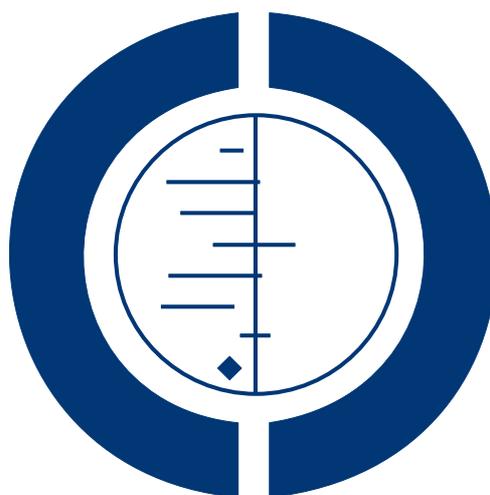


# Telephone counselling for smoking cessation (Review)

Stead LF, Perera R, Lancaster T



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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 proactive and reactive telephone support via helplines and in other settings to help smokers quit.

### Search strategy

We searched the Cochrane Tobacco Addiction Group trials register for studies using free text term 'telephone\*' or the keywords 'telephone counselling' or 'Hotlines' or 'Telephone'. Date of the most recent search: March 2009.

### Selection criteria

Randomized or quasi-randomized controlled trials in which proactive or reactive telephone counselling to assist smoking cessation was offered to smokers or recent quitters.

### Data collection and analysis

Trials were identified and data extracted by one person (LS) and checked by a second (TL). The main outcome measure was the risk ratio for abstinence from smoking after at least six months follow up. We selected the strictest measure of abstinence, using biochemically validated rates where available. We considered participants lost to follow up to be continuing smokers. Where trials had more than one arm with a less intensive intervention we used only the most similar intervention without the telephone component as the control group in the primary analysis. We assessed statistical heterogeneity amongst subgroups of clinically comparable studies using the  $I^2$  statistic. Where appropriate, we pooled studies using a fixed-effect model. A meta-regression was used to investigate the effect of differences in planned number of calls.

### Main results

Sixty-five trials met the inclusion criteria. Among smokers who contacted helplines, quit rates were higher for groups randomized to receive multiple sessions of proactive counselling (nine studies, >24,000 participants, risk ratio (RR) for cessation at longest follow up 1.37, 95% confidence interval (CI) 1.26 to 1.50). There was mixed evidence about whether increasing the number of calls altered quit rates but most trials used more than two calls. Two studies comparing different counselling approaches during a single quitline contact

did not detect significant differences. Of three studies that provided access to a hotline two detected a significant benefit and one did not.

Telephone counselling not initiated by calls to helplines also increased quitting (44 studies, >24,000 participants, RR 1.29, 95% CI 1.20 to 1.38). In the subgroup of studies offering 1-2 calls the effect was small and not significant.

A further seven studies were too diverse to contribute to meta-analyses and are discussed separately.

### Authors' conclusions

Proactive telephone counselling helps smokers interested in quitting. There is some evidence of a dose response; one or two brief calls are less likely to provide a measurable benefit. Three or more calls increase the chances of quitting compared to a minimal intervention such as providing standard self-help materials, brief advice, or compared to pharmacotherapy alone. Telephone quitlines provide an important route of access to support for smokers, and call-back counselling enhances their usefulness.

## PLAIN LANGUAGE SUMMARY

### Is telephone counselling effective as part of a programme help people stop smoking

Smoking contributes to many health problems including cancers and heart and lung diseases. People trying to quit smoking can be helped with medication or through behavioural support such as specialist counselling and group therapy. Support, information and counselling are offered either face-to-face or by telephone. Counselling via telephone hotlines can be provided as part of a programme or separately, and can potentially reach large numbers of people. Our review of trials found telephone counselling to be effective; multiple sessions are likely to be most helpful.

## BACKGROUND

Behavioural and pharmacological interventions help people to quit smoking. Behavioural approaches range from brief advice from a physician to intensive specialist counselling (Stead 2008; Lancaster 2005a; Stead 2005). Support can be given in individual counselling sessions (Lancaster 2005a) or in group therapy (Stead 2005) where clients can share problems and derive support from one another. Standard self-help materials have at best a small effect helping quitting while those tailored to the characteristics of individuals are more likely to be effective (Lancaster 2005b). Telephone counselling may supplement face-to-face support, or substitute for face-to-face contact as an adjunct to self-help interventions or pharmacotherapy. Counselling may be helpful in planning a quit attempt, and helping prevent relapse during the initial period of abstinence (Brandon 2000). Although intensive face-to-face intervention increases quit rates, there are difficulties in delivering it to large numbers. Telephone counselling may be a way of providing individual counselling more cheaply. 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.

Telephone counselling can be proactive or reactive (Lichtenstein 1996). In a proactive approach the counsellor initiates one or more

calls to provide support in making a quit attempt or avoiding relapse. This can be offered as part of an intervention including face-to-face counselling, or provided as an adjunct to a mailed self-help programme, or to pharmacotherapy. 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 (Ossip-Klein 2003; Anderson 2007). They 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. When contact is initiated by the client, any counselling during a call is reactive. In some services, people may be enrolled in a formal programme, with further proactive calls from counsellors (Zhu 1996; Zhu 2000; Anderson 2007; Cummins 2007a). Hotlines 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 under-served populations such as ethnic minorities (Zhu 2000) or younger people (Gilbert

2005; Chan 2008). A further development of hotlines uses computers and expert systems to provide a menu of automated responses (Burke 1993; Schneider 1995; Ramelson 1999).

Telephone-based services may be specific to smoking, as for example the California Smokers' Helpline (Zhu 2000), the Quitlines in Australia (Borland 2001) or in the UK (Owen 2000), or they may be embedded in broader health information services such as the Cancer Information Service in the USA (La Porta 2007). They 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 a part of a cessation programme including pharmacotherapy.

Controlled evaluation of reactive helplines has been limited by a reluctance among providers to refuse support to those requesting help. Evaluations usually compare variants in service rather than including a no-intervention control (e.g. Thompson 1993; Orleans 1998). Proactive services have been more widely evaluated because they can more easily be compared with a minimal intervention. For example, Zhu 2002 used an innovative approach for evaluating the benefit of the counselling component for callers to a quitline. Because the number of requests for counselling sometimes exceeded the quitline's capacity, all callers at these times were sent a self-help pack and invited to call back. Counselling capacity could then be equitably allocated by randomizing some callers to a group who were contacted proactively, whilst the control group were counselled only if and when they called back.

## OBJECTIVES

The review evaluated 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 cessation interventions alone?
- Do telephone calls from a counsellor increase quit rates compared to pharmacotherapy 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? There were limited data to address this question
- Does the availability of a reactive helpline increase quit rates?

## METHODS

### Criteria for considering studies for this review

#### Types of studies

Randomized or quasi-randomized controlled trials, with the unit of allocation individual participants, group, intervention site or geographical area.

#### Types of participants

Smokers or recent quitters. 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 (Hajek 2009). We included trials recruiting exclusively teens 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 (Lumley 2004; Grimshaw 2006).

#### 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 face-to-face counselling. We included studies which combined telephone counselling with self-help materials as the effect of self-help materials alone is limited (Lancaster 2005b).

#### Types of outcome measures

Smoking cessation at least six months after the start of intervention. We excluded trials with shorter follow up.

#### Search methods for identification of studies

We identified studies from the Tobacco Addiction Group Specialised Register using the free text terms 'telephone\*', 'quitline\*' or 'helpline\*' or the keywords 'telephone counselling' or 'Hotlines' or 'Telephone'. This register incorporates the results of systematic searches for trials on tobacco addiction in MEDLINE, EMBASE, PsycINFO and Science Citation Index electronic databases and includes trials reported in conference abstracts including Society for Research on Nicotine and Tobacco meetings. The register was searched in March 2009 for records indexed in these databases in mid February 2009. More recent papers were identified by a search of PubMed on 11th March 2009 using the search (('telephone\*' or 'quitline\*' or 'helpline\*') and smoking).

## Data collection and analysis

We identified controlled studies where an intervention arm included telephone contact. Data from included studies were extracted by one author (LS) and checked by a second (TL). We recorded the following information in the [Characteristics of included studies](#) table and in the [Risk of bias in included studies](#) table:

- The country and setting of the trial
- The method of recruitment to the study
- The method of randomization and allocation concealment
- Details of participants, including whether they were selected according to motivation to quit, and their age, sex 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 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](#) table, we describe studies not meeting the inclusion criteria because of short follow up, or use of an intervention that combined telephone and face-to-face counselling, or because they were uncontrolled evaluations of helplines.

## Assessment of risk of bias

Items in the risk of bias table were judged adequate (Yes), unclear, or having potential for bias (No) for each study.

The quality of the procedure for sequence generation was judged adequate if a method for generating a randomization sequence was described, unclear if the study was described as 'random' but no further information given, and potentially biased if based on, for example, record number.

The quality of the allocation concealment was judged adequate if the group to which a participant was to be allocated remained unknown to investigators and participant until enrolment was complete.

## Choice of outcome & 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 and/or 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 randomized 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 socio-economic status. Drop-out 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 generalized 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 summarized individual study results as a risk ratio (RR), calculated as: (number of quitters in intervention group/ number randomized to intervention group) / (number of quitters in control group/ number randomized to control group). Where appropriate we performed meta-analysis using a Mantel-Haenszel fixed-effect method to estimate a pooled risk ratio with 95% confidence intervals (Greenland 1985). 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.

We also ran a meta-regression in STATA to test the association of intensity - defined as maximum number of calls - with effect size. The effect size was summarized using the (natural) logarithm of the risk ratio per trial with weights given by the standard error of the logarithm of the risk ratio. The only independent variable used was intensity defined as the maximum number of calls allowed in the intervention arm of the trial.

## Subgroup analysis and investigation of heterogeneity

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 early 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 (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 in other populations.

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. Therefore a priori we treated as separate subgroups those studies in which telephone counselling was the most intensive component of a minimal contact intervention and studies in which telephone counselling was assessed as an adjunct to face-to-face counselling. 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, the counselling strategy used, and the characteristics of the participants, in particular their motivation to quit or stage of change at baseline.

## RESULTS

### Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

Sixty-five controlled studies met the criteria for inclusion in the review, with a total of almost 73,000 participants, and a median trial size of 820. Only four studies had fewer than 100 participants (Brown 1992; Osinubi 2003; Duffy 2006; Ebbert 2007), whilst six studies, all involving callers to quitlines, had more than 3,000 (Zhu 1996; Zhu 2002; Rabius 2004; Hollis 2007; Rabius 2007; Joyce 2008)

Most trials were conducted in North America (52). Six were in Australia (Brown 1992; Borland 2001; Borland 2003; MacLeod 2003; Borland 2008; Young 2008), two in Spain (Miguez 2002; Miguez 2008), two in the UK (Aveyard 2003; Gilbert 2006), one in Hong Kong (Abdullah 2005), one in Norway (Hanssen 2007), and one in Germany (Metz 2007). Participants were predominantly older adults with an average age typically in the 40s. One study recruited teenagers (Lipkus 2004), and three recruited older people aged over 50 (Rimer 1994), over 60 (Ossip-Klein 1997), or over 65 (Joyce 2008). Three recruited pregnant women (McBride 1999b; Stotts 2002; McBride 2004) and a further four recruited only women (McBride 1999a; Solomon 2000; McClure 2005;

Solomon 2005). Four predominantly recruited men (Osinubi 2003; Abdullah 2005; An 2006; Sorensen 2007a).

Most of the studies were trials of proactive calls from a counsellor, or from an automated interactive voice response system (IVR) (Velicer 2006, IVR only; Reid 2007 IVR with counsellor follow up in case of need). Only five assessed interventions that did not involve a counsellor contacting a participant (Ossip-Klein 1991; McFall 1993; Thompson 1993; Orleans 1998; Sood 2009). Seven studies recruited participants who had phoned a quitline, but the intervention evaluated the addition of further proactive contacts (Borland 2001; Borland 2003; Rabius 2004; Smith 2004; Gilbert 2006; Hollis 2007; Rabius 2007). Three studies recruited participants in healthcare settings and referred them to services provided by quitlines, involving proactive counselling for those following through referral (Duffy 2006; Ebbert 2007; Borland 2008). One study offered either a proactive or reactive service as covered benefit (Joyce 2008). Additional details are in the [Characteristics of included studies](#) table.

The number, duration and content of the telephone calls was variable. The potential number of calls ranged from one to twelve (Solomon 2005) and in some studies was flexible. The length of calls was also varied; a duration of 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 individualized 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), in the other two, women ex-smokers (Solomon 2000; Solomon 2005).

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 six trials (Miller 1997; Hennrikus 2002; Roski 2003; Swan 2003; Katz 2004; Halpin 2006) that do not fit into any of these categories, so are considered individually.

### I Trials of interventions for people calling helplines

Twelve 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. Nine studies tested proactive calls back to people who had initiated the contact with the quitline. The number of calls varied, with three studies comparing more than one schedule. 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 (Zhu 2002; Borland 2003; Gilbert 2006) and in the others the control group received self-help materials (Zhu 1996; Rabiuss 2004; Smith 2004; Hollis 2007; Rabiuss 2007).

Three 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. Thompson 1993 and Orleans 1998 compared different counselling interventions provided during the initial call; Thompson 1993 compared a counselling approach based on the stage of change model to the provision of more general information; Orleans 1998 compared counselling and materials targeted at African-American smokers to standard advice and materials.

## 2 Trials providing access to a helpline

Two studies assessed the impact of offering reactive counselling by providing access to a helpline/quitline/hotline. One randomized 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 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). Joyce 2008 compared four different levels of benefit for Medicare beneficiaries aged 65 or older. The most intense 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.

## 3 Trials of proactive counselling, not initiated by calls to quitlines

There were 44 trials in this category that were judged to have sufficient common features 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.

### 3.1 Studies with minimal intervention controls

In 19 studies (Orleans 1991; Lando 1992; Prochaska 1993; Rimer 1994; Curry 1995; Ossip-Klein 1997; McBride 1999a; McBride 1999b; Lichtenstein 2000; Prochaska 2001; Miguez 2002; Aveyard 2003; Lipkus 2004; Abdullah 2005; Emmons 2005; McClure 2005; Sorensen 2007a; Lichtenstein 2008; Miguez 2008) proactive telephone counselling calls were the only form of personal contact in the cessation intervention, and the control groups had mailed self-help materials. In six studies in health-care settings the telephone intervention was an adjunct to usual care that involved at most a brief smoking intervention (Stotts 2002; Duffy 2006; Rigotti 2006; Hanssen 2007; Holmes-Rovner

2008; Young 2008). In two further studies that recruited patients 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 (Lipkus 1999; An 2006;). 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 (McClure 2005; An 2006). 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. An 2006 encouraged the use of nicotine replacement therapy (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.

### 3.2 Studies with brief intervention/counselling controls

Nine trials incorporated what we judged to be more substantial face-to-face advice for all participants, but without systematic use of pharmacotherapy (Ockene 1991; Brown 1992; Osinubi 2003; McBride 2004; Chouinard 2005; Metz 2007; Ebbert 2007; Reid 2007; Borland 2008). The support common to all participants ranged from 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 Ockene 1991; Borland 2008) or hygienist/dentist (Ebbert 2007); advice from an occupational physician to consult a personal physician (Osinubi 2003); inpatient nurse counselling (Chouinard 2005; Reid 2007); or multisession group counselling (Metz 2007).

### 3.3 Studies of counselling added to pharmacotherapy

Nine trials provided telephone counselling as an adjunct to pharmacotherapy. In eight trials there was a systematic offer or provision of NRT (Ockene 1991; Lando 1997; Reid 1999; Solomon 2000; MacLeod 2003; Fiore 2004; Solomon 2005; Velicer 2006). Boyle 2007 recruited health maintenance organization (HMO) members who were filling a prescription for any cessation medication. The support common to all participants in other trials ranged from: physician advice and 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 1999); a single 90 minute session, a free prescription for nicotine patch and access to a helpline (Lando 1997), or provision of free nicotine patch (two week supply only) but no face-to-face contact (MacLeod 2003; Solomon 2000; Solomon 2005; Velicer 2006). Velicer 2006 provided nicotine patch to participants meeting criteria for readiness to make a quit attempt; 86% received some during the study.

### 3.4 Telephone counselling intensity

The number of calls and the period over which they were delivered in this group of 44 studies was very varied. A summary is given 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	Lando 1992; Lipkus 1999; Lichtenstein 2000; Lichtenstein 2008	Ossip-Klein 1997; Stotts 2002 (in late pregnancy)	Rimer 1994	
3 calls	Ebbert 2007,	Ockene 1991; Curry 1995; McBride 1999a; Reid 1999; Lipkus 2004; Abdullah 2005	Prochaska 2001; Aveyard 2003	McBride 1999b (part, during pregnancy)
4 calls	Young 2008	Lando 1997; Reid 2007 (average 2 automated and 2 counsellor)	Prochaska 1993; McClure 2005	Orleans 1991
5 calls		MacLeod 2003; Osinubi 2003; Metz 2007		Rigotti 2006 (4 in pregnancy and 1 postpartum)
6 calls	Brown 1992	Miguez 2002; Chouinard 2005; Sorensen 2007a; Borland 2008; Holmes-Rovner 2008	Emmons 2005	McBride 1999b (part) & McBride 2004 (3 during pregnancy & 3 postpartum)
7 or more		Solomon 2000; An 2006	Boyle 2007 (up to 9, average 5); Duffy 2006 (9-11); (Hanssen 2007 (9)); (Velicer 2006 (up to 10 automated calls); (Solomon 2005 (up to 12).	

The average number of calls, where reported, is typically considerably smaller than the maximum available. For studies where the intervention involved a process of referral to proactive support from another source (e.g. An 2006; Ebbert 2007; Borland 2008; Young 2008), the proportion of participants reached and accepting counselling was small, but those accepting intervention generally had multisession support

### 3.5 Recruitment and motivation of participants

We attempted to categorise this set of 44 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 14 trials in the 'Selected' subgroup, nine recruited from the general population using advertisements for smokers planning to or interested in quit-

ting (Orleans 1991; Brown 1992; Rimer 1994; Ossip-Klein 1997; Solomon 2000; Miguez 2002; MacLeod 2003; Solomon 2005; Miguez 2008). Two recruited during healthcare visits (Fiore 2004; Reid 1999); Lando 1997 and Boyle 2007 recruited HMO members, and An 2006 mailed invitations to patients of Veterans Administration Medical Centres.

There were 30 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; Stotts 2002; McBride 2004; Rigotti 2006); 11 recruited people during healthcare visits including in family practices, dental practices and hospitals (Ockene 1991; Osinubi 2003; Chouinard 2005; Duffy 2006; Ebbert 2007; Hanssen 2007; Metz 2007; Reid 2007; Borland 2008; Holmes-Rovner 2008; Young 2008); five others recruited via healthcare system records (Lipkus 1999; Prochaska 2001; Aveyard 2003; McClure 2005; 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, Abdullah 2005 recruited smoking parents of children in a birth cohort study, Emmons 2005 recruited smokers from a cohort study of childhood cancer survivors, 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 (Lando 1992; Curry 1995; McBride 1999a).

#### 4. Other studies

We identified six other studies where we judged the nature of the main intervention or the conditions compared to be so distinctively different to any other included studies that they are described separately rather than being pooled.

Two studies (Roski 2003; Katz 2004) used telephone counselling as a core component of a system level intervention. Roski 2003 investigated providing access to a telephone counselling referral service as a means to increase healthcare providers' adherence to clinical practice guidelines. Patient smoking outcomes were assessed but telephone counselling was not offered to all eligible smokers in intervention clinics. Katz 2004 also tested an intervention based on clinical practice guidelines. The intervention was implemented in primary care clinics and included training intake clinicians in giving brief advice, recording smoking status as a vital sign, and offering telephone counselling for smokers willing to set a quit date. Nicotine replacement therapy (NRT) was also offered to heavier smokers.

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, US\$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. Hennrikus 2002 was a cluster randomized study in workplaces that compared the provision of telephone counselling, a group format programme, or a choice of programme format.

Two studies (Miller 1997; Swan 2003) did not have a no-telephone support control and compared interventions with different numbers of calls. Miller 1997 assessed the effect of increasing the amount of telephone follow up after an inpatient counselling intervention. Swan 2003 compared two intensities of behavioural support, both of which involved telephone contact without face-to-face support, for smokers also randomized to one of two doses of bupropion.

#### Risk of bias in included studies

A summary of the evaluation of risk of bias for each study is shown in Figure 1.

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

	Random sequence generation?	Allocation concealment?	Incomplete outcome data addressed?
Abdullah 2005	?	?	?
An 2006	?	?	?
Averyard 2003	?	?	?
Borland 2001	?	?	?
Borland 2003	?	?	?
Borland 2004	?	?	?
Boyle 2007	?	?	?
Brown 1992	?	?	?
Chouinard 2005	?	?	?
Curry 1995	?	?	?
Duffy 2006	?	?	?
Ebbert 2007	?	?	?
Emmons 2005	?	?	?
Fiore 2004	?	?	?
Gilbert 2006	?	?	?
Halpin 2006	?	?	?
Hanssen 2007	?	?	?
Henrikus 2002	?	?	?
Hollis 2007	?	?	?
Holmes-Romer 2006	?	?	?
Joyce 2006	?	?	?
Kiatz 2004	?	?	?
Lando 1992	?	?	?
Lando 1997	?	?	?
Lichtenstein 2000	?	?	?
Lichtenstein 2006	?	?	?
Lipkus 1995	?	?	?
Lipkus 2004	?	?	?
MacLeod 2003	?	?	?
McBride 1999a	?	?	?
McBride 1999b	?	?	?
McBride 2004	?	?	?
McClure 2005	?	?	?
McFall 1993	?	?	?
Metz 2007	?	?	?
Miguez 2002	?	?	?
Miguez 2006	?	?	?
Miller 1997	?	?	?
Ockene 1991	?	?	?
Orleans 1991	?	?	?
Orleans 1998	?	?	?
Osuobi 2003	?	?	?
Ossip-Klein 1991	?	?	?
Ossip-Klein 1997	?	?	?
Prochaska 1993	?	?	?
Prochaska 2001	?	?	?
Rabius 2004	?	?	?
Rabius 2007	?	?	?
Reid 1995	?	?	?
Reid 2007	?	?	?
Rigotti 2006	?	?	?
Rimer 1994	?	?	?
Roski 2003	?	?	?
Smith 2004	?	?	?
Solomon 2000	?	?	?
Solomon 2005	?	?	?
Soed 2006	?	?	?
Sorensen 2007a	?	?	?
Stots 2002	?	?	?
Swan 2003	?	?	?
Thompson 1993	?	?	?
Velicer 2006	?	?	?
Young 2006	?	?	?
Zhu 1998	?	?	?
Zhu 2002	?	?	?

## Allocation

All studies described treatment allocation as random, but few gave clear details about the method for generating the sequence. Methods for concealing the allocation were also poorly reported. Only 12 (18%) reported sufficient detail to be classified as adequate for avoiding selection bias (Miller 1997; Aveyard 2003; Swan 2003; Katz 2004; Smith 2004; Abdullah 2005; Chouinard 2005; Gilbert 2006; Rigotti 2006; Velicer 2006; Reid 2007; Sood 2009). Concealment was judged to be potentially inadequate in four cases (Zhu 1996; Orleans 1998; MacLeod 2003; Ebbert 2007). In two of these, allocation was based on the digits of a phone number (Orleans 1998; Zhu 1996). Because of the small number of studies with clear information, not all of which contributed to a meta-analysis, we did not conduct any sensitivity analyses based on quality of concealment.

Eleven trials used cluster randomization, six of which contributed to a meta-analysis. In two of these, households were the unit of randomization, and about 54% of households contained more than one smoker (Lichtenstein 2000; Lichtenstein 2008). The reported intra-class correlation was small. Borland 2008 randomized general practitioners. The reported odds ratio that adjusted for clustering and other factors was similar to that generated by the crude data. Lando 1997 randomized by orientation session attended. Chouinard 2005 randomized clusters of two to six participants. Ebbert 2007 randomized by dental practice. Excluding these studies did not alter any meta-analysis findings. The other five were not pooled 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), another randomized four workplaces to each of six conditions, (Hennrikus 2002). Joyce 2008 randomized areas within states to different Medicare benefits. The other two randomized clinics to different organisational support systems (Roski 2003; Katz 2004).

## Incomplete outcome data

All studies reported the numbers randomized to each group, so that we could use these in the meta-analysis. Most studies reported findings based on treating all drop-outs 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 drop-outs), 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.

## Other potential sources of bias

### Validation of self-reported abstinence

The studies in quitline callers typically did not attempt to use biochemical verification of self-reported quitting. Two tested a local convenience sample (Zhu 1996; Rabinus 2004).

Studies in other settings were more likely to require biochemical verification of all self-reported abstinence. Ossip-Klein 1991, Lando 1992 and Aveyard 2003 measured cotinine levels. Lando 1997, Miguez 2002, Fiore 2004 and Rigotti 2006 measured carbon monoxide (CO) levels. Chouinard 2005 used a mixture of CO and cotinine assessment. Miller 1997 tested for cotinine but allowed family member verification of some self-reports. Some other studies attempted biochemical verification but did not report validated abstinence (Orleans 1991; Brown 1992; Thompson 1993; Curry 1995; McBride 1999a; McBride 1999b; Reid 1999; Solomon 2000; Hennrikus 2002; Katz 2004; Lipkus 2004; McBride 2004; McClure 2005). Stotts 2002 validated abstinence at an early follow up.

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

### Definitions of abstinence

Many trials reported both short-term point prevalence (seven day or 24-hour) abstinence and sustained abstinence, at one or more follow ups. We were able to use long-term sustained abstinence, or abstinence at both the longest and earlier follow ups as the outcome for 39/65 (60%) trials. 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 (Abdullah 2005; Ockene 1991; Orleans 1998 (12 month follow up not reported for entire sample); Ossip-Klein 1997; Solomon 2000; Swan 2003), to 30 months (Velicer 2006) or 12 months postpartum (McBride 2004). One trial reported both self-reported continuous abstinence and validated seven day abstinence (Abdullah 2005). We used the validated outcome; this gave a larger effect favouring the intervention group. We include one trial based on preliminary 12 month data for 75% of the original cohort (Rimer 1994).

## Effects of interventions

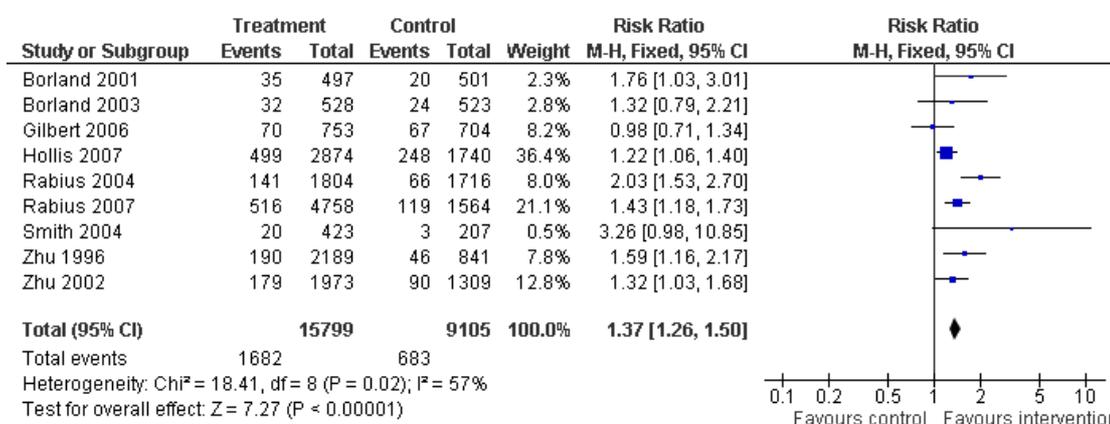
### I Trials of interventions for people calling helplines

#### I.1 Effect of additional proactive support

Nine studies that compared multisession proactive counselling to provision of self-help materials or brief counselling at a single call showed evidence of a benefit from the additional support, moderately consistent across studies ( $I^2 = 57\%$ ). The pooled risk ratio (RR) was 1.37 (N = 24,904; 95% CI 1.26 to 1.50; Figure 2, Comparison 1.1). In the main analysis we pooled more than one intensity of intervention into the treatment arms of four studies (Zhu 1996; Smith 2004; Hollis 2007; Rabinus 2007). Using only the more intensive interventions in the two trials that reported outcomes for two different interventions (Zhu 1996; Hollis 2007)

marginally increased the pooled effect size (data not shown). Smith 2004 did not detect a difference between groups receiving two or six follow-up calls after an initial 50 minute session, and results have not been reported separately. Rabinus 2007 tested six different intervention formats, varying the number of calls, their duration and the use of 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

**Figure 2. Comparison 3. Interventions for callers to quitlines. Cessation at longest follow-up**



Using only the Hollis 2007 trial data for intervention and control arms that were not offered nicotine replacement therapy (NRT) also had minimal impact on the pooled effect. Direct comparison between the more and less intensive interventions tested in two trials showed marginally significant differences in favour of the more intensive intervention in one (Zhu 1996, RR 1.32, 95% CI 1.01 to 1.74), but not the other (Hollis 2007, RR 1.05 95% CI 0.89 to 1.23, data not shown).

### 1.2 Comparisons between different types of support at initial call

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. No effect of the intervention was detected (N = 490; RR 0.96; 95% CI 0.71 to 1.30).

Two studies compared different reactive support for helpline callers during a single session. They failed to detect a significantly increased benefit from either counselling and materials designed for

African-Americans (Orleans 1998) or stage-based counselling designed for blue-collar workers (Thompson 1993) compared to standard support. Quit rates in these trials were from 15% to 20% for point prevalence rates at six months. In the first of these trials, extended follow up for early enrollers found some evidence that quit rates were higher after 12 months in the experimental group. (Relative effects for all three studies are displayed but not pooled in Comparison 2.1).

### 2 Trials providing access to a helpline

In one trial (Ossip-Klein 1991), provision of a hotline was associated with an increase in quit rates from 4.0% amongst smokers sent self-help materials only, to 6.6% amongst smokers in areas where an advertised hotline was provided in addition to materials. This difference was statistically significant using the unit of allocation (the county) as the unit of analysis.

In a second trial (McFall 1993), smokers who had enrolled to be sent materials for a self-help programme with a televised compo-

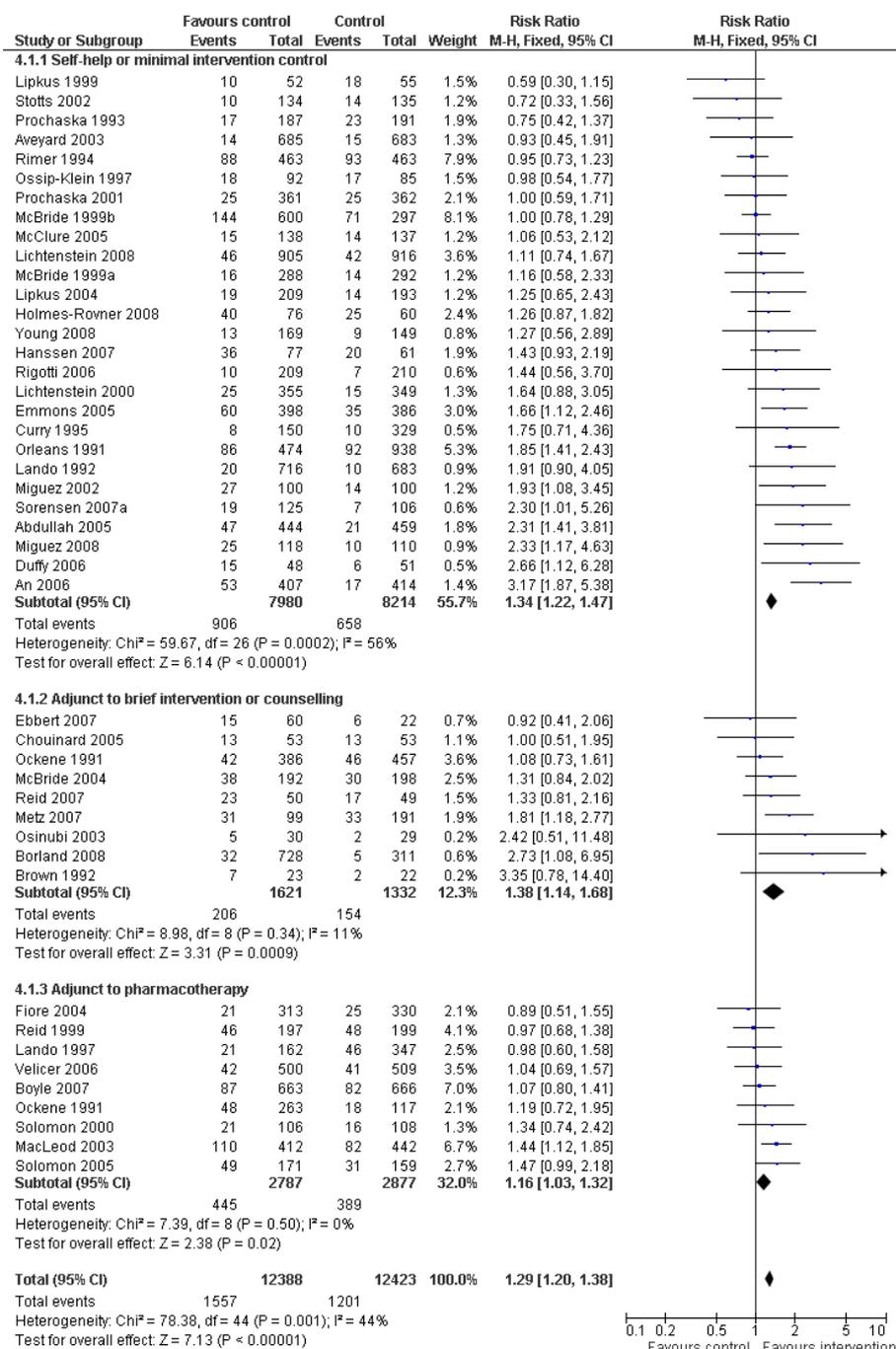
ment were randomized to receive follow-up newsletters and access to a helpline for six months. Although the intervention combined a helpline and written materials, quit rates were non-significantly lower in the intervention than control condition after 24 months. In a third trial (Joyce 2008), enrollees for a Medicare Stop Smoking Programme were randomized to different benefits. The intervention was access 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 coverage for the nicotine patch. The control group had pharmacotherapy coverage only. The quitline significantly increased quitting at 12 months, from 15.8% to 19.3% (RR 1.22, 95% CI 1.07 to 1.39). (Relative effects for all three studies are displayed but not pooled in Comparison 3.1).

### **3 Trials of proactive counselling, not initiated by calls to quitlines**

#### **3.1 Overall effect of counselling**

There were 44 trials (N = 24,811) in this comparison. (One contributed different data to two subgroups making a total of 45 in the analysis). The pooled effect suggested a modest benefit of proactive telephone counselling (RR 1.29; 95% CI 1.20 to 1.38) with moderate heterogeneity ( $I^2 = 44\%$ ) (Figure 3, Comparison 4.1). Our prespecified categories based on the intensity of support common to the control and intervention groups did not explain the heterogeneity, nor was heterogeneity reduced by excluding the trials amongst teenagers or pregnant women.

**Figure 3. Comparison 4. Interventions for smokers not calling quitlines - subgroups by baseline support. Cessation at longest follow-up**



In 27 trials telephone counselling was the main component of a cessation intervention and the control group had only self-help materials or very brief support. In this subgroup the effect estimate was similar to that for all 44 trials (RR 1.34; 95% CI 1.22 to 1.47) and with slightly more evidence of heterogeneity ( $I^2 = 56\%$ ).

In the group of nine trials ( $N = 2,953$ ; part of [Ockene 1991](#); [Brown 1992](#); [Osinubi 2003](#); [McBride 2004](#); [Chouinard 2005](#); [Ebbert 2007](#); [Metz 2007](#); [Reid 2007](#); [Borland 2008](#)), where the telephone support followed on from a face-to-face intervention, the point estimate and confidence intervals were again broadly similar and there was low heterogeneity ( $I^2 = 11\%$ , RR 1.38, 95% CI 1.14 to 1.68). The effect estimate in this comparison became significant after the inclusion of five studies in the current update.

In the nine trials ( $N = 5,664$ ; part of [Ockene 1991](#); [Lando 1997](#); [Reid 1999](#); [Solomon 2000](#); [MacLeod 2003](#); [Fiore 2004](#); [Solomon 2005](#); [Velicer 2006](#); [Boyle 2007](#)) where counselling was used as an adjunct to the systematic use or offer of NRT, there was a relatively small and marginally significant effect without evidence of heterogeneity ( $I^2 = 0\%$ , RR 1.16, 95% CI 1.03 to 1.32).

We concluded that these subgroups were not especially helpful in investigating differences in effect between trials. Although we had expected that the relative effect of the telephone component might be less when used as follow up to face-to-face advice or counselling, the amount of behavioural support common to both experimental and control groups was relatively limited in all cases, and it was difficult to categorize some trials.

### 3.2 The effect of counselling intensity

A second subgroup analysis of the same 44 trials explored the impact of the number of calls, using three categories; two or fewer sessions; three to six sessions, or seven or more. We initially analysed these categories within the grouping by control condition used above, but since the pattern of results was largely consistent we simplified the comparisons (Comparison 5.1).

There were nine trials ( $N = 6,274$ ) in the lowest intensity category: [Lando 1992](#); [Rimer 1994](#); [Ossip-Klein 1997](#); [Lipkus 1999](#); [Lichtenstein 2000](#); [Stotts 2002](#); [Fiore 2004](#); [Lichtenstein 2008](#) and [Miguez 2008](#) all provided one or two calls. There was moderate heterogeneity ( $I^2 = 45\%$ ) and no significant effect was detected (RR 1.07; 95% CI 0.91 to 1.26).

Twenty-eight trials ( $N = 14,597$ ) offered between three and six sessions. There was low heterogeneity ( $I^2 = 32\%$ ) and a significant effect showing a benefit of counselling (RR 1.34, 95% CI 1.23 to 1.47).

Seven trials ( $N = 3,940$ ) offered seven or more sessions ([Solomon 2000](#); [Solomon 2005](#); [Duffy 2006](#); [Velicer 2006](#); [An 2006](#); [Boyle 2007](#); [Hanssen 2007](#)) ([Solomon 2000](#) did not specify a set number of calls, but the average provided was seven). There was a significant benefit (RR 1.39, 95% CI 1.18 to 1.63) but clear het-

erogeneity ( $I^2 = 64\%$ ) attributable to the large effect of [An 2006](#). The effect seen in this study might have been increased by the effect of counselling on increasing use of pharmacotherapy in the intervention group. The pooled estimate remained just significant after excluding this study. Another source of clinical heterogeneity was that four of the trials ([Solomon 2000](#); [Solomon 2005](#); [Velicer 2006](#); [Boyle 2007](#)) offered counselling as an adjunct to pharmacotherapy; in a post hoc subgroup these studies did not show evidence of an effect when pooled. A further source of heterogeneity was that [Velicer 2006](#) used an automated voice response system to provide tailored but prerecorded support.

We had no strong a priori rationale for the choice of cut points, although the 1-2 call group predominantly captured trials with 'brief' interventions. Because the categories were not pre-specified we also conducted a meta-regression analysis in STATA 8.2 using the maximum number of planned calls for each study as a measure of intensity. In the previous version of the review the model showed a significant association between intensity and effect size. In this update there was no significant association. This could be due partly to the change of outcome from odds ratio to risk ratio, and to the increased number of studies leading to more reliable estimates.

We also considered whether including the nine trials of proactive counselling for quitline callers in their intensity subgroups would alter these conclusions. This confirmed the benefit of more intensive interventions (data not shown). Two of the quitline trials included a test of a brief intervention, and when these were included in the one- or two-session categories the estimate just reached significance, although the relative effect was small. One of these trials offered a single session lasting 50 minutes ([Zhu 1996](#)) and the other a session of 30 to 40 minutes followed by a second briefer call, with tailored self-help materials ([Hollis 2007](#)). These were considerably longer than the sessions used in the other 1-2 session trials, suggesting that their results might not be generalizable outside the quitline setting or to interventions with a small number of short calls.

### 3.3 The effect of motivation

A third subgroup analysis for the 44 trials explored the effect of motivation (Comparison 6.1). Fourteen studies ( $N = 8,084$ ) specifically recruited smokers who wanted to make a quit attempt, including most of the studies where pharmacotherapy was common to both intervention and control. Thirty studies ( $N = 16,727$ ) did not state that participants were included on the basis of motivation, although relatively high proportions may have been interested in quitting. In this update the effect sizes in the two subgroups were similar and significant, although there was less heterogeneity in the 'unselected' subgroup.

#### 4. Other studies

Six other studies were judged too dissimilar for pooling. Two studies compared different intensities of telephone support. [Miller 1997](#) compared a hospital-based intervention followed by a single call with an intensive intervention in which patients could receive up to four calls after discharge from hospital. The more intensive intervention increased the continuous one-year quit rate from 14% to 19%, a difference which just reached statistical significance ( $P = 0.05$ ). [Swan 2003](#) compared two intensities of telephone support as an adjunct to bupropion. This study found a significant benefit of the Free & Clear programme which offered a telephone assessment and counselling intervention with four brief prescheduled follow-up calls, compared to the Zyban Advantage Plan which included a single scripted call ( $N = 1524$ , RR 1.31, 95% CI 1.12 to 1.54). These two studies provide further evidence that higher numbers of calls are associated with greater benefit.

[Roski 2003](#) and [Katz 2004](#) evaluated systems-level interventions for changing the organization of care for smoking cessation, with telephone counselling being the main method for providing cessation support. [Roski 2003](#) failed to detect any benefit of introducing a smoker registry and referral system on cessation rates. Few of the smokers surveyed at the participating clinics reported using any counselling services, and only 25 to 30% of eligible smokers were estimated to have been referred. [Katz 2004](#) tested an intervention to implement clinical practice guideline recommendations including the offer of telephone counselling and/or NRT; this showed a significant increase in sustained abstinence at six months (10.9% versus 3.8%, adjusted odds ratio 3.4, 95% CI 1.8 to 6.3).

[Halpin 2006](#) compared benefit designs. There was no significant difference between groups; the quit rate at six months was 19% in the group given access to pharmacotherapy, 18% for the group who could access pharmacotherapy if enrolled for telephone counselling (24% accessed TC), and 13% for those who could access either (only 8% enrolled in counselling).

[Hennrikus 2002](#) compared the offer of telephone counselling or group programmes or a choice in a workplace setting. Programmes were offered three times, and the primary evaluation was based on all smokers irrespective of participation. No difference in six-month sustained quit rates was detected at 24 month follow up, although point prevalence quit rates favoured the telephone condition. Quit rates for programme participants were also similar. Incentives increased participation but did not appear to increase cessation rates.

## DISCUSSION

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 of the review continues to provide evidence of a benefit from providing proactive telephone counselling for smokers who initiate contact with quitlines. 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 randomized to one or more additional calls increase their chance of quitting by 25 to 50%. Six out of nine trials in this meta-analysis had statistically significant effects including the three that cumulatively contribute of the weight ([Zhu 2002](#); [Hollis 2007](#); [Rabius 2007](#)). Only one trial ([Gilbert 2006](#)) had lower quit rates in the intervention group. Because the trials in this area have been so large, the estimated effect size, although statistically significant, is small. In an exploratory analysis we pooled the trial outcomes expressed as risk differences to estimate the absolute increase in quit rates attributable to the additional counselling. Risk differences may be much more heterogeneous than risk ratios if trials have very different definitions of abstinence. In this group of nine trials the definitions of smoking cessation were relatively similar, with seven having final follow up at around 12 months, of which six required an extended period of self-reported abstinence. None used biochemical validation, which is not judged to be necessary in large population based studies ([SRNT 2002](#)). The quit rate in the control groups ranged from 1.5% ([Smith 2004](#)) to 12%, or 17% when free nicotine replacement therapy (NRT) was also offered ([Hollis 2007](#)). The intervention group quit rates ranged from 5% ([Smith 2004](#)) to 14%, or 21% when NRT was offered ([Hollis 2007](#)). Despite the variation in quit rates, pooling trial outcomes expressed as risk differences showed no evidence of heterogeneity, and the estimated absolute increase in quit rates was 3% (95% CI 2% to 4%). These estimates are based on treating all people lost to follow up as continuing smokers. Excluding losses to follow up from all conditions, reducing the total numbers by about 35%, would increase the estimate of absolute effect, but only by a percentage point.

All these trials provided multisession counselling, with a variety of schedules. Evidence for a dose response effect is unclear, with [Zhu 1996](#) suggesting a benefit from additional calls, but neither [Smith 2004](#) nor [Hollis 2007](#) detecting differences between two different protocols. The most detailed investigation, [Rabius 2007](#), suggested that fewer shorter calls could be as effective as more and longer ones. They observed that "The 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.

One recent trial ([Sood 2009](#)) compared reactive counselling for quitline callers with a control condition of mailed self-help mate-

rials only. No difference was detected, although the upper confidence interval was 1.30. Because the counselling was reactive, with no further contact initiated by a counsellor, we did not pool it with the trials discussed above. It is not clear how many further calls to the quitline the intervention group participants subsequently made. Whilst this study fails to support the benefit of reactive helplines, it does not exclude the possibility of an effect.

### 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. There is also evidence of benefit from telephone counselling under these conditions. Estimates from pooling studies suggested a 20 to 40% increase in quitting. There was only a moderate level of heterogeneity, and this was not explained by considering subgroups of trials based on the amount of support common to both intervention and control groups. In the largest subgroup of studies this consisted of mailed self-help materials but some trials included brief face-to-face advice and some offered pharmacotherapy to all participants. The telephone intervention was associated with significantly higher quit rates in each subgroup, but the estimate was smaller and less certain when participants had access to pharmacotherapy.

In the subgroup by intervention intensity, the effect was small and not significant when the intervention consisted of only one or two calls. In this update a meta-regression no longer showed a significant relationship between larger effect size and increasing number of calls. This analysis used the maximum possible number of calls as the measure of intervention intensity. Alternative measures include the average number of calls delivered, which is generally considerably lower than the number intended, and the total contact time. These process measures are less consistently reported. Unless there were particular problems with contacting participants, the planned number of calls is probably a reasonable measure of the 'dose' of support provided for those who were receptive to the intervention. We also modelled the different categories for motivation and baseline support using the same technique and neither were effect modifiers.

### Completeness, applicability and quality of the evidence

Rigorous evaluation of reactive services (quitlines, hotlines or helplines) has been difficult because of a reluctance to undertake randomized trials that would require callers who sought help to be refused support. This review restricted formal inclusion to randomized or quasi-randomized trials. A single large trial provides the main evidence that hotlines are beneficial (Ossip-Klein 1991). In this study 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. The hotline appeared most effective for those people who enrolled face-to-face, despite the fact that telephone enrollees made more use of the service. There is much more evidence about the benefit of counselling once smokers have called a telephone-based service. One study was able to evaluate the impact of the proactive counselling element of a helpline by capitalising on the constraints on capacity at certain times (Zhu 2002). One recent study (Sood 2009) did allocate 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 2007a)

### Evidence from other sources

Evaluations have followed up quitline users in a number of places including Scotland (Platt 1997); Australia (Borland 1989; Wakefield 1999; Miller 2003), England (Owen 2000), Sweden (Helgason 2004); California (Zhu 2000) and Hong Kong (Abdullah 2004), and all report encouraging quit rates. Estimates of the proportion of smokers that call a quitline has varied by country; 6% in Scotland (Platt 1997); 3.6% in Australia (Miller 2003); 4% in England (Owen 2000). Although estimates of a reach of 4% to 6% of the smoking population over a year are encouraging, they are likely to be at the upper end of what can be expected, even with the help of mass media campaigns. In the USA the average usage ranges from 0.01% to 4.28% across states, with the states that spent the most on quitlines services having the highest use (Cummins 2007a).

Promotion of quitlines by mass media antismoking campaigns helps to attract callers (Farrelly 2007; Mosbaek 2007), and the use of targeted advertising may increase calls from specific minority or underserved groups (Cummings 1989; Pierce 1992; Cummings 1993; Owen 2000; Zhu 2000; Cummins 2007b; Maher 2007). There are a number of models for quitlines, using various methods to provide initial support for callers and pass them to specialist counsellors where requested and available (Ossip-Klein 2003). Callers do not necessarily ask for or want counselling, and services can increase population quitting just by mailing self-help materials, even though the effect of this minimal intervention may not be large (Lancaster 2005b). Using the telephone contact to collect sufficient data to provide tailored materials may be a useful strategy for enhancing the effect of self-help materials (Borland 2004; Lancaster 2005b). One strategy that has been used in a pilot project for increasing access to treatment for underserved populations is to provide a cellular phone, allowing smokers to receive proactive counselling (Lazev 2004).

In North America a third of quitlines distribute free NRT (Cummins 2007a). Evaluations suggest that this increases call volume, and pre-post comparisons also suggest that quit rates are in-

creased (An 2006a; Cummings 2006; Fellows 2007; Tinkelman 2007; Bush 2008; Campbell 2008).

Telephone-based services can provide support for users of medications such as NRT, or bupropion. One trial in this review (Fiore 2004) tested the Committed Quitters<sup>®</sup> programme as an adjunct to free nicotine patch therapy, but did not detect an additional benefit of the single counselling call even though this was supported by tailored self-help materials. One short-term randomized trial (Shiffman 2000) failed to detect an effect of a single telephone call after the target quit date compared to mailed, tailored self-help materials alone for purchasers of nicotine gum. In both trials the lack of effect may be attributed to the insufficient dose of the telephone component. Another trial compared multiple to single calls for users of bupropion, and there was a clear benefit of the four call protocol (Swan 2003). Support provided by pharmaceutical companies may also be underused. In their trial of proactive calls as an adjunct to nicotine patch, Lando and colleagues noted that fewer than 1% of participants called the company helpline, whether they were scheduled to receive calls or simply encouraged to call the helpline themselves (Lando 1997). It may be possible to use brief proactive calls to encourage use of quitline services (Boyle 2004b; Holtrop 2005).

Telephone counselling may also have a role in increasing the appropriate use of pharmacotherapy. In a trial with one of the largest effects, part may 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 2000a). 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 nonsmokers 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.

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)

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). Other countries where national or state quitlines are known to be established include Australia (Miller 2003), New Zealand (Wilson 2005), United Kingdom (Gilbert 2006), Sweden (Helgason 2004), Hong Kong (Abdullah 2005) and Korea (Myung 2008). The evaluation of systems that encourage and facilitate healthcare providers to refer patients to specialist quitline services for extended support is an important area of current research (Perry 2005; Winickoff 2006; Sherman 2008; Wolfenden 2008). Possible future developments include the use of direct mail or 'cold-calling' to initiate contact with smokers (van Deusen 2007; O'Connor 2008).

## AUTHORS' CONCLUSIONS

### Implications for practice

Proactive telephone counselling helps smokers interested in quitting. There is evidence of a dose response; one- or two-call protocols are less likely to provide a measurable benefit. Three or more calls increase the odds of quitting compared to a minimal intervention such as providing standard self-help materials, brief advice, or compared to pharmacotherapy. Telephone quitlines provide an important route of access to support for smokers, and call-back counselling enhances their usefulness.

### Implications for research

Further research on ways to combine face-to-face counselling with telephone follow up to support quit attempts and reduce relapse rates may be useful. Research on reactive helpline services which compares 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 [ordered by study ID]

#### Abdullah 2005

Methods	Setting: Parents of children in a birth cohort study, Hong Kong Recruitment: by mail, current smokers, not selected for motivation
Participants	903 current smokers with young children (49 recent quitters not included here); 84% M, >50% aged 36-45, 91% smoked ≤ 20/day
Interventions	1. Single mailing of stage-matched S-H (either preparation/action or contemplation/precontemplation) 2. As 1, plus 20-30 mins of TC at time of enrollment by trained nurse counsellor. Hotline number, further counselling at 1m & 3m
Outcomes	Abstinence at 6m, validated 7-day PP. (Unvalidated self-reported continuous abstinence also reported). Validation: CO <9ppm or urine cotinine <100 mmol/mol
Notes	Comparisons 4-6. Effect on self-reported continuous abstinence was non-significant Average duration of counselling 38 mins over 3 contacts

#### *Risk of bias*

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Yes	Numbered sealed opaque envelopes
Incomplete outcome data addressed? All outcomes	Yes	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 > 7d abstinence in prev 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 & bupropion avail on formulary 2. As 1, plus proactive TC, modified California helpline protocol, 7 calls over 2m, relapse sensitive schedule. NRT & bupropion available, could be mailed directly after screening

An 2006 (Continued)

	& primary provider approval for bupropion	
Outcomes	Abstinence at 12m (sustained from 6m, 7-day PP also reported) Validation: none	
Notes	Comparisons 4-6. TC increased use of pharmacotherapies (86% vs 30% reported use at 3m). Effect greater for sustained quitting than PP. 72% completed 3 or more calls. Mean (SD) 7.7 (4.1) including courtesy calls, relapses, repeat attempts. Mean (SD) duration of total contact 123 (71) mins.	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Losses to follow up included as smokers, 16 deaths excluded

Aveyard 2003

Methods	Setting: 65 general practices, UK Recruitment: volunteers from random selection of smoking patients, not selected for motivation Randomization: centralised, minimization to balance SoC, addiction and SES	
Participants	2471 smokers (2058 in relevant arms); >80% in precontemplation or contemplation, 10-14% in preparation, 54% F, 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 3m & 6m 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 12m, (reported sustained for 6m) Validation: saliva cotinine < 14.2 ng/ml	
Notes	Comparisons 4-6. 3 vs 2. Sensitivity analysis 3 vs 2+1. 66% received 1st phone call, 36% 2nd, 31% 3rd.	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>

**Aveyard 2003** (Continued)

Adequate sequence generation?	Yes	Centralised randomization procedure, with minimization to balance SoC, addiction and SES
Allocation concealment?	Yes	Centralised
Incomplete outcome data addressed? All outcomes	Yes	Loss to follow up 24% in group 1, 31% in 2 & 3. All included as smokers. Sensitivity analysis allowing for differential drop out did not change findings.

**Borland 2001**

Methods	Setting: community, Australia Recruitment: callers to a quitline
Participants	998 smokers interested in quitting; 52% F, 37% aged 15-29, 26% aged 30-39, av. cigs/day 23
Interventions	1. Proactive callback TC following initial call to quitline: Multiple calls, first pre-quit, quit, then according to need. Up to 6m. Mailed materials 2. Control: Mailed materials Both groups also received the standard motivational counselling in response to their first call.
Outcomes	Abstinence at 12m (sustained for 9m) Validation: none
Notes	Comparison 1. 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***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	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; 54% F, 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 3m & 6m 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 wks, could extend further. Some participants in all groups received brief reactive counselling before enrollment
Outcomes	Abstinence at 12m (sustained for 9m) Validation: none
Notes	Comparison 1. 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***

Item	Authors' judgement	Description
Adequate sequence generation?	No	Allocation by shuffling questionnaires
Allocation concealment?	Unclear	Author states 'no opportunity for interviewers to influence choice'; baseline characteristics balanced, likelihood of bias judged low.
Incomplete outcome data addressed? All outcomes	Yes	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; 55% F, 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 & offer of pharmacotherapy if appropriate

**Borland 2008** (Continued)

Outcomes	Sustained abstinence at 12m ( $\geq 1m$ at 3m and $\geq 10m$ at 12m) Validation: none	
Notes	New for 2009 update. Comparisons 4-6, TC as adjunct to face-to-face intervention. 30.5% of referral group used callback service. McKay-Brown discusses GP retention and patient recruitment problems. Reported analysis adjusts for age, gender and nicotine dependence and controls for clustering. Adjusted OR is 3.08 (1.02 to 9.28) compared to 2.81 (1.09 to 7.29) using crude data in MA	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Yes	Cluster randomized by GP (1:2 ratio). Computer allocation before GPs attended education session for their assigned intervention
Allocation concealment?	Unclear	Initially concealed but 13 referral (30%) and 11 (42%) control GPs failed to recruit patients. Allocation not blind at time of recruitment of individual patients so further selection bias possible. Measured characteristics at baseline were similar
Incomplete outcome data addressed? All outcomes	Yes	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 Organization, USA Recruitment: proactive recruitment of members filling a prescription for cessation medications (motivated)
Participants	1329 HMO members; 58% F, 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 12m (repeated 7-day PP at 3m & 12m) Validation: none

**Boyle 2007** (Continued)

Notes	New for 2009 update. Comparisons 4-6. 49% of intervention group reached, 36% of those declined, 31% of total accepted counselling. Average no of calls 5. There was no evidence of a greater relative effect in those reached or those accepting counselling	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Randomized, stratified by presence of chronic disease. Method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	~33% lost to follow up, balanced across groups, included in MA as smokers

**Brown 1992**

Methods	Setting: community, Australia Recruitment: advertising for smokers interested in cessation	
Participants	45 smokers attending an information evening on smoking cessation; 62% F, 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 wks which asked about use of manual, and gave additional information about any techniques or skills proving difficult	
Outcomes	Abstinence at 12m (7-day PP) Validation: Saliva samples collected but not apparently tested - 1 participant refusing to provide a sample was classified as smoking.	
Notes	Comparisons 4-6, effect of TC compared to S-H and single information session alone	

<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Unclear	No details given

**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 (1x, 10-60 mins, av. 40 mins, based on Transtheoretical Model, included component to enhance social support from a significant family member) , 23% used pharmacotherapy. 2. As 1, plus telephone follow up, 6 calls over 2m post-discharge, 29% used pharmacotherapy 3. Usual care cessation advice (not used in review)
Outcomes	Abstinence at 6m (sustained at 2m & 6m) Validation: Urine cotinine or CO
Notes	New for 2009 update. Comparisons 4-6, TC as adjunct to face-to-face counselling, 75% received 6 calls TC as adjunct to face-to-face counselling.

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Cluster randomized in groups of 3-6 'to prevent contamination between groups', method not described
Allocation concealment?	Yes	'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.'
Incomplete outcome data addressed? All outcomes	Yes	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.

**Curry 1995**

Methods	Setting: Health Maintenance Organization, USA Recruitment: Smokers identified via 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; 52% F, av. age 41, av. cigs/day 17

Curry 1995 (Continued)

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 wks	
Outcomes	Abstinence at 12m, from 3m-12m Validation: saliva cotinine requested but not obtained for all self-reported quitters. Dis-confirmation rates (cut off >20ng/ml) not significantly different between groups.	
Notes	Comparisons 4-6. 4 vs 3, effect of TC compared to S-H and feedback alone. Over completed 3 calls, rates did not differ by SoC	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	88% provided data at all 3 & 12m. 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 & 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 6m . Demographics are for all participants; 16% F, 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 6m (sustained) Validation: none	
Notes	New for 2009 update, in comparisons 4-6	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>

**Duffy 2006** (Continued)

Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given. Smokers were a higher proportion of the intervention than control groups, and a higher proportion of those randomized than those who refused, raising possibility of selection bias
Incomplete outcome data addressed? All outcomes	Unclear	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 1w & 2w, further calls if requested.	
Outcomes	Abstinence at 6m (PP) Validation: none	
Notes	New for 2009 update. Comparisons 4-6, TC adjunct to face to face intervention	

**Risk of bias**

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Cluster randomized by practice, method not described
Allocation concealment?	No	Hygienists who recruited patients after screening not blind, large difference in numbers recruited, not possible to establish baseline similarity
Incomplete outcome data addressed? All outcomes	Unclear	No description of number lost at follow up

**Emmons 2005**

Methods	Setting: Childhood Cancer Survivors Study cohort, USA Recruitment: Smokers contacted via telephone to assess eligibility and enrol, not selected for motivation
Participants	794 smokers (excludes 2 deaths in control); 47% F, av. age 31, av. cigs/day 12
Interventions	1. S-H control. Mailed manual (Clearing the Air) & letter from study physician 2. Peer counselling. Up to 6 calls in 7m period, by trained cancer survivor. Motivational, tailored to SoC. Free NRT available. Individually tailored materials before 1st call & other materials during intervention.
Outcomes	Abstinence at 12m (7-day PP) Validation: none (warning that samples might be requested)
Notes	Comparisons 4-6. 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. PP rates increased from 12m and remained higher in counselling group (20.6% vs 17.6%, P<.0003)

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Unclear	19% lost in intervention vs 24% in control at 12m. all included as smokers in MA. Excluding losses does not affect MA

**Fiore 2004**

Methods	Setting: Primary care patients, 16 clinics, USA Recruitment: Clinic attenders willing to accept treatment
Participants	961 smokers of $\geq 10$ cigs/day. (643 in relevant arms, a further 908 were allowed to select treatment. Demographic details based on 1869); 58% F, av. age 40, av. cigs/day 22
Interventions	(Self-selected group of factorial trial not included in MA) 1. Nicotine patch, 22mg, 8 wks incl tapering. 2. As 1, plus Committed Quitters 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 wks (not used in this review)
Outcomes	Continuous abstinence at 1 year (no relapse lasting 7 days, also PP) Validation: CO, cut off not specified. 2 discordant

**Fiore 2004** (Continued)

Notes	Comparisons 4-6, 2 vs 1, TC as adjunct to pharmacotherapy 69% of those randomized to group 2 enrolled in CQ programme	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	19% lost at 1 year, no difference by condition.

**Gilbert 2006**

Methods	Setting: Quitline, UK Recruitment: quitline callers who engaged in counselling	
Participants	1457 smokers planning quit attempt within 2 wks; 66% F, av. age 39, av. cigs/day NS	
Interventions	1. Standard QUIT information pack & counselling at initial contact. 2. As 1, plus offered 5 proactive calls, starting TQD if possible, 2 in wk 1, 1 in wks 2 & 4. Client centred.	
Outcomes	Abstinence at 12m (sustained for 6m, also PP) Validation: none	
Notes	Comparison 1. 26% received no additional calls, 42% had 4+ calls, 31% had 1-3 calls	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	No	Pseudo random by day of week
Allocation concealment?	Yes	Recruiters blind so concealment judged adequate
Incomplete outcome data addressed? All outcomes	Yes	37% lost to follow-up in both groups. Missing counted as smoking in MA

**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; 66% female, 67% aged 40 or older, 84% smoked less than a pack/day
Interventions	1. Coverage for TC and pharmacotherapy (bupropion or NRT, US\$15 co-pay) 2. Coverage for TC; coverage for pharmacotherapy (bupropion or NRT, US\$15 co-pay) only if enrolled in TC 3. Coverage for pharmacotherapy only (control)
Outcomes	Abstinence at 6m (PP) Validation: none
Notes	New for 2009 update. Not included in MA, results discussed separately, alongside trials for TC as adjunct to pharmacotherapy

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Number lost to follow up not described, all participants included in analyses

**Hanssen 2007**

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 wks and primary care follow up 2. Structured but individualized proactive TC addressing lifestyle issues including smoking, diet and exercise. Nurse-initiated calls at 1,2,3,4,6,8,12, 24 wks post-discharge. Smoking not explicitly addressed at each call. Reactive phone support line available 6 hrs/wk
Outcomes	Abstinence at 6m (not defined). Primary trial outcome was health-related quality of life Validation: none
Notes	New for 2009. Comparisons 4-6. Smoking was addressed as part of a multicomponent intervention. TC as adjunct to brief/minimal intervention

**Hanssen 2007** (Continued)

<i>Risk of bias</i>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Randomized by computer-generated list
Allocation concealment?	Unclear	Sequence in sealed opaque envelopes but not stated to be numbered. Fewer control group participants raises possibility of selection bias so not classified as adequate
Incomplete outcome data addressed? All outcomes	Yes	Losses 22% in 1, 20% in 2. Losses reincluded as smokers in this MA

**Henrikus 2002**

Methods	Setting: 24 worksites, USA Recruitment: Baseline survey to identify smokers.	
Participants	2402 smokers at baseline survey; 38-48% in precontemplation, 50-64% F, av age 36-40 (large between-company variations in prevalence and smoker characteristics).	
Interventions	Factorial design, 6 conditions: Incentives for participation and cessation/no incentive crossed with telephone, group or choice of programme format. Telephone counselling: 3-6 sessions + mailed ALA S-H materials. Group therapy: 13 sessions. Each programme offered 3 times over approx 18m	
Outcomes	Abstinence at 24m, sustained for 6m & 7-day PP Validation: saliva cotinine from a sample. No correction for misreporting	
Notes	Cluster randomized, and no other trial compared TC to group so not used in MA, reported narratively	

<i>Risk of bias</i>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Cluster randomized by company, 4/condition, method not described
Allocation concealment?	Unclear	Individuals recruited from baseline survey so selection bias less likely
Incomplete outcome data addressed? All outcomes	Yes	Results based on respondents only. Does not contribute to MA

**Hollis 2007**

Methods	Setting: Quitline, Oregon, USA Recruitment: callers to quitline
Participants	4500 smokers willing to make a quit attempt; 60% F, av. age 41, av.cigs/day 22
Interventions	Factorial design; 3 levels of counselling, +/- offer of nicotine patch (5wk supply, 80% accepted, option for 3wk more, 25-28% requested) 1. Brief counselling (usual care), 15 min + referral information & tailored S-H 2. Moderate TC: 30-40 min motivational interview, 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 12m Validation: none
Notes	2&3 +/- NRT combined vs 1 in comparison 1. First included as Hollis 2005 based on unpublished abstract. Offer of NRT increased mean number of calls and contact time. 1 session, 20 mins in brief no NRT, 2.9 sessions, 60 mins in Intensive +NRT

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	69% reached at 12m. 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 patients 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 wks post discharge. Pharmacotherapy encouraged for cessation. Intervention could address multiple behaviours.
Outcomes	Abstinence at 8m ('remained quit for the period') Validation: none

**Holmes-Rovner 2008** (Continued)

Notes	New for 2009 update. Comparisons 4-6. Data on smoking outcomes provided by authors from in Press paper by Holtrop et al.	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Blocked randomization, method not described
Allocation concealment?	Unclear	Change in methodology from randomization at recruitment/consent to randomization after baseline interview due to initial Imbalance in numbers. Data collectors were blind to group
Incomplete outcome data addressed? All outcomes	Unclear	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

**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), ~60% F, ~69% contemplation, 30% preparation
Interventions	Trial of 4 levels of Medicare benefit. All participants mailed a self-help 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 US\$5 co-pay, up to 2x 12 wk 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 wk cycle, up to 2 cycles in the year. Also S-H manual and coverage for nicotine patch for US\$5 co-pay
Outcomes	Abstinence at 12m (7-day PP) Validation: none
Notes	New for 2009 update. 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, estimated effect displayed in comparison 3

Joyce 2008 (Continued)

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Cluster randomized, states divided into quarters balancing smoking prevalence & aged, restricted randomization to different conditions
Allocation concealment?	Unclear	Participants unaware of programme differences when enrolling and allocation determined by address. Low enrolment in one condition does not seem to have been due to bias.
Incomplete outcome data addressed? All outcomes	Unclear	25% lost to follow up at 12m, absolute differences between groups small. Main analysis includes losses as smokers

**Katz 2004**

Methods	Setting: 8 primary care clinics, USA Recruitment: smokers attending for non-emergency visits
Participants	1141 smokers (>1 cig/day) 56% F, age 43/40, median cigs/day 20/15
Interventions	1. Intervention based on AHRQ guidelines. Training in brief advice for intake clinicians, vital signs stamp. Patients willing to set TQD offered proactive TC (2 calls, pre & post TQD) by trained nurse, smokers of over 10 cigs/day offered NRT 2. Control. Information about guidelines, no specific advice on counselling.
Outcomes	Sustained abstinence at 2m & 6m Validation: saliva cotinine. Poor response, similar return & misreport rates. Validated sustained rates not reported.
Notes	TC part of a multicomponent intervention, not included in MA. Study also included a baseline assessment. Data from smokers recruited during implementation period used here. 29% used NRT in intervention versus 11% in control.

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Cluster randomized by clinic, method not described

**Katz 2004** (Continued)

Allocation concealment?	Yes	Participants enrolled by completing an exit interview with researcher.
Incomplete outcome data addressed? All outcomes	Yes	4-8% lost to follow up.

**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% F, av. age 47, av. cigs/day 22
Interventions	1. Proactive TC, 2 calls over 3 wks. Offered S-H materials 2. No intervention, contacted at follow up only
Outcomes	Abstinence at 18m (no puff, > 3m and validated abstinent at 6m) Validation: Saliva cotinine <10ng/ml at 6m
Notes	Comparisons 4-6. High level of cotinine disconfirmation. 70% agreed to second call.

**Risk of bias**

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	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
Incomplete outcome data addressed? All outcomes	Yes	Only a sample of intervention and control participants were selected for follow up. Of this sample 91% reached at 18m in both groups. Numbers followed up used as denominator in MA

**Lando 1997**

Methods	Setting: Health Maintenance Organization, USA Recruitment: physician referral and HMO clinic newsletters
Participants	509 smokers of >20 cigs/day, motivated to quit; 56% F, av. age 42, av. cigs/day 28
Interventions	All participants received prescriptions for free nicotine patch (Prostep), 22mg for a maximum of 6wks plus 2wks 11mg. Proactive vs Reactive Attended 90 mins 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 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 wks from quit date) . Reinforced success or negotiated a new quit date
Outcomes	Abstinence at 12m (from quit date) Validation: CO at 6m. 96% of quitters were confirmed.
Notes	Comparisons 4-6, 3 vs 1+2, effect of proactive TC compared to contact & 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 wks were called by telephone. Average number of calls completed 3.76

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Cluster randomized, method not described
Allocation concealment?	Unclear	Allocation by orientation session attended; participants did not know condition in advance so risk of selection bias probably low
Incomplete outcome data addressed? All outcomes	Yes	82% response rate at 12m, no difference between groups, missing treated as smoking

**Lichtenstein 2000**

Methods	Setting: community, USA Recruitment: via 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

**Lichtenstein 2000** (Continued)

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 min) proactive TC sessions
Outcomes	Abstinence at 12m (sustained at 3m, 12m) Validation: none
Notes	Comparisons 4-6. 3 vs 2, effect of TC versus S-H alone Cluster randomization, 54% of smokers lived with another smoker. Intraclass correlation for sustained abstinence was .010. Analyses did not correct for this. 82% received at least 1 call, 40% > one. Mean (SD) duration 10.4 (5.4) in for 1st call, 5.8 (4.9) for 2nd.

**Risk of bias**

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized by household, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	80% of households reached at 3 & 12m, no difference across conditions. Missing treated as smoking

**Lichtenstein 2008**

Methods	Setting: Community, USA Recruitment: via 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 15mins video S-H materials. All households given <i>A Citizens Guide to Radon</i> 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 interest 2. No calls
Outcomes	Abstinence at 12m, sustained at 3 & 12m Validation: none
Notes	New for 2009 update. Comparisons 4-6. Results of analyses accounting for clustering of multiple smokers in households reported to yield results generally consistent with simple analyses.

Lichtenstein 2008 (Continued)

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Responding households sequentially randomized to 4 conditions subject to stratification on radon test status
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	83% of households completed 12m assessment, 76% completed both 3 & 12m

Lipkus 1999

Methods	Setting: Health centre, USA Recruitment: from telephone survey of patients
Participants	Low income African-American smokers, 266 randomized, 160 followed up, 107 in relevant arms. Unselected by motivation; 52% F, 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 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	Abstinence 16m after last intervention, 30 day quit Validation: none
Notes	Comparisons 4-6. 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. Provider compliance reported to be 48%

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	38% loss to follow up primarily due to disconnected phone numbers. Reported rates based on numbers followed up. Authors re-

**Lipkus 1999** (Continued)

		port that an analysis with missing treated as smoking did not alter findings
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**Lipkus 2004**

Methods	Setting: community, USA Recruitment: proactive in shopping malls
Participants	412 teen smokers (aged 15-18, smoked in past 7 days); 51% F, 56% aged >=17, av cigs/day 10, 21% contemplation
Interventions	1. S-H, 2 booklets for teen smokers & video 2. as 1, plus proactive TC, 3 calls (12-15 mins) using motivational interviewing and problem solving
Outcomes	Abstinence at 8m (7-day PP at 4m & 8m) Validation method: Saliva cotinine <=10 ng/mL at 4m only. Low response, high failure to confirm. Abstinence based on self report only
Notes	Comparisons 4-6. TC as adjunct to targeted S-H. 72% received at least 1 call, 52% at least 5, 36% at least 3.

**Risk of bias**

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described, stratified by SoC
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Unclear	46% Int & 51% Cont reached at both follow ups. Losses included as smokers.

**MacLeod 2003**

Methods	Setting: community, Australia Recruitment: Community volunteers
Participants	854 smokers interested in quitting; 51% F, av. age 42, av. cigs/day 24
Interventions	1. Free 2 wk 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 & 10 wks. 20 min session 1, 10 min others. Toll-free hotline, S-H materials.

**MacLeod 2003** (Continued)

Outcomes	Abstinence at 6m (90-day continuous) Validation: none, warning of CO test only.	
Notes	Comparisons 4-6, TC as adjunct to NRT Average number of calls 4.7. 9% of participants called hotline	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	No	'Randomized' by shuffling folders each day after participants to be included were listed
Allocation concealment?	No	Potential for bias since allocation sequence not fixed in advance. Baseline characteristics similar across groups
Incomplete outcome data addressed? All outcomes	Yes	17% lost in NRT only, 15% in + counselling. Missing treated as smoking in MA

**McBride 1999a**

Methods	Setting: Health Maintenance Organization, USA Recruitment: health survey of women following a cervical smear (pap) test	
Participants	580 female current smokers, not selected for motivation for quit; av. age 36, av. cigs/day 13	
Interventions	1. Usual care - no smoking cessation intervention 2. Mailed cessation kit, letter personalised to SoC and quit motivation, proactive TC, 3 counselling calls (13-15 min) 2 wks after mailing then monthly. Motivational & stage-based.	
Outcomes	Abstinence at 15m (7 day at 6m & 15m), telephone interview Validation: saliva cotinine <20ng/ml, quit rates not corrected, low level of misreport	
Notes	Comparisons 4-6. 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 one call, 60% all 3.	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Randomized, method not stated, stratified on test result

**McBride 1999a** (Continued)

Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Loss to follow up at 15m 20% in Int, 18% in Cont. Losses included as smokers.

**McBride 1999b**

Methods	Setting: 2 Health Maintenance Organizations, USA Recruitment: pregnant women who had booked a prenatal appointment, by mail
Participants	897 pregnant smokers & 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 8.5 mins, approx 2 wks after S-H mailing, and 1m & 2m later. Tailored letter, S-H book. After 28 wk follow up sent relapse prevention kit. 3. Pre- & Postpartum intervention: as 2, plus 3 calls within first 4m postpartum, av 7.7 mins. 3 newsletters
Outcomes	Abstinence at 12m postpartum (7 day PP) Validation: Saliva cotinine requested by mail, <20ng/mL. Self-reported rates used in analyses, no difference in confirmation rates between groups
Notes	Comparisons 4-6. 3+2 vs 1, effect of TC versus S-H only

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Loss to follow up 13% at 12m, 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 female current smokers and recent quitters (390 in relevant arms); av. age 24

**McBride 2004** (Continued)

Interventions	1. Usual care - provider advice and S-H guide 2. As 1, plus 6 proactive TC calls, 3 in pregnancy, 3 postpartum within 4m + late pregnancy relapse prevention kit 3. Partner-assisted intervention, not used in this review	
Outcomes	Abstinence at 12m postpartum (PP at all 4 follow ups) Validation: Saliva cotinine request, incomplete return, rates based on self report.	
Notes	Comparisons 4-6, effect of TC as adjunct to brief advice Effect at 6m not sustained longer term. Mean number of calls received 5	
<b><i>Risk of bias</i></b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Randomized, method not described, stratified by smoking status
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Loss to follow up higher in Int (22%) than Cont (16%). Losses included as smokers

**McClure 2005**

Methods	Setting: Health Maintenance Organization, USA Recruitment: women with an abnormal cervical smear or colposcopy	
Participants	275 female 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 6m.	
Outcomes	Abstinence at 12m (PP) Validation: Cotinine saliva strip test, but judged over-conservative so self report used. Relative effect not altered	
Notes	Comparisons 4-6. Effect of TC versus S-H only 82% completed all 4 calls, 90% 3 or 4. Mean duration 16 min	
<b><i>Risk of bias</i></b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given

**McClure 2005** (Continued)

Incomplete outcome data addressed? All outcomes	Unclear	No information on numbers not reached at follow up. All participants included in analysis
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**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; 70% F, 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 6m following programme with details of hotline with taped messages and counsellors
Outcomes	Abstinence at 24m (7-day) Validation: none
Notes	Effect of access to hotline combined with S-H materials for maintenance of cessation. Estimated effect displayed in comparison 3 Use of the hotline was low - only 7% called and spoke to a counsellor

**Risk of bias**

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	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; 41% F, 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 10wks from female psychologists

**Metz 2007** (Continued)

	(not original therapist) 2. No boosters	
Outcomes	Abstinence at 12m (PP) Validation: none	
Notes	New for 2009 update. Comparisons 4-6, effect of TC as adjunct to intensive support	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Randomized, 1:2 ratio, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	17/316 randomized to I excluded, no contact post discharge. Differential drop-out from remainder, 17% Int, 40% Cont. No detected differences in characteristics of drop-outs. Sensitivity analyses excluding losses to follow up removes significance

**Miguez 2002**

Methods	Setting: community, Spain Recruitment: volunteers interested in quitting	
Participants	200 smokers; 38% F, av. age 35, av. cigs/day 28	
Interventions	1. Proactive TC, 6 x weekly 10 min calls. 4 on motivation & cessation, 2 on maintenance, + S-H 2. S-H only. Personalized intro letter, manual & 6 similar mailing with self monitoring and self evaluation forms	
Outcomes	Abstinence at 12m (not even a puff since quitting) Validation: CO at 12m	
Notes	Comparisons 4-6. 10 year follow up reported in 2008, not used in MA.	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given

**Miguez 2002** (Continued)

Incomplete outcome data addressed? All outcomes	Unclear	No information on numbers not reached at follow up. All participants included in analysis
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**Miguez 2008**

Methods	Setting: Community, Spain Recruitment: volunteers interested in quitting
Participants	228 smokers of $\geq 10$ cigs/day; 46% F, 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 wk 4 2. As 1. + single proactive 5-10 min counsellor call in wk 4, to increase motivation & adherence
Outcomes	Abstinence at 12m (sustained since end of treatment) Validation: none ('bogus pipeline' warning)
Notes	New for 2009 update. Comparisons 4-6.

**Risk of bias**

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Unclear	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)
Participants	1942 smokers (excludes deaths); 49% F, av. age 51, av cigs/day 20
Interventions	All groups received standardized physician advice 1. Intensive intervention: 30 min nurse face-to-face counselling, proactive TC, 4 at 48 hrs post discharge, 7, 21, 90 days, optional session for relapsers 2. Minimal: 30 min counselling + 1 phone call at 48 hrs 3. Usual Care (not used in review)

Miller 1997 (Continued)

Outcomes	Abstinence at 12m (sustained at 3m, 6m, 12m) (Paper also reports 12m PP confirmed and self-reported cessation rates) Validation: saliva cotinine <15ng/ml, or family member verification	
Notes	Effect of additional telephone follow up. Not pooled. Intensive intervention was significantly better than usual care for confirmed PP 12m abstinence, other differences not significant	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Yes	'Nurses opened sealed envelopes in front of patients'.
Incomplete outcome data addressed? All outcomes	Yes	Number lost to follow up not specified, all randomized patients, excluding 82 deaths, included in analyses

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); 57% F, av. age 35, av. cigs/day 23	
Interventions	2x3 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, 3m) approx 10 mins, behavioural recommendations. Letters 2. No follow up	
Outcomes	Abstinence at 6m (7-day); (3m sustained abstinence rates not given by condition) Validation: none	
Notes	Comparisons 4-6, 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. 12m abstinence rates reported in Ockene 1994 but not given by follow-up condition	

**Risk of bias**

**Ockene 1991** (Continued)

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	Allocated prior to physician encounter
Incomplete outcome data addressed? All outcomes	Yes	19% lost to follow up, higher in telephone follow-up group. All included as smokers in analysis

**Orleans 1991**

Methods	Setting: Health Maintenance Organization, USA Recruitment: Largely through publicity in HMO magazine
Participants	2021 smokers of 3+ cigs/day, wanting to quit (1412 in relevant arms); 63% F, 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 wks) from a counsellor and invitation to call a quit line 4. Control - Referral guide
Outcomes	Abstinence at 16m for >6m, by blinded telephone interview. Validation: Saliva cotinine <10ng/ml, or thiocyanate <2,400 umol/l for gum users. Self-report rates reported in analyses
Notes	Comparisons 4-6. 3 vs 1+2, effect of telephone counselling compared to S-H materials alone. (No significant difference between 1 and 2)

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described, stratified by living alone/not, advice to quit in last 12m/not and nicotine content of cig.brand
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Loss to follow up 6% at 16m, 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; 64% F, 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. Personalized quitting plan. 2. Standard NCIS telephone counselling and standard guide 'Clearing the Air'
Outcomes	Abstinence at 6m, 7-day PP Validation: none (12m abstinence also assessed in sample of 445 smokers and there were significant differences; 15.0% vs 8.8% using ITT.)
Notes	Comparison 2, 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 min (interdecile range 10-28 min) for tailored, 13 min ( 8-23) for standard

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	No	Pseudo-randomized by last digit of caller's contact phone number
Allocation concealment?	No	Potential for selection bias but unlikely given low contact
Incomplete outcome data addressed? All outcomes	Yes	37% lost to follow up at 6m. No differential drop-out, losses included as smokers.

**Osinubi 2003**

Methods	Setting: occupational health service, USA Recruitment: asbestos-exposed workers & 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 & resources

**Osinubi 2003** (Continued)

Outcomes	Abstinence at 6m, 30 day PP, telephone Validation: none	
Notes	Comparisons 4-6	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	Sealed envelopes, not stated if opaque & numbered
Incomplete outcome data addressed? All outcomes	Yes	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 3m; 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 hr hotline with daytime access to counsellors.	
Outcomes	Abstinence at 18m, sustained from 3m. 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 randomization. The higher quit rate in the hotline counties was consistent in all analyses. 36% called hotline, 8.7% spoke with counsellors. Estimated effect displayed in comparison 3	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Matched pairs of counties assigned to condition in a restricted procedure to minimize media spill-over.

**Ossip-Klein 1991** (Continued)

Allocation concealment?	Unclear	Participant recruitment not linked to county assignment so selection bias unlikely
Incomplete outcome data addressed? All outcomes	Yes	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 $\geq 60$ , planning to quit in next 3m; 61% F, av. cigs/day 25
Interventions	1. S-H manual (Clear Horizons), access to 24 hr hotline, 2 letters of support and hotline reminders 2. As 1, plus proactive TC, 2 calls at 4 & 8 wks. Counsellors followed structured format to provide strategies based on SoC.
Outcomes	Abstinence at 6m (7-day PP) Validation: no biochemical. Significant others only. Refusals and nonconfirmations classified as smokers.
Notes	Comparisons 4-6. 42% had called hotline and 17.5% spoken to counsellor by 6m.

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	97% reached at 12m

**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); 62% F, av. age 43, av. cigs/day 27

**Prochaska 1993** (Continued)

Interventions	<ol style="list-style-type: none"> <li>1. ALA S-H manuals</li> <li>2. Tailored manuals - 5 covering precontemplation, contemplation, action, maintenance, relapse. Participants sent manual for their SoC and subsequent ones.</li> <li>3. Interactive - in addition to tailored manuals, sent personally tailored reports in response to questionnaires</li> <li>4. Proactive TC - short (15 min) calls at 0, 1m, 3m, 6m. Materials as in 3.</li> </ol>
Outcomes	<p>Sustained abstinence at 18m (12m &amp; 18m)</p> <p>Validation: none. Participants asked for names of significant others but these not contacted</p>
Notes	Comparisons 4-6. 4 vs 3, TC vs S-H alone. Numbers randomized to groups and quit rates as shown in graphs obtained from authors.

**Risk of bias**

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described, stratified by SoC
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	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 randomized, sensitivity analysis does not alter conclusions

**Prochaska 2001**

Methods	<p>Setting: Managed care organization, USA</p> <p>Recruitment: Smokers identified by survey of members. 85% recruited to a study, unselected for motivation to quit</p>
Participants	1447 smokers (723 in comparisons used); 38% were precontemplators, 56% F, av. age 38, av. cigs/day 20
Interventions	<ol style="list-style-type: none"> <li>1. Assessment only (completed questionnaires on 4 occasions)</li> <li>2. Expert System S-H. Tailored 2-3 page report at 0, 3m, 6m and SoC matched manual</li> <li>3. As 2, plus proactive TC, short calls at 0, 3m, 6m. Similar to <a href="#">Prochaska 1993</a> protocol but more emphasis on alternative targets for those unwilling to set quit date.</li> <li>4. As 3, plus computer scheduled cig reduction.</li> </ol>
Outcomes	<p>Abstinence at 18m, sustained for 6m. (Other measures of abstinence also reported)</p> <p>Validation: None</p>

**Prochaska 2001** (Continued)

Notes	Comparisons 4-6. 3 vs 2, TC vs S-H alone. Other arms compared in Self-help review	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	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 & 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 wks ( $\leq 25$ / $> 25$ ): 61%/67% F, 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 wks
Outcomes	Abstinence at 6m (sustained). Only people abstinent at 3m followed at 6m. Validation: none for most, small local sample tested, no responders disconfirmed, 4/19 did not attend (reported in McAlister 2004)
Notes	Comparison 1. 58% did not complete more than one session of counselling (McAlister paper)

<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Loss to follow up 50% in Int, 55% in Cont (from McAlister paper). Differed by age - higher loss in younger participants. All

**Rabius 2004** (Continued)

	losses treated as smokers
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**Rabius 2007**

Methods	Setting: National Cancer Society quitline, USA Recruitment: Callers to NCIS, interested in quitting
Participants	6322 smokers; 70% F, av. age 43, median cigs/day 20
Interventions	1/4 allocated to S-H control, remainder into 3x2 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 & last sessions) 3. 5 sessions with 50 mins counselling (Schedule as 1, 10 mins duration) Booster conditions: 2 x15min calls at 4 & 8 wks after last counselling call
Outcomes	Abstinence at 7m post randomization (PP) Validation: none
Notes	New for 2009 update. All interventions pooled vs control in comparison 1, results of different intensities discussed in more detail in text

**Risk of bias**

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Computer-generated random number sequence without stratification
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Loss to follow up ~50%, similar in all groups. Analysis includes losses as smokers.

**Reid 1999**

Methods	Setting: community, Canada Recruitment: community volunteers
Participants	396 smokers interested in quitting within 30 days, smoking $\geq 15$ cigs/day; 48% F, av. age 38, av. cigs/day 23-24
Interventions	1. Nicotine patch (15mg x 8 wks, 10mg x 2 wks, 5mg x 2 wks) free, physician advice (x 3 15 min, 2 wks before, 4 wks, 12 wks after quit date) 2. As 1, plus proactive TC, nurse counsellors, stage-based, 3 sessions at 2, 6, 13 wks.

**Reid 1999** (Continued)

Outcomes	Abstinence at 12m (PP) Validation: CO, but self-reported rates reported. Only 1 disconfirmation	
Notes	Comparisons 4-6, effect of adjunct TC compared to NRT and counselling alone. Similar counselling scripts to <a href="#">Orleans 1991</a>	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Randomized using table of random numbers, stratified by sex and nicotine dependence
Allocation concealment?	Unclear	Concealment unclear but physician blind to allocation
Incomplete outcome data addressed? All outcomes	Yes	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; 32% F, 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 patients 3, 14 & 30 days post-hospital discharge. Patients identified as needing support contacted by nurse counsellor for up to 3 x20 min sessions over 8 wks 2. Usual care	
Outcomes	Abstinence at 1 year (PP) Validation: none	
Notes	New for 2009 update. Comparisons 4-6, mean 2.1 IVR calls completed, 46% received at least one counselling call, mean 1.8, so total calls categorised as 4	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Yes	'mediated through the Clinical Epidemiology Unit's data centre, using a computer generated randomization list' Block size 6

**Reid 2007** (Continued)

Allocation concealment?	Yes	'Research staff were unaware of the treatment allocation prior to randomization'
Incomplete outcome data addressed? All outcomes	Yes	~15% lost to follow up, similar between groups. 1 Cont death excluded, others included

**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 & mailed a pregnancy-tailored S-H booklet 1. Pro-active counselling, up to 90 mins during pregnancy & 15 mins postpartum & targeted written materials 2. Usual care
Outcomes	Abstinence 3m postpartum (sustained at end of pregnancy & 3m) Validation: saliva cotinine $\leq 20$ ng/mL
Notes	New for 2009 update. Comparisons 4-6. Mean of 5 calls received, 4 in pregnancy, av. 68 mins in total.

**Risk of bias**

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	'computer-generated randomization list arranged in balanced blocks of 4 and stratified by referral source'
Allocation concealment?	Yes	'... the application revealed the next assignment only after the smoker had consented to participate in the study'
Incomplete outcome data addressed? All outcomes	Yes	21 miscarriages excluded. 33% Int, 28% Cont 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 (12m data based on 1391, 1225 in relevant arms) interested in finding out about quitting; 63% F, 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) 3. Tailored manual and 2 x 10-15 min proactive TC at 4-8 wks and 16-20 wks. Also access to a quitline
Outcomes	Abstinence at 12m. Validation: none
Notes	Comparisons 4-6. 3 vs 2. Preliminary 12m results used.

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	~75% reached at 12m with no treatment group differences in follow-up rate

**Roski 2003**

Methods	Setting: 40 clinics, USA Recruitment: smokers identified by survey
Participants	3436 smokers identified by survey, 2729 followed up, 1664 in relevant arms
Interventions	Access to proactive service 1. Financial incentives for clinical performance targets 2. As 1, plus smoker registry allowing referral to proactive TC for smokers ready to quit; 7 calls over 2m. (Control arm not included in review)
Outcomes	Abstinence at 6m for 7 days Validation: none
Notes	Does not contribute to MA. Test of providing TC to increase provider adherence to guidelines. Most of the smokers surveyed did not report use of counselling services

***Risk of bias***

**Roski 2003** (Continued)

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Cluster randomized by clinic, method not stated
Allocation concealment?	Unclear	Smokers identified by survey, selection bias unlikely
Incomplete outcome data addressed? All outcomes	Unclear	80.5% response to telephone survey, no difference by condition

**Smith 2004**

Methods	Setting: 10 communities, Canada Recruitment: Volunteers calling a quitline Randomization: centralised, stratified by community, sequential envelope, random sequence
Participants	632 smokers intending to quit; 61% F, 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 & 7 days post TQD 2. As 1, plus 4 further calls at 14, 21, 35, 40 days 3. Control: S-H only
Outcomes	Abstinence at 12m, sustained at 3m & 6m follow ups, also PP. Validation: none
Notes	All TC arms compared to S-H only control in comparison 1. 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**

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, stratified by community, method not described
Allocation concealment?	Yes	'opening next in a series of envelopes' after enrolment

**Smith 2004** (Continued)

Incomplete outcome data addressed? All outcomes	Yes	30% not available at 12m, no difference across 5 groups, missing treated as smoking
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**Solomon 2000**

Methods	Setting: community, USA Recruitment: volunteers for free nicotine patch trial
Participants	214 female smokers, >4 cigs/day, intending to quit in next 2 wks; av. age 33, av cigs/day 24
Interventions	1. Free nicotine patch (dose based on smoking level) for up to 10 wks. 2. Free patch plus proactive TC from female ex-smoker, 7 hrs training. Calls for up to 3m, starting pre quit, quit day, day 4, average 7.
Outcomes	Abstinence at 6m (7 days at 3m & 6m) Validation: CO $\leq$ 8ppm. 7-12% disconfirmation rate. Participants who did not provide samples remained classified as quitters
Notes	Comparisons 4-6. 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**

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	~27% lost in both groups, included as smokers

**Solomon 2005**

Methods	Setting: community, USA Recruitment: volunteers for free nicotine patch trial
Participants	330 female smokers >4 cigs /day, intending to quit in next 2 wks; av. age 34, av. cigs/day 24
Interventions	1. Free nicotine patch (dose based on smoking level) for up to 10 wks. 2. Free patch plus proactive TC from female ex smoker, 7 hrs training. Calls for up to 4m, up to 12m, starting pre quit, quit day, day 4

**Solomon 2005** (Continued)

Outcomes	Abstinence at 6m (30 days at 3m & 6m) Validation: none	
Notes	Comparisons 4-6, replication of <a href="#">Solomon 2000</a> with more extended telephone contact. Average number of calls 8.2, average duration 10 min	
<b><i>Risk of bias</i></b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	13% lost to follow up in both groups, included as smokers

**Sood 2009**

Methods	Setting: American Lung Association Quitline, USA Recruitment: Quitline callers	
Participants	990 callers; 62% F, av. age 43, av. cigs/day 22	
Interventions	1. Reactive counselling 2. Mailed S-H materials (Freedom from Smoking)	
Outcomes	Abstinence at 12m (PP) Validation: Saliva cotinine only for convenience sample, refusals not recorded	
Notes	New for 2009 update. Test of different interventions for people calling a quitline. Comparison 2	
<b><i>Risk of bias</i></b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Yes	Random number list created by independent statistician
Allocation concealment?	Yes	Enrollment & assignment by researchers independent of helpline staff. Concealment until assigned
Incomplete outcome data addressed? All outcomes	Yes	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 nonsmokers
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 3m (fruit & veg consumption also addressed) , tailored feedback report & tip sheets, NRT offered to those interested in quitting. 2. Control; Nothing during programme, targeted materials at study end.
Outcomes	Abstinence at 6m (7-day PP) Validation: none
Notes	New for 2009. Comparisons 4-6. Baseline denominators confirmed by author

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	18-20% lost, assumed smokers

**Stotts 2002**

Methods	Setting: antenatal clinics, USA Recruitment: pregnant continuing smokers
Participants	269 pregnant smokers at wk 28; av. age 28, approx 50% smoked <60 cigs/wk
Interventions	All participants had received brief counselling and 7 mailed S-H booklets in early pregnancy. 1. 20-30 min motivational interviewing-based proactive TC call in 28th-30th wk of pregnancy, tailored letter, 2nd call. 2. No further contact.
Outcomes	Abstinence or 'a few puffs' at 6m postpartum Validation: none postpartum, cotinine at wk 34
Notes	Comparisons 4-6. The common intervention in early pregnancy was not treated as face-to-face contact within the trial. 55% received complete intervention

***Risk of bias***

Item	Authors' judgement	Description
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**Stotts 2002** (Continued)

Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Unclear	39% lost at follow up in both groups, assumed to be smoking

**Swan 2003**

Methods	Setting: Group Health Co-operative, USA Recruitment: volunteers for a trial of medication
Participants	1524 smokers $\geq 10$ cigs/day; 57% F, 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 & S-H materials 2. Zyban Advantage Program (ZAP) tailored S-H materials, single telephone call after TQD, access to Zyban support line
Outcomes	Abstinence at 12m (7-day PP) Validation: none
Notes	Compares different intensity of TC. No dose/behavioural treatment interaction at 12m so bupropion arms collapsed.

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Randomization procedure built into study database
Allocation concealment?	Yes	Procedure ensured concealment
Incomplete outcome data addressed? All outcomes	Yes	Loss to follow up at 12m 17% Int, 12% Cont, treated as smokers

**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 randomization
Participants	382 (341 smokers, 41 recent quitters). Majority in contemplation or action SoC, 24% 'blue collar', 59% F, 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 6m (PP) (subset followed to 12m) Validation: saliva samples sought but not tested. Surrogates asked to confirm status
Notes	Comparison 2, 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 min for stage-based, 20 min for standard

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	17% lost to follow up at 6m, no significant difference between groups, included as smokers

**Velicer 2006**

Methods	Setting: Community, USA Recruitment: Proactive approach to smokers at Veterans Administration Medical Centre. Passive consent via mail then phone screening, not selected for motivation
Participants	2054 smokers (1009 in relevant arms); 23% F, 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 wk nicotine patch if in appropriate stage, reassessed for NRT eligibility at 6 & 10m. (not used in this review) 3. As 2. plus one expert system written feedback report 4. As 3. plus regular automated TC (prerecorded voice files tailored to responses). People

**Velicer 2006** (Continued)

	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	Abstinence at 30m, sustained for 6m Validation: none	
Notes	New for 2009 update. Comparisons 4-6, 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	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Yes	Computer-based random number generator
Allocation concealment?	Yes	Allocation done after completion of survey. Randomized participants who did not return consent form are excluded from further analyses
Incomplete outcome data addressed? All outcomes	Yes	39% lost incl 8% refused by 30m, no significant differences between groups. Different treatments of missing data reported not to have altered pattern of results.

**Young 2008**

Methods	Setting: General Practices, Australia Recruitment: Patients attending for routine consultations, not selected for motivation	
Participants	318 smokers; 53% F, 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. 5A's counselling framework. If willing to make a quit attempt mailed quit kit, encouraged to buy NRT, phoned again on TQD, 1wk, 3 wks. 2. Usual care (GPs given quit kits to distribute to patients)	
Outcomes	Abstinence at 12m (PP) Validation: none	
Notes	New for 2009 update. Comparisons 4-6. We classified control as minimal intervention (4.1.1) 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.	

Young 2008 (Continued)

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Questionnaires randomly ordered and coded prior to delivery to the practice by selecting sequential numbers from a computer generated random number list.
Allocation concealment?	Unclear	Patients (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
Incomplete outcome data addressed? All outcomes	Yes	31% Int, 41% Cont 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 wk; 57% F, 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 TC at 1,3, 7, 14 & 30 days
Outcomes	Abstinence at 13m, sustained for 12m Validation: Cotinine <10mg/nl in a convenience sample. Disconfirmation rate not used to correct data, but refusal and misreport rates similar in all groups
Notes	Comparison 1, 2 & 3 vs 1. 3 vs 2 in effect of multiple sessions Approx 65% of single session & 67% of multisession group received some counselling. Multisession participants received 4 calls on average.

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	No	Pseudo-random, according to last 2 digits of telephone number

**Zhu 1996** (Continued)

Allocation concealment?	No	Potential for selection bias but unlikely given low contact
Incomplete outcome data addressed? All outcomes	Yes	12-16% lost to follow up at 13m, included as smokers

**Zhu 2002**

Methods	Setting: Quitline, USA Recruitment: callers to a quitline
Participants	3282 smokers calling quitline, ready to quit within 1 wk & wanting counselling; 56% F, 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 3m. Included quitting history, motivation, self efficacy, social support, planning, relapse prevention
Outcomes	Abstinence at 13m, sustained for 12m Validation: none
Notes	Comparison 1. Authors also analysed subgroups of control who did and didn't seek counselling. 32% of Cont and 72% of Int group received counselling

**Risk of bias**

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described. 60/40 split. Only randomized when counselling demand exceeded capacity
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	~30% lost to follow up at 13m in both groups, included as smokers

AHRQ: Agency for Healthcare Research and Quality

ALA: American Lung Association

CO: carbon monoxide

HMO: health maintenance organization

hrs: hours

ITT: intention-to-treat (analysis)

m: months

MA: meta-analysis

NCIS: National Cancer Information Service  
 NRT: nicotine replacement therapy  
 PP: point prevalence  
 SES: socio-economic status  
 S-H: Self-help materials  
 SoC: Stage of Change  
 TC: Telephone counselling  
 TQD: Target quit date

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

Study	Reason for exclusion
Ahijevych 1995	Pilot study with 12 wks follow up, after which the advice and control groups were offered the intervention. The intervention was 4 weekly mailings and telephone calls from a lay facilitator. No participants in any group (n = 64) quit smoking.
Alonso-Perez 2007	Not a fully randomized 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 3m 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 3m.
An 2008	Intervention was to increase clinic referrals to a quitline. No smoking outcomes.
Balanda 1999	Callers to a helpline were randomized to 1 of 2 S-H materials. No counselling was given. Follow up only 1m after receipt of materials. There was no difference in cessation rates between the booklet groups. Overall 16% of 515 respondents reported 7-day abstinence at 1m.
Best 1977	Allocation not stated to be random. Telephone follow up compared to group behavioural treatment with aversive smoking only. Abstinence rates were lower for the telephone group.
Bliksrud 2002	Not a randomized 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 ( <a href="#">Lancaster 2005b</a> ).
Boyle 2004b	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 ( <a href="#">Hajek 2009</a> ).
Buchanan 2004	Multicomponent intervention, only 12 wks follow up

(Continued)

Carlini 2008	Intervention to increase re-enrollment in quitline services. No smoking outcomes
Carreras 2007	Not a randomized trial. Compared intensive counselling delivered face-to-face or by telephone
Conway 2004	Focus on preventing relapse. See Cochrane review on relapse prevention ( <a href="#">Hajek 2009</a> ).
Cummings 1988	Callers to a helpline were randomized to one of 4 different S-H programmes or an information control. No counselling was given. There was no difference in outcome between any of the S-H booklets or the control, with sustained abstinence rates of 4-8% at 6m.
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. Campaign increased call rates 10 times compared to control markets. Proportion of calls from target group also increased. Cost per caller estimated at US\$61.
Cummings 2006a	Not a randomized trial. Evaluated impact of free NRT as adjunct to telephone support.
Curry 2003	Telephone component cannot be evaluated independently of face-to-face counselling.
Davis 1992	All participants were women with young children who called a hotline and received same stage-based counselling. They were randomized to receive 3 different S-H guides. See Cochrane review of S-H ( <a href="#">Lancaster 2005b</a> )
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 randomized to access to recorded messages, not a counsellor. Short follow up (4 wks).
Gies 2008	Only 3m 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.
Gordon 2007	Only 3m follow up reported at present.
Hasuo 2004	Telephone component cannot be evaluated independently of face-to-face counselling. The intervention included in-hospital counselling by a nurse.
Hokanson 2006	Telephone component cannot be evaluated independently of face-to-face counselling and offer of pharmacotherapy.

(Continued)

Holtrop 2005	The purpose of the telephone call was to encourage participants to enroll 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.
Killen 2008	Main intervention component was face-to-face support. Telephone contact in both arms.
Koffman 1998	Three 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 (Hajek 2009)
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.
Mahabee-Gittens 2008	Quitline referral confounded with brief advice, only 3m 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 wks.
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.
Mermelstein 2003	Compares two telephone-based interventions for preventing relapse following group therapy. Now included in Cochrane relapse prevention review (Hajek 2009)
Ockene 1992	Telephone support could not be evaluated independently of combined intervention.
Owen 2000	Not a controlled trial. Survey of callers to UK quitline. Conservatively assuming that non-responders at 1 year were continuing smokers and assuming 20% of reported successes would fail biochemical validation gave an adjusted quit rate of 15.6% (95% CI 12.7% to 18.9%).
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.
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. The quit rate was 23.6%, 8.2% reported not smoking for >80% of the previous year. It was estimated that 5.9% of the adult smokers in Scotland called during the year.
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.

(Continued)

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 program of 4 calls from a trained nurse counsellor. 36% quit rate at 8m.
Ringen 2002	Not randomized. Smokers chose intensity of support.
Rodgers 2005	Intervention used mobile phone (including text messaging). To be covered by separate Cochrane review ( <a href="#">Whittaker 2007</a> ).
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.
Sherman 2008	Abstinence data given only for intervention group
Shiffman 2000	Follow up 12 wks. At this point there was no evidence that the addition of a single proactive call 2 days after the TQD increased cessation rates over 6 mailings of tailored materials.
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, 2m 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.
Sutton 2007	All participants had same counselling intervention. Test of tailored written materials, see Cochrane self-help review ( <a href="#">Lancaster 2005b</a> ).
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.

(Continued)

Urso 2003	Only 12 wks follow up.
Vidrine 2006	Intervention used mobile phone (including text messaging). To be covered by separate Cochrane review (Whittaker 2007).
Wadland 1999	Not randomized. 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 3m follow up.
Wadland 2007	Trial of methods for clinic referral to quitline support. No quitting outcomes.
Westman 1993	Telephone component cannot be evaluated independently of face-to-face counselling.
Wetter 2007	Only 12 wks follow up.
Wolfenden 2008a	Quitline component was part of a comprehensive intervention including face-to-face support.
Zhu 2000a	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)

NRT: nicotine replacement therapy

S-H: self help

## 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	9	24904	Risk Ratio (M-H, Fixed, 95% CI)	1.37 [1.26, 1.50]

### Comparison 2. Interventions for callers to quitlines - comparison of different support during a single call

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, Fixed, 95% CI)	Totals not selected
1.1 Reactive counselling vs self-help materials	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 Stage based counselling versus general information	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 Tailored counselling versus standard counselling	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

### Comparison 3. Offer of counselling via quitlines/helplines/hotlines

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Long term cessation	3		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 Hotline and self help materials compared to self help only	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 Hotline and self-help materials for cessation maintenance compared to nothing	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 Reactive or proactive counselling vs provider counselling	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

**Comparison 4. 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 - All trials, subgroups by amount of control group support	44	24811	Risk Ratio (M-H, Fixed, 95% CI)	1.29 [1.20, 1.38]
1.1 Self-help or minimal intervention control	27	16194	Risk Ratio (M-H, Fixed, 95% CI)	1.34 [1.22, 1.47]
1.2 Adjunct to brief intervention or counselling	9	2953	Risk Ratio (M-H, Fixed, 95% CI)	1.38 [1.14, 1.68]
1.3 Adjunct to pharmacotherapy	9	5664	Risk Ratio (M-H, Fixed, 95% CI)	1.16 [1.03, 1.32]

**Comparison 5. Interventions for smokers not calling quitlines - subgroups by intensity: 1-2, 3-6, >6 calls**

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cessation at longest follow-up	44	24811	Risk Ratio (M-H, Fixed, 95% CI)	1.29 [1.21, 1.39]
1.1 Two sessions or fewer	9	6274	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [0.91, 1.26]
1.2 3-6 sessions	28	14597	Risk Ratio (M-H, Fixed, 95% CI)	1.34 [1.23, 1.47]
1.3 7 sessions or more	7	3940	Risk Ratio (M-H, Fixed, 95% CI)	1.39 [1.18, 1.63]

**Comparison 6. Interventions for smokers not calling quitlines - subgroups by motivation**

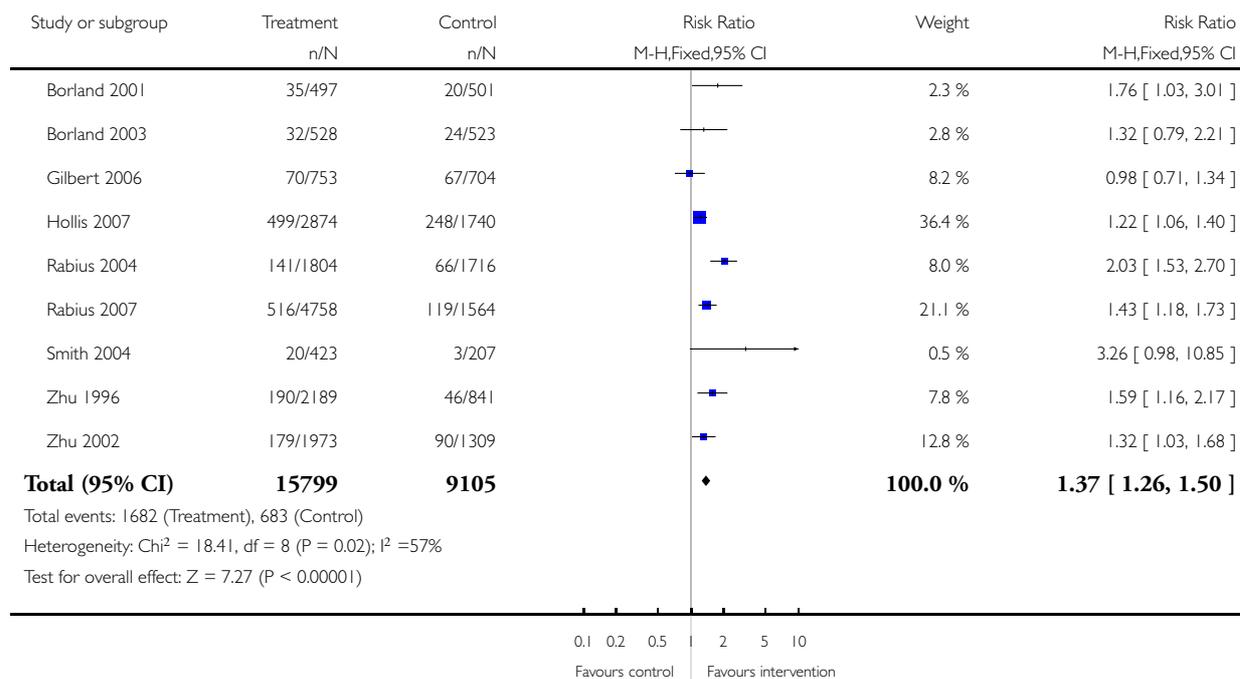
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Long term cessation	44	24811	Risk Ratio (M-H, Fixed, 95% CI)	1.29 [1.21, 1.39]
1.1 Selected for motivation/ interest in quitting	14	8084	Risk Ratio (M-H, Fixed, 95% CI)	1.32 [1.20, 1.47]
1.2 Not selected by motivation	30	16727	Risk Ratio (M-H, Fixed, 95% CI)	1.27 [1.16, 1.40]

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

Review: Telephone counselling for smoking cessation

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

Outcome: 1 Cessation at longest follow-up

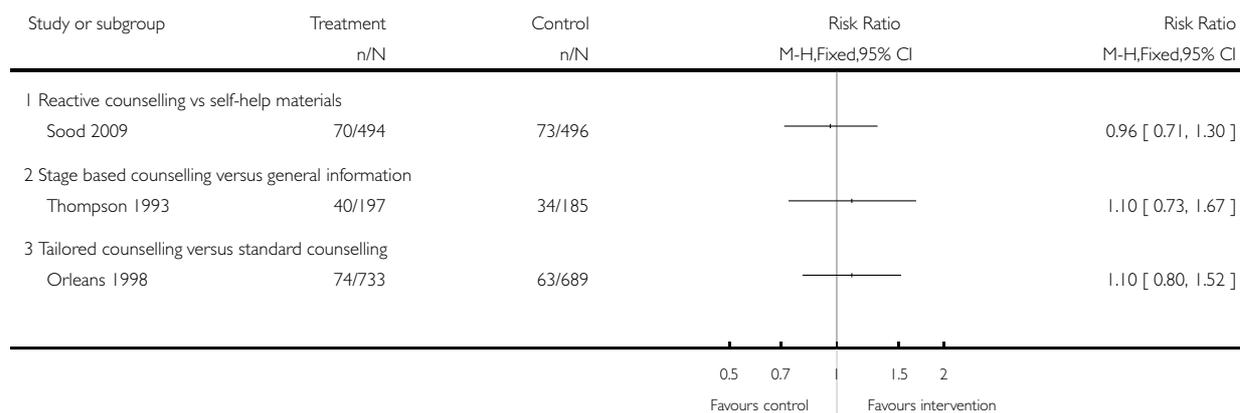


**Analysis 2.1. Comparison 2 Interventions for callers to quitlines - comparison of different support during a single call, Outcome 1 Cessation at longest follow-up.**

Review: Telephone counselling for smoking cessation

Comparison: 2 Interventions for callers to quitlines - comparison of different support during a single call

Outcome: 1 Cessation at longest follow-up

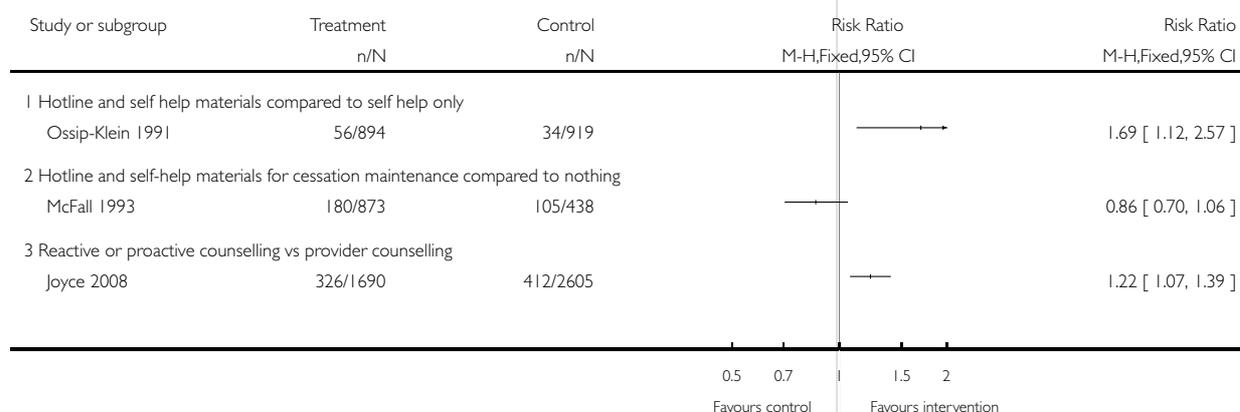


**Analysis 3.1. Comparison 3 Offer of counselling via quitlines/helplines/hotlines, Outcome 1 Long term cessation.**

Review: Telephone counselling for smoking cessation

Comparison: 3 Offer of counselling via quitlines/helplines/hotlines

Outcome: 1 Long term cessation

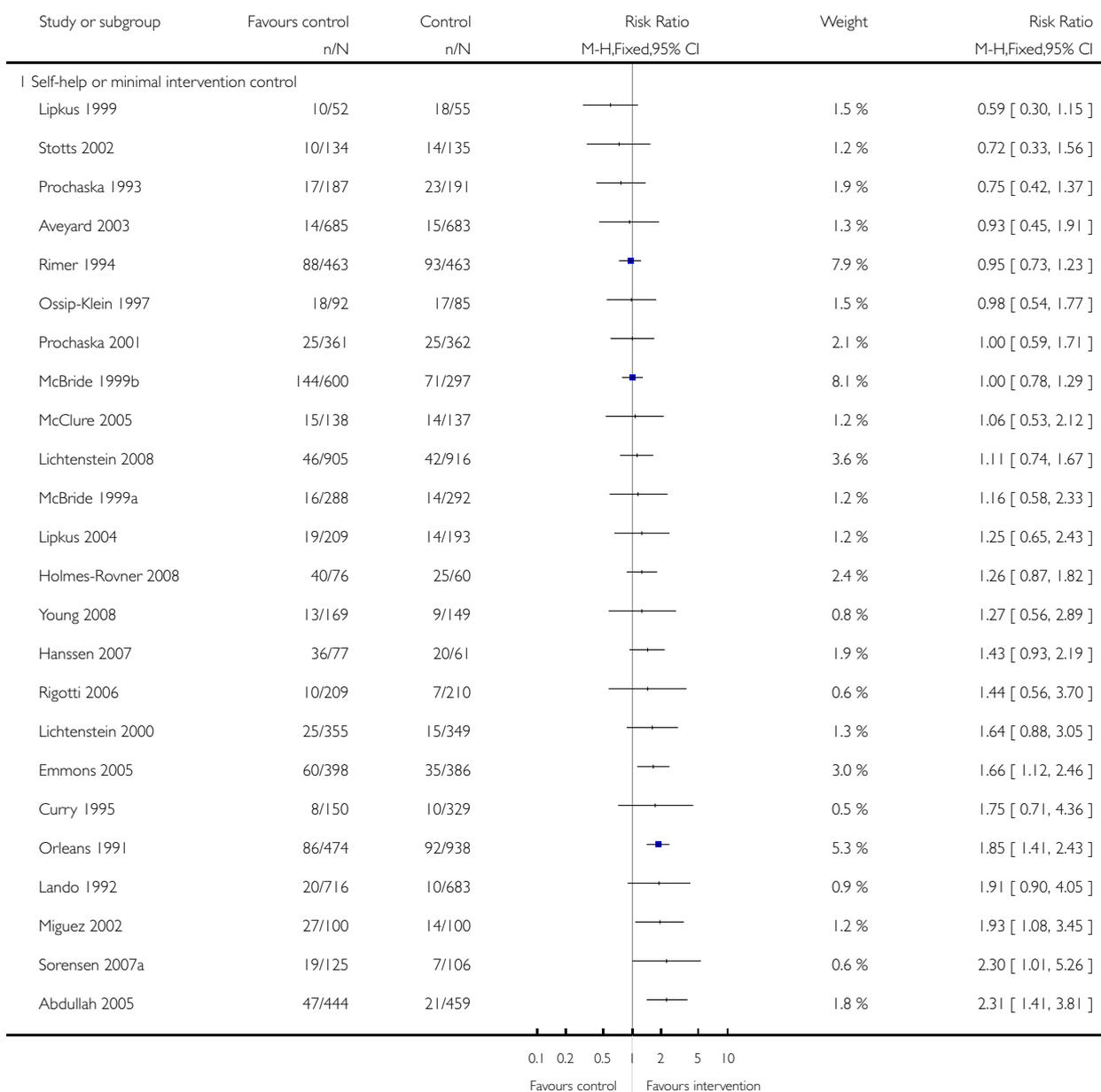


**Analysis 4.1. Comparison 4 Interventions for smokers not calling quitlines - subgroups by baseline support, Outcome 1 Cessation at longest follow-up - All trials, subgroups by amount of control group support.**

Review: Telephone counselling for smoking cessation

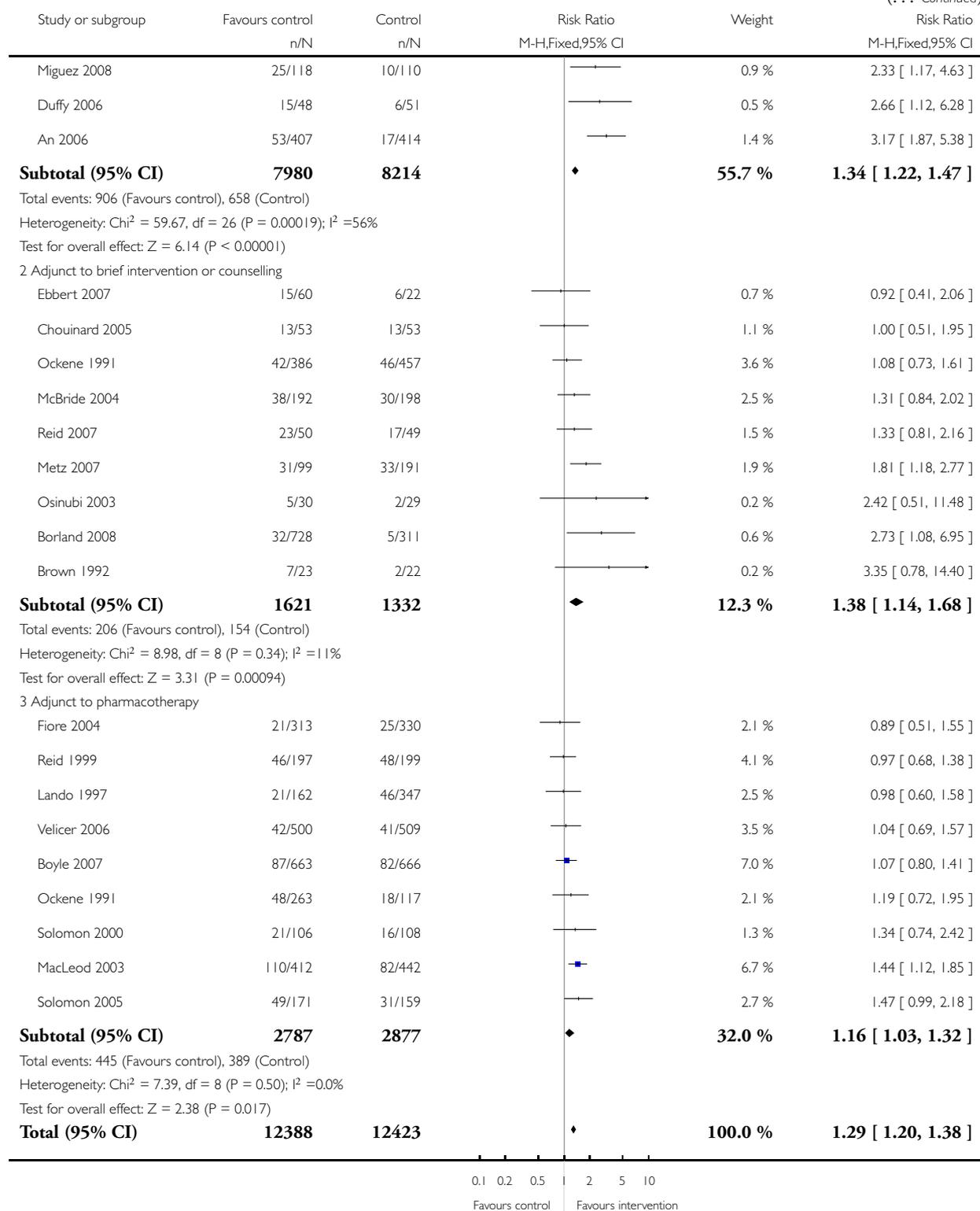
Comparison: 4 Interventions for smokers not calling quitlines - subgroups by baseline support

Outcome: 1 Cessation at longest follow-up - All trials, subgroups by amount of control group support



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Study or subgroup	Favours control n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
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Total events: 1557 (Favours control), 1201 (Control)  
 Heterogeneity:  $\chi^2 = 78.38$ ,  $df = 44$  ( $P = 0.001$ );  $I^2 = 44\%$   
 Test for overall effect:  $Z = 7.13$  ( $P < 0.00001$ )

0.1 0.2 0.5 | 2 5 10  
 Favours control Favours intervention

**Analysis 5.1. Comparison 5 Interventions for smokers not calling quitlines - subgroups by intensity: 1-2, 3-6, >6 calls, Outcome 1 Cessation at longest follow-up.**

Review: Telephone counselling for smoking cessation

Comparison: 5 Interventions for smokers not calling quitlines - subgroups by intensity: 1-2, 3-6, >6 calls

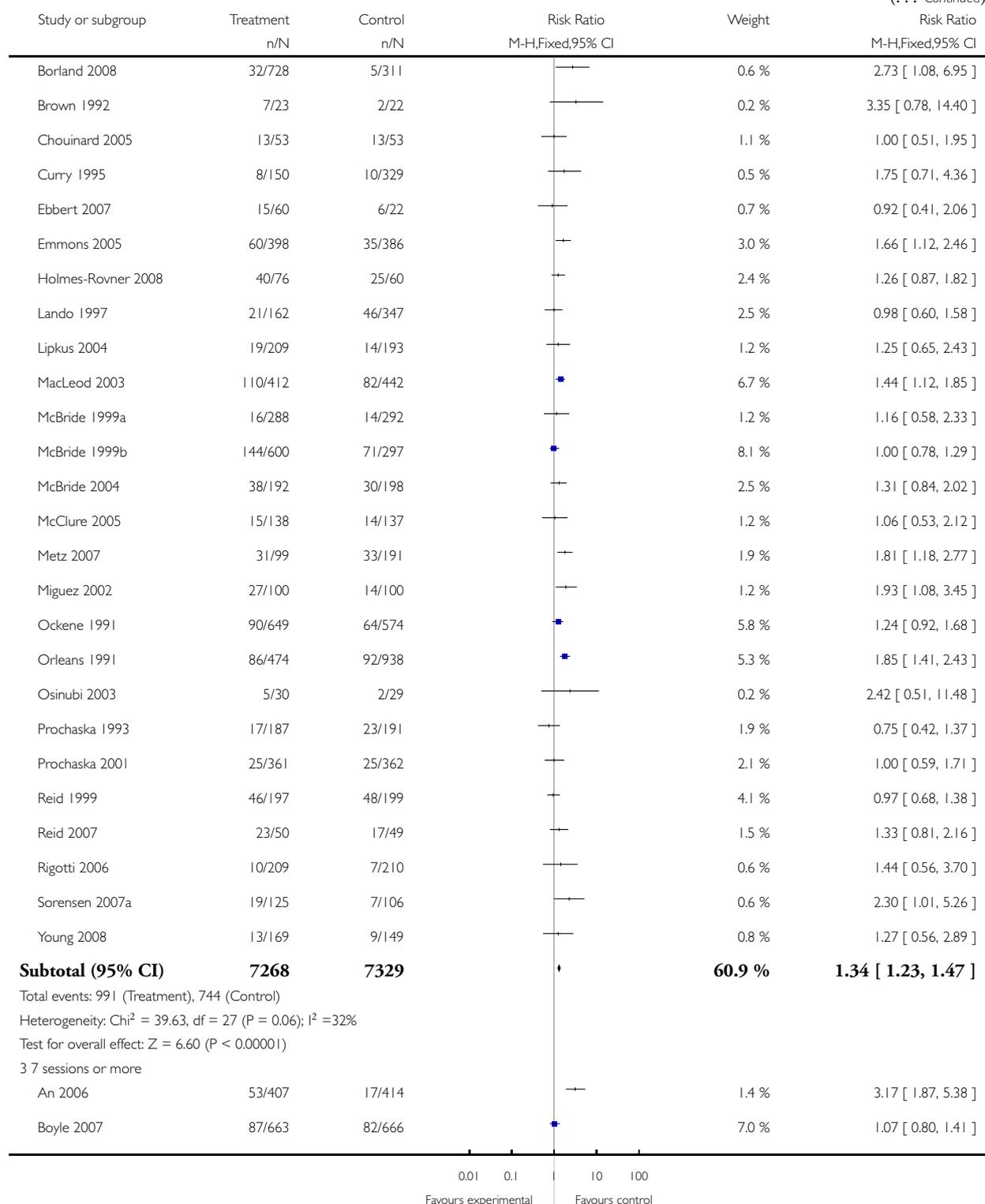
Outcome: 1 Cessation at longest follow-up

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
<b>I Two sessions or fewer</b>					
Fiore 2004	21/313	25/330		2.1 %	0.89 [ 0.51, 1.55 ]
Lando 1992	20/716	10/683		0.9 %	1.91 [ 0.90, 4.05 ]
Lichtenstein 2000	25/355	15/349		1.3 %	1.64 [ 0.88, 3.05 ]
Lichtenstein 2008	46/905	42/916		3.5 %	1.11 [ 0.74, 1.67 ]
Lipkus 1999	10/52	18/55		1.5 %	0.59 [ 0.30, 1.15 ]
Miguez 2008	25/118	10/110		0.9 %	2.33 [ 1.17, 4.63 ]
Ossip-Klein 1997	18/92	17/85		1.5 %	0.98 [ 0.54, 1.77 ]
Rimer 1994	88/463	93/463		7.9 %	0.95 [ 0.73, 1.23 ]
Stotts 2002	10/134	14/135		1.2 %	0.72 [ 0.33, 1.56 ]
<b>Subtotal (95% CI)</b>	<b>3148</b>	<b>3126</b>		<b>20.7 %</b>	<b>1.07 [ 0.91, 1.26 ]</b>
Total events: 263 (Treatment), 244 (Control) Heterogeneity: $\chi^2 = 14.49$ , $df = 8$ ( $P = 0.07$ ); $I^2 = 45\%$ Test for overall effect: $Z = 0.85$ ( $P = 0.39$ )					
<b>2 3-6 sessions</b>					
Abdullah 2005	47/444	21/459		1.8 %	2.31 [ 1.41, 3.81 ]
Aveyard 2003	14/685	15/683		1.3 %	0.93 [ 0.45, 1.91 ]

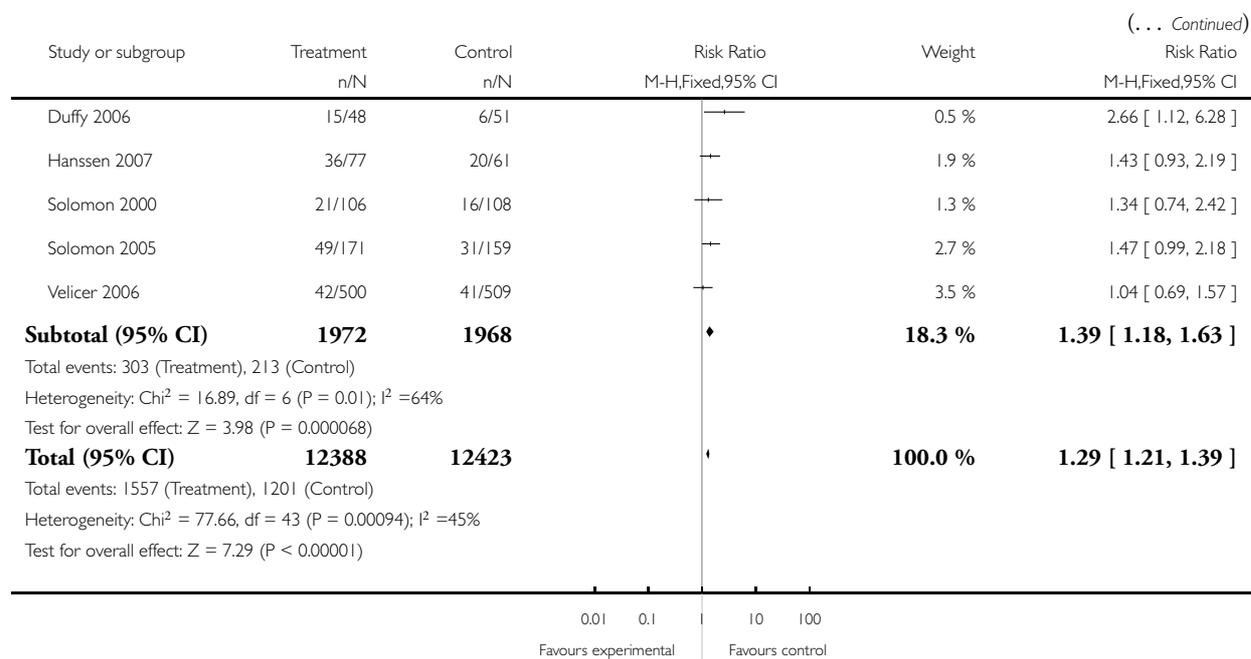
0.01 0.1 | 10 100  
 Favours experimental Favours control

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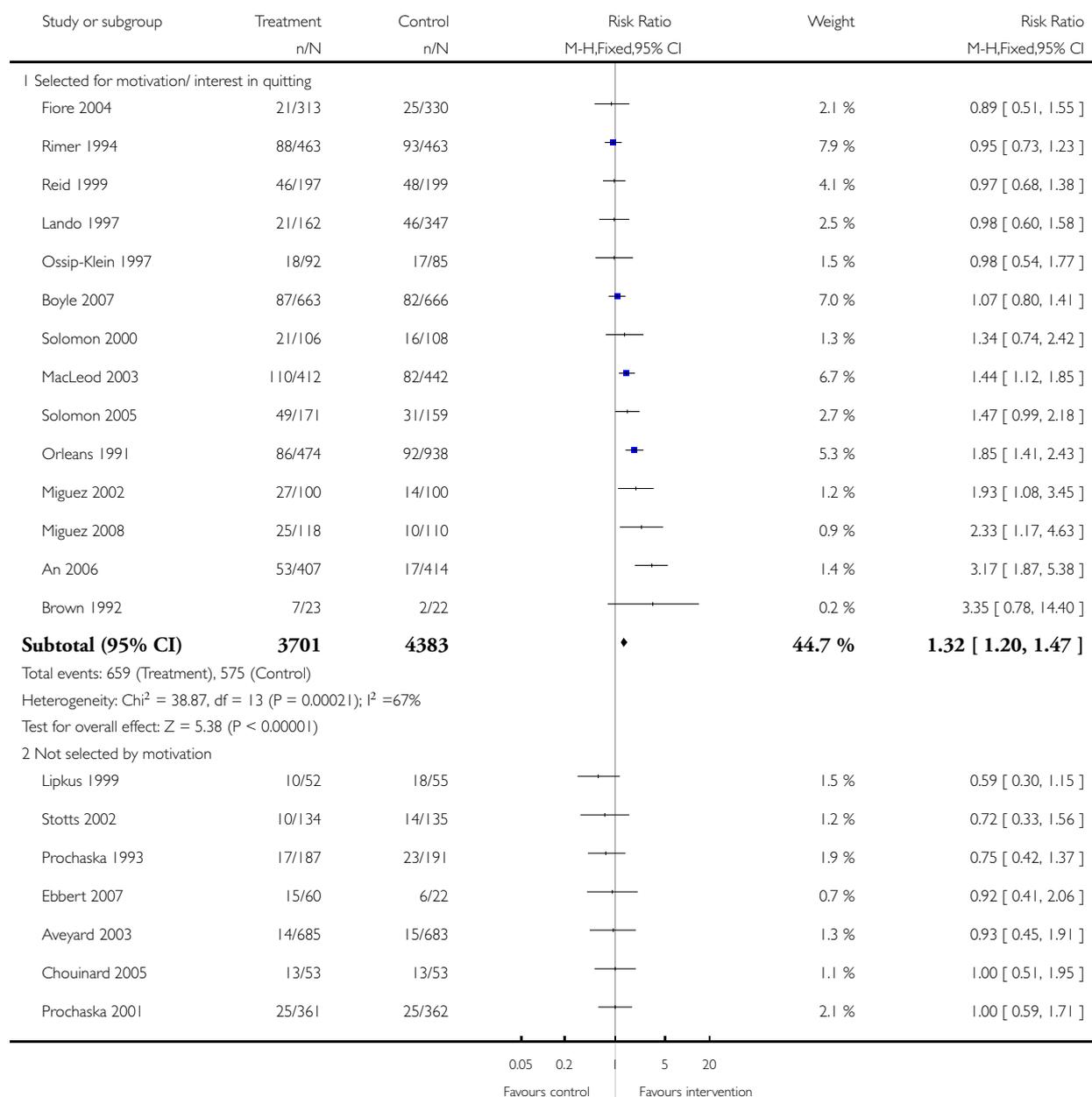


### Analysis 6.1. Comparison 6 Interventions for smokers not calling quitlines - subgroups by motivation, Outcome 1 Long term cessation.

Review: Telephone counselling for smoking cessation

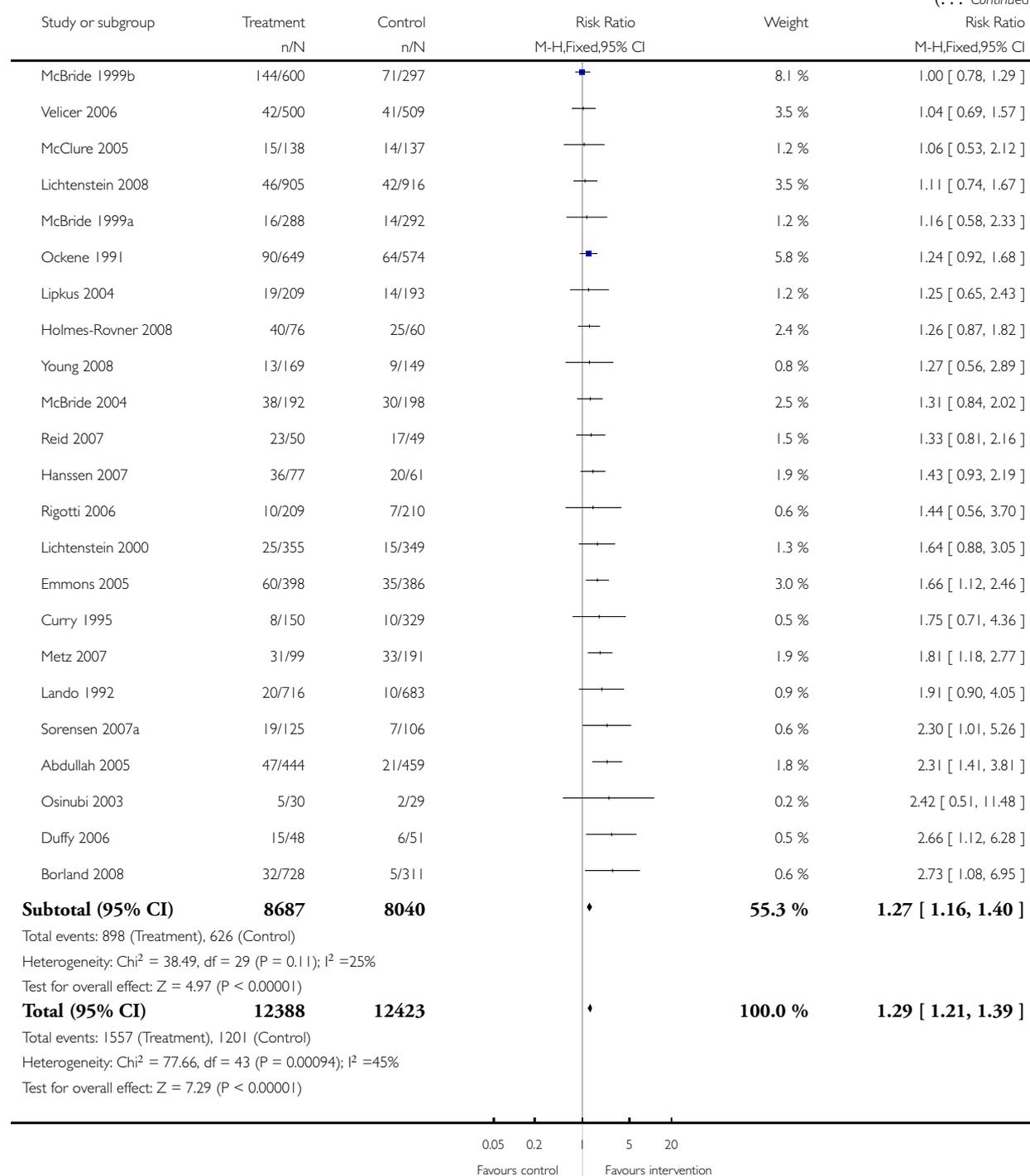
Comparison: 6 Interventions for smokers not calling quitlines - subgroups by motivation

Outcome: 1 Long term cessation



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## WHAT'S NEW

Last assessed as up-to-date: 17 March 2009.

Date	Event	Description
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.

## HISTORY

Protocol first published: Issue 4, 2000

Review first published: Issue 2, 2001

Date	Event	Description
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

LS and TL contributed to developing the protocol, extracting data and writing the review. RP became an author from issue 1 2003 and extracted data and contributed to updating the text.

## DECLARATIONS OF INTEREST

None known

## **SOURCES OF SUPPORT**

### **Internal sources**

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

### **External sources**

- NHS Research & Development Programme, UK.

## **INDEX TERMS**

### **Medical Subject Headings (MeSH)**

\*Hotlines; \*Smoking Cessation; Counseling [methods]; Randomized Controlled Trials as Topic

### **MeSH check words**

Humans