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Additional behavioural support as an adjunct to pharmacotherapy for smoking cessation (Review)

Hartmann-Boyce J, Hong B, Livingstone-Banks J, Wheat H, Fanshawe TR

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[Intervention Review]

Additional behavioural support as an adjunct to pharmacotherapy for smoking cessation

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ABSTRACT

Background

Pharmacotherapies for smoking cessation increase the likelihood of achieving abstinence in a quit attempt. It is plausible that providing support, or, if support is offered, offering more intensive support or support including particular components may increase abstinence further.

Objectives

To evaluate the effect of adding or increasing the intensity of behavioural support for people using smoking cessation medications, and to assess whether there are different effects depending on the type of pharmacotherapy, or the amount of support in each condition. We also looked at studies which directly compare behavioural interventions matched for contact time, where pharmacotherapy is provided to both groups (e.g. tests of different components or approaches to behavioural support as an adjunct to pharmacotherapy).

Search methods

We searched the Cochrane Tobacco Addiction Group Specialised Register, clinicaltrials.gov, and the ICTRP in June 2018 for records with any mention of pharmacotherapy, including any type of nicotine replacement therapy (NRT), bupropion, nortriptyline or varenicline, that evaluated the addition of personal support or compared two or more intensities of behavioural support.

Selection criteria

Randomised or quasi-randomised controlled trials in which all participants received pharmacotherapy for smoking cessation and conditions differed by the amount or type of behavioural support. The intervention condition had to involve person-to-person contact (defined as face-to-face or telephone). The control condition could receive less intensive personal contact, a different type of personal contact, written information, or no behavioural support at all. We excluded trials recruiting only pregnant women and trials which did not set out to assess smoking cessation at six months or longer.

Data collection and analysis

For this update, screening and data extraction followed standard Cochrane methods. The main outcome measure was abstinence from smoking after at least six months of follow-up. We used the most rigorous definition of abstinence for each trial, and biochemically-validated rates, if available. We calculated the risk ratio (RR) and 95% confidence interval (CI) for each study. Where appropriate, we performed meta-analysis using a random-effects model.

Main results

Eighty-three studies, 36 of which were new to this update, met the inclusion criteria, representing 29,536 participants. Overall, we judged 16 studies to be at low risk of bias and 21 studies to be at high risk of bias. All other studies were judged to be at unclear risk of bias. Results were not sensitive to the exclusion of studies at high risk of bias. We pooled all studies comparing more versus less support in the main analysis. Findings demonstrated a benefit of behavioural support in addition to pharmacotherapy. When all studies of additional behavioural therapy were pooled, there was evidence of a statistically significant benefit from additional support (RR 1.15, 95% CI 1.08 to 1.22, I^2 = 8%, 65 studies, n = 23,331) for abstinence at longest follow-up, and this effect was not different when we compared subgroups by type of pharmacotherapy or intensity of contact. This effect was similar in the subgroup of eight studies in which the control group received no behavioural support (RR 1.20, 95% CI 1.02 to 1.43, I^2 = 20%, n = 4,018). Seventeen studies compared interventions matched for contact time but that differed in terms of the behavioural components or approaches employed. Of the 15 comparisons, all had small numbers of participants and events. Only one detected a statistically significant effect, favouring a health education approach (which the authors described as standard counselling containing information and advice) over motivational interviewing approach (RR 0.56, 95% CI 0.33 to 0.94, n = 378).

Authors' conclusions

There is high-certainty evidence that providing behavioural support in person or via telephone for people using pharmacotherapy to stop smoking increases quit rates. Increasing the amount of behavioural support is likely to increase the chance of success by about 10% to 20%, based on a pooled estimate from 65 trials. Subgroup analysis suggests that the incremental benefit from more support is similar over a range of levels of baseline support. More research is needed to assess the effectiveness of specific components that comprise behavioural support.

PLAIN LANGUAGE SUMMARY

Does more support increase success amongst people using medications to quit smoking?

Background

Medications (including all types of nicotine replacement therapy, bupropion and varenicline) have been shown to help people quit smoking, and people who want help to quit will often be offered medication (pharmacotherapy). Behavioural support also helps people to quit. Behavioural support may include brief advice or more intensive counselling, and may be provided face-to-face on a one-to-one basis or in groups, or by telephone, including 'quitlines'. It has been unclear how much additional benefit is gained from adding support, or providing more intensive support for people who are using medication to help them quit.

Study characteristics

We looked for studies that included smokers and provided or offered medication to everyone. People in the studies were then randomly split into groups which received different amounts or kinds of behavioural support. To assess whether the support given helped people to quit, the studies had to count the number of people not smoking after six months or more. We did not look at studies that only included pregnant women.

Key results

We searched for studies in June 2018. We included 83 studies, with almost 30,000 people. Most studies included people who wanted to quit smoking, but a small number of studies offered support to people who were not trying to quit. Combining results from 65 trials suggested that increasing the amount of behavioural support for people using a stop-smoking medication increases the chances of quitting smoking. About 17% of people in the groups receiving less or no support quit smoking, compared to about 20% in the groups receiving more support. Providing some support via personal contact, face-to-face or telephone, is helpful. Few studies compared different types of support. More research is needed to find out if some types of behavioural support help more people using medication to quit smoking.

Quality of the evidence

We judged the overall quality of evidence to be high, meaning further research is very unlikely to change our results. This review has been updated twice and both times the findings remained very similar, even though many new studies were added.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Behavioural interventions as adjuncts to pharmacotherapy for smoking cessation

Patient or population: People using smoking cessation pharmacotherapy
Settings: Healthcare and community settings
Intervention: Behavioural interventions as adjuncts to pharmacotherapy

Outcomes	Illustrative absolute effects* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed successful quitters without intervention	Estimated quitters with intervention				
	Pharmacotherapy (with variable level of behavioural support)	Additional behavioural support (in addition to pharmacotherapy)				
Smoking cessation at longest follow-up Follow-up: 6 - 24 months	**Study population**[1]		**RR 1.15** (1.08 to 1.22)	23,331 (65 studies)	⊕⊕⊕⊕ **high**[2,3]	Effect very stable over time: updates of this analysis (15 new studies added 2015; 18 new studies added 2019) have had minimal impact on the effect estimate. Little evidence of differences in effect based on amount of support or type of pharmacotherapy provided
	171 per 1000	**197 per 1000** (185 to 209)				

The estimated rate of quitting with behavioural intervention (and its 95% confidence interval) is based on the assumed quit rate in the control group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1]Based on the control group crude average

[2]Sensitivity analysis removing studies at high risk of bias yielded results consistent with those from the overall analysis. A funnel plot was inconclusive but suggested there may have been slightly more small studies with large effect sizes than with small effect sizes. However, asymmetry was not clear and we did not downgrade on this basis; given the large number of included studies and the degree of homogeneity between them, it is unlikely that smaller unpublished studies showing no effect, if they existed, would significantly alter our results.

BACKGROUND

Description of the condition

Giving up smoking is the most effective way for people who smoke to reduce their risk of premature death and disability. People who smoke need to quit as soon as possible using evidence-based aids to increase their chances of success. These aids include behavioural support and pharmacotherapies.

Description of the intervention

Behavioural support interventions range from written materials containing advice on quitting to multisession group therapy programmes or repeated individual counselling in person or by telephone. Providing standard self-help materials alone seems to have a small effect on success, but there is good evidence of a benefit of individually tailored self-help materials or more intensive advice or counselling (Lancaster 2017; Livingstone-Banks 2019). There is also good evidence that nicotine replacement therapy products (NRT), varenicline, and bupropion all increase the long-term success of quit attempts (Cahill 2016; Hartmann-Boyce 2018; Hughes 2014).

How the intervention might work

Clinical practice guidelines recommend that healthcare providers offer people who are prepared to make a quit attempt both pharmacotherapy and behavioural support. The two types of treatment are believed to have complementary modes of action, and to independently improve the chances of maintaining long-term abstinence (Cofta-Woerpel 2007; Hughes 1995). Although guidelines recommend intensive support to improve abstinence rates, it is also recognised that many people will not attend multiple sessions. NRT products are available over the counter without a prescription in many countries, and people who purchase them may not access any specific behavioural support. People who obtain prescriptions for pharmacotherapies may receive some support, but this may be focused on explaining the proper use of the drug and not on counselling. It therefore may be that offering additional behavioural support increases quit rates above those seen in people given pharmacotherapy alone.

Why it is important to do this review

Other Cochrane Tobacco Addiction reviews have evaluated the evidence on behavioural and pharmaceutical interventions individually (Cahill 2016; Hartmann-Boyce 2018; Hughes 2014; Lancaster 2017; Livingstone-Banks 2019; Matkin 2019; Stead 2017). These reviews restrict inclusion to trials where interventions are unconfounded. Trials of pharmacotherapies must provide the same amount of behavioural support (materials, advice, counselling contacts) to all participants, whether they receive active treatment, or a placebo or no medication. Likewise, when behavioural interventions are evaluated there should be no systematic difference in the offer of medications between the active and control arms of the trial. Only reviews that evaluate interventions by specific providers (e.g. nurses, Rice 2017), or in specific settings (e.g. hospitals, Rigotti 2012), may include trials of interventions that combine behavioural therapies and various medications (e.g. NRT, bupropion, varenicline).

This review is one of two that systematically identify trials of interventions that combine effective pharmacotherapies (NRT, varenicline, bupropion, nortriptyline) with behavioural support (tailored materials, brief advice, in-person or telephone counselling). This review evaluates trials that compare different levels of behavioural intervention for people receiving any pharmacotherapy for smoking cessation, to provide an estimate of the effectiveness of intensifying behavioural support as an adjunct to pharmacotherapy, and, as such, overlaps with some separate reviews evaluating intervention types included here (e.g. Matkin 2019), which include studies of relevant behavioural therapies both on their own and as adjuncts to pharmacotherapy. The companion review (Stead 2016) includes trials in which an intervention combining pharmacotherapy and behavioural support is compared to standard care or a brief behavioural intervention without pharmacotherapy.

OBJECTIVES

To evaluate the effect of adding or increasing the intensity of behavioural support for people using smoking cessation medications, and to assess whether there are different effects depending on the type of pharmacotherapy, or the amount of support in each condition. We also look at studies which directly compare behavioural interventions matched for contact time, and where pharmacotherapy is provided to both groups (e.g. tests of different components or approaches to behavioural support as an adjunct to pharmacotherapy).

METHODS

Criteria for considering studies for this review

Types of studies

Randomised or quasi-randomised controlled trials.

Types of participants

We included trials that recruited people who smoke, recruited in any setting. We excluded trials that only recruited pregnant women; this population is considered in Coleman 2015. Trial participants did not need to be selected according to their interest in quitting, or their suitability for pharmacotherapy. However, since pharmacotherapy was offered or provided, participants were expected to be relatively motivated and prepared to use medication as part of their quit attempt.

Types of interventions

We included trials of smoking cessation interventions where all participants had access to a smoking cessation pharmacotherapy (including NRT, varenicline, bupropion and nortriptyline, or a combination or choice of these) and in which one or more intervention conditions received more intensive behavioural support than the control condition. Control group participants could be offered any level of support from minimal (e.g. written information provided as part of the medication prescription) to multisession counselling. The intervention could use different or additional types of therapy content (e.g. cognitive behaviour therapy, motivational interviewing). The additional support had to involve person-to-person contact which could be face-to-face or by telephone. In this update, we also included trials testing specific behavioural components that used a control matched for contract frequency and duration.

Types of outcome measures

Following the standard methodology of the Cochrane Tobacco Addiction Group, the primary outcome was smoking cessation at the longest follow-up using the strictest definition of abstinence, i.e. preferring sustained over point prevalence abstinence and using biochemically-validated rates, where available. In addition we noted any other abstinence outcomes reported, and conducted sensitivity analyses if the choice of outcome in a study might have altered the results of a meta-analysis. We excluded studies which did not set out to assess smoking cessation at six months or longer.

Search methods for identification of studies

We identified trials from the Cochrane Tobacco Addiction Group's Specialised Register (the Register), and the clinical trials registries: clinicaltrials.gov, and the ICTRP. The Register is generated from regular searches of the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, Embase, and PsycINFO, for trials of smoking cessation or prevention interventions. We ran our most recent searches in June 2018. At the time of the search, the Register included the results of searches of the Cochrane Central Register of Controlled trials (CENTRAL), issue 1, 2018; MEDLINE (via OVID) to update 20180531; EMBASE (via OVID) to week 201824; PsycINFO (via OVID) to update 201800528. See the Cochrane Tobacco Addiction Group website for full search strategies and list of other resources searched.

We searched the Register for records with any mention of pharmacotherapy, including any type of NRT, bupropion, nortriptyline or varenicline in title, abstract or indexing terms (see Appendix 1 for the final search strategy). We checked titles and abstracts to identify trials of interventions for smoking cessation that combined pharmacotherapy with behavioural support. We also considered for inclusion trials with a factorial design that varied both pharmacotherapy and behavioural conditions. For the first version of this review, we also tested an additional MEDLINE search using the smoking-related terms and design limits used in the standard Register search and the MeSH terms 'combined modality therapy' or (Drug Therapy and (exp Behavior therapy or exp Counseling)). This search retrieved a subset of records already screened for inclusion in the Register, and was used to assess whether it might retrieve studies where there was no mention of a specific cessation pharmacotherapy in the title, abstract or indexing. We did not find any additional studies from this approach, and so did not use it for subsequent updates.

Data collection and analysis

Selection of studies

For this version of the review, two reviewers (BH, HW, JHB) independently screened all studies for inclusion, with disagreements resolved by discussion or referral to a third reviewer.

Data extraction and management

For this version of the review, two reviewers (BH, HW, JHB, CM, JLB) independently extracted data and assessed risk of bias for each included study, with disagreements resolved by discussion or referral to a third reviewer. We extracted the following information:

- Country and setting of trial
- Study design
- Method of recruitment, including any selection by motivation to quit
- Characteristics of participants including gender, age, smoking rate
- Characteristics of intervention deliverer
- Common components: type, dose and duration of pharmacotherapy
- Intervention components: type and duration of behavioural support
- Control group components: type and duration of behavioural support
- Outcomes: primary outcome length of follow-up and definition of abstinence, other follow-up and abstinence definitions, use of biochemical validation, adverse events

- Sources of funding & potential conflicts of interest
- Information used to assess risk of bias (see below)

Assessment of risk of bias in included studies

We evaluated studies on the basis of the randomisation procedure, allocation concealment, incomplete outcome data assessment and any other bias using the standard Cochrane methods (Cochrane Handbook 2011). We also judged studies on the basis of detection bias, according to standard methods of the Cochrane Tobacco Addiction Group. For trials of behavioural interventions (such as those included here), it is not relevant to assess performance bias as blinding of participants and personnel is not feasible due to the nature of the intervention. In these trials, we assessed detection bias based on the outcome measure; e.g. if the outcome was objective (biochemically-validated) or if contact was matched between arms, or both, we judged the studies as having low risk of bias, but if the outcome was self-reported and the intervention arm received more support than the control arm, we judged differential misreport to be possible and rated these studies as having high risk of bias.

Measures of treatment effect

We expressed trial effects as a risk ratio (RR) (calculated as: quitters in treatment group/total randomised to treatment group)/(quitters in control group/total randomised to control group), alongside 95% confidence intervals (CIs). A risk ratio greater than 1 indicates a better outcome in the intervention group than in the control condition.

Unit of analysis issues

We included both individually and cluster-randomised trials. In extracting data from cluster-randomised trials, we considered whether study authors had made allowance for clustering in the data analysis reported, and planned to use data adjusted for clustering effects, where available.

Dealing with missing data

We reported numbers lost to follow-up by group in the 'Risk of bias' table. Following standard Cochrane Tobacco Addiction Group methods, we assumed people lost to follow-up to be smoking and included them in the denominators for calculating the risk ratio. We have reported any exceptions to this assumption in the 'Risk of bias' table. We noted separately any deaths during follow-up and excluded them from denominators.

Assessment of heterogeneity

We assessed statistical heterogeneity using the I^2 statistic (Higgins 2003). As guided by Higgins 2003, we considered a value greater than 50% as evidence of substantial heterogeneity.

Assessment of reporting biases

We used funnel plots to assess small-study effects and investigate the possibility of publication bias.

Data synthesis

For groups of trials where we judged meta-analysis appropriate, we pooled RRs using a Mantel-Haenszel random-effects model, and reported a pooled estimate with a 95% CI.

If trials had more than one intervention condition, we compared the most intensive combination of behavioural support and pharmacotherapy to the control in the main analysis.

We categorised the intensity of behavioural support in both intervention and control conditions based on two of the categories used in the US Guidelines (Fiore 2008): 'Total amount of contact time' (Categories: 0, 1 to 30*, 31 to 90, 91 to 300, > 300 minutes (*guideline categories '1 to 3' and '4 - 30' combined for this review)) and 'Number of person-to-person sessions' (Categories: 0*, 1 to 3*, 4 to 8, > 8 (*guideline categories '0 to 1', and '2 to 3' combined for this review)). Additionally we used the number and duration of contacts as continuous predictors in meta-regression, described below.

Subgroup analysis and investigation of heterogeneity

We used the difference in average intensity of support (number or duration of contacts) between intervention and control conditions as the main potential feature to explain any heterogeneity. In an exploratory analysis new to this version of the review, we planned to use a non-linear meta-regression model in R version 3.5.2 (R program) to explore the effect of difference in number and duration of contacts on intervention effect, anticipating that differences in the intensity of support would have the largest impact when the amount of contact in the control group was smallest. However, graphs of intervention effect against these factors did not provide evidence of this non-linear trend, and so instead results were presented graphically and summarised using a standard meta-regression model with each of the factors as a linear predictor. Studies where the intensity of support could not be determined for one or more treatment groups were excluded from the meta-regression.

Sensitivity analysis

We considered whether the main results were sensitive to the exclusion of studies at high risk of bias in any domain. We also considered whether the definition and duration of follow-up or the inclusion of intermediate-intensity arms in trials with more than two relevant arms had any impact on treatment effect.

Summary of findings table

Following standard Cochrane methodology, we created a 'Summary of findings' table for our primary outcome using the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the certainty of the body of evidence for each outcome, and to draw conclusions about the certainty of evidence within the text of the review.

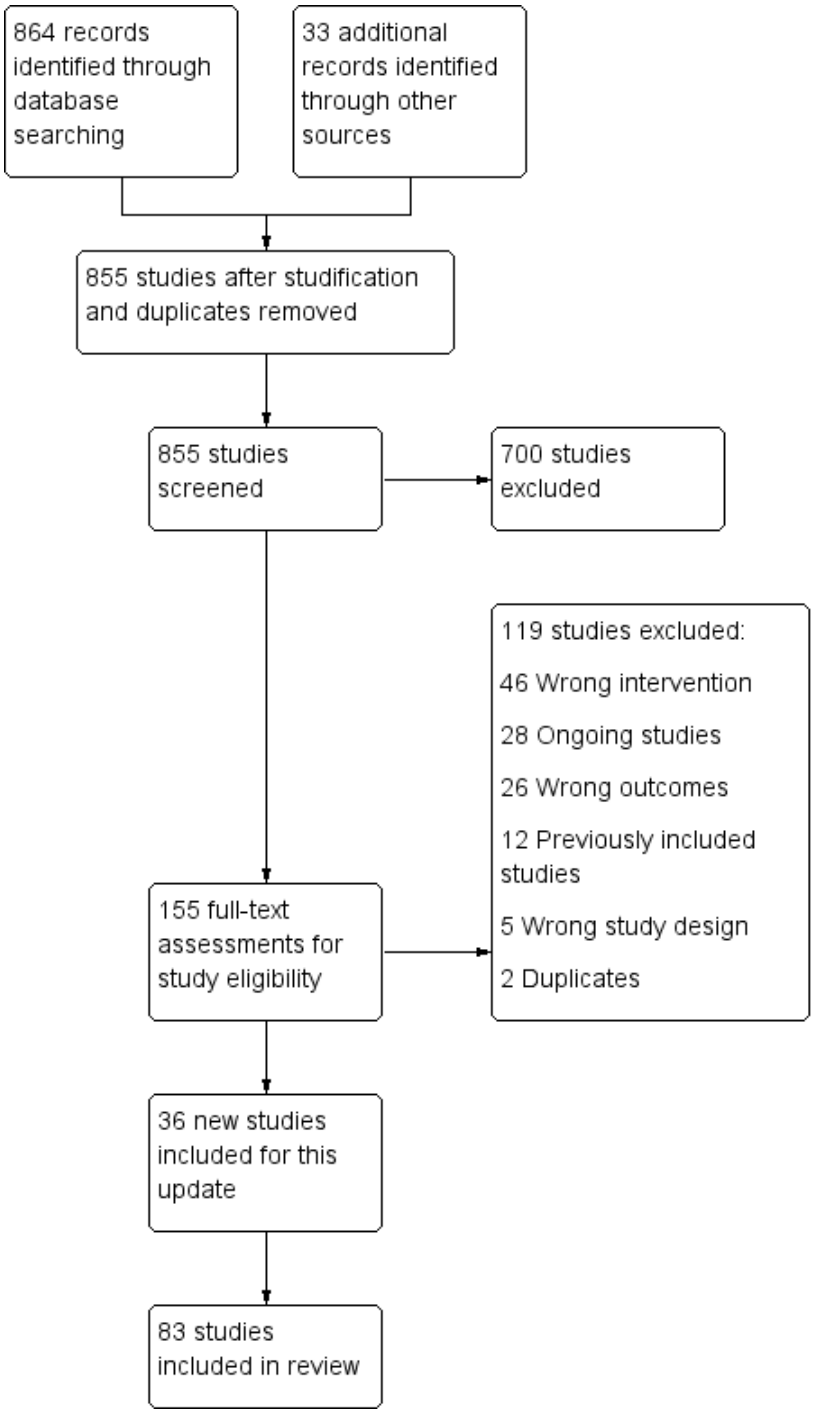
RESULTS

Description of studies

Results of the search

Our combined searches for all versions of this review retrieved approximately 3837 records. We excluded most of them as not relevant based on title and abstract. Of the records that did relate to trials of interventions for smoking cessation, most were not relevant because they were placebo-controlled trials of pharmacotherapies, in which the behavioural support was the same for intervention and control conditions. We identified 83 studies for inclusion and listed 63 as excluded. We identified 36 ongoing studies. Further studies of combined pharmacotherapy and behavioural support that did not offer pharmacotherapy to the control group are included in Stead 2016. Some studies had multiple study arms and contributed to both Stead 2016 and to this review. The flow of studies is reported in Figure 1.

Figure 1. Study flow diagram for 2019 update



Included studies

We identified 83 studies as relevant for inclusion, of which 36 were new for the 2019 update. 29,536 participants are now included in relevant arms of these studies. Details of each study are given in the Characteristics of included studies table, and a summary of intervention and control group characteristics in Table 1.

Study setting, participant recruitment and motivation

Twenty-nine studies were conducted in a healthcare setting (excluding smoking cessation clinics); this included ten studies in primary care (Aveyard 2007; Bock 2014; Cook 2016; Ellerbeck 2009; Fiore 2004; Ockene 1991; Schlam 2016; Smith 2014; Stanton 2015; Van Rossem 2017; Wagner 2016), one in a chest clinic (Tonnesen 2006), one in a cardiovascular disease outpatient clinic (Wiggers 2006), one in a rheumatology clinic (Aimer 2017), one in an immunology clinic (Stanton 2015), three in HIV clinics (Lloyd-Richardson 2009; Humfleet 2013; O'Cleirigh 2018), one in a lesbian, gay, bisexual, and transgender health centre (Matthews 2018), one in mental health clinics (Williams 2010), one in a mental health research centre (Baker 2015), three in substance abuse clinics (Lifrak 1997; Rohsenow 2014; Stein 2006), two in a Veterans Administration hospital (Brody 2017; Simon 2003), and three in cardiac wards (Berndt 2014; Busch 2017; Hasan 2014) or any ward (Warner 2016).

Since the intervention included the provision of pharmacotherapy, many of the studies recruiting in a healthcare setting recruited volunteers who were interested in making a quit attempt, but motivation to quit was not always an explicit eligibility criterion. Wiggers 2006 used a motivational interviewing approach and participants did not all make quit attempts. Ockene 1991 offered nicotine replacement therapy (NRT) and participants were not initially selected by motivation, and Ellerbeck 2009 included a small proportion of people in the 'precontemplation stage' of the transtheoretical model.

A further four studies recruited members of health maintenance organisations (HMOs) (Boyle 2007; Lando 1997; Swan 2003; Swan 2010). Boyle 2007 proactively recruited HMO members who had filled a prescription for smoking cessation medication, while the others sought volunteers by advertising to HMO members. Universities or research facilities were the study sites for five studies (Baker 2015; Bloom 2017; Prapavessis 2016; Schmitz 2007a; Webb Hooper 2017).

Forty studies recruited community volunteers interested in quitting, including three which recruited people who were attending cessation clinics (Alterman 2001; Rovina 2009; Yalcin 2014). The study setting was not explicitly stated in four studies (LaChance 2015; Macpherson 2010a; Strong 2009; Vidrine 2016).

One study recruited adolescents (Bailey 2013); all other studies were conducted in adults.

Characteristics of intervention and control conditions

Pharmacotherapy

NRT was offered in the majority of studies, with 41 providing nicotine patch only. While most of these provided a supply of NRT for between eight and 12 weeks, three studies offered only a two-week supply (Bricker 2014; MacLeod 2003; Warner 2016). Eight studies used nicotine gum only (Ahluwalia 2006; Ginsberg 1992; Hall 1985; Hall 1987; Hall 1994; Huber 2003; Ockene 1991; Wewers 2017), one used sublingual tablets (Tonnesen 2006), and three did not specify the type (Aimer 2017; Bushnell 1997; Wagner 2016). Five studies offered patch and/or gum (Bricker 2014; Cook 2016; Humfleet 2013; Schlam 2016; Smith 2013a). Seven studies provided bupropion alone (Cropsey 2015; Gifford 2011; McCarthy 2008; Rovina 2009; Schmitz 2007a; Strong 2009; Swan 2003), one provided nortriptyline alone (Hall 1998) and four provided varenicline alone (NCT00879177; Smith 2014; Swan 2010; Van Rossem 2017). Three studies offered a choice of pharmacotherapy; NRT or bupropion (Boyle 2007; Ellerbeck 2009), or NRT, bupropion, or varenicline (Yalcin 2014). Gariti 2009 randomised participants to NRT or bupropion using a double-dummy design. Hall 2002 randomised participants to either bupropion or nortriptyline (placebo arms not used in this review). Three studies provided combination therapy of both NRT and bupropion (Hall 2009; Killen 2008; Vander Weg 2016).

Behavioural support

The intensity of the behavioural support, in both the number of sessions and their duration, was very varied for both intervention and control conditions.

In seven trials, there was no counselling contact for the controls: in six, participants received pharmacotherapy by mail (Boyle 2007; Ellerbeck 2009; MacLeod 2003; Solomon 2000; Solomon 2005; Vander Weg 2016), and in Fiore 2004 there was no counselling or advice for the control group although there was face-to-face contact with study staff. In 30 studies, the control arms had between one and three contacts (which could be face-to-face or by telephone) and most of these had a total contact duration of between four and 30 minutes, although three had between 31 and 90 minutes contact scheduled (Gifford 2011; Lando 1997; Reid 1999). In 34 studies, the control group was scheduled to receive between four and eight contacts, with all except eight (Aveyard 2007; Bricker 2014; Cook 2016; Gariti 2009; Kim 2015; Smith 2013a;

Vidrine 2016; Wu 2009) involving a total contact duration of over 90 minutes. Twelve studies offered over eight contacts for the controls (Bailey 2013; Baker 2015; Begh 2015; Bloom 2017; Brody 2017; McCarthy 2008; Patten 2017; Prapavessis 2016; Strong 2009; Webb Hooper 2017; Williams 2010; Yalcin 2014).

Typically, the intervention involved only a little more contact than the control, so that the most intensive interventions were compared with more intensive control conditions. In five trials, the intervention consisted of between one and three sessions, with a total duration of 31 to 90 minutes in most of them (Calabro 2012; Rohsenow 2014; Stein 2006; Wiggers 2006), although Calabro 2012 also provided access to a tailored internet programme. Warner 2016 offered a brief (under 5 minutes) quitline facilitation intervention. Forty-five studies tested interventions of between four and eight sessions, about half of which were in the 91 to 300 minute-duration category. The remaining 32 studies offered more than eight sessions, typically providing over 300 minutes of counselling in total. The number of contacts planned was not always delivered, but generally using the average number delivered would not have changed the coding category. In a few cases where the number of contacts was either not specified or open-ended, we coded the average number delivered and noted this in the Characteristics of included studies table.

In Analysis 1.2, we grouped trials by the number of intervention and control contacts. In 12 trials, the intervention and control condition fell into the same coding category for number of contacts (one to three contacts: Calabro 2012; Rohsenow 2014; Stein 2006; Wiggers 2006; four to eight contacts: Aveyard 2007; Bushnell 1997; Huber 2003; Tonnesen 2006; Wu 2009; more than eight contacts: McCarthy 2008; Williams 2010; Yalcin 2014). A summary of the number of sessions and duration for intervention and control conditions for each trial is provided in Table 1.

Length of follow-up and definitions of abstinence

The majority of the included studies followed participants for a duration of six to 12 months from the target quit date, or entry into the study. Exceptions were Hall 2009 and Ellerbeck 2009 which each had a two-year follow-up, and Baker 2015 with a three-year follow-up. The design of the Ellerbeck study, in which participants were repeatedly offered support to quit, means that participants who had quit at the end of follow-up would not necessarily have been quit for as long as two years. Thirty-five studies only followed participants for six months.

The majority of studies reported abstinence as a prevalence measure, rather than requiring reported sustained abstinence, or abstinence at multiple follow-up points. Fifteen studies did not attempt any biochemical verification of self-reported abstinence; this is discussed further in Risk of bias in included studies.

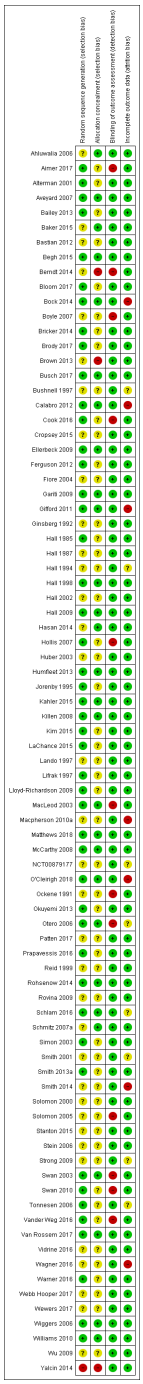
Excluded studies

We listed 63 studies as excluded, along with reasons for their exclusion, in the Characteristics of excluded studies table. The majority were excluded because they provided less than six months follow-up. Studies in which the intervention group received both pharmacotherapy and behavioural support and the control group received neither (or just brief behavioural support) were eligible for the companion review and are included or excluded there (Stead 2016).

Risk of bias in included studies

Overall, we judged 16 studies to be at low risk of bias (low risk of bias across all domains) and 21 studies to be at high risk of bias (high risk of bias in at least one domain). All other studies were judged to be at unclear risk of bias. A summary of 'risk of bias' judgements can be found in Figure 2.

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Allocation

We judged 24 studies to be at low risk of selection bias, based on the reported method of random sequence generation and allocation concealment. We judged three studies to be at high risk of selection bias, due to the method of sequence generation (Yalcin 2014), or allocation concealment (Berndt 2014; Brown 2013; Yalcin 2014). The remaining studies did not given enough detail on one or both of these aspects so we rated the risk of bias as unclear.

Blinding (detection bias)

Following standard Cochrane Tobacco Addiction Group guidance, we did not formally assign a risk of performance bias for each trial as, due to the nature of the intervention, people providing the behavioural support could not be blinded.

We judged detection bias on the basis of biochemical validation of abstinence and, where biochemical validation was not provided, on the basis of differential levels of contact. Twelve studies were judged to be at high risk of detection bias as outcomes were via self-report only and the intervention and control arms received different levels of support, making differential misreport possible (Aimer 2017; Berndt 2014; Boyle 2007; Cook 2016; Hollis 2007; MacLeod 2003; Ockene 1991; Otero 2006; Solomon 2005; Swan 2003; Swan 2010; Vander Weg 2016). The remainder of studies were judged to be at low risk for this domain.

Incomplete outcome data

Loss to follow-up is often relatively high in smoking cessation trials. If trials lost fewer than 20% of participants at longest follow-up, we judged the risk of bias to be low in this domain. In most of the included trials, the proportion lost to follow-up was more than 20% but losses were balanced across groups and less than 40%; for these, we also classified the risk of bias as low. We rated eight studies as having unclear risk of bias, either because attrition was not reported or because overall losses to follow-up of greater than 20% were reported and a breakdown by treatment arm was not provided (Bushnell 1997; Hall 1994; NCT00879177; Otero 2006; Schlam 2016; Smith 2001; Strong 2009; Tonnesen 2006). We judged seven studies to be at high risk of bias due to high (> 50%) attrition overall or differential rates of attrition between arms (> 20% difference between arms), as per Cochrane Tobacco Addiction Group guidance (Bock 2014; Calabro 2012; Gifford 2011; Macpherson 2010a; O'Cleirigh 2018; Smith 2014; Wagner 2016).

Other potential sources of bias

We found no studies to be at risk of other potential sources of bias.

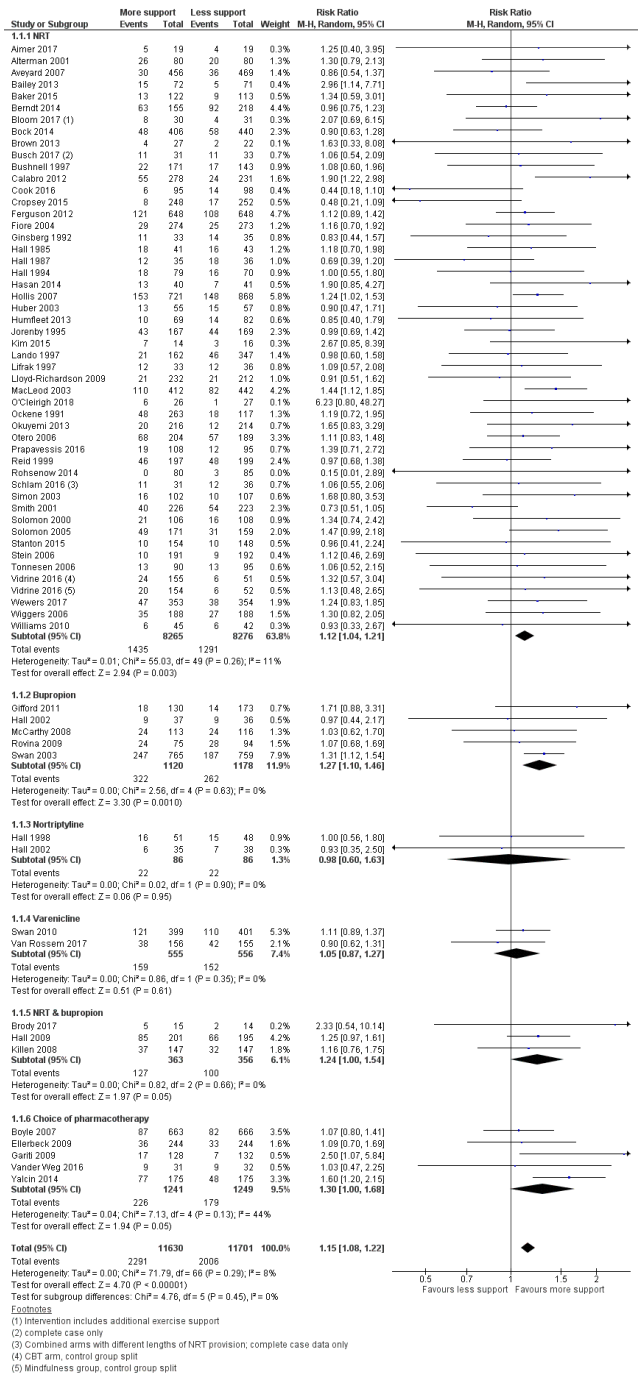
Effects of interventions

See: **Summary of findings for the main comparison** Behavioural interventions as adjuncts to pharmacotherapy for smoking cessation

Intensive versus less intensive or no support

When comparing more intensive versus less intensive behavioural support or to no support, we pooled 65 studies contributing data to this comparison, including a total of over 23,331 participants (note: in subgroups by intervention intensity, a slightly smaller number of studies was included as, in some cases, intensity of intervention or control group contact was not clear). There was little evidence of statistical heterogeneity (I^2 = 8%). Hall 2002 contributed separate data to two subgroups in the primary meta-analysis. Seventeen of the studies had point estimates below 1, that is, with higher quit rates in the less intensive condition, but all these had wide confidence intervals (CIs) which crossed the line of no effect. Seven studies detected benefits of the intervention with confidence intervals that excluded 1. The estimated risk ratio (RR) was 1.15, with 95% CI 1.08 to 1.22. This suggests that increasing the intensity of behavioural support for people making a cessation attempt with the aid of pharmacotherapy increases the proportion who are quit at six to 12 months (Figure 3; Analysis 1.1; Summary of findings for the main comparison).

Figure 3. Effect of increasing behavioural support. Abstinence at longest follow-up. Subgroups by type of pharmacotherapy



Difference in pharmacotherapy

The effect size was similar across subgroups (test for subgroup differences, P = 0.45, I^2 = 0%). Though in some subgroups the confidence interval included no effect, this was likely to reflect the smaller number of studies and lower precision rather than a true difference in effect.

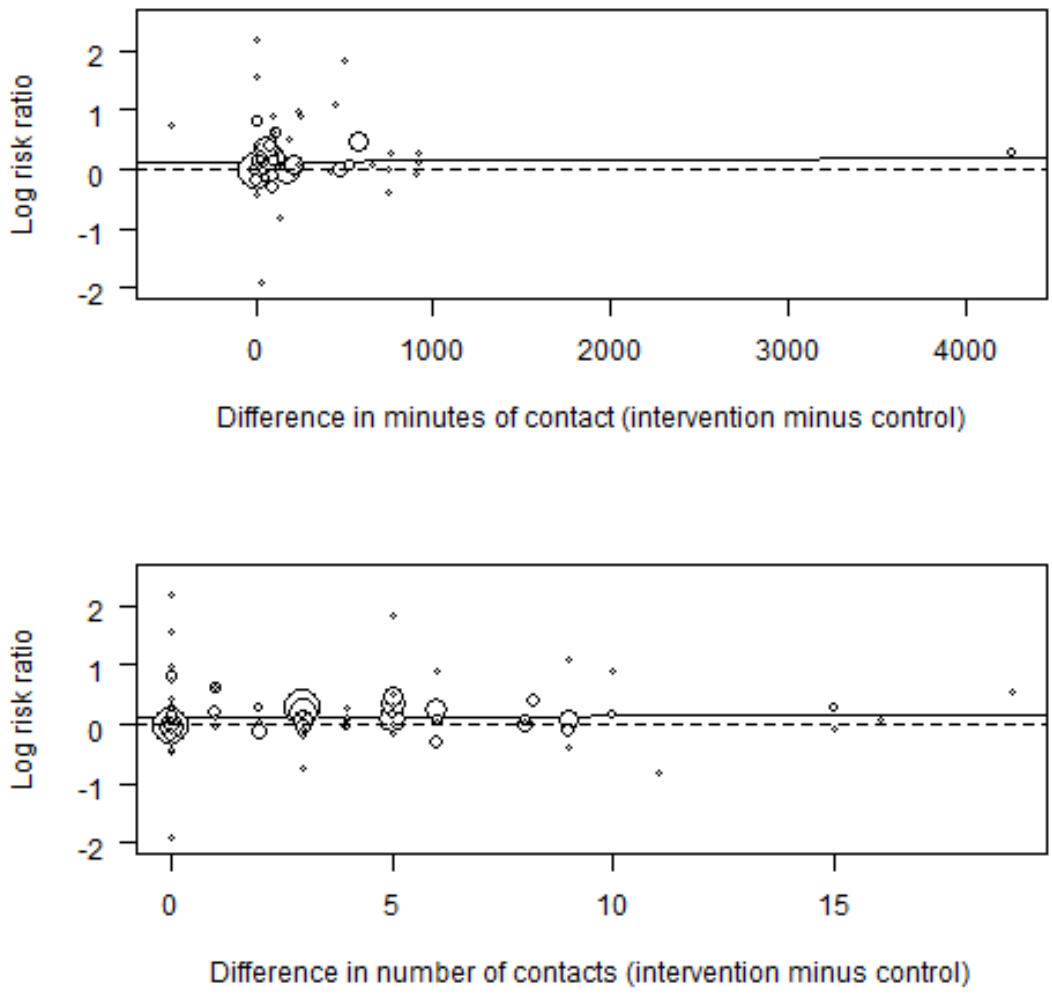
Subgroups by difference in intensity

Analysis 1.2 categorised trials based on the relative difference in the number of contacts between groups, with the subgroups with the largest contrast in intensities listed first and studies where the intensity of intervention and control fell into the same category shown last. There was little evidence of subgroup differences (P = 0.21, I^2 = 32%) nor was there evidence of any dose-response. We did not repeat this approach for duration of intervention categories, as inspection suggested that the number of studies falling into different categories was small and that further subgroup analysis could be misleading.

At the suggestion of a peer reviewer, we conducted two additional subgroup analyses. In Analysis 1.3, we categorised by the level of control group contact to investigate whether there might be a difference between trials where the control could be categorised as a brief intervention (up to 30 minutes) and trials which might be characterised as testing a dose-response for behavioural support, which we defined as being where the controls received more than 30 minutes of behavioural support. The eight trials where controls had no advice or contact formed a third subgroup. Twenty-two trials and just over half the participants were in the 'brief intervention' subgroup, and 32 trials and a third of participants were in the 'dose-response' category. Again, there was no significant difference between the subgroups (P = 0.41, I^2 = 0%).

In this version of the review, we also conducted an exploratory meta-regression to explore associations between effect sizes and number and duration of contacts. A comparison of the intervention effect (log risk ratio) by the difference between the treatment groups in the duration and number of contacts is shown in Figure 4. There was no clear effect of either increasing duration of contact (RR 1.00 per 100 minutes additional contact time, 95% CI 0.99 to 1.01) or increasing number of contacts (RR 1.00 per additional contact, 95% CI 0.99 to 1.02).

Figure 4. Meta-regression results (the fitted meta-regression trend is shown as the solid line)



Differences in modality of intervention contact

In the second non-prespecified analysis, we categorised studies according to whether there was some face-to-face contact as part of the intervention, or whether all support was given by telephone (Analysis 1.4). Here, the test for subgroup differences was significant (P = 0.03, I^2 = 78%), with telephone counselling showing greater relative benefit than face-to-face support. In the subgroup of eight studies using telephone counselling (which had some overlap with studies where there was no personal contact for the control), the point estimate was 1.25 (95% CI 1.15 to 1.37, I^2 = 0%, 6670 participants) in favour of additional behavioural support. In the remaining 57 studies where all intervention and most control conditions had face-to-face support, there was also evidence of benefit of additional behavioural support in this update, although the estimate was slightly smaller (RR 1.11, 95% CI 1.03 to 1.19, I^2 = 9%; 16,661 participants).

Inclusion of medium-intensity intervention from studies with multiple intervention conditions

Eight studies (Alterman 2001; Ellerbeck 2009; Fiore 2004; Hollis 2007; Humfleet 2013; Jorenby 1995; Prapavessis 2016; Smith 2001; Swan 2010) included an intervention condition intermediate in intensity between the highest intensity and the control. We have not included these arms in the primary analysis in case they reduced the contrast between intervention and control. In a sensitivity analysis, we added in these arms. This had almost no impact on the estimated effect (RR 1.13, 95% CI 1.07 to 1.20, I^2 = 8%; 65 studies, n = 27,425; Analysis 2.1), tending to support the finding that there was not a clear dose-response relationship with the amount of support.

Definition of abstinence

We considered whether the way in which abstinence was defined was related to the effect size, and also to absolute quit rates. Here again, there were no significant subgroup differences (P = 0.22, I^2 = 30%, Analysis 2.2). Some studies that reported sustained outcomes also reported point prevalence rates, but substituting the less stringent definition did not change the overall findings. However, studies with point prevalence outcomes had, on average, higher quit rates in both intervention and control arms. A study comparing outcomes based on different abstinence definitions reported within studies found that, for pharmacotherapy studies, point prevalence and sustained abstinence outcomes were strongly related, with sustained abstinence averaging around 74% of point prevalence rates (Hughes 2010).

Unit of analysis issues

Two included studies were cluster-randomised trials (Berndt 2014; Lando 1997). One of these (Berndt 2014) performed an analysis adjusting for clustering effects and found them to be not significantly different from zero, and so we used the original data values. The other (Lando 1997) also allowed for clustering but did not report adjusted results, and so the magnitude of clustering effects was unknown. As the number of included studies in the review was large, this was not likely to have any noticeable effect on our overall conclusions.

Risk of bias

In a sensitivity analysis, removing studies judged to be at high risk of bias in at least one domain, the effect observed was consistent with that of the main analysis (RR 1.09, 95% CI 1.01 to 1.17, I^2 = 0%; 47 studies, n = 13355).

Studies not included in meta-analysis

Two studies comparing more versus less intensive support were not included in the meta-analysis due to a lack of usable data. NCT00879177 is a completed study that was not yet published at the time of searching, and while numerical data were not available, the author indicated that results were broadly comparable between groups. Wagner 2016 compared individual counselling with group counselling, and although follow-up was conducted at later time points, the only data available at time of searching was for 12-week quit rates, where there was no evidence of difference in quit rates (RR 0.96, 95% CI 0.51 to 1.81; n = 400).

Studies matched for contact time

Seventeen studies compared interventions matched for contact time. Fifteen of these provided usable data, which is available in Analysis 3.1. Of the 12 comparisons, all had small numbers of participants and events. Only one, comparing motivational interviewing to health education (which the authors described as standard counselling containing information and advice), detected a statistically significant effect, in this case in favour of health education (RR 0.56, 95% CI 0.33 to 0.94, n = 378). Only one comparison included more than one study; this group of studies compared culturally-tailored support with non-tailored support. Four studies (n = 929) contributed to this comparison (RR 1.14, 95% CI 0.68 to 1.92). Statistical heterogeneity was substantial (I^2 = 78%) and was driven by one small study (Wu 2009; n = 139) in Chinese smokers which found a significant benefit in favour of the culturally-tailored intervention (RR 2.26, 95% CI 1.47 to 3.49). For comparisons in which only one study contributed, see Analysis 3.1 for data and effect estimates.

A further two studies compared interventions matched for contact time but had insufficient data to be recorded in Analysis 3.1:

- Schmitz 2007a compared cognitive behavioural therapy to standard therapy but quit rates in the control group could not be accessed.
- Strong 2009 also compared cognitive behavioural therapy (CBT) to standard therapy (ST) but we could not access quit rates beyond 12 weeks. At 12 weeks, there was "no significant difference in the risk of lapse or relapse across CBT and ST psychosocial treatments" (abstinence data not reported).

DISCUSSION

Summary of main results

A meta-analysis pooling 65 studies with a total of over 23,000 participants found high-certainty evidence that providing more intensive behavioural support for people making a cessation attempt with the aid of pharmacotherapy will typically increase the success rates by about 10% to 20% (Summary of findings for the main comparison). This held true when comparing more versus less support and when comparing behavioural support to no behavioural support. This effect estimate has remained stable over time: with the addition of nine trials in 2015, the number of participants increased by 20% and yet the risk ratio remained almost

the same, changing from 1.16 to 1.17; and with the addition of a further 18 trials in 2019, the number of participants increased by a further 25% and the risk ratio was 1.15. This increases confidence that there is a benefit. There continues to be little evidence of statistical heterogeneity overall, despite the variability in the amount and nature of the behavioural support tested. Direct comparisons indicate a benefit of providing more support regardless of the baseline level of support provided. Sensitivity analyses suggest that this estimate is quite robust. Although the relative effect is generally smaller than when testing behavioural support in the absence of pharmacotherapy, it is important to put the effect in the context of control conditions that were offering effective pharmacotherapy and, typically, some behavioural support, i.e. a level of support consistent with guideline best practice. Quit rates in the control groups reflected this, with a median quit rate across trials of around 17%, meaning the estimated relative increase translates into an absolute increase of around two to three percentage points. Given the importance of smoking cessation for future health outcomes, this is a clinically relevant difference (West 2007).

Overall completeness and applicability of evidence

The studies identified for this review have largely been conducted in the USA or Europe. It is possible that we have failed to find relevant studies conducted in other places. Participants were typically moderate to heavy smokers and were interested in quitting. Most studies recruited participants who had already tried to quit a number of times. Most of the evidence came from studies testing additional face-to-face support. The eight trials which tested the addition of telephone counselling found a stronger effect in favour of additional contact, but we are unable to determine if this was based on true differences in effects or other differences between the studies.

A potential limitation of the review is that the between-trial analysis focussed on the amount of behavioural support rather than the specific components, or the quality of delivery. However, in this update, we included studies directly comparing interventions matched for contact time (e.g. testing different behavioural approaches or types of support). Only one of the 15 comparisons detected a significant effect, but most comparisons only included one study, and all comparisons had small numbers of participants. The question of specific components of behavioural support and associations with effectiveness is being investigated further in a separate Cochrane review (Hartmann-Boyce 2018a).

Certainty of the evidence

We judged the evidence regarding additional behavioural support to be of high certainty, meaning further research is judged very unlikely to change our confidence in the effect. This judgement is supported by the consistency of the effect estimate over time, and this is likely to be the last update of this review. However, despite high certainty in results, some areas relating to the five GRADE considerations (risk of bias, imprecision, indirectness, inconsistency, and publication bias) warrant discussion, namely risk of bias, inconsistency, and publication bias.

Risk of bias

While we judged most of the trials to be at low or unclear risk of bias, we rated 21 studies as having high risk of bias. Reassuringly, sensitivity analysis excluding studies at high risk of bias did not change the overall effect. The quality of the trials was typical of smoking cessation research in general. We did not formally evaluate whether there was a risk of performance bias due to a lack of blinding of providers or participants. Blinding of providers would not have been possible, and it was difficult to determine whether participants knew how their treatment compared to the other options offered. All participants were getting an active pharmacotherapy and would have been aware of this (apart from a small proportion in placebo-controlled factorial studies). Expectancy effects for the behavioural components would probably have been small, and we do not think the small effect of the interventions could be attributed entirely to higher expectancies in intervention conditions.

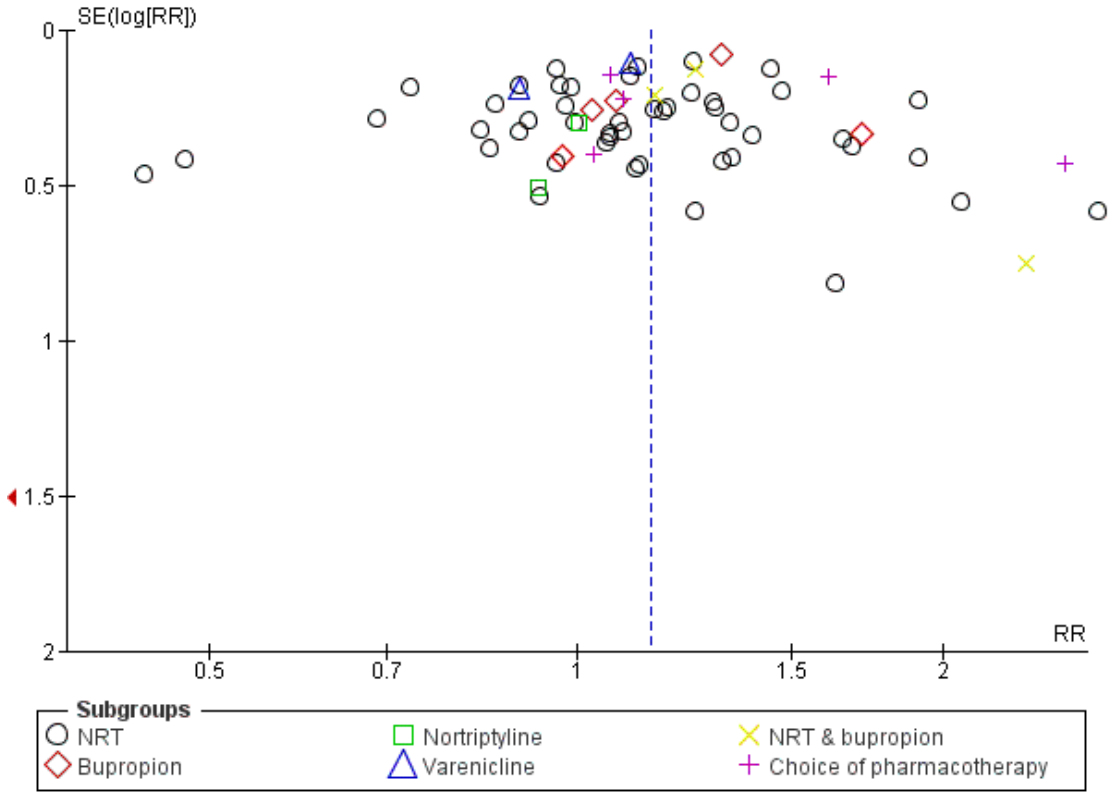
Inconsistency

There were potentially important differences between trials in the relative difference in the support given to the intervention and control groups. Despite the lack of statistical heterogeneity, we undertook a number of subgroup analyses, including some that were not prespecified. In response to a concern that we were combining tests of behavioural support versus no support with tests of a dose-response to intensity of support, we divided trials into those where the control did not involve personal contact; where the control group provided a brief intervention, operationalised as under 30 minutes contact; and those where the control condition was more intensive (Analysis 1.3). There was no evidence of a difference in the relative effect between these three subgroups. In this update, we also conducted an exploratory meta-regression, in which results continue to suggest that the dose-response curve is shallow for behavioural support. We drew similar conclusions in a companion review to this, which compared combined pharmacotherapy and behavioural support to minimal support; indirect comparisons between trials using more and less intensive behavioural interventions also failed to detect large differences (Stead 2016). The present review also detected a clearer benefit of more support in studies where all contact was delivered by telephone, but this too was not prespecified and may reflect the larger size of trials done in quitline settings, or possibly that most of these studies did not use biochemical validation of abstinence.

Publication bias

A funnel plot was inconclusive, suggesting there may have been slightly more small studies with large effect sizes than with small effect sizes (Figure 5). However, asymmetry was not clear and when we investigated further by conducting sensitivity analyses excluding outliers this did not substantially alter the effect. Given the large number of included studies and the degree of homogeneity between them, it is unlikely that smaller unpublished studies showing no effect, if they existed, would significantly alter our results.

Figure 5. Funnel plot of comparison: 1 Effect of increasing behavioural support. Abstinence at longest follow-up, outcome: 1.1 Subgroups by type of pharmacotherapy.



Potential biases in the review process

We used the Cochrane Tobacco Addiction Group's Specialised Register and searched trial registries to identify studies. The Register includes reports of trials identified from the major bibliographic databases. There is no straightforward term for the type of intervention we were interested in but we screened any trial report that mentioned a pharmacotherapy. It is possible that the Register does not include all relevant trial reports or that we failed

to identify some. Our methods for data extraction and analysis are those used for other Cochrane reviews. The practice of imputing missing data as smoking has been traditionally used for primary and secondary research in smoking cessation and has the advantage that absolute cessation rates are not inflated by ignoring loss to follow-up. Bias in the relative effect will only be introduced if misclassification differs for people who are lost from the intervention condition compared to the control. If proportionately more of those who are lost in the control group are assumed to be smokers but have in fact quit, then the treatment effect would be overestimated.

Agreements and disagreements with other studies or reviews

The major source of systematic data about the dose-response to behavioural support is the US Public Heath Service Clinical Practice Guideline, last updated in 2008 (Fiore 2008). This includes meta-analyses (last updated in 2000) for different levels of support and contact time. The analyses included trials of different levels of support versus control. These showed trends towards increasing effects in trials that had more sessions and more contact time, compared to minimal conditions. For example, estimated effects compared to minimal contact differed between trials with four to 30 minutes of contact time (OR 1.9, 95% CI 1.5 to 2.3) and trials with 91 to 300 minutes (OR 3.2, 95% CI 2.3 to 4.6) (Fiore 2008 Table 6.9) and between two to three treatment sessions (OR 1.4, 95% CI 1.1 to 1.7) and over eight sessions (OR 2.3, 95% CI 2.1 to 3.0) compared to 0 to 1 sessions (Fiore 2008 Table 6.10). These analyses were not limited to direct (within trial) comparisons of treatment intensity. They also did not distinguish between studies with and without pharmacotherapy, and the majority of studies in our analysis were published after 2000 so would not have been included. Our review is likely to give a more precise estimate of the effect of additional support alongside pharmacotherapy, based on the analysis of trials directly comparing different levels of support. There is observational evidence that access to more behavioural support is associated with greater success in quitting. For example, a study of English Stop Smoking Services, in which there was a high use of pharmacotherapy, found a positive association between the number of scheduled sessions and short-term quit rates (West 2010). A study of NRT users calling the California quitline found that people who received multiple sessions of counselling had higher quit rates after one year (Zhu 2000).

Increasingly, studies which test the effects of behavioural support provide pharmacotherapy to both arms. That means that many of the studies included here are covered (as subsets only) in other reviews of behavioural interventions. These include telephone counselling and face-to-face counselling, both in person and in groups (Lancaster 2017; Matkin 2019; Stead 2017). Our results from the subgroup of trials in which additional support was delivered via telephone are remarkably consistent with those from the Cochrane review of telephone counselling (Matkin 2019). Matkin 2019 also included studies without pharmacotherapy and thus had substantially more studies than our eight, but the point estimate was the same as ours in studies that recruited smokers who did not call a helpline (RR 1.25, 95% CI 1.15 to 1.35; 65 trials; 41,233 participants, I^2 = 52%). In the Cochrane review of individual behavioural counselling (Lancaster 2017), effects were again consistent with our findings: there was moderate-quality evidence (downgraded due to imprecision) of a modest benefit of counselling when all participants received pharmacotherapy (RR 1.24, 95% CI 1.01 to 1.51; 6 studies, 2662 participants; I^2 = 0%). The effect was stronger in studies in which participants did not receive pharmacotherapy. Similarly, in the Cochrane review of group behaviour therapy programmes (Stead 2017), the effect was stronger in studies in which participants did not receive pharmacotherapy; only five trials included pharmacotherapy, with a point estimate indicating a modest benefit but with wide confidence intervals incorporating no effect (RR 1.11, 95% CI 0.93 to 1.33, I^2 = 0%; n = 1523).

Finally, one explanation for the relatively small impact of providing more behavioural support is that it is not provided at the time when it could be most effective. Relapse after initial success is the norm for quit attempts, and by the time people are getting additional calls they may already have relapsed. Various study authors commented on this (e.g. Reid 1999; Smith 2001). Although these studies are not typically characterised as being about 'relapse prevention', there is a small overlap between this review and the Cochrane review of relapse prevention interventions (Livingstone-Banks 2019a), which concluded that there was no evidence of a benefit of additional behavioural support to prevent relapse. On the other hand, in some cases, an initial benefit of the intervention disappeared once treatment ended, and authors suggested that further extended support might have made a difference (e.g. Killen 2008; Solomon 2000), although replication of one of these studies with more extended support (Solomon 2005) still showed the same pattern of late relapse. Another possible explanation is that uptake of extended treatment may be poor, so the actual number of contacts received may not vary substantially by group. Few studies reported uptake measures.

AUTHORS' CONCLUSIONS

Implications for practice

Providing behavioural support for smokers using established medication in an attempt to stop smoking will increase the proportion of successful attempts. This is true when comparing more versus less support and when comparing behavioural support to no behavioural support.

Implications for research

Identifying the optimal amount of behavioural support to use alongside pharmacotherapy remains a challenge. Studies need to be appropriately powered for small treatment effects, and test interventions that are acceptable and accessible to smokers, and affordable to deliver. More studies are needed outside of the USA and Europe. Further research is needed to test associations between effectiveness and different behavioural components of interventions (which will be covered by a separate review moving forward).

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Lindsay Stead and Tim Lancaster conceived of and were authors of the first and second versions of this review. Pria Koilpillai was an author of the second version. Their input is greatly appreciated.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Ahluwalia 2006

Methods	Setting: community health centre, USA Recruitment: African-American light smokers recruited from the clinic and using various routes of advertisement
Participants	755 smokers of ≤ 10 cigarettes per day; the characteristics of 378 participants in the relevant arm were as follows: 66.1% to 68.3% female; average age 43.5 to 45.2; average cigarettes per day 7.5 to 7.8 Therapists: trained counsellors who followed semi-structured scripts
Interventions	Pharmacotherapy: NRT; 2 mg nicotine gum for 8 weeks including weaning period. Dose depended on the number of cigarettes smoked per day 1. Motivational interviewing: 3 sessions in person and 3 sessions by telephone, each lasting 20 minutes 2. Health education: 3 sessions in person and 3 sessions by telephone, each lasting 20 minutes
Outcomes	7-day point prevalence abstinence at weeks 1, 3, 6, 8, 16 and 6 months Validation: cotinine-verification (≤ 20 ng/mL), expired carbone monoxide ≤ 10 ppm
Source of Funding/CoI	National Cancer Institute at the National Institutes of Health (R01CA091912) GlaxoSmithKline provided study medication. No declarations of interest
Notes	New for 2019 update. Previously excluded. Reason: Conselling conditions had same number of contacts and duration. Compared Motivational Interviewing and Health Education (HE) in a factorial trial with nicotine gum or placebo (results favoured HE (control) condition). Included in Lindson-Hawley 2015 Cochrane review of motivational interviewing

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No details given
Allocation concealment (selection bias)	Low risk	Sealed envelope with pre-assigned randomisation numbers
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	11.1% to 16.9% lost to follow-up at 6 months

Aimer 2017

Methods	Setting: rheumatology clinic (single centre), Christchurch, New Zealand Recruitment: smokers with rheumatoid arthritis. No mention of intended selection for motivation but the authors mentioned that the study population was likely to have been highly motivated
Participants	39 smokers; 55% female; average age 56.5; average cigarettes per day 16.5 Therapists: community-based arthritis educators trained in smoking cessation
Interventions	Pharmacotherapy: NRT for 8 weeks 1. usual care (brief advice and subsidised NRT) for 3 months 2. usual care + rheumatoid arthritis-specific programme for 3 months via face-to-face, telephone and email; 4 sessions at week 0, 1, 4, 8
Outcomes	Continuous abstinence at 3 and 6 months Validation: none
Source of Funding/CoI	New Zealand Health Research Council, Arthritis New Zealand and University of Otago Research Fund. Authors declared receipt of consultant fees, speaking fees, and/or honoraria from AbbVie and Janssen (less than $10,000 each)
Notes	New for 2019 update One participant was excluded from analysis after intervention and follow-up when found not to have rheumatoid arthritis. Did not contribute to analysis 1.2 or analysis 1.3 as duration of control group contact not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random sequence generated by a biostatistician using an Excel spreadsheet in 6 blocks x 8 allocations
Allocation concealment (selection bias)	Unclear risk	Insufficient details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-report only
Incomplete outcome data (attrition bias) All outcomes	Low risk	0-15.8% lost to follow-up at 6 months

Alterman 2001

Methods	Setting: cessation clinic, USA Recruitment: community volunteers
Participants	240 smokers of > 1 pack/day; 45% to 54% female, average age 40, average cpd 27 Therapists: Nurse practitioners (NP) and trained counsellors
Interventions	Pharmacotherapy: NRT; 21 mg patch for 8 weeks (including weaning period) 1. Low intensity. Single 30-minute session with nurse practitioners 2. Moderate intensity. as 1 plus additional 3 x 15 to 20-minute sessions at weeks 3, 6, 9 with nurse practitioners 3. High intensity. As 2 plus 12 45 to 50-minute sessions cognitive behavioural therapy with trained therapist within 15 weeks
Outcomes	Abstinence at 1 year Validation: urine cotinine < 50 ng/mL, CO ≤ 9 ppm
Source of Funding/CoI	National Institute on Drug Abuse. No declarations of interest
Notes	3 versus 1 in main analysis. Quit rates significantly lower in 2 than 1 or 3. 35/160 quit when 2 & 3 combined

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Urn technique"
Allocation concealment (selection bias)	Unclear risk	No details given. Allocation took place after baseline session common to all conditions
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Small and similar rate lost to follow-up in each group (approx 7%). "Intent to treat" analyses reported in the paper excluded 2 deaths and 2 who did not provide cotinine samples

Aveyard 2007

Methods	Setting: 26 general practices (primary care clinics), UK Recruitment: 92% volunteers in response to mailings
Participants	925 smokers; 51% F, av. age 43, 50% smoked 11 to 20 cpd Therapists: practice nurses trained to provide cessation support & manage NRT

Aveyard 2007 (*Continued*)

Interventions	Pharmacotherapy: NRT; 16 mg patch for 8 weeks 1. Basic support; 1 visit (20 to 40 mins) before quit attempt, phone call on TQD, visits/ phone calls at 7 to 14 days & at 21 to 28 days (10 to 20 mins); 4 contacts, ~80 mins 2. Weekly support; as 1. plus additional call at 10 days & visits at 14 & 21 days; 7 contacts, ~140 mins
Outcomes	Abstinence at 12 months (sustained at 1, 4, 12, 26 weeks) Validation: CO < 10 ppm at treatment visits, saliva cotinine < 15 ng/mL at follow-up
Source of Funding/CoI	Cancer Research UK. Authors declared interests.
Notes	Therapists were not full-time specialist counsellors. Difference between support conditions relatively small

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random number generator
Allocation concealment (selection bias)	Low risk	Numbered sealed envelopes
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Over 30% lost to follow-up but similar percentage followed up in both groups (69% intervention vs 68% control, no evidence of differential attrition)

Bailey 2013

Methods	Setting: high schools in San Francisco, USA Recruitment: adolescent smokers were recruited over a period of 3 years on a non-rolling basis, with a new cohort participating each academic school year. Selected for motivation to quit
Participants	143 smokers; 37.6% female; average age 16.9; average cigarettes smoked per week 97.1 Therapists: research intervention staff with Bachelor's degree or higher. Supervised by the project director (clinical psychologist)
Interventions	Pharmacotherapy: NRT (nicotine patch); 9 weeks (dosage and titration schedule determined by number of cigarettes smoked per day) 1. Group based cognitive behavioural therapy and skills training (10 weeks) 2. Group based cognitive behavioural therapy and skills training (10 weeks) + extended

Bailey 2013 (*Continued*)

	face-to-face group sessions (9 sessions over 14 weeks)
Outcomes	7-day point prevalence abstinence at 6 months Validation: expired carbon monoxide using Bedfont Smokerlyzers
Source of Funding/CoI	National Cancer Institute at the National Institutes of Health (R01 CA 118035 to JDK) . No declarations of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated
Allocation concealment (selection bias)	Unclear risk	Insufficient details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Lost to follow-up rate: extended group 16. 7%; other 16.9%

Baker 2015

Methods	Setting: Centre for Brain and Mental health Research, University of Newcastle, New South Wales; School of Public Health, University of New South Wales, Sydney; Monash Alfred Psychiatry Research Centre, Monash University and the Alfred, Melbourne, Australia Recruitment: smokers recruited from three sites in Newcastle, Sydney and Melbourne, Australia. Referral sources included health services, media advertisement and other research programmes or registers
Participants	235 smokers; 41.3% female; average age 41.6; average cigarettes smoked per day 28.6 Therapists: psychologists guided by intervention manuals
Interventions	Pharmacotherapy: NRT; 24 weeks' supply of NRT delivered at weeks 1, 4 and 8 and thereafter by arrangement. Participants smoking $\geq$ 30 cigarettes per day were eligible to receive double patching in addition to up to 12 x 2 mg lozenges per day, with NRT tapering occurring in the last month of delivery 1. Predominantly telephone-based (17 sessions; 290 minutes in total) 2. Face-to-face healthy lifestyle therapy (17 sessions; 1050 minutes in total)
Outcomes	7-day point prevalence abstinence at week 15 and months 12, 18, 24, 30, 36 Validation; carbon monoxide $\leq$ 10 ppm

Baker 2015 (*Continued*)

Source of Funding/CoI	Australian National Health and Medical Research Council and the Commonwealth Department of Health and Aging. NRT was provided free of charge by GlaxoSmithKline. No declarations of interest
Notes	New for 2019 update

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Permuted block randomisation approach mentioned but no further detail
Allocation concealment (selection bias)	Low risk	Sealed randomisation envelope by an independent person displaying a participant identification code. Participants opened the envelope at the end of the initial intervention session
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	39.8 to 45.9% lost to follow-up at 3 years

Bastian 2012

Methods	Setting: USA Recruitment: participants identified from electronic medical records. Eligibility assessment in person and selected for motivation to quit
Participants	471 smoker; 8.5% female, average age 59; heaviness of smoking index mean 2.8 Therapists: masters-level counsellors with training
Interventions	Pharmacotherapy: NRT; inhaler, patch, spray and/or bupropion (regimen and dosage dependent on the number of cigarettes smoked per day and tobacco cessation anxiety) 1. Usual care: 5 telephone sessions every 3-4 weeks; each session lasting 20 minutes 2. Family-supported 5 telephone sessions every 3-4 weeks; each session lasting 20 minutes
Outcomes	7-day point prevalence abstinence at 5 and 12 months Validation: attempted verification by mailing saliva-sampling kits to test for cotinine level but the return rates were low (50.5%)
Source of Funding/CoI	Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, and Health Services Research and Development. Authors declared a consultancy to Gilead Sciences and Watermark Research Partners

Bastian 2012 (*Continued*)

Notes	New for 2019 update	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Insufficient details given
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Low rates of return when biochemical validation was attempted, but contact-matched so differential misreport judged unlikely
Incomplete outcome data (attrition bias) All outcomes	Low risk	21.7 to 28.4% lost to follow-up rate

Begh 2015

Methods	Setting: NHS Stop Smoking clinic, UK Recruitment: smokers recruited from the participating general practices and Stop Smoking services. Selected for motivation to quit	
Participants	119 smokers; 69% female; average age 44.8; average cigarettes smoked per day 20.8 Therapists: trained research nurses and Stop Smoking advisors	
Interventions	Pharmacotherapy: NRT; 21 mg per 24 hour nicotine patches for 8 to 12 weeks 1. 7 weekly sessions of withdrawal support, of which 5 sessions included placebo training (16 minutes each) starting one week prior to quit date 2. 7 weekly sessions of withdrawal support, of which 5 sessions included attentional retraining (16 minutes each) starting one week prior to quit date	
Outcomes	Prolonged abstinence at weeks 4, 8, and at 6 months Validation: exhaled carbon monoxide < 10 ppm	
Source of Funding/CoI	National Institute for Health Research. Authors declared research and consultancy for manufacturers of smoking cessation medication, including consultancy for GlaxoSmithKline Consumer Healthcare and research-initiated project grant funding from Pfizer	
Notes	New for 2019 update	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Begh 2015 (*Continued*)

Random sequence generation (selection bias)	Low risk	Computer-generated simple randomisation scheme
Allocation concealment (selection bias)	Low risk	An independent programmer entered the sequence onto a dedicated online database which was accessed by study staff in clinics
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	30.0% to 40.7% lost to follow-up at 6 months

Berndt 2014

Methods	Setting: cardiac wards, Netherlands Recruitment: inpatients by ward nurses, at the bedside
Participants	372 in relevant arms, excl 7 deaths (5 TC, 2 FC) 73% M, av age 56, av cpd 21 Therapists: face-to-face counselling (FC) provided by recently trained cardiac nurses, telephone counselling (TC) provided by experienced telephone counsellors
Interventions	Pharmacotherapy: NRT; patches (21 mg/day or 14 mg/day (10 to 20 cpd) for 8 weeks incl weaning) 1. UC (control): brief quit advice from ward nurses + brochure; no NRT (historical control, before wards assigned to interventions, not used in review) 2. TC: usual care + 7 x 15-min telephone sessions, weekly for 5 weeks, week 7, week 12 3. FC: usual care + 6 x 45-min + 1 x 15 min face-to-face sessions, same schedule as TC
Outcomes	Abstinence at 6 months (90 day PP since last counselling session) Validation: none
Source of Funding/CoI	ZonMw, the Dutch Organization for Health Research and Development. Authors declared no conflicts of interest
Notes	3 vs 2 in analyses, patch use was similar across TC & FC groups Intraclass correlation coefficient assessed; "intraclass correlations were small and not statistically different from zero"

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Cluster randomisation with sequential cross-over design. Method of randomising wards to begin with FC or TC not de-

Berndt 2014 (*Continued*)

		scribed
Allocation concealment (selection bias)	High risk	Nurses knew assignment when recruiting patients. "Although not reported by the nurses, they may have been selective in their recruitment because patients in the intervention groups appeared more motivated in their drive to quit smoking". However, this probably had greater impact on comparison with usual care, not used in this review
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-report only
Incomplete outcome data (attrition bias) All outcomes	Low risk	Approximately 20% lost to follow up in each group (TC = 22%, FC = 21%)

Bloom 2017

Methods	Setting: research fitness facility, USA Recruitment: smokers recruited from newspaper and radio advertisements
Participants	61 smokers; 63.3% to 67.7% female; average age 47; average cigarettes smoked per day 19.4 to 20.3 Therapists: aerobic exercise sessions were supervised by exercise physiologist. Unclear who provided health education sessions
Interventions	Pharmacotherapy: NRT; 8 weeks of transdermal nicotine patch (21 mg for weeks 5 to 8, 14 mg for weeks 9 to 10, 7 mg for weeks 11 to 12) 1. 8 sessions of telephone counselling (20 minutes each) + 12 weekly group health education sessions (60 minutes each) 2. 8 sessions of telephone counselling (20 minutes each) + 12 weekly sessions of group aerobic exercise (20 to 40 minutes) + 12 weekly cognitive behavioural sessions just before the exercise sessions (20 minutes each)
Outcomes	Continuous abstinence at months 3, 6, 12 Validation: expired carbon monoxide < 10 ppm
Source of Funding/CoI	National Institute on Drug Abuse. No declarations of interest
Notes	New for 2019 update Authors confirmed a typographical error in the abstinence rate in Bloom 2017 paper and stated the figures in Abrantes 2014 are correct.
Risk of bias	

Bloom 2017 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Urn randomisation
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	10.0-12.9% lost to follow-up at 12 months

Bock 2014

Methods	Setting: 3 primary care clinics, New England, USA Recruitment: smokers identified by clinic personnel during registration. Research assistants screened interested individuals
Participants	846 smokers 69% F, av age: 40, av cpd not described Therapists: smoking cessation specialists
Interventions	Pharmacotherapy: NRT; patch for 8 weeks 1. Standard care: brief physician advice, patch education 2. Motivational enhancement treatment: standard care + 45-min individual counselling session & 2 counselling calls either on quit day & 2 weeks later or at 2 & 4 weeks after 1st session
Outcomes	Abstinence at 12 months (7-day PP) Validation: carbon monoxide < 5 ppm
Source of Funding/CoI	National Institute on Drug Abuse. Authors declared no conflicts of interest
Notes	Data previously confirmed with authors for another review; 48/406 vs 58/440

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer randomised
Allocation concealment (selection bias)	Low risk	Research assistants enrolled prior to computer randomisation

Bock 2014 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	High risk	Dropout over 50%; 58.6% in SC 238/440) and 52.7% in ME (232/406)

Boyle 2007

Methods	Setting: Health Maintenance Organization, USA Recruitment: proactive recruitment of members filling a prescription for cessation medications; selected if motivated to quit
Participants	1329 HMO members; 58% F, av age 47, 66% smoked > pack/day
Interventions	Pharmacotherapy: all participants had filled a prescription. Almost 95% used; ~51% only bupropion, 26% only NRT, remainder both 1. No further intervention 2. Proactive call to offer counselling, up to 9 calls, given choice of structured course or unstructured format
Outcomes	Abstinence at 12 months (repeated 7-day PP at 3 months & 12 months) Validation: none
Source of Funding/CoI	Robert Wood Johnson Foundation Addressing Tobacco in Managed Care Program. No declarations of interest
Notes	49% of intervention group reached, 36% of those declined, 31% of total accepted counselling. Average N of calls 5. There was no evidence of a greater relative effect in those reached or those accepting counselling

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised, stratified by presence of chronic disease. Method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-report only
Incomplete outcome data (attrition bias) All outcomes	Low risk	Over 30% lost to follow-up but similar percentage followed up in both groups (66% intervention vs 65% control, no evidence of differential attrition)

Bricker 2014

Methods	Setting: Quitline in South Carolina, USA Recruitment: recruited uninsured callers to the South Carolina State Quitline
Participants	121 smokers; 69% female; average age 39.1; 65% smoked more than half pack per day Therapists: counsellors were Bachelors or Masters level providers with at least 3 years of general counselling experience
Interventions	Pharmacotherapy: NRT; 2-week course of nicotine patch or gum (participant's choice) 1. 5 sessions of cognitive behavioural therapy telephone intervention (1^{st} call 30 minutes and each subsequent call 15 minutes) 2. 5 sessions of acceptance and commitment therapy telephone intervention (1^{st} call 30 minutes and each subsequent call 15 minutes)
Outcomes	30-day point prevalence abstinence at 6 months Validation: none
Source of Funding/CoI	National Institute on Drug Abuse, National Cancer Institute. Authors declared consultancy for Pfizer
Notes	New for 2019 update. Previously excluded. Reason: both the control and the intervention received equal amounts behavioural counselling; telephone-delivered acceptance and commitment therapy (ACT) versus cognitive behavioral therapy (CBT) for smoking cessation was being assessed

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation sequence
Allocation concealment (selection bias)	Unclear risk	Insufficient details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Self-report only but contact matched in both groups so differential misreport judged unlikely
Incomplete outcome data (attrition bias) All outcomes	Low risk	27.1-38.7% lost to follow-up at 6 months

Brody 2017

Methods	Setting: Veterans Affairs Los Angeles Healthcare System, USA Recruitment: smokers recruited via flyer advertisement from the smoking and schizophrenia treatment programmes. Selected for motivation
Participants	42 smokers; 100% male; average age 56.3 to 57.5 years; average cigarettes smoked per day 18.5 to 19.6 Therapists: cognitive behavioural therapy by a psychologist; home visits by the study investigators
Interventions	Pharmacotherapy: NRT; - combination extended treatment groups (with or without home visit): combination of three medications (bupropion, nicotine patch, nicotine lozenge) for 6 months - usual care: single smoking cessation medication (patch, bupropion or varenicline) typically for at least 2 to 4 weeks 1. combination extended treatment without home visit: 12 weekly sessions of cognitive behavioural therapy (60 minutes each) 2. combination extended treatment plus home visit: 12 weekly sessions of cognitive behavioural therapy (60 minutes each) + biweekly home visits (20 to 30 minutes each) 3. usual care (excluded from our meta-analyses due to different pharmacotherapy to the other groups)
Outcomes	7-day point prevalence abstinence at week 12 and at 6 months Validation: exhaled carbon monoxide $\leq$ 3 ppm
Source of Funding/CoI	National Institute on Drug Abuse, Department of Veterans Affairs Office of Research and Development and Tobacco-Related Disease Research Program. No declarations of interest
Notes	New for 2019 update Lost to follow-up numbers were obtained from the authors via email correspondence

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation sequence
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Lost to follow-up rates were 21.4% to 28.6% in combination extended treatment groups and 7.1% in usual care group at 6 months

Brown 2013

Methods	Setting: community, USA Recruited: community volunteers who had "previous difficulty quitting for even short periods of time." Selected if motivated to quit
Participants	N = 49; dropouts: 7 49% F, av age: standard = 48.30; distress tolerance = 47.19, av. cpd standard = 22; distress = 21 Therapists: doctoral-level psychologists or trainees (psychology interns/postdoctoral fellows) delivered the treatment
Interventions	Pharmacotherapy: "8 weeks of nicotine replacement therapy in the form of the nicotine patch (Nicoderm CQ) beginning on quit day, including 4 weeks of the 21 mg patch, 2 weeks of 14 mg, and 2 weeks of 7 mg." 1. standard smoking cessation treatment 2. distress tolerance treatment = incorporated elements of exposure-based therapies and Acceptance and Commitment Therapy
Outcomes	Abstinence at 26 weeks (7-day PP) Validation: expired carbon monoxide (CO, 5 ppm or less) + cotinine verification (cotinine, 10 ng/mL or less)
Source of Funding/CoI	National Institute on Drug Abuse. Authors declared no conflicts of interest
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Participants treated in groups, 3 groups for each condition; "each treatment assignment was randomly selected from the fixed pool of possible assignments"
Allocation concealment (selection bias)	High risk	Type of treatment allocated for next group likely to have been known before participant recruitment
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Overall 14% lost; standard 9% (2/22), distress 19% (5/27)

Busch 2017

Methods	Setting: Miriam and Rhode Island Hospitals in Providence, USA Recruitment: inpatient cardiac units at the Miriam and Rhode Island Hospitals in Providence
Participants	64 smokers; 27.1% female; average age 55.6; average cigarettes smoked per day 16.4 Therapists: research team members (licenced clinical psychologist and clinical psychology post-doctoral fellow)
Interventions	Pharmacotherapy: NRT; 8 weeks of nicotine patches starting on 21 mg patch for those smoking > 10 cigarettes per day and on 14 mg for those starting ≤ 10 cigarettes per day 1. Usual care: one in-hospital counselling session (50 minutes) + 5 mailings of print materials + 5 brief "check-in" calls from a health educator following each mailing (5 to 10 minutes each) 2. One in-hospital counselling session + > 5 post-discharge contacts at 1, 3, 6, 9 and 12 weeks. Sessions 1 & 2 (50 minutes each) in-person at a research clinic or in the participant's home; Sessions 3 to 6 (30 minutes each) by phone
Outcomes	7-day point prevalence abstinence at weeks 12 and 24 post-discharge from the hospital Validation: carbon monoxide < 10 ppm
Source of Funding/CoI	National Heart, Lung, and Blood Institute of the National Institutes of Health. No declarations of interest
Notes	New for 2019 update

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation
Allocation concealment (selection bias)	Low risk	The study statistician provided sequenced randomisation envelopes. The randomisation envelopes were opened by counsellors following the completion of each in-hospital smoking cessation session. Counsellors then immediately informed the participant of their treatment condition
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	21.2 to 22.6% lost to follow-up at 24 weeks post-discharge

Bushnell 1997

Methods	Setting: community with large military population, USA Recruitment: community volunteers Group size: max 50 American Cancer Society (ACS) or 15 Vanderbilt University Medical Center (VUMC)
Participants	314 military and civilian smokers, excluded 198 people, assignment NS, who did not attend any sessions after randomisation. 44% F, age and smoking not described Therapists: ACS-trained volunteers, VUMC-healthcare professionals
Interventions	All participants offered free NRT (in group 2 conditional on attending 75% classes) 1. ACS: 4 x 1 hour large group sessions (max 50), no TQD 2. VUMC: 8 x 1 hour group sessions (max 15), relapse prevention model including stress management, diet, exercise
Outcomes	Abstinence at 6 months (PP) Validation: CO < 8 ppm, salivary cotinine ≤ 10 mg/mL
Source of Funding/CoI	
Notes	Early benefit of VUMC lost at 6 months. No observed effect in active duty participants at any time

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"randomly assigned", method not stated, stratified by military or civilian
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	198 (out of 512 randomised) did not participate, group not stated, not clear if participants knew what group they were assigned to before attending first session

Calabro 2012

Methods	Setting: university student body, USA Recruitment: advertised through flyers in campus halls, newsletters, email, and during presentations in classes Smoking cessation counsellors enrolled participants

Calabro 2012 (*Continued*)

Participants	509 smokers (≥ 1 cpd) 53% F, av age 24.5, 39% smoked 11-20 cpd Therapists: counsellors trained specifically in behaviour change/cigarette counselling
Interventions	Pharmacotherapy: NRT; patch offered to participants smoking ≥ 5 cpd 1. Self-help written material, ≤ 5 mins minimal counselling, and no persuasive communication or assistance to participants 2. In-person motivational counselling with health feedback, 2 x 60 to 120 mins over 3 months, and access to 5 web-based booster sessions
Outcomes	Abstinence at 12 m (30-day PP) Validation: 46 of 79 who reported abstinence provided a salivary cotinine value ≤ 5 ng/mL
Source of Funding/CoI	National Cancer Institute. Authors declared no conflicts of interest
Notes	Coded as validated, however not all self-reported quitters were validated due to problems with sample collection

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Statistical software package generated randomisation.
Allocation concealment (selection bias)	Low risk	Randomisation by computer occurred after enrolment.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	High risk	Dropout high and differential; intervention 43% (120/278), control 66% (153/231)

Cook 2016

Methods	Setting: primary care clinics, USA Recruitment: adult smokers recruited during primary care visits who were willing to reduce their smoking but not quit
Participants	517 smokers; 63.4% female, average age 47.0; average number of cigarettes smoked per day 17.5 Therapists: no details given

Cook 2016 (*Continued*)

Interventions	Pharmacotherapy: NRT; 14 mg patches daily for 6 weeks and/or 2 mg gum for 6 weeks (≥ 9 per day, 1 piece for 1 to 2 hours) 1. behavioural reduction: an initial 20 minute in-person counselling session followed by 6 weekly 10-minute counselling calls; 7 sessions in total 2. motivational interviewing: an initial 20-minute in-person counselling session followed by three biweekly, 10-minute counselling calls over 6 weeks; 4 sessions in total
Outcomes	7-day point prevalence abstinence at week 12 and at 6 months Validation: none
Source of Funding/CoI	National Cancer Institute, the Wisconsin Partnership Program. Authors supported by National Research Service Award from the Health Resources and Services Administration, NSF grant, NIH grants, Merit Review Award from the US Department of Veterans Affairs. No declarations of interest
Notes	New for 2019 update Abstinence data received from authors via email correspondence

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated
Allocation concealment (selection bias)	Unclear risk	"staff were blinded to randomisation until eligibility was confirmed but not beyond that point; participants were blinded until consent was provided"
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-report only
Incomplete outcome data (attrition bias) All outcomes	Low risk	Lost to follow up n = 66; withdrawn n = 17

Cropsey 2015

Methods	Setting: community corrections offices, USA Recruitment: smokers under community corrections supervision were recruited via flyers posted at the community corrections offices
Participants	500 smokers; 33.0% female, average age 37.4; average number of cigarettes smoked per day 17.9 Therapists: counsellors were doctoral or masters level clinical psychologists who had been trained in smoking cessation counselling

Cropsey 2015 (*Continued*)

Interventions	Pharmacotherapy: NRT; 12 weeks' supply of bupropion 1. one session of face-to-face brief advice 2. four weekly sessions of face-to-face brief advice and intensive counselling, each lasting 20 to 30 minutes
Outcomes	Abstinence (carbon monoxide level ≤ 3 ppm) at all study visits (weeks 8, 12 and months 6, 9, 12) Validation: carbon monoxide level (≤ 3 ppm) measured using the Vitalograph Breath Carbone Monoxide monitor
Source of Funding/CoI	The National Cancer Institute and the National Institute of Heatlh. No declarations of interest
Notes	New for 2019 update Data on the number of abstinent participants received from the authors via email correspondence

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"randomisation scheme was blocked on race…". No further details given
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Lost to follow-up rates at 12 months: no counselling arm 25.8%; counselling arm 23.4%

Ellerbeck 2009

Methods	Settng: primary care patients, 50 rural practices, Kansas, USA Recruitment: smoking patients not selected for motivation, but 67% of those eligible enrolled, only 8.7% in pre-contemplation stage of change
Participants	750 smokers of > 10 cpd, 59% F, av age 47, av cpd 24, 61% contemplation, 30% preparation
Interventions	All participants mailed an offer of free pharmacotherapy every 6 months, 4 times in total. Nicotine patch 21 mg for 6 weeks or bupropion SR (150 mg twice daily) for 7 weeks 1. Control. No other contact 2. Moderate intensity disease management: up to 2 calls from counsellor in each cycle encouraging uptake of pharmacotherapy, newsletter mailings & periodic progress reports

	with counselling suggestions faxed to physician 3. High-intensity disease management, up to 6 calls at approx 1, 3, 6, 9, 12 weeks from start of each cycle
Outcomes	Abstinence at 24 months (PP). Study also reported analysis based on combination of effects at all follow-up points. Sustained abstinence not a suitable outcome since no quit date and repeated intervention Validation: attempted saliva cotinine (< 15 ng/mL) by mail at 12 and 24 months. Proxy report used at 24 months for non-returners. Rate of validation similar across groups
Source of Funding/CoI	National Cancer Institute. Medication provided by GlaxoSmithKline, "The funding sources were not involved in the design, conduct or analysis of this study or the decision to submit the study for publication". No declarations of interest
Notes	Participants could have multiple courses of pharmacotherapy; 23%, 33%, 23%, 12%, and 9% of participants requested 0, 1, 2, 3, or 4 courses, Disease management conditions increased use in first cycle and reduced it later. 41% of cycles used bupropion & 59% patch. Over 24 months, average number of calls 3.6 in 2. and 8.2 in 3. Fewer calls in later cycles No evidence of effect based on PP, but some evidence of benefit when all follow-ups taken into account High intensity vs control in main comparison. Moderate intensity quit almost identical (35/238 14.7%)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "computer generated random numbers table was utilized to generate allocation cards in blocks of 24 with allocation equally distributed across treatment groups"
Allocation concealment (selection bias)	Low risk	Quote: "cards were placed in sequentially numbered, opaque, sealed envelopes"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated and proxy report used for non-returners; rate of non-return similar across groups
Incomplete outcome data (attrition bias) All outcomes	Low risk	Less than 20% lost to follow-up, similar distribution amongst groups (11% control, 16% in both moderate- and high-intensity intervention arms)

Ferguson 2012

Methods	Setting: National quitline, Engalnd Recruitment: non-pregnant smokers aged ≥ 16 years, residing in England who called the quitline and agreed to set a quit date
Participants	2591 smokers in total (1295 in the relevant arms); 52.3% female, average age 38; average number of cigarettes smoked per day: 497 in ≤ 10 cpd category; 1226 in 11 to 20 cpd category; 547 in 21 to 30 cpd category; 230 in ≥ 31 cpd category Therapists: trained advisors from two helpline centres
Interventions	Pharmacotherapy: NRT; no cost vouchers for 21 days' supply of 15 mg per 16 hour transdermal nicotine patches which were redeemed by a telephone call. A second 21 days' supply could be redeemed in the same way three weeks after the initial batch 1. usual care (support materials by email, letter or text message before, on and after quit date + proactive telephone contact + brief motivational messages) 2. 6 sessions of more intensive, proactive support by telephone
Outcomes	Prolonged abstinence at months 1 and 6 Validation: a minority of participants (255 out of 2591 had face-to-face follow-up for validation of abstinence by carbon monoxide (cut-off of < 10 ppm))
Source of Funding/CoI	The English Department of Health, the UK Centre for Tobacco Control Studies. No declarations of interest
Notes	New for 2019 update Previously excluded. Contact amount not known so excluded from analyses 1.2 and 1.3 Use of pharmacotherapy was low; only 42.9% of those offered NRT reported receiving any and of those only 51.3% used every day. There was also little difference between number of calls completed between proactive and standard telephone counselling conditions

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Lost to follow-up rate: NRT + usual care arm 44.7%; NRT + proactive support arm 45.5%

Fiore 2004

Methods	Setting: primary care patients, 16 clinics, USA Recruitment: clinic attenders willing to accept treatment
Participants	961 smokers of ≥ 10 cpd. (a further 908 were allowed to select treatment, not included in review. Demographic details based on 1869); 58% F, av age 40, av cpd 22 Therapists: trained cessation counsellors
Interventions	Pharmacotherapy: NRT (patch, 22 mg, 8 weeks including tapering) 1. NRT alone 2. As 1 plus Committed Quitters programme, single telephone session and tailored self-help 3. As 2 plus face-to-face individual counselling, 4 x 15 to 25-min sessions, pre-quit, ~TQD, next 2 weeks
Outcomes	Continuous abstinence at 1 year (no relapse lasting 7 days), also PP Validation: CO, cut-off not specified. 2 discordant
Source of Funding/CoI	National Cancer Institute. SmithKline Beecham provided nicotine patches and access to the CQ program, but did not participate in any aspect of study design or data analysis
Notes	3 versus 1 used in primary analysis. 3 & 2 versus 1 was more conservative since 2 had lower quit rates than 1. Use of PP outcome did not alter findings

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	People who did not pick up patches were excluded from analyses, similar distribution amongst groups (17% control, 16% in intervention arm 1, 14% intervention arm 2). No reported loss to follow-up for remaining participants

Gariti 2009

Methods	Setting: academic research centre, USA Recruitment: community volunteers, interested in quitting
Participants	260 light smokers (6 - 15 cpd), 57% F, av age ~43, av cpd 11, approx 1/3 smoked < 10 cpd, approx 50% had history of smoking 20 cpd Therapists: cessation counsellors
Interventions	2 x 2 double-blind double-dummy. Participants randomised to either nicotine patch (21 mg/day or 14 mg/day (< 10 cpd) for 8 wks incl weaning) or bupropion (9 wks) 1. Pharmacotherapy & medication management, 4 x 5-10 min visits over 6 wks 2. Pharmacotherapy & counselling, 10 weekly individual 10-15 min sessions
Outcomes	Abstinence at 1 yr, sustained with no relapse of over 7 days smoking (study primary outcome was PP abstinence) Validation: CO ≤ 9 ppm & cotinine (NicAlert) ≤ 200 ng/mL or cotinine < 50 ng/mL
Source of Funding/CoI	National Institute on Drug Abuse. No declarations of interest
Notes	NRT & bupropion conditions not reported separately by counselling condition, so 2 vs 1 entered in NRT or bupropion section. Favoured NRT but no significant difference at any follow-up. More evidence of effect on sustained than PP rates at 1 yr, but substituting PP in MA did not affect findings

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated "urn" randomisation by independent data analyst
Allocation concealment (selection bias)	Low risk	Randomisation after enrolment, not predictable
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	108 (84%) intervention and 108 (82%) control reached at 1 yr

Gifford 2011

Methods	Setting: academic research centre, USA Recruitment: community volunteers
Participants	303 smokers with at least 1 quit attempt in past 2 years 58.7% F, av age: 45.99, av cpd 24 Therapists: abuse therapist + clinical psychology doctoral students

Gifford 2011 (*Continued*)

Interventions	Pharmacotherapy: bupropion for 10 weeks. 1. Control; 1 hr of "medication instruction group presenting the rationale for bupropion" 2. Bupropion plus functional analytic psychotherapy (FAP) and acceptance and commitment therapy (ACT), 20 sessions, 1 group & 1 individual session per wk for 10 wks
Outcomes	Abstinence at 1 yr (7-day PP). Continuous abstinence also reported but denominators not clear Validation: CO ≤ 10 ppm
Source of Funding/CoI	National Institute on Drug Abuse. No declarations of interest
Notes	Numbers quit calculated from percentages. Included in brief intervention subgroup 1.1.1, sensitivity analysis in dose-response did not alter estimates

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomised using generator www.randomizer.org
Allocation concealment (selection bias)	Low risk	Randomisation did not occur until after enrolment.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	High risk	38% intervention & 67% control lost to follow-up, including 10 intervention & 2 control dropouts before treatment

Ginsberg 1992

Methods	Setting: academic research centre, USA Recruitment: community volunteers
Participants	99 smokers with an acquaintance willing to participate as a support partner; 54% F, av age 38, av cpd 26
Interventions	Pharmacotherapy: nicotine gum, 2 mg, duration not specified 1. Instruction for gum use & educational materials, 2 brief sessions over 2 weeks 2. Instructions as 1. included with a group-based behavioural programme including skill training, 5 sessions over 4 weeks. Duration not specified, assumed to be 91 to 300 min 3. As 1. plus behavioural programme and partner-support programme, 8 sessions over 5 weeks. Not included in this review

Ginsberg 1992 (*Continued*)

Outcomes	Abstinence at 52 weeks (not clear if abstinence required at prior assessment at wks 4, 12, 26) Validation: CO < 10 ppm, urine cotinine < 50 ng/mL. Paper stated that cotinine levels failed to confirm self-report in 7 people, 3 of whom were still coded as abstinent on the balance of evidence
Source of Funding/CoI	
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "randomly assigned to 3-6 member groups in order of entrance into treatment within time constraints. Treatment for each group was randomly selected ..."
Allocation concealment (selection bias)	Unclear risk	No details reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	9 participants lost to follow-up counted as smokers. 1 participant who died excluded from analyses

Hall 1985

Methods	Setting: clinic, USA Recruitment: referred by physicians, friends or self
Participants	84 smokers in relevant arms; 53% M, av age 38, av cpd 30.5 Therapists: 2 psychologists
Interventions	Pharmacotherapy: NRT; gum (2 mg, available for 6 months) 1. Intensive behavioural treatment (incl relapse prevention skill training, relaxation, 30 seconds aversive smoking of 3 cigs). 14 x 75 min sessions over 8 weeks 2. Low-contact . Met x 4 in 3 weeks, educational materials, written exercises, group discussion 3. Intensive behavioural, no gum. Not included in this review
Outcomes	Abstinence at 52 weeks (assume PP) Validation: CO < 10 ppm, thiocyanate < 85 mg/mL, reports of significant others (biochemical measures failed to confirm self-report in 3 instances)

Hall 1985 (*Continued*)

Source of Funding/CoI	National Institute on Drug Abuse. No declarations of interest
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomly assigned within time constraints." Author clarification: "There were two or more treatment conditions available within any time block, and participants were randomly assigned to conditions within that time block"
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	3 dropouts from group 2 and 3 from group 3. Assumed to be included in denominator for reported % abstinent used to derive numbers quit

Hall 1987

Methods	Setting: clinic, USA Recruitment: community volunteers or referrals
Participants	139 smokers; 53% M, av age 39, av cpd 30 (71 in relevant arms) Therapists: advanced graduates in clinical psychology or health psychology
Interventions	Pharmacotherapy: NRT (gum). Placebo arms of factorial trial not used in review 1. Intensive behavioural treatment, 14 x 75 min sessions (period not stated) (incl 6 seconds aversive smoking, RP skills training, written exercises) 2. 'Low contact' 5 x 60 min sessions (incl written exercises, educational materials, group discussions, quitting techniques)
Outcomes	Abstinence at 52 wks (assume PP) Validation: thiocyanate < 95 mm/L (unless marijuana use reported), CO < 8 ppm, significant other
Source of Funding/CoI	National Institute on Drug Abuse. No declarations of interest
Notes	

Hall 1987 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised; method not described
Allocation concealment (selection bias)	Unclear risk	No details reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	2 dropouts in 1 & 2 in 2 included in ITT analyses. "Differences between conditions were not statistically significant."

Hall 1994

Methods	Country: USA Recruitment: community volunteers or referrals
Participants	149 smokers (> 10 cpd) 52% F, av age 41, av cpd 25, 31% had history of MDD Therapists: physician, psychologist. Both received training.
Interventions	Pharmacotherapy: NRT (gum, 2 mg for up to 12 wks, tapering from wk 4) 1. Mood Management. 10 x 2 hr sessions over 8 wks. Similar to control, plus specific cognitive-behavioural components for developing skills for coping with situations leading to poor mood. Thought stopping, rational-emotive techniques, relaxation etc 2. Standard group therapy. 5 x 90 min sessions over 8 wks. Information and group support for planning and implementing individual strategies
Outcomes	Continuous abstinence at 52 wks (confirmed quit at all prior assessments and no smoking in previous wk) Validation: CO $\leq$ 10 ppm and urine cotinine $\leq$ 60 ng/mL
Source of Funding/CoI	National Institute on Drug Abuse. Merrell Dow Pharmaceuticals Inc. provided drugs. No declarations of interest
Notes	Both behavioural interventions were relatively intensive. Positive effect reported for sub-group with history of major depression

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Hall 1994 (*Continued*)

Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Dropouts included as smokers, but numbers not specified

Hall 1998

Methods	Setting: cessation clinic, USA Recruitment: community volunteers. Exclusion criteria included MDD within 3 m of baseline
Participants	199 smokers of ≥ 10 cpd; 55% F, av age 40, av cpd 21-25; 33% had history of MDD Therapists: 3 doctoral-level clinical psychologists
Interventions	Pharmacotherapy: nortriptyline (titrated to therapeutic levels - usually 75-100 mg/day for 12 wks). Placebo arms of factorial trial not used in review 1. Mood management. 10 x 2 hr sessions over 8 wks 2. Standard group therapy control. 5 x 90 min sessions over 8 wks (see Hall 1994 for description of each intervention)
Outcomes	Abstinence at 64 wks (1 yr post-treatment). Continuous abstinence rates not reported by psychological treatment group Validation: CO < 10 ppm and cotinine < 341 nmol/L
Source of Funding/CoI	National Institute on Drug Abuse. No declarations of interest
Notes	Both behavioural interventions were relatively intensive.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomised by computer, after stratification on history of MDD and number of cigs smoked
Allocation concealment (selection bias)	Low risk	Computer randomisation after data collection

Hall 1998 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	16% lost to follow-up at 1 yr, no difference by group, included in denominators for MA

Hall 2002

Methods	Country: USA Recruitment: community volunteers. Exclusion criteria included current MDD
Participants	220 smokers (146 in relevant arms); ≥ 10 cpd; 40%-47% F, av age 37-43, av cpd 20-23; 33% had history of MDD
Interventions	Pharmacotherapy: bupropion (300 mg for 12 wks) or nortriptyline (titrated to therapeutic levels, typically 75 or 100 mg/d). Factorial 3 x 2 design, placebo arms not used in this review 1. Medical Management (MM) control: physician advice, S-H, 10-20 min 1st visit, 5 min at 2, 6, 11 wks 2. Psychological Intervention (PI) as MM plus 5 x 90 min group sessions in wks 4, 5, 7 & 11
Outcomes	PP abstinence at 1 yr (47 wks post-quit date). Continuous abstinence not reported by subgroup Validation: CO ≤ 10 ppm, urine cotinine ≤ 60 ng/mL
Source of Funding/CoI	National Institute on Drug Abuse. No declarations of interest
Notes	Bupropion PI vs MM & nortriptyline PI vs MM used in relevant subgroups. Trial also contributed to review of combined interventions Stead 2016, using different combination of arms.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised, method not specified, "double blind"
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated

Hall 2002 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	19% lost to follow-up at 12 m, similar numbers across groups

Hall 2009

Methods	Setting: cessation clinic, USA Recruitment: community volunteers
Participants	402 smokers (≥ 10 cpd) aged ≥ 50; 40% F, av age 57, av cpd 21
Interventions	Pharmacotherapy: NRT (gum, 10 weeks, 2 or 4 mg) & bupropion (12 weeks). 2 arms had extended access to gum 1. "Standard treatment"; 5 group sessions over 8 weeks, 'Clear Horizons' manual 2. Extended CBT; 11 individual 20 to 40 min sessions from week 10 to week 52, schedule front-loaded. Incl motivation, mood management, weight control, social support, coping with withdrawal 3. Extended NRT. nicotine gum available until week 52, no additional behavioural support 4. Extended combined, CBT & NRT; 3 & 4
Outcomes	Abstinence at 104 weeks (one year after end of all treatment) (PP) Validation: CO ≤ 10 ppm and urine anatabine/anabasine ≤ 2 mg/mL
Source of Funding/CoI	National Institute on Drug Abuse. No declarations of interest
Notes	Meta-analysis comparison was 2 & 4 vs 1 & 3

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomised at end of initial treatment, computerised allocation list by statistician who had no contact with participants. Stratified on gender, history of MDD, current cigarette abstinence status
Allocation concealment (selection bias)	Low risk	"The assignment of individual participants by subject number was then transmitted electronically to clinical staff."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Less than 20% lost to follow-up in each group, denominator excluded participants

		who died during the study but counted all others lost to follow-up as smokers

Hasan 2014

Methods	Setting: North Shore Medical Center in Salem, USA Recruitment: smokers admitted with a cardiac or pulmonary illness were electronically identified
Participants	122 smokers in total (81 in the relevant arms); 39.5% female, average age 54.4 to 55.3; average number of cigarettes smoked per day 20.5 to 21.2 Therapists: no details given
Interventions	Pharmacotherapy: NRT; free one-month supply of nicotine patches with the initial dose based on the number of cigarettes they smoked prior to hospitalisation. Also given nicotine gum or lozenges to administer as needed 1. one intensive in-hospital counselling (30 minutes) + five telephone calls with additional counselling at 1, 2, 4, 8 and 12 weeks post-discharge (15 minutes each) 2. one intensive in-hospital counselling (30 minutes) + five telephone calls with additional counselling at 1, 2, 4, 8 and 12 weeks post-discharge (15 minutes each) + one in-person hypnotherapy session within 1 to 2 weeks of hospital discharge (90 minutes)
Outcomes	7-day point prevalence abstinence at week 12 and at 6 months Validation: urinary cotinine levels (< 15 mg/mL). In case of no urine sample returned, abstinence was confirmed by contacting a household proxy
Source of Funding/CoI	The Norman H. Read CharitableTrust Foundation. No declarations of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"permuted blocks of three (1:1:1)". No further details given
Allocation concealment (selection bias)	Low risk	"Assignments sequentially numbered and schedule was maintained independent of the study by the project coordinator. Randomised assignments were concealed from both patients and research staff until patients had signed the informed consent document and were enrolled in the study"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated

Hasan 2014 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Lost to follow-up rates: Counselling arm 29.3%; counselling + hypnotherapy arm 32.5%

Hollis 2007

Methods	Setting: community-based telephone quitline programme, Oregon, USA Recruitment: callers invited to participate; assumed to be fully or partly motivated to quit
Participants	4614 smokers randomised to: brief counselling (872, no NRT; 868, with NRT); moderate counselling (718, no NRT; 715, with NRT); intensive counselling (720, no NRT; 721, with NRT) 40% M, av age 41, 90% white, av cpd 21
Interventions	Factorial design; arms that were offered free NRT (patches, initial 5-wk supply, 3 more wks available) contributed to this review Intervention 1. Brief counselling (usual care), 15-min call + referral material + tailored S-H materials Intervention 2. Moderate counselling: 40 mins counselling based on MI + 1 brief call to encourage use of community services, tailored S-H materials Intervention 3. Intensive counselling: As 2, plus offer of up to 4 additional telephone calls. Each call incorporated MI techniques, stage assessment, RP as needed
Outcomes	30-day PPA at 6 and 12 months Validation: none
Source of Funding/CoI	National Cancer Institute. GlaxoSmithKline supplied nicotine patches. Two authors employed by Free & Clear, Inc, a for-profit company providing telephone counselling services
Notes	3 vs 1 in main comparison. Actual contact in 3; mean 2.9 sessions, 60.6-min contact Also contributed to review of combined interventions Stead 2016

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"a computer algorithm randomly assigned participants".
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-report only and different amounts of contact between arms

Hollis 2007 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Moderate level of attrition but balanced between groups, and participants lost to follow-up counted as smokers (72% followed up in groups 1 and 2, 68% followed up in group 3)

Huber 2003

Methods	Setting: academic research centre, Germany Recruitment: community volunteers
Participants	225 smokers (102 in relevant arms); 55% F, av age 38, av cpd 28
Interventions	Pharmacotherapy: nicotine gum, 2 or 4 mg 1. 5 x 90-min weekly meetings. Included contracting, reinforcement, relaxation, skills training 2. Same schedule of meetings, 45-min only, focus on sharing experiences 3. As 1, no nicotine gum. Not included in this review 4. Wait-list control for 6 m. Not included in this review
Outcomes	PP abstinence at 12 m Validation: CO $\leq$ 4 ppm
Source of Funding/CoI	Not specified. No declarations of interest
Notes	Control and intervention fell into same categories for number and duration of sessions

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	31 people attending 2 or fewer meetings not included in analysis. Said to be evenly distributed. Later dropouts included as smokers; 90% of those receiving therapy (excluded wait-list group 4, who were also excluded from this review) followed up at 12 m

Humfleet 2013

Methods	Setting: HIV clinics, USA Health Care Recruitment: HIV clinic patients, volunteering for study
Participants	209 smokers 82% M, av age 45, av cpd 20 Therapists: clinicians specialising in smoking cessation/social work/psychology
Interventions	Pharmacotherapy: NRT; patch or gum for 10 weeks, available to those who smoked ≥ 5 cpd, number not eligible, not specified 1. Self help: "How to Quit Smoking"; brief meeting with study staff who reviewed guide and recommended establishing a quit date 2. Individual counselling: 6 x 40 to 60-min sessions of CBT targeted towards needs of HIV positive smokers, weeks 1, 2, 3, 4, 8 & 12 3. Computer-based: each component structured into a "step" roughly corresponding to the first 5 sessions of the counselling intervention. Individuals were directed to complete self-assessment exercises and homework assignments
Outcomes	Abstinence at 52 weeks (7-day PP) Validation: CO ≤ 10 ppm
Source of Funding/CoI	National Institute on Drug Abuse. California Tobacco-Related Disease Research Program. Authors declared no conflicts of interest
Notes	Individual counselling compared to self-help in main MA, added computer-based arm in sensitivity analysis

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Smokers stratified based on N cpd, gender, history of depression and then within each stratum randomised via computer algorithm to 1 of 3 conditions in 1:1:1 fashion into a parallel-group design
Allocation concealment (selection bias)	Low risk	Randomisation occurred after enrolment & stratification.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	19% overall loss to follow-up

Jorenby 1995

Methods	Country: 2 academic research sites, USA Recruitment: community volunteers
Participants	504 smokers (≥ 15 cpd); ~53% F, av age 44, av cpd 26-29 Therapists: trained smoking cessation counsellors
Interventions	Compared 22 mg vs 44 mg nicotine patch and 3 types of adjuvant treatment. Patch groups collapsed. All participants had 8 weekly assessments by research staff 1. Minimal: Given S-H pamphlet by physician during screening visit for trial entry, and instructed not to smoke whilst wearing patch. No further contact with counsellors 2. Individual: Given S-H pamphlet at screening visit along with motivational message. Also met nurse counsellor x 3 following quit date. Nurse helped generate problem-solving strategies and provided praise and encouragement. 3. Group: Given S-H pamphlet at screening visit along with motivational message. Received 8 x 1-hour weekly group sessions. Skills training, problem-solving skills
Outcomes	7-day PP abstinence at 26 wks Validation: CO < 10 ppm
Source of Funding/CoI	Elan Pharmaceutical Research Corporation. Authors declared potential conflicts of interest
Notes	No significant difference in dose-related outcome and no dose-counselling interaction at 26 weeks reported. Patch arms collapsed in analysis. 3 vs 1 used in primary comparison, RR 0.99 (95% CI 0.69 to 1.42). RRs for other comparisons: 2 & 3 vs 1 = 1.10 (95% CI 0.81 to 1.49), 2 vs 1 = 1.21 (95% CI 0.86 to 1.70), 3 vs 2 = 0.82 (95% CI 0.58 to 1.15)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomised, method not stated
Allocation concealment (selection bias)	Unclear risk	"In a double blind manner" for NRT, but not specified for counselling
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Losses not specified by group, relatively low rate lost to follow-up overall (16.3%), Counted as smokers in report & MA

Kahler 2015

Methods	Setting: community, USA Recruitment: smokers recruited through advertisements on multiple media
Participants	77 smokers; 50% female, average age 47.4 to 44.5; average number of cigarettes smoked per day 18.7 to 18.8 Therapists: six female doctoral level counsellors with prior experience in behavioural health counselling
Interventions	Pharmacotherapy: NRT; 8 weeks of nicotine patches beginning on their scheduled quit date, which coincided with the third session (2 weeks after the initiation of treatment). Dosage dependent on the number of cigarettes smoked per day 1. Usual care: six sessions (five weekly and a final session that occurred 2 weeks later); session 1 lasted 60 minutes and the later sessions 30 minutes; 30 minutes of the session 1 and 20 minutes of the subsequent sessions were dedicated to teaching progressive muscle relaxation 2. Positive psychotherapy: same as the usual care in terms of the number and duration of the sessions but 30 minutes of the session 1 and 20 minutes of the subsequent sessions were dedicated to positive psychotherapy-specific content
Outcomes	Continous abstinence at weeks 8, 16, 26 Validation: alveolar carbon monoxide (≤ 8 ppm) using a Bedfont Scientific Smokelyzer breath carbon monoxide monitor; saliva cotinine (≤15 ng/mL) radioimmune assay analysis
Source of Funding/CoI	The National Cancer Institute. No declarations of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated
Allocation concealment (selection bias)	Low risk	"data for the randomisation were sent by research assistant to the project coordinator who conducted the computer-based urn randomisation and informed the treatment provider of treatment assignment"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Lost to follow-up rates: Usual care arm 31.6%; positive psychotherapy arm 25.6%

Killen 2008

Methods	Setting: community cessation clinic, USA Recruitment: community volunteers
Participants	301 smokers (≥ 10 cpd or 3.5 packs/wk) (excluded 3 participants who received wrong treatment); 40% F, av age ~46, av cpd ~20
Interventions	Pharmacotherapy: bupropion (300 mg, 9 wks) & NRT (21 mg patch, 8 wks incl tapering) Common behavioural therapy: 6 x 30-min individual CBT sessions at baseline, TQD, 1, 2, 4, 6 wks 1. Extended therapy: 4 x 30-min sessions at 8, 12, 16, 20 wk, & weekly check-in calls to automated system; report of relapse or craving prompted proactive calls 2. Control: 5-min general support calls at 8, 12, 16, 20 wks
Outcomes	Abstinence at 52 wks (7-day abstinence at both 20 & 52 wks) (continuous abstinence also reported but not used in MA as could underestimate any effect on recycling) Validation: CO < 10 ppm (11 self-reported quitters no longer living in study area accepted as quitters without validation)
Source of Funding/CoI	National Institute on Drug Abuse. Authors declared no conflicts of interest
Notes	Tested extended duration therapy

Risk of bias

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

Kim 2015

Methods	Setting: community centre or office, USA Recruitment: smokers recruited via advertisements in Korean newspapers. Selected for motivation to quit
Participants	30 smokers; 23.3% female, average age 46.5; average number of cigarettes smoked per day 19.0 Therapists: two Korean bilingual clinicians
Interventions	Pharmacotherapy: NRT; 8 weeks' supply of nicotine patches 1. Eight weekly sessions of face-to-face individualised counselling focusing on medication management, each lasting 10 minutes 2. Eight weekly sessions of face-to-face individualised and culturally tailored cognitive behavioural therapy, each lasting 40 minutes
Outcomes	Continuous abstinence at weeks 1, 4 and months 3, 6 Validation: carbon monoxide (< 6 ppm) measured by a Micro+ Smokerlyzer Carbone Monoxide monitor; saliva cotinine (≤ 1 ng/mL) assessed by the NicAlert test
Source of Funding/CoI	National Institute of Drug Abuse. No declarations of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Lost to follow-up rates: Control 25.0%; intervention 21.4%

LaChance 2015

Methods	Setting: USA (no further detail reported) Recruitment: from the community via newspaper and television advertisement
Participants	49 participants, 32.7% female, average age: 42.8 ± 11.2, average cigs/day: 18.2 ± 5.2 Therapists: five therapists; a licensed psychologist, a master's level clinician, an intern, and two bachelor's level therapists

LaChance 2015 (*Continued*)

Interventions	Pharmacotherapy: 8 weeks of transdermal nicotine replacement therapy Intervention: behavioural couples treatment. Total contact time: 60 minutes each x 7 = 420 minutes Control: individual standard treatment. Total contact time: 60 minutes each x 7 = 420 minutes
Outcomes	7-day point prevalence abstinence at 3 and 6 months Validation: CO ≤ 8 ppm, or urinary cotinine
Source of Funding/CoI	Funding: National Institute on Durg Abuse and National Heart Lung and Blood Institute at the National Institutes of Health, and the Department of Veterans Affairs No declaration of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Urn randomisation
Allocation concealment (selection bias)	Unclear risk	No detail given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar drop-out rates (BCT-S: 23.0%; ST: 21.7%)

Lando 1997

Methods	Setting: Health Maintenance Organization, USA Recruitment: physician referral and HMO clinic newsletters
Participants	509 smokers of > 20 cpd, motivated to quit; 56% F, av age 42, av cpd 28
Interventions	All participants received prescriptions for free nicotine patch (Prostep), 22 mg for a maximum of 6 weeks plus 11 mg for 2 wks. All attended 90-min group orientation session describing study, use of patch, behavioural information, set quit date. Standard written materials with patch included description of a toll-free telephone help line. 1. No further support 2. Orientation session included encouragement to call toll-free number and a registration card. 3. Additional proactive telephone counselling, 4 x 10 to 15-min calls (approx 1, 4, 7, 9, 12 weeks from quit date). Reinforced success or negotiated a new quit date

Lando 1997 (*Continued*)

Outcomes	Abstinence at 12 months (from quit date) Validation: CO at 6 months. 96% of quitters were confirmed.
Source of Funding/CoI	Lederle Laboratories. No declarations of interest
Notes	Also contributed to Cochrane review of telephone counselling (Matkin 2019) Effect of counselling 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 weeks were called by telephone. Average number of calls completed 3.76 Cluster-randomised trial: analysis reported stated that it was adjusted for clustering effects via a mixed model, but these results were not reported except that group comparisons did not "approach statistical significance"

Risk of bias

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

Lifrak 1997

Methods	Setting: substance abuse outpatient facility, USA Recruitment: community volunteers
Participants	69 smokers; 61% F, av age 39, av cpd 25
Interventions	Pharmacotherapy: nicotine patch (24-hr, 10-wk tapered dose) 1. Moderate intensity - 4 meetings with nurse practitioner who reviewed S-H materials and instructed in patch use 2. High intensity. As 1 plus 16 weekly 45-min cognitive behavioural relapse prevention therapy from clinical social worker or psychiatrist experienced in addiction treatment

Lifrak 1997 (*Continued*)

Outcomes	Abstinence at 12 months, 1-week PP Validation: urine cotinine for some participants, but no corrections made for misreporting	
Source of Funding/CoI	None stated	
Notes		

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Block randomisation (block size 10)
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low rate of attrition (though breakdown by group not provided): 12 administrative dropouts/exclusions not included in analyses

Lloyd-Richardson 2009

Methods	Setting: 6 outpatient HIV clinics & 2 primary care clinics, USA Recruitment: eligible patients identified by physicians, motivation to quit not required	
Participants	444 HIV+ smokers; 37% F, av age 42, av cpd 18	
Interventions	Pharmacotherapy: nicotine patch for up to 8 weeks if willing to set quit date 1. 2 brief counselling sessions, biweekly patch collection without counselling contact 2. 4 x 30-min sessions plus quit day call, using motivational interviewing approach	
Outcomes	7-day point prevalence abstinence at 12 months Validation: carbon monoxide < 10 ppm	
Source of Funding/CoI	National Institute on Drug Abuse. Authors declared no conflicts of interest	
Notes	72% used patch at some point during study.	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Lloyd-Richardson 2009 (*Continued*)

Random sequence generation (selection bias)	Low risk	Block randomised, stratified by gender and motivation to quit
Allocation concealment (selection bias)	Unclear risk	No details provided
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	75% intervention, 71% control followed up at 6 m. ITT and available-case analyses reported

MacLeod 2003

Methods	Setting: community, Australia Recruitment: community volunteers
Participants	854 smokers interested in quitting; 51% F, av age 42, av cpd 24
Interventions	All participants received a free 2-wk supply of nicotine patch by mail, instructed to purchase further supply; 14 or 21 mg depending on body weight 1. No further intervention 2. As 1. + 5 proactive telephone counselling calls at 1, 2, 3, 6 & 10 wks. 20-min session 1 wk, 10-min others. Toll-free hotline, S-H materials
Outcomes	Abstinence at 6 m (90-day continuous) Validation: none, warning of CO test only
Source of Funding/CoI	GlaxoSmithKline funded study and all authors were employed by GSK. "The conduct of the study was independently monitored and the data verified by Datapharm Australia. GlaxoSmithKline took part in discussions about study design, but had no direct role in the analysis or interpretation of the results or preparation of the report for publication."
Notes	Also contributed to Cochrane review of telephone counselling (Matkin 2019). No face-to-face contact Average number of calls 4.7. 9% of participants called hotline

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Randomized" by shuffling folders each day after participants to be included were listed. Since there was no personal contact with participants, risk of bias judged to be low

MacLeod 2003 (*Continued*)

Allocation concealment (selection bias)	Low risk	Potential for bias since allocation sequence not fixed in advance; however, baseline characteristics similar across groups so no evidence of selection bias
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-report only and differential levels of support
Incomplete outcome data (attrition bias) All outcomes	Low risk	No significant difference in loss to follow-up, 17% in NRT only, 15% in NRT+ at 6 m

Macpherson 2010a

Methods	Setting: USA (no further detail reported) Recruitment: using radio, web-based, and newspaper advertisements
Participants	68 participants, 48.6% female, average age: intervention: 45 ± 12.2, control: 42.6 ± 11.5, average cigs/day: intervention: 18.8 ± 7.1, control: 17.3 ± 8.1 Therapists: two therapists with clinical psychology doctoral degrees and three therapists who were clinical psychology doctoral students
Interventions	Pharmacotherapy: NRT; nicotine patches from quit date with an initial dose of 21 mg for 4 weeks, followed by 2 weeks of 14 mg, and 2 weeks of 7 mg. Participants who smoked on average 10 to 12 cigarettes per day started with 14 mg for the first 6 weeks Intervention: 8 weekly sessions of behavioural activation treatment. Total contact time: 60 minutes each x 8 = 480 minutes Control: 8 weekly sessions of standard treatment. Total contact time: 60 minutes each x 8 = 480 minutes
Outcomes	Abstinence: continuous abstinence at 1, 4, 16 weeks, and 6 months Validation: carbon monoxide ≤ 10 ppm, cotinine ≤ 5 ng/mL
Source of Funding/CoI	Funding: National Institute on Drug Abuse No declarations of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No detail given
Allocation concealment (selection bias)	Unclear risk	No detail given

Macpherson 2010a (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	High risk	High losses to follow-up in both arms: control: 63.6%; intervention: 57.1%

Matthews 2018

Methods	Setting: USA, LGBT health centres Recruitment: from the community
Participants	345 participants, 20.3% to 22.8% female, average age: 38.6-39.4, average cigs/day: 12.1 to 13.8 Therapists: a professional and a lay counsellor who identified as lesbian, gay, bisexual or transgender facilitated each group
Interventions	Pharmacotherapy: NRT; nicotine patches for 8 weeks (dose regimen dependent on the number of cigarettes) Intervention: 6 weekly culturally tailored smoking cessation therapy sessions commencing two weeks before the quit date Control: 6 weekly standard smoking cessation therapy sessions commencing two weeks before the quit date
Outcomes	Abstinence: 7-day point prevalence at 1, 3, 6, and 12 months Validation: carbon monoxide at 1 and 3-month follow-up
Source of Funding/CoI	Funding: National Institute on Drug Abuse, National Ceneter for Advancing Translational Sciences, National Institutes of Health, and National Cancer Institute Declarations of interest: one of the authors consulted with the Respiratory Health Association and served on a Health Advisory Board for Pfizer Inc
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"The study statistician conducts the permuted-block randomization using a software program developed by programmers at UIC."
Allocation concealment (selection bias)	Low risk	"The study statistician place the results of the assignments in sealed, solid envelopes. All study participants are blinded and retain no knowledge of CTQ or CTQ-CT group"

Matthews 2018 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar attrition between groups: intervention: 33.7%; control: 34.1%

McCarthy 2008

Methods	Setting: clinic, USA Recruitment: community volunteers
Participants	463 smokers; 50% F, av age 36 to 41 across arms, av cpd 22 Therapists: trained college-aged or bachelor's level staff, supervised by experienced counsellor
Interventions	Factorial trial of bupropion or placebo pharmacotherapy and counselling versus support 1. Bupropion & counselling; 13 office visits, 8 included additional 10-min counselling, 2 prequit, TQD, 5 over 4 weeks (classified as > 300 mins contact) 2. Bupropion & psychoeducation about medication, support & encouragement. 13 office visits, 80 mins less contact time than 1. (classified as 91 to 300 mins contact) 3. Placebo & counselling. Not included in this review 4. Placebo & psychoeducation. Not included in this review
Outcomes	7-day PP abstinence at 12 months (prolonged abstinence reported but not verified so PP used in MA) Validation: CO $\leq$ 10 ppm
Source of Funding/CoI	National Institute on Drug Abuse & National Cancer Institute. GlaxoSmithKline provided complimentary active and placebo medication used in this study. "GlaxoSmithKline was not involved in the design, data collection, analysis, or reporting of this study." Authors declared potential conflicts of interest
Notes	1 vs 2 used as test of adjunct behavioural support Also contributed to Cochrane reviews of combined interventions (1 vs 4) (Stead 2016) , antidepressants (collapsing behavioural conditions) (Hughes 2014) and individual behavioural counselling (collapsing pharmacotherapy) (Lancaster 2017)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Low risk	Staff who screened and enrolled participants were unaware of the experimental condition to be assigned

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	63% reached at 12 m, but attrition rates did not differ by condition at any point

NCT00879177

Methods	Setting: University of Connecticut Health Center, USA Recruitment: smokers with self-reported desire to stop smoking
Participants	203 smokers Therapists: no details given
Interventions	Pharmacotherapy: NRT; varenicline 1 tablet 0.5 mg once a day for three days followed by 1 tablet 0.5 mg twice a day for four days and then 1 tablet 1 mg twice a day for 11 weeks 1. Brief smoking cessation counselling weekly for five weeks 2. Brief smoking cessation counselling weekly for five weeks + behavioural therapy for weeks 2 to 5; ≥ 9 sessions in total
Outcomes	Abstinence at 12 months Validation: carbon monoxide and cotinine levels
Source of Funding/CoI	Unpublished study
Notes	New for 2019 update Contacted Professor White (Co-principal investigator) by email who informed us that the results were comparable for the two groups with quit rates about 50% in each group at 6 months. The results have not yet been published so we were only able to report this study narratively

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Unpublished study
Allocation concealment (selection bias)	Unclear risk	Unpublished study
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated

NCT00879177 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unpublished study

O'Cleirigh 2018

Methods	Setting: HIV primary care clinics, USA Recruitment: providers told potentially eligible patients about the study and offered them study coordinator's contact details. Selected for motivation to quit
Participants	53 smokers; 15.1% female; average age 49.7-51.2; average number of cigarettes smoked per day 14.4 Therapists: intervention was provided by doctoral level clinical psychology interns and postdoctoral fellows supervised by the first author. The control group sessions were conducted by the study coordinator or research associate
Interventions	Pharmacotherapy: transdermal nicotine replacement therapy provided on the quit day 1. Psychoeducation session before randomisation (60 minutes) + face-to-face hybrid treatment that targeted smoking cessation, anxiety and depression simultaneously (60 minutes x 9 sessions) 2. Psychoeducation session before randomisation (60 minutes) + post-quit sessions in person (10 minutes x 4 sessions)
Outcomes	7-day point prevalence abstinence at 1, 2, 4, 6 months Validation: carbon monoxide level $\leq$ 4 ppm
Source of Funding/CoI	National Institute on Drug Abuse. Authors declared potential conflicts of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Block randomisation in blocks of 4 conducted by the study coordinator
Allocation concealment (selection bias)	Low risk	"Before the study's start, a randomisation chart was created, corresponding to each study identification number. The chart was secured on a password-protected document accessible only by the study coordinator and the principal investigator. Assignment to study condition was concealed from participants and study clinicians until the end of session 1"

O'Cleirigh 2018 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	High risk	Lost to follow-up rate: intervention group 50.0%; control group 22.2%

Ockene 1991

Methods	Setting: primary care clinics, USA Recruitment: clinic attenders, not selected for interest in quitting
Participants	380 smokers in relevant arms (excluded deaths and some who did not receive intervention); of 1223 smokers in study; 57% F, av age 35, av cpd 23
Interventions	Pharmacotherapy: nicotine gum; offer of free gum 2 x 3 factorial design, physician intervention ± follow-up 1. Physician counselling (initial session and 1 follow-up) and offer of NRT. Follow-up telephone counselling by psychologist or health educator, 3 calls (1, 2, 3 months) approx 10 mins, behavioural recommendations. Letters 2. Physician counselling as 1. No additional follow-up
Outcomes	Abstinence at 6 m (7-day); (3 m sustained abstinence rates not given by condition) Validation: none
Source of Funding/CoI	
Notes	Marginal to include since relatively low use of pharmacotherapy; in intervention condition; of those reached, 33% refused use and 18% tried for 2 days or less 12 m abstinence rates reported in Ockene 1994 but not given by follow-up condition. Also contributed to review of combined interventions (Stead 2016)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	Allocated prior to physician encounter
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-report only and differential support between arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	19% lost to follow-up, higher in telephone follow-up group. All included as smokers in analysis

Okuyemi 2013

Methods	Setting: homeless shelters, Minnesota, USA community Recruitment: homeless adults willing to use nicotine patch
Participants	430 smokers (≥ 1 cpd for last 7 days) 25.3% female, av age 44.4, av cpd 19.3 Therapists: trained counsellors
Interventions	Pharmacotherapy: NRT; 21 mg patch for 8 weeks 1. Single session 10 to 15-min brief advice 2. Motivational interviewing, 6 x 15 to 20-min sessions, baseline, 1, 2, 4. 6 & 8 weeks Focus on encouraging cessation and NRT adherence
Outcomes	Abstinence at 26 weeks (7-day PP) Validation: CO < 5 ppm
Source of Funding/CoI	National Heart Lung and Blood Institute. No declarations of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"At the baseline visit, pre-assigned randomization numbers prepared by the study statistician determined which study arm the participant would be enrolled."
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Overall 25% lost to follow-up, not significantly different across groups

Otero 2006

Methods	Setting: Brazil Recruitment: community volunteers
Participants	1199 smokers (included 254 non-attenders); 63% F, av age 42, 46% smoked > 20 cpd Therapists: trained doctors, nurses or psychologists

Otero 2006 (*Continued*)

Interventions	Factorial design with NRT (21 mg or 14 mg patch for 8 weeks including tapering) or no NRT and 5 levels of behavioural support collapsed into 3 for analysis. Arms without NRT did not contribute to this review. 1. Single 20-min session - classified as brief intervention control in meta-analysis 2. Cognitive behavioural, 1 or 2 weekly x 1 hour sessions 3. As 2, with 3 or 4 weekly sessions. Maintenance or recycling sessions provided to all groups at 3, 6, 12 months
Outcomes	Abstinence at 12 months (7-day PP) Validation: none
Source of Funding/CoI	
Notes	3 vs 1 in patch condition only in primary analysis. Also contributed to review of combined interventions (Stead 2016)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised, stratified by age & sex, by independent specialist
Allocation concealment (selection bias)	Low risk	Trial administrators blind
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-report only and differential levels of support between arms
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Number lost to follow-up not provided. Non-participants and losses to follow-up included as smokers

Patten 2017

Methods	Setting: USA, YMCA and worksite fitness centres Recruitment: by provider referrals and flyers posted in the clinics, and radio and newspaper advertisements. Willing to quit
Participants	30 participants, 100% female, average age: control: 38.0 ± 11.0; intervention: 37.0 ± 10.0, average cigs/day: ≥ 10 Therapists: certified wellness coaches with a master's degree in clinical psychology or bachelor's degree in health education
Interventions	Pharmacotherapy: 4-week supply of nicotine patches at weeks 2 and 6 Intervention: exercise counselling delivered while the participant was engaged in exercise. The individual-based counselling included social cognitive theory-based assessment and problem-solving of exercise barriers, reinforcement (shaping) of exercise, and methods to

Patten 2017 (*Continued*)

	enhance exercise self-efficacy, using a motivational interviewing counselling style. Total contact time: 36 X 30- to 40-minute sessions = 1080 minutes Control: health education. Individual-based sessions, lectures, handouts, films, and discussions covered various women's health and lifestyle issues. Total contact time: 36 X 30- to 40-minute sessions = 1080 minutes
Outcomes	Abstinence: 7-day point prevalence at 12 weeks and 6 months Validation: saliva cotinine (abstinent if < 10 ng/mL)
Source of Funding/CoI	Funding: National Center for Advancing Translational Sciences of the National Institutes of Health No declarations of interest
Notes	New for 2019 update A small number of participants attended all 36 sessions (n = 3 for intervention and n = 1 for control)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No details reported
Allocation concealment (selection bias)	Unclear risk	"[A]llocation to treatment conditions was unknown to the study staff or investigators prior to assignment and participants completed baseline assessments prior to being informed of their allocation to treatment condition. A study coordinator blinded to allocation group conducted all follow-ups in-person". However, no description of how allocation was concealed
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition in each group: 15.6%

Prapavessis 2016

Methods	Setting: Exercise and Health Psychology Laboratory, Canada Recruitment: from local businesses, hospitals, academic institutions and organisations and through advertisements placed in newspapers, radio stations and city buses in London, Ontario. Motivated to quit
Participants	409 participants, 100% female, average age: exercise plus smoking maintenance: 41.96 (± 12.70); exercise plus contact control 43.47 (± 14.02); smoking maintenance plus contact control: 43.45 (± 12.22); contact control: 40.36 (± 11.92) Average cigs/day: exercise plus smoking maintenance: 17.04 (± 6.79); exercise plus contact control 16.71 (± 6.96); smoking maintenance plus contact control: 16.88 (± 5.16); contact control: 16.41 (± 6.78) Therapists: trained facilitator
Interventions	Pharmacotherapy: transdermal NRT after 4 weeks of exercising (10 week programme: 21 mg once daily for weeks 4 to 9, followed by 14 mg once daily for weeks 10 to 11 and 7 mg once daily during weeks 12 to 13) **Exercise maintenance + smoking cessation maintenance** - 14-week exercise-aided smoking cessation programme (33 x 45-minute sessions) - Weeks 8 to 14: five 25-minute weekly cognitive behavioural therapy group sessions, for long-term exercise adherence - Received a set of Brandon's "Forever Free" booklets after first 14 weeks - After week 14: seven 15-minute telephone counselling sessions biweekly for the first months + monthly for the next two months + bimonthly for the last 8 months to maintain exercise behaviour - Total contact: 64 sessions, 1985 minutes **Exercise maintenance + contact control** - 14-week exercise-aided smoking cessation programme (33 x 45-minute sessions) - Weeks 8 to 14: five 25-minute weekly cognitive behavioural therapy group sessions, for long-term exercise adherence - After week 14: seven 15-minute telephone counselling sessions biweekly for the first months + monthly for the next two months + bimonthly for the last 8 months - to maintain exercise behaviour - Total contact: 64 sessions, 1985 minutes **Smoking cessation maintenance + contact control** - 14-week exercise programme (33 x 45-minute sessions) and 10 weeks NRT (starting from week 4) - Weeks 8 to 14: received messages reinforcing women's health issues - Received a set of Brandon's 'Forever Free' booklets after first 14 weeks - After week 14: seven 15-minute telephone counselling sessions biweekly for the first months + monthly for the next two months + bimonthly for the last 8 months - messages reinforcing the Forever Free booklets and/or women's health issues (e.g. vitamin D intake, oral hygiene, sleep disorders) - Total contact: 59 sessions, 1860 minutes **Contact control** - 14-week exercise programme (33 x 45-minute sessions) and 10 weeks NRT (starting from week 4) - Weeks 8 to 14: received messages reinforcing women's health issues - After week 14: seven 15-minute telephone counselling sessions biweekly for the first months + monthly for the next two months + bimonthly for the last 8 months - messages

Prapavessis 2016 (*Continued*)

	reinforcing the Forever Free booklets and/or women's health issues (e.g. vitamin D intake, oral hygiene, sleep disorders) - Total contact: 59 sessions, 1860 minutes
Outcomes	Abstinence: continuous abstinence at 14, 26, and 56 weeks Validation: CO < 6 ppm considered abstinent
Source of Funding/CoI	Funding: Canadian Cancer Society No declarations of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated
Allocation concealment (selection bias)	Unclear risk	The project manager for trial used numbered containers to implement the random allocation sequence, and the sequence was concealed until interventions were assigned. However, the method of concealment was not specified
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	54.8% of participants lost to follow-up, but attrition similar between groups

Reid 1999

Methods	Setting: community, Canada Recruitment: volunteers
Participants	396 smokers interested in quitting within 30 days, smoking ≥ 15 cpd; 48% F, av age 38, av cpd 23 to 24
Interventions	Pharmacotherapy: NRT; patch (15 mg x 8 wks, 10 mg x 2 weeks, 5 mg x 2 weeks) free 1. Physician advice (3 x 15-min, 2 weeks before, 4 weeks, 12 weeks after quit date) 2. As 1, plus telephone calls from nurse counsellors, x 3 at 2, 6, 13 weeks
Outcomes	Abstinence at 12 m (PP) Validation: CO, but self-reported rates reported. Only 1 disconfirmation

Reid 1999 (*Continued*)

Source of Funding/CoI	National Cancer Institute of Canada with funds from the Canadian Cancer Society Nicotine replacement therapy was provided at no cost by McNeil Consumer Products. "The University of Ottawa Heart Institute Research Corporation has a contract with Johnson & Johnson-Merck Consumer Pharmaceuticals to manage the 'Stop Smoking Now!' telephone counselling service offered to users of Nicotrol NRT. The authors received a grant from Johnson & Johnson-Merck to conduct a pilot study before the clinical trial; no payment was received from the company for the clinical trial or its analysis and write-up."
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised using table of random numbers, stratified by sex and nicotine dependence
Allocation concealment (selection bias)	Unclear risk	Concealment unclear but physician blind to allocation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	84% intervention, 86% control, followed up at 12 m

Rohsenow 2014

Methods	Setting: residential substance abuse treatment programme, USA Recruitment: research therapist assessed patients for eligibility
Participants	165 alcoholic smokers (≥ 10 cpd for 6 m), 60% M, av age 34, av cpd 21 Therapists: research therapists
Interventions	Pharmacotherapy: NRT; patch preferred, mostly used for 2-3 months 1. Brief advice ~15 mins, assessed smoking rate and interest in quitting, ± 2 x 5 to 15-min boosters at 7 & 30 days 2. Motivational interviewing, 45 min, ± 2 x 5 to 15-min boosters at 7 & 30 days
Outcomes	Abstinence at 12 months (7-day PP) Validation: CO < 10 ppm
Source of Funding/CoI	National Institute of Alcohol Abuse and Alcoholism, United States Department of Veterans Affairs. No declarations of interest

Rohsenow 2014 (*Continued*)

Notes	Booster and no-booster conditions combined in analyses. Only 51% used NRT during the first month, 34% during the subsequent 2 months	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random numbers table
Allocation concealment (selection bias)	Low risk	Assignment in sealed envelope opened just before the first treatment session
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Overall 32% lost to follow-up; MI 35%, (28/80 including 1 death), BA 29% (25/85 including 3 deaths)

Rovina 2009

Methods	Setting: smoking cessation clinic, Greece Recruitment: clinic attenders invited to participate
Participants	205 smokers
Interventions	Pharmacotherapy: bupropion 300 mg/day for 19 weeks 1. Control: 15 mins physician counselling 2. Nonspecific group therapy (NSGT), 1-hour weekly for 1 month, then every 3 weeks until 19 weeks 3. Cognitive behavioral group therapy (CBGT), same schedule 4. CBGT without bupropion - not used in review
Outcomes	Abstinence at 12 months after end of treatment (continuous) Validation: CO $\leq$ 10 ppm
Source of Funding/CoI	No source of funding reported. Authors declared no conflicts of interest
Notes	2 & 3 vs 1 in primary analysis, same intensity
Risk of bias	
Bias	**Authors' judgement**	**Support for judgement**

Rovina 2009 (*Continued*)

Random sequence generation (selection bias)	Unclear risk	Randomised, method not stated, 3:1:1:1 ratio
Allocation concealment (selection bias)	Unclear risk	No details reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	90% followed up at 12 months

Schlam 2016

Methods	Setting: USA, primary care clinics Recruitment: from primary care clinics, participants willing to quit
Participants	544 participants, 59% female, average age: 46.2 ± 12.8, average cigs/day: 18.6 ± 8.8 Therapists: bachelor's level study staff supervised a licensed clinical psychologist
Interventions	Pharmacotherapy: 8 weeks OR 26 weeks of nicotine patch plus nicotine gum (factorial design) Intervention: 4 sessions of face-to-face counselling plus 8 sessions of telephone counselling Control: 4 sessions of face-to-face counselling
Outcomes	Abstinence: 7-day point prevalence abstinence at 6 and 12 months Validation: none
Source of Funding/CoI	National Cancer Institute, Wisconsin Partnership Program, and Department of Veterans Affairs. No declarations of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated
Allocation concealment (selection bias)	Low risk	Staff could not view the allocation sequence. The database did not reveal participants' treatment condition to staff until participants' eligibility was confirmed. Participants did not know treatment allocation until they provided consent

Schlam 2016 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "The percentage of participants missing abstinence outcome data was 20. 4% at Week 26 and 30.0% at Week 52, with no differences observed in missingness across the two levels (on vs. off) of any of the factors." No further details provided

Schmitz 2007a

Methods	Setting: outpatient treatment research clinic, Department of Psychiatry and Behavioral Sciences Substance Abuse Research Center, USA Recruitment: by local radio, television and print adverts. Motivated to quit
Participants	154 participants (78 in 2 groups receiving pharmacotherapy), 100% female, average age: 47.8 ± 9.3, average cigs/day: 21.4 ± 9.1 Therapists: a therapist and co-therapist pair; four female, master's level therapists were trained on each therapy manual and supervised weekly by a doctoral-level clinical psychologist
Interventions	Pharmacotherapy: 6 weeks of sustained-release bupropion (300 mg/day; 150 mg/day for 3 days, followed by 150 mg twice daily) Intervention: 7 x 60-minute sessions of cognitive behavioural therapy (CBT) Control: 7 x 60-minute sessions of standard therapy (ST)
Outcomes	Abstinence: 7-day point prevalence at 3, 6, 9, and 12 months Validation: CO (abstinent if ≤ 10 ppm) and salivary cotinine (abstinent if ≤ 15 ng/mL)
Source of Funding/CoI	Funded by National Institute on Drug Abuse. GlaxoSmithKline provided the bupropion. No declarations of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not specified
Allocation concealment (selection bias)	Low risk	Quote: "Investigators and research staff were blind to the randomization codes, which were kept by a faculty member independent of the research and treatment team."

Schmitz 2007a (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition was high, but similar between study arms. Control: 56.8%; intervention: 53.7%

Simon 2003

Methods	Setting: hospital for military veterans, USA Recruitment: inpatients (all diagnoses) invited to participate
Participants	223 smokers, ≥ 20 cigs in week before admission, contemplation or action stage of change, able to use NRT, av age 55, av cpd 23
Interventions	Pharmacotherapy: NRT; patches (tailored dose) in hospital and for 8 weeks post-discharge 1. Intervention: nurse or health educator counselling; 30 to 60 mins initial session. 5 calls at 1, 3 weeks, 1 month, 2 months, 3 months, < 30 min/call & S-H materials 2. Control: brief counselling (10 mins) + S-H only
Outcomes	Abstinence: 7-day PP at 12 months Validation: saliva cotinine < 15 ng/mL (alternative analysis allowed spousal corroboration)
Source of Funding/CoI	California Tobacco-Related Disease Research Program. No declarations of interest
Notes	Relative effect similar if spousal corroboration allowed

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomised using computer algorithm
Allocation concealment (selection bias)	Unclear risk	No details reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Losses to follow-up (3 intervention, 4 control) included as smokers. Deaths (5 intervention, 9 control) excluded from denominator

Smith 2001

Methods	Setting: clinic, USA Recruitment: community volunteers
Participants	677 smokers (> 10/day) attempted to quit for 1 week; 57% F, av age 42; av cpd 25
Interventions	Pharmacotherapy: NRT, patches for 8 wks. All participants had attended 3 brief (5 to 10-min) individual counselling sessions pre-quit, quit day and 8 days post-TQD & NCI booklet 'Clearing The Air'. 1. Cognitive behavioural skills training, x 6 from 1 week post-TQD, incl managing negative affect, homework, manual 2. Motivational interviewing, supportive group counselling, x 6 from 1 week post-TQD. No homework or manual 3. No further intervention
Outcomes	Abstinence at 12 months (7-day PP) Validation: CO < 10 ppm
Source of Funding/CoI	National Institute on Drug Abuse. Lederle Laboratories supplied the nicotine patches. No declarations of interest
Notes	Marginal to include as the counselling was intended for relapse prevention 1 vs 3 in primary analysis. Including 2 did not alter findings; 17.6% quit in 1, 18.8% in 2. No evidence found for hypothesised differences in relative efficacy for smokers at high or low risk of relapse. High-risk smokers expected to do better with motivational intervention

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised 1 wk after TQD, stratified by ± any smoking post-TQD. Method not stated
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Number lost to follow-up not reported, all missing included as smokers

Smith 2013a

Methods	Setting: quitline, USA Recruitment: adult smokers willing to quit who called the Wisconsin Tobacco Quit Line
Participants	987 participants, 57.6% female, average age: 41.9 ± 13, average cigs/day: 20.7 ± 9.6 Therapists: trained cessation counsellors
Interventions	Pharmacotherapy: 2 or 6 weeks of NRT (nicotine patch only vs patch plus nicotine gum) (factorial design) Intervention: 4 telephone counselling sessions including medication adherence counselling Control: 4 telephone counselling sessions
Outcomes	Abstinence: 7-day point prevalence at 2, 6, and 12 weeks, and at 6 months Validation: none
Source of Funding/CoI	National Cancer Institute. Authors declared potential conflicts of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Allocation computer-randomised
Allocation concealment (selection bias)	Unclear risk	No detail reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Self-report only but similar amounts of contact between groups
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition low and similar between groups. Intervention: 24.9%, control: 21.6%

Smith 2014

Methods	Setting: Menominee Tribal Clinic (primary care centre), USA Recruitment: all participants were receiving health care at the Menominee Tribal Clinic and were motivated to quit smoking
Participants	103 participants, 62.1% female, average age: 39.8 (SD 13.1), average cigs/day: 14.4 (SD 7.9) Therapists: a study coordinator who was an enrolled member of the Menominee Tribe and trained as a counsellor
Interventions	Pharmacotherapy: 12 weeks of varenicline Intervention: 5 x face-to-face culturally tailored counselling sessions, duration not reported

Smith 2014 (*Continued*)

	Control: 5 x face-to-face standard counselling sessions, duration not reported
Outcomes	Abstinence: 7-day point prevalence abstinence at weeks 1, 3, and 7, and at 3 and 6 months Validation: CO < 10 ppm
Source of Funding/CoI	Wisconsin Partnership Program, the Spirit of Eagles Community Network Program, the University of Wisconsin Carbone Cancer Center, and the University of Wisconsin Center for Tobacco Research and Intervention. No declarations of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No detail given
Allocation concealment (selection bias)	Unclear risk	No detail given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition rate high and differed between study arms: intervention: 47.2%; control: 66.0%

Solomon 2000

Methods	Setting: community, USA Recruitment: volunteers for free nicotine patch trial
Participants	214 female smokers, > 4 cpd, intending to quit in next 2 weeks; av age 33, av cpd 24
Interventions	Pharmacotherapy: NRT; free nicotine patch (dose based on smoking level) for up to 10 weeks, after 1 m contingent on abstinence 1. Access to Nicoderm support line 2. As 1. and proactive telephone counselling from female ex-smoker, 7 hours training. Up to 12 calls for up to 3 months, starting pre-quit, quit day, day 4, average 7
Outcomes	Abstinence at 6 months (multiple PP; 7 days at 3 months & 6 months) Validation: CO ≤ 8 ppm. 7% to 12% disconfirmation rate. Participants who did not provide samples remained classified as quitters
Source of Funding/CoI	Vermont Department of Health (part). SmithKline Beecham provided nicotine patches. No declarations of interest

Solomon 2000 (*Continued*)

Notes	Intervention participants received on average 7 calls of 9 mins. Classified in 4 to 8 subgroup analysis. 95% received at least 1 call. Participants could call Nicoderm support line, 21% of control vs 8% of intervention did so

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Approximately 73% followed up in each group

Solomon 2005

Methods	Setting: community, USA Recruitment: volunteers for free nicotine patch trial
Participants	330 female smokers > 4 cpd, intending to quit in next 2 weeks; av age 34, av cpd 24
Interventions	Pharmacotherapy: NRT; free nicotine patch (dose based on smoking level) for up to 10 weeks, 2nd & 3rd prescriptions dependent on reporting abstinence 1. No additional support 2. Proactive telephone counselling from female ex-smoker, 8 hrs training. Calls for up to 4 months, starting pre-quit, quit day, day 4
Outcomes	Abstinence at 6 m (30 days at 3 months & 6 months) Validation: none
Source of Funding/CoI	Vermont Department of Health. SmithKline Beecham provided nicotine patches. No declarations of interest
Notes	Similar to Solomon 2000 with more extended telephone contact Average number of calls 8.2, average duration 10 min. Classified in 4 to 8 subgroup analysis

Risk of bias

Bias	Authors' judgement	Support for judgement

Solomon 2005 (*Continued*)

Random sequence generation (selection bias)	Unclear risk	Randomised, method not described
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-report only and differential amounts of contact between groups
Incomplete outcome data (attrition bias) All outcomes	Low risk	87% response in both conditions at 6 m

Stanton 2015

Methods	Setting: immunology clinics, USA Recruitment: adult smokers who have been diagnosed with HIV and identified themselves as Latino/Hispanic. Not selected for motivation to quit
Participants	302 participants, 36% female, average age: 45, average cigs/day: not reported but stated 50% of the participants were heavy (> 10 cigarettes per day) smokers Therapists: 10 health educators who were at least Masters level professionals or had equivalent years of clinical research experience
Interventions	Pharmacotherapy: 8 weeks of nicotine patches Intervention: self-help and culturally sensitive print materials and videos, tailored behavioural counselling, two in-person sessions, two additional in-person sessions focused on tailored relapse prevention, one phone call on the quit date, two 10-minute booster phone calls, option to bring a social support buddy to attend all sessions Control: self-help print materials, two in-person sessions, one phone call on the quit date
Outcomes	Abstinence: 7-day point prevalence at 3, 6 and 12 months Validation: exhaled carbon monoxide level < 10 ppm
Source of Funding/CoI	National Institute on Drug Abuse, National Cancer Institute, National Institute of Allergy and Infectious Diseases, Lifespan/Tufts/Brown Center for AIDS Research, Clinical Core of the Center for AIDS Research at the Albert Einstein College of Medicine and Montefiore Medical Center funded by the National Institutes of Health. Authors declared no conflicts of interest
Notes	New for 2019 update Not included in analysis 1.3 because durations of sessions were not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Stanton 2015 (*Continued*)

Random sequence generation (selection bias)	Unclear risk	No details provided
Allocation concealment (selection bias)	Unclear risk	No details provided
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar follow-up rates (control 67%; intervention 60%)

Stein 2006

Methods	Setting: 5 methadone maintenance treatment programme centres, USA Recruitment: smokers routinely attending maintenance clinic. Willingness to quit not required
Participants	383 methadone-maintained adult smokers. 53% M, av age 40, av cpd 27
Interventions	Pharmacotherapy: NRT; all participants willing to make quit attempt offered patches (8 to 12 weeks, dose and duration tailored to smoking rate) 1. Motivational interview-based tailored intervention: up to 3 visits from study counsellor, i.e. 1 x 30-min + 15 to 30-min quit-date session, + follow-up relapse prevention session. Those not ready to quit only received 2 sessions. 2. Control: Brief advice using NCI's 4As model (< 3 mins), + S-H materials. Up to 2 visits, i.e. baseline and quit date (if set)
Outcomes	Abstinence at 6 months (PP) Validation: CO < 8 ppm
Source of Funding/CoI	National Cancer Institute. GlaxoSmithKline provided nicotine patches. No declarations of interest
Notes	Included since most participants in both conditions did make quit attempts and received NRT; 81% intervention and 80% control

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised, methods not stated
Allocation concealment (selection bias)	Unclear risk	No details reported

Stein 2006 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Approx 82% followed up in both groups at 6 months

Strong 2009

Methods	Setting: USA Recruitment: via newspaper, radio, and television advertisements
Participants	524 participants, 47.5% female, average age: 44.27 ± 10.38, average cigs/day: 24.6 ± 10 Therapists: doctoral level therapist
Interventions	Pharmacotherapy: 12 weeks of bupropion, initiated during the second week of treatment, 2 weeks prior to quit day Intervention: 12 x 120-minute sessions of standard cessation group counselling with CBT for depression Control: 12 x 120-minute sessions of standard cessation group counselling
Outcomes	Abstinence: 7-day point prevalence abstinence at 2, 6, and 12 months Validation: CO (abstinent if ≤ 10 ppm) and salivary cotinine (abstinent if ≤ 15 ng/mL)
Source of Funding/CoI	Funding: National Institutes of Health Declarations of interest: one of the authors served on the Pfizer Speakers Bureau and a Pfizer Scientific Advisory Board
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No detail given
Allocation concealment (selection bias)	Unclear risk	No detail given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Study reported "8 smokers did not provide any follow-up data". However, this was only for the 12-week follow-up

Swan 2003

Methods	Setting: HMO, USA Recruitment: volunteers from Group Health Co-op membership
Participants	1524 smokers ≥ 10 cpd; 57% F, av age 45, av cpd 23, 44% history of depression
Interventions	Pharmacotherapy: randomised to bupropion 300 mg/day or 150 mg/day 1. Free & Clear proactive telephone counselling (4 brief calls), access to quitline and S-H materials 2. Zyban Advantage Program (ZAP); tailored S-H materials, single telephone call after TQD, access to Zyban support line
Outcomes	Abstinence at 12 m (7-day PP) Validation: none
Source of Funding/CoI	National Cancer Institute. "The authors have no relevant financial interest in this article, and received no financial support or medication from GlaxoSmithKline"
Notes	Prescription was mailed. No face-to-face contact during enrolment or prescription. Estimated as 31 to 90 minutes contact No dose/behavioural treatment interaction at 12 m, bupropion arms collapsed

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Open-label randomized trial...The computer code for the procedure calculated probabilities of group assignment that were dynamically modified based on the number of members in each group so that final group sizes were equal. No restrictions such as stratification or blocking were used as part of the randomization process."
Allocation concealment (selection bias)	Low risk	Procedure built into study database
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-report only and differential levels of support
Incomplete outcome data (attrition bias) All outcomes	Low risk	83% intervention, 88% control followed up at 12m

Swan 2010

Methods	Setting: HMO (Group Health), Seattle, WA, USA Recruitment: Group Health members contacted by phone & mail from Free & Clear
Participants	1202 smokers (≥ 10 cpd); 67% F, av age 47, av cpd 22
Interventions	Pharmacotherapy: varenicline for 12 weeks (1 mg x 2/day, titrated 1st week). All received 5 to 10-min orientation call, printed Quit Guides and access to a free support line for ad hoc calls. 1. Web-based counselling: access to online programme, including quit plan, online library, quit calendar, cost calculator, progress tracker, email links to friends and family and discussion forums 2. Proactive telephone-based counselling: Free & Clear Quit for Life programme. Up to 5 'brief' one-to-one phone sessions initiated by F&C counsellor. Timed for convenience and at relapse-sensitive stages. Used MI techniques 3. Combination: proactive calls + web access; counsellor could view info entered online. Participants encouraged to use website for additional info and social support, and to track cpd. Counsellors could view quit status, last log-in and last use of discussion forum
Outcomes	Abstinence at 6 m (PP) Validation: none
Source of Funding/CoI	National Cancer Institute. "Varenicline and nominal support for recruiting participants was provided by Pfizer, Inc. Neither entity [NCI or Pfizer] had any role in the study design; the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the report for publication." Authors declared potential conflicts of interest
Notes	3 vs 1 in main analysis, 2 & 3 vs 1 had little effect on result. 60-min contact on average for 3 64% were no longer taking varenicline at 3 months, but no between-group differences in non-compliance or reasons for stopping

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Group assignment was randomly allocated using an automated algorithm built into the study database"
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-report only and differential levels of support
Incomplete outcome data (attrition bias) All outcomes	Low risk	Participants lost to follow-up counted as smokers in ITT analysis; equal losses between groups (103 web, 107 phone, 100

		web + phone)

Tonnesen 2006

Methods	Setting: 7 chest clinics, Denmark Recruitment: outpatient attender
Participants	370 smokers of > 1 cpd with COPD (185 in relevant arms); 52% F, av age 61, av cpd 20 Therapists: 20 nurses with cessation experience, trained to support medication use and provide standardised counselling
Interventions	Pharmacotherapy: NRT; sublingual. Factorial trial included placebo tablets; only active treatment groups used in this review. 1. High support: 7 x 20 to 30-min clinic visits (0, 2, 4, 8, 12 wks, 6 m, 12 m) & 5 x 10-min phone calls (1, 6, 10 wks, 4½ m, 9 m), total contact time 4½ hrs 2. Low support: 4 clinic visits (0, 2 wks, 6 m, 12 m) & 6 phone calls (1, 4, 6, 9, 12 wks, 9 m), total time 2½ hrs
Outcomes	Sustained abstinence at 12 m (validated at all visits from wk 2, PP also reported) Validation: CO < 10 ppm
Source of Funding/CoI	"The Danish Medical Research Council provided the major grant for this study ($375, 000). Pfizer Consumer Healthcare, Sweden, supplied the study drugs used in the trial and provided grant support ($25,000)." First author declared potential conflicts of interest
Notes	Also contributed to review of combined therapy review (Stead 2016), using placebo low-support arm as control. Therapists were not full-time specialist counsellors. Using PP outcome did not alter effect. Only contacts before 12 wks counted for classification of intensity

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Block randomisation list at each centre
Allocation concealment (selection bias)	Unclear risk	Allocation process not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	42/185 (23%) of active NRT participants not followed up at 12 m and counted as smokers. Not reported by support condition. Of those who were followed up at 12

Tonnesen 2006 (*Continued*)

		m, 52% had withdrawn from study treatment. Authors stated: "One potential bias may have been the large early dropout of failures from the study. Consequently, these patients were not exposed to the possible effect of more intensive support."

Van Rossem 2017

Methods	Setting: Netherlands, primary care Recruitment: by practice assistants, GPs, and practice nurses and via a leaflet displayed in the waiting room
Participants	311 participants, 52.9% female, average age: 48 ± 13.2, average cigs/day: 19 ± 8.1 Therapists: practice nurse or general practitioner
Interventions	Pharmacotherapy: 12-week course of varenicline Intervention: intensive counselling with practice nurse. 3 face-to-face plus 7 telephone sessions Control: brief advice with GP
Outcomes	Abstinence: prolonged abstinence (maximum of five cigarettes after a grace period of 9 weeks) at weeks 9 and 26, and at 12 months Validation: CO < 10 ppm
Source of Funding/CoI	Eindhoven Corporation of Primary Health Care Centres, Pfizer, and Research School CPHRI. Authors declared potential conflicts of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Allocation randomised by computer
Allocation concealment (selection bias)	Low risk	Quote: "The computer disclosed the allocation once during a phone call by a member of the research team with the assistants of the health-care centre, who then contacted the patient to schedule an appointment with the GP or PN."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated

Van Rossem 2017 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Dropout rates similar. Intervention: 18.6%, control: 25.8%

Vander Weg 2016

Methods	Setting: quitline, USA Recruitment: by mail to rural veteran daily cigarette smokers aged ≥ 18 years. Selected for motivation to quit
Participants	63 participants Therapists: doctoral-level social worker with expertise in substance abuse and a masters-level counsellor
Interventions	Pharmacotherapy: free of charge 12-week supply of pharmacotherapy mailed to the participants. Medication options included several forms of nicotine replacement therapy (patch, gum, lozenge), bupropion and varenicline. Combinatoin therapy was also available, as appropriate 1. Quitline referral 2. Tailored tobacco intervention: 6 weekly sessions over phone each lasting 20 to 30 minutes
Outcomes	7-day point prevalence abstinence at 12 weeks and 6 months after quit-date Validation: none
Source of Funding/CoI	Department of Veterans Affairs Office of Rural Health. No declarations of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated
Allocation concealment (selection bias)	Unclear risk	Insufficient details provided
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-report only and differential levels of support
Incomplete outcome data (attrition bias) All outcomes	Low risk	Tailored tobacco intervention 25.8%; quitline referral 12.5%

Vidrine 2016

Methods	Setting: USA Recruitment: from the Houston metropolitan area via local print media. Motivated to quit
Participants	412 participants, 54.9% female, average age: 48.7 ± 11.9, average cigs/day: 19.9 ± 10.1 Therapists: two master's level therapists
Interventions	Pharmacotherapy: 6 weeks of NRT patches Mindfulness-based addiction treatment (MBAT): 8 x 120-minute in-person group counselling sessions Cognitive behavioural treatment (CBT): 8 x 120-minute in-person group counselling sessions Control: 4 x 5- to 10-minute individual counselling sessions
Outcomes	Abstinence: 7-day point prevalence abstinence at 4 weeks and 6 months Validation: CO (abstinent if < 6 ppm) and salivary cotinine (abstinent if < 20 ng/mL)
Source of Funding/CoI	National Institute on Drug Abuse, Centers for Disease Control and Prevention, National Cancer Institute, National Center for Complementary and Integrative Health, and the Oklahoma Tobacco Settlement Endowment Trust. No declarations of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No detail given
Allocation concealment (selection bias)	Unclear risk	No detail given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Dropout rates similar between groups. Control: 35.9%; MBAT: 33.1%; CBT: 34.8%

Wagner 2016

Methods	Setting: USA, community-based primary health care clinic Recruitment: word of mouth and flyers
Participants	400 participants, 58.7% female, average age: 45 ± 10.5, average cigs/day: ≥ 3 Therapists: individual sessions by a nurse practitioner or a physician. Group sessions by a social worker and a nurse practitioner

Wagner 2016 (*Continued*)

Interventions	Pharmacotherapy: NRT (unclear about duration or type) Group counselling: could attend up to 12 sessions but frequency and scheduling determined by clinician according to the standard of care at the healthcare facility Individual counselling: could attend up to 12 sessions but frequency and scheduling determined by clinician according to the standard of care at the healthcare facility
Outcomes	Abstinence: planned follow-up at 1, 2, 3, 4, 5, 6, and 9 months Validation: carbon monoxide
Source of Funding/CoI	National Institute on Minority Health and Health Disparities, National Institute on Drug Abuse, and Pfizer Inc. No declarations of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method not specified
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "In addition, because of the very low follow-up rates that could be achieved with this population, in spite of intensive efforts, the data was censored at the end of the 12th week, i.e., at the end of the intervention."

Warner 2016

Methods	Setting: Mayo Clinic Hospitals, USA Recruitment: recruited from Mayo Clinic Hospitals
Participants	600 participants Sex: control: 49% female; intervention: 48% female, average age: control: 46.0 (± 14.7) ; intervention: 46.7 (± 14.9), average cigs/day: control: 14.2 (± 9.6); intervention: 14.6 (± 9.0) Therapists: study personnel
Interventions	Pharmacotherapy: NRT while hospitalised and a free 2-week supply of NRT at discharge, with instructions to purchase over-the-counter patches if desired Intervention: brief quitline facilitation session designed to overcome cognitive barriers

Warner 2016 (*Continued*)

	to quitline utilisation. Also given a written brochure and a wallet-sized 'quit-card'. If amenable, directly referred to a quitline provider (1 x 5-minute session) Control: brief advice (1 x 5-minute session)
Outcomes	Abstinence: 7-day point prevalence abstinence at 7 days, 1 month, and 6 months Validation: urine continine < 2 ng/mL
Source of Funding/CoI	ClearWay Minnesota. No declarations of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "randomized using dynamic randomization allocation based on the Mayo Clinic Study Data Management System, a proprietary web application for data entry and management."
Allocation concealment (selection bias)	Unclear risk	No detail given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar attrition rates. Intervention: 30.3%; control: 26.0%

Webb Hooper 2017

Methods	Setting: USA, university-based research clinic Recruitment: through advertisements on public transportation, community-based organisations, street outreach, and word-of-mouth. Inclusion criteria included motivation to quit
Participants	342 participants, intervention: 39% female; control: 48% female; average age: intervention: 49.48 (± 9.44); control: 49.52 (± 8.73); average cigs/day: intervention:18.20 (± 11.53); control: 17.88 (± 10.03) Therapists: doctoral and masters or bachelors level co-therapy pairs and supervision by the principal investigator or a co-investigator
Interventions	Pharmacotherapy: 8 weeks of nicotine patches, including 4 weeks at 21 mg, 2 weeks at 14 mg, and 2 weeks at 7 mg (doses adjusted for smoking history) Intervention: NRT plus culturally-specific CBT (9 x 90- to 120-minute sessions) Control: NRT plus standard CBT (9 x 90- to 120-minute sessions)

Webb Hooper 2017 (*Continued*)

Outcomes	Abstinence: 7-day point prevalence abstinence at 3 and 6 months Validation: saliva cotinine < 7 ng/mL, exhaled CO < 8 ppm
Source of Funding/CoI	National Cancer Institute of the National Institutes of Health. No declarations of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No detail given
Allocation concealment (selection bias)	Unclear risk	No detail given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar attrition rates: culturally-specific CBT: 15.5%; standard CBT: 19.5%

Wewers 2017

Methods	Setting: USA, community Recruitment: recruited from Ohio Appalachian counties. Inclusion criteria included willingness to participate in study protocol
Participants	707 participants Female: Community Health Worker Face-to-Face (CHWF2F): 65.7%; Community Health Worker Quitline (CHWQL): 69.8% Age: • CHWF2F: 18 to 24: 4.5%; 25 to 54: 62.9%; ≥ 55: 32.6% • CHWQL: 18 to 24: 5.4%; 25 to 54: 65.8%; ≥ 55: 28.8% Average cigs/day: CHWF2F: 22.3 (SD 11.7); CHWQL: 20.9 (SD 9.2) Therapists: • CHWF2F: community health worker and a registered nurse employed in the county public health department clinic • CHWQL: community health worker and quitline services provided by trained counsellors from National Jewish Health
Interventions	Pharmacotherapy: • CHWF2F: a new 21 mg nicotine patch at the start of each visit, beginning on quit-day and lasting for 8 weeks • CHWQL: up to two mailings of a 4-week supply of free 21 mg nicotine patches. To receive the second 4-week supply of free NRT, each participant was required to have completed at least two proactive counselling calls

Wewers 2017 (*Continued*)

	1. CHWF2F: 7 face-to-face 30-minute sessions with a community health worker 2. CHWQL: 1 face-to-face 30-minute session with a community health worker, followed by up to five proactive telephone counselling sessions, and unlimited reactive calls from the participant, with a quitline
Outcomes	Abstinence: prolonged abstinence at 3, 6, and 12 months, after a 2-week post-quit date grace period Validation: saliva cotinine level < 15 ng/mL, expired air CO level < 8 ppm
Source of Funding/CoI	National Institutes of Health. No declarations of interest
Notes	New for 2019 update

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No detail given
Allocation concealment (selection bias)	Unclear risk	No detail given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar attrition in study groups. CHWF2F: 14.4%; CHWQL: 14.7%

Wiggers 2006

Methods	Setting: cardiovascular outpatient department, Netherlands Recruitment: patients attending regular consultation; consenting patients referred to nurse practitioner
Participants	385 smokers (8 deaths excluded from outcomes). 37% F, av age 59, av cpd 21 Therapist: nurse practitioner
Interventions	Pharmacotherapy: NRT; patch (8 wks, dose based on smoking rate) for smokers making a quit attempt. In both groups, participants planning to quit received 8 wks nicotine patch with instruction from nurse 1. "Minimal Intervention Strategy for cardiology patients" (C-MIS). 15 to 30 mins at baseline, 1 phone call at 2 wks, additional session on request. Assessment of dependency & motivation, barriers; TQD set for motivated participants 2. Usual care without motivational counselling

Wiggers 2006 (*Continued*)

Outcomes	Abstinence at 12 m (7-day PP) Validation: Urine or saliva nicotine/cotinine/thiocyanate. Self-reported smokers also tested; validated rates included smokers with negative biochemical results, so self-reported non-smoking used in MA
Source of Funding/CoI	Netherlands Heart Foundation. Novartis Consumer Health provided nicotine patches 'for prime cost'
Notes	Participants were referred to nurse practitioner for counselling; not part of usual care. Unclear how many participants used NRT; in a subgroup who responded to a questionnaire (Wiggers Int J Behav Med 2006), 16% did not start patch therapy

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"A computerized balanced randomization programme taking prognostic factors (e.g. clinic attendance, age and gender) into account."
Allocation concealment (selection bias)	Low risk	"While patients completed their baseline questionnaire (and signed a written informed consent) nurses randomly assigned ...". Judged low risk as participant data had to be entered
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	89% intervention and 85% control followed up at 12 m. 8 deaths excluded from final denominators

Williams 2010

Methods	Setting: mental health outpatient clinics, USA Recruitment: patients with schizophrenia or schizoaffective disorder, willing to use NRT
Participants	100 smokers (> 10 cpd) using an atypical antipsychotic; 16% F, av age ~46, av cpd 23 Therapists: trained mental health clinicians provided both conditions
Interventions	Pharmacotherapy: nicotine patch (21 mg for 16 wks incl tapering) 1. Treatment of Addiction to Nicotine in Schizophrenia (TANS); 24 x 45-min individual counselling sessions over 26 wks 2. Medical Management (MM); 9 x 20-min over 26 wks

Williams 2010 (*Continued*)

Outcomes	Continuous abstinence at 12 m Validation: CO < 10 ppm
Source of Funding/CoI	National Institute on Drug Abuse. Authors also reported support from Pfizer but unclear how it related to this study; "The authors are also supported in part by grants from the National Institute of Mental Health (JMW); National Institute on Drug Abuse (to MLS); Pfizer, Inc.; and the New Jersey Department of Health and Senior Services, Office of the State Epidemiologist, through funds from New Jersey Comprehensive Tobacco Control Program (JMW, MLS)."
Notes	

Risk of bias

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

Wu 2009

Methods	Setting: research unit for Asian health, NYC, USA Recruitment: via Asian Community Health Coalition member organisations
Participants	Chinese smokers (any smoking in previous wk); 12% F, av age 44, av cpd NS, 25% smoked < 10 cpd, 49% had never attempted to quit
Interventions	Pharmacotherapy: NRT. Patch for 8 wks (could start at any time in 6 m period) 1. Culturally-tailored counselling in Chinese, 4 x 60-min & S-H 2. Health education in Chinese: 4 x 60-min, including general health, nutrition, exercise & tobacco
Outcomes	Abstinence at 6 m (PP) Validation: CO < 6 ppm

Wu 2009 (*Continued*)

Source of Funding/CoI	National Cancer Institute Community Network Program. Authors declared no conflicts of interest	
Notes	Conditions had same contact time, but control did not focus on smoking	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised, method not stated
Allocation concealment (selection bias)	Unclear risk	Details not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	10% intervention and 14% control lost to follow-up at 6 m and counted as smokers in ITT analysis

Yalcin 2014

Methods	Setting: general practice smoking cessation clinic, Turkey Recruitment: smokers motivated to quit within 6 months	
Participants	350 smokers 50% M, av age 36.22, cpd not reported Therapists: smoking cessation clinic specialists	
Interventions	Pharmacotherapy: NRT (gum or patch), bupropion, or varenicline for 3 m or as long as necessary 1. Control; 8 visits & 1 call; baseline, day 8, 20, 23, 30, 45, 60, 120, 210, ~150 mins 2. Same as control plus CBT-oriented anger management and stress control programme, 5 x 90-min sessions, in 1st month, ~730 mins total	
Outcomes	Abstinence at 180 days, continuous abstinence (from quit-day) Validation: CO $\leq$ 10 ppm	
Source of Funding/CoI	No funding. Authors declared no conflicts of interest.	
Notes	Pharmacotherapy was only used if the participant wanted to.	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Yalcin 2014 (*Continued*)

Random sequence generation (selection bias)	High risk	Alternated allocation, based on order that they were added to the participant list
Allocation concealment (selection bias)	High risk	Not specified whether this randomisation order was known to those enrolling
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically validated
Incomplete outcome data (attrition bias) All outcomes	Low risk	6.3% lost to follow-up

ACS:AmericanCancerSociety

ACT: acceptance and commitment therapy
av.: average
BCT-S: behavioural couples treatment
CBGT: cogntive behavioural group therapy
CBT: cognitive behavioural therapy
CHWF2F: community health worker face-to-face
CHWQL: community health worker quitline
cigs: cigarettes
C-MIS: "Minimal intervention strategy for cardiology patients"
CO: carbon monoxide
cpd: cigarettes per day
CQ: Committed Quitters programme
F: female
FAP: functional analytic psychotherapy
FC: face-to-face counselling
F&C:Free&Clear

HE: health education
HMO: health maintenance organisation
hr: hour
incl: included
ITT: intention-to-treat
LGBT: lesbian, gay, bisexual, transgender
M: male
m: month
MA: meta-analysis
MBAT: mindfulness-based addiction treatment
MDD: major depressive disorder
MI: motivational interviewing
mins: minutes
NCI: National Cancer Institute
NP: nurse practitioners
NRT: nicotine replacement therapy
NS: not specified
NSGT: non-specific group therapy

PI: principal investigator
PP: point prevalence abstinence
ppm: parts per million
RP: relapse prevention
SC: smoking cessation
SD: standard deviation
S-H: self help
TANS: treatment of addiction to nicotine in schizophrenia
TC: telephone counselling
TQD: target quit date
UC: usual care
VUMC: Vanderbild University Medical Center
vs: versus
wk(s): week(s)
yr: year
ZAP: Zyban advantage programme

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

Study	Reason for exclusion
Asfar 2010	Compared delivery of quitline counselling: counsellor- versus participant-initiated
Bastian 2013	Tested motivational interviewing to promote smoking cessation. Low use of NRT; only 59% of participants requested nicotine patches. Included in Lindson-Hawley 2015 Cochrane review of motivational interviewing
Batra 2010	Experimental intervention was tailored for at-risk subgroups, and included recommendation to use combination NRT. Standard treatment control recommended single type of NRT
Bock 2008	Only participants interested in quitting (17% at baseline) were offered NRT. Main intervention was motivational interviewing
Bonevski 2018	Pharmacotherapy was only offered to the participants in the intervention arm
Borland 2008	Pharmacotherapy was only offered to participants interested in quitting; 24% reported use
Brandon 2017	Only 3 months follow-up
Breland 2014	Intervention delivered by computer, no personal support.
Brown 2007	Factorial trial of bupropion/placebo and mood management CBT or standard cessation CBT. Both behavioural interventions were intensive, and experimental treatment was specifically devised for people with depression
Buchanan 2004	Only 3 months follow-up (42 participants)
Carlin-Menter 2011	Only 3 months follow-up. Compared 2 versus 4 counselling callbacks for smokers calling a quitline who received up to 6 weeks of free NRT

(*Continued*)

Chandrashekar 2015	Only 12 weeks follow-up
Chouinard 2005	Pharmacotherapy was only offered to participants interested in quitting; 24% used
Christenhusz 2007	Pharmacotherapy differed by arm: control arm advised to use pharmacotherapy but had to pay for it; intervention arm provided with bupropion free of charge
Cooney 2007	Both pharmacotherapy and behavioural components varied by trial arm
Cooper 2004	Main study results have not been published.
Costello 2011	Only 5 weeks follow-up. Compared 2 intensities of pharmacist-led behavioural support for participants using NRT
Cropsey 2017	Only 12 weeks follow-up
Cummins 2016	Control group participants may or may not have received NRT.
Dezee 2013	Only 12 weeks follow-up
Emmons 2013	Compared web-based versus print formats of smoking cessation intervention
Evins 2007	Only 12 weeks follow-up
Fang 2006	Only 3 months follow-up
Garvey 2012a	Both behavioural interventions were of similar intensity, differing only in scheduling of sessions
Hall 1996	Both behavioural interventions were of similar intensity.
Hall 2004	Factorial trial crossing extended behavioural support (CBT) with medical management only, and nortriptyline or placebo, for 1 year, as adjuncts to nicotine patch and 5 group counselling sessions. Placebo arms could have been compared, but no other trials confounded behavioural support with placebo, and the support common to all conditions was also much more intensive than in other trials
Hall 2011	Similar design to Hall 2004: factorial trial crossing extended behavioural support (CBT) with medical management only, and bupropion or placebo, as adjunct to nicotine patch and 5 group support sessions over 11 weeks. As with Hall 2004, placebo arms could have been compared, but no other trials confounded behavioural support with placebo, and the support common to all conditions was also much more intensive than in other trials
Hegaard 2003	Study population pregnant smokers, not eligible
Ingersoll 2009	Only 3 months follow-up. Test of motivational interviewing as adjunct to nicotine patch therapy for HIV+ smokers
Japuntich 2006	Intervention was access to an internet site; no person-to-person behavioural support

(*Continued*)

Joseph 2004	Intervention and control did not differ on use of pharmacotherapy or intensity of behavioural support. Test of timing in relation to alcohol dependence treatment
Joyce 2008	Test of reimbursement for pharmacotherapy and counselling
Kim 2012	Pilot study of a culturally-tailored intervention for Koreans, with only 30 participants
Kinnunen 2008	Main intervention was exercise, not eligible for this review. Recruitment to the standard care control was halted early
Klesges 2015	Compared proactive and reactive telephone counselling. Both conditions could get same intensity of counselling
Kotz 2009	Tested a specific behavioural intervention: feedback of biomedical information
Levine 2010	Behavioural interventions were matched for intensity; specifically tested a weight-related intervention
Marshall 1985	Only offer of nicotine gum
McCarthy 2016	Only 10 weeks follow-up
Moadel 2012	Only 3 months follow-up
Mochizuki 2004	Only 3 months follow-up. Small study of pharmacist advice as adjunct to NRT
NCT00781599	Only 3 months follow-up
Nilsson 1996	Only 4 months follow-up. Intervention was offer of group support and free NRT
Nollen 2007	No difference in intensity of behavioural support
Nollen 2011	Only 3 months follow-up. Study of an intervention to increase adherence to varenicline
Okuyemi 2006	All participants received same intensity of motivational interviewing, group sessions and offer of NRT. Tested different targets for motivational interviewing
Pakhale 2015	Pharmacotherapy not offered in same way to both arms
Peckham 2015	Pharmacotherapy not offered in same way to both arms
Ramon 2013	Not all participants were offered pharmacotherapy.
Reid 2007	Intervention participants did not automatically receive additional behavioural support; intervention consisted of automated telephone calls to identify participants at risk of relapse. Only this subgroup then received further counselling
Schnoll 2005	Only 3 months follow-up, behavioural interventions similar in intensity as adjuncts to nicotine patch

(*Continued*)

Severson 2015	Participants were smokeless tobacco users not smokers
Shiffman 2000	Only 12 weeks follow-up from start of treatment. Study of computer-tailored materials as adjunct to nicotine gum
Shiffman 2001	Only 12 weeks follow-up from start of treatment. Study of computer-tailored materials as adjunct to nicotine patch
Sorensen 2003	Short follow-up (preoperative period)
Strecher 2005	Only 12 weeks follow-up from start of treatment. No personal behavioural support, study of web-based tailored materials as adjunct to nicotine patch
Velicer 2006	Intervention was automated telephone counselling messages, no personal contact
Vial 2002	Compared intervention from 2 different types of pharmacist, not between different intensities of support
Ward 2001	Compared 2 group-based behavioural interventions similar in intensity as adjuncts to nicotine patch, see Stead 2017.
Wilson 1988	Use of nicotine gum was substantially different between the relevant arms of the trial, and the intervention condition was also a test of the impact of training
Wolfenden 2005	Only 3 month follow-up. Test of multifaceted intervention including offer of NRT at preoperative clinics
Yu 2006	Only 12 weeks follow-up from start of treatment
Zwar 2015	Trial of methods of delivery of care rather than of intensity of support

CBT:cognitivebehaviouraltherapy

NRT: nicotine replacement therapy

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

ACTRN12614000876695

Trial name or title	Improving radiotherapy outcomes in head and neck cancer patients: a preliminary comparison of smoking cessation intervention 'Varenicline plus support' with 'treatment as usual'
Methods	Study design: randomised controlled trial Setting: New South Wales, Australia Recruitment: potential participants identified in the month preceding the new patient clinic using treatment planning software

ACTRN12614000876695 (*Continued*)

Participants	Target: 40
Interventions	Pharmacotherapy: varenicline for 3 months course initially then an offer of an additional 3 months course depending on the successful completion of the first course 1. Treatment as usual: standard New South Wales Health Tobacco assessment and smoking cessation advice 2. Multicomponent smoking cessation programme including 10 behaviour change sessions with a psychologist
Outcomes	Abstinence at 6 months post-radiotherapy Validation: not specified
Starting date	August 2014
Contact information	Benjamin Britton, University of Newcastle
Notes	Stopped due to a higher than anticipated number of ineligible patients and time-limited funding Only the intervention group was offered varenicline.

Asfar 2018

Trial name or title	A cluster-randomised pilot trial of a tailored worksite smoking cessation intervention targeting Hispanic/Latino construction workers: intervention development and research design
Methods	Study design: cluster-randomised pilot trial Setting: South Florida, USA Recruitment: identification of potential participants through research partnership with local construction companies
Participants	Target: 126 Hispanic/Latino smokers (63 per arm)
Interventions	Pharmacotherapy: 8 weeks of free NRT (6 weeks supply provided by the study team and 2 weeks by the quitline) 1. Enhanced care: single face-to-face behavioural group counselling session delivered at the food truck + two brief follow-up counselling phone calls + usual care 2. Usual care: fax referral to the Florida quitline (quitline to provide four brief counselling sessions by phone) + informative handout about the quitline
Outcomes	Abstinence at 6 months Validation: saliva cotinine < 15 ng/mL
Starting date	April 2017
Contact information	David Lee, University of Miami
Notes	

Choi 2011

Trial name or title	Culturally-tailored smoking cessation for American Indians
Methods	Study design: RCT (cluster randomisation) Setting: American Indian and Alaskan Native smokers in 2 sites (Kansas and Oklahoma) Participants will form temporal clusters in recruiting order, and then pairs of clusters will be assigned to the groups using randomised permuted blocks based on computer-generated random numbers
Participants	58 groups totaling 448 participants
Interventions	Pharmacotherapy: choice of free pharmacotherapy, including Chantix®, Zyban®, Nicotine Replacement Therapy (NRT, patches, gum, or lozenges), or a combination of the latter 2 1. Non-native tailored intervention using American Cancer Society guide to educate about the risks of smoking + assisting with planning for cessation (included pharmacotherapy) 2. "All Nations Breath of Life" (ANBL) programme (culturally-tailored) = group support sessions, telephone motivational interviewing, culturally-tailored educational curriculum, pharmacotherapy, and participants' incentives
Outcomes	Abstinence: continuous abstinence Validation: salivary cotinine analysis for verification
Starting date	September 2010
Contact information	Won Choi, University of Kansas
Notes	Both usual care and intervention received intensive behaviour counselling; however the types of counselling were different. The study aimed to assess culturally-tailored smoking cessation interventions among American Indian populations - study completed in January 2015

Cummins 2012

Trial name or title	Nicotine patches and quitline counselling to help hospitalised smokers stay quit: study protocol for a randomised controlled trial
Methods	Setting: hospitalised patients recruited from 2 healthcare systems in San Diego county Recruitment: motivation: respiratory therapists/research recruiters at bedside; interested in quitting, selected if they were motivated
Participants	1640 participants
Interventions	Pharmacotherapy: 6 to 10 cpd = 6 weeks 14 mg + 2 weeks 7 mg; ≥ 11 cpd = 4 weeks 21 mg, 2 weeks 14 mg & 2 weeks 7 mg nicotine patches 1. Usual care - brief bedside intervention (< 10 minutes), educational materials & state quitline number provided 2. Just nicotine patches (8 weeks, step-down programme) 3. Proactive telephone counselling provided by the state quitline after discharge 4. Both patch + telephone counselling

Cummins 2012 (*Continued*)

Outcomes	Abstinence at 6 months - 30-day PP Validation: cotinine-validated smoking status
Starting date	Date of registration: February 1, 2011; date of first participant: August 3, 2011
Contact information	Shu-Hong Zhu, University of California San Diego
Notes	Analysis will use 4 vs 2

Garvey 2012b

Trial name or title	Duration of behavioural counselling treatment needed to optimise smoking abstinence
Methods	RCT
Participants	450
Interventions	Pharmacotherapy: 1. 3 months of counselling 2. 6 months of counselling 3. 12 months of counselling
Outcomes	Abstinence: 1 year Validation: not specified
Starting date	February 2008
Contact information	arthur_garvey@hms.harvard.edu
Notes	There are no study results yet.

Kim 2017

Trial name or title	A pilot study of a smoking cessation intervention for women living with HIV: study protocol
Methods	Study design: randomised controlled trial Setting: USA Recruitment: convenience sampling. To be recruited offline and online across the nation
Participants	50 women diagnosed with HIV and residing in a community
Interventions	Pharmacotherapy: eight weeks of nicotine patches Eight weekly individualised counselling sessions of 30-minute cognitive behavioural therapy via: 1. telephone video call 2. telephone voice call

Kim 2017 (*Continued*)

Outcomes	Abstinence at 6 months Validation: salivary cotinine < 10ng/mL
Starting date	Protocol published in February 2017
Contact information	Sun S Kim, University of Massachusetts Boston
Notes	

NCT00851357

Trial name or title	Telephone counselling and the distribution of nicotine patches to smokers
Methods	Study design: randomised controlled trial (factorial) Setting: University of California, California Smokers' Helpline, USA Recruitment: recruitment of eligible participants through the Helpline
Participants	4200 participants
Interventions	Pharmacotherapy: eight weeks of nicotine patch 1. Telephone counselling: pre-quit session + five proactive follow-up calls 2. Self-help materials: reading materials mailed to the participants
Outcomes	Abstinence at 6 months Validation: unspecified in the trials registry
Starting date	February 2009
Contact information	Shu-Hong Zhu, University of California
Notes	

NCT00937235

Trial name or title	Treatment of smoking among individuals with PTSD: a phase II, randomised study of varenicline and cognitive behavioural therapy
Methods	RCT
Participants	166
Interventions	Pharmacotherapy: varenicline 1 mg tablets, orally, twice daily x 12 weeks 1. Control = 5-min weekly counselling x 12 weeks, focused on medication adherence and smoking cessation 2. Control = 75 to 90-min weekly psychotherapy sessions x 12 weeks, focused on gradually confronting distressing trauma-related memories and reminders

NCT00937235 (*Continued*)

Outcomes	Abstinence: 7-day PP at 6 months
Starting date	January 2009
Contact information	Edna B Foa, University of Pennsylvania
Notes	

NCT00984724

Trial name or title	Reducing tobacco-related health disparities
Methods	Study design: randomised controlled trial Setting: not known Recruitment: not known
Participants	639 participants
Interventions	Pharmacotherapy: 300 pieces of nicotine gum issued at baseline visit 1. Standard treatment: mailed packet with standard self-help materials delivered four times + referral to quitline 2. MAPS-6 (standard treatment + six phone counselling sessions over a two-year period) 3. MAPS-12 (standard treatment + 12 phone counselling sessions over a two-year period) 4. Standard treatment + NRT 5. MAPS-6 + NRT 6. MAPS-12 + NRT
Outcomes	Abstinence at 24 months Validation: carbon monoxide < 10 ppm, saliva cotinine < 20 ng/mL
Starting date	January 2011
Contact information	Larkin Strong, M.D. Anderson Cancer Center
Notes	

NCT01063972

Trial name or title	Smoking cessation in rural hospitals
Methods	Study design: randomised controlled trial Setting: Recruitment:
Participants	606 participants (303 in each arm)

NCT01063972 (*Continued*)

Interventions	Pharmacotherapy: not specified in the trials registry 1. In-hospital smoking cessation counselling by phone + four outpatient counselling sessions by phone 2. Counselling as above but with coordination of pharmacotherapy with their insurance coverage and their health care provider
Outcomes	Abstinence at 12 months Validation: not specified in the trials registry
Starting date	March 2010
Contact information	Edward Ellerbeck, University of Kansas Medical Center
Notes	

NCT01098955

Trial name or title	Smoking cessation treatment for head & neck cancer patients: acceptance and commitment therapy
Methods	RCT
Participants	108
Interventions	Pharmacotherapy: varenicline 2 mg daily for 12 weeks 1. Acceptance and Commitment Therapy (ACT): 6 x 60-min counselling sessions delivered over a 5-week period 2. Motivational and Behavioral Counselling (MBC): 6 x 60-min counselling sessions delivered over a 5-week period
Outcomes	Abstinence: 14 and 26 weeks Validation: cotinine verification
Starting date	March 2010
Contact information	Jan Blalock M. D. Anderson Cancer Center
Notes	

NCT01162239

Trial name or title	Maintaining nonsmoking
Methods	Setting: USA
Participants	271

NCT01162239 (*Continued*)

Interventions	Pharmacotherapy: varenicline: 12 weeks, 1 mg bid 1. Participants have monthly meetings with medical staff 2. Participants receive monthly counselling with content based on a health education model 3. Participants receive monthly counselling with content based on a relapse prevention model plus access to ongoing medication treatment with varenicline 4. Participants receive monthly counselling with content based on a relapse prevention model
Outcomes	Abstinence at 12, 24, 52, 64, 104 months
Starting date	May 2010
Contact information	University of California. No PI listed
Notes	

NCT01186016

Trial name or title	Developing genetic education for smoking cessation
Methods	Study design: randomised controlled trial Setting: USA Recruitment: not given in the trials registry
Participants	103 participants
Interventions	Pharmacotherapy: 6 weeks of transdermal nicotine replacement therapy 1. Two educational sessions about genetics and smoking 2. Two educational sessions about nutrition
Outcomes	Abstinence at 6 months Validation: not given in the trials registry
Starting date	April 2012
Contact information	Julia F Houfek, University of Nebraska
Notes	

NCT01257490

Trial name or title	Integrated smoking cessation treatment for low-income community corrections
Methods	RCT
Participants	689

NCT01257490 (*Continued*)

Interventions	Pharmacotherapy: bupropion 1. Brief physician advice to quit plus bupropion 2. 4 sessions of intensive counselling plus bupropion
Outcomes	Abstinence: at 3, 6, 9, 12 months Validation: verified by expired carbon monoxide
Starting date	October 2009
Contact information	Karen L Cropsey, University of Alabama at Birmingham
Notes	

NCT01736085

Trial name or title	Providing free Nicotine patches to quitline smokers
Methods	Study design: randomised controlled trial Setting: USA Recruitment: smokers aged 18 years or older recruited from the quitline
Participants	3710 participants
Interventions	Pharmacotherapy: nicotine patches 1. self-help materials only 2. self-help materials + a voucher for 2 weeks' worth of nicotine patches 3. self-help materials + 2 weeks' worth of nicotine patches 4. up to 5 sessions of telephone counselling 5. up to 5 sessions of telephone counselling + a voucher for 2 weeks' worth of nicotine patches 6. up to 5 sessions of telephone counselling + 2 weeks' worth of nicotine patches
Outcomes	6 months prolonged abstinence Validation: none specified in the trials registry
Starting date	April 2013
Contact information	Shu-Hong Zhu, University of California
Notes	

NCT01800019

Trial name or title	The Canadian HIV Quit Smoking Trial: tackling the comorbidities of depression and cardiovascular disease in HIV+ smokers
Methods	RCT
Participants	256
Interventions	Pharmacotherapy: NRT = 7 mg to 42 mg depending on cpd; varenicline = 0.5 mg/daily for 3 days, 0.5 mg twice daily for 4 days and 1 mg twice daily for the remainder of the treatment period 1. NRT only 2. NRT + HIV-tailored smoking cessation counselling 3. Varenicline only 4. Varenicline + HIV-tailored smoking cessation counselling
Outcomes	Abstinence: 7-day PP at week 48 Validation: expired carbon monoxide levels measured using a piCO+ Smokerlyzer; CO < 10 ppm
Starting date	January 2014
Contact information	Louise Balfour, Ottawa Research Hospital
Notes	

NCT01901848

Trial name or title	CPT and smoking cessation
Methods	Study design: randomised controlled trial Setting: USA Recruitment: US veteran smokers with post-traumatic stress disorder, aged between 18 and 65 years. Selected for motivation to quit smoking
Participants	69 participants
Interventions	Pharmacotherapy: bupropion, nicotine patches and a rescue method (e.g. nicotine gum, lozenge, inhaler) 1. 12 sessions of combined cognitive processing therapy and integrated care for smoking cessation, involvement in smokefreeVET.gov's text messaging programme for smoking cessation 2. 12 sessions of integrated care for smoking cessation, involvement in smokefreeVET.gov's text messaging programme for smoking cessation
Outcomes	Abstinence at 6 months Validation: exhaled carbon monoxide < 4ppm
Starting date	December 2013
Contact information	Eric A Dedert, Durham VA Medical Center
Notes	

NCT01965405

Trial name or title	Behavioural smoking cessation for people living with HIV/AIDS
Methods	Study design: randomised controlled trial Setting: USA Recruitment: smokers with HIV or AIDS diagnosis and aged 18 years or older
Participants	400 participants
Interventions	Pharmacotherapy: a prescription for bupropion for all groups 1. Brief counselling 2. Brief counselling + brief high-magnitude prize contingency management 3. Continued counselling + monitored support to quit smoking 4. Monitored support to quit smoking + prize contingency management for abstinence 5. Pharmacotherapy only 6. Continued monitoring + low intensity prize contingency management
Outcomes	Abstinence at 6 and 12 months Validation: urinary cotinine, carbon monoxide
Starting date	August 2013
Contact information	David Ledgerwood, Wayne State University
Notes	

NCT02048917

Trial name or title	Smoking cessation strategies in community cancer programmes for lung and head and neck cancer patients
Methods	Setting: USA
Participants	180
Interventions	1. High-intensity counselling + long-acting NRT + PRN NRT 2. High-intensity counselling + bupropion + PRN NRT 3. High-intensity counselling + varenicline + PRN NRT 4. High-intensity counselling + long-acting NRT 5. High-intensity counselling + bupropion 6. High-intensity counselling + varenicline 7. Low-intensity counselling + long-acting NRT + PRN NRT 8. Low-intensity counselling + bupropion + PRN NRT 9. Low-intensity counselling + varenicline + PRN NRT 10. Low-intensity counselling + long-acting NRT 11. Low-intensity counselling + bupropion 12. Low-intensity counselling + varenicline
Outcomes	Abstinence: 7-day PP at 8 weeks Validation: CO

NCT02048917 (*Continued*)

Starting date	July 2014
Contact information	Joseph Valentino, University of Kentucky
Notes	

NCT02164383

Trial name or title	A quit smoking study using smartphones
Methods	RCT
Participants	30
Interventions	Pharmacotherapy: nicotine patch 1.Nicotine patch plus behavioural cessation counselling without access to Mobile Games 2. Nicotine patch plus behavioural cessation counselling with access to Mobile Games
Outcomes	Abstinence: change between baseline mean cigarettes smoked per day and mean cigarettes smoked per day during the first 4 weeks of the quit attempt
Starting date	October 2014
Contact information	Tanya R. Schlam, University of Wisconsin Center for Tobacco Research and Intervention
Notes	

NCT02378714

Trial name or title	Behavioural activation and varenicline for smoking cessation in depressed smokers
Methods	Study design: randomised controlled trial Setting: Chicago, USA Recruitment: smokers with major depressive disorder
Participants	576 participants
Interventions	Pharmacotherapy: varenicline or placebo for 12 weeks 1. Standard behavioural cessation treatment (45 minutes x 8 sessions) 2. Behavioural activation integrated with standard behavioural cessation treatment (45 minutes x 8 sessions)
Outcomes	Abstinence at 27 weeks Validation: expired carbon monoxide $\leq$ 8 ppm
Starting date	June 2015

NCT02378714 (*Continued*)

Contact information	Brian L Hitsman, Northwestern University
Notes	

NCT02460900

Trial name or title	Optimising smoking cessation for people with HIV/AIDS who smoke
Methods	Study design: randomised controlled trial (factorial) Setting: University of Maryland Medical Center, USA Recruitment: not specified in the trials registry
Participants	300 participants
Interventions	Pharmacotherapy: varenicline 1. Standard care: low intensity, brief counselling 2. Positively Smoke Free (details unspecified in the trials registry)
Outcomes	Abstinence at 24 weeks Validation: not specified in the trials registry
Starting date	July 2016
Contact information	Seth Himelhoch, University of Maryland
Notes	

NCT02767908

Trial name or title	Hospital to home, smoker support trial
Methods	Study design: randomised controlled trial Setting: hospital and home Recruitment: smokers leaving hospital
Participants	404 participants
Interventions	Pharmacotherapy: nicotine replacement products 1. Usual care: behavioural support before leaving hospital, referral to NHS Stop Smoking Services after discharge 2. Home visit as soon as practicable after discharge and typically within 48 hours to deliver a multicomponent intervention; tailored support package including telephone support, carbon dioxide measurements, home air quality measurements, signposting to support groups, self-help materials
Outcomes	Abstinence at 4 weeks and 12 weeks post-discharge according to the information on the trials registry Validation: exhaled carbone monoxide < 6 ppm

NCT02767908 (*Continued*)

Starting date	June 2016
Contact information	John Britton, University of Nottingham
Notes	

NCT02898597

Trial name or title	Smoking cessation intervention for women with HIV/AIDS
Methods	Study design: randomised controlled trial Setting: USA Recruitment: smokers with diagnosis of HIV infection and aged between 18 and 75 years
Participants	50 participants
Interventions	Pharmacotherapy: nicotine replacement therapy (habitrol patch) 1. cognitive behavioural therapy via video-conferencing 2. cognitive behavioural therapy via telephone
Outcomes	Abstinence at 6 months Validation: saliva cotinine
Starting date	June 2016
Contact information	Sun S Kim, University of Massachusetts
Notes	

NCT02905656

Trial name or title	Strategies to promote cessation in smokers who are not ready to quit (PACE)
Methods	Study design: randomised controlled trial Setting: USA Recruitment: smokers aged 18 years or older
Participants	828 participants
Interventions	Pharmacotherapy: nicotine gum 1. brief advice + typical smoking cessation resources 2. motivational interviewing 3. rate reduction 4. motivational interviewing + rate reduction
Outcomes	Abstinence at 12 months Validation: not specified in the trials registry

NCT02905656 (*Continued*)

Starting date	September 2016
Contact information	Robert Klesges, University of Virginia
Notes	

NCT03072511

Trial name or title	Pilot trial of a smoking cessation intervention informed by construal level theory
Methods	Study design: randomised controlled trial Setting: USA Recruitment: not specified in the trials registry
Participants	23 participants
Interventions	Pharmacotherapy: eight weeks of transdermal nicotine patch 1. Standard informational treatment: in-person session, text messaging 2. Spotlight on smoke-free living 1.5 hour intervention session combined with daily text messaging for up to 1 week pre-quit and 4 weeks post-quit
Outcomes	Abstinence at 13 weeks Validation: not specified in the trials registry
Starting date	December 2016
Contact information	Richard Yi, University of Florida
Notes	

NCT03342027

Trial name or title	Smoking cessation interventions for people living with HIV in Nairobi, Kenya
Methods	Study design: randomised controlled trial (factorial) Setting: Nairobi, Kenya Recruitment: smokers living with HIV and receiving care in a methadone maintenance programme in Nairobi, Kenya
Participants	300 participants
Interventions	Pharmacotherapy: bupropion 1. Standard care: brief advice to quit provided in a standardised format 2. Positively smoke free: eight sessions of tailored behavioural treatment for smoking cessation

NCT03342027 (*Continued*)

Outcomes	Abstinence at 36 months Validation: carbon monoxide level < 7ppm
Starting date	January 2019
Contact information	Seth Himelhoch, University of Maryland
Notes	

NCT03538938

Trial name or title	Improving quitline support study: optimising remotely delivered smoking cessation services for low-income smokers
Methods	Study design: four-factor, fully-crossed randomised controlled trial Setting: USA Recruitment: smokers aged 18 years or older selected for motivation to quit
Participants	1600 participants
Interventions	Pharmacotherapy: 2 weeks of nicotine patches and lozenges 16 conditions of four factors: phone call, SmokefreeTXT, financial incentive, nicotine replacement (patches +/- lozenges)
Outcomes	Abstinence at 6 months Validation: saliva cotinine < 4ng/mL
Starting date	July 2018
Contact information	Danielle E McCarthy, University of Wisconsin
Notes	

NCT03603496

Trial name or title	Post-discharge smoking cessation strategies: helping HAND 4
Methods	Study design: randomised controlled trial Setting: three hospitals in USA Recruitment: not specified in the trials registry
Participants	1350 participants
Interventions	Pharmacotherapy: eight weeks of nicotine replacement therapy 1. Electronic referral to State tobacco quitline 2. Personalised tobacco care management: seven proactive contacts over three months delivered by automated interactive voice response phone calls, text messaging and/or email + offer of a return call from the hospital-

NCT03603496 (*Continued*)

	based tobacco coach who offer counselling, medication advice and coordination of care with the patient's outpatient health care team
Outcomes	Abstinence at 6 months after hospital discharge Validation: not specified in the trials registry
Starting date	August 2018
Contact information	Nancy Rigotti, Massachusetts General Hospital
Notes	

Ojo-Fati 2015

Trial name or title	Integrating smoking cessation and alcohol use treatment in homeless populations
Methods	Study design: randomised controlled trial Setting: homeless shelters Recruitment: homeless smokers aged 18 years or older
Participants	645 participants
Interventions	Pharmacotherapy: 12 weeks of nicotine patch plus nicotine gum or lozenge 1. Integrated intensive smoking plus alcohol intervention using cognitive behavioural therapy 2. Intensive smoking intervention using cognitive behavioural therapy 3. Usual care: brief smoking cessation and brief alcohol counselling
Outcomes	Abstinence at 52 weeks Validation: cotinine-verified 7-day smoking abstinence
Starting date	January 2015
Contact information	Olamide Ojo-Fati, Universtiy of Minnesota
Notes	

Powers 2016

Trial name or title	Efficacy of smoking cessation therapy alone or integrated with prolonged exposure therapy for smokers with PTSD
Methods	Study design: randomised controlled trial Setting: USA Recruitment: smokers with post-traumatic stress disorder aged between 18 and 64 years selected for motivation to quit
Participants	80 participants

Powers 2016 (*Continued*)

Interventions	Pharmacotherapy: nicotine patch 1. Standard smoking cessation treatment: once-weekly 45-minute sessions of cognitive behavioural therapy over a 12-week period 2. Integrated PTSD and smoking treatment: once-weekly 90-minute sessions over a 12-week period. Incorporated standard treatment with therapy for reducing PTSD symptoms and anxiety sensitivity and enhancing tolerance for nicotine withdrawal sensations
Outcomes	Abstinence at 24 weeks Validation: saliva cotinine < 10ng/mL for stated abstinence of 2 weeks or more, carbon monoxide analysis of breath samples < 8ppm for stated abstinence of 24 hours to 2 weeks
Starting date	October 2013
Contact information	Mark B Powers, University of Texas
Notes	

Reid 2011

Trial name or title	Interactive voice response telephone technology for the treatment of smoking in patients with heart disease (IVR)
Methods	Setting: smokers recently hospitalised with CHD, Canada Health Care Recruitment: study co-ordinator recruited within 24 hours of admission
Participants	N randomised: 100 (but 99 used in calculations). Dropouts: 15 + 1 death Sex: 67.4% M, Age: 54, av cpd 16-25 Therapists: nurse specialist
Interventions	Pharmacotherapy: NRT in hospital before quit date 1. Access to NRT during hospitalisation, brief bedside counselling by nurse, self-help guide 2. Interactive Voice Response system posted questions "concerning current smoking status, confidence in staying smoke-free, use of pharmacotherapy, and self-help materials"
Outcomes	Abstinence at 12 m, 7-day PP Validation: none
Starting date	July 2006
Contact information	Robert Reid, University of Ottawa Heart Institute
Notes	

Salgado 2018

Trial name or title	Planning a change easily: a randomised controlled trial for smokers who are not ready to quit
Methods	Study design: randomised controlled trial Setting: not specified in the protocol Recruitment: smokers recruited via flyers, business cards, medical referrals, Facebook, Pandora Radio, and 'refer-a-friend' programme
Participants	840 participants
Interventions	Pharmacotherapy: 4 mg nicotine gum for rate reduction group and motivational interviewing + rate reduction group 1. Brief advice 2. Motivational interviewing 3. Rate reduction 4. Motivational interviewing + rate reduction
Outcomes	Abstinence at 12 months Validation: saliva cotinine
Starting date	Not specified in the protocol
Contact information	Francisco I Salgado Garcia, Universtiy of Tennesse
Notes	

Vander Weg 2018

Trial name or title	Community-based physical activity as adjunctive smoking cessation treatment: rationale, design, and baseline data for the Lifestyle Enhancement Program (LEAP) randomised controlled trial
Methods	Study design: randomised controlled trial Setting: community, USA Recruitment: smokers who are sedentary or minimally active during leisure time, and aged between 18 and 65 years
Participants	392 participants
Interventions	Pharmacotherapy: 6 weeks of transdermal nicotine 1. Behavioural counselling + physical activity intervention 2. Behavoural counselling + wellness intervention
Outcomes	Abstinence at 12 months Validation: expired carbon monoxide < 10ppm
Starting date	January 2003
Contact information	Kenneth D Ward, University of Memphis

Vander Weg 2018 (*Continued*)

Notes	

Vidrine 2012

Trial name or title	Enhancing cancer outreach for low-income adults with innovative smoking cessation. Project ACTION (Adult smoking Cessation Treatment through Innovative Outreach to Neighborhoods)
Methods	Cluster RCT Setting: community, USA
Participants	756
Interventions	1. Standard care: brief coach advice to quit smoking, nicotine replacement therapy (NRT), and self-help written materials 2. Enhanced care: As 1. plus a single motivational interviewing counselling session and a cell phone-delivered text/graphical messaging component 3. Intensive care: As 2. plus a series of 11 cell phone-delivered proactive counselling sessions and a cell phone-delivered text/graphical messaging component
Outcomes	Abstinence at 12 months
Starting date	June 2010
Contact information	Alex Prokhorov, University of Texas MD Anderson Cancer Center
Notes	

Webb 2018

Trial name or title	Reducing racial/ethnic tobacco cessation disparities via cognitive behavioural therapy: design of a dual-site randomised controlled trial
Methods	Study design: randomised controlled trial Setting: USA Recruitment: African American/black, Hispanic, or white non-Hispanic smokers aged 18 years or older
Participants	354 participants
Interventions	Pharmacotherapy: up to 8 weeks of transdermal nicotine patch 1. Group cognitive behavioural therapy 2. General health education
Outcomes	Abstinence at 12 months Validation: not specified in the trials registry
Starting date	August 2015

Contact information	Monica Webb Hooper, Case Western Reserve University School of Medicine
Notes	

ACT:*Acceptanceandcommitmenttherapy*
bid:*bisindie*(*twiceaday*)

CHD: cornary heart disease
cpd: cigarettes per day
CPT: cognitive processing therapy
IVR: interactive voice response
NRT: nicotine replacement therapy
PI: prinicipal investigator
PRN: pro re nata (when necessary)
PTSD: post-traumatic stress disorder

DATA AND ANALYSES

Comparison 1. Effect of increasing behavioural support. Abstinence at longest follow-up

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Subgroups by type of pharmacotherapy	65	23331	Risk Ratio (M-H, Random, 95% CI)	1.15 [1.08, 1.22]
1.1 NRT	49	16541	Risk Ratio (M-H, Random, 95% CI)	1.12 [1.04, 1.21]
1.2 Bupropion	5	2298	Risk Ratio (M-H, Random, 95% CI)	1.27 [1.10, 1.46]
1.3 Nortriptyline	2	172	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.60, 1.63]
1.4 Varenicline	2	1111	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.87, 1.27]
1.5 NRT & bupropion	3	719	Risk Ratio (M-H, Random, 95% CI)	1.24 [1.00, 1.54]
1.6 Choice of pharmacotherapy	5	2490	Risk Ratio (M-H, Random, 95% CI)	1.30 [1.00, 1.68]
2 Subgroups by contrast in number of contacts between intervention & control	63	21997	Risk Ratio (M-H, Random, 95% CI)	1.15 [1.08, 1.22]
2.1 4 to 8 or > 8 contacts versus no contact	8	4018	Risk Ratio (M-H, Random, 95% CI)	1.20 [1.02, 1.43]
2.2 More than 8 contacts versus 1 to 3 contacts	4	1063	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.70, 1.57]
2.3 4 to 8 contacts versus 1 to 3 contacts	18	9579	Risk Ratio (M-H, Random, 95% CI)	1.10 [1.01, 1.19]
2.4 More than 8 contacts versus 4 to 8 contacts	12	1737	Risk Ratio (M-H, Random, 95% CI)	1.15 [0.98, 1.33]
2.5 Intervention & control in same contact category	21	5600	Risk Ratio (M-H, Random, 95% CI)	1.32 [1.16, 1.50]
3 Subgroups by duration of contact in control condition (not prespecified)	62	21695	Risk Ratio (M-H, Random, 95% CI)	1.15 [1.08, 1.22]
3.1 No contact for control	8	4018	Risk Ratio (M-H, Random, 95% CI)	1.20 [1.02, 1.43]
3.2 'Brief intervention' for control	22	10565	Risk Ratio (M-H, Random, 95% CI)	1.09 [0.99, 1.21]
3.3 'Dose response', over 30 minutes contact for control	32	7112	Risk Ratio (M-H, Random, 95% CI)	1.19 [1.08, 1.32]
4 Subgroup by modality of intervention contact (not prespecified)	65	23331	Risk Ratio (M-H, Random, 95% CI)	1.15 [1.08, 1.22]
4.1 Intervention delivered by telephone	8	6670	Risk Ratio (M-H, Random, 95% CI)	1.25 [1.15, 1.37]
4.2 Intervention included face-to-face contact	57	16661	Risk Ratio (M-H, Random, 95% CI)	1.11 [1.03, 1.19]

Comparison 2. Effect of increasing behavioural support: Sensitivity analyses

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Sensitivity analysis including intermediate intensity conditions. Adjunct behavioural support versus pharmacotherapy alone	65	27425	Risk Ratio (M-H, Random, 95% CI)	1.13 [1.07, 1.20]
1.1 NRT	49	18666	Risk Ratio (M-H, Random, 95% CI)	1.10 [1.03, 1.19]
1.2 Bupropion	5	2298	Risk Ratio (M-H, Random, 95% CI)	1.27 [1.10, 1.46]
1.3 Nortriptyline	2	172	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.60, 1.63]
1.4 Varenicline	2	1513	Risk Ratio (M-H, Random, 95% CI)	1.06 [0.90, 1.26]
1.5 NRT & bupropion	3	719	Risk Ratio (M-H, Random, 95% CI)	1.24 [1.00, 1.54]
1.6 Choice of pharmacotherapy	5	4057	Risk Ratio (M-H, Random, 95% CI)	1.23 [1.00, 1.51]
2 By outcome definition	65	23389	Risk Ratio (M-H, Random, 95% CI)	1.15 [1.08, 1.22]
2.1 12 months validation PP outcomes only	21	6036	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.90, 1.17]
2.2 12 months validated sustained outcomes	11	3604	Risk Ratio (M-H, Random, 95% CI)	1.10 [0.93, 1.30]
2.3 < 12 months, but validated	19	5581	Risk Ratio (M-H, Random, 95% CI)	1.25 [1.12, 1.39]
2.4 No validation at all	13	7933	Risk Ratio (M-H, Random, 95% CI)	1.18 [1.08, 1.30]
2.5 > 12 months validation PP outcomes only	1	235	Risk Ratio (M-H, Random, 95% CI)	1.34 [0.59, 3.01]

Comparison 3. Studies matched for contact time. Abstinence at longest follow-up point

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Abstinence at longest follow-up	15	4138	Risk Ratio (M-H, Random, 95% CI)	1.02 [0.84, 1.25]
1.1 Family support versus usual care telephone counselling	1	471	Risk Ratio (M-H, Random, 95% CI)	1.02 [0.72, 1.45]
1.2 Face-to-face, tests attentional training v placebo training	1	119	Risk Ratio (M-H, Random, 95% CI)	1.09 [0.48, 2.50]
1.3 ACT versus CBT telephone counselling	1	121	Risk Ratio (M-H, Random, 95% CI)	1.35 [0.74, 2.46]
1.4 Positive psychotherapy versus usual care (face-to-face)	1	77	Risk Ratio (M-H, Random, 95% CI)	8.78 [0.49, 157.62]
1.5 Couples treatment versus individual treatment (face-to-face)	1	49	Risk Ratio (M-H, Random, 95% CI)	0.72 [0.37, 1.43]

1.6 Behavioural activation versus standard treatment (face-to-face)	1	68	Risk Ratio (M-H, Random, 95% CI)	4.72 [0.24, 94.85]
1.7 Culturally tailored versus standard (face-to-face)	4	929	Risk Ratio (M-H, Random, 95% CI)	1.14 [0.68, 1.92]
1.8 Exercise counselling versus health education (face-to-face)	1	30	Risk Ratio (M-H, Random, 95% CI)	0.67 [0.23, 1.89]
1.9 Adherence counselling versus standard care (telephone)	1	987	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.83, 1.15]
1.10 MIndfulness versus CBT (face-to-face)	1	309	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.48, 1.45]
1.11 Quitline facilitation session versus brief advice (telephone)	1	600	Risk Ratio (M-H, Random, 95% CI)	1.57 [0.62, 4.00]
1.12 Motivational interviewing versus health education	1	378	Risk Ratio (M-H, Random, 95% CI)	0.56 [0.33, 0.94]

Analysis 1.1. Comparison 1 Effect of increasing behavioural support. Abstinence at longest follow-up, Outcome 1 Subgroups by type of pharmacotherapy.

Review: Additional behavioural support as an adjunct to pharmacotherapy for smoking cessation

Comparison: 1 Effect of increasing behavioural support. Abstinence at longest follow-up

Outcome: 1 Subgroups by type of pharmacotherapy

Study or subgroup	More support n/N	Less support n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 NRT					
Aimer 2017	5/19	4/19		0.3 %	1.25 [0.40, 3.95]
Alterman 2001	26/80	20/80		1.3 %	1.30 [0.79, 2.13]
Aveyard 2007	30/456	36/469		1.4 %	0.86 [0.54, 1.37]
Bailey 2013	15/72	5/71		0.4 %	2.96 [1.14, 7.71]
Baker 2015	13/122	9/113		0.5 %	1.34 [0.59, 3.01]
Berndt 2014	63/155	92/218		4.4 %	0.96 [0.75, 1.23]
Bloom 2017 (1)	8/30	4/31		0.3 %	2.07 [0.69, 6.15]
Bock 2014	48/406	58/440		2.3 %	0.90 [0.63, 1.28]
Brown 2013	4/27	2/22		0.1 %	1.63 [0.33, 8.08]
Busch 2017 (2)	11/31	11/33		0.7 %	1.06 [0.54, 2.09]

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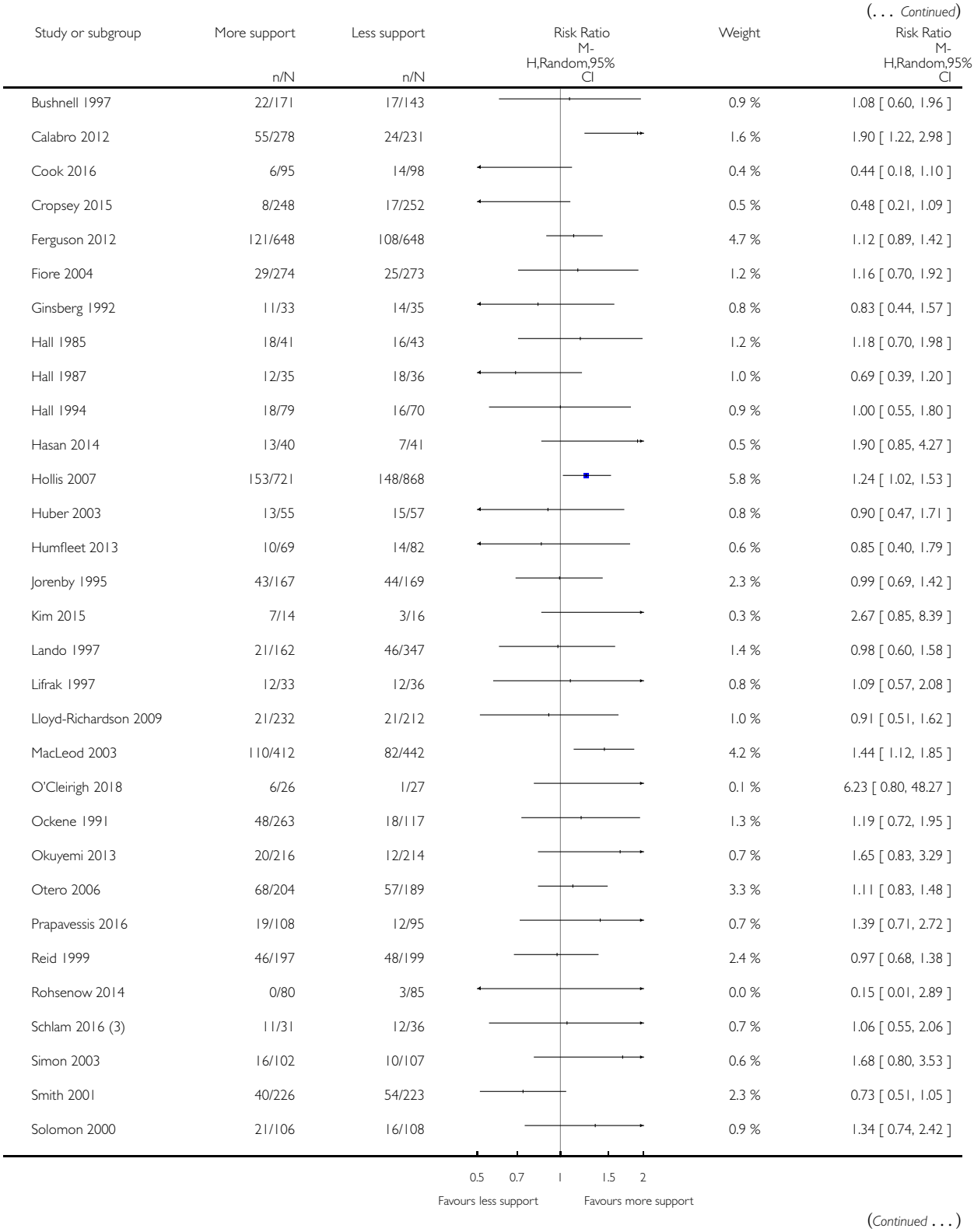

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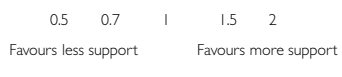
Study or subgroup	More support n/N	Less support n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Solomon 2005	49/171	31/159		2.0 %	1.47 [0.99, 2.18]
Stanton 2015	10/154	10/148		0.5 %	0.96 [0.41, 2.24]
Stein 2006	10/191	9/192		0.4 %	1.12 [0.46, 2.69]
Tonnesen 2006	13/90	13/95		0.6 %	1.06 [0.52, 2.15]
Vidrine 2016 (4)	24/155	6/51		0.5 %	1.32 [0.57, 3.04]
Vidrine 2016 (5)	20/154	6/52		0.5 %	1.13 [0.48, 2.65]
Wewers 2017	47/353	38/354		1.9 %	1.24 [0.83, 1.85]
Wiggers 2006	35/188	27/188		1.5 %	1.30 [0.82, 2.05]
Williams 2010	6/45	6/42		0.3 %	0.93 [0.33, 2.67]
Subtotal (95% CI)	**8265**	**8276**		**63.8 %**	**1.12 [1.04, 1.21]**
Total events: 1435 (More support), 1291 (Less support)					
Heterogeneity: Tau^2 = 0.01; Chi^2 = 55.03, df = 49 (P = 0.26); I^2 =11%					
Test for overall effect: Z = 2.94 (P = 0.0032)					
2 Bupropion					
Gifford 2011	18/130	14/173		0.7 %	1.71 [0.88, 3.31]
Hall 2002	9/37	9/36		0.5 %	0.97 [0.44, 2.17]
McCarthy 2008	24/113	24/116		1.3 %	1.03 [0.62, 1.70]
Rovina 2009	24/75	28/94		1.5 %	1.07 [0.68, 1.69]
Swan 2003	247/765	187/759		7.9 %	1.31 [1.12, 1.54]
Subtotal (95% CI)	**1120**	**1178**		**11.9 %**	**1.27 [1.10, 1.46]**
Total events: 322 (More support), 262 (Less support)					
Heterogeneity: Tau^2 = 0.0; Chi^2 = 2.56, df = 4 (P = 0.63); I^2 =0.0%					
Test for overall effect: Z = 3.30 (P = 0.00097)					
3 Nortriptyline					
Hall 1998	16/51	15/48		0.9 %	1.00 [0.56, 1.80]
Hall 2002	6/35	7/38		0.3 %	0.93 [0.35, 2.50]
Subtotal (95% CI)	**86**	**86**		**1.3 %**	**0.98 [0.60, 1.63]**
Total events: 22 (More support), 22 (Less support)					
Heterogeneity: Tau^2 = 0.0; Chi^2 = 0.02, df = 1 (P = 0.90); I^2 =0.0%					
Test for overall effect: Z = 0.06 (P = 0.95)					
4 Varenicline					
Swan 2010	121/399	110/401		5.3 %	1.11 [0.89, 1.37]
Van Rossem 2017	38/156	42/155		2.1 %	0.90 [0.62, 1.31]
Subtotal (95% CI)	**555**	**556**		**7.4 %**	**1.05 [0.87, 1.27]**
Total events: 159 (More support), 152 (Less support)					
Heterogeneity: Tau^2 = 0.0; Chi^2 = 0.86, df = 1 (P = 0.35); I^2 =0.0%					



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Study or subgroup	More support n/N	Less support n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Test for overall effect: Z = 0.51 (P = 0.61)					
5 NRT % bupropion					
Brody 2017	5/15	2/14		0.2 %	2.33 [0.54, 10.14]
Hall 2009	85/201	66/195		4.2 %	1.25 [0.97, 1.61]
Killen 2008	37/147	32/147		1.8 %	1.16 [0.76, 1.75]
Subtotal (95% CI)	**363**	**356**		**6.1 %**	**1.24 [1.00, 1.54]**
Total events: 127 (More support), 100 (Less support)					
Heterogeneity: Tau^2 = 0.0; Chi^2 = 0.82, df = 2 (P = 0.66); I^2 =0.0%					
Test for overall effect: Z = 1.97 (P = 0.049)					
6 Choice of pharmacotherapy					
Boyle 2007	87/663	82/666		3.5 %	1.07 [0.80, 1.41]
Ellerbeck 2009	36/244	33/244		1.6 %	1.09 [0.70, 1.69]
Gariti 2009	17/128	7/132		0.5 %	2.50 [1.07, 5.84]
Vander Weg 2016	9/31	9/32		0.5 %	1.03 [0.47, 2.25]
Yalcin 2014	77/175	48/175		3.3 %	1.60 [1.20, 2.15]
Subtotal (95% CI)	**1241**	**1249**		**9.5 %**	**1.30 [1.00, 1.68]**
Total events: 226 (More support), 179 (Less support)					
Heterogeneity: Tau^2 = 0.04; Chi^2 = 7.13, df = 4 (P = 0.13); I^2 =44%					
Test for overall effect: Z = 1.94 (P = 0.053)					
Total (95% CI)	**11630**	**11701**		**100.0 %**	**1.15 [1.08, 1.22]**
Total events: 2291 (More support), 2006 (Less support)					
Heterogeneity: Tau^2 = 0.00; Chi^2 = 71.79, df = 66 (P = 0.29); I^2 =8%					
Test for overall effect: Z = 4.70 (P < 0.00001)					
Test for subgroup differences: Chi^2 = 4.76, df = 5 (P = 0.45), I^2 =0.0%					

(1) Intervention includes additional exercise support

(2) complete case only

(3) Combined arms with different lengths of NRT provision; complete case data only

(4) CBT arm, control group split

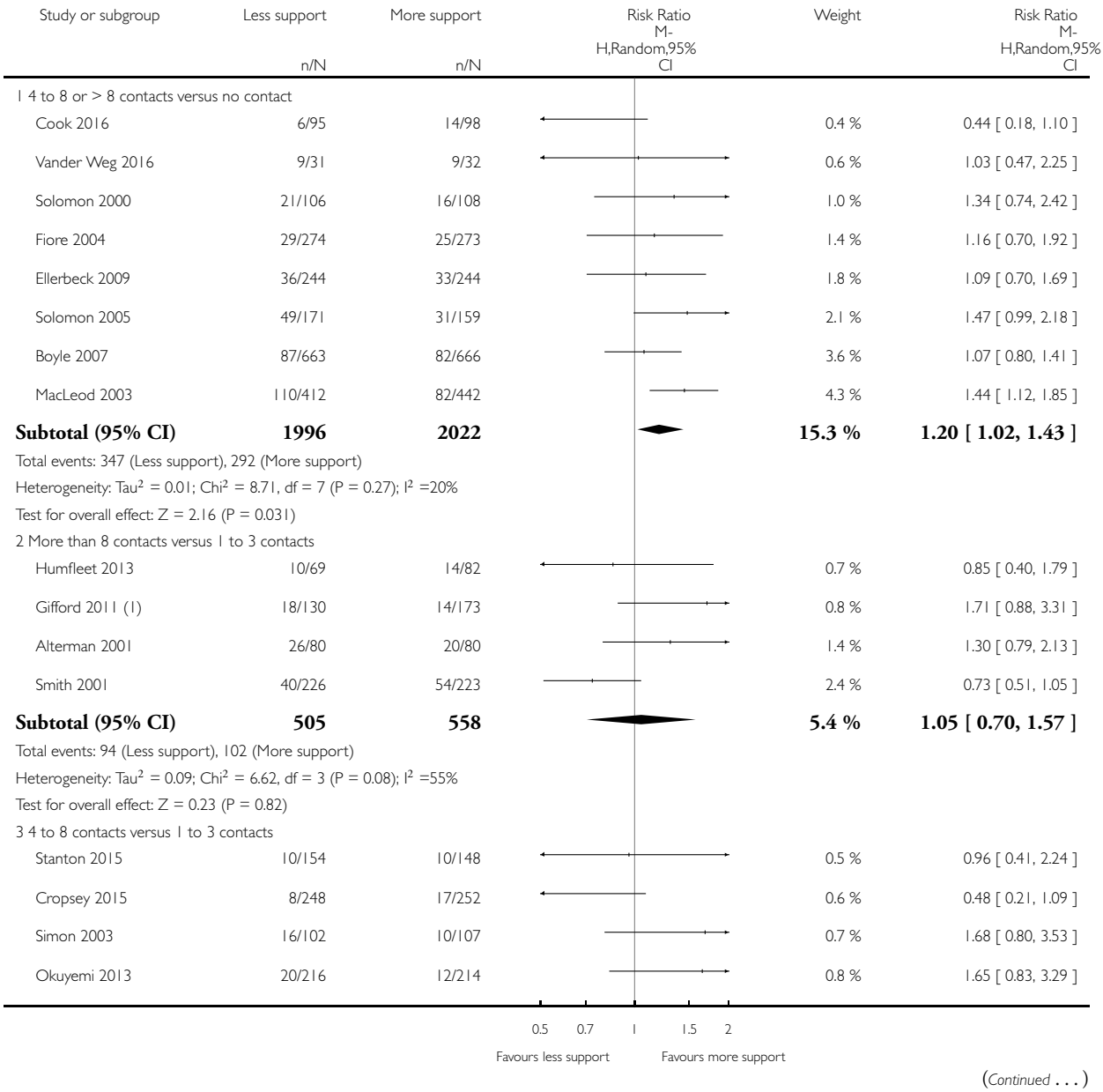
(5) Mindfulness group, control group split

Analysis 1.2. Comparison 1 Effect of increasing behavioural support. Abstinence at longest follow-up, Outcome 2 Subgroups by contrast in number of contacts between intervention & control.

Review: Additional behavioural support as an adjunct to pharmacotherapy for smoking cessation

Comparison: 1 Effect of increasing behavioural support. Abstinence at longest follow-up

Outcome: 2 Subgroups by contrast in number of contacts between intervention % control



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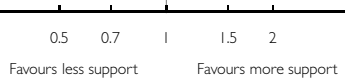
Study or subgroup	Less support n/N	More support n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Ginsberg 1992	11/33	14/35		0.9 %	0.83 [0.44, 1.57]
Lloyd-Richardson 2009	21/232	21/212		1.1 %	0.91 [0.51, 1.62]
Ockene 1991	48/263	18/117		1.4 %	1.19 [0.72, 1.95]
Lando 1997	21/162	46/347		1.5 %	0.98 [0.60, 1.58]
Rovina 2009	24/75	28/94		1.7 %	1.07 [0.68, 1.69]
Van Rossem 2017	38/156	42/155		2.3 %	0.90 [0.62, 1.31]
Jorenby 1995	43/167	44/169		2.5 %	0.99 [0.69, 1.42]
Bock 2014	48/406	58/440		2.5 %	0.90 [0.63, 1.28]
Reid 1999	46/197	48/199		2.6 %	0.97 [0.68, 1.38]
Otero 2006	68/204	57/189		3.5 %	1.11 [0.83, 1.48]
Berndt 2014	63/155	92/218		4.4 %	0.96 [0.75, 1.23]
Swan 2010	121/399	110/401		5.2 %	1.11 [0.89, 1.37]
Hollis 2007	153/721	148/868		5.7 %	1.24 [1.02, 1.53]
Swan 2003	247/765	187/759		7.3 %	1.31 [1.12, 1.54]
Subtotal (95% CI)	**4655**	**4924**		**45.0 %**	**1.10 [1.01, 1.19]**
Total events: 1006 (Less support), 962 (More support)					
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 18.30$, df = 17 (P = 0.37); $I^2 = 7\%$					
Test for overall effect: Z = 2.23 (P = 0.026)					
4 More than 8 contacts versus 4 to 8 contacts					
O'Cleirigh 2018	6/26	1/27		0.1 %	6.23 [0.80, 48.27]
Brown 2013	4/27	2/22		0.1 %	1.63 [0.33, 8.08]
Gariti 2009	17/128	7/132		0.5 %	2.50 [1.07, 5.84]
Schlam 2016 (2)	11/31	12/36		0.8 %	1.06 [0.55, 2.06]
Lifrak 1997	12/33	12/36		0.9 %	1.09 [0.57, 2.08]
Hall 2002	15/72	16/74		0.9 %	0.96 [0.52, 1.80]
Hall 1994	18/79	16/70		1.0 %	1.00 [0.55, 1.80]
Hall 1998	16/51	15/48		1.1 %	1.00 [0.56, 1.80]
Hall 1987	12/35	18/36		1.1 %	0.69 [0.39, 1.20]
Hall 1985	18/41	16/43		1.3 %	1.18 [0.70, 1.98]
Killen 2008	37/147	32/147		2.0 %	1.16 [0.76, 1.75]
Hall 2009	85/201	66/195		4.2 %	1.25 [0.97, 1.61]
Subtotal (95% CI)	**871**	**866**		**14.1 %**	**1.15 [0.98, 1.33]**
Total events: 251 (Less support), 213 (More support)					



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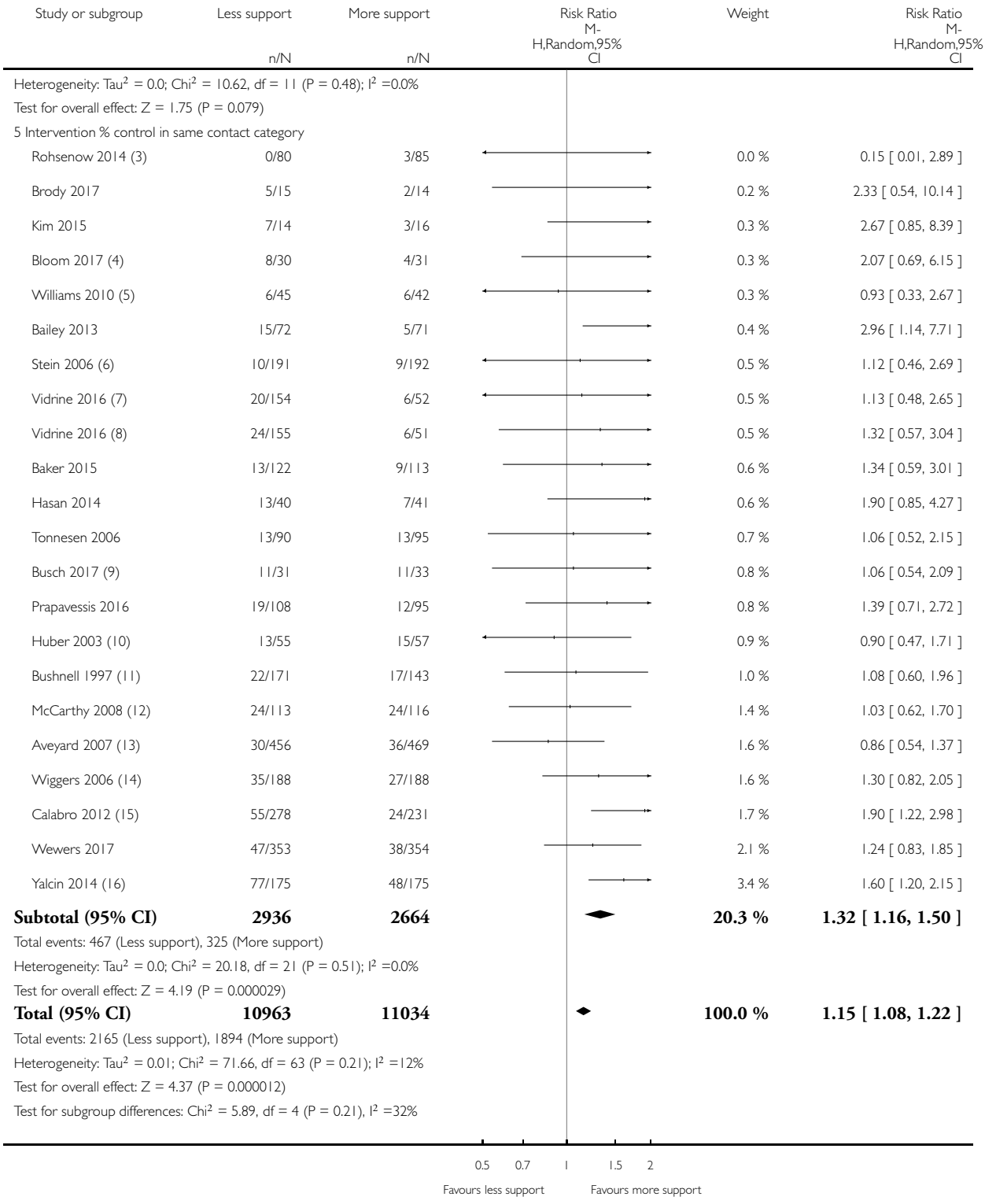


(1) counselling = 1 hour of medication instruction group presenting the rationale for bupropion

(2) Combined arms with different lengths of NRT provision; complete case data only

(3) Longer duration category for intervention group

(4) Intervention includes additional exercise support

(5) Longer sessions for intervention

(6) Longer duration category for intervention group

(7) Mindfulness group, control group split

(8) CBT arm, control group split

(9) complete case only

(10) Longer sessions for intervention

(11) 8 sessions vs 4 sessions

(12) Longer duration category for intervention group

(13) Longer duration category for intervention group

(14) Longer duration category for intervention group

(15) Longer duration category for intervention group

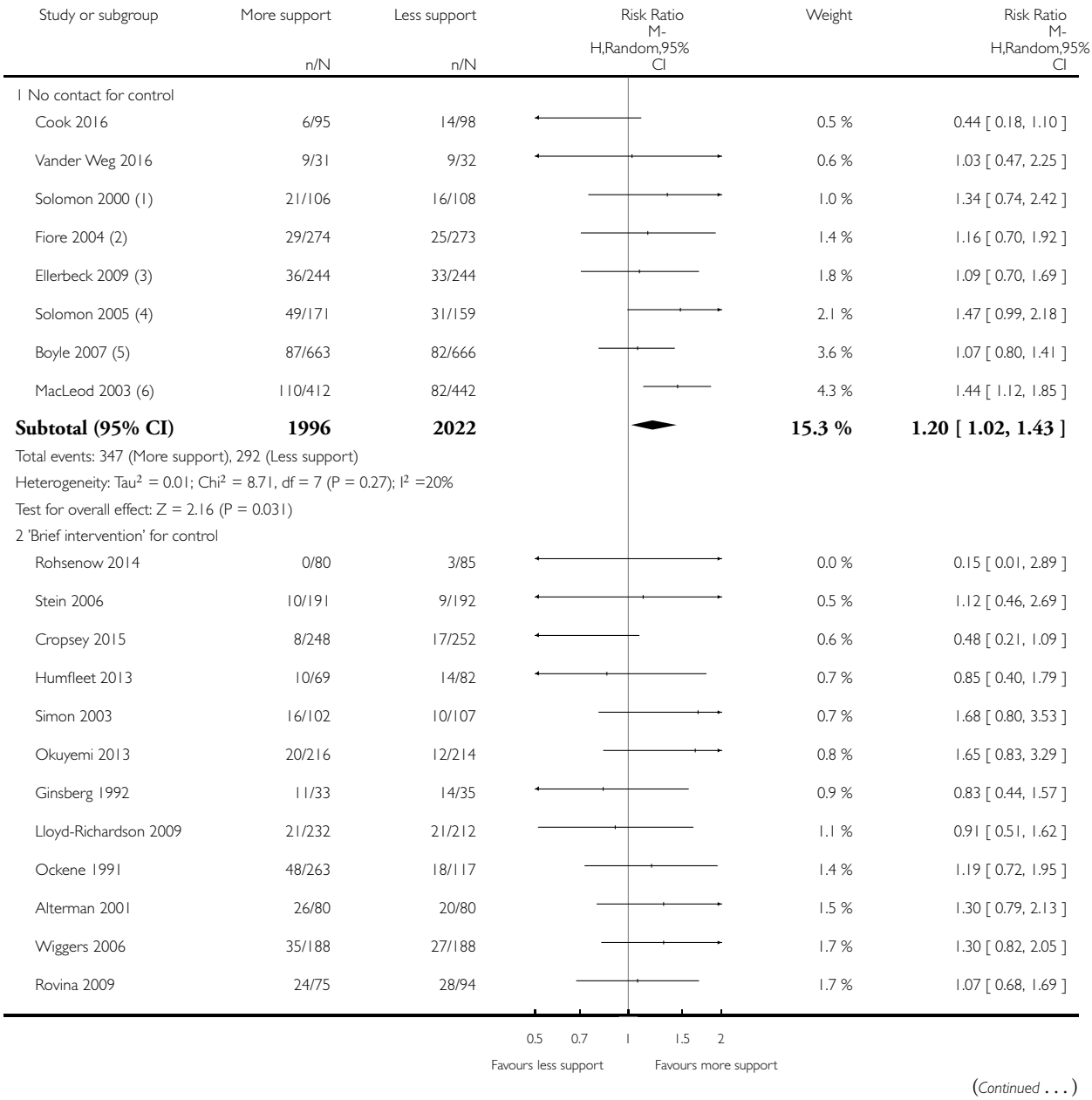
(16) 24 vs 9 sessions

Analysis 1.3. Comparison 1 Effect of increasing behavioural support. Abstinence at longest follow-up, Outcome 3 Subgroups by duration of contact in control condition (not prespecified).

Review: Additional behavioural support as an adjunct to pharmacotherapy for smoking cessation

Comparison: 1 Effect of increasing behavioural support. Abstinence at longest follow-up

Outcome: 3 Subgroups by duration of contact in control condition (not prespecified)



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Study or subgroup	More support n/N	Less support n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Calabro 2012	55/278	24/231		1.7 %	1.90 [1.22, 2.98]
Van Rossem 2017	38/156	42/155		2.3 %	0.90 [0.62, 1.31]
Smith 2001	40/226	54/223		2.4 %	0.73 [0.51, 1.05]
Jorenby 1995	43/167	44/169		2.5 %	0.99 [0.69, 1.42]
Bock 2014	48/406	58/440		2.5 %	0.90 [0.63, 1.28]
Otero 2006	68/204	57/189		3.5 %	1.11 [0.83, 1.48]
Berndt 2014	63/155	92/218		4.4 %	0.96 [0.75, 1.23]
Swan 2010	121/399	110/401		5.2 %	1.11 [0.89, 1.37]
Hollis 2007	153/721	148/868		5.6 %	1.24 [1.02, 1.53]
Swan 2003	247/765	187/759		7.1 %	1.31 [1.12, 1.54]
Subtotal (95% CI)	**5254**	**5311**		**48.8 %**	**1.09 [0.99, 1.21]**
Total events: 1105 (More support), 1009 (Less support)					
Heterogeneity: Tau^2 = 0.02; Chi^2 = 30.99, df = 21 (P = 0.07); I^2 =32%					
Test for overall effect: Z = 1.72 (P = 0.085)					
3 'Dose response', over 30 minutes contact for control					
O'Cleirigh 2018	6/26	1/27		0.1 %	6.23 [0.80, 48.27]
Brown 2013	4/27	2/22		0.2 %	1.63 [0.33, 8.08]
Brody 2017	5/15	2/14		0.2 %	2.33 [0.54, 10.14]
Kim 2015	7/14	3/16		0.3 %	2.67 [0.85, 8.39]
Bloom 2017 (7)	8/30	4/31		0.3 %	2.07 [0.69, 6.15]
Williams 2010	6/45	6/42		0.4 %	0.93 [0.33, 2.67]
Bailey 2013	15/72	5/71		0.4 %	2.96 [1.14, 7.71]
Vidrine 2016 (8)	20/154	6/52		0.5 %	1.13 [0.48, 2.65]
Gariti 2009	17/128	7/132		0.5 %	2.50 [1.07, 5.84]
Vidrine 2016 (9)	24/155	6/51		0.5 %	1.32 [0.57, 3.04]
Baker 2015	13/122	9/113		0.6 %	1.34 [0.59, 3.01]
Hasan 2014	13/40	7/41		0.6 %	1.90 [0.85, 4.27]
Tonnesen 2006	13/90	13/95		0.7 %	1.06 [0.52, 2.15]
Busch 2017 (10)	11/31	11/33		0.8 %	1.06 [0.54, 2.09]
Prapavessis 2016	19/108	12/95		0.8 %	1.39 [0.71, 2.72]
Schlam 2016 (11)	11/31	12/36		0.8 %	1.06 [0.55, 2.06]
Gifford 2011	18/130	14/173		0.9 %	1.71 [0.88, 3.31]

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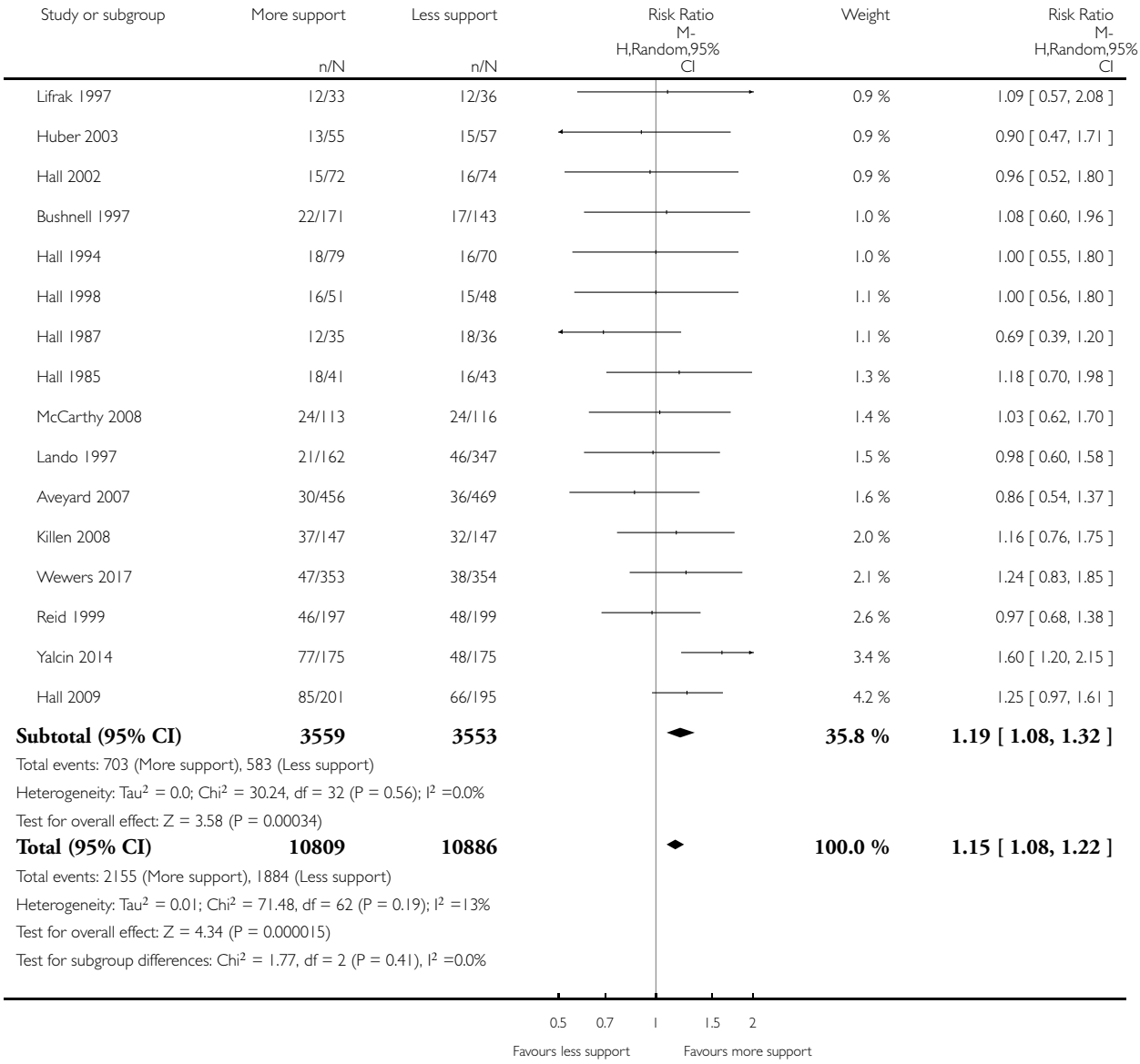


(1) No contact for control

(2) No advice or counselling for control, but contact with study staff

(3) No contact for control

(4) No contact for control

(5) No contact for control

(6) No contact for control

(7) Intervention includes additional exercise support

(8) Mindfulness group, control group split

(9) CBT arm, control group split

(10) complete case only

(11) Combined arms with different lengths of NRT provision; complete case data only

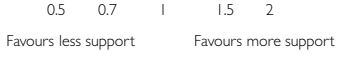
Analysis 1.4. Comparison 1 Effect of increasing behavioural support. Abstinence at longest follow-up, Outcome 4 Subgroup by modality of intervention contact (not prespecified).

Review: Additional behavioural support as an adjunct to pharmacotherapy for smoking cessation

Comparison: 1 Effect of increasing behavioural support. Abstinence at longest follow-up

Outcome: 4 Subgroup by modality of intervention contact (not prespecified)

Study or subgroup	More support n/N	Less support n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Intervention delivered by telephone					
Ferguson 2012	121/648	108/648		4.6 %	1.12 [0.89, 1.42]
Hollis 2007	153/721	148/868		5.7 %	1.24 [1.02, 1.53]
MacLeod 2003 (1)	110/412	82/442		4.2 %	1.44 [1.12, 1.85]
Solomon 2000 (2)	21/106	16/108		0.9 %	1.34 [0.74, 2.42]
Solomon 2005 (3)	49/171	31/159		2.0 %	1.47 [0.99, 2.18]
Swan 2003	247/765	187/759		7.6 %	1.31 [1.12, 1.54]
Swan 2010	121/399	110/401		5.2 %	1.11 [0.89, 1.37]
Vander Weg 2016	9/31	9/32		0.6 %	1.03 [0.47, 2.25]



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Study or subgroup	More support n/N	Less support n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Subtotal (95% CI)	**3253**	**3417**	◆	**30.7 %**	**1.25 [1.15, 1.37]**
Total events: 831 (More support), 691 (Less support)					
Heterogeneity: Tau^2 = 0.0; Chi^2 = 4.50, df = 7 (P = 0.72); I^2 =0.0%					
Test for overall effect: Z = 5.00 (P < 0.00001)					
2 Intervention included face-to-face contact					
Aimer 2017	5/19	4/19		0.3 %	1.25 [0.40, 3.95]
Alterman 2001	26/80	20/80		1.3 %	1.30 [0.79, 2.13]
Aveyard 2007	30/456	36/469		1.5 %	0.86 [0.54, 1.37]
Bailey 2013	15/72	5/71		0.4 %	2.96 [1.14, 7.71]
Baker 2015	13/122	9/113		0.5 %	1.34 [0.59, 3.01]
Berndt 2014	63/155	92/218		4.3 %	0.96 [0.75, 1.23]
Bloom 2017 (4)	8/30	4/31		0.3 %	2.07 [0.69, 6.15]
Bock 2014	48/406	58/440		2.4 %	0.90 [0.63, 1.28]
Boyle 2007 (5)	87/663	82/666		3.5 %	1.07 [0.80, 1.41]
Brody 2017	5/15	2/14		0.2 %	2.33 [0.54, 10.14]
Brown 2013	4/27	2/22		0.1 %	1.63 [0.33, 8.08]
Busch 2017 (6)	11/31	11/33		0.7 %	1.06 [0.54, 2.09]
Bushnell 1997	22/171	17/143		0.9 %	1.08 [0.60, 1.96]
Calabro 2012	55/278	24/231		1.6 %	1.90 [1.22, 2.98]
Cook 2016	6/95	14/98		0.4 %	0.44 [0.18, 1.10]
Cropsey 2015	8/248	17/252		0.5 %	0.48 [0.21, 1.09]
Ellerbeck 2009 (7)	36/244	33/244		1.6 %	1.09 [0.70, 1.69]
Fiore 2004 (8)	29/274	25/273		1.3 %	1.16 [0.70, 1.92]
Gariti 2009	17/128	7/132		0.5 %	2.50 [1.07, 5.84]
Gifford 2011	18/130	14/173		0.8 %	1.71 [0.88, 3.31]
Ginsberg 1992	11/33	14/35		0.8 %	0.83 [0.44, 1.57]
Hall 1985	18/41	16/43		1.2 %	1.18 [0.70, 1.98]
Hall 1987	12/35	18/36		1.0 %	0.69 [0.39, 1.20]
Hall 1994	18/79	16/70		0.9 %	1.00 [0.55, 1.80]
Hall 1998	16/51	15/48		1.0 %	1.00 [0.56, 1.80]
Hall 2002	15/72	16/74		0.8 %	0.96 [0.52, 1.80]
Hall 2009	85/201	66/195		4.1 %	1.25 [0.97, 1.61]

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Study or subgroup	More support n/N	Less support n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Hasan 2014	13/40	7/41		0.5 %	1.90 [0.85, 4.27]
Huber 2003	13/55	15/57		0.8 %	0.90 [0.47, 1.71]
Humfleet 2013	10/69	14/82		0.6 %	0.85 [0.40, 1.79]
Jorenby 1995	43/167	44/169		2.3 %	0.99 [0.69, 1.42]
Killen 2008	37/147	32/147		1.8 %	1.16 [0.76, 1.75]
Kim 2015	7/14	3/16		0.3 %	2.67 [0.85, 8.39]
Lando 1997	21/162	46/347		1.4 %	0.98 [0.60, 1.58]
Lifrak 1997	12/33	12/36		0.8 %	1.09 [0.57, 2.08]
Lloyd-Richardson 2009	21/232	21/212		1.0 %	0.91 [0.51, 1.62]
McCarthy 2008	24/113	24/116		1.3 %	1.03 [0.62, 1.70]
O'Cleirigh 2018	6/26	1/27		0.1 %	6.23 [0.80, 48.27]
Ockene 1991	48/263	18/117		1.3 %	1.19 [0.72, 1.95]
Okuyemi 2013	20/216	12/214		0.7 %	1.65 [0.83, 3.29]
Otero 2006	68/204	57/189		3.3 %	1.11 [0.83, 1.48]
Prapavessis 2016	19/108	12/95		0.7 %	1.39 [0.71, 2.72]
Reid 1999	46/197	48/199		2.4 %	0.97 [0.68, 1.38]
Rohsenow 2014	0/80	3/85		0.0 %	0.15 [0.01, 2.89]
Rovina 2009	24/75	28/94		1.5 %	1.07 [0.68, 1.69]
Schlam 2016 (9)	11/31	12/36		0.8 %	1.06 [0.55, 2.06]
Simon 2003	16/102	10/107		0.6 %	1.68 [0.80, 3.53]
Smith 2001	40/226	54/223		2.3 %	0.73 [0.51, 1.05]
Stanton 2015	10/154	10/148		0.5 %	0.96 [0.41, 2.24]
Stein 2006	10/191	9/192		0.4 %	1.12 [0.46, 2.69]
Tonnesen 2006	13/90	13/95		0.7 %	1.06 [0.52, 2.15]
Van Rossem 2017	38/156	42/155		2.1 %	0.90 [0.62, 1.31]
Vidrine 2016 (10)	24/155	6/51		0.5 %	1.32 [0.57, 3.04]
Vidrine 2016 (11)	20/154	6/52		0.5 %	1.13 [0.48, 2.65]
Wewers 2017	47/353	38/354		1.9 %	1.24 [0.83, 1.85]
Wiggers 2006	35/188	27/188		1.5 %	1.30 [0.82, 2.05]
Williams 2010	6/45	6/42		0.3 %	0.93 [0.33, 2.67]
Yalcin 2014	77/175	48/175		3.3 %	1.60 [1.20, 2.15]

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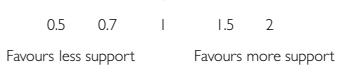
Study or subgroup	More support n/N	Less support n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Subtotal (95% CI)	**8377**	**8284**	◆	**69.3 %**	**1.11 [1.03, 1.19]**
Total events: 1460 (More support), 1315 (Less support)					
Heterogeneity: $Tau^2 = 0.01$; $Chi^2 = 62.34$, df = 57 (P = 0.29); $I^2 = 9\%$					
Test for overall effect: Z = 2.77 (P = 0.0057)					
Total (95% CI)	**11630**	**11701**	◆	**100.0 %**	**1.15 [1.08, 1.22]**
Total events: 2291 (More support), 2006 (Less support)					
Heterogeneity: $Tau^2 = 0.01$; $Chi^2 = 71.75$, df = 65 (P = 0.26); $I^2 = 9\%$					
Test for overall effect: Z = 4.62 (P < 0.00001)					
Test for subgroup differences: $Chi^2 = 4.55$, df = 1 (P = 0.03), $I^2 = 78\%$					



(1) Control group received pharmacotherapy by mail

(2) Control group received pharmacotherapy by mail

(3) Control group received pharmacotherapy by mail

(4) Intervention includes additional exercise support

(5) Control group had no face to face contact

(6) complete case only

(7) Control group had no face to face contact

(8) Control group had brief contact with study staff

(9) Combined arms with different lengths of NRT provision; complete case data only

(10) CBT arm, control group split

(11) Mindfulness group, control group split

Analysis 2.1. Comparison 2 Effect of increasing behavioural support: Sensitivity analyses, Outcome 1 Sensitivity analysis including intermediate intensity conditions. Adjunct behavioural support versus pharmacotherapy alone.

Review: Additional behavioural support as an adjunct to pharmacotherapy for smoking cessation

Comparison: 2 Effect of increasing behavioural support: Sensitivity analyses

Outcome: 1 Sensitivity analysis including intermediate intensity conditions. Adjunct behavioural support versus pharmacotherapy alone

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 NRT					
Aimer 2017	5/19	4/19		0.2 %	1.25 [0.40, 3.95]
Alterman 2001	35/160	20/80		1.2 %	0.88 [0.54, 1.41]
Aveyard 2007	30/456	36/469		1.3 %	0.86 [0.54, 1.37]
Bailey 2013	15/72	5/71		0.3 %	2.96 [1.14, 7.71]
Baker 2015	13/122	9/113		0.5 %	1.34 [0.59, 3.01]
Berndt 2014	63/155	92/218		4.0 %	0.96 [0.75, 1.23]
Bloom 2017 (1)	8/30	4/31		0.3 %	2.07 [0.69, 6.15]
Bock 2014	48/406	58/440		2.1 %	0.90 [0.63, 1.28]
Brown 2013	4/27	2/22		0.1 %	1.63 [0.33, 8.08]
Busch 2017 (2)	11/31	11/33		0.6 %	1.06 [0.54, 2.09]
Bushnell 1997	22/171	17/143		0.8 %	1.08 [0.60, 1.96]
Calabro 2012	55/278	24/231		1.4 %	1.90 [1.22, 2.98]
Cook 2016	26/298	14/98		0.8 %	0.61 [0.33, 1.12]
Cropsey 2015	8/248	17/252		0.4 %	0.48 [0.21, 1.09]
Ferguson 2012	121/648	108/648		4.3 %	1.12 [0.89, 1.42]
Fiore 2004	50/537	25/273		1.4 %	1.02 [0.64, 1.61]
Ginsberg 1992	11/33	14/35		0.7 %	0.83 [0.44, 1.57]
Hall 1985	18/41	16/43		1.1 %	1.18 [0.70, 1.98]
Hall 1987	12/35	18/36		0.9 %	0.69 [0.39, 1.20]
Hall 1994	18/79	16/70		0.8 %	1.00 [0.55, 1.80]
Hasan 2014	13/40	7/41		0.5 %	1.90 [0.85, 4.27]
Hollis 2007	297/1436	148/868		6.4 %	1.21 [1.01, 1.45]
Huber 2003	13/55	15/57		0.7 %	0.90 [0.47, 1.71]

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Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Humfleet 2013	21/127	14/82		0.8 %	0.97 [0.52, 1.79]
Jorenby 1995	96/335	44/169		2.8 %	1.10 [0.81, 1.49]
Kim 2015	7/14	3/16		0.2 %	2.67 [0.85, 8.39]
Lando 1997	21/162	46/347		1.2 %	0.98 [0.60, 1.58]
Lifrak 1997	12/33	12/36		0.7 %	1.09 [0.57, 2.08]
Lloyd-Richardson 2009	21/232	21/212		0.9 %	0.91 [0.51, 1.62]
MacLeod 2003	110/412	82/442		3.8 %	1.44 [1.12, 1.85]
O'Cleirigh 2018	6/26	1/27		0.1 %	6.23 [0.80, 48.27]
Ockene 1991	48/263	18/117		1.2 %	1.19 [0.72, 1.95]
Okuyemi 2013	20/216	12/214		0.6 %	1.65 [0.83, 3.29]
Otero 2006	136/408	57/189		3.7 %	1.11 [0.86, 1.43]
Prapavessis 2016 (3)	46/314	12/95		0.8 %	1.16 [0.64, 2.10]
Reid 1999	46/197	48/199		2.2 %	0.97 [0.68, 1.38]
Rohsenow 2014	0/80	3/85		0.0 %	0.15 [0.01, 2.89]
Schlam 2016 (4)	11/31	12/36		0.7 %	1.06 [0.55, 2.06]
Simon 2003	16/102	10/107		0.5 %	1.68 [0.80, 3.53]
Smith 2001	83/454	54/223		2.8 %	0.75 [0.56, 1.02]
Solomon 2000	21/106	16/108		0.8 %	1.34 [0.74, 2.42]
Solomon 2005	49/171	31/159		1.8 %	1.47 [0.99, 2.18]
Stanton 2015	10/154	10/148		0.4 %	0.96 [0.41, 2.24]
Stein 2006	10/191	9/192		0.4 %	1.12 [0.46, 2.69]
Tonnesen 2006	13/90	13/95		0.6 %	1.06 [0.52, 2.15]
Vidrine 2016 (5)	24/155	6/51		0.4 %	1.32 [0.57, 3.04]
Vidrine 2016 (6)	20/154	6/52		0.4 %	1.13 [0.48, 2.65]
Wewers 2017	47/353	38/354		1.7 %	1.24 [0.83, 1.85]
Wiggers 2006	35/188	27/188		1.4 %	1.30 [0.82, 2.05]
Williams 2010	6/45	6/42		0.3 %	0.93 [0.33, 2.67]
Subtotal (95% CI)	**10390**	**8276**	◆	**62.4 %**	**1.10 [1.03, 1.19]**
Total events: 1831 (Experimental), 1291 (Control)					
Heterogeneity: Tau^2 = 0.01; Chi^2 = 55.46, df = 49 (P = 0.24); I^2 =12%					
Test for overall effect: Z = 2.62 (P = 0.0087)					
2 Bupropion					

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Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Gifford 2011	18/130	14/173		0.7 %	1.71 [0.88, 3.31]
Hall 2002	9/37	9/36		0.5 %	0.97 [0.44, 2.17]
McCarthy 2008	24/113	24/116		1.1 %	1.03 [0.62, 1.70]
Rovina 2009	24/75	28/94		1.4 %	1.07 [0.68, 1.69]
Swan 2003	247/765	187/759		7.2 %	1.31 [1.12, 1.54]
Subtotal (95% CI)	**1120**	**1178**		**10.9 %**	**1.27 [1.10, 1.46]**
Total events: 322 (Experimental), 262 (Control)					
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 2.56$, df = 4 (P = 0.63); $I^2 = 0.0\%$					
Test for overall effect: Z = 3.30 (P = 0.00097)					
3 Nortriptyline					
Hall 1998	16/51	15/48		0.9 %	1.00 [0.56, 1.80]
Hall 2002	6/35	7/38		0.3 %	0.93 [0.35, 2.50]
Subtotal (95% CI)	**86**	**86**		**1.2 %**	**0.98 [0.60, 1.63]**
Total events: 22 (Experimental), 22 (Control)					
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.02$, df = 1 (P = 0.90); $I^2 = 0.0\%$					
Test for overall effect: Z = 0.06 (P = 0.95)					
4 Varenicline					
Swan 2010	244/801	110/401		5.8 %	1.11 [0.92, 1.34]
Van Rossem 2017	38/156	42/155		1.9 %	0.90 [0.62, 1.31]
Subtotal (95% CI)	**957**	**556**		**7.8 %**	**1.06 [0.90, 1.26]**
Total events: 282 (Experimental), 152 (Control)					
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.96$, df = 1 (P = 0.33); $I^2 = 0.0\%$					
Test for overall effect: Z = 0.71 (P = 0.47)					
5 NRT % bupropion					
Brody 2017	5/15	2/14		0.1 %	2.33 [0.54, 10.14]
Hall 2009	85/201	66/195		3.8 %	1.25 [0.97, 1.61]
Killen 2008	37/147	32/147		1.6 %	1.16 [0.76, 1.75]
Subtotal (95% CI)	**363**	**356**		**5.6 %**	**1.24 [1.00, 1.54]**
Total events: 127 (Experimental), 100 (Control)					
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.82$, df = 2 (P = 0.66); $I^2 = 0.0\%$					
Test for overall effect: Z = 1.97 (P = 0.049)					
6 Choice of pharmacotherapy					
Boyle 2007	87/663	82/666		3.2 %	1.07 [0.80, 1.41]
Boyle 2007	87/663	82/666		3.2 %	1.07 [0.80, 1.41]
Ellerbeck 2009	71/482	33/244		1.9 %	1.09 [0.74, 1.60]
Gariti 2009	17/128	7/132		0.4 %	2.50 [1.07, 5.84]
Vander Weg 2016	9/31	9/32		0.5 %	1.03 [0.47, 2.25]

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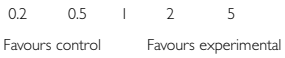
Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Yalcin 2014	77/175	48/175		3.0 %	1.60 [1.20, 2.15]
Subtotal (95% CI)	**2142**	**1915**		**12.2 %**	**1.23 [1.00, 1.51]**
Total events: 348 (Experimental), 261 (Control)					
Heterogeneity: Tau^2 = 0.02; Chi^2 = 8.42, df = 5 (P = 0.13); I^2 =41%					
Test for overall effect: Z = 1.96 (P = 0.050)					
Total (95% CI)	**15058**	**12367**		**100.0 %**	**1.13 [1.07, 1.20]**
Total events: 2932 (Experimental), 2088 (Control)					
Heterogeneity: Tau^2 = 0.00; Chi^2 = 73.31, df = 67 (P = 0.28); I^2 =9%					
Test for overall effect: Z = 4.46 (P < 0.00001)					
Test for subgroup differences: Chi^2 = 4.95, df = 5 (P = 0.42), I^2 =0.0%					



(1) Intervention includes additional exercise support

(2) complete case only

(3) Intervention combines exercise and smoking cessation conditions

(4) Combined arms with different lengths of NRT provision; complete case data only

(5) CBT arm, control group split

(6) Mindfulness group, control group split

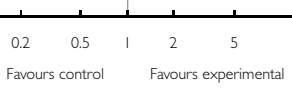
Analysis 2.2. Comparison 2 Effect of increasing behavioural support: Sensitivity analyses, Outcome 2 By outcome definition.

Review: Additional behavioural support as an adjunct to pharmacotherapy for smoking cessation

Comparison: 2 Effect of increasing behavioural support: Sensitivity analyses

Outcome: 2 By outcome definition

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 12 months validation PP outcomes only					
Alterman 2001	26/80	20/80		1.3 %	1.30 [0.79, 2.13]
Bock 2014	48/406	58/440		2.4 %	0.90 [0.63, 1.28]
Calabro 2012 (1)	55/278	24/231		1.6 %	1.90 [1.22, 2.98]
Cropsey 2015 (2)	8/248	17/252		0.5 %	0.48 [0.21, 1.09]
Gifford 2011	18/130	14/173		0.8 %	1.71 [0.88, 3.31]
Ginsberg 1992	11/33	14/35		0.8 %	0.83 [0.44, 1.57]
Hall 1985	18/41	16/43		1.2 %	1.18 [0.70, 1.98]
Hall 1987	12/35	18/36		1.0 %	0.69 [0.39, 1.20]
Hall 1998	16/51	15/48		1.0 %	1.00 [0.56, 1.80]
Hall 2002	15/72	16/74		0.9 %	0.96 [0.52, 1.80]
Huber 2003	13/55	15/57		0.8 %	0.90 [0.47, 1.71]
Humfleet 2013	21/127	16/82		1.0 %	0.85 [0.47, 1.53]
Killen 2008	37/147	32/147		1.8 %	1.16 [0.76, 1.75]
Lando 1997	21/162	46/347		1.4 %	0.98 [0.60, 1.58]
McCarthy 2008	24/113	24/116		1.3 %	1.03 [0.62, 1.70]
Reid 1999	46/197	48/199		2.4 %	0.97 [0.68, 1.38]
Rohsenow 2014	0/80	3/85		0.0 %	0.15 [0.01, 2.89]
Simon 2003	16/102	10/107		0.6 %	1.68 [0.80, 3.53]
Smith 2001	40/226	54/223		2.3 %	0.73 [0.51, 1.05]
Stanton 2015	10/154	10/148		0.5 %	0.96 [0.41, 2.24]
Wiggers 2006	35/188	27/188		1.5 %	1.30 [0.82, 2.05]
Subtotal (95% CI)	**2925**	**3111**		**25.0 %**	**1.03 [0.90, 1.17]**
Total events: 490 (Experimental), 497 (Control)					
Heterogeneity: Tau^2 = 0.02; Chi^2 = 25.80, df = 20 (P = 0.17); I^2 =22%					



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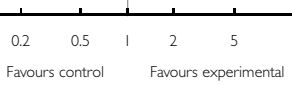
Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Test for overall effect: Z = 0.39 (P = 0.69)					
2 12 months validated sustained outcomes					
Aveyard 2007	30/456	36/469		1.5 %	0.86 [0.54, 1.37]
Bloom 2017 (3)	8/30	4/31		0.3 %	2.07 [0.69, 6.15]
Fiore 2004	29/274	25/273		1.3 %	1.16 [0.70, 1.92]
Gariti 2009	17/128	7/132		0.5 %	2.50 [1.07, 5.84]
Hall 1994	18/79	16/70		0.9 %	1.00 [0.55, 1.80]
Prapavessis 2016	19/108	12/95		0.8 %	1.39 [0.71, 2.72]
Rovina 2009	24/75	28/94		1.5 %	1.07 [0.68, 1.69]
Tonnesen 2006	13/90	13/95		0.7 %	1.06 [0.52, 2.15]
Van Rossem 2017	38/156	42/155		2.1 %	0.90 [0.62, 1.31]
Wewers 2017	47/353	38/354		1.9 %	1.24 [0.83, 1.85]
Williams 2010	6/45	6/42		0.3 %	0.93 [0.33, 2.67]
Subtotal (95% CI)	**1794**	**1810**		**11.8 %**	**1.10 [0.93, 1.30]**
Total events: 249 (Experimental), 227 (Control)					
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 8.21$, df = 10 (P = 0.61); $I^2 = 0.0\%$					
Test for overall effect: Z = 1.12 (P = 0.26)					
3 < 12 months, but validated					
Bailey 2013	15/72	5/71		0.4 %	2.96 [1.14, 7.71]
Brody 2017	5/15	2/14		0.2 %	2.33 [0.54, 10.14]
Brown 2013	4/27	2/22		0.1 %	1.63 [0.33, 8.08]
Busch 2017 (4)	11/31	11/33		0.7 %	1.06 [0.54, 2.09]
Bushnell 1997	22/171	17/143		0.9 %	1.08 [0.60, 1.96]
Ellerbeck 2009	36/244	33/244		1.6 %	1.09 [0.70, 1.69]
Ferguson 2012 (5)	121/648	108/648		4.6 %	1.12 [0.89, 1.42]
Hall 2009	85/201	66/195		4.1 %	1.25 [0.97, 1.61]
Hasan 2014	13/40	7/41		0.5 %	1.90 [0.85, 4.27]
Jorenby 1995	43/167	44/169		2.3 %	0.99 [0.69, 1.42]
Kim 2015	7/14	3/16		0.3 %	2.67 [0.85, 8.39]
Lifrak 1997	12/33	12/36		0.8 %	1.09 [0.57, 2.08]
Lloyd-Richardson 2009	21/232	21/212		1.0 %	0.91 [0.51, 1.62]
O'Cleirigh 2018	6/26	1/27		0.1 %	6.23 [0.80, 48.27]
Okuyemi 2013	20/216	12/214		0.7 %	1.65 [0.83, 3.29]



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Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Solomon 2000	21/106	16/108		0.9 %	1.34 [0.74, 2.42]
Stein 2006	10/191	9/192		0.4 %	1.12 [0.46, 2.69]
Vidrine 2016 (6)	24/155	6/51		0.5 %	1.32 [0.57, 3.04]
Vidrine 2016 (7)	20/154	6/52		0.5 %	1.13 [0.48, 2.65]
Yalcin 2014	77/175	48/175		3.3 %	1.60 [1.20, 2.15]
Subtotal (95% CI)	**2918**	**2663**		**24.0 %**	**1.25 [1.12, 1.39]**
Total events: 573 (Experimental), 429 (Control)					
Heterogeneity: Tau^2 = 0.0; Chi^2 = 17.15, df = 19 (P = 0.58); I^2 =0.0%					
Test for overall effect: Z = 3.93 (P = 0.000084)					
4 No validation at all					
Aimer 2017	5/19	4/19		0.3 %	1.25 [0.40, 3.95]
Berndt 2014	63/155	92/218		4.3 %	0.96 [0.75, 1.23]
Boyle 2007	87/663	82/666		3.5 %	1.07 [0.80, 1.41]
Cook 2016	6/95	14/98		0.4 %	0.44 [0.18, 1.10]
Hollis 2007	153/721	148/868		5.6 %	1.24 [1.02, 1.53]
MacLeod 2003	110/412	82/442		4.1 %	1.44 [1.12, 1.85]
Ockene 1991	48/263	18/117		1.3 %	1.19 [0.72, 1.95]
Otero 2006	68/204	57/189		3.3 %	1.11 [0.83, 1.48]
Schlam 2016 (8)	11/31	12/36		0.8 %	1.06 [0.55, 2.06]
Solomon 2005	49/171	31/159		2.0 %	1.47 [0.99, 2.18]
Swan 2003	247/765	187/759		7.5 %	1.31 [1.12, 1.54]
Swan 2010	121/399	110/401		5.1 %	1.11 [0.89, 1.37]
Vander Weg 2016	9/31	9/32		0.6 %	1.03 [0.47, 2.25]
Subtotal (95% CI)	**3929**	**4004**		**38.8 %**	**1.18 [1.08, 1.30]**
Total events: 977 (Experimental), 846 (Control)					
Heterogeneity: Tau^2 = 0.00; Chi^2 = 13.72, df = 12 (P = 0.32); I^2 =13%					
Test for overall effect: Z = 3.69 (P = 0.00022)					
5 > 12 months validation PP outcomes only					
Baker 2015	13/122	9/113		0.5 %	1.34 [0.59, 3.01]
Subtotal (95% CI)	**122**	**113**		**0.5 %**	**1.34 [0.59, 3.01]**
Total events: 13 (Experimental), 9 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.70 (P = 0.48)					
Total (95% CI)	**11688**	**11701**		**100.0 %**	**1.15 [1.08, 1.22]**
Total events: 2302 (Experimental), 2008 (Control)					
Heterogeneity: Tau^2 = 0.01; Chi^2 = 72.17, df = 65 (P = 0.25); I^2 =10%					

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Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Test for overall effect: Z = 4.57 (P < 0.00001)					
Test for subgroup differences: Chi^2 = 5.70, df = 4 (P = 0.22), I^2 =30%					

(1) Not all of the participants that self reported quitting could be validated due to problems with sample collection

(2) did not specify whether PP or continuous, so assuming PP for this analysis

(3) Intervention includes additional exercise support

(4) complete case only

(5) only subset of participants were validated

(6) CBT arm, control group split

(7) Mindfulness group, control group split

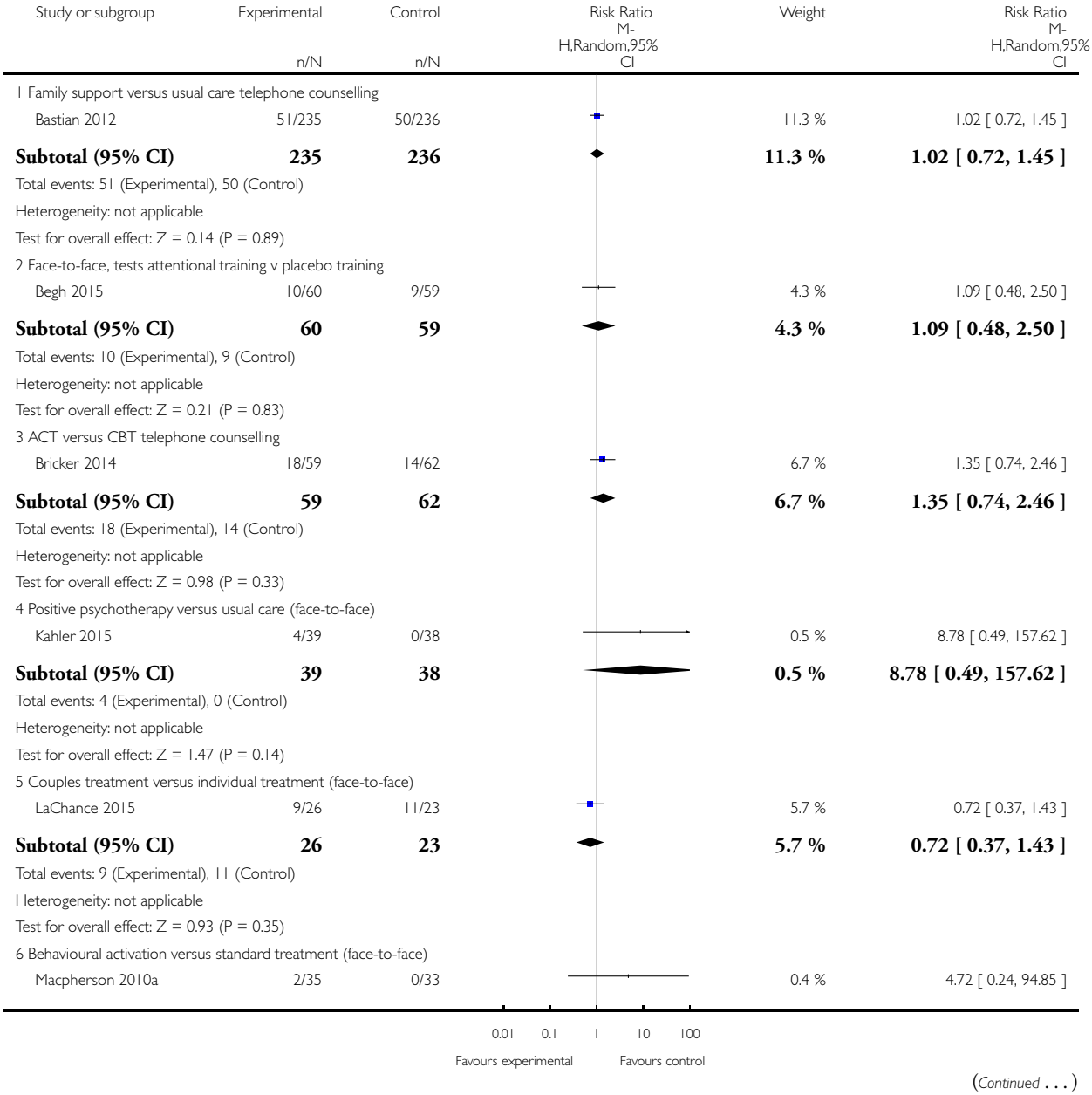
(8) Combined arms with different lengths of NRT provision; complete case data only

Analysis 3.1. Comparison 3 Studies matched for contact time. Abstinence at longest follow-up point, Outcome 1 Abstinence at longest follow-up.

Review: Additional behavioural support as an adjunct to pharmacotherapy for smoking cessation

Comparison: 3 Studies matched for contact time. Abstinence at longest follow-up point

Outcome: 1 Abstinence at longest follow-up



(*Continued . . .*)

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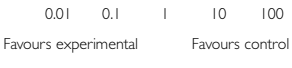
Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Subtotal (95% CI)	**35**	**33**		**0.4 %**	**4.72 [0.24, 94.85]**
Total events: 2 (Experimental), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.01 (P = 0.31)					
7 Culturally tailored versus standard (face-to-face)					
Matthews 2018	35/172	42/173		10.2 %	0.84 [0.56, 1.25]
Smith 2014	7/50	12/53		4.2 %	0.62 [0.26, 1.44]
Webb Hooper 2017	39/168	34/174		10.0 %	1.19 [0.79, 1.79]
Wu 2009	40/67	19/72		9.5 %	2.26 [1.47, 3.49]
Subtotal (95% CI)	**457**	**472**		**33.8 %**	**1.14 [0.68, 1.92]**
Total events: 121 (Experimental), 107 (Control)					
Heterogeneity: Tau² = 0.21; Chi² = 13.80, df = 3 (P = 0.003); I² =78%					
Test for overall effect: Z = 0.51 (P = 0.61)					
8 Exercise counselling versus health education (face-to-face)					
Patten 2017	4/15	6/15		3.0 %	0.67 [0.23, 1.89]
Subtotal (95% CI)	**15**	**15**		**3.0 %**	**0.67 [0.23, 1.89]**
Total events: 4 (Experimental), 6 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.76 (P = 0.45)					
9 Adherence counselling versus standard care (telephone)					
Smith 2013a	184/502	182/485		15.4 %	0.98 [0.83, 1.15]
Subtotal (95% CI)	**502**	**485**		**15.4 %**	**0.98 [0.83, 1.15]**
Total events: 184 (Experimental), 182 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.28 (P = 0.78)					
10 MIndfulness versus CBT (face-to-face)					
Vidrine 2016	20/154	24/155		7.4 %	0.84 [0.48, 1.45]
Subtotal (95% CI)	**154**	**155**		**7.4 %**	**0.84 [0.48, 1.45]**
Total events: 20 (Experimental), 24 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.63 (P = 0.53)					
11 Quitline facilitation session versus brief advice (telephone)					
Warner 2016	11/300	7/300		3.6 %	1.57 [0.62, 4.00]
Subtotal (95% CI)	**300**	**300**		**3.6 %**	**1.57 [0.62, 4.00]**
Total events: 11 (Experimental), 7 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.95 (P = 0.34)					
12 Motivational interviewing versus health education					
Ahluwalia 2006	19/189	34/189		7.8 %	0.56 [0.33, 0.94]



(*Continued* . . .)

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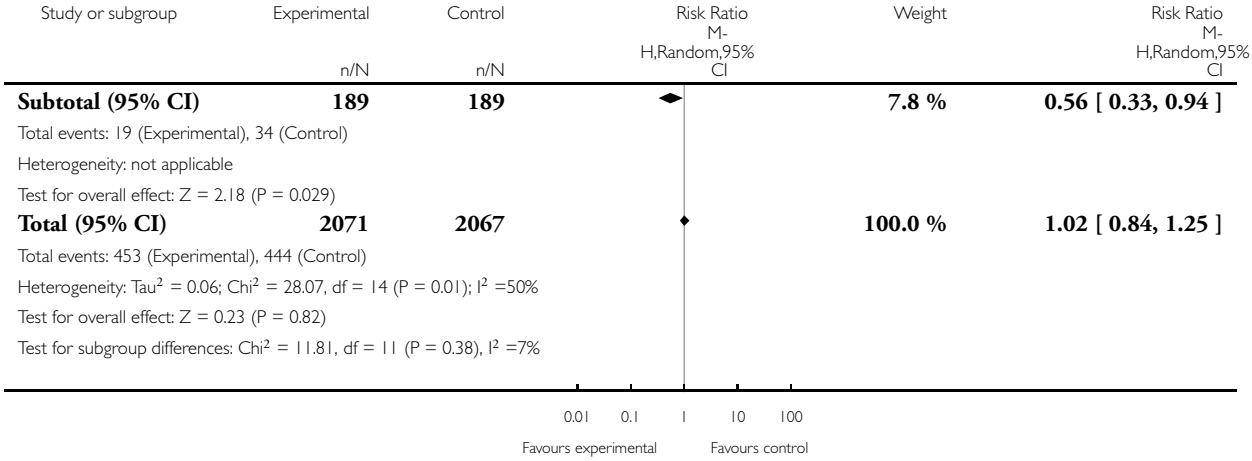

ADDITIONAL TABLES

Table 1. Summary of control and intervention characteristics

			Intervention		Control		
Study ID	**Pharmacotherapy**	**Modality (included face-to-face/ telephone only)**	**Number of contacts**	**Total duration (minutes)**	**Number of contacts**	**Total duration (minutes)**	**Comments**
Ahluwalia 2006	NRT	Face-to-face	6	120	6	120	
Aimer 2017	NRT	Face-to-face	4	Unclear	Unclear	Unclear	
Alterman 2001	NRT	Face-to-face	16	4290	1	30	Multiple arms - highest vs lowest intensity
Aveyard 2007	NRT	Face-to-face	7	140	4	80	
Bailey 2013	NRT	Face-to-face	19	950	10	500	
Baker 2015	NRT	Face-to-face	17	1050	17	290	
Bastian 2012	NRT	Telephone	5	100	5	100	

Table 1. Summary of control and intervention characteristics (*Continued*)

Begh 2015	NRT	Face-to-face	7	112	7	112	
Berndt 2014	NRT	Face-to-face	7	285	7	105	
Bloom 2017	NRT	Face-to-face	20	400	20	880	Exercise sessions/ time excluded
Bock 2014	NRT	Face-to-face	3	Unclear	1	Unclear	
Boyle 2007	Choice	Face-to-face	9	Unclear	0	0	
Bricker 2014	NRT	Telephone	5	90	5	90	
Brody 2017	NRT & Bupropion	Face-to-face	22	970	12	720	
Brown 2013	NRT	Face-to-face	Unclear	Unclear	Unclear	Unclear	
Busch 2017	NRT	Face-to-face	6	220	6	87.5	
Bushnell 1997	NRT	Face-to-face	8	480	4	240	
Calabro 2012	NRT	Face-to-face	2	120	1	5	Intervention also had "access to 5 web-based booster sessions"
Cook 2016	NRT	Face-to-face	11	130	0	0	Multifactorial - highest vs lowest intensity
Cropsey 2015	NRT	Face-to-face	4	100	1	Unclear	
Ellerbeck 2009	Choice	Face-to-face	6	Unclear	0	0	Multiple arms - highest vs lowest intensity
Ferguson 2012	NRT	Telephone	6	Unclear	Unclear	Unclear	
Fiore 2004	NRT	Face-to-face	5	Unclear	0	0	Multiple arms - highest vs lowest intensity

Table 1. Summary of control and intervention characteristics (*Continued*)

Gariti 2009	Choice	Face-to-face	10	125	4	30	
Gifford 2011	Bupropion	Face-to-face	20	Unclear	1	60	
Ginsberg 1992	NRT	Face-to-face	5	Unclear	2	Unclear	
Hall 1985	NRT	Face-to-face	14	1050	4	Unclear	
Hall 1987	NRT	Face-to-face	14	1050	5	300	
Hall 1994	NRT	Face-to-face	10	1200	5	450	
Hall 1998	Nortriptyline	Face-to-face	10	1200	5	450	
Hall 2002	Bupropion/ Nortriptyline	Face-to-face	5	450	4	30	
Hall 2009	NRT & Bupropion	Face-to-face	11	330	5	Unclear	Multifactorial study design
Hasan 2014	NRT	Face-to-face	7	195	6	105	
Hollis 2007	NRT	Telephone	4	100	1	15	Multiple arms - highest vs lowest intensity
Huber 2003	NRT	Face-to-face	5	450	5	225	
Humfleet 2013	NRT	Face-to-face	6	300	1	'Brief'	Multiple arms - highest vs lowest intensity
Jorenby 1995	NRT	Face-to-face	8	480	0	0	Multiple arms - highest vs lowest intensity
Kahler 2015	NRT	Face-to-face	6	210	6	210	
Killen 2008	NRT & Bupropion	Face-to-face	10	300	10	200	
Kim 2015	NRT	Face-to-face	8	320	8	80	
LaChance 2015	NRT	Face-to-face	7	420	7	420	

Table 1. Summary of control and intervention characteristics (*Continued*)

Lando 1997	NRT	Face-to-face	4	48	0	0	Multiple arms - highest vs lowest intensity
Lifrak 1997	NRT	Face-to-face	20	736.5	4	82.5	
Lloyd-Richardson 2009	NRT	Face-to-face	5	Unclear	2	Unclear	
MacLeod 2003	NRT	Telephone	5	60	0	0	
Macpherson 2010a	NRT	Face-to-face	8	480	8	480	
Matthews 2018	NRT	Face-to-face	6	540	6	540	
McCarthy 2008	Bupropion	Face-to-face	13	Unclear	13	Unclear	Control received 80 minutes less contact than intervention
NCT00879177	NRT & Varenicline	Face-to-face	9	Unclear	5	Unclear	
Ockene 1991	NRT	Face-to-face	5	45	2	15	
O'Cleirigh 2018	NRT	Face-to-face	10	600	5	100	
Okuyemi 2013	NRT	Face-to-face	6	105	1	12.5	
Otero 2006	NRT	Face-to-face	4	240	1	20	Multiple arms - highest vs lowest intensity
Patten 2017	NRT	Face-to-face	36	1080	36	1080	Intervention group: "exercise counselling delivered while the participant was en-

Table 1. Summary of control and intervention characteristics (*Continued*)

							gaged in exercise" - have left this time in as also counselling
Prapavessis 2016	NRT	Face-to-face	64	1985	59	1860	Multiple arms - highest vs lowest intensity
Reid 1999	NRT	Face-to-face	6	Unclear	3	45	
Rohsenow 2014	NRT	Face-to-face	3	65	3	35	
Rovina 2009	Bupropion	Face-to-face	9	540	1	15	Multiple arms - highest vs lowest intensity
Schlam 2016	NRT	Face-to-face	12	320	4	200	Multifactorial study design
Schmitz 2007a	Bupropion	Face-to-face	7	420	7	420	
Simon 2003	NRT	Face-to-face	6	195	1	10	
Smith 2001	NRT	Face-to-face	6	90	0	0	Multiple arms - highest vs lowest intensity
Smith 2013a	NRT	Telephone	4	67	4	60	Exact duration of contact not recorded, but averages given, intervention: 67.0 (± 25.8) , control: 60.1 (± 23.9)
Smith 2014	Varenicline	Face-to-face	5	Unclear	5	Unclear	Comparing culturally-tailored with standard counselling -

Table 1. Summary of control and intervention characteristics (*Continued*)

							duration of sessions not stated
Solomon 2000	NRT	Telephone	See note	See note	0	0	Control = "access to quitline"; intervention = "up to 12 calls" - averaged 7 calls at 9 minutes each
Solomon 2005	NRT	Telephone	8.2	80	0	0	Intervention numbers based on average number/duration of calls
Stanton 2015	NRT	Face-to-face	7	Unclear	3	Unclear	
Stein 2006	NRT	Face-to-face	3	65	2	5	Control offered "up to 2 visits", intervention only offered 3rd visit if ready to quit
Strong 2009	Bupropion	Face-to-face	12	1440	12	1440	
Swan 2003	Bupropion	Telephone	4	Unclear	1	7.5	Multiple arms - highest vs lowest intensity
Swan 2010	Varenicline	Telephone	5	67	0	0	
Tonnesen 2006	NRT	Face-to-face	12	270	10	150	
Van Rossem 2017	Varenicline	Face-to-face	10	120	1	20	Duration of sessions not stipulated, but maximum amounts recorded in paper. Inter-

Table 1. Summary of control and intervention characteristics (*Continued*)

							vention: 120, control: 20
Vander Weg 2016	Choice	Telephone	6	150	0	0	Intervention sessions listed as 20 to 30 minutes - control was referral to a quitline, but there were no mandated sessions, so contact listed as 0
Vidrine 2016 (CBT)	NRT	Face-to-face	8	960	4	40	Vidrine study intervention 2 (control split)
Vidrine 2016 (MBAT)	NRT	Face-to-face	8	960	4	40	Vidrine study intervention 1 (control split)
Wagner 2016	NRT	Face-to-face	12	Unclear	12	Unclear	Sessions' duration not reported
Warner 2016	NRT	Face-to-face	1	5	1	5	
Webb Hooper 2017	NRT	Face-to-face	9	945	9	945	Exact duration not listed, but approximate range given
Wewers 2017	NRT	Face-to-face	7	210	6	180	Compared 2 interventions, less intensive counted as control
Wiggers 2006	NRT	Face-to-face	3	Unclear	1	Unclear	
Williams 2010	NRT	Face-to-face	24	1080	9	180	
Wu 2009	NRT	Face-to-face	4	240	4	240	

Table 1. Summary of control and intervention characteristics (*Continued*)

Yalcin 2014	Choice	Face-to-face	14	730	9	150	

APPENDICES

Appendix 1. Register Search

Search used in the Cochrane Register of Studies.

1. NRT:TI,AB,KW
2. (nicotine NEAR (replacement OR patch* OR transdermal OR gum OR lozenge* OR sublingual OR inhaler* OR inhalator* OR oral OR nasal OR spray)):TI,AB,KW
3. (bupropion OR zyban OR wellbutrin):TI,AB,KW,MH,EMT
4. (varenicline OR champix OR chantix):TI,AB,KW,MH,EMT
5. combined modality therapy:MH,KW
6. ((behavio?r therapy) AND (drug therapy)):KW,MH,EMT,TI,AB
7. ((counsel*) AND (*drug therapy)):KW,MH,EMT,TI,AB
8. #1 OR #2 OR #3 OR #4 OR #5
9. #6 OR #7 OR #8
10. #9 AND INREGISTER

WHAT'S NEW

Date	Event	Description
13 March 2019	New search has been performed	Updated with 36 new included studies. Searches run June 2018
13 March 2019	New citation required but conclusions have not changed	New studies and analyses added; now includes contact-matched studies and meta-regression. Conclusions not changed

HISTORY

Protocol first published: Issue 2, 2012

Review first published: Issue 12, 2012

Date	Event	Description
10 August 2015	New citation required but conclusions have not changed	New author PK added for update
10 August 2015	New search has been performed	Searches updated, 9 new included studies
21 February 2013	Amended	Correction to 2 forest plot labels

CONTRIBUTIONS OF AUTHORS

For this version of the review: JLB ran the searches; BH, HW and JHB screened search results; BH, HW, JHB, CM and JLB extracted data; JLB, JHB and TF conducted analyses; BH, TF, JLB and JHB updated the text; and all authors reviewed and commented on the text.

For the original and second version of the review, LS developed the search strategy, screened search results and extracted data. For the original review TL agreed inclusion or exclusion of potentially relevant studies and checked data extraction. For the second version of the review, PK agreed inclusion or exclusion of potentially relevant studies and extracted data. All authors contributed to the text.

DECLARATIONS OF INTEREST

JHB: none known

BH: none known

JLB: none known

HW: none known

TRF: none known

SOURCES OF SUPPORT

Internal sources

- Nuffield Department of Primary Care Health Sciences, Oxford University, UK.

External sources

- NHS National Institute for Health Research, UK.
- Faculty of Medicine Marvin Burke Summer Studentship, Dalhousie University, Canada.

Funding for travel and accommodation

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We added two additional subgroup analyses. We had initially planned to assess risk of bias based on blinding of participants and personnel, but given the nature of the studies, we provided a narrative discussion of this instead.

In this version of the review, we switched from fixed-effect to random-effects meta-analyses in accordance with revised guidance from the Cochrane Tobacco Addiction Group. We also introduced a new, exploratory meta-regression based on the number of contacts. In addition, we included eligible studies where contact was matched between arms (previously excluded). We expanded our inclusion criteria to include studies in adolescents.

INDEX TERMS

Medical Subject Headings (MeSH)

*Tobacco Use Cessation Devices; Antidepressive Agents [therapeutic use]; Behavior Therapy [*methods]; Benzazepines [therapeutic use]; Bupropion [therapeutic use]; Combined Modality Therapy [methods]; Counseling [methods]; Nicotinic Agonists [therapeutic use]; Nortriptyline [therapeutic use]; Quinoxalines [therapeutic use]; Randomized Controlled Trials as Topic; Smoking [*therapy]; Smoking Cessation [*methods]; Varenicline [therapeutic use]

MeSH check words

Humans