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Community pharmacy personnel interventions for smoking cessation (Review)

Carson-Chahhoud KV, Livingstone-Banks J, Sharrad KJ, Kopsaftis Z, Brinn MP, To-A-Nan R, Bond CM

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[Intervention Review]

Community pharmacy personnel interventions for smoking cessation

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ABSTRACT

Background

Community pharmacists could provide effective smoking cessation treatment because they offer easy access to members of the community. They are well placed to provide both advice on the correct use of smoking cessation products and behavioural support to aid smoking cessation.

Objectives

To assess the effectiveness of interventions delivered by community pharmacy personnel to assist people to stop smoking, with or without concurrent use of pharmacotherapy.

Search methods

We searched the Cochrane Tobacco Addiction Group Specialised Register, along with clinicaltrials.gov and the ICTRP, for smoking cessation studies conducted in a community pharmacy setting, using the search terms pharmacist* or pharmacy or pharmacies. Date of the most recent search: January 2019.

Selection criteria

Randomised controlled trials of interventions delivered by community pharmacy personnel to promote smoking cessation amongst their clients who were smokers, compared with usual pharmacy support or any less intensive programme. The main outcome measure was smoking cessation rates at six months or more after the start of the intervention.

Data collection and analysis

We used standard methodological procedures expected by Cochrane for study screening, data extraction and management. We conducted a meta-analysis using a Mantel-Haenszel random-effects model to generate risk ratios (RRs) and 95% confidence intervals (CIs).

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Main results

We identified seven studies including 1774 participants. We judged three studies to be at high risk of bias and four to be at unclear risk. Each study provided face-to-face behavioural support delivered by pharmacy staff, and required pharmacy personnel training. Typically such programmes comprised support starting before quit day and continuing with weekly appointments for several weeks afterwards. Comparators were either minimal or less intensive behavioural support for smoking cessation, typically comprising a few minutes of one-off advice on how to quit. Participants in both intervention and control arms received equivalent smoking cessation pharmacotherapy in all but one study. All studies took place in high-income countries, and recruited participants visiting pharmacies. We pooled six studies of 1614 participants and detected a benefit of more intensive behavioural smoking cessation interventions delivered by community pharmacy personnel compared with less intensive cessation interventions at longest follow-up (RR 2.30, 95% CI 1.33 to 3.97; I^2 = 54%; low-certainty evidence).

Authors' conclusions

Community pharmacists can provide effective behavioural support to people trying to stop smoking. However, this conclusion is based on low-certainty evidence, limited by risk of bias and imprecision. Further research could change this conclusion.

PLAIN LANGUAGE SUMMARY

Does quit-smoking support delivered by community pharmacy staff help people to stop smoking?

Background

Tobacco smoking is the leading cause of preventable death and disease worldwide. Community pharmacists are respected healthcare professionals who provide easily accessible and convenient healthcare services to their communities, and they are well placed to provide their clients with help to quit smoking. Indeed, many governments recognise community pharmacies as a useful way of delivering many healthcare services. However, we need evidence that these services are effective before we develop them more widely.

Study characteristics

We searched for relevant studies in January 2019, and found seven studies including 1774 people. Three studies took place in the UK, and one each in Australia, United States, Qatar, and Italy. Each study provided face-to-face behavioural support delivered by pharmacy staff, who received specific training. Studies compared the structured programme to less intensive support to stop smoking.

Key results

We found evidence that more intensive structured care given by community pharmacy staff probably helps more people to quit smoking than less intensive support to quit.

Quality of the evidence

We found low-quality evidence that community pharmacy support helps people to quit smoking. Limitations of the evidence came from potential problems with the ways some of the studies were carried out and the low numbers of people who quit smoking across the included studies, which means we are not sure how effective these programmes really are.

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SUMMARY OF FINDINGS

Summary of findings for the main comparison. Community pharmacy personnel interventions compared with standard care or less intensive support for smoking cessation

Community pharmacy personnel interventions compared with standard care or less intensive support for smoking cessation

Patient or population: people who smoke who were motivated to change their smoking behavior
Setting: Community pharmacies (Australia, Italy, Qutar, UK, USA)
Intervention: higher-intensity smoking cessation support delivered by community pharmacy personnel
Comparison: lower-intensity smoking cessation support delivered by community pharmacy personnel

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with control	Risk with community pharmacy personnel interventions				
Smoking cessation Follow up: range 6 months to 12 months	60 per 1000	138 per 1000 (80 to 237)	RR 2.30 (1.33 to 3.97)	1614 (6 RCTs)	⊕⊕⊖⊖ Low[a,b]	

***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

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

[a]Downgraded by one level due to risk of bias: we rated all studies at unclear or high risk of bias.
[b]Downgraded by one level due to imprecision: there were fewer than 300 events across studies.

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BACKGROUND

Description of the condition

Tobacco smoking is one of the leading causes of preventable morbidity and mortality worldwide, responsible for the deaths of approximately six million people across the world each year (WHO 2015). Smoking is a major cause of fatal diseases such as cancer, cardiovascular diseases, and stroke (USDHHS 2014). The cost of healthcare services relevant to disorders caused by smoking is high; in 2004 to 2005, it was estimated to cost Australia AUD 31.5 billion in social, health and economic costs, in both prevention and treatment of smoking-induced diseases (Collins 2008). In the USA the annual economic tobacco cost is estimated at USD 289 billion (USDHHS 2014).

Description of the intervention

Governments and national bodies have long recognised the important role that pharmacists have in the delivery of healthcare services within the community pharmacy setting (Commonwealth of Australia 2018; WHO 1994). Pharmacists are believed to be valuable sources of specialised knowledge for both health professionals and patients alike (WHO 1994). They are easily-reached avenues of reliable information that are often considered more accessible to the general population than general practices (Agomo 2018).

United Kingdom (UK) and USA guidelines (Public Health England 2017; Boutwell 2014 respectively) recommend pharmacists advise on the correct use of nicotine replacement therapy (NRT) at point of sale and provide structured support to aid smoking cessation (West 2000). Evidence suggests that wider provision of smoking cessation through community pharmacies may be: associated with improved cessation (Blenkinsopp 2003; Brown 2016; Saba 2014); is valued by pharmacy customers (Brown 2014; Hudmon 2003; McMillan 2014); is beneficial for health-related quality of life of participants during their cessation attempt (Bauld 2011; Zillich 2002); and is cost-effective (Bauld 2011; Cantor 2015; Csikar 2015; Tran 2002). However, data from randomised trials are needed to examine whether these outcomes are a result of the service.

Although smoking cessation training for pharmacy students has been shown to increase perceived confidence and ability to provide counselling (Brown 2014; Hudmon 2004), the lack of curriculum time and experiential training opportunities still prevent some pharmacy schools from covering this topic adequately (Hudmon 2005). Evidence from trials that these programmes are effective may change this.

How the intervention might work

Healthcare professionals play a pivotal role in smoking cessation promotion (West 2015), and pharmacists are well placed to provide smoking cessation advice, given their broad interaction with the general community. NRT is available in most pharmacies without prescription and pharmacists may be the only health professional available to offer advice. Other pharmacotherapies, such as varenicline and bupropion, are also supplied largely through pharmacies, and collecting stop-smoking medication represents a key opportunity for smoking cessation support in a community setting. Repeat visits to collect further pharmacotherapy also means that there are multiple opportunities for continued support without the need for follow-up appointments with multiple types of healthcare professionals. Besides potentially increasing access to smoking cessation support, support from pharmacists may help to increase adherence to stop-smoking medications (Hollands 2019), and assist cessation by providing additional behavioural support as an adjunct to pharmacotherapy, which is an effective way to support cessation (Hartmann-Boyce 2019).

Why it is important to do this review

A systematic review of interventions by community pharmacy personnel is required to provide evidence-based conclusions of their efficacy to inform policy, clinical practice, and future research.

OBJECTIVES

To assess the effectiveness of interventions delivered by community pharmacy personnel to assist people to stop smoking, with or without concurrent use of pharmacotherapy.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs), including cluster-RCTs.

Types of participants

Community pharmacy clients who were current tobacco smokers and motivated to change their smoking behaviour.

Types of interventions

Eligible interventions included a behavioural component and were provided by community pharmacy personnel to aid smoking cessation. The intervention may have been delivered by one or more pharmacists or members of pharmacy staff, or both They may have included brief advice or more intensive behavioural therapy, with or without the use of any form of smoking cessation pharmacotherapy. Pharmaceutical trials that compared only the use of a pharmacotherapy with a control in the community pharmacy setting do not fall within the scope of this review.

The comparison intervention could be either no or less intensive behavioural support.

Types of outcome measures

Primary outcomes

- Abstinence from smoking six months or more after the start of the intervention. In the event that a study recorded multiple smoking abstinence measures, we used the longest period of follow-up and the strictest definition of abstinence, with preference given to those where biochemical validation occurred.
- Adverse effects

Secondary outcomes

- Cost effectiveness

Search methods for identification of studies

We searched the Cochrane Tobacco Addiction Group Specialised Register of trials. This is derived from regular systematic searches of bibliographic databases including the Cochrane Central Register of Controlled trials (CENTRAL), MEDLINE, Embase, and PsycINFO (see the Cochrane Tobacco Addiction Group website for how the Regis-

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ter is populated). At the time of the search on 11 January 2019, the Register included the results of searches of CENTRAL, issue 1, 2018; MEDLINE (via OVID) to update 20190108; Embase (via OVID) to week 201902; PsycINFO (via OVID) to update 20181231. Our search strategy is listed in Appendix 1 and Appendix 2.

We also searched online clinical trial registries (clinicaltrials.gov, and the WHO International Clinical Trials Registry Platform) for ongoing and recently completed studies.

Data collection and analysis

Selection of studies

Two review authors (from KVCC, JLB, MB, and RT) independently reviewed the literature searches from the title, abstract or descriptors. We excluded all studies that were clearly not RCTs or that clearly did not fit the inclusion criteria. Two review authors then read all other citations in full text, assessing for inclusion based on study design, population, intervention and outcome. We resolved disagreements through discussion and consensus. Had disagreements persisted, we would have resolved them by a third arbiter (CMB). We did not exclude trials on the basis of language or date of publication.

Data extraction and management

Two review authors (from KVCC, JLB, MB, ZK and KJS) independently extracted data in duplicate from the eligible trials using a standardised data extraction form. We attempted to contact study authors to obtain missing and raw data where required.

Assessment of risk of bias in included studies

Two review authors (KVCC, JLB) assessed risks of bias in duplicate, in line with recommendations made in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017), and guidance specific to the Cochrane Tobacco Addiction Group. We assessed each eligible study for the following domains: random sequence generation and allocation concealment (selection bias), blinding/objectivity of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective outcome reporting (reporting bias), and other potential bias. For each study, we judged each domain to be at low, high, or unclear risk of bias. We judged studies to be at high risk of detection bias where abstinence was not biochemically validated and the intervention arm received more face-to-face contact than the control arm, as we considered differential misreport a possibility in these cases.

Given that participants and study personnel cannot be blinded in studies of behavioural interventions, and in line with guidance from the Cochrane Tobacco Addiction Group, we did not judge studies based on performance bias.

Measures of treatment effect

We measured our primary outcome (smoking abstinence) using risk ratios (RRs) with 95% confidence intervals (CIs). We used the strictest definition of abstinence at longest follow-up, and preferred biochemically validated abstinence where available.

Unit of analysis issues

Unit of analysis errors occur in studies where the unit of randomisation is clusters (e.g. pharmacies and states), but the unit of analysis is individual participants. This can result in overestimation of the statistical significance of the results by not accounting for the clustering of individuals in the data (Rooney 1996). For studies that did not include adjustments for clustering, we reduced the size of the trial to the effective sample size using the original sample size from each study, divided by a design effect figure, as recommended in the *Cochrane Handbook* (Higgins 2019). We used a design effect of 1.2.

Dealing with missing data

Where statistics essential for analysis were missing and could not be calculated from other data, we attempted to contact the authors to obtain data. We assumed that loss of participants that occurred prior to performance of baseline measurements had no effect on the eventual outcome data of the study. We regarded any participants lost to follow-up after the baseline measurement as being continuing smokers.

Assessment of heterogeneity

We assessed the characteristics of the included studies to determine whether there was sufficient clinical or methodological heterogeneity to preclude meta-analysis. We assessed statistical heterogeneity in our meta-analyses using the I^2 statistic, interpreted using the following overlapping bands, as given in the *Cochrane Handbook* (Higgins 2019):

0% to 40%: might not be important;
30% to 60%: may represent moderate heterogeneity;
50% to 90%: may represent substantial heterogeneity;
75% to 100%: considerable heterogeneity.

Assessment of reporting biases

In the event that we included 10 or more studies in any one comparison, we planned to assess potential reporting biases using a funnel plot. We also assessed reporting bias in individual studies as part of our 'Risk of bias' assessments. We judged studies to be at high risk of reporting bias if the outcomes reported differed from those planned.

Data synthesis

We conducted a meta-analysis for our primary outcome (smoking abstinence) using a Mantel-Haenszel random-effects model to generate a pooled RR and its 95% CI. We used the strictest definition of abstinence at longest follow-up, and preferred biochemically-validated abstinence where available. We used an intention-to-treat analysis, and considered participants lost to follow-up as still smoking.

Subgroup analysis and investigation of heterogeneity

We did not plan or carry out any subgroup analyses.

Sensitivity analysis

We conducted the following sensitivity analyses:

- removing a study where the provision of pharmacotherapy potentially differed between study arms. This is because between-arm differences in the provision of medications found to be effective in helping people to quit smoking would be expected to inflate the effect size attributed to the behavioural intervention being tested.
- removing studies judged to be at a high risk of bias.

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'Summary of findings' table

Following standard Cochrane methods (Schünemann 2017), we created a 'Summary of findings' table for our primary outcome (smoking abstinence), and assessed the certainty of the evidence using the five GRADE considerations (risk of bias, inconsistency, imprecision, indirectness and publication bias).

RESULTS

Description of studies

See Characteristics of included studies and Characteristics of excluded studies.

Results of the search

The searches for this update found 145 records relating to 126 studies. Of these, we included five new studies in the review, making a total of seven when combined with the two previously included studies. We also found three ongoing studies, and list 37 excluded studies. See Figure 1 for study flow information relating to the most recent update search. We report information about ongoing studies in the Characteristics of ongoing studies tables, and we list reasons for the exclusion of studies in the Characteristics of excluded studies tables.

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Figure 1. Study flow diagram for 2019 update

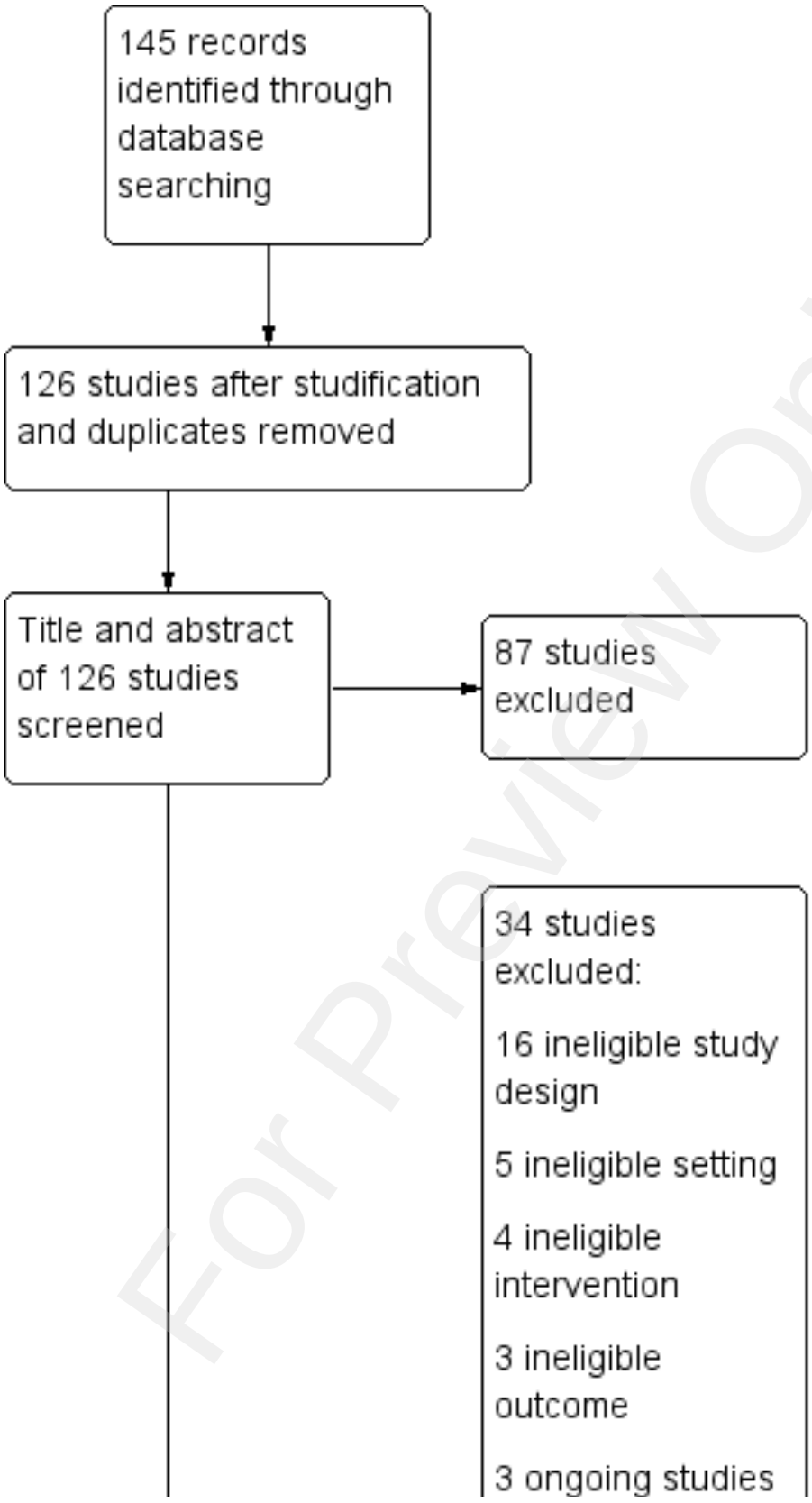

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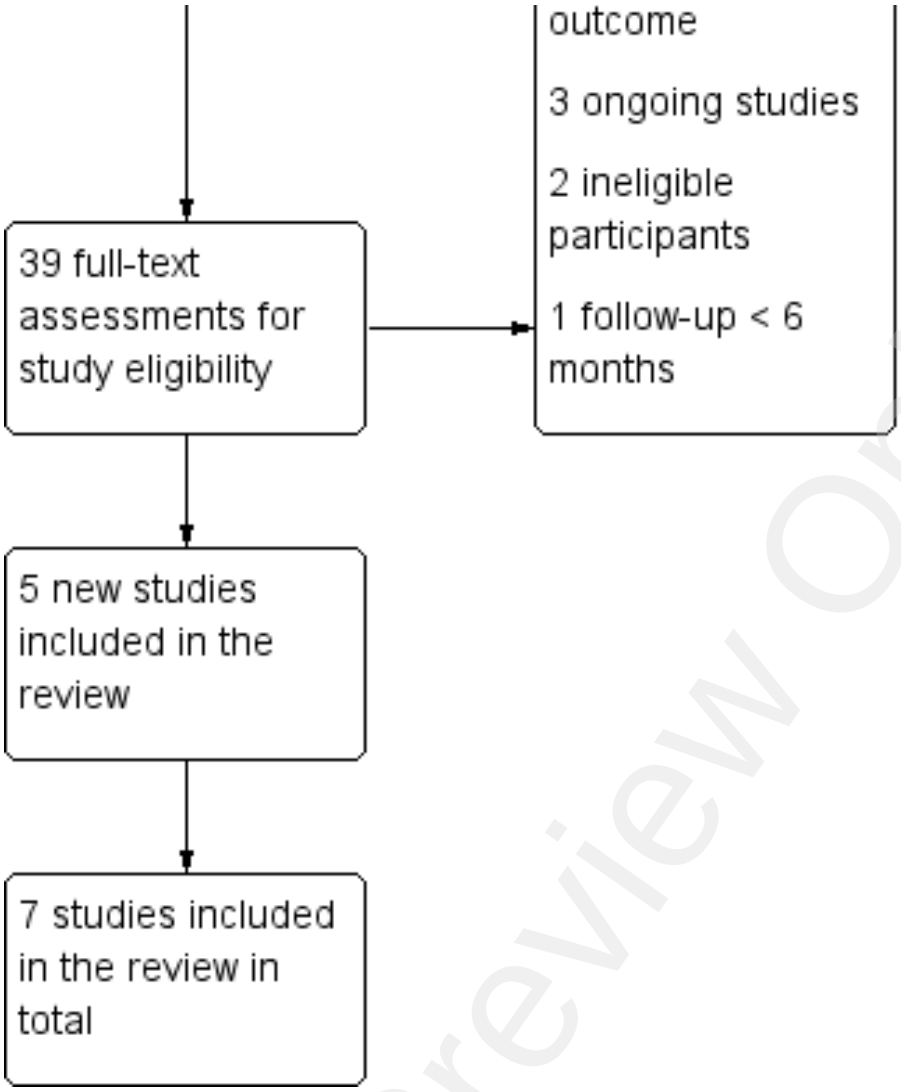
Figure 1. (Continued)



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Included studies

We report details of the seven included and completed studies in the Characteristics of included studies tables.

Study design and settings

All of the included studies were RCTs. Three studies took place in the UK (Farley 2017; Maguire 2001; Sinclair 1998) and one each in Australia (Burford 2013), USA (Dent 2009), Qatar (El Hajj 2017), and Italy (Caponnetto 2017). All studies were conducted at community pharmacies, either recruiting customers of the pharmacies and randomising them (Burford 2013; Dent 2009; Farley 2017; Maguire 2001), or cluster-randomising using the pharmacists themselves to recruit participants (Caponnetto 2017; El Hajj 2017; Sinclair 1998). All studies were based at multiple pharmacies, except for Dent 2009, which was based at a single pharmacy.

Participant characteristics

The studies recruited a total of 1774 tobacco smokers attending 186 pharmacies. Sample sizes varied from 68 to 492 participants across studies. Farley 2017 recruited smokers with no intention to quit in the next four weeks, but who did want to reduce their tobacco consumption. All of the other studies recruited smokers who were motivated to quit or visiting a pharmacy in preparation for quitting. All studies recruited adults, with Burford 2013 recruiting 18- to 30-year olds specifically. The other studies did not select based on age.

Interventions characteristics

Each study provided face-to-face interventions delivered by pharmacists (with a pharmacy assistant also involved in Sinclair 1998), and required pharmacy personnel training. Farley 2017 provided two two-hour training workshops for pharmacy personnel; Maguire 2001 provided a three-hour workshop for pharmacists plus one outreach visit; Sinclair 1998 provided a single two-hour workshop for pharmacists and pharmacy assistants; El Hajj 2017 provided literature and a subsequent two-day (8-hour day) training workshop for pharmacy staff; Caponnetto 2017 provided a six-hour training session in addition to a three-hour session also provided to pharmacists in the control group. Burford 2013 and Dent 2009 did not report on the nature of training provided.

Each study provided an intervention broadly based on various psychological theories of behaviour change. Farley 2017 used behavioural support counselling to disrupt learnt associations between cues and smoking behaviour; Maguire 2001 used the Pharmacists' Action on Smoking (PAS) scheme (Maguire 1995; Maguire 1996; Maguire 1997); Sinclair 1998 used personalised counselling based on the stage-of-change model; Caponnetto 2017 used the stage-of-change model and motivational interviewing; Burford 2013 used computer software to digitally age photographed images of participants; Dent 2009 used the treatment programme 'Vets without Cigarettes' (Veterans Health Administration 2000), which provides peer support, behavioural strategies and cognitive techniques based on the transtheoretical model of change; El Hajj 2017 developed a training model with the help of various industry experts also based on the transtheoretical model for behaviour change, along with other counselling and behavioural techniques.

The amount of contact intervention group participants received varied between studies. Burford 2013 provided a brief session comparing and discussing the photo-aged images. Dent 2009 provided three two-hour face-to-face sessions in small groups, plus additional follow-up over the phone as necessary. El Hajj 2017 provided four face-to-face sessions over eight weeks. Farley 2017 provided eight face-to-face sessions of approximately 10 minutes length over either four or 16 weeks. Maguire 2001 provided an individual face-to-face session of 10 to 30 minutes, followed by follow-up advice once a week for four weeks, and then once a month for three months. Caponnetto 2017 and Sinclair 1998 did not report the amount of contact provided to participants.

Four studies compared the various support programmes with what they described as 'usual care' (Burford 2013; El Hajj 2017; Maguire 2001; Sinclair 1998). In Burford 2013, El Hajj 2017 and Maguire 2001 'usual care' comprised one-off brief behavioural advice, ranging from two minutes to 10 minutes; in Sinclair 1998, however, 'usual care' was described as anything mandated by UK law, which is the display of health education material at a minimum. Three studies compared the support programmes with other less intensive smoking cessation programmes (Caponnetto 2017; Dent 2009; Farley 2017). Caponnetto 2017 provided pharmacists with a three-hour training session to provide support based on US national smoking cessation guidelines; Dent 2009 provided comparator participants with a one-off five- to 10-minute session of advice over the phone, as detailed above, and Farley 2017 provided the same support for smoking reduction as in the intervention group, but in written booklet form rather than as behavioural support.

In all studies, participants had access to pharmacotherapy. Dent 2009 and Maguire 2001 offered pharmacotherapy to participants in both study groups; Farley 2017 prescribed nicotine replacement therapy (NRT) to all participants. Caponnetto 2017 and Sinclair 1998 did not specify, but we presumed that pharmacotherapy was, or could have been, offered to participants in both groups. El Hajj 2017 reported that they 'provided' pharmacotherapy to intervention group participants, but only 'offered' it to control group participants. It is unclear whether this represents a true difference in the treatment provided or just a difference in how the treatment is described. Burford 2013 did not provide or offer pharmacotherapy to participants in either group.

Outcomes

Farley 2017 reported biochemically-validated prolonged abstinence, with the longest follow-up at six months. Maguire 2001 used self-reported continuous abstinence at three, six and 12 months, with biochemical validation at 12 months. Sinclair 1998 used self-reported continuous abstinence at one, four and nine months. Burford 2013 used self-reported continuous abstinence, with biochemical validation at six months. Dent 2009 used self-reported 30-day or continuous abstinence at six months with biochemical validation. El Hajj 2017 used biochemically-validated continuous abstinence at three, six and 12 months. Caponnetto 2017 reported biochemically-validate abstinence at 24 weeks, without specifying a definition of abstinence.

Only one study reported on adverse effects (Dent 2009) and two on cost effectiveness (Burford 2013; Sinclair 1998).

Excluded studies

Thirty-seven studies appeared relevant from the initial screen but did not meet all the inclusion criteria for further investigation. The main reasons for exclusion were: having no control group; not being an RCT; comparing non-relevant forms of intervention; comparing an intervention not delivered by community pharmacy per-

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sonnel; including participants that were not community pharmacy clients; not reporting smoking cessation outcomes; and having a follow-up duration less than six months.

Risk of bias in included studies

Of the seven included studies, we judged none to be at low risk of bias across all domains, three to be at high risk of bias in at least one domain (Burford 2013; Caponnetto 2017; Farley 2017), and the remaining four studies to be at unclear risk of bias (Dent 2009; El Hajj 2017; Maguire 2001; Sinclair 1998). 'Risk of bias' judgements are summarised in Figure 2 and Figure 3. Full details of 'Risk of bias' judgements can be found in the Characteristics of included studies tables.

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

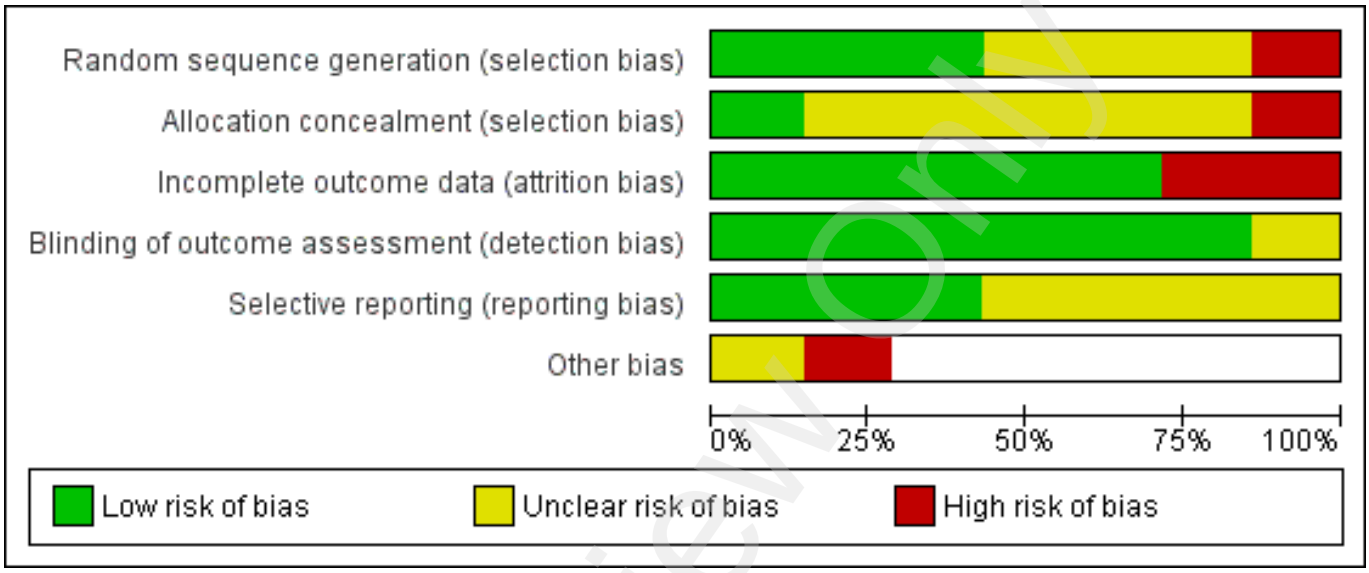

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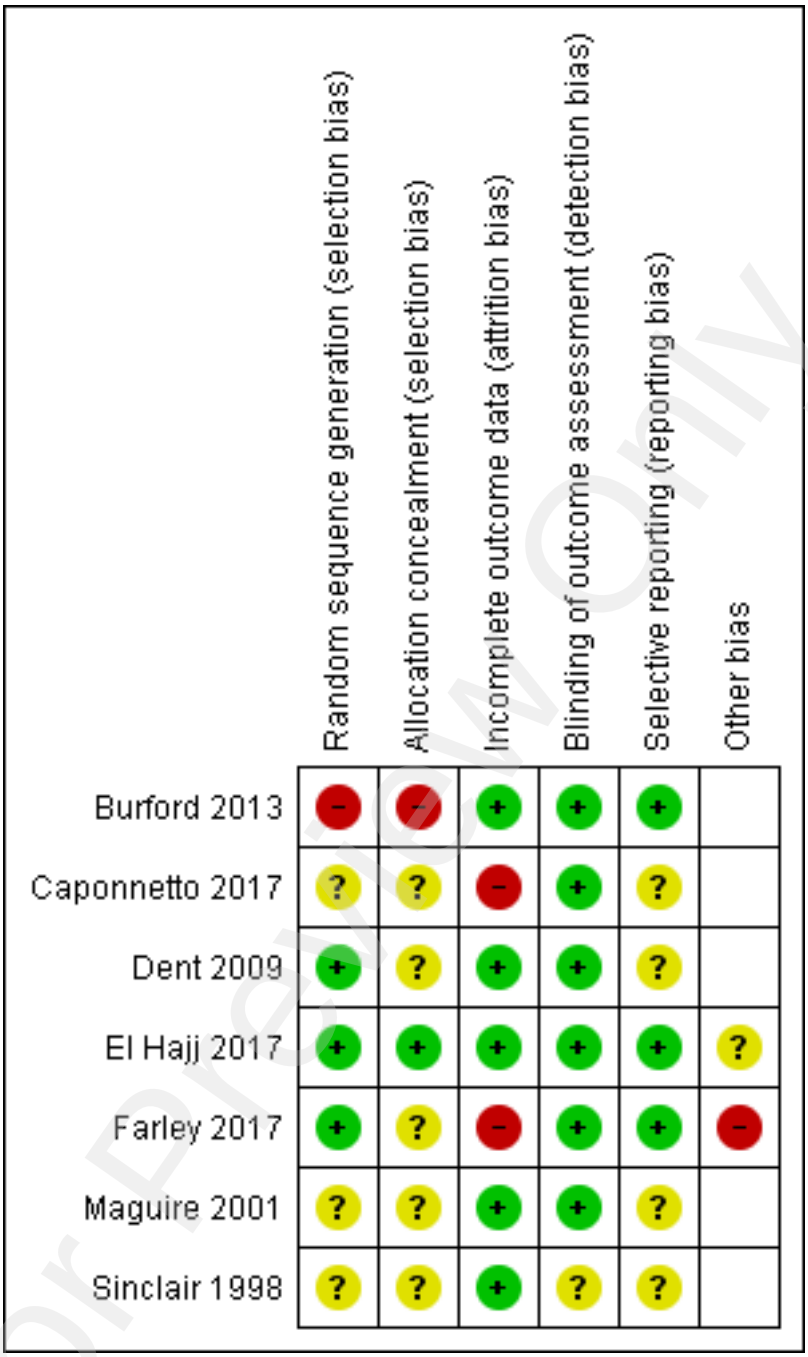
Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



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Random sequence generation (selection bias)

We judged one study to be at high risk of selection bias due to random sequence generation because participant allocation was alternated weekly (Burford 2013), and we judged three studies to be at an unclear risk of bias due to a lack of information (Caponnetto 2017; Maguire 2001; Sinclair 1998). We judged the remaining three studies to be at low risk of bias.

Allocation concealment (selection bias)

We judged one study to be at high risk of selection bias due to allocation concealment; whilst there was no mention of concealment, we deemed it unlikely, given that the study was not blinded (Burford 2013). We judged one study to be at low risk of bias (El Hajj 2017), and judged the remaining five studies to be at an unclear risk of bias because of a lack of information.

Incomplete outcome data (attrition bias)

We judged two studies to be at high risk of attrition bias. Caponnetto 2017 suffered significant loss of study clusters, with only 13 of 21 intervention pharmacies and 8 of 21 control pharmacies completing the study; participant follow-up rates were not reported. Farley 2017 also suffered from substantial attrition, with follow-up rates

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differing between study arms. We judged the remaining five studies to be at low risk of bias.

Blinding of outcome assessment (detection bias)

We judged six studies to be at low risk of detection bias because abstinence was biochemically validated. We judged Sinclair 1998 to be at unclear risk of bias because whilst there was no biochemical validation of abstinence, it was unclear whether contact amounts differed between study arms. We judged no studies to be at high risk of detection bias.

Selective reporting (reporting bias)

We judged three studies to be at low risk of reporting bias because all outcomes planned in the protocol were reported in the results (Burford 2013; El Hajj 2017; Farley 2017). We judged the remaining four studies to be at unclear risk of bias because we could not find a study protocol. We judged no studies to be at high risk of bias.

Other potential sources of bias

We judged Farley 2017 to be at high risk of 'other' bias because the study authors reported evidence that pharmacists had not been following the randomisation protocol, and had been routinely providing additional support to participants in the control arm. This may have increased the smoking cessation rates in the comparator group, affecting the magnitude of the overall pooled result.

We judged El Hajj 2017 to be at unclear risk of 'other' bias because the study authors reported that it is plausible that the pharmacists, who were overall extremely motivated and enthusiastic, might have inadvertently contaminated the usual-care group by providing extra care, and because it was unclear whether the pharmacotherapy provided in the study arms was matched. The study report suggested that NRT was provided in the intervention arm, but only offered in the control arm. The latter could have inflated the effect of the more intensive behavioural support in the intervention arm.

Effects of interventions

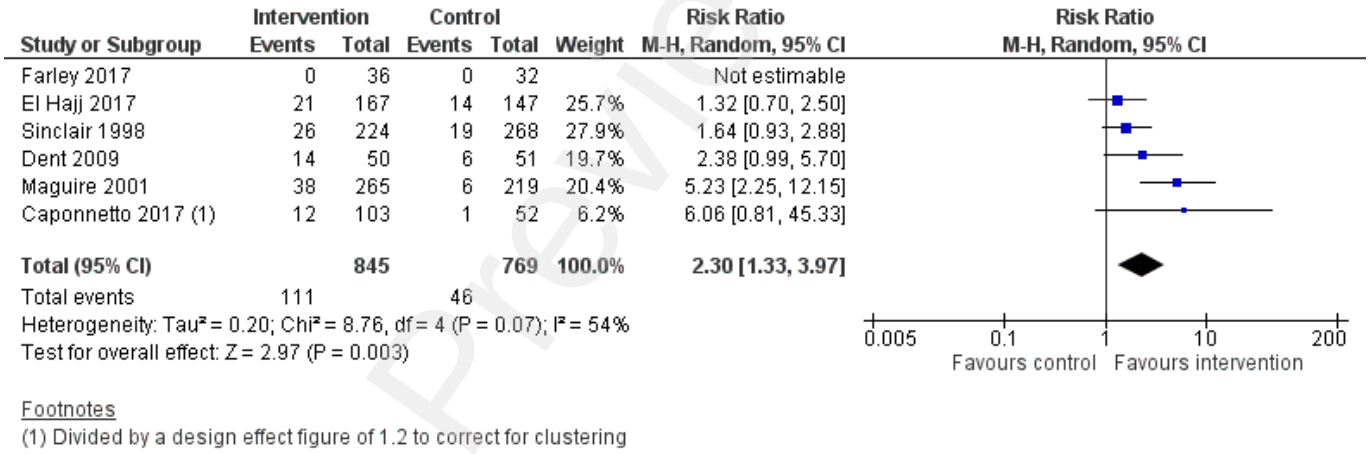
See: **Summary of findings for the main comparison** Community pharmacy personnel interventions compared with standard care or less intensive support for smoking cessation

Primary outcomes

Smoking abstinence at six months

We pooled six of the seven eligible studies, including 1614 participants. Studies all compared more intensive face-to-face behavioural smoking cessation support with less intensive smoking cessation support. We detected a benefit of the more intensive interventions, with moderate statistical heterogeneity detected: RR 2.30, 95% CI 1.33 to 3.97; I^2 = 54%; Figure 4; Analysis 1.1.

Figure 4. Forest plot of comparison: 1 More versus less intensive SC support, outcome: 1.1 Smoking cessation.



We conducted a sensitivity analysis to test whether removing the only study that may not have provided identical pharmacotherapy in both study arms had any notable effect on the overall result (El Hajj 2017). The removal of this study did not change the interpretation of the pooled result (RR 2.79, 95% CI 1.46 to 5.33; I^2 = 51%; 5 studies, 1300 participants).

A sensitivity analysis removing the two studies deemed to be at high risk of bias (Caponnetto 2017; Farley 2017) also resulted in no meaningful change in the pooled effect (RR 2.15, 95% CI 1.22 to 3.78; I^2 = 60%; 4 studies, 1391 participants).

We did not combine Burford 2013 with the other studies, as we judged it to be clinically heterogeneous. The intervention combined the use of face-aging software with brief smoking cessation advice, compared to brief advice alone This study detected a benefit of the face-aging intervention: RR 11.00, 95% CI 1.45 to 83.21; 160 participants; Analysis 2.1. However, the CI was extremely wide, so this result should be treated with caution.

Adverse effects

Adverse effects were not among the prespecified outcomes in any of the included studies. However, Dent 2009 reported adverse effects during the intervention period. This study provided a variety of smoking cessation medications, together with the behavioural pharmacy personnel intervention, and adverse effects were attributable to those concomitant medicines. All adverse events from medications were mild. One participant discontinued bupropion hydrochloride because of a rash, and one participant experienced dizziness, possibly related to nicotine toxicity, whilst using the 21 mg nicotine transdermal patch. At final follow-up, participants re-

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ported whether or not they experienced any of eight withdrawal symptoms commonly associated with smoking cessation, with 96% of participants reporting at least one withdrawal symptom.

Secondary outcomes

Cost effectiveness

Only Burford 2013 and Sinclair 1998 reported data for this outcome. Burford 2013 reported the cost of implementing the intervention as AUD 463.00, or AUD 5.79 per participant. The cost offset from the reduction in healthcare costs from each successful non-smoking participant was AUD 2144.00, resulting in net total savings of AUD 1778.00. We calculated an incremental cost-effectiveness ratio of AUD 46 per additional quitter. The mean cost that participants reported they would be willing to pay for the digital aging service was AUD 20.25, which exceeded the mean cost per participant for delivering the service (AUD 5.79).

Sinclair 1998 reported the overall cost of the intervention as GBP 14,915.76 compared with control costs of GBP 14,121.13. The intervention resulted in seven more quitters at a cost of GBP 794.63, and they derived incremental cost-effectiveness ratios for the intervention of GBP 300 per person quit and GBP 83 per life year saved.

DISCUSSION

Summary of main results

This review includes seven studies assessing the effectiveness of community pharmacy personnel interventions to assist clients with smoking cessation. A meta-analysis of six studies, with 1614 participants, found a statistically and clinically significant benefit in favour of a more intensive community pharmacy intervention when compared with a less intensive control. We judged the evidence contributing to this result to be of low certainty, because of imprecision and risk of bias. We did not include Burford 2013 in the meta-analysis, as the intervention focused on face-aging software combined with brief advice and we deemed it too dissimilar to be pooled. However, this study produced similar findings to the meta-analysed studies with a benefit in favour of the intervention, with the caveat of substantial imprecision. Only one study reported adverse effects during the intervention period (Dent 2009). However, all adverse events were mild and were associated with medication to aid smoking cessation, and were not related directly to the community pharmacy personnel intervention. Only Burford 2013 and Sinclair 1998 reported on cost effectiveness, with results favouring the community pharmacy intervention.

Overall completeness and applicability of evidence

All of the studies deemed eligible for this review measured and reported on our primary outcome of smoking abstinence. However, other outcomes were only reported in a very small subset of studies, with adverse events only mentioned in one of the seven studies (Dent 2009) and cost effectiveness in two (Burford 2013; Sinclair 1998). Because our inclusion criteria were based on the smoking cessation outcome, there may be evidence on the cost effectiveness of pharmacy personnel interventions that we did not identify and include in this review.

Studies varied in the type and intensity of support offered, but mostly started before quit day and followed up with continued appointments for several weeks afterwards. These support programmes were compared with either minimal or less intensive behavioural support for smoking cessation, typically comprising a few minutes of one-off advice on how to quit. Participants in both the intervention and control arms received equivalent smoking cessation pharmacotherapy in all but one study. This review cannot tell us about the efficacy of pharmacy-based support in comparison with no support or relative to other forms of delivery. Similarly, no studies assessed the effectiveness of pharmacists compared with other health professionals providing a comparable programme, nor with pharmacy personnel other than pharmacists. We have therefore only been able to draw conclusions on the intensity of the support provided.

Certainty of the evidence

Using the GRADE criteria, we judged the evidence contributing to our primary outcome (smoking cessation) to be of low certainty. We downgraded the evidence for two reasons: 1) risk of bias - we rated all of the included studies at high or unclear risk of bias; 2) imprecision - fewer than 300 of the 1600+ participants included in the meta-analysis had quit at six months follow-up or more, meaning the number of events was low.

Another potential limitation of our analysis is that because the interventions in the studies we included took place in pharmacies, where pharmacotherapy is readily available, it is difficult to tell what proportion of participants received pharmacotherapy as part of or outside of the study protocol. This difficulty is compounded by gaps in reporting for some studies, and problems with protocol adherence among pharmacy staff in other studies.

Potential biases in the review process

Cochrane methods are designed to minimise potential biases in the review process. The criteria for potential bias assessment during screening, data extraction, and analyses of the included trials strictly complied with the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017). Two review authors independently assessed risks of bias. When conflicts arose we resolved them by discussion, with ongoing conflicts assessed using a third opinion from another review author. No conflicts of interests, financial or otherwise, were reported for any of the review authors involved in screening, extracting and interpreting data for this review. Of note, CM Bond was a principal investigators in Sinclair 1998, included in this review. However, she was not involved in the screening, data extraction or interpretation phases of this review pertaining to that study. Potentially relevant research findings may have been inadvertently missed from this review, due to presentation in forms other than peer-reviewed publications and lodgement with online clinical trial registries. However, we believe our comprehensive search strategy was sufficient to optimise identification of potentially relevant studies. Potential for selection bias was also minimised by the practice of two independent review authors screening and extracting data for potential review inclusion.

Agreements and disagreements with other studies or reviews

In line with findings observed in this review, potential benefits from community pharmacy personnel interventions have been observed in other systematic reviews investigating smoking cessation outcomes (Brown 2016; Dent 2012; Saba 2014) and other health improvement outcomes (Blenkinsopp 2003; Brown 2016). Within all these reviews there is a clear benefit of training pharmacists and pharmacy assistants to provide dedicated behavioural change in-

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terventions, with or without the use of pharmacological aids, to provide long-term improvements in outcomes for smokers attending these pharmacies. Although it would seem that pharmacy personnel would be an obvious choice for members of the public to obtain health advice, pharmacies are being under-used, particularly in their capacity to provide health prevention advice (Mdege 2016; Sunderland 2006). There have therefore been calls for the role of community pharmacists in public health to be investigated further (Agomo 2011). One realist review identified that few policy-relevant conclusions can be drawn from the existing evidence base due to a lack of reporting translation-relevant information, such as the use of theoretical models to underpin intervention development (Greenhalgh 2016). This is important, given concerns about the quality of services and lack of consistency in provision of information (Mdege 2016). A lack of theoretical background for health promotion to sustain the professional education of personnel has been highlighted in other studies as a factor contributing to issues of inconsistency in service quality (Nakamura 2014), while training aimed at increasing pharmacist confidence in providing services has been identified as a potential solution from multiple sources (Eades 2011; Peletidi 2016). Based on evidence from our review and others reported above, there is a clear role for community pharmacists in delivering health improvement services, particularly for smoking cessation, and the use of more intensive programmes of support may be justified.

AUTHORS' CONCLUSIONS

Implications for practice

- Pharmacists trained to provide behavioural support for smoking cessation appear to be effective in supporting smoking cessation compared with either no support or lower intensity support.

Implications for research

- Future trials of pharmacists providing behavioural support for smoking cessation are likely to enhance the certainty of the evidence and may change the conclusions of this review.
- Future studies should try to record in detail what pharmacotherapy participants received, and whether this differed between study arms.
- There was some evidence of challenges associated with studying interventions in a pharmacy setting, and future studies would benefit from concerted efforts to maintain randomisation and adherence to study protocol.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Burford 2013

Methods	*Country:* Australia *Design:* Randomised controlled trial *Study objective:* To conduct a randomised controlled trial of a computer-generated photo-aging intervention to promote smoking cessation among young adult smokers within a community pharmacy setting *Method of analysis:* Logistic regression model, random-effects regression model, incremental cost-effectiveness ratio *Clustering adjustments made:* Not applicable
Participants	*Eligible for study:* 213 *Randomised:* Intervention n = 80; Control n = 80 *Completed:* Intervention n = 59; Control n = 63 *Age:* Intervention 24.2; Control 25.1 *Gender:* Men n = 60; Women n = 100 *Inclusion criteria:* Smokers aged 18 to 30, presenting at pharmacy to collect prescribed or OTC medications *Exclusion criteria:* Already using NRT, bearded, body dysmorphic
Interventions	*Setting:* Community pharmacies across Western Australia

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Burford 2013 *(Continued)*

	Intervention description: Faces of participants were photographed and their images were digitally aged as both a smoker and a nonsmoker (using internet-based APRIL Face Ageing software; a 3D age progression software, creating aged images of faces using algorithms based on reference data). Participants were invited to view the age-processed images. Although the intervention did not include pharmacotherapy, participants were recruited when they presented to pharmacy to collect prescribed or OTC medications *Control description:* Standard 2-minute smoking cessation advice from the pharmacist *Duration of intervention:* 2-minute smoking cessation advice
Outcomes	*Prespecified outcomes:* Successful quitting, quit attempts, and progression along transtheoretical stages-of-change model. Cost effectiveness of intervention (incremental cost per additional quitter and per additional lifetime quitter) *Follow-up period:* 6 months
Notes	Funding: none reported Declarations of interest: none declared.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Allocation performed based on pharmacy attendance in alternating weeks. Quote: "Allocation into the groups alternated weekly so that all participants recruited in any specific week received the same treatment"
Allocation concealment (selection bias)	High risk	No mention of concealment, but unlikely to be concealed, as not blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition (< 50% overall) similar between groups (intervention: 17/80, control = 21/80)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The researcher collecting the data was not blinded to group allocation. Biochemical verification of abstinence was carried out and there were similar amounts of contact in the intervention and control arms
Selective reporting (reporting bias)	Low risk	All outcomes planned in the protocol and Methods section reported on in the Results

Caponnetto 2017

Methods	*Country:* Italy *Design:* Cluster-randomised controlled trial *Study objective:* To evaluate the effect of the training on smoking cessation outcomes and to help participants (pharmacists) develop an understanding of the key principles of the stage-of change model and MI approach *Method of analysis:* Descriptive statistics (i.e. frequencies/percentages, means/standard deviations) used to describe the intervention content (active vs control group); Smoking cessation rates reported and cessation rates analysed using the Fisher test; ITT analysis used in the context of analysis of variance (ANOVA) the Wilcoxon/Mann–Whitney test applied assuming that all those smokers who were lost to follow-up were classified as failures

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Caponnetto 2017 *(Continued)*

	Clustering adjustments made: No mention of correction for clustering
Participants	*Eligible for study:* n = 46 pharmacies *Randomised:* n = 42 pharmacies; n = 187 participants (Intervention n = 124; Control n = 63) *Completed:* n = 21 pharmacies; Participant numbers not reported; assume same numbers with lost-to-follow-up reported as smoking *Age:* not reported *Gender:* not reported *Inclusion criteria:* all smokers who sought advice on smoking cessation or those who bought an OTC anti-smoking product in preparation for a new attempt to stop smoking were eligible for inclusion *Exclusion criteria:* not reported
Interventions	*Setting:* Training conducted by Centro per la Prevenzione e Cura del Tabagismo at the University of Catania. During the recruitment period, all smokers who sought advice on smoking cessation or those who bought an OTC anti-smoking product in preparation for a new attempt were recruited from the pharmacy *Intervention description:* Same as control, plus an additional 6-hour training session; Smokers were informed that their pharmacists were trained in specific anti-smoking counselling based on stage-of-change and MI theories; Intervention personnel offered their customers the professional anti-smoking counselling; pharmacy staff maintained a confidential participant record which documented their progress in smoking cessation, any product supplied, points raised by the participant, and advice given. At each of the planned follow-up visits, telephone call reminders were carried out to improve participation; Intervention pharmacotherapy was not provided as standard practice but could be provided if requested *Control description:* Control group pharmacists attended a 3-hour conference training session based on the US Public Health Services 2008 Clinical Practice Guidelines for Treating Tobacco Use and Dependence, and aligned with the principles of MI and the stage-of-change model. Smokers were informed that their pharmacists recently attended a conference on “Clinical Practice Guidelines for Treating Tobacco Use and Dependence”; The control group asked customers to register and then continued to provide standard professional support; Pharmacy staff maintained a confidential participant record which documented their progress in smoking cessation, any product supplied, points raised by the participant, and advice given; at each of the planned follow-up visits, telephone call reminders were carried out to improve participation *Duration of intervention:* Not specified
Outcomes	*Prespecified outcomes:* Number of treated smokers, smoking reduction at 24 weeks with validation through exhaled CO *Follow-up period:* 24 weeks
Notes	Funding: "The author(s) received no financial support for the research, authorship, and/or publication of this article." Declarations of interest: "The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote "Successively, pharmacies were randomly allocated, by sequential allocation, to the intervention or control group"

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Caponnetto 2017 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Significant loss of study clusters: only 13/21 intervention pharmacies and 8/21 control pharmacies completed the study. Participant follow-up rates not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Abstinence biochemically validated
Selective reporting (reporting bias)	Unclear risk	No published protocol available; outcomes reported in the Methods were reported in analyses

Dent 2009

Methods	*Country*: USA *Design*: Open-label, prospective, randomised controlled trial *Study objective*: To assess the effectiveness on smoking cessation of a face-to-face group programme conducted by the pharmacist team compared with a brief standard-care session delivered by a pharmacist over the telephone *Method of analysis*: Participant data and testing results were recorded in a Microsoft SQL Server 2000 database. Baseline categorical variables by intervention group were compared using the Chi^2 test and the 2-sample t-test *Clustering adjustments made*: Not applicable
Participants	*Eligible for study*: n = 120 *Randomised*: n = 101 *Completed*: Intervention n = 49; Control n = 48 *Age*: Intervention 56.7; Control 55.0 *Gender:* Men 93% *Inclusion criteria:* daily tobacco users for 7 days or more motivated to quit smoking *Exclusion criteria:* Had recently started NRT
Interventions	*Setting:* Single outpatient pharmacy department in the Rocky Mountain region of the USA *Intervention description:* Motivational programme delivered in 3 x 2-hour sessions in small groups by pharmacists using the transtheoretical model of change and health belief model. Specifically consisted of peer support, goal setting, behavioural strategies and cognitive strategies tailored to individual's current motivation to quit. Follow-up support was provided as necessary in person or over the phone. NRT and bupropion were offered as appropriate *Control description:* Participants received 1 timed 5- to 10-minute session over the phone that included all the components of standard care recommended by the Clinical Practice Guidelines and practiced within the VA for brief interventions delivered by healthcare providers, referred to as "The 5 A's". NRT and bupropion were offered as appropriate *Duration of Intervention:* 3 in-person sessions (3 hours for session 1, 2 hours for session 2 and 1 hour for session 3) delivered at 2-week intervals over 5 weeks

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Dent 2009 *(Continued)*

Outcomes	*Prespecified outcomes:* 7-day, 30-day and continuous abstinence rates, self-reported by participants at 6 months following the intervention *Follow-up period:* 6 months
Notes	Funding: The Prevent Cancer Foundation Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization codes assigned to each participant were computer generated by the study statistician and stratified by sex in blocks of 6."
Allocation concealment (selection bias)	Unclear risk	No mention of whether or how allocation was concealed: Quote: "The pharmacist team conducted a baseline assessment over the telephone, then notified participants of their group assignment."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition rates low and similar between groups (1/51 lost to intervention, 3/51 lost to control)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Abstinence biochemically verified using urinary cotinine
Selective reporting (reporting bias)	Unclear risk	No published protocol available. Outcomes reported in the Methods were reported in analyses

El Hajj 2017

Methods	*Country:* Qatar *Design:* Prospective cluster- randomised controlled trial *Study objective:* To test the effect of a structured smoking cessation programme delivered by trained pharmacists on smoking cessation rates in Qatar *Method of analysis:* Chi^2 test, independent t-test *Clustering adjustments made:* The main analysis did not change when adjusted for the possible clustering effect by the pharmacists
Participants	*Eligible for study:* 361 *Randomised:* Intervention n = 167; Control n = 147 *Completed:* Intervention n = 68; Control n = 68 *Age:* Intervention 32.5% aged 30 to 39; Control 38.7% aged 30 to 39 *Gender:* Men n = 307; Women n = 54 *Inclusion criteria:* Smokers 18 years and older who smoked one or more cigarettes daily, were able to communicate in Arabic or English, and who were motivated to quit

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El Hajj 2017 *(Continued)*

	Exclusion criteria: use of NRT in the last 30 days, pregnancy, major medical or psychiatric conditions
Interventions	*Setting:* 8 public and private pharmacies in Qatar *Intervention description:* Smokers assigned to the intervention group participated in a face-to-face 4-session programme at the pharmacy by the study pharmacist at 2- to 4-week intervals over 8 weeks. NRT was provided *Control description:* Participants in the control group received 5 to 10 minutes of unstructured one-to-one brief smoking cessation counselling by the pharmacist emulating current practice. NRT was offered *Duration of intervention:* 4 sessions over 8 weeks
Outcomes	*Prespecified outcomes:* Self-reported 7-day point prevalence abstinence, self-reported 30-day point prevalence abstinence, self-reported continuous abstinence defined as having smoked no cigarettes since quit day – validated by exhaled CO levels *Follow-up period:* 3, 6 and 12 months
Notes	Funding: "This publication was made possible by a grant from the Qatar National Research Fund under its National Priorities Research Program (NPRP 4–716 - 3–203). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Qatar National Research Fund." Declarations of interest: "The authors declare that have no competing interests."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: “The [randomization] sequences were generated by the study statistician using a computer program from the website randomization.com”
Allocation concealment (selection bias)	Low risk	Quote: “Serially numbered, opaque, sealed randomization envelopes were then provided to each study pharmacist.”
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up rates less than 50% overall and similar between groups (68/167 of intervention, 68/147 of control participants completed all 3 follow-ups)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: “at 12 months, participants who self-reported not smoking were invited to come to their study clinic to measure their exhaled CO level by the clinic nurse who was blinded to the participants’ group.” Comment: Only 8/35 participants self-reporting abstinence attended and the amount of face-to-face contact differed between groups
Selective reporting (reporting bias)	Low risk	Protocol available. All outcomes of interest to this review reported as planned. All outcomes planned in the Methods section reported on in the Results
Other bias	Unclear risk	Authors report that it is plausible that the pharmacists, who were overall extremely motivated and enthusiastic, might have inadvertently contaminated the usual-care group with extra care. This may have increased the smoking cessation rates in this group. It was unclear whether the NRT offered in study arms was matched. The wording suggested that the NRT may have been provided in the intervention arm and only offered in the control arm. However, this uncertainty could just be the result of the terms used rather than an actual difference in practice

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Farley 2017

Methods	*Country:* United Kingdom *Design:* Randomised controlled trial *Study objective:* To investigate the feasibility of implementing a smoking reduction programme in community pharmacies, when compared to self-help methods *Method of analysis:* Relative risks and risk differences, generalised linear mixed model. t-test to compare continuous outcomes *Clustering adjustments made:* Not applicable
Participants	*Eligible for study:* 70 *Randomised:* Intervention n = 36; Control n = 32 *Age:* Intervention 44; Control 44 *Gender:* Men n = 34; Women n = 34 *Inclusion criteria:* Smokers aged 18 and over who were not planning to quit within the next 4 weeks but wanted to reduce consumption *Exclusion criteria:* currently using pharmacological, behavioural or alternative therapies for smoking cessation, pregnancy, severe medical or psychiatric conditions
Interventions	*Setting:* Community pharmacies across the United Kingdom 2 x 2 factorial trial in which participants received either behavioural support or self-help, and were encouraged to reduce their smoking either over 4 weeks or over 16 weeks. We consider only the support/self-help comparison, and include both reduction times in each study arm *Intervention description:* Pharmacists provided behavioural support to promote smoking cessation; suggesting that learning a new pattern of smoking would prevent consumption increasing again by disrupting learnt associations between cues and smoking behaviour. They encouraged participants to use NRT and choose 1 of 3 methods of reduction *Control description:* In the control arm, the smoking reduction methods were exactly the same as above, but they were explained in a written booklet. We asked pharmacists to hand out the booklets without further advice or interaction *Duration of intervention:* 8 visits *Pharmacotherapy*: Participants in both study arms were prescribed NRT, and encouraged to take it for 9 months, regardless of intention to reduce or stop, or failure of either reduction or cessation.
Outcomes	*Prespecified outcomes:* Biochemically confirmed prolonged abstinence measured at 6 months *Follow-up period:* 6 months
Notes	Funding: "The trial was funded by the National Prevention Research Initiative of the UK, administered by the MRC. The funding partners are Alzheimer's Research UK, Alzheimer's Society, Biotechnology and Biological Sciences Research Council, British Heart Foundation, Cancer Research UK, Chief Scientist Office, Scottish Government Health Directorate, Department of Health, Diabetes UK, Economic and Social Research Council, Engineering and Physical Sciences Research Council, Health and Social Care Research Division, Public Health Agency, Northern Ireland, Medical Research Council, Stroke Association, Wellcome Trust, Welsh Government, and World Cancer Research Fund." Declarations of interest: "The authors declare that they have no competing interests."

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Farley 2017 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The research team generated the randomisation sequence using a computer algorithm at http://www.randomization.com"
Allocation concealment (selection bias)	Unclear risk	Allocations given to pharmacists in numbered, sealed envelopes, but unclear if sequentially numbered and opaque
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "The percentage of participants successfully contacted each month fell steadily in all trial arms, with 18, 24, 26 and 13% being followed up at 12 months in the behavioural/standard, self-help/ standard, behavioural/short and self-help/short groups respectively" Comment: Dropout differed across study arms
Blinding of outcome assessment (detection bias) All outcomes	Low risk	6-month abstinence biochemically verified
Selective reporting (reporting bias)	Low risk	All outcomes planned in the protocol and Methods section reported on in the Results
Other bias	High risk	Authors report that there was evidence that pharmacists did not follow randomisation protocols, as they strongly believed that their support was essential to participants in the control arm. Quote: "Participants randomised to the self-help conditions should not have received behavioural support when returning to collect further NRT prescriptions. However, there was evidence that pharmacists were routinely recording reduction targets, setting new reduction targets, and less commonly recording reduction methods used in the self-help participants, suggesting that they were in fact providing support" Quote: "There was evidence that pharmacists did not follow randomisation protocols… In both cases of duplicate enrolment, pharmacists opened a second envelope in order to offer behavioural support."

Maguire 2001

Methods	*Country:* United Kingdom *Design:* Randomised controlled trial *Study objective:* To evaluate whether a structured community pharmacy-based smoking cessation programme (the PAS model) would produce a higher smoking cessation rate compared with ad hoc advice from pharmacists *Method of analysis:* Clustering of data from tape recordings were analysed through the Gestault method to focus on similar key themes and concepts and to examine how they were related to variables within the same population *Clustering adjustments made:* Not applicable
Participants	*Eligible for study:* Smokers n = 484 (Pharmacies n = 51) *Randomised:* Intervention n = 265; Control n = 219

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Maguire 2001 *(Continued)*

	Completed: Intervention n = 38 (14.3%); Control n = 6 (2.7%) *Age:* Intervention 42; Control 38 *Gender:* Men n = 281; Women n = 203 *Inclusion criteria:* Smokers expressing a wish to stop smoking, > 18 years, not pregnant, no minimum cigarettes/day
Interventions	*Setting:* One-to-one counselling interventions were carried out in community pharmacies in Northern Ireland and in London, England 3-hour training workshop for pharmacists plus 1 support visit to each pharmacist. The workshop covered epidemiology, smoking statistics, NRT use, cycle of change model and Pharmacists' Action on Smoking (PAS) model *Intervention description:* The PAS intervention involved a structured counselling programme, information leaflet and record keeping. They were required to attend a weekly follow-up for the first 4 weeks then monthly for 3 months as needed. NRT was offered if appropriate *Control description:* Unstructured brief advice. The normal pharmaceutical service was provided by the pharmacist (including an offer of NRT if appropriate). Participants were not counselled using the PAS resources, were not given the PAS information leaflet and were not asked to attend follow-up interviews. Demographic details were collected from this group *Duration of intervention:* Pharmacy follow-up advice weekly for 4 weeks, then monthly for 3 months
Outcomes	*Prespecified outcomes:* Smoking status or self-reported continuous abstinence at 3, 6 and 12 months and positive and negative aspects of experiences during smoking cessation study *Follow-up period:* 12 months
Notes	Pharmacists paid GBP 15 per smoker enrolled and followed up for 12 months. No recruit attended for counselling after 4 weeks Funding: the Medical Research Council and the N. Ireland Department of Health and Social Services Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomization was achieved using a sealed envelope technique (Altman & Gore, 1982). The randomization envelopes were provided to each site for the use of one pharmacist only" Comment: No further information provided
Allocation concealment (selection bias)	Unclear risk	Quote: "Randomization was achieved using a sealed envelope technique (Altman & Gore, 1982). The randomization envelopes were provided to each site for the use of one pharmacist only" Comment: Not specified if opaque
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up reported for both groups at 3-month follow-up (10.2% (27/265) of the PAS group; 14.2% (31/219) of the non-PAS group). Loss to follow-up was reported to stay the same at 6- and 12-month follow-up
Blinding of outcome assessment (detection bias)	Low risk	Abstinence was biochemically verified using urinary cotinine

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Maguire 2001 *(Continued)*
All outcomes

Selective reporting (reporting bias)	Unclear risk	No published protocol available. All outcomes planned in the Methods section report on in the Results

Sinclair 1998

Methods	*Country:* United Kingdom *Design:* Cluster-randomised controlled trial of community pharmacies and pharmacy customers *Study objective:* To evaluate a training workshop for community pharmacy personnel to improve their counselling in smoking cessation based on the stage-of-change model *Method of analysis:* Multiple logistic regression *Clustering adjustments made:* "The estimates of intra-cluster correlation (p) for the outcomes at each time point were calculated". The effects of clustering were negligible
Participants	*Eligible for study:* Pharmacies n = 76 (775 patients) *Randomised:* Pharmacies n = 62 (Patients: Intervention n = 224; Control n = 268) *Completed:* Pharmacies: Intervention n = 31; Control n = 29 (Patients: Intervention n = 159; Control n = 188) *Age:* Intervention 41.7; Control 41.5 *Gender:* Men n = 185; Women n = 302 *Inclusion criteria:* Pharmacy customers seeking advice on stopping smoking or buying an OTC anti-smoking product in preparation for a new attempt to stop smoking; Recruitment period 12 months; No limit to number of recruits per pharmacy
Interventions	*Setting:* rural community pharmacies, Grampian, Scotland *Intervention description:* 2-hour training workshop for pharmacists and pharmacy assistants: based on stages-of-change model and communication skills for negotiating change and providing ongoing support; no focus on smoking cessation products. Trained pharmacy staff offered participants the Pharmacy Support Programme which involved participant registration, counselling and ongoing record keeping at each subsequent purchase of OTC medications *Control description:* Usual care, mandated by UK law as a minimum of the display of health education material *Duration of intervention:* "Brief", exact time not specified
Outcomes	*Prespecified outcomes:* Self-reported point prevalence of smoking at 1 month and continuous abstinence at 4 and 9 months; Age, gender, postcode (proxy for socioeconomic status), nicotine dependence (Fagerström test) recorded at 1 month post-intervention; Consumer response to structured questionnaire assessing perception of the support package at 4 months *Follow-up period:* 1, 4 and 9 months Self-reported point prevalence at 1 month, continuous abstinence at 4 and 9 months
Notes	No additional pharmacy reimbursement. Evaluated effects of clustering by calculating ICCs for each outcome; concluded no evidence of significant cluster effect Funding: The Scottish Office, Department of Health

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Sinclair 1998 *(Continued)*

	Declarations of interest: not stated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details of randomisation methods
Allocation concealment (selection bias)	Unclear risk	No information on allocation concealment methods
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Nine-month smoking data were provided by a total of 73.2% (347) of the recruited customers: 73.3% (159) intervention and 73.2% (188) controls"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Abstinence not biochemically validated Quote: "Intervention personnel offered their customers the Pharmacy Support Programme, which involved client registration, counselling, and record keeping. The control group asked customers to register and then continued to provide standard professional support." Comment: Based on this description it is not clear if different amounts of face-to-face contact were provided
Selective reporting (reporting bias)	Unclear risk	No published protocol. All outcomes planned in the Methods section report on in the Results

CO: carbon monoxide; ICC: intra-class correlation coefficient; ITT: intention-to-treat; MI: motivational interviewing; OTC: over the counter;

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

Study	Reason for exclusion
Anderson 2002	Feasibility study; No 6-month follow-up; No comparators
Babar 2007	No control group
Baluch 1995	No control group
Barnes 2006	No control group. All participants received pharmacist support and St John's Wort
Bauld 2011	Observational study comparing group-based support to one-on-one counselling, not random
Bock 2010	RCT comparing electronically-delivered smoking cessation programme alone compared with a smoking cessation programme plus NRT with observational no-intervention arm, not random
Carroll 2000	No control group
Condinho 2015	No control group
Costello 2011	RCT of 2 behavioural interventions; 1 with NRT and 1 without; No control group, 5-week follow-up
Dent 2004	No control group

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Study	Reason for exclusion
Doescher 2002	No control group
Gauen 1995	No control group
Hasford 2003	No control group (evaluated OTC nicotine patch)
Hodges 2010	No control group; Follow-up less than 6 months after the intervention
Hoving 2010	Intervention was not delivered by pharmacy personnel
Howard-Pitney 1999	Randomised to receive NRT or placebo; both groups received same behavioural treatment
Isacson 1998	No control group
Jansen 2014	No control group
Kennedy 2002	No control group
Liang 2017	Intervention took place in a primary care setting and incorporates different types of primary care staff
Madurasinghe 2017	Less than 6 months follow-up
McEwen 2006	Non-randomised study with 4-week follow-up. Some individual counselling participants were treated by pharmacists
Mochizuki 2004	Randomised study with only 3 months follow-up (pilot study, 28 participants)
NCT02433860	Not community pharmacy clients
NCT02554071	No control group
NCT03518476	Participants not community pharmacy clients
Patwardhan 2012	Feasibility study, no smoking cessation outcomes
Prokhorov 2006	Study of pharmacist and physician training with 3-month follow-up, smoking cessation outcomes not reported in abstract
Prokhorov 2010	Study of pharmacist and physician training with 12-month follow-up, smoking cessation outcomes not reported
Purcell 2006	No control group; Follow-up less than 6 months after the intervention
Roth 2001	No control group
Sonderskov 1997	NRT versus placebo, no other intervention
Swartz 1995	No control group
UMIN000029545	Follow-up 3 months only
Vial 2002	Participants did not meet the criteria for consideration in this review, i.e. were not community pharmacy clients who were smokers wishing to stop. Participants recruited in a hospital setting and randomised to 1 of 3 arms of the study; support programme of counselling and nicotine patches initiated in hospital with the first consultation with a research pharmacist common to 2 groups,

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Study	Reason for exclusion
	then continued by hospital- or community pharmacy-based pharmacists compared with minimal intervention without nicotine patches
Vitale 2000	Descriptive paper, no control group
Wongwiwatthananukit 2010	Not community pharmacy clients

OTC: over the counter; NRT: nicotine replacement therapy

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

ISRCTN16351033

Trial name or title	STOP study
Methods	*Country:* United Kingdom *Design:* Cluster-randomised controlled trial *Study objective:* To test whether a service improvement and training programme (called the STOP intervention) for pharmacy staff will improve the uptake and reduce dropouts in the National Health Service (NHS) Stop Smoking Programme and improve quit rates *Method of analysis:* Not reported *Clustering adjustments made:* Community pharmacists (the cluster level) will be randomised; no mention of adjustments for clustering, though number of smokers attending a treatment session and setting a quit date is the primary outcome
Participants	*Intended to randomise:* n = 60 pharmacies with 1320 smokers *Age:* 18 and over to be recruited *Gender:* Not reported *Inclusion criteria:* Current smokers aged 18 and above; All types of smoking (cigarettes, cigar, pipe) *Exclusion criteria:* For community pharmacies and pharmacy staff: 1. Sites that lack the facilities for secure storage and transfer of the study data; 2. Advisors who refuse GCP training; Exclusion criteria for service users who will be part of the study exploring individual participant-level outcomes: 1. Non-smokers; 2. Unable to understand the STOP study service user information sheet and consent form; 3. Unable/unwilling to give written informed consent for STOP study additional data collection procedures for detailed analysis
Interventions	*Setting:* Community pharmacies *Intervention description:* STOP intervention - "based on behavioural theory involving training for pharmacy staff and associated study materials (e.g. badges, posters). The intervention training focuses on team approach in delivering the NHS STOP smoking service. " *Control description:* "The National Centre for Smoking Cessation and Training (NCSCT) offers a range of training, assessment and certification programmes for both clinical and non-clinical health and social care workers to become more skilled in smoking cessation. Control pharmacies will only receive NCSCT training (Level 1 or Level 2 depending on staff experience)." *Duration of intervention:* At least 1 stop-smoking session with a community pharmacist, but it is unclear if there are additional sessions

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ISRCTN16351033 *(Continued)*

Outcomes	*Prespecified outcomes:* Primary outcome: number of smokers who join the NHS Stop Smoking Program (SSP), attend a treatment session and set a firm date (i.e. a treated smoker); Secondary outcomes: 4-week retention rate, defined as proportion of treated smokers retained at 4 weeks; 4-week quit rate, defined as proportion of smokers who quit smoking at 4 weeks from set quit date, i.e. a "carbon monoxide (CO)-verified 4-week quitter"; Continuous abstinence rate, defined as proportion of smokers who quit at 4 weeks (CO-verified) and remained so at 6 months; Effect of the training intervention on additional (routine) data provided by the consented service users; Additional process outcomes include: Satisfaction about the NHS SSP by questionnaire; Self-efficacy in smoking cessation delivery by questionnaire; Study recruitment and retention rates of pharmacies and pharmacy staff, reasons for non-participation and dropout, service user consent/recruitment rates for additional data collection and retention rates; Intervention training attendance and completion rates, reasons for non-attendance and dropout; Acceptability of intervention training and delivery in practice by questionnaire; Delivery of skills in practice at the pharmacy counter around engagement of service users into the NHS SSP by simulated client using checklist; Skills around retention of service users in pharmacy consultation room by audio-recording of consultations; Views and experiences about the STOP training and its delivery in practice; Views and experiences about the NHS SSP with a focus on engagement and retention, reasons for completion and non-completion of the NHS SSP; Health economic outcomes included: Cost data from advisers: time spent (in minutes) by advisers on smoker service user delivering the NHS SSP and taking individual consent for STOP study additional data collection procedures and carrying out the data collection, e.g. saliva samples; Cost data from study researchers: cost of delivery of training to pharmacy staff and costs associated with delivery of training such as travel expenses, refreshments, room hire, use of printed materials, use of assistive technology; provision of financial incentive; attending feedback meeting with trainer *Follow-up period:* 4-week quit rates and 6 months continuous abstinence
Starting date	May 2017 to August 2019
Contact information	Ms Wai Yee James; STOP Trial Manager; Blizard Institute; Yvonne Carter Building; 58 Turner Street, London, E1 2AB; United Kingdom
Notes	*Funding:* National Institute for Health Research (NIHR) Central Commissioning Facility (CCF); Grant Codes: RP-PG-0609-10181 *Study registration*: ISRCTN16351033 Declarations of interest: none stated

Thomas 2013

Trial name or title	
Methods	*Country:* Australia *Design:* Randomised controlled trial, multicentre, single-blinded *Study objective:* The primary aim of the study is to determine the effectiveness of a pharmacist-led system change intervention ('GIVE UP FOR GOOD') compared to usual care on biochemically verified 7-day point prevalence abstinence at 6 months and 12 months *Method of analysis:* Characteristics of study participants will be compared using the Chi^2 test for categorical variables and the Student's t-test or a non-parametric equivalent for continuous and discrete variables; Multivariable analysis will be used to compare outcomes between the 2 treatment groups while adjusting for prognostic variables and potential confounders; All the statistical tests will be interpreted with a significance level of 5% (2-tailed); Data will be analysed according to ITT principles; all randomised participants will be included in the analysis and those lost to fol-

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Thomas 2013 *(Continued)*

	low-up will be regarded as smokers; Participants who die during the study will be excluded from the analysis *Clustering adjustments made:* None reported
Participants	*Intended to randomise:* n = 300 per arm (n = 600 in total) *Age:* 18 years or older *Gender:* Not specifically reported *Inclusion criteria:* Inpatients 18 years old or older, are smokers at the time of hospital admission, and are available for follow-up on discharge, and up to 12 months post-discharge *Exclusion criteria:* Physical or mental inability to participate in the study, inability to provide written informed consent, inability to communicate in English, terminal illness, pregnancy or on another active smoking cessation therapy or programme at the time of hospital admission (pharmacotherapy including NRT or active involvement in a smoking cessation programme in the last 7 days prior to the hospital admission with support from a trained counsellor, health professional or service provider)
Interventions	*Setting: 3* Victorian public hospitals: The Alfred, Austin Health and Barwon Health *Intervention description:* Smoking cessation support sessions with a trained pharmacist; The conceptual framework for the intervention is based on the systems change approach, which has 6 systems-level strategies to facilitate treatment of tobacco dependence: 1. Implement a system of identifying smokers; 2. Provide education and resources to promote provider intervention; 3. Dedicate staff to provide smoking cessation services; 4. Promote hospital policies that support and provide tobacco dependence services; 5. Include tobacco dependence treatments (both counselling and pharmacotherapies) identified as effective; and 6. Reimburse healthcare providers for delivery of effective tobacco dependence treatments and include these services among their defined duties. *Control description:* Participants randomised to the usual care (control) group will continue to receive routine care provided by the hospital. They may receive brief counselling by hospital staff and/or free NRT or pharmacotherapy during their hospital stay as per hospital policy *Duration of intervention:* The intervention will be delivered over at least 3 sessions, with the final session taking place within 1 month after hospital discharge
Outcomes	*Prespecified outcomes:* The primary aim of the study is to determine the effectiveness of a pharmacist-led system change intervention ('GIVE UP FOR GOOD') compared to usual care on biochemically-verified 7-day point prevalence abstinence at 6 months and 12 months; The secondary objectives are: 1. To evaluate the effectiveness of the 'GIVE UP FOR GOOD' intervention compared to usual care on self-reported continuous abstinence at discharge and at 1, 6 and 12 months post-discharge; 2. To evaluate the effectiveness of the 'GIVE UP FOR GOOD' intervention compared to usual care on self-reported 24-hour, 7-day and 30-day point prevalence abstinence at 1, 6 and 12 months post-discharge *Follow-up period:* 1, 6 and 12 months
Starting date	

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Thomas 2013 *(Continued)*

Contact information	Dennis Thomas: Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University (Parkville Campus), 381 Royal Parade, Parkville, VIC, 3052, Australia; Dennis.Thomas@monash.edu
Notes	Funding: "This trial is funded by the Australian Research Council through the Linkage Scheme (LP110200724) and an investigator-initiated research (IIR) grant from Pfizer. BB is supported by a Cancer Institute NSW Career Development Fellowship." Declarations of interest: "The study is supported by an investigator initiated research (IIR) grant from Pfizer. However, Pfizer was not involved in the design of the study, protocol development or implementation and will not be involved in the analysis and publication of findings. Recommendations for pharmacotherapy will be evidence-based and according to guidelines based on a participant's nicotine dependence and participant preference. Professor Abramson was a member of the Scientific Committee for a workshop on an unrelated topic that was sponsored by GlaxoSmithKline, but did not receive any honorarium"

Zillich 2013

Trial name or title	
Methods	*Country:* USA (Connecticut and Washington) *Design:* Randomised controlled trial *Study objective:* The study aims to estimate and compare the effectiveness of 2 interventions (academic detailing and mailed materials) for engaging community pharmacy personnel (pharmacists and pharmacy technicians) in applying the Ask-Advise-Refer method to generate referrals to the tobacco quitline *Method of analysis:* The monthly numbers and percentages of quitline calls from callers who report hearing about the quitline from a pharmacy between the baseline and 12-month follow-up will be tested for statistical significance using generalised linear regression modelling with the numbers and percentages regressed on study period and state (Connecticut or Washington); The number of quitline callers who register for cessation counselling, the total number of quitline cards distributed, and the number of calls per 100 cards distributed at each pharmacy will be compared and analysed at the pharmacy level; comparisons between study conditions will be made using generalised linear regression models with the outcome regressed on the study condition variable, state, and pharmacy type *Clustering adjustments made:* None reported
Participants	*Intended to randomise:* n = 32 pharmacies for each arm (n = 64 pharmacies in total) *Age:* Not specified *Gender:* Not specified *Inclusion criteria:* Licensed pharmacies were identified from a list obtained from the Connecticut and Washington State Boards of Pharmacy *Exclusion criteria:* Pharmacies that were not community-based (e.g. not hospital, mail order, or clinic-based pharmacies)
Interventions	*Setting:* Pharmacies in Connecticut and Washington *Intervention description:* Both mailed (control) and academic detailing interventions advocated for implementation of the Ask-Advise-Referstrategy; academic detailing interventions were provided on-site by an experienced pharmacist; the detailer assessed current cessation activities, determined knowledge of quitlines, and identified barriers and/or facilitators to cessation-related activ-

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Zillich 2013 *(Continued)*

	ities; videos were used to demonstrate the Ask-Advise-Refer model for tobacco cessation; The other intervention materials were selectively introduced, at the detailer's discretion, to facilitate incorporation of Ask-Advise-Refer into routine pharmacy practice; The detailer concluded the session by answering questions and offering to assist with placement of the materials in the pharmacy *Control description:* Mailed paper-based quitline materials (videos not included) *Duration of intervention:* 1 training session
Outcomes	*Prespecified outcomes:* The primary study outcomes include (1) between-group comparisons of the total number of quitline registrants referred from the 64 study pharmacies during the intervention period and (2) changes in the number of quitline registrants referred from all pharmacies in Connecticut and Washington during the baseline monitoring period versus the intervention period; Secondary outcomes include (1) the number of quitline cards and brochures distributed to participants (assessed by on-site card and brochure counts by study personnel at 3 and 6 months) and (2) changes in self-reported cessation counselling and referral behaviour (measured by written surveys completed by participating pharmacists and pharmacy technicians at baseline, 3 months, and 6 months) *Follow-up period:* 3 and 6 months
Starting date	
Contact information	Karen Suchanek Hudmon: Department of Pharmacy Practice, Purdue University College of Pharmacy, 1001 W. 10th Street – W7555 Myers, Indianapolis, IN 46202, USA; Department of Clinical Pharmacy, University of California, 521 Parnassus Ave, C-152, Box 0622, San Francisco, CA 94143, USA: khudmon@purdue.edu; Tel.: +1 317 613 2315x311; fax: +1 317 613 2316
Notes	Funding: "Funded by the National Cancer Institute grant R01 CA 129312 to K Hudmon. A portion of Dr. Zillich's time was supported by a Career Development award RCD 06-304-1 from the Department of Veterans Affairs, Health Services Research and Development." Declarations of interest: not reported

ITT: intention-to-treat; NRT: nicotine replacement therapy

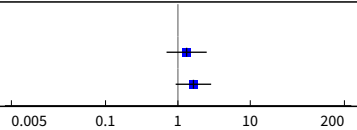
DATA AND ANALYSES

Comparison 1. More versus less intensive SC support

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Smoking cessation	6	1614	Risk Ratio (M-H, Random, 95% CI)	2.30 [1.33, 3.97]

Analysis 1.1. Comparison 1 More versus less intensive SC support, Outcome 1 Smoking cessation.

Study or subgroup	Intervention n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Farley 2017	0/36	0/32			Not estimable
El Hajj 2017	21/167	14/147		25.72%	1.32[0.7,2.5]
Sinclair 1998	26/224	19/268		27.86%	1.64[0.93,2.88]



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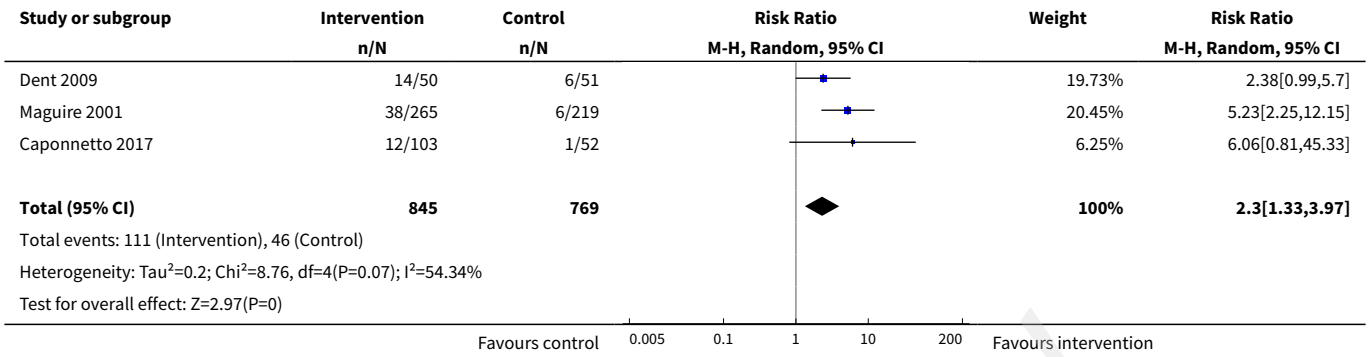
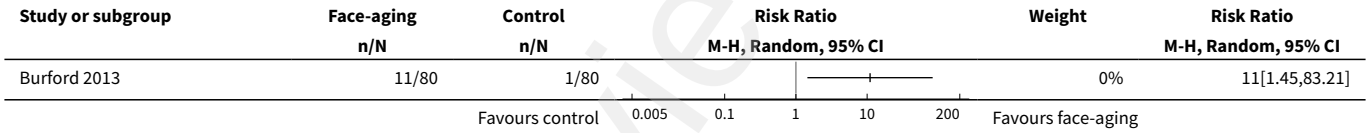


Comparison 2. Face-aging + brief advice versus brief advice alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Smoking cessation	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only

Analysis 2.1. Comparison 2 Face-aging + brief advice versus brief advice alone, Outcome 1 Smoking cessation.



APPENDICES

Appendix 1. Cochrane register search strategy

#1 (pharmacy OR pharmacies OR pharmacist*):TI,AB

#2 (pharmacy OR pharmacies OR pharmacist):MH

#3 (pharmacy OR pharmacies OR pharmacist):EMT

#4 (pharmacy OR pharmacies OR pharmacist):KW,KY

#5 (pharmacy OR pharmacies OR pharmacist*):XKY

#6 #1 OR #2 OR #3 OR #4 OR #5

Appendix 2. Online clinical trial registry search strategy

Pharmacy AND smoking cessation

WHAT'S NEW

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Date	Event	Description
11 January 2019	New search has been performed	Searches updated
15 October 2018	New citation required and conclusions have changed	7 new studies included, risks of bias updated, 'Summary of findings' table added, text of review updated

HISTORY

Protocol first published: Issue 3, 2002
Review first published: Issue 1, 2004

Date	Event	Description
18 June 2008	Amended	Converted to new review format.
31 October 2007	New search has been performed	Search update for Issue 1, 2008. No new studies included. New references added to the Excluded studies and Background.

CONTRIBUTIONS OF AUTHORS

For this update, KVCC and JLB screened studies for inclusion, extracted data, and updated the analyses and text. MB, ZK, RT and KS searched the updated literature and extracted data. All authors approved the final text.

DECLARATIONS OF INTEREST

KVCC: none known.
JLB: none known.
KS: none known.
ZK: none known.
MP: none known.
RT: none known.
CM Bond was a principal investigator in the (Sinclair 1998) study included in this review.

SOURCES OF SUPPORT

Internal sources

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

External sources

- NIHR Cochrane Infrastructure Grant, UK.
- NIHR Cochrane Programme Grant, UK.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We added adverse effects as a primary outcome, in line with Cochrane guidelines. We also added cost effectiveness as a secondary outcome.

We conducted meta-analysis using the random-effects model because of expected heterogeneity between studies, in line with updated practice for the Cochrane Tobacco Addiction Group. We added sensitivity analyses removing studies where the provision of pharmacotherapy potentially differed between study arms.

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