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Telephone counselling for smoking cessation (Review)

Matkin W, Ordóñez-Mena JM, Hartmann-Boyce J

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[Intervention Review]

Telephone counselling for smoking cessation

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ABSTRACT

Background

Telephone services can provide information and support for smokers. Counselling may be provided proactively or offered reactively to callers to smoking cessation helplines.

Objectives

To evaluate the effect of telephone support to help smokers quit, including proactive or reactive counselling, or the provision of other information to smokers calling a helpline.

Search methods

We searched the Cochrane Tobacco Addiction Group Specialised Register, clinicaltrials.gov, and the ICTRP for studies of telephone counselling, using search terms including 'hotlines' or 'quitline' or 'helpline'. Date of the most recent search: May 2018.

Selection criteria

Randomised or quasi-randomised controlled trials which offered proactive or reactive telephone counselling to smokers to assist smoking cessation.

Data collection and analysis

We used standard methodological procedures expected by Cochrane. We pooled studies using a random-effects model and assessed statistical heterogeneity amongst subgroups of clinically comparable studies using the I^2 statistic. In trials including smokers who did not call a quitline, we used meta-regression to investigate moderation of the effect of telephone counselling by the planned number of calls in the intervention, trial selection of participants that were motivated to quit, and the baseline support provided together with telephone counselling (either self-help only, brief face-to-face intervention, pharmacotherapy, or financial incentives).

Main results

We identified 104 trials including 111,653 participants that met the inclusion criteria. Participants were mostly adult smokers from the general population, but some studies included teenagers, pregnant women, and people with long-term or mental health conditions. Most trials (58.7%) were at high risk of bias, while 30.8% were at unclear risk, and only 11.5% were at low risk of bias for all domains assessed. Most studies (100/104) assessed proactive telephone counselling, as opposed to reactive forms.

Among trials including smokers who contacted helplines (32,484 participants), quit rates were higher for smokers receiving multiple sessions of proactive counselling (risk ratio (RR) 1.38, 95% confidence interval (CI) 1.19 to 1.61; 14 trials, 32,484 participants; I^2 = 72%)

compared with a control condition providing self-help materials or brief counselling in a single call. Due to the substantial unexplained heterogeneity between studies, we downgraded the certainty of the evidence to moderate.

In studies that recruited smokers who did not call a helpline, the provision of telephone counselling increased quit rates (RR 1.25, 95% CI 1.15 to 1.35; 65 trials, 41,233 participants; I^2 = 52%). Due to the substantial unexplained heterogeneity between studies, we downgraded the certainty of the evidence to moderate. In subgroup analysis, we found no evidence that the effect of telephone counselling depended upon whether or not other interventions were provided (P = 0.21), no evidence that more intensive support was more effective than less intensive (P = 0.43), or that the effect of telephone support depended upon whether or not people were actively trying to quit smoking (P = 0.32). However, in meta-regression, telephone counselling was associated with greater effectiveness when provided as an adjunct to self-help written support (P < 0.01), or to a brief intervention from a health professional (P = 0.02); telephone counselling was less effective when provided as an adjunct to more intensive counselling. Further, telephone support was more effective for people who were motivated to try to quit smoking (P = 0.02). The findings from three additional trials of smokers who had not proactively called a helpline but were offered telephone counselling, found quit rates were higher in those offered three to five telephone calls compared to those offered just one call (RR 1.27, 95% CI 1.12 to 1.44; 2602 participants; I^2 = 0%).

Authors' conclusions

There is moderate-certainty evidence that proactive telephone counselling aids smokers who seek help from quitlines, and moderate-certainty evidence that proactive telephone counselling increases quit rates in smokers in other settings. There is currently insufficient evidence to assess potential variations in effect from differences in the number of contacts, type or timing of telephone counselling, or when telephone counselling is provided as an adjunct to other smoking cessation therapies. Evidence was inconclusive on the effect of reactive telephone counselling, due to a limited number studies, which reflects the difficulty of studying this intervention.

PLAIN LANGUAGE SUMMARY

Does telephone counselling help people stop smoking?

Background

There are a number of interventions available to help people stop smoking. One of them is using telephone calls to give smokers information, advice, and help to stop smoking. People can use these services by calling quitlines or by signing up to get calls from counsellors. We wanted to find out whether telephone counselling can help people quit smoking. Our most recent search for evidence was in May 2018.

Study characteristics

We found 104 studies (including 111,653 participants) testing the effect of any type of telephone counselling. The participants were mostly adult smokers from the general population, but some studies also looked at teenagers, pregnant women, and people with long-term or mental health conditions.

Some studies included participants who had called helplines that provide smoking counselling (quitlines). Other studies included people who had not called quitlines, but received calls from counsellors or other healthcare providers.

Some studies provided telephone counselling alone, but many others provided telephone counselling along with minimal support such as self-help leaflets, or more active support such as face-to-face counselling, or with stop-smoking medication. The number of calls offered ranged from a single call to 12 calls. Some studies only recruited people trying to stop smoking, while others offered support even to those not actively trying to stop.

Studies needed to compare groups whose participants had similar characteristics at the start of the study, to investigate whether the participants had stopped smoking for at least six months, and ideally would test whether people had quit with blood or urine tests.

We judged few studies to be well designed and conducted. Most had at least one issue that could have affected the results.

Key results

In people who had called helplines, providing additional telephone counselling increased their chances of stopping smoking from 7% to 10%. In people who had not called a helpline, but received telephone calls from counsellors or other healthcare providers, their chances of stopping smoking increased from 11% to 14%. In studies which directly compared more versus fewer calls, people who were offered more calls (three to five) tended to be more likely to quit than those who received only one call. Telephone counselling appears to increase the chances of stopping smoking, whether or not people are motivated to quit or are receiving other stop-smoking support.

Certainty of evidence

The overall certainty of the evidence was moderate, meaning that further research is likely to have an important impact on our conclusions.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Interventions for callers to quitlines - effect of additional proactive calls for smoking cessation

Interventions for callers to quitlines - effect of additional proactive calls for smoking cessation

Patient or population: callers to quitlines
Intervention: additional proactive calls

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Additional proactive calls				
Smoking cessation Self-reported abstinence (majority) Follow-up: 6+ months	**Study population**		**RR 1.38** (1.19 to 1.61)	32,484 (14 studies)	⊕⊕⊕⊖ **moderate**[b,c]	-
	72 per 1000	**100 per 1000** (85 to 116)				
	Low					
	50 per 1000[a]	**69 per 1000** (59 to 81)				
	High					
	150 per 1000[a]	**208 per 1000** (178 to 242)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (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: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[a]Low control rate reflects lower end of range evident in trials; 4/14 had control rates < 50 per 1000. High control rate likely to be applicable for smokers also using pharmacotherapy.

[b]Effect estimate not sensitive to exclusion of studies judged at high risk of bias, so not downgraded on this basis.
[c]Downgraded by one level due to unexplained statistical heterogeneity (I^2 = 72%).

Summary of findings 2. Interventions for smokers not calling quitlines - effect of proactive telephone counselling

Proactive telephone counselling for smokers not calling quitlines

Patient or population: smokers not calling quitlines
Intervention: proactive telephone counselling

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Proactive telephone counselling				
Smoking cessation Self-reported abstinence (majority) Follow-up: 6+ months	**Study population**		**RR 1.25** (1.15 to 1.35)	41,233 (65 studies)	⊕⊕⊕⊖ **moderate**[a,b]	
	110 per 1000[a]	**137 per 1000** (127 to 149)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (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: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[a]Based on crude average of events/total, with participants lost to follow-up assumed to be smoking. Interquartile range in trials 63 - 200 per 1000. Higher baseline cessation rates typical amongst motivated populations receiving pharmacotherapy and some support. Relative additional benefit of telephone intervention may be smaller in this setting.
[b]Effect estimate not sensitive to exclusion of studies judged at high risk of bias, so not downgraded on this basis.
[c]Downgraded by one level due to statistical heterogeneity, which was only partially explained by differences in baseline support. In subgroup analyses, evidence of effect was clearer when telephone counselling was offered as an adjunct to print-based self-help, or brief face-to-face counselling. Effect smaller and less certain when telephone counselling was offered as an adjunct to pharmacotherapy. However, statistical heterogeneity ranged from small to substantial within the subgroups.

BACKGROUND

Description of the condition

Worldwide, tobacco smoking kills more than seven million people each year, shortening life by an average of 10 to 11 years in people who smoke their whole lives (Doll 2004; Pirie 2013; WHO 2018). This increase in mortality is primarily due to cardiovascular disease, lung cancer, and chronic obstructive pulmonary disease, but smoking is also causally associated with other cancer- and non-cancer-related health conditions (USDHHS 2014; WHO 2018). Smoking cessation reverses much of the damage, and most smokers who are aware of these health hazards wish to quit (Doll 2004; Mons 2015; Müezzinler 2015; Ordóñez-Mena 2016; WHO 2018).

Description of the intervention

Telephone counselling is a behavioural intervention to help people stop smoking. It can act as a stand-alone intervention or one that runs alongside other interventions (e.g. an added component to face-to-face counselling). It can be proactive (the counsellor initiates contact) or reactive (the smoker initiates contact) (Lichtenstein 1996). In many areas, reactive services are available through helplines or quitlines, which may be specific to smoking, as for example the California Smokers' Helpline (Zhu 2000a) and the Quitlines in Australia (Borland 2001), the UK (Owen 2000), Sweden (Lindqvist 2013), and Denmark (Skov-Ettrup 2016), or they may be embedded in broader health information services such as the Cancer Information Service in the USA (La Porta 2007). Quitlines may provide a regional or national service. They are often advertised in conjunction with population-wide campaigns such as No-Smoking Days. Helplines may also be provided on a smaller scale for a specific project or population. In some services, people may be enrolled in a formal smoking cessation programme, with further proactive calls from counsellors. Telephone counselling may also be provided as part of an integrated smoking cessation support service (e.g. Glasgow 1991). Access to hotlines or the opportunity to register to receive calls from a counsellor may also be offered as part of a cessation programme, including pharmacotherapy.

How the intervention might work

Behavioural and pharmacological interventions help people to quit smoking. Behavioural support can be given in individual counselling sessions (Lancaster 2017) or in group therapy (Stead 2017), where clients can share problems and derive support from one another. Standard self-help materials have at best a small effect in helping people to quit, while those tailored to the characteristics of individuals are more likely to be effective (Livingstone-Banks 2019a). Telephone counselling may supplement face-to-face support, or be a substitute for it as an adjunct to self-help interventions or pharmacotherapy. Counselling may be helpful in planning a quit attempt, and in helping to prevent relapse during the initial period of abstinence (Livingstone-Banks 2019b). Although intensive face-to-face interventions increase quit rates, there are difficulties with scalability. Telephone counselling may be a more feasible way to provide individual counselling to large populations. In addition, telephone contact can be timed to maximise the level of support around a planned quit date, and can be scheduled in response to the needs of the recipient. In a proactive approach the counsellor initiates one or more calls to provide support in making a quit attempt or avoiding relapse. Reactive counselling, in contrast, is available on demand to people calling specific services; quitlines, helplines or hotlines. These services take calls from people who smoke, or their friends and family (Zhu 2006). These telephone services may offer information, recorded messages, personal counselling or a mixture of components (Anderson 2007; Ossip-Klein 2003).

Why it is important to do this review

Telephone counselling services have the potential to provide access to information for large numbers of people. Some services have reported reaching substantial proportions of the target population (Ossip-Klein 1991; Platt 1997). They have the potential to reach underserved populations such as ethnic minorities (Zhu 2000a) or younger people (Chan 2008; Gilbert 2005).

Telephone counselling is a widely used intervention for smoking cessation, and is often supported through public funds. It is therefore important to evaluate its effects, as well as different variations of telephone counselling that may impact on quit rates.

OBJECTIVES

To evaluate the effect of telephone support to help smokers quit, including proactive or reactive counselling, or the provision of other information to smokers calling a helpline.

We tried to address the following questions:

- Do telephone calls from a counsellor increase quit rates, compared to other brief non-pharmacological interventions or to no intervention?
- Do telephone calls from a counsellor offered together with other interventions increase quit rates, compared to other interventions alone?
- Does an increase in the number of telephone contacts increase quit rates?
- Do differences in counselling protocol related to the type or timing of support lead to differences in quit rates?
- Does the availability of a reactive helpline increase quit rates?

METHODS

Criteria for considering studies for this review

Types of studies

Randomised or quasi-randomised controlled trials (RCTs), with the unit of allocation being one of the following: the individual smoker; counsellor; group; intervention site; or geographical area.

Types of participants

Individuals who were current smokers at the time of inclusion in the trial. We included trials with a mixture of current smokers and recent quitters if the recent quitters were only a small proportion of the entire study population. The definition of recent quitters was that used by the trial recruitment protocols, or by the participants themselves. We excluded trials that exclusively recruited quitters or were focused on telephone counselling as an intervention for relapse, as they fall within the scope of a separate Cochrane Review on preventing relapse (Livingstone-Banks 2019b).

We included trials recruiting exclusively teenagers or pregnant women, but we considered them as a potential source of

heterogeneity in meta-analyses. There are separate Cochrane Reviews for these population groups (Chamberlain 2017; Fanshawe 2017).

Types of interventions

Provision of proactive or reactive telephone counselling to assist smoking cessation, to any population. We excluded studies if the contribution of the telephone component could not be evaluated independently of another therapy. We included studies that compared a combination of telephone counselling and self-help materials versus no telephone counselling, as the effect of self-help materials alone is limited (Livingstone-Banks 2019a). We also included studies in which the effect of telephone counselling as an adjunct to another smoking cessation treatment was evaluated, e.g. print-based self-help, brief face-to-face intervention, pharmacotherapy, or incentives. We also included studies that compared different modalities or strategies of telephone counselling, and different theories of behavioural change.

Types of outcome measures

Long-term smoking cessation (i.e. at least six months after the start of intervention). We excluded trials with shorter follow-up. We used the strictest definition of smoking cessation available in a trial and biochemically-validated abstinence data whenever available.

Search methods for identification of studies

We identified studies from the Cochrane Tobacco Addiction Group Specialised Register (until May 3, 2018), World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) and ClinicalTrials.gov (until July 30, 2018) using the MeSH term 'hotlines' or free-text terms telephone* OR phone* OR quitline* OR helpline. See Appendix 1 for the full search strategy. At the time of the search the Register included the results of searches of the Cochrane Central Register of Controlled trials (CENTRAL), issue 1, 2018; MEDLINE (via OVID) to update 20180404; Embase (via OVID) to week 201814; PsycINFO (via OVID) to update 20180212. See the Cochrane Tobacco Addiction Group website for full search strategies and a list of other resources searched.

Data collection and analysis

We identified trials where at least one of the arms included telephone contact. For this update, two review authors (WM and JMOM) extracted data from included studies, compared extraction and discussed disagreements with a third review author (JHB). We recorded the following information in the Characteristics of included studies tables:

- The country and setting of the trial
- The method of recruitment to the study
- The method of randomisation and allocation concealment
- Details of participants, including whether they were selected according to motivation to quit, and their age, gender and average baseline cigarette consumption
- Description of intervention and control, including the schedule of telephone contacts
- Definition of smoking abstinence used for the primary outcome, including timing of longest follow-up and whether quit status was based on recent behaviour (point prevalence abstinence, e.g. in the past seven days) or on abstinence for an extended period since a quit date or a previous follow-up (continuous or sustained abstinence)
- Description of method of any biochemical validation or other method used to confirm self-reported quitting
- Description of numbers lost to follow-up by treatment condition

In the Characteristics of excluded studies tables, we describe key trials that did not meet all inclusion criteria.

Assessment of risk of bias

We assessed each included study for risks of bias in the following domains: random sequence generation (allocation bias), allocation concealment (allocation bias), blinding of outcome assessor (detection bias), and incomplete outcome data (attrition bias). Following standard Cochrane guidance, we rated items in the 'Risk of bias' tables as being at low, unclear, or high risk of bias.

We judged studies to be at low risk of bias for sequence generation if an acceptable method for generating a randomisation sequence was described, at unclear risk if the study was described as 'random' but with no further information, and at high risk if it did not use a true randomisation method, e.g. alternation by calendar week. We judged the quality of the allocation concealment to be at low risk if the group to which a participant was to be allocated remained unknown to investigators and participant until enrolment was complete. We did not assess studies for performance bias, because blinding of participants and study personnel is not possible due to the nature of the intervention. We rated the quality of the blinding of outcome assessment at low risk if a biochemical verification of abstinence was carried out in the entire study population or in a random subsample, or if smoking status was measured by self-report but the intervention and control arms received similar amounts of person-to-person contact, and at high risk otherwise. We judged attrition bias to be at low risk if the percentage of loss to follow-up was less than 50% and if the difference between arms in percentage loss to follow-up was less than 20%.

Choice of outcome and treatment of missing data

The primary outcome was the number of quitters at the longest follow-up, using the strictest measure of abstinence reported. We preferred sustained and biochemically-validated abstinence to point prevalence or to self-reported quitting. If a less strict definition of quitting seemed more appropriate for showing an effect of the intervention on recovery from lapses or relapses, we planned a sensitivity analysis.

Where possible and appropriate, we used as denominators the number randomised to each condition, with losses to follow-up assumed to be continuing smokers. We noted any exceptions in the 'Risk of bias' table for a study. Population-based studies typically have relatively high loss to follow-up, because of change of address or disconnected telephones. Non-response might be independent of both treatment condition and smoking status, although possibly associated with other variables such as age or socioeconomic status. Dropout might be related to smoking status but not to treatment condition. Imputing as smoking all those missing, irrespective of, for example, whether they could not be contacted, or declined to respond, may not be appropriate. For individual studies it is possible to use analysis methods such as generalised estimating equations (GEE) for imputing missing data

(Hall 2001). We noted whether studies that explored alternative assumptions about missing data reported any impact on the conclusions. When proportions lost are similar across conditions, and trial arms are balanced, the choice of denominator does not alter the relative effect, although the percentage quit and the absolute difference between conditions will be conservative.

Data synthesis

We summarised individual study results as a risk ratio (RR), calculated as: (number of quitters in intervention group/number randomised to intervention group)/(number of quitters in control group/number randomised to control group). Where appropriate, we performed meta-analysis using a Mantel-Haenszel random-effects model to estimate a pooled risk ratio with a 95% confidence interval (CI). When trials had more than one arm with a less intensive intervention we used only the most similar intervention without a telephone component as the control group in the primary analysis. We considered pooling of study results if both the intervention and control arms were sufficiently similar across trials. We assessed statistical heterogeneity between trials using the I^2 statistic which describes the percentage of total variation between studies that is due to heterogeneity rather than chance (Higgins 2003). We used threshold values of 50% and 70% as suggesting moderate and substantial heterogeneity respectively.

Investigations of heterogeneity: meta-regression and subgroup analyses

We ran a meta-regression in R version 3.5.0 (R 2018) using the *meta* and *metafor* packages (Schwarzer 2007; Viechtbauer 2010) to test the moderation of the effect of telephone counselling on smoking cessation by telephone counselling intensity (continuous: defined as maximum number of calls offered as part of the telephone counselling intervention), trial selection of participants that were motivated to quit (binary: yes/no), and type of baseline support offered in both the intervention and control arms (categorical: print-based self-help, brief face-to-face counselling, pharmacotherapy, or financial incentives). In meta-regression, the effect size was summarised using the trial-specific (natural) logarithm of the RR with its standard errors as weights. We fitted these trial characteristics separately in univariate models, and also together in a multivariate model to adjust for each moderator simultaneously.

We did not combine proactive and reactive approaches to counselling, so studies that provided access to a telephone helpline but did not call participants form a separate category. In earlier versions of this review we noted heterogeneity between studies of proactive telephone counselling, which was not explained by using subgroups based on the amount of support given for the control group. Lichtenstein 2002a has suggested that studies recruiting smokers who call quitlines should be considered separately. These studies share the characteristics that participants were actively seeking support at the time of their call, and that telephone counselling was the primary intervention. We therefore distinguish between trials in quitline callers and trials in smokers not calling a quitline.

We expected differences between the relative effect of telephone support, depending on whether it was being tested as the main intervention to aid cessation, or as an extra part of a multicomponent cessation programme. We therefore conducted a priori defined subgroup analysis to distinguish those studies in which telephone counselling was the most intensive component of a minimal contact intervention (print-based self-help was provided), from studies in which telephone counselling was assessed as an adjunct to a brief face-to-face counselling, or to pharmacotherapy. Where results of studies differed within the broad groupings described above we considered the following possible explanations: the difference between the intensity of the counselling based on the number of calls (two sessions or fewer, three to six sessions, and seven sessions or more), the counselling strategy used, and the characteristics of the participants, in particular their motivation to quit or stage of change at baseline.

'Summary of findings' table

Following standard Cochrane methodology, we created 'Summary of findings' tables for the two main subgroups of participants, i.e. callers to a quitline and those not calling a quitline. Both 'Summary of findings' tables include data for the same primary outcome of long-term smoking cessation. Also following standard Cochrane methodology, we used the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the certainty of the body of evidence for each outcome, and to draw conclusions about the certainty of evidence within the text of the review.

RESULTS

Description of studies

One hundred and four studies met the criteria for inclusion in the review, with a total of 111,653 participants, and a median trial size of 735. Only seven studies had fewer than 100 participants (Brown 1992; Cossette 2011; Duffy 2006; Ebbert 2007; McClure 2011; Osinubi 2003; Vander Weg 2016), whilst seven studies, all involving callers to quitlines, had more than 3000 (Hollis 2007; Joyce 2008; Rabius 2004; Rabius 2007; Sherman 2017; Zhu 1996; Zhu 2002).

The most recent search resulted in 511 studies to screen (Figure 1). After title, and abstract, and then full-text screening, we found 30 new studies to include in this update, plus 15 new ongoing studies.

Figure 1. Study flow diagram for most recent update

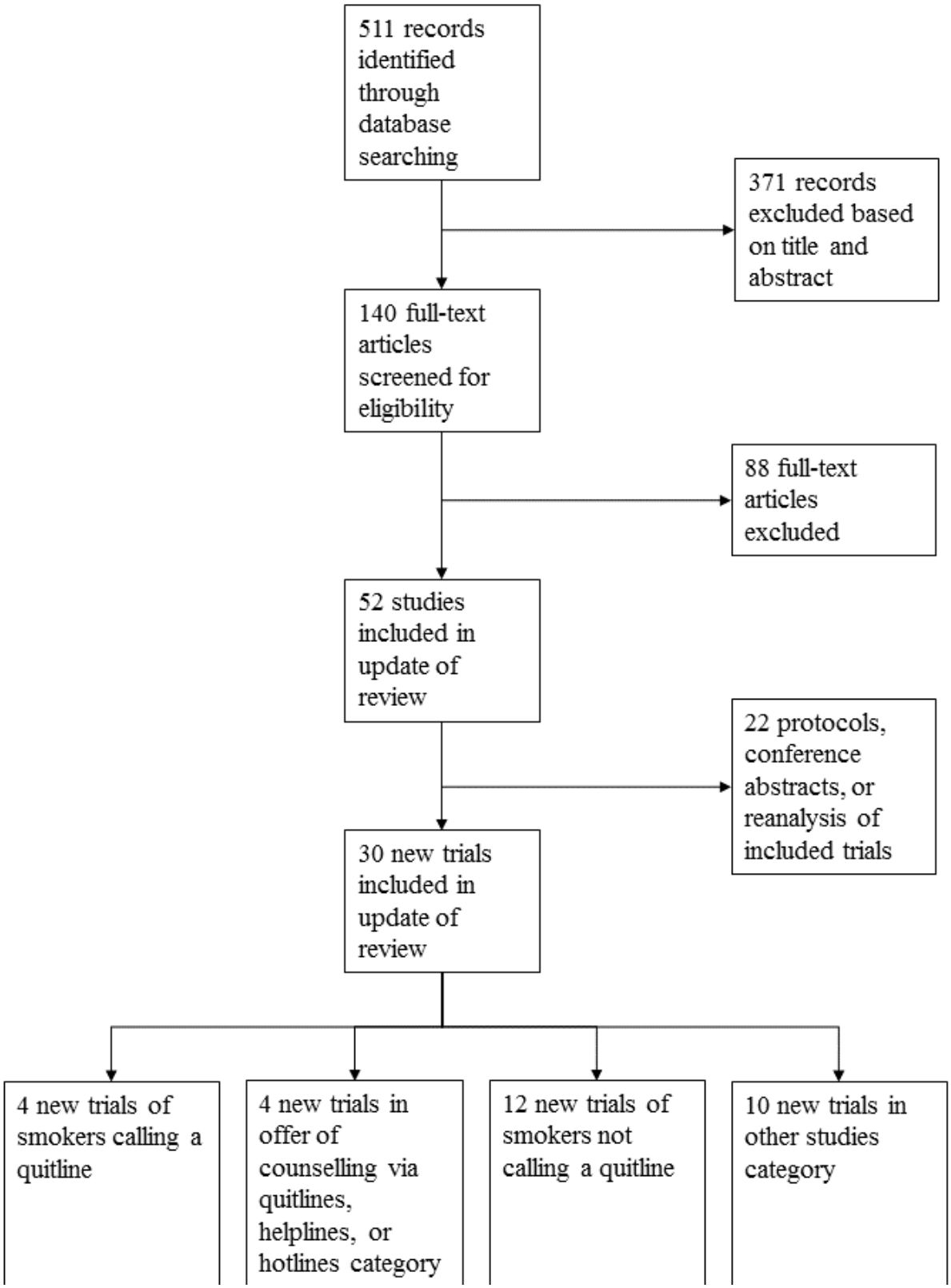


Figure 1. (Continued)

Most trials were conducted in North America (72). Nine were in Australia (Borland 2001; Borland 2003; Borland 2008; Brown 1992; Girgis 2011; MacLeod 2003; Tzelepis 2011a; Young 2008; Zwar 2015), six in Canada (Chouinard 2005; Cossette 2011; Reid 1999a; Reid 2007; Reid 2018; Smith 2004), three in Spain (Miguez 2002; Miguez 2008; Ramon 2013), three in the UK (Aveyard 2003; Gilbert 2006; Ferguson 2012), two in Hong Kong (Abdullah 2005; Chan 2015), two in Germany (Flöter 2009; Metz 2007), two in Sweden (Lindqvist 2013; Nohlert 2014), one in Norway (Hanssen 2009), one in Malaysia (Blebil 2014), one in the Netherlands (Schuck 2014), one in Denmark (Skov-Ettrup 2016), and one in China (Wu 2017). Participants were predominantly older adults with an average age typically in the 40s. One study recruited teenagers (Lipkus 2004), one high school students (Peterson 2016), one young people aged 18 to 24 (Sims 2013), and three recruited older people, aged over 50 (Rimer 1994), over 60 (Ossip-Klein 1997), or over 65 (Joyce 2008). Four recruited pregnant women (Cummins 2016b; McBride 1999b; McBride 2004; Stotts 2002) and a further five recruited only women (McBride 1999a; McClure 2005; Flöter 2009; Solomon 2000; Solomon 2005). Four predominantly recruited men (Abdullah 2005; An 2006; Osinubi 2003; Sorensen 2007a). One was culturally tailored for Chinese, Korean and Vietnamese smokers (Zhu 2012) and one recruited Arabic smokers in Australia (Girgis 2011).

Most of the studies were trials of proactive calls from a counsellor, or from an automated interactive voice response system (IVR) (Reid 2007 IVR with counsellor follow-up in case of need, Velicer 2006 IVR only). Only five assessed interventions that did not involve a counsellor contacting a participant (McFall 1993; Orleans 1998; Ossip-Klein 1991; Sood 2009; Thompson 1993). Sixteen studies recruited participants who had phoned a quitline, but evaluated the addition of further proactive contacts (Borland 2001; Borland 2003; Bricker 2014; Cummins 2016b; Ferguson 2012; Gilbert 2006; Hollis 2007; Lindqvist 2013; Nohlert 2014; Rabius 2004; Rabius 2007; Sims 2013; Smith 2004; Zhu 1996; Zhu 2002; Zhu 2012). One study recruited proactively to quitline counselling (Tzelepis 2011a). Sixteen studies recruited participants in healthcare settings and referred them to services provided by quitlines, involving proactive counselling for those following through referral (Bastian 2012; Blebil 2014; Borland 2008; Brunette 2017; Collins 2018; Cummins 2016a; Duffy 2006; Ebbert 2007; Piper 2016; Ramon 2013; Rogers 2016; Schlam 2016; Sherman 2017; Warner 2016; Wu 2017; Zwar 2015). Ellerbeck 2009 repeatedly mailed primary care patients an offer of free pharmacotherapy and tested two levels of disease management, including proactive calls or no contact. One study offered either a proactive or reactive service as covered benefit (Joyce 2008). Additional details are in the Characteristics of included studies tables.

The number, duration and content of the telephone calls was variable. The potential number of calls ranged from one to 12 and in some studies was flexible. The duration of the calls also varied; 10 to 20 minutes was common, although the initial call might be longer. The call schedule could be spaced over weeks or months. Amongst studies that did not recruit participants on the basis of their willingness to make a quit attempt, the content was typically individualised to enhance motivation in those undecided about quitting, or to support a quit attempt where appropriate. Counselling was most commonly provided by professional counsellors or trained healthcare professionals. One trial used trained postgraduate students (Aveyard 2003). Three trials used trained peer counsellors, in one case survivors of childhood cancer (Emmons 2005), and in the other two women ex-smokers (Solomon 2000; Solomon 2005).

Many trials reported both short-term point prevalence abstinence (seven-day or 24-hour) and sustained abstinence, at one or more longer follow-ups. Long-term sustained abstinence was available for 53 of the 104 trials (51%). For the remainder, the outcome was based on point prevalence abstinence at the longest follow-up. Length of longest follow-up ranged from six months from start of intervention (35 trials), to seven years (Peterson 2016).

We grouped trials into three broad categories: trials of interventions for smokers who contacted a helpline; trials assessing the effect of providing access to a helpline; and trials that offered support proactively in other settings. Finally there are 10 trials that do not fit into any of these categories, so are considered individually (Bastian 2012; Collins 2018; Halpin 2006; Klemperer 2017; Reid 2018; Smith 2013; Sumner 2016; Vander Weg 2016; Warner 2016; Wu 2017).

Trials of interventions for people calling helplines

Nineteen trials recruited people who had phoned helplines/quitlines. We distinguished between trials where the intervention involved further proactive contact by the counsellor, and those that tested different interventions at the initial call. Fourteen studies tested proactive calls back to people who had initiated the contact with the quitline. The number of calls varied, with four studies comparing more than one schedule (Hollis 2007; Rabius 2007; Smith 2004; Zhu 1996). There were small differences in the support for the control group. In one trial, all participants had brief counselling during their initial call (Borland 2001); in three, some control group participants received some counselling (Borland 2003; Gilbert 2006; Zhu 2002). Ferguson 2012 was a factorial trial comparing proactive counselling to standard support, which included further contact by email, letter or text, and the offer of proactive calls. Participants were also randomised to an offer of nicotine replacement therapy (NRT). In the others the control group received self-help materials (Cummins 2016b; Hollis 2007; Nohlert 2014; Rabius 2004; Rabius 2007; Sims 2013; Smith 2004; Zhu 1996; Zhu 2012).

Five trials compared different interventions at the time a participant called the helpline. Sood 2009 compared counselling at the initial call to mailed self-help materials only. Orleans 1998 and Thompson 1993 compared different counselling interventions provided during the initial call; Orleans 1998 compared counselling and materials targeted at African-American smokers to standard advice and materials, and Thompson 1993 compared a counselling approach based on the 'stage of change' model to the provision

of more general information. Two trials offered two different modalities of proactive telephone counselling. Bricker 2014 compared Acceptance and Commitment Therapy (ACT) counselling with Cognitive Behavioural Therapy (CBT), with both arms receiving a two-week supply of NRT. Lindqvist 2013 compared Motivational Interviewing (MI) telephone counselling with standard telephone counselling.

Trials providing access to a helpline

Three studies assessed the impact of offering reactive counselling by providing access to a helpline/quitline/hotline, compared to not being provided access to a telephone helpline/quitline/hotline. One randomised counties to hotline access or not, and followed up smokers who were planning to stop and had registered for a smokers' self-help project (Ossip-Klein 1991). One compared a referral to a quitline to the usual care of a GP practice (Zwar 2015). One combined newsletter mailings and hotline access compared to no follow-up support for smokers who had registered for a self-help televised cessation programme (McFall 1993). Three studies compared referral to a quitline to proactive telephone counselling (Rogers 2016; Sherman 2017; Skov-Ettrup 2016). Joyce 2008 compared four different levels of benefit for Medicare beneficiaries aged 65 or older. The most intensive intervention offered a choice of accessing either a reactive hotline or multisession proactive counselling, along with self-help materials and coverage of nicotine patch with a small co-payment. Other arms offered coverage of brief provider counselling with or without coverage of pharmacotherapy, and usual care.

Trials of proactive counselling, not initiated by calls to quitlines

There were 65 trials in this category that we judged to have sufficient features in common to consider pooling their results. There were some differences in the intensity of the telephone component, the amount of cessation support that was common to both the control and intervention groups, and the populations recruited.

Studies with minimal intervention controls

There were 33 studies in this subgroup. In 26 studies proactive telephone counselling calls were the only form of personal contact in the cessation intervention. The control groups generally received mailed self-help materials, but Graham 2011 provided access to a cessation website. In six studies in healthcare settings the telephone intervention was an adjunct to usual care that involved at most a brief smoking intervention (Duffy 2006; Hanssen 2009; Holmes-Rovner 2008; Rigotti 2006; Stotts 2002; Young 2008). In two further studies that recruited participants through healthcare systems, advice and support were part of usual care but not all participants had clinic visits; the telephone counselling was delivered independently of any clinic visit rather than being an adjunct to a specific episode of care (An 2006; Lipkus 1999). Pharmacotherapy was not systematically offered to all intervention participants in any of the above trials, but in two there was greater use of pharmacotherapy by intervention participants (An 2006; McClure 2005). An 2006 encouraged the use of NRT or bupropion for intervention group participants making a quit attempt and this increased their use, although pharmacotherapy was available to all participants as part of their usual care. In McClure 2005 all participants could enrol in the *Free & Clear* phone-based support programme, which could also provide access to pharmacotherapy; this was used more by intervention than control groups.

Studies with brief intervention/counselling controls

Thirteen trials incorporated what we judged to be more substantial face-to-face advice for all participants, but without systematic use of pharmacotherapy (Borland 2008; Brown 1992; Brunette 2017; Chouinard 2005; Cossette 2011; Ebbert 2007; Flöter 2009; McBride 2004; Metz 2007; Ockene 1991; Osinubi 2003; Ramon 2013; Reid 2007). The support common to all participants included: a single information session and the provision of a self-help manual (Brown 1992); usual prenatal care including provider advice and self-help materials (McBride 2004); assessment, advice or brief counselling from a physician (relevant arms of Borland 2008; Ockene 1991; Ramon 2013) or hygienist/dentist (Ebbert 2007); advice from an occupational physician to consult a personal physician (Osinubi 2003); inpatient nurse counselling (Brunette 2017; Chouinard 2005; Cossette 2011; Reid 2007); or multisession group counselling (Flöter 2009; Metz 2007).

Studies of counselling added to pharmacotherapy

Eighteen trials provided telephone counselling as an adjunct to pharmacotherapy. In 15 trials there was a systematic offer or provision of NRT (Bastian 2013; Blebil 2014; Cummins 2016a; Fiore 2004; Fraser 2014; Hughes 2010; Lando 1997; MacLeod 2003; NCT00534404; Ockene 1991; Reid 1999a; Schlam 2016; Solomon 2000; Solomon 2005; Velicer 2006). Swan 2010 provided varenicline. Boyle 2007 recruited health maintenance organisation (HMO) members who were filling a prescription for any cessation medication, and Ellerbeck 2009 offered free medication four times over two years. The support common to all participants in other trials included: access to a website (Swan 2010); physician advice and an offer of free nicotine gum (relevant arms of Ockene 1991); provision of free nicotine patch after a primary care visit (Fiore 2004); three sessions of physician advice and free nicotine patch (Reid 1999a); a single 90-minute session, a free prescription for nicotine patch and access to a helpline (Lando 1997); or provision of free nicotine patches (two-week supply only) but no face-to-face contact (Bastian 2013; Blebil 2014; Fraser 2014; MacLeod 2003; Solomon 2000; Solomon 2005; Velicer 2006). Cummins 2016a provided up to six weeks of NRT with the number of weeks depending on how many cigarettes smoked per day , whereas NCT00534404 and Schlam 2016 provided up to eight weeks' free supply of NRT. Velicer 2006 provided nicotine patches to participants meeting criteria for readiness to make a quit attempt; 86% received some during the study.

Studies of counselling added to incentives

One study provided telephone counselling as an adjunct to incentives. Thomas 2016 compared the effect of adding telephone counselling as an adjunct to entry into a 'Quit and win' contest.

Telephone counselling intensity

The number of calls and the period over which they were delivered in this group of 65 studies was very varied. We provide a summary in the following table.

Maximum no. of calls	Within 4 weeks	Within 3 months	Within 6 months	Over longer period/other
Single call	Fiore 2004; Miguez 2008	-	-	-
2 calls	Ellerbeck 2009 (moderate intensity arm, up to 2 after each offer of pharmacotherapy); Lando 1992; Lichtenstein 2000; Lichtenstein 2008; Lipkus 1999	Ossip-Klein 1997; Stotts 2002 (in late pregnancy)	Rimer 1994	-
3 calls	Ebbert 2007; Flöter 2009	Abdullah 2005; Curry 1995; Lipkus 2004; McBride 1999a; Ockene 1991; Reid 1999a	Aveyard 2003; Prochaska 2001	McBride 1999b (part, during pregnancy)
4 calls	Blebil 2014; Young 2008	Lando 1997; Reid 2007 (average 2 automated and 2 counsellor)	McClure 2005; Prochaska 1993; Ramon 2013; Tzelepis 2011a (if not setting TQD)	Chan 2015; Orleans 1991
5 calls	Fraser 2014	Graham 2011; Hughes 2010; MacLeod 2003; Metz 2007; NCT00534404; Osinubi 2003; Swan 2010		Rigotti 2006 (4 in pregnancy and 1 postpartum)
6 calls	Brown 1992; Tzelepis 2011a (if setting TQD)	Bastian 2013; Borland 2008; Chouinard 2005; Cossette 2011; Ellerbeck 2009 (high intensity arm, up to 6 after each offer of pharmacotherapy); Girgis 2011; Holmes-Rovner 2008; Miguez 2002; Sorensen 2007a	Emmons 2005	McBride 1999b (part) and McBride 2004 (3 during pregnancy and 3 postpartum)
7 or more	Brunette 2017	An 2006; Schuck 2014; Solomon 2000	Boyle 2007 (up to 9, average 5); Duffy 2006 (9 to 11); (Hanssen 2009 (9); (Velicer 2006 (up to 10 automated calls); (Solomon 2005 (up to 12); McClure 2011 (up to 12, also covering depression and physical activity); Schlam 2016 (up to 8)	Cummins 2016a (up to 10); Peterson 2016 (up to 10)

The average number of calls completed, where reported, was typically considerably smaller than the maximum available. For studies where the intervention involved a process of referral to proactive support from another source, the proportion of participants reaching and accepting counselling was small, but those accepting the intervention generally had multisession support.

Recruitment and motivation of participants

We tried to categorise this set of 65 trials according to whether or not they selected participants with an interest in stopping smoking, or whether they were non-selective or designed to reach a wider population of smokers. Of the 25 trials in the 'Selected' subgroup, 13 recruited from the general population using advertisements for smokers planning to quit or interested in quitting (Brown 1992; Fraser 2014; Graham 2011; MacLeod 2003; Miguez 2002; Miguez 2008; NCT00534404; Orleans 1991; Ossip-Klein 1997; Rimer 1994; Solomon 2000; Solomon 2005; Swan 2010). Seven recruited during healthcare visits (Blebil 2014; Brunette 2017; Cummins 2016a; Fiore 2004; Ramon 2013; Reid 1999a; Schlam 2016); Boyle 2007 and Lando 1997 recruited HMO members, and An 2006 mailed invitations to patients of Veterans Administration Medical Centres. Schuck 2014 recruited parents of children through their primary schools, and Thomas 2016 recruited higher education students.

There were 38 trials in which motivation or interest in quitting was not an explicit entry criterion. Many recruited people in healthcare settings and the level of motivation to quit as assessed by stage of change at baseline, or other measures, was often high. Four recruited pregnant women (McBride 1999b; McBride 2004; Rigotti 2006; Stotts 2002); 15 recruited people during healthcare visits including in family practices, dental practices and hospitals (Bastian 2013; Borland 2008; Chouinard 2005; Cossette 2011; Duffy 2006; Ebbert 2007; Flöter 2009; Girgis 2011; Hanssen 2009; Holmes-Rovner 2008; Metz 2007; Ockene 1991; Osinubi 2003; Reid 2007; Young 2008); seven others recruited through healthcare system records (Aveyard 2003; Ellerbeck 2009; Lipkus 1999; McClure 2005; McClure 2011; Prochaska 2001; Velicer 2006). Of the other miscellaneous methods, Lichtenstein 2000 and Lichtenstein 2008 recruited smokers in households that were offered free radon testing kits, Lipkus 2004 recruited teens approached in shopping malls, Chan 2015 recruited adults approached in shopping malls, Peterson 2016 recruited students from high schools, Abdullah 2005 recruited smoking parents of children in a birth cohort study, Emmons 2005 recruited smokers from a cohort study of childhood cancer survivors, and Sorensen 2007a recruited union members. Prochaska 1993 advertised for community volunteers, irrespective of quitting interest. In three trials contact was initiated with smokers who had not been specifically recruited to a trial (Curry 1995; Lando 1992; McBride 1999a).

Studies comparing intense versus minimal telephone counselling

Three studies did not have a no-telephone support control and compared interventions with different numbers of calls (Miller 1997; Piper 2016; Swan 2003). Miller 1997 assessed the effect of increasing the amount of telephone follow-up after an inpatient counselling intervention. Piper 2016 compared three 15-minute phone sessions within a 10-day period versus a single 10-minute session on the quit date in a factorial design. Swan 2003 compared two intensities of behavioural support, both of which involved telephone contact without face-to-face support, for smokers also randomised to one of two doses of bupropion.

Other studies

We identified 10 other studies where we judged the nature of the main intervention or the conditions compared to be so distinctively different from any other included studies that we describe them separately rather than pooling them.

Bastian 2012 compared standard telephone counselling with family-supported telephone counselling, which included a support skills booklet and additional telephone counselling content focusing on social support skills that aimed to help increase positive interactions between the participant and their designated support person, to facilitate smoking cessation. Participants randomised to family support-based intervention also received an eight-page disease-specific family support booklet.

Collins 2018 compared an individual behavioural telephone counselling intervention that focused on reducing child second-hand smoke exposure and parent smoking cessation, to an individual telephone health education attention control intervention that focused on improving family nutrition on a budget.

Halpin 2006 compared different benefit designs for tobacco treatment. The control group was given coverage for pharmacotherapy only. One intervention group had coverage for telephone counselling and pharmacotherapy (bupropion or NRT, USD 15 co-payment) whilst the other had pharmacotherapy coverage only if enrolled for telephone counselling. Participants were not required to take up any treatment during the study period.

Klemperer 2017 compared three different arms of telephone counselling: smoking reduction telephone counselling, brief motivational telephone counselling, and a usual care five-minute call.

Reid 2018 included an automated telephone follow-up system that posed a series of questions to participants about their smoking status, confidence in staying smoke-free, use of smoking cessation aids (medication and behavioural support), and need for assistance. This flagged eligible participants for contact by a nurse-counsellor, who provided additional assistance as appropriate. The effect of this intervention was compared to standard care.

Smith 2013 tested the addition of a medication adherence counselling component to standard four-session counselling in a factorial trial that also compared two durations of free NRT and a combination of patch and gum versus patch alone.

Sumner 2016 tested different approaches to telephone counselling, comparing nondirective with directive telephone coaching. In nondirective counselling, the quitline coach allowed the participant to set the agenda for each call, whereas in directive counselling the quitline coach followed a prespecified agenda for each call, and did not allow the participant to deviate from the agenda.

Vander Weg 2016 compared tailored telephone counselling, which combined counselling on tobacco use and related issues including depressive symptoms, risky alcohol use, and weight concern, with referral to a state tobacco quitline. Both arms received an offer of NRT, bupropion or varenicline.

Warner 2016 compared the effects of a brief (approximately five-minute) quitline facilitation intervention with brief (approximately five-minute) cessation advice. Both arms received a free two-week supply of nicotine patches.

Wu 2017 compared smoking-reduction telephone counselling consisting of a minimal face-to-face individual smoking reduction intervention lasting for about one minute, and five follow-up interventions lasting for about one minute each, with brief face-to-face individual exercise and dietetic advice lasting for the same intervention time as the smoking reduction intervention, and five follow-up interventions lasting for about one minute each with different intervention contents.

Risk of bias in included studies

A summary of the evaluation of risks of bias for each study is shown in Figure 2. Overall, we judged 12 studies (11.5%) to be at low risk of bias across all domains, 60 (57.7%) to be at high risk of bias in at least one domain, and the remaining 32 (30.8%) to be at unclear risk of bias. Full details for 'Risk of bias' judgements for all included studies can be found in the Characteristics of included studies table.

Figure 2. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

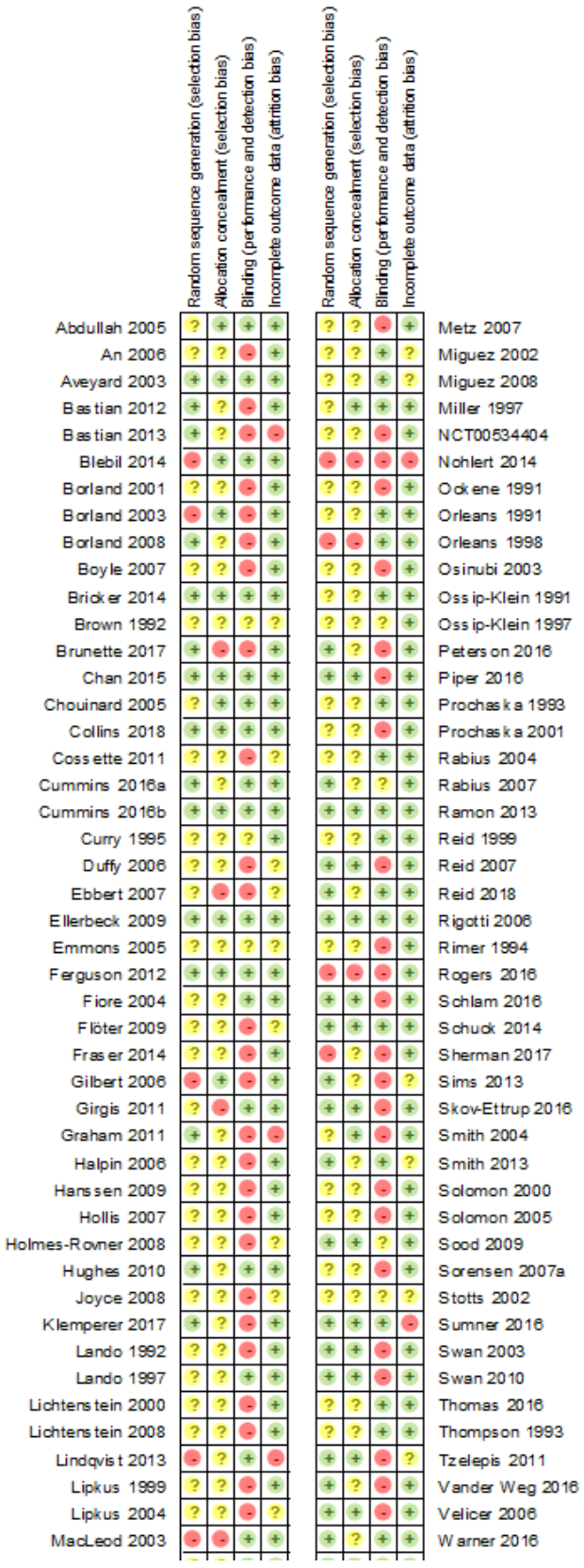
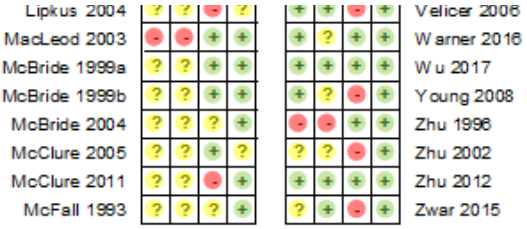


Figure 2. (Continued)



Allocation

We judged 13 studies to be at high risk of selection bias because of the way the sequence was generated or concealed; we rated 21 at low risk of selection bias, and the remainder to be at unclear risk.

All included studies described treatment allocation as 'random', but most did not give sufficient details about the method for generating the sequence. Thirty-eight (36%) gave sufficient detail to be judged at low risk for sequence generation. We judged 10 (10%) to be at high risk of bias for sequence generation (Borland 2003; Blebil 2014; Gilbert 2006; Lindqvist 2013; MacLeod 2003; Nohlert 2014; Orleans 1998; Rogers 2016; Sherman 2017; Zhu 1996). We judged the remaining studies to be at unclear risk of bias.

Twelve trials used cluster randomisation, nine of which contributed to a meta-analysis. In two of these, households were the unit of randomisation, and about 54% of households contained more than one smoker (Lichtenstein 2000; Lichtenstein 2008). The reported intraclass correlation was small. Borland 2008 randomised general practitioners. The reported odds ratio that adjusted for clustering and other factors was similar to that generated by the crude data. Lando 1997 randomised by the orientation session attended. Chouinard 2005 randomised clusters of two to six participants. Ebbert 2007 randomised by dental practice, and Zwar 2015 randomised by general practice. Peterson 2016 randomised by high school and Lindqvist 2013 by quitline counsellor. Excluding these studies did not have a major effect on any of the meta-analysis findings.

We did not pool the other three cluster-randomised trials with other studies in a meta-analysis. In one, participants were given access to a hotline according to county of residence, so that the availability of a hotline could be advertised in the intervention counties (Ossip-Klein 1991). Joyce 2008 randomised areas within states to different Medicare benefits. Sumner 2016 randomised families to either directive or nondirective telephone coaching.

Methods for concealing the allocation were also incompletely reported in most studies. Thirty (29%) reported sufficient detail to be judged at low risk. We judged eight (8%) to be at high risk of bias due to lack of concealment (Brunette 2017; Ebbert 2007; Girgis 2011; MacLeod 2003; Nohlert 2014; Orleans 1998; Rogers 2016; Zhu 1996). .

Blinding of outcome measurement (detection bias)

Overall, we judged most studies to be at high risk of detection bias (54 studies, 51.9%), while 41 studies (39.4%) were at low risk of detection bias. We rated the remaining nine studies (8.7%) at unclear risk of detection bias.

As set out in the Methods, we assessed detection bias based on whether abstinence was biochemically validated. If abstinence was not validated, we considered whether the intervention group received substantially more contact than the control group, in which case we suspected that differential misreport was possible.

The studies in quitline callers typically did not attempt to use biochemical verification of self-reported quitting. Two tested a local convenience sample (Rabius 2004; Zhu 1996). Ferguson 2012 reported carbon monoxide- (CO) validated rates, although only 52% of self-reported quitters provided samples. Studies in other settings were more likely to require biochemical verification of all self-reported abstinence. Aveyard 2003, Collins 2018, Cummins 2016a, Cummins 2016b, Lando 1992 and Ossip-Klein 1991 measured cotinine levels. Blebil 2014, Fiore 2004, Hughes 2010, Lando 1997, Miguez 2002, Ramon 2013, Reid 2018, Rigotti 2006, and Wu 2017 measured CO levels. Brunette 2017, Chan 2015, Chouinard 2005, and Schuck 2014 used a mixture of CO and cotinine assessments. Ellerbeck 2009 and Miller 1997 tested for cotinine but allowed family-member verification of some self-reports. Warner 2016 measured urine anabasine levels. Thomas 2016 used NicCheck test strips. Some other studies attempted biochemical verification but did not report validated abstinence (Bastian 2012; Bastian 2013; Brown 1992; Curry 1995; Lipkus 2004; McBride 1999a; McBride 1999b; McBride 2004; McClure 2005; Orleans 1991; Reid 1999a; Solomon 2000; Sumner 2016; Thompson 1993). Stotts 2002 validated abstinence at an early follow-up but not at the follow-up used in this review.

One trial in teenagers reported particularly high misreport rates (45% to 55%) in both groups; some admitted smoking in the seven days before returning the sample (Lipkus 2004).

Incomplete outcome data

All studies reported the numbers randomised to each group. We judged five studies (4.8%) to be at high risk of attrition bias (Bastian 2013; Graham 2011; Lindqvist 2013; Nohlert 2014; Sumner 2016), due to the large proportion of participants lost to follow-up, while 16 were at unclear risk of attrition bias as the number followed up was not provided (Brown 1992; Cossette 2011; Duffy 2006; Ebbert 2007; Emmons 2005; Flöter 2009; Holmes-Rovner 2008; Joyce 2008; Lipkus 2004; McClure 2005; Miguez 2002; Miguez 2008; Sims 2013; Smith 2004; Stotts 2002; Tzelepis 2011a). We rated most studies (83 studies, 79.8%) at low risk of attrition bias.

Most studies reported findings based on treating all dropouts as smokers, although some did not note the number lost to follow-up who were assumed to be continuing smokers. Many also reported complete-case analyses (excluding dropouts), or used methods

for imputing missing data. In most cases this had little impact on the relative effect, because numbers lost were similar across conditions. We did not identify any studies where using complete cases or using adjusted estimates of quit rates would have changed the relative effect enough to alter the conclusions of a meta-analysis.

We detected no other biases.

Effects of interventions

See: **Summary of findings for the main comparison** Interventions for callers to quitlines - effect of additional proactive calls for smoking cessation; **Summary of findings 2** Interventions for smokers not calling quitlines - effect of proactive telephone counselling

Trials of interventions for people calling helplines

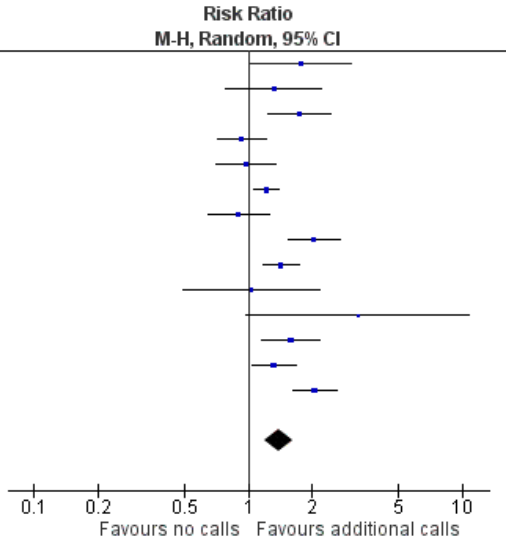
Effect of additional proactive support

Fourteen studies (N = 32,484) that compared an intervention involving multisession proactive counselling with a control condition providing self-help materials or brief counselling at a single call showed evidence of a benefit from the additional support. With the addition of two new studies published since the last update (Cummins 2016b; Nohlert 2014), the pooled risk ratio (RR) was unchanged but the confidence interval is now wider, given the substantial heterogeneity in the effect size between studies and the random-effects model now being used: RR 1.38, 95% confidence interval (CI) 1.19 to 1.61; I^2 = 72%; Figure 3, Analysis 1.1). Exclusion of eight studies that were at high risk of bias for any of the domains (Borland 2001; Borland 2003; Gilbert 2006; Hollis 2007; Nohlert 2014; Smith 2004; Zhu 1996; Zhu 2002) resulted in a slightly larger effect size, but the confidence intervals overlapped (RR 1.52, 95% CI 1.16 to 1.98; 6 trials, 16,293 participants; I^2 = 80%).

Figure 3. Comparison 1. Interventions for callers to quitlines. Effect of additional proactive calls.

Study or Subgroup	Treatment Events	Treatment Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI
Borland 2001	35	497	20	501	4.8%	1.76 [1.03, 3.01]
Borland 2003	32	528	24	523	5.0%	1.32 [0.79, 2.21]
Cummins 2016b	83	584	48	589	7.4%	1.74 [1.25, 2.44]
Ferguson 2012	100	1296	107	1295	8.6%	0.93 [0.72, 1.21]
Gilbert 2006	70	753	67	704	7.7%	0.98 [0.71, 1.34]
Hollis 2007	499	2874	248	1740	10.5%	1.22 [1.06, 1.40]
Nohlert 2014	60	588	61	541	7.4%	0.90 [0.65, 1.27]
Rabius 2004	141	1804	66	1716	8.3%	2.03 [1.53, 2.70]
Rabius 2007	516	4758	119	1564	9.8%	1.43 [1.18, 1.73]
Sims 2013	14	209	13	201	3.2%	1.04 [0.50, 2.15]
Smith 2004	20	423	3	207	1.4%	3.26 [0.98, 10.85]
Zhu 1996	190	2189	46	841	7.8%	1.59 [1.16, 2.17]
Zhu 2002	179	1973	90	1309	8.9%	1.32 [1.03, 1.68]
Zhu 2012	184	1124	92	1153	9.1%	2.05 [1.62, 2.60]
Total (95% CI)		**19600**		**12884**	**100.0%**	**1.38 [1.19, 1.61]**
Total events	2123		1004			

Heterogeneity: Tau² = 0.05; Chi² = 46.23, df = 13 (P < 0.0001); I² = 72%
Test for overall effect: Z = 4.15 (P < 0.0001)



The two studies with the largest weights in the meta-analysis detected statistically significant effects, as did six other studies, suggesting that there is a benefit from these types of interventions in most settings but perhaps not in all. We examined the characteristics of the six studies in which the point estimates suggested no effect of counselling (Borland 2003; Ferguson 2012; Gilbert 2006; Nohlert 2014; Sims 2013; Smith 2004). These studies were conducted mainly in the USA (n = 8), but also in the UK (n = 2), Australia (n = 2), Sweden (n = 1), and Canada (n = 1). In the earliest UK trial (Gilbert 2006), the authors thought that the unstructured counselling might have explained the lack of effect, but in the second trial (Ferguson 2012) a more structured protocol was used. In both cases the control groups would have received some support at the original call, as well as mailed or emailed materials. The context of the UK healthcare system may contribute to the difference, since there has historically been a well-developed Stop Smoking Service with access to support and medication. Ferguson 2012 also failed to detect an effect of offering free nicotine replacement therapy (NRT), in a factorial design. The difference in the healthcare setting may also explain the lack of effect for the Australian (Borland 2003), Swedish (Nohlert 2014) and Canadian (Smith 2004) studies. In addition, in the Australian study (Borland 2003), the group in the control arm received an intensive tailored self-help programme, the efficacy of which may be more similar to that of a proactive telephone counselling programme. In the Swedish study (Nohlert 2014), most of the bias domains were at high risk, which could have obscured an effect of the proactive telephone counselling. In the only American study with a point estimate suggesting no effect (Sims 2013), the participants were young adults, for whom there is limited evidence for any effective interventions (Fanshawe 2017). However, the confidence interval for this study was wide and encompassed the possibility of effects consistent with the other studies.

Using only the Hollis 2007 trial data for intervention and control arms that were not offered NRT as an adjunct slightly decreased the effect size (RR 1.36, 95% CI 1.14 to 1.62; 31,048 participants), while using the data for the arms that had NRT as an adjunct therapy increased the effect size (RR 1.41, 95% CI 1.21 to 1.64; 31,046 participants). This is because the addition of NRT enhanced

the effect of the combined telephone counselling arms, despite the study reporting no evidence of interaction.

Counselling intensity

In the main analysis we pooled more than one intensity of intervention into the treatment arms of four studies (Hollis 2007; Rabius 2007; Smith 2004; Zhu 1996). Using only the more intensive interventions in the two trials that reported outcomes for two different interventions (Hollis 2007; Zhu 1996) marginally increased the pooled effect size (RR 1.40, 95% CI 1.20 to 1.64; 29,908 participants; I^2 = 72%;). Smith 2004 did not detect a difference between groups receiving two or six follow-up calls after an initial 50-minute session, and we were unable to obtain separate results for different telephone counselling intensities. Rabius 2007 tested six different intervention formats, varying the number of calls, their duration and the use of two brief booster calls at four and eight weeks after counselling. There was no clear dose-response effect: five brief counselling calls plus boosters were no less effective than the standard American Cancer Society protocol of five longer calls and boosters.

Analysis 2.1 includes comparisons of different telephone counselling intensities across studies. In Rabius 2007, a higher number of calls was associated with higher cessation rates. Seven calls, including five brief or standard calls with two booster calls (RR 1.44, 95% CI 1.09 to 1.89; 1,908 participants), and five calls, including brief or standard calls with or without booster calls (RR 1.28, 95% CI 1.00 to 1.64; 3669 participants) were more effective in increasing cessation rates than the three standard calls without booster calls. However in the same study, seven calls were no more effective than five calls in increasing cessation rates (RR 1.12, 95% CI 0.93 to 1.36; 3939 participants). In Hollis 2007, intensive counselling (five calls) was not more effective than moderate counselling (two calls) (RR 1.05, 95% CI 0.89 to 1.23; 2874 participants). Lastly, in Zhu 1996 multiple counselling (five calls) was more effective than a single counselling session (RR 1.32, 1.01 to 1.74; 2189 participants).

In a post hoc subgroup analysis by telephone counselling intensity (Analysis 3.1), there were no statistically significant subgroup differences (Chi^2 = 1.32, df = 2 (P = 0.52), I^2 = 0%). Subgroups of low and medium intensity detected a statistically significant benefit of the intervention (two sessions or fewer: RR 1.22, 95% CI 1.02 to 1.46; 2 trials, 3867 participants; I^2 = 0%; three to six sessions: RR 1.38, 95% CI 1.17 to 1.63; 11 trials, 22,612 participants; I^2 = 67%); the difference was not statistically significant for seven or more sessions, but the confidence interval was wide and narrowly missed one (RR 1.49, 95% CI 0.98 to 2.25; 4 trials, 6005 participants; I^2 = 77%).

Comparisons between different types of support at initial call

Five studies compared different modalities of telephone counselling with varying support at initial call (Analysis 4.1).

One study (Sood 2009) compared reactive counselling to mailed self-help materials alone. All participants in the intervention group had counselling at the time of their call and had the option to get repeated support. We found no effect of the intervention (RR 0.96, 95% CI 0.71 to 1.30; 990 participants).

Two studies compared different reactive support for helpline callers during a single session. They did not detect a significantly increased benefit from either counselling and materials designed for African-Americans (Orleans 1998) (RR 1.10, 95% CI 0.80 to 1.52; 1422 participants), or stage-based counselling designed for blue-collar workers (Thompson 1993) (RR 1.10, 95% CI 0.73 to 1.67; 382 participants) compared to standard support. Quit rates in these trials were from 15% to 20% for point prevalence rates at six months.

In this latest update we found two new trials that compared telephone counselling interventions using different behavioural change theories. Bricker 2014 compared acceptance and commitment therapy to cognitive behavioural therapy, but observed no difference between the two (RR 1.35, 95% CI 0.74 to 2.46; 121 participants). Lindqvist 2013 found that motivational interviewing may be more effective than standard telephone counselling (RR 1.39, 95% CI 1.01 to 1.92; 772 participants).

Trials providing access to a helpline

Two studies (Ossip-Klein 1991; Zwar 2015) compared the provision of a hotline versus a minimal intervention. When we combined them, we noted a substantial increase in quit rates (RR 1.62, 95% CI 1.16 to 2.25; 3327 participants; I^2 = 0%; Analysis 5.1).

In McFall 1993 smokers who had enrolled to be sent materials for a self-help programme with a televised component were randomised to receive follow-up newsletters and access to a helpline for six months. The intervention combined a helpline and written materials, but quit rates were not lower in the intervention than in the control condition after 24 months (RR 0.86, 95% CI 0.70 to 1.06; 1311 participants).

In another four trials (Joyce 2008; Rogers 2016; Sherman 2017; Skov-Ettrup 2016), reactive or proactive calls were compared with provider counselling (quitline service), demonstrating a moderate increase in cessation rates for reactive or proactive counselling (RR 1.40, 95% CI 1.07 to 1.84; 7780 participants; I^2 = 73%) compared with provider counselling. The four trials were very heterogeneous in terms of target populations and interventions provided: in Joyce 2008 enrollees for a Medicare Stop Smoking Programme were randomised to a quitline that offered the choice of a reactive hotline with prerecorded messages and ad hoc counselling, or a proactive service, in addition to insurance coverage for the nicotine patch. The control group received pharmacotherapy coverage only. In Rogers 2016, people with mental health conditions were randomised to proactive telephone counselling for mental health patients or counselling provided by the state quitline. In Sherman 2017 smokers attending the Department of Vereran Affairs outpatient primary care clinics were recruited, and in Skov-Ettrup 2016 the participants were a nationally representative sample of the Danish population. In both studies the participants were randomised to either proactive or reactive telephone counselling, or to self-help. The cessation rates were much larger in the three trials in which the participants had been offered pharmacotherapy (Joyce 2008; Rogers 2016; Sherman 2017). Also in these three trials, point prevalence abstinence was reported, compared to Skov-Ettrup 2016 which reported prolonged abstinence at 12 months.

Two studies identified for this latest update (Sherman 2017; Skov-Ettrup 2016) provided data for comparisons of proactive and reactive telephone counselling versus each other, and versus self-help. Proactive counselling was not associated with an improvement in cessation rates compared with reactive counselling (RR 2.06, 95% CI: 0.58 to 7.31; 2908 participants; I^2

= 90%). However, neither proactive (RR 1.42, 95% 0.76 to 2.63; 2498 participants; I^2 = 74%) nor reactive (RR 0.78, 95% CI 0.44 to 1.40; 2364 participants; I^2 = 51%) were significantly associated with increased cessation rates when compared with self-help.

Trials of proactive counselling, not initiated by calls to quitlines

Overall effect of counselling

There were 65 trials in this comparison (Ockene 1991 contributed different data to two subgroups, making a total of 66 estimates in the analysis). The pooled effect suggested a modest benefit of proactive telephone counselling: RR 1.25, 95% CI 1.15 to 1.35; 41,233 participants; I^2 = 52% (Figure 4, Analysis 6.1). Our prespecified subgroup analyses based on the baseline support provided to both intervention and control, counselling intensity, or motivation did not fully explain the heterogeneity, nor was heterogeneity reduced by excluding the trials amongst teenagers or pregnant women. Exclusion of 38 trials that were at high risk of bias in at least one of the domains did not have a large influence on the pooled effect size, but widened the confidence interval (RR 1.23, 1.05 to 1.45; 26 trials, 15,701 participants; I^2 = 62%).

Figure 4. Comparison 6. Interventions for smokers not calling quitlines - subgroups by baseline support.

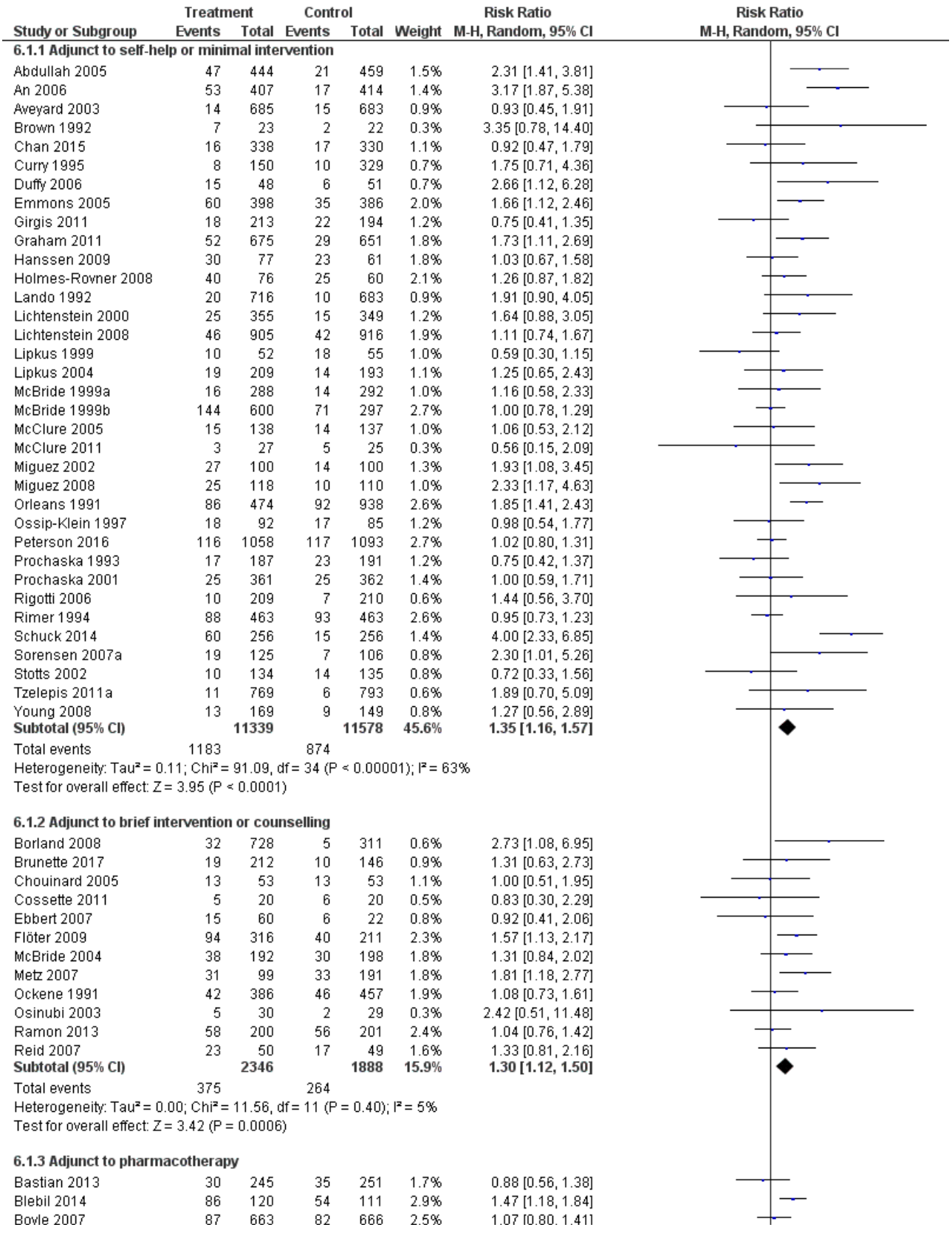
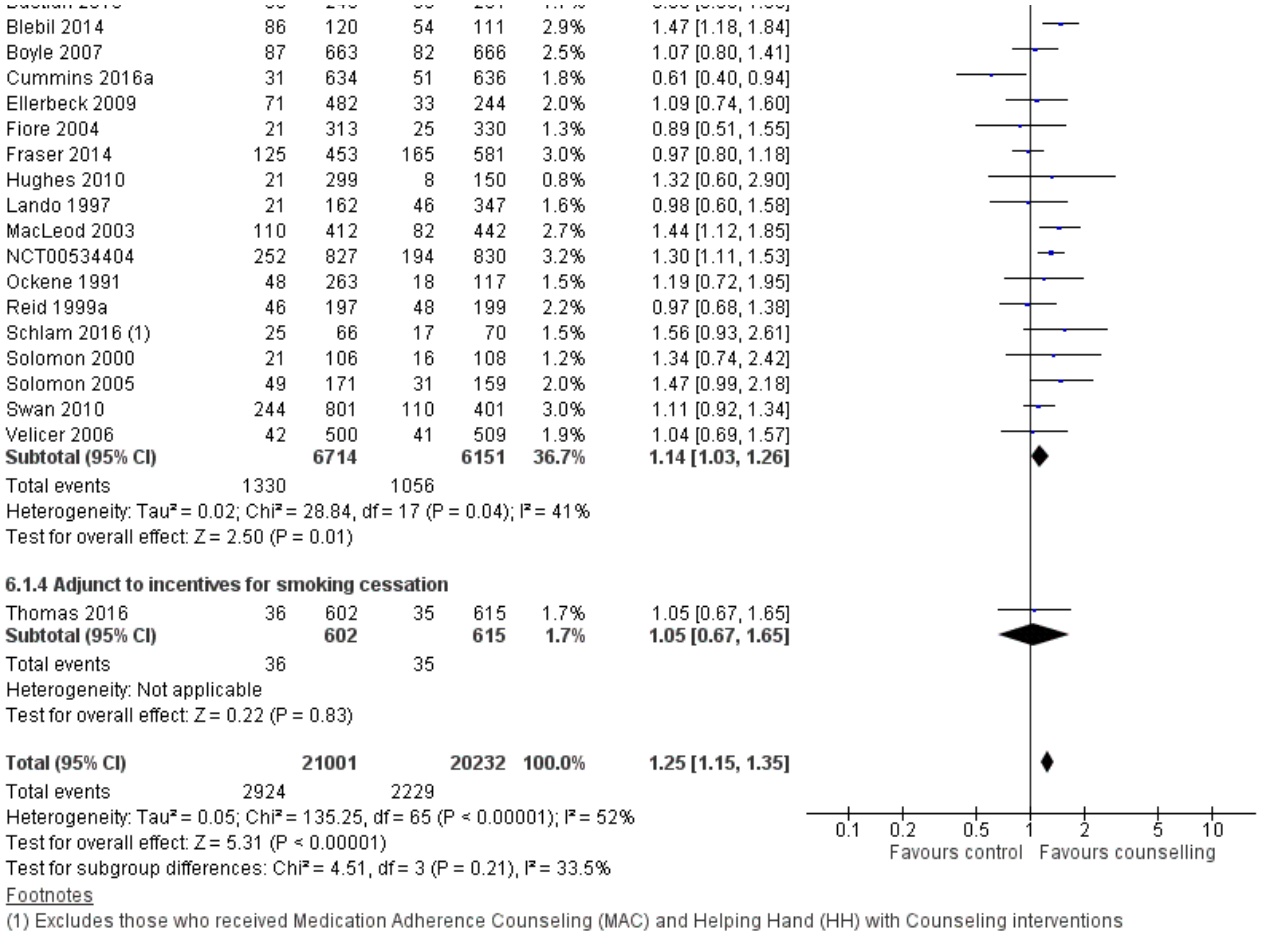


Figure 4. (Continued)



Footnotes

(1) Excludes those who received Medication Adherence Counseling (MAC) and Helping Hand (HH) with Counseling interventions

Baseline support offered

Thirty-five trials tested the effect of telephone counselling as an adjunct to self-help or to a minimal intervention. In this subgroup the effect of telephone counselling was slightly stronger: RR 1.35, 95% CI 1.16 to 1.57; 22,917 participants, than that for all 65 trials, although the heterogeneity was more pronounced within this subgroup (I^2 = 63%).

Twelve trials tested the effect of telephone counselling as an adjunct to face-to-face counselling or to a brief intervention. In this subgroup the effect of telephone counselling was also slightly stronger: RR 1.30, 95% CI 1.12 to 1.50; 4234 participants, than that for all 65 trials but with less evidence of statistical heterogeneity (I^2 = 5%).

Eighteen trials tested the effect of telephone counselling as an adjunct to the systematic use or offer of NRT (patch or gum), bupropion, or varenicline. In this subgroup the effect of telephone counselling was slightly smaller: RR 1.14, 95% CI 1.03 to 1.26; 12,865 participants, than that for all 65 trials, and the heterogeneity was slightly lower (I^2 = 41%).

One additional trial tested the effect of telephone counselling as an adjunct to incentives. In this trial, telephone counselling had no effect on smoking cessation: RR 1.05, 95% CI 0.67 to 1.65; 1217 participants.

Counselling intensity

Three trials directly compared moderate-intensity telephone counselling (three to five calls) to low-intensity telephone counselling (one call). The pooled effect suggests that moderate-intensity telephone counselling is more effective than minimal telephone counselling: RR 1.27, 95% CI 1.12 to 1.44; 2602 participants, with no evidence of heterogeneity (I^2 = 0%) (Analysis 7.1).

A subgroup analysis of the 65 trials comparing telephone counselling to control explored the impact of the number of calls planned as part of the intervention, using three categories; two or fewer, three to six, and seven or more calls. We had no strong a priori rationale for the choice of cut points, although the one-to-two-call group predominantly captured trials with 'brief' interventions. We initially analysed these categories within the grouping by the control condition used above, but since the pattern of results was largely consistent we simplified the comparisons (Analysis 8.1). There was no evidence of statistically significant differences between subgroups (Chi^2 = 1.70, df = 2 (P = 0.43), I^2 = 0%). In two of the three subgroups in this analysis, we did not find a statistically significant effect, but confidence intervals were wide; these were the smaller subgroups. Nine trials provided low-intensity telephone counselling, i.e. two or fewer calls: RR 1.09, 95% CI 0.86 to 1.40; 6274 participants; I^2 = 45%, and 13 provided high-

intensity telephone counselling, i.e. seven or more calls: RR 1.22, 95% CI 0.98 to 1.51; 8273 participants; I^2 = 63%.

The largest subgroup was the group of 44 trials providing medium-intensity telephone counselling, i.e. three to six calls. For studies in this subgroup telephone counselling had a statistically significant effect on smoking cessation rates: RR 1.29, 95% CI 1.18 to 1.42; 26,686 participants; I^2 = 48%.

We also considered whether including the 14 trials of proactive counselling for quitline callers in their intensity subgroups would alter these conclusions. The overall effect of telephone counselling was slightly stronger: RR 1.28, 95% CI 1.19 to 1.37; 73,717 participants; I^2 = 56%; *analysis not shown,* and the test for heterogeneity between subgroups was not statistically significant (P = 0.33).

To explain the higher heterogeneity among trials of high-intensity telephone counselling, we conducted another post hoc subgroup analysis by baseline support. High-intensity telephone counselling had no effect on cessation rates when provided as an adjunct to self-help: RR 1.45, 95% CI 0.85 to 2.46, 3261 participants, I^2 = 80%, *analysis not shown;* to pharmacotherapy: RR 1.10, 95% CI 0.88 to 1.38; 4654 participants; I^2 = 48%; *analysis not shown;* or to a brief intervention or counselling: RR 1.31, 95% CI 0.63 to 2.73; 358 participants; *analysis not shown*. A further source of methodological heterogeneity between high-intensity telephone counselling trials is that Velicer 2006 used an automated voice response system to provide tailored but prerecorded support. However, exclusion of this study did not have an effect on the pooled effect estimate or on statistical heterogeneity.

Motivation

A third subgroup analysis for the 65 trials explored the effect of motivation (Analysis 9.1). Twenty-six studies specifically recruited smokers who wanted to make a quit attempt, including most of the studies (14/18) where pharmacotherapy was common to both intervention and control. Thirty-nine studies did not state that participants were included on the basis of motivation, although a relatively high proportion may have been interested in quitting. The effect size was slightly larger for those 'selected' for motivation: RR 1.31, 95% CI 1.15 to 1.49; 17,877 participants; I^2 = 70%, than for those 'unselected': RR 1.20, 95% CI 1.09 to 1.33; 23,356 participants; I^2 = 26%, but the test for subgroup differences was non-significant (Chi^2 = 0.99, df = 1 (P = 0.32), I^2 = 0%).

Results of a meta-regression

In univariate meta-regression analyses none of the potential moderators tested was a significant predictor of the effect (RR) of telephone counselling on smoking cessation rates. When all potential moderators were fitted together in a multivariate meta-regression analysis (Appendix 2), the relative difference in the RR compared to pharmacotherapy as an adjunctive treatment was 35% greater for self-help (RR change 1.35, 95% CI 1.10 to 1.67, P < 0.01), and 37% greater for a brief face-to-face intervention (RR change 1.37, 95% CI 1.05 to 1.79, P = 0.02). In the same multivariate model, studies that selected participants for motivation were associated with a 26% greater RR (RR change 1.26, 95% CI 1.04 to 1.52, P = 0.02), compared to studies that did not select participants for motivation. When telephone counselling intensity was fitted as a categorical variable, only medium intensity, compared to low intensity, was statistically significantly associated with a change in the RR (RR change 1.34, 95% CI 1.03 to 1.74, P = 0.02; *analysis not shown*).

Other studies

We judged 10 other studies to be too dissimilar for pooling, but their results are shown in Analysis 10.1.

Seven studies compared counselling matched in contact time, but using different approaches or containing different content, or both.

Bastian 2012 compared family-supported telephone counselling with standard telephone counselling, and found no difference in self-reported seven-day point prevalent cessation at the 12-month follow-up: RR 1.02, 95% CI 0.72 to 1.45; 471 participants.

Collins 2018 compared individual behavioural telephone counselling focusing on parental smoking cessation and reduction of child second-hand smoke exposure to individual telephone health education focusing on improving family nutrition on a budget. There was no statistically significant difference in cotinine-verified seven-day point prevalence abstinence at 12 months: RR 2.01, 95% CI 0.97 to 4.17; 327 participants.

Klemperer 2017 tested the effects of three different interventions: smoking reduction telephone counselling, brief motivational telephone counselling, and standard telephone counselling. There was a significant difference in seven-day point prevalence abstinence at 12 months for the brief motivational versus standard telephone counselling: RR 2.63, 95% CI 1.12 to 6.14; 374 participants, but not for smoking reduction versus brief motivational telephone counselling: RR 0.88, 95% CI 0.47 to 1.68; 371 participants, or for smoking reduction versus standard telephone counselling: RR 2.32, 0.98 to 5.52, 375 participants.

Sumner 2016 compared nondirective telephone coaching with directive telephone coaching and found no difference in 12-month abstinence: RR 1.15, 95% CI 0.82 to 1.62; 518 participants.

Vander Weg 2016 compared the offer of tailored telephone counselling with referral to a state tobacco quitline, but there was no significant difference in the quit rates at six months: RR 1.03, 95% CI 0.47 to 2.25; 63 participants.

Warner 2016 compared a brief (approximately five-minute) quitline facilitation intervention with brief (approximately five-minute) cessation advice, and found no significant difference in quit rates at six months: RR 1.62, 95% CI 0.96 to 2.72; 600 participants.

Wu 2017 tested different focuses of a telephone intervention, with one group focusing on smoking reduction and the other on exercise and diet advice. There was no significant difference in quit rates at 12 months: RR 2.86, 95% CI 0.93 to 8.81; 369 participants.

Two studies evaluated additional features added to telephone counselling. Smith 2013 did not detect any additional benefit of a counselling component to increase adherence to the NRT that was provided to all participants who received counselling from the Wisconsin Tobacco Quit Line. There was no difference in 30-day abstinence at six months: RR 0.98, 95% CI 0.83 to 1.15; 987 participants. Reid 2018 compared an automated telephone follow-up with standard care, and found no significant difference in

continuous abstinence at 52 weeks: RR 1.22, 95% CI 0.92 to 1.60; 440 participants.

Halpin 2006 compared benefit designs that included telephone counselling and pharmacotherapy. There was no significant difference between the group offered coverage for telephone counselling and pharmacotherapy compared with the group offered pharmacotherapy alone: RR 0.68, 95% CI 0.38 to 1.18; 266 participants.

DISCUSSION

Summary of main results

This review considers telephone services for delivering behavioural counselling and support, both proactively and reactively. Interventions studied in trials range from brief contact with the potential to motivate a quit attempt, to intensive support for smokers already engaged in quitting.

Interventions for callers to quitlines

This update continues to provide moderate-certainty evidence of a benefit from providing proactive telephone counselling for smokers who initiate contact with quitlines (Summary of findings for the main comparison), limited by unexplained statistical heterogeneity. Compared to smokers who have only a single contact with the quitline, and are either sent self-help materials or receive brief counselling, or both, those who are randomised to one or more additional calls increase their chances of quitting by between 20% and 60%. This estimate remains almost unchanged after the inclusion of two new trials contributing over 2300 participants to this update.

In this update we conducted new post hoc subgroup analyses by counselling intensity. Even though the risk ratios increased from low-, to medium-, to high-intensity telephone counselling, the confidence intervals overlapped. Single estimates from included trials comparing higher versus lower number of calls were also inconclusive. Although in some trials many telephone counselling sessions were planned, the mean number of calls completed was often smaller. In Rabius 2007, the authors proposed that fewer shorter calls could be as effective as more and longer ones. They observed that "[t]he finding that different protocols generally yielded similar outcomes may be because they all contained the same basic elements and because those with five or more sessions had similar completion rates". If only a minority of participants are willing to accept all sessions, differences between more and less intensive protocols will have little impact.

Five further trials including callers to quitlines evaluated different telephone counselling interventions in comparisons that were too heterogeneous to be pooled. None of these studies showed an effect on quit rates except for one (Lindqvist 2013), in which motivational interviewing appeared to be more effective than standard telephone counselling; however, we judged this trial to be at high risk of bias.

Offer of counselling through quitlines/helplines/hotlines

Different types of interventions have been offered through quitlines, but their results are inconsistent, and relatively few studies contribute to each analysis in this group, leading to uncertainty. Two trials combined (Ossip-Klein 1991; Zwar 2015) suggest that provision of a quitline may be more effective than a minimal intervention, but another trial showed that a hotline and self-help materials may not be more effective in increasing quit rates than self-help materials alone (McFall 1993). Similarly, proactive and reactive telephone counselling appeared to increase quit rates compared to healthcare provider counselling (Joyce 2008; Rogers 2016; Sherman 2017; Skov-Ettrup 2016), but proactive counselling was not more effective than reactive counselling (Sherman 2017; Skov-Ettrup 2016), and there was no statistically significant effect when these studies compared proactive and reactive counselling to self-help materials.

Interventions for people not calling quitlines

Proactive telephone counselling may also be offered to people who have not contacted quitlines, but are being offered cessation support in other settings. These people may or may not be motivated to make a quit attempt when recruited. There is moderate-certainty evidence of benefit from telephone counselling under these conditions (Summary of findings 2). Estimates from pooling studies suggest a 15% to 35% increase in quitting. Based on a control group quit rate of 11%, this is equivalent to an absolute increase of 2 to 4 percentage points. The certainty of the evidence was again limited by statistical heterogeneity, which was only partially explained by the baseline support offered.

In the subgroups by intervention intensity, confidence intervals overlapped for all three subgroups, but the effect was strongest in the medium-intensity group. The effect was small and the confidence interval did not exclude no effect when the intervention consisted of only one or two calls (low-intensity telephone counselling). This is consistent with findings from three trials that directly compared medium-intensity to low-intensity counselling, and found medium-intensity counselling to be more effective. No studies directly compared high intensity to medium or low intensity.

In univariate and multivariate meta-regression models there was no evidence of a linear trend between the total number of calls offered and the effectiveness of telephone counselling on quit rates. However, there was evidence that the baseline support offered to both intervention and control groups, and whether participants were selected for motivation to quit at the time of recruitment, may have had some influence on the effect size.

Overall completeness and applicability of evidence

A substantial number of randomised controlled trials have now tested the effect of offering telephone counselling to smokers not calling quitlines. However, rigorous evaluation of reactive services (quitlines, hotlines or helplines) has been difficult because of a reluctance to undertake randomised trials that would require callers who sought help to be refused support. This review restricted formal inclusion to randomised or quasi-randomised trials. Two trials provide evidence that hotlines are beneficial (Ossip-Klein 1991; Zwar 2015). In Ossip-Klein 1991 use of the hotline was relatively high: 36% of the intervention participants called the hotline for recorded messages of support, and 8.7% spoke to counsellors.

There is much more evidence about the benefit of proactive counselling once smokers have called a telephone-based service. One study was able to evaluate the impact of the counselling element of a helpline by capitalising on the constraints on capacity

at certain times (Zhu 2002). In Sood 2009 the authors allocated callers to immediate reactive counselling, or self-help only. This study did not detect an effect of the counselling; the evidence of a relationship between the number of calls and the effect suggests that it may be important to engage callers into a multisession protocol as used by most quitlines, at least in North America (Cummins 2007).

A further issue with this evidence base is that the vast majority of studies were conducted in high-income countries. Only four out of the 104 studies were conducted in low- and middle-income countries, three of which we identified for this update. None of the studies was conducted in Latin America or Africa. Smoking rates and, accordingly, the burden of tobacco-related diseases are highest (and increasing) in lower- and middle-income countries.

A final consideration is that quitlines may exert an impact beyond that which can be measured by quit rates amongst callers. They may have a symbolic role, emphasising the importance of smoking cessation (Wakefield 2000), and may increase the number of smokers making a quit attempt each year because of awareness generated by the campaigns to promote them (Ossip-Klein 2003). Their availability may alter provider behaviour and encourage referral (Boldemann 2006). This is not something we could evaluate in this review.

Certainty of evidence

For the two main analyses presented in this review (studies of additional proactive calls offered to callers of quitlines, and studies of telephone counselling for people not calling quitlines) we judged results to be of moderate certainty (Summary of findings for the main comparison; Summary of findings 2), meaning that further research is likely to have an important impact on our confidence in the estimate of effect, and may change the estimate. Although both analyses contained a substantial number of randomised controlled trials, we downgraded our certainty in the effect estimate due to substantial unexplained statistical heterogeneity. It could be that the content of the calls contributed to the statistical heterogeneity but as we did not set out to evaluate programme content we are unable to investigate this here. This would be a useful topic for further research. An additional limitation of the evidence base is that we rated most of the included studies at unclear or high risk of bias; however, we did not downgrade on this basis, as results were not significantly different when we conducted sensitivity analyses removing those studies at high risk of bias.

Potential biases in the review process

As in standard Cochrane Tobacco Addiction Group methodology, estimates are based on treating all people lost to follow-up as continuing smokers. In this group of studies, loss to follow-up was relatively high. However, in a post hoc sensitivity analysis in the group of trials providing additional proactive telephone calls to people calling quitlines, excluding losses to follow-up from all conditions reduced the total numbers by about 35% and increased the estimate of absolute effect, but only by a percentage point.

Another potential source of bias in this process is access to grey literature. Although we searched clinical trials registries, it is still possible that we did not identify some relevant unpublished data. Our concerns here are somewhat alleviated by the fact that funnel plots showed no evidence of asymmetry (Figure 5; Figure 6).

Figure 5. Funnel plot of studies in Comparison 1: Interventions for callers to quitlines - effect of additional proactive calls.

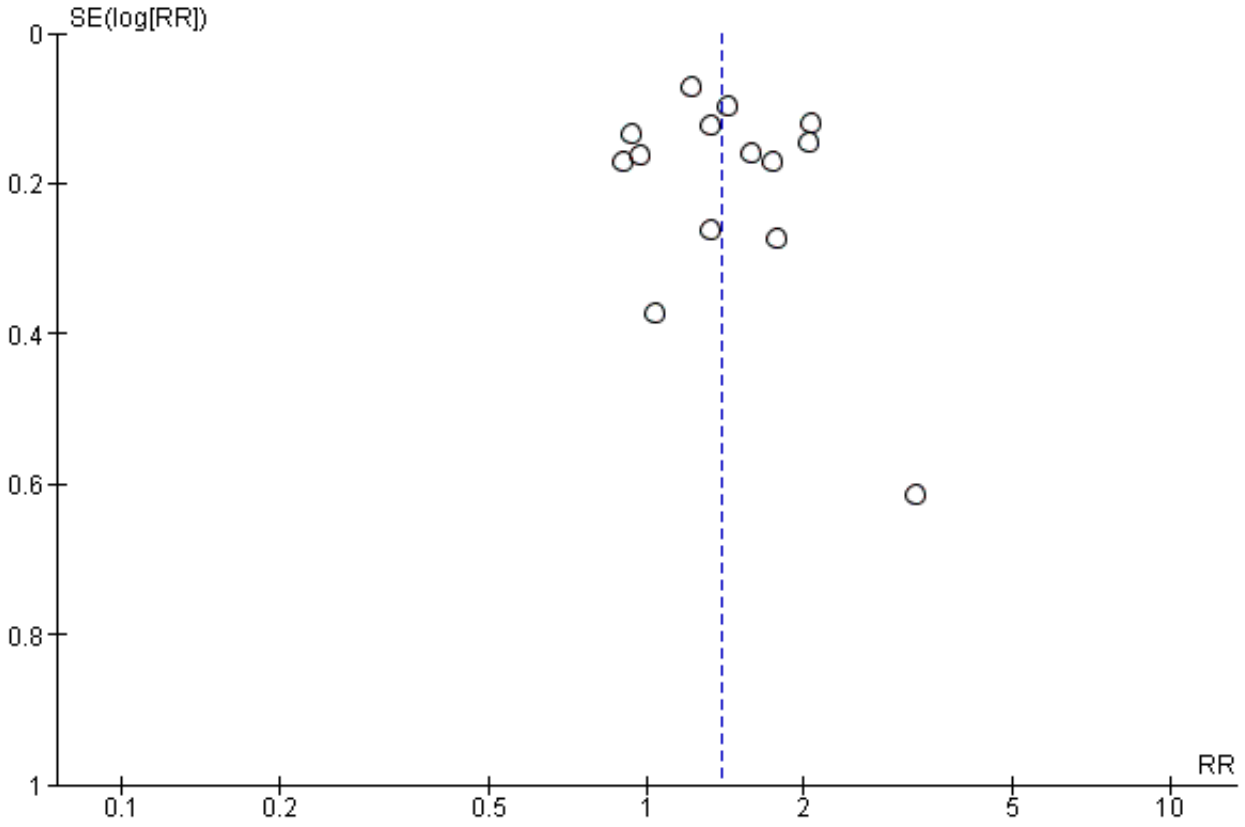
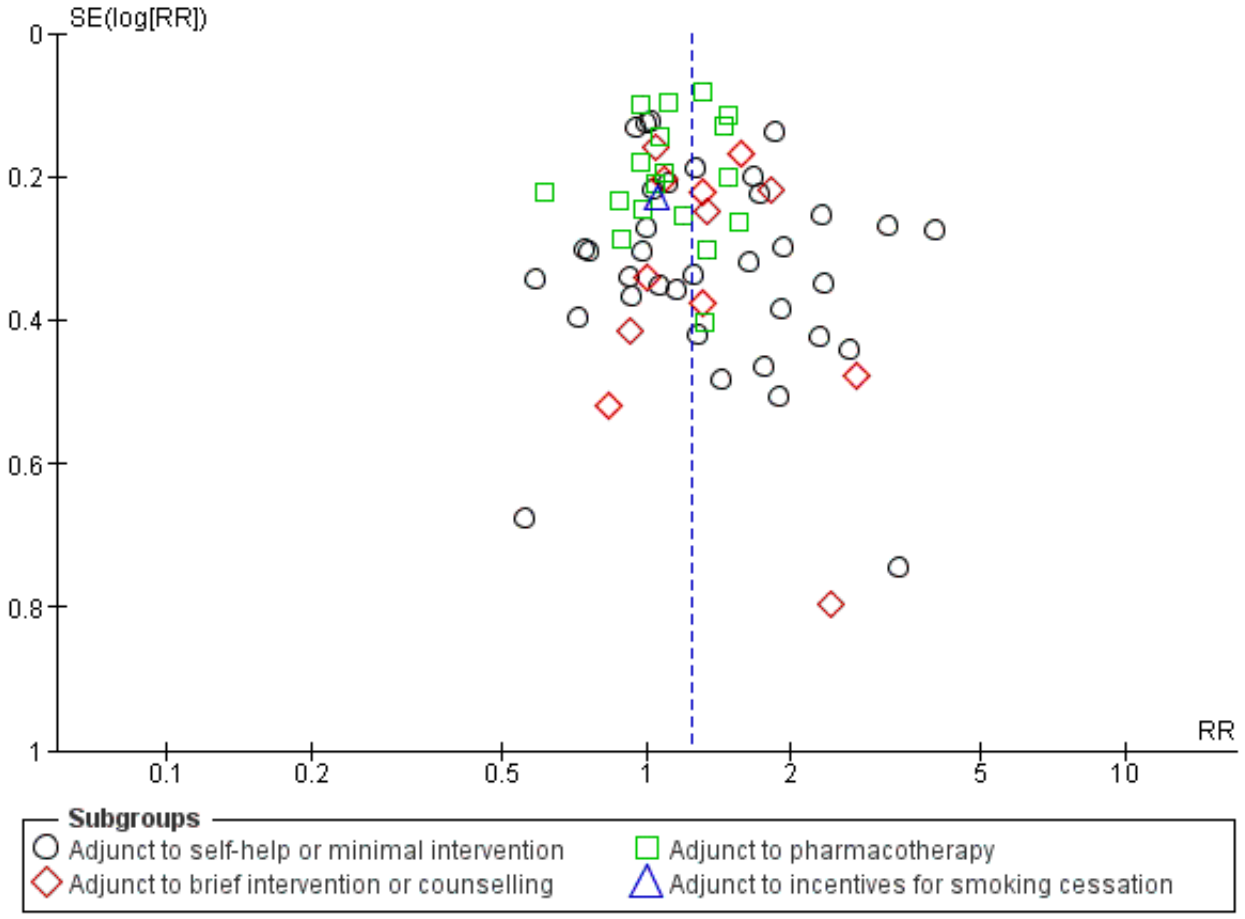


Figure 6. Funnel plot of studies in Comparison 6: Interventions for smokers not calling quitlines - subgroups by baseline support.



Agreements and disagreements with other studies or reviews

Our updated results suggest a more modest effect estimate for proactive telephone counselling than that estimated in the 2008 update of the US Clinical Practice Guideline *Treating Tobacco Use and Dependence* (Fiore 2008) (odds ratio (OR) 1.6, 95% CI 1.4 to 1.8; table 6.16). This is probably due to the fact that our review covers a longer period and thus includes more trials with tighter confidence intervals. The guideline also identified a benefit of adding quitline counselling to pharmacotherapy (OR 1.3, 95% CI 1.1 to 1.6; table 6.17). Our subgroup analysis in Analysis 6.1.3 also suggests a smaller estimate.

A 2011 meta-analysis of proactive telephone counselling (Tzelepis 2011b) distinguished between trials that proactively recruited participants and those with reactive recruitment, showing benefits in each subgroup. The seven trials they classified as active recruitment (Aveyard 2003; Abdullah 2005; Curry 1995; Lichtenstein 2000; Lichtenstein 2008; McBride 1999a; Prochaska 2001) were all in our subgroup of studies that did not select participants on the basis of motivation to quit. We also found a benefit of intervention in this group. A recent systematic review (Schwindt 2018) evaluated tobacco quitlines for smoking cessation in people with mental illness, and also found promising results within these populations.

In North America a third of quitlines distribute free NRT (Cummins 2007). Evaluations suggest that this increases call volume, and pre-post comparisons also suggest that quit rates are increased (e.g. An 2006a; Bush 2008; Campbell 2008; Cummings 2006b; Davis 2013; Fellows 2007; Miller 2009; Tinkelman 2007; Zawertailo 2013). In our group of studies evaluating telephone counselling as an adjunct to pharmacotherapy, we found a small and statistically significant benefit of the intervention. These findings are consistent with the results of a separate Cochrane Review of behavioural interventions as adjuncts to pharmacotherapy (Stead 2015), which also found a relatively small although clinically important benefit from increasing the amount of behavioural support. Studies that offered pharmacotherapy, with or without behavioural support, to all participants and evaluated the additional effect of telephone counselling were eligible for inclusion in both reviews. That review found that in a post hoc subgroup of trials in which all contact was by telephone, there was a clearer benefit of the telephone counselling over and above the pharmacotherapy. In our review some trials provided both pharmacotherapy and face-to-face support to all participants, and in these the addition of the telephone component did not show as strong an effect.

Telephone counselling may also have a role in increasing the appropriate use of pharmacotherapy. In a trial with one of the largest effects, the authors comment that the large effect observed

may in part be attributable to the greater use of pharmacotherapy amongst those receiving counselling, even though NRT and bupropion were also available in the usual-care condition (An 2006). Increased use of pharmacotherapy was also noted in the intervention groups in Emmons 2005. A study of callers to the California Smokers' Helpline provides useful information about the acceptability of a telephone referral service as an adjunct to pharmacotherapy (Zhu 2000). Participants in this follow-up study all planned to use NRT and had a pre-quit counselling session. Those who chose to receive further counselling were more likely to attempt to quit, and to remain non-smokers for up to a year. Seventy-nine per cent of participants continued with counselling, and 26% of these stayed quit for a year. Of the 21% who had only a single session of counselling, 16% quit. More than half the smokers had called the helpline as a requirement for obtaining free NRT, and the high uptake of further behavioural support suggests that it was popular as an adjunct to pharmacotherapy. However a UK trial did not show a benefit of additional calls or of offering free NRT (Ferguson 2012).

Telephone-based support systems are increasingly well established as part of comprehensive tobacco treatment initiatives (Borland 2006; Lichtenstein 2007; McAfee 2007). The US Department of Health & Human Services has introduced a single national quitline number, allowing access to the National Network of Tobacco Cessation Quitlines (Anon 2005). The North American Quitline Consortium promotes and supports evidence-based quitline services in the USA, Canada and Mexico. The European Network of Quitlines had 30 member quitlines in 2010. There is also a Global Quitline Network. The evaluation of systems that encourage and facilitate healthcare providers to refer people to specialist quitline services for extended support is an important area of research (Perry 2005; Sherman 2008; Winickoff 2006; Wolfenden 2008). Possible future developments include the use of direct mail or 'cold calling' to initiate contact with smokers (O'Connor 2008; Tzelepis 2011b; Van Deusen 2007; Vidrine 2011).

AUTHORS' CONCLUSIONS

Implications for practice

Proactive telephone counselling aids smokers who seek help from quitlines and smokers in other settings. The benefits of telephone counselling appear most pronounced when provided as an adjunct to print-based self-help materials, or brief face-to-face advice, and less pronounced when provided as an adjunct to pharmacotherapy. There is not enough evidence to suggest that a higher number of calls would result in a larger effect, although limited evidence suggests interventions offering three to six calls may be more effective than those offering one call only. Evidence was inconclusive on the effect of reactive telephone counselling, due to a limited number studies, which reflects the difficulty of studying this intervention.

Implications for research

Further research directly comparing the provision of different numbers of telephone counselling calls would be useful, particularly as there is some evidence that suggests that higher numbers of calls may be more effective than a single call. Research on reactive helpline services that compare different counselling protocols and different schedules of call-back sessions may also lead to improved outcomes.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [author-defined order]

Abdullah 2005

Methods	Setting: Parents of children in a birth cohort study, Hong Kong Recruitment: Active; by mail, current smokers, not selected for motivation

Abdullah 2005 *(Continued)*

Participants	903 current smokers with young children (49 recent quitters not included here); 84% M, > 50% aged 36 to 45, 91% smoked ≤ 20/day
Interventions	1. Single mailing of stage-matched S-H (either preparation/action or contemplation/precontemplation) 2. As 1, plus 20 to 30 mins of TC at time of enrolment by trained nurse counsellor. Hotline number, further counselling at 1 month and 3 months. Average duration of counselling 38 mins over 3 contacts
Outcomes	Validated abstinence at 6 m (7-day PP). Validation: CO < 9 ppm or urine cotinine < 100 mmol/mol
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Low risk	Numbered sealed opaque envelopes
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Independent interviewer...was unaware of subjects' group allocation... All respondents who reported they were not smoking during the preceding 7 days were invited to attend the research centre for biochemical validation."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Losses to follow-up 11% intervention/ 4% control. Included as continuing smokers

An 2006

Methods	Setting: 5 Veterans Administration medical centres, USA Recruitment: By mail, planning to quit in next 30 days
Participants	821 smokers interested in quitting (excludes 16 deaths, 1 withdrawal); 91% M, av. age 57, av. cigs/day 26. 26% had > 7-day abstinence in previous year, 44% ever use of bupropion, 82% ever use NRT
Interventions	1. Mailed S-H and standard care; opportunity for intervention during routine health care and referral to individual or group cessation programmes. NRT and bupropion avail on formulary 2. As 1, plus proactive TC, modified California helpline protocol, 7 calls over 2 m, relapse-sensitive schedule. NRT and bupropion available, could be mailed directly after screening and primary provider approval for bupropion
Outcomes	Abstinence at 12 m (sustained > 6 m, 7-day PP also reported) Validation: none
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement

An 2006 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Losses to follow-up included as smokers, 16 deaths excluded

Aveyard 2003

Methods	Setting: 65 general practices, UK Recruitment: Active; volunteers from random selection of smoking patients, not selected for motivation Randomisation: Centralised, minimisation to balance SoC, addiction and SES
Participants	2471 smokers (2058 in relevant arms); > 80% in precontemplation or contemplation, 10% to 14% in preparation, 46% M, av. age 41, av. cigs/day 20
Interventions	1. Standard S-H materials, single mailing 2. S-H manual based on Transtheoretical model, expert-system letter tailored on baseline questionnaire. Further questionnaires at 3 and 6 m for additional letters (approx 50% received 3 letters) 3. As 2, plus proactive TC after receipt of each questionnaire (max 3 calls). Designed as reminders, scripted, delivered by trained postgraduate students
Outcomes	Abstinence at 12 m (sustained for 6 m) Validation: saliva cotinine < 14.2 ng/ml
Notes	We included arms 3 vs 2 in the analyses. Sensitivity analysis comparing arms 3 vs 2+1. 66% received 1st phone call, 36% 2nd, 31% 3rd

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Centralised randomisation procedure, with minimisation to balance SoC, addiction and SES
Allocation concealment (selection bias)	Low risk	Centralised
Blinding of outcome assessment (detection bias) All outcomes	Low risk	12 m PP "was confirmed with salivary cotinine, so that we had unconfirmed and confirmed prevalence of quitting." Confirmed figures used in analysis
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up 24% in group 1, 31% in 2 and 3. All included as smokers. Sensitivity analysis allowing for differential dropout did not change findings

Bastian 2012

Methods	Setting: North Carolina, USA; Medical Center Recruitmenet: Mailed smokers an introductory letter from the Chief of Cardiology, Chief of Oncology, or a primary care physician (the Principal Investigator (PI)) informing them of the study and encouraging smoking cessation
Participants	471 smokers enrolled in Durham Veterans Affairs Medical Center, receiving treatment for chronic illnesses (i.e. cancer, cardiovascular disease, HTN, diabetes, COPD) and wanting to quit in the next 30 days; 91.5% M, av. age 59.2, av. cigs/day not reported
Interventions	1. Standard telephone counselling, a letter from a VA physician encouraging smoking cessation, NRT, if not contra-indicated, a S-H cessation kit, and up to 5 TC calls (every 3 - 4 weeks, av. duration 20 minutes) 2. "Family-supported telephone counseling, included all components of the standard TC arm plus an enhanced family-supported intervention that included a support skills booklet and additional telephone counseling content focusing on social support skills [...] The main distinction between the two arms of this comparative effectiveness study was the family-supported intervention that aimed to help increase positive interactions between the participant and their designated support person, to facilitate smoking cessation [...] Participants randomized to family support-based intervention also received an 8-page disease-specific family support booklet."
Outcomes	Abstinence at 12 m (7-day PP) Validation: available for only 50.5% of the participants
Notes	New for 2018 update Funding: "This material is based upon work supported by the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, and Health Services Research and Development. IIR-05-202." Declarations of interest: "SCG serves as a consultant to Gilead Sciences and Watermark Research Partners. Although these relationships are not perceived to represent a conflict with the present work, it is included in the spirit of full disclosure. Presented in part at the Society of General Internal Medicine Annual Meeting, Phoenix AZ May 2011."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "blocked randomization, stratified by sex and disease type"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	The investigators mailed participants saliva-sampling kits to measure cotinine, but the return rates for saliva samples were low at all follow-ups. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Follow-up rates were 86% and 81.1% at 5 months and 12 months, respectively. Loss to follow-up was similar in both arms."

Bastian 2013

Methods	Setting: North Carolina, USA; Academic setting Recruitment: Investigators asked lung cancer patients' permission to contact members of their social networks who smoked and were aged 18 and older; these received a letter describing the study and providing them a toll-free number to call to decline participation
Participants	496 relatives of lung cancer patients, 41.5% M, av. age 46.9, av. cigs/day 19.5. More than half the participants have made more than 3 quit attempts before inclusion in the study
Interventions	1. Tailored self-directed materials and nicotine patches 2. As above, plus proactive TC, 6 x weekly sessions scheduled over an intervention period of 12 weeks, with an av. duration of each session of 30 mins. The mean number of sessions completed was 2.4. 81 participants in this group (33%) did not complete at least 1 session
Outcomes	Abstinence at 12 m (7-day PP) Validation: saliva cotinine, not possible due to low return rates
Notes	New for 2018 update. Funding: "This work was supported by National Cancer Institute grant 5U01-CA-92622. This research was also supported in part by the Intramural Program of the National Human Genome Research Institute, National Institutes of Health." Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was blocked by patient, with entire social network units stratified by site and size of social network enrolled (one vs. two or more) assigned to the same condition."
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	High risk	Large withdrawal of participants after 12 months of follow-up (> 50%), although similar across arms

Blebil 2014

Methods	Setting: Malaysia; Outpatient Quit Smoking Clinic based at 2 hospitals Recruitment: Quote: "All individuals who attended the clinics during the period under review were invited to participate in the research."
Participants	231 outpatient smokers, 96.1% M, av. age 48.3, av. cigs/day 13.8
Interventions	1. Usual care, which included a combination of nicotine gum and CBT (4 counselling sessions during the 1st month, 2 counselling sessions during the 2nd month + 2 phone calls (av. duration 20 - 30 mins), and 1 counselling session during the 3rd month plus 2 phone calls (av. duration 20 - 30 mins))

Blebil 2014 *(Continued)*

	2. As above, + 1 extra weekly proactive call (av. duration 10 - 15 mins) during the first month of the quit attempt
Outcomes	Abstinence at 6 months (4-week PP) Validation: exhaled CO level < 7 ppm
Notes	New for 2018 update Funding: not reported Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Even though "urn design was used to achieve balanced groups", participants walking in the study and being referred from outpatient clinics at the hospitals were more likely to be assigned to the intervention than those coming from other hospitals
Allocation concealment (selection bias)	Low risk	Quote: "the assignments of treatment within a sequence created by the urn design are not as predictable as those of other types of restricted randomisation processed"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation of self-reported outcome. The data were collected by another research member not connected with counselling and the data analysis
Incomplete outcome data (attrition bias) All outcomes	Low risk	Percentage lost to follow-up was overall low (8%), although larger in the usual-care (12%) than in the intervention group (4%).

Borland 2001

Methods	Setting: Community, Australia Recruitment: Callers to a quitline
Participants	998 smokers interested in quitting; 48% M, 37% aged 15 - 29, 26% aged 30 - 39, av. cigs/day 23
Interventions	1. Proactive call-back TC following initial call to quitline: Multiple calls, first pre-quit, quit, then according to need. Up to 6 m. Mailed materials 2. Control: Mailed materials Both groups also received the standard motivational counselling in response to their first call
Outcomes	Self-reported abstinence at 12 m (sustained for 9 m) Validation: none
Notes	Average number of calls 2.8, 67% received 1 or more. 20% refused call-back or wanted to initiate the calls, further 7% did not receive any

Risk of bias

Bias	Authors' judgement	Support for judgement

Borland 2001 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up 37% intervention, 30% control. All participants included as smokers in the meta-analysis

Borland 2003

Methods	Setting: Community, Australia Recruitment: Callers to a quitline
Participants	1578 smokers; 46% M, modal age 30 - 49, av. cigs/day 23
Interventions	1. Standard S-H quit pack based around SoC 2. Additional tailored letters at baseline, and at 3 and 6 m based on mailed assessments 3. As 2, plus proactive cognitive behavioural stage-base TC, calls at negotiated times, ˜10 - 15 mins. Usually over 2 - 3 weeks, could extend further. Some participants in all groups received brief reactive counselling before enrolment
Outcomes	Self-reported abstinence at 12 m (sustained for 9 m) Validation: none
Notes	3 vs 2, sensitivity analysis 3 vs 2+1 68% received calls, av. 4.8 for those receiving any, 23% received ≥ 7

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Allocation by shuffling questionnaires
Allocation concealment (selection bias)	Low risk	Author states "no opportunity for interviewers to influence choice"; baseline characteristics balanced, likelihood of bias judged low
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up 21% in 1, 23% in 2, 26% in 3. All participants included as smokers in the MA

Borland 2008

Methods	Setting: General practice, Australia Recruitment: 45 participating GPs recruiting patients who smoked
Participants	1039 smokers, not selected for motivation but ~80% had previously tried to quit; 45% M, av. age: 41, av. cigs/day 17
Interventions	1. Referral: Smokers with any interest in quitting referred by fax to Victorian Quitline. Proactive contact attempted with up to 2 pre-quit and 4 post-quit sessions typically using relapse-sensitive schedule. Internet support available as an alternative (4.4% reported use) 2. In-practice support, could include external referral if this was clinical preference All participants given guideline-based assessment of readiness to quit and offer of pharmacotherapy if appropriate
Outcomes	Self-reported abstinence at 12 m (sustained ≥ 10 m) Validation: none
Notes	TC as adjunct to face-to-face intervention.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Cluster-randomised by GP (1:2 ratio). Computer allocation before GPs attended education session for their assigned intervention
Allocation concealment (selection bias)	Unclear risk	Initially concealed but 13 referral (30%) and 11 (42%) control GPs failed to recruit participants. Allocation not blind at time of recruitment of individual participants, so further selection bias possible. Measured characteristics at baseline were similar
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "Three- and 12-month questionnaires were administered...by trained interviewers who were blind to treatment condition until after the outcome data were collected." However, reliant on self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	33% lost in referral condition, 39% in control, all included as smokers in MA. Excluding losses does not affect MA

Boyle 2007

Methods	Setting: Health Maintenance Organisation, USA Recruitment: Proactive recruitment of members filling a prescription for cessation medications (motivated)
Participants	1329 HMO members; 42% M, av. age 47, 66% smoked > pack/day
Interventions	All participants had filled a prescription. Almost 95% used; ~51% only bupropion, 26% only NRT, remainder both 1. No further intervention 2. Proactive call to offer counselling, up to 9 calls, given choice of structured course or unstructured format
Outcomes	Abstinence at 12 m (repeated 7-day PP at 3 and 12 m)

Boyle 2007 *(Continued)*

	Validation: none
Notes	49% of intervention group reached, 36% of those declined, 31% of total accepted counselling. Average no of calls 5.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, stratified by presence of chronic disease. Method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "The follow-up survey was conducted by the Data Collection Center within the Health Partners Research Foundation, using staff not involved in the intervention." However, reliant on self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	˜33% lost to follow-up, balanced across groups, included in MA as smokers

Bricker 2014

Methods	Setting: South Carolina, USA Recruitment: Staff advertised the study to the quitline callers
Participants	121 uninsured callers to the South Carolina State Quitline who wanted to quit in the following 30 days
Interventions	1. Telephone counselling (CBT) + NRT 2. Telephone counselling (ACT) + NRT 5 weekly calls, 30-min first session and 15-min subsequently, were offered. All participants received standard 2-week NRT (patch or gum) of choice
Outcomes	Self-reported abstinence at 6 m (30-day PP) Validation: none
Notes	New for 2018 update Funding: "This study was supported by the National Institutes of Health (T32MH082709 to RV, K23DA026517 to JLH, R21DA030646 to JB) and the Fred Hutchinson Cancer Research Center." Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomized study arm assignments were computer generated"

Bricker 2014 *(Continued)*

Allocation concealment (selection bias)	Low risk	Quote: "Randomized study arm assignments were [...] concealed"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Abstinence not biochemically validated, but same level of personal contact in different study arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Proportion of individuals lost to follow-up was greater in CBT than in ACT arm (39% and 27%, respectively) but less than 50% overall

Brown 1992

Methods	Setting: Community, Australia Recruitment: Advertising for smokers interested in cessation
Participants	45 smokers attending an information evening on smoking cessation; 38% M, av. age 40, av. cigs/day 23
Interventions	1. S-H manual 2. S-H manual and proactive TC; 6 calls at 1, 2, 4, 6, 8, 10 weeks which asked about use of manual, and gave additional information about any techniques or skills proving difficult
Outcomes	Abstinence at 12 m (7-day PP) Validation: Saliva samples collected but not apparently tested - 1 participant refusing to provide a sample was classified as smoking
Notes	Effect of TC compared to S-H and single information session alone

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Saliva samples collected but not apparently tested
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No details given

Brunette 2017

Methods	Setting: New Hampshire, USA; community mental health centres Recruitment: Through flyers, clinician referral, and direct mail
Participants	661 medicaid beneficiaries with mental illness and low income (< USD 1317 a month) willing to initiate cessation treatment within 30 days, 36% M, av. age 45, av. cigs/day 17.3

Brunette 2017 *(Continued)*

Interventions	1. Usual care, a prescriber visit for smoking cessation (NRT or cessation medications, i.e. bupropion/varenicline) 2. As in 1, plus referral to New Hampshire Tobacco Helpline which provides an average of 3 manualised TC sessions 3. As in 1, plus TC (av. 9 sessions) CBT initiated by a CBT therapist
Outcomes	Abstinence at 12 m (7-day PP) Validation: breath CO ≤ 4 ppm and urine cotinine < 100 ng/ml (or solely breath CO if using NRT)
Notes	New for 2018 update. Funding: "This research received financial support from the Centers for Medicare and Medicaid Services (Medicaid Incentives for the Prevention of Chronic Diseases grant 1B1CMS330880) and from the New Hampshire Department of Health and Human Services (NHDHHS)." Declarations of interest: "Dr. Brunette reports receipt of research funding from Alkermes. The other authors report no financial relationships with commercial interests."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Computer-generated tables for each strata within each site were used for random assignment."
Allocation concealment (selection bias)	High risk	Quote: "We used equipoise randomization [...] that allowed participants to opt out of one of the cessation treatment conditions or allowed randomization to any of the three options. [...] Randomization strata were defined by conditions to which the participant was willing to be randomly assigned. Within the stratum, a participant was then randomly assigned with equal probability to the selected treatment condition options." Not a true randomisation method; participants can choose what intervention they do not want to be allocated to and this can lead to selection bias. This led to different numbers between arms, and significant baseline age differences
Blinding of outcome assessment (detection bias) All outcomes	High risk	Biochemical validation for only half of the participants in the trial (those receiving an incentive), and there are significant differences between those receiving and not receiving an incentive. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Proportion of participants lost to follow-up was lower than 50% overall

Chan 2015

Methods	Setting: Hong-Kong, China; community-based Recruitment: Participants were approached by investigators at shopping malls or public areas in 16 out of the 18 districts in Hong Kong. Participants who expressed an interest in joining the contest were screened for eligibility and tested on their exhaled CO to ascertain their smoking status

Chan 2015 *(Continued)*

Participants	1003 Hong Kong residents aged 18 or older, who smoked 1 or more cig/day in the past 6 months, 82% M; 38% 18 – 39 years, 49% 40 – 59 years, 13% 60+ years, 42% 1 – 10 cigs/day, 43% 11 – 20 cigs/day, 15% > 20 cigs/day
Interventions	1. S-H booklet and the contact information of the smoking cessation services at the enrolment 2. As 1, plus 8 mobile phone text messages corresponding to the 8 pages of the S-H booklet (not used in review) 3. As 1, plus 4 sessions (within 1 week, after 2, 6 and 12 m) of 5-min smoking cessation telephone counselling provided by a trained nurse, using the AWARD Protocol
Outcomes	Abstinence at 12 m (7-day PP) Validation: exhaled CO < 4 ppm and salivary cotinine level < 10 ng/ml
Notes	New for 2018 update Funding: "This work was funded by Hong Kong Council on Smoking and Health." Declarations of interest: "Prof. Tai-hing Lam is the principal investigator of the FAMILY project, which was funded by the Hong Kong Jockey Club Charities Trust. All other authors do not have connection with the tobacco, alcohol, pharmaceutical or gaming industries, and nobody was substantially funded by these organizations."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Block randomisation was used to ensure similar group sizes.
Allocation concealment (selection bias)	Low risk	Quote: "The randomization and allocation were conducted by the author who did not participate in subject recruitment to ensure allocation concealment"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Abstinence biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Efforts were made to minimise loss to follow-up: Quote: "at least seven call attempts at different times were made before participants were considered as loss to follow-up." In the end follow-up was comparable across arms. Reasons for losses to follow-up are provided

Chouinard 2005

Methods	Setting: Canada Recruitment setting: Inpatients with cardiovascular disease (myocardial infarction, angina, congestive heart failure) or peripheral vascular disease, unselected by motivation
Participants	168 past-month smokers; 27% M, av. age 56, 60 % in preparation or action SoC
Interventions	1. Counselling by research nurse (1 x 10 - 60 mins, av. 40 mins, based on Transtheoretical Model, included component to enhance social support from a significant family member) 2. As 1, plus telephone follow-up, 6 calls over 2 m post-discharge 3. Usual care cessation advice (not used in review)

Chouinard 2005 *(Continued)*

Outcomes	Abstinence at 6 m (sustained at 2 and 6m) Validation: Urine cotinine or CO
Notes	TC as adjunct to face-to-face counselling. 75% received 6 calls

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Cluster-randomised in groups of 3 - 6 "to prevent contamination between groups", method not described
Allocation concealment (selection bias)	Low risk	Quote: "Individuals not familiar with the study were in charge of the randomization procedure which included inserting the information into envelopes that were sealed and would be opened by the investigator only at the time of recruitment."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation used
Incomplete outcome data (attrition bias) All outcomes	Low risk	4 deaths (3 in Grp 1, 1 in Grp 2) and 3 not meeting follow-up criteria excluded from MA denominators. Other losses to follow-up included

Collins 2018

Methods	Setting: North and West Philadelphia, PA, US; 4 paediatric clinics Recruitment: Clinic providers referred smoking parents of children exposed to SHS to the cessation resources, including the current study
Participants	327 smoking parents from predominantly low-income, racial- and ethnic-minority families of children under the age of 11, 16.5% M, av. age 33, av. cigs/day 11.5
Interventions	1. Individual TC health education attention control (AC) intervention that focuses on improving family nutrition on a budget 2. Individual behavioural TC intervention that focuses on reducing child SHS exposure and parent smoking cessation The TC dosage (5 sessions over 12 weeks) was similar between arms
Outcomes	Abstinence at 12 m (7-day PP) Validation: cotinine-verified (cut-off not reported)
Notes	New for 2018 update Funding: "Supported by Temple University. Funded by the National Cancer Institute, National Institutes of Health, grant CA158361. Funded by the National Institutes of Health (NIH)." Declarations of interest: "The authors have indicated they have no potential conflicts of interest to disclose."

Risk of bias

Collins 2018 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was seeded using values obtained from random.org."
Allocation concealment (selection bias)	Low risk	Quote: "The project biostatistician provided the allocations to the data collection team in opaque sealed security envelopes."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Cotinine-verified smoking cessation
Incomplete outcome data (attrition bias) All outcomes	Low risk	The percentage of participants lost to follow-up is minimal (12%), although slightly different between intervention (17%) and control (8%) arms.

Cossette 2011

Methods	Setting: Specialised cardiac hospital, Canada Recruitment: All smokers who were hospitalised were asked to participate by the study nurse (not selected by motivation)
Participants	40 current daily smokers with cardiovascular disease, 60% M, av. age 57. Most in preparation stage Therapists: nurse specialised in smoking cessation
Interventions	All participants had 1 or more sessions with the study nurse during hospitalisation. Conditions differed after discharge 1. Intervention: 6 phone calls by study nurse at weeks 1, 2, 3, 4, 8, 12. If needed additional phone calls could be arranged between 3 and 6m post-discharge. At week 3 appointment with the study nurse if requested by participant 2. Control: referral to a national quitline or a community centre for smoking cessation Pharmacotherapy: NRT, bupropion or varenicline were suggested during hospitalisation and follow-up
Outcomes	Self-reported abstinence at 6 m (7-day PP) Validation: only for 1 participant
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not specified, but generated by a centre for randomised controlled trials
Allocation concealment (selection bias)	Unclear risk	Opaque sealed envelopes
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms

Cossette 2011 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	High loss to follow-up, but missing data similar in both groups and analyses are ITT, participants lost to follow-up considered smokers

Cummins 2016a

Methods	Setting: California, USA; hospital-based Recruitment: Quote: "Recruitment procedures differed between healthcare systems based on the personnel involved and the hospital's reliance on electronic medical records (EMRs)". In 1 study site recruitment was part of the therapists' workflow, while in another academic site, research staff were involved instead
Participants	1270 hospitalised adult smokers who smoked 6 or more cigs/day, were interested in quitting, spoke English or Spanish, and were not pregnant, 56.7% M, av. age 49.9, av. cigs/day 14.6
Interventions	Factorial 2 x 2 design comparing TC vs no TC, and NRT vs no NRT 1. No TC (usual care) ± NRT patches. In general usual care consisted of providing smokers with the quitline number, but some hospitals may have also provided counselling or prescribed quitting aids 2. TCg ± NRT patches, with 10 calls scheduled, but on av. 3.6 completed. The av. number of calls in the usual care arm was 1.7
Outcomes	Abstinence at 6 m (7-day PP) Validation: saliva cotinine < 10 ng/mL
Notes	New for 2018 update. Previously listed under ongoing studies as Cummins 2012 Funding: "This research was supported by a grant from the National Cancer Institute (CA159533)." Declarations of interest: none reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "randomly assigned by computer"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically-confirmed abstinence
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar loss to follow-up across arms (˜33%)

Cummins 2016b

Methods	Setting: California USA; pregnant women

Cummins 2016b *(Continued)*

	Recruitment: Callers to University of California San Diego California Smokers' Helpline
Participants	1173 pregnant (< 27 weeks) women, willing to quit within 1 month or recent quitters, av. age 26.3, av. cigs/day 11.2
Interventions	1. Self-help American Cancer Society's *Make Yours a Fresh Start Family* fact sheets, and additional tips for quitting while pregnant 2. As 1, plus proactive TC specifically developed for pregnant smokers, including 9 x 30 - 45-min sessions on days 0, 1, 3, 7, 14, and 30 after quit date, at 32 weeks of gestation, and 2 and 4 weeks after delivery
Outcomes	Abstinence at 6 m post-partum (180-day abstinence) Validation: saliva cotinine < 13 ng/mL
Notes	New for 2018 update. Previously listed under studies awaiting assignment as Zhu 2004 Funding: "This research was supported by the Tobacco-Related Disease Research Program (Grant 8RT-0103) and First 5 California (Contract CCFC-6810) and by funds received from the California Department of Health Services Tobacco Control Section (Contract 00–90605)." Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Random allocation to condition was done by computer using blocks of 20"
Allocation concealment (selection bias)	Low risk	Quote: "staff were blind to group assignment until the end of the intake, when the appropriate script was presented"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Abstinence biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Higher % lost to follow-up in intervention arm

Curry 1995

Methods	Setting: Health Maintenance Organisation, USA Recruitment: Active; smokers identified through a telephone survey of health behaviour in a random sample of HMO members, not selected for motivation
Participants	1137 smokers, 479 in relevant arms, not selected by motivation to quit; 48% M, av. age 41, av. cigs/day 17
Interventions	1. Control - no materials or counselling 2. S-H booklet (*Breaking Away*) 3. As 2, plus feedback based on computer analysis of initial survey 4. As 3, plus proactive TC; up to 3 calls at 2, 6, 10 weeks
Outcomes	Abstinence at 12 m (sustained from 3 m - 12 m)

Curry 1995 *(Continued)*

	Validation: saliva cotinine requested but not obtained for all self-reported quitters. Disconfirmation rates (cut off > 20 ng/ml) not significantly different between groups
Notes	4 vs 3, effect of TC compared to S-H and feedback alone.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Collecting saliva cotinine...was challenging because participants had neither explicitly volunteered for a study of smoking behavior nor requested treatment for smoking cessation... nearly one fourth of those contacted refused to provide a sample." Higher disconfirmation in control group but difference was not significant
Incomplete outcome data (attrition bias) All outcomes	Low risk	88% provided data at all 3 and 12 m. No difference in response rates across groups. Missing counted as smoking in MA

Duffy 2006

Methods	Setting: ENT clinics at 4 hospitals, USA Recruitment: Patients with head and neck cancer who screened positive for smoking, alcohol problem or depression, not selected for motivation
Participants	89 current smokers used in MA, out of 184 trial participants who also included 26 quit within last month and 21 within last 6 m . Demographics are for all participants; 84% M, av. age 57
Interventions	1. Proactive counselling; 9 - 11 CBT-based calls from trained nurses, linked to use of CBT workbook. Smokers with problem drinking or depression received counselling for these too 2. Enhanced usual care with assessment and referral
Outcomes	Abstinence at 6 m (sustained) Validation: none
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given. Smokers were a higher proportion of the intervention than control groups, and a higher proportion of those randomised than those who refused, raising possibility of selection bias
Blinding of outcome assessment (detection bias)	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms.

Duffy 2006 *(Continued)*

All outcomes		
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	22 in total (including non-smokers) lost to follow-up, evenly distributed. Losses appear to have been included as smokers

Ebbert 2007

Methods	Setting: 8 dental practices, USA Recruitment: Patients screened by questionnaire at routine hygiene appointments, not selected for motivation
Participants	82 smokers (60 intervention, 22 control). No baseline data for controls
Interventions	1. Control: Brief counselling (10 mins) from hygienist, reinforced by dentist 2. As 1 plus faxed referral to quitline, proactive counselling, 45 mins baseline, 20 mins at 1 week and 2 weeks, further calls if requested
Outcomes	Abstinence at 6 m (7-day PP) Validation: none
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Cluster-randomised by practice, method not described
Allocation concealment (selection bias)	High risk	Hygienists who recruited participants after screening not blind, large difference in numbers recruited, not possible to establish baseline similarity
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No description of number lost at follow-up

Ellerbeck 2009

Methods	Settng: Primary care patients, 50 rural practices, Kansas, USA Recruitment: Smokers not selected for motivation, but 67% of those eligible enrolled, only 8.7% in precontemplation stage of change
Participants	750 smokers of > 10 cigs/day, 41% M, av. age 47, av. cigs/day 24, 61% contemplation, 30% preparation
Interventions	All participants mailed an offer of free pharmacotherapy every 6 m, 4 times in total. Nicotine patch 21 mg for 6 weeks or bupropion SR (150 mg twice daily) for 7 weeks 1. Control. No other contact.

Ellerbeck 2009 *(Continued)*

	2. Moderate-intensity disease management: up to 2 calls from counsellor in each cycle encouraging uptake of pharmacotherapy, newsletter mailings and periodic progress reports with counselling suggestions faxed to physician 3. High-intensity disease management, up to 6 calls at approx 1, 3, 6, 9, 12 weeks from start of each cycle
Outcomes	Abstinence at 24 m (PP). Study also reported analysis based on combination of effects at all follow-up points. Sustained abstinence not a suitable outcome since no quit date and repeated intervention Validation: attempted saliva cotinine (< 15 ng/ml) by mail at 12 and 24 m. Proxy report used at 24 m for non-returners. Rate of validation similar across groups
Notes	For analysis on counselling intensity, classified on basis of average calls; moderate in 3 - 6 sessions, high in 7+ subgroups

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "computer generated random-number table" in blocks of 24
Allocation concealment (selection bias)	Low risk	Quote: "To conceal allocation, we placed these cards in sequentially numbered, opaque, sealed envelopes."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation used
Incomplete outcome data (attrition bias) All outcomes	Low risk	Differential rates of loss to follow-up (1: 22.0%; 2: 31.3%; 3: 31.1%). Participants lost to follow-up counted as smokers but sensitivity analysis shows no significant difference in analysis outcome if excluding those lost to follow-up

Emmons 2005

Methods	Setting: Childhood Cancer Survivors Study cohort, USA Recruitment: Smokers contacted by telephone to assess eligibility and enrol, not selected for motivation
Participants	794 smokers (excludes 2 deaths in control); 53% M, av. age 31, av. cigs/day 12
Interventions	1. S-H control. Mailed manual (*Clearing the Air*) and letter from study physician 2. Peer counselling. Up to 6 calls in 7-m period, by trained cancer survivor. Motivational, tailored to SoC. Free NRT available. Individually-tailored materials before 1st call and other materials during intervention
Outcomes	Abstinence at 12 m (7-day PP) Validation: none (warning that samples might be requested)
Notes	No data on average number of calls. Longer-term follow-up, assessed at 2 - 4 years, reported in Emmons 2009. Not used in MA - sustained rates not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement

Emmons 2005 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Bogus pipeline procedure used, no further details provided
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	19% lost in intervention vs 24% in control at 12 m. All included as smokers in MA. Excluding losses does not affect MA

Ferguson 2012

Methods	Setting: English Quitline Recruitment: Callers to the NHS Smoking Helpline from any location in England
Participants	2591 smokers aged 16 or older, motivated to quit in 4 days - 4 weeks. 45% M; av. age 38; 47% smoking 11 - 20 cigs/day
Interventions	1. Standard telephone support (after call, further support by email, letter or text message, offer of proactive contact) 2. As 1 plus additional proactive telephone support (up to 2 calls pre-quit date, 1 call on quit date, then calls at 3, 7, 14 and 21 days post-quit date). Structured call content using MI template (except for 7- and 14-day calls) 3. As 1, plus offer of free NRT 4. As 2, plus offer of free NRT
Outcomes	Prolonged abstinence at 6 m (allowing grace period of up to 5 cigs smoked). 7-day PP also recorded Validation: exhaled CO < 10 ppm
Notes	Arms 1 and 3 combined and compared with arms 2 and 4 combined. No difference in cessation outcomes between participants offered NRT and those not offered NRT

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "computer generated random number sequence"
Allocation concealment (selection bias)	Low risk	Subjects allocated by central computerised system
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation rates used
Incomplete outcome data (attrition bias)	Low risk	High rates of dropout but similar across groups (standard 43%, proactive 45%). Dropouts counted as smokers

Ferguson 2012 *(Continued)*

All outcomes	Quote: "this conservative supposition could possibly mask variation...and we explored this possibility by trying alternative associations between missingness and smoking status. This analysis did not change our findings."

Fiore 2004

Methods	Setting: Primary care patients, 16 clinics, USA Recruitment: Clinic attenders willing to accept treatment
Participants	961 smokers of ≧ 10 cigs/day. (643 in relevant arms, a further 908 were allowed to select treatment. Demographic details based on 1869); 42% M, av. age 40, av. cigs/day 22
Interventions	(Self-selected group of factorial trial not included in MA) 1. Nicotine patch, 22 mg, 8 weeks incl tapering 2. As 1, plus Committed Quitters (CQ) programme, single TC session and tailored S-H 3. As 2, plus individual counselling, 4 x 15 - 25-min sessions, pre-quit, ˜TQD, next 2 weeks (not used in this review)
Outcomes	Continuous abstinence at 1 year (no relapse lasting 7 days, also 7-day PP) Validation: CO, cut-off not specified. 2 discordant
Notes	Arms 2 vs 1, TC as adjunct to pharmacotherapy 69% of those randomised to group 2 enrolled in CQ programme

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically-validated cessation
Incomplete outcome data (attrition bias) All outcomes	Low risk	19% lost at 1 year, no difference by condition

Flöter 2009

Methods	Setting: Germany Recruitment: 21 prevention or rehabilitation clinics
Participants	527 hospitalised female smokers ≥ 1 cig during the 30 days preceding hospitalisation. Av. age 35.9, motivation to quit not required
Interventions	1. 3 face-to-face courses (60 mins each) in groups during clinic hospitalisation featuring CBT and MI 2. As 1, plus 3 proactive phone calls (10 mins duration) post-discharge in a structured and directive

Flöter 2009 *(Continued)*

	3. As 2, but calls delivered in non-directive style
Outcomes	Self-reported abstinence at 6 m (30-day PP) Validation: none
Notes	Intervention arms combined

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	Method not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcome with participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Number lost to follow-up unclear (conflicting data available)

Fraser 2014

Methods	Setting: USA; population-based Recruitment: 5-step process: (1) clicked link to study; (2) completed eligibility screening questions; (3) reviewed consent and confirm willingness to participate; (4) completed baseline questionnaire; (5) call to an automated answering machine to confirm their participation
Participants	1034 smokers of ≥ 5 cigs/day, aged 17 or older, interest in quitting smoking within the next 30 days, 32% M, av. age 39.3, av. cigs/day 19.3
Interventions	Factorial design of the following 5 conditions: website (active/lite), S-H brochure (full/lite), text messaging, NRT, and proactive TC - 5 sessions of a duration of 30 mins upon enrolment, and 15 mins on quit day or day after, and weekly for 3 weeks
Outcomes	Self-reported abstinence at 7 m (7-day PP) Validation: none
Notes	New for 2018 update Funding: "The project was funded through a contract to our university from Matthews Media Group, underwritten by ARRA funding to the National Cancer Institute. Additional funding was provided by the National Cancer Institute (5K05CA139871)." Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No detail on exactly how the participants were randomised:

Fraser 2014 *(Continued)*

		Quote: "Randomization occurred immediately after the confirmation call, and participants completing this step were sent an automated email welcoming them to the study and outlining services they would receive (based on their randomization)."
Allocation concealment (selection bias)	Unclear risk	As above
Blinding of outcome assessment (detection bias) All outcomes	High risk	Abstinence not biochemically validated. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Small percentage of lost to follow-up in each arm

Gilbert 2006

Methods	Setting: Quitline, UK Recruitment: Quitline callers who engaged in counselling
Participants	1457 smokers planning quit attempt within 2 weeks; 34% M, av. age 39, av. cigs/day NS
Interventions	1. Standard QUIT information pack and counselling at initial contact. 2. As 1, plus offered 5 proactive calls, starting TQD if possible, 2 in week 1, 1 in weeks 2 and 4. Client-centred
Outcomes	Self-reported abstinence at 12 m (sustained for 6 m, also 7-day PP) Validation: none
Notes	26% received no additional calls, 42% had 4+ calls, 31% had 1 - 3 calls

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Pseudo-random by day of week
Allocation concealment (selection bias)	Low risk	Recruiters blind so concealment judged adequate
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	37% lost to follow-up in both groups. Missing counted as smoking in MA

Girgis 2011

Methods	Setting: Australia

Girgis 2011 *(Continued)*

	Recruitment: Arabic-speaking GPs in 29 practices in southwest Sydney
Participants	407 Arabic smokers, aged 18 - 65 48% M, av. age 29, av. cigs/day 19
Interventions	1. Offer of free referral by GP to proactive TC provided by bilingual psychologist. If accepted offer, participants called by counsellor for 20-min initial session. If prepared to quit, called again on quit date, 1, 3, 6 weeks and 3 m after specified quit date. If not ready to set quit date, assigned "less intensive schedule." Mailed quit kit and materials in Arabic and English 2. Usual care
Outcomes	Self-reported abstinence at 6 and 12 m (1-day PP) Validation: none
Notes	Low uptake: 101 of 213 participants agree to receive call, 46 receive at least 1 call, 8 completed all calls. Described narratively in 'Other studies' section

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	High risk	Quote: "From each participating GP, we recruited a consecutive sample of patients of Arabic background aged 18-65 years during a specified 4-week period, irrespective of their smoking status" using an "unobtrusive mark visible to only the GP to convey group randomization" on the baseline questionnaire. Suggests allocation not concealed
Blinding of outcome assessment (detection bias) All outcomes	Low risk	No biochemical validation, but research assistants conducting follow-up blind to assignment, low uptake of actual contact suggests risk of differential misreport low
Incomplete outcome data (attrition bias) All outcomes	Low risk	Significantly more participants in intervention group lost to follow-up at 12 m than control (45% vs 34%), all dropouts counted as smokers in ITT analysis

Graham 2011

Methods	Setting: USA Recruitment: US residents searching for stop-smoking advice on a major internet search engine who clicked on a link to www.quitnet.com, assumed to be motivated
Participants	2005 adult smokers of 5 or more cigs/day. 48.9% , av. age 35.9, av. cigs/day 20, av. FTND 5.0. 1326 contribute to this review
Interventions	1. Free 6 m access to www.quitnet.com (interactive commercial cessation website) 2. As 1, + up to 5 sessions of proactive TC for 3 m; counsellors had access to www.quitnet.com info and encouraged participants' use of it; counsellors sent individual emails after counselling sessions to reinforce key points

Graham 2011 *(Continued)*

	3. Control: access to static, info-only (non-interactive) version of the content on QuitNet (not used in this review)
Outcomes	Multiple 30-day PP (at 3, 6, 12 and 18 m). Validation: none
Notes	Arm 2 versus 1

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "random numbers table…stratified by sex and baseline motivation to quit"
Allocation concealment (selection bias)	Unclear risk	Method not specified
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcome measure from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	High risk	Participants missing data counted as smokers. Sustained PP data not available for 46% EI, 49% EI+P 49% and 43% BI. Difference due to differential rate of follow-up at 3 m. Quote: "The lower follow-up assessment rate among EI+P participants at 3 months may have been owing to 'telephone fatigue'...Telephone counselling was providing within the first 3 months of the study, which was the only assessment period for which higher loss to follow-up was observed. If present, this bias could have attenuated the effectiveness of the combined intervention."

Halpin 2006

Methods	Setting: Health Maintenance Organisation, USA Recruitment: Health plan members without current smoking cessation benefit, recruited for a study giving access to coverage
Participants	388 smokers; 34% M, 67% age 40+, 84% smoked < a pack/day
Interventions	1. Coverage for TC and pharmacotherapy (bupropion or NRT, USD 15 co-pay) 2. Coverage for TC; coverage for pharmacotherapy (bupropion or NRT, USD 15 co-pay) only if enrolled in TC 3. Coverage for pharmacotherapy only (control)
Outcomes	Abstinence at 6 m (7-day PP) Validation: none
Notes	Not included in MA, results discussed separately, alongside trials for TC as adjunct to pharmacotherapy

Risk of bias

Bias	Authors' judgement	Support for judgement

Halpin 2006 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Number lost to follow-up not described, all participants included in analyses

Hanssen 2009

Methods	Setting: Hospital/community, Norway Recruitment: Inpatients with diagnosis of myocardial infarction, not selected for motivation
Participants	133 daily smokers amongst 288 participants. Demographics not given for smoking subgroup
Interventions	1. Usual care; outpatient visit at 6 - 8 weeks and primary care follow-up 2. Structured but individualised proactive TC addressing lifestyle issues including smoking, diet and exercise. Nurse-initiated calls at 1, 2, 3, 4, 6, 8, 12, 24 weeks post-discharge. Smoking not explicitly addressed at each call. Reactive phone support line available 6 hours/week
Outcomes	Abstinence at 6, 12 and 18 m (assumed PP, not defined). Primary trial outcome was health-related quality of life Validation: none
Notes	18-m follow-up data added in 2013. Smoking was addressed as part of a multicomponent intervention. TC as adjunct to brief/minimal intervention

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised by computer-generated list
Allocation concealment (selection bias)	Unclear risk	Sequence in sealed opaque envelopes but not stated to be numbered. Fewer control group participants raises possibility of selection bias, so not classified as low risk
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	At 18 m, losses amongst baseline smokers 29% in 1, 30% in 2 . Losses reincluded as smokers in this MA

Hollis 2007

Methods	Setting: Quitline, Oregon, USA Recruitment: Callers to quitline
Participants	4500 smokers willing to make a quit attempt; 40% M, av. age 41, av. cigs/day 22
Interventions	Factorial design; 3 levels of counselling, ± offer of nicotine patch (5-week supply, 80% accepted, option for 3 weeks more, 25 - 28% requested) 1. Brief counselling (usual care), 15 mins + referral information and tailored S-H 2. Moderate TC: 30 - 40 mins MI, brief call to encourage use of community services, tailored S-H 3. Intensive; as 2, plus offer of up to 4 further calls (*Free & Clear*)
Outcomes	Abstinence > 30 days at 12 m Validation: none
Notes	First included as Hollis 2005, based on unpublished abstract.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	69% reached at 12 m. Losses assumed smoking in main analysis, sensitivity analyses reported

Holmes-Rovner 2008

Methods	Setting: 5 hospitals, Michigan, USA Recruitment: Inpatients with acute coronary syndrome, not selected for motivation
Participants	525 participants, including 136 who smoked at admission and could be followed up. Smoker demographics not given
Interventions	1. In-hospital care according to American College of Cardiology Guideline Applied to Practice quality improvement (QI) programme, including written discharge contract 2. Heart After-Hospital Recovery Planner (HARP), 6 session telephone coaching, 15 - 30-min weekly sessions initiated 0 - 4 weeks post-discharge. Pharmacotherapy encouraged for cessation. Intervention could address multiple behaviours
Outcomes	Abstinence at 8 m ("remained quit for the period") Validation: none
Notes	Data on smoking outcomes provided by authors from in-press paper by Holtrop et al

Risk of bias

Holmes-Rovner 2008 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Blocked randomisation, method not described
Allocation concealment (selection bias)	Unclear risk	Change in methodology from randomisation at recruitment/consent to randomisation after baseline interview due to initial imbalance in numbers. Data collectors were blind to group
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	15 people whose smoking status not confirmed and 15 losses to follow-up excluded because group not stated. ITT analysis said not to alter results

Hughes 2010

Methods	Setting: Columbia, SC, Albuquerque, NM and Florence, SC; Recruitment: Through newspaper and radio ads
Participants	746 adult smokers of ≥ 15 cigs/day, interested in quitting gradually in the next 30 days, 46% M, av. age 46, av. cigs/day 23
Interventions	1. Brief advice TC (2 sessions - 5 mins before, and 10 mins after quit day) 2. Abrupt cessation TC (5 sessions - 30 mins between 7 and 21 days before quit day, 10 mins subsequently 2 days before, 2, 7 and 14 days after quit day) 3. Gradual cessation TC (not used in this review due NRT being administered before and after quit day) In arms 1 and 2, participants were sent the US National Cancer Institute's *Clearing the Air* booklet, as well as nicotine lozenges after quit day
Outcomes	Abstinence at 6 m (prolonged 2 weeks post-quit day to 6 m abstinence) Validation: CO level (cut-off not reported)
Notes	New for 2018 update Funding: "The conduct of this study and preparation of the manuscript was funded by grant DA-017825 (JH), Senior Scientist Award DA-00490 (JH) and Institutional Training Grant DA-07242 (EP) from the US National Institute on Drug Abuse." Declarations of interest: "Since 1/1/2007, Dr Hughes has received research grants from the National Institute on Health and Pfizer. Pfizer develops and sells smoking cessation medications. During this time, he has accepted honoraria or consulting fees from several non-profit and for-profit organizations and companies that develop, sell or promote smoking cessation products or services or educate/advocate about smoking cessation: Abbot Pharmaceuticals; Acrux; Aradigm; American Academy of Addiction Psychiatry; American Psychiatric Association; Begbies Traynor; Cambridge Hospital, Cline, Davis and Mann; Constella Group; Consultants in Behavior Change; Dean Foundation, DLA Piper, EPI-Q, European Respiratory Society, Evotec; Exchange Limited; Fagerstrom Consulting; Free and Clear Glaxo-Smith Kline; Golin Harris; Healthwise; Insyght; Informed, Invivodata; Johns Hopkins University; JL Reckner; Maine Medical Center; McNeil Pharmaceuticals; Novartis Pharmaceuticals; Oglivy Health PR, Ottawa Heart Institute, Pfizer Pharmaceuticals; Pinney Associates; Propagate Pharmaceuticals. Reuters; Scientia, Selecta; Temple University of Health Sciences; University of Arkansas; University of California-San

Hughes 2010 *(Continued)*

	Francisco; University of Cantabria; University of Kentucky, US National Institutes on Health; Wolters Publishing, and Xenova."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "statistician generated a concealed allocation sequence and randomized participants to the gradual, abrupt, or minimal treatment conditions in a 2:2:1 ratio using blocked randomization (stratified by city and counselor) based on the SAS procedure PLAN"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical verification
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar low percentage (˜21%) lost to follow-up between groups

Joyce 2008

Methods	Setting: 7 states, USA Recruitment: Smokers responding to mailings and media coverage of new service for Medicare beneficiaries
Participants	7354 smoking Medicare beneficiaries aged 65+ (4295 contribute to review), ˜40% M, ˜69% contemplation, 30% preparation
Interventions	Trial of 4 levels of Medicare benefit. All participants mailed a S-H kit 1. Usual care (not used in MA) 2. Provider counselling benefit; up to 4 sessions of 3 - 10 mins of stage-based counselling (not used in MA) 3. As 2, plus pharmacotherapy benefit; nicotine patch or bupropion for USD 5 co-pay, up to 2 x 12-week courses 4. Quitline benefit; choice of a reactive hotline with prerecorded messages/ad hoc counselling, or a proactive helpline of up to 5 calls per 12-week cycle, up to 2 cycles in the year. Also S-H manual and coverage for nicotine patch for USD 5 co-pay
Outcomes	Abstinence at 12 m (7-day PP) Validation: none
Notes	Main comparison 4 vs 3, which had similar levels of self-reported use of any pharmacotherapy (60% vs 63.4%). Participants were not called unless they enrolled, so treated as trial of quitline availability

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Cluster-randomised, states divided into quarters balancing smoking prevalence and aged, restricted randomisation to different conditions

Joyce 2008 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Participants unaware of programme differences when enrolling and allocation determined by address. Low enrolment in 1 condition does not seem to have been due to bias
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	25% lost to follow-up at 12 m, absolute differences between groups small. Main analysis includes losses as smokers

Klemperer 2017

Methods	Setting: USA, population-based Recruitment: Through email invitations to a nationally representative consumer panel
Participants	560 adult smokers of ≥ 10 cigs/day with a desire to quit some day, but not in the next 30 days, 33% M, av. age 51, av. cigs/day 20
Interventions	1. Usual care 5-min TC 2. Brief motivational TC 3. Smoking reduction TC Groups 2 and 3 were dosage-matched with 1 x 15-min call (week 0), followed by 2 x 10 – 15-min calls (weeks 2 and 4)
Outcomes	Abstinence at 12 m (7-day PP) Validation: none
Notes	New for 2018 update Funding: "This work was supported by research grant NCI CA163176 from the National Cancer Institute (J.R.H.) and training grant T32 DA 7242–23 from the National Institute on Drug Abuse (E.M.K.)." Declarations of interest: "One of the authors received consulting and speaking fees from several companies that develop or market pharmacological and behavioral treatments for smoking cessation or harm reduction and from several non-profit organizations that promote tobacco control. He also consults (without payment) for Swedish Match."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	One of the investigators designed a computer-generated block randomisation schedule stratified by counsellor to assign participants to receive either intervention
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported abstinence. Level of personal contact differed between arms

Klemperer 2017 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	Large percentage (> 50%) of participants lost to follow-up but according to authors: Quote: "The amount of missing data for all outcomes did not differ among conditions, nor were baseline characteristics associated with missing data". Sensitivity analyses were used to confirm robustness of their findings

Lando 1992

Methods	Setting: Community, Minnesota, USA Recruitment: From 4 groups of previously identified smokers
Participants	1827 smokers, not selected by motivation to quit; 50% M, av. age 47, av. cigs/day 22
Interventions	1. Proactive TC, 2 calls over 3 weeks. Offered S-H materials 2. No intervention, contacted at follow-up only
Outcomes	Abstinence at 18 m (no puff, > 3 m and validated abstinent at 6 m) Validation: Saliva cotinine < 10 ng/ml at 6 m
Notes	High level of cotinine disconfirmation. 70% agreed to second call

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	Minimal contact intervention, likelihood of bias small but since control group participants were not contacted at baseline and a large number of intervention group participants could not be reached, impossible to compare baseline characteristics
Blinding of outcome assessment (detection bias) All outcomes	High risk	No biochemical validation at 18 m. At 6 m, validated abstinence rates "considerably lower" than self-report
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only a sample of intervention and control participants were selected for follow-up. Of this sample, 91% reached at 18 m in both groups. Numbers followed up used as denominator in MA

Lando 1997

Methods	Setting: Health Maintenance Organisation, USA Recruitment: Physician referral and HMO clinic newsletters
Participants	509 smokers of > 20 cigs/day, motivated to quit; 44% M, av. age 42, av. cigs/day 28
Interventions	All participants received prescriptions for free nicotine patch (Prostep), 22 mg for a maximum of 6 weeks plus 2 weeks 11 mg. Proactive vs Reactive Attended 90-min group orientation session describing study, use of patch, behavioural information, set quit date. Standard written materials with patch included description of a toll-free telephone help line 1. No further support

Lando 1997 *(Continued)*

	2. Orientation session included encouragement to call toll-free number and a registration card 3. Additional proactive TC, 4 10 - 15-min calls (approx 1, 4, 7 - 9, 12 weeks from quit date). Reinforced success or negotiated a new quit date
Outcomes	Abstinence at 12 m (from quit date) Validation: CO at 6 m. 96% of quitters were confirmed
Notes	Arms 3 vs 1+2, effect of proactive TC compared to contact and quitline alone. (1 & 2 combined since fewer than 1% called quitline and no difference between quit rates). Participants who did not return questionnaires at 2, 5, 8, 12 weeks were called by telephone. Average number of calls completed 3.76

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Cluster-randomised, method not described
Allocation concealment (selection bias)	Unclear risk	Allocation by orientation session attended; participants did not know condition in advance, so risk of selection bias probably low
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically-validated quit rates
Incomplete outcome data (attrition bias) All outcomes	Low risk	82% response rate at 12 m, no difference between groups, missing treated as smoking

Lichtenstein 2000

Methods	Setting: Community, USA Recruitment: Active; by electric utility mailing to identify households with smokers and low radon concentrations
Participants	1006 smokers in 714 households (651 in relevant arms); av. cigs/day 20
Interventions	1. Standard Environmental Protection Agency leaflet on risks of radon (this arm not used in review) 2. Pamphlet highlighting risk of smoking in low concentrations of radon, with tips for quitting, or not smoking indoors 3. Pamphlet as 2, plus up to 2 brief (mean about 6 mins) proactive TC sessions
Outcomes	Self-reported abstinence at 12 m (sustained at 3 and 12 m) Validation: none
Notes	Arms 3 vs 2, effect of TC versus S-H alone Cluster-randomisation, 54% of smokers lived with another smoker. Intraclass correlation coefficient for sustained abstinence was .010. Analyses did not correct for this.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised by household, method not described

Lichtenstein 2000 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	80% of households reached at 3 and 12 m, no difference across conditions. Missing treated as smoking

Lichtenstein 2008

Methods	Setting: Community, USA Recruitment: Active; by electric utility mailing with offer of radon test kit to identify households with smokers
Participants	1364 households with 1821 smokers, ˜18 cigs/day
Interventions	Factorial design crossing ± brief phone counselling with 15-min video S-H materials. All households given *A Citizens Guide to Radon* and letter tailored to results of radon level test 1. 1 - 2 calls after receipt of radon test results. Clarified risk and encouraged quitting or no smoking in house. Second call scheduled if interested 2. No calls
Outcomes	Self-reported abstinence at 12 m (sustained at 3 and 12 m) Validation: none
Notes	Results of analyses accounting for clustering of multiple smokers in households reported to yield results generally consistent with simple analyses

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Responding households sequentially randomised to 4 conditions subject to stratification on radon test status
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	83% of households completed 12 m assessment, 76% completed both 3 and 12 m

Lindqvist 2013

Methods	Setting: Sweden; clinic-based

Lindqvist 2013 *(Continued)*

	Recruitment: Callers to Swedish National Tobacco Quitline were invited to participate in the study, if consented to participate, they were sent a postal baseline registration questionnaire
Participants	772 smokers distributed among 9 and 8 counsellors, missing baseline patients' characteristics, only characteristics of completers at 12 m are provided, 20% M, av. age 48, > 80% used NRT or other medications
Interventions	1. Standard TC 2. Motivational interviewing TC Total contact was similar between arms, with a duration ~50', and av. number of sessions 3
Outcomes	Self-reported abstinence at 12 m (continuous) Validation: none
Notes	New for 2018 update Funding: "The research was funded by the Swedish Cancer Society, Stockholm County Council, the Swedish Heart and Lung Association, the Swedish Research Council, the Swedish Council for Working Life and Social Research and the Swedish National Institute of Public Health." Declarations of interest: none reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Allocation of counsellors was semi-randomised (with a flip of a coin) Quote: "The allocation of the counsellors resulted in an uneven distribution of total working hours between the groups. In order to achieve a more equal distribution between the two arms, the groups were readjusted (again by coin flip)"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Self-reported abstinence, but same level of personal contact in different study arms
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "In total, 9 counsellors were allocated to ST and 8 counsellors to MI. During the study period, 2 (out of 8 - 25%) of the MI counsellors left SNTQ. Consequently, the MI arm eventually came to consist of six counsellors."

Lipkus 1999

Methods	Setting: Health centre, USA Recruitment: From telephone survey of patients
Participants	Low-income African-American smokers, 266 randomised, 160 followed up, 107 in relevant arms. Unselected by motivation; 48% M, 49% aged > 50
Interventions	1. Physician prompts attached to chart (included other screening tests). Providers trained to use 4As (Ask/ Advise/ Assist/ Arrange follow-up) model. Only received if participants visited doctor 2. As 1, plus 1 mailing of tailored print communication around birthday

Lipkus 1999 *(Continued)*

	3. As 2, plus proactive TC; 1 or 2 (for women also due other screening), stage-based, barriers and reasons for quitting, approx 6 mins
Outcomes	Self-reported abstinence 16 m after last intervention (30-day PP) Validation: none
Notes	Arms 3 vs 2, TC without face-to-face contact; physician advice was not an integral part of the intervention - participants not required to have visited the doctor or received advice during the intervention period

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	38% loss to follow-up primarily due to disconnected phone numbers. Reported rates based on numbers followed up. Authors report that an analysis with missing treated as smoking did not alter findings

Lipkus 2004

Methods	Setting: Community, USA Recruitment: Proactive in shopping malls
Participants	412 teenage smokers (aged 15 - 18, smoked in past 7 days); 49% M, 56% aged ≥ 17, av cigs/day 10, 21% contemplation
Interventions	1. S-H, 2 booklets for teen smokers and video 2. as 1, plus proactive TC, 3 calls (12 - 15 mins) using MI and problem-solving
Outcomes	Abstinence at 8 m (7-day PP) Validation method: Saliva cotinine ≤ 10 ng/mL at 4 m only. Low response, high failure to confirm. Abstinence based on self report only
Notes	TC as adjunct to targeted S-H.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described, stratified by SoC
Allocation concealment (selection bias)	Unclear risk	No details given

Lipkus 2004 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	High risk	Biochemical validation done but final outcome figures based on self-report only. High failure to confirm and low response rate. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	46% Intervention and 51% Control reached at both follow-ups. Losses included as smokers

MacLeod 2003

Methods	Setting: Community, Australia Recruitment: Community volunteers
Participants	854 smokers interested in quitting; 49% M, av. age 42, av. cigs/day 24
Interventions	1. Free 2-week supply of nicotine patch by mail, instructed to purchase further supply. 14 or 21 mg depending on body weight 2. As 1, + 5 proactive TC sessions at 1, 2, 3, 6 and 10 weeks. 20-min session 1, 10 mins others. Toll-free hotline, S-H materials
Outcomes	Self-reported abstinence at 6 m (90-day continuous) Validation: none, warning of CO test only
Notes	TC as adjunct to NRT Average number of calls 4.7. 9% of participants called hotline

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	"randomized" by shuffling folders each day after participants to be included were listed
Allocation concealment (selection bias)	High risk	Potential for bias, since allocation sequence not fixed in advance. Baseline characteristics similar across groups
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "To minimise misleading reports of abstinence, a bogus pipeline technique was used, with the possibility of carbon monoxide breath testing mentioned in the consent form and at the 3- and 6-month monitoring calls."
Incomplete outcome data (attrition bias) All outcomes	Low risk	17% lost in NRT only, 15% in + counselling. Missing treated as smoking in MA

McBride 1999a

Methods	Setting: Health Maintenance Organisation, USA Recruitment: Active; health survey of women following a cervical smear (pap) test
Participants	580 current women smokers, not selected for motivation to quit; av. age 36, av. cigs/day 13
Interventions	1. Usual care; no smoking cessation intervention

McBride 1999a *(Continued)*

	2. Mailed cessation kit, letter personalised to SoC and quit motivation, proactive TC, 3 counselling calls (13 - 15 min) 2 weeks after mailing, then monthly. Motivational- and stage-based
Outcomes	Abstinence at 15 m (7-day PPA) obtained by telephone interview Validation: saliva cotinine < 20 ng/ml, quit rates not corrected, low level of misreport
Notes	Effect of TC and S-H materials compared to no intervention Counsellor discussed smoking and cervical cancer but not individual's pap results. > 80% received at least 1 call, 60% all 3

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not stated, stratified on test result
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation, quit rates not corrected but low level of misreport and Quote: "no differences between the two groups in the proportion of women who returned samples, the proportion confirmed/disconfirmed, or the confirmation rate."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up at 15 m 20% in Intervention, 18% in Control. Losses included as smokers

McBride 1999b

Methods	Setting: 2 Health Maintenance Organisations, USA Recruitment: Pregnant women who had booked a prenatal appointment, by mail
Participants	897 pregnant smokers and recent quitters (44% already quit) not selected for motivation to quit; av. age 28, av. cigs/day 15 before pregnancy, 5 if still smoking
Interventions	1. S-H booklet only 2. Prepartum intervention: 3 proactive TC calls av 8½ mins, approx 2 weeks after S-H mailing, and 1 m and 2 m later. Tailored letter, S-H book. After 28-week follow-up sent relapse prevention kit 3. Pre- and postpartum intervention: as 2, plus 3 calls within first 4 m postpartum, av 7.7 mins. 3 newsletters
Outcomes	Abstinence at 12 m postpartum (7-day PP) Validation: Saliva cotinine requested by mail, < 20 ng/mL. Self-reported rates used in analyses, no difference in confirmation rates between groups
Notes	Arms 3+2 vs 1, effect of TC versus S-H only

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described

McBride 1999b *(Continued)*

Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation used, not reported: Quote: "since there were no between-group differences in the proportion of saliva samples returned or the proportion confirmed, the primary trial outcomes were based on self-reported smoking status."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up 13% at 12 m, not different by group, losses included as smokers

McBride 2004

Methods	Setting: Army Medical Centre, USA Recruitment: Pregnant women at first prenatal visit
Participants	583 pregnant current smokers and recent quitters (390 in relevant arms); av. age 24
Interventions	1. Usual care: provider advice and S-H guide 2. As 1, plus 6 proactive TC calls, 3 in pregnancy, 3 postpartum within 4 m + late pregnancy relapse prevention kit 3. Partner-assisted intervention, not used in this review
Outcomes	Abstinence at 12 m postpartum (7-day PP at all 4 follow-ups) Validation: Saliva cotinine request, incomplete return, rates based on self-report
Notes	Effect of TC as adjunct to brief advice Effect at 6 m not sustained longer term. Mean number of calls received was 5

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described, stratified by smoking status
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Biochemical validation conducted but not used in outcome data. Quote: "Saliva return rates did not differ by condition at either follow-up" but rates of return low and level of misreport not specified
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up higher in Intervention (22%) than Control (16%). Losses included as smokers

McClure 2005

Methods	Setting: Health Maintenance Organisation, USA

McClure 2005 *(Continued)*

	Recruitment: Women with an abnormal cervical smear or colposcopy
Participants	275 women smokers, not selected for motivation to quit; av. age 33, av. cigs/day 14
Interventions	1. Usual care, S-H, contact details for *Free & Clear*, a covered benefit 2. As 1, plus up to 4 x 15-min proactive TC calls over 6 m
Outcomes	Abstinence at 12 m (7-day PP) Validation: Cotinine saliva strip test, but judged over-conservative so self-report used. Relative effect not altered
Notes	Effect of TC versus S-H only

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Bogus pipeline for short follow-up, biochemical validation at 12 m. Results from saliva strip test judged overly conservative, hence self-report used in final outcome data, but relative effect not altered
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information on numbers not reached at follow-up. All participants included in analysis

McClure 2011

Methods	Setting: Pacific Northwest, USA Recruitment: Members of large regional health plan identified through automated records
Participants	52 adults with evidence of smoking in last year, depression in last 2 years, and without high levels of physical activity. 33% M; av. age 44.5; av. cigs/day 10.6; av. FTND 2.37
Interventions	1. Intervention: usual care + phone-based Step Up proactive counselling programme (1 motivational call, 9 weekly CBT calls and 2 follow-up 'booster calls' according to participant need) 2. Control: usual care treatment for depression, smoking and physical activity (incl. S-H material and referral information for phone-based smoking cessation programme)
Outcomes	Self-reported abstinence at 6 m (7-day PP) Validation: none
Notes	Pilot study of an intervention also addressing physical activity and depression Number abstinent not provided and hence extrapolated from percentages given

Risk of bias

McClure 2011 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomly assigned," stratified by baseline antidepressant use". Method of sequence generation not specified
Allocation concealment (selection bias)	Unclear risk	Method not specified
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcome, participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Participants lost to follow-up counted as smokers, similar numbers lost in each group (4/27 intervention, 2/25 control)

McFall 1993

Methods	Setting: Community, USA Recruitment: Registrants for a S-H TV programme who received manual or watched at least 1 programme
Participants	1745 smokers; 30% M, 23% age 18 - 30, 40% age 31 - 45, 30% 45 - 64
Interventions	1. TV programme and S-H manual (ALA *Freedom From Smoking in 20 Days*) 2. As 1, plus 10 newsletters over 6 m following programme with details of hotline with taped messages and counsellors
Outcomes	Abstinence at 24 m (7-day PP) Validation: none
Notes	Effect of access to hotline combined with S-H materials for maintenance of cessation Use of the hotline was low; only 7% called and spoke to a counsellor

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Self-reported outcomes from participants not blinded to treatment condition. Unclear if level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	24% lost in maintenance condition, 27% in control. MA includes only responders; Including losses would give less conservative effect

Metz 2007

Methods	Setting: 13 rehabilitation centres, Germany Recruitment: Recent smokers having rehabilitation, not formally selected for motivation
Participants	290 smokers; 59% M, av. age 47, av cigs/day 15, control group significantly more dependent
Interventions	All participants had inpatient group therapy of 7 x 60-min sessions. ˜26% abstinent at discharge 1. Telephone boosters; 5 x ˜10-min proactive calls over 10 weeks from female psychologists (not original therapist) 2. No boosters
Outcomes	Abstinence at 12 m (7-day PP) Validation: none
Notes	Effect of TC as adjunct to intensive support

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, 1:2 ratio, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	17/316 randomised to intervention excluded, no contact post-discharge. Differential dropout from remainder, 17% Intervention, 40% Control. No detected differences in characteristics of dropouts. Sensitivity analyses excluding losses to follow-up removes significance

Miguez 2002

Methods	Setting: Community, Spain Recruitment: Volunteers interested in quitting
Participants	200 smokers; 62% M, av. age 35, av cigs/day 28
Interventions	1. Proactive TC, 6 x weekly 10-min calls. 4 on motivation and cessation, 2 on maintenance, + S-H 2. S-H only. Personalised intro letter, manual and 6 similar mailings with self-monitoring and self-evaluation forms
Outcomes	Abstinence at 12 m (not even a puff since quitting) Validation: CO at 12 m
Notes	10-year follow-up reported in 2008, not used in MA

Risk of bias

Bias	Authors' judgement	Support for judgement

Miguez 2002 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation used
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information on numbers not reached at follow-up. All participants included in analysis

Miguez 2008

Methods	Setting: Community, Spain Recruitment: Volunteers interested in quitting
Participants	228 smokers of ≥ 10 cigs/day; 54% M, av. age 37, av. cigs/day 27, 44% had prior year quit attempt
Interventions	1. Mailed S-H programme; 6 weekly manuals, quit date intended to be set at end of week 4 2. As 1. + single proactive 5 - 10-min counsellor call in week 4, to increase motivation and adherence
Outcomes	Abstinence at 12 m (sustained since end of treatment) Validation: none ('bogus pipeline' warning)
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Telephone interviews were conducted by a trainer interviewer who was blind with respect to the group to which each subject was assigned. To improve the reliability of these self-reports of smoking status, all follow-up questionnaires and interviews commenced with a reminder that the subject might at some point be asked to undergo a carbon monoxide test."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Missing data treated as failure, no statement of numbers lost to follow-up

Miller 1997

Methods	Setting: Hospitals, USA Recruitment: Inpatient smokers (excl those with no intention of quitting, or wishing to quit unaided)

Miller 1997 *(Continued)*

Participants	1942 smokers (excludes deaths); 51% M, av. age 51, av cigs/day 20
Interventions	All groups received standardised physician advice 1. Intensive intervention: 30-min nurse face-to-face counselling, proactive TC, 4 at 48 hours post-discharge, 7, 21, 90 days, optional session for relapsers 2. Minimal: 30-min counselling + 1 phone call at 48 hours 3. Usual care (not used in review)
Outcomes	Abstinence at 12 m (sustained at 3 m, 6 m, 12 m) (Paper also reports 12 m PP confirmed and self-reported cessation rates) Validation: saliva cotinine < 15 ng/ml, or family member verification
Notes	Effect of additional telephone follow-up. Not pooled.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Low risk	Quote: "Nurses opened sealed envelopes in front of patients"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation; verification by family member used when biochemical validation not possible
Incomplete outcome data (attrition bias) All outcomes	Low risk	Number lost to follow-up not specified, all randomised participants, excluding 82 deaths, included in analyses

NCT00534404

Methods	Setting: USA Recruitment: Quote: "Interested individuals completed a screening survey to determine eligibility. Following study consent, participants completed two emailed surveys over the next two days and a phone confirmation call before being randomized. These check-ins confirmed the participant had valid contact information and maintained their desire to quit smoking."
Participants	2485 adult smokers of ≥ 10 cigs/day, willing to set a quit date within 2 to 4 weeks, willing to use a nicotine patch, 31% M, av. age 44.
Interventions	1. NRT patch (free 8-week) + Internet (iQuit Smoking website) 2. As 1, plus 5 sessions of TC after 0, 2, 4, 6 and 8 weeks
Outcomes	Self-reported abstinence at 9 m (6 m prolonged) Validation: none
Notes	New for 2018 update Funding: not reported Declarations of interest: not reported

Risk of bias

NCT00534404 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information provided on ClinicalTrials.gov website
Allocation concealment (selection bias)	Unclear risk	Insufficient information provided on ClinicalTrials.gov website
Blinding of outcome assessment (detection bias) All outcomes	High risk	Abstinence not biochemically validated. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low percentage (19%) of participants lost to follow-up and comparable across arms

Nohlert 2014

Methods	Setting: Sweden; population-based Recruitment: Tobacco user calls the quitline, the counsellor invites the user to participate in the study, and if the user consents verbally, the registration form and baseline questionnaire are sent by mail. If baseline questionnaire is returned the user is included in the study
Participants	1129 smokers, 22% M, age: ≤ 34: 20%, 35 - 49 25%, 50 - 64 39%, ≥ 65 17%, average cigs/day: 0: 27%; 1 - 14: 34%; ≥ 15: 39%. Participants were interested in quitting
Interventions	1. Reactive quitline service: The study was performed within the normal run of the Sweedish national tobacco quitline. Participants in this arm were not offered to be called back 2. Proactive quitline service: The study was performed within the normal run of the Swedish national tobacco quitline. Participants in this arm were offered to be called back. The first call was about 25 mins and subsequent calls were 5 - 10 mins, with a mean of 4.3 calls
Outcomes	Self-reported abstinence at 12 m (6 m continued) Validation: none
Notes	New for 2018 update Funding: "The study was supported by grants from the Swedish Heart and Lung Association, the Swedish Heart Lung Foundation, the Swedish Cancer Society, the Swedish Research Council, the Swedish Research Council for Health, Working Life and Welfare, and the County Council of Västmanland, Sweden." Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Semi-randomised Quote: "randomized to proactive service (even dates) and reactive service (odd dates)"

Nohlert 2014 *(Continued)*

Allocation concealment (selection bias)	High risk	Quote: "As the randomization was performed at the time for the clients' first call, the intervention has started and was known by the clients when they decided to return the baseline questionnaire and thus be included in the study base"
Blinding of outcome assessment (detection bias) All outcomes	High risk	Abstinence not biochemically validated. Level of personal contact probably differed between arms
Incomplete outcome data (attrition bias) All outcomes	High risk	Similar dropout across trial arms but > 50%

Ockene 1991

Methods	Setting: Primary care clinics, USA Recruitment: Clinic attenders, not selected for interest in quitting
Participants	1223 smokers (excludes deaths and 237 who did not receive intervention); 43% M, av. age 35, av. cigs/day 23
Interventions	2 x 3 factorial design, physician intervention ± follow-up (a) AO: Physician advice only (b) CI: Physician-provided patient-centered counselling, written agreement and schedule follow-up, letter (c). CI+NCG: as (b), plus informed of availability of free nicotine gum 1. Follow-up counselling by psychologist or health educator, 3 calls (1, 2, 3 m) approx 10 mins, behavioural recommendations. Letters 2. No follow-up
Outcomes	Abstinence at 6 m (7-day PP). 3 m sustained abstinence rates not given by condition Validation: none
Notes	Arm 1 vs 2, AO and CI effect of TC in addition to physician intervention. NCG arm in pharmacotherapy adjunct, both pooled in intensity and motivation subgroup analyses. 12-m abstinence rates reported in Ockene 1994, but not given by follow-up condition

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	Allocated prior to physician encounter
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	19% lost to follow-up, higher in telephone follow-up group. All included as smokers in analysis

Orleans 1991

Methods	Setting: Health Maintenance Organisation, USA Recruitment: Largely through publicity in HMO magazine
Participants	2021 smokers of 3+ cigs/day, wanting to quit (1412 in relevant arms); 37% M, av. age 44, av. cigs/day 26
Interventions	1. S-H manual, Quit Kit and ALA *Lifetime of Freedom from Smoking* 2. Same materials as 1, plus 2 copies of a social support guide 3. Same as 2, plus proactive TC (6, 18, 34, 60 weeks) from a counsellor and invitation to call a quit line 4. Control: Referral guide
Outcomes	Abstinence at 16 m (sustained for > 6 m) obtained by blinded telephone interview Validation: Saliva cotinine < 10 ng/ml, or thiocyanate < 2400 umol/l for gum users. Self-report rates reported in analyses
Notes	Arms 3 vs 1 and 2 combined, effect of telephone counselling compared to S-H materials alone.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described, stratified by living alone/not, advice to quit in last 12 m/not, and nicotine content of cig. brand
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation in sample at 16 m Quote: "to improve the veracity of smoking self-report, all follow-up questionnaires and interviews began with a reminder that the subjects might be asked for a saliva specimen for nicotine assessment, creating a sort of 'bogus pipeline'"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up 6% at 16 m, did not differ across treatment groups. Analyses based on respondents; including losses would marginally increase estimated effect

Orleans 1998

Methods	Setting: Community, USA Recruitment: African-American smokers calling the NCIS telephone counselling line in response to targeted campaign
Participants	1422 African-American smokers; 36% M, av. age not stated, 62% in 20 - 39 age group, median cigs/day 20
Interventions	Reactive, for callers to quitline 1. Tailored TC and tailored 36-page *Pathways to Freedom* guide. Guide used African-American models and addressed specific obstacles. Personalised quitting plan 2. Standard NCIS TC and standard guide *Clearing the Air*
Outcomes	Abstinence at 6 m (7-day PP) Validation: none

Orleans 1998 *(Continued)*

	(12-m abstinence also assessed in sample of 445 smokers and there were significant differences; 15.0% vs 8.8% using ITT)
Notes	Comparison between 2 types of counselling. Also included in Cochrane Self-help review since effects of counselling and S-H materials cannot be separated Median call length 19 mins (interdecile range 10 - 28 min) for tailored, 13 min (8 - 23) for standard

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Pseudo-randomised by last digit of caller's contact phone number
Allocation concealment (selection bias)	High risk	Potential for selection bias but unlikely given low contact
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Self-reported outcomes from participants not blinded to treatment condition, but similar levels of personal contact in different study arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	37% lost to follow-up at 6 m. No differential dropout, losses included as smokers

Osinubi 2003

Methods	Setting: Occupational health service, USA Recruitment: Asbestos-exposed workers and retirees attending medical screening, not selected for motivation
Participants	58 smokers; 93% M, av. age 52, av. cigs/day 22
Interventions	All participants received brief physician advice at screening 1. Enrolment in *Free & Clear*, proactive TC, 5 calls, hotline access, pharmacotherapy available 2. Instructions to obtain support from personal physician, S-H materials and resources
Outcomes	Self-reported abstinence at 6 m (30-day PP) Validation: none
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	Sealed envelopes, not stated if opaque and numbered
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms

Osinubi 2003 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	32% lost to follow-up, comparable across groups, losses included as smokers

Ossip-Klein 1991

Methods	Setting: 10 counties, USA Recruitment: Media advertising, local sign-ons, brochures
Participants	1813 smokers planning to quit within 3 m; av. age 43, av. cigs/day 28 Therapists (hotline): ex-smoker counsellors
Interventions	Reactive 1. ALA S-H manuals 2. as 1, plus materials promoting 24-hour hotline with daytime access to counsellors
Outcomes	Abstinence at 18 m (sustained from 3 m) Validation: by significant other for 90% of claims, saliva cotinine for 52% of claims. Cotinine-validated rates used
Notes	The authors report a range of analyses based on alternative measures of smoking status and using logistic regression to allow for cluster randomisation. The higher quit rate in the hotline counties was consistent in all analyses. 36% called hotline, 8.7% spoke with counsellors

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Matched pairs of counties assigned to condition in a restricted procedure to minimise media spill-over
Allocation concealment (selection bias)	Unclear risk	Participant recruitment not linked to county assignment so selection bias unlikely
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Self-reported abstinence verified by significant other and/or saliva cotinine
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up over 90% at all points and did not differ by condition

Ossip-Klein 1997

Methods	Setting: Community, USA Recruitment: Advertising for S-H cessation for over-60 yr-olds
Participants	177 smokers aged ≥ 60, planning to quit in next 3 m; 39% M, av. cigs/day 25
Interventions	1. S-H manual (*Clear Horizons*), access to 24-hour hotline, 2 letters of support and hotline reminders 2. As 1, plus proactive TC, 2 calls at 4 and 8 weeks. Counsellors followed structured format to provide strategies based on SoC

Ossip-Klein 1997 *(Continued)*

Outcomes	Abstinence at 6 m (7-day PP) Validation: not biochemical. Significant others only. Refusals and non-confirmations classified as smokers
Notes	42% had called hotline and 17.5% spoken to counsellor by 6 m

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Validation by significant other, number refused/misreported not specified
Incomplete outcome data (attrition bias) All outcomes	Low risk	97% reached at 12 m

Peterson 2016

Methods	Setting: Washington State, USA; High school-based Recruitment: High school smokers were identified by self-report using a study-administered baseline classroom survey
Participants	2151 smokers, 52.7% M, Age: < 16 years old: 0.1%; 16 years old 30.5%; 17 years old: 62.0%; > 17 years old: 7.4%; smokers were of variable motivation and wish for help with quitting
Interventions	1. No intervention 2. Proactive telephone intervention - 10 calls of about 15 mins each
Outcomes	Self-reported abstinence at 7 years (6-year prolonged) Validation: none
Notes	New for 2018 update Funding: "This study was supported by NCI grant R01-CA082569" Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A matched-pair randomization was performed via a computerized coin flip for each of 25 pairs of high schools, using pair-matching of schools based on number of smokers, smoking prevalence, fraction of students eligible for free/reduced-priced meals, and average stage of readiness to quit, so that the experimental and control conditions were balanced on these criteria"

Peterson 2016 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Abstinence not biochemically validated. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Even after 7 years percentage of participants lost to follow-up is small and comparable between arms

Piper 2016

Methods	Setting: Winsconsin, USA; primary care clinics Recruitment: Quote: "During clinic visits, clinical care staff (i.e. medical assistants) were prompted by electronic health record technology to invite identified smokers to participate in a research program to help them to quit smoking"
Participants	637 smokers, 45% M, mean age 45.8, average cigs/day 17.7, participants were motivated to quit
Interventions	1. Minimal phone counselling ± preparation gum ± preparation patch ± in-person counselling ± medication duration. Quote: "Participants assigned to the minimal condition received one 10-minute session on the TQD that provided support and addressed motivation to quit, strategies for coping with craving and medication use." 2. Intense phone counselling ± preparation gum ± preparation patch ± in-person counselling ± medication duration Quote: "Participants in the intensive condition received three 15-minute phone sessions (TQD, days 2 and 10). These calls emphasized intra-treatment social support, skill execution and avoidance of danger situations"
Outcomes	Self-reported abstinence at 26 weeks (7-day PP) Validation: none
Notes	New for 2018 update Funding: "This research was supported by grants 9P50CA143188 and 1K05CA139871 from the National Cancer Institute to the University ofWisconsin Center for Tobacco Research and Intervention and by theWisconsin Partnership Program. L.M. C. is also supported by NIH grants P50DA10075 and R01DK097364. This work was carried out in part while T.R.S. was a Primary Care Research Fellow supported by a National Research Service Award (T32HP10010) from the Health Resources and Services Administration to the University of Wisconsin Department of Family Medicine. J.W.C. is also supported by Merit Review Award 101CX00056 from the US Department of Veterans Affairs. W.-Y.L. is also supported by NSF grant DMS-1305725." Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement

Piper 2016 *(Continued)*

Random sequence generation (selection bias)	Low risk	Quote: "stratified permuted block randomization; we stratified by gender and clinic with a fixed block size of 32 based on the 32 unique treatment conditions (in random order within each block)"
Allocation concealment (selection bias)	Low risk	Quote:"Staff were blinded to randomization until eligibility was confirmed; participants were blinded until consent was provided"
Blinding of outcome assessment (detection bias) All outcomes	High risk	Abstinence not biochemically validated. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Higher attrition in the intensive counselling arm but difference is less than 20%

Prochaska 1993

Methods	Setting: Community, USA Recruitment: Advertisements for volunteers to test S-H materials, not selected for motivation
Participants	756 smokers (12% precontemplation, 58% contemplation, 30% preparation) (378 in relevant arms); 38% M, av. age 43, av. cigs/day 27
Interventions	1. ALA S-H manuals 2. Tailored manuals - 5 covering precontemplation, contemplation, action, maintenance, relapse. Participants sent manual for their SoC and subsequent ones 3. Interactive - in addition to tailored manuals, sent personally-tailored reports in response to questionnaires 4. Proactive TC - short (15-min) calls at 0, 1 m, 3 m, 6 m. Materials as in 3
Outcomes	Self-reported abstinence at 18 m (sustained at 12 m and 18 m) Validation: none. Participants asked for names of significant others but these not contacted
Notes	Arms 4 vs 3, TC vs S-H alone. Numbers randomised to groups and quit rates as shown in graphs obtained from authors

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described, stratified by SoC
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	'Bogus pipeline' approach; names of significant others asked for but not contacted
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition at each assessment averaged 4.1% - 7.1% across all treatment conditions, not significantly different. 70% provided data at every assessment. MA uses numbers randomised, sensitivity analysis does not alter conclusions

Prochaska 2001

Methods	Setting: Managed care organisation, USA Recruitment: Active; smokers identified by survey of members. 85% recruited to a study, unselected for motivation to quit
Participants	1447 smokers (723 in comparisons used); 38% were precontemplators, 44% M, av. age 38, av. cigs/day 20
Interventions	1. Assessment only (completed questionnaires on 4 occasions) 2. Expert System S-H. Tailored 2 - 3-page report at 0, 3 m, 6 m, and SoC-matched manual 3. As 2, plus proactive TC, short calls at 0, 3 m, 6 m. Similar to Prochaska 1993 protocol but more emphasis on alternative targets for those unwilling to set quit date. 4. As 3, plus computer-scheduled cig reduction
Outcomes	Self-reported abstinence at 18 m (sustained for 6 m). Other measures of abstinence also reported Validation: None
Notes	Arms 3 vs 2, TC vs S-H alone. Other arms compared in Self-help review

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Abstinence not biochemically validated. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Greater loss to follow-up in TC (44%) than S-H (38%). Denominators here include losses to follow-up and refusals. Author analysis suggests this treatment of missing data is biased, but sensitivity analysis excluding losses and refusals does not alter our MA conclusions

Rabius 2004

Methods	Setting: Quitline, USA Recruitment: Callers to quitline
Participants	3522 smokers willing to make a quit attempt within 2 weeks (≤ 25/ > 25): 39%/33% M, av. age 22/44, av. cigs/day 24/18
Interventions	1. 3 American Cancer Society S-H booklets 2. As 1, plus offer of 5 proactive TC calls, 2 before TQD, 3 within 2 weeks
Outcomes	Abstinence at 6 m (sustained). Only people abstinent at 3 m followed at 6 m Validation: none for most, small local sample tested, no responders disconfirmed, 4/19 did not attend (reported in McAlister 2004)
Notes	58% did not complete more than 1 session of counselling (McAlister 2004)

Rabius 2004 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Small local sample biochemically tested, no responders disconfirmed
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up 50% in Intervention, 55% in Control (from McAlister 2004). Differed by age, with higher loss in younger participants. All losses treated as smokers

Rabius 2007

Methods	Setting: National Cancer Society quitline, USA Recruitment: Callers to NCIS, interested in quitting
Participants	6322 smokers; 30% M, av. age 43, median cigs/day 20
Interventions	¼ allocated to S-H control, remainder into 3 x 2 factorial design Counselling conditions: 1. 5 sessions, 210 mins (35 - 45-min calls 10 - 14 days pre-quit, 2 - 3 days pre-quit, 1 - 2 days, 6 - 9 days, 13 - 16 days post-quit) 2. 3 sessions with 105 mins counselling (As 1, omitting 1st and last sessions) 3. 5 sessions with 50 mins counselling (schedule as 1, 10 mins duration) Booster conditions: 2 x 15-min calls at 4 and 8 weeks after last counselling call
Outcomes	Abstinence at 7 m post-randomisation (PP) Validation: none
Notes	All interventions pooled vs control, results of different intensities included in post hoc analyses and discussed in more detail in text.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random number sequence without stratification
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Self-reported outcomes from participants not blinded to treatment condition. Varying levels of contact between arms in multifactorial trial
Incomplete outcome data (attrition bias)	Low risk	Loss to follow-up ~50%, similar in all groups. Analysis includes losses as smokers

Rabius 2007 *(Continued)*
All outcomes

Ramon 2013

Methods	Setting: Spain; smoking cessation outpatient clinics Recruitment: smokers attending smoking cessation outpatient clinics
Participants	600 smokers, 51.3% M, mean age 47.4, average cigs/day 25.3. Paticipants attended clinics to "receive medical assistance" - they were interested in quitting
Interventions	1. Individual counselling: "seven individual sessions at 3, 5, 7, 10, 12, 24, and 52 weeks after the pre-quit session." 2. Telephone counselling + Individual Counseling: "individual counselling interventions at weeks 3, 5, and 12 after the pre-quit session, telephone counselling at weeks 7, 10, and 24, and a control session at the clinic at week 52." Sessions were between 15 and 20 mins
Outcomes	Abstinence at 52 weeks (sustained from week 2 to 52) Validation: CO concentrations of < 10 ppm
Notes	New for 2018 update Funding: "This study was supported by a grant from the Spanish Health Institute, Carlos III PI080418." Declarations of interest: several authors "have received honoraria for conferences from manufacturers of smoking cessation products."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "used a computer-generated randomization system based on a permuted block randomization list where each block was used by one centre. An independent researcher in the coordination centre generated a random sequence, and centres were informed about smoker allocation after consent to participation during the pre-quit session."
Allocation concealment (selection bias)	Low risk	Quote: "used a computer-generated randomization system based on a permuted block randomization list where each block was used by one centre. An independent researcher in the coordination centre generated a random sequence, and centres were informed about smoker allocation after consent to participation during the pre-quit session."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Used biochemical verification to validate self-reported outcome
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition was around 20% and comparable across arms

Reid 1999a

Methods	Setting: Community, Canada Recruitment: Community volunteers
Participants	396 smokers interested in quitting within 30 days, smoking ≥ 15 cigs/day; 52% M, av. age 38, av. cigs/day 23 - 24
Interventions	1. Nicotine patch (15 mg x 8 weeks, 10 mg x 2 weeks, 5 mg x 2 weeks) free, physician advice (x 3 15-min, 2 weeks before, 4 weeks, 12 weeks after quit date) 2. As 1, plus proactive TC, nurse counsellors, stage-based, 3 sessions at 2, 6, 13 weeks
Outcomes	Abstinence at 12 m (PP) Validation: CO, but self-reported rates reported. Only 1 disconfirmation
Notes	Effect of adjunct TC compared to NRT and counselling alone Similar counselling scripts to Orleans 1991

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised using table of random numbers, stratified by gender and nicotine dependence
Allocation concealment (selection bias)	Unclear risk	Concealment unclear but physician blind to allocation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	'Bogus pipeline' procedures used for early follow-ups; proportion of participants who provided breath samples did not differ between 2 groups; only 1 misreport identified; adjustment of abstinence rates for validation did not affect conclusions
Incomplete outcome data (attrition bias) All outcomes	Low risk	15% lost/dropped out in each groups, included as smokers

Reid 2007

Methods	Setting: Tertiary care cardiac hospital, Canada Recruitment: Inpatients with CHD, not explicitly selected by motivation, 90% of eligible enrolled
Participants	100 smokers; 68% M, av. age 54, 48% quit attempt in previous year
Interventions	All participants received in-hospital brief counselling, access to NRT, S-H materials 1. Interactive Voice Response (IVR) system contacted participants 3, 14 and 30 days post-hospital discharge. Participants identified as needing support contacted by nurse counsellor for up to 3 x 20-min sessions over 8 weeks 2. Usual care
Outcomes	Abstinence at 1 year (PP) Validation: none
Notes	Mean 2.1 IVR calls completed, 46% received at least 1 counselling call, mean 1.8, so total calls categorised as 4

Risk of bias

Reid 2007 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "mediated through the Clinical Epidemiology Unit's data centre, using a computer generated randomization list" Block size 6
Allocation concealment (selection bias)	Low risk	Quote: "Research staff were unaware of the treatment allocation prior to randomization"
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	˜15% lost to follow-up, similar between groups. 1 Control death excluded, others included

Reid 2018

Methods	Setting: Canada; hospital-based Recruitment: Smokers admitted to the hospital were automatically referred to an in-house smoking cessation programme
Participants	410 hospital-admitted CHD smokers, 74.4% M, av. age 54.2, 16% < 11 cigs/day, 33% 11 - 20 cigs/day, 40% 21 - 30 cigs/day, 11% > 30 cigs/day Not selected for motivation
Interventions	1. Standard care including in-hospital counselling by nurse, written information about smoking cessation and NRT 2. As in 1, plus 8 automated follow-up calls after 3, 14, 30, 60, 90, 120, 150, 180 days post-hospitalisation. If smokers had low motivation, had a relapse or desired a call back, a nurse counsellor provided additional assistance
Outcomes	Abstinence at 52 weeks (continuous abstinence) Validation: CO ≤ 4 ppm done in a random subsample with high verification rates after 52 weeks of follow-up (˜90%)
Notes	New for 2018 update Funding: "Heart and Stroke Foundation of Ontario Grant # NA5845" Declarations of interest: "RDR and ALP have received speaking and/or consulting fees and research grants from Pfizer and Johnson & Johnson. KAM has received speaking fees from Pfizer. AGL is supported by a Canadian Institutes of Health Research–Ottawa Model for Smoking Cessation Health Impact Fellowship"

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "computer generated sequence"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias)	Low risk	Validation of self-reports in a random subsample achieving high rates of verified abstinence

Reid 2018 *(Continued)*

All outcomes		
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar percentage of participants lost to follow-up across arms (˜30%)

Rigotti 2006

Methods	Setting: Prenatal care services, USA Recruitment: Pregnant women in a managed care plan or referred by a care provider, not selected by motivation
Participants	442 pregnant women smoking at least 1 cig in previous 7 days; av. age 29, av. cigs/day 21 prior to pregnancy, 10 at recruitment, 84% planned to quit
Interventions	All participants received brief counselling at enrolment call and mailed a pregnancy-tailored S-H booklet 1. Proactive counselling, up to 90 mins during pregnancy and 15 mins postpartum, + targeted written materials 2. Usual care
Outcomes	Abstinence 3 m postpartum (sustained at end of pregnancy and 3 m) Validation: saliva cotinine ≤ 20 ng/mL
Notes	Mean of 5 calls received, 4 in pregnancy, av. 68 mins in total

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "computer-generated randomization list arranged in balanced blocks of 4 and stratified by referral source"
Allocation concealment (selection bias)	Low risk	Quote: "... the application revealed the next assignment only after the smoker had consented to participate in the study"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation; those who failed biochemical validation or did not provide a sample counted as smokers
Incomplete outcome data (attrition bias) All outcomes	Low risk	21 miscarriages excluded. 33% Intervention, 28% Control lost to follow-up, included as smokers

Rimer 1994

Methods	Setting: Community, USA Recruitment: Volunteers from American Association for Retired Persons
Participants	1867 smokers aged 50 - 75 (12-m data based on 1391, 1225 in relevant arms) interested in finding out about quitting; 37% M, av age 61, av cigs/day 27
Interventions	1. Standard S-H manual (not included in this review) 2. S-H manual tailored for older smokers (*Clear Horizons*)

Rimer 1994 *(Continued)*

	3. Tailored manual and 2 x 10 - 15-min proactive TC at 4 - 8 weeks and 16 - 20 weeks. Also access to a quitline
Outcomes	Abstinence at 12 m (7-day PP) Validation: none
Notes	Arms 3 vs 2. Preliminary 12 m results used

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	~75% reached at 12 m with no treatment group differences in follow-up rate

Rogers 2016

Methods	Setting: NY, NJ, MA, VT, NH, RI, USA; 6 Veterans Health Administration (VHA) facilities in the U.S. Northeast Recruitment: Quote: "All smokers who saw a VHA mental health provider at participating sites were eligible for referral to the care coordination program by their usual mental health providers via an EMR consult created for the study"
Participants	577 smokers, 92% M, av. age 54, av. cigs/day 15.9. Participants were referred from a VHA mental health provider and were interested in quitting
Interventions	1. State quit-line counselling 2. Specialised proactive telephone counselling protocol developed by the study for mental health patients - 10 or fewer calls, weekly and for 30 - 60 mins Participants in both groups also received mailed S-H materials and smoking cessation medications
Outcomes	Self-reported abstinence at 6 m (30-day PP) Validation: none
Notes	New for 2018 update Funding: "This trial was funded by the U.S. Department of Veterans Affairs Health Services Research and Development Quality Enhancement Research Initiative (#SDP 07-034)." Declarations of interest: none declared

Risk of bias

Rogers 2016 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Pseudo-randomised using social security number last digit (odd/even number). This resulted in nearly balanced groups except for the fact that participants in the specialised counselling arm smoked a significantly higher number of cigarettes than participants in the quitline arm
Allocation concealment (selection bias)	High risk	Unlikely to apply to this method of randomisation
Blinding of outcome assessment (detection bias) All outcomes	High risk	Abstinence not biochemically validated. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar rates of attrition in both arms

Schlam 2016

Methods	Setting: Winsconsin, USA; primary care clinics Recruitment: Recruited during primary care visits (11 primary care clinics in 2 healthcare systems). Existing clinical care staff (i.e. medical assistants), prompted by electronic health record technology, invited identified smokers during clinic visits to participate in a research programme to help them quit smoking
Participants	544 smokers, 41% M, av. age 46.2, av. cigs/day 18.6, motivated to quit
Interventions	1. No maintenance (phone) counselling ± extended medication ± (on site) medication adherence counselling ± automated adherence calls ± helping hand (HH) with feedback and counselling 2. No automated adherence calls ± extended medication ± (on site) medication adherence counselling ± maintenance (phone) counselling ± helping hand (HH) with feedback and counselling (not used in analysis) 3. Automated adherence calls ± extended medication ± (on site) medication adherence counselling ± maintenance (phone) counselling ± helping hand (HH) with feedback and counselling (not used in analysis) 4. Maintenance (phone) counselling ± extended medication ± (on site) medication adherence counselling ± automated adherence calls ± helping hand (HH) with feedback and counselling - 8 x 15-min calls at weeks 3, 4, 6, 8, 10, 14, 18 and 22 Quote: "All participants received a standard cessation intervention: 8 weeks of nicotine patch+nicotine gum and 50 minutes of counseling delivered over four sessions [in visits 1 week before and 1 week after the target quit day (TQD), and in calls on the TQD and at week 2]."
Outcomes	Self-reported abstinence at 52 weeks (7-day PP) Validation: none
Notes	New for 2018 update Funding: "This research was supported by grants 9P50CA143188 and 1K05CA139871 from the National Cancer Institute to the University ofWisconsin Center for Tobacco Research and Intervention and by theWisconsin Partnership Program. L.M. C. is also supported by NIH grants P50DA10075 and R01DK097364. This work was carried out in part while T.R.S. was a Primary Care Research Fellow supported

Schlam 2016 *(Continued)*

by a National Research Service Award (T32HP10010) from the Health Resources and Services Administration to the University of Wisconsin Department of Family Medicine. J.W.C. is also supported by Merit Review Award 101CX00056 from the US Department of Veterans Affairs. W.-Y.L. is also supported by NSF grant DMS-1305725."

Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: “Participants were randomized to one of 32 unique experimental conditions… via a database that used stratified, computer-generated, permuted block randomization…”
Allocation concealment (selection bias)	Low risk	Quote: “Staff could not view the allocation sequence. The database did not reveal participants’ treatment condition to staff until participants’ eligibility was confirmed; participants were blinded to treatment condition until they provided consent.”
Blinding of outcome assessment (detection bias) All outcomes	High risk	Abstinence not biochemically validated. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition is much larger in Maintenance Counselling arm (51%) than in No Maintenance Counselling arm (44%)

Schuck 2014

Methods	Setting: Netherlands; school-based Recruitment: Quote: "Smoking parents were recruited through their children’s primary schools across the Netherlands. Primary schools were contacted by research assistants and asked to distribute study invitation letters to parents through children." [...] "Parents registered to take part by mail, e-mail, telephone or via a website."
Participants	512 daily or weekly smokers and parents or caretakers of a child aged between 9 and 12 years. They were considering quitting smoking (currently or in the future). 47.5% M, av. age 42.2, av. cigs/day 16.2
Interventions	1. "Standard Self-Help Brochure: Participants received a 40-page, colour-printed self-help brochure including didactic information on nicotine dependence and the health benefits of quitting smoking, tips and advice on how to initiate and maintain abstinence, instruction in the use of cognitive and behavioural skills to avoid triggers to smoke and cope with urges to smoke, and strategies for managing a lapse or relapse to smoking 2. Intensive Proactive Quitline Counselling + supplementary materials tailored to smoking parents; mean number of calls completed was 5.5 and these were scheduled for 10 days before quit day, 3 days, 1, 2, 4 weeks, 2, and 3 months after quit day." Quote: "In addition, all participants received three accompanying booklets entitled *Smoke-free parents* which were designed for this study as tailored supplementary materials. Each booklet (four pages, colour-print) contained didactic information, tips and advice, motivational messages, as well as ‘parent-relevant information’; e.g. effects of second-hand smoke (SHS) on children, strategies to manage parent-specific stressors]."
Outcomes	Abstinence at 12 m (6-m prolonged)

Schuck 2014 *(Continued)*

	Validation: breath CO and saliva cotinine analysis in a random subsample (36 out of 133)
Notes	New for 2018 update Funding: "This work was supported by ZonMW, the Netherlands Organization for Health Care Research and Development (grant number: 50-50110-96-639)." Declarations of interest: none reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "To ensure equal group sizes, allocation was performed in blocks of 10. To ensure balance of key characteristics, stratified randomization was used based on the stratifying variables gender, educational level (low: no high school diploma/no vocational training, medium: vocational training or high school diploma, high: college degree) and cigarettes per day (fewer than 10, 10–20, 21 or more)."
Allocation concealment (selection bias)	Low risk	Quote: "Allocation of participants to trial conditions was conducted by an independent member of the research group using a computer-generated allocation sequence." [...] "The independent researcher prepared a list of study participants and their allocated treatment. Based on this list, the first author prepared the mailings which informed study participants about the treatment they would receive."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation not done in the entire sample, but just in a random subset. However, verified abstinence rate of 82% (18 of 22) overall in the subsample was acceptable, with no significant different across arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Even though "There was a significant difference in the follow-up rate between treatment groups (85.5% in the quitline condition and 89.5% in the self-help condition, $\chi 2 = 4.98$, $P = 0.03$)", overall attrition was low (11%). Furthermore "Participants lost at follow-up did not differ on baseline characteristics compared with the remaining participants, neither across nor within conditions (all $P > 0.05$)."

Sherman 2017

Methods	Setting: California and Nevada, USA; Department of Veteran Affairs outpatient primary care clinics Recruitment: Healthcare "providers were encouraged to refer any patient who smoked and was interested in quitting"
Participants	3120 smokers, 94% M, av. age 54.2, av. cigs/day 18.3. Participants were interested in quitting
Interventions	1. Reactive Self-Help: "Participants referred during a reactive week were mailed an invitational letter, and the co-ordinator waited for the patient to initiate a call. If patients in the reactive condition called, they only received medication co-ordination along with their self-help materials." 2. Proactive Self-Help: "Participants referred during a proactive week were sent self-help materials and telephoned by the care co-ordinator only to discuss medication." 3. Reactive Telephone Counselling: "Participants referred during a reactive week were mailed an invitational letter, and the co-ordinator waited for the patient to initiate a call."

Sherman 2017 *(Continued)*

	4. Proactive Telephone Counseling: "Participants referred during a proactive week were contacted by the care co-ordinator, who tried up to five times by phone over 2 weeks to reach them." 5 or fewer calls occurred per participant "All patients referred received standard care from their primary care provider prior to referral, which typically included brief cessation advice. [...] Patients in both studies received cessation medication [...] 2 months of nicotine patches or 2 months of bupropion"
Outcomes	Self-reported abstinence at 6 m (7-day PP) Validation: none
Notes	New for 2018 update Funding: "This work was supported by VA HSR&D grant number #IMV 04–088." Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "We randomised all participating sites to either self-help or multisession quitline counselling using a random number table." Randomisation to proactive/reactive subarm was done by alternating calendar week
Allocation concealment (selection bias)	Unclear risk	No method to conceal allocation was mentioned
Blinding of outcome assessment (detection bias) All outcomes	High risk	Abstinence not biochemically validated. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition was low, around 17% - 29% across arms

Sims 2013

Methods	Setting: Wisconsin, USA Recruitment: Young adult callers to the Wisconsin Tobacco Quit Line (WTQL)
Participants	410 smokers age 18 - 24 years, smoked at least 1 cig in past 30 days and motivated to quit. 42% M; av. age 21.3 years, av. cigs/day 15
Interventions	1. S-H only, stage-based booklets 2. S-H + up to 4 proactive cessation counselling calls over 4 - 6 weeks through the WTQL
Outcomes	Abstinence at 6 m (7-day PP) Self-report
Notes	

Sims 2013 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	List of random numbers
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Abstinence not biochemically validated. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	53% not followed in Intervention, 50% in Control. Missing treated as smoking. Responder analysis did not change results

Skov-Ettrup 2016

Methods	Setting: Denmark; population-based Recruitment: Quote: "Participants were recruited from two national health surveys: the Danish Health Examination Survey (DANHES) (2007–08) and the Danish Health and Morbidity Survey (DHMS) (2010) [...] The invitation letter was sent by e-mail or letter"
Participants	1810 smokers aged 16 and over, 42% M, av. age 51, av. cigs/day 16. Participants were willing to quit smoking within the next 12 weeks
Interventions	1. Self-help booklet: Participants received a 36-page booklet by letter. It was developed by the Danish National Board of Health, and included advice on how to identify difficult situations and develop coping strategies at specific stages in the smoking cessation process. Setting a quit date was encouraged. The Fagerström Test for Nicotine Dependence was also included along with information about pharmacotherapy 2. Reactive telephone counselling: A session lasted for approximately 13 – 15 mins 3. Proactive telephone counselling: 5 counsellor-initiated sessions
Outcomes	Self-reported abstinence at 12 m (prolonged) Validation: none
Notes	New for 2018 update Funding: "The study was funded by the Danish Cancer Society" Declarations of interest: none reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "In order to assure equal group sizes, participants were sorted by exact date and time of enrolment and a fixed sequence of four numbers was assigned repeatedly." Not truly random method but still groups are well-balanced

Skov-Ettrup 2016 *(Continued)*

Allocation concealment (selection bias)	Low risk	Quote: "The procedure was conducted by a research assistant who was blinded to the participants' names and ID numbers during the procedure." "there is little indication of bias related to the allocation procedure, as the participants were unknown to the person allocating them and a large number of participants were allocated at the same time."
Blinding of outcome assessment (detection bias) All outcomes	High risk	Abstinence not biochemically validated. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition was low, ~20% and similar across arms

Smith 2004

Methods	Setting: 10 communities, Canada Recruitment: Volunteers calling a quitline Randomisation: Ccentralised, stratified by community, sequential envelope, random sequence
Participants	632 smokers intending to quit; 39% M, av. age 42, 61% had prior use of NRT
Interventions	Factorial design comparing 2 intensities of TC and 2 types of S-H (collapsed in this review) 1. 50-min proactive TC, quit date set, 2 calls at 2 and 7 days post-TQD 2. As 1, plus 4 further calls at 14, 21, 35, 40 days 3. Control: S-H only
Outcomes	Self-reported abstinence at 12 m (sustained). Also at 3 m and 6 m follow-ups, also PP Validation: none
Notes	All TC arms compared to S-H-only control Results not reported by factorial groups; "no significant interactions or main effects at any follow-up"; no data from authors, estimate used in test of intensity. Findings sensitive to choice of outcome, control PP rates increase over time 76% received at least 1 call, 22% of intensive condition received all calls, 56% of minimal condition received both calls

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, stratified by community, method not described
Allocation concealment (selection bias)	Low risk	Quote: "opening next in a series of envelopes' after enrolment"
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	30% not available at 12 m, no difference across 5 groups, missing treated as smoking

Smith 2013

Methods	Seting: Quitline, USA Recruitment: Quitline callers, motivated
Participants	987 smokers, > 10 cigs/day, willing to set quit date within 30 days: av. age 42, av. cigs/day 21
Interventions	Factorial trial testing medication adherence counselling, 2 vs 6 weeks NRT, and nicotine patch alone vs patch + gum All participants received the same standard TC: 4 sessions over 4 weeks Medication adherence counselling involved additional content at each call assessing and addressing adherence
Outcomes	Abstinence at 6 m (30-day PP). 7-day PP also reported Validation: none
Notes	Not included in any MA as tested adjuncts to TC, not the efficacy of TC. Results reported narratively

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	List of randomised numbers
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Abstinence not biochemically validated, but similar levels of personal contact in different study arms
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	24% lost at 6-m follow-up, no difference across treatment groups

Solomon 2000

Methods	Setting: Community, USA Recruitment: Volunteers for free nicotine patch trial
Participants	214 women smokers, > 4 cigs/day, intending to quit in next 2 weeks; av. age 33, av cigs/day 24
Interventions	1. Free nicotine patch (dose based on smoking level) for up to 10 weeks 2. Free patch plus proactive TC from woman ex-smoker, 7 hours training. Calls for up to 3 m, starting pre-quit, quit day, day 4, average 7
Outcomes	Abstinence at 6 m (7-day at 3 m and 6 m) Validation: CO ≤ 8 ppm. 7% - 12% disconfirmation rate. Participants who did not provide samples remained classified as quitters

Solomon 2000 *(Continued)*

Notes	Intervention participants received an average of 7 calls. 95% received at least 1. Participants could call Nicoderm support line, 21% of control vs 8% of intervention did so

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Biochemical validation but 7% - 12% disconfirmation rate. Differential rates of return at 6 m (59% of self-reported quitters in intervention group and 67% in control). Participants who did not provide samples classified as quitters
Incomplete outcome data (attrition bias) All outcomes	Low risk	˜27% lost in both groups, included as smokers

Solomon 2005

Methods	Setting: Community, USA Recruitment: Volunteers for free nicotine patch trial
Participants	330 women smokers > 4 cigs /day, intending to quit in next 2 weeks; av. age 34, av. cigs/day 24
Interventions	1. Free nicotine patch (dose based on smoking level) for up to 10 weeks 2. Free patch plus proactive TC from F ex-smoker, 7 hrs training. Calls for up to 4 m, up to 12 m, starting pre-quit, quit day, day 4
Outcomes	Abstinence at 6 m (30-day at 3 m and 6 m) Validation: none
Notes	Replication of Solomon 2000 with more extended telephone contact Average number of calls 8.2, average duration 10 mins

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	13% lost to follow-up in both groups, included as smokers

Sood 2009

Methods	Setting: ALA Quitline, USA Recruitment: Quitline callers
Participants	990 callers; 38% M, av. age 43, av. cigs/day 22
Interventions	1. Reactive counselling 2. Mailed S-H materials (*Freedom from Smoking*)
Outcomes	Abstinence at 12 m (PP) Validation: Saliva cotinine only for convenience sample, refusals not recorded
Notes	Test of different interventions for people calling a quitline. Comparison 2

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random-number list created by independent statistician
Allocation concealment (selection bias)	Low risk	Enrolment and assignment by researchers independent of helpline staff. Concealment until assigned
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Interviewer assessing outcomes was blinded"; biochemical validation in a convenience sample (16/28 agreed); participants who did not agree to biochemical validation but self-reported abstinence counted as abstinent
Incomplete outcome data (attrition bias) All outcomes	Low risk	47% loss to follow-up, similar across groups, included as smokers

Sorensen 2007a

Methods	Setting: Workplaces, USA Recruitment: Members of LIUNA (construction workers union), included non-smokers
Participants	231 smokers completed baseline survey. Demographics for all participants followed up; 94% M, av. age 40
Interventions	1. Proactive counselling; up to 6 calls over 3 m (fruit and veg consumption also addressed), tailored feedback report and tip sheets, NRT offered to those interested in quitting 2. Control; Nothing during programme, targeted materials at study end
Outcomes	Abstinence at 6 m (7-day PP) Validation: none
Notes	Baseline denominators confirmed by author

Risk of bias

Bias	Authors' judgement	Support for judgement

Sorensen 2007a *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	18% - 20% lost, assumed smokers

Stotts 2002

Methods	Setting: Antenatal clinics, USA Recruitment: Pregnant continuing smokers
Participants	269 pregnant smokers at week 28; av. age 28, approx 50% smoked < 60 cigs/week
Interventions	All participants had received brief counselling and 7 mailed S-H booklets in early pregnancy 1. 20 - 30-min MI-based proactive TC call in 28th - 30th week of pregnancy, tailored letter, 2nd call 2. No further contact
Outcomes	Abstinence or 'a few puffs' at 6 m postpartum Validation: none postpartum, cotinine at week 34
Notes	The common intervention in early pregnancy was not treated as face-to-face contact within the trial. 55% received complete intervention

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Although no biochemical validation postpartum, cotinine in subsample at week 34; no differences between experimental and control groups; Quote: "the urine samples appeared not to have been collected in a systematically biased manner." Level of misreport and refusal not specified
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	39% lost at follow-up in both groups, assumed to be smoking

Sumner 2016

Methods	Setting: Illinois and Missouri, USA; worksite employees & spouses Recruitment: Quote: "Participants called a toll free number (866-902-QUIT) to initiate enrolment. [...] Both organizations promoted Call-2-Quit through multiple channels including health fairs, employee web sites, employee news, promotional posters, fliers, and department managers. Each organization promoted Call-2-Quit to help smokers adapt to tobacco control policies implemented during the trial. In 2006, the hospital system implemented health insurance discounts of $10/month for employees who committed, during open enrolment in November, to pursue several health promoting activities. Smokers obtained the discount by “enrolling” in a qualifying smoking cessation program, such as Call-2-Quit"
Participants	518 employee and spouse smokers, 34% M, av. age 46.5, av. cigs/day 12.9. Participants were seeking treatment as they called the toll-free number
Interventions	1. Directive telephone coaching - Directive coaching included the following distinctive features: - Calls scheduled about 1 week apart, except calls #4 and #7 - Fixed topic schedule 2. Nondirective telephone coaching - Nondirective coaching included these distinctive features: - 7 calls planned over 90 days, as convenient to smoker and coach - Quit date set according to individual preference - Coach offers topics at each call, smoker selects 1, or may choose a novel topic There were up to 7 weekly calls, for 15 - 20 mins each
Outcomes	Self-reported abstinence at 12 m (7-day PP) Validation: mailed saliva cotinine assays or witnessed cheek swabs attempted, but low return rate
Notes	New for 2018 update Funding: "The Centers for Disease Control grant number R01 DP000098 funded this study." Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "New families were randomized to directive or nondirective coaching mode in a 1:1 ratio, based on a randomization table, when the first member enrolled. Consent to randomization was required to participate."
Allocation concealment (selection bias)	Low risk	Quote: "After baseline data were entered, members of a previously randomized family were assigned to the family coaching mode."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome validation attempted but low return rate. Similar levels of personal contact in different study arms
Incomplete outcome data (attrition bias) All outcomes	High risk	After 12 months of follow-up the proportion lost to follow-up was larger than half the initial sample, although similar across arms

Swan 2003

Methods	Setting: Group Health Co-operative, USA

Swan 2003 *(Continued)*

	Recruitment: Volunteers for a trial of medication
Participants	1524 smokers ≥ 10 cigs/day; 43% M, av. age 45, av. cigs/day 23, 44% history of depression
Interventions	Proactive Factorial design, 300 mg/day and 150 mg/day bupropion doses collapsed. Prescription was mailed. No face-to-face contact during enrolment or treatment 1. *Free & Clear* proactive TC (4 brief calls), access to quitline and S-H materials 2. Zyban Advantage Program (ZAP) tailored S-H materials, single telephone call after TQD, access to Zyban (bupropion) support line
Outcomes	Abstinence at 12 m (7-day PP) Validation: none
Notes	Compares different intensities of TC. No dose/behavioural treatment interaction at 12 m so bupropion arms collapsed

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation procedure built into study database
Allocation concealment (selection bias)	Low risk	Procedure ensured concealment
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up at 12 m 17% Intervention, 12% Control, treated as smokers

Swan 2010

Methods	Setting: Community, Idaho and Washington, USA Recruitment: Community advertising, physician referral, and quitline callers
Participants	1202 adult current smokers of at least 10 cigs/day in past year and 5 cigs/day in past week, motivated to quit. 33.1% M; av. age 47.3; av. cigs/day 19.7; av.FTND 4.9
Interventions	All participants received: 12-week course of varenicline; 5 - 10-min orientation call; S-H materials; access to toll-free support line for ad hoc calls 1. Telephone counselling. Proactive; from quitline counsellor using MI techniques; max 5 calls 2. Web programme with standardised content and interactive tools modelled on those used in phone intervention 3. 1+2. Phone counsellors had access to info participants entered online
Outcomes	Abstinence at 6 m (30-day PP) (abstinence at 3 m, 7-day PP also reported) Validation: none

Swan 2010 *(Continued)*

Notes	Number abstinent not provided, estimated from percentages given in published report TC and TC+web had similar outcomes so pooled 1 + 3 vs 2

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Group assignment was randomly allocated using an automated algorithm built into the study database"
Allocation concealment (selection bias)	Low risk	Central computerised allocation, see above
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcome measure used from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Participants lost to follow-up counted as smokers in ITT analysis; equal losses between groups (103 Web, 107 Phone, 100 Web + phone)

Thomas 2016

Methods	Setting: Minnesota, Ohio, Texas, Wisconsin, USA; higher education students Recruitment: Quote: "e-mails and promotional postcards direct-mailed to all enrolled students"
Participants	1217 adult undergraduate smokers willing to set a quit date approximately 1 month from study eligibility assessment, 45% M, av. age 26.2, av. cigs/day 11.5
Interventions	1. No TC ± single/multiple contests 2. TC ± single/multiple contests: 6 telephone-administered Motivation and problem solving (MAPS) counselling sessions during the 12 week treatment, each over 20 minutes, 10 days prior to quit date, and at the discretion of the participant
Outcomes	Abstinence at 6 months (continuous) Validation: Biochemical verification using urine, using NicCheck and (if NicCheck was negative) NicAlert test strips to verify self-reported abstinence. Also, Quote: “if a participant reported that he or she had used NRT within the past 7 days, the sample was sent instead to the laboratory for analysis of concentrations of anatabine/anabasine”
Notes	New for 2018 update Funding: "This study was funded by the National Heart, Lung, and Blood Institute (5R01-HL094183-04S1, J.L.T., Principle Investigator)." Declarations of interest: none reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not stated

Thomas 2016 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not blinded but biochemical validation so differential misreport judged unlikely
Incomplete outcome data (attrition bias) All outcomes	Low risk	Around 19% of participants did not complete or were lost to follow-up (similar n lost to follow-up in each arm (1. 47/306; 2. 50/309; 3/ 67/296; 4. 71/306). Authors tested impact in sensitivity analyses and state it did not affect conclusions

Thompson 1993

Methods	Setting: Workplace and community, USA Recruitment: Callers to a hotline, initially from 4 workplaces, targeting blue-collar workers, widened to general community to meet targets. Callers gave oral consent and baseline assessment of smoking characteristics prior to randomisation
Participants	382 (341 smokers, 41 recent quitters). Most in contemplation or action SoC, 24% 'blue-collar', 41% M, av. age 41, av. cigs/day 18 - 22
Interventions	1. Callers to hotline received general information based on fact sheets, and sent S-H material 2. Callers were given information based on stage, and encouraged to take next step in cessation process. Script tailored to blue-collar workers using focus groups
Outcomes	Abstinence at 6 m (PP) (subset followed to 12 m) Validation: saliva samples sought but not tested. Surrogates asked to confirm status
Notes	Comparison between stage-based and non-specific brief counselling The stage-model counselling was based on the approach used by the NCIS. Kinne 1991 gives data about call rates from original target worksites. Average call length 34 mins for stage-based, 20 mins for standard

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Saliva samples sought but not tested; surrogates asked to confirm status
Incomplete outcome data (attrition bias) All outcomes	Low risk	17% lost to follow-up at 6 m, no significant difference between groups, included as smokers

Tzelepis 2011a

Methods	Setting: Community, New South Wales, Australia Recruitment: Active telephone recruitment (cold-calling) of NSW residents, motivation to quit not required
Participants	1562 adult daily smokers. 50% M, av. cigs/day 19.4, av. age 45
Interventions	1. 6 proactive counselling calls for smokers willing to quit within 1 m, 4 for those not willing using MI techniques. Those who relapsed and set new quit date within a month offered additional 5 calls; those relapsed but did not set quit date offered a call in 1 m. Those initially not willing to quit who became motivated to quit offered additional 5 support calls. Standard S-H materials 2. S-H materials only
Outcomes	Self-reported abstinence at 13 m (prolonged for 12 m with 1 m grace period). Other prolonged and PP rates at 4, 7, 13 m also reported Validation: none
Notes	7.8% of control group called quitline during study period.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "random number generator"
Allocation concealment (selection bias)	Low risk	Quote: "computer assisted telephone interview used a random number generator created by an independent programmer to allocate the smoker"
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcome measure used, participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Participants lost to follow-up counted as smokers; similar numbers in both groups (163 intervention, 154 control (21% and 19% respectively))

Vander Weg 2016

Methods	Setting: USA; rural setting Recruitment: People meeting basic eligibility criteria were sent a letter offering them participation in the trial, to which they could respond by returning a self-addressed postcard or contacting study staff by phone. Those expressing interest were mailed an informed consent document and baseline questionnaire, which included Vander Weg et al. BMC Public Health (2016) 16:811 Page 2 of 11 screening items to assess for eligibility for the supplemental behavioral counselling modules (described below)
Participants	63 rural Veteran daily cigarette smokers who were interested in quitting, 87.3% M, av. age 56.8, av. cigs/day 24.7
Interventions	1. Referral to state tobacco quitline: Referred by fax to the tobacco quitline for their state of residence. Quitlines subsequently contacted participants to initiate treatment 2. Tailored telephone counselling: Combines counselling on tobacco use and related issues including depressive symptoms, risky alcohol use, and weight concerns. 6 calls, 1 per week, for 20 - 30 mins

Vander Weg 2016 *(Continued)*

	The approach to pharmacotherapy was the same for both groups - NRT, bupropion, varenicline
Outcomes	Self-reported abstinence at 6 m (7-day PP) Validation: none
Notes	New for 2018 update Funding: "The work reported in this manuscript was funded by the Department of Veterans Affairs Office of Rural Health (Project number 12-CR6)." Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "randomly assigned to treatment conditions based on a computer-generated algorithm on a 1:1 allocation ratio using simple randomization without blocking. The computerized random allocation sequence was generated by the study data manager."
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Abstinence not biochemically validated. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Dropout was twice as high in the tailored intervention as in the standard tobacco quitline group

Velicer 2006

Methods	Setting: Community, USA Recruitment: Proactive approach to smokers at Veterans Administration Medical Centre. Passive consent by mail then phone screening, not selected for motivation
Participants	2054 smokers (1009 in relevant arms); 76% M, av. age 51, 40% precontemplators, 40% contemplators, 20% preparers
Interventions	1. Stage-based S-H manuals; participants sent manual for current stage and next stage. (not used in this review) 2. As 1, plus 6-week nicotine patch if in appropriate stage, reassessed for NRT eligibility at 6 and 10 m (not used in this review) 3. As 2, plus 1 expert system written feedback report 4. As 3, plus regular automated TC (pre-recorded voice files tailored to responses). People receiving NRT had weekly calls in month 1, biweekly in month 2, then monthly to month 6. People not receiving NRT had monthly calls. Participants could also initiate calls
Outcomes	Self-reported abstinence at 30 m (sustained for 6 m) Validation: none
Notes	Comparison of arms 4 vs 3 for proactive TC. In NRT eligible groups 350 (67%) received NRT at baseline and 448 (86%) received NRT at some point, so classified as adjunct to pharmacotherapy, and in > 6 call category

Velicer 2006 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-based random-number generator
Allocation concealment (selection bias)	Low risk	Allocation done after completion of survey. randomised participants who did not return consent form are excluded from further analyses
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	39% lost includes 8% refused by 30 m, no significant differences between groups. Different treatments of missing data reported not to have altered pattern of results

Warner 2016

Methods	Setting: Olmsted County, MN, USA; hospital-based Recruitment: Identified through electronic medical records. Study personnel then approached the potential participants to confirm eligibility
Participants	600 adult smokers, 51% M, av. age 46.3, av. cigs/day 14.4
Interventions	1. Brief (˜5-min) cessation advice: Quote: "Consisted of the first four of the 5A's (Ask, Advise, Assess, Assist, and Arrange), including advice and brief assistance in reviewing tips to help maintain abstinence using a brochure. The brochure included the study quitline number but did not specifically encourage its use." 2. Brief (˜5-minute) quitline facilitation intervention: Quote: "A single brief quitline facilitation intervention (also ˜5 minutes in duration, slightly modified from that piloted in the authors' prior studies of presurgical patients) was delivered. Based on principles of Social Cognitive Therapy, it included advice to quit and quitline information. Its purpose was to facilitate quitline utilization, not to provide assistance with quitting, but to overcome cognitive barriers to quitline utilization. A written brochure that included information about the quitline and a wallet-sized "quit-card" were provided. If patients were amenable, study personnel then contacted the quitline provider, preferably by direct phone call ("warm handoff") to enroll the patient for quitline services and arrange for an initial counseling call. If this direct contact could not be made, faxed referrals were sent to the quitline provider. Based on early experiences that it was difficult for the quitline to re-contact patients while in hospital, the goal was to complete the first counseling session immediately after the in-hospital quitline intake. Subsequent counseling sessions were scheduled by quitline counselors." NRT was offered to all participants: free 2-week supply of nicotine patches
Outcomes	Abstinence at 6 m (7-day PP) Validation: Urine anabasine levels < 2 ng/mL
Notes	New for 2018 update Funding: "This work was supported by grant RC-2012-0001 from ClearWay Minnesota." Declarations of interest: none reported

Warner 2016 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "using dynamic randomization allocation based on the Mayo Clinic Study Data Management System, a proprietary web application for data entry and management. Randomization was stratified based on nursing unit to ensure the number of subjects assigned to each of the two intervention groups remained balanced within that unit, enhancing the homogeneity of admitting diagnoses between groups"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically-confirmed smoking cessation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition ˜30% and comparable across arms

Wu 2017

Methods	Setting: Beijing, China; 2 Endocrinology and Acupuncture out-patient clinics of a general hospital Recruitment: Asked all people who attended the clinic for participation in the study
Participants	369 adult smokers who smokers 10 or more cigs/day and were not interested in quitting, 100% M, av. age 40, 43% 10 – 19 cigs/day, 57% ≥ 20 cigs/day
Interventions	1. Exercise and diet advice (EDA) control group 2. Smoking-reduction intervention (SRI) group Both groups received a single face-to-face brief advice (˜1 min) + 5 x TC follow-up sessions of the same duration (˜1 min) after 1 week, and after 1, 3, 6 and 12 m
Outcomes	Abstinence at 12 m (7-day PP) Validation: Exhaled CO level < 6 ppm
Notes	New for 2018 update Funding: "This study was supported by a research grant from the National Natural Science Foundation of China (81373080), a research grant from the Beijing Municipal Science and Technology Commission (Z121107001012070) and Clinical Research Grants from the Chinese PLA General Hospital (2013FC-TSYS-1021 and MJ201447)." Declarations of interest: none reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A research assistant of the project generated the random numbers for group assignment using a computer"
Allocation concealment (selection bias)	Low risk	Quote: "After written consent, a trained counsellor who was not involved in preparing the randomization sequence opened a serially numbered, opaque

Wu 2017 *(Continued)*

		and sealed envelope with a card inside indicating intervention or control and randomly allocated the participant accordingly, thus ensuring allocation concealment"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically-validated outcome. Validation rate achieved 43.2% by February 2017 (45.8% in the SRI group and 38.5% in the EDA control group)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Percentage of participants lost to follow-up was around 30% and similar across groups. There were no differences between those who completed and those who were lost to follow-up

Young 2008

Methods	Setting: General practices, Australia Recruitment: People attending for routine consultations, not selected for motivation
Participants	318 smokers; 47% M, av. age ˜37, modal cigs/day 11 - 20, 56% in contemplation/precontemplation
Interventions	1. GP offered referral; telephone call from a nurse trained in cessation within 3 days. 5As counselling framework. If willing to make a quit attempt mailed quit kit, encouraged to buy NRT, phoned again on TQD, 1 week, 3 weeks 2. Usual care (GPs given quit kits to distribute to participants)
Outcomes	Abstinence at 12 m (PP) Validation: none
Notes	We classified control as minimal intervention rather than brief intervention, MA not sensitive to classification. Referral was to a research nurse not to a dedicated quitline. 5 control participants received intervention, analysed with controls as ITT

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Questionnaires randomly ordered and coded prior to delivery to the practice by selecting sequential numbers from a computer-generated random-number list.
Allocation concealment (selection bias)	Unclear risk	Participants (including non-smokers) completed the precoded questionnaire before the consultation. GP identified allocation from unobtrusive marks on questionnaire, could not influence allocation. But unclear whether selection bias by recruiters, given imbalance in numbers
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	31% Intervention, 41% Control lost to follow-up, included as smokers

Zhu 1996

Methods	Setting: Quitline, USA Recruitment: Callers to a quitline
Participants	3030 smokers calling smokers' helpline and were ready to quit in next week; 43% M, av. age 36, av. cigs/day 20
Interventions	1. S-H materials only 2. S-H materials and 50-min pre-quit TC 3. As 2, plus up to 5 further sessions of TC at 1,3, 7, 14 and 30 days
Outcomes	Abstinence at 13 m (sustained for 12 m) Validation: Cotinine < 10 mg/nl in a convenience sample
Notes	Arms 2 and 3 vs 1. Arms 3 vs 2 in effect of multiple sessions Approx 65% of single session and 67% of multisession group received some counselling. Multisession participants received 4 calls on average

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Pseudo-random, according to last 2 digits of telephone number
Allocation concealment (selection bias)	High risk	Potential for selection bias but unlikely, given low contact
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical validation in a convenience sample. Disconfirmation rate not used to correct data, but refusal and misreport rates similar in all groups
Incomplete outcome data (attrition bias) All outcomes	Low risk	12% - 16% lost to follow-up at 13 m, included as smokers

Zhu 2002

Methods	Setting: Quitline, USA Recruitment: Callers to a quitline
Participants	3282 smokers calling quitline, ready to quit within 1 week and wanting counselling; 44% M, av. age 38, av. cigs/day 20
Interventions	1. S-H pack, motivational materials, counselling provided if smoker made contact to request it 2. S-H as 1, plus prequit and up to 6 post-quit calls within 3 m. Included quitting history, motivation, self-efficacy, social support, planning, relapse prevention
Outcomes	Self-reported abstinence at 13 m (sustained for 12 m) Validation: none
Notes	Authors also analysed subgroups of controls who did and did not seek counselling. 32% of Control and 72% of Intervention group received counselling

Risk of bias

Zhu 2002 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described. 60/40 split. Only randomised when counselling demand exceeded capacity
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes from participants not blinded to treatment condition. Level of personal contact differed between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	˜30% lost to follow-up at 13 m in both groups, included as smokers

Zhu 2012

Methods	Setting: Quitline, USA Recruitment: Callers to a quitline
Participants	2278 Chinese-, Korean- and Vietnamese-speaking daily smokers, ready to quit within 1 m; 90% M; aged 18 - 75 (approx. 45% 25 - 44 and 45% 45 - 64); av. cigs/day 15.6
Interventions	1. S-H pack, culturally-tailored, translated into Chinese, Korean and Vietnamese 2. S-H pack + proactive TC; Social Learning Theory; MI; CBT techniques. 30 - 40 mins, pre-quit, up to 5 relapse prevention calls (10 - 15 min) 0, 3, 7, 14, 30 days
Outcomes	Prolonged abstinence at 7 m post-intervention, 1 m grace period immediately post-quit Validation: none (but saliva samples collected)
Notes	Number abstinent at 6 m not specified; data used in MA calculated back from percentages

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "randomly assigned…using blocks of 20 to keep a balance of language and sex…Random assignment tables for each strata were created using SAS 9.2."
Allocation concealment (selection bias)	Low risk	Quote: "The allocation was done by the computer so that staff were blinded to group assignment until the intake call"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Self-reported outcomes but saliva samples collected. No statistically significant differences in saliva sample return rates at 7 m between intervention and control groups and between self-reported quitters and non-quitters
Incomplete outcome data (attrition bias) All outcomes	Low risk	Simlar rate of dropouts in both groups (18% in 1, 16% in 2). Participants lost to follow-up included as smokers in outcome data

Zwar 2015

Methods	Setting: Australia; community-based Recruitment: Patients were approached in the waiting room of participating practices by trained research assistants over a 2-week period and assessed for eligibility
Participants	2390 adult smokers, 46% M, av. age 42.8, av. cigs/day 17.1
Interventions	1. Usual care: In control group practices, the GPs were asked to assess participants' willingness to quit and offer assistance in accordance with their usual practice. This could include advice within the practice, referral to Quitline or both, but no provision was made to facilitate either. 2. Quit with practice nurse: Individual face-to-face counselling with nurse. Quit kits (a printed resource used by Quitlines nationally) were also distributed to participants. Nurses were also supported by 3 proactive telephone calls from an experienced counsellor. 3. Quitline referral: GPs were asked to assess the participants' willingness to quit and to offer brief advice. Participants with interest in quitting were offered referral to the Quitline and, if they agreed, GP completed a fax referral form to Quitline. On receiving a GP referral, the Quitline telephoned the participant to offer services to meet their needs. Participants expressing interest in quitting and willing to engage with the Quitline counselling service were offered a series of free evidence-based proactive call-back counselling/advice sessions. All were offered, according to clinical practice guidelines, free patches of NRT for 8 weeks
Outcomes	Self-reported abstinence at 12 m (sustained ≥ 10 m) Validation: none
Notes	New for 2018 update Funding: "Australian National Health and Medical Research Council Project Grant (568617)" Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not described
Allocation concealment (selection bias)	Low risk	Quote: "patients were given a card indicating their enrolment and the allocation group of the practice to take into the GP consultation"
Blinding of outcome assessment (detection bias) All outcomes	High risk	Abstinence not biochemically validated, but similar levels of personal contact in different study arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar % of lost to follow-up across arms

AHRQ: Agency for Healthcare Research and Quality; ACT: Acceptance and Commitment therapy; ALA: American Lung Association; av: average; CHD: chronic heart disease; CBT: cognitive behavioural therapy; CO: carbon monoxide; COPD: chronic obstructive pulmonary disease; F: female; FTND: Fagerström Test for Nicotine Dependence; HMO: health maintenance organisation; hrs: hours; HTN: hypertension; ITT: intention-to-treat (analysis); m: months; M: male; MA: meta-analysis; MI: motivational interviewing; NCIS: National Cancer Information

Service; NRT: nicotine replacement therapy; PP: point prevalence; ppm: parts per million; SES: socio-economic status; S-H: Self-help materials; SHS: Second-hand smoking; SoC: Stage of change; TC: Telephone counselling; TQD: Target quit date

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

Study	Reason for exclusion
Abroms 2014	Text message intervention which encouraged participants to call a quitline
Ahijevych 1995	Pilot study with 12 weeks follow-up, after which the advice and control groups were offered the intervention. The intervention was 4 x weekly mailings and telephone calls from a lay facilitator.
Alonso-Perez 2007	Not a fully randomised trial. Smokers assigned to behavioural condition by clinic attended
Amos 1995	Not a controlled trial. Callers to a workplace helpline set up in conjunction with a non-smoking policy were followed up. 16% of smokers reported they had quit 3 m later, 28% of those who had tried to quit. It was estimated that between 3 and 3.3% of smokers in the company had called in the first 3 m
An 2008	Intervention was to increase clinic referrals to a quitline. No smoking outcomes
Asfar 2010	Previously listed as ongoing. Compared proactive with reactive telephone counselling but the NRT dosage provided varied between arms
Augustine 2015	Effect of TC cannot be evaluated independently of NRT
Baker 2015	Telephone compared to face-to-face counselling
Balanda 1999	Callers to a helpline were randomised to 1 of 2 S-H materials. No counselling was given. Follow-up only 1 m after receipt of materials. There was no difference in cessation rates between the booklet groups.
Berndt 2014	Effect of TC cannot be evaluated independently of NRT
Bernstein 2018	Insufficient length of follow-up (3 months)
Best 1977	Allocation not stated to be random. Telephone follow-up compared to group behavioural treatment with aversive smoking only.
Bliksrud 2002	Not a randomised trial
Bock 2008	All participants received brief TC calls. Intervention was a face-to-face motivational interview
Borland 1989	Not a controlled trial. Evaluation of calls to a helpline
Borland 2004	All participants called a quitline, test of different S-H materials. Included in Cochrane Review of S-H (Livingstone-Banks 2019a)
Boyle 2004	Intervention for smokeless tobacco use, not smoking
Boyle 2008	Intervention for smokeless tobacco use, not smoking
Brandon 2000	Focus on preventing relapse. See Cochrane Review on relapse prevention (Livingstone-Banks 2019b)
Bronshtein 2016	No data on smoking cessation

Study	Reason for exclusion
Brunner-Frandsen 2010	Intervention condition included intensive face-to-face counselling as well as telephone contact
Buchanan 2004	Multicomponent intervention, only 12 weeks follow-up
Buller 2012	Previously listed as ongoing. Compares an online intervention against telephone counselling with self-help
Burns 2010	Not randomised; historical and non-equivalent controls
Bush 2012	Evaluated a counselling component to address cessation-related weight concerns. Will be evaluated in Cochrane Review of interventions for preventing weight gain after smoking cessation (Farley 2012)
Bush 2016	Evaluated a counselling component to address cessation-related weight concerns. Will be evaluated in Cochrane Review of interventions for preventing weight gain after smoking cessation (Farley 2012)
Carlin-Menter 2011	Only 3 months follow-up
Carlini 2008	Intervention to increase re-enrolment in quitline services. No smoking outcomes
Carlini 2012	Intervention was IVR to re-engage relapsed smokers, no cessation outcomes
Carreras 2007	Not a randomised trial. Compared intensive counselling delivered face-to-face or by telephone
Cheung 2013	Participants in quitline arm could choose between email, telephone or sms contacts
Cheung 2017	Participants in quitline arm could choose between email, telephone or sms contacts
Choi 2014	Addition of Tobacco Tactics website to nurse-delivered TC plus NRT
Conway 2004	Focus on preventing relapse. See Cochrane Review on relapse prevention (Livingstone-Banks 2019b)
Cooper 2004	Trial identified from a paper reporting secondary outcomes. Compared 3 levels of behavioural intervention in a primary care setting. Full results have not been published and not available
Cummings 1988	Callers to a helpline were randomised to one of 4 different S-H programmes or an information control. No counselling was given.
Cummings 1989	Does not measure smoking cessation. Assesses impact of a media campaign to get women smokers with young children to call a quit line. Call rates compared in media markets with and without a campaign.
Cummings 2006a	Not a randomised trial. Evaluated impact of free NRT as adjunct to telephone support
Cummings 2010	Not a randomised trial. Evaluated impact of different amounts of free NRT as adjunct to telephone support
Cummings 2011	All participants eligible for same telephone counselling intervention; test of different amounts of NRT
Curry 2003	Telephone component cannot be evaluated independently of face-to-face counselling
Danaher 2011	Study of smokeless tobacco users only

Study	Reason for exclusion
Danaher 2015	Study of smokeless tobacco smokers
Davis 1992	All participants were women with young children who called a hotline and received same stage-based counselling. They were randomised to receive 3 different S-H guides. See Cochrane Review of S-H (Livingstone-Banks 2019a)
De Azevedo 2010	Telephone component cannot be evaluated independently of face-to-face counselling. The intervention included in-hospital motivational interviewing as well as post-discharge telephone contact, and was compared to usual care
DeBusk 1994	Telephone component cannot be evaluated independently of face-to-face counselling. The intervention included in-hospital physician advice and counselling by a nurse as well as post-discharge telephone contact, and was compared to usual care
Decker 1989	Not random or pseudo-random. Interventions ran sequentially. Participants receiving mailed materials had access to a hotline
Dent 2009	Single telephone call was the brief intervention control for a 3-session group-based pharmacist-conducted intervention
Dubren 1977	Recent quitters were randomised to access to recorded messages, not a counsellor. Short follow-up (4 weeks)
Edelman 2014	No data on smoking cessation
Fellows 2016	Multicomponent intervention including TC, individual and group counselling and an interactive web-based programme
Fu 2016	TC as an adjunct of NRT. However, NRT is offered in a different manner in the TC arm (free) and usual care arm (discounted price)
Garvey 2012	Compares 3 different lengths of telephone and face-to-face cognitive behavioural counselling (3, 6 and 12 months duration)
Gianos 2015	Telephone component cannot be evaluated independently of text messaging
Gies 2008	Only 3-m follow-up. Comparison between 1 and 4 telephone follow-ups as adjunct to face-to-face counselling. 19 participants per group
Glasgow 2009	Intervention aimed at reduction in cigarette use for people not wishing to attempt cessation
Gong 2016	Insufficient length of follow-up (12 weeks)
Gordon 2010	Telephone component cannot be evaluated independently of face-to-face counselling delivered by dental practitioner
Gritz 2012	Intervention used cell phone. Will be evaluated in Cochrane Review of mobile phone-based interventions for smoking cessation (Whittaker 2016)
Haas 2015	Multicomponent intervention that includes TC and free NRT versus usual care
Hackbarth 2006	Insufficient detail in abstract to include, no full report identified
Hammett 2018	Effect of TC cannot be evaluated independently of NRT

Study	Reason for exclusion
Han 2010	Study of 2 different frequencies of telephone counselling for high blood pressure, including smoking cessation counselling. Smoking cessation not reported as an outcome, unclear if smoking cessation measured
Harris 2015	TC arm compared to a web-based intervention
Hasuo 2004	Telephone component cannot be evaluated independently of face-to-face counselling. The intervention included in-hospital counselling by a nurse
Hawkes 2013	No data on smoking
Hebert 2011	Only 3 m follow-up
Hennrikus 2002	Included in previous updates of this review. Excluded in 2018 update due to TC being compared to group counselling
Hokanson 2006	Telephone component cannot be evaluated independently of face-to-face counselling and offer of pharmacotherapy
Holtrop 2005	The purpose of the telephone call was to encourage participants to enrol in quitline services
Johnson 1999	Telephone component cannot be evaluated independently of face-to-face counselling. The intervention included in-hospital counselling by a nurse. Quasi-random design
Joseph 2011	Complex intervention; all participants received telephone counselling
Katz 2004	Included in previous updates of this review. Excluded in 2018 update due to the fact that the effect of TC cannot be evaluated independently of NRT
Keten 2013	Insufficient length of follow-up
Killen 2008	Main intervention component was face-to-face support. Telephone contact in both arms
Kim 2013	Insufficient length of follow-up
Kim 2016	TC compared with videoconferencing among Korean-American women. This study will be covered in a new Cochrane review about real-time video counselling for smoking cessation (see Tzelepis 2017)
Kim 2017	TC compared with videoconferencing among women living with HIV. This study will be covered in a new Cochrane review about real-time video counselling for smoking cessation (see Tzelepis 2017)
Klesges 2015	Effect of TC cannot be evaluated independently of NRT
Koffman 1998	3 worksites allocated to different interventions. No way to distinguish variation due to worksite from effect of intervention
Lando 1996	Previously included, recruited only recent quitters so now covered in Cochrane Review of relapse prevention (Livingstone-Banks 2019b)
Leed-Kelly 1996	The intervention included 1 session of face-to-face counselling with telephone follow-up. Results, which did not show any intervention effect, are given in Bobo 1998
Lichtenstein 2002b	No long-term outcomes yet reported
Linder 2014	Effect of TC cannot be evaluated independently of NRT

Study	Reason for exclusion
Lindinger 2012	Not randomised. Compared participants accepting proactive calls to those choosing only 1 session
Little 2009	Systems change intervention; trained dental staff in to assess, advise and refer to telephone counselling
Mahabee-Gittens 2008	Quitline referral confounded with brief advice, only 3 m follow-up
Manfredi 1999	The intervention included the opportunity of a motivational telephone call following provider advice and S-H components. Follow-up was only 5 - 8 weeks
Manfredi 2011	Smoking status not measured
Mayer 2010	Trial of a relapse prevention intervention; participants were abstinent at time of randomisation
McAfee 2008	All participants had same quitline counselling
McBride 2002	The focus of the intervention was on genetic susceptibility feedback. Effect of telephone support cannot be evaluated independently
McClure 2018	Telephone component cannot be evaluated independently of website and text messaging
McDaniel 2015	This study includes exclusively recent quitters. This falls within the scope of a separate review on preventing relapse (Hajek 2009).
McGrath 2014	Insufficient length of follow-up (3 months)
Mermelstein 2003	Compares 2 telephone-based interventions for preventing relapse following group therapy. Now included in Cochrane Review of relapse prevention (Livingstone-Banks 2019b)
Miller 2009	Trial of NRT as opposed to telephone support; same telephone support intervention offered to both groups
Morris 2011	All participants received telephone counselling and NRT, test of additional group counselling
Mullen 2016	No data on smoking abstinence
Nair 2017	Insufficient length of follow-up (1 month)
Ockene 1992	Telephone support could not be evaluated independently of combined intervention
Oddone 2017	The outcome of this trial is enrolment of veterans in smoking cessation services
Owen 2000	Not a controlled trial. Survey of callers to UK quitline.
Papadakis 2013	Insufficient length of follow-up
Parker 2007	Trial in pregnant women
Partin 2006	Telephone intervention purpose was to assess smoking status, interest in making another quit attempt, quit challenges, and treatment preferences, not to assist cessation per se
Patten 2009	Intervention was telephone counselling for non-smokers wanting to help a smoker. Outcome was calls by smoker to quitline, not cessation

Study	Reason for exclusion
Patten 2011	Intervention was telephone counselling for non-smokers wanting to help a smoker. Outcome was calls by smoker to quitline, not cessation
Peng 2011	Short follow-up
Peterson 2009	School as unit of randomisation. Telephone counselling confounded by other school-based initiatives
Peterson 2015	Telephone counselling cannot be evaluated independently of telehealth counselling
Platt 1997	Not a controlled trial. A panel sample of callers to the Scottish Smokeline was followed up for 1 year. 607 (71% of original sample) were reached.
Prue 1983	The amount and timing of telephone contact is unclear. The main component was a S-H programme, compared to a waiting list control. Total of 40 participants
Racelis 1998	Intervention addressed multiple risk factors, number of smokers enrolled not specified
Ratner 2004	Telephone support could not be evaluated independently of face-to-face counselling
Reid 1999b	Not a controlled trial. Followed 258 nicotine patch purchasers who enrolled for support programme of 4 calls from a trained nurse counsellor.
Richter 2015	Traditional TC compared with telemedicine. This study will be covered in a new Cochrane Review about real-time video counselling for smoking cessation (see Tzelepis 2017)
Rigotti 2014	Effect of TC cannot be evaluated independently of NRT
Rigotti 2016	Effect of TC cannot be evaluated independently of pharmacotherapy
Rigotti 2017	Effect of TC cannot be evaluated independently of pharmacotherapy
Ringen 2002	Not randomised. Smokers chose intensity of support
Rodgers 2005	Intervention used mobile phone (including text messaging). To be covered by separate Cochrane Review (Whittaker 2016)
Rogers 2018	Telephone component cannot be evaluated independently of NRT
Roski 2003	Included in previous updates of this review. Excluded in 2018 update due to TC being compared to financial incentives
Rothemich 2010	Systems change intervention; referral to quitline was only 1 component
Schiebel 2007	Small (n = 39) feasibility study in Emergency Department. Very low rate of follow-up especially for sustained abstinence outcome (2/39 reached at both follow-ups)
Schneider 1995	Evaluated a telephone support system. All smokers recruited had access to the interactive programme. Random subsets were selected for access to messages about nicotine gum, sent a reminder to call, or sent a user's manual
Segan 2011	Study of phone counselling for relapse prevention
Sharifirad 2012	Telephone component cannot be evaluated independently of NRT
Sherman 2008	Abstinence data given only for intervention group

Study	Reason for exclusion
Sherman 2016	Effect of TC cannot be evaluated independently of NRT
Shiffman 2000	Follow-up 12 weeks.
Sidhu 2015	Multicomponent intervention which included telephone counselling, a pedometer, supporting written materials and a self-monitoring diary
Simon 1997	Telephone component cannot be evaluated independently of face-to-face counselling. The intervention included brief counselling and NRT
Simon 2003	Telephone component cannot be evaluated independently of face-to-face counselling. The intervention included in-hospital nurse counselling as well as post-discharge telephone contact, and was compared to a minimal intervention
Sivarajan 2004	Telephone component could not be evaluated independently of combined intervention
Sorensen 2007b	Telephone intervention was a 10-min reminder call, 2 m after face-to-face advice to quit prior to surgery. Outcomes combined with an arm given reminder at a face-to-face meeting
Stevens 1993	Telephone component cannot be evaluated independently of face-to-face counselling. The intervention included in-hospital physician advice and counselling by a nurse as well as post-discharge telephone contact, and was compared to usual care
Stoltzfus 2011	Not a controlled trial. Pre-test/post-test study of different referral methods
Strong 2012	All participants had same basic counselling intervention. Test of a mood management component
Sutton 2007	All participants had same counselling intervention. Test of tailored written materials, see Cochrane self-help Review (Livingstone-Banks 2019a)
Szklo 2010	Not an evaluation of counselling; compared 2 strategies to encourage calls to a quitline
Taylor 1990	Telephone component cannot be evaluated independently of face-to-face counselling. The intervention included in-hospital physician advice and counselling by a nurse, as well as post-discharge telephone contact, and was compared to usual care
Terazawa 2001	Telephone component could not be evaluated independently of combined intervention
Terry 2011	Not randomised; comparison of work-based intervention programmes
Toll 2010	Only 3 m follow-up
Tseng 2016 2015	Insufficient length of follow-up (12 weeks)
Urso 2003	Only 12 weeks follow-up
Van der Meer 2010	All participants received telephone counselling. Test of a mood management component
Vidrine 2006	Intervention used mobile phone (including text messaging). To be covered by separate Cochrane Review (Whittaker 2016)
Wadland 1999	Not randomised. The treated groups were recruited by different means and given different interventions, both of which included telephone counselling by nurses or counsellors
Wadland 2001	Only 3 m follow-up

Study	Reason for exclusion
Wadland 2007	Trial of methods for clinic referral to quitline support. No quitting outcomes
Walker 2011a	Recruitment by quitline, but test of providing samples of NRT
Walker 2011b	Recruitment by quitline, but test of nicotine-free cigarettes as an adjunct to NRT
Wang 2017	Comparison of different leaflets/booklets. One of the arms also includes referral to the quitline and other smoking cessation services
Warner 2011	Comparison of physician-provided general help to quit smoking with intervention primarily aimed at facilitating quitline use. Both groups had same access to quitline
Weaver 2015	Multicomponent intervention which includes NRT, telephone and face-to-face counselling
Westman 1993	Telephone component cannot be evaluated independently of face-to-face counselling
Wetter 2007	Only 12 weeks follow-up
Wewers 2017	TC compared to face-to-face counselling
Willemsen 2008	Uncontrolled evaluation. Quitline callers followed up at 1 year
Wolfenden 2008a	Quitline component was part of a comprehensive intervention including face-to-face support
Zanis 2011	Only 12 weeks follow-up
Zawertailo 2013	Not randomised; uses a concurrent matched control
Zhu 2000	Not an RCT. All participants called the California Smokers' Helpline and received 1 session of counselling and planned to use NRT. Those who chose to receive further counselling were compared to those who did not

CI: confidence interval; m: month(s); IVR: interactive voice response; NRT: nicotine replacement therapy; S-H: self-help; TC: telephone counselling; TQD: target quit date

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

Argyropoulou 2005

Trial name or title	Smoking cessation: data for two years from two different interventions
Methods	9-week open-label bupropion phase 300 mg daily and NRT for 3 weeks combined with behavioural support; smokers randomised in 2 groups, follow-up for 3, 6, 12 and 24 months
Participants	No information
Interventions	Group A: 7 weekly one-to-one counselling sessions; Group B: telephone counselling
Outcomes	PP and continuous abstinence
Starting date	
Contact information	
Notes	

Humfleet 2012

Trial name or title	Reaching and treating lesbian, gay, bisexual, and transgender (LGBT) cigarette smokers
Methods	Randomised, open-label, factorial (4 arm)
Participants	≥ 18 years; identify as LGBT
Interventions	1) self-help manual; 2) mail-based self-help plus internet-based smoking treatment; 3) self-help manual + telephone counselling; 4) self-help manual plus internet-based Intervention plus telephone counselling
Outcomes	Primary: smoking status at 3, 6 and 12 months post-enrolment
Starting date	February 2008
Contact information	
Notes	

Mak 2015

Trial name or title	Acceptance and commitment therapy for smoking cessation in the primary care setting (ACT)
Methods	RCT, parallel assignment, double masking
Participants	Aged 18 years and older, currently smoking at least 1 cigarette a day in the past 30 days, Hong Kong residents, able to communicate in Cantonese, currently residing in Hong Kong and expecting to continue to do so for the next 6 months, have access to a telephone
Interventions	2 telephone ACT counselling sessions, minimal face-to-face ACT counselling, printed self-help leaflet on smoking cessation
Outcomes	Primary outcome: self-reported 7-day point prevalence Secondary outcome: validated abstinence
Starting date	July 2012
Contact information	www.researchgate.net/profile/Yim_Mak; www.researchgate.net/profile/Alice_Loke
Notes	Only protocol and baseline results have been published so far

NCT00311948

Trial name or title	Telephone and web-based teen tobacco cessation in HMOs
Methods	RCT, parallel assignment, single (Investigator) masking
Participants	600 teenagers
Interventions	Telephone counselling plus interactive website

NCT00311948 *(Continued)*

Outcomes	Self-reported 30 days point prevalence assessed at 12 months
Starting date	March 2006
Contact information	hollisja@chr.mts.kpnw.org
Notes	

NCT00851357

Trial name or title	Telephone counseling and the distribution of nicotine patches to smokers
Methods	RCT, factorial assignment, quadruple masking
Participants	4200 adults residing in California including English and Spanish speakers
Interventions	Telephone counselling ± nicotine patch ± self-help ± placebo
Outcomes	6 months continuous abstinence assessed after 7 months of follow-up
Starting date	February 2009
Contact information	szhu@ucsd.edu
Notes	

NCT01892813

Trial name or title	Dissemination of a tailored tobacco quitline for rural veteran smokers
Methods	RCT, Parallel Assignment, Double Masking
Participants	411 rural veteran smokers, older than 18, receive primary care from the Iowa City VA Health Care System or an affiliated community-based outpatient clinic (CBOC), live in a non-metropolitan area (based on Rural-Urban Commuting Area Codes (RUCA)), willing to make an attempt to quit smoking in the next 30 days, capable of providing informed consent, have access to a telephone (land line or cell phone) and have a stable residence.
Interventions	Tailored tobacco quitline for rural veteran smokers
Outcomes	30-day abstinence assessed after 6 months of follow-up
Starting date	July 2013
Contact information	mark-vanderweg@uiowa.edu
Notes	

NCT01893502

Trial name or title	Smoke-free randomised controlled trial
Methods	RCT, parallel assignment, single masking
Participants	11 Singaporean current smokers among outpatients, including hospital employees, who provide informed consent for enrolment in the smoking cessation programme
Interventions	Proactive telephone counselling weekly for 6 months
Outcomes	7-day point prevalence assessed after 6 months of follow-up
Starting date	June 2013
Contact information	kay_choong_see@nuhs.edu.sg
Notes	

NCT02157610

Trial name or title	Smoking cessation for cervical cancer survivors
Methods	RCT, parallel assignment, open-label
Participants	350 women with a history of cervical cancer
Interventions	Self-help + nicotine patch + referral to Oklahome quitline + 6 behavioural counselling calls
Outcomes	Smoking abstinence after 18 months of follow-up
Starting date	January 2015
Contact information	Jennifer-vidrine@ouhsc.edu
Notes	Recruiting

NCT02397369

Trial name or title	Evaluation of efficacy of different methods of tobacco cessation interventions among BEST employees in Mumbai
Methods	RCT, 4 arms, double masking
Participants	4000 Mumbai male BEST employees
Interventions	Telephonic counselling
Outcomes	Tobacco cessation after 1 year of follow-up
Starting date	March 2015
Contact information	www.researchgate.net/profile/Sharmila_Pimple gauravi2005@yahoo.co.in

NCT02397369 *(Continued)*

Notes	Recruiting

NCT02421991

Trial name or title	Telephone-delivered interventions for smoking cessation (TALK)
Methods	RCT, parallel assignment, single masking
Participants	1168 American adult smokers
Interventions	Telephone counselling (ACT) 5 weeks
Outcomes	30-day point prevalence abstinence after 12 months of follow-up
Starting date	2 November 2015
Contact information	jbricker@fredhutch.org
Notes	

NCT03002883

Trial name or title	STAND Community College tobacco cessation trial
Methods	RCT, 3 arms, open-label
Participants	113 Californian adult smokers
Interventions	Usual care + referral to quitline
Outcomes	Biochemically-validated smoking cessation after 6 months of follow-up
Starting date	September 2014
Contact information	ektong@ucdavis.edu
Notes	Cannot find a full-text report

NCT03194958

Trial name or title	Helping poor smokers quit
Methods	RCT, factorial design, double masking
Participants	2000 Missouri resident adult smokers
Interventions	Specialised quitline services ± basic needs navigator
Outcomes	7-day point prevalence abstinence after 6 months of follow-up

NCT03194958 *(Continued)*

Starting date	5 June 2017
Contact information	mkreuter@wustl.edu
Notes	Recruiting

NCT03236025

Trial name or title	A video-led smoking cessation intervention in helping male smokers who is planning to have a baby to quit
Methods	RCT, parallel assignment, single masking
Participants	888 male adult Chinese-speaking Hong Kong-resident smokers
Interventions	Telephone counselling + pamphlet
Outcomes	Self-reported 7-day point prevalence quit rate after 6 months of follow-up
Starting date	1 June 2017
Contact information	www.researchgate.net/profile/Ho_Li2 william3@hku.hk
Notes	Recruiting

NCT03538938

Trial name or title	Improving quitline support study (IQS)
Methods	RCT, factorial design, single masking
Participants	1600 Winsconsin-resident adult smokers
Interventions	4-call quitline counselling ± NRT ± text messaging ± financial incentives
Outcomes	7-day point prevalence abstinence after 6 months of follow-up
Starting date	7 June 2018
Contact information	www.researchgate.net/profile/Danielle_Mccarthy demccarthy@ctri.wisc.edu
Notes	Enrolling

NTR6092

Trial name or title	Recruitment strategies for an effective smoking cessation programme for parents (De implementatie van een effectieve interventie om te stoppen met roken voor ouders)

NTR6092 *(Continued)*

Methods	RCT, parallel assignment, single masking
Participants	144 smoking parents of children younger than 12
Interventions	Proactive telephone counselling based on MI and cognitive-behavioural skill building
Outcomes	7-day point prevalence abstinence after 12 months of follow-up Prolonged abstinence (at least 6 months) after 12-months of follow-up
Starting date	15 September 2016
Contact information	tscheffers@trimbos.nl
Notes	Enroling

Salgado Garcia 2018

Trial name or title	Planning a change easily (PACE)
Methods	RCT, 4 arms
Participants	US adult smokers not ready to quit
Interventions	Motivational Interviewing Telephone Counseling
Outcomes	7-day point prevalence after 12 months of follow-up Prolonged abstinence after 12 months of follow-up Biochemically validated (saliva cotinine) abstinence after 12 months of follow-up
Starting date	
Contact information	fsalgado@uthsc.edu
Notes	Only protocol published so far

Sienkiewicz-Jarosz 2015

Trial name or title	Antismoking interventions in stroke patients - Polish perspective
Methods	RCT, 3 arms
Participants	198 participants with first ischaemic stroke
Interventions	4 telephone calls 6 weeks after discharge from hospital + brief (20-min) counselling by physician 1 telephone call 7 days post-stroke + brief (20-min) counselling by physician
Outcomes	Smoking cessation rate after 12 months of follow-up
Starting date	
Contact information	www.researchgate.net/profile/Halina_Sienkiewicz-Jarosz sekretariatdn-sl@ipin.edu.pl

Sienkiewicz-Jarosz 2015 *(Continued)*

Notes	Conference abstract. First author contacted but no response received

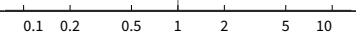
DATA AND ANALYSES

Comparison 1. Interventions for callers to quitlines - effect of additional proactive calls

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cessation at longest follow-up	14	32484	Risk Ratio (M-H, Random, 95% CI)	1.38 [1.19, 1.61]

Analysis 1.1. Comparison 1 Interventions for callers to quitlines - effect of additional proactive calls, Outcome 1 Cessation at longest follow-up.

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Borland 2001	35/497	20/501		4.8%	1.76[1.03,3.01]
Borland 2003	32/528	24/523		5.02%	1.32[0.79,2.21]
Cummins 2016b	83/584	48/589		7.42%	1.74[1.25,2.44]
Ferguson 2012	100/1296	107/1295		8.64%	0.93[0.72,1.21]
Gilbert 2006	70/753	67/704		7.7%	0.98[0.71,1.34]
Hollis 2007	499/2874	248/1740		10.52%	1.22[1.06,1.4]
Nohlert 2014	60/588	61/541		7.42%	0.9[0.65,1.27]
Rabius 2004	141/1804	66/1716		8.26%	2.03[1.53,2.7]
Rabius 2007	516/4758	119/1564		9.79%	1.43[1.18,1.73]
Sims 2013	14/209	13/201		3.2%	1.04[0.5,2.15]
Smith 2004	20/423	3/207		1.43%	3.26[0.98,10.85]
Zhu 1996	190/2189	46/841		7.81%	1.59[1.16,2.17]
Zhu 2002	179/1973	90/1309		8.94%	1.32[1.03,1.68]
Zhu 2012	184/1124	92/1153		9.06%	2.05[1.62,2.6]
Total (95% CI)	**19600**	**12884**		**100%**	**1.38[1.19,1.61]**
Total events: 2123 (Treatment), 1004 (Control)					
Heterogeneity: Tau^2=0.05; Chi^2=46.23, df=13(P<0.0001); I^2=71.88%					
Test for overall effect: Z=4.15(P<0.0001)					



Favours no calls — Favours additional calls

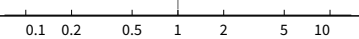
Comparison 2. Interventions for callers to quitlines - comparison of different intensities

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cessation at longest follow-up	3		Risk Ratio (M-H, Random, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Seven versus three phone calls	1	1908	Risk Ratio (M-H, Random, 95% CI)	1.44 [1.09, 1.89]
1.2 Five versus three phone calls	1	3669	Risk Ratio (M-H, Random, 95% CI)	1.28 [1.00, 1.64]
1.3 Seven versus five phone calls	1	3939	Risk Ratio (M-H, Random, 95% CI)	1.12 [0.93, 1.36]
1.4 Five versus two phone calls	1	2874	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.89, 1.23]
1.5 Five versus one phone call	1	2189	Risk Ratio (M-H, Random, 95% CI)	1.32 [1.01, 1.74]

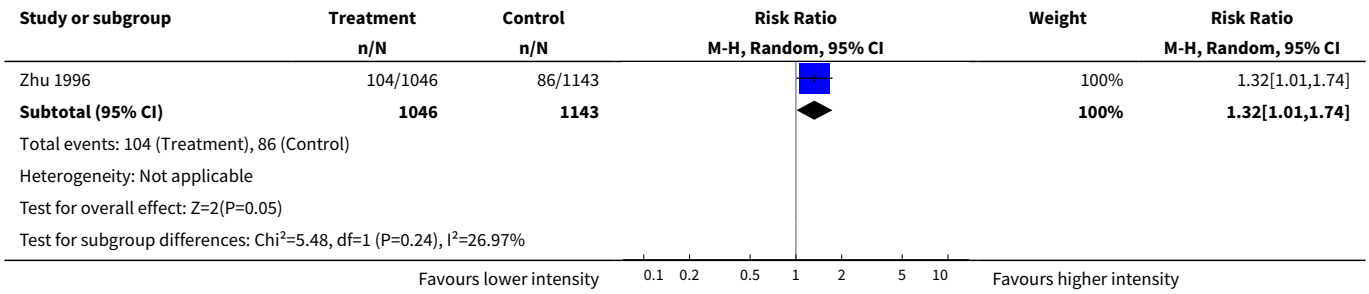
Analysis 2.1. Comparison 2 Interventions for callers to quitlines - comparison of different intensities, Outcome 1 Cessation at longest follow-up.

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
2.1.1 Seven versus three phone calls					
Rabius 2007	134/1089	70/819		100%	1.44[1.09,1.89]
Subtotal (95% CI)	**1089**	**819**		**100%**	**1.44[1.09,1.89]**
Total events: 134 (Treatment), 70 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=2.6(P=0.01)					
2.1.2 Five versus three phone calls					
Rabius 2007	312/2850	70/819		100%	1.28[1,1.64]
Subtotal (95% CI)	**2850**	**819**		**100%**	**1.28[1,1.64]**
Total events: 312 (Treatment), 70 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.96(P=0.05)					
2.1.3 Seven versus five phone calls					
Rabius 2007	134/1089	312/2850		100%	1.12[0.93,1.36]
Subtotal (95% CI)	**1089**	**2850**		**100%**	**1.12[0.93,1.36]**
Total events: 134 (Treatment), 312 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.21(P=0.23)					
2.1.4 Five versus two phone calls					
Hollis 2007	256/1441	243/1433		100%	1.05[0.89,1.23]
Subtotal (95% CI)	**1441**	**1433**		**100%**	**1.05[0.89,1.23]**
Total events: 256 (Treatment), 243 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.57(P=0.57)					
2.1.5 Five versus one phone call					



Favours lower intensity

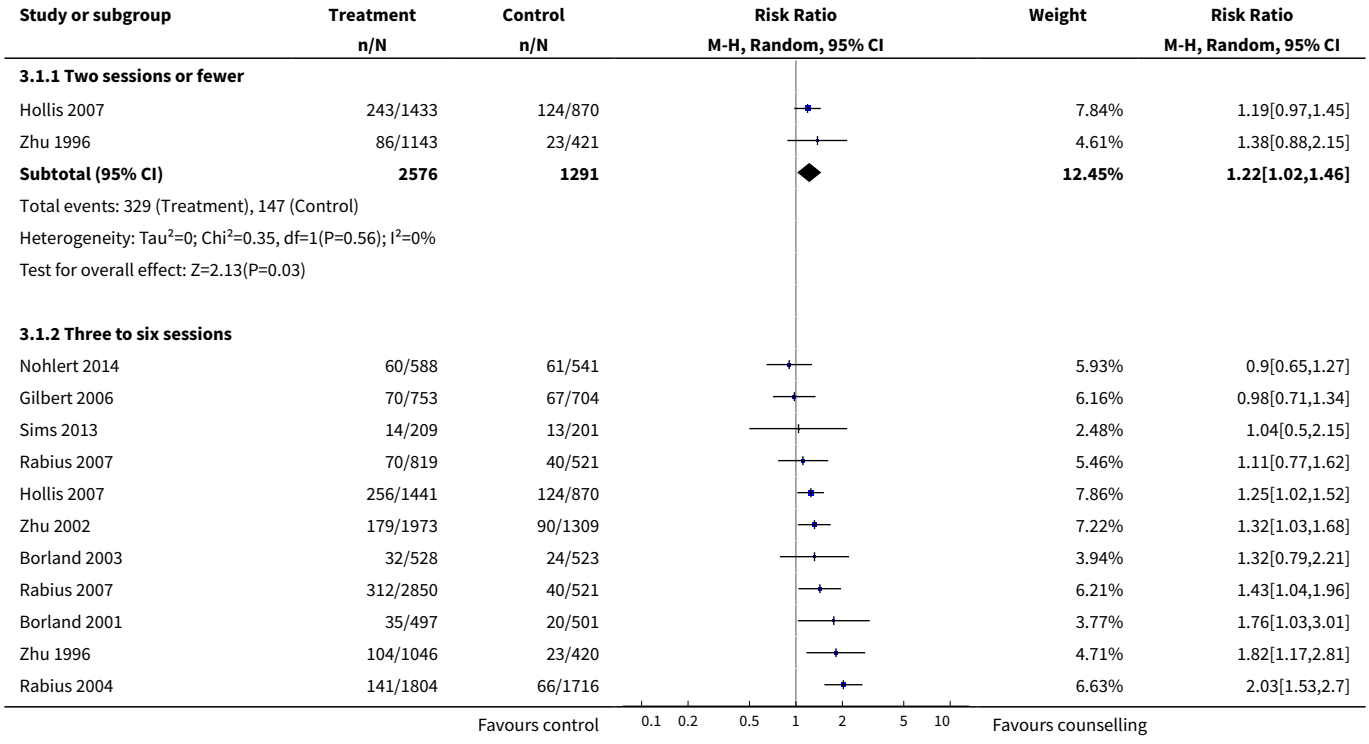
Favours higher intensity

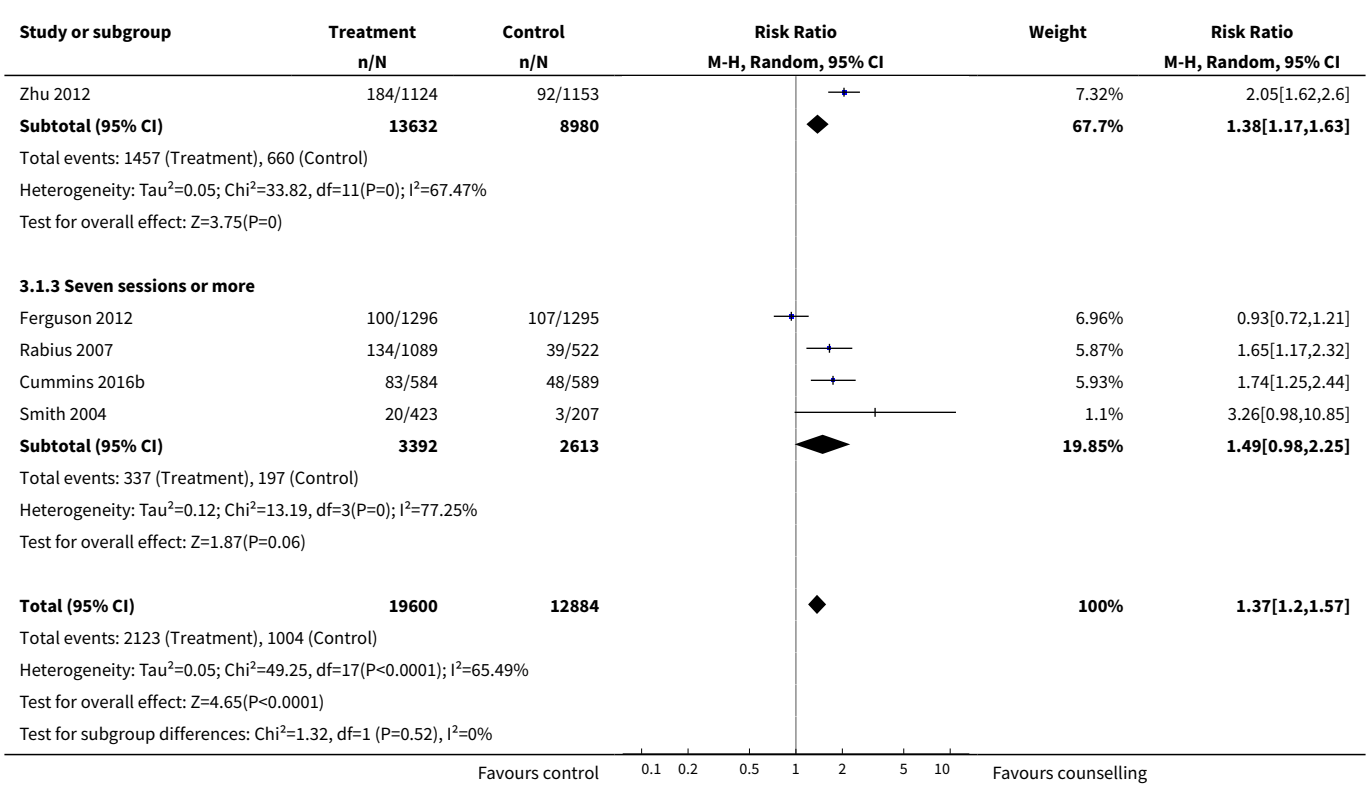


Comparison 3. Interventions for callers to quitlines - subgroups by counseling intensity

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cessation at longest follow-up	14	32484	Risk Ratio (M-H, Random, 95% CI)	1.37 [1.20, 1.57]
1.1 Two sessions or fewer	2	3867	Risk Ratio (M-H, Random, 95% CI)	1.22 [1.02, 1.46]
1.2 Three to six sessions	11	22612	Risk Ratio (M-H, Random, 95% CI)	1.38 [1.17, 1.63]
1.3 Seven sessions or more	4	6005	Risk Ratio (M-H, Random, 95% CI)	1.49 [0.98, 2.25]

Analysis 3.1. Comparison 3 Interventions for callers to quitlines - subgroups by counseling intensity, Outcome 1 Cessation at longest follow-up.

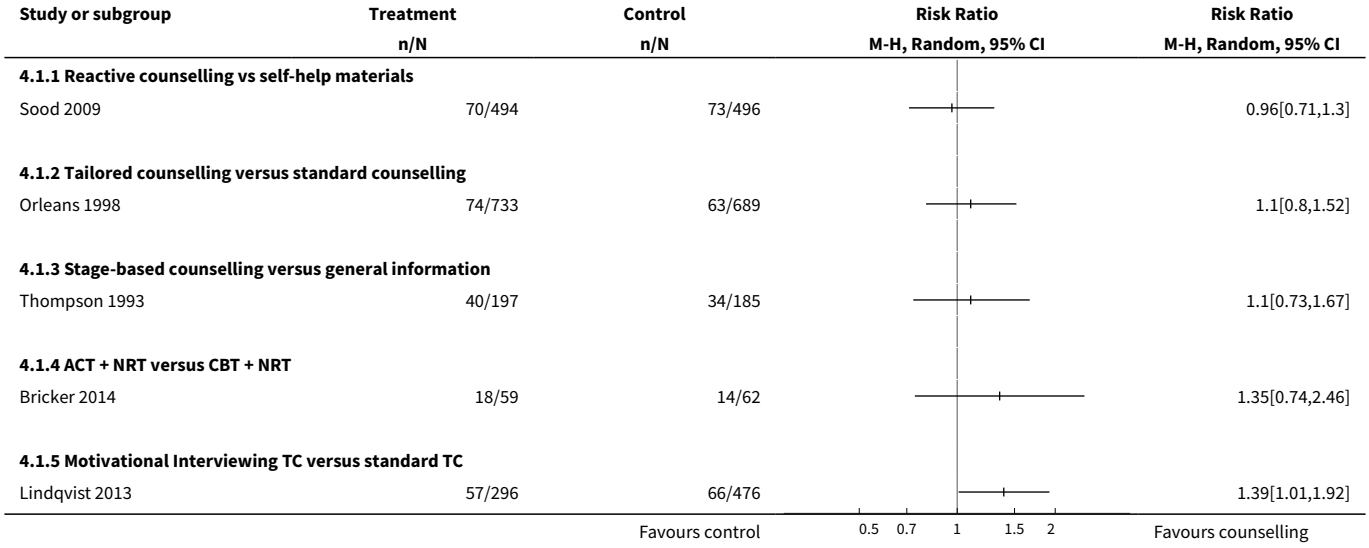




Comparison 4. Interventions for callers to quitlines - comparison of different support at initial call

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cessation at longest follow-up	5		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
1.1 Reactive counselling vs self-help materials	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
1.2 Tailored counselling versus standard counselling	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
1.3 Stage-based counselling versus general information	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
1.4 ACT + NRT versus CBT + NRT	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
1.5 Motivational Interviewing TC versus standard TC	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]

Analysis 4.1. Comparison 4 Interventions for callers to quitlines - comparison of different support at initial call, Outcome 1 Cessation at longest follow-up.

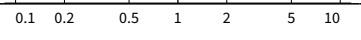


Comparison 5. Offer of counselling via quitlines/helplines/hotlines

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cessation at longest follow-up	7		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 Hotline and self-help materials compared to minimal intervention	2	3327	Risk Ratio (M-H, Random, 95% CI)	1.62 [1.16, 2.25]
1.2 Hotline and self-help materials for cessation maintenance compared to nothing	1	1311	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.70, 1.06]
1.3 Reactive or proactive counselling vs provider counselling	4	7780	Risk Ratio (M-H, Random, 95% CI)	1.40 [1.07, 1.84]
1.4 Proactive counselling vs reactive counselling	2	2908	Risk Ratio (M-H, Random, 95% CI)	2.06 [0.58, 7.31]
1.5 Proactive counselling vs self-help	2	2498	Risk Ratio (M-H, Random, 95% CI)	1.42 [0.76, 2.63]
1.6 Reactive counselling vs self-help	2	2364	Risk Ratio (M-H, Random, 95% CI)	0.78 [0.44, 1.40]

Analysis 5.1. Comparison 5 Offer of counselling via quitlines/ helplines/hotlines, Outcome 1 Cessation at longest follow-up.

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
5.1.1 Hotline and self-help materials compared to minimal intervention					
Ossip-Klein 1991	56/894	34/919		62.27%	1.69[1.12,2.57]
Zwar 2015	37/836	20/678		37.73%	1.5[0.88,2.56]
Subtotal (95% CI)	**1730**	**1597**		**100%**	**1.62[1.16,2.25]**
Total events: 93 (Treatment), 54 (Control)					
Heterogeneity: Tau^2=0; Chi^2=0.12, df=1(P=0.73); I^2=0%					
Test for overall effect: Z=2.87(P=0)					
5.1.2 Hotline and self-help materials for cessation maintenance compared to nothing					
McFall 1993	180/873	105/438		100%	0.86[0.7,1.06]
Subtotal (95% CI)	**873**	**438**		**100%**	**0.86[0.7,1.06]**
Total events: 180 (Treatment), 105 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.4(P=0.16)					
5.1.3 Reactive or proactive counselling vs provider counselling					
Joyce 2008	326/1690	412/2605		36.58%	1.22[1.07,1.39]
Rogers 2016	49/270	38/307		21.99%	1.47[0.99,2.17]
Sherman 2017	157/1069	120/934		31.7%	1.14[0.92,1.43]
Skov-Ettrup 2016	33/452	8/453		9.74%	4.13[1.93,8.85]
Subtotal (95% CI)	**3481**	**4299**		**100%**	**1.4[1.07,1.84]**
Total events: 565 (Treatment), 578 (Control)					
Heterogeneity: Tau^2=0.05; Chi^2=10.94, df=3(P=0.01); I^2=72.58%					
Test for overall effect: Z=2.42(P=0.02)					
5.1.4 Proactive counselling vs reactive counselling					
Sherman 2017	157/1069	120/934		54.12%	1.14[0.92,1.43]
Skov-Ettrup 2016	33/452	8/453		45.88%	4.13[1.93,8.85]
Subtotal (95% CI)	**1521**	**1387**		**100%**	**2.06[0.58,7.31]**
Total events: 190 (Treatment), 128 (Control)					
Heterogeneity: Tau^2=0.76; Chi^2=10.26, df=1(P=0); I^2=90.25%					
Test for overall effect: Z=1.12(P=0.26)					
5.1.5 Proactive counselling vs self-help					
Sherman 2017	157/1069	71/525		58.57%	1.09[0.84,1.41]
Skov-Ettrup 2016	33/452	16/452		41.43%	2.06[1.15,3.69]
Subtotal (95% CI)	**1521**	**977**		**100%**	**1.42[0.76,2.63]**
Total events: 190 (Treatment), 87 (Control)					
Heterogeneity: Tau^2=0.15; Chi^2=3.9, df=1(P=0.05); I^2=74.34%					
Test for overall effect: Z=1.1(P=0.27)					
5.1.6 Reactive counselling vs self-help					
Sherman 2017	120/934	71/525		69.64%	0.95[0.72,1.25]
Skov-Ettrup 2016	8/453	16/452		30.36%	0.5[0.22,1.15]
Subtotal (95% CI)	**1387**	**977**		**100%**	**0.78[0.44,1.4]**
Total events: 128 (Treatment), 87 (Control)					
Heterogeneity: Tau^2=0.11; Chi^2=2.06, df=1(P=0.15); I^2=51.38%					
Test for overall effect: Z=0.83(P=0.41)					



Favours control — Favours counselling offer

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Test for subgroup differences: Chi²=16.29, df=1 (P=0.01), I²=69.3%					

Favours control | Favours counselling offer

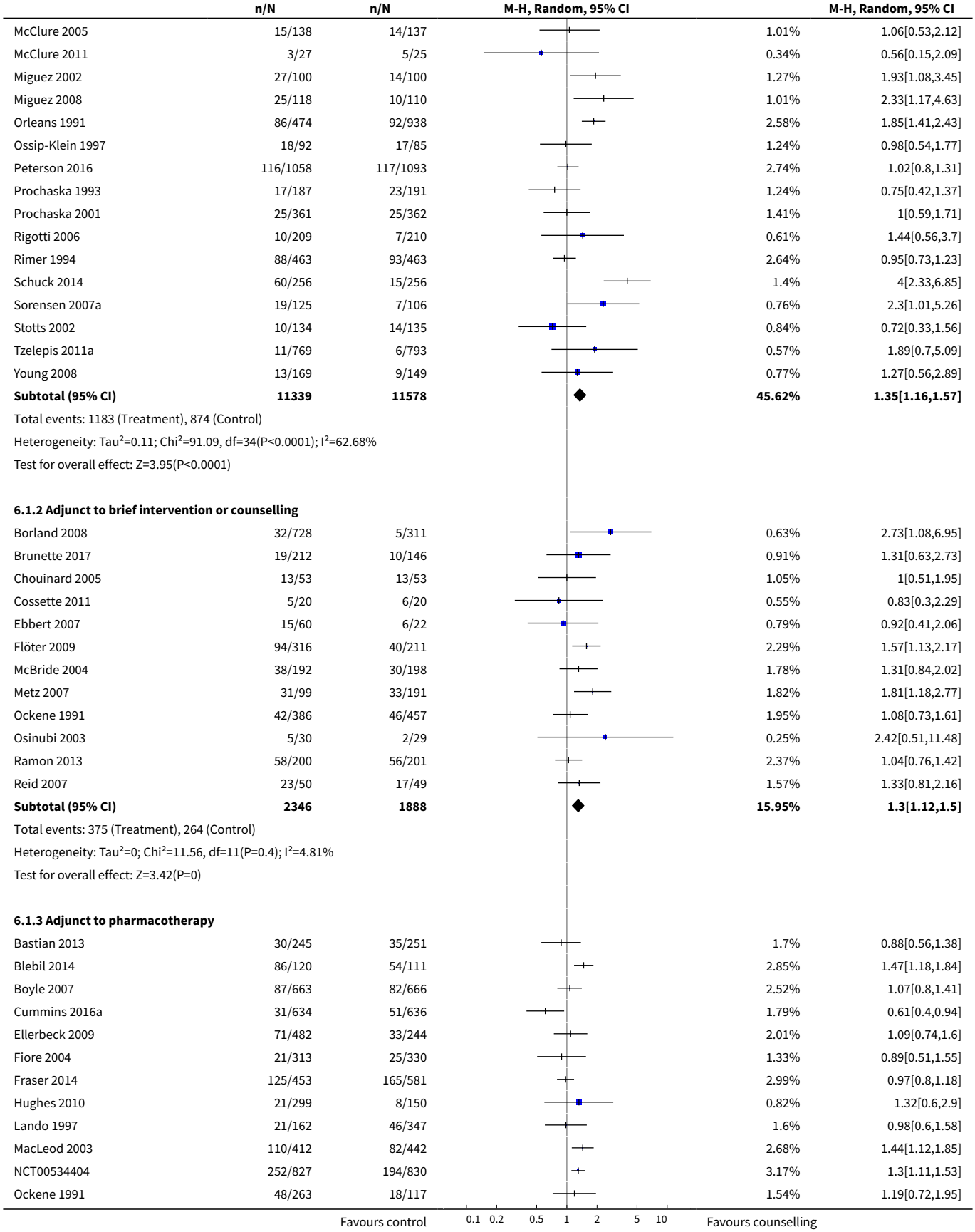
Comparison 6. Interventions for smokers not calling quitlines - subgroups by baseline support

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cessation at longest follow-up	65	41233	Risk Ratio (M-H, Random, 95% CI)	1.25 [1.15, 1.35]
1.1 Adjunct to self-help or minimal intervention	35	22917	Risk Ratio (M-H, Random, 95% CI)	1.35 [1.16, 1.57]
1.2 Adjunct to brief intervention or counselling	12	4234	Risk Ratio (M-H, Random, 95% CI)	1.30 [1.12, 1.50]
1.3 Adjunct to pharmacotherapy	18	12865	Risk Ratio (M-H, Random, 95% CI)	1.14 [1.03, 1.26]
1.4 Adjunct to incentives for smoking cessation	1	1217	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.67, 1.65]

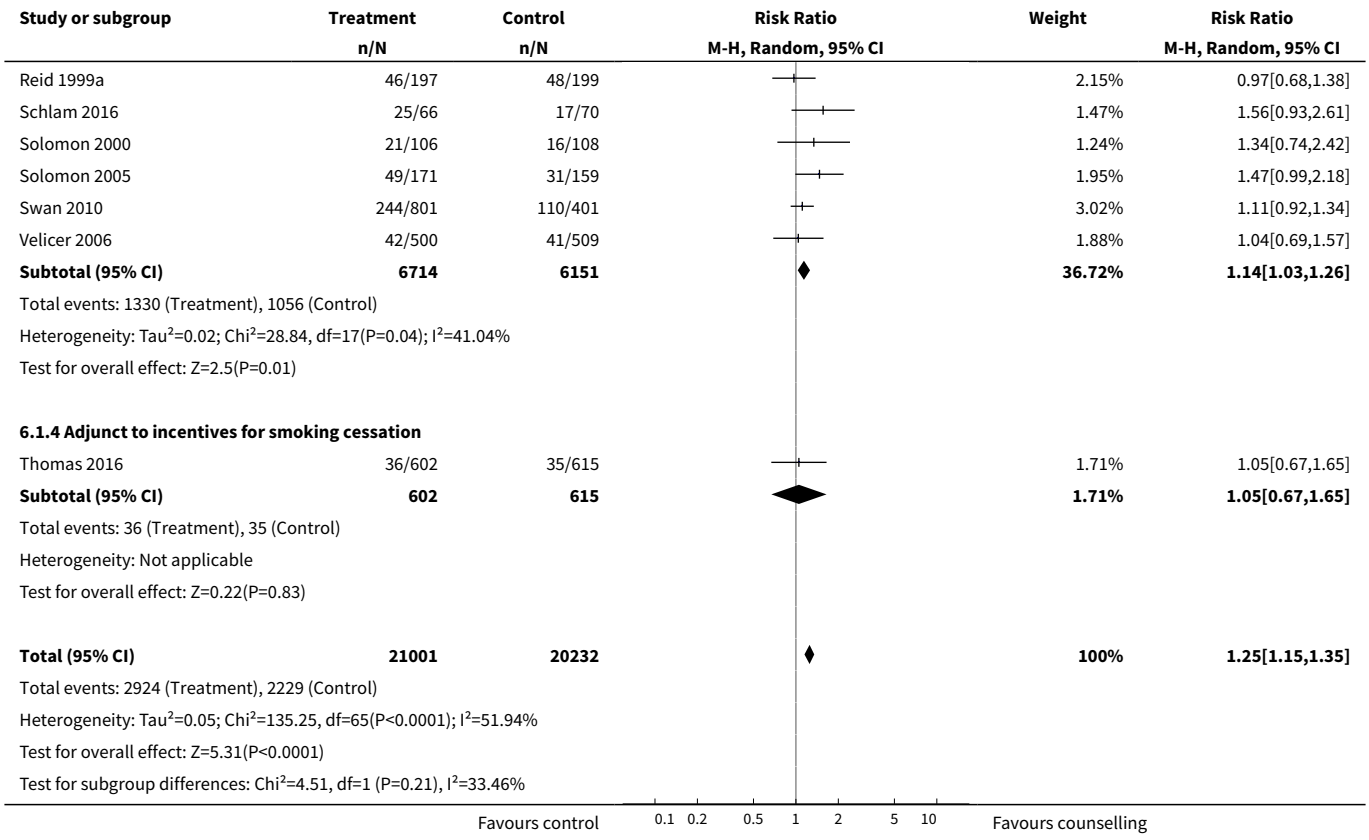
Analysis 6.1. Comparison 6 Interventions for smokers not calling quitlines - subgroups by baseline support, Outcome 1 Cessation at longest follow-up.

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
6.1.1 Adjunct to self-help or minimal intervention					
Abdullah 2005	47/444	21/459		1.54%	2.31[1.41,3.81]
An 2006	53/407	17/414		1.43%	3.17[1.87,5.38]
Aveyard 2003	14/685	15/683		0.94%	0.93[0.45,1.91]
Brown 1992	7/23	2/22		0.29%	3.35[0.78,14.4]
Chan 2015	16/338	17/330		1.06%	0.92[0.47,1.79]
Curry 1995	8/150	10/329		0.65%	1.75[0.71,4.36]
Duffy 2006	15/48	6/51		0.72%	2.66[1.12,6.28]
Emmons 2005	60/398	35/386		1.96%	1.66[1.12,2.46]
Girgis 2011	18/213	22/194		1.24%	0.75[0.41,1.35]
Graham 2011	52/675	29/651		1.75%	1.73[1.11,2.69]
Hanssen 2009	30/77	23/61		1.81%	1.03[0.67,1.58]
Holmes-Rovner 2008	40/76	25/60		2.08%	1.26[0.87,1.82]
Lando 1992	20/716	10/683		0.88%	1.91[0.9,4.05]
Lichtenstein 2000	25/355	15/349		1.16%	1.64[0.88,3.05]
Lichtenstein 2008	46/905	42/916		1.89%	1.11[0.74,1.67]
Lipkus 1999	10/52	18/55		1.04%	0.59[0.3,1.15]
Lipkus 2004	19/209	14/193		1.06%	1.25[0.65,2.43]
McBride 1999a	16/288	14/292		0.99%	1.16[0.58,2.33]
McBride 1999b	144/600	71/297		2.71%	1[0.78,1.29]

Favours control | Favours counselling



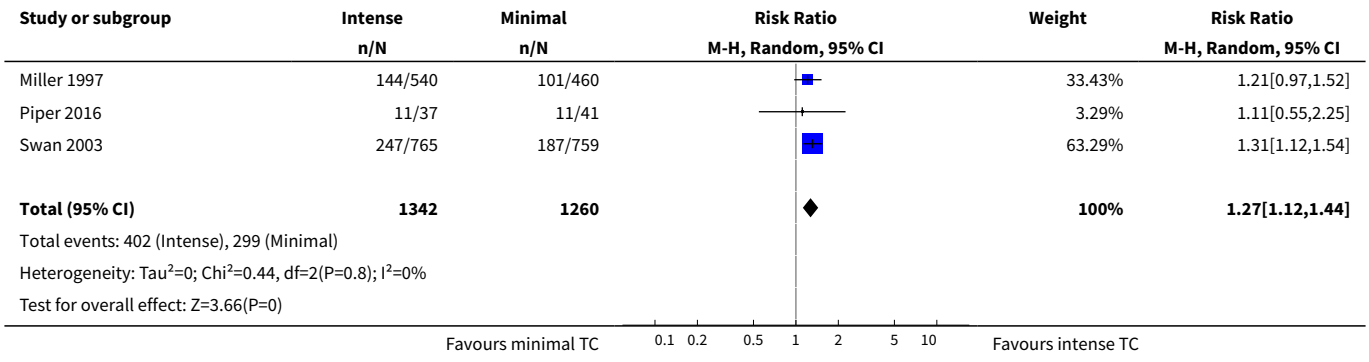
Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
McClure 2005	15/138	14/137		1.01%	1.06[0.53,2.12]
McClure 2011	3/27	5/25		0.34%	0.56[0.15,2.09]
Miguez 2002	27/100	14/100		1.27%	1.93[1.08,3.45]
Miguez 2008	25/118	10/110		1.01%	2.33[1.17,4.63]
Orleans 1991	86/474	92/938		2.58%	1.85[1.41,2.43]
Ossip-Klein 1997	18/92	17/85		1.24%	0.98[0.54,1.77]
Peterson 2016	116/1058	117/1093		2.74%	1.02[0.8,1.31]
Prochaska 1993	17/187	23/191		1.24%	0.75[0.42,1.37]
Prochaska 2001	25/361	25/362		1.41%	1[0.59,1.71]
Rigotti 2006	10/209	7/210		0.61%	1.44[0.56,3.7]
Rimer 1994	88/463	93/463		2.64%	0.95[0.73,1.23]
Schuck 2014	60/256	15/256		1.4%	4[2.33,6.85]
Sorensen 2007a	19/125	7/106		0.76%	2.3[1.01,5.26]
Stotts 2002	10/134	14/135		0.84%	0.72[0.33,1.56]
Tzelepis 2011a	11/769	6/793		0.57%	1.89[0.7,5.09]
Young 2008	13/169	9/149		0.77%	1.27[0.56,2.89]
Subtotal (95% CI)	**11339**	**11578**		**45.62%**	**1.35[1.16,1.57]**
Total events: 1183 (Treatment), 874 (Control)					
Heterogeneity: Tau^2=0.11; Chi^2=91.09, df=34(P<0.0001); I^2=62.68%					
Test for overall effect: Z=3.95(P<0.0001)					
6.1.2 Adjunct to brief intervention or counselling					
Borland 2008	32/728	5/311		0.63%	2.73[1.08,6.95]
Brunette 2017	19/212	10/146		0.91%	1.31[0.63,2.73]
Chouinard 2005	13/53	13/53		1.05%	1[0.51,1.95]
Cossette 2011	5/20	6/20		0.55%	0.83[0.3,2.29]
Ebbert 2007	15/60	6/22		0.79%	0.92[0.41,2.06]
Flöter 2009	94/316	40/211		2.29%	1.57[1.13,2.17]
McBride 2004	38/192	30/198		1.78%	1.31[0.84,2.02]
Metz 2007	31/99	33/191		1.82%	1.81[1.18,2.77]
Ockene 1991	42/386	46/457		1.95%	1.08[0.73,1.61]
Osinubi 2003	5/30	2/29		0.25%	2.42[0.51,11.48]
Ramon 2013	58/200	56/201		2.37%	1.04[0.76,1.42]
Reid 2007	23/50	17/49		1.57%	1.33[0.81,2.16]
Subtotal (95% CI)	**2346**	**1888**		**15.95%**	**1.3[1.12,1.5]**
Total events: 375 (Treatment), 264 (Control)					
Heterogeneity: Tau^2=0; Chi^2=11.56, df=11(P=0.4); I^2=4.81%					
Test for overall effect: Z=3.42(P=0)					
6.1.3 Adjunct to pharmacotherapy					
Bastian 2013	30/245	35/251		1.7%	0.88[0.56,1.38]
Blebil 2014	86/120	54/111		2.85%	1.47[1.18,1.84]
Boyle 2007	87/663	82/666		2.52%	1.07[0.8,1.41]
Cummins 2016a	31/634	51/636		1.79%	0.61[0.4,0.94]
Ellerbeck 2009	71/482	33/244		2.01%	1.09[0.74,1.6]
Fiore 2004	21/313	25/330		1.33%	0.89[0.51,1.55]
Fraser 2014	125/453	165/581		2.99%	0.97[0.8,1.18]
Hughes 2010	21/299	8/150		0.82%	1.32[0.6,2.9]
Lando 1997	21/162	46/347		1.6%	0.98[0.6,1.58]
MacLeod 2003	110/412	82/442		2.68%	1.44[1.12,1.85]
NCT00534404	252/827	194/830		3.17%	1.3[1.11,1.53]
Ockene 1991	48/263	18/117		1.54%	1.19[0.72,1.95]



Comparison 7. Interventions for smokers not calling quitlines - intense versus minimal telephone counselling

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cessation at longest follow-up	3	2602	Risk Ratio (M-H, Random, 95% CI)	1.27 [1.12, 1.44]

Analysis 7.1. Comparison 7 Interventions for smokers not calling quitlines - intense versus minimal telephone counselling, Outcome 1 Cessation at longest follow-up.

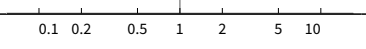


Comparison 8. Interventions for smokers not calling quitlines - subgroups by counseling intensity

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cessation at longest follow-up	65	41233	Risk Ratio (M-H, Random, 95% CI)	1.25 [1.15, 1.35]
1.1 Two sessions or fewer	9	6274	Risk Ratio (M-H, Random, 95% CI)	1.09 [0.86, 1.40]
1.2 Three to six sessions	44	26686	Risk Ratio (M-H, Random, 95% CI)	1.29 [1.18, 1.42]
1.3 Seven sessions or more	13	8273	Risk Ratio (M-H, Random, 95% CI)	1.22 [0.98, 1.51]

Analysis 8.1. Comparison 8 Interventions for smokers not calling quitlines - subgroups by counseling intensity, Outcome 1 Cessation at longest follow-up.

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
8.1.1 Two sessions or fewer					
Lipkus 1999	10/52	18/55		1.04%	0.59[0.3,1.15]
Stotts 2002	10/134	14/135		0.84%	0.72[0.33,1.56]
Fiore 2004	21/313	25/330		1.34%	0.89[0.51,1.55]
Rimer 1994	88/463	93/463		2.65%	0.95[0.73,1.23]
Ossip-Klein 1997	18/92	17/85		1.24%	0.98[0.54,1.77]
Lichtenstein 2008	46/905	42/916		1.9%	1.11[0.74,1.67]
Lichtenstein 2000	25/355	15/349		1.16%	1.64[0.88,3.05]
Lando 1992	20/716	10/683		0.88%	1.91[0.9,4.05]
Miguez 2008	25/118	10/110		1.01%	2.33[1.17,4.63]
Subtotal (95% CI)	**3148**	**3126**		**12.06%**	**1.09[0.86,1.4]**
Total events: 263 (Treatment), 244 (Control)					
Heterogeneity: Tau^2=0.06; Chi^2=14.49, df=8(P=0.07); I^2=44.79%					
Test for overall effect: Z=0.71(P=0.48)					
8.1.2 Three to six sessions					
Girgis 2011	18/213	22/194		1.24%	0.75[0.41,1.35]
Prochaska 1993	17/187	23/191		1.24%	0.75[0.42,1.37]
Cossette 2011	5/20	6/20		0.55%	0.83[0.3,2.29]
Bastian 2013	30/245	35/251		1.7%	0.88[0.56,1.38]
Ebbert 2007	15/60	6/22		0.79%	0.92[0.41,2.06]
Chan 2015	16/338	17/330		1.06%	0.92[0.47,1.79]
Aveyard 2003	14/685	15/683		0.94%	0.93[0.45,1.91]
Reid 1999a	46/197	48/199		2.16%	0.97[0.68,1.38]
Fraser 2014	125/453	165/581		3%	0.97[0.8,1.18]
Lando 1997	21/162	46/347		1.6%	0.98[0.6,1.58]
Chouinard 2005	13/53	13/53		1.05%	1[0.51,1.95]
Prochaska 2001	25/361	25/362		1.41%	1[0.59,1.71]
McBride 1999b	144/600	71/297		2.72%	1[0.78,1.29]
Ramon 2013	58/200	56/201		2.38%	1.04[0.76,1.42]
Thomas 2016	36/602	35/615		1.72%	1.05[0.67,1.65]



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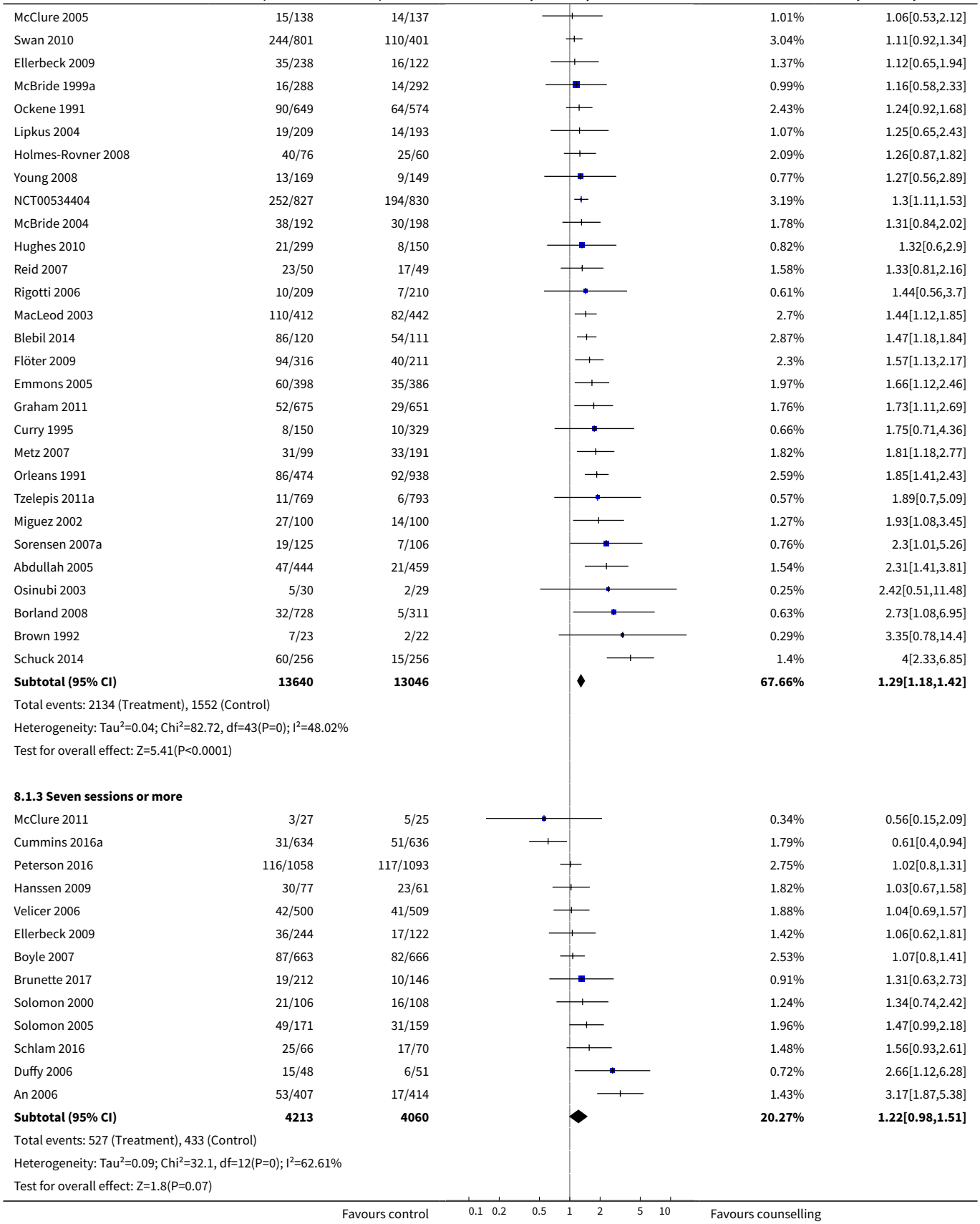
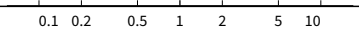


Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Total (95% CI)	**21001**	**20232**		**100%**	**1.25[1.15,1.35]**
Total events: 2924 (Treatment), 2229 (Control)					
Heterogeneity: Tau²=0.05; Chi²=134.91, df=65(P<0.0001); I²=51.82%					
Test for overall effect: Z=5.36(P<0.0001)					
Test for subgroup differences: Chi²=1.7, df=1 (P=0.43), I²=0%					



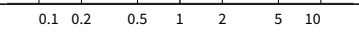
Favours control | Favours counselling

Comparison 9. Interventions for smokers not calling quitlines - subgroups by motivation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cessation at longest follow-up	65	41233	Risk Ratio (M-H, Random, 95% CI)	1.25 [1.15, 1.36]
1.1 Selected for motivation/interest in quitting	26	17877	Risk Ratio (M-H, Random, 95% CI)	1.31 [1.15, 1.49]
1.2 Not selected for motivation	39	23356	Risk Ratio (M-H, Random, 95% CI)	1.20 [1.09, 1.33]

Analysis 9.1. Comparison 9 Interventions for smokers not calling quitlines - subgroups by motivation, Outcome 1 Cessation at longest follow-up.

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
9.1.1 Selected for motivation/interest in quitting					
An 2006	53/407	17/414		1.45%	3.17[1.87,5.38]
Blebil 2014	86/120	54/111		2.88%	1.47[1.18,1.84]
Boyle 2007	87/663	82/666		2.55%	1.07[0.8,1.41]
Brown 1992	7/23	2/22		0.29%	3.35[0.78,14.4]
Brunette 2017	19/212	10/146		0.92%	1.31[0.63,2.73]
Cummins 2016a	31/634	51/636		1.81%	0.61[0.4,0.94]
Fiore 2004	21/313	25/330		1.35%	0.89[0.51,1.55]
Fraser 2014	125/453	165/581		3.01%	0.97[0.8,1.18]
Graham 2011	52/675	29/651		1.77%	1.73[1.11,2.69]
Hughes 2010	21/299	8/150		0.83%	1.32[0.6,2.9]
Lando 1997	21/162	46/347		1.61%	0.98[0.6,1.58]
MacLeod 2003	110/412	82/442		2.71%	1.44[1.12,1.85]
Miguez 2002	27/100	14/100		1.28%	1.93[1.08,3.45]
Miguez 2008	25/118	10/110		1.03%	2.33[1.17,4.63]
NCT00534404	252/827	194/830		3.2%	1.3[1.11,1.53]
Orleans 1991	86/474	92/938		2.6%	1.85[1.41,2.43]
Ossip-Klein 1997	18/92	17/85		1.25%	0.98[0.54,1.77]
Ramon 2013	58/200	56/201		2.39%	1.04[0.76,1.42]
Reid 1999a	46/197	48/199		2.17%	0.97[0.68,1.38]



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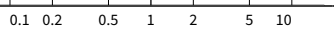
Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Rimer 1994	88/463	93/463		2.66%	0.95[0.73,1.23]
Schlam 2016	25/66	17/70		1.49%	1.56[0.93,2.61]
Schuck 2014	60/256	15/256		1.41%	4[2.33,6.85]
Solomon 2000	21/106	16/108		1.25%	1.34[0.74,2.42]
Solomon 2005	49/171	31/159		1.98%	1.47[0.99,2.18]
Swan 2010	244/801	110/401		3.05%	1.11[0.92,1.34]
Thomas 2016	36/602	35/615		1.73%	1.05[0.67,1.65]
Subtotal (95% CI)	**8846**	**9031**		**48.67%**	**1.31[1.15,1.49]**
Total events: 1668 (Treatment), 1319 (Control)					
Heterogeneity: Tau^2=0.07; Chi^2=82.92, df=25(P<0.0001); I^2=69.85%					
Test for overall effect: Z=4.02(P<0.0001)					
9.1.2 Not selected for motivation					
Abdullah 2005	47/444	21/459		1.55%	2.31[1.41,3.81]
Aveyard 2003	14/685	15/683		0.95%	0.93[0.45,1.91]
Bastian 2013	30/245	35/251		1.72%	0.88[0.56,1.38]
Borland 2008	32/728	5/311		0.64%	2.73[1.08,6.95]
Chan 2015	16/338	17/330		1.07%	0.92[0.47,1.79]
Chouinard 2005	13/53	13/53		1.06%	1[0.51,1.95]
Cossette 2011	5/20	6/20		0.55%	0.83[0.3,2.29]
Curry 1995	8/150	10/329		0.66%	1.75[0.71,4.36]
Duffy 2006	15/48	6/51		0.73%	2.66[1.12,6.28]
Ebbert 2007	15/60	6/22		0.8%	0.92[0.41,2.06]
Ellerbeck 2009	71/482	33/244		2.03%	1.09[0.74,1.6]
Emmons 2005	60/398	35/386		1.98%	1.66[1.12,2.46]
Flöter 2009	94/316	40/211		2.31%	1.57[1.13,2.17]
Girgis 2011	18/213	22/194		1.26%	0.75[0.41,1.35]
Hanssen 2009	30/77	23/61		1.83%	1.03[0.67,1.58]
Holmes-Rovner 2008	40/76	25/60		2.1%	1.26[0.87,1.82]
Lando 1992	20/716	10/683		0.9%	1.91[0.9,4.05]
Lichtenstein 2000	25/355	15/349		1.17%	1.64[0.88,3.05]
Lichtenstein 2008	46/905	42/916		1.91%	1.11[0.74,1.67]
Lipkus 1999	10/52	18/55		1.05%	0.59[0.3,1.15]
Lipkus 2004	19/209	14/193		1.08%	1.25[0.65,2.43]
McBride 1999a	16/288	14/292		1%	1.16[0.58,2.33]
McBride 1999b	144/600	71/297		2.73%	1[0.78,1.29]
McBride 2004	38/192	30/198		1.8%	1.31[0.84,2.02]
McClure 2005	15/138	14/137		1.02%	1.06[0.53,2.12]
McClure 2011	3/27	5/25		0.35%	0.56[0.15,2.09]
Metz 2007	31/99	33/191		1.84%	1.81[1.18,2.77]
Ockene 1991	90/649	64/574		2.45%	1.24[0.92,1.68]
Osinubi 2003	5/30	2/29		0.26%	2.42[0.51,11.48]
Peterson 2016	116/1058	117/1093		2.76%	1.02[0.8,1.31]
Prochaska 1993	17/187	23/191		1.25%	0.75[0.42,1.37]
Prochaska 2001	25/361	25/362		1.43%	1[0.59,1.71]
Reid 2007	23/50	17/49		1.59%	1.33[0.81,2.16]
Rigotti 2006	10/209	7/210		0.62%	1.44[0.56,3.7]
Sorensen 2007a	19/125	7/106		0.77%	2.3[1.01,5.26]
Stotts 2002	10/134	14/135		0.85%	0.72[0.33,1.56]
Tzelepis 2011a	11/769	6/793		0.58%	1.89[0.7,5.09]
Velicer 2006	42/500	41/509		1.9%	1.04[0.69,1.57]
Young 2008	13/169	9/149		0.78%	1.27[0.56,2.89]



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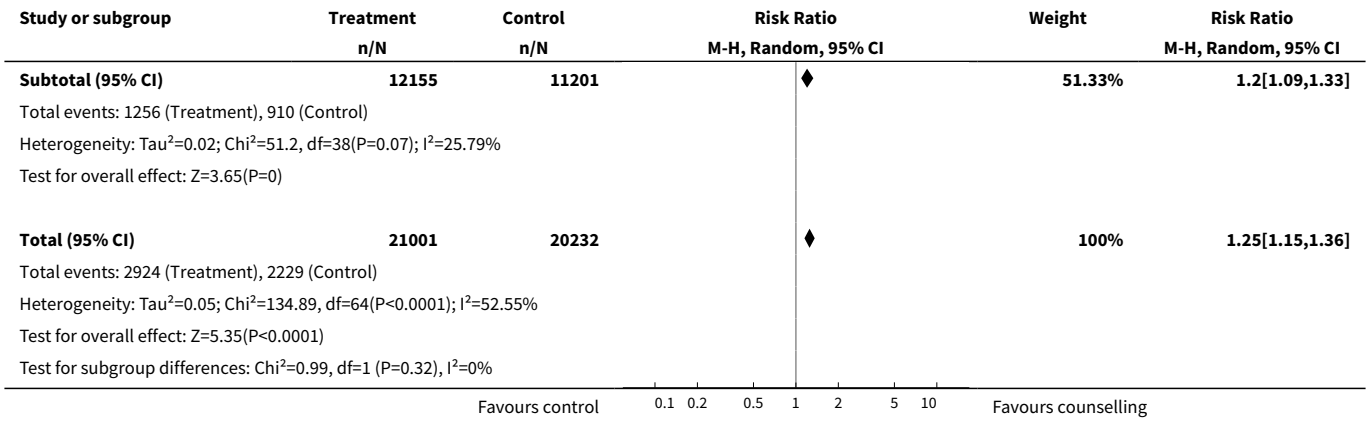


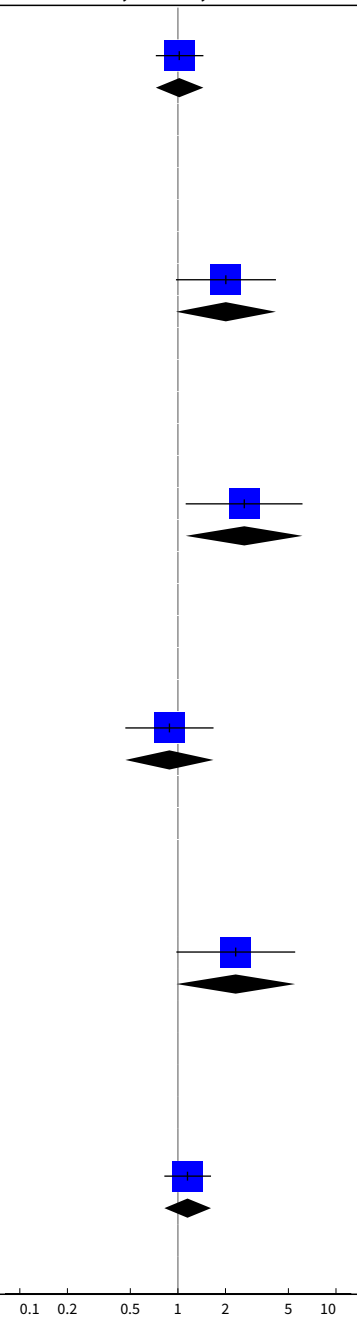
Comparison 10. Other studies

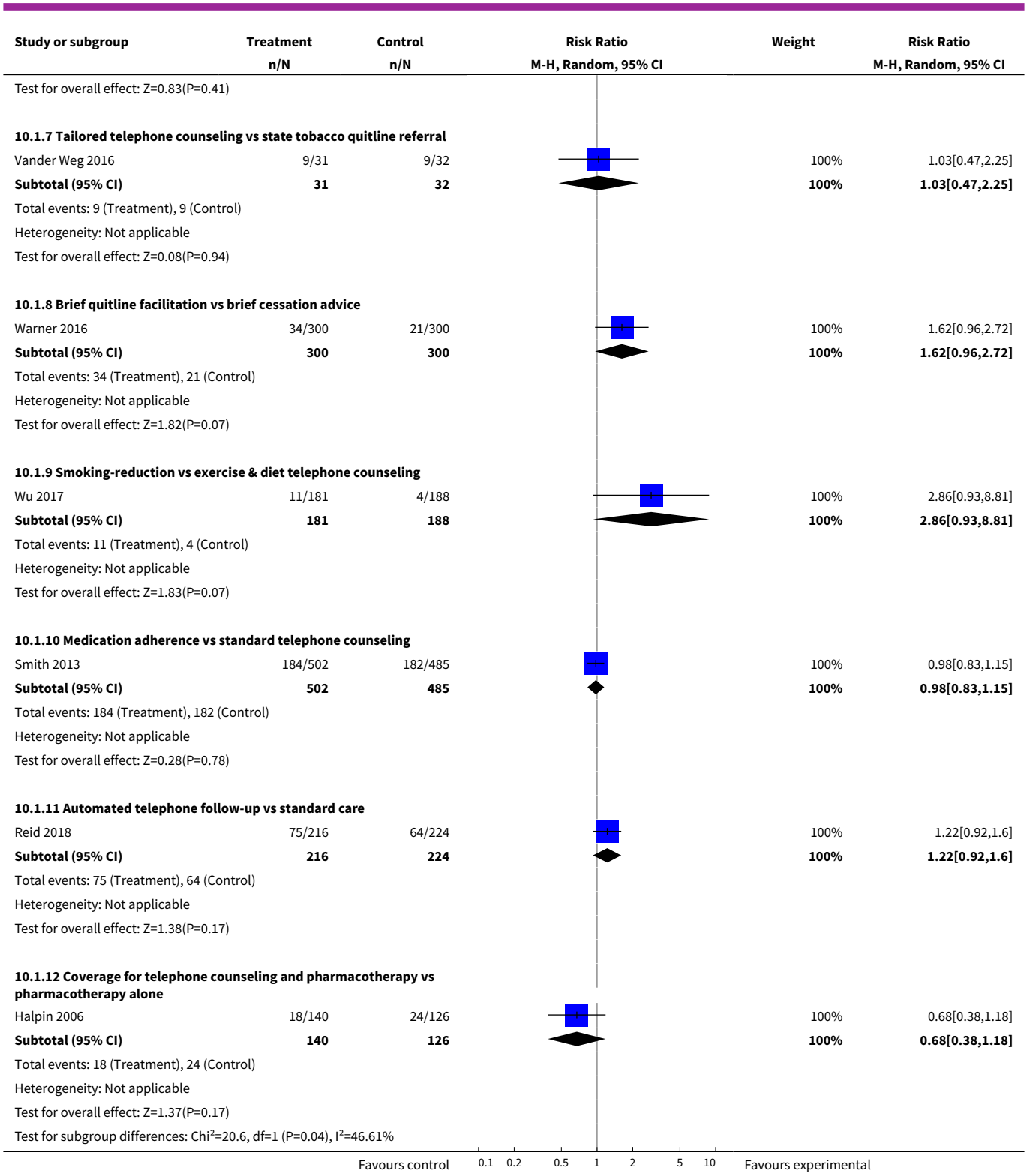
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cessation at longest follow-up	10		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 Family-supported vs standard telephone counseling	1	471	Risk Ratio (M-H, Random, 95% CI)	1.02 [0.72, 1.45]
1.2 Parental focused telephone counseling vs nutrition counseling	1	327	Risk Ratio (M-H, Random, 95% CI)	2.01 [0.97, 4.17]
1.3 Brief motivational vs standard telephone counseling	1	374	Risk Ratio (M-H, Random, 95% CI)	2.63 [1.12, 6.14]
1.4 Smoking reduction vs brief motivational telephone counseling	1	371	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.47, 1.68]
1.5 Smoking reduction vs standard telephone counseling	1	375	Risk Ratio (M-H, Random, 95% CI)	2.32 [0.98, 5.52]
1.6 Nondirective vs directive telephone coaching	1	518	Risk Ratio (M-H, Random, 95% CI)	1.15 [0.82, 1.62]
1.7 Tailored telephone counseling vs state tobacco quitline referral	1	63	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.47, 2.25]
1.8 Brief quitline facilitation vs brief cessation advice	1	600	Risk Ratio (M-H, Random, 95% CI)	1.62 [0.96, 2.72]
1.9 Smoking-reduction vs exercise & diet telephone counseling	1	369	Risk Ratio (M-H, Random, 95% CI)	2.86 [0.93, 8.81]
1.10 Medication adherence vs standard telephone counseling	1	987	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.83, 1.15]
1.11 Automated telephone follow-up vs standard care	1	440	Risk Ratio (M-H, Random, 95% CI)	1.22 [0.92, 1.60]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.12 Coverage for telephone counseling and pharmacotherapy vs pharmacotherapy alone	1	266	Risk Ratio (M-H, Random, 95% CI)	0.68 [0.38, 1.18]

Analysis 10.1. Comparison 10 Other studies, Outcome 1 Cessation at longest follow-up.

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
10.1.1 Family-supported vs standard telephone counseling					
Bastian 2012	51/235	50/236		100%	1.02[0.72,1.45]
Subtotal (95% CI)	**235**	**236**		**100%**	**1.02[0.72,1.45]**
Total events: 51 (Treatment), 50 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.14(P=0.89)					
10.1.2 Parental focused telephone counseling vs nutrition counseling					
Collins 2018	20/163	10/164		100%	2.01[0.97,4.17]
Subtotal (95% CI)	**163**	**164**		**100%**	**2.01[0.97,4.17]**
Total events: 20 (Treatment), 10 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.88(P=0.06)					
10.1.3 Brief motivational vs standard telephone counseling					
Klemperer 2017	18/185	7/189		100%	2.63[1.12,6.14]
Subtotal (95% CI)	**185**	**189**		**100%**	**2.63[1.12,6.14]**
Total events: 18 (Treatment), 7 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=2.23(P=0.03)					
10.1.4 Smoking reduction vs brief motivational telephone counseling					
Klemperer 2017	16/186	18/185		100%	0.88[0.47,1.68]
Subtotal (95% CI)	**186**	**185**		**100%**	**0.88[0.47,1.68]**
Total events: 16 (Treatment), 18 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.38(P=0.71)					
10.1.5 Smoking reduction vs standard telephone counseling					
Klemperer 2017	16/186	7/189		100%	2.32[0.98,5.52]
Subtotal (95% CI)	**186**	**189**		**100%**	**2.32[0.98,5.52]**
Total events: 16 (Treatment), 7 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.91(P=0.06)					
10.1.6 Nondirective vs directive telephone coaching					
Sumner 2016	57/260	49/258		100%	1.15[0.82,1.62]
Subtotal (95% CI)	**260**	**258**		**100%**	**1.15[0.82,1.62]**
Total events: 57 (Treatment), 49 (Control)					
Heterogeneity: Not applicable					





APPENDICES

Appendix 1. Specialised Register Search Strategy

Searched using CRS (Cochrane Register of Studies software)

#1 MeSH DESCRIPTOR Hotlines
#2 (telephone* OR phone* OR quitline* OR helpline):TI,XKY,MH,EMT,KW
#3 (quitline* OR helpline):AB
#4 ((telephone* NEAR counsel*) OR (phone NEAR counsel*)):AB
#5 #1 OR #2 OR #3 OR #4

MH - MeSH descriptor. EMT - Embase descriptor. KW & XKY - other keywords including those assigned as part of Tobacco addiction group coding

Appendix 2. Results of meta-regression

Mixed-Effects Model (k = 67; tau^2 estimator: DL)

I^2 (residual heterogeneity/unaccounted variability): 49.91%

R^2 (amount of heterogeneity accounted for): 0.87%

Test for Residual Heterogeneity:

QE(df = 61) = 121.7906, p-value < 0.0001

Test of Moderators (all coefficient included):

QM(df = 5) = 10.4926, p-value = 0.0264

Parameter	β	(95% CI)	RRC[a]	(95% CI)	P value
Intercept	−0.17	(−0.45 to 0.12)	0.85	(0.64 to 1.13)	0.25
Baseline Support	-	-	-	-	-
Pharmacotherapy	0	Reference	1.00	Reference	
Self-help	0.30	(0.10 to 0.51)	1.35	(1.10 to 1.67)	< 0.01
Brief intervention	0.31	(0.05 to 0.58)	1.37	(1.05 to 1.79)	0.02
Incentives	−0.12	(−0.75 to 0.51)	0.89	(0.47 to 1.67)	0.71
Per each additional call	0.02	(−0.02 to 0.05)	1.02	(0.98 to 1.05)	0.29
Selected for motivation	-	-	-	-	-
No	0.00	Reference	1.00	Reference	-
Yes	0.23	(0.04 to 0.42)	1.26	(1.04 to 1.52)	0.02

[a]RRC: Relative Risk Change compared to reference category (categorical moderators) and no change in units (continuous moderator).

WHAT'S NEW

Date	Event	Description
30 October 2018	New citation required but conclusions have not changed	30 new studies added, no major change to conclusions. Additional authors: WM and JMOM
3 May 2018	New search has been performed	Searches updated

HISTORY

Protocol first published: Issue 4, 2000
Review first published: Issue 2, 2001

Date	Event	Description
23 October 2013	Amended	Information added to ongoing studies tables.
20 June 2013	New search has been performed	Searches updated
20 June 2013	New citation required but conclusions have not changed	Twelve new studies added, no major change to conclusions. Additional author JHB.
12 May 2009	New search has been performed	Updated for issue 3, 2009. Nineteen new studies, no change to conclusions, strengthened evidence of effect overall and for some subgroups.
4 August 2008	Amended	Converted to new review format.
11 April 2006	New citation required but conclusions have not changed	Updated for Issue 3, 2006. Twenty two new studies, studies of relapse prevention now excluded. Comparisons reorganised, additional subgroup analyses.
14 October 2002	New citation required but conclusions have not changed	Updated for Issue 1, 2003. Four new trials, of which 3 contribute to meta-analysis. No major changes to conclusions

CONTRIBUTIONS OF AUTHORS

JH-B became an author from 2013 and contributed to extracting data and updating the text.
WM became an author in 2018 and contributed to titles, abstracts, and full-text screening, data extraction, meta-analyses, and updating the text.
JMOM became an author in 2018 and contributed to titles, abstracts, and full-text screening, data extraction, meta-analyses, meta-regression and updating the text.

DECLARATIONS OF INTEREST

WM: none known.
JOM: none known.
JHB: none known.

SOURCES OF SUPPORT

Internal sources

- National Institute for Health Research (NIHR) School for Primary Care Research, UK.
- Department of Primary Care Health Sciences, University of Oxford, UK.
- NIHR Community Healthcare Medtech and In Vitro Diagnostics Cooperative (MIC), UK.

Partly funded the work of JMOM
- NIHR Biomedical Research Centre, Oxford, UK.

Partly funded the work of JMOM

External sources

- NHS Research & Development Programme, UK.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

As of the 2018 update of the review, we changed the meta-analyses from a fixed-effect to a random-effects model, in line with new Cochrane Tobacco Addiction Group policy, to account for the expected variability in the interventions delivered.

For this update, we added two new post hoc subgroup analyses, looking at baseline support provided and intensity of counselling, operationalised as the number of phone calls offered.

INDEX TERMS

Medical Subject Headings (MeSH)

*Telephone; Counseling [*methods]; Hotlines; Randomized Controlled Trials as Topic; Smoking Cessation [*methods] [*statistics & numerical data]

MeSH check words

Adult; Female; Humans; Male; Middle Aged; Pregnancy