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Motivational interviewing for smoking cessation (Review)

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[Intervention Review]

Motivational interviewing for smoking cessation

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ABSTRACT

Background

Motivational Interviewing (MI) is a directive patient-centred style of counselling, designed to help people to explore and resolve ambivalence about behaviour change. It was developed as a treatment for alcohol abuse, but may help people to a make a successful attempt to stop smoking.

Objectives

To evaluate the efficacy of MI for smoking cessation compared with no treatment, in addition to another form of smoking cessation treatment, and compared with other types of smoking cessation treatment. We also investigated whether more intensive MI is more effective than less intensive MI for smoking cessation.

Search methods

We searched the Cochrane Tobacco Addiction Group Specialised Register for studies using the term motivat* NEAR2 (interview* OR enhanc* OR session* OR counsel* OR practi* OR behav*) in the title or abstract, or motivation* as a keyword. We also searched trial registries to identify unpublished studies. Date of the most recent search: August 2018.

Selection criteria

Randomised controlled trials in which MI or its variants were offered to smokers to assist smoking cessation. We excluded trials that did not assess cessation as an outcome, with follow-up less than six months, and with additional non-MI intervention components not matched between arms. We excluded trials in pregnant women as these are covered elsewhere.

Data collection and analysis

We followed standard Cochrane methods. Smoking cessation was measured after at least six months, using the most rigorous definition available, on an intention-to-treat basis. We calculated risk ratios (RR) and 95% confidence intervals (CI) for smoking cessation for each study, where possible. We grouped eligible studies according to the type of comparison. We carried out meta-analyses where appropriate, using Mantel-Haenszel random-effects models. We extracted data on mental health outcomes and quality of life and summarised these narratively.

Main results

We identified 37 eligible studies involving over 15,000 participants who smoked tobacco. The majority of studies recruited participants with particular characteristics, often from groups of people who are less likely to seek support to stop smoking than the general population. Although a few studies recruited participants who intended to stop smoking soon or had no intentions to quit, most recruited a population without regard to their intention to quit. MI was conducted in one to 12 sessions, with the total duration of MI ranging from five to 315



minutes across studies. We judged four of the 37 studies to be at low risk of bias, and 11 to be at high risk, but restricting the analysis only to those studies at low or unclear risk did not significantly alter results, apart from in one case - our analysis comparing higher to lower intensity MI.

We found low-certainty evidence, limited by risk of bias and imprecision, comparing the effect of MI to no treatment for smoking cessation (RR = 0.84, 95% CI 0.63 to 1.12; $I^2 = 0\%$; adjusted N = 684). One study was excluded from this analysis as the participants recruited (incarcerated men) were not comparable to the other participants included in the analysis, resulting in substantial statistical heterogeneity when all studies were pooled ($I^2 = 87\%$). Enhancing existing smoking cessation support with additional MI, compared with existing support alone, gave an RR of 1.07 (95% CI 0.85 to 1.36; adjusted N = 4167; $I^2 = 47\%$), and MI compared with other forms of smoking cessation support gave an RR of 1.24 (95% CI 0.91 to 1.69; $I^2 = 54\%$; N = 5192). We judged both of these estimates to be of low certainty due to heterogeneity and imprecision. Low-certainty evidence detected a benefit of higher intensity MI when compared with lower intensity MI (RR 1.23, 95% CI 1.11 to 1.37; adjusted N = 5620; $I^2 = 0\%$). The evidence was limited because three of the five studies in this comparison were at risk of bias. Excluding them gave an RR of 1.00 (95% CI 0.65 to 1.54; $I^2 = n/a$; N = 482), changing the interpretation of the results.

Mental health and quality of life outcomes were reported in only one study, providing little evidence on whether MI improves mental well-being.

Authors' conclusions

There is insufficient evidence to show whether or not MI helps people to stop smoking compared with no intervention, as an addition to other types of behavioural support for smoking cessation, or compared with other types of behavioural support for smoking cessation. It is also unclear whether more intensive MI is more effective than less intensive MI. All estimates of treatment effect were of low certainty because of concerns about bias in the trials, imprecision and inconsistency. Consequently, future trials are likely to change these conclusions. There is almost no evidence on whether MI for smoking cessation improves mental well-being.

PLAIN LANGUAGE SUMMARY

Does motivational interviewing help people to guit smoking?

Background

Motivational interviewing is a type of counselling that can be used to help people to stop smoking. It aims to help people explore the reasons that they may feel unsure about quitting and find ways to make them feel more willing and able to stop smoking. Rather than telling the person why and how they should change their behaviour, counsellors try to help people to choose to change their own behaviour, increasing their confidence that they can succeed. This review explores whether motivational interviewing helps more people to stop smoking than no treatment, or other types of stop smoking treatment. It also looks at whether longer motivational interviewing, with more counselling sessions, helps more people to quit than shorter motivational interviewing with fewer sessions.

Study characteristics

This review included 37 trials covering over 15,000 people who smoked tobacco. Studies were conducted in a lot of different types of people, including people with health problems or drug use problems, young people, homeless people, and people who had been arrested or were in prison. Some people felt ready to quit smoking and others did not. Motivational interviewing was provided in one to 12 sessions and took from as little as five minutes, to as much as eight hours, to deliver. Studies lasted for at least six months. The evidence is up to date to August 2018.

Key results

There was not enough information available to decide whether motivational interviewing helped more people to stop smoking than no stop smoking treatment. People were slightly more likely to stop smoking if they were provided with motivational interviewing rather than another type of treatment to stop smoking, but our findings suggest that there is still a chance that motivational interviewing could also reduce a person's chances of quitting compared with other stop smoking treatments. This means more research is needed to decide whether motivational interviewing can help more people to quit than other types of treatment. Using longer motivational interviewing with more treatment sessions may help more people to give up smoking than shorter motivational interviewing with fewer sessions, however more research is needed to be sure that this is the case.

We also looked at whether being provided with motivational interviewing to quit smoking increased people's well-being. Most studies did not provide any information about this, and so more studies are needed to answer this question.

Quality of the evidence

There is low-quality evidence looking at whether motivational interviewing helps more people to quit smoking than no treatment. This means it is difficult to know whether motivational interviewing helps people to quit smoking or not, and more studies are needed. The quality of the evidence was also low for all of the other questions we asked about quitting smoking, which means that our findings may



change when new research is carried out. The quality of the research is rated as low because there were problems with the design of studies, findings of studies were very different to one another, and there were not enough data, making it difficult to determine whether motivational interviewing or more intense motivational interviewing helped people to quit smoking or not.



Summary of findings for the main comparison. Motivational interviewing compared with no treatment for smoking cessation

Motivational interviewing compared with no treatment for smoking cessation

Patient or population: tobacco smokers (adolescents, university students, adult primary care patients)

Setting: high schools, university & primary care (USA)

Intervention: motivational interviewing **Comparison:** no smoking cessation treatment

Outcomes	Anticipated abso (95% CI)	olute effects*	Relative effect (95% CI)	№ of partici- pants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with no treatment	Risk with MI				
Smoking ces- sation at ≥ 6	Study population		RR 0.84 - (0.63 to 1.12)	adjusted N = 684	⊕⊕⊝⊝ I OW 1, 2	One eligible study (Naik 2014) has been excluded from this pooled analysis as it recruited a substantially dif-
months fol- low-up	22 per 100	19 per 100 (14 to 25)	(0.03 to 1.12)	(4 RCTs)	LOW +, +	ferent population (incarcerated men) compared with the other studies, which recruited adults and adolescents from the general population. When included in the analysis, it resulted in substantial heterogeneity - removal of Naik 2014 decreased statistical heterogeneity to zero.

^{*}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

¹ Downgraded one level as all studies were at high or unclear risk of bias; removing the studies at high risk changed the direction of the effect estimate so that it favoured MI, however the CIs still spanned one and suffered substantial imprecision

² Downgraded one level due to imprecision: the upper and lower limits of the confidence intervals included both meaningful benefit and harm, and the overall number of events was low (n = 144)

Summary of findings 2. Motivational interviewing in addition to other smoking cessation treatment for smoking cessation

Motivational interviewing in addition to other smoking cessation treatment for smoking cessation

Patient or population: tobacco smokers (general population, low income, inpatients and outpatients with mixed diagnoses)

Setting: community, hospital, healthcare clinics (Australia, Brazil, South Africa, USA)

Intervention: motivational interviewing in addition to other smoking cessation (SC) treatment

Comparison: other smoking cessation treatment alone

Outcomes	Anticipated absolute eff	ects* (95% CI)	Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence	Comments
	Risk with other SC treatment only	Risk with MI in addition to other SC treatment			(GRADE)	
Smoking ces- sation at ≥ 6	Study population		RR 1.07 - (0.85 to 1.36)	adjusted N = 4167 (12 RCTs)	⊕⊕⊝⊝ LOW 1, 2, 3	
months follow-up	15 per 100	16 per 100 (13 to 20)	(3.33.13.1.30)	(==)	LOW	

^{*}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

- ¹ Five studies judged to be at high risk of bias, however sensitivity analysis suggested this is unlikely to impact on the result not downgraded
- ² Downgraded one level due to inconsistency: study effects differed across studies, demonstrated by moderate unexplained statistical heterogeneity (I² = 47%)
- ³ Downgraded one level due to imprecision: the upper and lower limits of the confidence intervals included both meaningful benefit and harm

Summary of findings 3. Motivational interviewing compared with another smoking cessation intervention for smoking cessation

Motivational interviewing compared with another smoking cessation intervention for smoking cessation

Patient or population: tobacco smokers (general population, adolescents, offenders, homeless, substance users, hospital inpatients, HIV-positive) Setting: community, universities, homeless shelters, inpatient and outpatient healthcare clinics, primary care (Australia, Brazil, China, Spain, UK, USA) **Intervention:** motivational interviewing

Comparison: another SC intervention							
Outcomes	Anticipated absolute effects* (95% CI)	Relative effect . (95% CI)	№ of partici- pants (studies)	Certainty of the evidence (GRADE)	Comments		
	Risk with other SC interven- Risk with MI tion						
Smoking cessation at ≥ 6 months follow-up	· · ·	RR 1.24 - (0.91 to 1.69)	5192 (19 RCTs)	⊕⊕⊙⊝ LOW 1, 2, 3			

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

9 per 100

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

11 per 100

(8 to 15)

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

- ¹ Three studies judged at high risk of bias, however sensitivity analysis suggested this was unlikely to impact on the result not downgraded
- ² Downgraded one level due to inconsistency: study effects differ across studies, demonstrated by moderate unexplained statistical heterogeneity (I² = 54%)
- ³ Downgraded one level due to imprecision: the upper and lower limits of the confidence intervals included both meaningful benefit and harm

Summary of findings 4. Higher compared with lower intensity motivational interviewing for smoking cessation

Higher compared with lower intensity motivational interviewing for smoking cessation

Patient or population: tobacco smokers (general population, hospital inpatients with mixed diagnoses)

Setting: community-based telephone quit-line, primary care, hospital, inpatient substance abuse treatment centre (USA)

Intervention: higher intensity motivational interviewing **Comparison:** lower intensity motivational interviewing

Outcomes	Anticipated absolute effects* (95% CI)	Relative effect	№ of participants (studies)	Certainty of the evidence	Comments
	Risk with lower inten- Risk with higher intensity MI sity MI	(40% 6.7)	(common)	(GRADE)	

^{*}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).

Smoking cessation Study population RR 1.23 adjusted N = 5620 ⊕⊕⊝⊝ at ≥ 6 months fol-(1.11 to 1.37) (5 RCTs) LOW 1 low-up 17 per 100 21 per 100 (19 to 23)

*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

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

¹ Downgraded two levels due to risk of bias: three of the five studies were judged to be at high risk of bias and removing these studies in a sensitivity analysis changed the interpretation of the effect, so that the confidence intervals encompassed both appreciable benefit and harm of higher intensity motivational interviewing for smoking cessation



BACKGROUND

Description of the condition

Tobacco use is one of the leading causes of preventable illness and death worldwide, accounting for over seven million deaths annually (GBD 2015 Risk Factors Collaborators 2016). Extrapolation based on current smoking trends suggests that, without widespread quitting, approximately 400 million tobaccorelated deaths will occur between 2010 and 2050, mostly among current smokers (Jha 2011). Most smokers would like to stop (CDC 2017); however, quitting is difficult.

Description of the intervention

The concept of motivational interviewing (MI) evolved from experiences in treating alcohol abuse, and was first described by Miller in 1983. It is defined as "a directive, client-centred counselling style for eliciting behaviour change by helping clients to explore and resolve ambivalence" (Miller 1983). The four guiding principles: (a) expressing empathy, (b) developing discrepancy, (c) rolling with resistance, (d) supporting self efficacy, have been detailed elsewhere (Miller 2002).

The MI process is a brief psychotherapeutic intervention intended to increase the likelihood that a person will make an attempt to change their harmful behaviour. Adaptations of MI have ranged from brief 20-minute office interventions (motivational consulting) to Motivation Enhancement Therapy (MET), a multisession course of treatment, including a lengthy assessment, personalised feedback and follow-up interviews (Lawendowski 1998; Rollnick 1992). MI has also been provided by telephone consultations and in a group format. MI and its various forms have been applied both as a stand-alone intervention or with other treatments, and in a range of settings. These include health settings such as general hospital wards, emergency departments, and general medical practice (Britt 2002).

How the intervention might work

Miller 1994 suggests that motivation may fluctuate over time or from one situation to another, and can be influenced to change in a particular direction. Thus, lack of motivation (or resistance to change) is seen as something fluid, that is open to change. Therefore, the main focus of MI is facilitating behaviour change using a directive approach, by helping people to explore and resolve any ambivalence they may have toward this change (Rollnick 1995), and in turn making them more likely to choose to change their behaviour in the desired direction. In this case, that behaviour is smoking and so the goal of MI is to increase motivation to quit, making smoking cessation more likely. Rollnick 1995 also suggests that adopting an aggressive or confrontational style is likely to produce negative responses from people (such as arguing), which may be interpreted by the practitioner as denial or resistance. MI guides people to explore and confront their behaviour, instead of telling them what to do.

Why it is important to do this review

MI has been used primarily for the management of health behaviours in those with behavioural disorders, such as alcohol abuse, drug addiction, weight loss, and treatment compliance, as well as for smoking cessation. Systematic reviews have shown some beneficial effects of MI on these behaviours (Cheng 2015;

Cowlishaw 2012; Foxcroft 2016; Gates 2016; Heckman 2010; Hettema 2010; Klimas 2018; Mbuagbaw 2012; Morton 2015; Smedslund 2011). However, these effects are minimal or nonexistent at long-term follow-up and included studies are generally deemed to be of limited quality, making it difficult to draw clear conclusions. For example, Morton 2015 concluded that the design of many studies - incorporating multi-component interventions made it very difficult to isolate the effects of MI. The previous version of this review (Lindson-Hawley 2015) resulted in a modest but significant increase in quitting smoking when MI was used in comparison to brief advice or usual care. However, this review encountered the same challenges described by Morton 2015 above, pooled studies with a range of different comparator types, and only included studies that reported providing a form of MI fidelity monitoring. This may have biased the inclusion of studies and thus the results. Therefore, inclusion criteria for this version of the review have been revised to reduce bias (although still control for fidelity monitoring), attempt to isolate the effects of MI, and to be mindful of the comparator group when pooling studies, to allow a range of useful comparisons.

OBJECTIVES

To evaluate the efficacy of MI for smoking cessation compared with no treatment, in addition to another form of smoking cessation treatment, and compared with other types of smoking cessation treatment. We also investigated whether more intensive MI is more effective than less intensive MI for smoking cessation.

We explored whether motivational interviewing for smoking cessation could enhance well-being.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) and cluster RCTs.

Types of participants

Tobacco smokers, excluding pregnant women. We excluded trials that only recruited pregnant women, as their particular needs and circumstances warrant them being treated as a separate population. Studies in pregnant women are covered in a separate Cochrane Review (Chamberlain 2017).

Types of interventions

Interventions labelled as either MI or MET, targeted at tobacco smoking cessation. Eligible interventions were based on the principles and practices of MI (e.g. engaging, focussing, evoking, planning, exploring ambivalence, assessment of motivation and confidence to quit, eliciting 'change talk' and supporting self-efficacy) as described in Miller 2013, and, in the opinion of the review authors, complied with these principles and practices beyond simply referring to the concepts. We included studies testing interventions that claimed to be based on both MI and another theoretical approach to counselling, such as cognitive behavioural therapy (CBT). However, we tested the effect of including these studies using sensitivity analysis.

MI is a specific motivational intervention, which has been incorrectly linked to other interventions or theories, such as



the transtheoretical model of change, the decisional balance technique, and client-centred counselling (Miller 2009). MI is conceptually and practically distinct from these interventions and principles. Therefore, we did not include trials that primarily tested these distinct approaches. Stage-based interventions, such as the transtheoretical model for smoking cessation, are covered in a separate Cochrane Review (Cahill 2010).

We included studies where the intervention arm included MI as part of a multi-component intervention (that may or may not have included pharmacotherapy), provided that the additional elements were also included in the control arm, and thus were not being tested. No exclusions were made based on the modality of the intervention.

Eligible studies included a comparison (control) intervention of either 1) no smoking cessation treatment, 2) another smoking cessation intervention, of any length or intensity (including usual care), or 3) another type of MI intervention (e.g. MI of a lower intensity).

Types of outcome measures

Primary outcomes

Our primary outcome was smoking cessation. We preferred continuous/prolonged cessation over point prevalence cessation, and biochemically validated over self-reported cessation, where multiple measures were available in included studies. We reported cessation at the longest follow-up, and excluded trials that did not include data on smoking cessation rates at least six months after baseline.

Secondary outcomes

MI has been linked to self-determination theory. Markland 2005 proposed that MI can provide the circumstances under which people can initiate and action their own behaviour through 'self-determination'. Self-determination theory hypothesises that this self-determination can lead to positive consequences, such as enhanced well-being (Ryan 2000). This suggests that MI may increase well-being as well as promote behaviour change. Therefore, we attempted to collect data on the following secondary outcomes:

- Mental health and well-being. Any measure of mental health and well-being as defined by included studies
- Quality of life (QOL). Any validated QOL scale reported in included studies. For example, the Quality of Life Scale (QOLS) (Burckhardt 2003); the Euro-Quality of Life Questionnaire (EQ-5D) (EuroQol Group 1990)

We considered including adverse events as an outcome but decided against this. MI and comparator interventions comprise talk about smoking, which rarely gives rise to strong emotions and attendance for counselling is voluntary. Thus, it is unlikely that people who find such talk distressing will attend MI. As a result, we believe that few or no trials will have assessed adverse events, making assessment impossible.

Search methods for identification of studies

Electronic searches

We conducted a search of the Cochrane Tobacco Addiction Group's Specialised Register in August 2018. The search strategy is available in Appendix 1. The Register has been developed from electronic searching of the Cochrane Central Register of Controlled trials (CENTRAL), MEDLINE, Embase and PsycINFO, together with handsearching of specialist journals, conference proceedings and reference lists of previous trials and overviews. See the Tobacco Addiction Group's website for full details of how the Register is compiled. At the time of the Register search, results from the following databases were included:

- Cochrane Central Register of Controlled trials (CENTRAL), issue 1, 2018;
- MEDLINE (via OVID) to update 20180726;
- Embase (via OVID) to week 201831;
- PsycINFO (via OVID) to update 20180723.

We also searched the following online trial registries to identify unpublished studies: ClinicalTrials.gov and the International Clinical Trials Registry Platform (ICTRP).

Although this review is an update of a previous review, we carried out full searches of the literature, from database inception. This was because inclusion criteria were updated for this version and we wanted to ensure we identified relevant studies that may have been excluded in previous versions.

Data collection and analysis

Selection of studies

Two authors (of AF, JL, NL, TT) independently screened the title and abstract of each record returned for eligibility. Where there was uncertainty, the record was put forward to the next round of screening. We then acquired the full-text reports of any trials deemed potentially relevant. Two authors (of AF, JL, NL, TT) independently assessed the full texts for inclusion, and any disagreements were referred to a third author.

Data extraction and management

Two authors (of AF, JL, NL, TT) independently extracted the following information about each eligible trial, where available:

- Details of study design, including methods of randomisation and recruitment
- Location and setting of the trial, e.g. hospital-based, clinicbased, community-based
- Participant characteristics, e.g. level of motivation, pre-existing conditions, demographic descriptors
- Intervention provider characteristics: e.g. type of provider and MI training provision
- Description of the intervention(s), including the nature, frequency and duration of MI, and any co-interventions used
- Description of comparator(s), including the nature, frequency and duration of MI, and any co-interventions used
- Any procedures followed to ensure MI fidelity, and the results of any monitoring



- Primary outcome measures: definition of smoking cessation used for primary outcome, timing of longest follow-up, any biochemical validation
- Secondary outcome measures: whether mental health and QoL were measured, definitions of outcomes (where measured), outcome data (where measured)
- Loss to follow-up
- Funding source
- Declarations of interest

Extraction was then compared and amalgamated for each study, with disagreements referred to a third author.

Assessment of risk of bias in included studies

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

Two authors (of AF, JL, NL, TT) independently rated each domain as being at high, low or unclear risk of bias, for each study. We resolved any disagreement between authors through discussion with a third author.

Measures of treatment effect

For our primary outcome, we extracted the most stringent definition of smoking cessation for each study (i.e. longest follow-up, continuous/prolonged versus point prevalence, and biochemically validated versus self-report). Where appropriate, we expressed trial effects as a risk ratio (RR), calculated as: (quitters in treatment group/total randomised to treatment group)/(quitters in control group/total randomised to control group), alongside 95% confidence intervals (CI). A risk ratio greater than 1 indicates a potentially better outcome in the intervention group than in the control group.

Secondary outcomes (mental health and QoL) were discussed narratively.

Unit of analysis issues

We included both individually and cluster-randomised trials. For cluster RCTs, we considered whether authors had accounted for clustering in their reported analyses. Where possible and appropriate, we adjusted for clustering using the trial's reported intra-class correlation (ICC), calculated an ICC from the information provided, or applied the reported ICC from a similar trial.

Dealing with missing data

We conducted our analyses on an intention-to-treat basis, i.e. using all participants randomised to their original groups as

denominators where data were available, and assuming that those lost to follow-up were continuing to smoke. We extracted numbers lost to follow-up from study reports and used these to assess the risk of attrition bias. Where any required primary outcome data were not available in study reports, we contacted the authors in an attempt to obtain these.

Assessment of heterogeneity

Before pooling studies, we considered both methodological and clinical variance between studies. Where pooling was deemed appropriate, we investigated statistical heterogeneity using the I^2 statistic (Higgins 2003). This describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance).

Assessment of reporting biases

We used funnel plots to assess small-study effects and investigate the possibility of publication bias for the 'MI as an adjunct' and 'MI versus other smoking cessation treatment' comparisons. There were not enough studies (fewer than ten) included in the other analyses to create funnel plots.

Data synthesis

For the primary outcome - smoking cessation - we synthesised groups of studies using Mantel-Haenszel random-effects models to estimate separate pooled treatment effects (as RRs and 95% CIs), for four types of comparison:

- MI versus no smoking cessation intervention (comparison 1)
- MI in addition to another smoking cessation treatment versus that smoking cessation treatment alone (comparison 2)
- MI alone versus another smoking cessation intervention (comparison 3)
- Higher intensity MI versus lower intensity MI (comparison 4)

Secondary outcomes - mental health and QoL - were reported sparsely and so were summarised narratively.

Subgroup analysis and investigation of heterogeneity

In view of possible heterogeneity between studies, where relevant and there were sufficient studies, we analysed the trials in the following subgroups:

- Stratified by whether intensity of smoking cessation support
 was matched between trial arms, or differed between the MI
 and comparison group. Intensity was defined as a combination
 of the number of treatment sessions provided and the overall
 intervention/comparator contact time.
- Stratified by age of participant: adult versus adolescent
- Stratified by intervention provider: GP, nurse, counsellor/ psychologist, lay healthcare worker
- Stratified by counselling modality: face-to-face contact (including interventions delivered completely face-to-face or partially face-to-face) versus no face-to-face contact (i.e. via telephone, text messages, virtual reality setting)
- Stratified by whether MI fidelity monitoring was reported or not
- Stratified by the participants' motivation to quit at baseline, i.e. whether those recruited were motivated to quit, were not motivated to quit, or had not been selected based on their motivation to quit



Sensitivity analysis

We carried out the following sensitivity analyses to see if the pooled results of analyses were sensitive to the removal of:

- Studies judged to be at high risk of bias
- Studies that measured the fidelity of MI and found that the requirements of MI were not met (fidelity subgroup analyses only)
- Studies where the MI intervention was also based on another theoretical approach, such as CBT

'Summary of Findings' table

Following standard Cochrane methodology (Higgins 2011), we created 'Summary of findings' tables for all comparisons:

- MI versus no smoking cessation intervention
- MI in addition to another smoking cessation treatment versus that smoking cessation treatment alone
- MI versus another smoking cessation intervention
- Higher intensity MI versus lower intensity MI

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 the smoking cessation outcome, and to draw conclusions about the certainty of the evidence within the text of the review.

RESULTS

Description of studies

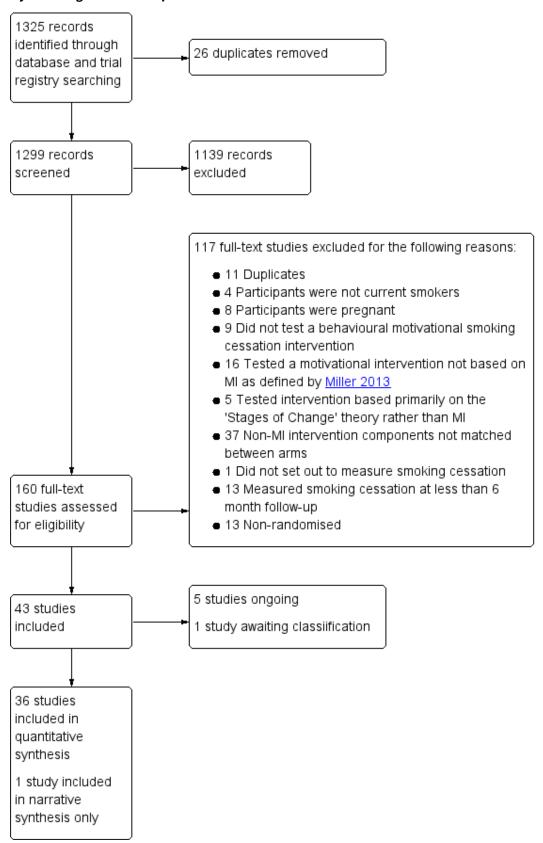
See Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies; Characteristics of studies awaiting classification; .

Results of the search

Our searches resulted in 1325 records. After duplicates were removed, 1299 records remained for title and abstract screening. We ruled out 1139 records at this stage, leaving 160 for full-text screening. We identified 37 completed studies, five ongoing studies, one study awaiting classification, and excluded 117 studies at the full-text screening stage. See Figure 1 for study flow information relating to the most recent search.



Figure 1. Study flow diagram for this update





Included studies

Included studies

This review includes 37 RCTs, including over 15,000 participants. Trials were conducted in Australia (two studies), Brazil (two studies), the USA (28 studies), China, India, South Africa, Spain and the UK (one study each).

Participants

All participants were tobacco smokers. Eleven of the 37 included studies (Butler 1999; Catley 2016; Cook 2016; Davis 2011; Demétrio Faustino-Silva 2018; Ellerbeck 2009; Hollis 2007; NCT02645838; Soria 2006; Vidrine 2019; Wu 2009) recruited from the general population, through advertisements, attendance at primary care or other community venues, or through calling a smoking quitline. However, the majority of studies in this review recruited from specialist populations:

- Adolescents or young people (eight studies; Audrain-McGovern 2011; Colby 2005; Colby 2012; Harris 2010; Helstrom 2007; Kelly 2006; Tevyaw 2009; Woodruff 2007). One of these studies specifically recruited adolescent offenders (Helstrom 2007). Participants had been arrested or given notice to appear in court for a variety of offences and had been given the option for a diversionary program, but were not incarcerated.
- People with substance abuse problems (three studies):
 Rohsenow 2015 recruited people with a range of substance abuse issues, whereas Rohsenow 2014 specifically recruited people with alcohol dependency and Stein 2006 recruited opoid dependent people receiving methadone treatment.
- People attending, or who had attended screening, for smokingrelated cancers (two studies): Marshall 2016 recruited people who were being screened for lung cancer, and McClure 2005 recruited women who had attended for cervical screening, and had been told that they had an elevated risk of cervical cancer.
- Patients with a variety of acute health problems (eight studies): In four studies, participants were being treated as hospital inpatients, for unspecified, varied health issues (De Azevedo 2010; Lewis 1998; Sherman 2016) or operative fractures (Matuszewski 2018). In the remaining four studies, patients were attending the emergency department for chest pain (Bock 2008), or receiving outpatient treatment for post traumatic stress disorder (PTSD) (Battaglia 2016), HIV (Lloyd-Richardson 2009), or tuberculosis (Louwagie 2014).
- African-American/black light smokers: defined as smoking ten or fewer cigarettes per day (Ahluwalia 2006)
- Incarcerated men in a prison in India (Naik 2014)
- Homeless adults recruited from homeless shelters (Okuyemi 2013)
- Friends and family of people who had been diagnosed with lung cancer (Bastian 2013)
- People with a low income: defined as primary care patients who were uninsured or receiving healthcare benefits (Bock 2014)

The majority of the included studies (29 of 37) did not recruit participants specifically based on their motivation to quit at baseline, i.e. there was not an eligibility criterion that specified that participants needed to be motivated to quit or not; however five studies only recruited participants motivated to quit (Ahluwalia 2006; Demétrio Faustino-Silva 2018; Hollis 2007; Lewis 1998; Vidrine

2019) and three studies specifically recruited participants who were not motivated to quit (Catley 2016; Cook 2016; Davis 2011). The studies that recruited people motivated to quit had an eligibility criteria specifying that participants had to be willing to quit smoking within a specific time period (e.g. the next two weeks, within a month); recruited people based on their willingness to receive smoking cessation treatment; or recruited people because they had expressed an interest in quitting. The studies that recruited people not motivated to quit advertised for participants who were not ready to quit smoking; had an eligibility criterion specifying that participants should have no interest in quitting over the next month; or participants were not told that the aim of the study was smoking cessation and, when asked about their quitting plans, were excluded if they said they were ready to quit.

Intervention

Motivational Interviewing (MI)

All of the studies included in this review made explicit reference to using MI principles defined by Miller and Rollnick (as described in Miller 2013). Most studies merely specified that the intervention was carried out according to established MI techniques, rather than providing a more detailed description of counselling content. Three studies reported that the counselling in the intervention arm was based on another theoretical approach in addition to MI: Bastian 2013 combined the principles of MI with adaptive coping skills, and both Lewis 1998 and Vidrine 2019 combined MI with principles of cognitive behavioural therapy (CBT). Another study combined the adolescent participant MI intervention with a parent MI intervention in the intervention arm only (Colby 2012). Researchers discussed participants' quit attempts and supporting it with their parents, using MI principles. This study was borderline for inclusion as one of our eligibility criteria was to exclude studies where extra non-MI components were not matched between study arms. However, we decided to include this study, as the extra component complied with the principles of MI, and we went on to test whether its exclusion impacted upon the results of metaanalysis using sensitivity analysis.

MI fidelity monitoring

Twenty-one of the 37 studies reported that they carried out MI fidelity monitoring during the study to assess whether the principles of MI were adhered to, to improve adherence to the principles, or both (Ahluwalia 2006; Audrain-McGovern 2011; Bastian 2013; Battaglia 2016; Bock 2008; Bock 2014; Catley 2016; Colby 2005; Colby 2012; Davis 2011; De Azevedo 2010; Ellerbeck 2009; Harris 2010; Hollis 2007; Kelly 2006; Lloyd-Richardson 2009; Okuyemi 2013; Rohsenow 2014; Rohsenow 2015; Sherman 2016; Tevyaw 2009). This usually comprised one or a range of the following methods: the observation of all or a subset of sessions by clinicians or the study lead; rating sessions on their adherence to MI using fidelity scales, such as the Motivational Interviewing Treatment Integrity (MITI) code (Pierson 2007) or study specific scales; supervision meetings with counselling providers to reflect on practice and learn and improve based on these experiences. Only ten of these 21 studies then went on to report on the results of this fidelity monitoring (Audrain-McGovern 2011; Catley 2016; Colby 2005; Colby 2012; Davis 2011; Harris 2010; Lloyd-Richardson 2009; Rohsenow 2014; Rohsenow 2015; Tevyaw 2009). Only one of these studies reported that some of the benchmarks for competency were not widely met (Audrain-McGovern 2011), and we accounted for this using sensitivity analysis; however,



criteria were very close to being met. As fidelity monitoring and benchmarks for fidelity differed across studies, it is plausible that studies that met their own adherence standards may not have met the standards of other studies and vice versa. For further details of fidelity monitoring (where this occurred) see Table 1.

Pharmacotherapy

Twenty of the 37 studies offered or recommended the use of pharmacotherapy for smoking cessation to all, or a subset of participants, in the study groups of interest for this review. This was typically nicotine replacement therapy (NRT) only (Ahluwalia 2006; Bastian 2013; Bock 2008; Bock 2014; Cook 2016; Hollis 2007; Lloyd-Richardson 2009; Okuyemi 2013; Rohsenow 2014; Rohsenow 2015; Sherman 2016; Stein 2006; Vidrine 2019; Wu 2009), however one study offered bupropion only (Soria 2006), and some studies provided a choice of pharmacotherapies from two or all three of the following: NRT, varenicline or bupropion (Battaglia 2016; Catley 2016; Ellerbeck 2009; Harris 2010; McClure 2005). In all cases, pharmacotherapy was offered or recommended in all relevant trial arms, and so the use and type of pharmacotherapy was not being tested. Where included studies did have trial arms testing additional components to MI, these study arms were not included in analyses (Ellerbeck 2009; Lewis 1998).

Modality

MI was delivered in face-to-face sessions in 17 of the 37 studies; in another 12 studies, the counselling was delivered in a combination of face-to-face and telephone sessions, usually with an initial session or sessions conducted face-to-face, followed by follow-up counselling over the phone. Six studies provided counselling over the phone only (Bastian 2013; Battaglia 2016; Ellerbeck 2009; Hollis 2007; McClure 2005; Sherman 2016); a further study had an MI intervention group that received calls and text messages based on CBT and MI and another MI group that received text messages only (Vidrine 2019), and a final study provided MI counselling for adolescents in an online virtual environment (Woodruff 2007). Participants were represented by an avatar in the online world and received MI group counselling with other participants and a counsellor within a virtual shopping mall.

Intensity

Nine studies provided a single session of MI in at least one of the MI intervention groups (Butler 1999; Davis 2011; Helstrom 2007; Kelly 2006; Louwagie 2014; Marshall 2016; Matuszewski 2018; Rohsenow 2014; Vidrine 2019); the number of sessions offered ranged from one to 12 across studies. Some studies had more than one MI intervention group of different intensities (Ellerbeck 2009; Hollis 2007; Matuszewski 2018; Rohsenow 2014; Sherman 2016; Vidrine 2019). These studies compared a lower intensity MI intervention comprised of one to two sessions to a higher intensity MI intervention which ranged from two to 11 sessions. The total duration of MI interventions varied greatly across studies, from five minutes to 315 minutes; however length of sessions was not reported in a minority of cases. For further detail on the content and intensity of interventions, see Table 2.

Provider

MI was delivered by physicians (Butler 1999; Marshall 2016; NCT02645838; Soria 2006), nurses (Battaglia 2016; Davis 2011; Lewis 1998), counsellors/psychologists (Ahluwalia 2006; Audrain-McGovern 2011; Bastian 2013; Bock 2008; Bock 2014; Catley

2016; Colby 2005; Colby 2012; Cook 2016; Ellerbeck 2009; Harris 2010; Kelly 2006; Lloyd-Richardson 2009; McClure 2005; Okuyemi 2013; Rohsenow 2014; Rohsenow 2015; Sherman 2016; Stein 2006; Tevyaw 2009; Vidrine 2019; Woodruff 2007; Wu 2009), some of whom were described as specialist smoking cessation advisors (De Azevedo 2010; Demétrio Faustino-Silva 2018; Hollis 2007; Matuszewski 2018), and lay healthcare workers (Louwagie 2014). Helstrom 2007 and Naik 2014 did not specify the type of provider delivering support.

Comparator

We grouped studies dependent on the nature of the relevant comparator. Comparators either consisted of no smoking cessation interventions (Cook 2016; Harris 2010; Naik 2014; Tevyaw 2009; Woodruff 2007), a non-MI smoking cessation intervention (Ahluwalia 2006; Audrain-McGovern 2011; Bastian 2013; Battaglia 2016; Bock 2008; Bock 2014; Butler 1999; Catley 2016; Colby 2005; Colby 2012; Cook 2016; Davis 2011; De Azevedo 2010; Demétrio Faustino-Silva 2018; Helstrom 2007; Kelly 2006; Lewis 1998; Lloyd-Richardson 2009; Louwagie 2014; Marshall 2016; Matuszewski 2018; McClure 2005; NCT02645838; Okuyemi 2013; Rohsenow 2014; Rohsenow 2015; Soria 2006; Stein 2006; Tevyaw 2009; Vidrine 2019; Wu 2009), or another MI intervention of lower intensity (Ellerbeck 2009; Hollis 2007; Matuszewski 2018; Rohsenow 2014; Sherman 2016; Vidrine 2019). Some studies had multiple study arms and so fell into more than one category. We further split the studies with a non-MI smoking cessation intervention into two groups those where the MI interventions stood alone and were directly compared with the other cessation interventions, and those where the intervention groups received the MI interventions in addition to the non-MI smoking cessation interventions, which were also offered in the comparator groups.

No smoking cessation treatment comparator

Three of the five studies that compared MI to no smoking cessation treatment provided no intervention (Cook 2016; Naik 2014; Woodruff 2007). Participants were simply followed up to assess the outcome. Naik 2014 offered participants in the comparator the opportunity to receive the MI intervention following the initial treatment period. Two of the studies provided participants with a 'dummy' intervention designed to match the intensity of the MI smoking cessation intervention. In Harris 2010, this was MI counselling focussed on increasing participants' fruit and vegetable consumption; both study arms received counselling over four sessions for an average duration of 100 minutes. In Tevyaw 2009, participants in the comparison group received 'progressive muscle relation training' over three sessions for an overall duration of 120 minutes.

Non-MI smoking cessation intervention comparator

In the minority of cases (7 of 31; Ahluwalia 2006; Catley 2016; Davis 2011; Demétrio Faustino-Silva 2018; Helstrom 2007; Kelly 2006; Wu 2009), the comparator group (or one of the comparator groups in the study) received smoking cessation counselling that was matched in intensity to the MI counselling in the intervention group. This was either described simply as smoking cessation counselling with information giving or advice, or as a specific approach, i.e. prescriptive interviewing (Davis 2011), CBT (Demétrio Faustino-Silva 2018), or the psychoeducation model (Kelly 2006). Wu 2009 provided participants in the comparator group with general health



education counselling, which covered smoking cessation, as well as nutrition and exercise.

In most cases, the support provided in the comparator group was of lower intensity than the MI intervention arm and consisted of brief advice on cessation, self-help materials (such as printed materials and contact details for smoking cessation services or quit-lines), or both. In one study, one of the comparator interventions was more intensive than the MI intervention (Cook 2016). Cook 2016 was a 16-arm factorial trial where some study arms were provided with a behavioural smoking reduction intervention. This reduction intervention was delivered over seven sessions with a total duration of 80 minutes, whereas the MI intervention was delivered over four sessions with a total duration of 50 minutes.

Two studies offered half of their participants payments contingent on them being abstinent from smoking (Rohsenow 2015; Tevyaw 2009). In both cases, these contingency payments were matched in the intervention arm.

Outcomes

The majority of studies measured cessation at six months follow-up (25 of 37); however, nine studies measured cessation at 12 months follow-up (Bastian 2013; Bock 2014; Hollis 2007; Marshall 2016; McClure 2005; Rohsenow 2014; Rohsenow 2015; Soria 2006; Woodruff 2007), and one study each measured cessation at nine months (Battaglia 2016), 11 months (Demétrio Faustino-Silva 2018) and 24 months (Ellerbeck 2009) follow-up. It was possible to use biochemically validated (using expired carbon monoxide or urinary/salivary cotinine) cessation rates for 22 of the 37 studies. We were unsure whether the rates reported in Naik 2014 and Demétrio Faustino-Silva 2018 were biochemically verified. The Naik 2014 study report stated that carbon monoxide was measured; however, it was unclear whether this was used to motivate participants, verify cessation rates, or both.

Only one study measured one of our secondary outcomes - mental health. Battaglia 2016 recruited veterans with PTSD attending Veterans Health Administration (VHA) healthcare clinics and investigated the effect of integrating MI smoking cessation counselling into the standard telehealth programme

already provided (which included access to pharmacological and behavioural smoking cessation treatments). Throughout the study, PTSD symptoms were assessed using the PTSD Checklist (range of 17 to 85 with a score > 50, indicating PTSD diagnosis), depression was monitored using the 15-item Geriatric Depression Scale-Short Form (GDS-SF), where a score greater than 6 indicated probable depression, and suicidal thoughts were assessed every 30 sessions via a single question. Some of the other studies measured markers of mental health or well-being at baseline or reported mental health at follow-up overall; however, only Battaglia 2016 measured mental health at follow-up and presented the results by study group.

Excluded studies

We listed 117 studies that were potentially relevant but excluded, with reasons, in the Characteristics of excluded studies table. Reasons that studies were excluded at full-text stage are also summarised in Figure 1. The reason why most studies were excluded at full-text screening stage was because the intervention group received non-MI intervention components that were not included in the comparator arm, such as pharmacotherapy, a text messaging intervention, or incentives.

We also classified five studies as ongoing (Lloyd-Richardson 2003; NCT01387516; NCT02905656; NCT03002883; Salgado Garcia 2018), which are likely to be relevant for inclusion once completed and/or reported. We classified Zhou 2014 as 'awaiting classification' as only a conference abstract was available and it was impossible to determine from this whether smoking cessation was definitely measured (reduction in cigarette consumption was reported) and at what time points. Attempts to contact the authors were unsuccessful.

Risk of bias in included studies

Full details of 'Risk of bias' assessments are given for each trial within the Characteristics of included studies tables. Overall, we judged four studies to be at low risk of bias (low risk of bias across all domains), 11 at high risk of bias (high risk of bias in at least one domain), and the remaining 22 at unclear risk of bias. A summary illustration of the 'Risk of bias' profile across trials is shown in Figure 2.

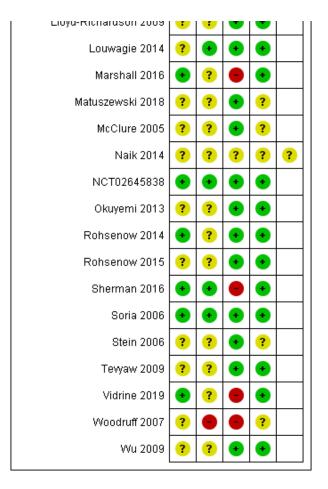


Figure 2. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Other bias
Ahluwalia 2006	•	?	•	•	
Audrain-McGovern 2011	?	?	•	•	
Bastian 2013	?	?	•	•	
Battaglia 2016	?	?	•	•	
Bock 2008	?	?	•	•	
Bock 2014	•	•	•	•	
Butler 1999	?	?	•	•	
Catley 2016	•	•	•	•	
Colby 2005	?	?	•	•	
Colby 2012	•	?	•	•	
Cook 2016	•	?	•	•	•
Davis 2011	?	?	•	•	
De Azevedo 2010	•	•	•	•	
Demétrio Faustino-Silva 2018	?	?	?	•	
Ellerbeck 2009	•	•	•	•	
Harris 2010	?	?	•	•	
Helstrom 2007	?	?	•	•	
Hollis 2007	•	•		•	
Kelly 2006	?	?	•	•	
Lewis 1998	•	?	•	?	
Lloyd-Richardson 2009	?	?	•	•	
Lauwania 2044	2				l l



Figure 2. (Continued)



Allocation

We assessed selection bias through investigating methods of random sequence generation and allocation concealment for each study. We rated 15 studies as having low risk for random sequence generation, and the remaining 22 as having unclear risk. We judged nine studies to be at low risk for allocation concealment, 27 at unclear risk, and one study at high risk (Woodruff 2007). Woodruff 2007 was judged as having high risk as clusters were randomised to treatments, and study personnel knew which condition a cluster was in before participant recruitment began. Recruitment was then tailored to this, using different recruitment materials dependent on assigned condition. This meant that participants may not have been equivalent across groups. We judged studies as having unclear risk of bias when authors provided insufficient information about methods used.

Outcome assessment (detection bias)

We did not formally assign a risk of performance bias for each trial. It is almost always impossible to blind providers of behavioural support to treatment allocation. Moreover, nonspecific effects of being in treatment are part of the intervention effect that studies were aiming to assess.

We judged detection bias on the basis of biochemical validation and, where biochemical validation was not provided, on the basis of differential levels of contact between participants and the study team across relevant study groups. We judged ten studies to be at high risk of detection bias as outcomes were defined as self-report only and the intervention and control arms received different levels of support, making differential misreporting possible (Bastian 2013; Bock 2008; Cook 2016; De Azevedo 2010; Hollis 2007; Kelly 2006; Marshall 2016; Sherman 2016; Vidrine 2019; Woodruff 2007). We judged two studies to be at unclear risk of detection bias (Demétrio Faustino-Silva 2018; Naik 2014) as we were unsure whether the rates reported were biochemically verified. We judged the remaining 25 studies to be at low risk of detection bias.

Incomplete outcome data

We judged studies to be at a low risk of attrition bias where the numbers of participants lost to follow-up were clearly reported, the overall number lost to follow-up was not more than 50%, and the difference in loss to follow-up between groups was no greater than 20%. This is in accordance with 'Risk of bias' guidance produced by the Cochrane Tobacco Addiction Group for assessing smoking cessation studies. We judged 29 of the studies to be at low risk of bias, six at unclear risk (Lewis 1998; Matuszewski 2018; McClure 2005; Naik 2014; Stein 2006; Woodruff 2007) and two at high risk (Bastian 2013; Bock 2014). These two studies were judged to be at high risk because overall loss to follow-up was more than 50%. Judgements of unclear risk were made either because information on follow-up was not reported in the sources available to us (Lewis 1998; Matuszewski 2018; McClure 2005; Naik 2014), or because loss



to follow-up was reported for the relevant time point overall, but not split by study group (Stein 2006; Woodruff 2007).

Other potential sources of bias

Two sources of other bias were identified for two of the included studies (Cook 2016; Naik 2014). The comparator intervention in Naik 2014 was a 'waiting list' to receive the MI intervention treatment following the intervention group (verified through contact with author); however, it was unclear whether participants knew that they were on a waiting list. We contacted the authors a second time to verify whether the intervention was delivered to the comparator group after the six-month assessment time point and received no further reply. However, the quit rates were much higher in the intervention group than in the comparator group (48/300 and 6/300, respectively), suggesting that this was the case. Due to this uncertainty, we have assigned this study a rating of unclear risk for 'other potential sources of bias'. Cook 2016 was a factorial trial with four factors: 1) MI/no MI; behavioural reduction counselling/ no behavioural reduction counselling; nicotine gum/no nicotine gum; and nicotine patch/no nicotine patch. The authors reported an unexpected interaction between MI and nicotine gum, where the combination of the two resulted in lower guit rates than any other interventions or combinations. As a result, we have assigned Cook 2016 a rating of high risk of other bias. For details of how data from Cook 2016 have been entered into meta-analyses, see the Characteristics of included studies table.

Effects of interventions

See: Summary of findings for the main comparison Motivational interviewing compared with no treatment for smoking cessation; Summary of findings 2 Motivational interviewing in addition to other smoking cessation treatment for smoking cessation; Summary of findings 3 Motivational interviewing compared with another smoking cessation intervention for smoking cessation; Summary of findings 4 Higher compared with lower intensity motivational interviewing for smoking cessation

MI versus no smoking cessation treatment (comparison 1)

Smoking cessation outcome

We pooled five studies, including an adjusted N of 1284 (adjusted for clustering in one study - Harris 2010), comparing an MI smoking cessation intervention with no smoking cessation treatment. However, heterogeneity was substantial (I2 = 87%; Analysis 1.1), and so we did not deem it appropriate to present the pooled result of this analysis. Examining the forest plots, individual RRs and 95% CIs provided evidence that this heterogeneity was due to the large positive effect of MI in Naik 2014 (RR 8.00; 95% CI 3.48 to 18.41; N = 600). This was confirmed by a sensitivity analysis removing Naik 2014 (Analysis 1.2; I² = 0%). None of the four remaining studies (Cook 2016; Harris 2010; Tevyaw 2009; Woodruff 2007) demonstrated a clear benefit of MI, as the confidence intervals spanned both clinical benefit and harm (pooled RR 0.84, 95% CI 0.63 to 1.12; $I^2 = 0\%$; adjusted N = 684). The heterogeneity introduced by Naik 2014 can potentially be explained by the nature of the population recruited, which differs substantially to the populations studied in Cook 2016, Harris 2010, Tevyaw 2009 and Woodruff 2007. Naik 2014 recruited incarcerated male smokers and, as a result, took place in a prison setting where participants were potentially unable to drop out, and also very unlikely to try to quit smoking in the no treatment group; whereas Cook 2016 recruited adults in a

primary care setting, Harris 2010 and Tevyaw 2009 recruited young college and university students (aged 18 to 24 years) and Woodruff 2007 recruited adolescents (aged 14 to 19 years).

Harris 2010 cluster-randomised 30 university fraternities and sororities rather than individuals. They reported an ICC of 0.003, allowing us to adjust for this in our analysis. Cook 2016 was a four factor, 16-arm, factorial RCT included in this comparison, as well as comparisons 2 and 3. Please refer to the Characteristics of included studies table for full details of how this study was included in all analyses.

Removing the two studies judged to be at high risk of bias in the pooled analysis (Cook 2016; Woodruff 2007) changed the direction of the pooled estimate so that it was in favour of motivational interviewing; however, confidence intervals still incorporated evidence of both benefit and harm, and so this did not change our interpretation of the result. The estimate resulting from this sensitivity analysis should be treated with caution as it was based on only two studies (Harris 2010; Tevyaw 2009) and there was substantial imprecision due to a paucity of participants and events (RR 1.50, 95% CI 0.22 to 10.14; I² = n/a; adjusted N = 434).

We did not carry out any subgroup analyses on the presented pooled analysis (Analysis 1.2) as there were insufficient data to draw meaningful conclusions.

Mental health and QoL outcomes

None of the studies relevant to this comparison measured mental health or QoL at any follow-up, by study group.

MI in addition to another smoking cessation treatment versus that smoking cessation treatment alone (comparison 2)

Smoking cessation outcome

We pooled twelve studies comparing a smoking cessation intervention supplemented by MI with the same smoking cessation intervention without the MI component (Analysis 2.1). This resulted in a pooled RR of 1.07 (95% CI 0.85 to 1.36; adjusted N = 4167). The point estimate suggests a small potential benefit of MI when offered in addition to other smoking cessation treatment; however, CIs spanned one and moderate heterogeneity was detected ($I^2 = 47\%$).

Two cluster RCTs were included in the analysis; Vidrine 2019 randomised neighbourhood sites and conducted adjusted analyses, accounting for the type of site (church, housing complex or community centre) and the individual site (46 sites). This allowed us to calculate an ICC of 0.06 and adjust for this in our analysis. We were unsure whether <code>Demétrio Faustino-Silva 2018</code> carried out adjustment for clustering and an ICC was not reported. As a result, we entered the data from the abstract into our main analysis and performed a sensitivity analysis replacing this data with data adjusted for the ICC calculated for <code>Vidrine 2019</code> (0.06). This sensitivity analysis had no effect on the interpretation of the result (RR 1.06, 95% CI 0.83 to 1.36; I² = 46%; adjusted N = 3965).

We also carried out sensitivity analyses removing three studies with interventions based on other theoretical approaches alongside MI (Bastian 2013 - MI + Adaptive coping skills; Lewis 1998 - MI + CBT; Vidrine 2019 - MI + CBT), and removing six studies judged to be at high risk of bias (Bastian 2013; Bock 2008; Bock 2014;



Cook 2016; Marshall 2016; Vidrine 2019). In neither case did this significantly affect the interpretation of the result, as confidence intervals continued to encompass both harm and benefit (RR 1.02; 95% CI 0.75 to 1.40; $I^2 = 53\%$; N = 3145; and RR 1.17; 95% CI 0.71 to 1.93; $I^2 = 65\%$; N = 1366, respectively).

Intensity of the comparator

We split the twelve included studies into two groups dependent on whether the intensities of the interventions provided to the MI groups and the comparator groups were matched, or whether the intensity of the intervention received by the MI group exceeded that in the comparator group (Analysis 2.2). One study matched the intensity of the intervention and comparator treatments (Demétrio Faustino-Silva 2018), and provided evidence of an effect of MI. Both groups received the standard CBT-based smoking cessation support advocated by the Brazilian Ministry of Health, but the intervention providers in the MI arm were also taught MI as an additional resource to use in their treatment sessions. However, in most studies the intervention provided in the comparator group was of a lower intensity, as the MI intervention was being offered as an additional element to a standard smoking cessation intervention. These eleven studies resulted in a pooled estimate of 1.01, with CIs encompassing both harm and benefit of MI in addition to other smoking cessation treatment. There was no evidence of statistically significant subgroup differences ($I^2 = 47.3\%$, P = 0.17).

Intervention provider

Interventions were provided by physicians (one study; N = 55), nurses (two studies; N = 298), counsellors (including those specifically trained as smoking cessation advisors; eight studies; N = 3405), or lay healthcare workers (one study; N = 409). When studies were split into these groups, there was evidence of moderate subgroup differences (I² = 66.2%, P = 0.03); with some evidence of a benefit of MI when delivered by lay healthcare workers (Analysis 2.3). However, the number of participants and events in most subgroups were low, resulting in imprecise effects, which should be treated with caution.

Counselling modality

We grouped studies into those where the intervention was delivered either wholly or partially face-to-face and those where none of the intervention was delivered face-to-face (Analysis 2.4). Eight studies involved face-to-face contact and four no face-to-face contact (interventions were delivered either solely by telephone or via telephone and text message). There was very little heterogeneity between subgroup effects ($I^2 = 4.1\%$, P = 0.31).

MI fidelity monitoring

Some included studies reported study mechanisms to monitor or ensure the fidelity of the MI intervention, or both; therefore, we split those that did and did not into separate subgroups (Analysis 2.5). For this comparison, five of the 12 studies reported that they had used a form of fidelity monitoring. There was no evidence of statistically significant heterogeneity between subgroups (I² = 16.9%, P = 0.27). The point estimate favoured the comparator in the studies that included fidelity monitoring and favoured MI in those that did not include fidelity monitoring; however, in both cases, CIs incorporated both potential benefit and harm of the intervention. We planned a sensitivity analysis to test the effect of removing studies that monitored fidelity and discovered fidelity to

the principles of MI was low; however, only one of the five studies that reported they carried out monitoring reported on the results, and fidelity was deemed to be high (Table 1).

Baseline participant motivation

Three studies in this comparison recruited participants who were already motivated to quit smoking at baseline, one recruited participants who were not motivated to quit, and the remaining eight studies recruited people regardless of motivation to quit. Although there was some heterogeneity between subgroups this did not reach statistical significance ($I^2 = 47.6\%$, P = 0.15) (Analysis 2.6).

Age of participants

We also planned to carry out subgroup analyses investigating the effects of MI in addition to another form of smoking cessation support in adolescent participants versus adult participants, however, all of the studies included in the analysis for this comparison recruited adults.

Mental health and QoL outcomes

One study relevant to this comparison, which recruited military veterans with PTSD, measured and reported on mental health outcomes (Battaglia 2016). At end of treatment, the MI intervention group had a mean score of 54.5 (SD = 13.2, N = 62) on the PTSD Checklist (range 17 to 85) and the comparator group had an average score of 55.9 (SD = 13.5, N = 59). However, at final follow-up, six months after the end of treatment (nine months post-baseline), the MI intervention group had a statistically significantly (P < 0.05 for analysis adjusting for covariates) lower PTSD symptom score (58.4; SD = 11.4, N = 61) compared with the comparator group (62.4; SD = 10.9, N = 59). For both groups, there had been an increase in PTSD scores between the end of treatment and final follow-up, however, this increase was smaller in the intervention group. At both the end of treatment and final follow-up, the average depression score was significantly higher in the comparator group than the MI group (P < 0.05 for analyses adjusting for covariates). In both groups, all scores indicated probable depression. There was no significant difference in the frequency of reported suicidal thoughts between groups during the intervention period (3.4% (n = 3) of the MI group and 10.5% (n = 9) of the comparator group reported thoughts of selfharm) and no participants died by suicide during the study.

MI versus another smoking cessation intervention (comparison 3)

Smoking cessation outcome

We pooled 19 studies comparing MI to another type of smoking cessation intervention (Analysis 3.1). The point estimate was in favour of MI; however the confidence intervals were compatible with potential harm as well as substantial benefit (RR 1.24, 95% CI 0.91 to 1.69; I² = 54%; N = 5192). In sensitivity analyses, we 1) removed Colby 2012, as parents also received an MI intervention to motivate them to support their child's quit attempt, making the intervention different to the other interventions included (RR 1.24, 95% CI 0.90 to 1.70; I² = 56%; N = 5030); and 2) removed Cook 2016, De Azevedo 2010 and Kelly 2006 as we judged these studies to be at high risk of bias (RR 1.32, 95% CI 0.89 to 1.98; I² = 63%; N = 4602). Neither of these analyses meaningfully changed the summary estimates.



Intensity of the comparator

In 14 studies, the treatment provided in the comparator group (or in some of the comparator groups) was of a lower intensity than in the MI intervention group. In one study, the comparator group in some of the study arms received a higher intensity treatment than the intervention group (Cook 2016 - behavioural reduction counselling); and in six studies the intensity of the treatments was similar in the intervention and comparator groups. In both Catley 2016 and Cook 2016, there was more than one comparator arm and the intensity of the comparators varied. Therefore, both studies were included in more than one subgroup and the total participants and number of events in the intervention group were split across subgroups. There was no evidence of heterogeneity between subgroups ($I^2 = 0\%$, P = 0.93; Analysis 3.2).

Age of participants

Of the 19 studies comparing MI to another type of smoking cessation intervention, five recruited adolescents only. There was no evidence of a subgroup difference for the effect of MI in adolescents compared with adult participants ($I^2 = 0\%$, P = 0.73; Analysis 3.3).

Intervention provider

Across the studies in this comparison, interventions were provided by physicians (three studies), nurses (one study), or counsellors/psychologists (including those specialised in smoking cessation; 14 studies). Helstrom 2007 was not included in this subgroup analysis because they did not report the treatment providers' main role. There was no evidence that the effect size differed by these subgroups ($I^2 = 17.2\%$, P = 0.30; Analysis 3.4).

MI fidelity monitoring

For this comparison, 12 of the 19 studies reported that they had monitored the fidelity of MI. There was evidence that this modified the effectiveness of MI relative to comparators in this subgroup $(I^2 = 84.0\%, P = 0.01; Analysis 3.5)$. There was no evidence that MI outperformed the comparator in studies where fidelity monitoring had taken place (RR 0.98, 95% CI 0.71 to 1.37; $I^2 = 41\%$; N = 3382), with stronger evidence of a benefit of MI in studies where fidelity was not assessed (RR 1.83, 95% CI 1.28 to 2.60; $I^2 = 9\%$; N = 1810). However, this latter effect appears to be partly driven by only two of the six studies in the group (Soria 2006; Wu 2009), which suggest a stronger benefit than the other studies in the subgroup. Eight of the 12 studies that reported they had carried out fidelity monitoring provided results of fidelity assessment (Audrain-McGovern 2011; Catley 2016; Colby 2005; Colby 2012; Davis 2011; Lloyd-Richardson 2009; Rohsenow 2014; Rohsenow 2015); all but one of these appeared to meet the study defined thresholds for good fidelity. The one study that did not meet prespecified thresholds only narrowly missed these (Audrain-McGovern 2011); removing this single study did not meaningfully change the subgroup estimate nor the difference between subgroups.

Baseline participant motivation

One study in this comparison recruited only participants motivated to quit smoking at baseline, three recruited participants not motivated to quit, and the remaining 15 recruited participants regardless of their motivation. There was substantial evidence of effect modification ($I^2 = 88.8\%$, P = 0.0001; Analysis 3.6). In the subgroup that recruited participants regardless of motivation,

there was evidence that MI interventions resulted in superior quit rates to other smoking cessation interventions (RR 1.44, 95% CI 1.09 to 1.90; $I^2 = 33\%$; N = 3703), whereas the one study that recruited participants motivated to quit (Ahluwalia 2006) found substantial evidence that MI worsened outcomes (RR 0.51, 95% CI 0.34 to 0.76; $I^2 = n/a$; N = 755). The comparator in Ahluwalia 2006 was termed 'health education', and was described as the current best smoking cessation support, focussed on providing information and advice by reviewing the addictive nature of nicotine, the health consequences of smoking, the benefits of quitting, and providing strategies to develop a quit plan and identify an alternative to smoking when meeting triggers to smoke. In trials where participants were recruited who were not motivated to quit smoking (Catley 2016; Cook 2016; Davis 2011) the confidence intervals provided evidence of substantial imprecision, and for potential harm and benefit of MI (RR 0.81, 95% CI 0.36 to 1.85; I² = 0%; N = 734).

Counselling modality

We also planned to assess whether the effect of MI might depend on whether face-to-face sessions or remote sessions were provided but all interventions incorporated at least one face-to-face session.

Mental health and QoL outcomes

No studies relevant to this comparison measured mental health or QoL at any follow-up, by study group.

Intensity of the MI intervention (comparison 4)

Smoking cessation outcome

Five included studies examined whether the intensity of MI affected smoking cessation rates. When pooled, these studies resulted in an RR of 1.23 (95% CI 1.11 to 1.37; adjusted N = 5620; $I^2 = 0\%$; Analysis 4.1) favouring more intensive over less intensive intervention. As described above, Vidrine 2019 randomised neighbourhood sites rather than individual participants and conducted adjusted analyses. This allowed us to calculate an ICC of 0.06 and adjust for this in our analysis. We carried out three sensitivity analyses to test the robustness of the effect of high versus low intensity MI: 1) we removed Sherman 2016 as the two MI interventions differed not only in intensity but also provider (RR 1.22, 95% CI 1.07 to 1.40; I² = 0%; adjusted N = 4002) (in the higher intensity arm, participants were treated by the study team, whereas in the lower intensity arm they were referred to a state quit-line); 2) we removed Vidrine 2019 as both relevant intervention groups were based on CBT as well as MI (RR 1.23, 95% CI 1.09 to 1.37; $I^2 = 0\%$; adjusted N = 5361); and 3) we removed Hollis 2007; Sherman 2016 and Vidrine 2019 together, as they were all judged to be at high risk of bias. The former two analyses did not meaningfully change the estimate of higher versus lower intensity; however, removing the three studies at higher risk of bias reduced the estimate to 1.00 (95% CI 0.65 to 1.54; $I^2 = n/$ a; N = 482), with CIs incorporating both a substantial benefit and harm of increased intensity MI interventions. Although there were two studies included in this analysis that were judged to be at low or unclear risk of bias (Ellerbeck 2009; Rohsenow 2014), the latter RR and CIs were calculated from Ellerbeck 2009 only as no participants quit in Rohsenow 2014, making it impossible to calculate a point estimate for that individual study.



Counselling modality

We grouped studies into those where the intervention was delivered either wholly or partially face-to-face and those where none of the intervention was delivered face-to-face (Analysis 4.2). One study involved face-to-face contact (Rohsenow 2014) and four studies involved no face-to-face contact (interventions were delivered either solely by telephone or via telephone and text message). However, this subgroup analysis had no effect ($I^2 = 0\%$, P = 0.80), as no participants quit in either group in Rohsenow 2014.

MI fidelity monitoring

Four of the five studies included in this comparison reported MI fidelity monitoring. There was no evidence of a difference between the four that did report monitoring and the single study that did not ($I^2 = 0\%$, P = 0.78; Analysis 4.3). We had planned to assess the sensitivity of the results to studies where fidelity was poor, but only one of the four studies that monitored fidelity reported the results, and that study found adequate fidelity.

Baseline participant motivation

Two studies in this comparison recruited participants who were already motivated to quit smoking at baseline, and the remaining three recruited participants regardless of their motivation to quit. Again, there was no evidence of a difference between these subgroups and both groups showed evidence of a benefit of higher intensity MI versus lower intensity MI for smoking cessation ($I^2 = 0\%$, P = 0.81; Analysis 4.4).

Age of participants

We also planned to carry out subgroup analyses investigating whether providing higher intensity MI in adolescents versus adults had any affect on smoking cessation; however, this was not possible, as all of the studies recruited adults.

Intervention provider

We also planned to carry out subgroup analyses investigating whether the effect varied dependent on intervention provider. However, this was not possible as all of the studies were delivered by counsellors.

Mental health and QoL outcomes

None of the studies in this comparison measured mental health or QoL at any follow-up, by study group.

Additional study

We included one additional study, which was relevant to more than one comparison, that we were unable to include in any meta-analyses (Matuszewski 2018). Matuszewski 2018 (N = 237) investigated two MI interventions delivered in addition to brief smoking cessation support (referral to a patient resource centre that provided details of a smoking quit-line and a quit-line brochure). The MI interventions both consisted of a single session of MI counselling (10 minutes); however the second MI group also received a brief follow-up session (5 minutes). Thus, this study investigated the intensity of MI counselling as well as MI in addition to another type of smoking cessation intervention. Analysis of study data was completed at the end of 2018 and has not yet been published. However, results were presented at a conference in 2018. The conference abstract stated that at six months, 35% of the comparison group had quit, and 21% and 30% of the lower

intensity and higher intensity MI groups had quit respectively, with no evidence of differences between these groups. The abstract did not state whether analysis was carried out on an intention-to-treat or complete case basis; however, the data presented suggests that this was probably not an intention-to-treat analysis and it was not possible to conduct one using data provided in the abstract alone.

DISCUSSION

Summary of main results

This review included 37 trials. Five of these trials compared MI to no smoking cessation intervention, 12 provided MI in addition to another smoking cessation intervention and compared this to the same intervention without MI, and 19 compared MI to another smoking cessation intervention. Five studies compared a more intensive MI intervention to a lower intensity one. One study could not be included in meta-analyses.

Pooling all available studies comparing MI to no smoking cessation treatment resulted in substantial heterogeneity between studies caused by one study carried out in incarcerated men. As this study differed considerably from the other included studies, we excluded this study from the analysis and pooled the remaining studies carried out in adults and adolescents representing the general population. This resulted in a pooled RR of 0.84 (95% CI 0.63 to 1.12; $I^2 = 0\%$; adjusted N = 684). The pooled estimate was in favour of no treatment; however the CIs incorporated the possibility of both benefit and harm. This estimate was judged to be of low certainty as it was imprecise, and all studies were judged to be at high or unclear risk of bias. When studies at high risk of bias were removed, the point estimate changed to be in favour of MI; however, the CIs were still imprecise and spanned one; suggesting the possibility of both harm and benefit. The comparison between MI plus another smoking cessation intervention and that smoking cessation intervention alone (RR 1.07, 95% CI 0.85 to 1.36; I² = 47%; adjusted N = 4167), and the comparison between MI and another smoking cessation intervention (RR 1.24, 95% CI 0.91 to 1.69; $I^2 = 54\%$; N = 5192) also produced CIs incorporating both benefit and harm. Concerns about unexplained inconsistency and imprecision resulted in low certainty relating to both of these estimates. We investigated the impact of studies at high risk of bias, the impact of face-to-face contact, fidelity monitoring, and participant motivation to quit. Across these sensitivity and subgroup analyses, there were some differences splitting by subgroup, but no consistent pattern emerged across the body of evidence.

Five trials examined the effectiveness of more intensive compared with less intensive MI smoking cessation interventions and produced an RR of 1.23 (95% CI 1.11 to 1.37; adjusted N = 5620; $I^2 = 0\%$) in favour of more intensive MI. However, this analysis included three studies at high risk of bias and removing these produced an RR of 1.00 (95% CI 0.65 to 1.54; $I^2 = n/a$; N = 482). We judged the overall summary estimate as having low certainty because of this.

Only one study investigated the effect of an MI smoking cessation intervention on the well-being of participants (Battaglia 2016). Battaglia 2016 studied participants with PTSD, and found modest benefits of MI on PTSD and depression scores at final follow-up, compared with a usual smoking cessation care group. However, due to the paucity of evidence, no conclusions can be drawn on



whether MI smoking cessation interventions can improve the wellbeing of people attempting to quit smoking.

Overall completeness and applicability of evidence

The studies identified for this review were mainly conducted in the USA; most others took place in other high-income countries, though some were conducted in middle-income countries. In addition, the majority of studies were carried out in specific populations rather than recruitment being carried out in the general population. The diversity of populations studied may have contributed to the moderate to substantial heterogeneity observed across all comparisons. We did not plan to, and therefore did not look for evidence that population characteristics (other than participants' baseline motivation to quit) modified the effectiveness of MI. Typically, the specialist populations studied represented what may be referred to as 'hard to reach' groups (people with substance use disorders, adolescents, offenders, hospital inpatients and outpatients) and this should be considered when interpreting results; however, where the characteristics of a population have led to low quit rates in the intervention arm, this is also likely to have affected quit rates in the comparator arm, and this may not have affected the relative effectiveness of MI.

The significant heterogeneity detected within analyses is likely to also have been influenced by considerable variation across the characteristics of both the intervention and comparator arms. Despite dividing studies into separate comparisons for this update and conducting preplanned subgroup analyses in an attempt to reduce and explain some of this variation, key differences remained in the components of the MI and more general smoking cessation support provided. Studies typically provided only limited explanation of the content of the MI interventions; most specifying simply that MI techniques were adhered to, but giving sparse description of the counselling overall. This made it hard to differentiate between studies based on the nature of the MI support provided, which could have given further insight into why heterogeneity existed between studies. There was substantial variation in the intensity of the support in both intervention and comparator groups, which we did attempt to control for. However, it would have been impossible to control for all possible sources of variation across studies and this means that although we can hypothesise about the causes of this heterogeneity, this remains largely unexplained.

MI can be a difficult technique to learn and enact and therefore monitoring the fidelity of the intervention can give assurance that MI was delivered as intended and was consonant with Miller and Rollnick's key principles (Miller 2002; Miller 2013). Jelsma 2015 gave guidance on why this is important and how trialists can ensure that they satisfy this suggested requirement. Scales have been developed, such as the motivational interviewing treatment integrity (MITI) code (Pierson 2007), in order to measure adherence to MI consistently. However, most of the studies in this review did not attempt to monitor and/or improve the fidelity of MI interventions; and when monitoring was reported, they often did not report the results of that monitoring. The inconsistency of monitoring techniques and standards to define acceptable fidelity across studies means it was impossible to report overall fidelity of implementation. This, in turn, makes it difficult to determine whether the minimal beneficial effects detected in this review were due to a genuine lack of MI efficacy, or whether the included studies were not delivering MI as intended.

Finally, MI is an intervention designed to help people change their behaviour by increasing motivation to quit; however, only a minority of the included studies specifically recruited smokers who were not motivated to quit (Catley 2016; Cook 2016; Davis 2011). Five studies specifically recruited smokers motivated to quit and the remainder did not specify that they had recruited based on motivation at baseline and, thus, we assume these were populations of mixed motivation. That said, it is likely that only people somewhat motivated to quit would join a study about smoking cessation and it is likely that most studies in this review presented themselves to potential participants in this manner. It is plausible that, if MI is effective, it would be more helpful for people with low motivation. However, there was no evidence of this in this review as too few studies have recruited this population.

Certainty of the evidence

Of the 37 studies included in this review, we judged four to be at low risk of bias for all domains, and 11 to be at high risk in one or more domains. In many cases, we had to rate studies 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 of studies that we judged to be at high risk of bias on results, we removed studies judged to be at high risk of bias in sensitivity analyses. In most cases, this did not materially change the estimates of effect. However, removing the three studies judged to be at high risk of bias from the analysis of higher versus lower intensity MI did affect the results, changing the summary estimate from clear evidence of modest benefit to no evidence of benefit.

We assessed the certainty of the evidence by creating 'Summary of findings' tables for all four comparisons and carrying out GRADE ratings for the smoking cessation outcome for each (Summary of findings for the main comparison; Summary of findings 2; Summary of findings 3; Summary of findings 4). For the MI versus no treatment comparison, we judged the certainty of the cessation evidence to be low. We downgraded the evidence as all of the included studies were at high or unclear risk of bias and the pooled estimate was imprecise, as the upper and lower limits of the CIs included both meaningful benefit and harm. We also judged the cessation evidence to be of low certainty for all of the remaining comparisons. When investigating MI in addition to another type of smoking cessation treatment or versus another type of smoking cessation intervention, this was due to imprecision, but also unexplained variation in effect size between studies. We judged the evidence contributing to the 'intensity of MI' comparison as low certainty because of the 'Risk of bias' assessment, where three of the five studies were at high risk of bias. As previously discussed, removing these studies in a sensitivity analysis changed the interpretation of the effect, so that the confidence intervals encompassed both appreciable benefit and harm of higher intensity motivational interviewing for smoking cessation.

We generated funnel plots for the two comparisons that included over ten studies ('MI in addition to another form of smoking cessation treatment' or 'MI versus another non-MI smoking cessation intervention') in an attempt to identify any differential reporting of studies finding negative effects of MI. In neither case did these plots provide evidence of publication bias (Figure 3; Figure 4).



Figure 3. Funnel plot of comparison: 2 MI in addition to other smoking cessation treatment, outcome: 2.1 cessation.

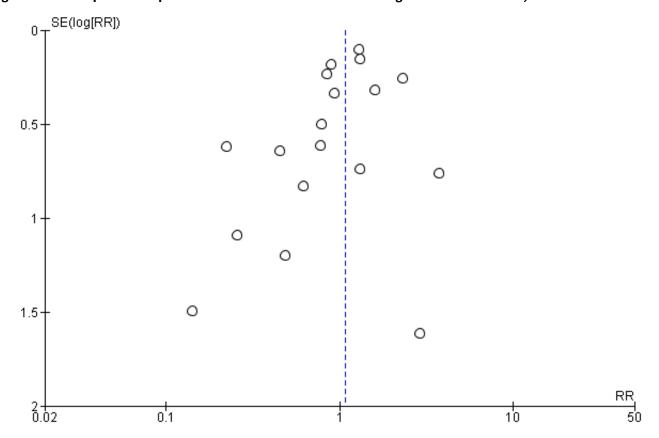
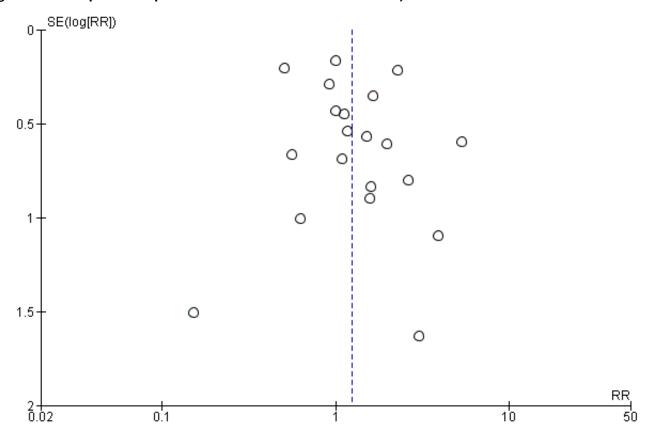




Figure 4. Funnel plot of comparison: 3 MI versus other SC intervention, outcome: 3.1 cessation.



Potential biases in the review process

We consider the review process used to be robust, and are unaware of any introduced bias. For outcome assessment, we followed the standard methods used for Cochrane Tobacco Addiction Review Group cessation reviews. Our search strategy included the Cochrane Tobacco Addiction Group Specialised Register and we also searched trial registries in an attempt to capture unpublished and ongoing studies. There may be unpublished data that our searches did not uncover; however funnel plots suggested that this is unlikely to bias results for the two relevant comparisons. For this update of the review, we modified the inclusion criteria and therefore conducted a full search of the literature (rather than just updating the searches run previously). As a result, we included 16 new studies and excluded ten previously included studies and two ongoing studies. We introduced an exclusion criterion to exclude studies that incorporated additional non-MI components in the MI intervention arm but not the comparison arm (nine previously included/ongoing studies have been now excluded for this reason). It is plausible that the apparent effect of MI seen in the previous review may have been partly because the interventions incorporated these other active elements. We excluded quasirandomised studies at this update as non-randomised studies are of lower quality and the larger body of randomised trials allowed us to draw conclusions on the best quality evidence (we excluded one previously included study for this reason). We also excluded one previously included study that tested an MI intervention to encourage people to participate in the trial rather than to aid them to quit smoking, and another study that was based primarily on the stages of change theory. We believe that these changes have reduced biases that previously existed in the review.

Agreements and disagreements with other studies or reviews

Two previous reviews of MI for smoking cessation (Heckman 2010; Hettema 2010) provided evidence of a very modest effect of MI at long-term follow-up (six months or more). Our own effect estimates are compatible when comparing MI (on its own or in addition to other smoking cessation care) to another form of smoking cessation treatment, with point estimates suggesting very modest benefit but, unlike the previous reviews, our summary estimate CIs incorporated potential harm of MI as well as benefit. A key difference is that these other reviews pooled together all comparisons whereas we separated ours into four based on the type and intensity of the comparator groups. Our findings reflect the findings of the MI literature more generally, across a variety of health behaviours (Cheng 2015; Cowlishaw 2012; Foxcroft 2016; Gates 2016; Klimas 2018; Mbuagbaw 2012; Morton 2015; Smedslund 2011). These systematic reviews typically found modest effects of MI that were not sustained at long-term follow-up. As in this review, these reviews often detected moderate unexplained heterogeneity, possibly relating to substantial differences between the intervention and comparator, other than the presence or absence of MI across the included studies.

Hettema 2010 found evidence that the baseline motivation of participants recruited moderated the effect of MI. The studies included in their meta-analysis that recruited participants with low



motivation to quit found a significant moderate effect of MI on quit rates at both short- and long-term follow-up, whereas those which recruited highly-motivated participants resulted in a very small, non-significant overall effect of MI on smoking cessation.

AUTHORS' CONCLUSIONS

Implications for practice

- There is insufficient evidence to assess whether MI to promote smoking cessation increases cessation compared with no intervention, and further evidence may change our estimate of the effect.
- MI may modestly increase the likelihood of long-term smoking cessation when used in addition to other smoking cessation intervention components or when compared with non-MI smoking cessation interventions; however, there is also the possibility that MI may reduce quit rates relative to other smoking cessation interventions. Further evidence is likely to strengthen or weaken this effect.
- There is no clear evidence to suggest that the effect of MI is moderated by the intervention provider, age of participant, participants' motivation to quit at baseline, whether MI is delivered face-to-face or whether MI fidelity monitoring takes place.
- Higher intensity MI may increase smoking cessation rates relative to lower intensity MI, however, due to risks of bias in the existing studies, further research could strengthen or weaken this effect.

Implications for research

- Greater clarity and consistency of study methods, components and counselling techniques would improve comparability between trials.
- Trials should aim to reduce confounding by minimising the number of co-interventions when testing MI, and where cointerventions are used, match these in the comparator arm.
- Future studies of MI should aim to maximise the fidelity to MI, consider independent monitoring of the fidelity of intervention

- delivery, and report these data. Standardising methods used to monitor fidelity would allow easier comparisons across studies.
- Future research should attempt to identify which core components of the motivational interviewing approach successfully help people to quit smoking, and whether modifying them enhances or reduces the likelihood of quitting.
- Future studies should monitor the well-being of participants throughout the study and at follow-up, reporting results by trial arm, to investigate whether MI for smoking cessation improves the well-being of smokers attempting to quit.
- Trialists should consider testing the effects of baseline motivation to quit when investigating MI interventions and recruiting participants where motivation could benefit from improvement.

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CHARACTERISTICS OF STUDIES

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Ahluwalia 2006

Methods	Study design: factorial RCT (2 x 2)
	Location: USA Setting: urban community-based clinic Recruitment: through clinic, media and community outreach efforts, including radio, television, gas pump, billboard advertising, community health fairs, posting signs in minority-owned businesses and mailing of referral letters from physicians
Participants	Defining eligibility criteria?: African-American or black adults who smoked 10 or fewer cigarettes a day for at least 6 months prior to enrolment (light smokers)
	Participant characteristics: 755 adult smokers; 505/755 (66.9%) female; mean age: 45; mean cpd: 7.5; nicotine dependence: mean Fagerstrom test for nicotine dependence (FTND) = 4.3

^{*} Indicates the major publication for the study



Ahluwalia 2006 (Continued)

Motivation to quit?: motivated

Interventions

Control 1: Health Education plus 2 mg nicotine gum (HE + NG): HE was a standard counselling approach, based on the current US Department of Health & Human Services treatment guidelines that focused on providing information and advice. Participants received the counselling over six 20-minute sessions (three in-person visits and three telephone calls). During HE sessions, trained counsellors used the 'KIS II Quit Smoking Guide' (a 36-page booklet developed for African-American light smokers) and semi-structured scripts to review the addictive nature of nicotine, health consequences of smoking and benefits of quitting, and provided concrete strategies on developing a quit plan and identifying alternatives against triggers to smoke. Participants were provided with an eight-week supply of 2 mg nicotine gum.

Control 2: Health Education plus placebo gum (HE + PG): As control 1, however participants received placebo gum rather than 2 mg nicotine gum.

Intervention 1: Motivational Interviewing plus 2 mg nicotine gum (MI + NG): MI counselling was provided by trained counsellors over six 20-minute sessions (three in-person visits and three telephone calls). Counsellors followed semi-structured scripts that explored the pros and cons of smoking/quitting, and motivation and confidence to quit. A values clarification strategy based on the work of Miller & Rollnick was used. Participants also received the 36-page 'KIS II Quit Smoking Guide'.

Intervention 2: Motivational Interviewing plus placebo gum (MI + PG): As intervention 1, however participants received placebo gum rather than 2 mg nicotine gum.

Provider: trained counsellors (counsellors participated in two days of in-service training). All counsellors participated in weekly group supervision to ensure the integrity of the respective counselling protocols.

Intensity: counselling took place during six 20-minute sessions (3 face-to-face and 3 telephone) over 16 weeks in all study arms.

Was MI fidelity monitored?: Yes. Each session was tape-recorded to maintain fidelity and consistency throughout the study. A subset of audiotapes were rated by investigators for adherence to MI principles using a modified version of the Motivational Interviewing Skills Code (results not reported). MI counsellors and supervisors reviewed audiotapes and discussed current issues at their weekly meetings.

Outcomes

Definition of cessation used: 7-day point prevalence

Length of longest follow-up: 26 weeks

Validation: saliva cotinine-verified. A salivary cotinine cut-off of ≤ 20 ng/mL was used.

Was mental health and/or well-being measured at follow-up?: No

Was quality of life measured at follow-up?: No

Funding source

National Cancer Institute at the National Institutes of Health (R01CA091912). Glaxo-SmithKline provided study medication but played no role in the design, conduct of the study or interpretation and analysis of the data.

Author conflicts of interest

None

Notes

For purposes of analysis, the two HE groups and the two MI groups were merged to create one HE group and one MI group. This was acceptable as there was no interaction detected between study factors

Risk of bias

Bias

Authors' judgement Support for judgement



Ahluwalia 2006 (Continued)		
Random sequence generation (selection bias)	Low risk	Quote: "a computer-generated random-numbers table was used to randomize patients".
Allocation concealment (selection bias)	Unclear risk	Quote: "a sealed envelope with pre-assigned randomization numbers was drawn to determine which form of counseling the participant would receive". Did not state that envelope was opaque.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Smoking outcome was biochemically verified.
Incomplete outcome data (attrition bias) All outcomes	Low risk	18.8% lost to follow-up in MI groups; 12.5% lost to follow-up in HE groups. Therefore, less than 50% overall and similar loss to follow-up between intervention groups of interest.

Audrain-McGovern 2011

Methods	Study design: RCT
	Location: USA Setting: children's hospitals Recruitment: through flyers and brochures advertising the study, available at the participating medical sites. Participants were also referred by their physicians.
Participants	Defining eligibility criteria?: adolescents aged 14 to 18 years
	Participant characteristics: 355 adolescent smokers; 195/355 (54.9%) female; mean age: 17.02; mean cpd: 9.8; nicotine dependence: mean modified Fagerstrom Tolerance Questionnaire (MFTQ)= 4.26
	Motivation to quit?: not selected on motivation
Interventions	Control: structured brief advice (SBA): based on clinical practice guidelines for treating nicotine dependence - the "5 A's" for those interested in quitting, and the "5 R's" for participants not interested in quitting smoking. In each session, the 5 A's/R's were followed by a review of self-help materials (smoking cessation print materials, list of resources), and a brief check-in to see if the adolescent needed help in gaining access to services (e.g. appointment with their physician for pharmacotherapy).
	Intervention: motivational interviewing (MI), based on motivational enhancement therapy (MET), an adaptation of motivational interviewing. MET adds personalised feedback about assessment results (e.g. adolescent's tobacco use at baseline and during treatment) and collaborative development of a formal change plan to the standard principles and techniques of MI.
	Provider: counsellor
	Intensity: the MI intervention consisted of three 45-minute office sessions and two 30-minute office or telephone sessions over 12 weeks.
	Was MI fidelity monitored?: "To promote treatment integrity, all treatment sessions were audio recorded and reviewed weekly by the treatment supervisor, who used an adherence checklist. MI and SBA counselors received extensive training on the treatment protocol and received weekly individual or group supervision."
Outcomes	Definition of cessation used: 7-day point prevalence
	Length of longest follow-up: 24 weeks
	Validation: Saliva cotinine (<= 15 ng/mL classified as abstinent)



Audra	in-McG	iovern	2011	(Continued)
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Was mental health and/or well-being measured at follow-up?: yes, however results were not reported by group at follow-up.

Was quality of life measured at follow-up?: no

Funding source "This study was supported by grant SAP 4100027295 from the Commonwealth of Pennsylvania, Pennsylvania Department of Health".

Author conflicts of interest "The authors have indicated they have no financial relationships relevant to this article to disclose."

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	At this initial assessment, participants were randomly assigned (stratified by precontemplation stage of quitting smoking).
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessment of smoking outcome was blinded and cessation was biochemically verified.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up low and similar across study arms 14/177 (8%) in MI group; 4/178 (2%) in control group.

Bastian 2013

Methods	Study design: RCT
	Location: USA Setting: telephone support Recruitment: lung cancer patients identified relatives and friends who smoked through four clinical sites. A letter was written to the friend/relative explaining the study and asking them to call a toll-free number if they wanted to decline participation. Those who did not decline were called by the study team seven days later to assess eligibility.
Participants	Defining eligibility criteria?: in social network/family of someone diagnosed with lung cancer
	Participant characteristics: 496 adult smokers, randomised to intervention (245) control (251). 58% female. Mean age 47, mean cpd 19.5.
	Motivation to quit?: not selected on motivation
Interventions	Control: self-directed materials: letter from an oncologist encouraging participants to give up smoking, quit kit (including an ALA cessation guide, straws, candy, cards, and a notepad), and an individually-tailored information booklet. Mailing of 2-week nicotine patch starter kit and advised to call for a further 2-week supply as needed
	Intervention: As control, plus 6 weekly telephone calls over the 12-week intervention period - standard smoking cessation counselling using MI techniques and adaptive coping skills training
	Provider: counsellors



Bastian 2013 (Continued)	
	Intensity: 1 x 30-minute session a week for 6 weeks
	Was MI fidelity monitored?: not reported
Outcomes	Definition of cessation used: 7-day PPA
	Length of longest follow-up: 12 months
	Validation: none
	Was mental health and/or well-being measured at follow-up?: no
	Was quality of life measured at follow-up?:no
Funding source	Supported by the National Cancer Institute grant 5U01-CA-92622, also in part by the Intramural Program of the National Human Genome Research Institute, National Institutes of Health
Author conflicts of interest	Not reported
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomization was blocked by patient, with entire social network units stratified by site and size of social network enrolled (one vs. two or more) assigned to the same condition." No further information given
Allocation concealment (selection bias)	Unclear risk	Quote: "Randomization was blocked by patient, with entire social network units stratified by site and size of social network enrolled (one vs. two or more) assigned to the same condition." No further information given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "We attempted to verify self-report cessation at 2 weeks, 6 months and 12 months postintervention with saliva cotinine analysis, but were unable to do so because return rates (via mail) for saliva samples were low". Therefore, quit rates were not validated and the amount of support differed between arms.
Incomplete outcome data (attrition bias) All outcomes	High risk	136/245 lost to follow-up in intervention arm; 132/251 lost to follow-up in control arm. Therefore, loss to follow-up was high (more than 50%).

Battaglia 2016

Methods	Study design: RCT			
	Location: USA Setting: over the telephone within the VHA healthcare system Recruitment: recruited using informational flyers, provider referrals, and outreach letters			
Participants	Defining eligibility criteria?: veteran smokers with post traumatic stress disorder (PTSD) - Diagnostic and Statistical Manual of Mental Disorders IV criteria for diagnosis code 309.81 PTSD documented in their medical record			
	Participant characteristics: 175 adult smokers; $24/175$ (13.7%) female; mean age: 55.6; mean cpd: not provided; nicotine dependence: FTND: intervention arm: mean 5.4 (SD = 2.0); control arm: mean 5.1 (SD = 2.3)			



Battaglia 2016 (Continued)

Motivation to quit?: not selected on motivation

Interventions

Control: usual PTSD Health Buddy Care: PTSD home telehealth care management program (Health Buddy) and nurse care management alongside usually offered smoking cessation treatments. The Health Buddy (BoschHealthcare, Palo Alto,CA) is designed to help individuals with PTSD self-monitor and self-manage. This computer-like device is $12 \times 8 \times 4$ inches with an LCD screen, on which participants read information, and four large buttons for responding to questions. A typical session is completed in approximately 2 minutes. Participants given access to nicotine replacement therapy (patch, lozenge, gum, and inhaler), bupropion or varenicline

Intervention: enhanced PTSD Health Buddy and Motivational Interviewing: as control, plus MI-based written smoking cessation curricula on home telehealth and weekly telephone MI smoking cessation counselling with a nurse

Provider: nurses

Intensity: weekly (average duration 16.7 minutes)

Was MI fidelity monitored?: "To ensure fidelity, random calls made by the intervention research nurse are observed throughout the study. Additionally, the research nurse will participate in ongoing MI training and workshops throughout the study to diminish "drift" away from the principles of MI."

Outcomes

Definition of cessation used: 7-day point prevalence

Length of longest follow-up: 9 months post-baseline

Validation: exhaled CO ≤ 10 ppm

Was mental health and/or well-being measured at follow-up?: PTSD symptoms assessed using the PTSD Checklist. The 15-item Geriatric Depression Scale-Short Form was used to monitor depression. Suicidal thoughts were assessed every 30 sessions during the intervention period with a question on the Health Buddy.

Was quality of life measured at follow-up?: no

Funding source

"Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, Health Services Research and Development"

Author conflicts of interest

"The authors declare that they have no competing interests".

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	A research pharmacist who was unaffiliated with the study performed randomisation using a blocked randomisation process. Did not specify how the sequence was generated
Allocation concealment (selection bias)	Unclear risk	Study personnel were blinded to the randomisation process. Was not clear how this took place
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Smoking/quitting was reported by participants via a handheld computer and not directly to study personnel. Quitting was validated at end of treatment and final follow-up using exhaled CO verification (CO verified rates obtained through communication with author).
Incomplete outcome data (attrition bias)	Low risk	Overall loss to follow-up 31% and was evenly matched between trial arms.



Battaglia 2016 (Continued) All outcomes

Bock 2008			
Methods	Study design: RCT		
	Location: USA	of a bounded our construction	
		of a hospital emergency department records used to identify participants	
Participants	Defining eligibility criteria	a?: admitted to emergency department of hospital with chest pain	
	Participant characteristic 69.1% female; mean age	cs: 543 adult smokers, randomised to intervention (271) usual care (272). 47.7. Mean cpd 18.9	
	Motivation to quit?: not s	elected on motivation	
Interventions	Control: referral sheet to	local SC resources (usual care)	
	to quit versus continuing	nin MI session, including use of decision-balance tool, summation of reasons to smoke etc. If trying to quit, given ALA manual, 2 brief (< 15 min) follow-up weeks after counselling session	
	All participants offered N	RT if decided to quit, and received brief call on quit day and a week later	
	Provider: counsellors		
	Intensity: 1 x 30-minute session followed by 2 further 15-minute sessions		
	were audited by the stud decisional balance review	d?: "A subsample of 10% of all counseling sessions was audio-taped. Tapes y investigators for quality control and treatment fidelity. Counselors used a v tool and intervention component checklists to enhance treatment fidelity y of the intervention components and the amount of time spent on each com-	
Outcomes	Definition of cessation us	sed: continuous	
	Length of longest follow-	up: 6 months	
	Validation: continuous al	ostinence defined as self-reported abstinent at all time points	
	Was mental health and/o	r well-being measured at follow-up?: no	
	Was quality of life measured at follow-up?: no		
Funding source	A National Institutes of H	ealth, National Heart, Lung and Blood Institute grant (1 R01HL60986)	
Author conflicts of interest	"The authors report no co	ompeting interests".	
Notes			
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection bias)		QUOTE: "After providing informed consent, participants were randomly assigned" No further information given	



Bock 2008 (Continued)		
Allocation concealment (selection bias)	Unclear risk	QUOTE: "After providing informed consent, participants were randomly assigned" No further information given
Blinding of outcome assessment (detection bias) All outcomes	High risk	Continous cessation rates were not biochemically validated and contact differed between trial arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	133/271 (49%) of the intervention group and 118/272 (43%) of the control group were lost to follow-up. Therefore overall there was less than 50% loss to follow-up and rates were similar between groups.

Bock 2014

Methods	Study design: RCT
	Location: USA Setting: 3 hospital-based primary care clinics located in separate inner-city hospitals Recruitment: during routine healthcare visits at primary care clinics. Patients invited to participate in a study of smoking patterns and cessation
Participants	Defining eligibility criteria?: all attending routine primary care appointments for variety of reasons
	Participant characteristics: 846 adult smokers randomised to intervention (406) and control (440), 68.8% female; mean age 39.6. cpd of at least 10
	Motivation to quit?: not selected on motivation
Interventions	Control: smoking cessation assistance following guidelines for best practice, using the 5As. Participants asked about smoking status, assessed for nicotine dependence, advised to quit smoking and offered assistance with quitting (nicotine patches, self-help pamphlets and/or referral to the state quit-line)
	Intervention: As control, plus 45-min individual counselling session with Health Educators, using MI techniques. Participants ready to quit received behavioural skills training. Those who decided to quit during this baseline visit were given 2 follow-up telephone counselling calls (on quit day and 2 weeks later). Those choosing not to quit were called 2 and 4 weeks later.
	All participants received 8 weeks of nicotine patches.
	Provider: counsellor
	Intensity: 1 x 45-minute face-to-face session followed by 2 telephone calls at 2 and 4 weeks
	Was MI fidelity monitored?: "ME interventionists were trained and supervised by licensed clinical psychologists. Ongoing fidelity was monitored through selected session observation and weekly clinical supervision. All counselling sessions were tape recorded, and 20% of tapes were selected at random for review by the study intervention coordinator, a PhD psychologist who was certified in MI. Regular, weekly meetings were conducted to review the intervention procedures and results of counselling tape audits to enhance treatment fidelity."
Outcomes	Definition of cessation used: 7-day point prevalence
	Length of longest follow-up: 12 months
	Validation: Exhaled CO ≤ 5 ppm
	Was mental health and/or well-being measured at follow-up?: no
	Was quality of life measured at follow-up?: no



Bock	2014	(Continued)
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Funding source	A National Institutes of Health, National Institute on Drug Abuse grant (R01DA010860)	
Author conflicts of interest	"Authors declare no conflicts".	
Notes	Outcome data not clearly provided for ITT unadjusted analysis in the paper; therefore we obtained data directly from the author for meta-analyses.	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	QUOTE: "the computer used a random number program to assign participants at random to one of two treatment conditions".
Allocation concealment (selection bias)	Low risk	QUOTE: "the computer used a random number program to assign participants at random to one of two treatment conditions".
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	QUOTE: " reports of tobacco abstinence were confirmed using expired carbon monoxide testing with a Bedfont MicroSmokerlyzer™ machine with ≥ 5 ppm as the cutoff indicating a positive smoking result".
Incomplete outcome data (attrition bias) All outcomes	High risk	238/406 (59%) in the intervention arm and 232/440 (53%) in the control arm lost to follow-up. Therefore, more than 50% dropout overall.

Butler 1999

Study design: RCT		
Location: Wales, UK		
Setting: general practices		
Recruitment: GPs asked to recruit 1st smoker coming to each surgery		
Defining eligibility criteria?: all participants were consulting within primary care for various reasons.		
Participant characteristics: 536 adult smokers, randomised to MI (270) or brief advice (266). 29% M. Mean age 41. Mean cpd 25.5		
Motivation to quit?: not selected on motivation		
1. Control: standardised brief advice (2 mins)		
Intervention: structural motivational counselling for 1 session (mean 10 mins)Provider: physicians		
Intensity: 1 x 10-minute session		
Was MI fidelity monitored?: no		
Definition of cessation used: point prevalence		
Length of longest follow-up: 6 months		
Validation: attempted, but abandoned		
Was mental health and/or well-being measured at follow-up?: no		
Was quality of life measured at follow-up?: no		



(Continued)

Funding source The Welsh Office of Research and Development for Health and Social Care

Author conflicts of interest Not reported

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	QUOTE: "Clinicians then opened sealed envelopes assigning patients to an intervention group. These numbered envelopes were filed in a study pack and clinicians were instructed to open them in order. Sequential blocks of six envelopes contained three allocations to each group, but the order varied." No further information given. Therefore, the methods for generating the allocation sequence are unclear.
Allocation concealment (selection bias)	Unclear risk	QUOTE: "Clinicians then opened sealed envelopes assigning patients to an intervention group. These numbered envelopes were filed in a study pack and clinicians were instructed to open them in order. Sequential blocks of six envelopes contained three allocations to each group, but the order varied." Unclear if envelopes were opaque
Blinding of outcome assessment (detection bias) All outcomes	Low risk	QUOTE: "Biochemical validation of quitting was attempted, but uptake was low and results did not alter conclusions from self-report data". Cessation was measured by self-report only, however the amount of contact was similar between arms. This means the risk of misreporting was likely to be similar across study arms.
Incomplete outcome data (attrition bias) All outcomes	Low risk	64/270 (24%) in the motivational arm and 54/266 (20%) in the brief advice arm lost to follow-up at 6 months

Catley 2016

cattey 2010			
Methods	Study design: RCT		
	Location: USA		
	Setting: university		
	Recruitment: through word of mouth, newspaper ads, flyers, billboards, Internet advertising, and physician referral using printed cards		
Participants	Defining eligibility criteria?: adult community resident smokers reporting low motivation and readiness to quit		
	Participant characteristics: 255 adult smokers; $110/255$ (43%) female; mean age: MI = 45.0, HE = 46.7, BA = 45.5; mean cpd: MI = 16.2, HE = 16.9, BA = 18.0; nicotine dependence: Severity of Dependence Scale (five-item dependence scale, with a score ranging from 0 to 15): MI = 6.6, HE = 6.9, BA = 5.7		
	Motivation to quit?: not motivated		
Interventions	Control 1: brief smoking cessation advice		
	Control 2: Health Education (HE) (intensity-matched comparison): the four-session HE intervention was based on the relevant risks of smoking, rewards of quitting and roadblocks to cessation of the US Clin-		



Catley 2016 (Continued)

ical Practice Guideline but excluded elements characteristic of MI. To ensure HE was distinct from MI, counsellors followed a script and presented information via a computer during in-person visits.

Intervention 1: Motivational Interviewing (MI): "The MI sessions were unscripted and counselors used the style (e.g. empathic, collaborative, and autonomy-supportive) and methods (e.g. open-ended questions, affirmations, and reflections) of MI. Counselors encouraged patient engagement in the conversation by exploring patient ambivalence regarding smoking cessation; developing discrepancy between the client's goals/values (e.g. health) and current behaviors (i.e. smoking); and increasing "change talk" while avoiding arguing or disputing "sustain talk." Provision of information was minimized and offered only when judged necessary. For participants who expressed an interest in quitting, the MI counselor worked to strengthen the commitment for change and used an MI style to complete the guideline-based quit plan and follow-up sessions as described above."

All participants who expressed any interest in quitting were offered a self-help guide and, for those who set a quit date, free pharmacotherapy (varenicline and NRT offered)

Provider: counsellors

Intensity: four sessions over a 6-month period

Was MI fidelity monitored?: "Each counselor delivered all three treatments. This avoided confounding counselor and treatment effects. To prevent treatment contamination, the HE and BA arms were scripted and stringent measures were implemented to ensure fidelity. Training, practice, and supervision for each of the interventions continued until counselors met fidelity criteria for three consecutive sessions (training hours per counselor were 96 for MI and 28.5 for HE). Counselors then began counseling enrolled participants and received regular group supervision of a randomly selected recent audio recording from separate expert clinicians for each of the interventions (weekly for MI, every other week for HE, and monthly for BA). Study-specific rating scales were completed to verify fidelity. To verify treatment integrity, the duration of sessions was assessed and randomly selected 10% of regular sessions (i.e. excluding quit plans and follow-ups) for evaluation (38 MI and 37 HE), using the MI Treatment Integrity Code by an independent expert coding group blind to group assignment. The Code yields ratings of counselor adherence to MI, including overall ratings of the session (e.g. expression of empathy) and behavior counts (e.g. frequency of open-ended questions)."

Outcomes

Definition of cessation used: 7-day point prevalence

Length of longest follow-up: 6 months

Validation: saliva cotinine

Was mental health and/or well-being measured at follow-up?: no

Was quality of life measured at follow-up?: no

Funding source

"This study was supported by a grant (R01 CA133068) from NIH, National Cancer Institute. Pfizer provided varenicline (Chantix) through Investigator- Initiated Research Support (No. WS759405)".

Author conflicts of interest

"Delwyn Catley reports grants from NIH, Patient-Centered Outcomes Research Institute (PCORI), and the National Multiple Sclerosis (MS) Foundation and non-financial support from Pfizer during the conduct of the study; Delwyn Catley occasionally received fees for providing Motivational Interviewing training. Kathy Goggin reports grants from NIH, PCORI, and the National MS Foundation and consultant fees for providing Motivational Interviewing training. Karen Williams reports personal fees from Proctor and Gamble (P&G) and from P&G Global Advisory Committee, during the conduct of the study but outside of the submitted work. Ken Resnicow occasionally conducts Motivational Interviewing training and reports personal fees from University of Missouri, Kansas City during the conduct of the study. Edward Ellerbeck reports grants from NIH. James Grobe reports research consulting fees from the University of Texas, Southwestern & Texas Women's University unrelated to the study. No other financial disclosures were reported by the authors of this paper."

Notes

Control groups merged for all analyses apart from the intensity subgroup analysis, where the intervention group was split and compared with the two separate control groups in the appropriate subgroups.



Catley 2016 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	QUOTE: "A predetermined computer-generated randomization sequence was prepared by the study statistician".
Allocation concealment (selection bias)	Low risk	QUOTE: "A predetermined computer-generated randomization sequence was prepared by the study statistician and provided in sealed opaque envelopes. After research assistants enrolled participants and baseline measures were collected, research assistants opened envelopes to allocate participants to treatment group."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Abstinence was biochemically verified. QUOTE: "self-report 7-day point-prevalence smoking abstinence was collected at 3 and 6 months, and verified biochemically at 6 months using saliva cotinine." "Although participants can differentiate whether they are in the BA versus MI or HE because of the different number of sessions, they are not informed in any way regarding the names, the nature, or distinctions between HE and MI and therefore will be blind to which of these two treatments they receive."
Incomplete outcome data (attrition bias) All outcomes	Low risk	QUOTE: "Logistic regression analyses revealed no significant differences in attrition rates between the groups (Figure 1), with overall completion rates of 89.4% (n = 228) at Month 6. 12/102 of MI group, 7/51 of BA group and 8/102 of the HE group were lost to follow-up, therefore attrition did not differ greatly across groups".

Colby 2005

Methods	Study design: RCT
	Location: USA Setting: hospital outpatient clinic or Emergency Department (ED), then over the phone Recruitment: in an eating disorder and an adolescent outpatient clinic at an urban hospital in the Northeast
Participants	Defining eligibility criteria?: adolescents (12 to 19 years of age)
	Participant characteristics: 85 adolescents; 60/85 (71%) female; mean age: 16.3; mean cpd: 10.5; nicotine dependence: mean FTND = 5.9
	Motivation to quit?: not selected on motivation
Interventions	Control: Brief Advice; pamphlet on quitting smoking and list of local treatment referrals
	Intervention: Motivational interview (MI). As control, plus feedback sheet, goal sheet, and information about strategies for quitting and coping with withdrawal. Interventionists contacted participants by telephone 1 week after baseline.
	Provider: counsellors
	Intensity: one 15 to 20-minute face-to-face session, plus one telephone call the following week



Colby 2005 (Continued)	essential elements of the protocol were rated as either 0 (topic not introduced), 1 (not at all useful), 2 (somewhat useful), or 3 (very useful)."		
Outcomes	Definition of cessation used: 7-day point prevalence		
	Length of longest follow-up: 6 months		
	Validation: CO validated (> 8 ppm) or cotinine validated (>= 15 ng/mL)		
	Was mental health and/or well-being measured at follow-up?: no		
	Was quality of life measured at follow-up?: no		
Funding source	"This study was supported by grant number 030330 from the Robert Wood Johnson Foundation. Additional support was provided by grant #DA11204 from the National Institute on Drug Abuse, and by two Department of Veterans Affairs Career Research Scientist Awards to Dr. Monti and Dr. Rohsenow."		
Author conflicts of interest	None stated		
Notes			

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not specified - only specified that allocation was random
Allocation concealment (selection bias)	Unclear risk	Not specified - only specified that allocation was random
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Research assistants were blind to treatment condition and assured confidentiality at each assessment. Biochemically verified
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up rates were 80% at 1 and 6 months and 86% at 3 months, and did not differ by group.

Colby 2012

Methods	Study design: RCT
	Location: USA Setting: "in a private setting", conducted face-to-face and via telephone Recruitment: from various sites: emergency department, hospital-based adolescent outpatient clinic, paediatrician's office, high schools. In medical settings, flyers advertising the study were posted and research staff proactively screened and recruited patients waiting for appointments/treatment. In schools, classroom presentations were made and table displays in school cafeterias provided study information during lunch. Adolescents in the general community who heard about the study through flyers, radio ads, and word of mouth called the research office and were screened for eligibility.
Participants	Defining eligibility criteria?: adolescent smokers aged 14 to 18 years
	Participant characteristics: 162 adolescents; 77/162 (47.5%) female; mean age: 16.2; mean cpd: intervention: 11.3; control: 9.2; nicotine dependence: mean Stanford Dependence Index: intervention:14.1; control: 13.5



Colby 2012	(Continued)
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Motivation to quit?: not selected on motivation

Interventions

Control: brief advice (BA) followed by a 5-minute telephone booster. Participants who reported quit attempts were praised; those who reported continued smoking were strongly encouraged to try to quit as soon as possible. Baseline parent assessment by telephone. Handouts on quitting smoking mailed to adolescents and parents.

Intervention: motivational interviewing: "Interventionists' therapeutic style followed MI principles (Miller 2002). The MI manual included the following sections: 1) establishing rapport; 2) exploring pros and cons of smoking and quitting; 3) delivery of computer-generated personalized assessment feedback; 4) imagining the future with and without smoking; 5) reviewing a menu of change options and developing a change plan; and 6) enhancing self-efficacy for change." MI participants were provided with the same handouts as in BA, and also received an assessment feedback sheet and change plan. The length of the baseline session was 45 min, with a 15 to 20-min telephone booster one week later, designed to reinforce progress toward goals. The interventionist assisted in problem-solving, discussed coping skills, promoted self-efficacy for change, and updated change plans if appropriate. Revised change plans were mailed to participants afterwards. This group also received a parent intervention: parents of MI participants took part in a 15 to 20-min discussion. This intervention was also designed to be consistent with MI principles, emphasised the adolescent's responsibility for making decisions/changes related to smoking, and focussed on increasing parent support for the adolescent's goals for changing smoking, increasing clear communication, and establishing home smoking rules. Interventionists used open-ended questions to elicit information about the parent's attitudes and behaviour relevant to these topics and, based on parent interest, introduced strategies for enhancing communication, enforcing household smoking restrictions, and reinforcing adolescent efforts toward change goals.

Provider: counsellors

Intensity: 1 x 45-minute session and 1 x 15 to 20-minute booster call

Was MI fidelity monitored?: "Interventionists participated in weekly group supervision. Post-MI and BA, interventionists and adolescent participants completed session ratings."

Outcomes

Definition of cessation used: 7-day point prevalence

Length of longest follow-up: 6 months

Validation: expired air CO (< 9 ppm); saliva cotinine (< 14 ng/mL)

Was mental health and/or well-being measured at follow-up?: no

Was quality of life measured at follow-up?: no

Funding source

"Funded by NIDA grant # 1R01 DA11204. Preparation of the manuscript was also supported by NIAAA grant # 1R01 AA016000 and NIDA grant # 1T32 DA016184. NIDA and NIAAA had no further role in study design; in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the paper for publication."

Author conflicts of interest

"All authors declare that they have no conflicts of interest".

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	QUOTE: "A computer-generated random number sequence allocated participants to treatment groups prior to enrollment".
Allocation concealment (selection bias)	Unclear risk	QUOTE: "assignments were sealed in envelopes which were filed in a series of sequentially numbered folders. Interventionists used folders in order and



Colby 2012 (Continued)		completed baseline assessment before opening the envelope." However, it was not stated whether envelopes were opaque, hence unclear rating.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	QUOTE: "Two biochemical markers were used to validate self-reported abstinence at follow up"; QUOTE: "all interviewers were blind to condition assignment during assessments".
Incomplete outcome data (attrition bias) All outcomes	Low risk	QUOTE: "There were no significant group differences on booster or follow-up completion rates". Follow-up rates at 6 months: MI (n = 61; 77.2%); BA (n = 71; 85.5%)

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Study design: factorial RCT (4 factors, 16 trial arms)
Location: USA Setting: primary care clinics Recruitment: smokers were invited during primary care clinic visits to participate in a research program to help them to reduce their smoking. Those interested were referred electronically to the research office.
Defining eligibility criteria?: adult smokers with no interest in quitting in the next 30 days but willing to cut down
Participant characteristics: 517 adult smokers; 328/517 (63.4%) female; mean age: 47; mean cpd: 17.5; nicotine dependence: mean FTND = 4.8
Motivation to quit?: not motivated to quit
Intervention factors:

- 1. Motivational interviewing: initial 20-minute in-person counselling session followed by three biweekly, 10-minute counselling calls over the 6-week intervention period. Based on Miller & Rollnick (Miller 2002), the counselling sessions included motivation-building exercises to reinforce intrinsic motivation and to help participants overcome ambivalence about quitting. Case managers engaged participants
- and to help participants overcome ambivalence about quitting. Case managers engaged participants in a series of motivation building exercises such as reviewing feelings and thoughts about the pros and cons of quitting and smoking, reinforcing the positives of quitting, helping to dispel myths and concerns about the negatives of quitting, and posing questions about the "good" aspects of smoking.
- 2. Behavioural smoking reduction counselling: initial 20-minute in-person counselling session followed by six weekly 10-minute counselling calls. During these sessions, participants set smoking reduction goals and developed reduction strategies (e.g. delaying smoking, eliminating smoking in specific situations). Participants were also instructed to record daily smoking, which case managers used to identify successes and challenges.
- 3. Nicotine gum: participants were instructed to use 2 mg gum for the 6-week intervention period (≥ nine per day, one piece per 1–2 hours) in place of smoking.
- 4. Nicotine patch: participants were instructed to use 14 mg patches daily for the 6-week intervention period.

Where all intervention factors were OFF, this resulted in a 'no treatment' condition.

Provider: counsellors

Intensity: 1 x 20 minutes face-to-face session, followed by fortnightly 10-minute phone calls

Was MI fidelity monitored?: no

Outcomes Definition of cessation used: 7-day point prevalence



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Length of longest follow-up: 26 weeks

Validation: none

Was mental health and/or well-being measured at follow-up?: no

Was quality of life measured at follow-up?: no

Funding source

"This research was supported by grants 9P50CA143188 and 1K05CA139871 from the National Cancer Institute to the University of Wisconsin Center for Tobacco Research and Intervention and by the Wisconsin Partnership Program. This work was carried out in part while T.R.S. was a Primary Care Research Fellow supported by a National Research Service Award (T32HP10010) from the Health Resources and Services Administration to the University of Wisconsin Department of Family Medicine. W.-Y.L. is also supported by NSF grant DMS-1305725. L.M.C. is also supported by NIH grants P50DA10075 and R01D-K097364. J.W.C. is supported by Merit Review Award 101CX00056 from the US Department of Veterans Affairs."

Author conflicts of interest

"The authors have received no direct or indirect funding from, nor do they have a connection with, the tobacco, alcohol, pharmaceutical or gaming industries or anybody funded substantially by one of these organizations. W.-Y.L. is supported partially by a grant from Eli Lilly and Company for research that is unrelated to smoking or tobacco dependence treatment."

Notes

In-line with guidance in the Cochrane Handbook, we looked for potential interactions between the factors in this factorial trial. An interaction between the MI and nicotine gum factor was reported by the authors. Rather than exclude data from this trial from analyses, which we believe would introduce bias we accounted for the risk of bias potentially introduced by this interaction in our 'Risk of bias assessment' below and carried out sensitivity analyses removing it from analyses alongside other studies judged to be at high risk of bias.

For the MI versus no treatment analyses, we compared the one study arm with MI and no other smoking cessation treatment (behavioural reduction, gum and patch) to the one study arm with no MI and no other smoking cessation treatment. For the analyses comparing MI plus other SC treatment to other treatment alone, we compared any study arms receiving MI plus reduction and/or nicotine gum, and/or nicotine patch to study arms receiving reduction, and/or nicotine gum, and/or nicotine patch with no MI. For the analyses comparing MI to another form of smoking cessation treatment, we compared the one study arm receiving MI and no other smoking cessation treatment (behavioural reduction, gum and patch) to all study arms receiving reduction and/or nicotine gum, and/or nicotine patch.

Where relevant (analyses 2 and 3), we have ensured that study arms that received nicotine gum have been entered into analyses separately to study arms that did not receive nicotine gum.

Risk of bias

Bias Authors' judgement S		Support for judgement		
Random sequence generation (selection bias)	Low risk	Participants were randomised to treatment conditions using stratified permuted, computer-generated block randomisation; stratified by gender and clinic with a fixed block size of 16 based on the 16 unique possible combinations of intervention components (in random order within each block).		
Allocation concealment (selection bias)	Unclear risk	No information provided		
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-report (no biochemical validation). The lack of MI meant that participants had less face-to-face contact and less intensive support in some of the comparison trial arms.		
Incomplete outcome data (attrition bias) All outcomes	Low risk	There were no significant differences in missing data across the contrastilevels of each intervention factor. 46/253 (18%) were lost to follow-up in groups and 37/264 (14%) in the non-MI groups.		



Cook 2016 (Continued)

Other bias High risk This is a factorial trial and an interaction was found between motivational in-

terviewing and nicotine gum. This was not an a priori hypothesised interaction, and challenged the assumption that the factors studied were indepen-

dent.

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Bias	Authors' judgement Support for judgement		
Risk of bias			
Notes	The outcome used for meta-analysis was point prevalence reported at both 1 m and 6 m (i.e. cross between point prevalence and prolonged abstinence). This outcome was used as for all others, the manner of reporting made it impossible to tell which time point numbers referred to (i.e. abstinent at 1 m or 6 m).		
Author conflicts of interest	Not reported		
Funding source	A grant from The Arizona Disease Control Research Commission		
	Was quality of life measured at follow-up?: no		
	Was mental health and/or well-being measured at follow-up?: no		
	Validation: urinary cotinine		
	Length of longest follow-up: 6 months		
Outcomes	Definition of cessation used: point prevalence		
	Was MI fidelity monitored?: "All tapes were reviewed for adherence to the protocol and weekly meetings were held with the study nurses. Sessions not reaching criterion were removed from the analyses".		
	Intensity: 1 x 15-minute session		
	seeking to establish supportive and empathic alliance Provider: nurses		
	Intervention: 15-min motivational interview regarding smoking. Motivational interviewing described as		
Interventions	Control: Prescriptive 15-min interview regarding smoking. Described as the current dominant approach (i.e. usual care), which maintains a firm and authoritative approach		
	Motivation to quit?: not motivated		
	Participant characteristics: 218 adult smokers randomised to intervention (109) and control (109), 45% female; mean age 37.6. cpd: 25.4		
Participants	Defining eligibility criteria?: unmotivated adult smokers		
	Location: USA Setting: laboratory Recruitment: precontemplative and contemplative smokers were recruited from the community through advertisements and direct recruitment (no further explanation). Participants were offered USD 25 for participation.		
Methods	Study design: RCT		



Davis 2011 (Continued)		
Random sequence generation (selection bias)	Unclear risk	QUOTE: "participants completed informed consent, baseline assessments, and were randomized to receive either a 15-min motivational or prescriptive interview". No further information given
Allocation concealment (selection bias)	Unclear risk	QUOTE: "participants completed informed consent, baseline assessments, and were randomized to receive either a 15-min motivational or prescriptive interview". No further information given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Cessation was verified through urinary cotinine levels.
Incomplete outcome data (attrition bias) All outcomes	Low risk	47/116 (41%) in the motivational arm and 61/114 (54%) in the prescriptive arm were lost to follow-up at 6 months. Overall less than 50% loss to follow-up - similar rates between arms

De Azevedo 2010

Methods	Study design: RCT			
	Location: Brazil Setting: public university hospital Recruitment: patients admitted to a public university hospital approached by research team to take part - screening interview took place at patients' bedside within 72 hours of admission			
Participants	Defining eligibility criteria?: hospital inpatients for variety of reasons			
	Participant characteristics: 273 adult smokers randomised to intervention (141) and control (132), 63.6% M; mean age 47; cpd (range = 11 to 20)			
	Motivation to quit?: not selected on motivation			
Interventions	1. Control: 15-min session of individual counselling where participants were advised to stop smoking. Counsellor reviewed the dangers of smoking and benefits of quitting. The counsellor suggested that, after discharge, the participant should seek help to stop smoking.			
	2. Intervention: 30-min session of individual counselling consisting of a motivational interview, after hospital discharge. Participants were given 7 follow-up telephone calls over 6 m (at 1, 2 and 3 weeks, and at 1, 2, 3 and 4 m). Each call lasted 10 mins. It was an opportunity to reinforce motivation for stopping smoking (or maintaining abstinence). Style of interview was in line with MI performed during hospitalisation.			
	Intervention provider: smoking cessation advisor			
	Intensity: 1×30 -minute session with 7×15 -minute follow-up calls over 4 months			
	Was MI fidelity monitored?: "Counselors and main researchers met fortnightly along the study period for clarification of any doubt that might have arisen."			
Outcomes	Definition of cessation used: 7-day point prevalence			
	Length of longest follow-up: 6 months			
	Validation: none			
	Was mental health and/or well-being measured at follow-up?: no			
	Was quality of life measured at follow-up?: no			



D	e <i>F</i>	Azev	edo	2010	(Continued)
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Funding source	A grant from the Research Foundation of the State of São Paulo (grant no. 06/61885-6)
Author conflicts of interest	Not reported
Notes	There were 3 arms in the study; however, the usual-care arm was not randomised, so was not eligible for the review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	QUOTE: "An allocation sequence based on a random-number table was used to randomly assign all enrolled subjects to either LII or HII."
Allocation concealment (selection bias)	Low risk	QUOTE: "The allocation was maintained in a serially numbered, opaque envelope, which was opened at the Phase 2 interview to prevent counselor bias."
Blinding of outcome as- sessment (detection bias) All outcomes	High risk	Abstinence was obtained via self-report and the amount of researcher-participant contact varied between trial arms.
Incomplete outcome data (attrition bias) All outcomes	Low risk	34/141 (24%) participants in the MI intervention group and 24/132 (18%) in the control group were lost to follow-up. Less than 50% lost overall and similar between groups

Demétrio Faustino-Silva 2018

Methods	Study design: cluster RCT			
	Location: Brazil Setting: primary care smoking cessation clinics Recruitment: from smoking groups performed by the primary care teams of the Conceição Hospitalar Group, Porto Alegre, Brasil			
Participants	Defining eligibility criteria?: adult smokers motivated to quit			
	Participant characteristics: 329 adult smokers; gender not provided; mean age: not provided; mean cpd: not provided; nicotine dependence: not provided			
	Motivation to quit?: motivated (already attending smoking group)			
Interventions	Control: traditional CBT, as advocated by the Brazilian Ministry of Health's smoking programme			
	Intervention: motivational interviewing: "The professionals who coordinated the smoking groups were trained to use Motivational Interviewing as an additional resource to the motivation and cognitive-behavioral approach usually performed in the groups."			
	Provider: Smoking cessation advisors			
	Intensity: not reported			
	Was MI fidelity monitored?: none reported			
Outcomes	Definition of cessation used: 30-day point prevalence			
	Length of longest follow-up: 11 months			
	Validation: none			



Demétrio Faustino-S	silva 20:	18 (Continued)
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Was mental health and/or well-being measured at follow-up?: no

Was quality of life measured at follow-up?: no

Funding source	Not reported
Author conflicts of interest	Not reported
Notes	Information from conference abstract. Limited information available on how clustering dealt with. We entered data as presented in abstract and carried out sensitivity analysis applying the ICC of another similar study (Vidrine 2019).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised; no further information given
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Did not look as though any biochemical validation took place and it was unclear whether the amount of contact with investigators was the same across study arms
Incomplete outcome data (attrition bias) All outcomes	Low risk	The numbers lost to follow-up were less than 50% overall and similar between groups (34.8% in MI group; 42.4% in control group).

Ellerbeck 2009

Methods	Study design: randomised controlled trial			
	Location: Kansas, USA Setting: rural primary care practices Recruitment: from 50 rural primary care practices in the Kansas Physicians Engaged in Prevention Research network. Trained medical students systematically screened patients, identified smokers, and recruited them for the study, obtaining consent. Participants' contact information was forwarded to research staff who contacted them via telephone, verified eligibility, and conducted the baseline survey.			
Participants	Defining eligibility criteria?: primary care patients			
	Participant characteristics: 726 adult smokers randomised to intervention (482) and control (244), 58.5% female; mean age 47.2; cpd 23.7			
	Motivation to quit?: general population (not selected on motivation)			
Interventions	Intervention: high intensity: educational support, telephone counselling, periodic progress reports with counselling suggestions faxed to their physician, and a 6-monthly personalised KanQuit newsletter with tips on quitting smoking. Offered up to 6 counselling calls every 6 months to either promote quitting or prevent relapse. Counsellors used MI techniques and followed a semi-structured protocol.			
	Control: moderate-intensity MI: as intervention, however were only offered up to 2 telephone-based counselling sessions every 6 months (1 session to promote a quit attempt and 1 additional follow-up session for those who made a quit attempt).			
	Provider: counsellors			



Εl	lerbec	k 2009	(Continued)
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Intensity: twice every 6 months in moderate intensity arm; 6 times every 6 months in high intensity arm

Was MI fidelity monitored?: "After each session, counsellors were asked to complete a checklist asking about several of the key concepts of MI that served as process markers of appropriate MI delivery (e.g. rolling with resistance, making appropriate reflective statements, encouraging change talk) and a checklist asking about specific content that should have been covered per the MI protocol guiding the sessions (e.g. pros/cons of quitting, developing behavioural action plan). Counsellors rated themselves and during supervision they were also rated using motivational interview markers."

Outcomes

Definition of cessation used: 7-day point prevalence

Length of longest follow-up: 24 months

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 24 months was a mixture of the 2 approaches.

Was mental health and/or well-being measured at follow-up?: no

Was quality of life measured at follow-up?: no

Funding source

A grant from the National Cancer Institute (R01-101963). Study medication provided by GlaxoSmithK-

Author conflicts of interest

Authors reported no conflicts.

Notes

We compared the high intensity MI group and the moderate intensity MI group in this review and in our analyses investigating the intensity of MI counselling support. The study also included a 'pharma-cotherapy alone' condition; however this was not relevant to this review as it included non-MI intervention components that were not received by the two MI intervention groups.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	QUOTE: "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 (selection bias)	Low risk	QUOTE: "To conceal allocation, we placed these [allocation] cards in sequentially numbered, opaque, sealed envelopes. After research assistants verified participant eligibility and completed the baseline assessment, the project director opened the next sequential sealed envelope and determined the participant's treatment allocation."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	QUOTE: "Abstinence validated by salivary cotinine measurement (15 ng/mL) or a significant other."
Incomplete outcome data (attrition bias) All outcomes	Low risk	50/249 (20%) in the moderate intensity disease management group and 47/251 (19%) in the high intensity disease management were lost to follow-up at the final follow-up (month 24).

Harris 2010

Methods Study design: cluster RCT



Harris 2010 (Continued)	Location: USA Setting: university			
		e recruitment at fraternity and sorority chapter meetings at 1 large Midwestern of 3 academic years (2006 - 2008)		
Participants	Defining eligibility crite	eria?: university students (sorority or fraternity members)		
		stics: 452 adult smokers (college students) randomised to intervention (245) and ; mean age 19.5; cpd 3.5		
	Motivation to quit?: ge	neral population (not selected on motivation)		
Interventions	tion of fruits and veget ly every other week fol weeks after session 3. S	cessation treatment - up to 4 sessions of MI focussed on increasing consumpables to at least 5 servings a day. The first 3 sessions occurred approximate-lowing baseline assessment and the fourth session occurred approximately 4 Sessions were typically 20 to 30 mins. A self-help guide on the benefits and meth-l vegetables was given to participants.		
	rette smoking. The firs fourth approximately ² became motivated to o a 'plan module' in whic	sessions of MI focussed on motivating and assisting participants to quit cigatt 3 sessions occurred approximately every other week following baseline and the 4 weeks after session 3. Sessions were typically 20 to 30 mins. For students who change during the sessions, counsellors used a MI style to follow the outline of ch cognitive—behavioural principles were used to develop a change plan. A selfwas also given to participants.		
	All students who smok the university and othe	ed at a high level were encouraged to use pharmacotherapy obtainable througher resources.		
	Provider: clinical or counselling psychology students (counsellors)			
	Intensity: 4 x 20 to 30-min sessions over 7 weeks			
	Was MI fidelity monitored?: "We assessed fidelity to MI using supervisors' rating of counselors' in-session proficiency on 18 items, including reflective listening, asking permission, and MI spirit, used in prior studies".			
Outcomes	Definition of cessation used: 30-day point prevalence			
	Length of longest follo	w-up: 6 months		
	Validation: saliva cotin	ine ≤ 15 ng/mL		
	Was mental health and	l/or well-being measured at follow-up?: no		
	Was quality of life measured at follow-up?: no			
Funding source	A grant from the Nation	nal Cancer Institute (R01CA107191)		
Author conflicts of interest	"The authors declare that there are no conflicts of interest".			
Notes	An ICC of 0.003 is reported, which implied (30 clusters, n = 452) a design effect of $1 + (452/30 - 1) \times 0.003$ = 1.0422. We applied this design effect to account for clustering in our analysis.			
Risk of bias				
Bias	Authors' judgement	Support for judgement		
Random sequence generation (selection bias)	Unclear risk	QUOTE: "For each cohort, after all students completed the baseline survey, fraternities and sororities were randomized to either treatment (smoking) or comparison (fruits/vegetables) conditions without blocking". No further information given		



Harris 2010 (Continued)		
Allocation concealment (selection bias)	Unclear risk	QUOTE: "For each cohort, after all students completed the baseline survey, fraternities and sororities were randomized to either treatment (smoking) or comparison (fruits/vegetables) conditions without blocking". No further information given
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Cessation was verified using cotinine and amount of contact matched between trial arms.
Incomplete outcome data (attrition bias) All outcomes	Low risk	25/245 (10%) in the MI for smoking cessation group and 23/207 (11%) in the MI for fruits and vegetables group were lost to follow-up. Therefore, loss to follow-up was low and similar between groups.

Helstrom 2007

Methods	Study design: RCT			
	Location: USA Setting: community Recruitment: "Participants identified from larger longitudinal study of problem drinking in adolescents. Eligible adolescents were located through telephone calls to randomly generated telephone numbers."			
Participants	Defining eligibility criteria?: adolescent offenders who had been arrested or given notice to appear in court			
	Participant characteristics: 81 adolescent smokers; 34/81 (42%) female; mean age: 16; mean cpd: intervention: 11.22; control: 9.56; nicotine dependence: not reported			
	Motivation to quit?: not selected on motivation			
Interventions	Control: tobacco education: an information session based on a pamphlet about tobacco use by the American Cancer Society			
	Intervention: motivational enhancement therapy (MET): MET sessions began with individualised feed-back about participants' smoking based on information from the baseline assessment. Then, participants' likes/dislikes, beliefs, and pattern of tobacco use were discussed and participants were assisted in identifying goals for behaviour change and addressing their ambivalence about their smoking. For participants ready to make changes, cessation strategies were provided, goals were defined, and a behaviour change plan was developed.			
	Provider: not specified			
	Intensity: one session - duration not specified			
	Was MI fidelity monitored?: no			
Outcomes	Definition of cessation used: 28-day point prevalence			
	Length of longest follow-up: 6 months			
	Validation: salivary cotinine (<= 15 ng/mL)			
	Was mental health and/or well-being measured at follow-up?: no			
	Was quality of life measured at follow-up?: no			
Funding source	Research supported by "a grant from the National Institute on Drug Abuse awarded to the first author (DA13182-02)"			



Helstrom 2007 (Continued)

Author conflicts of interest Not reported

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection bias)	Unclear risk	No methods specified beyond reporting that participants were randomly allocated	
Allocation concealment (selection bias)	Unclear risk	No methods specified beyond reporting that participants were randomly allocated	
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Cessation was verified using salivary cotinine.	
Incomplete outcome data (attrition bias) All outcomes	Low risk	Fewer than 50% of participants dropped out overall; there was a difference in dropout rates between groups (6.7% in the MET arm and 25% in the education control arm), however this did not meet the threshold advised by the Cochrane Tobacco Addiction Group (difference of 20% or more in follow-up between arms) to signal a 'high' risk of bias.	

Hollis 2007

Methods	Study design: factorial RCT (3 x 2)
	Location: Oregon USA Setting: community-based telephone quit-line programme Recruitment: callers to quit-line invited to participate
Participants	Defining eligibility criteria?: quit-line callers
	Participant characteristics: 4614 smokers randomised to: brief counselling (872, no NRT; 868, with NRT), moderate counselling (718, no NRT; 715, with NRT), or intensive counselling (720, no NRT; 721, with NRT). 60% female, mean age 41. Mean cpd 21.
	Motivation to quit?: as participants were callers to a telephone quit-line, they were assumed to be fully or partly motivated to quit.
Interventions	Two factors: intensity of MI counselling and NRT versus no NRT. The three levels of the intensity factor were as follows:
	 Single brief (15-min) negotiation based on MI (usual care), 15-min call + referral material + tailored self-help materials Moderate counselling (40-min) based on MI + 1 brief call to encourage use of community services, tailored self-help materials
	3. Intensive counselling (as moderate counselling, plus offer of ≤ 4 additional telephone calls). Each call incorporated MI techniques, stage assessment and relapse prevention as needed.
	NRT offered free to the 'with NRT' groups
	NRT offered free to the 'with NRT' groups Provider: smoking cessation advisors



	ularly on adherence to	key elements of each protocol."		
Outcomes	Definition of cessation used: 30-day point prevalence			
	Length of longest follo	w-up: 12 months		
	Validation: none			
	Was mental health and	/or well-being measured at follow-up?: no		
	Was quality of life measured at follow-up?: no			
Funding source	A grant from the National Cancer Institute (R01 CA86242). Nicotine patches supplied by GlaxoSmithK-line			
Author conflicts of interest	"JFH, JLF and KR have no competing interests. TAMcA and SMZ are with Free & Clear, Inc, which is a for- profit company providing telephone counselling services."			
Notes	We compared the brief intensity MI to the high intensity MI in our analyses. NRT versus no NRT groups were combined as no interaction effects were detected.			
Risk of bias				
Bias	Authors' judgement	Support for judgement		
Random sequence genera-	Low risk	QUOTE: "a computer algorithm randomly assigned participants".		

tion (selection bias)				
Allocation concealment (selection bias)	Low risk	QUOTE: "a computer algorithm randomly assigned participants".		
Blinding of outcome assessment (detection bias) All outcomes	High risk	No validation of cessation and amount of contact varied between arms		
Incomplete outcome data (attrition bias) All outcomes	Low risk	550/1740 (32%) of the brief groups; 448/1433 (31%) of the moderate groups and 497/1441 (35%) of the intensive groups were lost to follow-up at the 12-month follow-up. Therefore, loss to follow-up overall was less than 50% and similar between arms.		

Kelly 2006

Methods	Study design: RCT				
	Location: Australia Setting: community Recruitment: high school students caught smoking were recruited. "Participants were included if the drug of concern was tobacco and if parent/guardian active informed consent was obtained."				
Participants	Defining eligibility criteria?: high school student smokers aged 14 to 16 years				
	Participant characteristics: 56 adolescent smokers; 19/56 (34%) female; mean age: 15; mean cpd: 7.4; nicotine dependence: mean nicotine dependence (MTFQ): 3.6				
	Motivation to quit?: not selected on motivation				



Kelly 2006 (Continued)

Interventions

Control: standard care: included an education about the broad effects of smoking regardless of the participant's experience. Built on a widely used psychoeducation model, where knowledge dissemination/attainment was assumed to result in change. This involved reviewing reading materials on the effects of smoking (and other drugs) and a 'Quit kit' on smoking.

Intervention: MI: explored the meaning of smoking in participants' lives, the positives and negatives of smoking/quitting, the impact of smoking on self-concept, health goals, and identification of obstacles to goal attainment. The intervention included information only where relevant to the participant's direct experiences (e.g. effects of smoking on respiration if breathlessness in sport was reported).

All participants provided with reading materials

Provider: "The two interventions were delivered by the second author (KL), a PhD candidate and registered psychologist, with 4 years experience in adolescent psychotherapy." (counsellor/psychologist)

Intensity: single 1-hour session

Was MI fidelity monitored?: "The therapy manual documented a number of behavioral indices that would normally characterize close adherence to the two interventions. Relative to the SC condition, the MI intervention would normally be characterized by: more talking by the participant than the therapist, open probes, summary statements aimed to develop discrepancy, asking permission of the student to extend/expand the content focus, and reflexive delivery of intervention components. The therapist regularly completed a behavioral checklist for each session to reduce content drift/contamination and promote discussion during supervision."

Outcomes

Definition of cessation used: 30-day point prevalence abstinence

Length of longest follow-up: 6 months

Validation: none

Was mental health and/or well-being measured at follow-up?: no

Was quality of life measured at follow-up?: no

Funding source

"The manuscript was completed during an NHMRC Career Development Award to the first author. The study was funded by NHMRC Project 189414 awarded to the first author."

Author conflicts of interest

Not reported

Notes

Risk of bias

Bias Authors' judgement Support for ju		Support for judgement
Random sequence generation (selection bias)	Unclear risk	QUOTE: "Students were randomly assigned to either the MI or SC conditions." No further information provided
Allocation concealment (selection bias)	Unclear risk	QUOTE: "Students were randomly assigned to either the MI or SC conditions." No further information provided
Blinding of outcome assessment (detection bias) All outcomes	High risk	Smoking status measured by self-report; MI was one hour but length of SC not stated. SC appeared to include less contact with therapist.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition was less than 50% overall and similar between groups according to the standard practice of the Cochrane Tobacco Addiction Group (6/30; 20% in MI group; 8/26; 31% in standard care group).



Methods	Study design: RCT			
	Location: USA Setting: hospital and over telephone Recruitment: from inpatients admitted to the University of Wisconsin Hospital and clinics who expressed an interest in quitting smoking			
Participants	Defining eligibility criteria?: hospital inpatient smokers interested in quitting			
	Participant characteristics: 185 adult smokers; 85/185 (46.0%) female; mean age: control: 43, intervention: 44.7; mean cpd: control: 22.5, intervention: 24.9; nicotine dependence: mean FTND = control: 6.6, intervention: 6.9			
	Motivation to quit?: motivated			
Interventions	Control: minimal care: brief (2–3 min) motivational message to quit smoking and a copy of the National Cancer Institute's Clearing the Air self-help smoking cessation pamphlet			
	Intervention: counselling and placebo patch: as control, plus a placebo nicotine replacement patch, and a study nurse provided brief (10 to 15 minute) phone counselling at 1, 3, 6, and 24 weeks after the initiation of patch treatment. Phone counselling incorporated basic techniques of cognitive-behavioural therapy and motivational interviewing. The nurse also frequently reminded participants of the Clearing the Air pamphlets and encouraged them to look over the pamphlet between sessions.			
	Provider: nurse			
	Intensity: five 10 to 15-minute sessions over 24 weeks			
	Was MI fidelity monitored?: no			
Outcomes	Definition of cessation used: 7-day point prevalence			
	Length of longest follow-up: 24 weeks			
	Validation: expired carbon monoxide <= 10 ppm			
	Was mental health and/or well-being measured at follow-up?: no			
	Was quality of life measured at follow-up?: no			
Funding source	"This research was supported by a research grant provided by the Elan Pharmaceutical Research Corporation, Gainsville, Georgia, and Athlone, Ireland."			
Author conflicts of interest	Not specified			
Notes	This study also included an additional intervention arm, which was the same as the intervention arm reported above but included active rather than placebo nicotine patch. This study arm was not eligible for this review and was not included in analyses as the use of pharmacotherapy was not matched to the control arm.			
Disk of higs				

Risk of bias

Random sequence genera- Low risk Quote		pport for judgement	
		Quote: "The patient was randomized to either the MC condition or a patch condition using a predetermined computer-generated randomization code."	
Allocation concealment (selection bias)	Unclear risk	Quote: "The patient was randomized to either the MC condition or a patch condition using a predetermined computer-generated randomization code."	



Lewis 1998	(Continued)
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Blinding of outcome assessment (detection bias) All outcomes Low risk Cessa

Cessation was biochemically verified.

Incomplete outcome data (attrition bias)
All outcomes

Unclear risk

Dropout rates not reported

Lloyd-Richardson 2009

Methods Study design: RCT

Location: USA

Setting: immunology clinics (6 outpatient HIV clinics and 2 primary care medical offices)

Recruitment: patients who smoked, were deemed eligible to participate by their physician, and were willing to speak with a health educator (HE) were referred to the study.

Participants

Defining eligibility criteria?: HIV-positive

Participant characteristics: 444 HIV-positive, adult smokers, randomised to intervention (232) and con-

trol (212); 56.7% female; mean age 42.0; cpd 18.3

Motivation to quit?: not selected on motivation

Interventions

1. Control: NRT + brief standard care intervention (SC). 2 brief sessions, including brief assessment of quitting plans. Participants returned to the clinic biweekly for distribution of additional patches, allowing the counsellors to briefly (5 mins) reinforce quit efforts, check on patch side effects and answer questions. HEs were instructed to provide praise of participant's efforts and answer any questions asked, but not to initiate additional discussion of the quit effort. Participants unwilling to set a quit date were instructed to contact the counsellor when ready. This reflects the minimum standard of care recommended by the Agency for Health Research and Quality (AHRQ).

2. Intervention: NRT + intensive motivationally enhanced counselling intervention (ME). Participants received 4 30-min intervention sessions, as well as a quit-day counselling call. Quit dates determined by individual participants in consultation with counsellors. MI elements delivered throughout all contacts. Participants not willing to set a quit date were engaged in discussion of 'quitting as a process' and barriers to quitting.

Provider: counsellors

Intensity: 4 biweekly medication contacts plus 5 counselling contacts

Was MI fidelity monitored?: "We monitored the delivery of both intervention conditions by: (i) audio-taped supervision on a random subsample of counseling sessions; (ii) patient exit interviews (conducted by the intervention-blinded research assistant); and (iii) documentation of time spent in each intervention. To examine fidelity to each intervention protocol, two independent raters reviewed audio tapes of 20% of all sessions and rated (i) the degree to which intervention providers of the ME intervention adhered faithfully to the spirit of motivational interviewing (i.e. establish rapport, express empathy, reflective listening, explore ambivalence); and (ii) the degree to which there was contamination across conditions."

Outcomes

Definition of cessation used: 7-day point prevalence

Length of longest follow-up: 6 months

Validation: exhaled CO (< 10 ppm)

Was mental health and/or well-being measured at follow-up?: no



Llo	vd-R	ichard	lson	2009	(Continued)
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Funding source	Grants from the National Institute of Drug Abuse (R01-DA12344-06), the National Heart, Lung and Blood Institute (K23-HL069987), the National Cancer Institute (K07-CA95623), the NIH-funded Transdiscipli-
	nary Tobacco Use Research Center (P50 CA084719), NIH-funded Lifespan/Tufts/Brown Center for AIDS Research (P30 AI42853), and by the Robert Wood Johnson Foundation

Author conflicts of interest Paper stated that authors had no declarations of conflicts of interests.

Notes Different Ns and different loss to follow-up allocated to intervention and cont

Different Ns and different loss to follow-up allocated to intervention and control arms in the results section in comparison to the participant flow chart. Table 1 seemed consistent with text. Data inferred based on this assumption as there was no response to a data request from authors

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	QUOTE: "Patients were then randomized (using block randomization) to ensure stratification by gender and level of motivation to quit smoking". No further information provided
Allocation concealment (selection bias)	Unclear risk	QUOTE: "Patients were then randomized (using block randomization) to ensure stratification by gender and level of motivation to quit smoking". No further information provided
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Cessation validated using exhaled carbon monoxide measures
Incomplete outcome data (attrition bias) All outcomes	Low risk	60/212 (28%) in the intervention (ME) group, and 66/232 (28%) in the control (SC) group were lost to follow-up at 6 months. Therefore, rates were similar between groups.

Louwagie 2014

Methods	Study design: RCT
	Location: South Africa Setting: tuberculosis (TB) clinics
	Recruitment: newly diagnosed adult patients initiating TB treatment were approached to participate.
Participants	Defining eligibility criteria?: TB patients initiating TB treatment
	Participant characteristics: 409 adult smokers newly diagnosed with TB randomised to intervention (205) and control (204); 10% female; mean age 41.3; cpd 10.0
	Motivation to quit?: not selected on motivation
Interventions	Control (brief smoking cessation advice): the following short standardised smoking cessation message from the TB nurse: "Tobacco use is extremely harmful for your health. If you stop smoking now, your TB will heal better and you will have a lower risk of getting TB again in the future. You will also reduce your risk of heart disease and cancer and protect your children against TB. As a professional nurse, I advise you to stop using tobacco in the interests of your health", plus a smoking cessation booklet supplied by the National Council against Smoking of South Africa
	2. Intervention (brief motivational interviewing): as control, plus a brief motivational interviewing session (15 to 20 mins) consisting of a quick assessment, the participant identifying problems and solu-



Louwagie 2014	(Continued)
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tions and the setting of targets. Participants already highly motivated to quit were helped to design a quit plan.

Provider: lay healthcare workers

Intensity: single 15 to 20-minute session

Was MI fidelity monitored?: no

Outcomes

Definition of cessation used: 7-day point prevalence

Length of longest follow-up: 6 months

Validation: only occurred in small subset of participants and so has not been used; however outcomes were the same with validation. As participants did not know whether the monitor was allocated to their clinics at specific time points, this approach introduced a 'bogus pipeline' procedure, thus increasing the likelihood of truthful answers.

Was mental health and/or well-being measured at follow-up?: no

Was quality of life measured at follow-up?: no

Funding source

Grants from the KNCV Tuberculosis Foundation (12.402.2/MvdW/U.10.0696/cal), and the National Research Foundation of South Africa (80843), and by the Global Bridges Health Care Alliance for Tobacco Dependence Treatment

Author conflicts of interest

"K.O. received Pfizer funding for an FDA-approved research project (unrelated to this project) involving the use of nicotine patch, bupropion and varenicline. O.A.A.-Y. is a sub-awardee of an unrestricted Pfizer Education grant to Mayo Clinic for the Global Bridges Health Alliance project and received an honorarium as a speaker at the 2012 congress of the South African Dental Association for a session on treatment funded by Pfizer".

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	QUOTE: "The randomization sequence was generated by an independent epidemiologist who was not otherwise involved in the research project, with a 1:1 allocation and random block sizes of 2, 4, 6, 8 and 10." No further information given therefore method of sequence generation unclear
Allocation concealment (selection bias)	Low risk	QUOTE: "Current smokers were then allocated by the LHCWs to either the intervention or the control arm by means of sequentially numbered sealed opaque envelopes, thus ensuring allocation concealment".
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Validation occurred in a small subset of participants and has not been applied to data; however, outcomes were the same with validation. As participants did not know whether the monitor was allocated to their clinics at specific time points, this approach introduced a 'bogus pipeline' procedure, thus increasing the likelihood of truthful answer.
Incomplete outcome data (attrition bias) All outcomes	Low risk	53/205 (26%) in the intervention arm and 43/204 (21%) in the control arm were lost to follow-up at 6 months. Therefore rates were similar between arms.



Marshall 2016			
Methods	Study design: RCT		
	Location: Australia		
	Setting: outpatient clir	nic	
		s in the Queensland Lung Cancer Screening Study were invited to enrol in the or to each scheduled CT screening scan".	
Participants	Defining eligibility criteria?: attending lung cancer screening (age 60 to 74 years; ≥ 30 pack year smoking)		
	Participant characteristics: 55 older smokers; 20/55 (36.4%) female; mean age: control = 63.0, intervention = 63.0; mean cpd: control = 25.0, intervention = 25.0; nicotine dependence: mean FTND = control = 6.0, intervention = 6.0		
	Motivation to quit?: no	t selected on motivation	
Interventions	Control: non-tailored printed materials, quit-line details		
	Intervention: MI counselling: single face-to-face counselling session on the day of attendance for lung cancer screening plus audio cessation advice (on mp3 player), plus written quit materials		
	Provider: physician		
	Intensity: one-off session lasting an average of 26.5 minutes		
	Was MI fidelity monitored?: no		
Outcomes	Definition of cessation used: 7-day point prevalence		
	Length of longest follow-up: 12 months		
	Validation: exhaled carbon monoxide >= 10 parts per million "However CO not always obtainable at the 12-month time point because the CT protocol allowed scans to take place between 11 and 15 months after the previous scan (one intervention group and three control group quitters had exhaled CO < 10 ppm, the remainder were not tested)."		
	Was mental health and/or well-being measured at follow-up?: no		
	Was quality of life measured at follow-up?: no		
Funding source	"Queensland Health, Smart State Research Grant (388600); National Health and Medical Research Council (NHMRC) National Research Centre for Asbestos-Related Diseases (NRCARD) (440812); The Prince Charles Hospital Foundation (FRC0207-24)."		
Author conflicts of interest	"None to declare"		
Notes			
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection bias)	Low risk	Group allocation sequence was generated at randomisation using a random number generator.	
Allocation concealment (selection bias)	Unclear risk	QUOTE: "Group allocation was concealed at randomization". No further detai given	



Marshall 2016 (Continued)		
Blinding of outcome assessment (detection bias) All outcomes	High risk	Although biochemical verification was planned, the investigators could not attempt it in all participants due to the timing of hospital appointments. Therefore, we have not been able to use verified rates. Amount and intensity of contact differed between study groups.
Incomplete outcome data (attrition bias) All outcomes	Low risk	3/28 (10.7%) intervention group participants and 2/27 (7.4%) control group participants did not return 12-month questionnaires and were assumed to be smokers.

Matuszewski 2018

Methods	Study design: RCT		
	Location: USA Setting: hospital Recruitment: inpatients with an operative fracture were enrolled from hospital		
Participants	Defining eligibility criteria?: hospital inpatients with an operative fracture		
	Participant characteristics: 237 smokers; sex: not reported; mean age: not reported; mean cpd: not reported; nicotine dependence: not reported		
	Motivation to quit?: not selected on motivation		
Interventions	Control: standard care: informational materials about smoking cessation, referred to the patient resource centre and provided with a quit-line brochure		
	Intervention 1: standard care + brief counselling + extended follow-up: as control, plus 10 to 30 minutes of guided discussion about the risks and benefits of smoking for the healing of their traumatic injuries, plus smoking educator checked in with participants' progress for approximately 5 minutes at follow-up appointments		
	Intervention 2: standard care + brief counselling: as control, plus 10 to 30 minutes of guided discussion about the risks and benefits of smoking for the healing of their traumatic injuries. No additional 'checkin' at follow-up		
	Provider: smoking cessation advisors		
	Intensity: single 20 to 30-minute face-to-face session. Intervention 1 also received 5-minute check-ins at 2 weeks, 6 weeks, 3 months and 6 months.		
	Was MI fidelity monitored?: unclear		
Outcomes	Definition of cessation used: 7-day point prevalence		
	Length of longest follow-up: 6 months		
	Validation: exhaled carbon monoxide (8 ppm)		
	Was mental health and/or well-being measured at follow-up?: no		
	Was quality of life measured at follow-up?: no		
Funding source	Not reported		
Author conflicts of interest	Not reported		
Notes	Completed trial, not published yet. Has been presented at 2018 Annual Meeting of the Orthopaedic Trauma Association in Kissimmee (Orlando), Florida, October 17-20 2018. Unable to calculate numbers		



Matuszewski 2018 (Continued)

quit from abstract, contacted authors for quit rates, however did not receive all the information needed. Study discussed narratively

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Allocation: randomised. No further information
Allocation concealment (selection bias)	Unclear risk	Allocation: randomised. No further information
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Cessation was CO validated.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Dropout at 6 months not reported in conference abstract. Paper not yet published

McClure 2005

Methods	Study design: RCT		
	Location: USA Setting: Group Health Co-operative, a staff-model integrated health care organisation Recruitment: women smokers with an abnormal pap smear or colposcopy were invited to participate.		
Participants	Defining eligibility criteria?: women with abnormal pap smear or a colposcopy within the preceding 2 months (i.e. elevated risk for cervical cancer)		
	Participant characteristics: 275 women, randomised to intervention (138) or control (137). Mean age 33, Mean cpd 14		
	Motivation to quit?: not selected on motivation		
Interventions	 Control: usual care: a letter explaining the association between cervical cancer and smoking, self-help booklet, contact information for a phone-based smoking cessation treatment programme. Encouraged to use NRT or bupropion Intervention: as control, plus ME telephone counselling (4 x 15-min proactive calls), focussed on motivation building and strengthening, action plans for quitting or relapse prevention strategies, depending on readiness to quit 		
	Provider: counsellors		
	Intensity: one off mailing plus four 15-minute calls over 6 months		
	Was MI fidelity monitored?: no		
Outcomes	Definition of cessation used: 7-day point prevalence		
	Length of longest follow-up: 12 months		
	Validation: CO < 10 ppm or salivary cotinine, at 12 months only		
	Was mental health and/or well-being measured at follow-up?: no		
	Was quality of life measured at follow-up?: no		



McClure 2005	(Continued)
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Funding source	Grants from the National Cancer Institute (CA84603; CA74517), and the National Institute on Drug

Abuse (DA11194)

Author conflicts of interest Not reported

Notes For this update, cessation rates were changed to 12-month verified rates (taking into account data in

table 2). The ones previously used were 6 m and 12 m combined self-report (from table 3).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	QUOTE: "Participants were randomly assigned to usual care (UC) or motivationally enhanced counseling (MEC)." No further information provided
Allocation concealment (selection bias)	Unclear risk	QUOTE: "Participants were randomly assigned to usual care (UC) or motivationally enhanced counseling (MEC)." No further information provided
Blinding of outcome assessment (detection bias) All outcomes	Low risk	QUOTE: "biochemical confirmation of abstinence was obtained only at the 12-month follow-up from nonsmokers. Women were given the option of providing a breath sample in person or returning a salivary cotinine test strip by mail". 12-month validated rates were used in our analyses as the amount of contact differed between groups.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Loss to follow-up not reported

Naik 2014

Methods	Study design: RCT
	Location: India
	Setting: prison
	Recruitment: random sampling of male prisoners at Central jail in Bangalore City
Participants	Defining eligibility criteria?: incarcerated males
	Participant characteristics: 600 adult smokers; 0/600 (0%) female; mode age: 21 to 30 years; mean cpd: 21 to 30 in intervention group, control not reported; nicotine dependence: not reported
	Motivation to quit?: not selected on motivation
Interventions	Control: waiting-list control
	Intervention: motivational interviewing: the topics for the intervention included: introduction to tobacco, prevalence of tobacco use, effects of tobacco use on general health and dental health, psychosocial factors influencing tobacco use, healthy diet and behavioural intervention for prevention of tobacco use.
	Provider: not specified
	Intensity: not specified
	Was MI fidelity monitored?: no
Outcomes	Definition of cessation used: unclear - "stopped smoking"



Naik 2014	(Continued)
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Length of longest follow-up: 6 months

Validation: Unclear - CO was measured but didn't specify if used for validation.

Was mental health and/or well-being measured at follow-up?: no

Was quality of life measured at follow-up?: no, quality of life was measured in the intervention group

only, not allowing comparison to the control group.

Funding source "Nil"

Author conflicts of interest "None declared"

Notes Contacted authors to confirm that the control group received no smoking cessation treatment as this

was unclear in the study report.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Among 600 prisoners, 300 were selected for each group (study and control) by simple random sampling". No further information provided
Allocation concealment (selection bias)	Unclear risk	"Among 600 prisoners, 300 were selected for each group (study and control) by simple random sampling". No further information provided
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear whether investigators were blind to treatment condition. Although carbon monoxide was measured, it was unclear whether these were used to validate cessation rates.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information on dropouts provided
Other bias	Unclear risk	As reported in the publication, the content of the control group was unclear, therefore we contacted the authors. The authors replied as follows: "Control group received 3 month smoking cessation motivational intervention after finishing the study group intervention", suggesting that the control group were a waiting-list control. Based on the extra information provided, it was unclear whether the control group received the intervention immediately after the study group, within the 6-month follow-up. We sought additional clarification on this from the authors but did not receive a response; however, the much higher result in the MI group suggested the control group did not receive the intervention before follow-up.

Methods	Study design: RCT
	Location: China Setting: primary care Recruitment: via general practice
Participants	Defining eligibility criteria?: adult smokers
	Participant characteristics: 210 adult smokers; $12/210$ (5.7%) female; mean age: 45.3; mean cpd: not reported; nicotine dependence: mean FTND = 4



NCT02645838 (Continued)			
	Motivation to quit?: no	t selected on motivation	
Interventions	Control: brief smoking	cessation advice	
	Intervention: motivational interviewing: 20-minute discussion with physician, determining stage of change in smoking cessation and using motivational interviewing skills		
	Provider: physicians		
	Intensity: single 20-mir	nute face-to-face session, plus up to six follow-up calls	
	Was MI fidelity monitor	red?: not stated	
Outcomes	Definition of cessation	used: 7-day point prevalence	
	Length of longest follo	w-up: 6 months	
	Validation: exhaled CO (< 10 ppm)		
	Was mental health and/or well-being measured at follow-up?: no		
	Was quality of life measured at follow-up?: no		
Funding source	Not reported		
Author conflicts of interest	Not reported		
Notes	Contacted authors and received extensive additional data and information, beyond what was reported in trial registry.		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection bias)	Low risk	SAS 9.4 was used to generate random numbers, random grouping was used to perform random grouping, and random grouping schemes were sequentially saved into opaque sealed envelopes with sequential numbers.	
Allocation concealment (selection bias)	Low risk	After the patient consented to take part in the study, the researcher opened the sealed opaque envelopes according to the envelope number sequence, and assigned the included smoking patients to the intervention group or the	

Blinding of outcome as-

All outcomes

(attrition bias)

All outcomes

sessment (detection bias)

Incomplete outcome data

Okuyemi 2013	
Methods	Stud

Location: USA

Study design: RCT

Low risk

Low risk

Setting: emergency homeless shelters and transitional housing units

arms.

control according to the assignment in the envelope.

19/105 participants in the MI group were lost to follow-up and 18/105 in the BA

group. Therefore, loss to follow-up was less than 20% and was similar between

Smoking cessation was biochemically validated.



Okuyemi 2013 (Continued)	Recruitment: through I mouth	nealth fairs, staff informational sessions, fliers at homeless shelters and word of	
Participants	Defining eligibility criteria?: homeless people		
	Participant characteristics: 430 homeless adult smokers randomised to intervention (216) and control (214); 74.7% M; mean age 44.4; cpd 19.3		
	Motivation to quit?: no	t selected on motivation	
Interventions	1. Control: single session of brief advice to quit smoking lasting approximately 10 to 15 mins. Included topics of smoking history, current smoking, direct advice about the health risks of smoking and the health benefits of quitting, affirmation of the participant's decision to quit, an assessment of preparedness to quit and addressing strategies for coping with smoking cues		
	2. Intervention: six individual MI counselling sessions, each lasting 15 to 20 minutes, which occurred at baseline and follow-up at weeks 1, 2, 4, 6 and 8. The focus of sessions was to encourage cessation and NRT adherence.		
	Pharmacotherapy: At baseline, participants in both groups received a 2-week supply of 21-mg nicotine patches, and every 2 weeks they received an additional 2-week supply of 21 mg nicotine patches, over the 8 week treatment period.		
	All participants received health educational resource called <i>The Power to Quit: A Quit Smoking Guide</i> , developed by the project investigators, and a 2-week supply of 21-mg nicotine patches. Every 2 weeks, they received an additional 2-week supply of 21 mg nicotine patches, over the 8-week treatment period.		
	Provider: counsellors		
	Intensity: six 15 to 20-minute sessions over 8 weeks		
	Was MI fidelity monitored?: "Sessions were audio recorded and reviewed during weekly supervision".		
Outcomes	Definition of cessation used: 7-day point prevalence		
	Length of longest follow-up: 6 months		
	Validation: expired carbon monoxide (\leq 10 ppm). Salivary cotinine testing was performed if the expired CO was greater than 10 ppm. for those who self-reported cessation. A cut-off of \leq 20 ng/mL for salivary cotinine was used to verify abstinence.		
	Was mental health and/or well-being measured at follow-up?: no, change in depression was measured but not reported by intervention group.		
	Was quality of life measured at follow-up?: no		
Funding source	A grant from the National Heart Lung and Blood Institute (R01HL081522)		
Author conflicts of interest	Paper stated that there were no conflicts.		
Notes			
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection bias)	Unclear risk	QUOTE: "pre-assigned randomization numbers prepared by the study statistician determined into which study arm the participant would be enrolled". No further information provided	



Okuyemi 2013 (Continued)		
Allocation concealment (selection bias)	Unclear risk	QUOTE: "pre-assigned randomization numbers prepared by the study statistician determined into which study arm the participant would be enrolled". No further information provided
Blinding of outcome assessment (detection bias) All outcomes	Low risk	A cessation was biochemically verified using exhaled CO and cotinine.
Incomplete outcome data (attrition bias) All outcomes	Low risk	47/216 (22%) in MI intervention group and 59/214 (28%) in control group lost to follow-up. Therefore, rates were similar between groups.

Rohsenow 2014

Rohsenow 2014			
Methods	Study design: RCT		
	Location: USA Setting: state-funded inner-city residential substance abuse treatment programme with state-wide catchment		
	Recruitment: residents of the abstinence-oriented programme were told the study would provide informational sessions about smoking without requiring cessation, and asked if they would like to take part.		
Participants	Defining eligibility criteria?: alcohol-dependent smokers		
	Participant characteristics: 165 adult smokers meeting current alcohol dependence criteria, randomised to intervention (80) and control (85); 32.4% female; mean age 33.8; cpd 21.2		
	Motivation to quit?: not selected on motivation		
Interventions	1. Control: brief advice used AHRQ-recommended methods. At the Initial session (15 mins), therapists assessed smoking rate and interest in quitting, directly advised participants to stop smoking now during substance use treatment for their health, and given advice about useful methods. 43 participants were randomised to receive booster sessions (5 to 15 mins each), 7 and 30 days after the initial session. The remaining 42 participants did not receive boosters.		
	2. Intervention: used motivational therapist style with assessment feedback, based on motivational interviewing. Initial session (45 mins) involved discussing pros and cons of smoking, interpreting health risks, costs of smoking, smoking rate, relationship of smoking to ongoing alcohol use, and barriers to change, with corrective information. 40 participants were randomised to booster sessions (5 to 15 mins each), 7 and 30 days after the initial session. The remaining 40 participants did not receive boosters.		
	All participants informed of free access to smoking cessation pamphlets, smoking cessation skills groups, hard candy, and free access to NRT (transdermal nicotine or nicotine gum) if medically eligible and willing to cease smoking while using it.		
	Provider: counsellors		
	Intensity: single 45-minute initial session, with two 5- to 15-minute booster sessions (in booster group only)		
	Was MI fidelity monitored?: "Treatment session audiotapes (24% of initial sessions, 19% of booster sessions) were reviewed in weekly group supervision with Dr. Rohsenow and a treatment coordinator, and		

rated for MI style and adherence to the manual (see 2.4.4), with immediate feedback to therapists to prevent drift. Treatment sessions were rated by the treatment coordinator (primary rater) or the first author on 1 (not at all) to 5 (extensively) scales for five motivational style measures (arguing, demonstrating empathy, reflective listening, supporting self-efficacy, emphasizing personal responsibility for change), and supervisors endorsed adequacy of six MI adherence items (discuss ambivalence (pros and



Rohsenow 2014 (Continued)	cons, goal discrepancies), discuss feedback about smoking effects, explore barriers to change, provide summaries, discuss various goals, discuss methods)."	
Outcomes	Definition of cessation used: 7-day point prevalence	
	Length of longest follow-up: 12 months	
	Validation: exhaled CO ≤ 10 ppm	
	Was mental health and/or well-being measured at follow-up?: no	
	Was quality of life measured at follow-up?: no	
Funding source	A grant from the National Institute of Alcohol Abuse and Alcoholism (1 RO1 AA11318) and two Senior Research Career Scientist Awards from the United States Department of Veterans Affairs	
Author conflicts of interest	Not reported	
Notes	The study was made up of 4 trial arms: MI with and without booster sessions and brief advice with and without booster sessions. For the purpose of MI versus other smoking cessation support analyses, we combined these into 2 groups: 1. MI and 2. brief advice. However, we also compared the two MI groups in our intensity analysis.	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	QUOTE: "Randomization to MI or BA and to booster sessions versus no boosters within each gender occurred in the first week of the program using a random numbers table".
Allocation concealment (selection bias)	Unclear risk	QUOTE: "Assignment was placed in a sealed envelope opened just before the first treatment session." Did not state whether envelopes were opaque.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Abstinence was validated by exhaled carbon monoxide.
Incomplete outcome data (attrition bias) All outcomes	Low risk	27/80 (34%) in the MI intervention group and 25/85 (29%) in the BA control group were lost to 12-month follow-up. Therefore, dropout rate was similar between arms.

Rohsenow 2015

Methods	Study design: factorial RCT (2 x 2)		
	Location: USA Setting: residential substance abuse treatment programme Recruitment: from the substance abuse treatment programme (no further information given)		
Participants	Defining eligibility criteria?: drug use disorder and in residential substance abuse treatment		
	Participant characteristics: 184 adult smokers; 102/184 (55.4%) female; mean age: 34.5; mean cpd: 22.3; nicotine dependence: mean FTND = 5.28		
	Motivation to quit?: not selected on motivation		



Rohsenow 2015 (Continued)

Interventions

Control 1: brief advice with non-contingent vouchers: participants received a session (15 minutes) of brief advice to promote motivation to quit used AHRQ-recommended methods, adapted for substance use disorder recovery issues. Counsellors assessed smoking rate and interest in quitting, directly advised participants to stop smoking now for their health, assisted by giving advice about useful methods, and asked them to set a quit-date within the next 2 weeks. If participants expressed concern about effects on sobriety, they were given corrective information. Additional sessions were provided at 7, 14 and 19 days after the first session (10 to 15 minutes each) where progress toward smoking cessation was checked, participants were engaged in problem-solving around barriers to quitting, successes in accomplishing goals were noted, repeated direct advice to quit was given, and reminders of methods available were given. Participants could earn payments per day for 19 days, simply for providing breath samples as scheduled (not contingent on abstinence). In the last session there was discussion addressing the transition away from the contingency payments provided in the study.

Control 2: brief advice with contingency vouchers: as control 1, however the payments participants could earn were awarded for providing reduced CO breath samples rather than just for providing samples.

Intervention 1: motivational interviewing with non contingent vouchers: As control 1, however participants received motivational interviewing rather than the brief advice intervention. "The initial session (45 minutes) involved discussing pros and cons of smoking, the health risks associated with their carbon monoxide (CO) level, the costs of smoking relative to their income, their smoking rate compared to state and national norms, the relationship of smoking to alcohol use and to sobriety, and their barriers to change with corrective information (since more barriers are associated with lower motivation). Patients chose goals and methods from a menu of suggestions, and were provided with their choice of a variety of smoking cessation pamphlets. At additional sessions at 7, 14 and 19 days after the first session (15–30 minutes each), patients were asked about progress toward their own stated goals, barriers and ways to overcome barriers, successes (focussing on self-efficacy), and revised goal preferences."

Intervention 2: motivational interviewing with contingency vouchers: as control 2, however participants received motivational interviewing rather than the brief advice intervention.

All participants received free access to NRT (patch or gum), smoking cessation pamphlets and hard candy.

Provider: counsellors

Intensity: single 45-minute face-to-face session plus three 15- to 30-minute sessions

Was MI fidelity monitored?: "Treatment session audiotapes (15% of initial sessions, 10% of additional sessions) were reviewed in weekly group supervision with the treatment coordinator and a psychologist trained in MI, and rated for MI style and adherence to the manual, with immediate feedback to therapists to prevent drift."

Outcomes	5
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Definition of cessation used: 7-day point prevalence

Length of longest follow-up: 12 months

Validation: CO level ≤ 4 ppm and salivary cotinine level ≤ 15 ng/mL

Was mental health and/or well-being measured at follow-up?: no

Was quality of life measured at follow-up?: no

Funding source

"Supported by 1 RO1 DA13616 from the National Institute on Drug Abuse; two Senior Career Research Scientist Awards from the Department of Veterans Affairs (DJR and PMM); and K05AA019681 from the National Institute on Alcohol Abuse and Alcoholism."

Author conflicts of interest

"No authors declare conflicts".

Notes

Two MI groups and 2 brief advice (BA) groups merged into one MI and one BA group to contribute to 'MI versus other smoking cessation treatment' comparison as no interaction effects were detected.



Rohsenow 2015 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Used stratified random assignment, using urn randomisation. No further detail given
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	Research interviewers blind to treatment condition conducted all assessments. Cessation was biochemically verified.
Incomplete outcome data (attrition bias) All outcomes	Low risk	45/184 (24.5%) lost to follow-up, with no significant differences by condition

Sherman 2016

Methods	Study design: RCT
	Location: USA
	Setting: hospital
	Recruitment: "Using the electronic medical record, a daily list was generated of inpatients documented as current smokers on admission screening. Research assistants (RAs) reviewed the list twice daily and went to the bedside of every patient on the list. In addition to the inpatient units, RAs approached admitted patients who remained in the emergency department and patients in the intensive care units."
Participants	Defining eligibility criteria?: admitted to hospital for various healthcare problems
	Participant characteristics: 1619 adult smokers; 346/1619 (21.4%) female; mean age: control: 48, intervention: 49; mean cpd: control: 12.5, intervention: 12.3; nicotine dependence: level of nicotine addiction, first cigarette within: 5 minutes: 685/1619 (42.3%), 6 to 30 minutes: 321/1619 (19.8%), 31 to 60 minutes: 180/1619 (11.1%), > 60 minutes: 422/1619 (26.1%).
	Motivation to quit?: not selected on motivation
Interventions	Control: referral to quit-line based on MI: participants referred to a quit-line and offered NRT. Participants received one 15 to 20-minute counselling session with a follow-up call to assess quit status and assure any requested NRT was received. Most participants were referred to the New York state quit-line where the counsellors are trained in MI.
	Intervention: MI intensive counselling plus 8 weeks of NRT if they had not received an NRT prescription at discharge. "The structured counselling protocol was based on Motivational Interviewing and Problem Solving Therapy".
	Provider: counsellors
	Intensity: single 15 to 20-minute initial call, followed by six 10 to 15-minute calls over 42 weeks
	Was MI fidelity monitored?: "The program staff members use a structured protocol to maintain a record of each of the counselling calls for internal quality assurance. To ensure intervention standardization and fidelity after study implementation, a random sample of the counsellors' phone calls will be audio taped and reviewed by a clinical psychologist and the study's counsellor supervisor".
Outcomes Definition of cessation used: 30-day point prevalence	



S	herman	2016	(Continued)
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Length of longest follow-up: 6 months

Validation: "Where possible salivary cotinine was used: several sites (including New York) made exhaustive efforts to obtain saliva from a consecutive subsample of participants reporting abstinence and no NRT or e-cigarette use in the past 7 days at 6-month follow-up."

Was mental health and/or well-being measured at follow-up?: no

Was quality of life measured at follow-up?: no

Funding source

"This work was supported by a grant from the National Heart, Lung and Blood Institute (NHLBI) of NIH (#1U01HL105229) and a Hurricane Sandy Supplement (#3U01HL105229-04S1), and also in part by the New York University CTSA grant UL1TR000038 from the National Center for Advancing Translational Sciences, NIH."

Author conflicts of interest

"None of the authors have any conflicts of interest to report".

Notes

Both intervention groups received counselling based on MI albeit from different providers. This study was included in our comparison investigating the intensity of MI; however, it was removed in a sensitivity analysis due to the difference in providers between arms, which made it different to other studies included in the same comparison.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The study database generated random assignments. QUOTE: "The randomisation scheme, designed by the biostatistician, employed a computerized random number generator and stratified participants on hospital site."
Allocation concealment (selection bias)	Low risk	The study database generated random assignments. QUOTE: "The randomisation scheme, designed by the biostatistician, employed a computerized random number generator and stratified participants on hospital site."
Blinding of outcome assessment (detection bias) All outcomes	High risk	Biochemical verification did not occur in full sample and intervention contact was not matched across study arms.
Incomplete outcome data (attrition bias) All outcomes	Low risk	247/804 (30.7%) lost to follow-up in the hospital intervention arm, and 278/814 (34.2%) lost to follow-up in the quit-line arm. Less than 50% overall and similar rates between groups

Soria 2006

Methods	Study design: RCT		
	Location: Spain Setting: family health centres Recruitment: smokers making routine GP visits		
Participants	Defining eligibility criteria?: patients attending primary care for variety of reasons		
	Participant characteristics: 200 smokers, randomised to intervention (114) or control (86). 53% female, mean age 38. Mean cpd 18		
	Motivation to quit?: not selected on motivation		
Interventions	Control: brief (3 mins) anti-smoking advice		



Soria 2006 (Continued)			
Total Lood (continued)	Intervention: three 20-min MI-based interviews, at intervals to suit doctor and participant Pharmacotherapy: bupropion offered to highly nicotine-dependent members of both groups		
	Provider: physicians		
Intensity: three 20-minute sessions			
	Was MI fidelity monitored?: no		
Outcomes	Definition of cessation used: point prevalence		
	Length of longest follow-up: 12 months		
	Validation: expired CO < 6 ppm		
	Was mental health and/or well-being measured at follow-up?: no		
	Was quality of life measured at follow-up?: no		
Funding source	Grant from the Department of Health, Health Science Institute of the Government of the Autonomous Communities of Castille - La Mancha (Spain)		
Author conflicts of interest	"The authors have stated that there are none".		
Notes			

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	QUOTE: "The patients were randomly assigned to either one of the actions groups by means of a non-block table of random numbers", "patient randomisation was achieved by applying a non-block table of random numbers as opposed to a block table, resulting in unbalanced group sizes".
Allocation concealment (selection bias)	Low risk	QUOTE: "Two hundred non-transparent sealed envelopes containing the interventions (either brief advice or MI) were prepared. Before the start of daily consultations, the GPs conducting the interventions would extract one of the envelopes, not knowing the type of action it contained. The first smoker patient who attended the consultation would be offered the possibility of taking part in the study. If they accepted and signed the informed consent form, the envelope would be opened, upon which the GP would learn of the patient's group assignment."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Cessation was validated using exhaled carbon monoxide measures.
Incomplete outcome data (attrition bias) All outcomes	Low risk	17/114 (14.9%) of the MI intervention group and 9/86 (10.5%) of the brief advice control group were lost to follow-up at the 12-month follow-up.

Stein 2006

Methods	Study design: RCT
	Location: USA Setting: methadone maintenance treatment programme centres



tein 2006 (Continued)			
	Recruitment: offered to smokers routinely attending maintenance clinic		
Participants	Defining eligibility criteria?: opiate-dependent people on methadone maintenance treatment for 3 months or more		
	Participant characteristics: 383 methadone-maintained adult smokers, randomised to maximal (191) or minimal (192) SC programmes. 48% female, mean age 40, mean cpd 27		
	Motivation to quit?: not selected on motivation		
Interventions	Control: up to 2 visits, i.e. baseline and quit-date (if set). Brief advice using National Cancer Institute's 4As model (< 3 mins), plus self-help materials Intervention: up to 3 visits from study counsellor, i.e. one 30-min MI-based tailored interview, plus 15 to 30-min quit-date session + follow-up relapse prevention session. Those not ready to quit only received 2 sessions.		
	All participants willing to make quit attempt offered NRT patches.		
	Provider: counsellors		
	Intensity: single 30-minute session, followed by two follow-up sessions within 30 days		
	Was MI fidelity monitored?: no		
Outcomes	Definition of cessation used: 7-day point prevalence		
	Length of longest follow-up: 6 months		
	Validation: Expired CO < 8 ppm		
	Was mental health and/or well-being measured at follow-up?: no		
	Was quality of life measured at follow-up?: no		
Funding source	A grant from the National Cancer Institute (R01CA84392). Transdermal nicotine therapy provided by GlaxoSmithKline		
Author conflicts of interest	"The authors have no conflicts of interest, financial or otherwise, to report for this article or this research."		
Notes			

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	QUOTE: "At this point, randomization and group assignment occurred." No further information provided
Allocation concealment (selection bias)	Unclear risk	QUOTE: "At this point, randomization and group assignment occurred." No further information provided
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Cessation was validated using exhaled carbon monoxide measurements.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	QUOTE: "A total of 383 participants were assessed at baseline; 312 (81.5%) were successfully located and assessed at 6 months". However, rates of follow-up were not reported by study arm.



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Methods Study design: RCT

Location: USA

Setting: colleges and universities

Recruitment: advertisements posted in campuses, in campus newspapers, and on the Internet (e.g.

Craigslist)

Participants Defining eligibility criteria?: young people 18-24 years

Participant characteristics: 110 adult (18 to 24 years), student, daily smokers verified by a CO > 10 ppm,

randomised to intervention (55) and control (55); 0.1% female; mean age 19.8; cpd 12.3

Motivation to quit?: not selected on motivation

Interventions

Control 1: progressive muscle relaxation (REL) with non-contingent payments: i.e. non-smoking cessation support, matched to the intervention for contact time. Therapists followed a standardised manual for implementation. In session 1, therapists guided the participant through progressive muscle REL exercises. Muscle REL techniques were then practiced during sessions 2 and 3. Participants received payments for providing breath samples, regardless of CO level across 3 weeks. Payments were provided to promote session attendance and to minimise differences in attendance between groups.

Control 2: progressive muscle relaxation (REL) with contingency payments: as control 1 however, as well as receiving the non-contingent payments participants received contingent reinforcement for CO reductions of 25% or greater from their baseline levels.

Intervention 1: MET with non-contingent payments: as control 1, however rather than REL therapy, participants received three sessions of motivational enhancement therapy (MET), incorporating central principles of MI. The first session (60 mins) focussed on enhancing motivation to cut down and quit smoking. Students received information about smoking effects, coping with withdrawal symptoms, and strategies for quitting. The therapist and student developed an action plan for behaviour change. Sessions 2 and 3 (each 30 mins) used MET principles, focussed on progress made and planning for the future.

Intervention 2: MET with contingency payments: as control 2, however, rather than REL therapy, participants received three sessions of motivational enhancement therapy (MET), incorporating central principles of MI. The first session (60 mins) focussed on enhancing motivation to cut down and quit smoking. Students received information about smoking effects, coping with withdrawal symptoms, and strategies for quitting. The therapist and student developed an action plan for behaviour change. Sessions 2 and 3 (each 30 mins) used MET principles, focussed on progress made and planning for the future.

Intervention provider: counsellors

Intensity: single 60-minute session, followed by two 30-minute sessions over the following two weeks

Was MI fidelity monitored?: "Students and therapists separately rated which of 19 possible session elements (15 MET elements and 4 REL elements) had been completed at posttreatment".

Outcomes

Definition of cessation used: 7-day point prevalence

Length of longest follow-up: 6 months

Validation: salivary cotinine < 15 ng/mL or CO ≤ 8 ppm

Was mental health and/or well-being measured at follow-up?: no

Was quality of life measured at follow-up?: no



Tevyaw 2009	(Continued)
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Funding source A grant from the National Institute on Drug Abuse (DA011204), and a Senior Career Research Scientist

Award from the Department of Veterans Affairs

Author conflicts of interest "None declared"

Notes The study was made up of 4 trial arms: MET with and without contingency reinforcement, and REL with

and without contingency reinforcement. We compared the two non-contingent groups for our MI versus no smoking cessation treatment comparison, and compared the two contingent groups for our MI as an adjunct comparison. The authors kindly provided the quit data for individual study arms in re-

sponse to an information request.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	QUOTE: "Participants were randomly assigned to one of four conditions". No further information provided
Allocation concealment (selection bias)	Unclear risk	QUOTE: "Participants were randomly assigned to one of four conditions". No further information provided
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Cessation was validated using saliva cotinine and exhaled carbon monoxide.
Incomplete outcome data (attrition bias) All outcomes	Low risk	3/55 (6%) in the MET intervention group and 3/55 (6%) in the relaxation control group were lost to follow-up at the 6-month follow-up. Therefore, dropout rate was low and the same across study arms.

Vidrine 2019

Methods	Study design: cluster RCT
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Location: USA

Setting: community (over telephone)

Recruitment: took place at churches, public housing sites, and community centres (no further informa-

tion given)

Participants Defining eligibility criteria?: adult smokers

> Participant characteristics: 624 adult smokers; 316/624 (50.6%) female; mean age: 45.8; cpd: 1 to 10: 188/624 (30.1%), 11 to 20: 285/624 (45.7%), >= 21: 151/624 (24.2%); nicotine dependence: mean FTND =

5.59

Motivation to quit?: motivated

Interventions Control: brief advice to quit smoking, self-help written materials, a quit-line referral, and a 10-week

supply of NRT patches

Intervention 1: as control, plus tailored text messaging. "Message delivery began several days before a scheduled quit date and continued for a 12-week period. Frequency of messages was highest (i.e. 5 per day) near the time of the quit date, but gradually reduced to 1 per day. Message content was informed by cognitive behavioral and motivational enhancement principles and was designed to increase health knowledge, quit motivation, use of coping skills, support, and self-efficacy. Messages were tailored based on participants' first name and current smoking status (proactively assessed weekly by mobile phone), and on disease history, future disease concerns, and preferred coping skills (each assessed at the baseline audio computer assisted self-interview)."



Vidrine 2019 (Continued)			
		vention 1, plus proactive telephone counselling. As with text messaging, counwas primarily drawn from cognitive-behavioural and MI techniques.	
	Provider: counsellors		
	Intensity: 11 10- to 12-r	ninute sessions over a 12-week period	
	Was MI fidelity monitor	red?: no	
Outcomes	Definition of cessation	used: 30-day point prevalence	
	Length of longest follo	w-up: 6 months	
	Validation: saliva cotin ment (N = 377; 60.4%)	ine (< 20 ng/mL) via postal swab but only introduced in second year of recruit-	
	Was mental health and	or well-being measured at follow-up?: no	
	Was quality of life mea	sured at follow-up?: no	
Funding source	"This study was supported by grant R01 CA141628 from the National Cancer Institute (principal investigators [PIs]: Drs D. J. Vidrine and Prokhorov); grant P30 CA225520 from the Stephenson Cancer Center (PI: Dr Robert S. Mannel, MD); grant P30 CA016672 from The University of Texas MD Anderson Cancer Center (PI: Louis L. Pisters, MD); grant 092-016-0002l from the Oklahoma Tobacco Settlement Endowment Trust (PI: Dr J. I. Vidrine); and grant U54GM104938 from the National Institute of General Medical Sciences (PI: Judith A. James, MD, PhD)."		
Author conflicts of interest	"Authors reported no conflicts of interest."		
Notes	Intervention groups merged and compared with control for MI as an adjunct comparison. Intervention groups compared with one another for intensity of MI comparison. The study randomised neighbourhood sites and conducted adjusted analyses, accounting for the type of site (church, housing complex or community centre) and the individual site (46 sites). This allowed us to calculate an ICC of 0.06 and adjust for this in our analyses.		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection bias)	Low risk	QUOTE: "Neighborhood sites were stratified based on type (i.e. church, community center, or public housing complex) and racial/ethnic composition, then randomized to a treatment group using a random number list generated by a staff statistician".	

mation

QUOTE: "Research staff who recruited, consented, and administered the assessments were blinded to the treatment group assignment." No further infor-

Research staff who recruited, consented, and administered the assessments

QUOTE: "The overall 6-month follow-up rate was 73.6%, and no significant

and the amount of contact with counsellors differed between groups.

group differences (P > .57 for all) were observed".

were blinded to the treatment group assignment. However, validation of absti-

nence only began at year 2 of recruitment so we have not used validated rates,

Allocation concealment

Blinding of outcome as-

sessment (detection bias)

Incomplete outcome data

(selection bias)

All outcomes

(attrition bias)

All outcomes

Unclear risk

High risk

Low risk



Methods	Study design: cluster RCT
	Location: USA Setting: high schools (via virtual environment) Recruitment: from 14 local high school using classroom presentations, lunch-hour sign-up tables, flyers, posters, school newspaper ads and articles, school-wide announcements, and school liaison referrals
Participants	Defining eligibility criteria?: high school students (adolescents)
	Participant characteristics: 136 adolescent smokers; 63/136 (46%) female; mean age: 16; mean cpd: 2 to 5; nicotine dependence: latency to first cigarette of the day assessed on a scale ranging from 1 (immediately after waking) to 6 (more than 2 hours after waking), mean: intervention; 4.44; control; 4.78
	Motivation to quit?: not selected on motivation
Interventions	Control: no treatment (measurement only)
	Intervention: "The Breathing Room" virtual world incorporating motivational interviewing: participant were represented by an avatar in the virtual world and received counselling in a group, delivered by a counsellor, in a shopping mall setting. "The Breathing Room virtual world", used proprietary interactive software known as ActiveWorlds that created a virtual mall environment with chat box communication
	Provider: counsellor
	Intensity: single 45-minute session per week for 7 weeks
	Was MI fidelity monitored?: no
Outcomes	Definition of cessation used: 7-day point prevalence
	Length of longest follow-up: 12 months
	Validation: none
	Was mental health and/or well-being measured at follow-up?: no
	Was quality of life measured at follow-up?: no
Funding source	"This research was funded by California's Tobacco-related Disease Research Program (TRDRP), grant number 11HT-3301".
Author conflicts of interest	Not reported
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomization to condition was done by school to avoid contamination between intervention and control groups". No further information given
Allocation concealment (selection bias)	High risk	Clusters knew which condition they were in, and recruitment was tailored to this. Participants recruited were different at each site due to recruitment materials associated with condition - this resulted in non-equivalent groups.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Smoking status measured by self-report and control group had no interaction with study counsellor (compared with seven sessions of MI/chat room).



Woodruff 2007 (Continued)

Incomplete outcome data (attrition bias)
All outcomes

Unclear risk

Overall loss to follow-up was 27% for the 12-month follow-up survey. QUOTE: "There was tendency for survey non-response to be higher among intervention participants than among controls. For example, at the post-intervention assessment, 15% of controls did not respond compared to 33% of intervention participants." Exact numbers per group lost to follow-up not reported and 18% difference between controls and intervention participants at post-intervention assessment (no report of difference at 12-month follow-up).

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Methods	Study design: RCT
	Location: USA Setting: Asian community health coalition's member organisations. Community setting in New York City
	Recruitment: participants were recruited through the Asian Community Health Coalition's Chinese member organisations by bilingual staff from Temple University's Center for Asian Health in cooperation with trained community volunteers.
Participants	Defining eligibility criteria?: self-identification as ethnic Chinese
	Participant characteristics: 139 adult ethnic Chinese smokers, randomised to intervention (67) and control (72); 12.3% female; mean age 44.4; cpd not stated
	Motivation to quit?: not selected on motivation
Interventions	Control: four 60-min 'health education' sessions and general self-help health information, covering nutrition, exercise, and harmful effects of tobacco. Quitting strategies were provided.
	Intervention: four in-person 60-min sessions of MI counselling for smoking cessation and self-help smoking cessation materials. The effects of tobacco use, secondhand smoke, and participants' experiences with smoking were discussed. Participants were counselled about the addictive nature of nicotine, encouraged to examine the pros and cons of smoking, and contemplate quitting behaviour.
	All participants were provided with nicotine patches.
	Provider: counsellors
	Intensity: four in-person 60-minute sessions. Frequency unclear
	Was MI fidelity monitored?: no
Outcomes	Definition of cessation used: 7-day point prevalence
	Length of longest follow-up: 6 months
	Validation: expired CO was measured; however results by arm not reported and so non-validated data used.
	Was mental health and/or well-being measured at follow-up?: no
	Was quality of life measured at follow-up?: no
Funding source	A grant from the National Cancer Institute Community Network Program (U01CA114582-02S2)
Author conflicts of interest	"None declared"
Notes	



Wu 2009 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	QUOTE: "Eligible participants/smokers aged 18 years and older were randomly assigned to MI or to the general health – counseling program". No further information provided
Allocation concealment (selection bias)	Unclear risk	QUOTE: "Eligible participants/smokers aged 18 years and older were randomly assigned to MI or to the general health – counseling program". No further information provided
Blinding of outcome assessment (detection bias) All outcomes	Low risk	QUOTE: "All participants were measured by breath CO as cross validation of their smoking status at two timepoints: baseline and 6-month follow-up".
Incomplete outcome data (attrition bias) All outcomes	Low risk	7/67 (11%) in the MI intervention group, and 10/72 (14%) of the general health control group were lost to follow-up at 6 months.

5As: 'Ask, Advise, Assess, Assist, and Arrange'

5Rs: 'Relevance, Risks, Rewards, Roadblocks, Repetition' AHRQ: Agency for Health care Research and Quality

ALA: American Lung Association
AMI: adapted motivational interviewing

BA: brief advice

CA: continuous abstinence

CBT: Cognitive Behavioural Therapy

CO: carbon monoxide cpd: cigarettes per day

CT: computerised tomography

FTND: Fagerstrom Test for Nicotine Dependence

HE: health education

HII: high intensity intervention HIV: Human Immunodeficiency Virus

ICC: intraclass correlation
ITT: intention to treat
LCD: liquid-crystal display
LHCW: lay health care workers
LII: low intensity intervention

M: male

m: month

MA: meta-analysis

ME: motivational enhancement

MEC: motivationally enhanced counselling MET: motivational enhancement therapy

MFTQ: modified Fagerstrom Tolerance Questionnaire

MI: motivational interviewing

MISC: Motivational Interviewing Skill Code

mp3: Moving Picture Experts Group Layer-3 Audio (audio file format/extension)

N: number of participants

NG:nicotine gum

NRT: Nicotine replacement therapy

PA: prolonged abstinence

PG: placebo gum



PPA: point prevalence abstinence

ppm: parts per million

PTSD: post-traumatic stress disorder RCT: randomised controlled trial REL: progressive muscle relaxation

RP: relapse prevention SBA: structured brief advice SC: smoking cessation

S-H: self help

SUD: substance use disorder

TB: tuberculosis TQD: target quit date UC: usual care

USD: United States dollars

VHA: Veterans Health Administration

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
ACTRN12609000627257	Non-MI intervention components not matched between arms
ACTRN12609001039279	Non-MI intervention components not matched between arms
ACTRN12612000016831	Was non-randomised or quasi-randomised
ACTRN12614000876695	Non-MI intervention components not matched between arms
ACTRN12614001147673	Was non-randomised or quasi-randomised
ACTRN12616000314426	Participants not current smokers
Aertsen Van Der Kuip 2006	Measured cessation at less than 6 m follow-up
Ahluwalia 1998	Did not test a behavioural motivational smoking cessation intervention
Auer 2016	Was non-randomised or quasi-randomised
Baker 2006	Non-MI intervention components not matched between arms
Bernstein 2018	Measured cessation at less than 6 m follow-up
Boccio 2017	Was non-randomised or quasi-randomised
Bolger 2010	Measured cessation at less than 6 m follow-up
Bonevski 2018	Non-MI intervention components not matched between arms
Borrelli 2002	Non-MI intervention components not matched between arms
Borrelli 2005	Non-MI intervention components not matched between arms
Borrelli 2016	Non-MI intervention components not matched between arms
Borrelli 2017	Non-MI intervention components not matched between arms



Study	Reason for exclusion
Boyle 2007	Tested a motivational intervention not based on M & R's MI
Breland 2014	Measured cessation at less than 6 m follow-up
Bronson 1989	Tested a motivational intervention not based on M & R's MI
Brooks 2017	Non-MI intervention components not matched between arms
Brown 2003	Non-MI intervention components not matched between arms
Caponnetto 2017	Intervention based on stages of change theory
Carpenter 2004	Tested a motivational intervention not based on M & R's MI
Cigrang 2002	Did not test a behavioural motivational smoking cessation intervention
Collicott 2001	Measured cessation at less than 6 m follow-up
Cornuz 2002	Tested a motivational intervention not based on M & R's MI
Curry 2003	Non-MI intervention components not matched between arms
Dornelas 2000	Intervention based on stages of change theory; only participants in precontemplative and contemplative stages received MI counselling, the rest received relapse prevention counselling only
Eakin 2014	Did not test a behavioural motivational smoking cessation intervention
Emmons 2001	Non-MI intervention components not matched between arms
Ershoff 1999	Participants were pregnant smokers
Gariti 2002	Non-MI intervention components not matched between arms
George 2000	Non-MI intervention components not matched between arms
Glasgow 2000	Non-MI intervention components not matched between arms
Ha 2012	Was non-randomised or quasi-randomised
Ha 2015	Was non-randomised or quasi-randomised
Haas 2015	Non-MI intervention components not matched between arms
Hennrikus 2002	Did not test a behavioural motivational smoking cessation intervention
Hennrikus 2005	Non-MI intervention components not matched between arms
Hokanson 2006	Non-MI intervention components not matched between arms
Horn 2007	Non-MI intervention components not matched between arms
Huang 2015	Non-MI intervention components not matched between arms
Hughes 2017	Participants not current smokers



Study	Reason for exclusion
Hutchinson 2017	Participants not current smokers
Hyman 2007	Did not test a behavioural motivational smoking cessation intervention
Idrisov 2013	Non-MI intervention components not matched between arms
Ingersoll 2005	Measured cessation at less than 6 m follow-up
IRCT2017080435257N1	Tested a motivational intervention not based on M & R's MI
ISRCTN11353250	Non-MI intervention components not matched between arms
ISRCTN50627997	Tested a motivational intervention not based on M & R's MI
Klemperer 2017	Tested a motivational intervention not based on M & R's MI
Krigel 2011	Measured cessation at less than 6 m follow-up
Lasser 2012	Did not test a behavioural motivational smoking cessation intervention
Lennox 1998	Intervention based on stages of change theory
Lindqvist 2013	Was non-randomised or quasi-randomised
Luna 2005	Measured cessation at less than 6 m follow-up
Ma 2005a	Was non-randomised or quasi-randomised
Ma 2005b	Was non-randomised or quasi-randomised
Mahajan 2017	Was non-randomised or quasi-randomised
Manfredi 1999	Measured cessation at less than 6 m follow-up
Manfredi 2004	Did not test a behavioural motivational smoking cessation intervention
Martin-Lujan 2011	Non-MI intervention components not matched between arms
Mazas 2007	Didn't measure smoking cessation
McCambridge 2005	Participants not current smokers
Menzie 2018	Measured cessation at less than 6 m follow-up
Metse 2017	Non-MI intervention components not matched between arms
Metz 2006a	Non-MI intervention components not matched between arms. NRT only recommended to participants in one trial arm
Metz 2006b	Tested a motivational intervention not based on M & R's MI
Meyer 2003	Tested a motivational intervention not based on M & R's MI
Mujcic 2018	Non-MI intervention components not matched between arms



Study	Reason for exclusion
NCT00169260	Tested a motivational intervention not based on M & R's MI
NCT00701896	Tested a motivational intervention not based on M & R's MI
NCT00907309	Did not test a behavioural motivational smoking cessation intervention
NCT01098955	Tested a motivational intervention not based on M & R's MI
NCT01846910	Non-MI intervention components not matched between arms
NCT01982617	Measured cessation at less than 6 m follow-up
NCT02086162	Tested a motivational intervention not based on M & R's MI
Nichter 2018	Tested a motivational intervention not based on M & R's MI
Pardavila-Belio 2015	Non-MI intervention components not matched between arms
Parker 2007	Participants were pregnant smokers
Persson 2006	Non-MI intervention components not matched between arms
Pineiro 2014	Was non-randomised or quasi-randomised
Polosa 2011	Intervention based on stages of change theory
Reitzel 2010	Participants were pregnant smokers
Rigotti 1997	Non-MI intervention components not matched between arms
Rigotti 2006	Participants were pregnant smokers
Rogers 2016	Was non-randomised or quasi-randomised
Schuck 2014	Non-MI intervention components not matched between arms
Severson 2009	Non-MI intervention components not matched between arms
Sherbot 2005	Intervention based on stages of change theory
Sims 2013	Tested a motivational intervention not based on M & R's MI
Skov-Ettrup 2016	Intervention based on stages of change theory
Smith 2001	Did not test a behavioural motivational smoking cessation intervention
Sobell 2017	Non-MI intervention components not matched between arms
Steinberg 2016	Measured cessation at less than 6 m follow-up
Stotts 2002	Participants were pregnant smokers
Stotts 2009	Participants were pregnant smokers
Tappin 2000	Participants were pregnant smokers



Study	Reason for exclusion
Tappin 2005	Participants were pregnant smokers
Thomsen 2010	Non-MI intervention components not matched between arms
Van Rossem 2015	Tested a motivational intervention not based on M & R's MI
Wakefield 2004	Non-MI intervention components not matched between arms
Weaver 2015	Measured cessation at less than 6 m follow-up

m: month

M & R: Miller & Rollnick
MI: Motivational Interviewing
NRT: Nicotine replacement therapy

Characteristics of studies awaiting assessment [ordered by study ID]

Zhou 2014

Methods	Study design: unclear
	Location: China
	Setting: not specified
	Recruitment: unclear
Participants	N: 139
	Defining eligibility criteria?: smokers with coronary heart disease
	Motivation to quit?: unknown
Interventions	Control: usual clinic care and health education
	Intervention: motivational interviewing: "MI participants received six MI sessions over 3 months. Interviews include: (1) To help patients recognize that smoking and coronary heart disease are closely related. (2) To help patients realize the dangers of smoking on cardiovascular health. (3) To help patients recognize the potential benefits of quitting smoking. (4) Encourage the patients to face obstacles and setbacks in the process of smoking cessation bravely, and provide a solution available for the patients, enhancing patient confidence and motivation. (5) Encountering with the patients do not want to try to change, repeat the above explanation optionally."
	Provider: not specified
	Intensity: 6 sessions over 3 months
	Was MI fidelity monitored?: unclear
Outcomes	Definition of cessation used: unclear (abstinence not reported in abstract)
	Length of longest follow-up: unclear
	Validation: unclear
	Was mental health and/or well-being measured at follow-up?: unclear
	Was quality of life measured at follow-up?: unclear



Z	hοι	ı 201	(Continued)
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Funding source	Not reported
Authors' declarations of interest	Not reported
Notes	Unclear whether smoking cessation was measured (although seems likely) and at what follow-up points, making it impossible to ascertain whether the study met eligibility criteria. No cessation rates were reported in the abstract. Tried to contact authors however was unable to identify any contact details and an email to a generic university email address did not receive a response.

Characteristics of ongoing studies [ordered by study ID]

Lloyd-Richardson 2003

Trial name or title	Informed development of smoking cessation interventions for college students
Methods	Study design: RCT
	Location: not specified
	Setting: not specified
	Recruitment: not specified
Participants	N: 136
	Defining eligibility criteria?: college students
	Motivation to quit?: not specified
Interventions	Control: brief individualised smoking cessation treatment plus 8 weeks of NRT
	Intervention: motivationally-enhanced group treatment plus NRT
	Provider: not specified
	Intensity: not specified
	Was MI fidelity monitored?: not specified
Outcomes	Definition of cessation used: 7-day point prevalence
	Length of longest follow-up: six months
	Validation: yes - details not stated
	Was mental health and/or well-being measured at follow-up?: no
	Was quality of life measured at follow-up?: no
Starting date	Not reported
Contact information	EE Lloyd-Richardson
Funding source	Not reported
Authors' declarations of interest	Not reported



Lloyd-Richardson 2003 (Continued)

Notes

Whole sample had not been recruited when abstract was submitted, therefore six-month cessation rates were not reported. Attempt made to contact the author with no response

Trial name or title	Motivation and skills for detained teen smokers
Methods	Study design: factorial RCT (2 x 2)
	Location: USA
	Setting: adolescent detention centre
	Recruitment: adolescents who had been detained at the Rhode Island Training School (no further details)
Participants	N: 314
	Defining eligibility criteria?: adolescents detained at the Rhode Island Training School
	Motivation to quit?: not selected on motivation
Interventions	Control 1: relaxation intervention (no smoking cessation treatment): "The Relaxation Therapy intervention is a 60-90 minute individual session. The session encompasses several techniques, including Progressive Muscle Relaxation and Visualization-Imagination, and as a whole is really a meditation protocol. The Relaxation Therapy intervention encompasses several techniques, including Progressive Muscle Relaxation and Visualization-Imagination, and meditation to reduce stress."
	Control 2: self-help programming: "Self Help intervention is administered during two 90 minute group sessions. The intervention modules are based on the principles of Nicotine Anonymous (NicA), to provide those who use nicotine but want a nicotine-free life, with a community of people that have also experienced nicotine addiction and strive to be nicotine free. Elements incorporated in this intervention include the 12 Steps and the NicA "tools" (i.e. meetings, phone list, literature, sponsorship, and service) to facilitate and maintain abstinence from nicotine."
	Control 3: cognitive behavioural therapy: "The Cognitive Behavioral Therapy (CBT) Intervention is administered during two 90 minute group sessions. The focus is on the interrelationship between thoughts, feelings, and behaviors. It is used to address specific deficits, such as improving problen solving skills and developing social supports, and behaviors such as substance abuse and smoking."
	Intervention 1: motivational intervention: "Motivational Interviewing (MI) will be a 60-90 minutes individual session. The focus is on establishing rapport and building motivation. The counselor ex plores youth's reasons for entering treatment, prior treatment experience, previous attempts to change use, possible goals for treatment, substance effect expectancy, and perceptions of self-efficacy. A personalized feedback report outlines assessment results, highlights any problems or concerns related to cigarette use expressed by teen, and compares tobacco use levels with national norms for same age and gender peers."
	Provider: counsellor
	Intensity: MI/RT: 60 to 90 minutes over one session; CBT/SHP: 60 to 75 minutes over two sessions
	Was MI fidelity monitored?: not specified
Outcomes	Definition of cessation used: 7-day point prevalence
	Length of longest follow-up: six months (post-release)



NCT01387516 (Continued)	Validation: CO levels & saliva cotinine tests Was mental health and/or well-being measured at follow-up?: no Was quality of life measured at follow-up?: no
Starting date	July 2007
Contact information	Lynda Stein, University of Rhode Island
Funding source	Not reported
Authors' declarations of interest	Not reported
Notes	Contacted author to ask about study status - author replied that the study was complete and that they were about to start study write-up. No data were supplied.

Trial name or title	Strategies to promote cessation in smokers who are not ready to quit (PACE)
Methods	Study design: factorial RCT
	Location: USA
	Setting: quit-line
	Recruitment: not specified
Participants	N: 828
	Defining eligibility criteria?: not specified
	Motivation to quit?: not motivated to quit
Interventions	Control: brief advice: "Participants will receive brief advice to quit smoking, and be provided psycho-education citing health consequences and the positive impact on mortality and morbidity".
	Intervention 1: motivational Interviewing (MI): "Motivational interviewing (MI) is a collaborative conversation style for strengthening a person's own motivation and commitment to change. MI attempts to avoid a confrontational style and, instead, guides participants toward choosing to make a change in their behavior."
	Intervention 2: rate reduction (RR): "Participants will be informed of the strong medical evidence of systematic reductions in smoking behavior can lead to long-term smoking cessation." This condition will receive Nicotine Replacement Therapy in the form of gum.
	Intervention 3: motivation interviewing + rate reduction: participants will receive both intervention 1 and intervention 2 combined.
	Provider: not specified
	Intensity: 3 to 6 30-minute sessions + 3 booster sessions
	Was MI fidelity monitored?: not specified
Outcomes	Definition of cessation used: prolonged abstinence (defined as continuous abstinence with a two-week grace period)



NCT02905656 (Continued)	
	Length of longest follow-up: 12 months
	Validation: not specified
	Was mental health and/or well-being measured at follow-up?: not specified
	Was quality of life measured at follow-up?: not specified
Starting date	September 2016
Contact information	Karen Derefinko: kderefin@uthsc.edu
	Sarah Hand: sarkbill@uthsc.edu
Funding source	"Funded by the US NIH".
Authors' declarations of interest	Not reported
Notes	Trial registry record stated that the study is due to complete in 2020.

Trial name or title	STAND community college tobacco cessation trial
Methods	Study design: RCT
	Location: USA
	Setting: community college
	Recruitment: from Sacremento Community Colleges (no further information)
Participants	N: 113
	Defining eligibility criteria?: community college students
	Motivation to quit?: motivated to quit
Interventions	Control 1: usual care: "Students educated about and referred to student health for tobacco cessation resources and provided with campus "Quit Kits" ("Quit Kit" water bottle with small cessation aids (e.g. sunflower seeds))"
	Control 2: direct referral to quit-line: as control 1 plus "Students were directly referred to the state quitline for follow-up counseling. Peer educator educates about state quitline services and gets verbal consent to use quitline's direct referral web portal for quitline to contact participant in 1-2 business days about free counseling services to make a quit plan".
	Intervention: brief motivational interviewing: as control 1, plus "students received brief motivational interviewing by a student peer educator about tobacco cessation and participant goals"
	Provider: student peer educator
	Intensity: one session
	Was MI fidelity monitored?: not specified
Outcomes	Definition of cessation used: point prevalence (period not defined)
	Length of longest follow-up: 6 months



NCT03002883 (Continued)						
•	Validation: saliva cotinine level					
	Was mental health and/or well-being measured at follow-up?: not specified					
	Was quality of life measured at follow-up?: not specified					
Starting date	September 2014					
Contact information	Elisa Tong, University of California, Davis					
Funding source	Not reported					
Authors' declarations of interest	Not reported					
	Contacted author to ask about study status - author replied that the study was complete and that they were currently writing up results. No data was supplied.					

Salgado Garcia 2018

outgado Garcia 2010	
Trial name or title	Planning a change easily (PACE): a randomized controlled trial for smokers who are not ready to quit
Methods	Study design: RCT
	Location: USA
	Setting: nationwide quit-line
	Recruitment: "Recruitment is multi-faceted, including local and regional strategies. Including traditional strategies, such as flyers, business cards, and medical referrals, and electronic strategies, such as Facebook, Pandora Radio. A "refer-a-friend" program is also used, where participants receive an extra \$20 gift card for referring a person who is eligible and enrolls in the study."
Participants	N: not specified
	Defining eligibility criteria?: not specified
	Motivation to quit?: not motivated to quit
Interventions	Control 1: brief advice (BA):
	Control 2: rate reduction (RR): participants encouraged to reduce the amount they smoke, and instructed on the benefits this will have to their health. 26 weeks' worth of 4 mg nicotine gum provided
	Intervention 1: motivational interviewing (MI): "Basic MI principles will be used for each call with the intention of eliciting language that indicates behavioral change (i.e. "change talk") using openended questions, affirmations, reflections, and summaries. First, each telephone call will include

Intervention 1: motivational interviewing (MI): "Basic MI principles will be used for each call with the intention of eliciting language that indicates behavioral change (i.e. "change talk") using openended questions, affirmations, reflections, and summaries. First, each telephone call will include an initial period of engagement. Then, motivation and confidence to change smoking behavior will be assessed separately using scales from 1 (not at all motivated/confident) to 10 (extremely motivated/confident). Next, the counsellor will focus the discussion using the "5Rs" to increase the participants' motivation for change and eventual odds of cessation. The 5Rs will provide opportunities to elicit information from participants. At the end of each session, a summary of the discussion will be provided, and motivation and confidence to change smoking behavior will, again, be assessed. Should the participant wish to quit at any point during the sessions, the interventionist may assist in creating a participant-centred cessation plan, but no specific skills will be provided in this condition (e.g. "it seems like distraction and exercise could help you quit"). At the end of each session, the interventionist will ask the participant about their willingness to set a quit date using the elic-



Salgado Garcia 2018 (Continued)

it-provide-elicit approach, where the interventionist will elicit permission to provide information, will provide the information (e.g. higher likelihood of quitting if setting a quit date), and will elicit the participant's thoughts about setting a quit date."

Intervention 2: motivational interviewing and rate reduction (MI + RR): control 2 and intervention 1 combined

Provider: "The interventionists will be recruited based on educational background and past experience with counselling or delivering behavioral interventions. All interventionists will be required to have at least master's degrees in diverse areas of study (e.g. social work, public health, counselling, and psychology)."

Intensity: 3 sessions provided over 3 to 6 weeks (weekly or biweekly); 3 booster sessions provided bimonthly; 30 minutes overall

Was MI fidelity monitored?: "Audio from all study sessions will be recorded, and approximately one out of every ten sessions will be reviewed and scored for fidelity and MI adherence (when applicable) by doctoral-level clinical supervisors. Interventionists will receive weekly clinical supervision from doctoral level supervisors for feedback on scored sessions and further training when needed. MI training by local and national experts will be provided periodically throughout the study period."

Outcomes

Definition of cessation used: prolonged abstinence (length of time since the quit-date with a two-week grace period)

Length of longest follow-up: 12 months

Validation: saliva cotinine

Was mental health and/or well-being measured at follow-up?: no

Was quality of life measured at follow-up?: no

Starting date	Not specified
Contact information	F.I. Salgado García: fsalgado@uthsc.edu
Funding source	"National Institutes of Health [grant number 1R01CA193245-01A1]"
Authors' declarations of interest	"All authors confirm that there are no known conflicts of interest".
Notes	Contacted author to ask about study status - author replied that the study was still recruiting. Recruitment was planned to end in summer 2019, with results expected autumn 2020.

BA: brief advice

CBT: Cognitive Behavioural Therapy

CO: carbon monoxide

MI: Motivational Interviewing

NicA: Nicotine Anonymous

NRT: nicotine replacement therapy

PACE: Planning a Change Easily

RR: rate reduction

RT: relaxation therapy

SHP:self-help programming

STAND: Sacramento Taking Action Against Tobacco Dependence



DATA AND ANALYSES

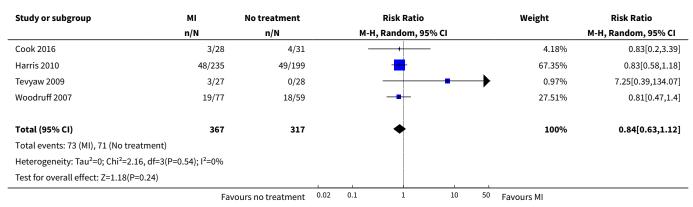
Comparison 1. MI versus no treatment

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size	
1 All studies: cessation	5		Risk Ratio (M-H, Random, 95% CI)	Totals not select- ed	
2 All studies: cessation - Naik 2014 removed	4	684	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.63, 1.12]	

Analysis 1.1. Comparison 1 MI versus no treatment, Outcome 1 All studies: cessation.

Study or subgroup	MI	No treatment			Risk Ratio			Risk Ratio
	n/N	n/N		М-Н,	Random, 9	5% CI		M-H, Random, 95% CI
Cook 2016	3/28	4/31		_	-	-		0.83[0.2,3.39]
Harris 2010	48/235	49/199			+			0.83[0.58,1.18]
Naik 2014	48/300	6/300						8[3.48,18.41]
Tevyaw 2009	3/27	0/28					-	7.25[0.39,134.07]
Woodruff 2007	19/77	18/59						0.81[0.47,1.4]
		Favours no treatment	0.01	0.1	1	10	100	Favours MI

Analysis 1.2. Comparison 1 MI versus no treatment, Outcome 2 All studies: cessation - Naik 2014 removed.



Comparison 2. MI in addition to other SC treatment versus that SC treatment alone

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 All studies: cessation	12	4167	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.85, 1.36]
2 Intensity subgroups: cessation	12	4167	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.85, 1.36]

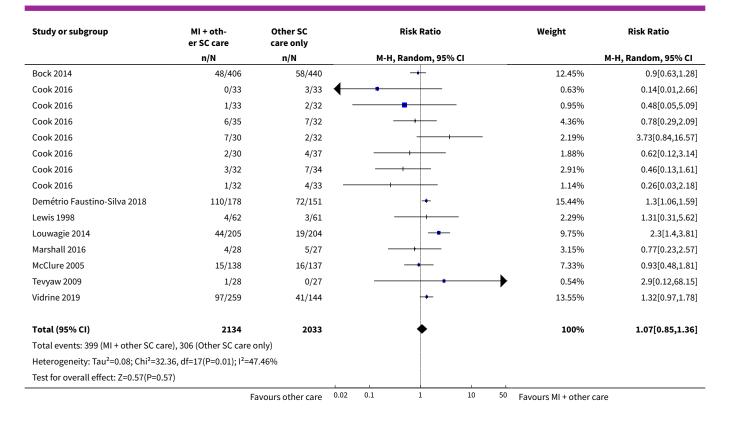


Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Intervention higher intensity	11	3838	Risk Ratio (M-H, Random, 95% CI)	1.01 [0.76, 1.35]
2.2 Intensity matched	1	329	Risk Ratio (M-H, Random, 95% CI)	1.30 [1.06, 1.59]
3 Provider subgroups: cessation	12	4167	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.85, 1.36]
3.1 Physician	1	55	Risk Ratio (M-H, Random, 95% CI)	0.77 [0.23, 2.57]
3.2 Nurse	2	298	Risk Ratio (M-H, Random, 95% CI)	0.52 [0.09, 2.95]
3.3 Counsellor	8	3405	Risk Ratio (M-H, Random, 95% CI)	1.08 [0.89, 1.32]
3.4 Lay healthcare worker	1	409	Risk Ratio (M-H, Random, 95% CI)	2.30 [1.40, 3.81]
4 Counselling modality sub- groups: cessation	12	4167	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.85, 1.36]
4.1 Some face-to-face	8	2818	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.87, 1.56]
4.2 No face-to-face	4	1349	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.53, 1.42]
5 Fidelity subgroups: cessation	12	4167	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.85, 1.36]
5.1 Fidelity monitoring reported	5	2115	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.57, 1.41]
5.2 No fidelity monitoring reported	7	2052	Risk Ratio (M-H, Random, 95% CI)	1.20 [0.93, 1.56]
6 Baseline motivation sub- groups: cessation	12	4167	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.85, 1.36]
6.1 Motivated	3	855	Risk Ratio (M-H, Random, 95% CI)	1.30 [1.10, 1.54]
6.2 Not selected on motiva- tion	8	2854	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.69, 1.55]
6.3 Not motivated	1	458	Risk Ratio (M-H, Random, 95% CI)	0.70 [0.36, 1.37]

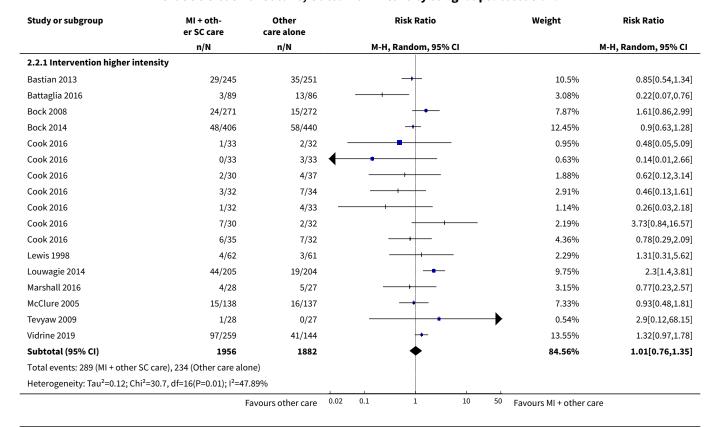
Analysis 2.1. Comparison 2 MI in addition to other SC treatment versus that SC treatment alone, Outcome 1 All studies: cessation.

Study or subgroup	MI + oth- er SC care	Other SC care only		Risk Ratio			Weight	Risk Ratio		
	n/N	n/N		M-H	, Random, 95	% CI				M-H, Random, 95% CI
Bastian 2013	29/245	35/251			+				10.5%	0.85[0.54,1.34]
Battaglia 2016	3/89	13/86							3.08%	0.22[0.07,0.76]
Bock 2008	24/271	15/272			+			1	7.87%	1.61[0.86,2.99]
		Favours other care	0.02	0.1	1	10) 5	0	Favours MI + other car	re

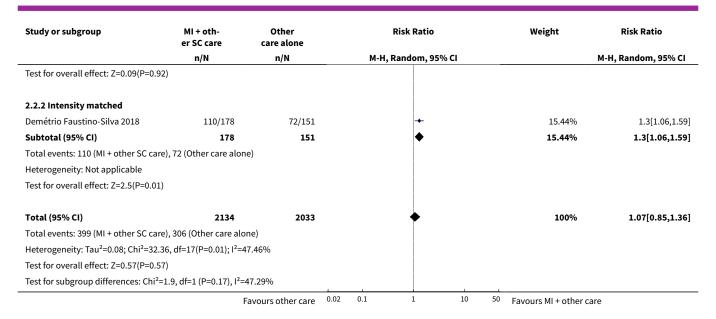




Analysis 2.2. Comparison 2 MI in addition to other SC treatment versus that SC treatment alone, Outcome 2 Intensity subgroups: cessation.



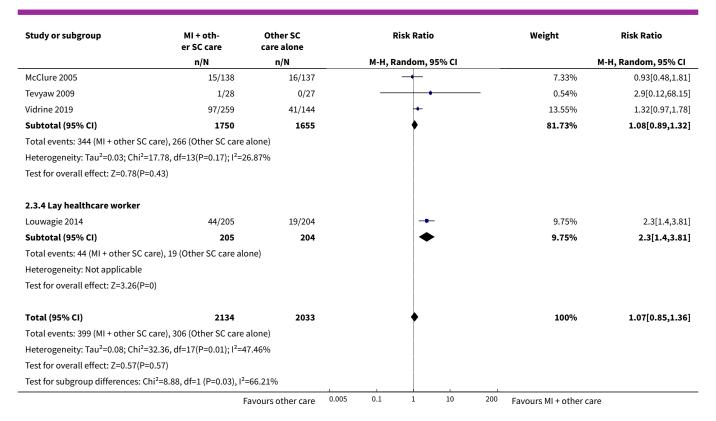




Analysis 2.3. Comparison 2 MI in addition to other SC treatment versus that SC treatment alone, Outcome 3 Provider subgroups: cessation.

Study or subgroup	MI + oth- er SC care	Other SC care alone	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
2.3.1 Physician					
Marshall 2016	4/28	5/27		3.15%	0.77[0.23,2.57]
Subtotal (95% CI)	28	27		3.15%	0.77[0.23,2.57]
Total events: 4 (MI + other SC care),	5 (Other SC care alone	e)			
Heterogeneity: Not applicable					
Test for overall effect: Z=0.42(P=0.6	7)				
2.3.2 Nurse					
Battaglia 2016	3/89	13/86		3.08%	0.22[0.07,0.76]
Lewis 1998	4/62	3/61	- 	2.29%	1.31[0.31,5.62]
Subtotal (95% CI)	151	147		5.37%	0.52[0.09,2.95]
Total events: 7 (MI + other SC care),	16 (Other SC care alo	ne)			
Heterogeneity: Tau ² =1.12; Chi ² =3.38	8, df=1(P=0.07); I ² =70.4	4%			
Test for overall effect: Z=0.74(P=0.4	6)				
2.3.3 Counsellor					
Bastian 2013	29/245	35/251	-+	10.5%	0.85[0.54,1.34]
Bock 2008	24/271	15/272	 • -	7.87%	1.61[0.86,2.99]
Bock 2014	48/406	58/440	+	12.45%	0.9[0.63,1.28]
Cook 2016	1/32	4/33		1.14%	0.26[0.03,2.18]
Cook 2016	6/35	7/32		4.36%	0.78[0.29,2.09]
Cook 2016	2/30	4/37		1.88%	0.62[0.12,3.14]
Cook 2016	3/32	7/34		2.91%	0.46[0.13,1.61]
Cook 2016	0/33	3/33		0.63%	0.14[0.01,2.66]
Cook 2016	7/30	2/32	 	2.19%	3.73[0.84,16.57]
Cook 2016	1/33	2/32		0.95%	0.48[0.05,5.09]

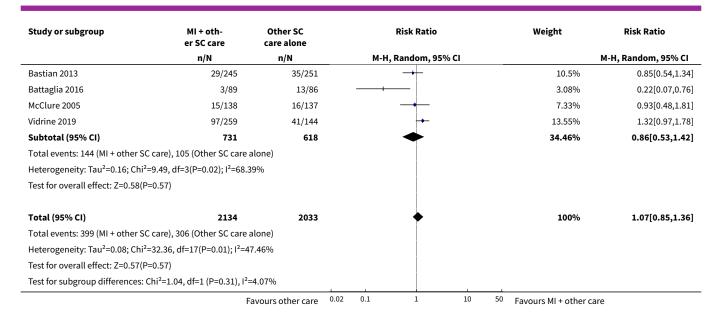




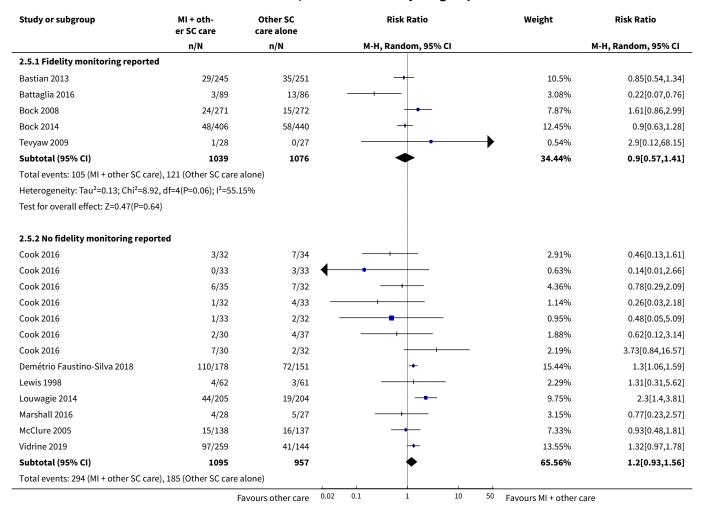
Analysis 2.4. Comparison 2 MI in addition to other SC treatment versus that SC treatment alone, Outcome 4 Counselling modality subgroups: cessation.

Study or subgroup	MI + oth- er SC care	Other SC care alone	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
2.4.1 Some face-to-face					
Bock 2008	24/271	15/272	 • -	7.87%	1.61[0.86,2.99]
Bock 2014	48/406	58/440		12.45%	0.9[0.63,1.28]
Cook 2016	3/32	7/34		2.91%	0.46[0.13,1.61]
Cook 2016	0/33	3/33		0.63%	0.14[0.01,2.66]
Cook 2016	7/30	2/32	+	2.19%	3.73[0.84,16.57]
Cook 2016	2/30	4/37		1.88%	0.62[0.12,3.14]
Cook 2016	1/32	4/33		1.14%	0.26[0.03,2.18]
Cook 2016	1/33	2/32		0.95%	0.48[0.05,5.09]
Cook 2016	6/35	7/32		4.36%	0.78[0.29,2.09]
Demétrio Faustino-Silva 2018	110/178	72/151	- +-	15.44%	1.3[1.06,1.59]
Lewis 1998	4/62	3/61		2.29%	1.31[0.31,5.62]
Louwagie 2014	44/205	19/204		9.75%	2.3[1.4,3.81]
Marshall 2016	4/28	5/27		3.15%	0.77[0.23,2.57]
Tevyaw 2009	1/28	0/27		0.54%	2.9[0.12,68.15]
Subtotal (95% CI)	1403	1415	*	65.54%	1.17[0.87,1.56]
Total events: 255 (MI + other SC ca	re), 201 (Other SC care	alone)			
Heterogeneity: Tau ² =0.08; Chi ² =21	.63, df=13(P=0.06); I ² =3	9.9%			
Test for overall effect: Z=1.04(P=0.3	3)				
2.4.2 No face-to-face					
	F	avours other care	0.02 0.1 1 10 5	Favours MI + other	care

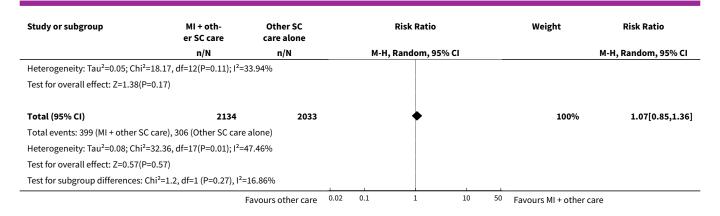




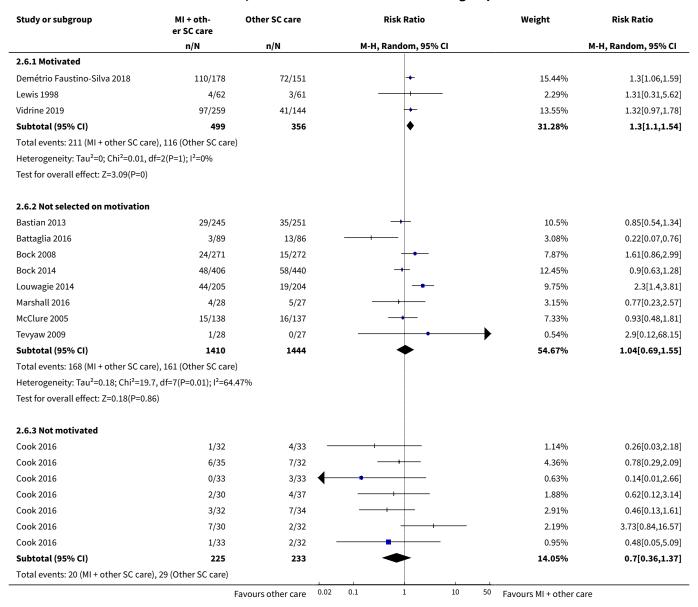
Analysis 2.5. Comparison 2 MI in addition to other SC treatment versus that SC treatment alone, Outcome 5 Fidelity subgroups: cessation.



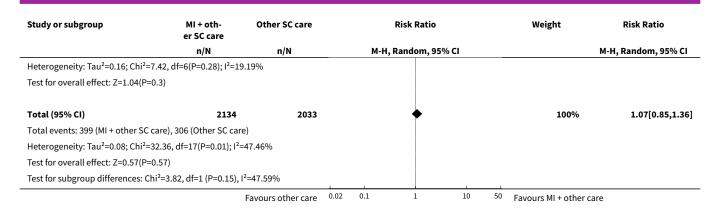




Analysis 2.6. Comparison 2 MI in addition to other SC treatment versus that SC treatment alone, Outcome 6 Baseline motivation subgroups: cessation.







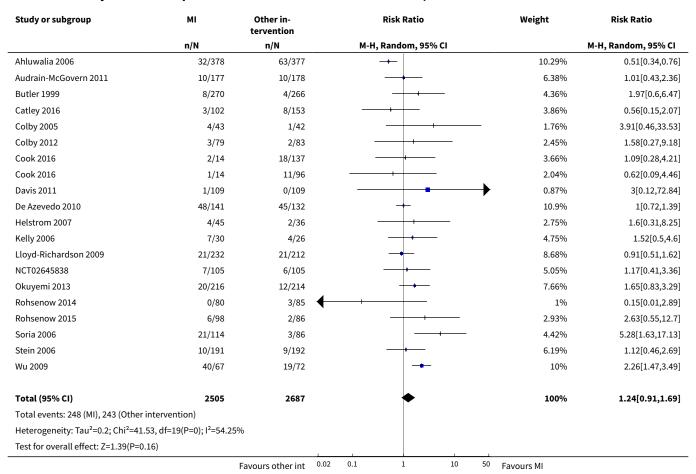
Comparison 3. MI versus other SC intervention

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 All studies: cessation	19	5192	Risk Ratio (M-H, Random, 95% CI)	1.24 [0.91, 1.69]
2 Intensity subgroups: cessation	19	5192	Risk Ratio (M-H, Random, 95% CI)	1.25 [0.93, 1.68]
2.1 Intervention higher intensity	14	3641	Risk Ratio (M-H, Random, 95% CI)	1.21 [0.95, 1.55]
2.2 Intensity matched	6	1402	Risk Ratio (M-H, Random, 95% CI)	1.14 [0.49, 2.65]
2.3 Comparator higher intensity	1	149	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.19, 4.42]
3 Age subgroups: cessation	19	5192	Risk Ratio (M-H, Random, 95% CI)	1.24 [0.91, 1.69]
3.1 Adults	14	4453	Risk Ratio (M-H, Random, 95% CI)	1.21 [0.84, 1.74]
3.2 Adolescents	5	739	Risk Ratio (M-H, Random, 95% CI)	1.36 [0.77, 2.41]
4 Provider subgroups: cessation	18	5111	Risk Ratio (M-H, Random, 95% CI)	1.24 [0.90, 1.70]
4.1 Physician	3	946	Risk Ratio (M-H, Random, 95% CI)	2.24 [0.92, 5.45]
4.2 Nurse	1	218	Risk Ratio (M-H, Random, 95% CI)	3.0 [0.12, 72.84]
4.3 Counsellor/psychologist	14	3947	Risk Ratio (M-H, Random, 95% CI)	1.11 [0.79, 1.55]
5 Fidelity monitoring sub- groups: cessation	19	5192	Risk Ratio (M-H, Random, 95% CI)	1.24 [0.91, 1.69]
5.1 Fidelity monitoring reported	12	3382	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.71, 1.37]
5.2 No fidelity monitoring reported	7	1810	Risk Ratio (M-H, Random, 95% CI)	1.83 [1.28, 2.60]



Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6 Baseline motivation sub-	19	5192	Risk Ratio (M-H, Random, 95% CI)	1.24 [0.91, 1.69]
groups: cessation		755	D' L D L' (M LL D L L OFF) CI	0.51[0.04.0.76]
6.1 Motivated 6.2 Not selected on motiva-	1 15	755 	Risk Ratio (M-H, Random, 95% CI) Risk Ratio (M-H, Random, 95% CI)	0.51 [0.34, 0.76]
tion			NISK Ratio (M-11, Randoni, 93% Ci)	1.44 [1.05, 1.50]
6.3 Not motivated	3	734	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.36, 1.85]

Analysis 3.1. Comparison 3 MI versus other SC intervention, Outcome 1 All studies: cessation.





Analysis 3.2. Comparison 3 MI versus other SC intervention, Outcome 2 Intensity subgroups: cessation.

Study or subgroup	MI	Other in- tervention	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
3.2.1 Intervention higher intensit	ty				
Audrain-McGovern 2011	10/177	10/178		6.24%	1.01[0.43,2.36
Butler 1999	8/270	4/266	+	4.18%	1.97[0.6,6.47
Catley 2016	1/51	0/51		0.81%	3[0.13,71.96
Colby 2005	4/43	1/42	+	1.65%	3.91[0.46,33.53
Colby 2012	3/79	2/83		2.31%	1.58[0.27,9.18
Cook 2016	1/7	7/32		1.98%	0.65[0.09,4.5
Cook 2016	1/7	7/66		1.96%	1.35[0.19,9.42
De Azevedo 2010	48/141	45/132	+	11.16%	1[0.72,1.39
Lloyd-Richardson 2009	21/232	21/212	-+	8.69%	0.91[0.51,1.62
NCT02645838	7/105	6/105		4.88%	1.17[0.41,3.36
Okuyemi 2013	20/216	12/214	+-	7.59%	1.65[0.83,3.29
Rohsenow 2014	0/80	3/85		0.93%	0.15[0.01,2.89
Rohsenow 2015	6/98	2/86		2.77%	2.63[0.55,12.7
Soria 2006	21/114	3/86		4.24%	5.28[1.63,17.13
Stein 2006	10/191	9/192		6.04%	1.12[0.46,2.69
Subtotal (95% CI)	1811	1830	•	65.42%	1.21[0.95,1.55
Total events: 161 (MI), 132 (Other in	ntervention)				
Heterogeneity: Tau ² =0.01; Chi ² =14.	92, df=14(P=0.38); I ² =6	17%			
Test for overall effect: Z=1.56(P=0.1	2)				
3.2.2 Intensity matched					
Ahluwalia 2006	32/378	63/377	 -	10.47%	0.51[0.34,0.76
Catley 2016	2/51	8/102		2.95%	0.5[0.11,2.27
Davis 2011	1/109	0/109		0.8%	3[0.12,72.84
Helstrom 2007	4/45	2/36		2.59%	1.6[0.31,8.25
Kelly 2006	7/30	4/26		4.58%	1.52[0.5,4.6
Wu 2009	40/67	19/72		10.14%	2.26[1.47,3.49
Subtotal (95% CI)	680				
		722		31.53%	1.14[0.49,2.65
Total events: 86 (MI), 96 (Other inte	ervention)	722		31.53%	
Total events: 86 (MI), 96 (Other inte Heterogeneity: Tau ² =0.71; Chi ² =27.				31.53%	
Total events: 86 (MI), 96 (Other inte Heterogeneity: Tau ² =0.71; Chi ² =27. Test for overall effect: Z=0.3(P=0.76	29, df=5(P<0.0001); I ² =			31.53%	
Heterogeneity: Tau ² =0.71; Chi ² =27.	29, df=5(P<0.0001); I ² = 5)			31.53%	
Heterogeneity: Tau ² =0.71; Chi ² =27. Test for overall effect: Z=0.3(P=0.76	29, df=5(P<0.0001); I ² = 5)			31.53% 2.05%	
Heterogeneity: Tau ² =0.71; Chi ² =27. Test for overall effect: Z=0.3(P=0.76 3.2.3 Comparator higher intensit	29, df=5(P<0.0001); l ² = 5)	31.68%			1.14[0.49,2.65 0.92[0.14,6.13
Heterogeneity: Tau ² =0.71; Chi ² =27. Test for overall effect: Z=0.3(P=0.76 3.2.3 Comparator higher intensit Cook 2016	29, df=5(P<0.0001); l ² = 5) y 1/7	11/71		2.05%	1.14[0.49,2.65
Heterogeneity: Tau ² =0.71; Chi ² =27. Test for overall effect: Z=0.3(P=0.76 3.2.3 Comparator higher intensit Cook 2016 Cook 2016 Subtotal (95% CI)	29, df=5(P<0.0001); l ² = 5) y 1/7 0/7 14	11/71 4/64		2.05% 1.01%	1.14[0.49,2.65 0.92[0.14,6.13 0.9[0.05,15.27
Heterogeneity: Tau ² =0.71; Chi ² =27. Test for overall effect: Z=0.3(P=0.76 3.2.3 Comparator higher intensit Cook 2016 Cook 2016	29, df=5(P<0.0001); l ² = 5) y 1/7 0/7 14 vention)	11/71 4/64		2.05% 1.01%	1.14[0.49,2.65 0.92[0.14,6.13 0.9[0.05,15.27
Heterogeneity: Tau ² =0.71; Chi ² =27. Test for overall effect: Z=0.3(P=0.76 3.2.3 Comparator higher intensit Cook 2016 Cook 2016 Subtotal (95% CI) Total events: 1 (MI), 15 (Other intersit	29, df=5(P<0.0001); l ² = y 1/7 0/7 14 vention) 1(P=0.99); l ² =0%	11/71 4/64		2.05% 1.01%	1.14[0.49,2.65 0.92[0.14,6.13 0.9[0.05,15.27
Heterogeneity: Tau ² =0.71; Chi ² =27. Test for overall effect: Z=0.3(P=0.76 3.2.3 Comparator higher intensit Cook 2016 Cook 2016 Subtotal (95% CI) Total events: 1 (MI), 15 (Other inter Heterogeneity: Tau ² =0; Chi ² =0, df=1	29, df=5(P<0.0001); l ² = y 1/7 0/7 14 vention) 1(P=0.99); l ² =0%	11/71 4/64		2.05% 1.01%	1.14[0.49,2.65 0.92[0.14,6.13 0.9[0.05,15.27 0.92[0.19,4.42
Heterogeneity: Tau ² =0.71; Chi ² =27. Test for overall effect: Z=0.3(P=0.76 3.2.3 Comparator higher intensit Cook 2016 Cook 2016 Subtotal (95% CI) Total events: 1 (MI), 15 (Other intented Heterogeneity: Tau ² =0; Chi ² =0, df=1 Test for overall effect: Z=0.11(P=0.9	29, df=5(P<0.0001); l ² = 5) y 1/7 0/7 14 vention) 1(P=0.99); l ² =0% 51)	11/71 4/64 135	•	2.05% 1.01% 3.05%	1.14[0.49,2.65 0.92[0.14,6.13 0.9[0.05,15.27
Heterogeneity: Tau ² =0.71; Chi ² =27. Test for overall effect: Z=0.3(P=0.76 3.2.3 Comparator higher intensit Cook 2016 Cook 2016 Subtotal (95% CI) Total events: 1 (MI), 15 (Other inter Heterogeneity: Tau ² =0; Chi ² =0, df=1 Test for overall effect: Z=0.11(P=0.9	29, df=5(P<0.0001); l ² = 5) y 1/7 0/7 14 vention) 1(P=0.99); l ² =0% 11) 2505 ntervention)	11/71 4/64 135		2.05% 1.01% 3.05%	1.14[0.49,2.65 0.92[0.14,6.13 0.9[0.05,15.27 0.92[0.19,4.42
Heterogeneity: Tau²=0.71; Chi²=27. Test for overall effect: Z=0.3(P=0.76 3.2.3 Comparator higher intensit Cook 2016 Cook 2016 Subtotal (95% CI) Total events: 1 (MI), 15 (Other inter Heterogeneity: Tau²=0; Chi²=0, df=1 Test for overall effect: Z=0.11(P=0.9) Total (95% CI) Total events: 248 (MI), 243 (Other in	29, df=5(P<0.0001); l ² = ;) y 1/7 0/7 14 vention) 1(P=0.99); l ² =0% it) 2505 htervention) 98, df=22(P=0.01); l ² =4	11/71 4/64 135		2.05% 1.01% 3.05%	1.14[0.49,2.65 0.92[0.14,6.13 0.9[0.05,15.27 0.92[0.19,4.42



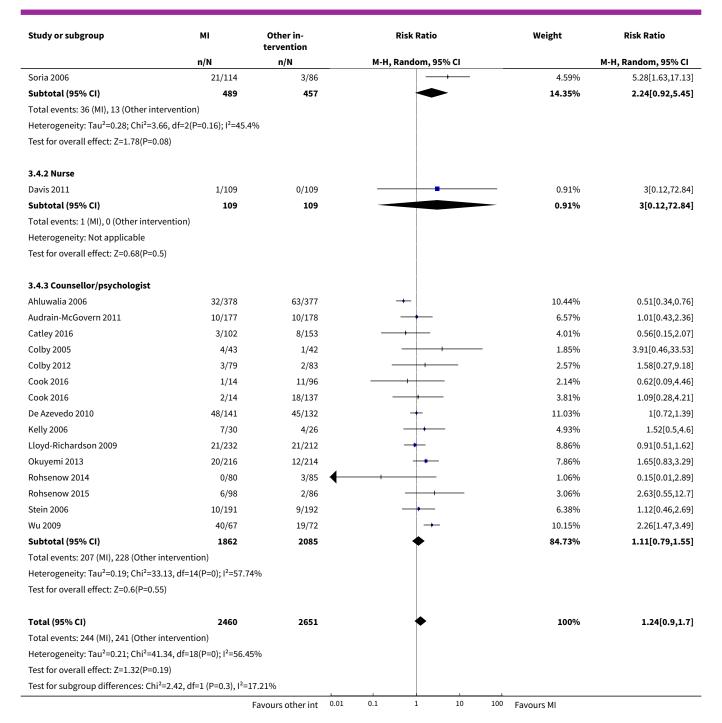
Analysis 3.3. Comparison 3 MI versus other SC intervention, Outcome 3 Age subgroups: cessation.

Study or subgroup	MI	Other in- tervention	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
3.3.1 Adults					
Ahluwalia 2006	32/378	63/377		10.29%	0.51[0.34,0.76]
Butler 1999	8/270	4/266	+	4.36%	1.97[0.6,6.47]
Catley 2016	3/102	8/153		3.86%	0.56[0.15,2.07]
Cook 2016	2/14	18/137		3.66%	1.09[0.28,4.21]
Cook 2016	1/14	11/96		2.04%	0.62[0.09,4.46]
Davis 2011	1/109	0/109		0.87%	3[0.12,72.84]
De Azevedo 2010	48/141	45/132	+	10.9%	1[0.72,1.39]
Lloyd-Richardson 2009	21/232	21/212	-	8.68%	0.91[0.51,1.62]
NCT02645838	7/105	6/105		5.05%	1.17[0.41,3.36]
Okuyemi 2013	20/216	12/214	+-	7.66%	1.65[0.83,3.29]
Rohsenow 2014	0/80	3/85		1%	0.15[0.01,2.89]
Rohsenow 2015	6/98	2/86		2.93%	2.63[0.55,12.7]
Soria 2006	21/114	3/86		4.42%	5.28[1.63,17.13]
Stein 2006	10/191	9/192		6.19%	1.12[0.46,2.69]
Wu 2009	40/67	19/72	-	10%	2.26[1.47,3.49]
Subtotal (95% CI)	2131	2322	•	81.9%	1.21[0.84,1.74]
Total events: 220 (MI), 224 (Other i	ntervention)				
Heterogeneity: Tau ² =0.25; Chi ² =39	.48, df=14(P=0); I ² =64.5	54%			
Test for overall effect: Z=1.01(P=0.	31)				
3.3.2 Adolescents					
Audrain-McGovern 2011	10/177	10/178		6.38%	1.01[0.43,2.36]
Colby 2005	4/43	1/42		1.76%	3.91[0.46,33.53]
Colby 2012	3/79	2/83		2.45%	1.58[0.27,9.18]
Helstrom 2007	4/45	2/36		2.75%	1.6[0.31,8.25]
Kelly 2006	7/30	4/26	- •	4.75%	1.52[0.5,4.6]
Subtotal (95% CI)	374	365	•	18.1%	1.36[0.77,2.41]
Total events: 28 (MI), 19 (Other into	ervention)				
Heterogeneity: Tau ² =0; Chi ² =1.52,	df=4(P=0.82); I ² =0%				
Test for overall effect: Z=1.07(P=0.	28)				
Total (95% CI)	2505	2687	•	100%	1.24[0.91,1.69]
Total events: 248 (MI), 243 (Other i	ntervention)				
Heterogeneity: Tau ² =0.2; Chi ² =41.		5%			
Test for overall effect: Z=1.39(P=0.					
rest for overall effect. Z=1.39(P=0.					

Analysis 3.4. Comparison 3 MI versus other SC intervention, Outcome 4 Provider subgroups: cessation.

Study or subgroup	MI	MI Other in- tervention		isk Ratio		Weight	Risk Ratio
	n/N	n/N	M-H, Ra	andom, 95% CI			M-H, Random, 95% CI
3.4.1 Physician							
Butler 1999	8/270	4/266		+		4.53%	1.97[0.6,6.47]
NCT02645838	7/105	6/105	-	- 		5.23%	1.17[0.41,3.36]
		Favours other int 0.01	L 0.1	1 10	100	Favours MI	

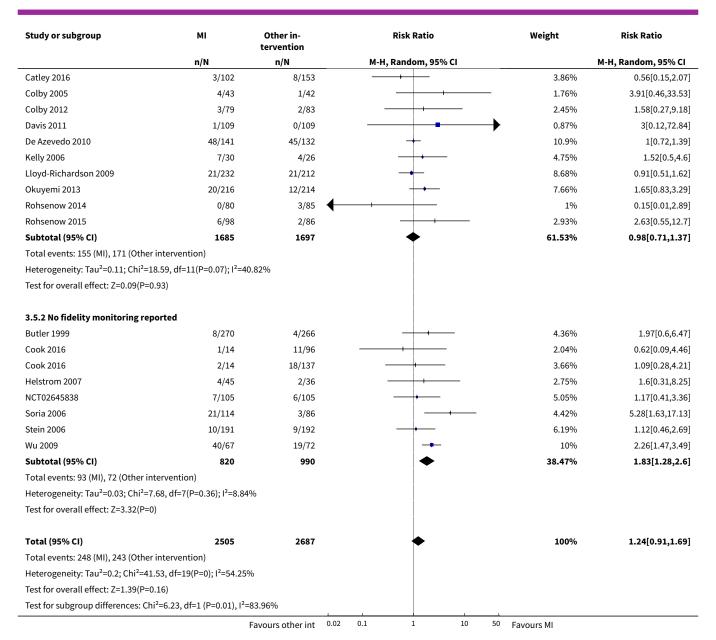




Analysis 3.5. Comparison 3 MI versus other SC intervention, Outcome 5 Fidelity monitoring subgroups: cessation.

Study or subgroup	MI Other in- tervention			Risk Ratio				Weight	Risk Ratio
	n/N	n/N		M-H, Ra	ndom, 9	5% CI			M-H, Random, 95% CI
3.5.1 Fidelity monitoring reported									
Ahluwalia 2006	32/378	63/377		-	-			10.29%	0.51[0.34,0.76]
Audrain-McGovern 2011	10/177	10/178		_	+			6.38%	1.01[0.43,2.36]
		Favours other int	0.02	0.1	1	10	50	Favours MI	

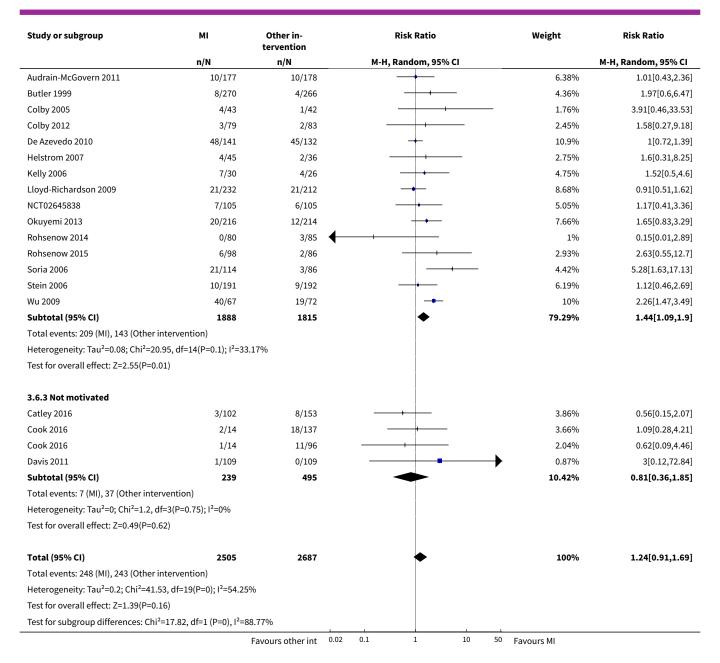




Analysis 3.6. Comparison 3 MI versus other SC intervention, Outcome 6 Baseline motivation subgroups: cessation.

Study or subgroup	MI	Other in- tervention		Risl	(Ratio		Weight	Risk Ratio
	n/N	n/N		M-H, Ran	dom, 95% CI			M-H, Random, 95% CI
3.6.1 Motivated								
Ahluwalia 2006	32/378	63/377		-			10.29%	0.51[0.34,0.76]
Subtotal (95% CI)	378	377		•			10.29%	0.51[0.34,0.76]
Total events: 32 (MI), 63 (Other interven	ention)							
Heterogeneity: Not applicable								
Test for overall effect: Z=3.33(P=0)								
3.6.2 Not selected on motivation			1			1		
		Favours other int	0.02	0.1	1 10	50	Favours MI	





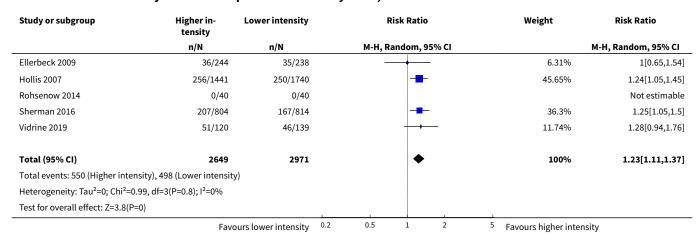
Comparison 4. Intensity of MI

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 All studies: cessation	5	5620	Risk Ratio (M-H, Random, 95% CI)	1.23 [1.11, 1.37]
2 Counsellor modality sub- groups: cessation	5	5620	Risk Ratio (M-H, Random, 95% CI)	1.23 [1.11, 1.37]
2.1 Some face-to-face	1	80	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
2.2 No face-to-face	4	5540	Risk Ratio (M-H, Random, 95% CI)	1.23 [1.11, 1.37]



Outcome or subgroup title	No. of studies	No. of partici-	Statistical method	Effect size
		pants		
3 Fidelity monitoring sub- groups: cessation	5	5620	Risk Ratio (M-H, Random, 95% CI)	1.23 [1.11, 1.37]
3.1 Fidelity monitoring reported	4	5361	Risk Ratio (M-H, Random, 95% CI)	1.23 [1.09, 1.37]
3.2 No fidelity monitoring reported	1	259	Risk Ratio (M-H, Random, 95% CI)	1.28 [0.94, 1.76]
4 Baseline motivation subgroups: cessation	5	5620	Risk Ratio (M-H, Random, 95% CI)	1.23 [1.11, 1.37]
4.1 Motivated	2	3440	Risk Ratio (M-H, Random, 95% CI)	1.25 [1.08, 1.44]
4.2 Not selected on motivation	3	2180	Risk Ratio (M-H, Random, 95% CI)	1.21 [1.03, 1.43]

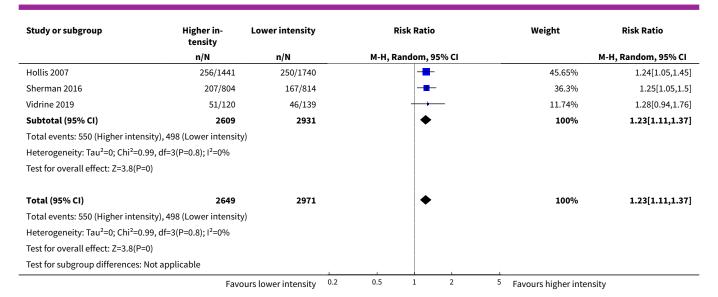
Analysis 4.1. Comparison 4 Intensity of MI, Outcome 1 All studies: cessation.



Analysis 4.2. Comparison 4 Intensity of MI, Outcome 2 Counsellor modality subgroups: cessation.

Study or subgroup	Higher in- tensity	Lower intensity		Risk Ra	tio		Weight	Risk Ratio
	n/N	n/N		M-H, Randon	ı, 95% CI			M-H, Random, 95% CI
4.2.1 Some face-to-face								
Rohsenow 2014	0/40	0/40						Not estimable
Subtotal (95% CI)	40	40						Not estimable
Total events: 0 (Higher intensity), 0	(Lower intensity)							
Heterogeneity: Not applicable								
Test for overall effect: Not applicab	le							
4.2.2 No face-to-face								
Ellerbeck 2009	36/244	35/238		. —	_ .		6.31%	1[0.65,1.54]
	Favo	ours lower intensity	0.2	0.5 1	2	5	Favours higher intens	ity





Analysis 4.3. Comparison 4 Intensity of MI, Outcome 3 Fidelity monitoring subgroups: cessation.

Study or subgroup	Higher in- tensity	Lower intensity	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
4.3.1 Fidelity monitoring reported	I				
Ellerbeck 2009	36/244	35/238		6.31%	1[0.65,1.54]
Hollis 2007	256/1441	250/1740	-	45.65%	1.24[1.05,1.45]
Rohsenow 2014	0/40	0/40			Not estimable
Sherman 2016	207/804	167/814	-	36.3%	1.25[1.05,1.5]
Subtotal (95% CI)	2529	2832	•	88.26%	1.23[1.09,1.37]
Total events: 499 (Higher intensity),	452 (Lower intensity	r)			
Heterogeneity: Tau²=0; Chi²=0.91, df	f=2(P=0.63); I ² =0%				
Test for overall effect: Z=3.47(P=0)					
4.3.2 No fidelity monitoring report	ted				
Vidrine 2019	51/120	46/139	+	11.74%	1.28[0.94,1.76]
Subtotal (95% CI)	120	139	-	11.74%	1.28[0.94,1.76]
Total events: 51 (Higher intensity), 4	6 (Lower intensity)				
Heterogeneity: Not applicable					
Test for overall effect: Z=1.56(P=0.12	2)				
Total (95% CI)	2649	2971	•	100%	1.23[1.11,1.37]
Total events: 550 (Higher intensity),	498 (Lower intensity	r)			
Heterogeneity: Tau²=0; Chi²=0.99, df	f=3(P=0.8); I ² =0%				
Test for overall effect: Z=3.8(P=0)					
Test for subgroup differences: Chi ² =	0.07, df=1 (P=0.78), I	2=0%			
	Favo	urs lower intensity 0.2	0.5 1 2	5 Favours higher inte	nsity



Analysis 4.4. Comparison 4 Intensity of MI, Outcome 4 Baseline motivation subgroups: cessation.

Study or subgroup	Higher in- tensity	Lower intensity	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
4.4.1 Motivated					
Hollis 2007	256/1441	250/1740	-	45.65%	1.24[1.05,1.45]
Vidrine 2019	51/120	46/139	+-	11.74%	1.28[0.94,1.76]
Subtotal (95% CI)	1561	1879	•	57.39%	1.25[1.08,1.44]
Total events: 307 (Higher intensity), 2	96 (Lower intensity	r)			
Heterogeneity: Tau ² =0; Chi ² =0.04, df=	1(P=0.83); I ² =0%				
Test for overall effect: Z=3.03(P=0)					
4.4.2 Not selected on motivation					
Ellerbeck 2009	36/244	35/238		6.31%	1[0.65,1.54]
Rohsenow 2014	0/40	0/40			Not estimable
Sherman 2016	207/804	167/814	-	36.3%	1.25[1.05,1.5]
Subtotal (95% CI)	1088	1092	•	42.61%	1.21[1.03,1.43]
Total events: 243 (Higher intensity), 2	02 (Lower intensity	·)			
Heterogeneity: Tau ² =0; Chi ² =0.89, df=	1(P=0.35); I ² =0%				
Test for overall effect: Z=2.3(P=0.02)					
Total (95% CI)	2649	2971	•	100%	1.23[1.11,1.37]
Total events: 550 (Higher intensity), 4	98 (Lower intensity	·)			
Heterogeneity: Tau ² =0; Chi ² =0.99, df=	3(P=0.8); I ² =0%				
Test for overall effect: Z=3.8(P=0)					
Test for subgroup differences: Chi ² =0.	05, df=1 (P=0.81), l	2=0%			
	Favo	urs lower intensity 0.2	0.5 1 2	5 Favours higher inte	nsity

ADDITIONAL TABLES

Table 1. Details of MI fidelity monitoring (studies that reported monitoring only)

Study ID	Details of monitoring	Monitoring results	Fidelity achieved? (defined by indi- vidual study para- meters)
Ahluwalia 2006	Weekly supervision; subset of sessions rated using MISC	Not reported	n/a
Audrain-McGovern 2011	Weekly supervision, subset of sessions rated using MITI code	Benchmarks for MI competency (>= 6) approached/achieved for 2 ratings of empathy (mean: 5.2; SD: 0.87) & spirit (mean: 5.9; SD: 0.81) using 7-point Likert scale. Behavioural counts met benchmarks for proficiency, including ratio of reflections to questions (1.8), percentage of open questions (61%), and MI adherence (96%). 28% of complex reflections approached benchmark for beginning proficiency (40%).	No, in some cases marker did not quite meet the benchmarks set; however were close
Bastian 2013	Each counsellors first 3 sessions monitored & feedback provid-	Not reported	n/a



	ed; weekly supervision; random sessions rated using MITI code		
Battaglia 2016	Random calls observed; nurse participated in ongoing MI training	Not reported	n/a
Bock 2008	Subset of sessions audited using a decisional balance review tool and intervention component checklists	Not reported	n/a
Bock 2014	Subset of sessions reviewed; weekly supervision	Not reported	n/a
Catley 2016	Training continued until counsellors met fidelity criteria for 3 consecutive sessions; subset of sessions rated using MITI code	Mean (SD) global ratings (1–5): Empathy MI = 4.5 (0.6) 95% above criterion, HE = 2.3 (1.2) 24% above criterion, MD = 2.3 (95% CI = 1.8, 2.8). Direction MI = 4.9 (0.4) 97% above criterion, HE = 4.7 (0.8) 95% above criterion, MD = 0.3 (-0.2, 0.8), P = 0.17. Collaboration MI = 4.2 (0.9) 79% above criterion, HE = 2.1 (1.2) 14% above criterion, MD = 2.1 (1.6, 2.5). Evocation MI = 4.4 (0.7) 92% above criterion, HE = 2.3 (1.1) 19% above criterion, MD = 2.2 (1.8, 2.7). Autonomy support MI = 4.3 (0.8) 87% above criterion, HE 2.8 (1.2) 27% above criterion, MD = 1.5 (1.1, 2.0). Giving information (counts): MI = 3.9 (4.8) n/a % above criterion, HE = 12.8 (9.5) n/a % above criterion, MD = 1.2 (95% CI 0.7, 1.7). Reflections: questions (ratio of counts): MI = 3.1 (2.4) 92% above criterion, HE = 0.2 (0.3) 5% above criterion, MD = 1.7 (95% CI 1.2, 2.1). Open-ended questions (%): MI = 66.0 (27.6) 76% above criterion, HE = 10.5 (11.0) 3% above criterion, MD = 2.6 (95% CI 2.2, 3.1). Complex reflections (%) MI = 53.9 (16.3) 82% above criterion, HE = 19.6 (27.6) 24% above criterion, MD = 1.5 (95% 1.1, 2.0). MI adherent (%) MI = 79.4 (37.9) 71% above criterion, HE = 30.3 (42.6) 22% above criterion, MD = 1.2 (95% CI 0.8, 1.7). MI adherent behaviour counts MI = 2.3 (1.7) n/a % above criterion, HE = 0.8 (1.3) n/a % above criterion, HE = 1.5 (3.0) n/a % above criterion, MD = 1.0 (95% 0.5, 1.5). MI non-adherent behaviour counts MI = 0.2 (0.7) n/a % above criterion, HE = 1.5 (3.0) n/a % above criterion, MD = 0.6 (95% CI 0.1, 1.1)	Yes
Colby 2005	Weekly group supervision; each session rated on scales from 1 (strongly disagree) to 4 (strongly agree) on rapport, counsellor empathy & self-efficacy enhancement; delivery of 15 essential elements of the protocol were also rated as 0 (topic not introduced), 1 (not at all useful), 2 (somewhat useful), or 3 (very useful)	Participant ratings high for counsellor rapport (M = 3.8, SD = 0.6), empathy (M = 3.5, SD = 0.8), and self-efficacy enhancement (M = 3.7, SD = 0.7). Participants recalled 94% of essential elements; interventionists reported discussing 98% of the elements. Utility judged high by participants (M = 2.4, SD = 0.5) and interventionists (M = 2.4, SD = 0.3)	Yes
Colby 2012	Weekly supervision; interven- tionists & adolescent partici- pants rated sessions	Interventionists & adolescents indicated that nearly all 16 MI session components were delivered (M = 15.6, SD = 0.80 and M = 15.4, SD = 1.39 respectively).	Yes



Davis 2011	Sessions reviewed for proto- col adherence and discussed at weekly meetings	Two cases did not meet treatment standard. Cases not reaching criterion were removed from the analyses.	Yes
De Azevedo 2010	Fortnightly supervision	n/a	n/a
Ellerbeck 2009	Each session rated on key concepts of MI and specific content of MI protocol; counsellors rated themselves and were rated during supervision using MI markers.	Not reported	n/a
Harris 2010	Counsellors had to demonstrate proficiency in MI; weekly supervision; supervisors rated counsellors' in-session proficiency on 18 items, including reflective listening, asking permission, and MI spirit; where fidelity scores dropped, additional supervision was provided until they increased or the counsellor was dismissed	Fidelity scores remained high throughout (mean rating of 6.12 (0.87 SD) on the MI-spirit item)	Yes
Hollis 2007	Calls monitored and rated on adherence	Not reported	n/a
Kelly 2006	Supervision, including a review of each session to reduce content drift/contamination	Not reported	n/a
Lloyd-Richardson 2009	Supervision on sample of sessions; participant exit interviews; documentation of time spent in intervention; subset of sessions rated on degree of adherence	Content delivered was appropriate, and exceeded SC arm	Yes
Okuyemi 2013	Sessions reviewed during week- ly supervision	Not reported	n/a
Rohsenow 2014	Subset of sessions reviewed in weekly supervision, rated for MI style & adherence with feedback given. Rated from 1 (not at all) to 5 (extensively) scale for 5 motivational style measures, and on adequacy of six MI adherence items	Therapist style ratings did not differ across conditions for arguing (on average not at all), but MI therapists showed more empathy, used more reflective listening, supported self-efficacy more, and emphasised personal responsibility more. MI therapists more likely to discuss topics to increase ambivalence (100% of MI, 4% of BA sessions), provide assessment feedback (100% of MI, 0% of BA sessions), explore barriers (82.1% of MI, 0% of BA sessions), provide summaries (100% of MI, 0% of BA sessions), and discuss possible goals (100% of MI, 14.8% of BA sessions)	Yes

Yes



Table 1. Details of MI fidelity monitoring (studies that reported monitoring only) (Continued)

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Subset of sessions reviewed in weekly supervision, rated for MI style & adherence & feedback given. Rated from 1 (not at all) to 5 (extensively) scale for 5 motivational style measures, and on adequacy of six MI adherence items

MI more likely to discuss: ambivalence about smoking (93% of MI, 4% of BA sessions), assessment feedback (100% of MI, 0% of BA sessions), barriers to quitting smoking (100% of MI, 17% of BA sessions), provide summaries (100% of MI, 0% of BA sessions), methods of quitting or preparing to quit (100% of MI, 58% of BA sessions), and possible goals (100% of MI, 14.8% of BA sessions). Therapist style ratings did not differ between conditions for arguing, empathy, or reflective listening, but MI therapists more likely to support self-efficacy & emphasise personal responsibility.

Sherman 2016

Subset of calls reviewed & feedback given on MI techniques; weekly supervision Not reported

n/a

Tevyaw 2009

Participants & counsellors rated which of 15 MET elements and 4 REL elements were completed

Therapists reported covering 14.9 (SD = 0.4) of 15 MET components and 0 (SD = 0.1) of 4 REL components during MET; and all 4 (SD = 0) of the REL components and 0.7 (SD = 0.5) of the MET components during REL. Student ratings reported that therapists covered 14.3 (SD = 1.3) of 15 MET components & 1.6 (SD = 1.5) of 4 REL components during MET sessions. They reported therapists covered 3.3 (SD = 1.1) of the 4 REL components and 6.3 (SD = 5.3) of the 15 MET components during REL sessions.

Yes

BA:brief advice

HE: Health Education

M: mean

MD: mean difference

MET: Motivational Enhancement Therapy
MISC: Motivational Interviewing Skills Code

MI: Motivational Interviewing

MITI: Motivational Interviewing Treatment Integrity

n/a: not applicable

REL: muscle relaxation training

SC: smoking cessation SD: standard deviation

Table 2. Details of intervention & comparator content & intensity

Study ID	MI intervention description	Intervention in- tensity (no. of sessions; total duration)	Non-MI comparator de- scription	Comparator intensity	Intensity matched?	Pharma- cotherapy used?	Other common intervention components
Ahluwalia 2006	MI counselling using se- mi-structured script	6 sessions; 2 h	SC counselling providing information & advice to develop a quit plan	6 sessions; 2 h	Yes	NRT in half each condi- tion; placebo NRT in other half	Tailored smok- ing cessation booklet
Audrain-Mc- Govern 2011	MET counselling	5 sessions; 3 h 15 min	Structured brief advice, using '5As' or '5Rs'	5 sessions; 1 h 15 min	No, compara- tor lower	n/a	n/a
Bastian 2013	MI & adaptive coping skills counselling + self-directed materials. Skills training in- formed by Transactional Model of Stress & Coping	6 sessions; 3 h	Self-help materials - letter from oncologist encour- aging quitting, quit kit (in- cluding SC guide), individ- ually tailored booklet	n/a	No, compara- tor lower	NRT	Self-help mate- rials
Battaglia 2016	MI counselling + written SC information	12 sessions; 3 h 20 min	PTSD home telehealth programme + electronic (Health Buddy) device	n/a	No, compara- tor lower	NRT, bupropion on or varenicline	PTSD home telehealth pro- gramme + elec- tronic (Health Buddy) device
Bock 2008	MI counselling + self help resources	5 sessions; 1 h 20 min	Non-MI counselling calls + self-help resources	2 sessions; 20 min	No, compara- tor lower	NRT	2 brief non-MI counselling calls, review of NRT use in- structions
Bock 2014	MI counselling + 5As intervention	3 sessions; ap- prox 1 h	5As intervention	1 session; 5 min	No, compara- tor lower	NRT	5As interven- tion
Butler 1999	Brief MI session	1 session; 10 min	Brief SC advice	1 session; 2 min	No, compara- tor lower	n/a	n/a
Catley 2016	MI counselling	4 sessions; length unclear	brief advice SC counselling based on clinical guidelines	1. 1 session 2. 4 sessions (lengths un- clear)	Yes (health education intensity matched) &	NRT or vareni- cline	Self-help guide

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 Table 2. Details of intervention & comparator content & intensity (Continued)

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				vice - lower)		
MI counselling	2 sessions; 50 min	Brief recommendation to quit + follow-up call	2 sessions; 10 min	No, compara- tor lower	n/a	SC pamphlet + treatment refer- rals information
MI counselling. Participants' parents also discussed child's quit attempt and supporting it with researchers, using MI principles.	2 sessions for adolescents + 1 for parents; 1 h adolescents; 15 min parents	Brief SC advice with fol- low-up session	2 sessions for adolescents; 10 min (none for parents)	No, compara- tor lower	n/a	SC pamphlet + treatment refer- rals information
MI counselling	4 sessions; 50 min	Behavioural smoking reduction guidance	1. 7 sessions; 1 h 20 min.	1. No, higher	NRT depen- dent on tri-	n/a
		2. No treatment	2. No sessions	2. No, tower	al arm (bal- anced across arms of inter- est)	
Mi counselling	1 session; 15 min	Prescriptive interview regarding smoking - firm & authoritative	1 session; 15 min	Yes	n/a	n/a
MI counselling	8 sessions; 1 h 40 min	Brief SC advice	1 session; 15 min	No, compara- tor lower	n/a	n/a
MI taught to SC advisors as additional resource to standard CBT approach used	Average 3 ses- sions; length un- clear	Standard CBT approach advocated by Brazilian Ministry of Health's smok- ing programme	Average 3 sessions, length unclear	Yes	n/a	CBT counselling approach
1. High intensity MI	1. 6 sessions	n/a	n/a		NRT or bupro- pion	Welcome let-
2. Moderate intensity MI	every 6 min; length unclear					ter, information about med-
	2. 2 sessions every 6 min; length unclear					ication, smoking cessation pamphlets, 6-monthly personalised newsletter, periodic progress reports with counselling suggestions
	MI counselling. Participants' parents also discussed child's quit attempt and supporting it with researchers, using MI principles. MI counselling MI counselling MI taught to SC advisors as additional resource to standard CBT approach used	MI counselling. Participants' parents also discussed child's quit attempt and supporting it with researchers, using MI principles. MI counselling MI counselling A sessions; 15 min parents MI counselling I sessions; 50 min MI counselling A sessions; 1 h 40 min MI taught to SC advisors as additional resource to standard CBT approach used Average 3 sessions; length unclear 1. High intensity MI 2. Moderate intensity MI 2. Sessions every 6 min; length unclear 2. 2 sessions every 6 min;	MI counselling. Participants' parents also discussed child's quit attempt and supporting it with researchers, using MI principles. MI counselling MI counselling 4 sessions; 50 min adolescents; 15 min parents 4 sessions; 50 min adolescents; 15 min parents I sessions; 50 min adolescents; 15 min parents MI counselling 1 sessions; 50 min adolescents; 15 min parents MI counselling 1 sessions; 15 min adolescents; 15 min parents Prescriptive interview regarding smoking - firm & authoritative MI counselling 8 sessions; 1 h 40 min MI taught to SC advisors as additional resource to standard CBT approach advocated by Brazilian Ministry of Health's smoking programme 1. High intensity MI 2. Moderate intensity MI 2. Sessions every 6 min; length unclear 2. 2 sessions every 6 min;	MI counselling. Participants' parents also discussed child's quit attempt and supporting it with researchers, using MI principles. MI counselling 4 sessions; 50 min adolescents; 15 min parents 4 sessions; 50 min adolescents; 15 min parents 1. Behavioural smoking reduction guidance 2. No treatment 2. No sessions 1. T sessions; 1 h 20 min. 2. No treatment 2. No sessions; 15 min principal supporting it with researchers, using MI principles. MI counselling 1 session; 15 min parents 1 session; 15 min prescriptive interview regarding smoking - firm & authoritative MI counselling 8 sessions; 1 h 40 min MI taught to SC advisors as additional resource to standard CBT approach used Average 3 sessions; length unclear 1. High intensity MI 2. Moderate intensity MI 2. Sessions every 6 min; length unclear 2. 2 sessions every 6 min; length unclear	MI counselling 2 sessions; 50 min quit + follow-up call 2 sessions; 10 No, comparator lower MI counselling, Participants' parents also discussed child's quit attempt and supporting it with researchers, using MI principles. MI counselling 4 sessions; 50 min parents MI counselling 1 session; 15 min parents MI counselling 2 sessions for adolescents; 15 min parents MI counselling 4 sessions; 50 min parents MI counselling 2 sessions; 50 min parents MI counselling 3 session; 15 min parents MI counselling 4 sessions; 50 min parents MI counselling 5 session; 15 min parents MI counselling 6 session; 15 min parents MI counselling 7 session; 15 min parents MI counselling 8 sessions; 1 h 40 min 2. No treatment 2. No sessions MI counselling 8 sessions; 1 h 40 min 2. No comparator lower MI counselling 8 sessions; 1 h 40 min 2. No comparator lower MI taught to SC advisors as additional resource to standard CBT approach used MI taught to SC advisors as additional resource to standard CBT approach used 1. 6 sessions every 6 min; length unclear 2. 2 sessions every	MI counselling MI counselling. Participants' parents also discussed child's quit attempt and supporting it with researchers, using MI principles. MI counselling MI counselling A sessions; 50 min parents MI counselling A sessions; 50 min parents A sessions; 15 min parents A sessions; 10 min parents A

 Table 2. Details of intervention & comparator content & intensity (Continued)

faxed to partic-ipants' physi-

							cians
Harris 2010	MI counselling	4 sessions; average 1 h 40 min	MI counselling focused on increasing fruit & veg- etable consumption	4 sessions; average 1 h 40 min	n/a	Pharma- cotherapy for highly depen- dent smokers	n/a
Helstrom 2007	MET counselling	1 session; length unclear	Information session on to- bacco use based on Amer- ican Cancer Society pam- phlet	1 session; length un- clear	Yes	n/a	n/a
Hollis 2007	 high intensity MI moderate intensity MI low intensity MI 	1. 5 sessions; at least 1 h 2. 2 sessions; at least 45 min 3. 1 session; 15 min	n/a	n/a	n/a	NRT for half of participants in each group	"Quit kit" in- cluding SC booklet
Kelly 2006	MI counselling	1 session; 1 h	SC counselling based on psychoeducation model	1 session; 1 h	Yes	n/a	Written materi- als
Lewis 1998	Brief motivational message to quit smoking, with follow-up counselling incorporating CBT & MI	5 sessions; approx 1 h	Brief motivational message to quit smoking + SC pamphlet	1 session; 3 min	No, compara- tor lower	Placebo NRT	Brief motiva- tional message to quit + SC pamphlet
Lloyd- Richardson 2009	MET counselling	5 sessions; at least 2 h	Brief assessment of quit- ting plans with brief in- person follow-up	2 sessions; approx 10 m	No, compara- tor lower	NRT	n/a
Louwagie 2014	Brief MI session + short stan- dardised SC message + SC booklet	1 session; 15-20 min	Short standardised SC message + SC booklet	1 session; 1 min	No, compara- tor lower	n/a	Short SC mes- sage + SC book- let
Marshall 2016	MI counselling session + audio quit material + printed materi- als + quit-line details	1 session; approx 25 min	Non-tailored printed ma- terials + quit-line details	n/a	No, compara- tor lower	n/a	Written mate- rials + quit-line details



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Table 2. Details of intervention & comparator content & intensity (co	Continued)
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Matuszewski 2018	 MI counselling + control intervention MI counselling intervention + 	 1. 1 session; average 10 min 2. 2 sessions; av- 	Referral to patient re- source centre + quit-line brochure	n/a	No, compara- tor lower	n/a	Referral to pa- tient resource centre + quit-
	additional brief follow-up	erage 15 min					line brochure
McClure 2005	MET counselling + control intervention	4 sessions; 1 h	Letter explaining associa- tion between cervical can- cer & smoking + SC book- let + quit-line details	n/a	No, compara- tor lower	NRT or bupro- pion	Letter explain- ing association between cer- vical cancer & smoking, SC booklet, quit- line details
Naik 2014	MI counselling	not reported	No intervention (waiting list control)	n/a	n/a	n/a	n/a
NCT02645838	MI counselling	7 sessions; un- clear- over 20 min	Brief SC advice	1 session; 5 min	No, compara- tor lower	n/a	n/a
Okuyemi 2013	MI SC and NRT adherence counselling	6 sessions; aver- age 1h 45 min	Brief smoking cessation advice + SC guide	1 session; 10-15 min	No, control lower	NRT	SC guide
Rohsenow 2014	MI counselling session MI counselling session +	1. 1 session; 45 min	1. Brief advice using US AHRQ method	1. 1 session; 15 min	No, compara-NRT tor lower	SC pamphlets, information on	
	booster sessions	2. 3 sessions 1h 5min	2. Brief advice + 2 booster sessions	2. 3 sessions; 35 min			SC skills groups & hard candy
Rohsenow 2015	MI session + booster sessions (half received non contingent payments & half contingent payments)	4 sessions; approx 2 h	Brief advice using US AHRQ methods (half re- ceived non contingent payments & half contin- gent payments)	4 sessions; approx 55 min	No, compara- tor lower	NRT	SC pamphlets & hard candy
Sherman 2016	1. MI & Problem Solving Thera- py counselling	1. 7 sessions; approx 1 h 30 min	n/a	n/a	n/a	NRT	n/a
	2. Referral to state Quitline (usually New York state) - coun- sellors trained in MI	2. 2 sessions; approx 30 min					

Soria 2006	MI counselling	3 sessions; 60 min	Brief anti-smoking advice	1 session; 3 min	No, compara- tor lower	Bupropion for highly depen- dent smokers	n/a
Stein 2006	MI counselling	3 sessions; ap- prox 1h	Brief advice using 4As + self-help materials	2 sessions; approx 5 min	No, compara- tor lower	NRT	n/a
Tevyaw 2009	MET (half received non contingent payments & half contingent payments)	3 sessions; 2 h	Progressive muscle re- laxation training (half re- ceived non contingent payments & half contin- gent payments)	3 sessions; 2 h	n/a	n/a	n/a
Vidrine 2019	Brief advice + text messages based on CBT & MI Brief advice + texts + counselling calls based on CBT & MI	1. 1 session; approx 5 min. 2. 11 sessions; approx 2 h	Brief SC advice	1 session; ap- prox 5 min	No, compara- tor lower	NRT	Brief quitting advice, writter materials, quit line details
Woodruff 2007	Online virtual world (The Breathing Room) - participants' avatars had MI group coun- selling with other participants & the counsellor within a virtual shopping mall setting	7 sessions; 5 h 15 min	No treatment	n/a	n/a	n/a	n/a
Wu 2009	MI counselling + SC self-help materials	4 sessions; 4 h	Health education counselling + self-help materials covering nutrition, exercise, and tobacco use	4 sessions; 4 h	Yes	NRT	n/a

5As: 'Ask, Advise, Assess, Assist, and Arrange'

5Rs: 'Relevance, Risks, Rewards, Roadblocks, Repetition'

AHRQ: Agency for Healthcare Research and Quality

approx: approximately

CBT: Cognitive Behavioural Therapy

h: hour(s)

m: month(s)

min: minute(s)

MI: Motivational interviewing

MET: Motivational Enhancement Therapy

n/a: not applicable

NRT:nicotine replacement therapy

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APPENDICES

Appendix 1. CRS Search Strategy 2019

#1 (motivat* NEAR2 interview*):TI,AB,MH,EMT,KY,XKY,KW,XRT

#2 (motivat* NEAR2 enhanc*):TI,AB,MH,EMT,KY,XKY,KW

#3 (motivat* NEAR2 (session* OR counsel* OR practi* OR behav*)):TI,AB

#4 #1 OR #2 OR #3 AND (INREGISTER) [SET 1]

#5 motivation*:MH,EMT,XKY,KY,KW AND (INREGISTER) [SET 2]

Notes: Set 1 identifies the most relevant records. Set 2 identifies records with the keyword 'motivation' not otherwise identified in set 1, and is over sensitive. Studies in both sets were screened for inclusion.

In lines 4 and 5 'motivat*' captures the variants of 'motivational' used in the original search strategy.

WHAT'S NEW

Date	Event	Description
23 May 2019	New search has been performed	Updated with 16 new studies and with ten previously included studies excluded due to changes in eligibility criteria
23 May 2019	New citation required and conclusions have changed	New authors added. Conclusions have changed - evidence for benefit of MI for smoking cessation is inconclusive - confidence intervals now incorporate both benefit and harm. The certainty of the evidence has changed from moderate to low, indicating that new evidence is likely to have an impact on the effect estimates and their 95% confidence intervals.

HISTORY

Protocol first published: Issue 1, 2008 Review first published: Issue 1, 2010

Date	Event	Description
5 January 2015	New citation required but conclusions have not changed	Authors have changed. Main conclusions remain stable, with only minor changes in subgroup findings
5 January 2015	New search has been performed	Updated with 14 new included studies
5 September 2011	Amended	Reference to companion review updated
10 February 2010	Amended	Spelling correction in tables and change in
21 October 2008	Amended	Converted to new review format

CONTRIBUTIONS OF AUTHORS

AF, JL, NL, PA and TT all reviewed the previous version of the review and amended eligibility criteria. AF, JL, NL, and TT assessed study eligibility and extracted data from eligible studies.



NL authored a draft of the review and AF, JL, PA and TT all provided comments that were incorporated into this final version.

DECLARATIONS OF INTEREST

AF is employed by the University of Oxford to work as a Senior Researcher in the Health Behaviours group on projects related to nicotine consumption. Anne has been the recipient of a grant funded by Cancer Research UK to explore clinician attitudes towards electronic cigarettes. None of this is deemed a conflict of interest.

JL has no known conflicts of interest.

NL is employed by the University of Oxford to work as Managing Editor for the Cochrane Tobacco Addiction Group (TAG). TAG's infrastructure is funded by the NIHR. Nicola has received payment for lectures on systematic review methodology, and has been an applicant on project funding to carry out priority setting and systematic reviews in the area of tobacco control (NIHR funded). None of this is deemed a conflict of interest.

PA has no known conflicts of interest.

TT has no known conflicts of interest.

SOURCES OF SUPPORT

Internal sources

- Nuffield Department of Primary Care Health Sciences, University of Oxford, UK.
- · Clinical Trials & Health Research Institute of Translational & Stratified Medicine; University of Plymouth, UK.
- College of Medicine & Health, University of Exeter, UK.

External sources

· NIHR Infrastructure funding, UK.

Funding for the infrastructure of the Cochrane Tobacco Addiction Group

• NIHR Cochrane Programme Grant funding, UK.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

- 1. The cost-effectiveness objective has been removed.
- 2. We excluded pregnant women, as their particular needs and circumstances warrant them being treated as separate populations. They are covered in another Cochrane Review (Chamberlain 2017).
- 3. We introduced a new eligibility criterion excluding studies incorporating additional non-MI components into the intervention group that were not matched in the comparator group, in order to reduce bias.
- 4. We have now included comparators of all intensities; however, we controlled for this using subgroup analyses.
- 5. We have now included studies regardless of whether they carried out fidelity monitoring; however, we controlled for this using subgroup analyses.
- 6. We excluded non-randomised controlled trials, to keep the quality of the evidence as high as possible.
- 7. We introduced secondary outcomes (mental health and quality of life) to assess whether MI for smoking cessation has any impact on the well-being of participants.
- 8. We grouped the included studies into four separate comparisons rather than incorporating all studies into one meta-analysis.
- 9. We added additional prespecified subgroup analyses, splitting studies by 1) the relative intensity of the intervention and comparator conditions; 2) participant motivation to quit; 3) and whether fidelity monitoring took place.

INDEX TERMS

Medical Subject Headings (MeSH)

Behavior Therapy [*methods]; Hotlines; Motivation; Motivational Interviewing [*methods]; Randomized Controlled Trials as Topic; Smoking [*psychology] [*therapy]; Smoking Cessation [psychology]

MeSH check words

Humans