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## Strategies to improve smoking cessation rates in primary care (Review)

Lindson N, Pritchard G, Hong B, Fanshawe TR, Pipe A, Papadakis S

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## [Intervention Review]

# Strategies to improve smoking cessation rates in primary care

Nicola Lindson<sup>1</sup>, Gillian Pritchard<sup>2,3</sup>, Bosun Hong<sup>4</sup>, Thomas R Fanshawe<sup>1</sup>, Andrew Pipe<sup>2</sup>, Sophia Papadakis<sup>2</sup>

<sup>1</sup>Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, UK. <sup>2</sup>Division of Prevention and Rehabilitation, University of Ottawa Heart Institute, Ottawa, Canada. <sup>3</sup>Canadian Public Health Association, Ottawa, Canada. <sup>4</sup>Oral Surgery Department, Birmingham Dental Hospital, Birmingham, UK

**Contact address:** Sophia Papadakis, [SPapadakis@ottawaheart.ca](mailto:SPapadakis@ottawaheart.ca).

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## ABSTRACT

### Background

Primary care is an important setting in which to treat tobacco addiction. However, the rates at which providers address smoking cessation and the success of that support vary. Strategies can be implemented to improve and increase the delivery of smoking cessation support (e.g. through provider training), and to increase the amount and breadth of support given to people who smoke (e.g. through additional counseling or tailored printed materials).

### Objectives

To assess the effectiveness of strategies intended to increase the success of smoking cessation interventions in primary care settings.

To assess whether any effect that these interventions have on smoking cessation may be due to increased implementation by healthcare providers.

### Search methods

We searched the Cochrane Tobacco Addiction Group's Specialized Register, the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, Embase, and trial registries to 10 September 2020.

### Selection criteria

We included randomized controlled trials (RCTs) and cluster-RCTs (cRCTs) carried out in primary care, including non-pregnant adults. Studies investigated a strategy or strategies to improve the implementation or success of smoking cessation treatment in primary care. These strategies could include interventions designed to increase or enhance the quality of existing support, or smoking cessation interventions offered in addition to standard care (adjunctive interventions). Intervention strategies had to be tested in addition to and in comparison with standard care, or in addition to other active intervention strategies if the effect of an individual strategy could be isolated. Standard care typically incorporates physician-delivered brief behavioral support, and an offer of smoking cessation medication, but differs across studies. Studies had to measure smoking abstinence at six months' follow-up or longer.

### Data collection and analysis

We followed standard Cochrane methods. Our primary outcome - smoking abstinence - was measured using the most rigorous intention-to-treat definition available. We also extracted outcome data for quit attempts, and the following markers of healthcare provider performance: asking about smoking status; advising on cessation; assessment of participant readiness to quit; assisting with cessation; arranging follow-up for smoking participants. Where more than one study investigated the same strategy or set of strategies, and measured the same outcome, we conducted meta-analyses using Mantel-Haenszel random-effects methods to generate pooled risk ratios (RRs) and 95% confidence intervals (CIs).

## Main results

We included 81 RCTs and cRCTs, involving 112,159 participants. Fourteen were rated at low risk of bias, 44 at high risk, and the remainder at unclear risk.

We identified moderate-certainty evidence, limited by inconsistency, that the provision of adjunctive counseling by a health professional other than the physician (RR 1.31, 95% CI 1.10 to 1.55;  $I^2 = 44\%$ ; 22 studies, 18,150 participants), and provision of cost-free medications (RR 1.36, 95% CI 1.05 to 1.76;  $I^2 = 63\%$ ; 10 studies, 7560 participants) increased smoking quit rates in primary care. There was also moderate-certainty evidence, limited by risk of bias, that the addition of tailored print materials to standard smoking cessation treatment increased the number of people who had successfully stopped smoking at six months' follow-up or more (RR 1.29, 95% CI 1.04 to 1.59;  $I^2 = 37\%$ ; 6 studies, 15,978 participants).

There was no clear evidence that providing participants who smoked with biomedical risk feedback increased their likelihood of quitting (RR 1.07, 95% CI 0.81 to 1.41;  $I^2 = 40\%$ ; 7 studies, 3491 participants), or that provider smoking cessation training (RR 1.10, 95% CI 0.85 to 1.41;  $I^2 = 66\%$ ; 7 studies, 13,685 participants) or provider incentives (RR 1.14, 95% CI 0.97 to 1.34;  $I^2 = 0\%$ ; 2 studies, 2454 participants) increased smoking abstinence rates. However, in assessing the former two strategies we judged the evidence to be of low certainty and in assessing the latter strategies it was of very low certainty. We downgraded the evidence due to imprecision, inconsistency and risk of bias across these comparisons. There was some indication that provider training increased the delivery of smoking cessation support, along with the provision of adjunctive counseling and cost-free medications. However, our secondary outcomes were not measured consistently, and in many cases analyses were subject to substantial statistical heterogeneity, imprecision, or both, making it difficult to draw conclusions.

Thirty-four studies investigated multicomponent interventions to improve smoking cessation rates. There was substantial variation in the combinations of strategies tested, and the resulting individual study effect estimates, precluding meta-analyses in most cases. Meta-analyses provided some evidence that adjunctive counseling combined with either cost-free medications or provider training enhanced quit rates when compared with standard care alone. However, analyses were limited by small numbers of events, high statistical heterogeneity, and studies at high risk of bias. Analyses looking at the effects of combining provider training with flow sheets to aid physician decision-making, and with outreach facilitation, found no clear evidence that these combinations increased quit rates; however, analyses were limited by imprecision, and there was some indication that these approaches did improve some forms of provider implementation.

## Authors' conclusions

There is moderate-certainty evidence that providing adjunctive counseling by an allied health professional, cost-free smoking cessation medications, and tailored printed materials as part of smoking cessation support in primary care can increase the number of people who achieve smoking cessation. There is no clear evidence that providing participants with biomedical risk feedback, or primary care providers with training or incentives to provide smoking cessation support enhance quit rates. However, we rated this evidence as of low or very low certainty, and so conclusions are likely to change as further evidence becomes available. Most of the studies in this review evaluated smoking cessation interventions that had already been extensively tested in the general population. Further studies should assess strategies designed to optimize the delivery of those interventions already known to be effective within the primary care setting. Such studies should be cluster-randomized to account for the implications of implementation in this particular setting. Due to substantial variation between studies in this review, identifying optimal characteristics of multicomponent interventions to improve the delivery of smoking cessation treatment was challenging. Future research could use component network meta-analysis to investigate this further.

## PLAIN LANGUAGE SUMMARY

### Are there ways to improve stop-smoking treatment in primary care to help more people to quit smoking?

#### What is stop-smoking treatment in primary care?

Primary care, also known as family medicine or general practice, is where people go to see a health professional for mostly day-to-day health issues. It is one of the best places for people who smoke tobacco to get help to quit. When people visit primary care they may be asked if they smoke. If they do, they may then be helped to quit, typically through counseling and medications.

#### Why we did this Cochrane Review

Support to stop smoking in primary care is not always delivered well or consistently. Health providers may be unsure how best to deliver treatment, may have limited time to deliver it, or lack the resources needed. Ways to improve the delivery and success of stop-smoking support in primary care have been suggested. Some of these are designed to make sure the treatment already available is delivered often and well, e.g. training providers on how best to help people quit, and some are designed to increase the support available for participants, e.g. providing additional counseling and printed materials. Our aim was to look at which of these approaches works best on their own or together.

#### What did we do?

We searched for studies that looked at ways to improve standard stop-smoking support within primary care, and where the treatments people received were decided at random.

We wanted to find out:

- how many people were asked about their smoking and provided with advice and support;
- how many people tried to quit smoking; and
- how many people stopped smoking for at least six months.

We included evidence published to 10th September 2020.

### **What we found**

We found 81 studies including 112,159 smokers in primary care patients. Studies looked at many ways to improve the delivery and success of stop-smoking support in primary care. Some looked at just one strategy, and some looked at two or more in combination. More than one study looked at each of the following individual strategies: additional counseling; free medications; feedback to participants on markers of their individual health risk linked to smoking; printed materials tailored to participants; health provider training; and rewards to health providers for providing support.

Most studies took place in Europe (39 studies) and the USA (26 studies).

### **What are the results of our review?**

More people probably stop smoking for at least six months when they are given additional counseling (22 studies, 18,150 people), free stop-smoking medications (10 studies, 7560 people), or printed materials tailored to them (6 studies, 15,978 people), as part of stop-smoking support in primary care. We are uncertain whether providing people with feedback on markers of their individual health risk, providing healthcare providers with training, or with rewards for providing stop-smoking support, help more people to quit.

Thirty-four studies looked at more than one strategy to improve stop-smoking treatment in primary care. Combinations differed greatly across studies, with different levels of success, and it was not possible to draw conclusions on what worked best.

There was not enough information to help us clearly understand whether there were increases in the amount of stop-smoking support provided or increases in the numbers of people making a quit attempt.

### **How reliable are these results?**

For some of our results the data varied widely, for some there was not enough data, and in some cases there were quality issues with included studies.

We are moderately confident that people are more likely to quit smoking if someone in addition to the primary care doctor also provides stop-smoking counseling, if free stop-smoking medications are provided, or if printed materials tailored to the participant are provided as part of stop-smoking support offered in primary care. However, results might change as further evidence becomes available.

We are less confident about the effectiveness of providing people with feedback on markers of their individual health risk, giving healthcare providers training on stop-smoking treatments, or giving healthcare providers rewards for giving stop-smoking support. These results are likely to change when more evidence becomes available.

## SUMMARY OF FINDINGS

### Summary of findings 1. Adjunctive counseling in addition to standard smoking cessation care in primary care

#### Adjunctive counseling in addition to standard smoking cessation care in primary care

**Patient or population:** people who attend primary care and smoke tobacco

**Setting:** primary care (Australia, Europe, South Korea, United States)

**Intervention:** adjunctive counseling plus standard or multicomponent smoking cessation support

**Comparison:** standard or multicomponent smoking cessation support

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with control	Risk with adjunctive counseling				
Smoking abstinence at 6-month follow-up or more. All studies	Study population		RR 1.31 (1.10 to 1.55)	18,150 (22 RCTs)	⊕⊕⊕⊖ MODERATE <sup>a</sup>	-
	7 per 100	9 per 100 (8 to 11)				
Smoking abstinence at 6-month follow-up or more. Subgroup comparator: standard care	Study population		RR 1.43 (1.15 to 1.78)	12,852 (17 RCTs)	⊕⊕⊕⊖ MODERATE <sup>b</sup>	-
	4 per 100	6 per 100 (5 to 8)				
Smoking abstinence at 6-month follow-up or more. Subgroup comparator: multicomponent intervention	Study population		RR 1.04 (0.87 to 1.23)	5298 (5 RCTs)	⊕⊕⊖⊖ LOW <sup>c</sup>	-
	14 per 100	14 per 100 (12 to 17)				

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

**CI:** Confidence interval; **RCT:** Randomized controlled trial; **RR:** Risk ratio

#### GRADE Working Group grades of evidence

**High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect

**Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

**Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

**Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

<sup>a</sup>Downgraded one level due to inconsistency. A subgroup analysis subgrouping by the nature of the comparator resulted in substantial subgroup differences ( $I^2 = 80\%$ ).

<sup>b</sup>Downgraded one level due to risk of bias. Removing the studies at high risk of bias shifted the confidence intervals so that they incorporated the potential for no benefit of adjunctive counseling.

<sup>c</sup>Downgraded two levels due to imprecision. CI encompassed both potential benefit and harm.

## Summary of findings 2. Cost-free medications used in addition to standard care in primary care

### Cost-free medications used in addition to standard care in primary care

**Patient or population:** people who attend primary care and smoke tobacco

**Setting:** primary care (Australia, Europe, Pakistan, United States)

**Intervention:** cost-free medications plus standard or multicomponent smoking cessation support

**Comparison:** standard or multicomponent smoking cessation support

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with placebo	Risk with cost-free medications				
Smoking abstinence at 6-month follow-up or more	Study population		RR 1.36 (1.05 to 1.76)	7560 (10 RCTs)	⊕⊕⊕⊖ MODERATE <sup>a,b</sup>	-
	12 per 100	17 per 100 (13 to 22)				

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

**CI:** Confidence interval; **RCT:** Randomized controlled trial; **RR:** Risk ratio

### GRADE Working Group grades of evidence

**High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect

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**Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

**Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

<sup>a</sup>Downgraded one level due to inconsistency.  $I^2 = 63\%$ .

<sup>b</sup>The funnel plot highlighted one outlier (the smallest study showed a large positive effect of the intervention). However, when this outlier was removed from the analysis the interpretation of the result remained consistent.



### Summary of findings 3. Biomedical feedback in addition to standard smoking cessation treatment in primary care

#### Biomedical feedback in addition to standard smoking cessation treatment in primary care

**Patient or population:** people who attend primary care and smoke tobacco  
**Setting:** primary care (Europe, USA)  
**Intervention:** biomedical feedback plus standard smoking cessation support  
**Comparison:** standard smoking cessation support

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with placebo	Risk with biomedical feedback				
Smoking abstinence at 6-month follow-up or more	Study population		RR 1.07 (0.81 to 1.41)	3491 (7 RCTs)	⊕⊕⊕⊖ LOW <sup>a</sup>	-
	10 per 100	11 per 100 (8 to 14)				

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

**CI:** Confidence interval; **RCT:** Randomized controlled trial; **RR:** Risk ratio

#### GRADE Working Group grades of evidence

**High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect

**Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

**Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

**Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

<sup>a</sup>Downgraded two levels due to imprecision. CI encompassed the potential for both benefit and harm.

### Summary of findings 4. Tailored print materials in addition to standard smoking cessation treatment in primary care

#### Tailored print materials in addition to standard smoking cessation treatment in primary care

**Patient or population:** people who attend primary care and smoke tobacco  
**Setting:** primary care (Europe)  
**Intervention:** tailored print materials plus standard smoking cessation support  
**Comparison:** standard smoking cessation support

Outcomes	Anticipated absolute effects* (95% CI)	Relative effect (95% CI)	Nº of participants	Certainty of the evidence	Comments
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	Risk with placebo	Risk with tailored print materials		(studies)	(GRADE)	
Smoking abstinence at 6-month follow-up or more	Study population		RR 1.29 (1.04 to 1.59)	15,978 (6 RCTs)	⊕⊕⊕⊖ MODERATE <sup>a</sup>	-
	3 per 100	4 per 100 (4 to 5)				

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

**CI:** Confidence interval; **RCT:** randomized controlled trial; **RR:** Risk ratio

#### GRADE Working Group grades of evidence

**High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect

**Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

**Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

**Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

<sup>a</sup>Downgraded one level due to risk of bias. Removing the two studies judged to be at high risk of bias shifted the CI so that it incorporated the potential for no difference in cessation rates between intervention and comparator groups.

### Summary of findings 5. Provider training in addition to standard smoking cessation treatment in primary care

#### Provider training in addition to standard smoking cessation treatment in primary care

**Patient or population:** people who attend primary care and smoke tobacco

**Setting:** primary care (Argentina, Canada, Europe, USA)

**Intervention:** provider training plus standard or multicomponent smoking cessation support

**Comparison:** standard or multicomponent smoking cessation support

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with placebo	Risk with provider training				
Smoking abstinence at 6-month follow-up or more	Study population		RR 1.10 (0.85 to 1.41)	13,685 (7 RCTs)	⊕⊕⊖⊖ LOW <sup>a,b</sup>	-
	5 per 100	6 per 100 (5 to 8)				

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

**CI:** Confidence interval; **RCT:** Randomized controlled trial; **RR:** Risk ratio

#### GRADE Working Group grades of evidence

**High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect

**Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

**Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

**Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

<sup>a</sup>Downgraded one level due to inconsistency.  $I^2 = 66\%$ .

<sup>b</sup>Downgraded one level due to imprecision. CI incorporated the potential for both benefit of the intervention and no difference between intervention and control (taking into account the anticipated absolute effects).

### Summary of findings 6. Provider incentives in addition to standard smoking cessation treatment in primary care

#### Provider incentives in addition to standard smoking cessation treatment in primary care

**Patient or population:** people who attend primary care and smoke tobacco

**Setting:** primary care (Germany, USA)

**Intervention:** provider incentives plus standard or multicomponent smoking cessation support

**Comparison:** standard or multicomponent smoking cessation support

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with placebo	Risk with provider incentives (provider-level)				
Smoking abstinence at 6-month follow-up or more	Study population		RR 1.14 (0.97 to 1.34)	2454 (2 RCTs)	⊕⊕⊕⊕ VERY LOW <sup>a,b</sup>	-
	18 per 100	21 per 100 (17 to 24)				

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

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

#### GRADE Working Group grades of evidence

**High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect

**Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

**Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

**Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

<sup>a</sup>Downgraded one level due to risk of bias: both included studies were judged to be at high risk of bias.  
<sup>b</sup>Downgraded two levels due to imprecision: CIs incorporate the potential of both benefit and harm.

## BACKGROUND

### Description of the condition

Tobacco use is the leading cause of premature death worldwide (World Health Organization 2017). From a chronic illness perspective, people who smoke have a 50% to 70% greater chance of dying from stroke or coronary heart disease than people who do not, and 85% of cancers of the trachea, bronchus, and lung are directly attributable to tobacco use (U.S. Department of Health and Human Services 2014). Tobacco use is also a leading risk factor for other major causes of death, including 16 types of cancer, chronic obstructive pulmonary disease, and lower respiratory tract infections (U.S. Department of Health and Human Services 2014; World Health Organization 2017).

There is overwhelming evidence to support both the health and economic benefits of smoking cessation. If a person smokes, supporting them with quitting is the single most effective intervention a clinician can provide to reduce the risk of premature disease, disability and death (Fiore 2008; Royal College of Physicians 2018; Tengs 1995). Quitting smoking reduces the excess risk of smoking-related coronary heart disease by approximately 50% within one year, and to normal levels within five years (U.S. Department of Health and Human Services 2014). Smoking cessation is also considered to be among the most cost-effective preventive interventions available to clinicians and health systems (Tengs 1995; Cromwell 1997; Roncker 2005; Franco 2007; Gaziano 2007; Royal College of Physicians 2018; U.S. Department of Health and Human Services 2020).

### Description of the intervention

Primary care practice, also known as family medicine or general practice, has been identified as an important setting for intervening with tobacco users because of the large reach of primary care settings, the long-term relationships with patients and their role in addressing disease prevention (U.S. Department of Health and Human Services 2020; World Health Organization 2020).

Evidence-based guidelines for the delivery of tobacco treatment emphasize the important role of primary care clinicians in tobacco treatment delivery (Verbiest 2017). The World Health Organization (WHO) and other international authorities have called for smoking cessation to be integrated into primary health care globally, as it is seen as the most suitable health system 'environment' for providing advice and support on smoking cessation (Fiore 2008; World Health Organization 2008; World Health Organization 2020; U.S. Department of Health and Human Services 2020). Specifically, the combination of behavioral support and stop-smoking pharmacotherapy have been shown to significantly enhance long-term cessation rates; it follows that increasing the use of these evidence-based treatments is an important target (Stead 2016). While models of delivery differ across international settings, clinical practice guidelines recommend that primary care providers support people who smoke with quitting by: asking them about their smoking status, providing advice on quitting to those identified as smoking, and supporting cessation by offering behavioral counseling and/or pharmaceutical treatment or both when smokers identify themselves as ready to quit (Verbiest 2017). See [Secondary outcomes](#) below for more information.

However, there is a well-documented 'practice gap' in the rates at which smoking cessation is addressed by practitioners in clinical settings. International studies have documented that between 40% and 70% of people who smoke report having received cessation advice from their physician (Bartsch 2016; Papadakis 2014; Reid 2019; World Health Organization 2020). While practitioners tend to deliver advice to quit at moderate rates, studies have shown that the rates of providing specific assistance (i.e. behavioral counseling, printed self-help materials, stop-smoking medications, or follow-up support) are much lower (Bartsch 2016; Papadakis 2014). When it is offered, the amount and breadth of assistance is also likely to differ considerably across practices, which may have an effect on rates of smoking cessation.

### How the intervention might work

Several barriers to optimal cessation practice in primary care have been identified at the patient, provider, and practice levels (Martin-Cantera 2020; Van Rossem 2015; Vogt 2005; Young 2001). Identified barriers include a lack of knowledge and skills among providers, provider attitudes and perceptions, lack of time and organizational supports, and a lack of patient motivation and other patient-level factors. Interventions which address these barriers are expected to enhance rates of tobacco treatment delivery by primary care providers, increase the use of evidence-based stop smoking treatment by patients, and subsequently lead to enhanced quit rates among patients identified in primary care (Van Rossem 2015; Martin-Cantera 2020; Vogt 2005; Young 2001).

Strategies to improve the delivery of standard smoking cessation support in primary care could include the provision of provider training, real-time counseling prompts, and provider performance feedback. These examples represent strategies that span practice- and provider-implementation levels. Another way to boost smoking quit rates in primary care could be to incorporate additional intervention components alongside those already commonly delivered as part of standard care, e.g. provision of tailored print materials, adjunctive counseling provided by allied health professionals and providing people with specific feedback about their smoking-related health risks. These strategies could be implemented either individually or as part of a multicomponent intervention (combining more than one strategy). While there is a lack of implementation knowledge to inform the design and delivery of tobacco treatment interventions in primary care practice, multicomponent interventions have previously been shown to be the most effective method for increasing both provider performance in the delivery of smoking cessation treatment and improving cessation rates among participants (Anderson 2004; Fiore 2008; Grimshaw 2001; Martin-Cantera 2015; Papadakis 2010). They are designed to address several barriers to treatment delivery in a synergistic manner, acknowledging the need for more complex or sophisticated intervention models, or both, to bring about changes in healthcare practice and behavior.

### Why it is important to do this review

Reflecting the challenges surrounding the effective implementation of smoking cessation treatment in primary care, much research has been carried out investigating how to improve both the implementation and success of these interventions. Some have focused on practice-level interventions (such as electronic medical record prompts or outreach facilitation (Cummings 1989a; Verbiest 2014); some have focused on provider-level

interventions, such as provider training and incentives (Lennox 1998; Olano Espinosa 2013; Roski 2003), and some have focused on patient-level interventions (over and above the standard advice delivered by primary care physicians; such as adjunctive counseling, cost-free medications, biomedical feedback, and tailored printed materials; An 2006; Meyer 2008; Minué-Lorenzo 2019; Ronaldson 2018). Others have tested a combination of these approaches in multicomponent interventions (e.g. Katz 2004; Twardella 2007; Unrod 2007). Bringing this evidence together allows us to summarize the research methodologies used and to synthesize the evidence in support of specific strategies, or the combination of strategies, that are effective in increasing rates of smoking cessation in the primary care setting. This can be used to inform both clinical practice and the implementation of health policy. Several published meta-analyses have examined the effect of physician advice and other provider interventions on smoking cessation, but many of these reviews have not been specific to the primary care setting (Boyle 2014; Carson 2012; Clair 2019; Fiore 2008; Rice 2017; Stead 2013; Van den Brand 2017). These previous reviews have also focused on the effect of providing advice on smoking abstinence only; they have not examined improvements in provider performance in the delivery of evidence-based smoking cessation treatments that may have ultimately led to any increase in effectiveness. Two published meta-analyses have aimed to do this: Anderson 2004 reviewed the literature published up to 2001, and Papadakis 2010 published an update which examined the literature prior to 2009. Additionally, Martin-Cantera 2015 narratively reviewed the literature examining multicomponent interventions in primary care, published up to 2014. This review provides an up-to-date synthesis of the literature in this field.

## OBJECTIVES

To assess the effectiveness of strategies intended to increase the success of smoking cessation interventions in primary care settings.

To assess whether any effect that these interventions have on smoking cessation may be due to increased implementation by healthcare providers.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

Randomized controlled trials (RCTs), cluster-RCTs (cRCTs).

#### Types of participants

Participants include adult primary healthcare patients. For the purposes of this review, we defined primary care as family medicine or general medical practice. We did not include public health or community interventions in our definition of primary care, nor did we assess interventions delivered in dental offices or pharmacies. We included trials which covered the whole practice population, as well as those which included specific subpopulations recruited from primary care settings (e.g. people with chronic obstructive pulmonary disease (COPD), or people with diabetes). We did not include studies that solely addressed the behavior of pregnant women or adolescents, as they are addressed by other Cochrane Reviews (Chamberlain 2017; Claire 2020; Fanshawe 2017).

For our primary outcome, and most of our secondary outcomes, all participants were required to be people who used tobacco at study baseline. However, for our secondary outcome, 'Number of patients asked whether they smoke', participants could include the general population of primary care patients (i.e. both people who used tobacco and people who did not use tobacco at baseline).

#### Types of interventions

To be included in this review, studies must have investigated an intervention strategy or strategies designed to improve the implementation or success of smoking cessation treatment in primary care. The interventions under investigation in this review were therefore not standard smoking cessation support incorporating brief advice delivered by a primary care physician, or the standard provision of smoking cessation medications in primary care. Interventions of interest could include any strategy or strategies designed to increase or enhance the quality of the support offered, or an adjunctive smoking cessation intervention offered in addition to standard care. Interventions could be implemented at any level (i.e. practice, provider or participant) and the patient-level components could be delivered by any health professional within a primary care practice setting. Examples of patient-level interventions investigated in this review included adjunctive counseling delivered by a health professional other than the physician, cost-free smoking cessation medications and the provision of tailored print materials. Examples of provider-level interventions included provider training and provider incentives. Examples of practice-level interventions were outreach facilitation and electronic medical record (EMR) prompts. The categorization of these interventions is subjective, and some interventions may fit equally well at more than one level. For example, we considered in detail whether cost-free medications should be categorized as a patient-level, practice-level, or system-level intervention (e.g. where medication costs are government-subsidized), and decided that it could be categorized as all of these. We decided on patient-level in this instance, as the participant is the beneficiary of the cost savings, which have the potential to increase medication use.

Valid intervention groups were tested as an adjunct to and in comparison with 'standard' smoking cessation support or 'usual care', in order to test the effect of the additional implementation strategy over and above standard care. Standard care is defined differently within and across different communities and studies; however, it typically involves brief behavioral support from the primary care physician, alongside an offer of smoking cessation medication. We also included studies with head-to-head comparisons of two or more active interventions, but only if it was possible to isolate the effects of a single strategy or component designed to enhance the delivery of tobacco cessation treatment in primary care.

We did not include studies which covered interventions to enhance tobacco treatment delivery as part of a multifactorial lifestyle intervention.

#### Types of outcome measures

##### Primary outcomes

The primary outcome measure was smoking abstinence at long-term follow-up in participants who reported smoking at baseline. To be eligible for inclusion, studies had to measure smoking status at least six months from the start of the intervention. We excluded



studies with abstinence measured at less than six months' follow-up.

In trials with more than one measure of abstinence, we preferred the measure using the longest follow-up and the strictest criteria, in line with the Russell Standard (West 2005). We used sustained or continuous abstinence over point prevalence abstinence, and biochemically-validated abstinence, such as exhaled carbon monoxide (CO), over self-report. We favored biochemically-validated point prevalence abstinence over self-reported continuous or prolonged abstinence. We considered participants lost to follow-up to be still smoking, in line with the practice of the Cochrane Tobacco Addiction Group.

We chose smoking abstinence as the primary outcome, as this is the most clinically relevant outcome; an increase in the number of people quitting is the ultimate goal of any attempt to increase the implementation of smoking cessation treatment.

### Secondary outcomes

Our secondary outcomes are deemed to be process outcomes. We therefore did not include studies that only reported on our secondary outcomes and did not investigate our primary outcome.

- Provider performance in tobacco treatment delivery (these outcomes were informed by the 5As; a sequence of actions proposed by US smoking cessation guidelines that can be applied in primary care settings; Fiore 2008)
  - \* Number of participants **asked** whether they smoke (the denominator for this also includes participants who were not smoking at baseline in studies that enrolled people who smoked and people that did not);
  - \* Number of participants identified as smoking who were **advised** to quit;
  - \* Number of participants identified as smoking whose readiness to quit was **assessed**;
  - \* Number of participants identified as smoking who were **assisted** to quit (further divided into general assistance, medications prescribed, quit date set, counseling provided, self-help materials provided);
  - \* Number of participants identified as smoking who had follow-up appointments **arranged** to address smoking.
- Participant quit attempts, as defined by individual studies.

### Search methods for identification of studies

#### Electronic searches

We searched the following databases to 10th September 2020:

- Cochrane Tobacco Addiction Group Specialized Register;
- Cochrane Central Register of Controlled Trials (CENTRAL);
- MEDLINE (via PubMed);
- Embase.

The search strategy used the following keyword terms: ('smoking' or 'smoking cessation' or 'tobacco-use cessation'; or 'tobacco-use-disorder') AND ('primary health care' or 'physicians' or 'family practice' or 'general practice' or 'general practitioners' or 'physicians, family'). We used standard search strings, using the Cochrane Highly Sensitive Search Strategy for identifying randomized controlled trials, as well as 'controlled trials' or

'evaluation studies'. We applied no restrictions by language or publication status. See [Appendix 1](#) and [Appendix 2](#) for the example PubMed and Specialized Register search strategies respectively.

### Searching other resources

We searched the following trial registers: [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and the International Clinical Trials Registration Platform (WHO ICTRP), and reference lists of eligible studies. We also contacted study authors for unpublished results of completed studies.

### Data collection and analysis

#### Selection of studies

SP, GP and BH independently reviewed titles and abstracts of reports for possible inclusion. We reviewed the full text of any reports which could not be fully assessed using the title and abstract, along with any reports that appeared to be eligible based on the available information. Two review authors (from SP, GP and BH) then independently assessed all of the full-text articles retrieved, and resolved discrepancies by discussion with a third review author (AP or NL), who acted as an arbiter. We then linked multiple reports of the same eligible study. We recorded all reports of studies excluded at the full-text screening phase, together with the reason for exclusion.

#### Data extraction and management

One review author (from SP, GP, BH) extracted data on study characteristics of eligible studies. Two review authors (from SP, GP, BH) independently extracted data on outcomes, and categorized studies according to the type and level of intervention. We extracted the following information from each of the included studies:

- lead author and year of publication;
- country in which intervention was delivered;
- methods of recruiting healthcare practices and participants within practices;
- inclusion criteria, including subpopulations;
- type of study design (RCT, cluster-RCT);
- target of intervention (participant, provider, practice);
- data collection method (interview, telephone, mail survey);
- characteristics of study participants (age, sex, comorbidities, readiness to quit);
- duration of intervention (in weeks);
- details of the intervention;
- description of the comparator intervention;
- outcomes measured, including definitions used and time point at which they were assessed (in weeks);
- use of biochemical validation and participant response rate;
- methods used to manage missing data;
- for each outcome: number of participants in each arm; loss to follow-up rate; number of events in each arm; intra-class correlation coefficient (ICC) (cluster-RCTs only);
- study funding source;
- authors' declarations of interest.

#### Methods for categorizing details of intervention

We categorized intervention strategies into three groups, based on the level at which they were designed to intervene (i.e. participant,

provider, practice). We further categorized interventions as either a single or a multicomponent intervention. For the purposes of this review, we defined single-component interventions as those which included only one intervention strategy. We defined multicomponent interventions as interventions which included two or more intervention strategies, at any level. We used a preliminary list of intervention strategies based on previous systematic reviews (Anderson 2004; Fiore 2008; Papadakis 2010) with further categories added as appropriate to describe other intervention modalities identified in the literature.

### Assessment of risk of bias in included studies

Two review authors (from SP, GP, BH, NL) independently assessed the risk of bias of the included studies, using Cochrane's RoB1 (Higgins 2011).

We assessed the following domains:

- sequence generation (as an indicator of selection bias)
- allocation concealment (as an indicator of selection bias)
- blinding of outcome assessors (as an indicator of detection bias)
- incomplete outcome data (as an indicator of attrition bias)

We did not assess any indicators of performance bias, as all of the studies were assessing a behavioral strategy, and therefore it would have been impossible to blind research staff and participants.

We also assessed the following other sources of bias for c-RCTs only:

- recruitment bias due to recruitment of participants to clusters after allocation;
- unbalanced baseline characteristics;
- whether statistical adjustment had been made to the analysis to account for the potential correlation of effects within clusters.

### Measures of treatment effect

For each study and outcome (smoking abstinence, physician performance outcomes, quit attempts) we calculated the risk ratio (RR) and 95% confidence interval (CI) for each relevant comparison investigated (intervention group versus control group). For smoking abstinence and quit attempts the denominators were the number of people randomized to each study arm, assuming that any participants lost to follow-up were continuing to smoke or had not made a quit attempt. For the physician performance outcomes we carried out a complete case analysis where possible.

### Unit of analysis issues

All analyses contain participant-level data from both RCTs and c-RCTs. We investigated the effect of adjusting for clustering in c-RCTs by inflating the standard error of the log RR using the design effect calculated from the estimated ICC that was reported in the study. If no ICC was reported, we assumed a typical ICC value for smoking cessation trials, based on Baskerville 2001. See below (Sensitivity analysis) for more details.

### Dealing with missing data

We recorded the proportions of participants lost to follow-up in each relevant arm of included studies and used this information in our risk of bias assessments. Any participants with missing smoking or quit attempts data at follow-up were deemed to have returned to active smoking or to have not made a quit attempt respectively, and

were included in the denominator for calculating the risk ratio. We did not impute missing data for physician performance outcomes.

### Assessment of heterogeneity

We assessed statistical heterogeneity within meta-analyses and between subgroups using the  $I^2$  statistic (Higgins 2003). We considered an  $I^2$  value greater than 50% to indicate moderate to substantial heterogeneity. Where an  $I^2$  of greater than 75% was recorded for the pooled result of a meta-analysis, and this remained unexplained by subgroup analyses, we judged whether it was appropriate to present the pooled estimate.

### Assessment of reporting biases

Where analyses included 10 or more studies we generated funnel plots to investigate potential publication bias.

### Data synthesis

We grouped studies by intervention type. Where there was more than one study testing an intervention type(s), and where appropriate, we performed meta-analyses using Mantel-Haenszel random-effect models for each outcome. In studies that tested a single intervention component, we did not calculate a pooled estimate across intervention types for each level of intervention (e.g. participant, provider, practice) due to clinical heterogeneity. We were able to carry out meta-analyses of our primary outcome for comparisons investigating the following singular intervention types:

#### Participant-level:

- adjunctive counseling
- cost-free medications
- biomedical feedback (e.g. spirometry, CO monitoring)
- tailored print materials

#### Provider-level:

- provider training
- provider incentives

Some of the studies included in the analyses tested the intervention components above alongside standard care and also used standard care as the comparator, whereas other studies tested the intervention component as part of a multicomponent intervention with a comparator that received the same multicomponent intervention minus the intervention component of interest. These two types of studies were combined in the same meta-analysis with subgrouping to investigate whether the study design had an impact on study findings.

We were also able to meta-analyze the following multicomponent interventions versus standard care alone, where more than one study tested the same combination of components:

- adjunctive counseling and cost-free medications
- adjunctive counseling and provider training
- provider training and flow sheet
- provider training and outreach facilitation

Again we carried out meta-analyses using random-effects Mantel-Haenszel methods to calculate RRs and 95% CIs. Where it was not



possible to conduct meta-analyses, i.e. there was only one study investigating the comparison, we summarized studies narratively, calculating and presenting their individual RRs and 95% CIs.

### Subgroup analysis and investigation of heterogeneity

We used subgroup analyses to investigate any differences in the effects observed between studies for the primary smoking abstinence outcome, where possible:

- for all comparisons: studies that tested the intervention component(s) of interest alongside and in comparison with standard care only versus studies that tested the intervention component(s) of interest alongside and in comparison with other intervention component(s) of interest;
- for all comparisons: participants with chronic disease versus those without chronic disease, e.g. diabetes, COPD;
- for adjunctive counseling comparisons: provider type; intensity; mode;
- for biomedical feedback: type of biomedical feedback, e.g. spirometry, CO monitoring;
- for tailored print materials: theoretical basis of tailoring.

### Sensitivity analysis

We used sensitivity analyses to examine the effects of excluding studies with the following characteristics for the primary smoking abstinence outcome:

- studies deemed to be at high risk of bias (i.e. judged to be at high risk for at least one risk of bias domain);
- individually randomized studies (as opposed to c-RCTs). c-RCTs provide the best evidence for the effects of the interventions tested when implemented in primary care, as they would be in the 'real world'.

We also carried out two sensitivity analyses adjusting for appropriate estimates of ICCs in those c-RCTs that did not report controlling for the clustered nature of the design, or those in which the ICC was not reported. Separate sensitivity analyses used estimated ICCs of 0.01 and 0.05 respectively (Baskerville 2001).

### Summary of findings and assessment of the certainty of the evidence

We used [GRADEpro GDT](#) to import data from Review Manager 5 in order to create summary of findings tables ([GRADEpro GDT](#); [Review Manager 2020](#)) for comparisons investigating the following single intervention components:

- adjunctive counseling;
- cost-free medications;
- biomedical feedback;
- tailored print materials;
- provider training;
- provider incentives.

A summary of the intervention effect for the primary smoking abstinence outcome was produced for each comparison, and we used the GRADE approach to assess the certainty of the body of evidence ([Schünemann 2013](#)), as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2021](#)). We used the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness, and publication bias) to assess the certainty of the body of evidence for our primary outcome - smoking abstinence, downgrading by one level for serious or by two levels for very serious limitations for each consideration.

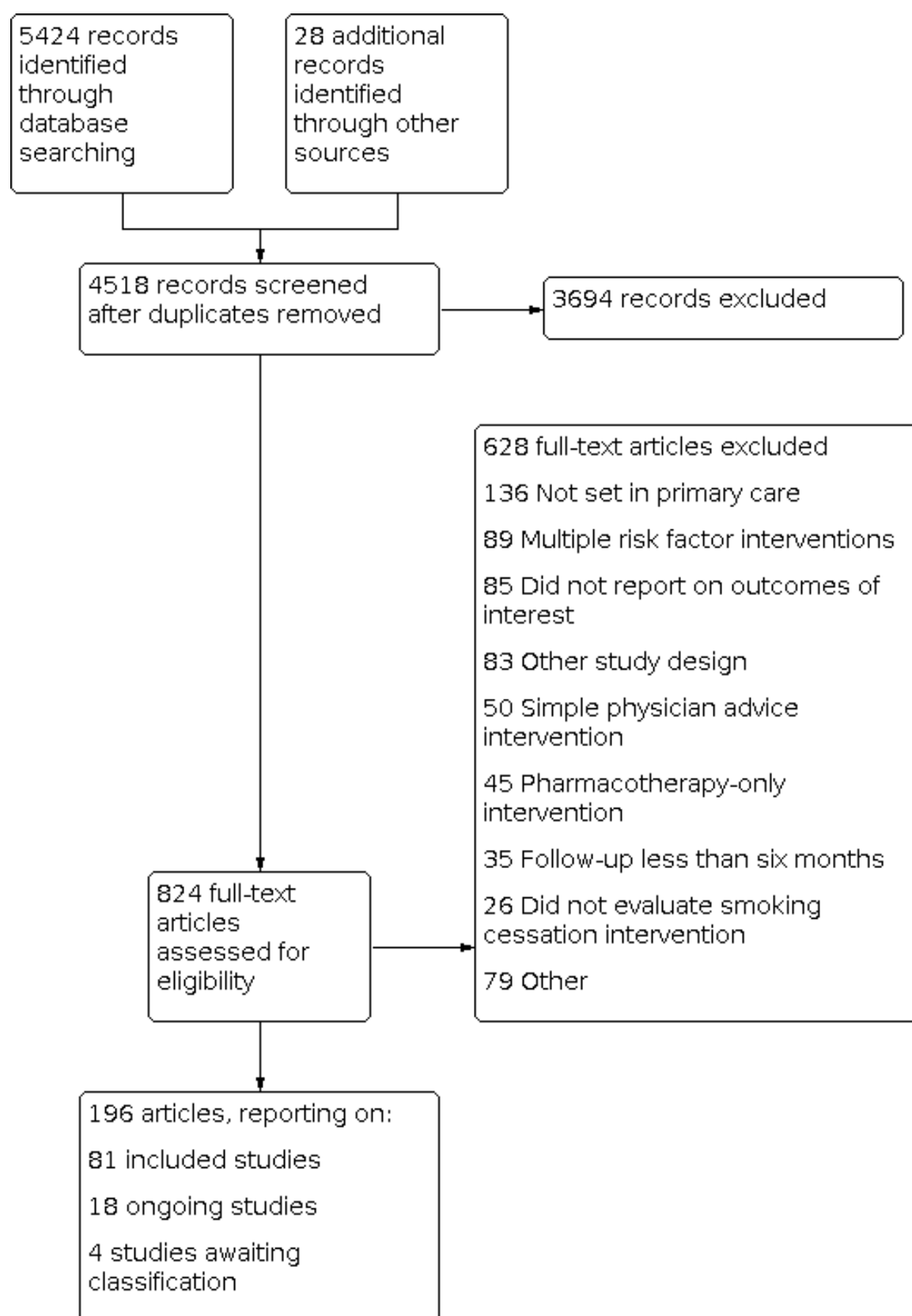
## RESULTS

### Description of studies

#### Results of the search

Our searches identified 4518 non-duplicate records. We screened all records and retrieved the full-text papers of 824 potentially relevant articles. After screening the full texts we included 81 studies (see [Characteristics of included studies](#)), and identified 18 ongoing studies (see [Characteristics of ongoing studies](#)) and four studies awaiting classification ([Studies awaiting classification](#)). [Figure 1](#) presents the PRISMA flow chart for this review.

**Figure 1. Study flow diagram.**



## Included studies

Of the 81 included studies 43 were individually-randomized RCTs, 37 were c-RCTs, and one was a factorial trial. Thirty-nine studies were conducted in Europe, 26 in the USA, seven in Australia, two each in South America, South Korea and Canada, and one each in China, Pakistan and Thailand. All studies were conducted in primary care settings.

## Participants

The 81 included studies represented 112,159 participants. Individual study sample sizes ranged from 48 to 6856. For all but one of the outcomes, all participants were people who attended the practices as patients and smoked tobacco at study baseline. However, where studies measured the number of patients who were asked whether they smoked, participants contributing to the outcome included anyone attending the primary care practice. These non-smoking participants are included in the total number of participants specified above, but very few studies assessed this outcome.

Five studies recruited from specific population groups; two of these specifically recruited participants with COPD, one recruited participants with diabetes and hypertension, another participants with diabetes only, and the final study recruited participants with a low or moderate household income. The average age of participants ranged from 33 to 64 across studies, and average cigarettes per day ranged from 14 to 26.

## Interventions and comparators

We classified study arms according to whether they offered any interventions designed to improve the delivery or success of smoking cessation treatment, over and above standard care. Standard smoking cessation support typically involves brief advice from a physician with a potential offer of medication, and generic printed self-help materials. Some study arms offered multiple additional components (multicomponent interventions), whereas others offered a single additional component. We classified these components as either patient-level, provider-level or practice-level. Within these classifications we identified the intervention types listed in the table below (for more detailed definitions of the strategies listed see [Appendix 3](#)):

PATIENT-LEVEL	PROVIDER-LEVEL	PRACTICE-LEVEL
Adjunctive counseling (offered by a health professional other than the primary care physician, i.e. via a practice nurse, counselor, or smoking quitline)	Provider training	Modified vital sign stamp
Tailored printed materials	Provider performance audit and feedback	Treatment flow sheets/consult forms
Biomedical feedback (including CO monitoring, gene testing for lung cancer, spirometry and a combination of CO monitoring and spirometry)	Provider incentives	Electronic medical record (EMR) and decision support
Medication prompts	-	Outreach facilitation
Patient incentives	-	-
SMS and Internet cessation programs	-	-
Information videos	-	-
Access to cost-free medications (as opposed to medications with a fee, which would be considered standard care)	-	-
Proactive outreach	-	-

Most of the included studies tested smoking cessation intervention components that were provided at the participant level, in addition to standard care (e.g. adjunctive behavioral support, tailored printed materials), rather than testing interventions that aimed to improve the implementation of an existing intervention (e.g. training health providers or EMR prompts), which were provided at the provider or practice level. The latter intervention types are highlighted in bold in the table above.

In order to be included in the review the intervention arm needed to include one or more of the components in the table above in

addition to standard smoking cessation care, and in comparison with standard care, in order to isolate the effect of one or more intervention components designed to improve the delivery of smoking cessation treatment in primary care. Studies were also included if they compared an intervention made up of a number of the components above, plus standard care, with the same multicomponent intervention minus one of the components. Again this allowed us to isolate the effect of a single intervention component of interest.

## Outcomes

In order to be included in the review, studies had to measure smoking abstinence at six-month follow-up or longer, so all 81 studies measured this primary outcome. Most studies had a longest follow-up of 12 months (42 studies) and 30 studies had a follow-up of six months. The maximum length of follow-up was 24 months, measured by five studies. Most studies measured point prevalence abstinence (35 studies), 20 studies measured continuous abstinence and 17 studies measured abstinence that was sustained for a period of time between two time points e.g. between three and six months follow-up. In nine cases the definition of abstinence used was unclear. Around half of the studies (42 studies) used biochemical validation, such as carbon monoxide monitoring or cotinine levels, to confirm smoking abstinence.

Twenty-five of the 81 included studies reported on the number of quit attempts made by study participants split by study arm,

and 21 of the studies reported on one of the provider performance outcomes in a way that allowed between-group comparison.

## Excluded studies

We list 155 studies excluded at full-text stage, along with reasons for exclusion, in the [Characteristics of excluded studies](#) table. Common reasons for exclusion were that studies were not conducted in a primary care setting, that participant care was focused on multiple risk factors as opposed to just smoking cessation, that follow-up was less than six months and that the study investigated standard smoking cessation support, such as brief physician advice.

## Risk of bias in included studies

Overall, we judged 14 studies to be at low risk of bias, 23 to be at unclear risk, and the remaining 44 at high risk of bias.

Details of 'Risk of bias' judgments for each domain of each included study can be found in the [Characteristics of included studies](#) table. [Figure 2](#) illustrates judgments for each included study.

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

	Sequence Generation	Allocation concealment	Blinding of outcome assessors: All outcomes	Incomplete outcome data: All outcomes	Recruitment bias (cluster RCTs only)	Balanced baseline characteristics? (cluster RCTs only)	Adjustment for clustering in analysis? (cluster RCTs only)	Other bias
Aleixandre 1998	?	?	+	+				
An 2006	+	+	+	+				
Aung 2019	+	+	+	+				
Aveyard 2003	?	+	+	+				
Bock 2014	+	+	+	+				
Borland 2008	+	+	+	+	+	+	+	
Buffels 2006	+	?	?	?				
Cabezas 2011	+	+	+	+	+	+	+	
Canga 2000	+	+	+	+				
Carpenter 2020	+	+	+	+	+	+	+	
Cobos-Campos 2016	+	+	+	+				
Cummings 1989a	?	?	+	+	+	+	+	
Cummings 1989b	+	+	+	+	+	+	+	
Dent 2009	+	+	+	+				
Ellerbeck 2009	+	+	?	+				
Fu 2014	?	?	+	+				
Gilbert 2013	+	+	+	+				
Gilbert 2017	+	+	+	+				
Girgis 2011	?	?	?	+				
Haas 2015	+	+	+	+				
Hilberink 2011	?	?	+	+	+	+	+	
Hollis 1993	+	+	+	+				
Hoving 2010	+	+	+	+				
Hughes 1991	?	+	+	+				
Irizar Aramburu 2013	+	?	+	+				
Jamrozik 1984	+	+	+	+				
Joseph 2004	?	?	?	+	+	+	+	
Juarranz 1998	+	+	+	+				

**Figure 2. (Continued)**

Josepn 2004	?	?	?	+	?	+	+	+
Juarranz 1998	-	-	+	+				
Kalkhoran 2018	+	+	+	+				
Katz 2004	+	?	+	+	+	+	+	
Kim 2003	+	?	+	+				
Kottke 1989	?	+	+	+	+	+	+	
Lancaster 1999	+	+	+	?				
Lasser 2017	+	+	+	+				
Lee 2016	-	-	+	-	+	+	+	
Lennox 1998	+	+	+	+	+	+	+	
Lennox 2001	+	?	+	+				
Leppänen 2019	+	+	+	+	?	+	+	
Lindsay 1989	?	?	+	?	+	+	+	
Lou 2013	?	?	+	+	+	+	+	
Marley 2014	+	+	+	+				
Mejia 2015	?	?	?	+	?	+	+	
Meyer 2008	-	-	+	+				
Meyer 2012	?	?	+	+	?	+	+	
Minué-Lorenzo 2019	+	+	+	+	+	?	+	
Morgan 1996	?	?	+	?	+	+	+	
Murray 2008	?	?	+	+	+	+	+	
Nebot 1992	?	?	+	?	+	+	+	
Nichols 2017	?	?	+	+				
Ockene 1994	?	?	+	?				
Olano Espinosa 2013	+	+	+	?	+	+	+	
Papadakis 2018	?	?	+	+	+	+	+	
Parkes 2008	+	+	+	+				
Pereira 2006	?	?	?	?	?	+	+	
Pérez Tortosa 2015	+	+	+	+	+	+	+	
Piper 2016	+	?	+	+				
Piper 2018	+	+	+	+				
Pisinger 2010	+	+	+	+	+	+	+	
Ramos 2010	?	+	+	+				
RBR-7yx9hd	?	?	?	?				
Richmond 1993	-	-	+	?				
Ronaldson 2018	+	+	+	+				+
Roski 2003	?	?	+	?	+	+	+	
Russell 1983	-	-	+	+				
Salkeld 1997	?	?	+	+	?	?	+	
Sanz-Pozo 2006	?	?	+	+				
Secades Villa 2009	?	?	+	+	+	+	+	
Segnan 1991	?	+	+	?				
Sherman 2007	+	?	+	+	+	+	+	
Sherman 2008	?	?	+	?	+	?	?	
Siddiqi 2013	+	?	+	+	+	+	+	
Sippel 1999	-	-	+	+				
Swartz 2006	?	?	+	?	+	+	+	

**Figure 2. (Continued)**

Sippei 1999	+	+	+	+					
Swartz 2006	?	?	+	?	+	+	+		
Twardella 2007	+	+	+	+	+	+	+		
Unrod 2007	+	?	+	+	+	+	+		
Van Rossem 2017	+	+	+	+					
Verbiest 2014	+	?	+	+	+	+	+		
Vetter 1990	?	?	+	?					
Yano 2008	?	?	+	+	+	+	+		
Young 2008	+	+	+	?					
Zwar 2015	?	?	+	+	+	+	+		

### Allocation

When judging sequence generation 10 of the included studies were judged to be at high risk of bias, 32 at unclear risk and 39 at low risk. When judging allocation concealment 12 studies were judged to be at high risk, 37 at unclear risk and 32 at low risk. As is common in many older trials, in many cases sequence generation and allocation concealment were not well described in study reports, hence the high numbers of unclear judgments. This does not necessarily mean that bias was present, but that we were unable to make a judgement based on the information available.

### Blinding (detection bias)

When judging the quality of outcome assessment for the primary outcome (smoking abstinence), 23 studies were deemed to be at high risk of bias, seven studies were deemed to be at unclear risk and 51 studies at low risk. Those studies at high risk of bias did not biochemically confirm abstinence and the level of participant contact varied between arms. This means that misreporting of abstinence may have been higher in those study arms with higher contact levels due to social pressures.

### Incomplete outcome data

Ten studies were judged to be at high risk of attrition bias, 21 studies were judged to be at unclear risk and 50 studies were judged to be at low risk. Studies at low risk had attrition rates of less than 50% overall and had a less than 20% difference in attrition rates between study arms. Studies in which this domain was judged to be unclear either did not report overall attrition, did not report attrition by study arm, or both.

### Recruitment bias due to recruitment of participants to clusters after allocation (cluster-RCTs only)

Of the 37 cRCTs, 32 were judged to be at low risk of bias for this domain, as participants were already patients at the primary care sites (clusters) before randomization of clusters took place. Five studies were deemed to be at unclear risk of bias.

### Unbalanced baseline characteristics (cluster-RCTs only)

Of the 37 cRCTs, five studies reported unbalanced baseline characteristics between study arms and were therefore deemed to be at high risk of bias. Twenty-nine studies were judged to be at low risk of bias and three at unclear risk.

### Statistical adjustment to account for potential correlation effects within clusters (cluster-RCTs only)

Twenty-nine of the 37 cRCTs were judged to be at low risk of bias for this domain, as they reported an attempt to test for, or control for the effects of clustering on the analysis. Two studies were judged to be at unclear risk of bias and six studies were deemed to be at high risk.

### Other potential sources of bias

One study ([Ronaldson 2018](#)) was deemed to be at high risk of 'other' bias due to it using a wait-list control design. It appeared that participants in the control group knew that they were on a waiting-list, meaning they may have postponed their quit attempt until after the trial when they knew that they would receive treatment.

### Effects of interventions

See: [Summary of findings 1](#) Adjunctive counseling in addition to standard smoking cessation care in primary care; [Summary of findings 2](#) Cost-free medications used in addition to standard care in primary care; [Summary of findings 3](#) Biomedical feedback in addition to standard smoking cessation treatment in primary care; [Summary of findings 4](#) Tailored print materials in addition to standard smoking cessation treatment in primary care; [Summary of findings 5](#) Provider training in addition to standard smoking cessation treatment in primary care; [Summary of findings 6](#) Provider incentives in addition to standard smoking cessation treatment in primary care

See: [Summary of findings 1](#); [Summary of findings 2](#); [Summary of findings 3](#); [Summary of findings 4](#); [Summary of findings 5](#); [Summary of findings 6](#) for summaries of effect estimates and GRADE ratings. See: [Supplementary file 1](#); [Supplementary file 2](#) for the results of analyses controlling for the effects of clustering in both individual studies and meta-analyses.

Studies were meta-analyzed where there was more than one study providing data for an outcome for a comparison. The first three comparisons (adjunctive counseling, cost-free medications, biomedical feedback) investigate patient-level interventions intended to directly improve smoking quit rates, whereas the fourth and fifth comparisons investigate provider-level interventions which are designed to boost provider implementation of smoking cessation support, in order to ultimately improve quit rates.



## Adjunctive counseling (patient-level strategy)

We found 22 studies that looked at the effect of adding counseling (delivered by an allied health professional rather than the primary care physician) to standard care or a multicomponent smoking cessation intervention. Pooling these studies provided evidence that additional counseling resulted in more favorable smoking quit rates (RR 1.31, 95% CI 1.10 to 1.55;  $I^2 = 44\%$ ; 18,150 participants; [Analysis 1.1](#)). The interpretation of the result remained the same when 12 studies judged to be at high risk of bias were removed from the analysis, when 15 individually-randomized studies were removed from the analysis, and when sensitivity analyses adjusting for clustering were carried out.

However, a subgroup analysis grouping the studies by whether counseling was provided as an adjunct to standard care alone or as an adjunct to an intervention that also included other strategies designed to improve smoking cessation treatment, found evidence of a subgroup difference ( $I^2 = 80\%$ ). Where the counseling was used as an add-on to standard care the RR was 1.43 (95% CI 1.15 to 1.78;  $I^2 = 39\%$ ; 18 studies, 12,852 participants), suggesting a beneficial effect of counseling. However, where the counseling was added to standard care with other potential improvement strategies the RR for counseling was 1.04, with CIs suggesting that the addition of counseling could provide no benefit or could potentially enhance or decrease the quit rate (95% CI 0.87 to 1.23;  $I^2 = 9\%$ ; 7 studies, 5298 participants). Further subgrouping by provider, mode of delivery and intensity of counseling did not provide evidence that the effect of adjunctive counseling was influenced by these factors ([Analysis 1.2](#); [Analysis 1.3](#); [Analysis 1.4](#)).

More than one of the included studies investigating the effects of adjunctive counseling measured each of the following process measures: advice rates; assistance rates; arrangement of follow-up; quit attempts. The evidence was inconclusive on whether adjunctive counseling improved rates of smoking cessation advice, the provision of self-help materials or counselling, or assistance to set a quit date ([Analysis 1.5](#); [Analysis 1.6](#)); however, there was some evidence that adjunctive counseling may have a beneficial impact on the provision of smoking cessation medications ([Analysis 1.6](#)), and the number of people who made a quit attempt ([Analysis 1.8](#)). There was also some evidence, limited by imprecision, that adjunctive counseling may increase the arrangement of patient follow-up by physicians ([Analysis 1.7](#)). When pooling the relevant data statistical heterogeneity was high ( $I^2 = 83\%$ ), but we decided not to suppress the pooled effect estimate as all of the point estimates demonstrated a beneficial effect of adjunctive counseling.

## Cost-free medications (patient-level strategy)

We pooled 10 RCTs looking at the effect of adding cost-free medications to standard smoking cessation care or including cost-free medications as part of a multicomponent smoking cessation intervention. There was evidence that providing cost-free medication increased the number of people who successfully quit smoking (RR 1.36, 95% CI 1.05 to 1.76;  $I^2 = 63\%$ ; 7560 participants; [Analysis 2.1](#)). Although moderate statistical heterogeneity was detected, subgrouping by whether cost-free medications were added to standard care alone or were delivered as part of a multicomponent intervention did not result in a meaningful subgroup effect ( $I^2 = 0\%$ ). We judged seven of the studies included in this analysis to be at high risk of bias, but a

sensitivity analysis removing these did not result in a meaningful change to the result. Likewise, sensitivity analyses removing the five studies individually randomized and investigating the potential impact of clustering on the effect estimate did not result in meaningful changes to the result.

Three of the studies that investigated cost-free medications also investigated their effect on participant quit attempts. There was evidence that their provision resulted in a higher number of quit attempts made (RR 1.21, 95% CI 1.02 to 1.43; 3 studies, 2669 participants; [Analysis 2.2](#)). Heterogeneity was substantial ( $I^2 = 72\%$ ), but in all cases the study effect estimates favored the intervention arm.

## Biomedical feedback (patient-level strategy)

We identified seven trials looking at the effects of adding biomedical feedback to smoking cessation treatment in primary care. Four of these studies investigated spirometry ([Irizar Aramburu 2013](#); [Parkes 2008](#); [Ronaldson 2018](#); [Segnan 1991](#)), one study investigated CO monitoring ([Jamrozik 1984](#)), one study CO monitoring and spirometry ([Sippel 1999](#)), and one study looked at the effect of gene testing for lung cancer risk ([Nichols 2017](#)). We pooled the seven studies and subgrouped according to feedback type. There was no clear evidence of a beneficial effect of biomedical feedback on smoking cessation rates (RR 1.07, 95% CI 0.81 to 1.41;  $I^2 = 40\%$ ; 3491 participants; [Analysis 3.1](#)). The result was imprecise, with a CI encompassing the potential for both an increase and a decrease in quit rates. There was no evidence of a difference in effect depending on the type of biomedical feedback used ( $I^2 = 0\%$ ), and a sensitivity analysis removing the three studies at high risk of bias did not change the interpretation of the results. None of the studies included in this meta-analysis were cluster-RCTs, so we did not conduct a sensitivity analysis removing individually-randomized studies or adjusting for clustering.

## Tailored print materials (patient-level strategy)

We pooled six studies assessing the addition of tailored printed materials to standard smoking cessation support, subgrouped based on the theoretical basis of the tailoring ([Analysis 4.1](#)). Two of the studies were based on the transtheoretical model, but four studies did not have a clear theoretical basis. Overall, there was evidence that providing participants with tailored printed materials increased their smoking cessation rates (RR 1.29, 95% CI 1.04 to 1.59;  $I^2 = 37\%$ ; 15,978 participants), and there was no evidence that the effect was moderated by the theoretical basis of the material. However, a sensitivity analysis removing two studies at high risk of bias resulted in increased imprecision, so that the resulting CIs encompassed the possibility of no effect of tailored printed materials on smoking cessation rates, as well as a potential positive impact (RR 1.25, 95% CI 0.92 to 1.70). This analysis contained no c-RCTs and therefore sensitivity analyses were not required to assess the potential effects of removing individually-randomized studies or adjusting for clustering.

Three of the studies that assessed the effects of tailored printed materials also looked at quit attempts as an outcome ([Gilbert 2013](#); [Gilbert 2017](#); [Hoving 2010](#)). The pooled effect estimates and 95% CIs incorporated the possibility that providing tailored printed materials led to no increase in attempts to quit smoking, as well as the possibility of an increase in quit attempts (RR 1.08, 95% CI 1.00 to 1.17;  $I^2 = 17\%$ ; 11,122 participants; [Analysis 4.2](#)).



## Provider training (provider-level strategy)

Seven RCTs looked at the effects of adding provider smoking cessation training to other smoking cessation strategies or standard treatment. Pooling these studies resulted in an RR of 1.10 (95% CI 0.85 to 1.41; 13,685 participants; [Analysis 5.1](#)). There was no evidence of a clear benefit of provider training, but there was evidence of both substantial imprecision and moderate statistical heterogeneity ( $I^2 = 66\%$ ). There was no evidence that the effect differed depending on whether provider training was offered in addition to and compared with standard care, or whether provider training was offered alongside other strategies to improve the delivery of smoking cessation and compared with those multicomponent interventions minus provider training ( $I^2 = 0\%$ ). Sensitivity analyses removing two studies judged to be at high risk of bias and adjusting for the effect of clustering had no appreciable impact on the result or its interpretation. As none of the studies was individually randomized a sensitivity analysis removing this study type was not required.

A number of studies examined the effect of training on provider performance and participant quit attempts outcomes. Evidence from meta-analyses suggested that provider training increased the amount that physicians asked participants whether they smoked tobacco, increased the number of people physicians advised about their smoking, and increased the amount of assistance given in the form of providing printed self-help materials and providing counseling ([Analysis 5.2](#); [Analysis 5.3](#); [Analysis 5.4](#)). In some of these cases statistical heterogeneity was high, but point estimates always favored the intervention, and so we deemed it appropriate to present a pooled estimate. In four cases (aiding the participant in setting a quit date; provision of smoking cessation medication, participant quit attempts and the arrangement of follow-up support), the point estimates favored provider training, but there was imprecision, so that the CIs incorporated the possibility of no effect of provider training, as well as a potential positive effect ([Analysis 5.4](#); [Analysis 5.5](#); [Analysis 5.6](#)).

## Provider incentives (provider-level strategy)

Two studies looked at the effects of the addition of provider incentives to standard smoking cessation care or as part of a multicomponent smoking cessation intervention. When pooled these studies resulted in an RR of 1.14 (95% CI 0.97 to 1.34;  $I^2 = 0\%$ ; 2454 participants; [Analysis 6.1](#)). There was imprecision, with CIs incorporating the potential for a reduction in quit rates as well as the potential for an increase, when provider incentives were implemented. Subgrouping by whether the intervention was provided alongside standard care alone or other delivery improvement strategies provided no evidence of effect moderation, and a sensitivity analysis adjusting for clustering did not affect our interpretation of the result. Neither of the studies was individually randomized and so a sensitivity analysis to remove this type of study was not required. However, we rated both studies at high risk of bias and so results should be interpreted with caution.

## Other single strategies

In addition, to the studies described as part of the comparisons above, [Supplementary file 3](#) narratively summarizes six additional included studies that investigated a single novel strategy. These strategies were reinforcement text messages ([Cobos-Campos 2016](#)), proactive patient outreach by mailings and telephone

([Fu 2014](#)), a smoking cessation video ([Lee 2016](#)), an internet smoking cessation program ([Pisinger 2010](#)), tailored letters to participants and a provider desktop resource with treatment advice ([Meyer 2012](#)). There was also a randomized factorial trial which investigated a number of different strategies ([Piper 2016](#)).

## Multi-component interventions

Thirty-four included studies compared the combination of two or more strategies to improve the delivery of smoking cessation treatment in primary care (multicomponent interventions) in addition to standard smoking cessation, in comparison with a control arm of standard care. These studies are summarized narratively in [Supplementary file 4](#) with RRs and their corresponding 95% confidence intervals. Twenty-seven (77%) of the multicomponent studies investigated patient-level strategies, 25 (71%) provider-level strategies, and 12 (34%) practice-level strategies. Some studies incorporated strategies from all three levels, with a maximum of five different strategies used in some studies. Where more than one of these studies investigated the same combination of strategies we conducted meta-analyses.

Three studies looked at the effect of adjunctive counseling and cost-free medications (both patient-level strategies designed to directly increase quit rates) on smoking abstinence rates. The pooled estimate suggested a benefit of providing these two intervention components in addition to standard support (RR 3.09, 95% CI 1.13 to 8.44; 1066 participants; [Analysis 7.1](#)). However, this result should be treated with caution, as we judged all of the studies to be at high risk of bias. There was also substantial statistical heterogeneity ( $I^2 = 75\%$ ), but as the point estimates all indicated benefit we deemed it appropriate to present a pooled estimate. None of the three studies in this analysis was a cRCT and so sensitivity analyses removing individually-randomized studies and adjusting for clustering were not necessary.

Six studies investigated the effects of both adjunctive counseling and provider training in addition to standard care (combining patient- and provider-level strategies intended to directly boost quit rates and increase implementation respectively). The pooled analysis suggested a benefit of these components on smoking cessation rates (RR 2.66, 95% CI 1.27 to 5.57; 11,310 participants; [Analysis 8.1](#)). Again, statistical heterogeneity was high ( $I^2 = 96\%$ ), but in all cases the point estimates of individual studies indicated a benefit of the interventions. A sensitivity analysis removing two studies at high risk of bias found that there was a marked impact on the interpretation of the results, with the CIs indicating that the interventions had the potential to decrease as well as the potential to increase quit rates (RR 2.88, 95% CI 0.89 to 9.28). Sensitivity analyses removing the one individually-randomized controlled trial and adjusting for clustering did not change the interpretation of the results.

We pooled three studies that looked at the effect of both provider training and treatment flow sheets to aid provider decision-making (provider- and practice-level strategies, both aimed at increasing provider implementation of smoking cessation support). The overall result suggested that these combined interventions boosted participant quit rates (RR 1.70, 95% CI 1.27 to 2.27;  $I^2 = 0\%$ ; 2651 participants; [Analysis 9.1](#)). The interpretation of this result remained the same when we removed the single study deemed to be at high risk of bias from the analysis, and the one study that was individually randomized was removed, and

when adjustments were made to control for any clustering effects. Two of the studies in this analysis also examined some of our secondary process outcomes (in this case rates physicians asked about smoking, rates physicians assisted participants to quit by supplying medications and rates physicians arranged follow-ups for participants). In all cases statistical heterogeneity was high ( $I^2 > 90\%$ ). For the arrangement of follow-up we still present the pooled estimate, as for both studies the point estimate was in favor of the intervention ([Analysis 9.4](#)). However, for the asking and assistance rates we have suppressed the pooled estimates, as in both cases the point estimates of one of the studies indicated a benefit of the intervention, whilst the other indicated harm ([Analysis 9.2](#); [Analysis 9.3](#)). All of the outcomes for this comparison were subject to considerable imprecision due to low event rates ( $< 300$  participants for all analyses).

Two studies investigated the effect of a combination of provider training and outreach facilitation (provider- and practice-level strategies, both aimed at increasing provider implementation of smoking cessation support) in addition to and in comparison with standard smoking cessation care. For the smoking abstinence outcome the pooled RR was 1.55 (95% CI 0.95 to 2.52;  $I^2 = 0\%$ ; 2972 participants; [Analysis 10.1](#)). Neither of the studies was judged to be at high risk of bias, or was individually randomized, and adjustments to account for clustering did not affect the interpretation of the result. However the result was imprecise with the confidence intervals indicating the potential for the intervention to result in no improvement in cessation rates, as well as a substantial improvement. The two studies in this analysis also measured a number of the provider performance outcomes, as well as the participant quit attempts outcome. These offered some evidence that the combination of provider training and outreach facilitation strategies resulted in providers assisting more patients to stop smoking by helping them to set a quit date, providing more patients with self-help materials ([Analysis 10.3](#)), and making arrangements to follow up more participants ([Analysis 10.4](#)). The point estimate for the rates providers asked their patients about their smoking was also in favor of provider training plus outreach facilitation, however, there was imprecision, with CIs incorporating the possibility of no effect of the intervention, as well as a potential positive effect ([Analysis 10.2](#)). There was no evidence that provider training and outreach facilitation increased the rate that physicians assisted patients by providing smoking cessation medication ([Analysis 10.3](#)), or increased the number of participants who made a smoking quit attempt ([Analysis 10.5](#)).

### Studies without data

There were five studies that we were unable to include in our syntheses as the relevant data were not presented, or they were not presented in a form that we could use ([Buffels 2006](#); [Canga 2000](#); [RBR-7yx9hd](#); [Salkeld 1997](#); [Sherman 2008](#)). In all cases we tried to contact the authors, but without success. Further information on these studies is available in the [Characteristics of included studies](#) tables.

## DISCUSSION

### Summary of main results

This review includes 81 studies investigating the effectiveness of interventions designed to improve the delivery, success, or both, of smoking cessation treatment in primary care. The

strategies tested across studies varied widely, with some focusing on additional components, such as more intensive counseling or tailored printed materials, to standard support, and some focusing on improving the implementation of standard care, by training providers or offering provider incentives. Most looked at the former rather than the latter. Some studies looked into singular strategies and others looked at the effects of multicomponent interventions. We were able to carry out analyses of studies investigating the following singular strategies when offered in addition to standard or other smoking cessation support: adjunctive counseling; cost-free medications; biomedical feedback; tailored print materials; provider training; provider incentives. We found moderate-certainty evidence that adjunctive counseling (delivered by a health professional other than the primary care physician), cost-free medications and tailored print materials all had a beneficial impact on smoking quit rates. However, there was some evidence that the beneficial impact of adjunctive counseling was only evident when offered in addition to standard smoking cessation care. When adjunctive counseling was offered as part of a multicomponent intervention to increase the delivery of smoking cessation treatment, there was no clear evidence that the isolated effect of adjunctive counseling was favorable. This could be because the multicomponent interventions in the comparison arms raised quit rates substantially on their own, and the relative utility of additional intervention support declines once a certain level of support is already available. There was some limited evidence that providing adjunctive counseling led to a higher provider implementation level, i.e. adjunctive counseling was associated with an increase in the provision of smoking cessation medications and in the arrangement of participant follow-up, and that both adjunctive counseling and cost-free medications increased the likelihood of participants making a quit attempt. There was also low-certainty evidence that biomedical feedback and provider training, and very low-certainty evidence that provider incentives did not have a clear beneficial impact on smoking cessation rates when used as strategies to improve the delivery of tobacco use treatment in primary care. However, there was some evidence of an improvement in some of the markers of physician performance in response to physician training, although not in patient quit attempts.

Among the multicomponent interventions assessed, a wide variety of individual strategies were tested, leading to considerable heterogeneity in our cessation outcomes across studies. However, where more than one study examined the effects of the same combination of strategies in comparison to standard care we were able to conduct meta-analyses. There was some evidence that adjunctive counseling combined with either cost-free medications or provider training, enhanced quit rates when compared to standard care alone. However, these results were limited by small numbers of events and high statistical heterogeneity, and the analyses included a large proportion of studies judged to be at high risk of bias. Two analyses looking at the effect of combining provider training with flow sheets to aid physician decision-making, and with outreach facilitation found no clear evidence that these combinations of strategies increased participant quit rates, but these analyses were again limited by imprecision. There was some limited evidence that these two latter combinations may have a positive impact on the number of patients assisted to make a quit attempt.

A number of studies investigated unique singular strategies or combinations of strategies. We reported on these narratively, with effects differing considerably across intervention types.

## Overall completeness and applicability of evidence

The searches conducted for this review were broad, in our attempt to find any smoking cessation study that took place in primary care. As well as medical databases, we also searched trial registers to identify any ongoing or completed but unpublished registered studies. We therefore feel confident in our search approach. Most of the studies identified in this review were conducted in Europe and the USA, and therefore are specific to these settings. As primary care and standard smoking cessation support differ globally this may affect the applicability of the evidence outside of these settings and may also have contributed to some of the heterogeneity in results.

Most studies were carried out in primary care patients in general, rather than in specific patient groups and so the results should be relevant to the former population; however, the characteristics of these groups are likely to differ across countries due to a variety of factors, including access to treatment services through public or private health care.

More than half of the studies included in this review individually randomized participants rather than being cluster-randomized. As such, these trials test whether interventions or strategies could be effective, for example showing evidence that adjunctive counseling is an effective intervention when delivered by primary care staff to patients in primary care willing to attempt to quit smoking with behavioral support. Individually, randomized studies can tell us very little in addition to the existing reviews of smoking cessation intervention components in the general population (Boyle 2014; Carson 2012; Clair 2019; Fiore 2008; Rice 2017; Stead 2013; Van den Brand 2017). The key issue that needs addressing, however, is interventions to increase the engagement of clinicians in primary care in proactively raising the topic of smoking and delivering effective support when they do so. Making adjunctive counseling available could do this because clinicians may feel that they have something active to offer their patients, motivating them to intervene. Only cluster-randomized trials could address this question, but none have done so. Arguably, the biggest gains in smoking cessation would come from interventions to increase the uptake of effective aids to cessation (pharmacotherapy and behavioral support), and interventions that achieve this through engaging primary care staff are needed. Cluster-randomized trials will be needed to test these interventions.

Studies had to assess long-term smoking abstinence as a criterion for inclusion; most studies were therefore able to contribute cessation data to the relevant comparisons. However, due to the wide range of relevant comparisons the data for each of these were sparse in places. In addition, some studies investigated our secondary process outcomes looking at provider performance and participant quit attempts. However, they were not measured as consistently as smoking abstinence, and in many cases were subject to substantial statistical heterogeneity, imprecision, or both. No clear conclusions could therefore be drawn from these secondary outcomes and their interpretation is likely to change as more evidence becomes available. As we were interested in our secondary outcomes as process outcomes, there were studies that could have contributed to these outcomes that were not included, as they did not measure cessation.

Due to the marked clinical variance in the nature of the strategies assessed in studies comparing multicomponent interventions to standard care in this review, we did not attempt to pool these studies, and we have drawn only a few tentative conclusions on the efficacy of interventions that used a number of different strategies to improve the delivery of smoking cessation treatment. Component network meta-analysis could be used in the future, to investigate the relative effectiveness of relevant intervention strategies and how they could be combined to build effective multicomponent strategies in primary care. This was unfortunately out of scope for this review.

## Quality of the evidence

Of the 81 studies included in this review, we judged 14 to be at low risk of bias for all domains, 44 to be at high risk in one or more domains, and the remainder to be at unclear risk. In many cases, studies were rated at an unclear risk because they did not report key information. In these cases, it is impossible to know whether these studies were at any risk of bias or whether the information was simply not reported. To investigate the potential impact on results of studies that we judged to be at high risk of bias, we removed these studies in sensitivity analyses. This only affected the interpretation of the overall pooled result in a single case; removing the two studies judged to be at high risk of bias in the tailored print materials analysis shifted the CI so that it incorporated the potential for no difference in cessation rates between the intervention and control group, as well as a beneficial effect of tailored print materials.

We assessed the certainty of the evidence by creating summary of findings tables for analyses investigating each of the singular strategies to improve the delivery of smoking cessation care: adjunctive counseling (Summary of findings 1); cost-free medications (Summary of findings 2); biomedical feedback (Summary of findings 3); tailored print materials (Summary of findings 4); provider training (Summary of findings 5); and provider incentives (Summary of findings 6). We carried out GRADE ratings for the smoking cessation outcome for each one.

The certainty of the evidence that adjunctive counseling, cost-free medications and tailored print materials resulted in an increase in long-term smoking quit rates was judged to be moderate. All of these comparisons were downgraded once; for adjunctive counseling and cost-free medications this was due to inconsistency. In the former case, a subgroup analysis resulted in substantial subgroup differences ( $I^2 = 80\%$ ), suggesting that there was only clear evidence of a beneficial effect of adjunctive counseling when it was offered alongside standard care alone, and not when it was offered alongside other strategies to increase the delivery of smoking cessation care. In the latter case, the pooling of eligible studies resulted in moderate unexplained statistical heterogeneity ( $I^2 = 63\%$ ). The evidence for tailored print materials was downgraded once due to risk of bias. Removing the two studies judged to be at high risk of bias from the analysis shifted the CI so that it incorporated the potential for no difference in cessation rates between the intervention and comparator groups.

We judged the evidence that biomedical feedback and provider training did not have a clear benefit for cessation rates to be of low certainty in both cases. In the case of biomedical feedback, we downgraded by two levels due to imprecision. The CIs accompanying the pooled estimate incorporated the possibility

of both an increase and a decrease in quit success rates as a result of providing biomedical feedback in addition to other smoking cessation treatment in primary care. We downgraded the evidence on provider training once due to imprecision and once due to inconsistency. The CI incorporated the potential for both benefit of the intervention and no difference between intervention and control, and unexplained statistical heterogeneity was identified between studies ( $I^2 = 66\%$ ).

Finally, we rated the evidence indicating no clear benefit of provider incentives to improve smoking quit rates in primary care as of very low certainty. The CIs incorporated the potential for the intervention to cause both benefit and harm, and so we downgraded the evidence twice for imprecision. In addition, both of the two included studies were judged to be at high risk of bias, and so we downgraded a third time due to risk of bias. As a result, we have very little confidence in the effect estimate, and the true effect of provider incentives is likely to be substantially different from our estimate of effect.

### Potential biases in the review process

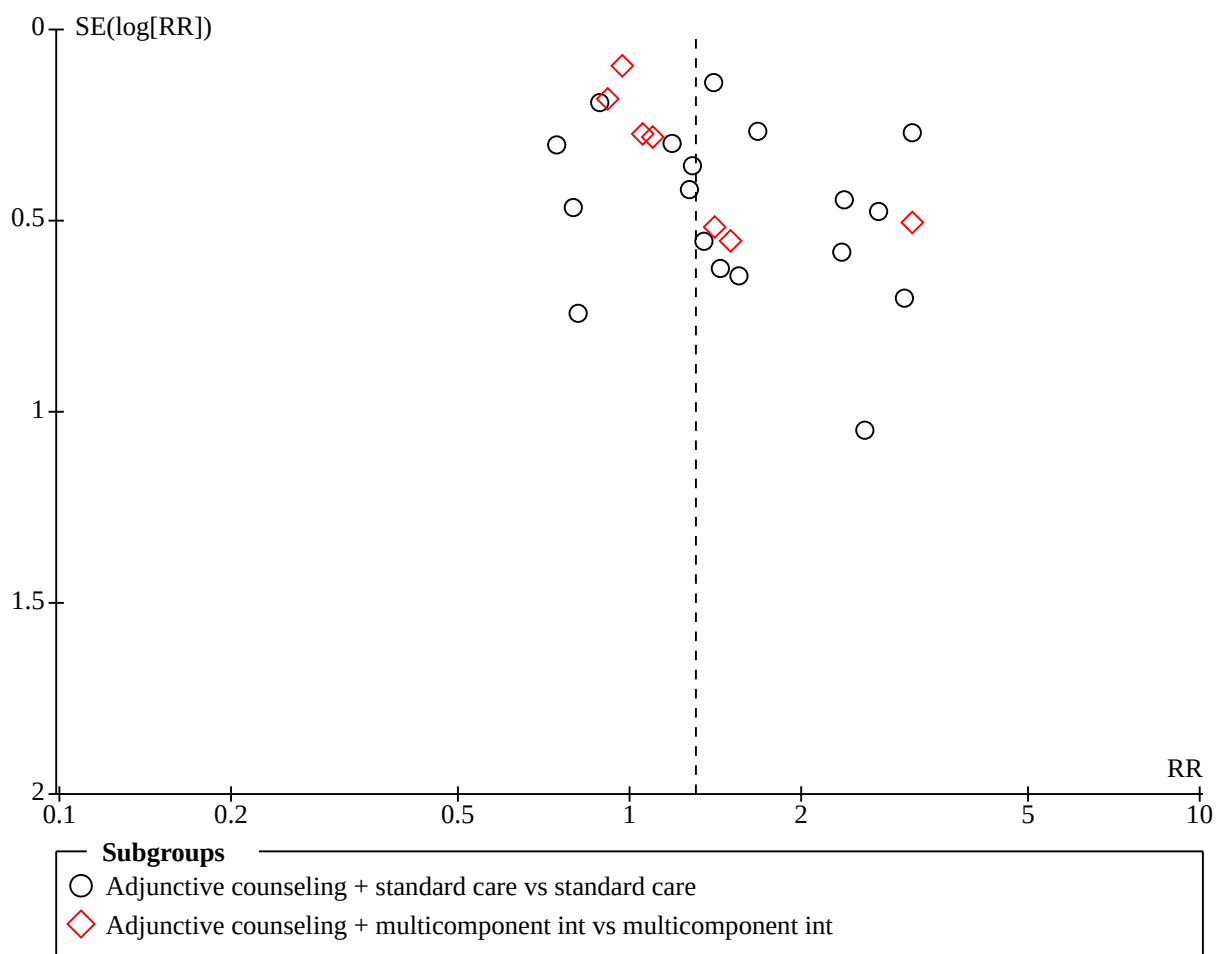
To conduct this review we followed standard Cochrane methods and consider the review process used to be robust. For risk of bias outcome assessment, we followed the standard methods used for all Cochrane Tobacco Addiction Group cessation reviews. We also considered participants lost to follow-up as continuing to smoke, which is standard practice in this field (West 2005). Our

search strategy included the Cochrane Tobacco Addiction Group Specialized Register, which incorporates results from trial registers, and we were able to identify a number of ongoing studies. However, there may be unpublished data that we did not uncover.

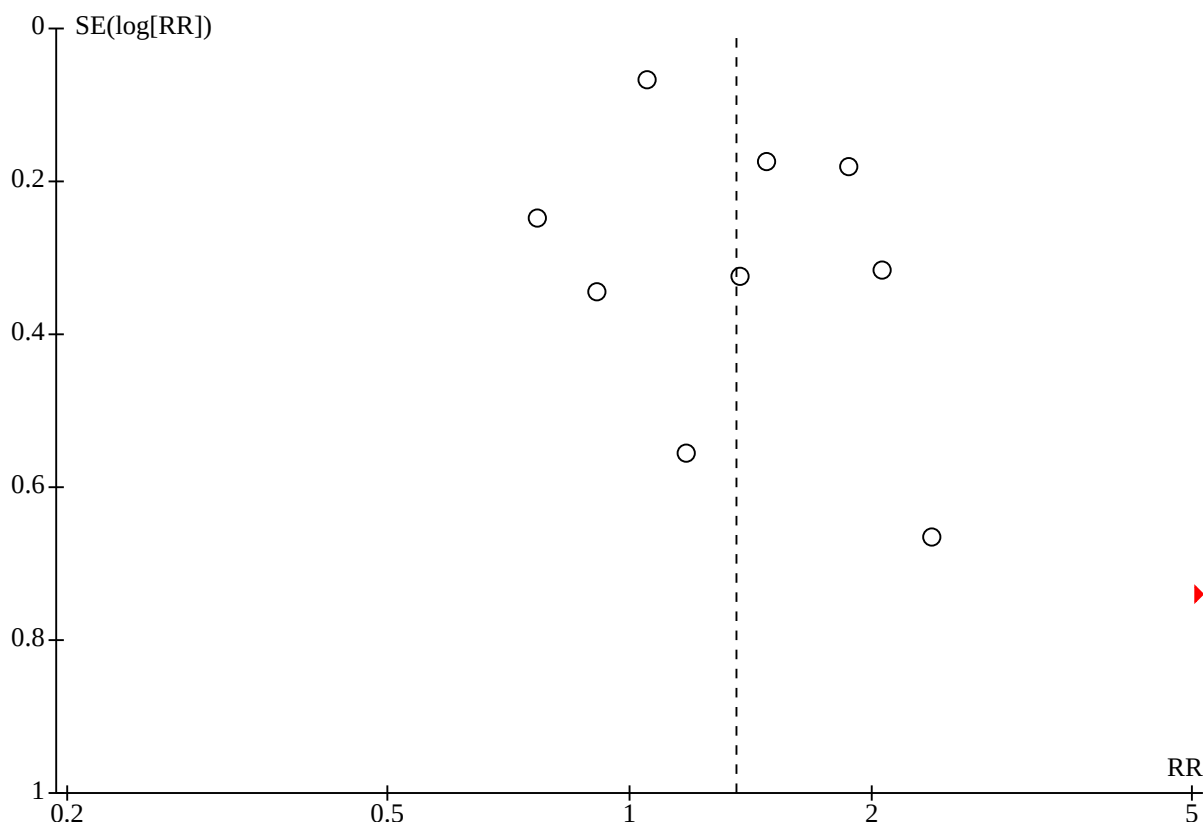
Behavioral smoking cessation interventions are not always well described, and it is possible that we may have misclassified interventions by misinterpreting them, or not identifying all of the strategies used within a study. In addition, comparator groups are often sparsely described in smoking cessation studies, making it difficult to be certain what is meant by the terms 'usual' or 'standard' care. This means that in some cases it was hard to be completely sure what usual or standard care entailed, and this may have differed substantially across studies (Black 2020). As studies took place over multiple different countries, where primary care practices differ, this seems particularly likely to be the case in this instance. However, we categorized the studies as rigorously as possible, given the information provided.

Two of our analyses included 10 or more studies, so we generated two funnel plots to investigate the potential for publication bias. Figure 3 illustrates the funnel plot for the adjunctive counseling comparison and found no evidence of publication bias. Figure 4 illustrates the funnel plot for the analysis of cost-free medications. In this case there was one outlier in the analysis, which resulted in a skewed funnel plot. However, when this study was removed from the analysis it had no impact on the interpretation of the result, and so is not biasing the result.

**Figure 3. Funnel plot of comparison: 1 Adjunctive counseling (patient-level), outcome: 1.1 Long-term abstinence (subgrouped by single vs. multicomponent intervention type).**





**Figure 4. Funnel plot of comparison: 2 Cost-free medications (patient-level), outcome: 2.1 Long-term abstinence.**

Where authors of this review were authors of included studies eligibility decisions, data extraction and risk of bias assessments were made independently by members of the team who were not authors of those studies.

#### Agreements and disagreements with other studies or reviews

This review follows two previous non-Cochrane reviews, examining strategies to influence provider smoking cessation support behaviors in the primary care setting. [Anderson 2004](#) reviewed the literature published up to 2001 and [Papadakis 2010](#) published an update which covered the literature prior to 2009. [Anderson 2004](#) focused solely on educational or practice-level interventions, and found evidence that educational programs for providers did increase smoking quit rates. This impact was higher for practitioners who were still in training than for established practitioners, and could help to explain the difference in our results. A Cochrane Review specifically looking at the effects of smoking cessation training for any health professional also found that quit rates were improved when professionals were trained in providing smoking cessation support ([Carson 2012](#)). It is worth noting that the certainty of the evidence on provider training in this review was low, so there is a possibility that the true effect is substantially different from our estimate of the effect. In addition, our provider implementation outcomes gave some indication that provider training did increase the amount of advice and support that physicians provided, bearing in mind that even brief smoking cessation interventions are effective in primary care

and an increase in smoking quit rates would be expected to follow ([Aveyard 2012](#)). Further research in this area would be beneficial and could also benefit from identifying those physicians that may gain the most from training.

In line with the findings of this review, [Papadakis 2010](#) found that adjunctive counseling significantly increased rates of smoking abstinence. [Papadakis 2010](#) also concluded that multicomponent interventions appeared to be particularly promising. In our review we took the decision not to pool all multicomponent interventions across strategy types, due to considerable clinical variation between studies, and so we are unable to draw conclusions on the effectiveness of multicomponent interventions as a whole. However, identifying all of the relevant studies and summarizing them narratively confirmed substantial heterogeneity in treatment effects, as was found in a similar review by [Martin-Cantera 2015](#). This unexplained variation identifies this as an important area in which to conduct future research to inform primary care practice. Although we could not explore all of the apparent complexity using standard meta-analysis methods, a component network meta-analysis would allow consideration of all the different strategies used, and look at the effects of both combining and comparing different approaches.

As well as [Carson 2012](#), a number of other Cochrane Reviews have looked at the effects of the strategies tested in this review in the wider population. A review that looked at the effect of adding or increasing the intensity of behavioral support for people using smoking cessation medications also found a benefit of

adjunctive counseling (RR 1.15, 95% CI 1.08 to 1.22,  $I^2 = 8\%$ ; 65 studies, 23,331 participants; [Hartmann-Boyce 2019](#)). [Van den Brand 2017](#) investigated healthcare financing systems for increasing the use of tobacco dependence treatment, incorporating the use of both cost-free medications and provider incentives. Like us, they found evidence that financial interventions directed at people who smoked had a favorable effect on abstinence at six months or longer, and no clear effect of provider incentives on smoking quit rates. A review of biomedical risk assessment for smoking cessation ([Clair 2019](#)) and a review of print-based self-help interventions ([Livingstone-Banks 2019](#)) also found similar results to those found in this review, i.e. no clear evidence of a benefit from a variety of biomedical feedback interventions, but a benefit of tailored print materials when provided as an adjunct to brief advice (RR 1.72, 95% CI 1.17 to 2.53;  $I^2 = 10\%$ ; 1839 participants).

## AUTHORS' CONCLUSIONS

### Implications for practice

- There is moderate-certainty evidence that the following patient-level strategies: counseling (provided by health professionals other than the primary care physician); cost-free medications; tailored print materials, may increase smoking quit rates when provided in addition to standard smoking cessation care in primary care practice.
- There is no clear evidence of increased long-term smoking quit rates when biomedical feedback is provided to patients, or when providers receive training or incentives to provide smoking cessation support, in addition to standard care. However this evidence was of low or very low certainty, and there was some evidence that provider training may increase provider implementation of smoking cessation support. Further evidence is therefore likely to change our conclusions.
- Research studies have tested a wide range of strategies and combinations of strategies designed to aid the delivery of tobacco use treatment in primary care. Effects differ substantially across studies and very few studies have investigated the same combinations of interventions; we were therefore unable to draw conclusions on the most effective multicomponent interventions based on the findings of this review.

### Implications for research

- Most studies in this review assessed smoking cessation interventions that have already been tested in the wider population, with similar results. Fewer studies assessed interventions to improve or increase the implementation of these techniques. It is likely that the most effective approach to increasing smoking quit rates in primary care would be to combine the smoking cessation interventions demonstrated to

be effective in this review with effective strategies to improve the implementation of these interventions. Future studies should consider testing this hypothesis.

- Trials are needed to test the effectiveness of interventions to increase the motivation and capacity of primary care staff to support people who smoke to stop. Necessarily, such trials will be cluster-randomized.
- Future studies, examining strategies to improve the delivery of tobacco use over and above standard care should clearly define what standard care incorporates, and provide clear descriptions of all intervention components, as well as the health professionals receiving or delivering the interventions.
- There is contradictory evidence on the effectiveness of physician training on smoking cessation to enhance smoking quit rates. Further research should investigate the circumstances under which this training is most beneficial and how it can be designed to maximize success.
- Researchers planning further evidence synthesis should take into account the substantial variation in the interventions used across the evidence base and consider using component network meta-analysis to assess the effects of individual strategies alone, in comparison with one another, and in combination. This would be particularly useful when trying to inform the content of multicomponent interventions to maximize effectiveness.

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Van Rossem C, Spigt MG, Kleijns JR, Hendricx M, Van Schayck CP, Kotz D. Smoking cessation in primary care: exploration of barriers and solutions in current daily practice from the perspective of smokers and healthcare professionals. *European Journal of General Practice* 2015;**21**(2):111-7. [DOI: [10.3109/13814788.2014.990881](https://doi.org/10.3109/13814788.2014.990881)]

## Verbiest 2017

Verbiest M, Brakema E, Van der Kleij R, Sheals K, Allistone G, Williams S, et al. National guidelines for smoking cessation in primary care: a literature review and evidence analysis. *NPJ Primary Care Respiratory Medicine* 2017;**27**:2. [DOI: [10.1038/s41533-016-0004-8](https://doi.org/10.1038/s41533-016-0004-8)]

## Vogt 2005

Vogt F, Hall S, Marteau TM. General practitioners' and family physicians' negative beliefs and attitudes towards discussing smoking cessation with patients: a systematic review. *Addiction* 2005;**100**(10):1423-31.

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West R, Hajek P, Stead L, Stapleton J. Outcome criteria in smoking cessation trials: proposal for a common standard. *Addiction* 2005;**100**(3):299-303. [DOI: [10.1111/j.1360-0443.2004.00995.x](https://doi.org/10.1111/j.1360-0443.2004.00995.x)]

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World Health Organization. WHO Report on the Global Tobacco Epidemic, 2008: The MPOWER package. Geneva: World Health Organization, 2008.

## World Health Organization 2017

World Health Organisation. WHO report on the global tobacco epidemic, 2017: monitoring tobacco use and prevention policies. World Health Organization: Geneva 2017. [ISBN 978-92-4-151282-4]

## World Health Organization 2020

World Health Organization. WHO report on the global tobacco epidemic 2019: offer help to quit tobacco use. Geneva: WHO, 2019. [ISBN: 978 92 4 151620 4]

## Young 2001

Young JM, Ward JE. Implementing guidelines for smoking cessation advice in Australian general practice: opinions,



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practice. *Cochrane Database of Systematic Reviews* 2015, Issue 3. Art. No: CD011556. [DOI: [10.1002/14651858.CD011556](https://doi.org/10.1002/14651858.CD011556)]

## References to other published versions of this review

\* Indicates the major publication for the study

### Papadakis 2015

Papadakis S, Pipe A, Kelly S, Pritchard G, Wells GA. Strategies to improve the delivery of tobacco use treatment in primary care

## CHARACTERISTICS OF STUDIES

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

#### Aleixandre 1998

##### Study characteristics

Methods	Design: Randomized controlled trial  Setting: Primary care clinic, Spain Recruitment: Clinic & community volunteers
Participants	48 people who smoked (excludes 6 dropouts) 65% female, av. age 36, av. cpd 24 - 27 Therapist: unclear, primary care clinic staff
Interventions	Intervention: participants received 4 x 30-minute sessions of counseling over 4 weeks, which consisted of video, cognitive therapy, social influences and relapse prevention Control: participants received 3 minutes of advice immediately after randomization
Outcomes	Abstinence at 12m (abstinence not defined) Validation: None
Funding Source	Not reported
Author's declarations of interest	Not reported
Notes	Strategy: Adjunctive counseling  Level: Patient  Comparison type: Single component vs. standard care

##### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	High risk	Participants self-reported smoking status in person or by telephone. Intervention group received greater face-to-face contact
Incomplete outcome data All outcomes	Low risk	Loss to follow-up low and similar between arms: 4/25 control, 2/29 intervention

An 2006

### Study characteristics

Methods	<p>Design: Randomized controlled trial</p> <p>Setting: Primary care clinics of Veterans Affairs Medical Centers, USA</p> <p>Recruitment: Invitation letter to primary care patients</p>
Participants	837 people who smoked daily, 26 cpd, av.age 57, 10% F
Interventions	<p>Intervention: participants received behavioral counseling via telephone (7 calls over 2 months) with mailing of smoking cessation medications as clinically indicated. Additional calls were placed over a 12-month period at the discretion of the counselor</p> <p>Control: participants were mailed self-help materials and had continued access to clinical smoking cessation services through their Veterans Affairs Medical Center. All of these had referral-based smoking cessation programs. Program structure varied by site (e.g., number of sessions and group or individual therapy). However, nicotine patches, nicotine gum, and slow-release bupropion were available at all sites</p>
Outcomes	<p>6m sustained abstinence at 12m</p> <p>Validation: None</p> <p>Measures of provider implementation: Assist-Meds, Arrange</p>
Funding Source	Department of Veterans Affairs Health Services Research and Development Service grant SUI 99101-1
Author's declarations of interest	Authors declared that they had no financial conflict of interest.
Notes	<p>Strategy: Adjunctive counseling</p> <p>Level: Patient</p> <p>Comparison type: Single component vs. standard care</p>

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Computer-generated randomization scheme stratified by primary care facility and blocked within sites
Allocation concealment	Low risk	Computer-generated
Blinding of outcome assessors All outcomes	High risk	Smoking status was self-reported. Intervention group had greater face-to-face contact.
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 14.6% (n = 122/838); 13.9% (n = 58/418) in the intervention group and 15.2% (n = 64/420) in the control group were lost to follow-up at 12 months

Aung 2019

### Study characteristics

Methods	<p>Design: randomized controlled trial</p> <p>Setting: 7 primary healthcare settings in rural districts where people often grow tobacco in their gardens and consume home-made hand-rolled cigarettes, Northern Thailand</p> <p>Recruitment: QUOTE: "Recruitment for the study started simultaneously at seven primary health care units within the mobile non-communicable diseases clinic network of Maetha district, Lampang province, in June 2012"</p>
Participants	319 people who smoked, aged between 35 and 80 years and have diabetes and/or hypertension; who had never succeeded in quitting smoking; 28.9% female; median age 64 years
Interventions	<p>Intervention:</p> <p>Participants received: 1) adjunctive counseling; 2) carbon monoxide testing; 3) NRT gum; 4) a family-assisted smoking cessation diary</p> <p>Nurses attended 2 pre-intervention training workshops to deliver the intervention service package</p> <p>Control: participants received brief advice and a reminder to quit by a healthcare worker on subsequent visits to the hospital. Participants were requested to inform the healthcare worker when and if they quit smoking</p>
Outcomes	<p>CO-validated smoking abstinence at 6m (self-reported rates were also collected at 12m, but are not used in our analysis)</p> <p>Validation: CO</p>
Funding Source	Ministry of Education, Japan
Author's declarations of interest	Authors declared that they had no competing interests.
Notes	<p>Strategy: multicomponent (adjunctive counseling, CO monitoring, cost-free medications, provider training)</p> <p>Level: patient, Provider</p> <p>Comparison type: multicomponent vs. standard care</p>

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	QUOTE: "Random sequences are generated by the statistician on the basis of blocks of 24"
Allocation concealment	Low risk	QUOTE: "The allocated arm for each participant will be provided to the study sites PCUs in opaque, sealed envelopes"
Blinding of outcome assessors All outcomes	Low risk	Abstinence was biochemically verified
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 3.8% (n = 12/319); 1.9% (n = 3/160) in the intervention group and 5.7% (n = 9/159) in the control group were lost to follow-up at 12 months

## Aveyard 2003

### Study characteristics

Methods	Design: 4-group randomized controlled trial  Setting: General practices in West Midlands, UK  Recruitment: Mailed invitations to patients of general practices.
Participants	65 practices  2471 people who smoked, 55% F, av.age 41, 20 cpd
Interventions	Intervention 1: participants received self help workbook and three tailored letters  Intervention 2: patients received self-help workbook, three tailored letters, and three telephone calls  Intervention 3: patients received self-help workbook, three tailored letters, and three appointments with a nurse  Control: patients received four standard items of self-help materials
Outcomes	6m sustained abstinence at 12m  Validation: Salivary cotinine <14.2 ng/ml
Funding Source	The health authorities of the West Midlands
Author's declarations of interest	Not reported.
Notes	Strategy: Adjunctive counseling + Tailored print materials  Level: Patient  Comparison type: 1) Single component vs. standard care; 2) multicomponent vs. standard care; 3) active vs. active

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Low risk	QUOTE: "Questionnaires were read optically and the data transferred automatically to the Access database that performed the minimization and controlled the contacts. There was no reason and no way that the clerical assistant running the database could alter the questionnaire reading schedule, which would have altered the allocation of particular individuals"
Blinding of outcome assessors All outcomes	Low risk	Smoking abstinence was biochemically validated
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 39.7% (n = 981/2471); 40.0% (n = 273/683) in the manual group, 43.6% (n = 299/685) in the phone group, 49.2% (n = 203/413) in the nurse group, and 29.9% (n = 206/690) in the control group were lost to follow-up at 12 months

## Bock 2014

### Study characteristics

Methods	Design: Randomized controlled trial  Setting: Inner-city hospital-based primary care clinics, UK  Recruitment: During routine healthcare visits in primary care clinics
Participants	846 adults who smoked randomized to intervention (n = 406) and control (n = 440), 68.7% female, average age 39, cpd of at least 10
Interventions	Intervention: participants received a 45-minute counseling session with health educators and follow-up calls at quit date and 2 weeks, in addition to the standard care (described below)  Control:  Healthcare professionals received training on smoking cessation guidelines and applying the 5 As  Participants received brief advice from their physician and 8 weeks of NRT
Outcomes	7-day PPA at 12m Validation: Expired CO $\leq$ 5 ppm
Funding Source	National Institutes of Health, National Institute on Drug Abuse (R01DA010860)
Author's declarations of interest	Authors declared that they had no conflict of interest.
Notes	Strategy: Provider training, adjunctive counseling, cost-free medication  Level: Patient, provider  Comparison type: Active vs. active

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	The computer used a random number program to assign participants at random to one of two treatment conditions
Allocation concealment	Low risk	Computerised system
Blinding of outcome assessors All outcomes	Low risk	Smoking status was validated by carbon monoxide
Incomplete outcome data All outcomes	High risk	Follow-up rate was low overall (< 50%) : Intervention: 47.3%, Control: 41.4%

## Borland 2008

### Study characteristics

Methods	Design: Cluster-randomized controlled trial with 2 active comparators
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## Borland 2008 (Continued)

	Setting: Primary care practices, Australia
	Recruitment: Conducted in clinic, by GP or practice staff
Participants	1039 adults who smoked, 55.4% female, 17 cpd  45 providers
Interventions	Common components in both groups: GPs were instructed to adhere to the National Guidelines, including a brief assessment of readiness to quit and if relevant, to deal with use of pharmacotherapy  Intervention 1: in-practice management  GPs were encouraged to provide people who smoked with additional information and help to stop smoking. GPs were not precluded from recommending external assistance or from referring participants to the quitline if this was their clinical practice  Intervention 2: referral  GPs were encouraged to offer people who smoked with any interest in quitting referral to the quitline and were provided with a brochure on quitline services. Participants received an introductory call/letter from quitline, followed by up to 2 pre-quitting and 4 post-quitting telephone counseling sessions
Outcomes	≥10m sustained abstinence at 12m  Validation: None  Quit attempts  Measures of provider implementation: Assist, Arrange
Funding Source	National Health and Medical Research Council (284346)
Author's declarations of interest	QUOTE: "RB, JB and NB are employees of The Cancer Council Victoria that runs the quitline service used in this study. None are involved in day to day operations of the service"
Notes	Strategy: Adjunctive counseling  Level: Patient  Comparison type: Single component vs. standard care

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	QUOTE: "GPs were randomised by computer prior to their attendance at an education session"
Allocation concealment	Low risk	Computerised system
Blinding of outcome assessors All outcomes	High risk	Smoking status was self-reported and not validated biochemically. The amount of contact differed between trial arms
Incomplete outcome data All outcomes	Low risk	Attrition rates were under 50% and similar across the groups. The overall loss to follow-up was 33.6% (n = 349/1039); 32.0% (n = 233/728) in the referral group and 37.3% (n = 116/311) in the in-practice group were lost to follow up at 12 months



## Borland 2008 (Continued)

Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization.  QUOTE: "Patients who presented for any reason who were current smokers...were eligible for recruitment"; "Method of patient recruitment did not differ by condition (P=0.79)"
Balanced baseline characteristics? (cluster RCTs only)	Low risk	No significant differences between groups
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	Statistical analyses were performed with Stata, controlling for practice as a clustering variable  QUOTE: "In order to take into account the correlated nature of the data and repeated measures over time, generalized estimating equations were used for a final analysis of outcomes"

## Buffels 2006

### Study characteristics

Methods	Design: Randomized controlled trial  Setting: General practices, Belgium  Recruitment: All patients screened for tobacco use
Participants	16 providers  1206 adults who smoked. Characteristics not described
Interventions	Common components in both groups: general practitioners received a 4-hour training in giving advice to quit smoking  Intervention: <ul style="list-style-type: none"><li>• General practitioners received training in performance and interpretation of spirometry, using a microspirometer</li><li>• Participants received the minimal intervention strategy during a 12-week period; those in a motivation stage 3 or 4 were asked to set a quit day and were offered a follow-up contact as well as NRT and/or bupropion</li><li>• Participants also underwent spirometry and were provided with lung function measurement values and their flow/volume curve</li></ul> Control: participants received the minimal intervention strategy as described above but no spirometry
Outcomes	Smoking abstinence (undefined) at 24m  Validation: Urinary cotinine (completed by 24.2% of self-reported quitters) (cut-off not reported)
Funding Source	Unconditional grant by Voorzorgskas voor Geneesheren, Brussels, Belgium
Author's declarations of interest	Not reported
Notes	Strategy: Provider training, spirometry

## Buffels 2006 (Continued)

Level: Provider, patient

Type: Active vs. active (isolates spirometry)

Unable to extract abstinence data for intervention group from full-text. Attempt was made to contact authors unsuccessfully - unable to include in meta-analysis

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Coin toss
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Unclear risk	Smoking status was validated by urinary cotinine, but response rate was very low.
Incomplete outcome data All outcomes	Unclear risk	No details reported

## Cabezas 2011

### Study characteristics

Methods	<p>Design: Cluster-randomized controlled trial</p> <p>Setting: Primary care practices, Spain</p> <p>Recruitment: Patients who attended primary care practice for any reason and who answered 'yes' to the question: 'Do you currently smoke cigarettes?'.</p>
Participants	<p>176 basic care units within 82 primary care centers</p> <p>2827 people who currently smoked, aged 14 – 85 years. Randomized to intervention (1482) or control (1345). 50% F, average age 43, 20 cpd</p>
Interventions	<p>Common components in both groups: brief advice for patients and training (of different breadth of content for each group) for healthcare professionals</p> <p>Intervention:</p> <ul style="list-style-type: none"> <li>• Healthcare professionals received a 20-hour workshop on smoking cessation interventions</li> <li>• Participants received intervention tailored to TTM stage: <ul style="list-style-type: none"> <li>- Precontemplation or contemplation stage: brief motivational interview and leaflet</li> <li>- Preparation or action who preferred no specific help: brief advice, leaflet, an offer of NRT and 1 follow-up contact</li> <li>- Preparation or action stage requesting specific help: 9 scheduled follow-up visits over 6 months that included behavioral interventions and pharmacological agents</li> </ul> </li> </ul> <p>Control:</p> <ul style="list-style-type: none"> <li>• Healthcare professionals only received the training session in the practical aspects of the protocol</li> </ul>

**Cabezas 2011** (Continued)

- Participants received usual care that included brief smoking cessation advice for diseases related to tobacco consumption

Outcomes	12m continuous abstinence at 24m follow-up  Validation: Expired CO < 10 ppm
Funding Source	Spanish Preventive Services Network (Red de Actividades Preventivas y Promoción de la Salud en Atención Primaria) granted by the Carlos III Health Institute (Instituto de Salud Carlos III) (G03/170 y RD06/0018) and from another project grant (PI021471) in 2002 also from the Carlos III Health Institute
Author's declarations of interest	Authors declared that they had no conflict of interest.
Notes	Strategy: Provider training + adjunctive counseling  Level: Patient + Provider  Comparison type: Multicomponent vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	QUOTE: "the random sequence was generated by an independent statistician who used a computer program and who was blinded to the basic care unit identities"
Allocation concealment	Low risk	QUOTE: "Basic care unit were informed about their allocation after giving final consent to participation"
Blinding of outcome assessors All outcomes	Low risk	Smoking status was validated by carbon monoxide levels
Incomplete outcome data All outcomes	Low risk	Attrition rates were under 50% and similar between groups. The overall loss to follow-up was 44.0% (n = 1244/2827); 43.3% (n = 641/1482) in the intervention group and 44.8% (n = 603/1345) in the control group were lost to follow-up at 2 years
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization.  QUOTE: "...recruited from 2003 to 2005 who consulted a primary care centre for any reason and who answered 'yes' to the question: 'do you currently smoke cigarettes?'"
Balanced baseline characteristics? (cluster RCTs only)	Low risk	Statistically significant differences between the study groups were found in the following variables: stage of change (precontemplation, contemplation, preparation, action), Richmond test, confidence in quitting and readiness to quit (P = 0.001); however, these differences were small and clinically irrelevant
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "...a multi-level analysis was conducted initially. Because no significant variation was found between basic care units, a logistic regression analysis of individual level data using methods for clustered data (adjusting the standard errors for the design effect) was used in order to analyse the intervention as a predictor of smoking cessation"

## Canga 2000

### Study characteristics

Methods	Design: Randomized controlled trial  Setting: 15 primary care centres, 2 hospitals, Spain Recruitment: Identified through practice records
Participants	280 people who smoked with diabetes (incl 16 recent quitters) aged 17 - 84 (133 control, 147 intervention), average age 40.7, 19 cpd, 15% female, did not need to be motivated to quit
Interventions	Intervention: participants received a 40-minute, face-to-face interview on smoking cessation with a nurse and set a quit date. Participants also received self-help materials. All of those who smoked heavily received nicotine patches unless contraindicated. In addition, participants were provided with a follow-up program consisting of 5 contacts: a telephone call the day before the quit date, a follow-up visit 2 weeks after the quit date, a letter 3 weeks after the quit day, a second follow-up visit 2 months after the quit date, and a final evaluation after 6 months.  Control: participants received usual care, established in the Navarre diabetes care program, including advice to quit smoking. No further details reported
Outcomes	> 5m sustained abstinence at 6m  Quit attempts Validation: Urine cotinine < 20 ng/ml
Funding Source	Not reported
Author's declarations of interest	Not reported
Notes	Strategy: Adjunctive counseling  Level: Patient  Comparison type: Single component vs. standard care  It is not possible to separate the primary care settings' data from the secondary care settings' data, and so this study is not included in any meta-analyses

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Computer-generated allocation method
Allocation concealment	Low risk	Sealed envelopes
Blinding of outcome assessors All outcomes	Low risk	Smoking status was validated by urinary cotinine
Incomplete outcome data All outcomes	Low risk	Overall, 0.7% of participants were lost to follow-up

## Carpenter 2020

### Study characteristics

#### Strategies to improve smoking cessation rates in primary care (Review)

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**Carpenter 2020** (Continued)

Methods	Design: Cluster-randomized trial  Setting: 22 primary care clinics in South Carolina, USA  Recruitment: patients identified at routine visits
Participants	1245 adults who smoked, 61% female, average age 50.7, average cpd 15
Interventions	Intervention: cessation advice and brochure with information on quitline, plus a 2-week supply of both nicotine patch and lozenge, with minimal instructions on use Control: cessation advice and brochure with information on quitline  Training given to providers was based on study procedures and standard care
Outcomes	7-day PPA at 6m  Validation: none  Quit attempts
Funding Source	National Institute on Drug Abuse (R01 DA 021619), with additional research support through NIH UL1 TR001450 and K23 DA 045766
Author's declarations of interest	Some authors have received consulting honoraria from Pfizer (does not produce NRT)
Notes	Strategy: Cost-free medication  Level: Patient  Comparison type: Single component vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Stratified randomization lists created at the outset of the study
Allocation concealment	Low risk	Accessible only to the study statistician
Blinding of outcome assessors All outcomes	Low risk	Smoking status was not validated, but both groups had minimal contact, with no difference in the face-to-face contact between the arms
Incomplete outcome data All outcomes	Low risk	At patient level, the number of participants lost was 41.1% (512/1245); 40.3% (263/652) in the standard care group and 42.0% (249/593) in the intervention group, no significant differences between groups, intention-to- treat used to analyze data
Recruitment bias (cluster RCTs only)	Low risk	22/24 clinics approached agreed to participants. Patient participants were affiliated with the practice before randomization. 6 eligible patients did not enrol
Balanced baseline characteristics? (cluster RCTs only)	High risk	Quote: "several baseline variables differed significantly between groups..." and adjusted for in the analysis

**Carpenter 2020** (Continued)

Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	adjustment for clustering was conducted
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**Cobos-Campos 2016**
**Study characteristics**

Methods	Design: Randomized controlled trial Setting: 2 health centres in the Basque Health Service, Spain Recruitment: Identified through EMR and sent invitation letter
Participants	320 adults who smoked, 44% female, average age 45
Interventions	Intervention: participants received health advice from a doctor or nurse, as in the other group, plus re-inforcement text messages to their mobile phones Control: participants received health advice provided by a doctor or a nurse
Outcomes	Continuous abstinence at 12m Validation: Expired CO < 7 ppm
Funding Source	This study was funded by the Departamento de Industria del Gobierno Vasco of the Basque Country under the 2012 Saiotek funding round (reference number SAI012-OA12BF001). This research was also supported by Departamento de Educación, Política Lingüística y Cultura del Gobierno Vasco (IT620-13)
Author's declarations of interest	Authors declared that they had no conflict of interest
Notes	Strategy: SMS messages Level: Patient Comparison type: Single component vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Computer-generated sequence
Allocation concealment	Low risk	QUOTE: "the Bioaraba Research Institute assigned patients to one of the two arms of the trial...after receiving the patient randomization form, and hence research nurse did not know about the treatment group until patient allocation"
Blinding of outcome assessors All outcomes	Low risk	Smoking status was validated by carbon monoxide
Incomplete outcome data All outcomes	High risk	The overall loss to follow-up was 87.5% (n = 280/320); 80.6% (n = 129/160) in the text messaging+health advice group and 94.4% (n = 151/160) in the health advice-only group were lost to follow-up at 12 months



## Cummings 1989a

### Study characteristics

Methods	<p>Design: Cluster-randomized controlled trial</p> <p>Setting: Private practices of internal medicine and family practice, USA</p> <p>Recruitment: Patients were recruited by primary care staff, or by research staff in clinics</p>
Participants	916 adult who smoked (446 control, 470 intervention). 56% F, 20 cpd, av.age 44
Interventions	<p>Intervention:</p> <ul style="list-style-type: none"> <li>Physicians received training on smoking cessation counseling in 3 x 1-hour seminars</li> <li>Practices were provided with free self-help materials, stickers, quit date prescription pads, and posters. Nurses and office staff were coached on the program and supporting materials by a member of the research staff</li> </ul> <p>Control: usual care. No further description on what the usual care entailed was reported</p>
Outcomes	<p>Continuous abstinence at 12m</p> <p>Validation: CO levels (cut-off not defined), salivary cotinine &lt; 30 ng/ml</p> <p>Quit attempts</p> <p>Measures of provider implementation: Ask, Assist-Self-help, Assist-Quit date, Assist-Meds, Arrange</p>
Funding Source	Grant # CA38337 from the National Cancer Institute and by the Henry J. Kaiser Foundation Faculty Fellowship in General Internal Medicine (SRC).
Author's declarations of interest	Not reported.
Notes	<p>Strategy: Provider training + Outreach facilitation</p> <p>Level: Provider + Practice</p> <p>Comparison type: Multicomponent vs. standard care</p>

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Low risk	Smoking status was biochemically validated
Incomplete outcome data All outcomes	Low risk	Attrition rates were under 50% and the difference between groups was less than 20%. The overall loss to follow-up was 22.7% (n = 208/916 survivors); 24.9% (n = 117/470 survivors) in the intervention group and 20.4% (n = 91/446) in the control group were lost to follow-up at 1 year

### Cummings 1989a (Continued)

Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	Balanced between arms
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "Individual patients were the units of analysis for the results we are presenting. A few physicians were clustered by offices and patients were clustered by physician. We tested the effect of this clustering in other analyses in which the sampling variances were adjusted for cluster sampling. These adjustments had no discernible effect on significance levels and did not alter our conclusions. We also analysed our results using the physician as the unit of analysis... These results were similar to the results of the analyses in which patients were the units of analysis. Thus, we omitted them to simplify the presentation"

### Cummings 1989b

#### Study characteristics

Methods	Design: Cluster-randomized controlled trial  Setting: 4 health maintenance organization medical centres, USA  Recruitment: Conducted in clinic waiting rooms
Participants	81 providers  2056 English-speaking people who made a visit to any doctor participating in the study were eligible for inclusion. (1032 control, 1024 intervention), av.age 45, 55% F, 17 cpd
Interventions	Intervention:  <ul style="list-style-type: none"> <li>Physicians received training on smoking cessation counseling in 3 x 1-hour seminars</li> <li>Practices were provided with free self-help materials, stickers, quit date prescription pads, and posters. Nurses and office staff were coached on the program and supporting materials by a member of the research staff</li> </ul> Control: usual care. No further description on what the usual care entailed was reported
Outcomes	Continuous 9m abstinence at 12m follow-up  Validation: CO levels (cut-off not defined), salivary cotinine < 30 ng/ml  Quit attempts  Measures of provider implementation: Ask, Assist-Self-help, Assist-Quit date, Assist-Prescribe, Arrange
Funding Source	Partial support by grant CA38337 from the National Cancer Institute. Dr. Cummings' work was supported in part by the Henry J. Kaiser Foundation Faculty Fellowship in General Internal Medicine
Author's declarations of interest	Not reported
Notes	Strategy: Provider training + Outreach facilitation  Level: Provider + Practice

### Strategies to improve smoking cessation rates in primary care (Review)

**Cummings 1989b** (Continued)

Comparison type: Multi-component vs. standard care

<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Sequence Generation	Low risk	QUOTE: "A computer randomly assigned the units to either the experimental or control group"
Allocation concealment	Low risk	QUOTE: "A computer randomly assigned the units to either the experimental or control group"
Blinding of outcome assessors All outcomes	Low risk	Smoking status was biochemically validated
Incomplete outcome data All outcomes	Low risk	Attrition rates were under 50% and similar between groups. The overall loss to follow-up was 24.7% (n = 507/2056); 23.5% (n = 241/1024) in the intervention group and 25.8% (n = 266/1032) in the control group were lost to follow-up at 1 year
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	Similar between experimental and control groups
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "We tested the effect of this two-stage cluster sampling design by estimating logistic regression models with random effects terms representing the groupings by physician. These adjustments had no substantial effect on comparisons between the experimental and control groups. Therefore, for simplicity, we present the results with the patient as the unit of analysis"

**Dent 2009**

<b>Study characteristics</b>	
Methods	<p>Design: Randomized controlled trial</p> <p>Setting: A Veterans Health Administration, community-based outpatient clinic in the Rocky Mountain region, USA</p> <p>Recruitment: Patients identified through EMR-generated list. Called by pharmacist and invited to participate</p>
Participants	101 adults who smoked 1 or more cigarettes daily for 7 days, were at least somewhat ready to quit in the next 2 weeks ( $\geq 4$ on a 10-point motivational scale), were willing and capable of attending 3 scheduled sessions at the clinic, and were interested in participating in the study. av.age 56, 19 cpd, 93% M
Interventions	<p>Common components in both groups: all people who smoked were referred to a clinical pharmacist via the electronic computerized patient record system. They were offered their choice of immediate-release bupropion tablets or nicotine patch at no cost.</p> <p>Intervention: participants who smoked participated in a face-to-face 3-session group program at the clinic, delivered by the pharmacist and pharmacy students. For follow-up, all participants were instructed to call the clinic for questions or to receive additional support as needed.</p>

## Dent 2009 (Continued)

Control: The pharmacist or pharmacy student used a structured script and delivered 1 timed 5- to-10 minute session to the participants over the telephone that included all the components of standard care recommended by the Clinical Practice Guidelines

Outcomes	Continuous abstinence at 6m  Validation: Urinary cotinine < 0.3 ug/ml
Funding Source	Not reported
Author's declarations of interest	Not reported.
Notes	Strategy: Adjunctive counseling  Level: Patient  Comparison type: Single component vs. standard care

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	QUOTE: "Randomization codes assigned to each participant were computer generated by the study statistician and stratified by sex in blocks of 6"
Allocation concealment	Low risk	QUOTE: "Randomisation codes assigned to each participant were computer generated by the study statistician and stratified by sex in blocks of 6"
Blinding of outcome assessors All outcomes	Low risk	Smoking status was validated by urinary cotinine
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 4.0% (n = 4/101); 2.0% (n = 1/50) in the intervention group and 5.9% (3/51) in the control group were lost to follow-up at 6 months. Therefore, dropout was low and balanced between arms

## Ellerbeck 2009

### Study characteristics

Methods	Design: Randomized controlled trial with 3 active trial arms Setting: Rural primary care practices, Kansas, USA
Participants	726 adults who smoked >10 cpd, randomized to intervention (n = 482) and control (n = 244), 41.5% M; av.age 47.2, 24 cpd
Interventions	Common component in all groups: offer of free pharmacotherapy  Intervention 1: pharmacotherapy only  At baseline and 6, 12, and 18 months, participants received a mailed offer of free pharmacotherapy that consisted of either 6-weeks of nicotine patch (21 mg/d) or 7-weeks of sustained-release bupropion (150 mg twice daily)  Intervention 2: moderate-intensity disease management

**Ellerbeck 2009** (Continued)

Participants received an offer of free pharmacotherapy (as above) with educational support and 2 telephone-based counseling sessions every 6 months

Intervention 3: high-intensity disease management

Participants received an offer of free pharmacotherapy (as above) with educational support and 6 telephone-based counseling sessions every 6 months

Outcomes	7-day PPA at 24m  Validation: Salivary cotinine level < 15 ng/mL in a mailed saliva sample. Because of resistance by participants to providing salivary samples at month 12, validation by proxy report from a significant other at month 24 was used for quitters who did not return a salivary sample. The validated quit rate at 24m is a mixture of the 2 approaches
Funding Source	National Cancer Institute (grant R01-101963). Study medication was provided by GlaxoSmithKline
Author's declarations of interest	Authors declared that they had no conflict of interest
Notes	Strategy: Adjunctive counseling + cost-free medication  Level: Patient  Comparison type: Active vs. active (isolating adjunctive counseling)

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	QUOTE: "randomization occurred at the participant level. A computer-generated random-number table was used to generate allocation cards in blocks of 24, with allocation equally distributed across treatment groups"
Allocation concealment	Low risk	QUOTE: "to conceal allocation, we placed these cards in sequentially numbered, opaque, sealed envelopes"
Blinding of outcome assessors All outcomes	Unclear risk	Smoking status was biochemically validated, but there was a low return rate and so proxy report was also used
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 17.3% (n = 130/750); 13.2% (n = 33/250) in the PM group, 20.0% (n = 50/249) in the MDM group and 18.7% (n = 47/251) in the HDM group were lost to follow-up at 24 months

**Fu 2014**
**Study characteristics**

Methods	Design: Randomized controlled trial  Setting: Veterans Affairs primary care sites, USA  Recruitment: Identified through VA's EMR Health Factors Dataset at each participating site
Participants	6400 veterans who were currently smoking, average age 56, average cpd 18



## Fu 2014 (Continued)

Interventions	Intervention: participants received proactive outreach (mailed invitation materials followed by telephone outreach) and offer of choice of smoking cessation services (telephone care or in-person care)  Control: participants had access to tobacco treatment services from their VA hospital
Outcomes	6m prolonged abstinence at 12m  Validation: None
Funding Source	Funded by the Department of Veterans Affairs (VA) Health Services Research and Development (HSR&D)
Author's declarations of interest	Authors declared that they had no conflict of interest
Notes	Strategy: Proactive mailings  Level: Patient  Comparison type: Single component vs. standard care

### **Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	High risk	Smoking abstinence was self-report and contact with the study team was differential across study arms
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 34.0% (n = 1741/5123); 35.9% (n = 905/2519) in the intervention group and 32.1% (n = 836/2604) in the control group were lost to follow-up at 12 months

## Gilbert 2013

### **Study characteristics**

Methods	Design: Randomized controlled trial  Setting: General practices from the MRC General Practice Research Framework, UK  Recruitment: People who smoked, identified using the computer system in participating practice
Participants	6697 adults who smoked, 56% F, av.age 44.6, 17.8 cpd
Interventions	Intervention: participants received non-tailored information plus a computer-tailored advice report based on the information obtained in the baseline assessment questionnaire, accompanied by a letter from the GP endorsing the information contained in the report. Participants were sent a follow-up assessment 1 month after baseline, and received a tailored progress report generated from these additional data  Control: participants received standard, non-tailored information (the NHS 'Stop Smoking Start Living' booklet)

**Gilbert 2013** (Continued)

Outcomes	3m prolonged abstinence at 6m  Validation: None  Quit attempts
Funding Source	The trial was supported by funding from Cancer Research UK
Author's declarations of interest	Authors declared that they had no conflict of interest
Notes	Strategy: Tailored print materials  Level: Patient  Comparison type: Single component vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Computer-generated.
Allocation concealment	Low risk	QUOTE: "These blocked randomisation codes were generated externally and given to an independent administrator in sealed envelopes upon receipt of completed questionnaires"
Blinding of outcome assessors All outcomes	Low risk	Smoking abstinence was self-reported, but person-to-person contact was similar between groups
Incomplete outcome data All outcomes	Low risk	The follow-up response rate, based on the analyzed sample (n = 6697), was 78.8% (2644) and 75.7% (2530) in the control and intervention groups respectively

**Gilbert 2017**
**Study characteristics**

Methods	Design: Randomized controlled trial  Setting: General practices in England, UK  Recruitment: People who were currently smoking were identified from medical records in participating practices and sent an invitation letter
Participants	4384 adults who smoked, 50% M, av. age 49, av. cpd 16  99 general practices in 18 Stop Smoking Service areas
Interventions	Intervention: participants received a brief personalized and tailored letter sent from the GP that included information specific to the participant and a personal invitation to attend a "come and try it" taster session for cessation services  Control: participants received a standard generic letter from the GP practice, which advertised the local SSS and asked the participant to contact the service to make an appointment to see an adviser
Outcomes	3m prolonged abstinence at 6m

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**Gilbert 2017** (Continued)

Validation: Salivary cotinine level &lt; 12 ng/mL

Quit attempts

Funding Source	This study was funded by the National Institute for Health Research Health Technology Assessment Programme (project number 08/58/02).
Author's declarations of interest	QUOTE: "Irwin Nazareth is a member of the National Institute for Health Research Health Technology Assessment Funding Commissioning Panel.
Notes	Strategy: Tailored materials  Level: Patients  Comparison type: Single component vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Computer-generated permuted block randomization
Allocation concealment	Low risk	Allocated by computer after participant consented
Blinding of outcome assessors All outcomes	Low risk	Abstinence was biochemically validated. Participant contact was minimal in both groups.
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 23.1% (n = 1012/4384); 23.4% (n = 616/2636) in the intervention group and 22.7% (n = 396/1748) in the control group were lost to follow-up at 6 months

**Girgis 2011**
**Study characteristics**

Methods	Design: Randomized controlled trial  Setting: General practices in South West Sydney, Australia  Recruitment: Asked by practice receptionists to complete a health questionnaire
Participants	213 adults who smoked of Arabic background, av.age 38, 48% M, 18 cpd
Interventions	Intervention: participants received an offer from their GP of free referral to telephone-based counseling by bilingual Arabic-speaking registered psychologists in the language of choice (Arabic or English) at times convenient to the participant. Within 2 weeks, 1 of the psychologists telephoned participants and offered counseling based on the '5As' approach  Control: participants received the GP's usual smoking cessation care. No further details on the usual care reported
Outcomes	24h PPA at 12m  Validation: None  Secondary outcomes: Quit attempts

## Girgis 2011 (Continued)

Funding Source	National Health and Medical Research Council project grant awarded to SG, NAZ and JEW (grant number 295000)	
Author's declarations of interest	Authors declared that they had no conflict of interest	
Notes	Strategy: Adjunctive counseling  Level: Patient  Comparison type: Single component vs. standard care	
<b><i>Risk of bias</i></b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	QUOTE: "...an unobtrusive mark visible only to the general practitioners, to convey group randomisation. General practitioners scanned the questionnaire to determine smoking status and group allocation". No further details reported.
Blinding of outcome assessors All outcomes	Unclear risk	Smoking abstinence was self-report. It is unclear whether 1 group had greater number of person-to-person contact than the other
Incomplete outcome data All outcomes	High risk	The overall loss to follow-up was 39.6% (n = 161/407); 44.6% (n = 95/213) in the intervention group and 34.0% (n = 66/194) in the control group were lost to follow-up at 12 months. But 52.6% (n = 112/213) of the participants who were allocated to intervention did not consent to the intervention. Also, of the 101 participants who consented, 54.5% (n = 55/101) did not receive counseling as they either refused, had already quit smoking, or could not be contacted. Therefore, 46 people in the intervention group actually received counseling and only 8 of those completed the 6 telephone calls

## Haas 2015

### Study characteristics

Methods	Design: Randomized controlled trial  Setting: General practices in greater Boston, USA  Recruitment: Eligible patients identified through electronic medical record and received a mailed invitation letter
Participants	707 adults who smoked, living in a low or moderate household income census tract. (399 intervention, 308 control) av.age 50, 68% F, 15 cpd
Interventions	Intervention: participants received up to 4 counseling calls, a 6-week supply of NRT patch, access to community-based referrals to address sociocontextual mediators of tobacco use, and integration of all components into their normal health care through the electronic health records system  Control: participants received usual care. No further details on the usual care reported
Outcomes	7d PPA at 9m

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**Haas 2015** (Continued)

Validation: None

Funding Source	Lung Cancer Disparities Center at the Harvard School of Public Health (funded by National Cancer Institute grant P50 CA148596) and the Harvard Catalyst and from the Harvard Clinical and Translational Science Center (funded by National Institutes of Health [NIH] grant 1 UL1 RR025758-01 and financial contributions from participating institutions)
Author's declarations of interest	Authors declared that they had no conflict of interest
Notes	Strategy: Adjunctive counseling + cost-free medications  Level: Patient  Comparison type: Multicomponent vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	High risk	QUOTE: "Randomisation was performed in batches based on the date of the clinic visit..."
Allocation concealment	High risk	QUOTE: "...The first patient randomised in each batch was randomised to intervention status; batches with an odd number of participants therefore resulted in an imbalance in the size of the intervention and control groups"
Blinding of outcome assessors All outcomes	High risk	Smoking status was self-report and there was variable contact between groups
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 34.2% (n = 242/707); 36.1% (n = 144/399) in the intervention group and 31.8% (n = 98/308) in the control group were lost to follow-up at 9 months

**Hilberink 2011**
**Study characteristics**

Methods	Design: 3-group cluster-randomized controlled trial  Setting: Primary care, The Netherlands  Recruitment: Patients with COPD identified from medical records in participating practices
Participants	667 patients with COPD (148 control, 243 intervention 1, 276 intervention 2), age > 35 years, av. age 60, 16 cpd, 49% M
Interventions	<i>Intervention 1:</i> counseling strategy, recommendation of NRT  • The general practice team received a 4-hour group training session about chronic obstructive pulmonary disease and smoking cessation, and 3 visits by an outreach visitor for additional individual support  • Participants received a leaflet especially developed for people with chronic obstructive pulmonary disease who smoked, a videotape, self-efficacy enhancing information, information about NRT, proactive telephone calls



**Hilberink 2011** (Continued)

*Intervention 2:* counseling strategy, recommendation of NRT, advice to use bupropion-SR

- The general practice team received a 4-hour group training session about chronic obstructive pulmonary disease and smoking cessation, and 3 visits by an outreach visitor for additional individual support
- Participants received a leaflet especially developed for people with chronic obstructive pulmonary disease who smoked, a videotape, self-efficacy enhancing information, information about NRT, proactive telephone call, and advice to use bupropion-SR

Control: usual care consisting of periodic regular check-ups and chronic obstructive pulmonary disease information

Outcomes	PPA at 12m  Validation: Urinary cotinine < 50 ng/mL
Funding Source	Financed by the Dutch Asthma Foundation, Netherlands Organization for Health Research and Development (ZonMW), and Pharmacia
Author's declarations of interest	Authors declared that they had no conflict of interest
Notes	Strategy: Provider training, outreach facilitation, adjunctive counseling  Level: Patient + Provider + Practice  Comparison type: Multicomponent vs. SC

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Low risk	Smoking status was biochemically validated
Incomplete outcome data All outcomes	Low risk	Attrition rates were under 50% and similar between groups. The overall loss to follow-up was 18.7% (n = 130/697); 3.6% (n = 9/252) in 'counseling + NRT' group, 5.2% (n = 15/291) in 'counseling+NRT+prescription of bupropion' group, 3.9% (n = 6/154) in the control group were lost to follow-up at 1 year.
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization.
Balanced baseline characteristics? (cluster RCTs only)	Low risk	Groups were balanced
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "We used multilevel analyses to test treatment effects because of the study's hierarchical structure..."

## Hollis 1993

**Study characteristics**

Methods	Design: Randomized controlled trial with 4 active trial arms Setting: 2 large primary care clinics, USA Recruitment: Recruited in practice by receptionists
Participants	2707 adults who smoked, av. age 40, 57% F, 18 cpd
Interventions	<p><i>Intervention 1:</i> participants received physician advice, carbon monoxide assessment, a quit-smoking video, a quit kit (gum, toothpicks and cinnamon sticks), self-help materials, mailed newsletters and a follow-up call at 2 - 4 weeks from a counselor. They were encouraged to set a quit date</p> <p><i>Intervention 2:</i> participants received physician advice, carbon monoxide assessment, a video encouraging them to attend a smoking cessation support group, self-help materials, coupon for quit-smoking group, postcards reminding them of group meeting times</p> <p><i>Intervention 3:</i> participants received the support offered to the control group and intervention 2 group combined</p> <p><i>Control:</i> participants received a 30-second advice message and a pamphlet</p>
Outcomes	7d PPA at 3m and 12m Validation: Salivary cotinine
Funding Source	Public Health Service Grant 1P01-CA44648 from the National Cancer Institute.
Author's declarations of interest	Not reported.
Notes	Strategy: Adjunctive counseling + CO monitoring Level: Patient Comparison type: Multicomponent vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	High risk	QUOTE: "two random digits contained in the patient's health record number were used to assign patients..."
Allocation concealment	High risk	QUOTE: "two random digits contained in the patient's health record number were used to assign patients..."
Blinding of outcome assessors All outcomes	Low risk	Smoking abstinence was biochemically validated
Incomplete outcome data All outcomes	Unclear risk	Response rates did not differ between groups. Rates not reported.

## Hoving 2010

### Study characteristics

Methods	Design: Randomized controlled trial  Setting: Dutch pharmacies and primary care clinics, The Netherlands  Recruitment: Passively recruited through baseline questionnaires in waiting rooms
Participants	474 adults who smoked (from GP sample) motivated to quit smoking within 6 months. 59% F, av. age 42, av. cpd 22
Interventions	Intervention: participants received a tailored letter based on responses to a questionnaire. Messages addressed perceived advantages and disadvantages of smoking cessation and anticipated difficult situations to refrain from smoking. Additionally, the tailored letter was personalized by including individual information. All personally relevant messages were then combined into a 5 - 7 page letter  Control: participants received a thank-you letter after completing a questionnaire
Outcomes	Continuous abstinence at 6m  Validation: None  Quit attempts
Funding Source	Not reported
Author's declarations of interest	Not reported.
Notes	Strategy: Tailored print material  Level: Patient  Comparison type: Single component vs. standard care

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	High risk	QUOTE: "Smokers were randomised based on the colour coding on their questionnaire..."
Allocation concealment	High risk	QUOTE: "Smokers were randomised based on the colour coding on their questionnaire..."
Blinding of outcome assessors All outcomes	Low risk	Smoking status was self-report, but contact was low, reducing potential risk of bias
Incomplete outcome data All outcomes	Unclear risk	No details on the number of participants lost to follow-up in the control group reported

## Hughes 1991

### Study characteristics

Methods	Design: Randomized controlled trial with 3 active trial arms
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### Strategies to improve smoking cessation rates in primary care (Review)

## Hughes 1991 (Continued)

Setting: 2 rural family practices, USA

Recruitment: Conducted in practice waiting room

Participants	106 adults who smoked who had never used NRT gum, did not need to be motivated to quit, 62% M, av.age 37, 26 cpd
Interventions	<p><i>Intervention 1:</i> participants received 10 minutes of brief advice from physician, instruction to use free nicotine gum and a stop-smoking booklet</p> <p><i>Intervention 2:</i> participants received 10 minutes of brief advice from physician, instruction to use cost-reduced NRT gum (USD 6/box) and a stop-smoking booklet.</p> <p><i>Intervention 3:</i> participants received 10 minutes of brief advice from physician, instruction to use nicotine gum (to purchase at a full price of USD 20/box) and a stop-smoking booklet</p>
Outcomes	<p>Sustained abstinence at 12m</p> <p>Validation: No biochemical validation. Observers were used to verify cessation</p> <p>Quit attempts</p>
Funding Source	Grant (DA-04066) and Research Scientist Development Award (DA-00109) from the National Institute on Drug Abuse. Merrell-Dow Research Institute provided nicotine gum
Author's declarations of interest	Not reported
Notes	<p>Strategy: Cost-free medications</p> <p>Level: Patient</p> <p>Comparison type: Single component vs. standard care</p>

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Low risk	QUOTE: "After the advice had been given, the physician opened a sealed envelope and signed a prescription that indicated the price group to which the smoker had been assigned"
Blinding of outcome assessors All outcomes	Low risk	Observers were used to verify cessation and contact matched between trial arms
Incomplete outcome data All outcomes	Unclear risk	No details reported

## Irizar Aramburu 2013

### Study characteristics

Methods	<p>Design: Randomized controlled trial</p> <p>Setting: Primary care practices in Gipuzkoa, Spain</p>
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**Irizar Aramburu 2013** (Continued)

Recruitment: Randomly selected from electronic medical record

Participants	335 adults who smoked, 52% F, av. age 53.6, av. cpd not reported
Interventions	Intervention: participants received a spirometry test delivered by a nurse and the same brief anti-smoking intervention as the control group Participant also received a short explanation of the spirometry results  Control: participants received brief anti-smoking intervention
Outcomes	7-day PPA at 12m  Validation: Expired CO < 10 ppm
Funding Source	International Centre of Research Excellence in Chronicity, Kronikgune and the Department of Health of the Basque Government
Author's declarations of interest	Authors declared that they had no conflict of interest
Notes	Strategy: Spirometry  Level: Patient  Comparison type: Single component  Some information obtained from study author

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	The randomization sequence was generated by computer and kept in the research unit
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Low risk	Smoking status was validated by carbon monoxide
Incomplete outcome data All outcomes	Unclear risk	No details reported

**Jamrozik 1984**
**Study characteristics**

Methods	Design: Randomized controlled trial with 3 active trial arms  Recruitment: Conducted in clinic waiting room  Setting: 6 primary care practices, UK
Participants	2110 people who smoked, over the age of 16, being seen for a medical appointment, av. age not reported, av. cpd not reported
Interventions	<i>Intervention 1:</i> participants received verbal advice from their doctor and a self-help booklet

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## Jamrozik 1984 (Continued)

*Intervention 2:* participants received verbal advice from their doctor, a self-help booklet and demonstration of carbon monoxide levels

*Intervention 3:* participants received verbal advice from their doctor, a self-help booklet and a card with information on how to contact a health visitor for further help with quitting smoking

*Control:* no intervention

Outcomes	7-day PPA at 12m  Validation: Urinary cotinine < 100 ng/ml in a subsample of participants (Results reported are for self-report)  Quit attempts - but unable to calculate data needed for analysis from paper
Funding Source	Health Education Council
Author's declarations of interest	Not reported
Notes	Strategy: CO monitoring  Level: Patient  Comparison type: Single component vs. standard care

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	High risk	According to day of attendance
Allocation concealment	High risk	Based on day of attendance, could have been foreseen
Blinding of outcome assessors All outcomes	Low risk	Smoking status was only validated in a subsample of participants by urinary cotinine; but contact was matched between trial arms, thereby minimizing risk of bias
Incomplete outcome data All outcomes	Unclear risk	72% returned 1-year follow-up questionnaire. No further details reported

## Joseph 2004

### Study characteristics

Methods	Design: Cluster-randomized controlled trial  Setting: 20 Veterans Affairs Medical Centers, USA  Recruitment: Calls to patients who visited primary care provider in the past 6 weeks
Participants	Pre-intervention 4254 adults who smoked who had visited their primary care provider in the past 6 weeks. av.age 64, 95% M, av. cpd not reported  Post-intervention 1424 adults who smoked who had visited their primary care provider in the past 6 weeks. av.age 64, 97% M, av. cpd not reported

**Joseph 2004** (Continued)

575 (280 in the intervention group and 295 in the control) participants made up the cohort of people who smoked and who were contacted both pre-and post-intervention

Interventions	<p>Intervention:</p> <ul style="list-style-type: none"> <li>• Providers (the site-based principal investigator and 1 other key advocate from each site) received a 2-day training meeting</li> <li>- Emphasis on options for increasing identification of people who smoked in the computerized patient record system</li> <li>- Promotion of treatment in the primary care setting rather than use of referral-based care</li> <li>- Encouragement of removal of formulary restrictions to prescription of smoking-cessation aids and provision of materials to address Pharmacy and Therapeutics Committees</li> <li>• Sites were visited by the interventionist for 2 or 3 days to provide academic detailing of the implementation strategies that was sensitive to local hurdles</li> </ul> <p>Control: no information provided on the care this group received or did not receive</p>
Outcomes	<p>PPA at 12m</p> <p>Validation: None</p> <p>Quit attempts</p> <p>Measures of provider implementation: Ask, Advise, Assist and Assist-Meds</p>
Funding Source	Grant from the Veterans Administration Health Services Research and Development Service: CPG 97-039
Author's declarations of interest	Not reported.
Notes	<p>Strategy: Provider training + EMR prompts + outreach facilitation</p> <p>Level: Provider + Practice</p> <p>Comparison type: Multicomponent vs. standard care</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported.
Allocation concealment	Unclear risk	No details reported.
Blinding of outcome assessors All outcomes	Unclear risk	Smoking status was self-reported and the number of contacts in the control group is not reported
Incomplete outcome data All outcomes	Low risk	At site level, there was no loss to follow-up (n = 0/20) at 1 year. At patient level, it was not the intention of this study to follow up the same participants from the outset. Patients were randomly selected at baseline and at 1 year and surveyed.
Recruitment bias (cluster RCTs only)	Unclear risk	Participants were affiliated with the practice before randomization.

## Joseph 2004 (Continued)

QUOTE: "...among a sample randomly selected from patients who had seen their primary care provider within 6 weeks..."

Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "There were no significant differences between subject characteristics in the 2 treatment groups"
Adjustment for clustering in analysis? (cluster RCTs only)	High risk	No adjustment for cluster nature of data reported

## Juarranz 1998

### Study characteristics

Methods	Design: Randomized controlled trial Setting: Primary care centre, Spain Recruitment: By telephone from healthcare centre lists
Participants	195 adults who smoked (aged 16 - 65), 48% female, av.age 37, 23 cpd
Interventions	Intervention: participants received the following from their doctor and nurse: - Brief standardized advice (3 - 5 minutes) about smoking cessation - An instruction booklet - Nicotine patches - A follow-up phone call 2 days after the quit date - Additional visits at 2 weeks, 3 months and 6 months Control: participants received usual care. No further details reported
Outcomes	Continuous abstinence at 6m Validation: Expired CO < 8 ppm
Funding Source	Not reported
Author's declarations of interest	Not reported
Notes	Strategy: Adjunctive counseling + cost-free medications Level: Patient Comparison type: Multicomponent vs. standard care

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	High risk	Potential participants were ranked randomly in a list, then assigned alternately from list

**Juarranz 1998** (Continued)

Allocation concealment	High risk	Assigned from open list
Blinding of outcome assessors All outcomes	Low risk	Smoking status was validated by carbon monoxide
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 4.9% (n = 10/205); 5.9% (n=6/102) in the intervention group and 3.9% (n = 4/103) in the control group were lost to follow-up at 6 months.

**Kalkhoran 2018**
**Study characteristics**

Methods	Design: Randomized controlled trial  Setting: Primary care network, USA Recruitment: interactive voice response technology was used for participant recruitment; contact information was identified from electronic health record
Participants	233 people who smoked, av. age 53, av. cpd 15
Interventions	<i>Intervention 1:</i> participants received brief counseling provided by a health center-based Tobacco Care Coordinator, coordinated medications with primary care physicians, and a referral to additional care (in-person, phone call or text)  <i>Intervention 2:</i> participants were transferred directly to a community-based Quitline for counseling and a free sample of nicotine replacement therapy  <i>Control:</i> participants were given the state quitline number and advised to contact their primary care physician for assistance to quit smoking. Each practice had a certified tobacco treatment specialist available 1 day per week to provide free in-person individual cessation support. Primary care physicians could also fax a referral to the quitline
Outcomes	30-day PPA at 6m Validation: None  Measures of provider implementation: Assist-counseling, Assist-medications
Funding Source	Pfizer Independent Grants for Learning and Change
Author's declarations of interest	QUOTE: "Drs. Rigotti and Kalkhoran receive royalties from UpToDate, Inc. Dr. Rigotti has been an unpaid consultant to Pfizer, Inc. and a paid consultant to Achieve Life Sciences. No other authors have any conflicts of interest to disclose"
Notes	Strategy: Adjunctive counseling, cost-free medications  Level: Patient  Comparison types: Multicomponent vs. standard care; single component (adjunctive counseling) vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Random-number generator

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**Kalkhoran 2018** (Continued)

Allocation concealment	Low risk	Implemented by interactive voice response
Blinding of outcome assessors All outcomes	High risk	Smoking status was self-report, and contact was differential between arms
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 45.4% (n = 106/233); 48.1% (n = 38/79) in the internal care coordination group, 47.4% (n = 37/78) in the external community referral group and 40.8% (n = 31/76) in the usual care group were lost to follow-up at 6 months

**Katz 2004**
**Study characteristics**

Methods	Design: Cluster-randomized controlled trial  Setting: Community-based primary care clinics in southern Wisconsin, USA  Recruitment: Patients willing to complete exit interviews
Participants	Pre-intervention: 1022 adults who smoked (> 10 cpd) (509 control, 513 intervention) av. age 42, 46% M, 17 cpd  Post-intervention: 1141 adults who smoked (> 10 cpd) (499 control, 642 intervention) av. age 40, 45% M, 17 cpd
Interventions	Intervention: <ul style="list-style-type: none"><li>• Clinicians received training tutorial on smoking cessation, and group and confidential individual feedback on whether they had assessed smoking status and whether they had provided cessation counseling</li><li>• A modified vital signs stamp was imprinted on each patient's encounter form for the clinical visit</li><li>• Participants were offered free NRT patches and/or proactive telephone counseling</li></ul> Control: usual care <ul style="list-style-type: none"><li>• Physicians were provided with general information about the Agency for Healthcare Research Quality guideline evaluation trial</li><li>• Participants who smoked were identified and counseled at the discretion of the clinical staff; neither intake clinicians nor primary care clinicians were instructed to provide (or to not provide) smoking cessation counseling</li></ul>
Outcomes	Repeated PPA at 2m and 6m  Validation: None (salivary cotinine validation was attempted but abandoned due to distribution and response issues)  Quit attempts  Measures of provider implementation: Ask, Advise, Assess, Assist-Self-help, Assist-Quit date, Assist-Meds
Funding Source	Funded by a Preventive Oncology Academic Award (K07-CA78540) from the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, with supplemental support

**Katz 2004** (Continued)

from the University of Wisconsin Comprehensive Cancer Center and the University of Wisconsin Medical School. GlaxoSmithKline donated transdermal nicotine patches for use in this trial

Author's declarations of interest	QUOTE: "M.C.Fiore has served as a consultant for, has given lectures sponsored by, or has conducted research sponsored by GlaxoSmithKline (Research Triangle Park, NC) and was appointed by the University of Wisconsin to a named Chair made possible by an unrestricted gift to the university from GlaxoSmithKline"
Notes	Strategy: Provider training + Vital signs stamp + Cost-free medications + Adjunctive counseling + Audit & feedback  Level: Patient + Provider + Practice  Comparison type: Multicomponent vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	QUOTE: "...the project statistician used a random number generator to randomly assign each clinic to receive either the intervention or usual care"
Allocation concealment	Unclear risk	QUOTE: "...we enrolled 2163 consecutive adult patients who smoked...". No further details reported.
Blinding of outcome assessors All outcomes	High risk	Smoking abstinence rates were not biochemically validated and contact with patients varied between arms
Incomplete outcome data All outcomes	Low risk	Attrition rates were under 50% and similar across the groups. The overall loss to follow-up was 9.6% (n = 208/2163); 10.2% (n = 118/1155) in the intervention group and 8.9% (n = 90/1008) in the control group were lost to follow-up at 6 months.
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "No statistically significant differences in sociodemographic characteristics (except educational level), self-rated health status, and cigarette or alcohol use"
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	Constructed 3-level hierarchical logistic regression models of performance and cessation outcomes across the test and control sites combined

**Kim 2003**
**Study characteristics**

Methods	Design: Randomized controlled trial  Setting: 1 family practice housed in a tertiary care hospital, South Korea  Recruitment: Participants were recruited from outpatient clinic of family medicine department
Participants	152 male adults who smoked (76 intervention, 76 control), av.age 46, av. cpd not reported



## Kim 2003 (Continued)

Interventions	Intervention: participants received telephone counseling (for 5 – 10 minutes using stage of change model and motivational interviewing techniques) delivered by a trained nurse at 8 weeks and 17 weeks. Participants also received educational material about smoking cessation provided to the control group	
	Control: participants received educational material about smoking cessation	
Outcomes	Abstinence (undefined) at 25 wks	
Funding Source	Not reported	
Author's declarations of interest	Not reported.	
Notes	Strategy: Adjunctive counseling  Level: Patient  Comparison type: Single component vs. standard care	
<b><i>Risk of bias</i></b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Sequence Generation	Low risk	Used a random-number table
Allocation concealment	Unclear risk	Not reported
Blinding of outcome assessors All outcomes	High risk	Smoking status was self-reported and the intervention group received additional face-to-face contact
Incomplete outcome data All outcomes	Low risk	19/76 (25%) in the control and 21/76 (28%) in the intervention group were lost. Loss to follow-up was therefore less than 50% overall and similar between groups

## Kottke 1989

<b>Study characteristics</b>		
Methods	<p>Design: 3-group cluster-randomized controlled trial</p> <p>Setting: Primary care, USA</p> <p>Recruitment: Providers were recruited through mailing with brochure. Participants were recruited in practice</p>	
Participants	<p>66 providers, 15% F, av. age 40, av. cpd 19</p> <p>1653 patients smoked</p>	
Interventions	<p><i>Intervention 1:</i> physicians received a 6-hour workshop on smoking cessation and smoking cessation manuals</p> <p><i>Intervention 2:</i> physicians received smoking cessation manuals (same as the one given for those in intervention 1) to hand out to people who smoked</p>	

**Kottke 1989** (Continued)

3. Control: no assistance. No further details reported

Outcomes	<p>Abstinence (undefined) at 12m</p> <p>Validation: Blood cotinine levels (cut-off not reported)</p> <p>Quit attempts</p> <p>Measures of provider implementation: Ask, Advise, Assist-Quit date, Assist-Self-help, Arrange</p>
Funding Source	This study was supported in part by National Institutes of Health grant CA38361, National Institute of Drug Abuse grant DA04066, and a National Institute of Drug Abuse Research Scientist Award, DA00109
Author's declarations of interest	Not reported
Notes	<p>Strategy: Provider training</p> <p>Level: Provider</p> <p>Comparison type: Single component versus standard care</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	High risk	QUOTE: "After the randomization had been initiated, it became apparent that some physicians had given home addresses while others had given work addresses. This had prevented the investigators from recognizing all cases in which multiple physicians from the same group had responded to the recruitment letter. To prevent contamination from having physicians of the same practice in different trial groups, all physicians in the same practice were either moved to the most intense level of intervention to which any of them had been originally randomized or, if not yet randomized at the time this problem was discovered, added to the group to which their partner(s) had been randomized"
Blinding of outcome assessors All outcomes	Low risk	Smoking status biochemically validated
Incomplete outcome data All outcomes	Low risk	Attrition rates were under 50% and similar across the groups. At physician level, there was no loss to follow-up (n = 0/66) at 1 year. At participant level, the overall loss to follow-up was 13.0% (n = 215/1653); 13.2% (n = 87/660) in the workshop intervention group, 12.5% (n = 74/593) in the materials group, and 13.3% (n = 53/400) in the control group were lost to follow-up at 1 year.
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "Neither the mean age of the physicians, nor the patient load on the physician differed significantly among the three groups"; "While a higher proportion of the patients of physicians in the no-assistance group had at least some education beyond high school (51.8% vs 42.1% for patients of physicians in the workshop group and 42.9% for patients of physicians in the materials group [P<.001]), the distributions for the other variables did not differ significantly among the patients in the three groups"

**Kottke 1989** (Continued)

Adjustment for clustering in analysis? (cluster RCTs only)

Low risk

QUOTE: "The physician was the unit of analysis...multivariate regression was used to adjust for potentially confounding effects of differences among the groups of doctors and their patients"

**Lancaster 1999**
**Study characteristics**

Methods	Design: Randomized controlled trial  Setting: 6 general practices in Oxfordshire, Buckinghamshire, and Berkshire, UK  Recruitment: Opportunistic recruitment of people who smoked visiting clinic, mailed invitation letters to those identified through practice records
Participants	497 adults who smoked, (249 intervention, 248 control) av.age 43, 52% F, 17 cpd
Interventions	Intervention: participants received smoking cessation counseling from a nurse, a carbon monoxide test and up to 5 follow-up visits  Control: participants received verbal or written advice from their physician to quit smoking and self-help materials
Outcomes	Sustained abstinence at 12m  Validation: Salivary cotinine < 113.5 mmol/l  Quit attempts
Funding Source	Not reported
Author's declarations of interest	Not reported
Notes	Strategy: Adjunctive counseling  Level: Patient  Comparison type: Single component vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	QUOTE: "an independent statistical adviser performed randomisation from computer-generated random numbers"
Allocation concealment	Low risk	QUOTE: "the allocations, in blocks of 20, were in sequential sealed, opaque envelopes opened by the research nurse at the time of recruitment"
Blinding of outcome assessors All outcomes	Low risk	Smoking abstinence biochemically validated
Incomplete outcome data All outcomes	Unclear risk	The overall loss to follow-up was 24.7% (n = 123/497) at 12 months. No further details on the number lost to follow-up by group were reported

## Lasser 2017

### Study characteristics

Methods	<p>Design: Randomized controlled trial</p> <p>Setting: Boston Medical Center's adult primary care, USA</p> <p>Recruitment: Calls and letters to potentially eligible identified from electronic medical record, and re-cruited from waiting rooms</p>
Participants	352 participants, av.age 50, 54% F, 15 cpd
Interventions	<p>Intervention: participants received a low literacy smoking cessation brochure and a list of hospital and community resources for smoking cessation. In addition, they received up to 4 hours of patient navigation delivered over 6 months, and financial incentives for biochemically-confirmed smoking cessation at 6 and 12 months following enrolment</p> <p>Control: participants received assessment of their smoking status, brief cessation counseling, a low-literacy smoking cessation brochure and a list of hospital and community resources for smoking cessation</p>
Outcomes	<p>7-day PPA at 12m</p> <p>Validation: Salivary cotinine &gt; 10 ng/mL or urinary anabasine &gt; 3 ng/mL</p>
Funding Source	This study was supported by American Cancer Society (grant No. 125785-RSG-14-034-01CPPB)
Author's declarations of interest	QUOTE: "Dr Quintiliani was a consultant on a research grant to Partners HealthCare Inc. unrelated to the work presented in this article. No other conflicts are reported"
Notes	<p>Strategy: Adjunctive counseling + Financial incentive</p> <p>Level: Patient</p> <p>Comparison type: Multicomponent vs. standard care</p>

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Random-number generator
Allocation concealment	Low risk	Sealed envelopes
Blinding of outcome assessors All outcomes	Low risk	Smoking status biochemically validated
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 28.7% (n = 101/352); 27.1% (n = 48/177) in the intervention group and 30.3% (n = 53/175) in the control group were lost to follow-up at 12 months

## Lee 2016

### Study characteristics

### Strategies to improve smoking cessation rates in primary care (Review)

## Lee 2016 (Continued)

Methods	<p>Design: Cluster-randomized controlled trial</p> <p>Setting: Outpatient clinic of the Department of Family Medicine and the Health Screening Center of Seoul National University Hospital, South Korea</p> <p>Recruitment: Opportunistically in practice</p>
Participants	414 adults who smoked, av. age 48, 92% M, av. cpd 17
Interventions	<p>Intervention: a 7-minute long animated video containing information and options about smoking cessation. Following this, physicians gave a brief consultation about smoking problems or prescribed medications if participants asked for them</p> <p>Control: routine medical care only. The participants were not provided with the decision aid, any proactive smoking cessation counseling or prescription</p>
Outcomes	<p>PPA (undefined) at 6m</p> <p>Validation: None</p> <p>Measures of provider implementation: Assist-Meds</p>
Funding Source	This work was supported by a grant for investigator-initiated research from Pfizer (Pfizer Reference #WS2033889). None of the sponsors had a role in any aspect of the present study, including design and conduct of study; collection, management, analysis, and interpretation of the data, and preparation, review, or approval of the manuscript
Author's declarations of interest	The authors declared that they had no conflict of interest and that none of the sponsors had a role in any aspect of the study
Notes	<p>Strategy: Video</p> <p>Level: Patient</p> <p>Comparison type: Single component vs. standard care</p>

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	High risk	Based on the month. Exam rooms were randomized based on their number and the month (i.e. odd numbered exam rooms were intervention rooms)
Allocation concealment	High risk	Could have been foreseen as randomization was based on the month
Blinding of outcome assessors All outcomes	Low risk	Smoking status was self-reported. The intervention was a decision aid video so there was no person-to-person contact in either group
Incomplete outcome data All outcomes	High risk	Attrition rates were under 50% but the difference between groups was greater than 20%. The overall loss to follow-up was 20.5% (n = 85/414); 33.8% (n = 66/195) in the intervention group and 8.7% (n = 19/219) in the control group were lost to follow-up at 6 months
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the Department of Family Medicine and the Health Screening Center of Seoul National University Hospital before randomization

**Lee 2016** (Continued)

Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "None of the characteristics was significantly different between the control and intervention groups"
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "To investigate the impact of the decision aid on the outcomes, univariate and multivariate logistic regression tests were used, with accounting for the clustering effect of nesting physicians"; "The intracluster correlation coefficient values were 0.21 for the primary outcome variable and 0.10 for the secondary outcome variable..."

**Lennox 1998**
**Study characteristics**

Methods	Design: Cluster-randomized controlled trial Setting: General practices in Aberdeen, UK Recruitment: Mailing of questionnaire to adults from practice list
Participants	16 providers (8 intervention, 8 control). 2588 people who smoked (aged 16 - 65) identified through questionnaires, av. age not reported, av. cpd not reported
Interventions	Intervention: 1-day training for providers on the stages of change for smoking cessation Control: usual care. No further details reported
Outcomes	Continuous abstinence from 8m to 14m Validation: None Secondary outcomes: Quit attempts Measures of provider implementation: Ask
Funding Source	Funded by the Chief Scientist Office. Scottish Office Department of Health. Grampian Health Board funded the running of the workshops
Author's declarations of interest	Not reported
Notes	Strategy: Provider training Level: Provider Comparison type: Single component vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	QUOTE: "A computer-generated random sample"
Allocation concealment	Low risk	QUOTE: "A computer-generated random sample"



## Lennox 1998 (Continued)

Blinding of outcome assessors All outcomes	Low risk	Smoking status was self-reported. The intervention was a 1-day training workshop aimed at staff so the number of face-to-face contacts differed between arms at practice level, but not at participant level
Incomplete outcome data All outcomes	Low risk	At practice level, no practices were lost to follow-up (n = 0/16). At participant level, attrition rates were under 50% and similar between groups. The overall loss to follow-up was 24.1% (n = 408/1693); 24.9% (n = 224/898) in the intervention group and 23.1% (n = 184/795) in the control group were lost to follow-up at 14 months
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "There was no significant difference between the two arms of the study in response rate, age, sex, addiction score or readiness to change smoking behaviour. Intervention subjects were less affluent than control subjects, and regression techniques were therefore used to adjust for deprivation"
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "A generalised linear mixed model (GLMM) approach used regression techniques which added the general practice, as a random factor nested within the treatment groups, to the other fixed-effect factors"

## Lennox 2001

### Study characteristics

Methods	Design: 3-group randomized controlled trial  Setting: 6 general practices in Aberdeen, UK  Recruitment: Mailed lettered to patients identified in EMR
Participants	2553 people who smoked aged 17 - 65, av. age not reported, av. cpd not reported
Interventions	<i>Intervention 1:</i> participants received an untailored letter on smoking cessation  <i>Intervention 2:</i> participants received a tailored letter on smoking cessation  <i>Control:</i> participants received a letter thanking them for participation and informing them that they would receive material at the end of the study (either a tailored or a non-tailored letter)
Outcomes	7-day PPA at 6m  Validation: Salivary cotinine, cut-off not reported (only completed in 3.5% of participants)
Funding Source	The Chief Scientist Office, Scottish Executive Health Department, with additional funding from the Engineering and Physical Sciences Research Council. The Health Economics Research Unit is funded by the Chief Scientist Office
Author's declarations of interest	Authors declared that they had no conflict of interest
Notes	Strategy: Tailored print materials  Level: Patient  Comparison type: Single component vs. standard care

### Strategies to improve smoking cessation rates in primary care (Review)

## Lennox 2001 (Continued)

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Computer-generated random numbers were used
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Low risk	Salivary cotinine, cut-off not reported (only completed in 3.5% of participants). Face-to-face contact was minimal in all groups
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 23.6% (n = 615/2610); 24.5% (n = 213/870) in the tailored letter group, 27.2% (n = 236/869) in the standard letter group and 19.1% (n = 166/871) in the control group were lost to follow-up at 6 months

## Leppänen 2019

### Study characteristics

Methods	Design: Cluster-randomized controlled trial  Setting: Primary healthcare centres, Sweden  Recruitment: QUOTE: "Eligibility was assessed using a short screening questionnaire before patients were invited to participate. The patients were recruited by one to three appointed PHC providers at each PHC centre that were responsible for the treatment of patients in the study"
Participants	250 adults who smoked from 18 primary healthcare centres in Sweden. Participants had a mean age of 54.4 years, av. cpd not reported, most had chronic disease (70%)
Interventions	Intervention: Tobacco Cessation on Prescription (TCP) consisting of 1) person-centered tobacco cessation counseling from a qualified healthcare professional for at least 10 minutes; 2) an individualized prescription of tobacco cessation treatment; 3) follow-up on at least 1 occasion; 4) providers received 3 hours of training. Healthcare providers could use the prescription form as a basis for tobacco cessation counseling with the patient, discussing available treatment options and deciding together what option(s) would suit the participant best  Control: participants received standard treatment (brief advice consisting of < 5 minutes of tobacco cessation counseling, but providers were free to offer whatever treatment they wanted as long as this was documented). Providers also received a written manual and 3 hours of training in tobacco cessation treatment
Outcomes	7-day PPA at 6m and 12m  Validation: none  Quit attempts (however, result only reported narratively and unable to extract data for analysis)
Funding Source	The study is funded by grants from the Stockholm County Council (grant no: HSN 1309-1029), The Public Health Agency of Sweden (grant no: 03074-2015-6.2) and Livförsäkringsbolaget Skandia.
Author's declarations of interest	None
Notes	Strategy: Adjunctive counseling, provider training

**Leppänen 2019** (Continued)

Level: Patient &amp; provider

Comparison type: Active vs. active (isolates adjunctive counseling)

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Computer-generated
Allocation concealment	Low risk	Quote: "A computer generated random allocation sequence will be applied to randomize the PHC centers to either intervention or control conditions"
Blinding of outcome assessors All outcomes	High risk	Self-reported outcomes and more contact in the intervention group
Incomplete outcome data All outcomes	High risk	56% participants responded to 6-month follow-up questionnaire. Imputation used for missing data
Recruitment bias (cluster RCTs only)	Unclear risk	77 PHC centers invited and 17 agreed
Balanced baseline characteristics? (cluster RCTs only)	Low risk	Quote: "The patients were similar in the treatment groups but patients in the intervention group were more often female, born in Sweden, had more previous quit attempts, experience of pharmacotherapy and lower prevalence of chronic disease compared to the control group."
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	Adjustment for clustering conducted

**Lindsay 1989**
**Study characteristics**

Methods	Design: 3-group cluster-randomized controlled trial  Setting: Primary care practices, Canada  Recruitment: Receptionists identified people who smoked while visiting provider for routine appointment
Participants	83 providers  1942 people who smoked aged > 16 years, 64% smoked at least 20 cpd, av. age not reported, av. cpd not reported
Interventions	<i>Intervention 1:</i> Gum only  <ul style="list-style-type: none"> <li>Physicians were cued by a project document indicating the participant's agreement to participate. Physicians in this group were instructed to advise the participant to quit smoking</li> <li>Participants were advised to use nicotine gum (at their own cost) by their physician</li> </ul> <i>Intervention 2:</i> Gum plus

**Lindsay 1989** (Continued)

- Physicians attended a training session on smoking cessation. Flow sheet provided to them to help them deliver intervention. Physicians in this group were instructed to advise the participant to quit smoking

- Participants received self-help materials and were advised to use nicotine gum (at their own cost) by their physician

Control: usual care. QUOTE: "If it was part of their usual practice to address the smoking issue with patients, this occurred. We gave no instructions to patients about whether they should mention their agreement to participate to their physician, and we had no way of assessing whether this, in fact, occurred"

Outcomes	3m continuous abstinence measured at 12 months  Validation: Salivary cotinine < 0.057 umol/L  Quit attempts  Measures of provider implementation: Ask, Advise, Assist, Assist-Meds, Assist-Self-help, Assist-Quit Date, Arrange
Funding Source	National Institute of Health (USA) and Canadian National Research and Development Program
Author's declarations of interest	Not reported
Notes	Strategy: Provider training + flow sheet  Level: Provider + Practice  Comparison type: Multi-component vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Low risk	Smoking abstinence was validated by cotinine
Incomplete outcome data All outcomes	Unclear risk	Authors reported that 21.3% (n = 129/606) of participants in the gum-plus group attended 4 or 5 follow-up visits and that no data were available for gum-only group. No further details reported
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization. QUOTE: "patients entered the study when they visited their physician for a routine office appointment"
Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "we observed no differences on physician characteristics among experimental groups"; "we observed some difference in motivation levels among groups and the main analyses of outcome adjusted for these differences"
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "treatment effect was assessed using analysis of covariance; the unit of analysis being the practice"

## Lou 2013

### Study characteristics

Methods	<p>Design: Cluster-randomized controlled trial</p> <p>Setting: 14 healthcare units in rural area of Xuzhou city, China</p> <p>Recruitment: Physicians recruited their patients</p>
Participants	<p>136 providers, 14 practices</p> <p>3562 participants diagnosed with chronic obstructive pulmonary disease, aged 35 or older, smoked 1 cpd or no quit attempts longer than 3m, , av. age not reported, av. cpd not reported</p>
Interventions	<p>Intervention:</p> <ul style="list-style-type: none"> <li>Healthcare professionals received a 6-hour training in behavioral interventions for quitting smoking</li> <li>Participants received a brief smoking cessation advice after the baseline interview, were provided with a plan to quit smoking (e.g. setting a quit date). Other measures to encourage smoking cessation included home visit by the providers at least once a week). They were followed up by the providers once a week in the first month and thereafter once a month until the end of study. Participants in healthcare centres were visited by 'the professional group' (e.g. respiratory, rehabilitation, nutrition, sports and psychology specialists) every 2 months and were provided with smoking-related and obesity-related psychological support</li> </ul> <p>Control: usual care. QUOTE: "The content and number of usual care services were not standardized. Participants were followed up every two months and asked whether the symptoms aggravated, what medication they used, etc." No further details reported</p>
Outcomes	<p>Continuous abstinence at 6m</p> <p>Validation: Expired CO <math>\leq</math> 10 ppm</p>
Funding Source	Science and Technology Projects of Xuzhou City
Author's declarations of interest	The authors declared that they had no competing interests
Notes	<p>Strategy: Adjunctive counseling &amp; provider training</p> <p>Level: Patient &amp; Provider</p> <p>Comparison type: Multicomponent vs. standard care</p>

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	QUOTE: "The healthcare centres were classified in two classes: with high or low task delegation from general practitioners to nurses. The healthcare centres in the classes were then randomly allocated to the groups". No further information.
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Low risk	Smoking status biochemically validated

## Lou 2013 (Continued)

Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 24.5% (n = 873/3562); 21.5% (n = 390/1814) in the intervention group and 27.6% (n = 483/1748) in the control group were lost to follow-up at 48 months
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with their family physicians before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	No statistically significant differences were found between groups
Adjustment for clustering in analysis? (cluster RCTs only)	High risk	None apparent

## Marley 2014

### Study characteristics

Methods	Design: Randomized controlled trial  Setting: 2 Aboriginal Controlled Community Health Services, Australia  Recruitment: Passive recruitment through visits to primary care clinics and active recruitment by researchers through community and family links
Participants	163 Aboriginal and/or Torres Strait Islanders, ≥ 16 years of age, reporting current smoking or quitting within 2 weeks of recruitment, thinking about cutting down or quitting smoking, regular client of 1 of 2 Aboriginal Health Services. av. age 39, 54% F, av. cpd 15
Interventions	Intervention: in addition to usual care, participants received in-person smoking cessation counseling scheduled weekly for the first 4 weeks, monthly to 6 months and 2-monthly to 12 months (12 sessions). Delivered by Aboriginal researchers  Control: participants received usual care - smoking cessation support at their local primary health care service, including advice regarding quitting, pharmacotherapy, and self-initiated follow-up
Outcomes	7-day PPA at 12m  Validation: Urinary cotinine < 50 ng/mL
Funding Source	National Health and Medical Research Council of Australia (NHMRC, project grant number 513818)
Author's declarations of interest	Authors declared that they had no competing interest.
Notes	Strategy: Adjunctive counseling  Level: Patient  Comparison type: Single component vs. standard care

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	QUOTE: "A computer generated random allocation sequence was used"

## Strategies to improve smoking cessation rates in primary care (Review)



## Marley 2014 (Continued)

Allocation concealment	Low risk	QUOTE: "Sealed envelopes containing the allocation were kept at the centralised coordinating site. Allocation occurred via telephone with envelopes being opened in sequential order"
Blinding of outcome assessors All outcomes	Low risk	Smoking status biochemically validated
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 14.3% (n = 24/168); 15.5% (n = 9/58) in the intervention group and 13.6% (n = 15/110) in the control group were lost to follow-up at 12 months

## Mejia 2015

### Study characteristics

Methods	Design: Cluster-randomized controlled trial  Setting: 6 clinical systems in the cities of Buenos Aires, La Plata and Olavarria, Argentina  Recruitment: Physicians were recruited from 6 clinical systems. All patients who saw their physician within 30 days of the intervention were included
Participants	254 physicians, 52.4% F  1378 patients (750 intervention, 628 control) 80.9% F, av. age not reported, av. cpd not reported
Interventions	Intervention: 2 x 3-hour training session on tobacco cessation. Physicians also received monthly emails as reminders with useful tips to help patients stop smoking or manage withdrawal  Control: usual care. No further details reported
Outcomes	7-day PPA at 12m  Validation: None  Quit attempts Measures of provider implementation: Ask, Advise, Assist-Quit date, Assist-Self-help
Funding Source	Funded by grant No.TW05935 from the Tobacco ResearchNetwork Program, Fogarty International Center, National Cancer Institute, NationalInstitute of Drug Abuse, National Institutes of Health, the National Cancer Institute for Redes en Acción (U01CA86117 and U54CA153511) and by grant No. 001726-037 from Research on International Tobacco Control, International Development Research Center, Canada
Author's declarations of interest	Authored declared that they had no conflict of interest
Notes	Strategy: Provider training  Level: Provider  Comparison type: Single component vs. standard care

### Risk of bias

Bias	Authors' judgement	Support for judgement
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**Mejia 2015** (Continued)

Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Unclear risk	Smoking status self-report. Amount of face-to-face contact unclear
Incomplete outcome data All outcomes	Low risk	At physician level, the overall loss to follow-up was 30.0% (n = 76/254); 25.8% (n = 32/124) in the intervention group and 33.8% (n = 44/130) in the control group were lost to follow-up at 12 months. At participant level, the overall loss to follow-up was 32.3% (n = 445/1378) at 12 months and the split of this between the groups was not reported
Recruitment bias (cluster RCTs only)	Unclear risk	QUOTE: "Lists of patients seen within 30 days after the study physicians were randomized (control) or had completed the smoking cessation course (intervention) were obtained"
Balanced baseline characteristics? (cluster RCTs only)	Low risk	Balanced between trial arms
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "P values for group by time interaction are from generalised linear mixed model analysis accounting for clustering of observations by physician and repeated measures per patient"

**Meyer 2008**
**Study characteristics**

Methods	Design: 3-group randomized controlled trial  Setting: Primary care in Germany  Recruitment: For a period of 3 weeks all consecutive patients were screened for smoking status by a research nurse covering complete office hours
Participants	1499 adults who smoked, 48% F, av. age 33, 16 cpd, 64% unmotivated
Interventions	<i>Intervention 1:</i> participants received by post up to 3 computer-generated tailored letters, accompanied by a series of self-help manuals  <i>Intervention 2:</i>  • Practitioners received 2-hour training on smoking cessation. The practitioners received a summary sheet of basic information about their patients' smoking-related variables, as a prompt to offer counseling  • Participants received brief advice, lasting 10 minutes, from their practitioner and self-help manuals. The intervention was delivered within the regular consultation  <i>Control:</i> QUOTE: "no intervention beside usual practice routine was provided for the control group. No information about the participants was given to the practice team or the practitioner and no self-help manuals have been provided"
Outcomes	6m sustained abstinence 24m

**Meyer 2008** (Continued)

Validation: None

Funding Source	Funded by the German Federal Ministry of Research and Education (grant no.01EB0120, 01EB0420), the Social Ministry of the State of Mecklenburg-Vorpommern (grant no. IX311a406.68.43.05) and the German Research Foundation (Deutsche Forschungsgemeinschaft, grant no. JO150/6-1)
Author's declarations of interest	Not reported
Notes	Strategy: Tailored materials, flow sheet, provider training  Level: Patient, provider, practice  Comparison types: Single component vs. standard care; multicomponent vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	High risk	Assigned based on the week they were seen at the practice
Allocation concealment	High risk	Assigned based on the week they were seen at the practice
Blinding of outcome assessors All outcomes	High risk	Smoking status was self-reported and participants in the brief advice group had additional 10 minutes in their consultation to listen to the advice
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 37.2% (n = 558/1499); 42.8% (n = 209/488) in the tailored letter group, 33.8% (n = 136/402) in the brief advice group and 35.0% (n = 213/609) in the control group were lost to follow-up at 24 months

**Meyer 2012**
**Study characteristics**

Methods	Design: Clustered randomized controlled trial with 3 active comparators  Setting: Primary care in North-Eastern Germany  Recruitment: Practices contacted by research team and invited to participate
Participants	151 practices  3086 participants, 43% F, av. age 40, av. cpd not reported
Interventions	<i>Intervention 1:</i> brief advice with desktop resource  Participants received a 10-minute brief advice which incorporated elements of health behavior change counseling and were provided with self-help materials. Physicians received a summary sheet of smoking-related characteristics to prompt counseling and also a desktop resource with a flow chart illustrating the elements of counseling and general communication strategies  <i>Intervention 2:</i> tailored letters  Participants received 2 tailored letters, based on their answers to 2 questionnaires. Letters were given while participant was in the practice  <i>Intervention 3:</i> combination

**Meyer 2012** (Continued)

Participants received both brief advice from the physician and a tailored letter. The same self-help manuals used in the other conditions were provided to the participants

Outcomes	6m prolonged abstinence at 12m  Validation: None  Provided some data on intervention 'reach' but it was not possible to classify this into our provider implementation outcomes
Funding Source	The German Federal Ministry of Research and EducationThe Social Ministry of the State of Mecklenburg-Vorpommern The German Research Foundation
Author's declarations of interest	Authors declared that they had no conflict of interest
Notes	Strategy: Tailored materials, flow sheet  Level: Patient, practice  Comparison type: Active vs. active (2 comparisons: int 1 vs. int 3 & int 2 vs. intervention 3)

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	High risk	Smoking status self-report, and contact differed between trial arms
Incomplete outcome data All outcomes	Low risk	Attrition rates were under 50% and the difference among groups was less than 20%. At practice level, no practice was reported to have been lost to follow up (n = 0/151), At participant level, the overall loss to follow-up was 26.8% (n = 863/3215); 30.6% (n = 189/618) in the brief advice group, 22.3% (n = 331/1484) in the tailored letters group, and 30.8% (n = 343/1113) in the combination group were lost to follow-up at 12 months
Recruitment bias (cluster RCTs only)	Unclear risk	Participants were affiliated with the practice before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "There were no significant differences in the characteristics of the participating practices and practitioners between study groups"
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "For all analyses at the patient level, we took clustering within practices into account using sample survey methods in STATA 10.1"

**Minué-Lorenzo 2019**
**Study characteristics**

Methods	Design: Cluster-randomized controlled trial
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**Strategies to improve smoking cessation rates in primary care (Review)**

**Minué-Lorenzo 2019** (Continued)

Setting: Primary care practice, Spain

Recruitment: Patients who attended the healthcare centre for any reason were approached by a general practitioner or a nurse

Participants	1154 adults who attended the primary healthcare centre for any reason between June and December 2009, smoking $\geq 10$ cigarettes/day, at any stage of the smoking cessation process, av. age 46, av. cpd 22
Interventions	<p>Intervention: participants received first-line quit-smoking medication (varenicline, bupropion or NRT) free of cost. Type of pharmacotherapy was chosen by the physician in accordance with participant preference. NRT provided for 8 weeks and dose based on CPD; Varenicline or bupropion standard doses for 12 weeks. Participants also received usual care as defined below</p> <p>Control: usual care described as behavioral treatment and recommendation for using pharmacological treatment in accordance with standard health services offered in primary care (prescribed pharmacological treatment but had to purchase it). No further details on the behavioral treatment reported</p>
Outcomes	CO-confirmed continuous abstinence at 12m (self-reported 12m rates also reported)  Validation: CO
Funding Source	Fondo de Investigaciones Sanitarias (FIS) del Instituto de Salud Carlos III (ISCIII), the European Regional Development Fund (ERDF)
Author's declarations of interest	QUOTE: "The authors declare that they have no competing interests, financial or otherwise, related to the current work. C.Minue-Lorenzo reports grants from Fondo de Investigaciones Sanitarias (FIS) del Instituto de Salud Carlos III (ISCIII), European Regional Development Fund (ERDF), grants from Fundacion para la Investigacion e Innovacion Biosanitaria en Atencion Primaria (FIIBAP), during the conduct of the study. The rest of the authors have also completed and submitted an ICMJE form for disclosure of potential conflicts of interest"
Notes	Strategy: Cost-free pharmacotherapy  Level: Patient  Comparison type: Single-component vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	QUOTE: "computer-generated random sequence"
Allocation concealment	Low risk	QUOTE: "Randomization was performed centrally by a researcher not involved in the study, and who was blind to the identity of the HCCs"
Blinding of outcome assessors All outcomes	Low risk	Abstinence was biochemically validated
Incomplete outcome data All outcomes	Low risk	32/387 (8.3%) in the usual care arm and 53/767 (6.9%) in the intervention arm were lost to follow-up
Recruitment bias (cluster RCTs only)	Low risk	Participants were members of the practices before they were randomized
Balanced baseline characteristics? (cluster RCTs only)	Unclear risk	QUOTE: "the intervention group comprised a larger percentage of men, smoked more cigarettes per day, and showed higher scores in the FTND (Table

**Minué-Lorenzo 2019** (Continued)

1). Additionally, the rate of patients at the preparation and action stages of the cessation process was significantly higher in the intervention group"

Adjustment for clustering in analysis? (cluster RCTs only)

Low risk

A multilevel logistic regression model was built and significant variables tested as covariates, taking into consideration sampling by clusters

**Morgan 1996**
**Study characteristics**

Methods	Design: Cluster-randomized controlled trial  Setting: Primary care practices in suburban Philadelphia and eastern Pennsylvania, USA  Recruitment: Conducted in practice
Participants	49 practices without a formalized smoking intervention program  1318 people who currently smoked aged 50 - 74 years, presenting for a non-emergency visit to the practice. 56% F, 20 cpd, av. age 60
Interventions	Intervention:  <ul style="list-style-type: none"> <li>• Practices received on-site training to implement a modified National Cancer Institute (NCI) smoking cessation intervention based on the 4 A's. Physicians were trained to praise participants for previous quit efforts, provide personalized feedback, discuss the health benefits of quitting for older people who are smoking, and give a clear message to quit smoking</li> <li>• Participants received a smoking cessation guide tailored to older people who smoke and were offered help with quitting. They were also sent a follow-up letter drafted by the Clear Horizons office from their physician within 1 week of their visit, a brief follow-up quitline counseling call from the project staff within 2 - 4 weeks of the intervention visit. They were also provided with a medical record flowchart specifically made for smoking cessation</li> <li>- people who smoked, in the precontemplation stage, who declined help: received brief guide-based counseling to overcome quitting barriers</li> <li>- people who smoked, in the contemplation stage received brief guide-based counseling to set up a quit plan and quit date and a prescription for nicotine gum (free 1-week samples)</li> </ul> Control (usual care): practices in this group were instructed to provide usual care to older people who smoked over the accrual and follow-up period. No further details reported
Outcomes	7-day PPA at 6m  Validation: None  Provider implementation outcomes were only measured in the intervention group
Funding Source	Not reported
Author's declarations of interest	Not reported
Notes	Strategy: Provider training + cost-free medications + adjunctive counseling + flowchart  Level: Patient, Provider, Practice



**Morgan 1996** (Continued)

Comparison type: Multicomponent vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Low risk	Smoking status self-report. At participant level, there was no variation in contact
Incomplete outcome data All outcomes	Unclear risk	QUOTE: "Of the 659 patients who completed the baseline questionnaire, 573 (87%) were contacted for a telephone interview at the 6-month follow-up". Follow-up rates by group were not reported
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization
Balanced baseline characteristics? (cluster RCTs only)	High risk	QUOTE: "Immediate and delayed intervention practices did not differ significantly in the mean number of patients enrolled, gender of patients enrolled, or reporting of quit attempts lasting 24 hr or more in the previous year... patients in the two conditions did differ in age, average number of cigarettes smoked daily, time elapsed until first cigarette of the morning, and contemplation status"
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "A correlated logistic regression model that accounted for dependencies among respondents within a given practice was utilized"

**Murray 2008**
**Study characteristics**

Methods	Design: Cluster-randomized controlled trial  Setting: 3 Nottingham Primary Care Trust areas, UK  Recruitment: Proactive identification of people who smoked via a letter offering smoking cessation support through the National Health Smoking Cessation Service
Participants	6856 adults who smoked, av. age 45, 51% M, av. cpd not reported
Interventions	Intervention: participants received brief advice on smoking cessation and information about their local NHS Stop Smoking Service by the research team via telephone  <ul style="list-style-type: none"> <li>• If participants wished, an initial consultation with the NHS stop smoking service was booked. Participants who attended this were offered the option of one-to-one or group behavioral support lasting an average of 8 weeks, and NRT or bupropion therapy, and set a quit date</li> <li>• If participants declined an appointment or were uncontactable, an information pack was sent. The pack included an information leaflet from the service, encouragement to use the service, and contact details for the research team and the local service</li> </ul>

**Murray 2008** (Continued)

Control: QUOTE: "for six months from baseline, smokers in the control practices received no further intervention other than that provided by usual care. Previous studies suggest that, in most cases, little or no advice or support would have been given". No further details reported

Outcomes	7-day PPA at 6m  Validation: Salivary cotinine < 15 ng/ml or exhaled CO < 10 ppm
Funding Source	Funded by the British Heart Foundation. The study was designed, conducted, analyzed and interpreted independently of all funding sources
Author's declarations of interest	Not reported
Notes	Strategy: Adjunctive counseling  Level: Patient  Comparison type: Single component vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Low risk	Smoking status biochemically validated
Incomplete outcome data All outcomes	Low risk	At participant level, the overall loss to follow-up was 48.8% (n = 3344/6856). The mean response was 47.9% (range 28.8 - 55.6) in the intervention group and 53.7% (range 39.6 - 63.3) in the control group at 6 months
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "The distribution of gender and age was similar for participants in intervention and control practices"
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "We used a two-level hierarchical model with subjects nested within practices, a random effect of practice, intervention fitted at the practice level, and age, sex, Townsend score and amount smoked per day at the subject level"; "...assuming an intracluster correlation coefficient of not more than 0.007..."

**Nebot 1992**
**Study characteristics**

Methods	Design: cluster-randomized controlled trial  Setting: 3 urban reformed primary care centres in Barcelona, Spain
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**Nebot 1992** (Continued)

	Recruitment: All people who smoked (> 1 cpd) visiting physician for any reason
Participants	15 primary care teams within 3 primary care centres  425 adults who smoked, 30% F, av. age not reported, av. cpd not reported
Interventions	<i>Intervention 1:</i> physician counseling  Participants received standard physician advice operatively defined as a personalized firm counsel to stop smoking, lasting 3 - 5 minutes  <i>Intervention 2:</i> physician counseling + nicotine gum  Participants received standard physician advice plus a free supply of nicotine gum sufficient to last 2 - 4 weeks  <i>Intervention 3:</i> nurse counseling  Participants received up to 15 minutes of nurse advice
Outcomes	Abstinence (undefined) at 12m follow-up  Validation: Expired CO < 8 ppm
Funding Source	Grant from the Fondo de Investigaciones Sanitarias de la Seguridad Social
Author's declarations of interest	Not reported
Notes	Strategy: Cost-free medication + Adjunctive counseling  Level: Patient  Comparison types: Single component vs. standard care (testing cost-free medications and adjunct counseling individually in separate trial arms)

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Low risk	Smoking status validated by carbon monoxide levels
Incomplete outcome data All outcomes	Unclear risk	Authors reported that 82% were followed up at 2 months, but they did not report the follow-up rate at 12 months
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "The three groups had no significant differences in these characteristics except for the proportion of smokers having tried to quit before (higher among the B group patients)"

**Nebot 1992** (Continued)

Adjustment for clustering in analysis? (cluster RCTs only)	High risk	None apparent
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**Nichols 2017**
**Study characteristics**

Methods	Design: Randomized controlled trial Setting: Primark care clinics, UK Recruitment: Mailed letters to patients in GP database
Participants	109 adults who smoked. 55.6% F; mean age 49 years; mean Fagerström score 4.9, av. cpd 18
Interventions	Intervention: participants received an 8-week smoking cessation program, where a participant is offered a fact sheet on the health risks of smoking (including lung cancer) and the option of the gene-based test for calculation of lung cancer susceptibility Control: participants received a smoking cessation program without option of gene-based test
Outcomes	Continuous abstinence at 6m Validation: Expired CO and salivary cotinine, cut-offs not reported
Funding Source	JN and PG are in receipt of research grants from Lab 21, Cambridge who are marketing the Respiragene test in the UK and Synergiz Bioscience Ltd. who financed the development of the test from its origins in New Zealand
Author's declarations of interest	Authors declared that they had no conflict of interest
Notes	Strategy: Gene-based test Level: Patient Comparison type: Single component vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Low risk	Smoking status biochemically validated
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 43.1% (n = 47/109); 37.0% (n=20/54) in the intervention group and 49.0% (n = 27/55) in the control group were lost to follow-up at 6 months

## Ockene 1994

### Study characteristics

Methods	Design: 3-group randomized controlled trial  Setting: Primary care, USA  Recruitment: Opportunistic recruitment from practice
Participants	1499 adults who smoked aged 18 - 75 years, 57% F, av.age 35.3, 23 cpd
Interventions	<i>Intervention 1:</i> participants received simple, individualized advice to stop smoking from their physician  <i>Intervention 2:</i> participants received counseling with a patient-centered approach, consisting of questions addressing motivation and a written plan for change. Participants also received a self-help booklet and a list of local smoking cessation programs and scheduling of a follow-up visit or telephone call  <i>Intervention 3:</i> participants received the same counseling as in intervention, plus a prescription of free 2 mg nicotine gum if agreed to set a quit date
Outcomes	Maintained 7-day PPA at 12m  Validation: None
Funding Source	National Cancer Institute Grant
Author's declarations of interest	Not reported
Notes	Strategy: Cost-free medications  Level: Patient  Comparison type: Single component vs. standard care

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	High risk	Self-reported smoking cessation plus varying contact between groups
Incomplete outcome data All outcomes	Unclear risk	The overall loss to follow-up was 15.9% (n = 238/1499) at 12 months. No further details on the number lost to follow-up by group were reported

## Olano Espinosa 2013

### Study characteristics

Methods	Design: Cluster- randomized controlled trial  Setting: Healthcare centres in Area 11 of the Spanish Madrid Health System, Spain
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**Olano Espinosa 2013** (Continued)

Recruitment: Participants selected from computerized clinic records

Participants	405 nurses and 425 doctors from the 35 clinics 5910 adults who smoked. av.age 43, 53% F, av. cpd not reported
Interventions	Intervention: professionals received 4 x 90-minute training sessions on smoking cessation Control: professionals were offered the training after finishing the follow-up period
Outcomes	Continuous abstinence at 6m Validation: Salivary cotinine < 13 ng/ml
Funding Source	Spanish Public Health Investigations Fund, with no role in the study
Author's declarations of interest	QUOTE: "Two authors (FJA and EOE) work as directors of Cantabria University Tobacco Control Master"
Notes	Strategy: Provider training Level: Provider Comparison type: Single component vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	QUOTE: "...randomly selected 15 patients for each quota by using number combinations generated with EPIDAT 2.0 software"
Allocation concealment	Low risk	QUOTE: "An independent research assistant assigned the 35 health care centers randomly using SPSS v.12 software...". No further detail provided.
Blinding of outcome assessors All outcomes	Low risk	Abstinence biochemically validated
Incomplete outcome data All outcomes	Unclear risk	Not reported
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "No significant differences were found between both groups with respect to profession, age, sex, professional experience, percentage of smokers, and previous training in treating tobacco addiction"
Adjustment for clustering in analysis? (cluster RCTs only)	High risk	Not apparent

**Papadakis 2018**
**Study characteristics**



**Papadakis 2018** (Continued)

Methods	<p>Design: Cluster-randomized controlled trial</p> <p>Setting: Family medicine practices in Ontario, Canada</p> <p>Recruitment: Invitation letters sent to practices. Participants recruited in the waiting room of the clinics</p>
Participants	<p>15 practices</p> <p>867 adults who smoked completed post-intervention exit survey, av. age not reported, av. cpd not reported</p>
Interventions	<p><i>Intervention 1:</i> all teams received the Ottawa Model for Smoking Cessation program which included outreach facilitation, provider training, real-time prompts, and an automated follow-up program</p> <p><i>Intervention 2:</i> all teams received the Ottawa Model for Smoking Cessation program (as described above). In addition, general practitioners and nurse practitioners received a supplemental 1½-hour coaching session for providers 4 weeks following the program launch at their clinic Providers were given a report of their performance in delivering tobacco use treatment interventions</p>
Outcomes	<p>12w prolonged abstinence at 6m</p> <p>Validation: None</p> <p>Measures of provider implementation: Ask, Advise, Assist-Meds, Assist-Quit date, Assist-Self-help, Arrange</p> <p>Secondary outcome: Quit attempts</p>
Funding Source	<p>This study was funded through a Grant-in-aid from the Heart and Stroke Foundation of Canada (Grant # NAT193)</p>
Author's declarations of interest	<p>QUOTE: "R.D.R. has received speaker and consulting fees from Pfizer and Johnson &amp; Johnson, K-A.M. has received speaker fees from Pfizer, A.L.P. has received speaker and consulting fees from Pfizer and Johnson &amp; Johnson that are not related to this study." All others report none</p>
Notes	<p>Strategy: Adjunctive counseling, Provider training, Audit &amp; feedback, Vital Sign Stamp, Consult Form, EMR prompts, Outreach facilitation, Performance coaching</p> <p>Level: Patient, Provider, Practice</p> <p>Comparison type: Active vs. active (isolates performance coaching)</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	QUOTE: "A simple blocked randomization scheme was used in which blocks of four clinics were randomized". No further detail given
Allocation concealment	Unclear risk	QUOTE: "The Methods Centre provided the principal investigator with the list of practice assignments". No further detail given
Blinding of outcome assessors All outcomes	Low risk	Smoking status was self-report; but contact with participants was balanced between arms
Incomplete outcome data All outcomes	Low risk	At participant level, 21.3% (n = 85/399) in the OMSC group and 18.1% (n = 86/475) in OMSC+ group were lost to follow-up at 6 months post-intervention

## Papadakis 2018 (Continued)

Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "There were no differences in practice and clinician characteristics between intervention groups"
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "Multilevel models account for the clustered design. A 3-level generalised linear mixed model estimated the effect of the intervention for each outcome measure..."

## Parkes 2008

### Study characteristics

Methods	Design: Randomized controlled trial  Setting: 5 general practices in Hertfordshire, UK  Recruitment: Identified potentially eligible participants by searching computerized patient records from the practices. A letter of invitation was sent to the identified patients. 2 weeks later, those who had not already responded were telephoned and offered an invitation to participate. Those who could not be contacted by telephone were sent a second letter
Participants	561 adults who smoked (> 35 years). av.age 53, 46% M, 17 cpd
Interventions	Intervention: Participant performed spirometry then was given their results verbally in the form of "lung age" with a graphic display. Within 4 weeks of data collection the research doctor sent all participants an individualized letter. Written results were given to the intervention group as "lung age."  Control: Participants were not told their spirometry results, but informed that they would be invited for a second test after 12 months to "see if there had been any change in lung function." Within 4 weeks of data collection the research doctor sent all participants an individualized letter. Written results were given to the control group as simple FEV1 (liters per second) with no further explanation
Outcomes	24-hour PPA at 12m  Validation: Salivary cotinine < 14.2 ng/ml
Funding Source	Funding: Leading practice through research award from the Health Foundation
Author's declarations of interest	Authors declared that they had no competing interest
Notes	Strategy: Spirometry (Lung age monitoring)  Level: Patient  Comparison type: Single component vs. standard care

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Clerk prepared 600 sequentially-numbered opaque sealed envelopes, each containing a card with allocation group determined by computer-generated random number

**Parkes 2008** (Continued)

Allocation concealment	Low risk	Opaque sequentially-numbered sealed envelopes
Blinding of outcome assessors All outcomes	Low risk	Smoking abstinence was biochemically validated
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 11.2% (n = 63/561); 11.1% (n = 31/280) in the intervention group and 11.4% (n = 32/281) in the control group were lost to follow-up at 12 months

**Pereira 2006**
**Study characteristics**

Methods	Design: Cluster-randomized controlled trial  Setting: General practitioners in the Languedoc-Roussillon region of France  Recruitment: Practices were sent a letter of invitation, participants recruited in practice
Participants	1075 adults who smoked, 52% F, av. age 41, av. cpd not reported
Interventions	1. Intervention: 3-day training program for GPs, consisted of concrete steps in creating and installing routine cessation interventions in general practice, taught by 8 professionals, whose expertise lay in cessation programs, teaching methods or patient education. Trained GPs offered 8 special consultations for smoking cessation  2. Control: Usual care. No further detail
Outcomes	Abstinence (undefined) at 12m  Validation: None  Measures of provider implementation: Assist-Self-help, Assist-Prescribe
Funding Source	All sources were either non governmental associations, either government and health department or public health assurance
Author's declarations of interest	Not reported
Notes	Strategy: Provider training  Level: Provider  Comparison type: Single component vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors	Unclear risk	Abstinence was self-report; hard to tell with contact different between arms

**Strategies to improve smoking cessation rates in primary care (Review)**

## Pereira 2006 (Continued)

### All outcomes

Incomplete outcome data All outcomes	Unclear risk	Follow-up rate: 68.5%. No further information
Recruitment bias (cluster RCTs only)	Unclear risk	No details reported
Balanced baseline charac- teristics? (cluster RCTs on- ly)	Low risk	No statistical differences in GPs by group. Participant differences were noted and controlled for in analysis
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "Marginal models, estimated by GEE and mixed generalised linear models are used for this type of design"

## Pérez Tortosa 2015

### Study characteristics

Methods	Design: Cluster-randomized controlled trial  Setting: Primary care teams from Barcelona, Spain  Recruitment: Opportunistically in practice
Participants	948 people with diabetes who smoked, aged 14 or older, that receive routine diabetes care in the participating practice (456 intervention, 492 control). 73% M, av.age 58, 17cpd.
Interventions	Intervention:  • Doctors and nurses received a full-day specific training workshop on motivational interview and pharmacological treatment. Workshops were focused on people with diabetes who smoked and were taught by trained experts. They also were trained in the dynamics of the follow-up visits according to the stages of change and in how to use the electronic data collection systems  • Participants received adjunctive counseling.  Control: providers attended a practical training session that covered the methodology of the study and the electronic data collection system
Outcomes	6m continuous abstinence at 12m  Validation: Expired CO < 6 ppm
Funding Source	Financial help from an Evaluation of Sanitary Technologies and Health Services grant (Evaluación de Tecnologías Sanitarias y Servicios de Salud), given by the Carlos III Health Institute (PI08/90345) in 2008
Author's declarations of interest	QUOTE: "the authors declare that they have no conflicts of interest in relation to this study"
Notes	Strategy: Provider training + Adjunctive counseling  Level: Provider + Patient  Comparison type: Multicomponent vs. standard care

### Risk of bias

## Strategies to improve smoking cessation rates in primary care (Review)

**Pérez Tortosa 2015** (Continued)

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	QUOTE: "...using a centralized, computerized randomisation system"
Allocation concealment	Low risk	QUOTE: "...using a centralized, computerized randomisation system"
Blinding of outcome assessors All outcomes	Low risk	Smoking status biochemically validated
Incomplete outcome data All outcomes	Low risk	At participant level, the overall loss to follow-up was 23.8% (n = 226/948); 24.3% (n = 111/456) in the intervention group and 23.4% (n = 115/492) in the control group at 12 months
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "Patients in the intervention arm as compared with controls showed significantly higher scores in the Richmond test". Statistically significant differences in baseline TTM stages, with a lower percentage of participants in the pre-contemplation stage (27.8% vs. 49.6%) and a higher percentage in the preparation/action stage in the intervention group than in controls. Adjusted for differences.
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "A multilevel mixed-effects logistic regression with random effect estimates for primary care team clusters was performed to assess the effect of intervention on smoking abstinence adjusted by TTM stage at inclusion in the study"

**Piper 2016**
**Study characteristics**

Methods	<p>Design: Fractional factorial screening experiment</p> <p>Setting: Primary care clinics in southern Wisconsin, USA</p> <p>Recruitment: participants were recruited from 11 primary care clinics. During clinic visits, clinical care staff were prompted by electronic health record technology to invite people identified as smoking to participate in the study</p>
Participants	637 participants, 55% F, av. age 45.8, average cpd not reported
Interventions	<p><i>Intervention 1.</i> Pre-quit nicotine patch</p> <p>Half the participants were assigned to the active condition and received 14 mg patches for the 3 weeks prior to the TQD, while the other half did not receive prequit patches</p> <p><i>Intervention 2.</i> Prequit nicotine gum</p> <p>Participants in the active condition received 2 mg nicotine gum for the 3 weeks prior to the TQD (<math>\geq 9</math> pieces of gum/day, 1 piece/1 – 2 hours); the other half did not. Participants who received both Prequit Patch and Gum were told to use at least 5 pieces/day of gum, unless such use produced adverse effects</p> <p><i>Intervention 3.</i> Preparation counseling</p> <p>Participants in the active condition received 3 x 20-min counseling sessions prior to the TQD, focused on coping skills, reduction, and making practice quit attempts, while the other half of participants did</p>

**Piper 2016** (Continued)

not. The sessions 3 weeks and 1 week before the TQD were in-person, and the week-2 session was over the phone

*Intervention 4. In-person counseling*

Participants in the intensive condition received 3 x 20-min face-to-face counseling sessions: 1 week pre-TQD, on the TQD, and at week 1. Sessions focused on skill building and intra-treatment social support. Participants assigned to the minimal level received 1 x 3-min in-person session at Week-1

*Intervention 5. Phone counseling*

Participants in the intensive condition received 3 x 15-min phone sessions (TQD, Days 2 and 10), focused on coping skills, avoiding smoking cues, and intra-treatment social support. Participants assigned to the minimal condition received 1 x 10-min session on the TQD. Thus, all participants received someTQD phone counseling

*Intervention 6. Extended medication*

All participants received combination NRT (nicotine patch + nicotine gum) starting on their TQD. Half were assigned to receive 8 weeks of patches and 8 weeks of nicotine gum. The other half received 16 weeks of patches and 16 weeks of gum

Outcomes	7-day PPA at 6m  Validation: None  Quit attempts
Funding Source	Grants from the National Cancer Institute to the University of Wisconsin Center for Tobacco Research and Intervention and by the Wisconsin Partnership Program. Dr. Collins is also supported by NIH grants
Author's declarations of interest	Authors declared that they had no conflict of interest
Notes	Strategy: Adjunctive counseling (preparation phase and cessation phase, in person and via telephone), cost-free medications (pre- and post-quit, gum and patch)  Level: Patient  Comparison types: Active vs. active  Due to the complexity of the intervention components and combinations of intervention components tested, it was impossible to include this study in any of our meta-analyses. Instead we describe the authors' conclusions narratively, in supplementary table 3.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Database that used stratified permuted block randomization
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	High risk	Smoking status self-report. Different contact between trial arms
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 41.3% (n = 263/637); the number lost to follow-up ranged from 36% to 46% across the 6 factors at 6 months

## Piper 2018

### Study characteristics

Methods	Design: randomized controlled trial  Setting: 7 primary care clinics within 2 Wisconsin healthcare systems, USA  Recruitment: Mailings to patients identified from electronic health record
Participants	623 people who smoked 57.3% F, av. age 49.7, av. cpd 16.8
Interventions	Common components in both groups: counseling and nicotine patches (duration different between the groups)  Intervention: participants received 3 weeks of prequit mini-lozenges, 26 weeks of nicotine patch + mini-lozenges, 3 in-person and 8 phone counseling sessions, and 7 – 11 automated prompts to use medication Control: participants received 10 minutes of in-person counseling, 8 weeks of nicotine patch, and referral to quitline services
Outcomes	PPA at 12m Validation: CO < 6 ppm
Funding Source	National Institutes of Health
Author's declarations of interest	Authors declared that they had no conflict of interest
Notes	Strategy: Adjunctive counseling, cost-free medications, medication prompts  Level: Patient  Comparison type: Multicomponent vs. standard care

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	QUOTE: "Computer-based randomization used a 1:1 randomization within blocks of six participants, stratified by gender"
Allocation concealment	Low risk	QUOTE: "Computer-based randomization used a 1:1 randomization within blocks of six participants, stratified by gender"
Blinding of outcome assessors All outcomes	Low risk	Smoking status was biochemically validated
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 45.1% (n = 281/623); 48.1% (n = 148/308) in the intervention group and 42.2% (n = 133/315) in the control group were lost to follow-up at 12 months

## Pisinger 2010

### Study characteristics



**Pisinger 2010** (Continued)

Methods	Design: 3-group cluster randomized controlled trial  Setting: Primary care, Denmark  Recruitment: Practices recruited by mailed invitation letter. All patients seen by GP were registered
Participants	1518 adults who smoked, 62.6% F, av. age 48, 17 cpd
Interventions	<i>Intervention 1:</i> GPs were instructed to briefly and freely talk about smoking with all people who smoked and refer those people who were motivated to quit to a group-based smoking cessation counseling.  <i>Intervention 2:</i> GPs were instructed to briefly and freely talk about smoking with all people who smoked and refer all those motivated to quit to an Internet-based smoking cessation program  <i>Control:</i> GPs were instructed to give smoking cessation advice and assistance to quit as they used to (not necessarily to all people who were smoking). The control group did not have any special program, beyond what is known from a national survey on Danish GPs ultimo 2004. In this study, the control group only registered whether they discussed smoking with the participant or not and the time consumed by counseling
Outcomes	7-day PPA at 12m  Validation: Urinary cotinine < 200 ng/ml
Funding Source	Danish Centre for Evaluation and Health and Technology Assessment
Author's declarations of interest	Not reported
Notes	Strategy: Adjunctive counseling + Internet program  Level: Patient  Component type: Single component vs. standard care (different single components tested in different intervention arms)

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	QUOTE: "The GPs were pre-randomised at the Research Centre by a computer generated list to one of the three groups"
Allocation concealment	Low risk	QUOTE: "The GPs were pre-randomised at the Research Centre by a computer generated list to one of the three groups"
Blinding of outcome assessors All outcomes	Low risk	Smoking status biochemically validated
Incomplete outcome data All outcomes	High risk	Overall, 50.2% (n = 758/1518) of participants were lost to follow-up at 12 months. No further details by group were reported
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "There were no significant differences between the groups in terms of the number of patients seen or smokers included"

**Pisinger 2010** (Continued)

Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	No additional effect on self-reported 1-year abstinence rates of either referral to group- based SC counseling was found in cluster analyses
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**Ramos 2010**
**Study characteristics**

Methods	Design: 3-group randomized controlled trial  Setting: A primary healthcare setting in Mallorca, Spain  Recruitment: Patients who met inclusion criteria were invited to participate
Participants	287 adults who smoked, who are preparing to quit. (81 in individual intervention, 111 in group intervention, 95 control), av. age 44, av. cpd 20
Interventions	<i>Intervention 1:</i> As control (below), plus individual counseling on pharmacological treatment  • Participants attended 6 visits during which the following were provided: counseling, pharmacotherapy, psychological support and standard follow-up  • Physicians and nurses received training on how to implement intensive interventions  <i>Intervention 2:</i> As control below, plus group counseling on pharmacological treatment  • Participants attended 6 visits during which the following were provided: counseling, pharmacotherapy, psychological support and standard follow-up  • Physicians and nurses received training on how to implement intensive interventions  <i>Control:</i>  • Participants received pharmacotherapy (nicotine derivatives or bupropion)  • Physician and nurse received basic training on how to diagnose smoking addiction and provide brief counseling  • Support provided by microteam, composed of 1 physician and 1 nurse
Outcomes	Continuous abstinence at 12m  Validation: Expired CO < 6 ppm
Funding Source	Health Research Fund of Spain's Ministry of Health and Consumer Affairs, Health Promotion and Preventive Activities in Primary Health Care Research Network
Author's declarations of interest	Authors declared that they had no competing interest
Notes	Strategy: Adjunctive counseling + Provider training  Level: Patient + Provider  Comparison type: Multicomponent vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
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**Strategies to improve smoking cessation rates in primary care (Review)**

## Ramos 2010 (Continued)

Sequence Generation	Unclear risk	No details reported.
Allocation concealment	Low risk	QUOTE: "an allocation concealment method based on the use of sequentially-numbered, opaque, sealed envelopes was used"
Blinding of outcome assessors All outcomes	Low risk	Smoking status biochemically validated.
Incomplete outcome data All outcomes	High risk	Follow-up at 12 months was very low and completed in 31% of cases in intervention 1 (individual), 28% in the intervention 2 (group) and 24% in the control group (minimal intervention).

## RBR-7yx9hd

### Study characteristics

Methods	Design: randomized controlled trial  Setting: primary healthcare unit, Brazil  Recruitment: no details provided
Participants	Target was 80 adults who smoked (final recruitment not confirmed). Eligible participants were adult daily cigarettes users for at least 1 year, av. age not reported, av. cpd not reported
Interventions	Intervention: participants received a 40-minute counseling session on cessation using brief intervention with motivational interviewing by a trained interviewer with a degree in psychology or medicine  Control: participants received 1 session per week of standard treatment for smoking with a cognitive-behavioral approach for 8 weeks
Outcomes	7-day PPA at 3m and 6m  Validation: none  Quit attempts
Funding Source	Universidade Federal de Juiz de Fora - Juiz de Fora, MG, Brazil
Author's declarations of interest	Not reported
Notes	Strategy: Adjunctive counseling  Level: Patient  Comparison type: Single component vs. standard care  Trial ID: <a href="#">RBR-7yx9hd</a> . The study lead investigator was contacted by email and she confirmed that they do not intend to analyse and publish study results.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	Not reported

## Strategies to improve smoking cessation rates in primary care (Review)

**RBR-7yx9hd** (Continued)

Allocation concealment	Unclear risk	Not reported
Blinding of outcome assessors All outcomes	Unclear risk	Not reported
Incomplete outcome data All outcomes	Unclear risk	Not reported

**Richmond 1993**
**Study characteristics**

Methods	Design: Randomized controlled trial with 3 active trial arms  Setting: GPs in Sydney, Australia  Recruitment: GPs invited their patients to participate.
Participants	450 adults who smoked (16 - 65 years) free from any condition which was contraindicated for the use of nicotine gum. 60% F, av.age 35, 22 cpd
Interventions	<i>Intervention 1:</i> Participant saw GP at baseline, 1w, 3w, 3m, 6m and received comprehensive counseling from GP on how to quit smoking  <i>Intervention 2:</i> Participant saw GP at baseline, 1w, 3w, 3m, 6m and received comprehensive counseling from GP on how to quit smoking Participants were given a supply of nicotine gum, an explanation of its use, and an instruction booklet  <i>Intervention 3:</i> Participants attended a baseline visit and follow-up visits at 3m and 6m. At baseline participants were advised to quit by GP and given a supply of nicotine gum, an explanation of its use, and an instruction booklet
Outcomes	PPA at 12m  Continuous abstinence at 12m  Validation: None
Funding Source	Funded by the Department of Health, Housing and Community Services, Community Health Anti-Tuberculosis Association, Glaxo Australia, and the Drug and Alcohol Directorate, NSW Department of Health
Author's declarations of interest	Not reported
Notes	Strategy: Cost-free medications, adjunctive counseling  Level: Patient  Type: Active vs. active (isolates cost-free medications)

**Risk of bias**

Bias	Authors' judgement	Support for judgement
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## Richmond 1993 (Continued)

Sequence Generation	High risk	All participants were allocated according to random weekly assignment to 1 of 3 intervention groups
Allocation concealment	High risk	Weekly allocation. Could have been foreseen
Blinding of outcome assessors All outcomes	High risk	Smoking status was self-reported, and different contact between groups
Incomplete outcome data All outcomes	Unclear risk	QUOTE: "a number of patients who were out of contact were eliminated from the predictor analyses...and 12 month follow-ups (n = 59, 13%)"; "After the initial consultation, 15-25% of the patients on each occasion did not attend the session and could not be contacted". No further details reported

## Ronaldson 2018

### Study characteristics

Methods	Design: Randomized controlled trial  Setting: Primary care practice, UK  Recruitment: QUOTE: "patients at participating practices who met eligibility criteria were sent a recruitment pack through the post), and opportunistic recruitment by general practitioners (GPs) and nurses at face-to-face consultations"
Participants	674 adults older than 35 years; 49% F; mean age 53 years; 16 cpd on average
Interventions	The smoking cessation advice for both groups typically involved participants being offered a stop smoking program lasting 6 to 8 weeks, either on a one-to-one basis or with group support, with or without medication, which could have comprised nicotine or non-nicotine products.  Intervention: participants received lung function tests (spirometry, microspirometry, peak flow meter measurement, and a Wheezometer) and case finding questionnaires  Control: participants were on waiting list for the intervention, as well as receiving usual care (above). Participants received the spirometry intervention after the final trial follow-up
Outcomes	Self-reported PPA at 6m  Validation: None
Funding Source	Department of Health Respiratory Programme
Author's declarations of interest	Authors declared that they had no conflict of interest
Notes	Strategy: Spirometry  Level: patient  Comparison type: Single component vs. standard care

### Risk of bias

Bias	Authors' judgement	Support for judgement
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**Ronaldson 2018** (Continued)

Sequence Generation	Low risk	QUOTE: "the sequence generated by an independent data manager"
Allocation concealment	Low risk	QUOTE: "The randomisation sequence was concealed using York Trials Unit's secure randomised system, which was accessed by computer"
Blinding of outcome assessors All outcomes	High risk	Abstinence was self-reported and there was different contact between trial arms
Incomplete outcome data All outcomes	Low risk	32/387 (8.3%) in the usual care arm and 53/767 (6.9%) in the intervention arm were lost to follow-up
Other bias	High risk	Waitlist control study. It appears that participants knew they were on a waiting list, based on the following statement: QUOTE: "Participants, clinicians, investigators, and evaluators were not blind to the participants' group allocation because of the nature of the trial design and analysis". This means participants in the control arm may have postponed their quit attempt until after the trial, when they received treatment

**Roski 2003**
**Study characteristics**

Methods	Design: 3-group cluster-randomized controlled trial  Setting: 40 clinics of a large multispecialty medical group practice providing primary care services, USA  Recruitment: Exit interviews with patients in the clinic
Participants	4813 patients (873 people who smoked) at baseline survey. 4734 patients (863 people who smoked) at follow-up. Patients were 18 years or older who had visited their provider in the past 30 days, av.age not reported, av. cpd not reported
Interventions	Common component in all groups: printed versions of the smoking cessation guidelines distributed to the practices.  <i>Intervention 1:</i> practices received printed versions of the smoking cessation guidelines, financial incentives for reaching preset clinical performance targets  <i>Intervention 2:</i> practices received printed versions of the smoking cessation guidelines, financial incentives for reaching preset clinical performance targets combined with access to a centralized registry of people who smoked and intervention system which delivered telephone counseling  <i>Control:</i> distribution of printed versions of the smoking cessation guidelines only
Outcomes	7-day PPA at 6m  Validation: None Measures of provider implementation: Ask, Advise, Assist
Funding Source	Supported in part by a grant from the Robert Wood Johnson Foundation (Grant 036023)
Author's declarations of interest	Not reported
Notes	Strategy: Adjunctive counseling + Provider incentive  Level: Patient + Practice + System

**Roski 2003** (Continued)

Comparison type: Single component (provider incentives vs. standard care), active vs. active (isolating adjunctive counseling) & multicomponent vs. SC (provider incentives & adjunctive counseling)

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	Randomly allocated by block randomization. No further details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	High risk	Smoking status self-report. Contact between arms was different
Incomplete outcome data All outcomes	Unclear risk	No details reported
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "At baseline no differences were found between the experimental conditions with respect to identification of tobacco use, provision of advice to quit, and assistance in quitting at the most recent clinic visit"
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "Analyses of practice pattern changes (identification, offer of advice to quit) and patient outcomes (quitting) made use of clustered logistic regression"

**Russell 1983**
**Study characteristics**

Methods	Design: 3-group randomized controlled trial  Setting: 6 group practices in London and Kent, UK  Recruitment: Completed in practice
Participants	2106 adults who smoked aged 16 years or more; 57% F; mean age 40.5 years; 17.5 cigarettes per day on average
Interventions	<i>Intervention 1:</i> participants were advised to quit smoking and given a booklet  <i>Intervention 2:</i> participants were advised to quit smoking, given a booklet and a prescription for free NRT gum  <i>Control:</i> no intervention, no advice. No further details reported
Outcomes	Abstinence (undefined) at 12m  Validation: Expired CO < 8 ppm  Quit attempts
Funding Source	Financial support was provided by the Medical Research Council and the AB Leo Research Foundation, Sweden



## Russell 1983 (Continued)

Author's declarations of interest	Not reported
Notes	Strategy: Cost-free medications Level: Patient Comparison type: Single component vs. standard care

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	High risk	Participants were assigned to groups according to their week of attendance
Allocation concealment	High risk	Not concealed
Blinding of outcome assessors All outcomes	High risk	Smoking status was self-reported. Authors state that the control group had no advice, which implies that face-to-face contact was greater in the intervention groups
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 8.0% (n = 168/2106); 8.8% (n = 65/740) in the 'advice+booklet' group, 6.9% (n = 50/729) in the 'advice+booklet+prescription' group and 8.3% (n = 53/637) in the control group were lost to follow-up at 12 months

## Salkeld 1997

### Study characteristics

Methods	Design: 3-group cluster-randomized controlled trial Setting: GPs practising in the Western Metropolitan Region of Sydney, Australia Recruitment: GPs recruited patients in practice
Participants	75 practices 82 providers 755 patients (255 people who currently smoked): 49% F, av.age 52; av. cpd not reported
Interventions	<i>Intervention 1:</i> <ul style="list-style-type: none"> <li>General practitioners received an education guide and a video to help them assess individual patient risk factors and plan a program for risk factor behavior change</li> <li>Participants received a risk factor assessment, education materials, a series of videos to watch on lifestyle behaviors</li> </ul> <i>Intervention 2:</i> as per Intervention 1. In addition, participants received a self-help booklet (not relevant to this review) <i>Control:</i> GP training and standard care. No further details reported
Outcomes	Undefined abstinence at 12m Validation: None

## Salkeld 1997 (Continued)

Funding Source	This work was funded by the General Practice Evaluation Program, Commonwealth Department of Human Services and Health, Australia
Author's declarations of interest	Not reported
Notes	<p>Strategy: Provider training &amp; video education</p> <p>Level: Patient and provider</p> <p>Type: Active vs. active (isolates video education)</p> <p>Multirisk factor study</p> <p>Data subgrouped and not usable for the whole sample. Attempts to contact authors unsuccessful, so data are not presented</p>

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Low risk	Smoking status was self-reported. The interventions were in the form of a video or a combination of a video and written material so face-to-face contact was similar in the routine care group and 2 intervention groups
Incomplete outcome data All outcomes	High risk	At participant level, the overall loss to follow-up was 36.1% (n = 273/757); 49.0% (n = 125/255) in the routine group, 26.3% (n = 71/270) in the video group and 33.2% (n = 77/232) in the video and self-help group. Although the number lost to follow-up was less than 50%, losses were different between groups and some clusters were lost in all groups (5 GPs in the routine group and 4 GPs in the video+self help group)
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization
Balanced baseline characteristics? (cluster RCTs only)	Unclear risk	No details reported
Adjustment for clustering in analysis? (cluster RCTs only)	High risk	QUOTE: "...No adjustment was made for clustering effects"

## Sanz-Pozo 2006

### Study characteristics

Methods	<p>Design: Randomized controlled trial</p> <p>Setting: Primary care clinic, Spain</p> <p>Recruitment: GPs recruited patients in practice</p>
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## Sanz-Pozo 2006 (Continued)

Participants	125 people who smoked daily, attending clinic, motivated to make a quit attempt but not interested in using pharmacotherapy, av.age ~ 40, av.cpd 19, 52% F (intervention), 62% F (control)
Interventions	Intervention: participants received brief advice from their doctor at recruitment, an appointment with clinic nurse 7 days before TQD, on TQD, 1w, 1m, 2m, 3m. Control: participants received brief advice only
Outcomes	12m sustained abstinence at 24m Validation: Expired CO < 8 ppm
Funding Source	Not reported
Author's declarations of interest	Not reported
Notes	Strategy: Adjunctive counseling  Level: Patient  Comparison type: Single component

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	QUOTE: "the patients recruited were randomised, according to the clinic from which they came, to the group that received...". No further detail.
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Low risk	Smoking abstinence was biochemically validated
Incomplete outcome data All outcomes	High risk	The overall loss to follow-up was 42.4% (n = 53/125); 75% (n = 45/60) in the intervention group and 12.3% (n = 8/65) in the control group were lost to follow-up at 2 years

## Secades Villa 2009

### Study characteristics

Methods	Design: 3-group cluster-randomized controlled trial  Setting: 3 primary care centers in Asturias, Spain  Recruitment: Opportunistic recruitment of people who smoked attending the practice
Participants	89 adults who smoked (> 10 cpd) ready to quit. 61% F, 22 cpd, av.age 43
Interventions	<i>Intervention 1:</i> participants received a 7-minute brief counseling in which they set a quit date, self-help materials and 4 follow-up telephone calls from a general practitioner or a primary care nurse  <i>Intervention 2:</i> participants received 1 x 20-min counseling session weekly for 5 weeks, delivered by a clinical psychologist  <i>Control:</i> participants received a 7-minute brief counseling and self-help materials

## Secades Villa 2009 (Continued)

Outcomes	Continuous abstinence at 12m Validation: Expired CO $\leq$ 4 ppm
Funding Source	Supported by research grant no. MB-02-506-2 from the University of Oviedo (Spain)
Author's declarations of interest	Not reported
Notes	Strategy: Adjunctive counseling Level: Patient Comparison type: Single component vs. standard care

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Low risk	Smoking status biochemically validated
Incomplete outcome data All outcomes	Low risk	At 6-month follow-up, 100% of participants were located
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization
Balanced baseline characteristics? (cluster RCTs only)	High risk	There were statistically significant differences among the groups ( $P < .05$ ) on 2 characteristics: age and years smoking
Adjustment for clustering in analysis? (cluster RCTs only)	Unclear risk	No details reported

## Segnan 1991

### Study characteristics

Methods	Design: Randomized controlled trial with 4 active comparators Setting: Primary care practices in Turin, Italy Recruitment: GPs recruited patients opportunistically in practice
Participants	44 providers: GPs with at least 400 individuals on patient list 923 patients: 20 - 60 years of age, currently smoking, no life-threatening disease. 32.3% F, av. age not reported, av. cpd not reported
Interventions	Common components in all groups:

## Segnan 1991 (Continued)

- Physicians attended 2 x 3-hour training sessions on counseling techniques and organizational aspects of the study

*Intervention 1: minimal intervention group*

Participants received 1 session of face-to-face counseling and an explanatory brochure

*Intervention 2: repeated counseling group*

Participants received 1 session of face-to-face counseling, an explanatory brochure and follow-up appointments at months 1, 3, 6, and 9 (non-relevant intervention group as GPs provided adjunctive counseling)

*Intervention 3: nicotine gum group*

Participants received 1 session of face-to-face counseling, an explanatory brochure, follow-up appointments at months 1, 3, 6, and 9, plus nicotine gum to last until the first follow-up visit

*Intervention 4: spirometry group*

Participants received 1 session of face-to-face counseling, an explanatory brochure, follow-up appointments at months 1, 3, 6, and 9, plus a prescription for spirometry test. Report showed results in the form of lung age

Outcomes	3m prolonged abstinence at 12m  Validation: Urinary cotinine < 100 ng/mg  Measures of provider implementation: Advise, Arrange
Funding Source	Piedmont Health Authority
Author's declarations of interest	Not reported
Notes	Strategy: Spirometry + Cost-free medications + Provider training  Level: Patient + Provider  Type: Active vs active

### **Risk of bias**

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Sequence Generation	Unclear risk	Authors state that a predetermined randomized sequence was used. No further detail provided
Allocation concealment	Low risk	Opaque envelopes were used
Blinding of outcome assessors All outcomes	Low risk	Abstinence was biochemically validated
Incomplete outcome data All outcomes	Unclear risk	The overall loss to follow-up was 13% at 12 months. No details on the number lost to follow-up by group were reported

## Sherman 2007

### Study characteristics

Methods	<p>Design: Cluster-randomized controlled trial</p> <p>Setting: 2 primary care teams at the Sepulveda VA Ambulatory Care Center, USA</p> <p>Recruitment: All patients with at least 3 primary care visits in the past year were invited to participate through a computer-assisted telephone interview</p>
Participants	482 adults who smoked within the Sepulveda Ambulatory Care Centre, av. age not reported, av. cpd not reported
Interventions	<p>Intervention:</p> <ul style="list-style-type: none"> <li>Providers had access to an on-call counselor who could be paged to provide 10 - 15 minutes of counseling and make a referral to a smoking cessation program or a quitline as required. The counselors provided case management for all participants for 2 months, making follow-up calls to them each lasting 5 - 15 minutes. Each provider received monthly educational outreach visits from the counselors or the opinion leader for the first 3 months. In addition, providers were posted profiling data. The provider who referred the most patients was presented with financial incentives (USD 25 gift certificate) at the end of each month. Participants received case management by the counselor and also medications.</li> </ul> <p>Control: usual care. No further details reported</p>
Outcomes	<p>30-day PPA at 6m</p> <p>Validation: None</p> <p>Quit attempts</p> <p>Measures of provider implementation: Ask, Assist-Prescribe (NRT), Assist-Prescribe Bupropion, Arrange-Quitline referral, Arrange-Cessation program</p>
Funding Source	This work was funded by a grant from the California Tobacco-Related Disease Research Program (#10RT-0023)
Author's declarations of interest	Authors declared that they had no conflict of interest
Notes	<p>Strategy: Adjunctive counseling &amp; cost-free medications + academic detailing + financial incentives + audit &amp; feedback</p> <p>Level: Patient, Provider, Practice</p> <p>Comparison type: Multicomponent vs standard care</p>

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	1 primary care team was randomly assigned by coin flip
Allocation concealment	Unclear risk	Coin flip to assign 1 team to the intervention and the other team to usual care
Blinding of outcome assessors All outcomes	High risk	Self-report. Different contact between groups

## Sherman 2007 (Continued)

Incomplete outcome data All outcomes	High risk	At participant level, the overall loss to follow-up was 47.9% (n = 231/482); 50.9% (n = 108/212) in the intervention group and 45.6% (n = 123/270) in the usual care group at post-intervention follow-up
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the primary care clinic before randomization
Balanced baseline characteristics? (cluster RCTs only)	High risk	Participants on the intervention team were more likely to have ever tried to quit smoking (OR (95% CI): 2.4 (1.4 - 4.2)) and to have quit for at least 1 day in the last year (OR (95% CI): 1.5 (1.1 - 2.2)). They were less likely than participants on the control team to have chronic obstructive pulmonary disease
Adjustment for clustering in analysis? (cluster RCTs only)	High risk	QUOTE: "Multilevel modeling could not be used to account for clustering at the team level, as there were only 2 teams"

## Sherman 2008

### Study characteristics

Methods	Design: Cluster-randomized controlled trial  Setting: 18 Veterans Health Administration (VA) sites in California, USA  Recruitment: Proactive calls to patients
Participants	2965 patients referred for smoking cessation telephone counseling. av.age 57, 93% M, av. cpd not reported
Interventions	Intervention:  <ul style="list-style-type: none"> <li>• Practices received telephone care coordination program which allowed providers to be able to make a simple 2-click referral. Practices were also provided with proactive care coordination</li> <li>• Participants, once connected to the quitline, were scheduled to receive a single 30 - 45-minute counseling sessions within 7 days. A Veterans Health Administration care coordinator monitored medications (nicotine patches or bupropion) prescribed by a designated smoking cessation clinician. The care coordinators also offered follow-up counseling telephone calls at 2, 4, 6 and 8 weeks after the quit date and at 6 months.</li> </ul> Control: usual care comprising direct treatment by a primary care provider, referral to a Veterans Health Administration smoking clinic, or informal referral to an outside resource such as a quitline
Outcomes	30-day PPA at 6m  Validation: None  Providers were asked to approximate the following provider implementation outcomes: Assist, Arrange;
Funding Source	Grant SUDCC 3.10 from the Veterans Affairs Substance Use Disorders Quality Enhancement Research Initiative and by grant HFP 94-028 from the Veterans Affairs Health Services Research and Development Center of Excellence for the Study of Healthcare Provider Behavior
Author's declarations of interest	QUOTE: "the authors (SES, NT, PK, EG, JWF, JC, JFK, GJJ, WK) report no relationship or financial interest with any entry that would pose a conflict of interest with the subject matter of this article"
Notes	Strategy: Adjunctive counseling + EMR prompts



## Sherman 2008 (Continued)

Level: Patient, practice

Comparison type: Multicomponent vs. standard care

Abstinence is only reported for the intervention arm and not the standard-care arm. Attempts to contact the authors were unsuccessful. Data are therefore not analyzed for any of the outcomes

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	High risk	Smoking status self-report. Person-to-person contact was different between groups
Incomplete outcome data All outcomes	Unclear risk	No details on loss to follow-up at participant level were reported
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the sites before randomization
Balanced baseline characteristics? (cluster RCTs only)	Unclear risk	No details reported
Adjustment for clustering in analysis? (cluster RCTs only)	Unclear risk	No details reported

## Siddiqi 2013

### Study characteristics

Methods	<p>Design: 3-group cluster-randomized controlled trial</p> <p>Setting: Health centers in Pakistan</p> <p>Recruitment: Opportunistic in practice</p>
Participants	1955 patients aged 18 years or older with suspected pulmonary tuberculosis (cough for 3 weeks without any other cause) who also regularly smoked tobacco ( $\geq 1$ cpd), av. age 41, 95% M, av. cpd 16
Interventions	<p><i>Intervention 1:</i> Behavioral support sessions (BSS)</p> <ul style="list-style-type: none"> <li>• Participants received 2 structured sessions delivered by directly-observed therapy facilitators using an educational flipbook (session 1: 30 minutes; session 2: 10 minutes on the quit day)</li> <li>• Directly-observed therapy facilitators received a 1-day training program delivered by the research team</li> <li>• Other healthcare professionals received briefing about BSS</li> </ul> <p><i>Intervention 2:</i> BSS+</p> <ul style="list-style-type: none"> <li>• Participants received a free 7-week course of sustained-release bupropion in addition to BSS</li> </ul>

### Strategies to improve smoking cessation rates in primary care (Review)

**Siddiqi 2013** (Continued)

- Physicians received training and written guidance on prescribing bupropion

*Control:*

- Participants received usual care and a self-help leaflet on smoking cessation. No further details on the usual care reported
- Directly-observed therapy facilitators received information on trial procedures only

Outcomes	Continuous abstinence at 6m  Valiation: Expired CO $\leq$ 9 ppm
Funding Source	International Development and Research Centre, Canada
Author's declarations of interest	Unable to access this information through the link provided in the paper
Notes	Strategy: Adjunctive counseling + Cost-free medications + Provider training  Level: Patient + Provider  Comparison type: Multicomponent vs. standard care; active vs active (isolating effect of cost-free medications)

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	QUOTE: "...computer generated random-number lists to generate the allocation sequence"
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	High risk	Smoking status is self-report and there was different contact between the control arm and the intervention arms
Incomplete outcome data All outcomes	Low risk	At participant level, the overall loss to follow-up was 5.8% (n = 114/1955 survivors); 8.0% (n = 53/659) in the BSS+ group, 3.1% (n = 20/640) in the BSS group, and 6.3% (n = 41/656) in the control group at 6-month follow-up
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the health centers before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "The 3 groups were generally similar with respect to the baseline characteristics, although mean age, sex, and smoking type differed slightly"
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "...adjusting for cluster effect using an intraclass correlation coefficient of 0.036"

**Sippel 1999**
**Study characteristics**

Methods	Design: Randomized controlled trial
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**Sippel 1999** (Continued)

Setting: 2 university-affiliated primary care clinics, USA

Recruitment: Patients approached by research staff in practice

Participants	205 adults who smoked, average age 38 years, 62% F, 20 cpd
Interventions	Intervention: participants received advice and cessation information. Additionally, they spent 10 - 15 minutes receiving spirometry, carbon monoxide analysis, interpretation and education  Control: participants received advice and cessation information
Outcomes	Continuous abstinence at 6m  Validation: None  Secondary outcomes: Quit attempts > 24 hours
Funding Source	Funded by the American Lung Association of Oregon and the American Academy of Family Practice
Author's declarations of interest	Not reported.
Notes	Strategies: Spirometry + CO monitoring  Level: Patient  Comparison type: Multi-component vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	High risk	QUOTE: "questionnaires were numbered consecutively at each clinic throughout the study period. Subjects receiving odd-numbered questionnaires were selected as the intervention group and those receiving even-numbered questionnaires were selected as the control group..."
Allocation concealment	High risk	QUOTE: "the nurses performing patient check-in were blinded to the questionnaire numbers. As four to six nurses conducted patient check-ins independently and simultaneously at each clinic, it is unlikely that any given patient would be preferentially enrolled into either study arm". It is unclear how the nurses were blinded to the questionnaire numbers.
Blinding of outcome assessors All outcomes	High risk	Smoking status was self-reported and face-to-face was different between the groups
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 15.6% (n = 32/205); 12.6% (n = 13/103) in the intervention group and 18.6% (n = 19/102) were lost to follow-up at 6 months

**Swartz 2006**
**Study characteristics**

Methods	Design: Cluster-randomized controlled trial  Setting: 50 primary care practices, USA
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**Swartz 2006** (Continued)

Recruitment: Practices were recruited by telephone invitations

Participants	1892 adults who smoked (807 eligible for abstinence analysis: av.age 42, 25% M, 15 cpd)
Interventions	<p>Common components in both groups: detailing sheet summarizing effective treatment, profiling data feedback (by mail in the control group) and a Treating Tobacco Together pen</p> <p>Intervention:</p> <ul style="list-style-type: none"> <li>• Providers received the same intervention as the control arm, plus:</li> </ul> <p>A 20 - 30 minute educational session on evidence-based tobacco treatment in their practice and a second educational session 5 - 6 months later. Providers were encouraged to use the ICD-9 diagnosis code 205.1 and given information about the Maine Tobacco HelpLine which offers counseling</p> <p>Control: providers received the detailing sheet and all profiling data feedback graphs with a summary of findings and a Treating Tobacco Together pen by mail</p>
Outcomes	<p>7-day PPA at 15 - 18 m</p> <p>Validation: None</p> <p>Measures of provider implementation: Advise, Assess, Assist-Self-help, Assist-Meds, Arrange</p> <p>Quit attempts</p>
Funding Source	Agency of Research and Healthcare Quality
Author's declarations of interest	QUOTE: "Dr Swartz has received honoraria and research support from Pfizer. At the time of the study, Dr Goldstein was employee of Bayer Pharmaceutical Corporation. After the study was conducted, Mr Cowan became an employee of Health Dialog Analytic Solutions. No conflicts: Mooney-Murray, Haskins, DePue, Thompson, Leighton, Salem-Schatz"
Notes	<p>Strategy: Outreach facilitation, Audit &amp; feedback, Provider training</p> <p>Level: Provider + Practice</p> <p>Comparison type: Active vs. active (isolates provider training)</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Low risk	Smoking status self-report. However, contact with participants did not differ
Incomplete outcome data All outcomes	Unclear risk	QUOTE: "Of 1,892 patients who smoked at baseline, 1,238 were contacted at follow-up (65.4% response)". No further details by group were reported
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practices before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	No significant differences between the clusters, except for more participants in the control group practices were Medicaid enrollees

**Swartz 2006** (Continued)

Adjustment for clustering in analysis? (cluster RCTs only)

Low risk

QUOTE: "Models were adjusted for the clustering effect of patients within practices using the survey logistic procedure"

**Twardella 2007**
**Study characteristics**

Methods	<p>Design: 4-group cluster-randomized controlled trial</p> <p>Setting: Primary care in the Rhine–Neckar region, Germany</p> <p>Recruitment: Providers recruited patients in practice</p>
Participants	587 adults aged 36 – 75 years who smoked at least 10 cigarettes/day, av. age not reported, av. cpd not reported
Interventions	<p><i>Intervention 1:</i></p> <ul style="list-style-type: none"> <li>• General medical practitioners received a 2-hour cost-free group tutorial in methods of promoting smoking cessation. The general medical practitioners were assured a financial remuneration of EUR 130 after study completion for each study participant they recruited who was abstinent at 12 months follow-up</li> </ul> <p><i>Intervention 2:</i></p> <ul style="list-style-type: none"> <li>• General medical practitioners received a 2-hour cost-free group tutorial in methods of promoting smoking cessation</li> <li>• Participants were reimbursed up to EUR 130 for the purchase of nicotine replacement therapy or bupropion for up to 12 months.</li> </ul> <p><i>Intervention 3:</i></p> <ul style="list-style-type: none"> <li>• General medical practitioners received a 2-hour cost-free group tutorial in methods of promoting smoking cessation. General practitioners were assured a financial remuneration of EUR 130 after study completion for each study participant they recruited who was abstinent at 12 months follow-up</li> <li>• Participants were reimbursed up to EUR 130 for the purchase of nicotine replacement therapy or bupropion for up to 12 months</li> </ul> <p><i>Control:</i> usual care. No further details reported</p>
Outcomes	<p>6m sustained at 12m</p> <p>Validation: Salivary cotinine &lt;15 ng/ml</p>
Funding Source	Funded by the German Ministry of Education and Research (Bundesministerium für Bildung und Forschung), project number 01EB0113, within the context of the Baden–Württemberg Research Network on Addiction (project 01EB0113)
Author's declarations of interest	Authors declared that they had no competing interests.
Notes	<p>Strategy: Provider training + Provider incentive + Cost-free medication</p> <p>Level: Provider + Patient</p>

**Twardella 2007** (Continued)

Comparison type: Active vs. active (isolating cost-free medications & provider incentive) & multicomponent vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Computer-generated random sequence used
Allocation concealment	Low risk	QUOTE: "Randomisation was performed centrally at the German Center for Research on Ageing, Heidelberg, Germany...". Computer-generated random sequence used
Blinding of outcome assessors All outcomes	Low risk	Smoking status validated biochemically
Incomplete outcome data All outcomes	Low risk	At participant level, the overall loss to follow-up was 15.0% (n = 88/588); 19.7% (n = 15/76) in the usual care group, 15.1% (n = 22/146) in the TI group, 15.9% (n = 23/145) in the TM group, 12.7% (n = 28/221) in the TM+TI group were lost at 12-month follow-up
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practice before randomization
Balanced baseline characteristics? (cluster RCTs only)	High risk	In arms TM and TI+TM, the proportion of participants in the pre-contemplation stage was lower, and the proportion of participants in both the contemplation and preparation stages were higher than in the usual care and TI arms (P < 0.001)
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "The effect of both interventions on smoking abstinence at 12 months follow-up was assessed simultaneously in a mixed logistic regression model accounting for cluster randomisation - that is, including a random effect for medical practice in the model..."

**Unrod 2007**
**Study characteristics**

Methods	<p>Design: Cluster-randomized controlled trial</p> <p>Setting: Physicians located in the 4 largest metropolitan boroughs of New York City; Bronx, Brooklyn, Manhattan, and Queens, USA</p> <p>Recruitment: Facsimile invitation to physicians followed by telephone calls from a physician recruiter. Participants were recruited in physician waiting rooms</p>
Participants	518 adults who smoked, who had smoked more than 100 cigarettes in their lifetime. av. age 43, 60% M, 14 cpd
Interventions	<p>Intervention:</p> <ul style="list-style-type: none"> <li>Physicians received a 40-minute training on brief smoking cessation counseling which followed an academic detailing approach. Physicians also received a copy of a 1-page computerized report that characterized the participants' smoking habit and history and offered tailored recommendations</li> <li>Participants received a copy of the same computerized report that their physicians received</li> </ul>

## Unrod 2007 (Continued)

Control: physicians were not given any training and were instructed to continue their usual smoking cessation practice. No further details reported

Outcomes	7-day PPA at 6m  Validation: Salivary cotinine < 25 ng/ml  Secondary outcomes: Quit attempts Measures of provider implementation: Ask, Advise, Assess, Assist-Self-help, Assist-Prescribe, Arrange
Funding Source	The Agency for Healthcare Research and Quality
Author's declarations of interest	Authors declared that they had no financial conflicts of interest
Notes	Strategy: Provider training + Tailored print materials  Level: Patient & Provider  Comparison type: Multicomponent vs. standard care

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Random-number generator used
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Low risk	Smoking status validated biochemically
Incomplete outcome data All outcomes	Low risk	At physician level, there was no loss to follow-up at 6-month follow-up (0% (n = 0/70)). At participant level, the overall loss to follow-up was 10.2% (n = 465/518); 12.2% (n = 33/270) in the intervention arm and 8.1% (n = 20/248) in the control group were lost to follow-up at 6 months
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practices before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "Intervention and control groups did not differ on any demographic variables"
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "Patient 7-day point-prevalence abstinence was analyzed via a generalized linear model using Logit Link function, with physician as clustering variable. Mixed linear modeling, with physician as clustering variable, was used to examine longest quit attempt, number of quit attempts, and stage-of-change progression"

## Van Rossem 2017

### Study characteristics

Methods	Design: Randomized controlled trial
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## Van Rossem 2017 (Continued)

Setting: Primary healthcare center in The Netherlands

Recruitment: Participants were recruited by practice assistants, general practitioners (GPs) and practice nurses (PNs) and via a brief and easily written leaflet displayed in the waiting room

Participants	295 participants, 19 cpd, av.age 48, 53% F
Interventions	PN Group: Participants were offered 3 face-to-face and 7 telephone sessions, starting 1 week prior to the quit attempt until 1 year after the quit attempt. Participants also received a prescription for varenicline GP Group: Participants received a minimum of 1 visit in which they received a prescription for varenicline. Participants were free to contact their GP in case of questions or side-effects
Outcomes	Prolonged abstinence from 9w to 26w  Validation: Expired CO < 10 ppm
Funding Source	This was an investigator-initiated trial, funded by a collaboration of Eindhoven Corporation of Primary Health Care Centres (SGE), Pfizer (grant number GPIHP_RG_2010014T1330) and Research School CAPHRI
Author's declarations of interest	QUOTE: "D.K. received an unrestricted grant from Pfizer Inc. and The Eindhoven Corporation of Primary Health Care Centers for this investigator-initiated smoking cessation trial. C.S. received funding for research proposals from GlaxoSmithKline and Pfizer. A.L. was a general practitioner at The Eindhoven Corporation of Primary Health Care Centers during the research. All other authors declare that they have no competing interests in relation to this paper"
Notes	Strategy: Adjunctive counseling  Level: Patient  Comparison type: Single component vs. standard care

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Computer-generated random-number sequence
Allocation concealment	Low risk	Computer-generated random-number sequence, allocation disclosed by phone
Blinding of outcome assessors All outcomes	Low risk	Smoking status biochemically validated
Incomplete outcome data All outcomes	Low risk	The overall loss to follow-up was 18.0% (n = 53/295); 14.8% (n = 22/149) in the PN group and 20.0% (n = 31/146) in the GP group were lost to follow-up at 6 months

## Verbiest 2014

### Study characteristics

Methods	Design: Cluster-randomized controlled trial  Setting: General practices, The Netherlands
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**Verbiest 2014** (Continued)

Recruitment: Physicians were recruited by letter and a follow-up telephone call. During the study period (January – August 2011), adult patients visiting participating GPs in both conditions were asked to complete a questionnaire after consultation

Participants	49 providers, 57.1% M, av. age 52  2068 patients at baseline, including 433 adults who smoked. No further demographic details specifically on those who smoked reported
Interventions	Intervention: general practitioners attended a single, 1-hour training session based on the 5-As behavior change model. In addition all general practitioners received a toolkit, which contained a smoking cessation care flowchart, a summary of pharmacological support, leaflets for patients, and an opportunity to receive additional feedback support  Control: usual care defined as QUOTE: "the smoking cessation care that is usually provided by the general practitioner when not being trained, which is likely to vary between the general practitioners". No further details reported
Outcomes	Continuous abstinence at 9m  Validation: None  Measures of provider implementation: Ask, Advise, Assist–Prescribe, Arrange
Funding Source	Unrestricted grant from Pfizer and CAPHRI
Author's declarations of interest	Authored declared that they had no conflict of interest
Notes	Strategy: Provider Training + Flow sheet  Level: Provider + Practice  Type: Multicomponent vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	QUOTE: "...using a simple randomization procedure (coin tossing) by an independent researcher not involved in the recruitment of the GPs"
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Low risk	Smoking status was self-reported. At participant level, person-to-person contact did not differ
Incomplete outcome data All outcomes	Low risk	At participant level, including only those who reported smoking at baseline, the overall loss to follow-up was 48.0% (n = 208/433); 42.6% (n = 83/195) in the intervention group and 52.5% (n = 125/238) in the control group at 9-month follow-up
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practices before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "At baseline, more patients in the control group reported a chronic airway disease compared to the intervention group (15.4% vs. 12.4%; p=0.03)". Authors report using generalized estimating equations to adjust for participant characteristics

**Verbiest 2014** (Continued)

Adjustment for clustering in analysis? (cluster RCTs only)

Low risk

QUOTE: "Generalized estimating equations adjusted for clustering and patient characteristics"

**Vetter 1990**
**Study characteristics**

Methods	Design: Randomized controlled trial  Setting: A health center in a small town in the countryside, UK  Recruitment: Postal questionnaire to practice patients
Participants	471 people who smoked aged 60 years and older, registered as a patient with the group practice; 48.0% F, av. age not reported, av. cpd not reported
Interventions	Intervention: Participants received physician advice and additional smoking cessation counseling by a practice nurse  Control: Participants received physician advice only
Outcomes	PPA at 6m  Validation: Expired CO, cut-off not reported
Funding Source	The Grand Charity
Author's declarations of interest	Not reported
Notes	Strategy: Adjunctive counseling  Level: Patient  Comparison type: Single component vs. standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Low risk	Abstinence was biochemically validated by carbon monoxide levels
Incomplete outcome data All outcomes	Unclear risk	QUOTE: "approximately 10% of subjects failed to respond to the second questionnaire". No further details were reported.

## Yano 2008

### Study characteristics

Methods	Design: Cluster-randomized controlled trial  Setting: Veterans Health Administration (VA) primary care practices across 5 southwestern states, USA  Recruitment: All eligible practices within the Veterans Health Administration were approached
Participants	1941 primary care patients who were currently smoking, av.age 57, 94% M, av. cpd not reported
Interventions	Intervention:  Each intervention practice received the following:  - 30-minute didactic sessions on population-based smoking cessation  - Implementation planning  - Evidence summaries  - Recommendations for minimum protocols and implementation strategies  - Smoking cessation resource materials and tools for participants and providers  - Quality improvement manual outlining intervention processes and linking sites with research team assistance  - Monthly audio or video conferences with site leadership to facilitate ongoing local adaptation of the prioritized interventions  - Bimonthly newsletters highlighting practice successes and challenges among participating sites  - Quarterly audit-and-feedback progress reports  Control: sites received guideline copies and audit-feedback reports from externally-audited random patient records
Outcomes	30 day PPA at 12m  Validation: None  Measures of provider implementation: Advise, Arrange
Funding Source	Funded by the VAHSR&D Service
Author's declarations of interest	QUOTE: "The authors have no relevant financial interests or advocacy positions pertaining to this manuscript. VA policy requires submission of a copy of manuscripts on acceptance for internal preparation of briefings and/or press release as needed in anticipation of publication, but they do not undergo or require internal peer review or comment periods..."
Notes	Strategy: Outreach facilitation + Audit & feedback + Provider training  Level: Provider + Practice  Comparison type: Multi-component vs. standard care

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported

**Yano 2008** (Continued)

Allocation concealment	Unclear risk	No details reported
Blinding of outcome assessors All outcomes	Low risk	Smoking status self-report, but contact did not differ between arms
Incomplete outcome data All outcomes	Low risk	At participant level, the overall loss to follow-up was 44.4% (n = 861/1941); 44.3% (n = 410/925) in the intervention group and 44.4% (n = 451/1016) in the control group were lost to follow-up at 12 months
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practices before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "We found no baseline differences in sociodemographics, health habits, readiness to change, or primary care visits. Control site patients were more likely to smoke everyday ( $p < 0.01$ ), wake up to smoke ( $p < 0.05$ ), and to have tried nicotine patches ( $p < 0.01$ ), attended a smoking cessation program ( $p < 0.0001$ ), and tried other ways to quit preintervention ( $p < 0.05$ )...". Authors report adjusting for baseline differences in their analyses.
Adjustment for clustering in analysis? (cluster RCTs only)	Low risk	QUOTE: "We assessed the intraclass correlation coefficient to determine the need for cluster adjustment; because the intraclass correlation coefficient was not statistically significant from zero, an unadjusted analytic approach was used"

**Young 2008**
**Study characteristics**

Methods	Design: Randomized controlled trial  Setting: General practices in South Western Sydney, Australia  Recruitment: Eligible GPs were approached by research staff and invited to participate. All eligible patients were approached in the waiting room and were given an information letter and self-administered questionnaire to complete before seeing their GP
Participants	318 adults who smoked (169 intervention, 149 control) av.age 38, 46% M
Interventions	Intervention: participants received a phone call from a nurse who delivered intervention based on the 5As. Participants were mailed a quit kit, encouraged to use NRT and set a quit date. Those that set a quit date were called on the specified quit day, then 1 week and 3 weeks after the quit date. During these 3 calls, participants were congratulated if they had quit, were encouraged to maintain quitting and assisted in resolving any problems arising. People who relapsed to smoking received motivation advice and were encouraged to 'reframe' relapse as a learning experience for future cessation  Control: QUOTE: "control group smokers received the GP's usual care. We also provided GPs with free copies of government-sponsored quit kits to distribute to smokers in this group". No further details reported
Outcomes	Undefined PPA at 12m  Validation: None  Quit attempts

## Young 2008 (Continued)

Measures of provider implementation: Advise, Arrange, Assist-Quit date, Assist-Self-help, Assist-Medication

Funding Source	Project Grant G00S0686 from the National Heart Foundation of Australia. At the time of the study, JY was supported by a National Health and Medical Research Foundation Public Health (Australia) Fellowship (No 007024)
Author's declarations of interest	Authors declared that they had no competing interest
Notes	Strategy: Adjunctive counseling  Level: Patient  Comparison type: Single component vs. standard care

### Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	QUOTE: "Questionnaires were randomly ordered and coded prior to delivery to the practice by selecting sequential numbers from a computer generated random number list"
Allocation concealment	High risk	QUOTE: "Pre-randomised questionnaires and allocated unobtrusive marks that were meaningful only to the GPs in order to convey group allocation". Does not specify that this was concealed
Blinding of outcome assessors All outcomes	High risk	Smoking status was self-reported and person-to-person contact differed between the groups
Incomplete outcome data All outcomes	Unclear risk	The response rate was 69% in the intervention group and 59% in the control group at 12 months - not reported by group

## Zwar 2015

### Study characteristics

Methods	Design: 3-group cluster-randomized controlled trial  Setting: General practices in Sydney and Melbourne, Australia  Recruitment: Practices were invited to participate during visits with study staff. Participants were recruited in waiting rooms by study staff
Participants	2390 adults who smoked (daily or weekly). av.age 42, 45% M, 17cpd
Interventions	<i>Intervention 1:</i> quit with practice nurse (PN)  <ul style="list-style-type: none"> <li>• Nurses attended a 1-day training program on 5A approach to smoking cessation counseling. The nurses were provided with checklists for use at each patient visit, a printed resource for distribution to patients and support from 3 proactive mentoring telephone calls from an experienced smoking cessation counselor</li> <li>• General practitioners encouraged all patients who smoked to see the practice nurse</li> </ul>

**Zwar 2015** (Continued)

- Participants were assisted by a practice nurse to develop a quit plan and were offered a flexible package of ongoing support with a further 3 face-to-face visits to the practice nurse. Participants who were unable to attend face-to-face consultations or preferred other modes were offered telephone support from the nurse or the quitline

*Intervention 2: quitline*

- General practitioners were asked to assess the patients' willingness to quit and to offer brief advice. The general practitioners were provided brief feedback from the quitline on uptake and outcome of services offered to their patients
- Patients interested in quitting were offered referral to the quitline. If agreed with patients, the quitline offered counseling service and a series of free evidence-based proactive call-back counseling/advice sessions

*Control:* QUOTE: "GPs were asked to assess patients' willingness to quit and offer assistance in accordance with their usual practice. This could include advice within the practice, referral to quitline or both, but no provision was made to facilitate either". No further details reported

Outcomes	> 10 m sustained abstinence at 12m  Validation: None
Funding Source	Australian National Health and Medical Research CouncilProject Grant (568617)
Author's declarations of interest	Authors declared no conflict of interest
Notes	Strategy: Provider training + Adjunctive counseling  Level: Patient + Provider  Comparison type: Multicomponent vs standard care

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	No details reported
Allocation concealment	Unclear risk	QUOTE: "Randomization of practices was performed after practice recruitment but prior to patient recruitment with allocation concealment by a researcher who took no further part in the study"
Blinding of outcome assessors All outcomes	High risk	Smoking status self-report. Person-to-person contact differed across the groups
Incomplete outcome data All outcomes	Low risk	At patient level, the overall loss to follow-up was 17.6% (n = 421/2390); 18.3% (n = 160/876) in the 'quit with PN' group, 16.9% (n = 141/836) in the quitline referral group, 17.7% (n = 120/678) in the usual care group at 12-month follow-up
Recruitment bias (cluster RCTs only)	Low risk	Participants were affiliated with the practices before randomization
Balanced baseline characteristics? (cluster RCTs only)	Low risk	QUOTE: "Groups were very similar on demographics and smoking behaviour at baseline"



**Zwar 2015** (Continued)

Adjustment for clustering in analysis? (cluster RCTs only)

Low risk

QUOTE: "Adjustment for clustering was made on the basis of the intraclass correlation coefficient of 0.013 observed by Lennox et al. in a smoking cessation trial in general practice"; "...multilevel logistic regression models were used with two dichotomous dependent variables adjusted for clustering of three occasions at level 1, patients at level 2 and practices at level 3"

BSS: behavioral support sessions; CA: continuous abstinence; CO: carbon monoxide; cpd: cigarettes per day; EMR: electronic medical record; F: female; NRT: nicotine replacement therapy; PPA: point prevalence abstinence; ppm: parts per million; SSS: Stop-smoking service; TTM: transtheoretical model [stages of change]

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

Study	Reason for exclusion
<a href="#">Adair 2013</a>	Addressed multiple risk factors. No specific intervention strategy for smoking cessation
<a href="#">Adam 2019</a>	Outcomes: Cessation not reported
<a href="#">Agarwal 2018</a>	Cessation outcome not reported. (Main outcome: quit attempts)
<a href="#">An 2008</a>	Follow-up < 6 months
<a href="#">Andrews 2001</a>	Cessation outcome not reported.
<a href="#">Aveyard 2007</a>	Compares 2 active interventions - unable to isolate a single component
<a href="#">Bachmann 2019</a>	Outcomes: Cessation not reported
<a href="#">Bakkevig 2000</a>	Intervention not conducted in primary care
<a href="#">Bentz 2007</a>	Follow-up < 6 months
<a href="#">Bosworth 2008</a>	Outcomes of interest not reported (Main outcome: Medication adherence and improvement of hypertension-related health behaviors)
<a href="#">Burke 1993</a>	Only evaluated the efficacy of pharmacotherapy
<a href="#">Butler 1999</a>	Counseling performed by general practitioners
<a href="#">Carey 2016</a>	Follow-up < 6 months
<a href="#">Cheung 2019</a>	Intervention not conducted in primary care
<a href="#">Cockburn 1992</a>	Intervention relates to marketing strategies for smoking cessation programs
<a href="#">Cohen 2011</a>	Outcomes of interest not reported (Main outcome: Change in proportion of participants achieving target glycemic and cardiac risk factor goals)
<a href="#">Coma 2019</a>	Outcomes: Cessation not reported
<a href="#">Conger 1987</a>	Only intervention was advice from GPs
<a href="#">de Ruijter 2018</a>	Did not assess smoking cessation
<a href="#">Dey 1999</a>	Follow-up < 6 months

**Strategies to improve smoking cessation rates in primary care (Review)**

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Study	Reason for exclusion
<a href="#">Dickinson 2013</a>	Addressed multiple risk factors. Tobacco users could choose to not participate in the smoking cessation part of the intervention
<a href="#">Dignan 2019</a>	Intervention not conducted in primary care
<a href="#">Drexel 2011</a>	Outcomes of interest not reported (Main outcome: Provision of evidence based COPD care)
<a href="#">Dubey 2006</a>	Follow-up < 6 months
<a href="#">Efraimsson 2008</a>	Follow-up < 6 months
<a href="#">Eikelenboom 2013</a>	Addressed multiple risk factors. No specific intervention strategy for smoking cessation
<a href="#">Emery 2019</a>	No specific intervention strategy for smoking cessation
<a href="#">Emmons 2014</a>	Outcomes of interest not reported (Main outcome: Multiple risk behavior score)
<a href="#">Engle 2019</a>	Intervention tests only simple counseling and medication
<a href="#">Escortell-Mayor 2020</a>	Multiple risk factor study
<a href="#">Etter 2000</a>	Follow-up < 6 months
<a href="#">Felton 2019</a>	Outcomes: Cessation not reported
<a href="#">Ferketich 2014</a>	Follow-up < 6 months
<a href="#">Ferrer 2009</a>	Multiple risk factor study
<a href="#">Fiore 2019</a>	Does not report on a cessation outcome.
<a href="#">Flocke 2014</a>	Follow-up < 6 months
<a href="#">Folz 2016</a>	Smoking was a secondary outcome and very few people who smoked were involved - 9 in intervention group and 1 in control group
<a href="#">Frank 2004</a>	Follow-up < 6 months
<a href="#">Fu 2015</a>	Outcomes of interest not reported (Main outcome: Perceived skill in use of 5As and confidence in addressing smoking cessation)
<a href="#">Fulton 2019</a>	Intervention not conducted in primary care
<a href="#">Gerbert 2003</a>	Outcomes of interest not reported (Main outcome: Acceptability of video-doctor program)
<a href="#">Gilbert 1989</a>	GP delivered counseling. NRT was not cost-free.
<a href="#">Gilbert 1992</a>	GP delivered follow-up counseling compared to no follow-up does not meet our criteria for adjunctive counseling
<a href="#">Gilbert 2007</a>	Follow-up < 6 months
<a href="#">Gilbody 2019</a>	Intervention tests simple counseling and medication.
<a href="#">Godycki-Cwirko 2014</a>	Addressed multiple risk factors. No specific intervention strategy for smoking cessation

Study	Reason for exclusion
<a href="#">Green 2020</a>	Does not report on a cessation outcome
<a href="#">Grischott 2019</a>	Tests simple counseling intervention
<a href="#">Groner 2000</a>	The participants of the study were not patients of the general practitioner, but rather the people accompanying the patient
<a href="#">Hall 2003</a>	Outcomes of interest not reported (Main outcome: Readiness to quit)
<a href="#">Harding 2019</a>	Does not report on a cessation outcome
<a href="#">Haug 1994</a>	Only brief advice intervention
<a href="#">Houston 2015</a>	Compares 2 active interventions - unable to isolate a single component
<a href="#">Hughes 1981</a>	Not conducted in primary care
<a href="#">Humphris 2004</a>	Outcomes of interest not reported (Main outcome: Knowledge of oral cancer)
<a href="#">Imperial Cancer Research Fund GP Research Group</a>	Only evaluated the efficacy of pharmacotherapy
<a href="#">Javitz 2004</a>	Compares 2 active interventions - unable to isolate a single component
<a href="#">Jennings 2014</a>	Follow-up < 6 months
<a href="#">Jolly 2017</a>	Not a smoking cessation intervention
<a href="#">Kalkhoran 2016</a>	Cessation outcome not reported
<a href="#">Kalkhoran 2019</a>	Counseling intervention tested, but no cluster randomization
<a href="#">Kamstrup-Larsen 2019</a>	Tests simple counseling intervention only.
<a href="#">Karner 2012</a>	No smoking cessation intervention tested
<a href="#">Kastaun 2021</a>	Compared 2 types of health provider training head to head. Did not allow for separation of effect of provider training
<a href="#">Kennedy 2019</a>	Not a smoking cessation intervention
<a href="#">Kim 2020</a>	Does not report on a cessation outcome
<a href="#">Kirkman 1994</a>	Multiple risk factor study
<a href="#">Knight 1989</a>	Outcomes of interest not reported (Main outcome: Predictors of quitting smoking)
<a href="#">Krones 2010</a>	Outcomes of interest not reported (Main outcome: Validity of the Theory of Planned Behavior in a decision aid)
<a href="#">Kruse 2020</a>	Follow-up < 6 months
<a href="#">Lasser 2013</a>	Outcomes of interest not reported (Main outcome: Engagement in smoking cessation treatment)
<a href="#">Leung 2019</a>	Tests simple pharmacotherapy only.

Study	Reason for exclusion
<a href="#">Liang 2019</a>	Tests simple counseling intervention only
<a href="#">Liebmann 2019</a>	Adjunctive counseling intervention tests but not cluster-randomized
<a href="#">Linder 2009</a>	Follow-up < 6 months
<a href="#">Lycett 2010</a>	All participants had identical treatment to stop smoking
<a href="#">Machline-Carrion 2019</a>	Does not include a cessation outcome.
<a href="#">Mahapatra 2019</a>	Not an RCT
<a href="#">Markun 2018</a>	Smoking cessation was never an intended outcome
<a href="#">McAlister 2009</a>	Multiple risk factor study
<a href="#">McEwen 2002</a>	Follow-up < 6 months
<a href="#">McGrath 2014</a>	Follow-up < 6 months
<a href="#">McPhee 1991</a>	Cessation outcome not reported.
<a href="#">McRee 2005</a>	Cessation outcome not reported. Main outcome:
<a href="#">McRobbie 2008</a>	Follow-up < 6 months
<a href="#">Mehring 2014</a>	Follow-up < 6 months
<a href="#">Minian 2019</a>	Not a smoking cessation intervention
<a href="#">Muckelbauer 2015</a>	Multiple risk factor study
<a href="#">Naughton 2014</a>	Compares 2 active interventions - unable to isolate a single component
<a href="#">NCT01072422</a>	follow-up < 6 months
<a href="#">NCT03221010</a>	follow-up < 6 months
<a href="#">NCT04200534</a>	Cessation measured < 6 months
<a href="#">NCT04316260</a>	Cessation measured < 6 months
<a href="#">Neuner-Jehle 2013</a>	Cessation outcome not reported.
<a href="#">Nilsson 1996</a>	Follow-up < 6 months
<a href="#">Ojedokun 2013</a>	Follow-up < 6 months
<a href="#">Papadakis 2013</a>	Follow-up < 6 months
<a href="#">Parchman 2019</a>	Multiple risk factor study
<a href="#">Peckham 2019</a>	Not conducted in primary care
<a href="#">Peprah 2019</a>	Multiple risk factor study

Study	Reason for exclusion
Persai 2020	Does not report on a cessation outcome
Persell 2013	Outcomes of interest not reported (Main outcome: LDL Cholesterol levels)
Pieterse 2001	GP delivered counseling
Piper 2003	Pre-post evaluation, not an RCT study design
Prabhakaran 2019	No smoking cessation intervention tested
Prochaska 2005	Multiple risk factor study
Prokhorov 2010	Follow-up < 6 months
Redfern 2014a	Addressed multiple risk factors. No specific intervention strategy for smoking cessation
Richmond 1985	GP delivered counseling.
Richmond 1998	Cessation outcome not reported.
Richter 2015	Compares 2 active interventions - unable to isolate a single component
Rigotti 2011	Follow-up < 6 months
Robson 1989	Follow-up < 6 months
Rodriguez Alvarez 2008	Compares 2 active interventions - unable to isolate a single component
Roski 1998	Cessation outcome not reported.
Rosser 1992	Follow-up < 6 months
Rothemich 2008	Follow-up < 6 months
Rothemich 2010	Follow-up < 6 months
Sanders 1989	Only brief advice intervention
Satterfield 2018	Follow-up < 6 months, cessation outcome not reported
Schwartz 2015	Multiple risk factor study
Sejourne 2010	Outcomes of interest not reported (Main outcome: Readiness to quit)
Senesael 2013	Addressed multiple risk factors. No specific intervention strategy for smoking cessation
Shaughnessy 1987	Counseling only on use of medications
Sheffer 2012	Cessation outcome not reported.
Shelley 2016	Did not set out to measure smoking abstinence
Sherman 2017	Compares 2 active interventions - unable to isolate a single component
Silveira 2019	Simple counseling intervention tested only

Study	Reason for exclusion
Silverman 2004	Cessation outcome not reported.
Slama 1990	GP delivered counseling
Smit 2010	Deviated from protocol, not set in primary care
Sperl-Hillen 2018	Multiple risk factor study
Stratelis 2006	Compares 2 active interventions - unable to isolate a single component
Strecher 1994	Follow-up < 6 months
Taylor 2019	Did not occur in primary care
Thompson 1988	GP delivered counseling
Thompson 2015	Follow-up < 6 months
Valdivieso-Lopez 2013	Study population is pregnant women
Velasquez 2014	Study population is pregnant women
Vidrine 2013	Follow-up < 6 months
Vogt 2009	Does not report on abstinence outcome.
Voogdt-Pruis 2011	Outcomes of interest not reported (Main outcome: Number of lifestyle and medical interventions)
Vorderstrasse 2013	Not a smoking cessation intervention
Waage 1997	No smoking cessation strategy conducted in primary care
Wadland 2007	Does not report on abstinence outcome.
Weingarten 1989	Follow-up < 6 months
West 1998	Follow-up < 6 months
Wilson 1982	GP delivered follow-up counseling
Woollard 1995	Outcomes of interest not reported (Main outcome: Blood pressure)
Yalcin 2014	Only evaluating different intensities of counseling
Yingst 2018	Follow-up < 6 months
Young 2002a	Follow-up < 6 months
Young 2002b	Follow-up < 6 months
Ziyash 2019	Tests simple counseling intervention only
Zwar 2016	Multiple risk factor study

## Characteristics of studies awaiting classification *[ordered by study ID]*

### Martin-Lujan 2011

Methods	Multicenter randomized clinical trial
Participants	Target: 600 people who smoked with a cumulative habit of more than 10 packs of cigarettes per year
Interventions	Intervention: participants will receive usual advice to quit by a general practitioner as well as a 20-minute personalized visit to provide detailed information about spirometry results  Control: participants will receive usual care
Outcomes	Smoking abstinence
Notes	NCT01194596

### Martin-Lujan 2016

Methods	Multicenter randomized clinical trial
Participants	Target: 1000 adults who smoke
Interventions	Intervention: participants will receive brief, 5-minute health counseling plus detailed personalized information about the results of a spirometry test  Control: participants will receive brief, 5-minute health counseling
Outcomes	Point-prevalence abstinence, prolonged abstinence
Notes	NCT02153047

### Ripoll 2012

Methods	Parallel randomized controlled trial with blind evaluation
Participants	942 adults who smoke
Interventions	Intervention: brief advice plus exhaled carbon monoxide measure  Control: brief face-to-face anti-smoking advice from the physician during patient consultation
Outcomes	Sustained abstinence (at 6 and 12 months) validated by urine cotinine test
Notes	ISRCTN67499921

### Smith 2003

Methods	Randomized controlled trial
Participants	Target: 2850 participants who smoke, 42 primary care providers



**Smith 2003** *(Continued)*

Interventions	Intervention 1: brief clinical intervention Intervention 2: enhanced clinical intervention control: usual care
Outcomes	Not reported
Notes	

**Characteristics of ongoing studies** *[ordered by study ID]*
**Avila-Tomas 2019**

Study name	Effectiveness of a chat-bot for the adult population to quit smoking: protocol of a pragmatic clinical trial in primary care
Methods	Randomized, controlled, multicentric, pragmatic clinical trial
Participants	Target: 460 people who smoke > 18 years of age who attend a healthcare center and accept help to quit smoking in the following month
Interventions	Use of a chat-bot with evidence-based contents to help quit smoking
Outcomes	Continuous abstinence at 6m
Starting date	07 October 2018
Contact information	joseavil@gmail.com
Notes	NCT03445507

**Bendtsen 2020**

Study name	Effects of a text messaging smoking cessation intervention among online help seekers and primary healthcare visitors in Sweden: a randomized controlled trial
Methods	2-arm parallel-group randomized controlled trial
Participants	People who smoke, aged 18 years or older
Interventions	12-week text message program with messages sent to participants' mobile phones on a daily basis
Outcomes	Prolonged abstinence at 3m and 6m 4-week point-prevalence abstinence at 3m and 6m
Starting date	01 January 2020
Contact information	marcus.bendtsen@liu.se
Notes	ISRCTN13455271

### Diaz-Gete 2013

Study name	Effectiveness of an e-mail tracking intervention among the continued abstinence of tobacco consumption
Methods	Randomized controlled multicentric trial
Participants	Target: 1060 people who smoke who regularly check their email
Interventions	2 face-to-face interviews and 4 emails
Outcomes	Point prevalence abstinence and continuous abstinence at 6m & 12m
Starting date	December 2012
Contact information	Carlos Martin Cantera, cardiocat@gmail.com
Notes	NCT01494246

### Gerber 2017

Study name	Patient navigation for lung cancer screening in an urban safety-net system: protocol for a pragmatic randomized clinical trial
Methods	Randomized controlled trial
Participants	Target: 340 participants eligible for lung cancer screening
Interventions	Patient navigation
Outcomes	Self-reported abstinence at 6m and 18m
Starting date	June 2017
Contact information	David E. Gerber, david.gerber@UTSouthwestern.edu
Notes	NCT02758054

### ISRCTN38129107

Study name	The coaching for smokers trial
Methods	Single-center double-blind cluster-randomized parallel controlled clinical trial
Participants	Target: 60 general practitioners and 200 patients with a target cluster size of four
Interventions	Intervention: general practitioners will be trained in coaching to promote a change in modifiable health risk factors including smoking, in group training sessions of 4 hours. Participants will receive individual coaching or counseling sessions from their general practitioners. The coaching will follow the principles of "Gesundheitscoaching-KHM"  Control: participants will receive state-of-the-art smoking cessation counseling

**ISRCTN38129107** (Continued)

Outcomes	Smoking cessation rates self-reported at 1, 6 and 12 months and verified by saliva cotinine at 12 months
Starting date	January 2017
Contact information	Stefan Neuner-Jehle, stefan.neuner-jehle@usz.ch
Notes	

**ISRCTN44559004**

Study name	Improving quit rates among smokers in primary care: pragmatic trial of effectiveness and cost effectiveness of a tailored web- and text message-based intervention for smoking cessation (iQuit in Practice)
Methods	Randomized controlled trial
Participants	Target: 1452 adults who smoke
Interventions	Tailored print report and supportive SMS messages
Outcomes	Continuous abstinence at 6m
Starting date	July 2016
Contact information	Joanna Mitchell, jm294@medschl.cam.ac.uk
Notes	<a href="#">ISRCTN44559004</a>

**ISRCTN54228638**

Study name	Lung age or exhaled carbon monoxide feedback combined with very brief advice and support for smoking cessation in Medical Faculty Skopje Macedonia
Methods	Multicenter non-blinded 3-armed randomized controlled trial
Participants	Target: 885 people who currently smoke, smoking at least 10 cigarettes per day and aged $\geq 35$ years
Interventions	Intervention 1: participants will receive lung age with very brief advice and support to quit smoking  Intervention 2: participants will receive feedback on exhaled carbon monoxide levels with very brief advice and support to quit smoking  Intervention 3: participants will receive very brief advice alone and support to quit smoking
Outcomes	7-day point prevalence abstinence, prolonged abstinence with smoking induction period of 3 weeks post-randomization, confirmed with salivary cotinine at 4, 12 and 26 weeks
Starting date	June 2017
Contact information	Radmila Ristovska
Notes	

## Mak 2015

Study name	The acceptance and commitment therapy for smoking cessation in the primary health care setting
Methods	Prospective randomized controlled trial
Participants	142 adults who smoke
Interventions	Intervention: participants will receive self-help materials, face-to-face session, 2 telephone acceptance and commitment therapy sessions at 1 week and 1 month following the first session  Control: participants will receive self-help materials
Outcomes	7-day point prevalence abstinence at 6 months
Starting date	2012
Contact information	Yim Wah Mak, yw.mak@polyu.edu.hk
Notes	NCT01652508

## NCT02500589

Study name	Telephone-based smoking cessation
Methods	Randomized comparative effectiveness trial
Participants	350 adults who smoke with significant depressive symptoms
Interventions	Intervention: participants receive telephone counseling on smoking cessation and mood management  Control: participants receive telephone counseling on smoking cessation
Outcomes	Prolonged abstinence at 6m and 12m
Starting date	February 2016
Contact information	Jennifer M Gierisch, jennifer.gierisch@va.gov
Notes	<a href="#">NCT02500589</a>

## NCT03612804

Study name	Promoting smoking cessation in lung cancer screening through proactive treatment
Methods	Cluster-randomized controlled trial
Participants	Target: 540 primary care patients
Interventions	Intervention: patients of providers assigned to the proactive study group will be contacted by specially trained counselors at the Veterans Affairs Quitline. Counselors will attempt to provide 2 sessions of proactive telephone support

**NCT03612804** (Continued)

	Control: usual care
Outcomes	Self-reported abstinence from smoking for 7 days, biochemically confirmed with saliva cotinine 12 months after lung cancer screening
Starting date	2019
Contact information	Steven B Zeliadt, Steven.Zeliadt@va.gov
Notes	<a href="#">NCT03612804</a>

**NCT04188873**

Study name	Cessation Screening Project
Methods	Randomized factorial experiment
Participants	608 adults who smoke
Interventions	Fully crossed, 2x2x2x2 factorial experiment that evaluates 4 different factors: 1. Medication type (Varenicline vs. Combination NRT) 2. Preparation Medication (4 Weeks vs. Standard) 3. Medication Duration (Extended [24 weeks] vs. Standard [12 weeks]) 4. Counseling (Intensive vs. Minimal)
Outcomes	7-day point-prevalence abstinence at 12m
Starting date	November 2020
Contact information	University of Wisconsin, Madison
Notes	<a href="#">NCT04188873</a>

**NCT04199117**

Study name	Centralized health system interventions to enhance reach: a factorial screening experiment
Methods	Randomized factorial experiment
Participants	Adult primary care patients smoked at least 5 cigarettes per day for at least 6 months at enrolment. Able to speak and read English
Interventions	2x2x2x2 factorial experiment: 1. Modest financial incentives (USD 40) for completing an initial counseling session in a smoking cessation treatment (vs. none) 2. Automated semi-annual outreach materials sent via participants' preferred communication modality using data in the electronic health record to tailor and personalize invitations to use available treatments to quit smoking (vs. untailored letters)

## NCT04199117 (Continued)

3. Direct, proactive telephone outreach from a tobacco care manager who will promote treatment use and deliver motivational intervention twice per year (vs. none)
4. Access to 3 no-cost telephone smoking cessation counseling calls with combination nicotine replacement therapy (C-NRT) or varenicline (vs. state tobacco quitline and primary care provider referral)

Outcomes	7-day point-prevalence abstinence at 3w, 3m, 6m, 2y
Starting date	11 March 2020
Contact information	Michael C Fiore <a href="mailto:mcf@ctri.wisc.edu">mcf@ctri.wisc.edu</a>
Notes	<a href="#">NCT04199117</a>

## NCT04223336

Study name	A web-enabled integrated care pathway (ICP) for addressing multiple modifiable risk factors as a part of smoking cessation treatment in primary care
Methods	Randomized controlled trial
Participants	5000 adults enrolled in the STOP program with at least 1 of the following 2 modifiable risk factors: low levels of physical activity and/or low levels of fruits/vegetable consumption
Interventions	Integrated care pathway for physical activity and fruits/vegetable consumption
Outcomes	7-day point-prevalence abstinence at 6m
Starting date	30 November 2019
Contact information	Peter Selby <a href="mailto:peter.selby@camh.ca">peter.selby@camh.ca</a>
Notes	<a href="#">NCT04223336</a>

## NCT04276116

Study name	Effectiveness of the evaluation and communication of "Pulmonary Age" as help for smoking cessation: a cluster randomized essay
Methods	Cluster-randomized trial in 2 parallel groups
Participants	Adults who smoke
Interventions	Communication of pulmonary age
Outcomes	Undefined abstinence at 12m
Starting date	March 2020
Contact information	Nicolas Roche <a href="mailto:nicolas.roche@htd.aphp.fr">nicolas.roche@htd.aphp.fr</a>
Notes	<a href="#">NCT04276116</a>

## Olano 2018

Study name	Effectiveness of a chat-bot for the adult population to quit smoking: protocol of a pragmatic clinical trial in primary care (Dejal@)
Methods	Multicenter, pragmatic randomized controlled trial
Participants	Target: 460 people aged over 18 years and smoking
Interventions	Intervention: participants will use a chat-bot with evidence-based contents to help quit smoking Control: participants will receive usual treatment
Outcomes	Smoking cessation rate, biochemically validated at 6 months
Starting date	October 2018
Contact information	Jose Avila-Thomas, joseavil@gmail.com
Notes	NCT03445507

## Parker 2013

Study name	Translating the GOLD COPD guidelines into primary care practice
Methods	Cluster-randomized trial
Participants	3593 patients aged 40 years or older and had been seen at least once in the past 2 years by their primary care provider
Interventions	<p>Intervention:</p> <ul style="list-style-type: none"> <li>• Practices will receive portable spirometer</li> <li>• Medical staff will receive: <ul style="list-style-type: none"> <li>- Training on spirometry and how to use the tools and integrate them into workflow</li> <li>- Web-based COPD guideline tool, patient activation tool, COPD patient education toolkit</li> <li>- 2 academic detailing visits</li> <li>- Baseline and post-intervention chart audits</li> <li>- Exit interviews</li> </ul> </li> </ul> <p>Usual care:</p> <ul style="list-style-type: none"> <li>• Practices will receive portable spirometer</li> <li>• Medical staff will receive: <ul style="list-style-type: none"> <li>- Spirometry training</li> <li>- 2 non-academic detailing visits</li> <li>- Baseline and post-intervention chart audits</li> <li>- Exit interviews</li> </ul> </li> </ul>

**Parker 2013** (Continued)

Outcomes	Adherence to COPD guidelines at 12 months
Starting date	October 2010
Contact information	Donna Parker, Donna_Parker@Brown.edu
Notes	NCT01237561

**Proctor 2020**

Study name	Assessment of the effectiveness and cost-effectiveness of tailored web- and text-based smoking cessation support in primary care (iQuit in Practice II): protocol for a randomized controlled trial
Methods	Two-arm, parallel-group, randomized controlled trial
Participants	Adults who smoke and have a mobile phone
Interventions	Tailored smoking cessation system designed for use by healthcare practitioners during the delivery of routine cessation support
Outcomes	Prolonged abstinence at 6m
Starting date	2020
Contact information	Stephen Sutton <a href="mailto:srs34@medschl.cam.ac.uk">srs34@medschl.cam.ac.uk</a> .
Notes	PMID: 32673255

**Sanchez-Aguadero 2017**

Study name	Effectiveness of an intensive intervention to improve lifestyles in people with intermediate cardiovascular risk (DATE study): Study protocol for a randomized controlled trial
Methods	Randomized controlled trial
Participants	208 participants with intermediate cardiovascular risk
Interventions	Intervention: participants will receive individual standardized counseling on lifestyles plus 4 weekly group sessions focusing on cardiovascular risk, healthy diet, moderation in alcohol consumption, daily physical activity, stress management and smoking cessation and 2 motivational follow-up calls  Control: participants will receive individual standardized counseling on lifestyles
Outcomes	Abstinence at 3m and 12m
Starting date	June 2017
Contact information	Natalia Sanchez-Aguadero, <a href="mailto:natalia.san.ag@gmail.com">natalia.san.ag@gmail.com</a>
Notes	NCT03164499



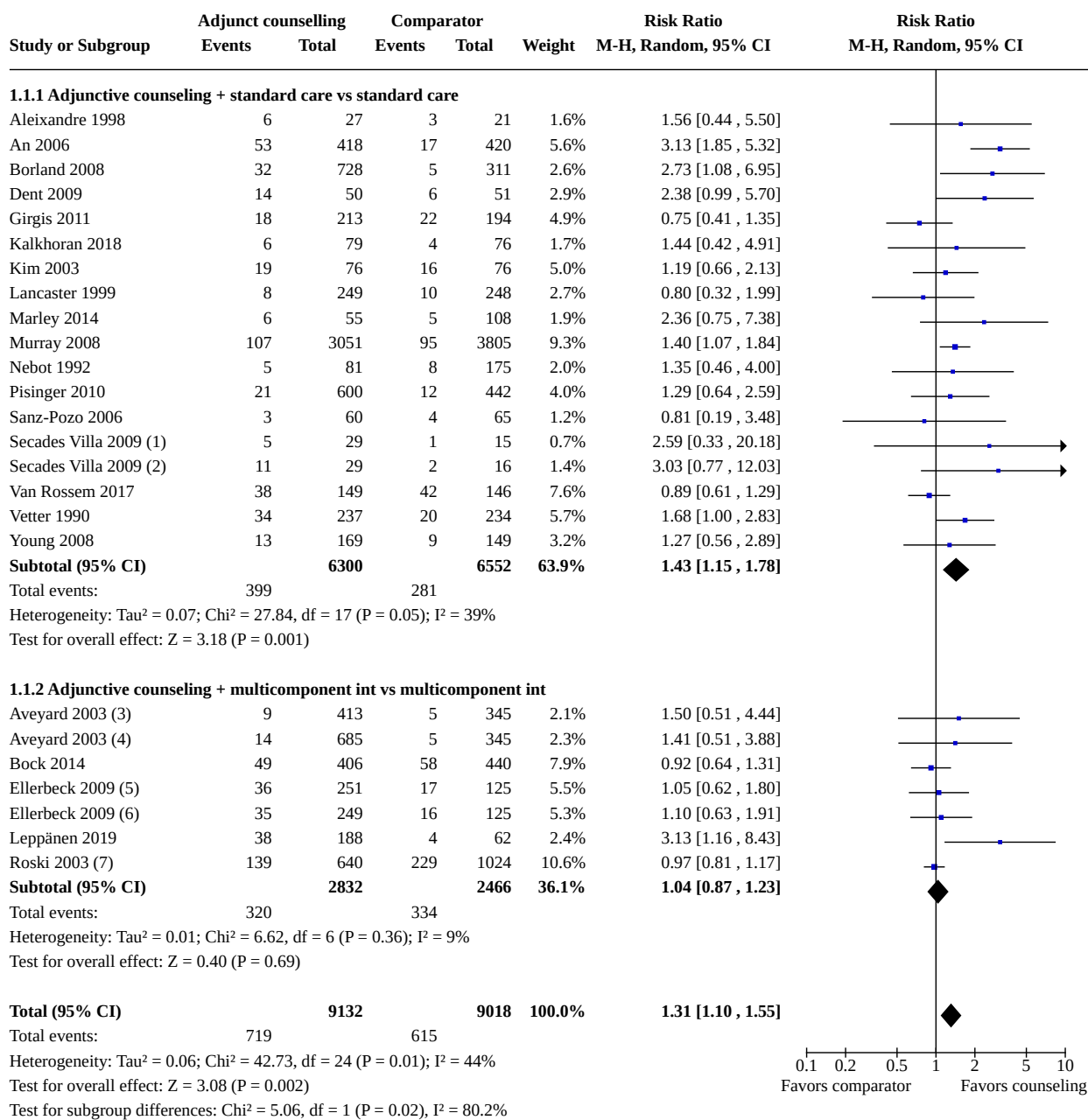
## DATA AND ANALYSES

### Comparison 1. Adjunctive counseling (patient-level)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
<a href="#">1.1 Long-term abstinence (subgrouped by single vs. multicomponent intervention type)</a>	22	18150	Risk Ratio (M-H, Random, 95% CI)	1.31 [1.10, 1.55]
1.1.1 Adjunctive counseling + standard care vs standard care	17	12852	Risk Ratio (M-H, Random, 95% CI)	1.43 [1.15, 1.78]
1.1.2 Adjunctive counseling + multicomponent int vs multicomponent int	5	5298	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.87, 1.23]
<a href="#">1.2 Long-term abstinence (subgrouped by provider)</a>	22	18150	Risk Ratio (M-H, Random, 95% CI)	1.31 [1.10, 1.55]
1.2.1 Nurses	11	3214	Risk Ratio (M-H, Random, 95% CI)	1.20 [0.97, 1.50]
1.2.2 Psychologists & counselors	12	14835	Risk Ratio (M-H, Random, 95% CI)	1.31 [1.03, 1.66]
1.2.3 Pharmacists	1	101	Risk Ratio (M-H, Random, 95% CI)	2.38 [0.99, 5.70]
<a href="#">1.3 Long-term abstinence (subgrouped by mode)</a>	22	18150	Risk Ratio (M-H, Random, 95% CI)	1.31 [1.10, 1.55]
1.3.1 Face to face	14	11753	Risk Ratio (M-H, Random, 95% CI)	1.31 [1.06, 1.61]
1.3.2 Telephone	10	6397	Risk Ratio (M-H, Random, 95% CI)	1.31 [0.98, 1.75]
<a href="#">1.4 Long-term abstinence (subgrouped by intensity)</a>	22	18150	Risk Ratio (M-H, Random, 95% CI)	1.31 [1.10, 1.55]
1.4.1 Brief/minimal	6	2533	Risk Ratio (M-H, Random, 95% CI)	1.42 [1.07, 1.88]
1.4.2 More substantial	18	15617	Risk Ratio (M-H, Random, 95% CI)	1.28 [1.04, 1.57]
<a href="#">1.5 Advise rates</a>	2	724	Risk Ratio (M-H, Random, 95% CI)	1.08 [0.93, 1.26]
1.5.1 Adjunctive counseling + standard care vs standard care	1	190	Risk Ratio (M-H, Random, 95% CI)	1.20 [0.94, 1.54]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.5.2 Adjunctive counseling + multi-component int vs multicomponent int	1	534	Risk Ratio (M-H, Random, 95% CI)	1.02 [0.87, 1.19]
<a href="#">1.6 Assistance rates</a>	5		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.6.1 Medication	3	1094	Risk Ratio (M-H, Random, 95% CI)	1.61 [1.20, 2.15]
1.6.2 Counseling	3	1460	Risk Ratio (M-H, Random, 95% CI)	1.64 [0.94, 2.88]
1.6.3 Quit date set	1	190	Risk Ratio (M-H, Random, 95% CI)	1.42 [0.58, 3.44]
1.6.4 Self-help materials	1	190	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.70, 1.42]
<a href="#">1.7 Arrange follow-up support rates</a>	3		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.7.1 Adjunctive counseling + standard care vs standard care	3	1718	Risk Ratio (M-H, Random, 95% CI)	4.65 [1.67, 12.90]
<a href="#">1.8 Quit attempts</a>	3		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.8.1 Adjunctive counseling + standard care vs standard care	3	1764	Risk Ratio (M-H, Random, 95% CI)	1.23 [1.02, 1.49]

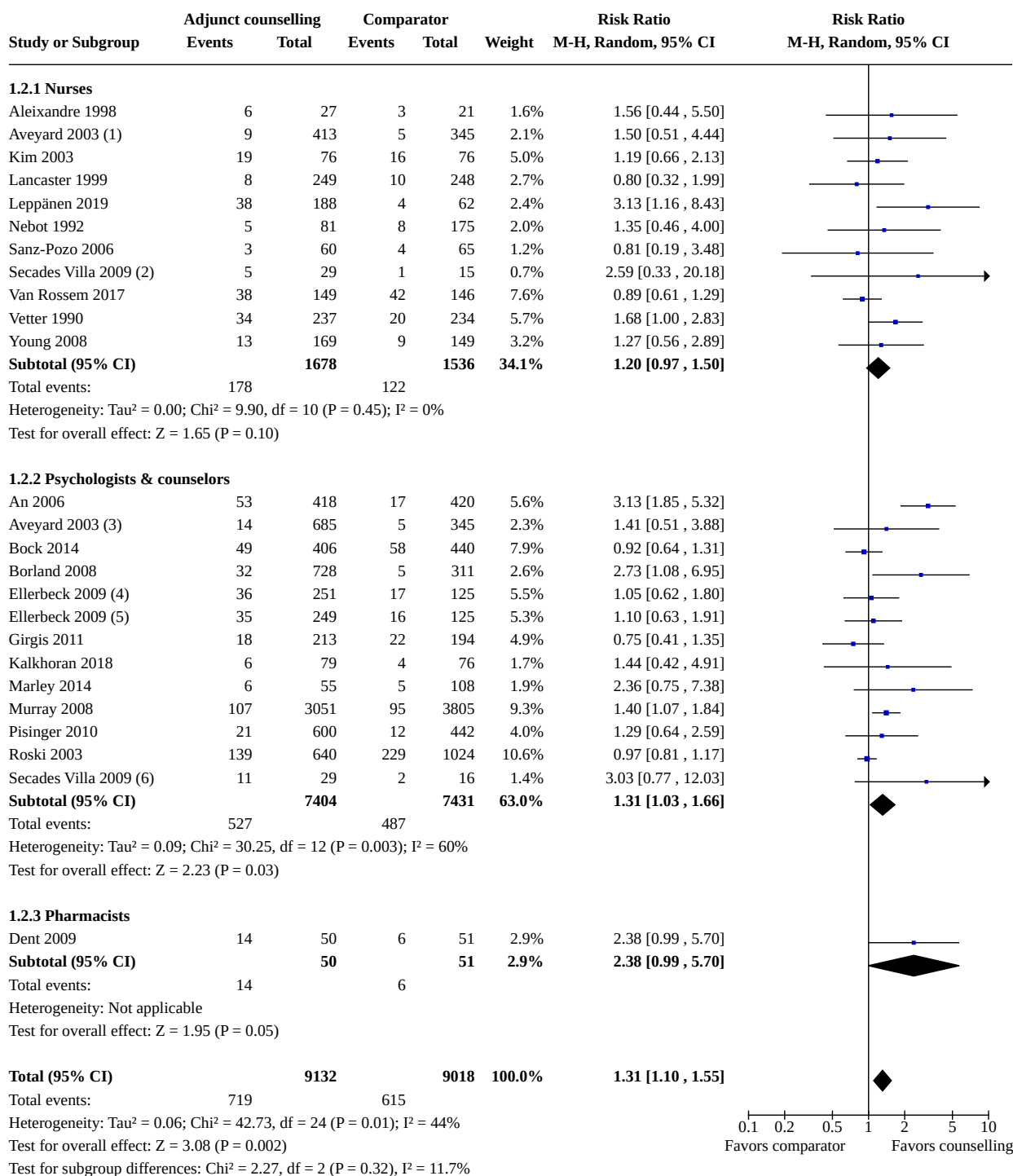
### Analysis 1.1. Comparison 1: Adjunctive counseling (patient-level), Outcome 1: Long-term abstinence (subgrouped by single vs. multicomponent intervention type)



#### Footnotes

- (1) Telephone counselling compared to half of usual care control
- (2) Intensive face-to-face counselling compared to half of usual care control
- (3) Adjunct counselling face-to-face. Control group (manual intervention) split
- (4) Adjunct counselling over the phone. Control group (manual intervention) split
- (5) Adjunct counselling was up to 6 counselling calls. Control group is the pharmacotherapy management group split
- (6) Adjunct counselling was up to 2 counselling calls. Control group is the pharmacotherapy management group split
- (7) Denominators are based on complete cases rather than ITT, as ITT not reported in paper

## Analysis 1.2. Comparison 1: Adjunctive counseling (patient-level), Outcome 2: Long-term abstinence (subgrouped by provider)



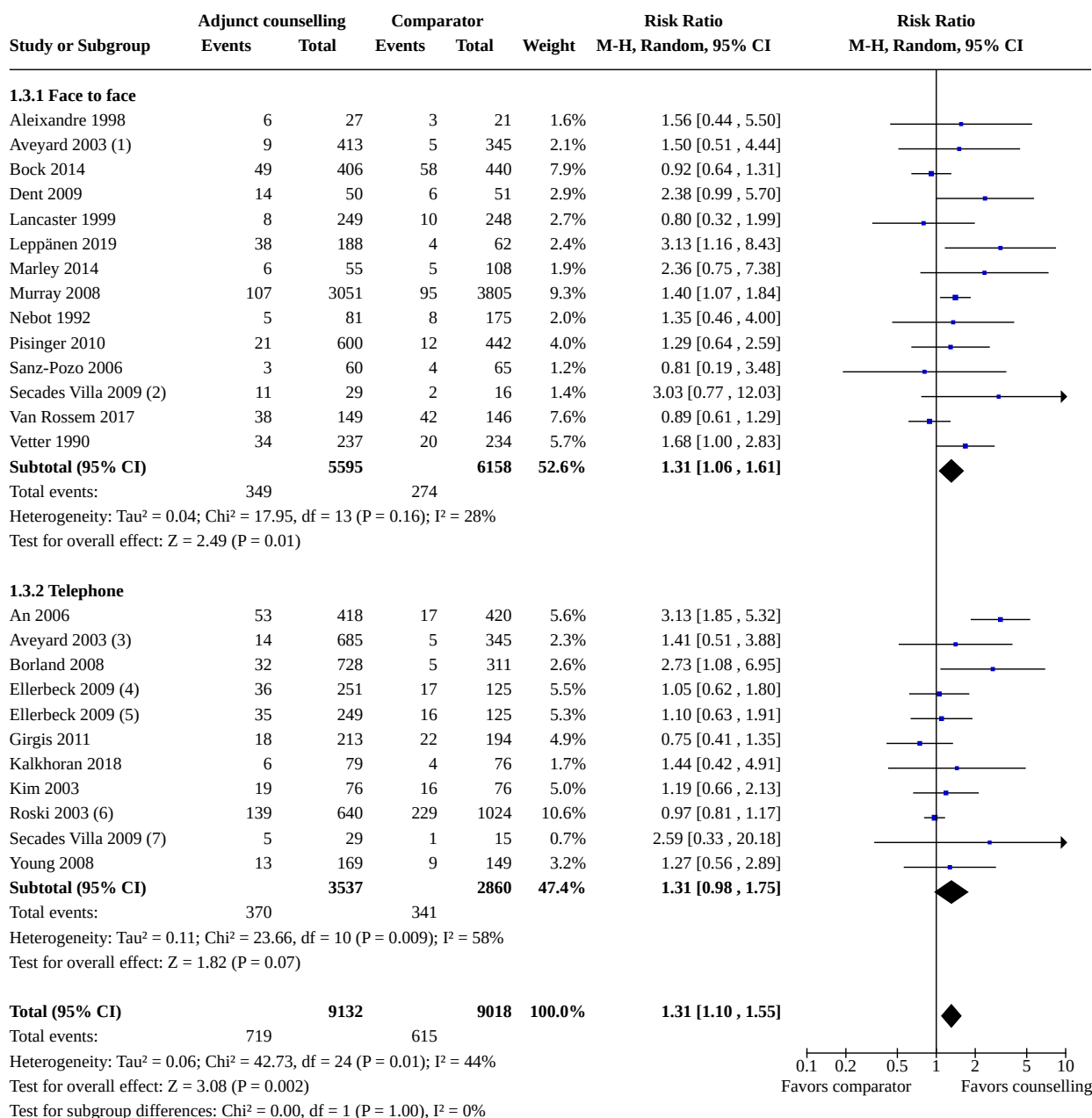
### Footnotes

- (1) Adjunct counselling face-to-face. Control group (manual intervention) split
- (2) Telephone follow-up intervention
- (3) Adjunct counselling over the phone. Control group (manual intervention) split
- (4) Adjunct counselling was up to 6 counselling calls. Control group is the pharmacotherapy management group split
- (5) Adjunct counselling was up to 2 counselling calls. Control group is the pharmacotherapy management group split

**Analysis 1.2. (Continued)**

- (4) Adjunct counselling was up to 6 counselling calls. Control group is the pharmacotherapy management group split
- (5) Adjunct counselling was up to 2 counselling calls. Control group is the pharmacotherapy management group split
- (6) Behavioural counselling intervention

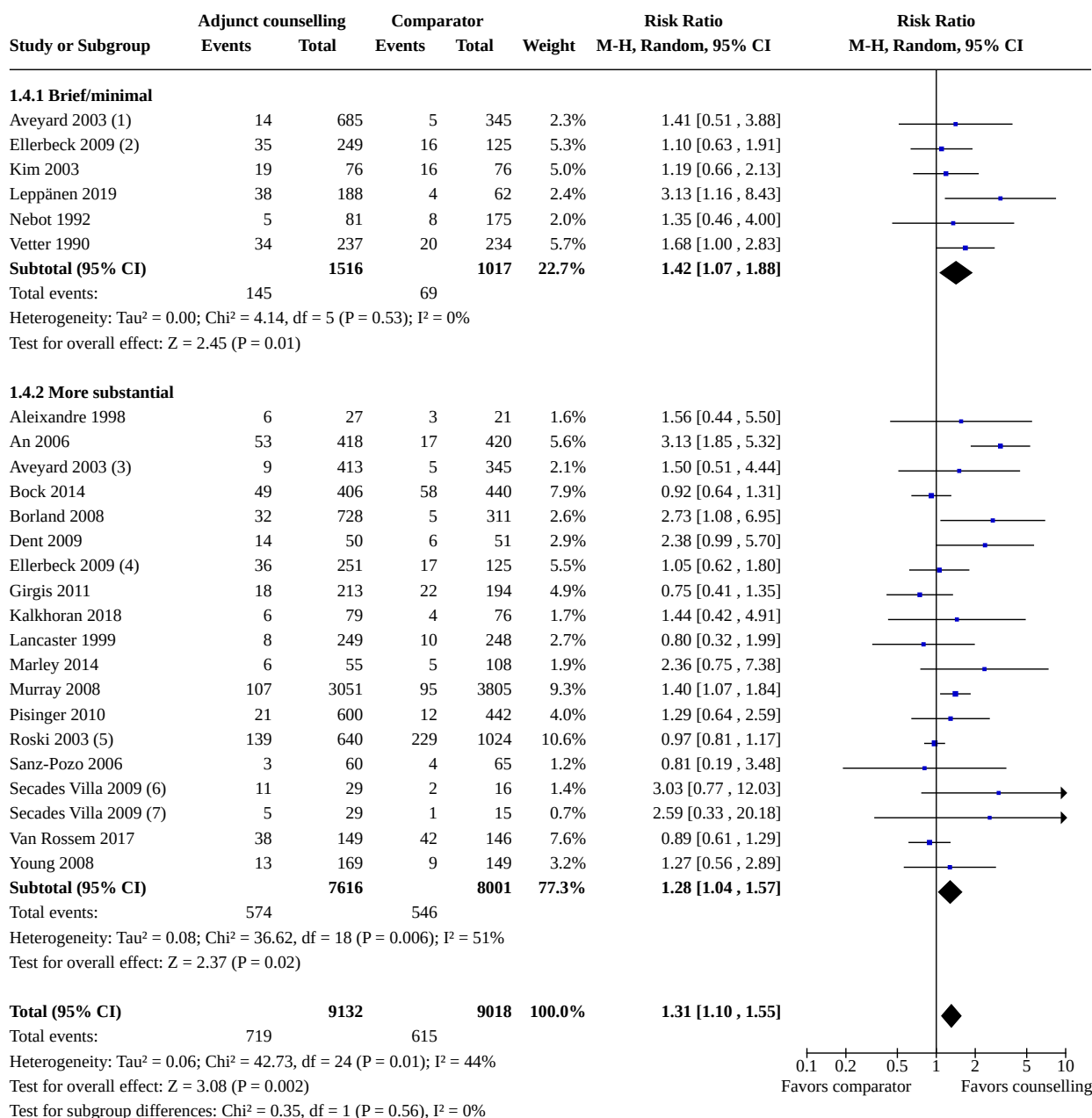
### Analysis 1.3. Comparison 1: Adjunctive counseling (patient-level), Outcome 3: Long-term abstinence (subgrouped by mode)



#### Footnotes

- (1) Adjunct counselling face-to-face. Control group (manual intervention) split
- (2) Behavioural treatment
- (3) Adjunct counselling over the phone. Control group (manual intervention) split
- (4) Adjunct counselling was up to 6 counselling calls. Control group is the pharmacotherapy management group split
- (5) Adjunct counselling was up to 2 counselling calls. Control group is the pharmacotherapy management group split
- (6) Denominators are based on complete cases rather than ITT, as ITT not reported in paper
- (7) Telephone follow-up treatment

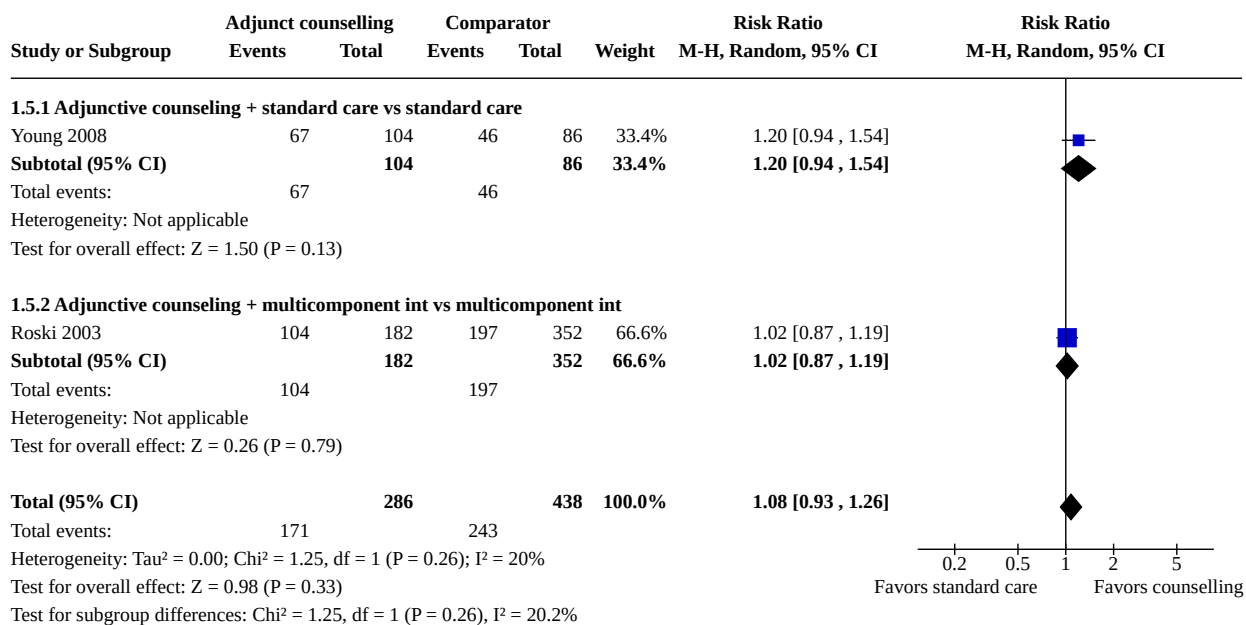
### Analysis 1.4. Comparison 1: Adjunctive counseling (patient-level), Outcome 4: Long-term abstinence (subgrouped by intensity)



#### Footnotes

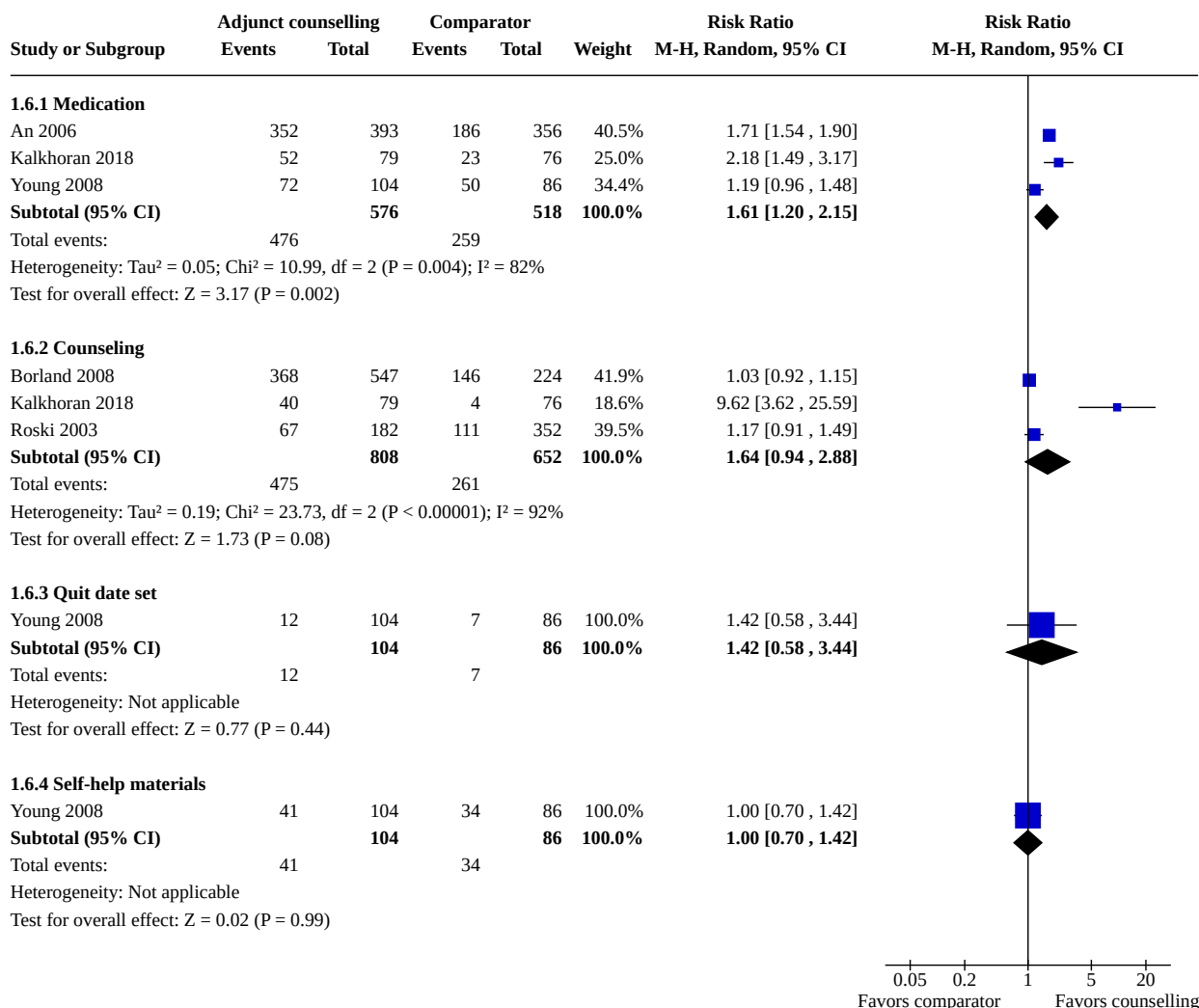
- (1) Adjunct counselling over the phone. Control group (manual intervention) split
- (2) Adjunct counselling was up to 2 counselling calls. Control group is the pharmacotherapy management group split
- (3) Adjunct counselling face-to-face. Control group (manual intervention) split
- (4) Adjunct counselling was up to 6 counselling calls. Control group is the pharmacotherapy management group split
- (5) Denominators are based on complete cases rather than ITT, as ITT not reported in paper
- (6) Behavioural treatment
- (7) Telephone follow-up treatment

### Analysis 1.5. Comparison 1: Adjunctive counseling (patient-level), Outcome 5: Advise rates

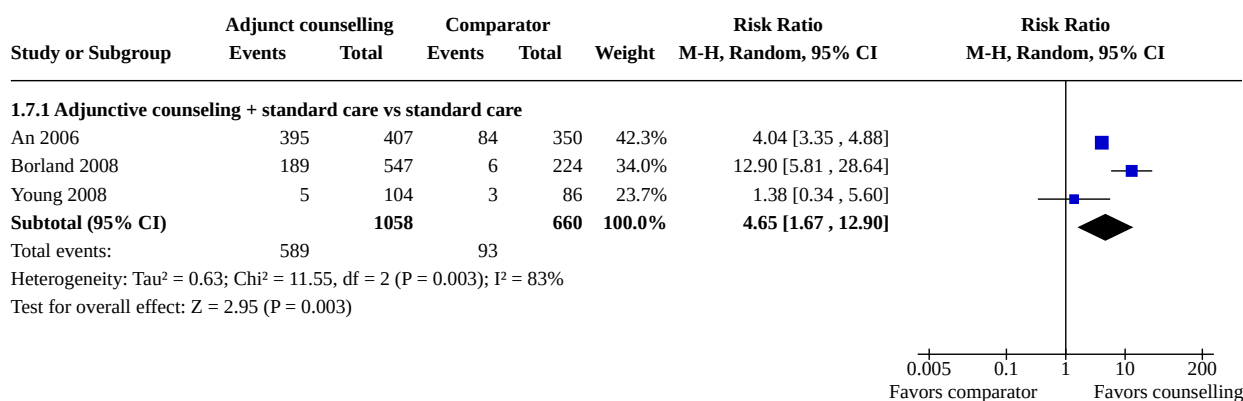




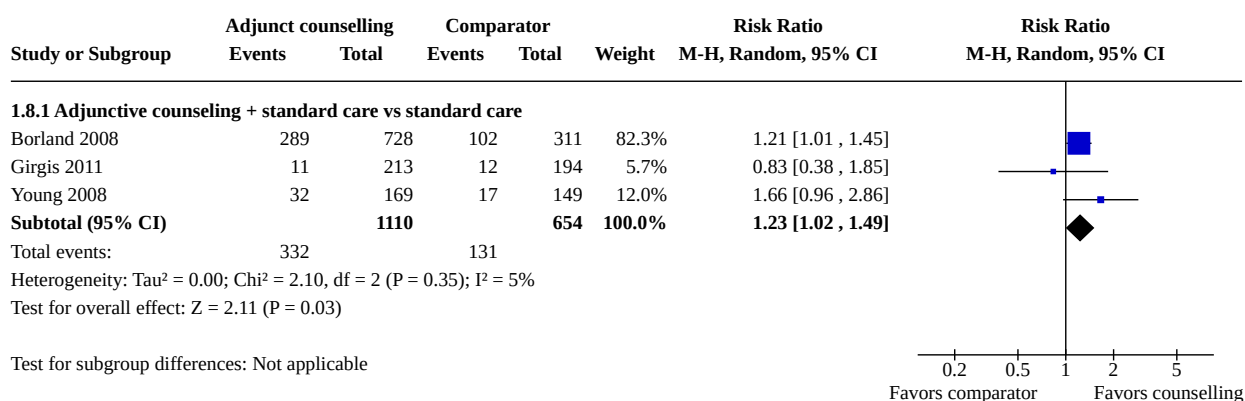
### Analysis 1.6. Comparison 1: Adjunctive counseling (patient-level), Outcome 6: Assistance rates



### Analysis 1.7. Comparison 1: Adjunctive counseling (patient-level), Outcome 7: Arrange follow-up support rates



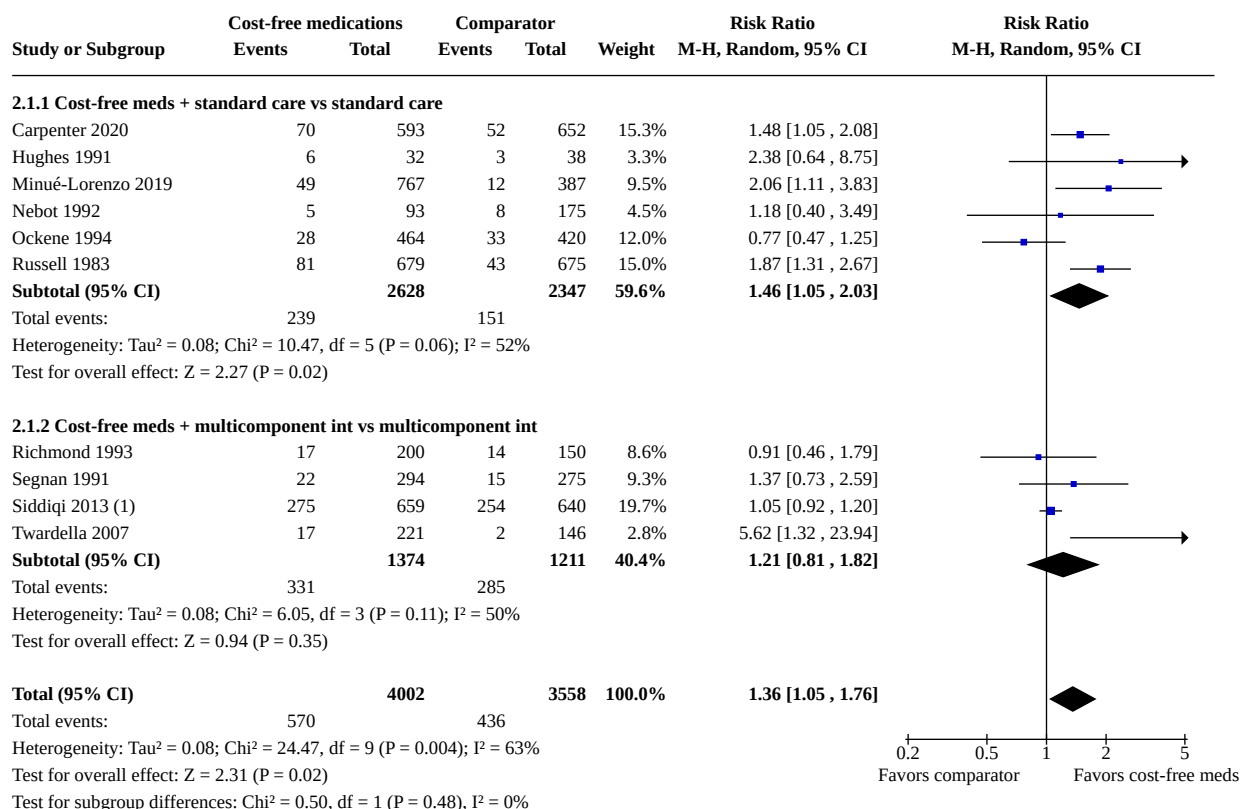
### Analysis 1.8. Comparison 1: Adjunctive counseling (patient-level), Outcome 8: Quit attempts



### Comparison 2. Cost-free medications (patient-level)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
<b>2.1 Long-term abstinence (subgrouped by single vs. multicomponent intervention type)</b>	10	7560	Risk Ratio (M-H, Random, 95% CI)	1.36 [1.05, 1.76]
2.1.1 Cost-free meds + standard care vs standard care	6	4975	Risk Ratio (M-H, Random, 95% CI)	1.46 [1.05, 2.03]
2.1.2 Cost-free meds + multicomponent int vs multicomponent int	4	2585	Risk Ratio (M-H, Random, 95% CI)	1.21 [0.81, 1.82]
<b>2.2 Quit attempts</b>	3		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.2.1 Cost-free meds + standard care vs standard care	3	2669	Risk Ratio (M-H, Random, 95% CI)	1.21 [1.02, 1.43]

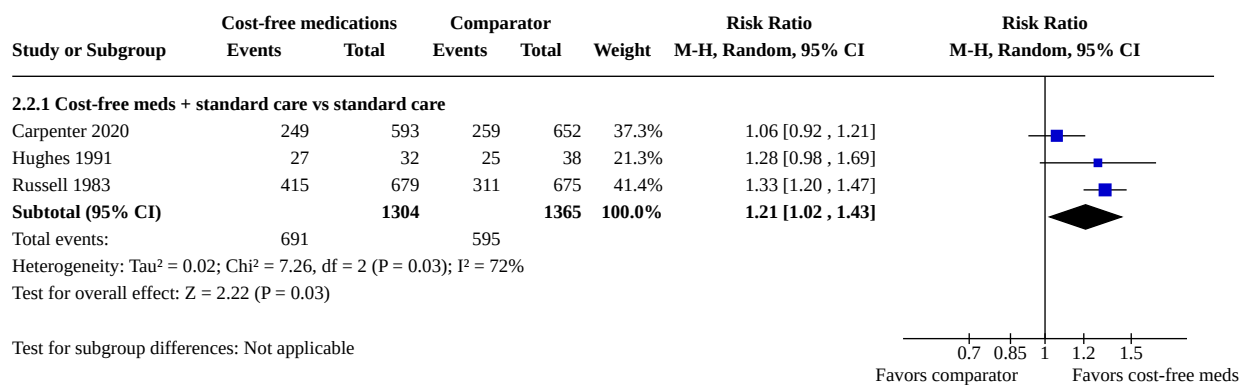
## Analysis 2.1. Comparison 2: Cost-free medications (patient-level), Outcome 1: Long-term abstinence (subgrouped by single vs. multicomponent intervention type)



### Footnotes

(1) BSS+ group versus BSS group

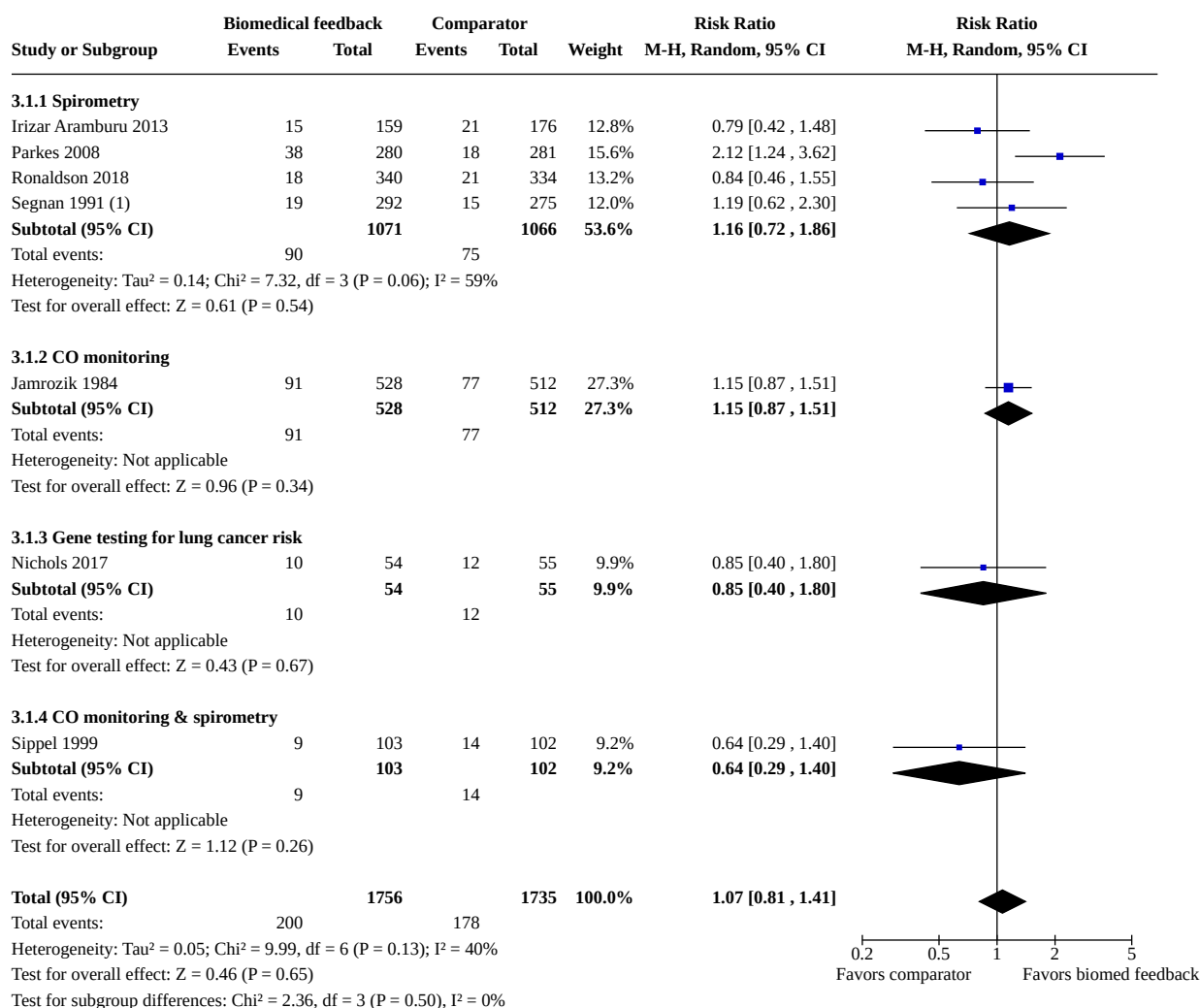
## Analysis 2.2. Comparison 2: Cost-free medications (patient-level), Outcome 2: Quit attempts



### Comparison 3. Biomedical feedback (patient-level)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Long-term abstinence (subgrouped by type)	7	3491	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.81, 1.41]
3.1.1 Spirometry	4	2137	Risk Ratio (M-H, Random, 95% CI)	1.16 [0.72, 1.86]
3.1.2 CO monitoring	1	1040	Risk Ratio (M-H, Random, 95% CI)	1.15 [0.87, 1.51]
3.1.3 Gene testing for lung cancer risk	1	109	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.40, 1.80]
3.1.4 CO monitoring & spirometry	1	205	Risk Ratio (M-H, Random, 95% CI)	0.64 [0.29, 1.40]

### Analysis 3.1. Comparison 3: Biomedical feedback (patient-level), Outcome 1: Long-term abstinence (subgrouped by type)



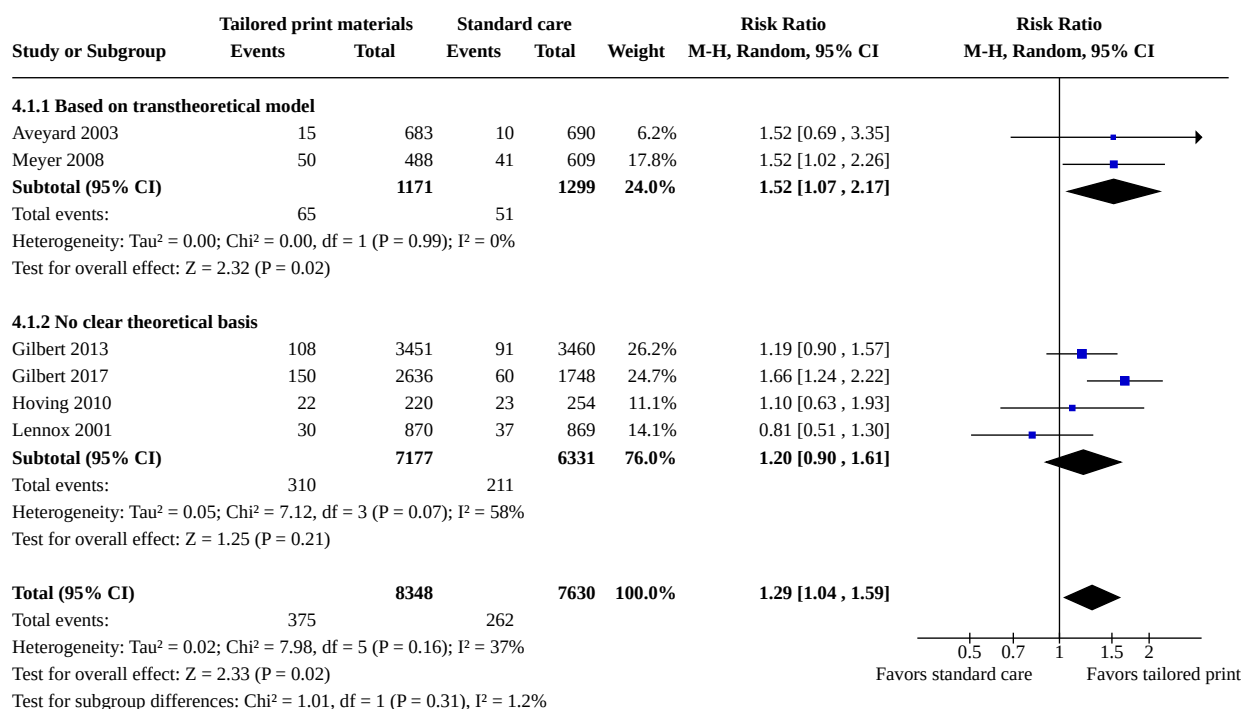
#### Footnotes

(1) Multicomponent vs multicomponent comparison that separates the effect of spirometry

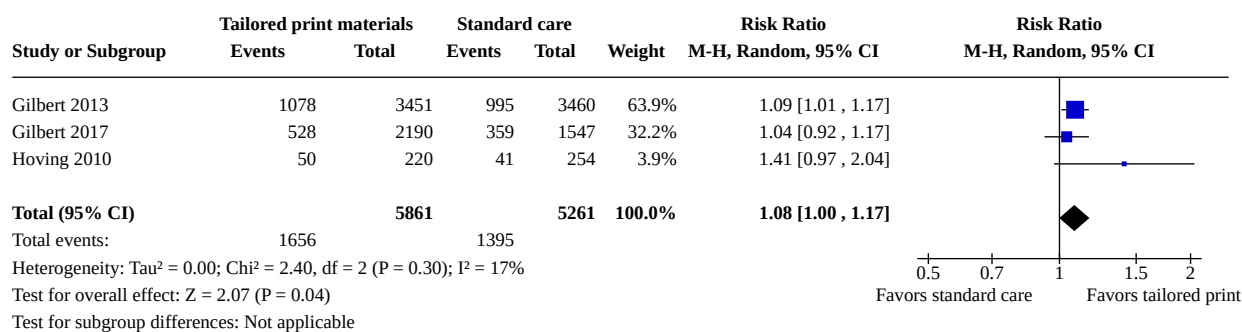
### Comparison 4. Tailored print materials (patient-level)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.1 Long-term abstinence (subgrouped by theoretical basis)	6	15978	Risk Ratio (M-H, Random, 95% CI)	1.29 [1.04, 1.59]
4.1.1 Based on transtheoretical model	2	2470	Risk Ratio (M-H, Random, 95% CI)	1.52 [1.07, 2.17]
4.1.2 No clear theoretical basis	4	13508	Risk Ratio (M-H, Random, 95% CI)	1.20 [0.90, 1.61]
4.2 Quit attempts	3	11122	Risk Ratio (M-H, Random, 95% CI)	1.08 [1.00, 1.17]

### Analysis 4.1. Comparison 4: Tailored print materials (patient-level), Outcome 1: Long-term abstinence (subgrouped by theoretical basis)



### Analysis 4.2. Comparison 4: Tailored print materials (patient-level), Outcome 2: Quit attempts

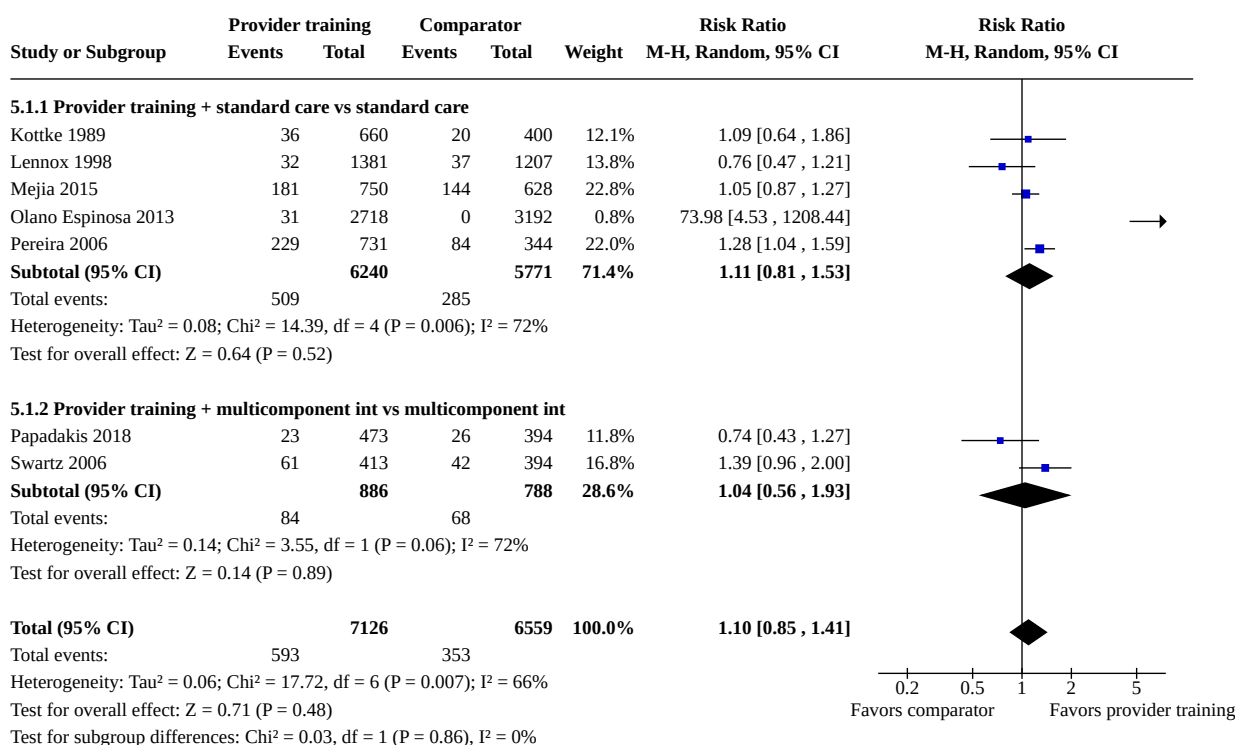


### Comparison 5. Provider training (provider-level)

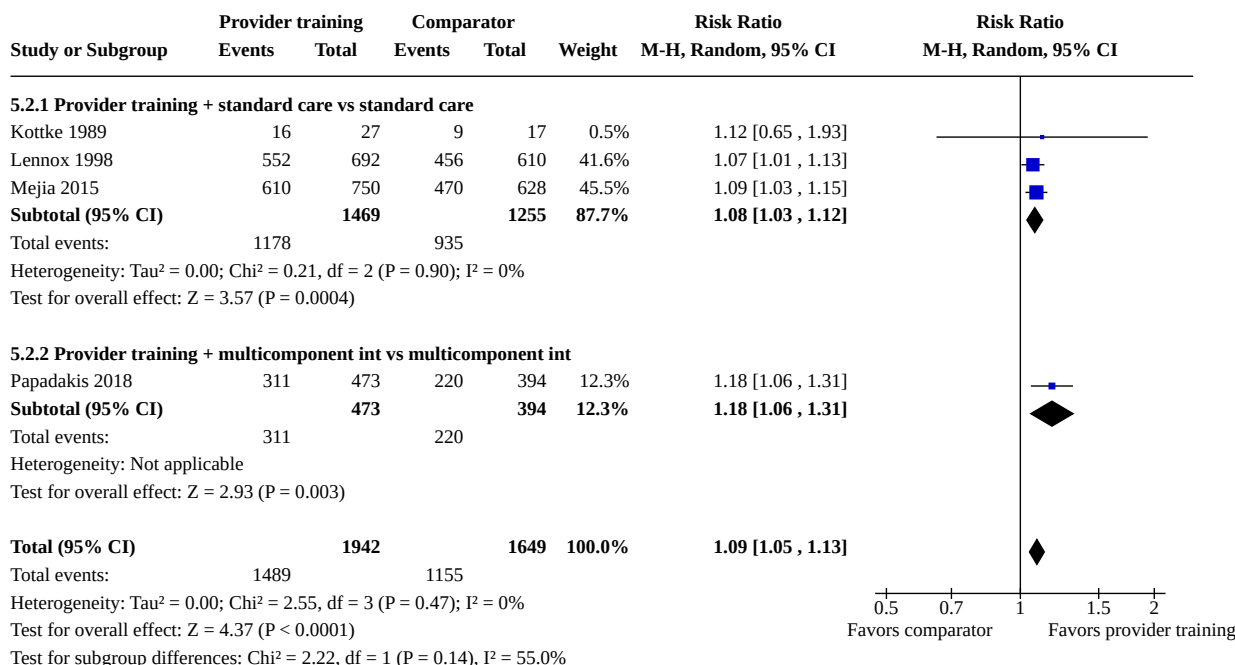
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1 Long-term abstinence	7	13685	Risk Ratio (M-H, Random, 95% CI)	1.10 [0.85, 1.41]
5.1.1 Provider training + standard care vs standard care	5	12011	Risk Ratio (M-H, Random, 95% CI)	1.11 [0.81, 1.53]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1.2 Provider training + multicomponent int vs multicomponent int	2	1674	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.56, 1.93]
<a href="#">5.2 Asking rates</a>	4	3591	Risk Ratio (M-H, Random, 95% CI)	1.09 [1.05, 1.13]
5.2.1 Provider training + standard care vs standard care	3	2724	Risk Ratio (M-H, Random, 95% CI)	1.08 [1.03, 1.12]
5.2.2 Provider training + multicomponent int vs multicomponent int	1	867	Risk Ratio (M-H, Random, 95% CI)	1.18 [1.06, 1.31]
<a href="#">5.3 Advise rates</a>	4	4112	Risk Ratio (M-H, Random, 95% CI)	1.12 [1.02, 1.24]
5.3.1 Provider training + standard care vs standard care	2	2438	Risk Ratio (M-H, Random, 95% CI)	1.21 [0.95, 1.54]
5.3.2 Provider training + multicomponent int vs multicomponent int	2	1674	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.98, 1.12]
<a href="#">5.4 Assistance rates</a>	5		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
5.4.1 Quit date set	3	3305	Risk Ratio (M-H, Random, 95% CI)	1.64 [0.86, 3.14]
5.4.2 Self-help materials	4	4380	Risk Ratio (M-H, Random, 95% CI)	2.32 [1.16, 4.62]
5.4.3 Medication	2	1674	Risk Ratio (M-H, Random, 95% CI)	1.15 [0.90, 1.47]
5.4.4 Counseling	1	867	Risk Ratio (M-H, Random, 95% CI)	1.26 [1.09, 1.45]
<a href="#">5.5 Arrange follow-up support rates</a>	3	2674	Risk Ratio (M-H, Random, 95% CI)	1.60 [0.95, 2.69]
<a href="#">5.6 Quit attempts</a>	5	6700	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.98, 1.10]
5.6.1 Provider training + standard care vs standard care	3	5026	Risk Ratio (M-H, Random, 95% CI)	1.02 [0.94, 1.10]
5.6.2 Provider training + multicomponent int vs multicomponent int	2	1674	Risk Ratio (M-H, Random, 95% CI)	1.08 [0.98, 1.19]

### Analysis 5.1. Comparison 5: Provider training (provider-level), Outcome 1: Long-term abstinence

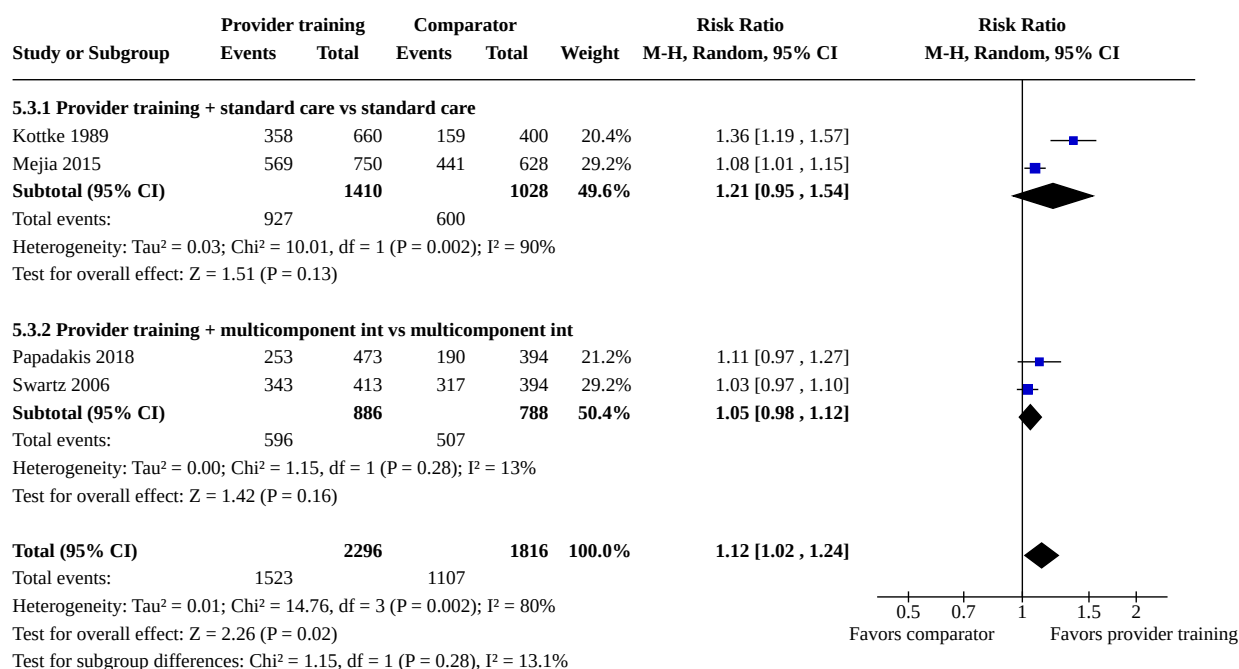


### Analysis 5.2. Comparison 5: Provider training (provider-level), Outcome 2: Asking rates

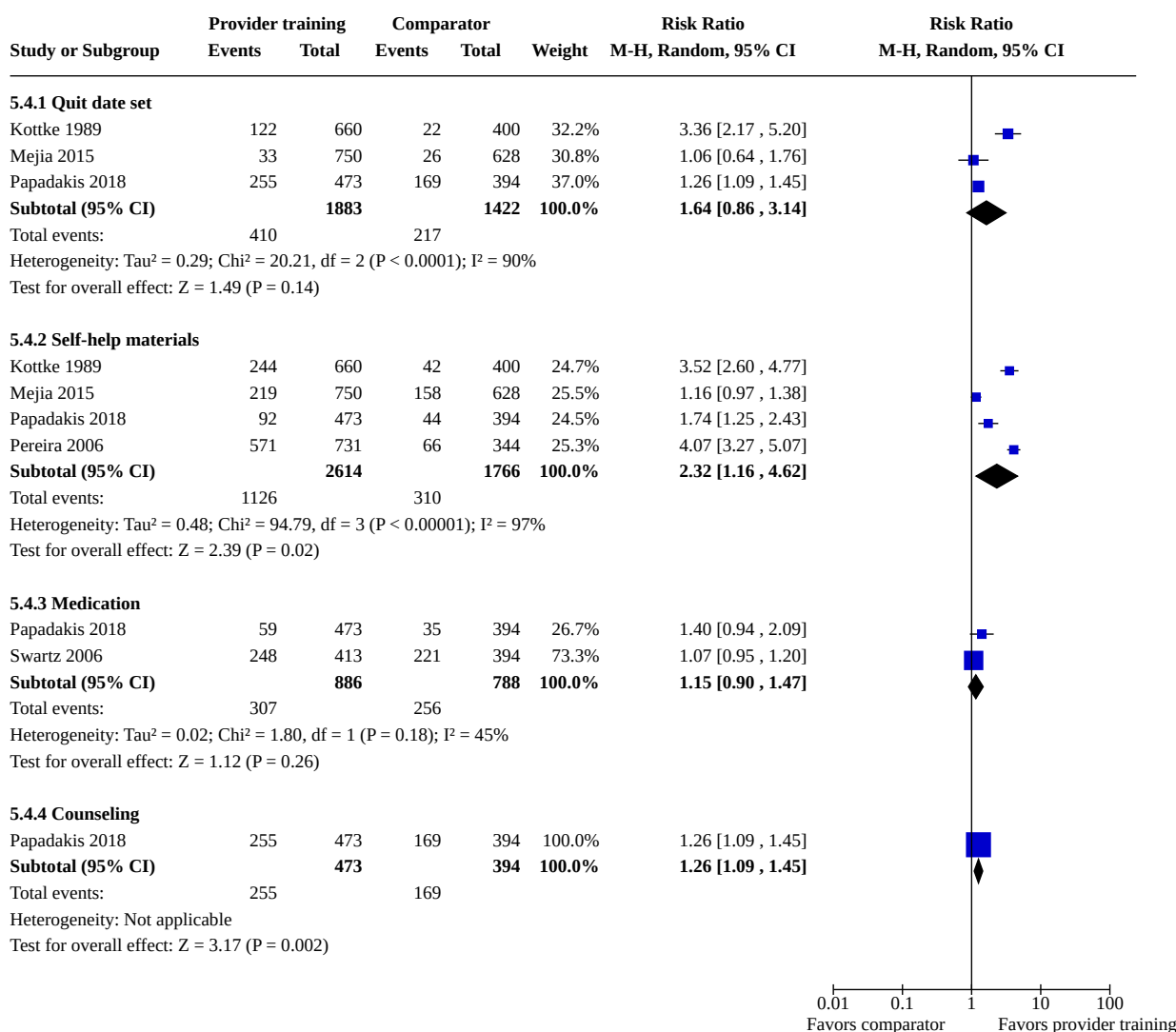




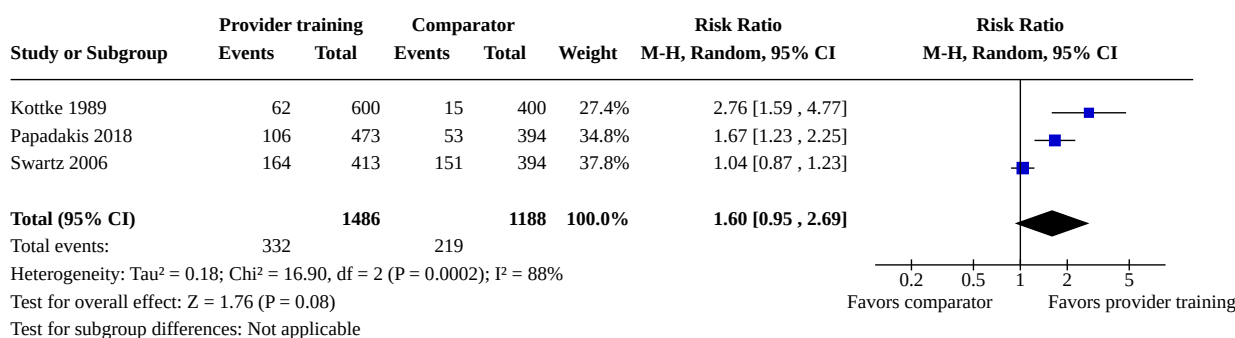
### Analysis 5.3. Comparison 5: Provider training (provider-level), Outcome 3: Advise rates



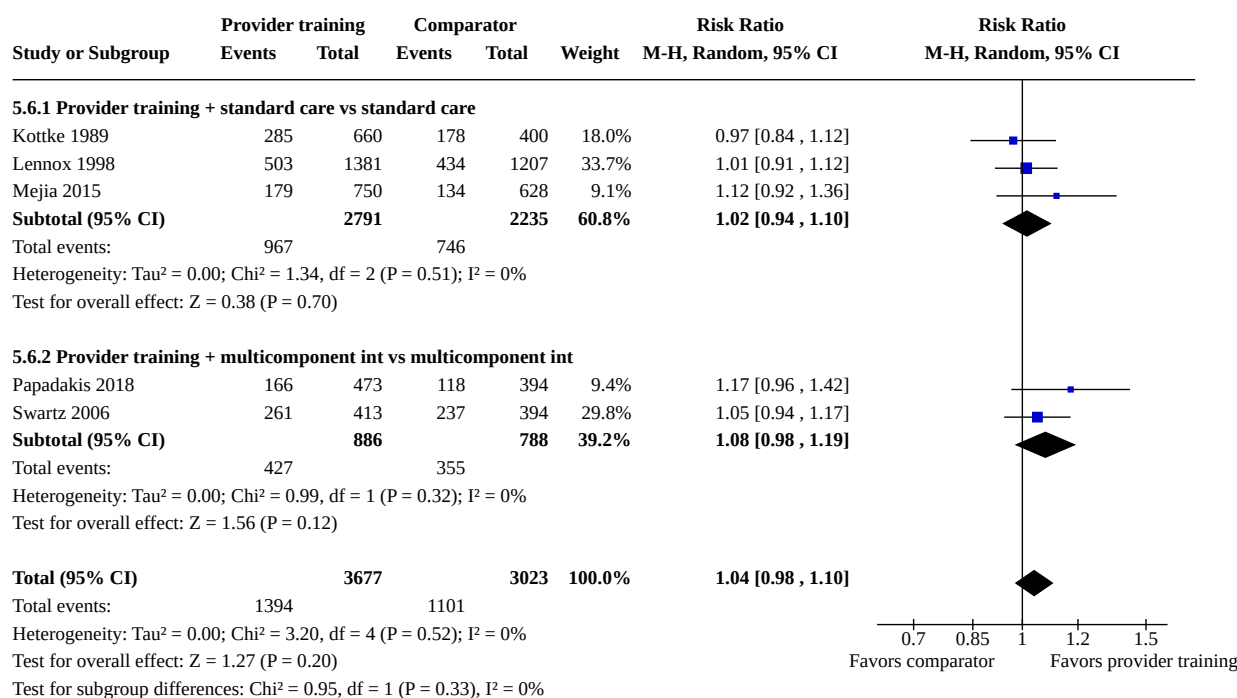
### Analysis 5.4. Comparison 5: Provider training (provider-level), Outcome 4: Assistance rates



### Analysis 5.5. Comparison 5: Provider training (provider-level), Outcome 5: Arrange follow-up support rates



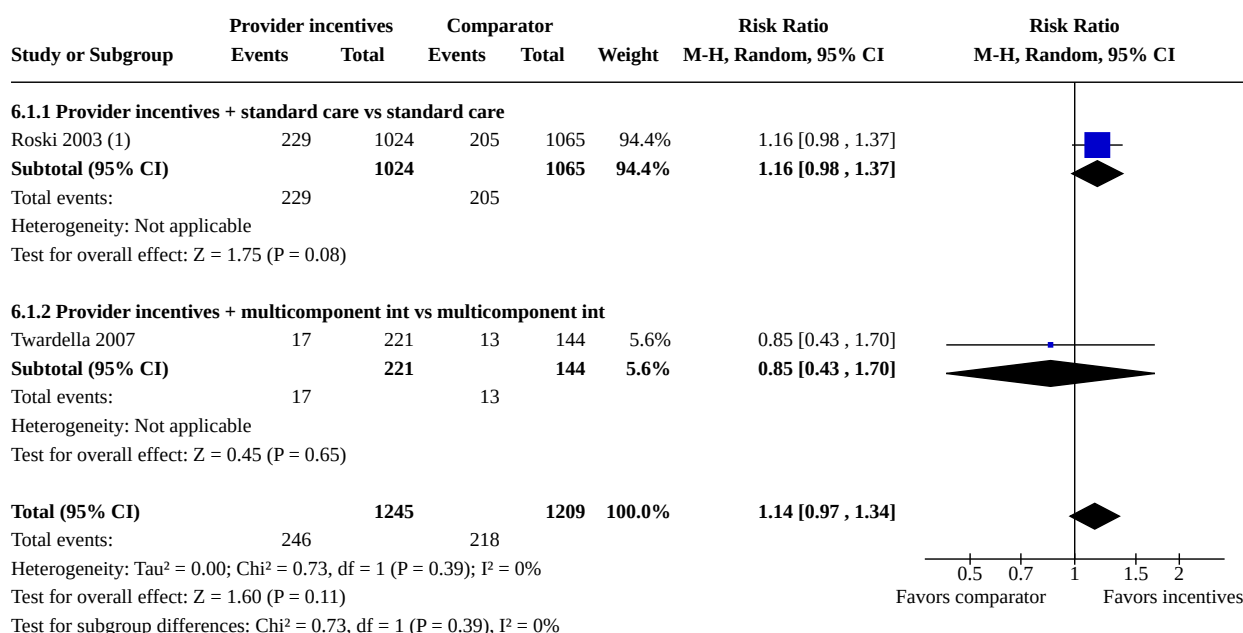
### Analysis 5.6. Comparison 5: Provider training (provider-level), Outcome 6: Quit attempts



### Comparison 6. Provider incentives (provider-level)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.1 Long-term abstinence	2	2454	Risk Ratio (M-H, Random, 95% CI)	1.14 [0.97, 1.34]
6.1.1 Provider incentives + standard care vs standard care	1	2089	Risk Ratio (M-H, Random, 95% CI)	1.16 [0.98, 1.37]
6.1.2 Provider incentives + multicomponent int vs multicomponent int	1	365	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.43, 1.70]

## Analysis 6.1. Comparison 6: Provider incentives (provider-level), Outcome 1: Long-term abstinence



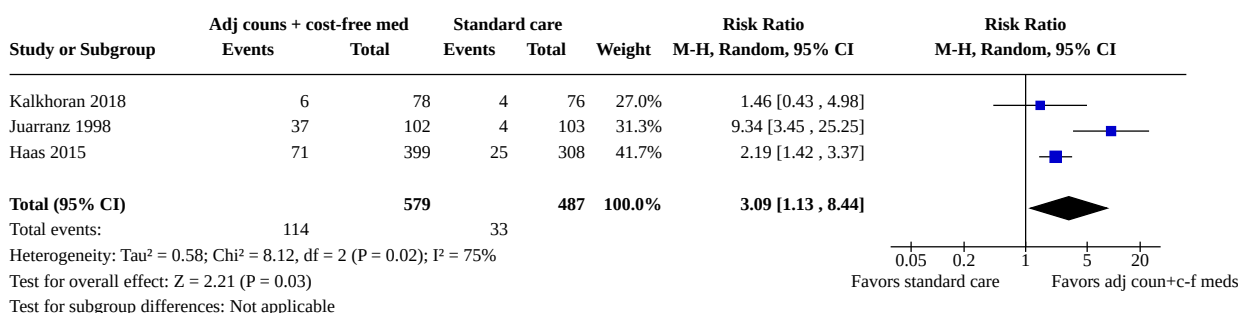
### Footnotes

(1) Denominators are based on complete cases rather than ITT, as ITT not reported in paper

## Comparison 7. Adjunctive counseling + cost-free meds versus standard care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.1 Long-term abstinence	3	1066	Risk Ratio (M-H, Random, 95% CI)	3.09 [1.13, 8.44]

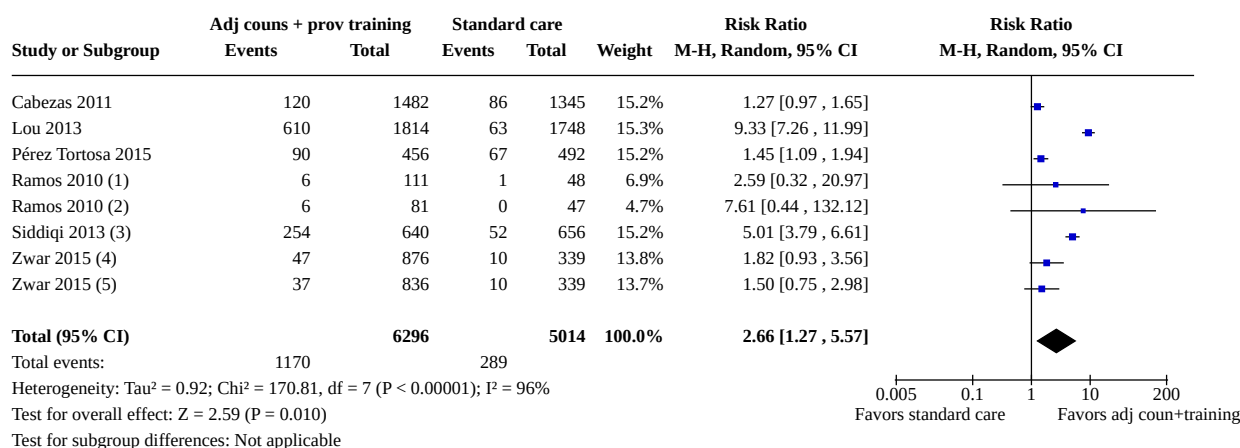
## Analysis 7.1. Comparison 7: Adjunctive counseling + cost-free meds versus standard care, Outcome 1: Long-term abstinence



## Comparison 8. Adjunctive counseling + provider training versus standard care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8.1 Long-term abstinence	6	11310	Risk Ratio (M-H, Random, 95% CI)	2.66 [1.27, 5.57]

### Analysis 8.1. Comparison 8: Adjunctive counseling + provider training versus standard care, Outcome 1: Long-term abstinence



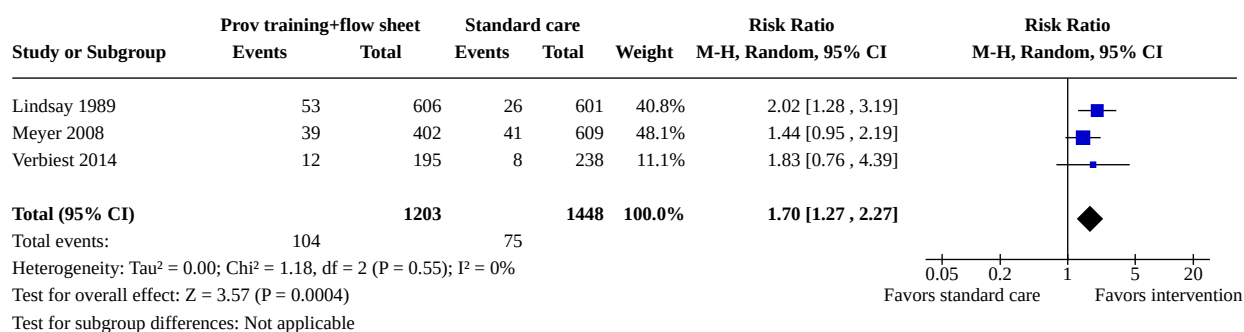
#### Footnotes

- (1) Group intervention versus standard care control. Control group split.
- (2) Individual intervention versus standard care control. Control group split.
- (3) BSS group versus control group
- (4) nurse delivered counselling
- (5) quitline delivered counselling

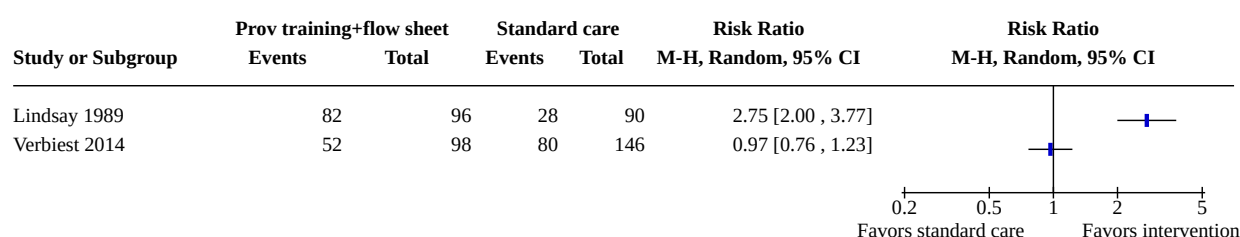
## Comparison 9. Provider training + flow sheet versus standard care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
9.1 Long-term abstinence	3	2651	Risk Ratio (M-H, Random, 95% CI)	1.70 [1.27, 2.27]
9.2 Asking rates	2		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
9.3 Assistance rates	2		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
9.3.1 Medication	2		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
9.4 Arrange follow-up support rates	2	430	Risk Ratio (M-H, Random, 95% CI)	5.53 [0.41, 73.81]

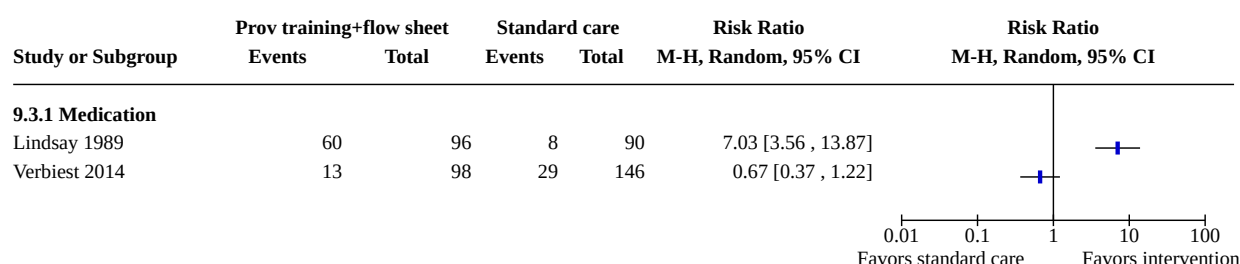
### Analysis 9.1. Comparison 9: Provider training + flow sheet versus standard care, Outcome 1: Long-term abstinence



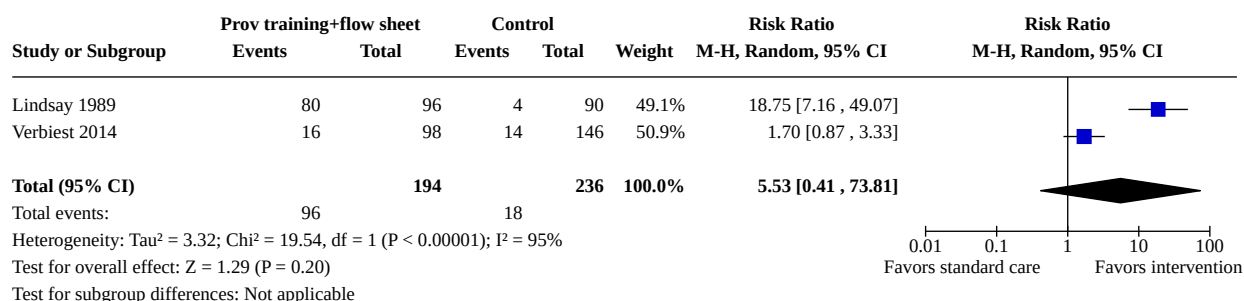
### Analysis 9.2. Comparison 9: Provider training + flow sheet versus standard care, Outcome 2: Asking rates



### Analysis 9.3. Comparison 9: Provider training + flow sheet versus standard care, Outcome 3: Assistance rates



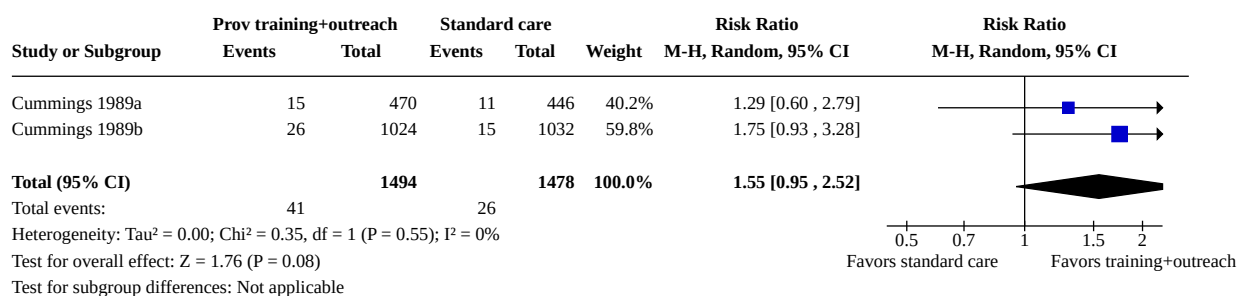
### Analysis 9.4. Comparison 9: Provider training + flow sheet versus standard care, Outcome 4: Arrange follow-up support rates



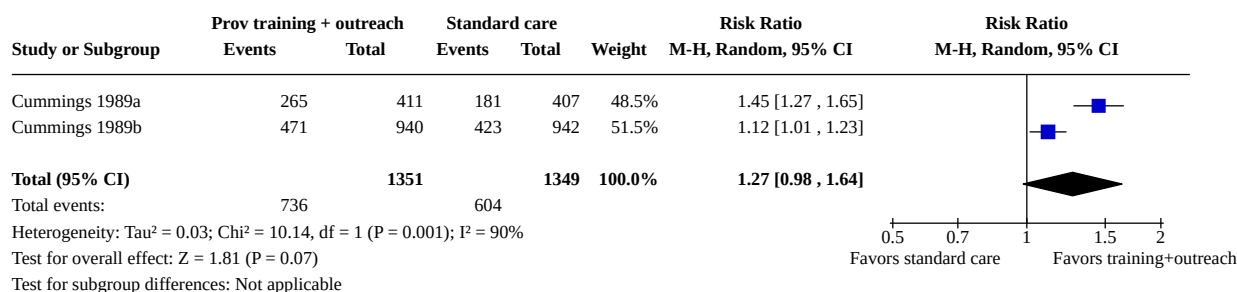
## Comparison 10. Provider training + outreach facilitation versus standard care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
10.1 Long-term abstinence	2	2972	Risk Ratio (M-H, Random, 95% CI)	1.55 [0.95, 2.52]
10.2 Asking rates	2	2700	Risk Ratio (M-H, Random, 95% CI)	1.27 [0.98, 1.64]
10.3 Assistance rates	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
10.3.1 Medication	2	1321	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.57, 1.22]
10.3.2 Quit date set	2	1701	Risk Ratio (M-H, Random, 95% CI)	5.73 [4.19, 7.83]
10.3.3 Self-help materials	2	2700	Risk Ratio (M-H, Random, 95% CI)	3.34 [2.54, 4.38]
10.4 Arrange follow-up support rates	2	1321	Risk Ratio (M-H, Random, 95% CI)	1.53 [1.15, 2.03]
10.5 Quit attempts	2	2972	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.96, 1.15]

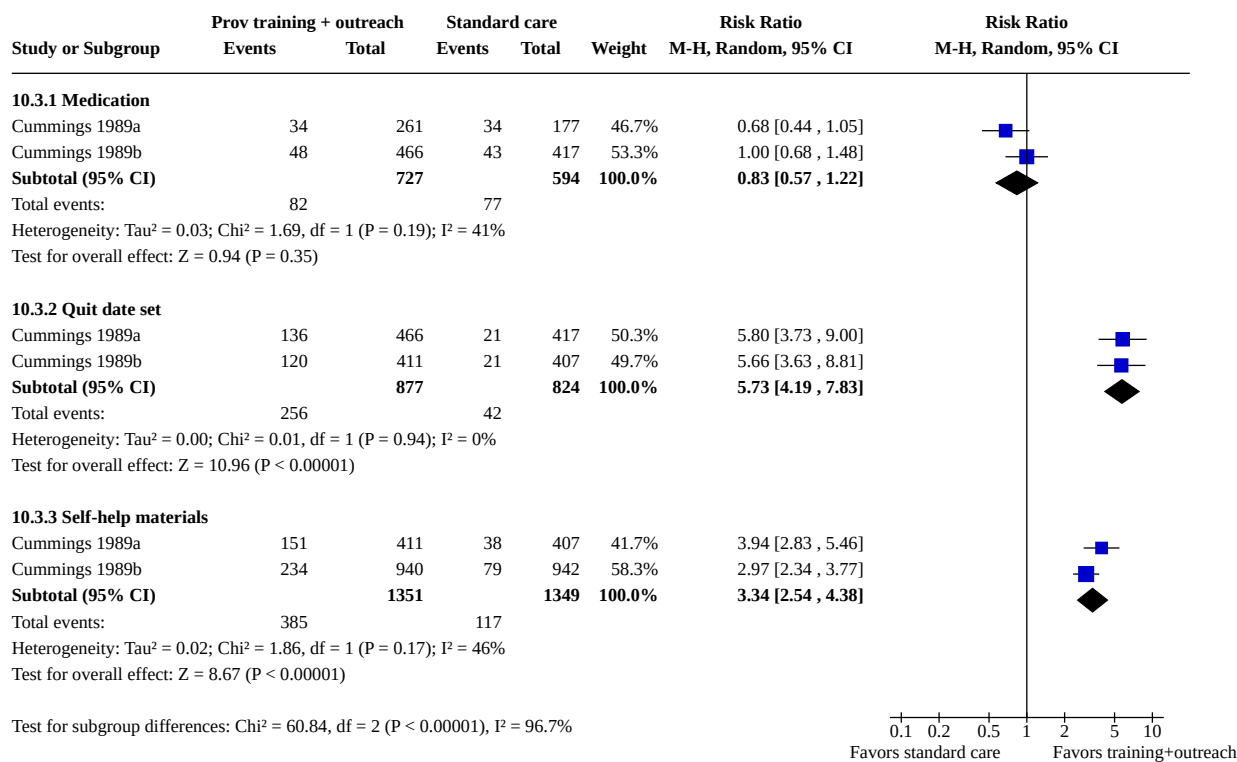
### Analysis 10.1. Comparison 10: Provider training + outreach facilitation versus standard care, Outcome 1: Long-term abstinence



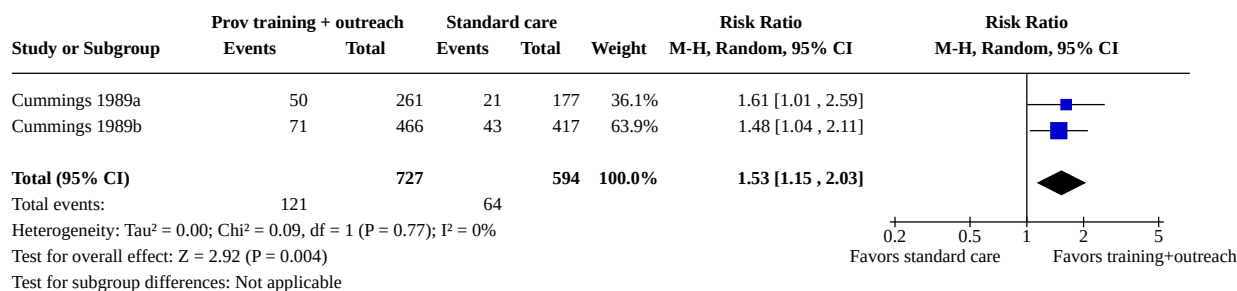
### Analysis 10.2. Comparison 10: Provider training + outreach facilitation versus standard care, Outcome 2: Asking rates



### Analysis 10.3. Comparison 10: Provider training + outreach facilitation versus standard care, Outcome 3: Assistance rates

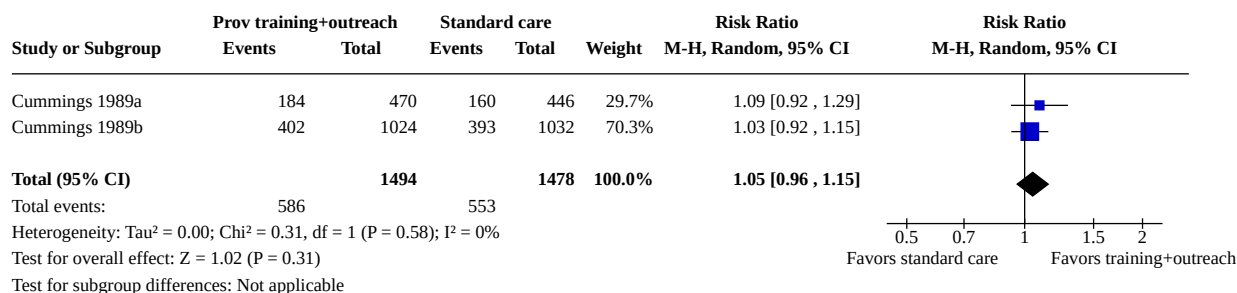


### Analysis 10.4. Comparison 10: Provider training + outreach facilitation versus standard care, Outcome 4: Arrange follow-up support rates





### Analysis 10.5. Comparison 10: Provider training + outreach facilitation versus standard care, Outcome 5: Quit attempts



## APPENDICES

### Appendix 1. Appendix: PubMed search strategy

Search	Query
#28	(#23 AND #24 AND #27) (smoking terms, primary care terms, study terms (no animals))
#27	(#26 NOT #20) (All study terms NOT animals)
#26	(#25 OR #21 OR #22) (Cochrane with eval and clinical)
#25	(#13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19) (Cochrane Search)
#24	(#8 OR #9 OR #10 OR #11 OR #12) (Primary Care Terms)
#23	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7) (Smoking Terms)
#22	clinical trial
#21	evaluation studies
#20	(animals [mh] NOT humans [mh])
#19	trial [ti]
#18	randomly [tiab]
#17	clinical trials as topic [mesh: noexp]
#16	placebo [tiab]
#15	randomized [tiab]
#14	controlled clinical trial [pt]
#13	randomized controlled trial [pt]
#12	general practitioner*

(Continued)

#11	general practice*
#10	family physician*
#9	primary care
#8	primary health care
#7	tobacco use disorder
#6	tobacco use cessation
#5	smoking/therapy
#4	smoking/prevention and control
#3	smoking cessation
#2	nicotine
#1	tobacco

## Appendix 2. Specialised Register search strategy

Searched 02/04/2015 in Cochrane Register of Studies, Tobacco Addiction Group segment

#1 general practitioner\*:TI,AB,XKY,MH,EMT,KY,KW

#2 general practice\*:TI,AB,XKY,MH,EMT,KY,KW

#3 family physician\*:TI,AB,XKY,MH,EMT,KY,KW

#4 primary care:TI,AB,XKY,MH,EMT,KY,KW

#5 primary health care:TI,AB,XKY,MH,EMT,KY,KW

#6 family medicine:TI,AB,XKY,MH,EMT,KY,KW

#7 family practice\*:TI,AB,XKY,MH,EMT,KY,KW

#8 physicians, family\*:XKY,MH,EMT,KY,KW

#9 physicians, primary care\*:XKY,MH,EMT,KY,KW

#10 MeSH DESCRIPTOR Physicians, Family

#11 MeSH DESCRIPTOR Physicians, Primary Care

#12 MeSH DESCRIPTOR Primary Health Care Explode All

#13 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #10 OR #11 OR #12

## Appendix 3. Glossary of strategies used to improve the delivery of smoking cessation treatment in primary care

### Patient-level

- Adjunctive counseling: counseling offered over and above standard care, i.e. brief advice, and provided by a health professional other than the primary care physician - this could be via a practice nurse or counselor, or through a smoking quitline.
- Biomedical feedback: measurements are taken from the body, for example exhaled carbon monoxide levels, genetic predisposition to lung cancer, lung function through spirometry testing. This is then fed back to the patient in the context of their smoking behavior

- Cost-free medications: the provision of smoking cessation medications at no cost to the participants (as opposed to medications with a charge, which is considered standard care). We considered in detail whether this intervention type should be categorized as a patient-level or practice-level intervention, and decided that it could be categorized as either. We decided on patient-level in this instance as the patient is the beneficiary of the lack of cost, which has the potential to increase medication use.
- Information videos: smoking cessation information provided by a video
- Medication prompts: participants are provided with prompts to take their medications, i.e. through automated phone calls or text messages.
- Patient incentives: rewards provided to participants for successful smoking cessation.
- SMS and internet cessation programs: smoking cessation programs offered in addition to standard smoking cessation support and delivered via text message or the internet.
- Proactive outreach: primary care staff proactively contact practice patients via the mail or telephone to raise the issue of their smoking and encourage them to quit and access support.
- Tailored print materials: printed self-help materials tailored to the individual, for example, based on their readiness to quit smoking

### Provider-level

- Performance audit and feedback: primary care providers are assessed on their performance of smoking cessation actions and care, e.g. asking patients about whether they smoke and providing smoking cessation medications and counseling. The results of this audit are then fed back to providers.
- Provider incentives: primary care providers are provided with financial incentives to meet key smoking cessation-related performance targets, e.g. assisting patients to quit smoking, patient quit rates.
- Provider training: additional training given to primary care smoking cessation support providers on the topic of smoking cessation (this did not include study specific training).

### Practice-level

- Electronic medical record (EMR) and decision support: encouragement to record patients smoking status in electronic medical records and to use linked system features such as treatment prompts.
- Modified vital sign stamps: an ink stamp used to imprint information on to a patient's medical record, which, as well as including traditional information on vital signs, also includes information on a patient's smoking status. This was designed to prompt adherence to smoking cessation guidelines.
- Outreach facilitation: external facilitators assist primary care physicians with the implementation and quality improvement of smoking cessation care within their practice.
- Treatment flow sheets/Consult forms: a document supplied to providers with details of how to provide smoking cessation care that the provider can use to prompt them during a consultation.

## HISTORY

Protocol first published: Issue 3, 2015

## CONTRIBUTIONS OF AUTHORS

Roles and responsibilities*	
Task	Who carried out this task?
Drafting of protocol	Sophia Papadakis, George Wells, Andrew Pipe
Development of search strategy	Sophia Papadakis, Gillian Pritchard, Lindsay Stead (editorial)
Searched for trials	Sophia Papadakis, Gillian Pritchard
Obtained copies of trials	Gillian Pritchard
Eligibility assessment	Sophia Papadakis, Gillian Pritchard, Andrew Pipe, Bosun Hong, Nicola Lindson
Extracted data	Sophia Papadakis, Gillian Pritchard, Nicola Lindson, Bosun Hong

Entered data into Review Manager 5	Sophia Papadakis, Gillian Pritchard, Nicola Lindson, Bosun Hong
Carried out analysis	Sophia Papadakis, Nicola Lindson, Thomas Fanshawe
Interpreted analyses	Nicola Lindson
Drafting the final review	Sophia Papadakis, Nicola Lindson, Thomas Fanshawe; Bosun Hong
Review of draft	All authors

## DECLARATIONS OF INTEREST

NL: none known

TF: none known

BH: none known

GP: none known

AP is employed by the University of Ottawa Heart Institute, which has received educational and research grants from Pfizer Canada, the Heart and Stroke Foundation of Ontario, Public Health Agency of Canada, Ontario Ministry of Health and Long Term Care. AP has received consulting fees and speaker honoraria from Pfizer, Johnson and Johnson, Merck, Glaxo-Smith Kline. AP is an inventor of the Ottawa Model for Smoking Cessation. A commercial organization uses the Ottawa Model for Smoking Cessation program, and the inventors have received royalty payments in the past, through the University of Ottawa Heart Institute.

GW: none known

SP is an inventor of the Ottawa Model for Smoking Cessation. A commercial organization uses strategies informed by the Ottawa Model for Smoking Cessation program, and SP has received royalty payments in the past, through the University of Ottawa Heart Institute.

## SOURCES OF SUPPORT

### Internal sources

- Nicola Lindson, UK

NL is employed by the University of Oxford

- The University of Ottawa Heart Institute, Ottawa, Canada provides salary, office space and library resources for SP, GP, AP, GW, Canada

### External sources

- Nicola Lindson, UK

NL's salary is funded through infrastructure funding for the Cochrane Tobacco Addiction Group from the NIHR. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, National Health Service (NHS) or the Department of Health.

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The following revisions were made to the published protocol for the present review:

- The title of the review was changed from '*Strategies to improve the delivery of tobacco use treatment in primary care practice*' to '*Strategies to improve smoking cessation rates in primary care*'. This was in response to peer review comments, which suggested that the title did not accurately reflect the inclusion criteria for the studies included in the review.
- Due to the volume of relevant studies, we excluded non-randomized studies (before-after controlled trials).
- We had originally planned to include studies which tested interventions to enhance tobacco treatment delivery as part of a multifactorial lifestyle intervention; however, due to the extensive literature identified and the high clinical and methodological heterogeneity between studies purely focusing on smoking and those looking at multiple risk factors we ultimately excluded them.
- One review author extracted data for study characteristics, due to the high number of included studies.

5. We excluded studies with short-term follow-up (less than six months). We had originally planned to include studies with a shorter follow-up, as we expected to find limited studies; but, based on the considerable body of evidence identified through our searches we deferred to the usual guidance of the Cochrane Tobacco Addiction Group.
6. We did not assess performance bias in line with the guidance provided by the Cochrane Tobacco Addiction Group on studies of behavioral interventions.
7. We did not assess funding source as a source of bias in line with Cochrane recommendations.
8. We assessed detection bias for the primary outcome only and considered biochemical validation of quitting in our judgment of this domain rather than as a separate domain.
9. We generated funnel plots for any outcomes with 10 or more studies contributing to the analysis.
10. Analyses were carried out using a random-effects model rather than a fixed-effect model, in line with the most recent guidance provided by the Cochrane Tobacco Addiction Group.
11. The protocol had assumed that studies would be grouped more broadly in analyses, but this was deemed inappropriate due to substantial clinical variance in the studies identified. Analyses were structured based on the strategies identified through the searches, and as such we chose appropriate subgroup analyses based on this restructuring.
12. Studies at high risk of bias only (i.e. not unclear risk) were removed in sensitivity analyses, in line with the common practice of the Cochrane Tobacco Addiction Group.
13. We carried out sensitivity analyses removing individually-randomized studies based on the comments of the Co-ordinating editor. c-RCTs are the most appropriate study type to test the interventions eligible for this review in primary care specifically.