials that offered pharmacotherapy (typically nicotine replacement therapy) to all participants had a smaller and less certain effect. Assuming a control quit rate of 11% reflecting the benefit of medication, the addition of counselling could result in an absolute increase of 0% to 5%. We rated this as moderate quality using GRADE, because of the imprecision of the estimate. 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, but the absolute benefit of counselling could be similar, whether or not pharmacotherapy is used.

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), which 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, proactive 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 analysed 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 people with cardiovascular disease (Ockene 1992 ; Dornelas 2000; Pedersen 2005). Quit rates tended to be lower in studies recruiting hospitalized patients unselected for their readiness to quit (Stevens 1993; Rigotti 1997; 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.

Whilst we took account of the broad nature of the support offered to the control group when pooling studies, variation in the components used as part of, for example, a usual care control, may still give rise to heterogeneity. Treatment effects could be underestimated if those studies using effective interventions tended to provide relatively helpful usual care or brief advice. An ongoing systematic review is conducting a detailed analysis of behavioural intervention and control elements, and is expected to provide more evidence about this (de Bruin 2016).

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 2013b).

The 11 trials that directly compared different intensities of individual support detected only weak evidence of a dose-response effect which was sensitive to exclusion of outlying trials, and restriction to trials judged to be at low risk of bias. 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. Eight of the trials provided pharmacotherapy to all participants, so were testing the additional benefit of more intensive individual counselling. As seen in the trials offering pharmacotherapy in the primary analysis, the relative effect of the additional support may be smaller in relation to the higher rates of cessation in the control arm receiving combined behavioural and pharmacological support. A separate Cochrane Review (Stead 2015) has assessed the effect of increasing the amount of any type of behavioural support when used alongside pharmacotherapy. It analysed 47 studies including relevant studies from this review, and concluded that "increasing the amount of behavioural support is likely to increase the chance of success by about 10% to 25%". The estimates in this review are consistent with that range.

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.

ACKNOWLEDGEMENTS

Our thanks to Peter Hajek and the late Roger Secker-Walker for their helpful comments on the first version of this review. Nete Villebro translated a Danish paper

REFERENCES

References to studies included in this review

Ahluwalia 2006 *{published data only}*

* Ahluwalia JS, Okuyemi K, Nollen N, Choi WS, Kaur H, Pulvers K, et al. The effects of nicotine gum and counseling among African American light smokers: A 2 x 2 factorial design. *Addiction* 2006;**101**(6):883-91.

Ho MK, Mwenifumbo JC, Al Koudsi N, Okuyemi KS, Ahluwalia JS, Benowitz NL, et al. Association of nicotine metabolite ratio and CYP2A6 genotype with smoking cessation treatment in African-American light smokers. *Clinical Pharmacology and Therapeutics* 2009;**85**(6):635-43. [CENTRAL: 701215; CRS: 9400123000013799; 28553; PUBMED: 19279561]

Nollen NL, Mayo MS, Sanderson CL, Okuyemi KS, Choi WS, Kaur H, et al. Predictors of quitting among African American light smokers enrolled in a randomized, placebo-controlled trial. *Journal of General Internal Medicine* 2006;**21**:590-5.

Okuyemi KS, Cox LS, Nollen NL, Snow TM, Kaur H, Choi W, et al. Baseline characteristics and recruitment strategies in a randomized clinical trial of African-American light smokers. *American Journal of Health Promotion* 2007;**21**:183-91.

Okuyemi KS, Faseru B, Sanderson CL, Bronars CA, Ahluwalia JS. Relationship between menthol cigarettes and smoking cessation among African American light smokers. *Addiction* 2007;**102**:1979-86.

Okuyemi KS, Pulvers KM, Cox LS, Thomas JL, Kaur H, Mayo MS, et al. Nicotine dependence among African American light smokers: a comparison of three scales. *Addictive Behaviors* 2007;**32**(10):1989-2002.

Aleixandre 1998 *{published data only}*

Aleixandre ME, Mitjans JF, Casanova MA, Sanchez J, Belloch A. Clinical trial of two interventions of tobacco cessation in primary care. *Atencion Primaria* 1996;**18**(Suppl 1):212.

* Aleixandre i Marti E, Casanova Matutano MA, Mitjans Lafont J, Sanchez Monfort J, Sanmartin Almenar A. Clinical trial of two tobacco use cessation interventions in primary care [Ensayo clinico de dos intervenciones de deshabituacion tabaquica en atencion primaria]. *Atencion Primaria* 1998;**22**(7):424-8.

Alterman 2001 *{published data only}*

Alterman AI, Gariti P, Mulvaney F. Short- and long-term smoking cessation for three levels of intensity of behavioral treatment. *Psychology of Addictive Behaviors* 2001;**15**(3):261-4.

Aveyard 2007 *{published data only}*

* Aveyard P, Brown K, Saunders C, Alexander A, Johnstone E, Munafò MR, et al. Weekly versus basic smoking cessation support in primary care: a randomised controlled trial. *Thorax* 2007;**62**(10):898-903.

Greaves C. Smoking cessation trial may be missing the point. [comment]. *Thorax* 2008;**63**(3):291-2.

Bobo 1998 *{published data only}*

* Bobo JK, McIlvain HE, Lando HA, Walker RD, Leed Kelly A. Effect of smoking cessation counseling on recovery from alcoholism: findings from a randomized community intervention trial. *Addiction* 1998;**93**(6):877-87. [MEDLINE: 98416786]

Leed Kelly A, Russell KS, Bobo JK, McIlvain H. Feasibility of smoking cessation counseling by phone with alcohol treatment center graduates. *Journal of Substance Abuse Treatment* 1996;**13**(3):203-10. [MEDLINE: 97170019]

Bronson 1989 *{published data only}*

Bronson DL, Flynn BS, Solomon LJ, Vacek PM, Secker-Walker RH. Smoking cessation counselling during periodic health examinations. *Archives of Internal Medicine* 1989;**149**:1653-6.

* Secker-Walker RH, Lynn BS, Solomon LJ, Vacek PM, Bronson DL. Predictors of smoking behavior change 6 and 18 months after individual counseling during periodic health examinations. *Preventive Medicine* 1990;**19**(6):675-85.

Brunner 2012 *{published data only}*

Brunner Frandsen N, Sorensen M, Hyldahl TK, Henriksen RM, Bak S. Smoking cessation intervention after ischemic stroke or transient ischemic attack. A randomized controlled pilot trial. *Nicotine & Tobacco Research* 2012;**14**(4):443-7. [CENTRAL: 814359; CRS: 9400123000012563; EMBASE: 2012192968; PUBMED: 22193575]

Burling 1991 *{published data only}*

Burling TA, Marshall GD, Seidner AL. Smoking cessation for substance abuse inpatients. *Journal of Substance Abuse* 1991;**3**(3):269-76.

Burling 2001 *{published data only}*

Burling TA, Burling AS, Latini D. A controlled smoking cessation trial for substance-dependent inpatients. *Journal of Consulting and Clinical Psychology* 2001;**69**(2):295-304.

Chan 2012 *{published data only}*

Chan SS, Leung DY, Lau C, Wong V, Lam T. Cost-effectiveness analysis of a low intensity nurse-led stage-matched smoking cessation intervention to cardiac patients in Hong Kong. *Circulation* 2010;**122**(2):E87. [CENTRAL: 792456; CRS: 9400123000006051]

* Chan SS, Leung DY, Wong DC, Lau CP, Wong VT, Lam TH. A randomized controlled trial of stage-matched intervention for smoking cessation in cardiac out-patients. *Addiction (Abingdon, England)* 2012;**107**(4):829-37. [CENTRAL: 831052; CRS: 9400123000012976; EMBASE: 22118418; PUBMED: 22118418]

Chan SSC, Lam TH, Lau C-P. The effectiveness of a nurse-delivered smoking cessation intervention for cardiac patients: a randomised controlled trial. *Nicotine & Tobacco Research* 2005;**7**(4):692. [CENTRAL: 527413; CRS: 9400123000003748]

Chen 2014 *{published data only}*

Chen J, Chen P. The individualized smoking counselling for smoking cessation in COPD patients and general smokers. *Respirology (Carlton, Vic.)* 2011;**16**:116. [CENTRAL: 814367; CRS: 9400123000012446; 7010]

* Chen J, Chen Y, Chen P, Liu Z, Luo H, Cai S. Effectiveness of individual counseling for smoking cessation in smokers with chronic obstructive pulmonary disease and asymptomatic smokers. *Experimental and Therapeutic Medicine* 2014;**7**(3):716-20. [CENTRAL: 977728; CRS: 9400129000000799; EMBASE: 2014068598; PUBMED: 24520273]

Cropsey 2015 *{published data only}*

Cropsey KL, Clark CB, Zhang X, Hendricks PS, Jardin BF, Lahti AC. Race and medication adherence moderate cessation outcomes in criminal justice smokers. *American Journal of Preventive Medicine* 2015;**49**(3):335-44. [PUBMED: 26091924]

Dornelas 2000 *{published data only}*

Dornelas EA, Sampson RA, Gray JF, Waters D, Thompson PD. A randomized controlled trial of smoking cessation counseling after myocardial infarction. *Preventive Medicine* 2000;**30**(4):261-8.

Fiore 2004 *{published data only}*

Fiore MC, McCarthy DE, Jackson TC, Zehner ME, Jorenby DE, Mielke M, et al. Integrating smoking cessation treatment into primary care: An effectiveness study. *Preventive Medicine* 2004;**38**(4):412-20.

Garvey 2012 *{published data only}*

Garvey AJ, Hoskinson RA, Wadler BA, Wood EE, Kinnunen T, Kalman D, et al. Effects of front-loaded vs. standard weekly counseling on 6-month abstinence rates (POS1-66). Society for Research on Nicotine and Tobacco 13th Annual Meeting February 21-24, Austin, Texas. 2007:54. [CENTRAL: 616128; CRS: 9400123000004541; 14531]

* Garvey AJ, Kalman D, Hoskinson RAJ, Kinnunen T, Wadler BM, Thomson CC, et al. Front-loaded versus weekly counseling for treatment of tobacco addiction. *Nicotine & Tobacco Research* 2012;**14**(5):578-85. [CENTRAL: 832525; CRS: 9400123000014483; EMBASE: 2012254939; PUBMED: 22058190]

Glasgow 2000 *{published data only}*

Glasgow RE, Whitlock EP, Eakin EG, Lichtenstein E. A brief smoking cessation intervention for women in low-income planned parenthood clinics. *American Journal of Public Health* 2000;**90**:786-9.

Hannover 2009 *{published data only}*

Hannöver W, Thyrian JR, Röske K, Grempler J, Rumpf HJ, John U, et al. Smoking cessation and relapse prevention for postpartum women: results from a randomized controlled trial at 6, 12, 18 and 24 months. *Addictive Behaviors* 2009;**34**(1):1-8. [CENTRAL: 702834; CRS: 9400123000005273; EMBASE: 2008517114; PUBMED: 18804331]

Hennrikus 2005 *{published data only}*

Hennrikus D, Lando HA, McCarty MC, Vessey JT. The effectiveness of a systems approach to smoking cessation in hospital inpatients. Society for Research on Nicotine and Tobacco 7th Annual Meeting March 23-23 Seattle Washington. 2001:47.

* Hennrikus DJ, Lando HA, McCarty MC, Klevan D, Holtan N, Huebsch JA, et al. The TEAM project: the effectiveness of smoking cessation interventions with hospital patients. *Preventive Medicine* 2005;**40**(3):249-58.

Lando H, Hennrikus D, McCarty M, Vessey J. Predictors of quitting in hospitalized smokers. *Nicotine & Tobacco Research* 2003;**5**(2):215-22.

Hennrikus 2010 *{published data only}*

Hennrikus D, Joseph AM, Lando HA, Duval S, Ukestad L, Kodl M, et al. Effectiveness of a smoking cessation program for peripheral artery disease patients: a randomized controlled trial. *Journal of the American College of Cardiology* 2010;**56**(25):105-12. [PUBMED: 21144971]

Jorenby 1995 *{published data only}*

Jorenby DE, Smith SS, Fiore MC, Hurt RD, Offord KP, Croghan IT, et al. Varying nicotine patch dose and type of smoking cessation counseling. *JAMA* 1995;**274**(17):1347-52.

Killen 2008 *{published data only}*

Bailey SR, Hammer SA, Bryson SW, Schatzberg AF, Killen JD. Using treatment process data to predict maintained smoking abstinence. *American Journal of Health Behavior* 2010;**34**(6):801-10. [CENTRAL: 766985; CRS: 9400123000005814]

* Killen JD, Fortmann SP, Schatzberg AF, Arredondo C, Murphy G, Hayward C, et al. Extended cognitive behavior therapy for cigarette smoking cessation. *Addiction* 2008;**103**(8):1381-90.

Kim 2005 *{published data only}*

Kim JR, Lee MS, Hwang JY, Lee JD. Efficacy of a smoking cessation intervention using the AHCPR guideline tailored for Koreans: a randomized controlled trial. *Health Promotion International* 2005;**20**(1):51-9.

Kim 2015 *{published data only}*

* Kim SS, Kim S-H, Fang H, Kwon S, Shelley D, Ziedonis D. A culturally adapted smoking cessation intervention for Korean Americans: A mediating effect of perceived family norm toward quitting. *Journal of Immigrant & Minority Health* 2015;**17**(4):1120-9. [CRS: 9400131000003387]

Kim SS, Kim SH, Ziedonis D. Tobacco dependence treatment for Korean Americans: preliminary findings. *Journal of Immigrant and Minority Health / Center for Minority Public Health* 2012;**14**(3):395-404. [CENTRAL: 833139; CRS: 9400123000015714; EMBASE: 21785963; PUBMED: 21785963]

Lifrak 1997 *{published data only}*

Lifrak P, Gariti P, Alterman AI, McKay J, Volpicelli J, Sparkman T, et al. Results of two levels of adjunctive treatment used with the nicotine patch. *American Journal on Addictions* 1997;**6**(2):93-8.

Marley 2014 *{published data only}*

Marley JV, Atkinson D, Kitaura T, Nelson C, Gray D, Metcalf S, et al. The Be Our Ally Beat Smoking (BOABS) study, a randomised controlled trial of an intensive smoking cessation intervention in a remote aboriginal Australian health care setting.. *BMC Public Health* 2014;**14**(32):1-10. [PUBMED: 24418597]

Marshall 2016 *{published data only}*

Marshall HM, Courtney DA, Passmore LH, McCaul EM, Yang IA, Bowman RV, et al. Brief tailored smoking cessation counseling in a lung cancer screening population is feasible: a pilot randomized controlled trial. *Nicotine & Tobacco Research* 2016;**18**(7):1665-9. [CRS: 9400131000006073; PUBMED: 26834052]

Marshall HM, Yang IA, Passmore L, Mccaul EM, Bowman R, Fong KM. A randomized controlled trial of brief counselling intervention and audio materials for smoking cessation in a low-dose CT screening study. *Journal of Thoracic Oncology* 2013;**8**(Supplement 2):S703. [CENTRAL: 996980; CRS: 9400129000001580; EMBASE: 71396835]

McCarthy 2008 *{published data only}*

McCarthy DE. Mechanisms of tobacco cessation treatment: Self-report mediators of counseling and bupropion sustained release treatment. *Dissertation Abstracts International: Section B: The Sciences and Engineering* 2007;**67**(9-B):5414.

McCarthy DE, Piasecki TM, Jorenby DE, Lawrence DL, Shiffman S, Baker TB. A multi-level analysis of non-significant counseling effects in a randomized smoking cessation trial. *Addiction (Abingdon, England)* 2010;**105**(12):2195-208. [CENTRAL: 780680; CRS: 9400123000005902; EMBASE: 20840173; PUBMED: 20840173]

* McCarthy DE, Piasecki TM, Lawrence DL, Jorenby DE, Shiffman S, Fiore MC, et al. A randomized controlled clinical trial of bupropion SR and individual smoking cessation counseling. *Nicotine & Tobacco Research* 2008;**10**(4):717-29.

Molyneux 2003 *{published data only}*

Molyneux A, Lewis S, Leivers U, Anderton A, Antoniak M, Brackenridge A, et al. Clinical trial comparing nicotine replacement therapy (NRT) plus brief counselling, brief counselling alone, and minimal intervention on smoking cessation in hospital inpatients. *Thorax* 2003;**58**(6):484-8.

Mueller 2012 *{published data only}*

Mueller SE, Petitjean SA, Wiesbeck GA. Cognitive behavioral smoking cessation during alcohol detoxification treatment: a randomized, controlled trial. *Drug and Alcohol Dependence* 2012;**126**(3):279-85. [CENTRAL: 845210; CRS: 9400123000014751; PUBMED: 22726914]

Nakamura 2004 *{published data only}*

Nakamura M, Masui S, Oshima A, Okayama A, Ueshima H. Effects of stage-matched repeated individual counseling on smoking cessation: A randomized controlled trial for the High-risk Strategy by Lifestyle Modification (HISLIM) study. *Environmental Health & Preventive Medicine* 2004;**9**(4):152-60.

Nohlert 2009 *{published data only}*

Nohlert E, Helgason AR, Tillgren P, Tegelberg A, Johansson P. Comparison of the cost-effectiveness of a high- and a low-intensity smoking cessation intervention in Sweden: a randomized trial. *Nicotine & Tobacco Research* 2013;**15**(9):1519-27. [CENTRAL: 871208; CRS: 9400107000001886; EMBASE: 2013526836; PUBMED: 23404735]

* Nohlert E, Tegelberg A, Tillgren P, Johansson P, Rosenblad A, Helgason AR. Comparison of a high and a low intensity smoking cessation intervention in a dentistry setting in Sweden: a randomized trial. *BMC Public Health* 2009;**9**:121.

Ockene 1992 *{published data only}*

* Ockene JK, Kristeller J, Goldberg R, Ockene IS, Merriam P, Barrett S, et al. Smoking cessation and severity of disease: The coronary artery smoking intervention study. *Health Psychology* 1992;**11**(2):119-26.

Rosal MC, Ockene JK, Ma YS, Hebert JR, Ockene IS, Merriam P, et al. Coronary Artery Smoking Intervention Study (CASIS): 5-year Follow-up. *Health Psychology* 1998;**17**(5):476-8.

Okuyemi 2013 *{published data only}*

Okuyemi KS, Goldade K, Whembolua GL, Thomas JL, Eischen S, Sewali B, et al. Motivational interviewing to enhance nicotine patch treatment for smoking cessation among homeless smokers: a randomized controlled trial. *Addiction (Abingdon, England)* 2013;**108**(6):1136-44. [CENTRAL: 921008; CRS: 9400107000001568; PEER: Reviewed Journal: 2013-16822-021; PUBMED: 23510102]

Pedersen 2005 *{published data only}*

Pedersen L, Johansen S, Eksten L. Smoking cessation among patients with acute heart disease. A randomised intervention project. *Ugeskrift for Laeger* 2005;**167**(33):3044-7.

Pederson 1991 *{published data only}*

Pederson LL, Wanklin JM, Lefcoe NM. The effects of counseling on smoking cessation among patients hospitalized with chronic obstructive pulmonary disease: a randomized clinical trial. *International Journal of the Addictions* 1991;**26**(1):107-19.

Ramon 2013 *{published data only}*

Ramon JM, Nerin I, Comino A, Pinet C, Abella F, Carreras JM, et al. A multicentre randomized trial of combined individual and telephone counselling for smoking cessation. *Preventive Medicine* 2013;**57**(3):183-8. [CENTRAL: 871209; CRS: 9400107000001894; EMBASE: 2013515081; PUBMED: 23732247]

Ramos 2010 *{published data only}*

Ramos M, Ripoll J, Estrades T, Socias I, Fe A, Duro R, et al. Effectiveness of intensive group and individual interventions for smoking cessation in primary health care settings: a randomized trial. *BMC Public Health* 2010;**10**:89. [CENTRAL: 761411; CRS: 9400123000005754; PUBMED: 20178617]

Rigotti 1997 *{published data only}*

Rigotti NA, Arnsten JH, McKool KM, Wood-Reid KM, Pasternak RC, Singer DE. Efficacy of a smoking cessation

program for hospital patients. *Archives of Internal Medicine* 1997;**157**(22):2653-60.

Schmitz 1999 *{published data only}*

Schmitz JM, Spiga R, Rhoades HM, Fuentes F, Grabowski J. Smoking cessation in women with cardiac risk: a comparative study of two theoretically based therapies. *Nicotine & Tobacco Research* 1999;**1**(1):87-94.

Simon 1997 *{published data only}*

Simon JA, Solkowitz SN, Carmody TP, Browner WS. Smoking cessation after surgery. A randomized trial. *Archives of Internal Medicine* 1997;**157**(12):1371-6.

Simon 2003 *{published data only}*

Simon JA, Carmody TP, Hudes ES, Snyder E, Murray J. Intensive smoking cessation counseling versus minimal counseling among hospitalized smokers treated with transdermal nicotine replacement: a randomized trial. *American Journal of Medicine* 2003;**114**(7):555-62.

Stevens 1993 *{published data only}*

Meenan RT, Stevens VJ, Hornbrook MC, La Chance PA, Glasgow RE, Hollis JF, et al. Cost-effectiveness of a hospital-based smoking cessation intervention. *Medical Care* 1998;**36**(5):670-8. [MEDLINE: 1998255497]

* Stevens VJ, Glasgow RE, Hollis JF, Lichtenstein E, Vogt TM. A smoking-cessation intervention for hospital patients. *Medical Care* 1993;**31**(1):65-72. [MEDLINE: 1993108828]

Thankappan 2013 *{published data only}*

* Thankappan KR, Mini GK, Daivadanam M, Vijayakumar G, Sarma PS, Nichter M. Smoking cessation among diabetes patients: results of a pilot randomized controlled trial in Kerala, India. *BMC Public Health* 2013;**13**:47. [CENTRAL: 853596; CRS: 9400107000000056; EMBASE: 23331722; PUBMED: 23331722]

Thankappan KR, Mini GK, Hariharan M, Vijayakumar G, Sarma PS, Nichter M. Smoking cessation among diabetic patients in Kerala, India: 1-Year follow-up results from a pilot randomized controlled trial. *Diabetes Care* 2014;**37**(12):e256-7. [CENTRAL: 1036654; CRS: 9400050000000130; EMBASE: 2014925711; PUBMED: 25414396]

Tonnesen 2006 *{published data only}*

Tonnesen P, Mikkelsen K, Bremann L. Nurse-conducted smoking cessation in patients with COPD using nicotine sublingual tablets and behavioral support. *Chest* 2006;**130**(2):334-42.

Weissfeld 1991 *{published data only}*

Weissfeld JL, Holloway JL. Treatment for cigarette smoking in a Department of Veterans Affairs outpatient clinic. *Archives of Internal Medicine* 1991;**151**:973-7. [MEDLINE: 1991221915]

Wiggers 2006 *{published data only}*

Wiggers LC, Oort FJ, Dijkstra A, De Haes JC, Legemate DA, Smets EM. Cognitive changes in cardiovascular patients following a tailored behavioral smoking cessation intervention. *Preventive Medicine* 2005;**40**(6):812-21.

* Wiggers LC, Smets EM, Oort FJ, Peters RJ, Storm-Versloot MN, Vermeulen H, et al. The effect of a minimal intervention strategy in addition to nicotine replacement therapy to support smoking cessation in cardiovascular outpatients: a randomized clinical trial. *European Journal of Cardiovascular Prevention and Rehabilitation* 2006;**13**(6):931-7.

Wiggers LC, Smets EM, Oort FJ, Storm-Versloot MN, Vermeulen H, Van Loenen LB, et al. Adherence to nicotine replacement patch therapy in cardiovascular patients. *International Journal of Behavioral Medicine* 2006;**13**(1):79-88.

Wiggers LCW, Oort FJ, Peters RJG, Legemate DA, De Haes HCJM, Smets EMA. Smoking cessation may not improve quality of life in atherosclerotic patients. *Nicotine & Tobacco Research* 2006;**8**(4):581-9.

Williams 2010 *{published data only}*

Williams JM, Steinberg ML, Zimmermann MH, Gandhi KK, Stipelman B, Budsock PD, et al. Comparison of two intensities of tobacco dependence counseling in schizophrenia and schizoaffective disorder. *Journal of Substance Abuse Treatment* 2010;**38**(4):384-93. [CENTRAL: 750682; CRS: 9400123000005641; PUBMED: 20363089]

Windsor 1988 *{published data only}*

Windsor RA, Lowe JB, Bartlett EE. The effectiveness of a worksite self-help smoking cessation program: a randomized trial. *Journal of Behavioral Medicine* 1988;**11**(4):407-21.

Wu 2009 *{published data only}*

Wu D, Ma GX, Zhou K, Zhou D, Liu A, Poon AN. The effect of a culturally tailored smoking cessation for Chinese American smokers. *Nicotine & Tobacco Research* 2009;**11**(12):1448-57. [CENTRAL: 732128; CRS: 9400123000005485; PUBMED: 19915080]

References to studies excluded from this review

Alonso-Pérez 2007 *{published data only}*

Alonso-Pérez F, Secades-Villa R, Duarte CG. Are psychological treatments effective to stop smoking? [Son eficientes los tratamientos psicológicos para dejar de fumar?]. *Trastornos Adictivos* 2007;**9**(1):21-30.

Berndt 2014 *{published data only}*

* Berndt N, Bolman C, Froelicher ES, Mudde A, Candel M, Vries H, et al. Effectiveness of a telephone delivered and a face-to-face delivered counseling intervention for smoking cessation in patients with coronary heart disease: A 6-month follow-up. *Journal of Behavioral Medicine* 2014;**37**(4):709-24. [CRS: 9400107000001638; PEER: Reviewed Journal: 2013-21268-001]

Berndt N, Bolman C, Lechner L, Mudde A, Verheugt FW, De Vries H. Effectiveness of two intensive treatment methods for smoking cessation and relapse prevention in patients with coronary heart disease: study protocol and baseline description. *BMC Cardiovascular Disorders* 2012;**12**:33. [CENTRAL: 840357; CRS: 9400123000016156; EMBASE: 2012574240; PUBMED: 22587684]

Bock 2014 *{published data only}*

Bock BC, Papandonatos GD, De Dios MA, Abrams DB, Azam MM, Fagan M, et al. Tobacco cessation among low-income smokers: Motivational enhancement and nicotine patch treatment. *Nicotine & Tobacco Research* 2014;**16**(4):413-22. [CENTRAL: 986341; CRS: 9400050000000050; EMBASE: 2014185069; PUBMED: 24174612]

Bolman 2002 *{published data only}*

Bolman C, De Vries H, Van Breukelen G. A minimal-contact intervention for cardiac inpatients: long-term effects on smoking cessation. *Preventive Medicine* 2002;**35**(2):181-92.

Borrelli 2005 *{published data only}*

Borrelli B, Novak S, Hecht J, Emmons K, Papandonatos G, Abrams D. Home health care nurses as a new channel for smoking cessation treatment: outcomes from project CARES (Community-nurse Assisted Research and Education on Smoking). *Preventive Medicine* 2005;**41**(5-6):815-21.

Calabro 2012 *{published data only}*

Calabro KS, Marani S, Yost T, Segura J, Mullin Jones M, Nelson S, et al. Project SUCCESS: results from a randomized controlled trial. ISRN Public Health 2012:Article ID 913713. [CENTRAL: 836719; CRS: 9400123000016091]

Camarelles 2002 *{published data only}*

Camarelles F, Asensio A, Jimenez-Ruiz C, Becerril B, Rodero D, Vidaller O. [Effectiveness of a group therapy intervention to quit smoking. Randomized clinical trial]. *Medicina Clinica - Barcelona* 2002;**119**(2):53-7.

Canga 2000 *{published data only}*

Canga N, De Irala J, Vara E, Duaso MJ, Ferrer A, Martinez-Gonzalez MA. Intervention study for smoking cessation in diabetic patients - A randomized controlled trial in both clinical and primary care settings. *Diabetes Care* 2000;**23**(10):1455-60.

Catley 2016 *{published data only}*

* Catley D, Goggin K, Harris KJ, Richter KP, Williams K, Patten C, et al. A randomized trial of motivational interviewing: Cessation induction among smokers with low desire to quit. *American Journal of Preventive Medicine* 2016;**50**(5):573-83. [CRS: 9400131000006612; EMBASE: 20160316060; PUBMED: 26711164]

Catley D, Harris KJ, Goggin K, Richter K, Williams K, Patten C, et al. Motivational Interviewing for encouraging quit attempts among unmotivated smokers: study protocol of a randomized, controlled, efficacy trial. *BMC Public Health* 2012;**12**:456.

Clarke 2013 *{published data only}*

Clarke JG, Stein LAR, Martin RA, Martin SA, Parker D, Lopes CE, et al. Forced smoking abstinence: Not enough for smoking cessation. *JAMA Internal Medicine* 2013;**173**(9):789-94. [CENTRAL: 863880; CRS: 9400107000000372; EMBASE: 2013308469]

Colby 1998 *{published data only}*

Colby SM, Monti PM, Barnett NP, Rohsenow DJ, Weissman K, Spirito A, et al. Brief motivational interviewing in a hospital setting for adolescent smoking: a preliminary study. *Journal of Consulting and Clinical Psychology* 1998;**66**(3):574-8.

Dezee 2013 *{published data only}*

Dezee KJ, Wink JS, Cowan CM. Internet versus in-person counseling for patients taking varenicline for smoking cessation. *Military Medicine* 2013;**178**(4):401-5. [CENTRAL: 959429; CRS: 9400130000000072; PUBMED: 23707824]

Emmons 2001 *{published data only}*

Emmons KM, Hammond SK, Fava JL, Velicer WF, Evans JL, Monroe AD. A randomized trial to reduce passive smoke exposure in low-income households with young children. *Pediatrics* 2001;**108**(1):18-24.

Froelicher 2004 *{published data only}*

Froelicher ESS, Miller NH, Christopherson DJ, Martin K, Parker KM, Amonetti M, et al. High rates of sustained smoking cessation in women hospitalized with cardiovascular disease - The Women's Initiative for Nonsmoking (WINS). *Circulation* 2004;**109**:587-93.

Gariti 2009 *{published data only}*

Gariti P, Lynch K, Alterman A, Kampman K, Xie H, Varillo K. Comparing smoking treatment programs for lighter smokers with and without a history of heavier smoking. *Journal of Substance Abuse Treatment* 2009;**37**(3):247-55. [CENTRAL: 720874; CRS: 9400123000005384; PUBMED: 19339135]

Ghanem 2014 *{unpublished data only}*

* Ghanem M. Evaluation of intensive outpatient antismoking counselling program in a low-income country. *Chest* 2014;**145**(3 Suppl):617A. [CRS: 9400129000001568; EMBASE: 71429168]

Ghanem M, Agmy G, Metwally M. Outcome of out-patient intensive anti-smoking counselling program in a low-income country [Abstract]. European Respiratory Society Annual Congress, Vienna, Austria, September 12-16. 2009:4633. [CENTRAL: 765833; CRS: 9400123000005802]

Gifford 2004 *{published data only}*

Gifford EV, Kohlenberg BS, Hayes SC, Antonuccio DO, Piasecki MM, Rasmussen Hall ML, et al. Acceptance-based treatment for smoking cessation. *Behavior Therapy* 2004;**35**(4):689-705.

Gifford 2011 *{published data only}*

Gifford EV, Kohlenberg BS, Hayes SC, Pierson HM, Piasecki MP, Antonuccio DO, et al. Does acceptance and relationship focused behavior therapy contribute to bupropion outcomes? A randomized controlled trial of functional analytic psychotherapy and acceptance and commitment therapy for smoking cessation. *Behavior Therapy* 2011;**42**(4):700-15. [CENTRAL: 814642; CRS: 9400123000012398; 6939; PUBMED: 22035998]

Gorini 2012 *{published data only}*

Chellini E, Gorini G, Carreras G, Giordano L, Anghinoni E, Iossa A, et al. The Pap smear screening as an occasion for smoking cessation and physical activity counselling: baseline

characteristics of women involved in the SPRINT randomized controlled trial. *BMC Public Health* 2011;**11**:906.

* Gorini G, Carreras G, Giordano L, Anghinoni E, Iossa A, Coppo A, et al. The Pap smear screening as an occasion for smoking cessation and physical activity counselling: effectiveness of the SPRINT randomized controlled trial. *BMC Public Health* 2012;**12**:740. [CENTRAL: 864643; CRS: 9400107000000033; EMBASE: 22950883; PUBMED: 22950883]

Harris 2010 *{published data only}*

Harris KJ, Catley D, Good GE, Cronk NJ, Harrar S, Williams KB. Motivational interviewing for smoking cessation in college students: a group randomized controlled trial. *Preventive Medicine* 2010;**51**(5):387-93. [CENTRAL: 769285; CRS: 9400123000005834; EMBASE: 2010585366; PUBMED: 20828584]

Hilberink 2005 *{published data only}*

Hilberink SR, Jacobs JE, Bottema BJ, De Vries H, Grol RP. Smoking cessation in patients with COPD in daily general practice (SMOCC): six months' results. *Preventive Medicine* 2005;**41**(5-6):822-7.

Hokanson 2006 *{published data only}*

Hokanson JM, Anderson RL, Hennrikus DJ, Lando HA, Kendall DM. Integrated tobacco cessation counseling in a diabetes self-management training program: a randomized trial of diabetes and reduction of tobacco. *Diabetes Educator* 2006;**32**(4):562-70.

Hyman 2007 *{published data only}*

Hyman DJ, Pavlik VN, Taylor WC, Goodrick GK, Moye L. Simultaneous vs sequential counseling for multiple behavior change. *Archives of Internal Medicine* 2007;**167**(11):1152-8.

Kadowaki 2000 *{published data only}*

Kadowaki T, Watanabe M, Okayama A, Hishida K, Ueshima H. Effectiveness of smoking-cessation intervention in all of the smokers at a worksite in Japan. *Industrial Health* 2000;**38**(4):396-403.

Lando 1992 *{published data only}*

Lando HA, Hellerstedt WL, Pirie PL, McGovern PG. Brief supportive telephone outreach as a recruitment and intervention strategy for smoking cessation. *American Journal of Public Health* 1992;**82**(1):41-6. [MEDLINE: 1992161042]

Lloyd-Richardson 2009 *{published data only}*

* Lloyd-Richardson EE, Stanton CA, GD Papandonatos, Shadel WG, Stein M, Tashima K, et al. Motivation and patch treatment for HIV+ smokers: a randomized controlled trial. *Addiction* 2009;**104**(11):1891-900.

Niaura R, Richardson EE, Stanton C, Carton-Lopez S, Morrow K, Shadel W. Motivation and patch treatment for HIV-positive smokers: psychosocial barriers to cessation (POS1-057). Society for Research on Nicotine and Tobacco 10th Annual Meeting February 18-21, Phoenix, Arizona. 2004.

Lopez 2007 *{published data only}*

Lopez ML, Iglesias JM, Del Valle MO, Comas A, Fernandez JM, De Vries H, et al. Impact of a primary care intervention on smoking, drinking, diet, weight, sun exposure, and work risk in families with cancer experience. *Cancer Causes & Control* 2007;**18**(5):525-35.

Malchodi 2003 *{published data only}*

Malchodi CS, Oncken C, Dornelas EA, Caramanica L, Gregonis E, Curry SL. The effects of peer counseling on smoking cessation and reduction. *Obstetrics and Gynecology* 2003;**101**(3):504-10.

Marks 2002 *{published data only}*

Marks DF, Sykes CM. Randomized controlled trial of cognitive behavioural therapy for smokers living in a deprived area of London: Outcome at one-year follow-up. *Psychology, Health and Medicine* 2002;**7**:17-24.

McCarthy 2016 *{published data only}*

McCarthy DE, Bold KW, Minami H, Yeh VM. A randomized clinical trial of a tailored behavioral smoking cessation preparation program. *Behaviour Research and Therapy* 2016;**78**:19-29. [CENTRAL: 1133297; CRS: 9400131000005793; EMBASE: 20160085215]

Mildestvedt 2007 *{published data only}*

Mildestvedt T, Meland E, Eide GE. No difference in lifestyle changes by adding individual counselling to group-based rehabilitation RCT among coronary heart disease patients. *Scandinavian Journal Of Public Health* 2007;**35**(6):591-8.

Mooney 2007 *{published data only}*

Mooney ME, Sayre SL, Hokanson PS, Stotts AL, Schmitz JM. Adding MEMS feedback to behavioral smoking cessation therapy increases compliance with bupropion: A replication and extension study. *Addictive Behaviors* 2007;**32**(4):875-80.

Niaura 1999 *{published data only}*

Niaura R, Abrams DB, Shadel WG, Rohsenow DJ, Monti PM, Sirota AD. Cue exposure treatment for smoking relapse prevention: A controlled clinical trial. *Addiction* 1999;**94**(5):685-96.

Okuyemi 2006 *{published data only}*

Okuyemi KS, Thomas JL, Hall S, Nollen NL, Richter KP, Jeffries SK, et al. Smoking cessation in homeless populations: A pilot clinical trial. *Nicotine & Tobacco Research* 2006;**8**(5):689-99.

Rabkin 1984 *{published data only}*

Kaufert JM, Rabkin SW, Syrotuik J, Boyko E, Shane F. Health beliefs as predictors of success of alternate modalities of smoking cessation: results of a controlled trial. *Journal of Behavioral Medicine* 1986;**9**(5):475-89.

* Rabkin SW, Boyko E, Shane F, Kaufert J. A randomized trial comparing smoking cessation programs utilizing behaviour modification, health education or hypnosis. *Addictive Behaviors* 1984;**9**(2):157-73. [MEDLINE: 1984253195]

Raja 2014 *{published data only}*

Raja M, Saha S, Mohd S, Narang R, Reddy LK, Kumari M. Cognitive behavioural therapy versus basic health education for tobacco cessation among tobacco users: A randomized clinical trail. *Journal of Clinical and Diagnostic Research*

2014;**8**(4):ZC47-9. [CENTRAL: 988479; CRS: 9400050000000056; EMBASE: 2014290928; PUBMED: 24959516]

Rodriguez 2003 *{published data only}*

Rodriguez-Artalejo F, Lafuente-Urdinguio P, Guallar-Castillon P, Garteizaurrekoa-Dublang P, Sainz-Martinez O, Diez-Azcarate JI, et al. One-year effectiveness of an individualized smoking cessation intervention at the workplace: a randomized controlled trial.. *Occupational Environmental Medicine* 2003;**60**(5):358-63.

Sanz-Pozo 2006 *{published data only}*

Sanz Pozo B, Miguel Díaz J, Aragón Blanco M, González González AI, Cortes Catalán M, Vázquez I. Effectiveness of non-pharmacological primary care methods for giving up tobacco dependency [Efectividad de los métodos no farmacológicos para la deshabituación tabáquica en atención primaria]. *Atencion Primaria* 2003;**32**(6):366-70.

* Sanz-Pozo B, Miguel-Díez J, Anegon-Blanco M, García-Carballo M, Gómez-Suárez E, Fernández-Domínguez JF. Effectiveness of a programme of intensive tobacco counselling by nursing professionals [Efectividad de un programa de consejo antitabaco intensivo realizado por profesionales de enfermería]. *Atencion Primaria* 2006;**37**(5):266-72.

Savant 2013 *{published data only}*

Savant SC, Hegde-Shetiya S, Agarwal D, Shirhatti R, Shetty D. Effectiveness of individual and group counseling for cessation of tobacco habit amongst industrial workers in Pimpri, Pune--an interventional study. *Asian Pacific Journal of Cancer Prevention* 2013;**14**(2):1133-9. [CENTRAL: 996880; CRS: 9400129000002967; PUBMED: 23621201]

Schnoll 2005 *{published data only}*

Schnoll RA, Rothman RL, Wielt DB, Lerman C, Pedri H, Wang H, et al. A randomized pilot study of cognitive-behavioral therapy versus basic health education for smoking cessation among cancer patients. *Annals of Behavioral Medicine* 2005;**30**(1):1-11.

Schwartz 1967 *{published data only}*

Schwartz JL, Dubitzky M. Clinical reduction of smoking: a California study. *Addiction* 1967;**14**:35-44.

Secades-Villa 2009 *{published data only}*

Secades-Villa R, Alonso-Pérez F, García-Rodríguez O, Fernández-Hermida JR. Effectiveness of three intensities of smoking cessation treatment in primary care. *Psychological Reports* 2009;**105**(3 Pt 1):747-58. [CENTRAL: 729739; CRS: 9400123000005462; PUBMED: 20099536]

Sherman 2007 *{published data only}*

Sherman SE, Estrada M, Lanto AB, Farmer MM, Aldana I. Effectiveness of an on-call counselor at increasing smoking treatment. *Journal of General Internal Medicine* 2007;**22**(8):1125-31.

Soria 2006 *{published data only}*

Soria R, Legido A, Escolano C, Yeste AL, Montoya J. A randomised controlled trial of motivational interviewing for smoking cessation. *British Journal of General Practice* 2006;**56**(531):768-74.

Stein 2006 *{published data only}*

Stein MD, Weinstock MC, Anderson BJ, Anthony JL. Relationship of depression to smoking outcomes in a methadone-maintained population. *Journal of Addictive Diseases* 2007;**26**(1):35-40.

* Stein MD, Weinstock MC, Herman DS, Anderson BJ, Anthony JL, Niaura R. A smoking cessation intervention for the methadone-maintained. *Addiction* 2006;**101**(4):599-607.

Stevens 2000 *{published data only}*

Stevens VJ, Glasgow RE, Hollis JF, Mount K. Implementation and effectiveness of a brief smoking-cessation intervention for hospital patients. *Medical Care* 2000;**38**(5):451-9.

Williams 2006 *{published data only}*

Figueroa-Moseley CD, Williams GC, Morrow GR, Jean-Pierre P, Carroll J, Ryan J. Empowered to stop smoking: The impact of a SDT smoking cessation intervention on economically disadvantaged whites and blacks. *Journal of Clinical Oncology* 2006;**24**(18 Suppl):51S.

* Williams GC, McGregor H, Sharp D, Kouides RW, Levesque CS, Ryan RM, et al. A self-determination multiple risk intervention trial to improve smokers' health. *Journal of General Internal Medicine* 2006;**21**(12):1288-94.

Williams GC, McGregor HA, Sharp D, Levesque C, Kouides RW, Ryan RM, et al. Testing a self-determination theory intervention for motivating tobacco cessation: supporting autonomy and competence in a clinical trial. *Health Psychology* 2006;**25**:91-101.

Williams GC, Minicucci DS, Kouides RW, Levesque CS, Chirkov VI, Ryan RM, et al. Self-determination, smoking, diet and health. *Health Education Research* 2002;**17**(5):512-21.

Wittchen 2011 *{published data only}*

Wittchen HU, Hoch E, Klotsche J, Muehlig S. Smoking cessation in primary care - a randomized controlled trial of bupropione, nicotine replacements, CBT and a minimal intervention. *International Journal of Methods in Psychiatric Research* 2011;**20**(1):28-39. [CENTRAL: 799983; CRS: 9400123000009843; 6422; PUBMED: 21574208]

Woodruff 2002 *{published data only}*

Woodruff SI, Talavera GA, Elder JP. Evaluation of a culturally appropriate smoking cessation intervention for Latinos. *Tobacco Control* 2002;**11**(4):361-7.

References to ongoing studies

Bonevski 2011 *{published data only}*

Bonevski B, Paul C, D'Este C, Sanson-Fisher R, West R, Girgis A, et al. RCT of a client-centred, caseworker-delivered smoking cessation intervention for a socially disadvantaged population. *BMC Public Health* 2011;**11**(1):70. [CENTRAL: 812695; CRS: 9400123000013400; 6412; PUBMED: 21281519]

Garvey 2012a *{published data only}*

Garvey AJ, Kalman D, Hoskinson RA, Kinnunen T, Armour CD, Copp S, et al. Effects of extended-duration counseling vs. shorter-duration counseling after 1.5 years of follow-up (POS4-49). Society for Research on Nicotine and Tobacco 18th Annual Meeting March 13-16, 2012, Houston, Texas. 2012:139. [CENTRAL: 814595; CRS: 9400103000000026]

Additional references

AHCPR 1996

Fiore MC, Bailey WC, Cohen SJ, et al. Smoking Cessation. Clinical Practice Guideline No 18. AHCPR Publication No. 96-0692. Rockville (MD): U.S. Department of Health and Human Services, Agency for Health Care Policy and Research, April 1996.

Cahill 2014

Cahill K, Lancaster T. Workplace interventions for smoking cessation. *Cochrane Database of Systematic Reviews* 2014, Issue 2. [DOI: 10.1002/14651858.CD003440.pub4]

Chamberlain 2013

Chamberlain C, O'Mara-Eves A, Oliver S, Caird JR, Perlen SM, Eades SJ, Thomas J. Psychosocial interventions for supporting women to stop smoking in pregnancy. *Cochrane Database of Systematic Reviews* 2013, Issue 10. [DOI: 10.1002/14651858.CD001055.pub4]

de Bruin 2016

de Bruin M, Viechtbauer W, Eisma MC, Hartmann-Boyce J, West R, Bull E, et al. Identifying effective behavioural components of Intervention and Comparison group support provided in SMOKing cEssation (IC-SMOKE) interventions: a systematic review protocol. *Systematic Reviews* 2016;**5**:77.

Fiore 2000

Fiore MC, Bailey WC, Cohen SJ, et al. Treating Tobacco Use and Dependence. A Clinical Practice Guideline. AHRQ publication No. 00-0032. Rockville, MD: US Dept of Health and Human Services, 2000.

Fiore 2008

Fiore MC, Jaén CR, Baker TB, et al. Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline; www.ncbi.nlm.nih.gov/books/NBK63952/. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service, May 2008.

Greenland 1985

Greenland S, Robbins J. Estimation of a common effect parameter from sparse follow-up data. *Biometrics* 1985;**41**(1):55-68.

Hartmann-Boyce 2014

Hartmann-Boyce J, Lancaster T, Stead LF. Print-based self-help interventions for smoking cessation. *Cochrane Database of Systematic Reviews* 2014, Issue 6. [DOI: 10.1002/14651858.CD001118.pub3]

Higgins 2003

Higgins JPT, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analysis. *BMJ* 2003;**327**(7414):557-60.

Lindson-Hawley 2015

Lindson-Hawley N, Thompson TP, Begh R. Motivational interviewing for smoking cessation. *Cochrane Database of Systematic Reviews* 2015, Issue 3. [DOI: 10.1002/14651858.CD006936.pub3]

Rice 2013

Rice VH, Hartmann-Boyce J, Stead LF. Nursing interventions for smoking cessation. *Cochrane Database of Systematic Reviews* 2013, Issue 8. [DOI: 10.1002/14651858.CD001188.pub4]

Rigotti 2012

Rigotti NA, Clair C, Munafò MR, Stead LF. Interventions for smoking cessation in hospitalised patients. *Cochrane Database of Systematic Reviews* 2012, Issue 5. [DOI: 10.1002/14651858.CD001837.pub3]

Stead 2008

Stead LF, Perera R, Bullen C, Mant D, Lancaster T. Nicotine replacement therapy for smoking cessation. *Cochrane Database of Systematic Reviews* 2008, Issue 1. [DOI: 10.1002/14651858.CD000146.pub3]

Stead 2013a

Stead LF, Buitrago D, Preciado N, Sanchez G, Hartmann-Boyce J, Lancaster T. Physician advice for smoking cessation. *Cochrane Database of Systematic Reviews* 2013, Issue 5. [DOI: 10.1002/14651858.CD000165.pub4]

Stead 2013b

Stead LF, Hartmann-Boyce J, Perera T, Lancaster T. Telephone counselling for smoking cessation. *Cochrane Database of Systematic Reviews* 2013, Issue 8. [DOI: 10.1002/14651858.CD002850.pub3]

Stead 2015

Stead LF, Koilpillai P, Lancaster T. Additional behavioural support as an adjunct to pharmacotherapy for smoking cessation. *Cochrane Database of Systematic Reviews* 2015, Issue 10. [DOI: 10.1002/14651858.CD009670.pub3]

Stead 2016

Stead LF, Koilpillai P, Fanshawe TR, Lancaster T. Combined pharmacotherapy and behavioural interventions for smoking cessation. *Cochrane Database of Systematic Reviews* 2016, Issue 3. [DOI: 10.1002/14651858.CD008286.pub3]

Stead 2017

Stead LF, Carroll AJ, Lancaster T. Group behaviour therapy programmes for smoking cessation. *Cochrane Database of Systematic Reviews* 2017, Issue 3. [DOI: 10.1002/14651858.CD001007.pub3]

References to other published versions of this review

Lancaster 2002

Lancaster TR, Stead LF. Individual behavioural counselling for smoking cessation. *Cochrane Database of Systematic Reviews* 2002, Issue 3. [DOI: 10.1002/14651858.CD001292]

Lancaster 2005b

Lancaster T, Stead LF. Individual behavioural counselling for smoking cessation. *Cochrane Database of Systematic Reviews* 2005, Issue 2. [DOI: 10.1002/14651858.CD001292.pub2]

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Ahluwalia 2006

Methods	Study design: Randomized controlled trial Setting: Community health centre, USA Recruitment: community volunteers interested in quitting
Participants	755 African-American light smokers (≤ 10 cpd) 67% women, av. age 45, av. cpd 8
Interventions	Therapists: trained counsellors Factorial trial, 2 mg nicotine gum/placebo arms collapsed for this review 1. Counselling using motivational interviewing (MI) approach. 3 in-person visits at randomization, wk 1, wk 8, and phone contact at wk 3, wk 6, wk 16, S-H materials 2. Counselling using health education (HE) approach. Same schedule and materials as 1
Outcomes	PP abstinence at 6m (7-day PP) Validation: cotinine ≤ 20 ng/ml
Notes	Not in main analysis; compares 2 counselling styles. No significant effect of gum, no evidence of interaction.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Centrally generated blocked scheme, block size 36
Allocation concealment (selection bias)	Low risk	Sealed envelopes opened sequentially
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence planned, but low level of cotinine validation. All participants received same level of contact so risk of differential misreporting judged to be low
Incomplete outcome data (attrition bias) All outcomes	Low risk	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

Aleixandre 1998

Methods	Study design: Randomized controlled trial Setting: Primary care clinic, Spain

Aleixandre 1998 *(Continued)*

	Recruitment: clinic and community volunteers
Participants	48 smokers (excludes 6 dropouts) 65% women, av. age 36, av. cpd 24 - 27
Interventions	Therapist: unclear, primary care clinic staff 1. 'Advanced', 4 x 30-min over 4 wks, video, cognitive therapy, social influences, relapse prevention 2. 'Minimal' 3-min advice immediately after randomization
Outcomes	Abstinence at 12 m Validation: no biochemical validation
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Stratified on cigarette consumption and age, block size 4.
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	No validation of abstinence and different levels of contact
Incomplete outcome data (attrition bias) All outcomes	Low risk	6 post-randomization dropouts excluded from ITT analyses. Their inclusion would marginally increase effect size

Alterman 2001

Methods	Study design: Randomized controlled trial Setting: cessation clinic, USA Recruitment: community volunteers
Participants	240 smokers of > 1 pack/day 45% - 54% women, av. age 40, av. cpd 27
Interventions	Therapists: Nurse practitioners (NP) and trained counsellors 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 < 50 ng/ml, CO ≤ 9ppm
Notes	Only contributes to intensive versus minimal intervention, using 3 vs 2+1. Quit rates significantly lower in 2 than 1 or 3. Using 3 vs 1; 26/80 vs 20/80; RR 1.30 [0.79, 2.13]. Using 3 vs 2; 26/80 vs 9/80; RR 2.89 [1.45, 5.77]. Overall estimate in 2016 no longer sensitive to choice of arms

Alterman 2001 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Urn technique'
Allocation concealment (selection bias)	Unclear risk	No details given. Allocation took place after baseline session common to all conditions
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	30 (12.5%) lost to follow-up included in ITT analysis

Aveyard 2007

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

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random-number generator
Allocation concealment (selection bias)	Low risk	Numbered sealed envelopes
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence; staff making follow-up calls were blind

Aveyard 2007 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	288 (31%) lost to follow-up, similar across groups, included in ITT analysis

Bobo 1998

Methods	Study design: Cluster-randomized controlled trial Setting: 12 residential centres for alcohol/drug treatment, USA Recruitment: inpatient volunteers
Participants	(50 participants in each of 12 sites) 67% men, av. age 33 50% smoked > 1 pack/day
Interventions	Therapists: centre staff for 1st session, trained counsellors for telephone sessions 1. 4 x 10 - 15 min sessions. 1st during inpatient stay. 3 by telephone, 8, 12, 16 wks post-discharge 2. No intervention
Outcomes	Abstinence at 12 m 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. Adjusted OR 1.02 (CI 0.50 to 2.49). Inclusion would not materially change results of analysis 1.1.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Matched pairs of centres allocated by coin toss, 2 centres declined participation after allocation
Allocation concealment (selection bias)	High risk	Cluster-randomized with participant recruitment (by research team) after centre allocation so potential for selection bias
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Biochemical validation of abstinence but validated results not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	22% lost to follow-up. Including them as smokers made little difference to estimates

Bronson 1989

Methods	Study design: Randomized controlled trial Setting: internal medicine practice, USA Recruitment: attenders for periodic health examinations
Participants	155 smokers 38% men, av. age 42, av. cpd 25

Bronson 1989 *(Continued)*

Interventions	Therapist: smoking cessation counsellor 1. 2 x 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
Outcomes	Abstinence at 18 m (sustained from 6 - 18 m) Validation: no biochemical validation at 18 m, limited sample for saliva cotinine at 6 m
Notes	18 m data reported in Secker-Walker 1990

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomized, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Physicians carrying out health examinations were blind to group assignment and would have given similar advice to all participants Long-term abstinence not validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	20 (13%) not contacted at 6 m and 18 m, included in ITT analysis

Brunner 2012

Methods	Study design: Randomized controlled trial Setting: Single hospital, Denmark Recruitment: Inpatients with acute ischaemic stroke or TIA invited to participate
Participants	94 inpatients
Interventions	Therapists: Single study nurse provided initial session for all participants, and 5 telephone and 1 outpatient session. Main counselling by"'authorized smoking cessation instructor" 1. Minimal intervention: 1 x 30-min session, offer of nicotine patch during hospital stay 2. Intensive intervention; additional 5 outpatient sessions from counsellor, duration NS. Study nurse also offered 30-min session at 6 wks and 5 telephone sessions at 2 days, 1 wk, 3 wks, 3 m, 4 m. Free samples of NRT
Outcomes	Abstinence 6m after discharge Validation: CO < 8 ppm
Notes	New for 2016 update Contributes to comparison of more versus less intensive Analysis 2.1 (no pharma subgroup) only. 8 minimal and 29 intensive intervention participants used NRT at some time

Brunner 2012 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patients were randomized using a computer-generated list of odd and even numbers. These numbers, representing minimal and intensive smoking cessation intervention, respectively, were used to create consecutive numbered sealed envelopes."
Allocation concealment (selection bias)	High risk	"After having obtained informed consent, the study nurse opened the randomization envelope and the patients were informed to which intervention they had been assigned." No mention that envelopes were opaque. Intensive intervention participants more likely to be younger, male, heavier smokers, suggesting possibility of selection bias
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up small and similar between conditions

Burling 1991

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

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomized, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	No validation, but no self-reported quitters

Burling 1991 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Loss to follow-up not reported

Burling 2001

Methods	Study design: Randomized controlled trial Setting: Inpatient veterans rehabilitation centre, USA Recruitment: inpatient volunteers
Participants	150 veteran drug- and alcohol-dependent smokers 95% men, av. age 40, av. cpd 17
Interventions	Therapists: Masters/Doctoral level counsellors All participants were receiving standard substance abuse treatment, smoking banned in building. 1. Multicomponent. 9-wk programme; 7 wks daily counselling, 2 wks bi-weekly. TQD 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 and alcohol relapse prevention 3. Usual care. Other programmes and NRT available
Outcomes	Abstinence at 12m (sustained at 1, 3, 6 m follow-ups) Continuous abstinence rates taken from graph and abstract. PP rates also reported Validation: CO and 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

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomized, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	12 (8%) lost to follow-up included in ITT analysis

Chan 2012

Methods	Study design: Randomized controlled trial Country: Hong Kong

Chan 2012 *(Continued)*

	Recruitment: Cardiac outpatient clinics at 10 major hospitals
Participants	1860 Chinese cardiac patients smoking ≥ 1 cig in past week. 91% men, av. age 58, av. cpd 12. Excluded from study if "too clinically ill."
Interventions	Therapist: nurse counsellors 1. Intervention: At baseline, 30-min individual face-to-face counselling matched to stage of readiness to quit. At 1 wk and 1 m: telephone calls from nurse counsellor, re-assessment of stage and counselling to suit that stage, av. phone call length 15 mins 2. Control: 15-min, individual face-to-face counselling on healthy diet from nurse counsellor at baseline Pharmacotherapy: No smoking cessation drugs provided, but stage-matched medication counselling on NRT was discussed with intervention participants "if deemed appropriate".
Outcomes	7-day PP at 12 m (30-day PP at 12 m and 3 m and 6 m outcomes also reported) Validation: CO ≤ 8 ppm, urinary cotinine < 100 ng/ml
Notes	New for 2016 update Validated rates used in MA; only about 25% of people self-reporting abstinence were validated. Participants in intervention group had higher stage of readiness to quit smoking than in the control group. Adjusted OR provided in text (unadjusted OR 1.35, 95% CI 0.91 to 2.00; adjusted OR 1.26, 95% CI 0.85 to 1.87); numbers used in MA are unadjusted. 54% intervention received all counselling.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The allocation sequence was generated sequentially by the project co-ordinator based on simple random sampling procedure using MS Excel."
Allocation concealment (selection bias)	Low risk	"serially numbered sealed and opaque envelope"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar rates of follow-up in both groups at 12 m (85.5% intervention and 84.3% control) "No statistically significant difference was found between the two groups." ITT analysis conducted, 25 who died during study removed from denominators

Chen 2014

Methods	Study design: Randomied controlled trial Setting: Hospital, China Recruitment: community volunteers and referrals from outpatient clinics
Participants	190 smokers, > 1 cpd, 97% men, av.age 50, av. cpd 20. All had lung function tests; 85 had COPD and 105 were asymptomatic

Chen 2014 *(Continued)*

Interventions	Therapist: "Interventions provided by 2 doctors with experience of professional smoking cessation treatment." 1. Cognitive counselling, 20 mins at baseline and 9 calls > 10 mins at 1 - 4 wks, 6 wks, 8 wks, 3 - 5 m. S-H materials 2. Brief advice
Outcomes	Abstinence at 6 m sustained from week 4 Validation: CO < 10 ppm
Notes	New for 2016 update

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"assigned to the intervention or control group according to the randomized digital table" stratified by motivation to quit
Allocation concealment (selection bias)	Unclear risk	No further details
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	12 withdrawals included as smokers

Cropsey 2015

Methods	Study design: Randomized controlled trial Setting: Community corrections facility, USA Recruitment: smokers under community corrections supervision
Participants	500 smokers; 33% women; av. age 37.4; av. cpd 17.9
Interventions	Therapist: Clincal psychologist 1. Control. Brief physician advice to set TQD 1 - 2 wks after starting bupropion, stressed adherence 2. Intervention. As 1. plus 4 x 20 - 30-min counselling sessions; cognitive and behavioural strategies Pharmacotherapy: All participants received bupropion for 12 wks
Outcomes	Abstinence at 12 m (PP) Validation: CO ≤ 3 ppm at all visits
Notes	New for 2016 update Paper reports differential abstinence by race. Author confirmed quit rates in Fig 2, used to calculate numbers quit

Cropsey 2015 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomized, blocked on race, no further details
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	23% I, 26% C lost to follow-up

Dornelas 2000

Methods	Study design: Randomized controlled trial Setting: Hospital inpatients, USA Recruitment: Acute MI patients (not selected for motivation to quit)
Participants	100 MI patients (98% smoked in previous wk) 23% women, aged 27 - 83, av. cpd 29
Interventions	Therapist: Psychologist 1. 8 x 20-min sessions, 1st during hospitalization, 7 by phone (< 1, 4, 8, 12, 20 and 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

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	"drawing random numbers from an envelope"
Allocation concealment (selection bias)	High risk	as above
Blinding of outcome assessment (detection bias) All outcomes	High risk	No biochemical validation
Incomplete outcome data (attrition bias) All outcomes	Low risk	20 (20%) lost to follow-up included in ITT analysis

Fiore 2004

Methods	Study design: Randomized controlled trial Setting: Primary care patients, 16 clinics, USA Recruitment: Clinic attenders willing to accept treatment
Participants	961 smokers of 10+ cpd. (A further 908 were allowed to select treatment. Demographic details based on 1869) 58% women, av. age 40, av. cpd 22
Interventions	Therapists: Trained cessation counsellors (Self-selected group of factorial trial not included in meta-analysis) 1. Nicotine patch, 22 mg, 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 and 2 used in meta-analysis. More conservative than 3 versus 2.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomized, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	Denominators in meta-analysis based on numbers who collected patches (85%, similar across arms)

Garvey 2012

Methods	Study design: Randomized controlled trial Setting: Smoking cessation research clinic, Boston USA Recruitment: Community volunteers, motivated to quit
Participants	278 smokers of ≥ 5 cpd. 53% women, av. age 47, av. cpd 18
Interventions	Therapist: MA or BA in psychology, 3 full days training Both group received nicotine patches for 12 weeks, dose tailored to baseline smoking

Garvey 2012 *(Continued)*

	1. Front-loaded CBT-based counselling; 2 pre-quit and 12 post-quit, 6 post-quit sessions received in first 2 weeks. Pre-quit sessions approx. 45 mins each, post-quit 20 - 30 mins. Last 3 sessions at 6 m, 9 m, 12 m 2. Weekly counselling. Same number and duration of sessions, but weekly to 12 wks
Outcomes	Continuous abstinence from quit date at 12 m, (never smoking for 7+ consecutive days nor for 7+ consecutive episodes and PP also reported) Validation: CO < 8 ppm
Notes	New for 2016 update Analysis 3, not pooled with other studies. Authors report significantly lower likelihood of relapse, using hazard ratio and continuous abstinence to define relapse. Risk ratio based on 11.7% versus 6.3% abstinent at 12 m is not significant

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Block randomization, method of sequence generation not described
Allocation concealment (selection bias)	Unclear risk	"randomization occurred at the end of the baseline visit following the consenting process and administration of baseline measures" but no additional information
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	20 (14%) front-loaded and 16 (11.5%) weekly did not start or dropped out before quit date. Not included in denominators for MA. Later losses treated as smokers

Glasgow 2000

Methods	Study design: Randomized controlled trial Setting: 4 Planned Parenthood clinics, USA Recruitment: Clinic attenders, unselected for motivation
Participants	1154 female smokers Av. age 24, av. cpd 12
Interventions	Therapists: 4 hours training Both groups received 20-sec provider advice. 1. Video (9 mins) 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 6 m (for 30 days) Validation: saliva cotinine ≤ 10 ng/ml
Notes	26% did not want telephone component, 31% of remainder not reached

Glasgow 2000 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomized, block size 4, fixed schedule
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	10% loss to follow-up included in ITT analysis

Hannover 2009

Methods	Study design: Randomized controlled trial Setting: Maternity wards in 6 hospitals, Germany Recruitment: Women in hospital post partum
Participants	379 women who were smoking postpartum (subgroup of trial participants). av. age for all participants 26, av. cpd 14
Interventions	Therapist: 4 counsellors trained in motivational interviewing 1. Counselling; face-to-face session in mothers' homes, duration NS, 2 phone boosters at 4 and 12 wks 2. Usual care and S-H materials at screening
Outcomes	Sustained abstinence at 24 m (PP also reported, followed up at 6, 12, 18 m) Validation: none
Notes	New for 2016 update Using earlier or PP outcome would not affect meta-analysis

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	"simple randomization .... allocating women to either intervention or control group alternating in the order on the screening forms". Whether the allocation sequence would begin with treatment or control condition was decided ad hoc.
Allocation concealment (selection bias)	High risk	No possibility of concealment
Blinding of outcome assessment (detection bias)	High risk	No biochemical validation of abstinence

Hannover 2009 *(Continued)*

All outcomes		
Incomplete outcome data (attrition bias) All outcomes	Low risk	16% intervention and 6% control lost or withdrew

Hennrikus 2005

Methods	Study design: Randomized controlled trial Setting: 4 hospitals, USA Recruitment: Newly-admitted inpatients invited to participate, not selected by motivation
Participants	2095 current smokers 53% women, av. age 47, cpd NS, 15 - 20% precontemplators
Interventions	Therapists: research nurses with 12 hours training 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 wks, 1 m, 6 m)
Outcomes	Abstinence at 12 m (7-day PP) Validation: saliva cotinine < 15 ng/ml
Notes	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. Authors reported relatively high and differential levels of refusal to provide samples, and samples that failed to confirm abstinence

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"randomly ordered within blocks of 30 assignments"
Allocation concealment (selection bias)	Unclear risk	Allocation by research assistant, concealment not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	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 from treatment than control

Hennrikus 2010

Methods	Study design: Randomized controlled trial Setting: 2 medical centres; USA

Hennrikus 2010 *(Continued)*

	Recruitment: probable smokers with lower extremity PAD
Participants	687 current smokers with PAD; 15% women, av. age 60, av. cpd 18
Interventions	Therapists: smoking cessation counsellor 1. Verbal advice to quit from vascular provider 2. Letter from vascular provider + intensive counselling, at least 6 sessions over 5 m, first in person then phone. Information about pharmacotherapies but not provided
Outcomes	Abstinence at 6 m (PP) Validation: saliva cotinine < 10 ng/ml, or CO < 8 ppm for people using NRT
Notes	New for 2016 update High use of pharmacotherapies in both groups; 87% in I, 67% in C

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"predetermined block randomization schedule stratified by medical center"
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	25% I, 17% C lost at 6 m. 4 deaths (3I, 1C) excluded from MA denominators

Jorenby 1995

Methods	Study design: Randomized controlled trial Setting: Clinical research centres, USA (2 sites) Recruitment: community volunteers
Participants	504 smokers 15+ cpd av. age 44, av. cpd 26 - 29
Interventions	Therapists: Trained smoking cessation counsellors 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 x 3 after TQD Counsellor helped generate problem-solving strategies and provided praise and encouragement 3. Group - S-H + motivational message. 8 x 1-hr weekly group sessions. Skills training, problem-solving skills

Jorenby 1995 *(Continued)*

Outcomes	7-day PP abstinence at 26 wks Validation; CO < 10 ppm
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

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomized, method not stated
Allocation concealment (selection bias)	Unclear risk	"In a double blind manner" for NRT, but not specified for counselling
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	16.3% lost to follow-up included in ITT analysis, no difference across conditions

Killen 2008

Methods	Study design: Randomized controlled trial Setting: Community cessation clinic, USA Recruitment: Community volunteers
Participants	301 smokers (≥ 10 cpd or 3.5 packs/wk) (excludes 3 participants who received wrong treatment); 40% women, av. age ˜46, av. cpd ˜20
Interventions	Therapists: 'one of three staff interventionists trained and supervised by the study psychologist and psychiatrist who had previous training in behavioral therapy' All participants received 6 x 30-min individual CBT sessions at baseline, TQD, 1, 2, 4, 6 wks, and combination pharmacotherapy (Bupropion (300 mg, 9 wks) and NRT (21 mg patch, 8 wks incl tapering)) 1. Extended therapy: 4 x 30-min sessions at 8, 12, 16, 20 wks, and weekly check in calls to automated system; report of relapse or craving prompted proactive calls 2. Standard therapy: 5-min general support calls at 8, 12, 16, 20 wks
Outcomes	Abstinence at 52 wks (7-day abstinence at both 20 and 52 wks) (Continuous abstinence also reported but not used in MA as could underestimate any effect on recycling) Validation: CO < 10 ppm (11 self-reported quitters no longer living in study area accepted as quitters without validation)
Notes	New for 2016 update. Tested extended duration therapy, contributes only to comparison of counselling intensity (Analysis 2.1)

Risk of bias

Killen 2008 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomized using a permuted block method (block size = 4), stratified on gender
Allocation concealment (selection bias)	Low risk	Participants assigned to next available ID number in corresponding gender. Researchers and participants were blinded to extended treatment assignment to the end of the open-label phase
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	89% followed up in standard-care group, 90% followed up intervention group

Kim 2005

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

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"random list determined by fixed randomization with an allocation ratio of 1:1, a block size of 6 and 12 allocation strata"
Allocation concealment (selection bias)	Low risk	"sealed opaque envelopes which the counselors opened at the formal enrollment of the study participants" (judged low based on level of detail provided)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence

Kim 2005 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	7 lost to follow-up included in ITT analysis

Kim 2015

Methods	Study design: Randomized controlled trial Setting: Korean community, USA Recruitment: Korean smokers wanting to quit
Participants	109 Korean smokers; 16% women, av. age 50, av. cpd 17
Interventions	Therapist: 1 of 2 Korean bilingual clinicians 1. Culturally-tailored counselling; 8 x 40-min weekly sessions, TQD between 2nd and 4th 2. Minimal counselling; 8 x 10-min weekly sessions focusing on medication management Pharmacotherapy: all participants received 8-week supply of nicotine patch
Outcomes	Abstinence at 6 m Validation: cotinine (Nicalert 1 < 10 - 30 ng/ml), CO < 6 ppm
Notes	New for 2016 update Contributes to comparison 2.1.2 more intensive vs less intensive counselling with pharmacotherapy Kim 2012 assumed to report a subset of these participants but unable to confirm with author

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated, stratified by gender
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	24% (13/55) I, 31% (17/54) C lost, included as smokers in analyses

Lifrak 1997

Methods	Study design: Randomized controlled trial Setting: substance abuse outpatient facility, USA

Lifrak 1997 *(Continued)*

	Recruitment: community volunteers
Participants	69 smokers av. age 39, av. cpd 25
Interventions	Therapists: nurse practitioner for 1 and 2, clinical social worker or psychiatrist experienced in addiction treatment for 2. 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 12 m, 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

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Block randomization (block size 10)
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Some biochemical validation of abstinence, all participants had active therapy
Incomplete outcome data (attrition bias) All outcomes	Low risk	12 administrative dropouts/exclusions not included, treatment group not specified. All others included

Marley 2014

Methods	Study design: Randomized controlled trial Setting: 2 Aboriginal Community Controlled Health Services (ACCHS) centres; Australia Recruitment: Active and passive - Aboriginal and Torres Strait Islander smokers (current or who had quit within 2 weeks of enrolling) wishing to quit smoking or cut down on the amount of cigarettes they smoked
Participants	163 smokers; 54% women; av. cpd 15
Interventions	Therapists: smoking cessation counsellors 1. Usual care: routine care relating to smoking cessation at local primary healthcare service, including advice on quitting, pharmacotherapy, and self-initiated follow-up 2. Usual care plus smoking cessation counselling at face-to-face visits, weekly for the first 4 wks, monthly to 6 m and 2-monthly to 12 m (12 sessions)
Outcomes	Abstinence at 12 m (7-day PP)

Marley 2014 *(Continued)*

	Validation: urine cotinine < 50 ng/mL
Notes	New for 2016 update

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated, held centrally
Allocation concealment (selection bias)	Low risk	Sealed envelopes held centrally. Allocation via telephone after enrolment
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence (and staff doing assay blinded)
Incomplete outcome data (attrition bias) All outcomes	Low risk	12% lost overall, 4 deaths (3I , 1C) and 1C withdrew consent not included in MA denominators

Marshall 2016

Methods	Study design: Randomized controlled trial Setting: Lung cancer screening study, Australia Recruitment: Smokers participating in a lung cancer screening study, volunteering for substudy
Participants	55 smokers, 36% women, av. age 63, av. cpd 25
Interventions	Therapist: single thoracic physician 1. Single counselling session; tailored motivational approach inducing discussion of lung function results and lung cancer risk (but not scan results). Planned duration not reported; mean duration 26.5 mins. Same materials and referral as control 2. Standard S-H materials and Quitline referral
Outcomes	Abstinence at 12 m (PP) Validation: CO < 10 ppm but only 4 tested
Notes	New for 2016 update Pilot study. Treated as counselling because physician not providing intervention as part of usual care

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"random number generator"
Allocation concealment (selection bias)	Low risk	"concealed randomization" - judged low risk

Marshall 2016 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Incomplete validation
Incomplete outcome data (attrition bias) All outcomes	Low risk	5 losses coded as smokers

McCarthy 2008

Methods	Study design: Randomized controlled trial Setting: Clinic, USA Recruitment: community volunteers
Participants	463 smokers 50% women, av. age 36 - 41 across arms, av. cpd 22
Interventions	Therapists: trained college-aged or bachelor's level staff, supervised by experienced counsellor Factorial trial. Bupropion/placebo pharmacotherapy arms collapsed 1. Counselling; 8 x 10-min sessions, 2 prequit, TQD, 5 over 4 wks 2. Psychoeducation about medication, support and encouragement. Same no. of sessions, 80 mins less contact time
Outcomes	7-day PP abstinence at 12 m Validation: CO ≤ 10 ppm
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Low risk	Staff who screened and enrolled participants were unaware of the experimental condition to be assigned
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	171 (37%) failed to attend quit date visit or lost to follow-up, included in ITT analysis

Molyneux 2003

Methods	Study design: Randomized controlled trial Setting: Hospital, UK Recruitment: Hospital inpatients

Molyneux 2003 *(Continued)*

Participants	274 smokers (183 in relevant arms) admitted to medical and surgical wards, smoked in last 28 days 60% men, av. age 60, median cpd 17, 81% had previous quit attempt
Interventions	Therapists: research doctor or nurse trained in cessation counselling 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 12 m Validation: CO < 10 ppm
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"List generated for each centre allocating equally in random permuted blocks of nine."
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	72 (39%) lost to follow-up included in ITT analysis

Mueller 2012

Methods	Study design: Randomized controlled trial Country: Switzerland Recruitment: Individuals enrolled in a 21-day inpatient alcohol detoxification treatment programme
Participants	103 alcohol-dependent smokers with stay long enough to complete 10-day treatment programme; 29% women, av. age 44; av. cpd 25.5 I/30.5 C
Interventions	Therapists: 2 psychologists 1 Intervention: 5 x 30-min cognitive behavioral therapy sessions focused on smoking cessation 2 Control: Autogenic training (relaxation) Participants intending to quit offered nicotine patch during inpatient phase
Outcomes	Abstinence at 6 m (PP) Verification: CO < 10 ppm, cotinine
Notes	New for 2016 update. Some participants were treated individually and some in small groups

Mueller 2012 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomized, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	High risk	High and differential loss to follow-up; 53% I, 34% C. (All participants lost to follow-up classified as non-abstinent in analyses)

Nakamura 2004

Methods	Study design: Randomized controlled trial Setting: communities and worksites, Japan Recruitment: Smokers with hypertension and/or hypercholesterolaemia having health check-ups
Participants	977 smokers 98% men, av. age 45, av. cpd 25, ~20% in preparation/ contemplation
Interventions	Therapists: mostly public health nurses 1. Intervention: Stage-base counselling, 1 x 40-min, 4 x 20 - 30-min at 1, 2, 4, 6 m. + phone call if TQD set 2. Control: Matched contact intervention for hypertension (161) or hypercholesterolaemia (318)
Outcomes	Abstinence at 6 m, sustained 4 PP at 1, 2, 4, 6 m Validation: CO ≤ 8 ppm
Notes	Recruited a largely unmotivated population

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method not stated
Allocation concealment (selection bias)	Unclear risk	No information given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	54 (5.5%) lost to follow-up included in ITT analysis

Nohlert 2009

Methods	Study design: Randomized controlled trial Setting: Dental clinics, Sweden Recruitment: smokers identified by dental and healthcare personnel screening, accepting support
Participants	300 smokers, 80% women, av. cpd 15
Interventions	Therapists: 3 trained dental hygienists 1. High-intensity counselling; 8 x 40-mins over 4 m 2. Low-intensity counselling; 1 x 30-min session explaining an 8 wk S-H programme Both conditions given information on NRT but no recommendation on whether to use
Outcomes	Continuous abstinence at 1 yr, PP also reported (Nohlert 2009). (6-yr follow-up in Nohlert 2013) Validation: none
Notes	New for 2016 update Half the participants had used NRT, no difference in use between conditions

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	randomized "... independent person using an envelope technique in blocks of four"
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding of outcome assessment (detection bias) All outcomes	High risk	No biochemical validation
Incomplete outcome data (attrition bias) All outcomes	Low risk	< 10% lost in each arm at 1 yr. 6 baseline dropouts not included in MA denominator

Ockene 1992

Methods	Study design: Randomized controlled trial 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 12 m follow-up) av. age 53, av. cpd 25
Interventions	Therapists: Masters-level health educators 1. Minimal intervention - 10-min advice and review of an information sheet

Ockene 1992 *(Continued)*

	2. Inpatient counselling session, 30 mins, outpatient visits and telephone calls. Opportunity to attend group programme
Outcomes	Abstinence at 12 m (sustained for 6 m) Validation: saliva cotinine < 20 ng/ml
Notes	Average length of contact for intervention was 1.22 hrs (20 mins to > 5 hrs)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method not stated
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	No mention of losses to follow-up and all survivors included in denominators.

Okuyemi 2013

Methods	Study design: Randomized controlled trial Setting: 8 emergency homeless shelters and transitional housing units in Minneapolis/St Paul, Minnesota, USA Recruitment: through health fairs, staff informational sessions, fliers at homeless shelters and word of mouth
Participants	430 homeless adult smokers; 75% men; av. age 44; cpd 19; motivated to quit
Interventions	Therapists: Counsellors 1. Control: Brief advice 10 - 15 mins 2. Intervention: 6 x 15 - 20-min MI counselling sessions, baseline and wks 1, 2, 4, 6 and 8 Pharmacotherapy: All participants in both groups received a 2-wk supply of 21 mg nicotine patches, every 2 wks over the 8-wk treatment period All participants received a health educational resource called *The Power to Quit: A Quit Smoking Guide*, developed by the project investigators
Outcomes	Abstinence at 6 m (7-day PP) Validation: CO ≤ 10 ppm. Salivary cotinine ≤ 20 ng/ml if CO > 10 ppm for those who self-reported abstinence
Notes	New for 2016 update

Okuyemi 2013 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomization schedule prepared by study statistician, but no detail given on how
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up, 22% (48/216) I 29% (63/214) C, all treated as smokers in MA

Pedersen 2005

Methods	Study design: Randomized controlled trial Setting: hospital, Denmark Recruitment: Inpatients with cardiac disease
Participants	105 smokers 36% women, ˜70% aged > 50
Interventions	Therapists: counsellors 1. Usual-care control: in-hospital advice to quit + information about NRT + NRT available 2. Intervention: As 1, plus 5 x 30-min post-discharge contacts
Outcomes	Abstinence at 12 m (PP) Validation: none
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomized, method not described
Allocation concealment (selection bias)	Unclear risk	Sealed envelopes, but not stated to be numbered
Blinding of outcome assessment (detection bias) All outcomes	High risk	No validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	10 (9.5%) lost to follow-up, included in ITT analysis

Pederson 1991

Methods	Study design: Randomized controlled trial Setting: Chest unit, USA Recruitment: Inpatients with COPD
Participants	74 cigarette smokers av. age 53, 75% smoked 20+ cpd
Interventions	Therapist: Non-specialist trained in counselling 1. Advice to quit 2. Individual counselling; between 3 and 8 15 - 20-min sessions on alternate days during hospitalizations S-H manual, support and encouragement
Outcomes	Abstinence at 6 m Sample validated by COHb
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Only sample validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	8 lost to follow-up were re-included in ITT analysis by review authors. 8 deaths excluded

Ramon 2013

Methods	Study design: Randomized controlled trial Setting: 6 smoking cessation clinics, Spain Recruitment: smokers of ≥ 10 cpd, motivated to quit
Participants	600 smokers (400 in relevant arms), 49% women, av. age 47, av. cpd ˜25
Interventions	Therapists: 'physician or psychologist specialized in smoking cessation' 1. Individual counselling; 8 x 15 - 20 mins, pre-quit then 3, 5, 7, 10, 12 , 24 and 52 wks 2. Telephone counselling; 3, 5, 7, 10, 12, 24 wks , and at the clinic at wk 52 3. Combination; 4 face-to-face and 3 telephone sessions

Ramon 2013 *(Continued)*

	All participants offered pharmacotherapy; 6% refused, of remainder 47% varenicline, 33% nicotine patches, 14% combination patches and gum/lozenges, 6% bupropion
Outcomes	Abstinence at 52 wks, sustained from wk 2 (PP also reported) Validation: CO < 10 ppm at wk 52 (8 misreports, evenly distributed)
Notes	New for 2016 update Comparison 3.1.5 1 and 3 vs 2, face-to-face or face-to-face and telephone-to-telephone only. Telephone condition split to avoid double counting

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"computer-generated randomization system based on a permuted block randomization list where each block was used by one centre."
Allocation concealment (selection bias)	Low risk	"An independent researcher in the coordination centre generated a random sequence, and centres were informed about smoker allocation after consent to participation"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up 12% Individual, 18% telephone

Ramos 2010

Methods	Study design: Randomized controlled trial Setting: Primary care clinics, Mallorca, Spain Recruitment; smokers "prepared and able to fix a date to quit smoking"
Participants	287 smokers, 54% women, av. age ˜44, av. cpd 20
Interventions	Therapists: “microteam,” composed of 1 physician and 1 nurse. They distributed the visits among themselves as they saw fit; all they were instructed to do was to conduct some of the visits together. 1. Intensive individual intervention, 6 sessions (duration and timing not described) 2. Intensive group-based intervention (duration and timing not described but stated to be longer than individual option) (not used in this review) 3. Minimal intervention
Outcomes	Abstinence at 12 m, continuous (PP also reported) Validation: CO, cut-off not described
Notes	New for 2016 update 1 vs 3 in comparison 1.1; comparison with group therapy covered in Cochrane review of group therapy

Ramos 2010 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomized, method not described
Allocation concealment (selection bias)	Low risk	"An allocation concealment method based on the use of sequentially-numbered, opaque, sealed envelopes was used ... A block of 60 envelopes (20 for III, 20 for IGI and 20 for MI) was prepared in the central research unit for each participating health centre and subsequently sent out."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	High risk	High loss to follow-up in all conditions; 69% Individual, 76% Minimal

Rigotti 1997

Methods	Study design: Randomized controlled trial 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
Interventions	Therapist: research assistant supervised by a nurse 1. Usual care 2. Single bedside counselling session (motivational interviewing, cognitive behavioural and relapse prevention techniques), av. 15 mins, S-H materials, chart prompts, 1 - 3 telephone calls post-discharge
Outcomes	Abstinence at 6 m (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

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Each day's list of eligible smokers put in random order and participants recruited consecutively in this order. Randomized by research assistant
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence for majority

Rigotti 1997 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	73 (22.4%) lost to follow-up included in ITT analysis, no evidence of differential loss. 35 (5.4%) deaths excluded

Schmitz 1999

Methods	Study design: Randomized controlled trial Setting: Hospital, USA Recruitment: women with or at risk of CAD
Participants	2 separate samples recruited: 53 inpatients with CAD who stopped smoking during hospitalization and wanted to stay quit 107 women volunteering for cessation treatment who had > 1 CAD risk factor
Interventions	Therapists: 2 smoking counsellors + 2 clinical psychology interns 1. Coping skills, relapse prevention, 6 x 1-hr including stress management, homework 2. Health Belief model, 6 x 1-hr, smoking-related health information about disease state or CAD profile Focus on benefits of stopping
Outcomes	Abstinence at 6 m (PP) Validation: CO < 9 ppm, urine cotinine < 10 ng/ml Not all quitters tested, confirmation rates not reported
Notes	Post-randomization dropouts 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

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Randomly assigned", stratified on smoking rate and myocardial infarction status
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Some validation of abstinence, arms had similar intensities of treatment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Pretreatment dropouts were excluded, all others included in ITT analysis

Simon 1997

Methods	Study design: Randomized controlled trial Setting: Veterans Administration hospital, USA Recruitment: smokers undergoing non-cardiac surgery

Simon 1997 *(Continued)*

Participants	299 smokers (smoked within 2 wks of admission) (excl 25 deaths) 98% men, av. age 54, av. cpd 20
Interventions	Therapist: public health educator 1. Multicomponent: single counselling session (30 - 60 mins) 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 3 m 2. Brief counselling (10 mins) and S-H materials
Outcomes	Abstinence at 12 m Validation: serum or saliva cotinine < 15 ng/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

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Random list of assignments"
Allocation concealment (selection bias)	Low risk	"Sealed opaque envelopes opened on formal enrollment"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	25 (8%) lost to follow-up included in ITT analysis, 25 (8%) died, excluded from denominator

Simon 2003

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

Simon 2003 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomly assigned using computerized algorithm"
Allocation concealment (selection bias)	Unclear risk	No details provided
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	7 (3%) lost to follow-up included in ITT analysis, 14 (6%) died and excluded from denominator

Stevens 1993

Methods	Study design: Controlled trial Setting: 2 Health Maintenance Organization hospitals, USA Recruitment: All hospitalized smokers or recent ex-smokers with stay > 36 hrs
Participants	1119 smokers or recent quitters (5%) av. age 44, av. cpd 20
Interventions	Therapists: Masters level cessation counsellors 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 12 m (2 PP, 3 and 12m) Validation: due to low success in obtaining samples for cotinine analysis, data are based on self-report only
Notes	We report a sensitivity analysis on the effect of exclusion of this non-random study

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Not random, intervention alternated between hospitals on a monthly basis in order to avoid contamination
Allocation concealment (selection bias)	High risk	Intervention or control status of hospital known when participants recruited
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported quitting only
Incomplete outcome data (attrition bias)	Low risk	6% loss to follow-up, no difference by group, included in ITT analysis

Stevens 1993 *(Continued)*
All outcomes

Thankappan 2013

Methods	Study design: Randomized controlled trial Setting: 2 diabetes clinics, India Recruitment: diabetic smokers attending clinic, not selected for readiness to quit
Participants	224 male diabetic smokers, av. age 53
Interventions	Therapist: trained non-physician counsellor 1. Physician advice 2. As 1, and counselling at each visit for 6 m; 4 x 30-min, baseline, 1, 3, 6 m, based on 5 As/5Rs
Outcomes	Abstinence at 6 m Validation: none at 6 m, samples collected for cotinine later
Notes	New for 2016 update 2014 paper gives longer-term outcome but not absolute numbers quit. Report on later validation using cotinine found reasonable accuracy with some misreporting likely due to environmental tobacco smoke

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Sequentially, every four patients enrolled were randomized into the two intervention groups using a computer generated random sequence to achieve a block size of four"
Allocation concealment (selection bias)	Unclear risk	Their medical records were then flagged with different coloured stickers by the counsellor in order to identify group assignment - unclear whether allocation concealed
Blinding of outcome assessment (detection bias) All outcomes	High risk	No validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	12.5% loss to follow-up at 6 m

Tonnesen 2006

Methods	Study design: Randomized controlled trial Setting: 7 chest clinics, Denmark Recruitment: outpatient attenders
Participants	370 smokers of > 1 cpd with COPD

Tonnesen 2006 *(Continued)*

	52% women, av. age 61, av. cpd 20
Interventions	Therapists: 20 nurses with cessation experience, trained to support medication use and provide standardized counselling Factorial trial. Nicotine sublingual tablet and placebo arms collapsed in MA 1. High support: 7 x 20 - 30-min clinic visits (0, 2, 4, 8, 12 wks, 6 m, 12 m) & 5 x 10-min phone calls (1, 6, 10 wks , 4½ m, 9 m), total contact time 4½ hrs 2. Low support: 4 clinic visits (0, 2 wks, 6 m, 12 m) and 6 phone calls (1, 4, 6, 9, 12 wks, 9 m), total time 2½ hrs
Outcomes	Sustained abstinence at 12 m (validated at all visits from wk 2, PP also reported) Validation: CO < 10 ppm
Notes	Compares higher- and lower-intensity counselling. Therapists were not full-time specialist counsellors

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Block randomization list at each centre
Allocation concealment (selection bias)	Unclear risk	Allocation process not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	82 (22%) lost to follow-up, included in ITT analysis

Weissfeld 1991

Methods	Study design: Randomized controlled trial Setting: Veterans Administration outpatient clinics, USA Recruitment: veterans attending walk-in and general medicine clinics invited to attend quit smoking programme
Participants	466 male smokers av. age 55 years, av. cpd 26
Interventions	Therapists: smoking cessation counsellors 1. Control: Pamphlet on hazards of smoking 2. Low-Intensity counselling: Single session 20 - 30 mins and S-H booklet 3. High-intensity counselling: Same initial session, with sustained contact of 3 m. 1 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 1 m at 6 m (9 m for high-intensity group, 6 m after last contact) Validation: nicotine metabolites in urine

Weissfeld 1991 *(Continued)*

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 and 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

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomization: 2 stages; initially in 1:2 to control or intervention, then 1:1 to high or low intensity occurred after delivery of low-intensity session. Random number table
Allocation concealment (selection bias)	Low risk	Consecutively-numbered envelopes containing treatment assignment
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	34 (7.3%) died or lost to follow-up included in ITT analysis. More lost in high-intensity group

Wiggers 2006

Methods	Study design: Randomized controlled trial Setting: Cardiovascular outpatient department, Netherlands Recruitment: People attending regular consultation; those consenting referred to nurse practitioner
Participants	385 smokers (8 deaths excluded from outcomes) 37% women, av. age 59, av. cpd 21
Interventions	Therapist: nurse practitioner In both groups, participants 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 and motivation, barriers; TQD set for motivated participants 2. Usual care without motivational counselling.
Outcomes	Abstinence for 7 days at 12 m 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	Included on grounds that participants were referred to nurse practitioner for counselling; not part of usual care

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A computerized balanced randomization programme taking prognostic factors (e.g. clinic attendance, age and gender) into account."

Wiggers 2006 *(Continued)*

Allocation concealment (selection bias)	Low risk	"While patients completed their baseline questionnaire (and signed a written informed consent) nurses randomly assigned ..."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	1 withdrawal due to cognitive problems and 8 deaths during follow-up not included in analyses. At 12 m 45 not reached by mail or phone, included in ITT. More unmarried participants lost

Williams 2010

Methods	Study design: Randomized controlled trial Setting: Mental health outpatient clinics, USA Recruitment: People with schizophrenia or schizoaffective disorder, willing to use NRT
Participants	100 smokers (> 10 cpd) using an atypical antipsychotic; 16% women, av. age ˜46, av. cpd 23
Interventions	Therapists: trained mental health clinicians provided both conditions Pharmacotherapy: nicotine patch (21 mg for 16 wks incl tapering) 1. Treatment of Addiction to Nicotine in Schizophrenia (TANS); 24 x 45-min individual counselling sessions over 26 wks 2. Medical Management (MM); 9 x 20 mins over 26 wks
Outcomes	Continuous abstinence at 12 m Validation: CO < 10 ppm
Notes	New for 2016 update Contributes to comparison 2.1.2, more versus less intensive counselling as adjunct to pharmacotherapy

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"adaptive urn randomization procedure that accounts for motivation, gender, ethnicity, and heavy versus light smoking status"
Allocation concealment (selection bias)	Low risk	Judged that process for randomization prevented prior knowledge of condition
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	75% followed up at 12 m, authors report "not different between groups"

Windsor 1988

Methods	Study design: Randomized controlled trial Setting: University worksite, USA Recruitment: Employees volunteering for a quit-smoking programme
Participants	378 smokers av. age 37, av. cpd 23 - 27
Interventions	Therapist: health educator All groups received a 10-min session of brief advice 1. + S-H manuals 2. + S-H and another session of counselling (20 - 30 mins) 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, 6 m, 1 yr, 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 and 2 vs 3 and 1. Number of quitters estimated from graphs

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated assignment
Allocation concealment (selection bias)	Low risk	Sealed numbered envelopes opened after informed consent and baseline questionnaire
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	37 lost to follow-up, included in ITT analysis

Wu 2009

Methods	Study design: Randomized controlled trial Setting: Research unit for Asian health, NYC, USA Recruitment: via Asian Community Health Coalition member organizations
Participants	139 Chinese smokers (any smoking in previous wk); 12% women, av. age 44, av. cpd NS, 25% smoked < 10 cpd, 49% had never attempted to quit
Interventions	Therapist: Chinese speaking counsellor Pharmacotherapy: NRT. Patch for 8 wks (could start at any time in 6 m period)

Wu 2009 *(Continued)*

	1. Culturally-tailored counselling in Chinese, 4 x 60 mins and S-H 2. Health education in Chinese: 4 x 60 mins, including general health, nutrition, exercise and tobacco
Outcomes	Abstinence at 6 m (PP) Validation: CO < 6 ppm
Notes	New for 2016 update Conditions had same contact time, but control did not focus on smoking

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomized, method not stated
Allocation concealment (selection bias)	Unclear risk	Details not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	10% intervention and 14% control lost to follow-up at 6 m and counted as smokers in ITT analysis

av - average (mean)
CAD: coronary artery disease
CI - confidence interval
CO - carbon monoxide
COHb - carboxyhaemoglobin
COPD - chronic obstructive pulmonary disease
cpd - cigarettes per day
ITT - intention-to-treat
m - month
MA - meta-analysis
MI - myocardial infarction
min - minute
NRT - Nicotine replacement therapy
OR - odds ratio
PP - point prevalence (abstinent at defined period)
PAD - peripheral artery disease
ppm - parts per million
S-H - Self help materials
TIA - transient ischaemic attack
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. Differences between outcomes could have been due to differences between patients in different clinics; no way to estimate effect of clustering
Berndt 2014	Face-to-face counselling confounded with provision of NRT, compared to usual care control. Comparison with telephone counselling confounded by different duration of treatment and therapists
Bock 2014	Main intervention component was motivational interviewing, see Lindson-Hawley 2015
Bolman 2002	Intervention provided by a nurse as part of usual care, included in Cochrane Review of nursing interventions (Rice 2013)
Borrelli 2005	Intervention provided by a nurse during normal duties, included in Cochrane Review of nursing interventions (Rice 2013)
Calabro 2012	Multicomponent intervention included access to internet-based resources and health feedback in addition to 2 counselling sessions, as adjunct to offer of NRT (see Stead 2015)
Camarelles 2002	Compares individual to group counselling, see Cochrane Review of group-based interventions (Stead 2017)
Canga 2000	Intervention provided by a nurse, included in Cochrane Review of nursing interventions (Rice 2013)
Catley 2016	Participants were smokers not planning to quit. Currently listed as an ongoing study in Lindson-Hawley 2015 'Motivational interviewing for smoking cessation' and will be included there
Clarke 2013	Short follow-up (˜4.5 months from start of intervention, 3 months from prison discharge). Participants were abstinent whilst in prison
Colby 1998	Short follow-up (3 months)
Dezee 2013	No brief-advice control, comparison was with internet support
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 2013)
Gariti 2009	Control group had multiple sessions for 'medication management'. Included in Stead 2015
Ghanem 2014	Unpublished study. Insufficient detail in either abstract to include or to enable contact with author for further information
Gifford 2004	Trial of an acceptance and commitment-based treatment intervention that included multiple group sessions in addition to individual counselling. Comparator was nicotine patch therapy
Gifford 2011	Trial of an acceptance and commitment-based treatment intervention that included multiple group sessions in addition to individual counselling as adjunct to bupropion
Gorini 2012	Counselling intervention was brief advice provided by midwives conducting PAP test, not by dedicated cessation counsellors
Harris 2010	Participants included smokers not planning to quit. See Lindson-Hawley 2015
Hilberink 2005	Intervention provided by physicians and nurses in usual care setting, not specialist counselling

Study	Reason for exclusion
Hokanson 2006	Participants included smokers not planning to quit, and recent quitters. See Lindson-Hawley 2015
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 proactive telephone calls
Lloyd-Richardson 2009	Compared motivational interviewing to less intensive counselling, as adjuncts to nicotine patch, see Lindson-Hawley 2015
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 (Chamberlain 2013)
Marks 2002	Intervention was provided in a self-help format
McCarthy 2016	All participants received counselling, intervention was a 'practice quitting' programme
Mildestvedt 2007	Multiple risk factor 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 2008)
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
Raja 2014	Short-term study, outcome was nicotine dependence
Rodriguez 2003	Intervention combined the systematic use of NRT with counselling; covered in Cochrane Review of worksite interventions (Cahill 2014)
Sanz-Pozo 2006	Intervention provided by nurses in a primary care clinic, included in Cochrane Review of nursing interventions (Rice 2013)
Savant 2013	Not restricted to smokers; more than half of participants used chewing tobacco. Cessation rates not given by type of tobacco use
Schnoll 2005	Short follow-up (3 months). Compared 2 counselling approaches, no difference detected
Schwartz 1967	Success was defined as reduction in smoking of over 85%, not complete abstinence
Secades-Villa 2009	Cluster-randomised by primary care centre with 1 centre per condition; no way to allow for intra-cluster correlation
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

Study	Reason for exclusion
Stein 2006	Test of motivational interviewing; not all participants attempted to quit
Stevens 2000	Intervention providers were respiratory therapists, not counsellors. Included in Cochrane Review of interventions in hospital inpatients, (Rigotti 2012)
Williams 2006	Study targeted multiple risk factors
Wittchen 2011	Counselling was delivered by non-specialist physicians
Woodruff 2002	Short follow-up (3 months)

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

Bonevski 2011

Trial name or title	Call it Quits
Methods	Block-randomized controlled trial
Participants	Socially disadvantaged population, target n = 400
Interventions	The smoking cessation (intervention) group will receive an intensive participant-centred smoking cessation intervention offered by the caseworker over a minimum of 3 face-to-face visits (each 2 weeks apart) which will begin immediately following baseline survey completion, followed by at least 2 phone contacts (1 week apart). This intervention will constitute an add-on to participants' usual regular counselling visits, reducing additional costs to the Centre and to participants. If a participant requires further contact, staff will provide further quitting assistance and record what they delivered on their checklist. The control group will receive minimum ethical care.
Outcomes	2 primary outcome measures obtained at 1-, 6-, and 12-month follow-up: 1) 24-hour expired air CO-validated self-reported smoking cessation; and 2) 7-day self-reported smoking cessation. Continuous abstinence will also be measured at 6- and 12-month follow-up
Starting date	01/02/2010
Contact information	billie.bonevski@newcastle.edu.au; Faculty of Health and Medicine, Centre for Translational Neuroscience and Mental Health, School of Medicine and Public Health, University of Newcastle, Callaghan, New South Wales, Australia
Notes	

Garvey 2012a

Trial name or title	Duration of Behavioral Counseling Treatment Needed to Optimize Smoking Abstinence
Methods	Randomized trial
Participants	450 daily smokers
Interventions	Participants are randomized to 1 of 3 behavioural treatments:

Garvey 2012a *(Continued)*

	(1) Brief Duration (3-month) smoking-cessation counselling; (2) Moderate Duration (6-month) counselling; or (3) Extended Duration (12 month) counselling
Outcomes	Primary: abstinence at 1 year. Secondary; abstinence at 2 years
Starting date	2008
Contact information	Arthur J. Garvey, Ph.D., Harvard School of Dental Medicine
Notes	

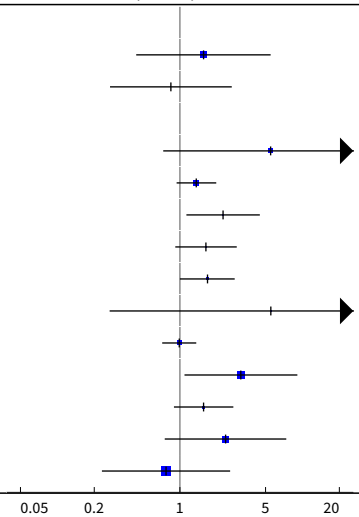
DATA AND ANALYSES

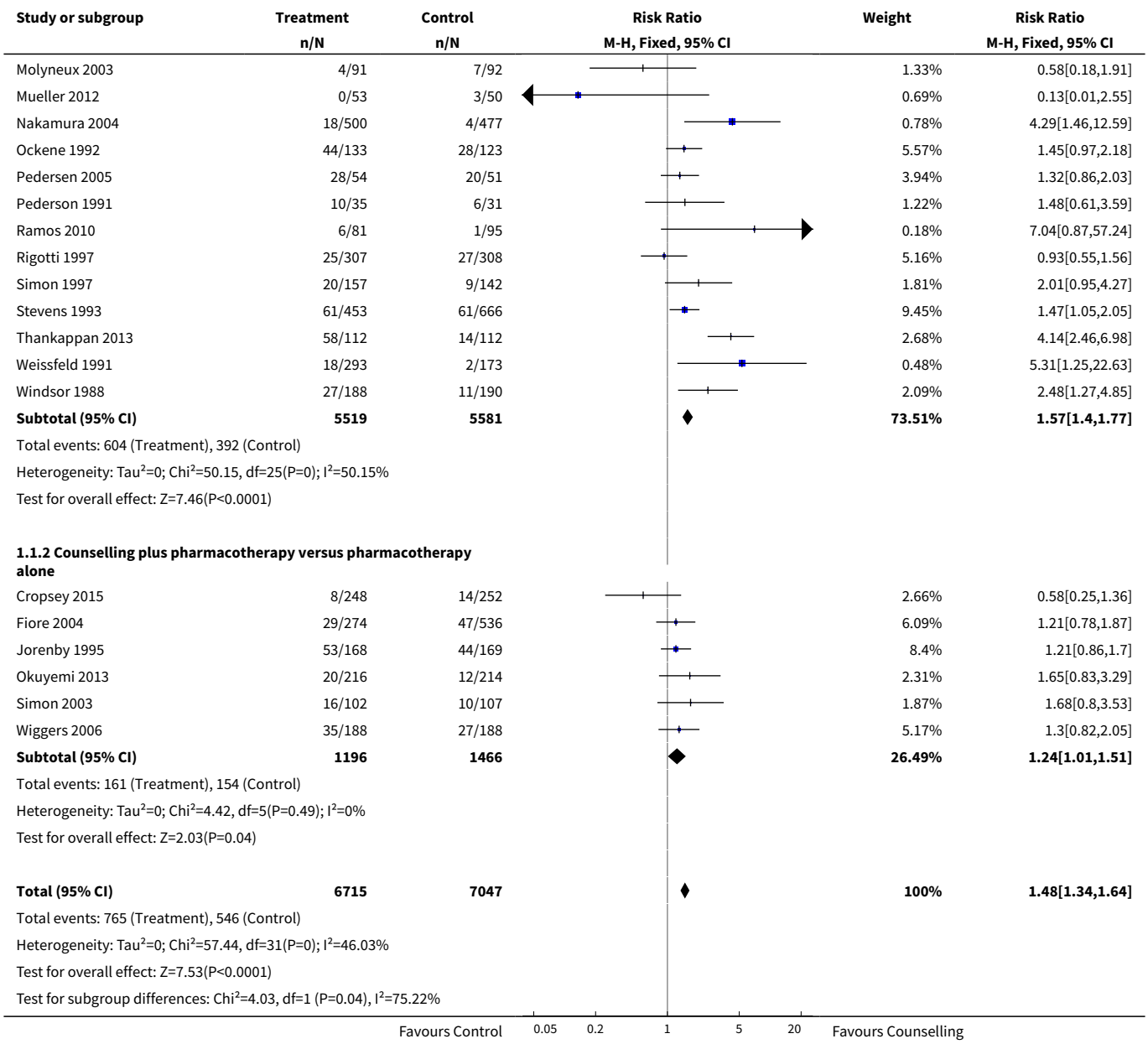
Comparison 1. Individual counselling compared to minimal contact control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Smoking cessation at longest follow-up	33	13762	Risk Ratio (M-H, Fixed, 95% CI)	1.48 [1.34, 1.64]
1.1 Counselling versus control (no systematic pharmacotherapy)	27	11100	Risk Ratio (M-H, Fixed, 95% CI)	1.57 [1.40, 1.77]
1.2 Counselling plus pharmacotherapy versus pharmacotherapy alone	6	2662	Risk Ratio (M-H, Fixed, 95% CI)	1.24 [1.01, 1.51]

Analysis 1.1. 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	Weight	Risk Ratio M-H, Fixed, 95% CI
1.1.1 Counselling versus control (no systematic pharmacotherapy)					
Aleixandre 1998	6/27	3/21		0.65%	1.56[0.44,5.5]
Bronson 1989	5/77	6/78		1.14%	0.84[0.27,2.65]
Burling 1991	0/20	0/19			Not estimable
Burling 2001	11/100	1/50		0.26%	5.5[0.73,41.41]
Chan 2012	62/922	45/913		8.66%	1.36[0.94,1.98]
Chen 2014	22/94	10/96		1.89%	2.25[1.13,4.49]
Dornelas 2000	23/54	12/46		2.48%	1.63[0.92,2.91]
Glasgow 2000	37/578	22/576		4.22%	1.68[1,2.8]
Hannover 2009	2/180	0/199		0.09%	5.52[0.27,114.31]
Hennrikus 2005	66/666	68/678		12.9%	0.99[0.72,1.36]
Hennrikus 2010	13/61	4/59		0.78%	3.14[1.09,9.09]
Kim 2005	28/200	18/201		3.44%	1.56[0.89,2.73]
Marley 2014	6/55	5/108		0.65%	2.36[0.75,7.38]
Marshall 2016	4/28	5/27		0.97%	0.77[0.23,2.57]

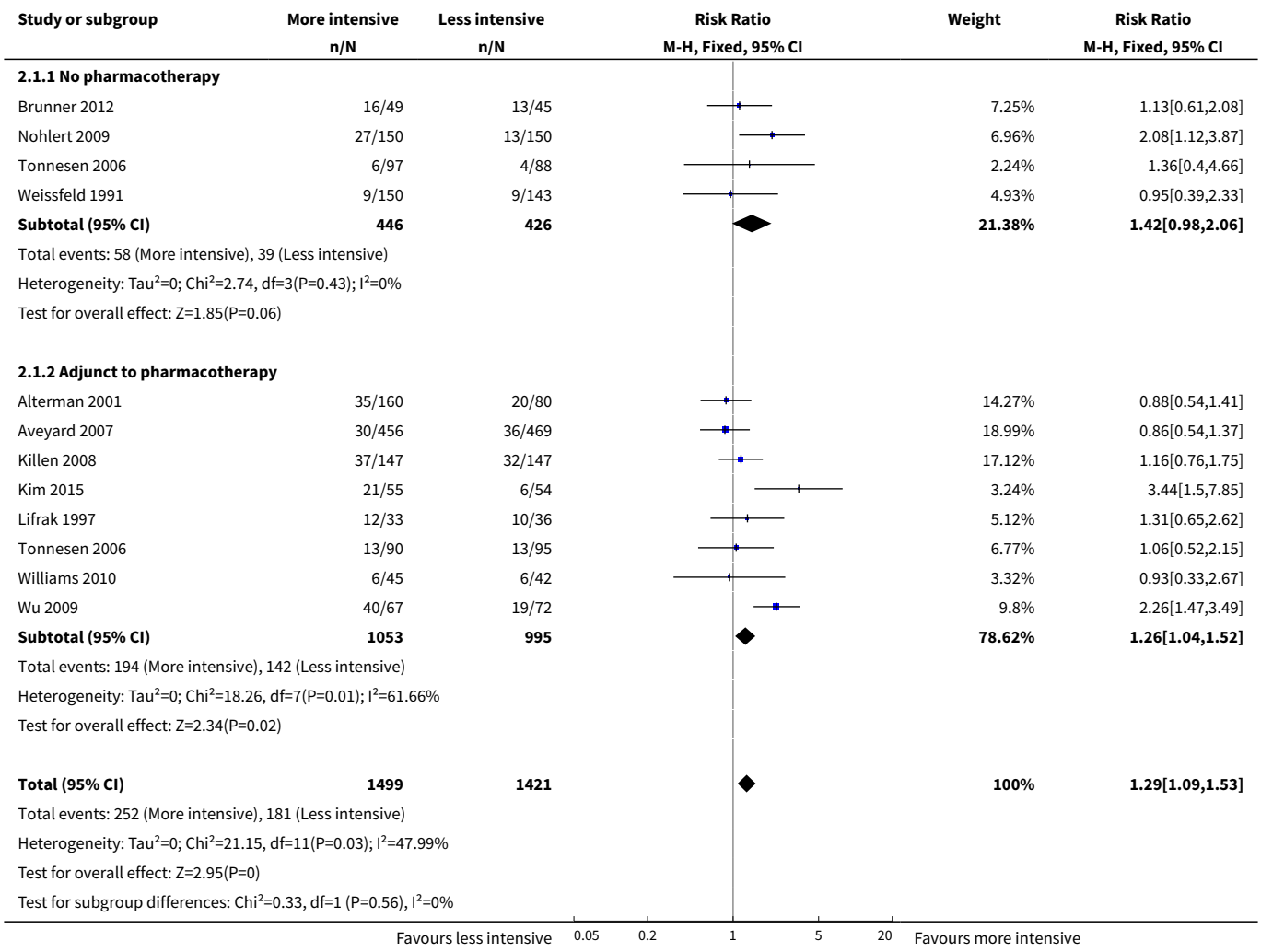




Comparison 2. More intensive versus less intensive counselling

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Smoking cessation at longest follow-up	11	2920	Risk Ratio (M-H, Fixed, 95% CI)	1.29 [1.09, 1.53]
1.1 No pharmacotherapy	4	872	Risk Ratio (M-H, Fixed, 95% CI)	1.42 [0.98, 2.06]
1.2 Adjunct to pharmacotherapy	8	2048	Risk Ratio (M-H, Fixed, 95% CI)	1.26 [1.04, 1.52]

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

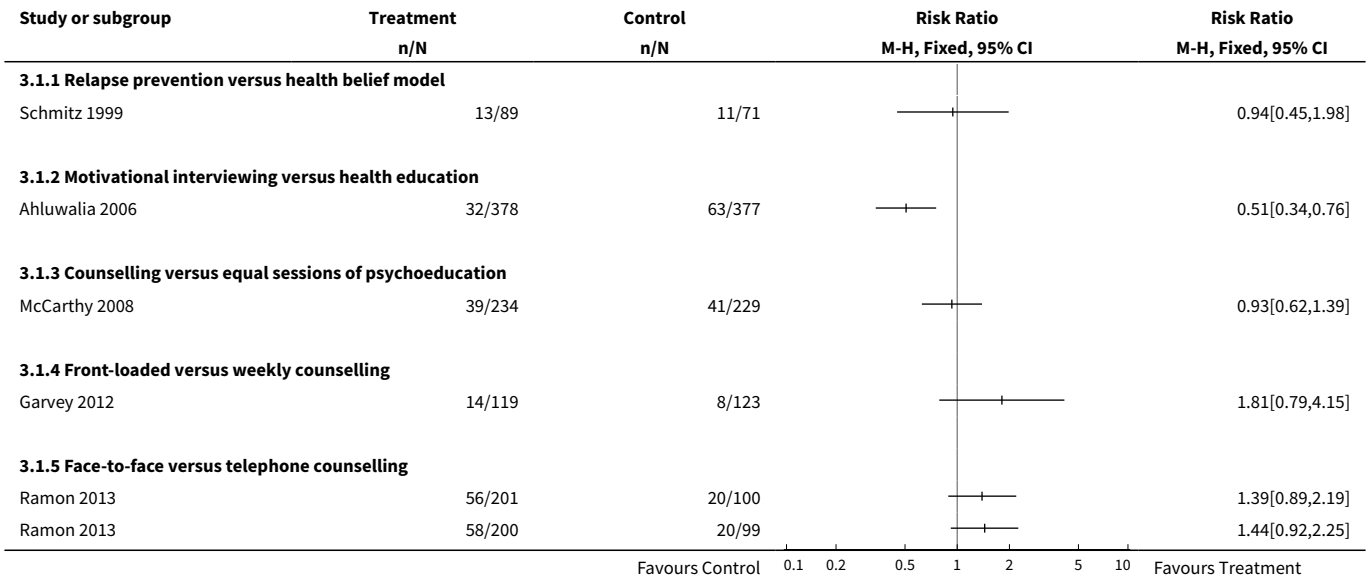


Comparison 3. Comparisons between counselling approaches of similar intensity

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Smoking cessation at longest follow-up	5		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 Relapse prevention versus health belief model	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.2 Motivational interviewing versus health education	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.3 Counselling versus equal sessions of psychoeducation	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.4 Front-loaded versus weekly counselling	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.5 Face-to-face versus telephone counselling	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

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



WHAT'S NEW

Date	Event	Description
12 March 2018	Amended	Correction to plain language summary to say that individual counselling could increase the chance of quitting by between 40% and 80%, so there is consistency with risk ratio (the bracket was previously, erroneously given as 40%-60%).

HISTORY

Protocol first published: Issue 4, 1998
Review first published: Issue 2, 1999

Date	Event	Description
23 November 2016	New citation required but conclusions have not changed	No change to main conclusions.
23 November 2016	New search has been performed	Searches updated, 19 new studies included. 'Summary of findings' table added.
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.
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

Tim Lancaster: None known.
Lindsay Stead: 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.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

For the 2017 update, we include 'Summary of findings' tables for the main comparisons.

INDEX TERMS

Medical Subject Headings (MeSH)

*Behavior Therapy; *Smoking Prevention; Counseling [*methods]; Psychotherapy, Group; Randomized Controlled Trials as Topic; Self-Help Groups; Smoking [drug therapy]; Smoking Cessation [*methods] [statistics & numerical data]; Tobacco Use Cessation Devices

MeSH check words

Humans