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(Review)

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[Intervention Review]

Community pharmacy interventions for health promotion: effects on professional practice and health outcomes

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ABSTRACT

Background

Community pharmacies are an easily accessible and cost-effective platform for delivering health care worldwide, and the range of services provided has undergone rapid expansion in recent years. Thus, in addition to dispensing medication, pharmacy workers within community pharmacies now give advice on a range of health-promoting behaviours that aim to improve health and to optimise the management of long-term conditions. However, it remains uncertain whether these health-promotion interventions can change the professional practice of pharmacy workers, improve health behaviours and outcomes for pharmacy users and have the potential to address health inequalities.

Objectives

To assess the effectiveness and safety of health-promotion interventions to change community pharmacy workers' professional practice and improve outcomes for users of community pharmacies.

Search methods

We searched MEDLINE, Embase, CENTRAL, six other databases and two trials registers to 6 February 2018. We also conducted reference checking, citation searches and contacted study authors to identify any additional studies.

Selection criteria

We included randomised trials of health-promotion interventions in community pharmacies targeted at, or delivered by, pharmacy workers that aimed to improve the health-related behaviour of people attending the pharmacy compared to no treatment, or usual treatment received in the community pharmacy. We excluded interventions where there was no interaction between pharmacy workers and pharmacy users, and those that focused on medication use only.

Data collection and analysis

We used standard procedures recommended by Cochrane and the Effective Practice and Organisation of Care review group for both data collection and analysis. We compared intervention to no intervention or to usual treatment using standardised mean differences (SMD) and 95% confidence intervals (95% CI) (higher scores represent better outcomes for pharmacy user health-related behaviour and quality

of life, and lower scores represent better outcomes for clinical outcomes, costs and adverse events). Interpretation of effect sizes (SMD) was in line with Cochrane recommendations.

Main results

We included 57 randomised trials with 16,220 participants, described in 83 reports. Forty-nine studies were conducted in high-income countries, and eight in middle-income countries. We found no studies that had been conducted in low-income countries. Most interventions were educational, or incorporated skills training. Interventions were directed at pharmacy workers ($n = 8$), pharmacy users ($n = 13$), or both ($n = 36$). The clinical areas most frequently studied were diabetes, hypertension, asthma, and modification of cardiovascular risk. Duration of follow-up of interventions was often unclear. Only five studies gave details about the theoretical basis for the intervention, and studies did not provide sufficient data to comment on health inequalities.

The most common sources of bias were lack of protection against contamination - mainly in individually randomised studies - and inadequate blinding of participants. The certainty of the evidence for all outcomes was moderate. We downgraded the certainty because of the heterogeneity across studies and evidence of potential publication bias.

Professional practice outcomes

We conducted a narrative analysis for pharmacy worker behaviour due to high heterogeneity in the results. Health-promotion interventions probably improve pharmacy workers' behaviour (2944 participants; 9 studies; moderate-certainty evidence) when compared to no intervention. These studies typically assessed behaviour using a simulated patient (mystery shopper) methodology.

Pharmacy user outcomes

Health-promotion interventions probably lead to a slight improvement in health-related behaviours of pharmacy users when compared to usual treatment (SMD 0.43, 95% CI 0.14 to 0.72; $I^2 = 89\%$; 10 trials; 2138 participants; moderate-certainty evidence). These interventions probably also lead to a slight improvement in intermediate clinical outcomes, such as levels of cholesterol or glycated haemoglobin, for pharmacy users (SMD -0.43, 95% CI -0.65 to -0.21; $I^2 = 90\%$; 20 trials; 3971 participants; moderate-certainty evidence).

We identified no studies that evaluated the impact of health-promotion interventions on event-based clinical outcomes, such as stroke or myocardial infarction, or the psychological well-being of pharmacy users.

Health-promotion interventions probably lead to a slight improvement in quality of life for pharmacy users (SMD 0.29, 95% CI 0.08 to 0.50; $I^2 = 82\%$; 10 trials, 2687 participants; moderate-certainty evidence).

Adverse events

No studies reported adverse events for either pharmacy workers or pharmacy users.

Costs

We found that health-promotion interventions are likely to be cost-effective, based on moderate-certainty evidence from five of seven studies that reported an economic evaluation.

Authors' conclusions

Health-promotion interventions in the community pharmacy context probably improve pharmacy workers' behaviour and probably have a slight beneficial effect on health-related behaviour, intermediate clinical outcomes, and quality of life for pharmacy users.

Such interventions are likely to be cost-effective and the effects are seen across a range of clinical conditions and health-related behaviours. Nevertheless the magnitude of the effects varies between conditions, and more effective interventions might be developed if greater consideration were given to the theoretical basis of the intervention and mechanisms for effecting behaviour change.

PLAIN LANGUAGE SUMMARY

Can community pharmacy interventions help improve pharmacy workers' skills and pharmacy users' health outcomes through health promotion?

What is the aim of this review?

We aimed to find out whether interventions that support people to change health behaviours, and are delivered in community pharmacies, can change the way that pharmacy workers interact with pharmacy users and can improve health outcomes for those users.

Key messages

Community pharmacies and their workers may have an important part to play in health promotion, and probably improve the health outcomes of pharmacy users slightly, at an acceptable cost and with no evidence of harm (adverse events may or may not have occurred, this is unclear as no adverse effects were reported by the studies).

What was studied in the review?

Community pharmacies are an easy place for many people to access healthcare advice. In the past this advice was limited to how best to take medicines, but, increasingly, community pharmacy workers are carrying out other activities, such as giving advice on healthy eating and management of long-term conditions. While some community pharmacy workers may offer the sale of products without a strong evidence-base, the professional guidance issued to pharmacists has attempted to reduce these transactions, and has placed more emphasis on developing evidence-based public health services. Many people find health-related lifestyle and self-management behaviours difficult. Pharmacies may be convenient for people to use, but it is important to understand whether health-promoting activities delivered in pharmacies are worthwhile and effective, so that those responsible for commissioning health care can decide whether it is worth spending resources to support them.

What are the main results of the review?

We identified 57 studies with a total of 16,220 participants that investigated the effects of health-promotion activities compared to normal treatment or no treatment. These were conducted across the world, 49 of them in high-income countries and eight in middle-income countries. Most studies (36/57) targeted both pharmacy workers and pharmacy users; eight were directed at pharmacy workers only, and 13 at pharmacy users only. The health areas most frequently studied were diabetes, hypertension, asthma and reduction of cardiovascular risk. The studies varied in quality. Some studies did not take enough precautions to stop the participants who should have received either no treatment or usual treatment (i.e. the control group) receiving parts of the intervention.

We found that pharmacy workers may be able to change their behaviour, for example improve their communication skills, to help people to manage their health conditions more effectively.

Overall these studies probably show a slight beneficial effect on pharmacy users' health-related behaviour, intermediate clinical outcomes (e.g. levels of cholesterol or glycated haemoglobin) and quality of life. No studies reported measuring pharmacy users' clinical events such as heart attacks or stroke. There was also no evidence of harm reported in any of the studies, but no studies reported measuring adverse events. Five out of seven studies that measured costs showed that health promotion delivered by pharmacy workers was cost effective.

These findings suggest that community pharmacy workers can probably slightly improve pharmacy users' health outcomes at a reasonable cost. The variety of studies includes different countries, conditions, interventions and outcomes, and suggests there is great interest in using the community pharmacy setting for workers to promote health-related behaviours. However, in order to make future studies easier to compare, there is a need for greater use of thorough, systematic approaches in the description of these interventions, use of a standardised set of outcomes, and for new studies to build on prior work.

How up to date is this review?

We searched for studies that had been published up to February 2018.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Health-promotion interventions within community pharmacy compared to usual treatment: effects on professional practice and health outcomes

Do health-promotion interventions improve professional practice of community pharmacy workers and improve health outcomes for community pharmacy users?

Patient or population: community pharmacy workers (examples pharmacists, counter assistants etc), community pharmacy users

Setting: community pharmacy - the majority of community pharmacies were in urban settings in high-income countries

Intervention: a health-promotion intervention delivered to pharmacy workers or users within community pharmacy commonly consisting of education and skills training

Comparison: no treatment or usual treatment received within the community pharmacy

Outcomes	Effect of intervention (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
Pharmacy worker behaviour ¹	Six of nine studies reported improvement in pharmacy worker behaviour, one study found no benefit, while two had mixed results	2944 (9 RTs)	⊕⊕⊕⊖ MODERATE ²	
Pharmacy user health-related behaviour ³ (Higher scores indicate a better outcome)	The mean score in the intervention group was 0.43 SD higher (0.14 higher to 0.72 higher)	2138 (10 RTs)	⊕⊕⊕⊖ MODERATE ^{2,4}	A SMD of 0.43 represents a small improvement in pharmacy user health-related behaviour, according to Cohen's rule of thumb (Higgins 2011b).
Pharmacy user intermediate clinical outcomes e.g. cholesterol, glycated haemoglobin ⁵ (Lower scores indicate a better outcome)	The mean score in the intervention group was 0.43 SD lower (0.65 lower to 0.21 lower)	3971 (20 RTs)	⊕⊕⊕⊖ MODERATE ^{2,4}	A SMD of 0.43 represents a small difference between groups with greater benefit in the intervention group, according to Cohen's rule of thumb Higgins 2011b
Pharmacy user event-based clinical outcomes e.g. stroke, myocardial infarction	No studies reported this outcome.	(0 studies)	-	
Pharmacy user quality of life ⁶ (Higher scores indicate better quality of life)	The mean score in the intervention group was 0.29 SD higher (0.08 higher to 0.5 higher)	2687 (10 RTs)	⊕⊕⊕⊖ MODERATE ^{2,4}	A SMD of 0.29 higher represents a small difference between groups with greater benefit in the intervention group according to Cohen's rule of thumb (Higgins 2011b).
Adverse events	No studies reported this outcome	(0 studies)	-	
Costs	Five of seven studies found the intervention to be cost-effective.	(7 RTs)	⊕⊕⊕⊖ MODERATE ²	

CI: confidence interval; **RT:** randomised trial; **SD:** standard deviation; **SMD:** standardised mean difference

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

¹Includes communication/consultation skills, referral to smoking quit line, demonstration of inhaler technique.

²Downgraded by one level for inconsistency (due to substantial heterogeneity in studies).

³Includes medication adherence (n = 3); inhaler technique (n = 4), alcohol consumption (n = 1), diabetes self-management (n = 1), activity impairment (n = 1).

⁴Asymmetric funnel plots - considered insufficient to require further downgrading.

⁵Includes asthma control (n = 8), blood glucose (n = 5), systolic blood pressure (n = 5), low-density lipoprotein (n = 2).

⁶Includes generic quality of life (n = 5), asthma quality of life (n = 5), diabetes quality of life (n = 1).

BACKGROUND

Description of the condition

Pharmacists are the third largest regulated healthcare professional group in the world (Chan 2006), with community pharmacy the most common discipline represented. Community pharmacies are an easily accessible platform for delivering healthcare worldwide (DOH 2005; WHO 1998). For example, in England there are over 11,500 community pharmacies, with approximately 89% of the population able to access one within a 20-minute walk (Todd 2014). In Australia, over 90% of the population visit a pharmacist during the course of a year (Benrimoj 2004). Pharmacies are more densely distributed in areas of high deprivation – a so-called ‘positive pharmacy care law’ - where better access to pharmacy care is available to those with greatest deprivation (Todd 2014). In low- and middle-income countries, but also increasingly in high-income countries, pharmacies are often seen as the first place to call for advice on symptoms and for early diagnosis of illness (Smith 2009).

The role of the pharmacist has undergone rapid expansion in recent years (Blouin 2017; Mossialos 2015; WHO 2006). For example, in addition to dispensing and medication-linked services, pharmacy workers are now required to give advice on public-health priorities, including modification of health behaviour to minimise risk of disease and to promote a healthy lifestyle in pharmacy users (DOH 2005; Public Health England 2017). Smoking cessation was one of the first behaviour-change roles to be delivered in community pharmacies (Anderson 2007), and now others, such as promotion of general healthy lifestyle behaviours, increasing uptake of screening and giving sexual health advice, have been added (Blouin 2017; NICE 2018; RSPH 2016). To address the needs of this changing role and to maintain high professional standards, international guidance for good pharmacy practice has been published which outlines health promotion as one of six components that contribute to the health improvement of the individuals who access community pharmacy services (WHO 2011).

The evidence base that underpins these wider health-promotion responsibilities has not yet been collated to determine effective methods of changing professional practice, or evaluation of the health gains that could result from these changes. Research evidence suggests that whilst pharmacy workers and their users hold positive attitudes to pharmacist involvement in public-health activities, pharmacist confidence in delivering the services is currently low, and additional training needs are perceived (Eades 2011; Lindsey 2017; Weir 2019).

Systematic reviews examining behaviour-change interventions delivered in community pharmacies have begun to emerge by clinical topic (Brown 2016; Garcia-Cardenas 2013; Sabater 2016; Soprovich 2019); but do not provide a comprehensive overview of the role of community pharmacy in health promotion. In addition, some reviews have included small numbers of poor quality studies (Gordon 2011; Sinclair 2004; Watson 2006), which limits conclusions regarding the effectiveness of these services (RSPH 2016). Thus a broad overview of studies of health-promotion interventions in community pharmacies is needed to inform current pharmacy practice and to identify areas for future research.

Description of the intervention

The World Health Organization (WHO) defines health promotion as "the process of enabling people to increase control over, and to improve, their health". The idea of health promotion has expanded beyond a focus on individual behaviour towards a wide range of social and environmental interventions (WHO 2009). Interventions that target a specific aspect of lifestyle - such as smoking - or that address wider aspects of clinical management - such as obesity or type 2 diabetes mellitus - therefore fall within this definition.

Interventions to support these broad health-promotion and behaviour-change tasks may be directed at pharmacy workers, pharmacy users (who may or may not be patients), or at both groups. The types of intervention vary from educational programmes (Sarayani 2012), to specific training that is targeted at behaviour change, such as motivational interviewing (Brackett 2015). Other interventions target management of medical conditions, for example blood pressure monitoring (Fikri-Benbrahim 2012), or managing asthma (Armour 2007). These types of interventions go beyond the traditional remit of community pharmacy workers, which has conventionally focused on the preparation, dispensing and management of medicines.

Previous Cochrane Reviews have examined non-dispensing services in pharmacies (De Barra 2018; Nkansah 2010; Pande 2013), however, these have still had a strong focus on medications, including medication reviews or stopping medications, and did not focus solely on community pharmacy. To avoid overlap with this previous work, we have excluded any purely medication-related interventions in this review, including those focused primarily at promoting medication adherence.

How the intervention might work

The way in which health-promotion and behaviour-change interventions work within the community pharmacy setting is likely to be dependent on the theoretical basis for the intervention (Michie 2010), and the behaviour-change techniques used (Michie 2008). For example, interventions may aim to increase self-efficacy (perceived confidence) in performing a behaviour that promotes health, or examine ways of overcoming barriers to performing that behaviour. The behavioural theory underpinning interventions and the mechanisms by which community pharmacy interventions might work have not previously been studied in detail. However, an understanding of the mechanisms by which health-behaviour change is achieved in successful community pharmacy interventions, and the behaviour-change theories used, is important for designing more effective interventions, both for existing clinical areas and to support the expansion of the future role of the community pharmacy.

This review sought to identify which underpinning theories and theoretical constructs are most effective in achieving health-behaviour change when interventions are delivered in a community pharmacy setting. We aimed to identify generic approaches that could be used to inform development of any health-promotion intervention delivered in a community pharmacy setting.

Many interventions involve training community pharmacists or pharmacy workers, however, evidence is sparse regarding the best methods of training to achieve health-behaviour change. Even if pharmacists and pharmacy workers can be trained effectively and

can deliver the intervention with fidelity, there still remains the question of whether pharmacy users follow the advice given and whether this results in meaningful improvements in health and well-being. There are no previous comprehensive reviews of the effectiveness of community pharmacy workers as agents for health-behaviour change (Anderson 2003). It is important, therefore, to consider the complete pathway from intervention to effects on health outcomes. Hence we examined study outcomes related to both the professional behaviour of pharmacy workers and to health-related behaviour and outcomes in their users.

Why it is important to do this review

This review is important because community pharmacists and their teams are increasingly taking on health-promotion activities as part of their rapidly expanding role in the delivery of health care and public-health services (Blouin 2017; Mossialos 2013). Much of this change has been driven by need for cost efficiencies in the health system, and the need to reduce health inequalities (Crombie 2005), which is predicted to continue in many countries.

OBJECTIVES

To assess the effectiveness and safety of health-promotion interventions to change community pharmacy workers' professional practice and improve outcomes for users of community pharmacies.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised trials (RTs) and cluster-randomised trials (cluster-RTs) (EPOC 2017a). Cluster-RTs were only eligible if there were at least two intervention sites and two control sites. Publication status of study (full text, unpublished data) was not a bar to inclusion, unless there was insufficient data, for example, regarding intervention content. For this reason, we excluded abstracts that were not supported with further information (Chandler 2013).

Types of participants

Participants in the review were pharmacy workers and users of community pharmacies (defined as regulated pharmacy outlets outside secondary healthcare), under the direction of a pharmacist. We included interventions directed at any worker within the community pharmacy, including pharmacists and other workers such as pharmacy technicians and assistants. We excluded studies where participants were seen in a hospital or non-community-based pharmacy, e.g. an outpatient clinic. We included studies that had mixed settings only if the majority of participants took part in the community pharmacy setting, or if the community pharmacy subset was analysed independently. Similarly, where the intervention was multidisciplinary we included studies only if the majority of the intervention was delivered in community pharmacy, or the community pharmacy aspect of the intervention was evaluated separately, for example, change in community pharmacists' behaviour.

Types of interventions

We included any health-promotion intervention targeted at, or delivered by, community pharmacy workers (including pharmacists, counter assistants etc.) which aimed to improve health behaviours of individuals attending the community pharmacy.

We excluded studies where the intervention was solely focused on medication. This included those interventions that were concerned only with prescription of medication, medication review, or those that focused on promoting adherence to medication. We included interventions where medication management was a single component of an intervention and other behavioural aspects (e.g. diet or exercise) were also targeted.

We excluded studies in which interventions did not involve active interaction between pharmacy workers and their users (e.g. displays of leaflets/posters on lifestyle in the pharmacy).

We have described interventions in terms of:

- mode of delivery (e.g. video/DVD, one-to-one or group-based or web-based sessions);
- agent delivering the intervention (e.g. pharmacist, pharmacy assistant);
- setting (e.g. on site in pharmacy); duration (including length and number of sessions and period over which the intervention was delivered);
- content (e.g. smoking cessation, lifestyle recommendations, condition management).

We also documented the intervention fidelity (i.e. the degree to which the intervention was delivered as intended), where this was assessed. Where necessary, we contacted authors of studies to obtain additional details of interventions and training of pharmacy workers.

Types of outcome measures

We present the results that were assessed closest to the end of the intervention but only after the intervention was finished.

Primary outcomes

To assess the effects of community pharmacy interventions on health promotion delivered by pharmacy workers, we looked at three categories of outcomes:

- Professional practice outcomes were primarily behavioural and included:
 - * uptake of intervention by pharmacy worker, adherence to the intervention (e.g. number of pharmacy users asked about smoking status);
 - * pharmacy worker behaviour (e.g. correct demonstration of inhaler technique).

- Pharmacy user outcomes included assessment of:
 - * health-related behaviour (e.g. smoking, exercise, inhaler technique);
 - * health status including:
 - intermediate clinical outcomes (e.g. cholesterol, glycated haemoglobin);
 - event-based clinical outcomes (e.g. stroke, myocardial infarction);
 - psychological well-being (e.g. anxiety and depression); and
 - quality of life.
- Adverse events included any effect defined as adverse by the included studies, either at the professional or user level.

In line with Cochrane Effective Practice and Organisation of Care Group (EPOC) recommendations (EPOC 2017a), we included only those studies where at least one outcome was assessed using an objective or validated tool, such as a validated questionnaire. For assessment of pharmacy workers, we considered simulated patients (mystery shoppers) to be an objective measurement tool, and trials using them to be eligible for inclusion (Watson 2006; Xu 2012).

Secondary outcomes

We included costs, as reported by the studies, as a secondary outcome. This included direct and indirect healthcare costs, including scheduled and unscheduled visits to other healthcare providers (healthcare utilisation) and cost-effectiveness.

Search methods for identification of studies

Electronic searches

The EPOC Cochrane Information Specialist wrote the search strategies in consultation with the review authors. We searched the Cochrane Database of Systematic Reviews and the Database of Abstracts of Reviews of Effects (DARE) for related systematic reviews, and searched the following databases for primary studies on 6 February 2018:

- Cochrane Central Register of Controlled Trials (CENTRAL; 2018, Issue 1) in the Cochrane Library;
- Health Technology Assessment Database (DARE; 2016; Issue 4) in the Cochrane Library;
- NHS Economic Evaluation Database (NHSEED; 2015, Issue 2) in the Cochrane Library;
- MEDLINE Ovid (including Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Versions) (1946 to 31 January 2018);
- EMBASE Ovid (1974 to 5 February 2018);
- PsycINFO Ovid (1967 to January Week 5 2018).

The finalised search strategies are provided in [Appendix 1](#). We tested the MEDLINE strategy by screening selected citations for

relevance, and validated it using a selection of exemplar papers on the topic of this review. We modified the MEDLINE strategy for other databases using appropriate syntax and vocabulary for those databases. We applied no limits regarding date or language.

Searching other resources

We searched the grey literature to identify studies that were not indexed in the databases listed above. We searched the following sources on 6 February 2018:

- Open Grey (www.opengrey.eu);
- ProQuest Dissertations & Theses Global (including COS Conference Papers Index);
- ProQuest Dissertations & Theses: UK & Ireland.

Trial Registries

We searched the following trial registries on 6 February 2018:

- International Clinical Trials Registry Platform (ICTRP), World Health Organization (WHO) (www.who.int/ictrp/en);
- ClinicalTrials.gov, US National Institutes of Health (NIH) (clinicaltrials.gov).

We also:

- reviewed reference lists of all included studies, relevant systematic reviews, primary studies and other publications;
- contacted authors of relevant studies or reviews to clarify reported information and to seek unpublished results and data;
- conducted cited reference searches for all included studies in citations indexes.

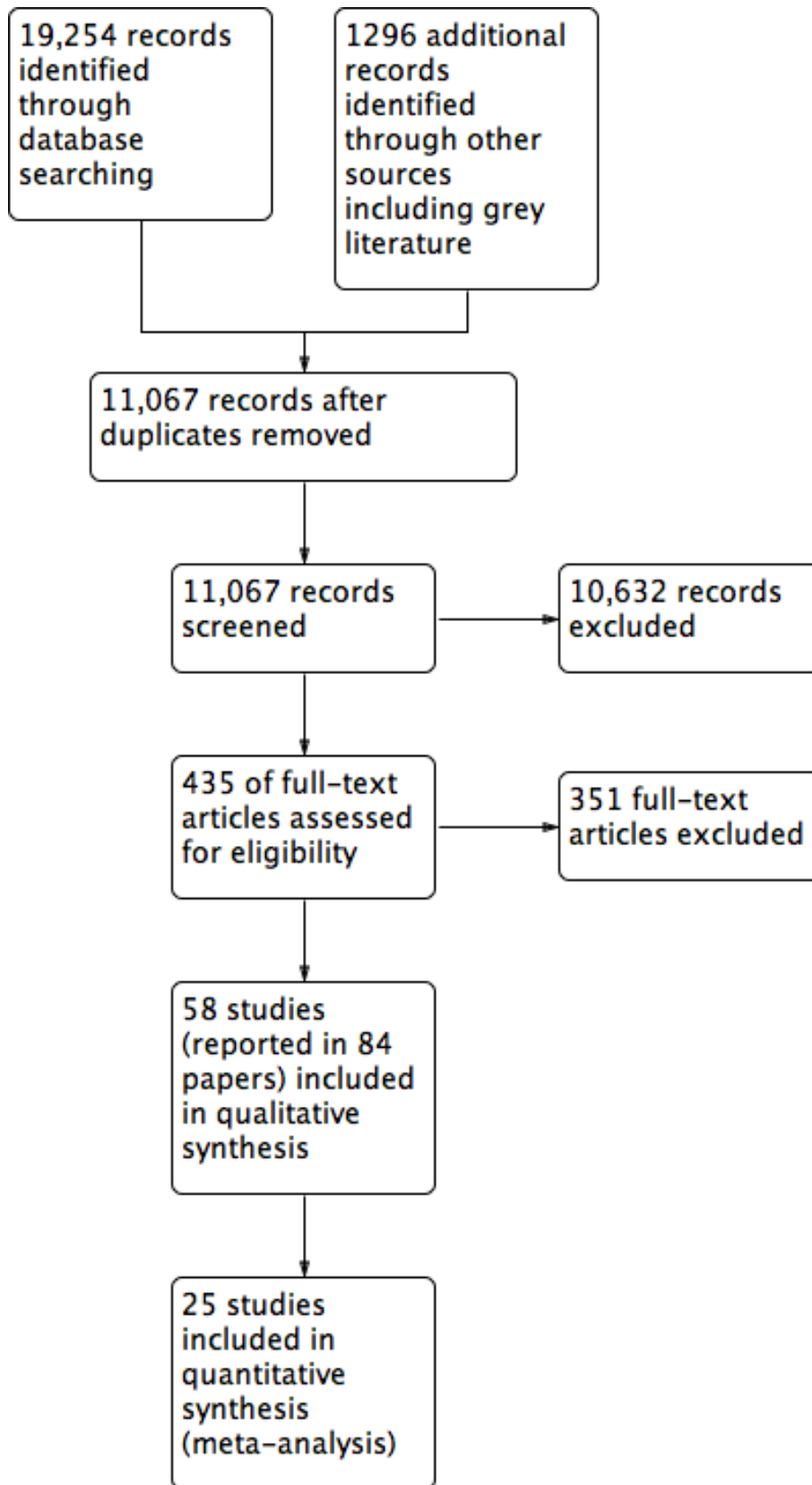
Data collection and analysis

Selection of studies

We imported results of each search into a reference management software package (Endnote 2013). One review author removed duplicates and screened titles and abstracts for obvious irrelevance to the review (e.g. not an intervention study). A second review author completed sequential 10% checks of titles and abstracts until we achieved an inter-rater reliability of 0.75 or greater (excellent agreement) (Orwin 1994). The emphasis was on over-inclusion at this stage. We then retrieved potentially relevant papers and two review authors independently screened all of these against the inclusion criteria. We resolved any disagreements through discussion, referring where necessary to a third review author for arbitration. Where such arbitration was necessary and a study was excluded, we added it to the [Characteristics of excluded studies](#) table, and gave reasons for its exclusion. We collated multiple reports for the same study, so that each study - rather than each report - was the unit of interest.

We have documented the full screening process in a PRISMA flow-chart [Figure 1](#).

Figure 1. Study flow diagram.



Data extraction and management

We extracted data from eligible studies using a tailored extraction form based on the generic EPOC data collection checklist (EPOC 2017b), and included the following data.

- Study details: author; year; research question; country where research was carried out; inclusion and exclusion criteria; study design (randomised trial (RT), cluster randomised trial (cluster-RT); recruitment method (e.g. self-referral, advertisement); description of usual care.
- Intervention details: intervention target (pharmacy workers, or pharmacy users, or both); behavioural target (smoking, diet, exercise, etc.); health condition targeted; intervention description (mode of delivery; theoretical basis as reported by study authors; and theoretical constructs targeted, as coded by mapping interventions to the Theoretical Domains Framework (TDF) (Cane 2012).
- Pharmacy worker details: number; age; socioeconomic status; ethnicity; gender; time since qualification.
- Pharmacy user details: number; age; socioeconomic status; ethnicity; gender; time since diagnosis (where applicable).
- Quality criteria (in line with EPOC recommendations) (EPOC 2017c).
- Results of primary and secondary outcomes.

Two review authors independently extracted all key information (inclusion criteria, e.g. design, participants, interventions and outcomes, quality criteria and results) from each included paper. As mentioned previously, we resolved any errors or disagreements through discussion, with recourse to a third review author for arbitration (RW), and discussion among the full author group where necessary. EK entered data into Review Manager 5.3 software

(RevMan 2014), while a second review author checked the data entry (LS, CR).

Assessment of risk of bias in included studies

We assessed the risk of bias of the studies using Cochrane's 'Risk of bias' assessment tool (Higgins 2011a), and following the EPOC 'suggested risk of bias criteria for EPOC reviews' (EPOC 2017c). There are nine standard criteria for all RTs:

- Was the allocation sequence adequately generated?
- Was the allocation adequately concealed?
- Were baseline outcome measurements similar?
- Were baseline characteristics similar?
- Was the study adequately protected against contamination?
- Were incomplete outcome data adequately addressed?
- Was knowledge of the allocated interventions adequately prevented during the study?
- Was the study free from selective outcome reporting?
- Was the study free from other risks of bias?

We scored each study as being at low, high or unclear (if not specified in the paper) risk of bias. For some studies it may not have been possible to blind participants to the intervention, e.g. an exercise intervention, but we still recorded this aspect in the quality assessment. Two review authors assessed each study's risk of bias, compared results, and resolved discrepancies by discussion and by recourse to a third review author when necessary. We measured inter-rater agreement using Cohen's kappa coefficient (Uebersax 1987). We have presented results in both a 'Risk of bias' table Figure 2, and graphically Figure 3. The authors of the current review were also authors of one included study (Madurasinghe 2017). AT was not an author of the study, and, therefore, screened it for inclusion, and extracted and checked all its data.

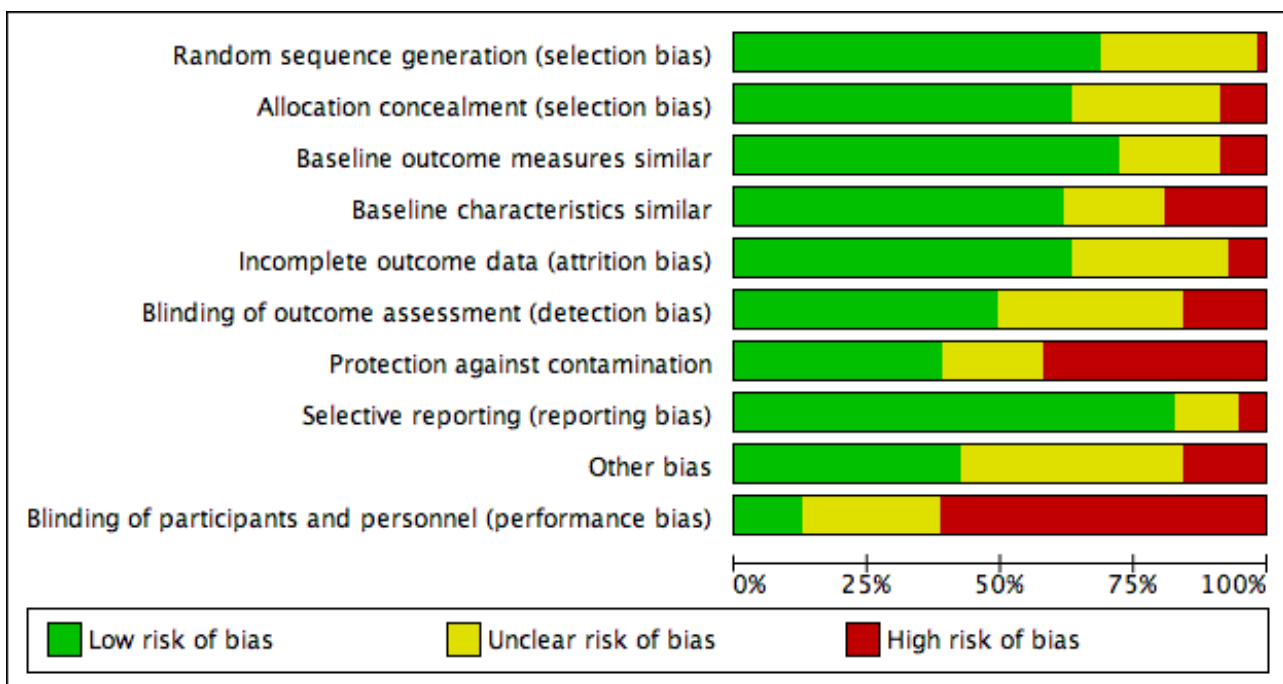
Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Baseline outcome measures similar	Baseline characteristics similar	Incomplete outcome data (attrition bias)	Blinding of outcome assessment (detection bias)	Protection against contamination	Selective reporting (reporting bias)	Other bias	Blinding of participants and personnel (performance bias)
Adepu 2007	?	?	?	-	?	-	-	+	?	?
Ali 2012	+	+	+	+	+	?	-	?	+	?
Amariles 2012	+	+	+	+	+	?	-	+	+	-
Armour 2007	+	+	+	+	+	?	+	+	+	+
Barbanel 2003	+	+	+	+	+	?	-	+	?	?
Basheti 2008	+	+	+	?	+	+	?	+	?	+
Bereznicki 2013	?	+	+	?	+	+	+	+	+	+
Bond 2007	+	+	+	+	+	+	?	+	+	?
Burford 2013	-	-	+	?	+	-	?	+	?	-
Bynum 2001	+	?	+	+	-	?	?	+	+	?
Charrois 2006	+	+	+	+	+	-	+	?	-	-
Cordina 2001	?	+	+	+	-	?	?	+	?	?
Crockett 2006	?	?	?	+	+	?	-	+	?	?
Dhital 2015	+	+	+	+	+	+	-	+	+	-
Dolovich 2007	+	+	?	+	+	+	?	+	?	-
Doucette 2009	?	?	+	+	?	?	?	+	?	-
Fuller 2016	+	-	+	+	+	-	+	+	-	-
Garcia 1998	?	+	?	?	?	+	+	+	?	-
Garcia 2003	+	+	?	?	+	+	+	?	+	+

Figure 2. (Continued)

Smith 2011	+	+	+	+	+	+	+	+	+	+
Svarstad 2013	+	+	+	-	?	+	?	+	+	-
Tommelein 2014	+	+	+	+	+	-	?	+	+	-
Tsuyuki 2002	+	+	+	+	+	-	-	+	?	-
Tsuyuki 2016 - RxACT	+	+	+	+	+	+	-	+	+	-
Tsuyuki 2016 - RxEACH	+	+	+	+	+	+	-	+	+	-
Venkatesan 2012	?	?	?	?	+	+	-	+	?	?
Villeneuve 2010	+	+	+	+	+	?	+	?	?	?
Weinberger 2002	+	+	+	+	-	+	+	+	-	-
Yuksel 2010	+	+	+	+	+	+	-	+	+	-

Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Measures of treatment effect

For continuous data we estimated treatment effect sizes as standardised mean differences (SMDs) for each outcome, or weighted mean differences where studies had a common outcome measure. We treated the available data as continuous unless there was a defensible cut-point available, in which case we considered the data to be dichotomous. We gave preference to final value scores over change scores where both were presented, although analysis with both results is presented where there were sufficient studies for both analyses.

Unit of analysis issues

Where cluster-RTs were included, we considered whether any unit of analysis errors had been made in the original analysis. Where we identified such errors, we performed a re-analysis using information on the size or number of clusters and the value of the intra-cluster correlation coefficient (ICC) where the information was available, or we excluded the study from analysis if necessary.

Dealing with missing data

When a study was missing data, we contacted the study authors and requested the additional data. After this, if data were still missing,

we calculated standard deviations for changes, where possible. When there was insufficient information available to calculate the standard deviations, we imputed missing standard deviations for changes from baseline using other available information (e.g. correlation coefficients) (Higgins 2011b). If it was not possible to impute data, we did not include the study in the analysis and we noted its absence.

For dichotomous data, where possible we derived missing treatment estimates and standard errors from the number of participants included or randomised, and from the numbers of individuals with and without the outcomes of interest. We used confidence intervals (CI) to derive missing standard error estimates.

Assessment of heterogeneity

Given the diverse nature of behavioural interventions, we anticipated some heterogeneity between studies. We assessed this both qualitatively (e.g. examining intervention characteristics, study populations, context, etc.) and quantitatively. We inspected forest plots visually for poorly overlapping CIs for the results of individual studies. We also discussed possible reasons for heterogeneity and considered this in interpretation of results.

We assessed the extent of statistical heterogeneity formally using the Cochran Q statistic and corresponding χ^2 and I^2 statistics. This latter statistic describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance) (Higgins 2003); the significance threshold is set at $P < 0.05$.

Assessment of reporting biases

To test for publication bias we drew funnel plots, if more than 10 studies were identified, and where standard errors and a unitary measure of effect were available (Higgins 2011a). For any given outcome we inspected funnel plots visually for asymmetry.

Data synthesis

We have provided details of all included studies in a [Characteristics of included studies](#) table, irrespective of whether the measured outcome data were reported in a useable way.

For the main analysis, we split outcomes into those that examined the effect on pharmacy workers and those that examined the effect on pharmacy users.

Firstly, we considered the suitability of studies for meta-analysis. If there was considerable evidence of heterogeneity, such that meta-analysis might be misleading, we reported a narrative synthesis of studies, and presented descriptive and summary data of interventions.

Where meta-analysis was deemed appropriate, given the likely heterogeneity in terms of intervention, setting, and population, we adopted the more conservative random-effects model. If an outcome was measured at different times in the same study, we selected the first value after the end of the intervention period. When there were related outcomes from the same study, we used the outcome most consistent across studies (e.g. SF-36 above condition-specific measures) or the most clinically rigorous measure (for asthma this was: severity or asthma control as measured by (for example) the asthma control questionnaire, followed by forced expiratory volume in one second, followed by peak expiratory flow; for diabetes this was: HbA1c followed by

plasma blood glucose; for hypertension this was: systolic blood pressure followed by diastolic blood pressure; for lipids this was: low density lipoproteins followed by cholesterol). In this way we pooled only a single effect size for each study. We used Review Manager 5.3 software to collate data and perform calculations.

Subgroup analysis and investigation of heterogeneity

We conducted subgroup analyses in RevMan 5 for different patient behaviours, clinical conditions, and generic versus specific quality of life measures, where there were sufficient studies for this to be meaningful.

We also planned to consider whether there were different effects from studies conducted within low- and middle-income countries (LMICs) compared with high-income countries (HMICs) as classified by the (World Bank Group 2009). We also planned to examine whether people from particular ethnic groups and those at extremes of adverse health behaviour (e.g. heavy smokers) were more likely to respond to pharmacy-based interventions. If there were sufficient studies we also planned to explore whether theory-based interventions were more effective than those not based on theory, and whether a financial incentive influences effectiveness. Unfortunately there were insufficient studies for these planned sub-group analyses to be conducted.

Meta regression

We planned to perform a meta-regression where there was an adequate amount of data, using Stata 12.1. This was to consider which features of interventions were more likely to be successful, and to examine effects of intervention delivery (e.g. single brief consultation, several brief consultations plus follow-up telephone contact etc.).

Sensitivity analysis

We conducted sensitivity analyses by excluding studies that we assessed as being at high risk of bias. This involved undertaking the meta-analysis twice, with and without the studies in question.

Summary of findings

We prepared [Summary of findings for the main comparison](#) for health-promotion interventions delivered within the community pharmacy compared to no intervention or usual care. We used the Grading of Recommendations and Assessment Development and Evaluation (GRADE) approach to evaluate our confidence in the findings (GRADE 2013). [Summary of findings for the main comparison](#) includes the seven most important outcomes for both community pharmacy workers and community pharmacy users. LS and RW assessed all outcomes for importance in line with EPOC recommendations (EPOC 2017d), and were in agreement. They assessed the certainty of the evidence independently, using standard procedures and resolving discrepancies by consultation with ST. We selected pharmacy workers' behaviour and pharmacy users' health-related behaviours, intermediate clinical outcomes (e.g. cholesterol, glycated haemoglobin), event-based clinical outcomes, quality of life, adverse events and costs for inclusion in [Summary of findings for the main comparison](#).

RESULTS

Description of studies

Studies are described in the [Characteristics of included studies](#), [Characteristics of excluded studies](#), and [Characteristics of ongoing studies](#) tables.

Results of the search

The search is summarised in [Figure 1](#) and yielded 20,550 citations, including 1296 from the grey literature. Following removal of duplicates, we screened 11,067 studies and assessed 435 full text papers. We excluded 352 papers, as they did not meet inclusion criteria. We did not categorise papers by individual reasons for exclusion, as many papers had multiple reasons for exclusion, and any categorisation would have misrepresented the situation. We included a total of 57 studies, which were reported in 83 papers. We identified five further studies as ongoing ([Davis 2016](#); [Ekers 2017](#); [Michiels 2017](#); [Porteous 2013](#); [Spadaro 2010](#)).

Included studies

Location

Although the included studies were conducted worldwide, none were undertaken in low-income countries (as defined by the World Bank) ([World Bank Group 2009](#)). Three studies were conducted in low-middle income countries, including India ([Adepu 2007](#); [Venkatesan 2012](#)), and Kenya ([Liambila 2010](#)); five were conducted in high-middle income countries, specifically Peru ([Garcia 1998](#); [Garcia 2003](#); [Garcia 2012](#)), and Bulgaria ([Petkova 2008](#); [Petkova 2009](#)). The remaining 49 studies were conducted in high-income countries, including Australia (9 studies), Belgium (4 studies), Germany (1 study), Malta (1 study), Poland (1 study), Spain (2 studies), Chile (1 study), Japan (1 study), the UK (7 studies), the USA (11 studies), and Canada (11 studies). Twenty nine studies were conducted in urban settings; thirteen studies did not report the type of setting i.e. rural or urban. It was not possible to determine whether interventions reached lower-socioeconomic status populations, as this was poorly described.

Participants

Overall, the studies involved a total of 16,220 participants. Twenty-seven studies were cluster-RCTs, while all the others were simple randomised trials. We excluded four of the cluster-RCTs from entry into meta-analysis, as their analysis did not adequately account for clustering effects ([Krass 2007](#); [Mehuys 2011](#); [Skowron 2011](#); [Smith 2011](#)). The majority of studies compared intervention to usual treatment, although eight studies compared the intervention to no treatment. These eight studies all had interventions which primarily targeted the community pharmacy worker ([Dolovich 2007](#); [Garcia 1998](#); [Garcia 2003](#); [Garcia 2012](#); [Liambila 2010](#); [Liekens 2014](#); [Mayer 1998](#); [Patwardhan 2012](#)).

Conditions

Most studies (47 of 57) were directed towards secondary prevention of conditions, including allergic rhinitis ([Smith 2011](#)), arthritis ([Petkova 2009](#)), asthma (13 studies), chronic obstructive pulmonary disease ([Tommelein 2014](#)), cardiovascular disease ([Bond 2007](#)), depression ([Crockett 2006](#); [Liekens 2014](#)), type 2 diabetes (10 studies), dyslipidaemia ([Nola 2000](#); [Paulos 2005](#); [Tsuyuki 2016 - RxACT](#); [Villeneuve 2010](#)), hypertension ([Okada 2018](#); [Park 1996](#);

[Skowron 2011](#); [Svarstad 2013](#)), low back pain ([Slater 2013](#)), osteoporosis ([McDonough 2005](#)); skin cancer ([Mayer 1998](#)), and insomnia ([Fuller 2016](#)). In approximately half of these conditions the intervention was described as being focused on the pharmacy user, whilst the other half mentioned some degree of training for the community pharmacy workers.

Six studies focused specifically on prevention of either diabetes ([Schmiedel 2015](#)), osteoporosis ([Yuksel 2010](#)), or cardiovascular risk factors ([Amariles 2012](#); [McLean 2008](#); [Tsuyuki 2002](#); [Tsuyuki 2016 - RxEACH](#)). A further nine studies targeted lifestyle behaviours including smoking ([Burford 2013](#); [Maguire 2001](#); [Patwardhan 2012](#); [Madurasinghe 2017](#)), illicit drug use ([Jaffray 2014](#)), family planning ([Liambila 2010](#)), and sexually transmitted infection prevention ([Garcia 1998](#); [Garcia 2003](#); [Garcia 2012](#)). All of these lifestyle interventions, with the exception of [Burford 2013](#), targeted behaviour change through intervening at the pharmacy worker level, for example by improving knowledge or skills.

Interventions

Most interventions were educational or incorporated skills training, for example asthma interventions typically trained pharmacy users in inhaler technique. Interventions directed at the community pharmacy workers typically consisted of group workshops supported by written materials for self-directed learning. Training ranged from a single session to sessions held over several weeks ([Mayer 1998](#)). In a number of instances the training involved interactive exercises, such as role-play, which are important for the development of skills ([Bond 2007](#); [Garcia 1998](#); [Garcia-Cardenas 2013](#); [Krass 2007](#); [Liekens 2014](#); [Madurasinghe 2017](#); [Petkova 2009](#); [Svarstad 2013](#)). Typically training was face to face, although other methods were used occasionally, for example video-conferencing ([Crockett 2006](#)), videotape-based training ([Mayer 1998](#)), or online training ([Tsuyuki 2016 - RxEACH](#)). Face-to-face delivery was also most common for user-directed interventions. Usually, this involved direct face-to-face communication with the community pharmacy worker.

The duration of follow-up was often unclear. Several studies reported assessment at what appeared to be a long-term follow-up (e.g. 12 months), however, this was often the length of the delivery period of the intervention. For this reason, we present the first set of results after the end of the intervention.

Funding

The majority of studies (34 of 57) were funded by grants from national funding bodies, charities, or institutional funds. Five studies were funded by industry and a further five by a combination of public and industry funding. Eight studies did not report their funding source.

Theory in interventions

Only five studies reported whether the intervention was based on a specific theoretical approach. [Svarstad 2013](#) based intervention development on Svarstad and Bultman's Health Collaboration Model and Rogers's Diffusion of Innovation Model ([Rogers 2003](#); [Svarstad 2000](#)). [Jaffray 2014](#) and [Nishita 2013](#) trained pharmacy workers in motivational interviewing. Although motivational interviewing is not underpinned by any specific theory, it is a recognised approach to behaviour change ([Miller 2012](#)). [Smith 2011](#) reported a 'goal setting self-management study' which, although

not specified, appeared to draw on Social Cognitive Theory (Bandura 1986). A summary of how many interventions addressed each theoretical domain, as coded using the theoretical domains framework (Cane 2012), is reported with the [Characteristics of included studies](#). Most commonly community pharmacy workers were trained to increase knowledge and skills, and frequently the intervention added some form of object to the environment, which could be as simple as having information leaflets to distribute. Pharmacy users were typically provided with information, and, particularly in interventions for asthma, were taught skills such as inhaler technique. Behavioural regulation approaches, such as self-monitoring, were used in 19 interventions. Of note, few interventions addressed the theoretical domains of beliefs about capabilities and consequences, or intentions and emotions.

Excluded studies

In total, we excluded 352 studies. Studies where consensus was not immediate were discussed amongst the team and are presented in the [Characteristics of excluded studies](#) table. We excluded studies for four reasons, namely:

1. not being conducted in a community pharmacy setting;
2. inappropriate design;
3. an intervention that did not fit our inclusion criteria;
4. no validated or appropriate outcome.

Often, there were multiple reasons for the exclusion of a study, however, in the table we report only the first reason of the four given above to optimise efficiency in screening. When we excluded studies on the basis of intervention, it was usually because they targeted medication adherence without a wider behavioural focus. There was some debate as to whether disease management interventions - particularly those related to cardiovascular risk (i.e. hypertension, dyslipidaemia) - should be included or excluded, as many of these were medication focused but also mentioned lifestyle-behaviour change. The extent to which lifestyle advice drew on behaviour-change principles was difficult to determine fully from descriptions; we included these studies, but evaluated them with this point in mind.

Risk of bias in included studies

We assessed risk of bias, and provide a summary table and graph of risk of bias in [Figure 2](#) and [Figure 3](#), respectively. The most common sources of bias were lack of protection against contamination, mainly in individually randomised studies, and inadequate blinding of pharmacy users and pharmacy workers.

Allocation

We included 27 cluster-RTs, which used the community pharmacy as the unit of randomisation. The remaining 30 studies used the pharmacy user as the unit of randomisation. Most individual-level RT studies conducted randomisation in a robust way and conserved allocation concealment. In cluster-RTs, allocation concealment at the pharmacy level was frequently conserved, but for individuals it was typically more complex (Eldridge 2012), and frequently was not clear.

Blinding

Due to the nature of the interventions, it was often not possible to blind providers (pharmacy workers) and recipients (pharmacy users). This is a common difficulty for interventions of a behavioural nature (Friedberg 2010), although risk can be minimised by the use of independent blinded assessors, which was done in some of the more robust studies (e.g. Amariles 2012; Bereznicki 2013; Liekens 2014; Svarstad 2013). Additionally, the use of objective outcomes - for example those used for intermediate clinical outcomes, such as HbA1c, or blood pressure - can help to minimise detection bias.

Incomplete outcome data

Some level of attrition was common in many studies, most commonly amongst pharmacy users, but also at the pharmacy level in some cases. While a number of studies reported how missing data were managed, this was unclear or not described in approximately half the studies. Therefore, attrition bias is a potential threat to the generalisability of the findings of this review.

Selective reporting

Examination of funnel plots for the main outcomes suggested possible publication bias for pharmacy users' intermediate clinical outcomes and quality of life ([Figure 4](#); [Figure 5](#); [Figure 6](#)).

Figure 4. Funnel plot of comparison: 1 Usual treatment versus Health-promotion intervention, outcome: 1.1 Pharmacy user health-related behaviour.

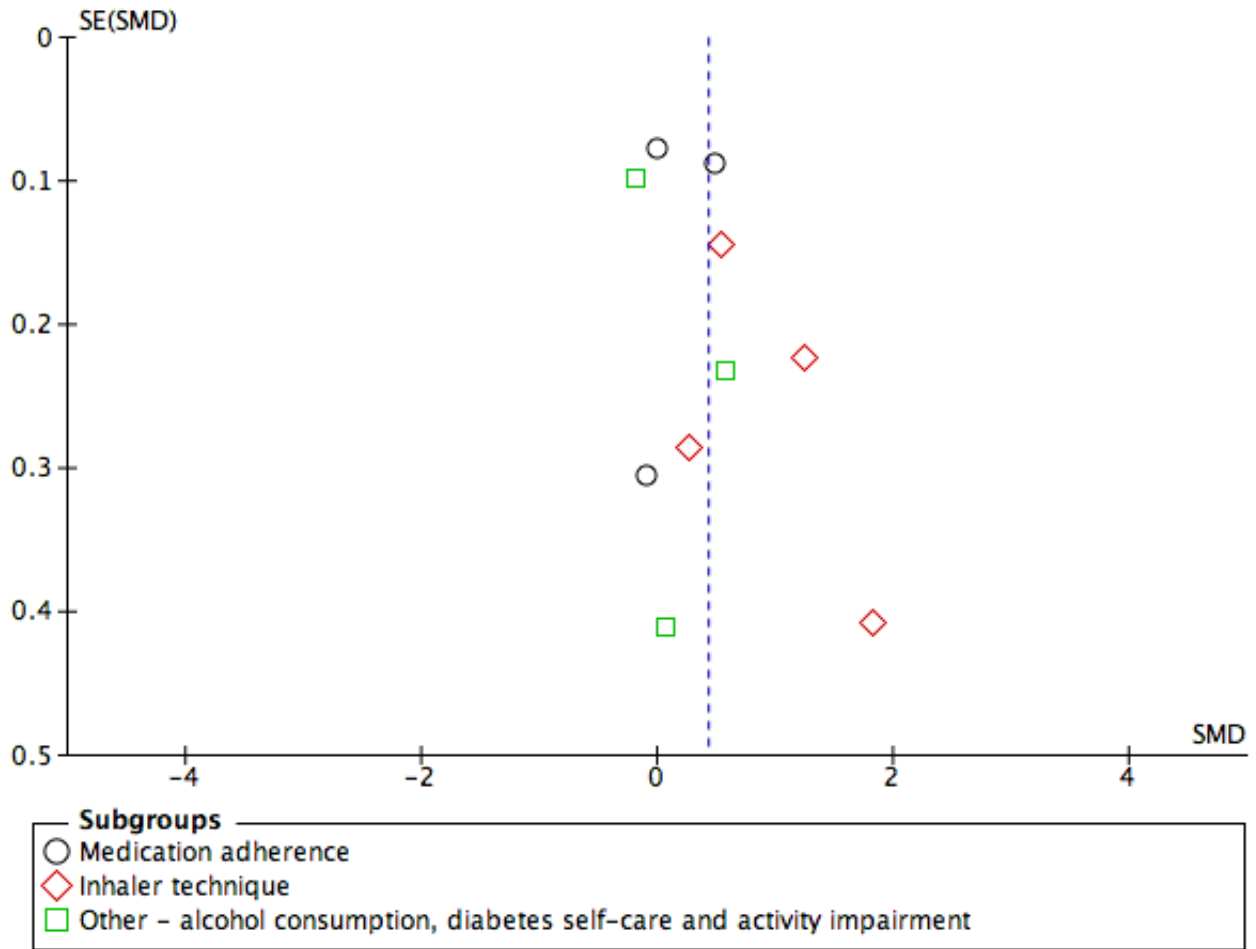


Figure 5. Funnel plot of comparison: 1. Health-promotion intervention versus Usual treatment outcome: Analysis 1.2 Pharmacy user intermediate clinical outcomes (final value scores)

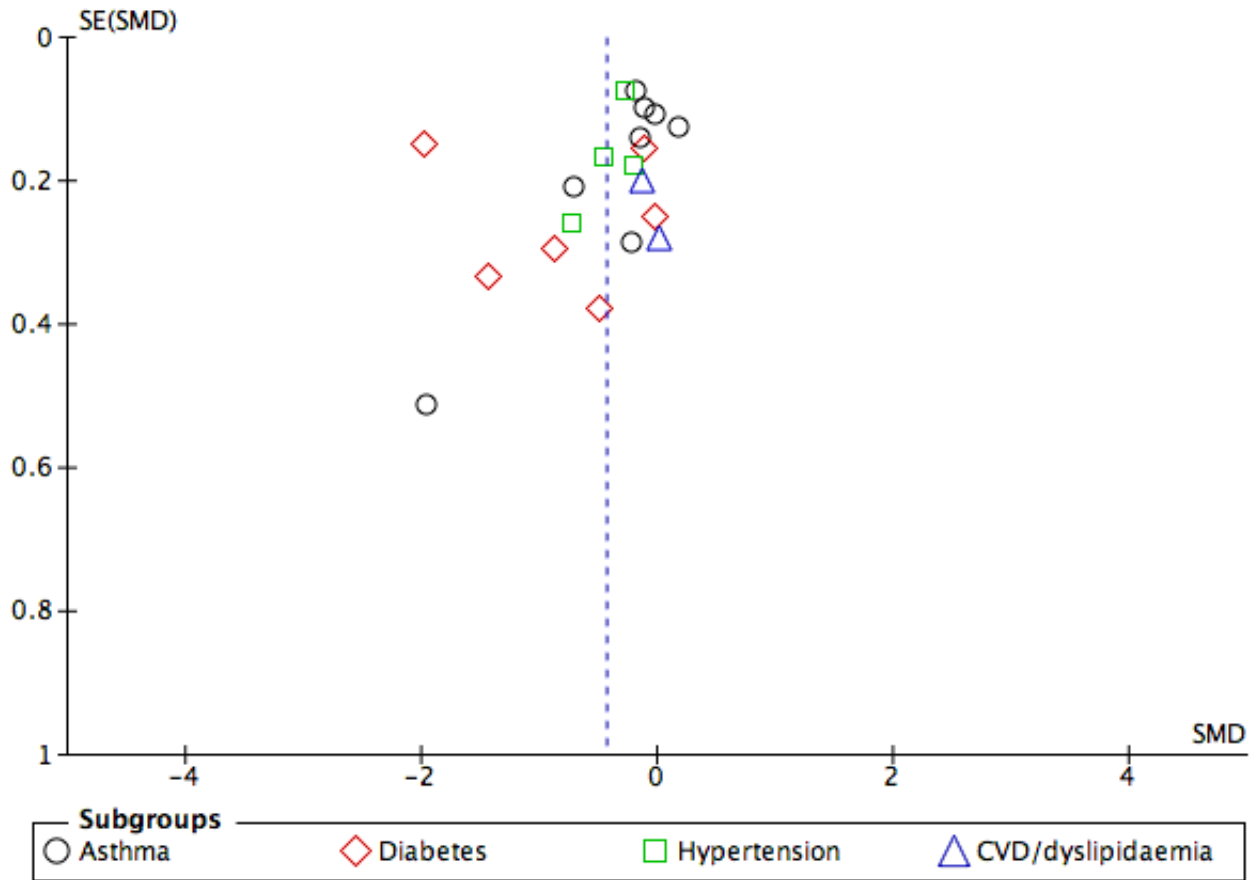
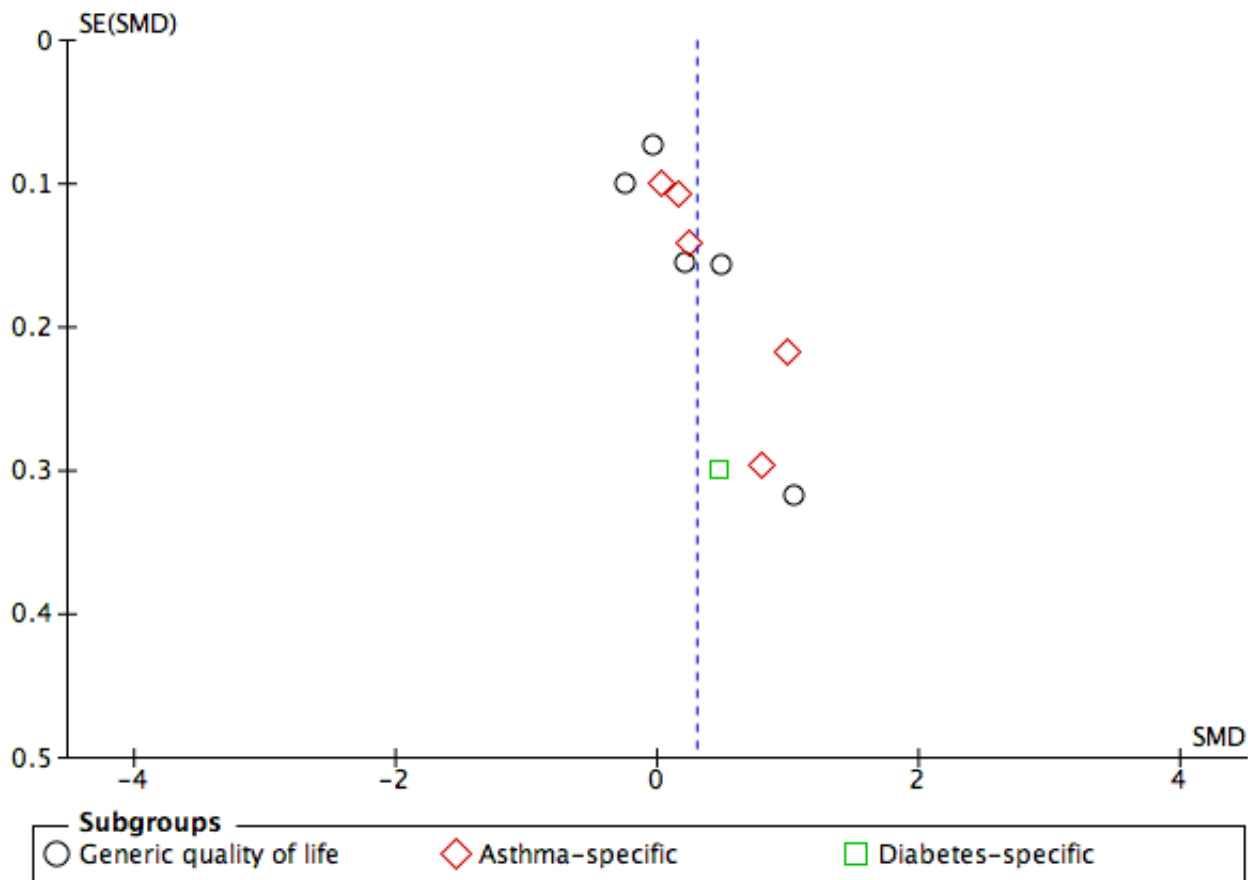


Figure 6. Funnel plot of comparison: 1. Usual treatment versus Health-promotion intervention outcome: Analysis 1.4 Pharmacy user quality of life



Other potential sources of bias

An important potential bias in the included studies was the possibility of contamination between intervention and control groups (see Figure 2). We judged this to be at high risk where randomisation occurred at the level of pharmacy user within the pharmacy, because it can be difficult for a pharmacy worker not to implement skills that have been learned, which risks contamination of the control participants.

Effects of interventions

See: [Summary of findings for the main comparison Health-promotion interventions within community pharmacy compared to usual treatment: effects on professional practice and health outcomes](#)

[Summary of findings for the main comparison](#) presents an overview of the effectiveness of interventions; we have used GRADE to indicate the certainty of the evidence. For all outcomes GRADE scores were downgraded to moderate, primarily due to the high heterogeneity present within the studies and evidence of potential publication bias.

Primary outcomes

1. Professional practice outcomes

Fourteen of the 57 studies reported the proportion of pharmacies or pharmacy workers participating in the study. Some studies were conducted in just one or two pharmacies, and others selected pharmacies with specific characteristics. Those studies that reported the proportion of pharmacy workers who consented to take part in the study compared to those invited to participate, reported relatively low figures, for example, 26% in the [Basheti 2008](#) study, and 33% in the [Armour 2007](#) study.

Nine studies assessed pharmacy worker outcomes and compared these to no intervention controls. All nine studies assessed the outcome of pharmacy worker behaviour. Eight of the studies were set in urban pharmacies. Seven studies assessed behaviour using a simulated patient model ([Dolovich 2007](#); [Garcia 1998](#); [Garcia 2003](#); [Garcia 2012](#); [Liambila 2010](#); [Liekens 2014](#); [Mayer 1998](#)). The behaviours measured by simulated patients ranged from communication skills - using validated measures such as the Roter Interaction Analysis ([Dolovich 2007](#); [Liekens 2014](#)) - to noting behaviours such as recommending use of condoms ([Garcia 2012](#)). [Patwardhan 2012](#) used an objective measure of behaviour, namely referrals to a smoking quit line following smoking cessation training. The [Basheti 2008](#) study assessed maintenance of pharmacy workers' ability to demonstrate asthma inhaler

technique two years post training. Two further studies, [Jaffray 2014](#) and [Nishita 2013](#), assessed behaviour as an assessment of fidelity to training but only in the intervention group, not in the control group, so these data were not included in our analysis.

Six of the studies reported improvement in community pharmacy worker behaviour ([Basheti 2008](#); [Dolovich 2007](#); [Garcia 2003](#); [Garcia 2012](#); [Mayer 1998](#); [Patwardhan 2012](#)), while one showed no benefits ([Liambila 2010](#)), and two had mixed results ([Garcia 1998](#); [Liekens 2014](#)). The [Dolovich 2007](#) study indicated a positive effect on both verbal and non verbal communication skills. The [Liekens 2014](#) study showed improved pharmacy worker counselling for depression, and the intervention used in [Mayer 1998](#) improved counselling to avoid ultra-violet radiation (i.e. sunlight). Sexual health counselling was improved in the [Garcia 2003](#) and [Garcia 2012](#) studies at six- and 12-month follow-up, respectively. The [Patwardhan 2012](#) study showed significant improvement in demonstration of inhaler behaviour post-intervention, and the [Basheti 2008](#) study showed maintenance of pharmacy workers' ability to demonstrate correct asthma inhaler technique two years after training. In contrast, interventions in the [Liambila 2010](#) and [Garcia 1998](#) studies produced mixed results for sexual health management.

Due to the heterogeneity of the behaviours measured and the methods used in the studies, we did not consider meta-analysis to be appropriate. We downgraded the certainty of evidence one level, to moderate, because of the high heterogeneity of studies ([GRADE 2013](#)).

2. Pharmacy user outcomes

2.1 Pharmacy user health-related behaviour e.g. smoking, exercise, inhaler technique

Health-related behaviour of pharmacy users was measured in 28 studies (summarised in [Table 1](#)). Twelve studies measured medication adherence (please note that this was not the primary target of the intervention, or the trial would have been excluded). Adherence was measured through prescription data, or validated adherence measures such as the medication adherence rating scale (MARS) ([Thompson 2000](#)). Seven studies measured inhaler technique within the asthma population specifically. Lifestyle behaviours that were assessed included smoking ([Burford 2013](#); [Maguire 2001](#); [Madurasinghe 2017](#)), alcohol consumption ([Dhital 2015](#)), diabetes self-care ([Doucette 2009](#); [Mansell 2016](#)), physical activity ([Okada 2018](#); [Schmiedel 2015](#)), and activity impairment ([Slater 2013](#)).

Ten studies provided suitable data for meta-analysis of overall health-related behaviour of pharmacy users ([Analysis 1.1](#)). Overall meta-analysis of health-related behaviour of community pharmacy users suggested a probable slight improvement relative to control (SMD 0.43, 95% CI 0.14 to 0.72; $I^2 = 89\%$; 10 trials, 2138 participants; moderate-certainty evidence). Inhaler technique was probably improved (SMD 0.92, 95% CI 0.35 to 1.48; $I^2 = 82\%$; 4 trials; 384 participants; moderate-certainty evidence), but interventions showed little or no effect on medication adherence (SMD 0.17, 95% CI -0.23 to 0.57; $I^2 = 89\%$; 3 trials, 1245 participants; moderate-certainty evidence), or other behaviours (SMD 0.14, 95% CI 0.41 to 0.68; $I^2 = 78\%$; 3 trials, 509 participants; moderate-certainty evidence). We downgraded the certainty of evidence one level to

moderate to take into account the high heterogeneity of studies as indicated by high I^2 values.

2.1.2 Intermediate clinical outcomes, e.g. cholesterol, HbA1c

Most studies (35 of 57) included some level of intermediate clinical outcome. The ones measured most consistently were in asthma (9 studies), diabetes (10 studies) and cardiovascular risk (hypertension (8 studies) and dyslipidaemia (4 studies)). We prioritised measures of glycaemic control (e.g. HbA1c) and asthma control (e.g. asthma control test) as the most clinically appropriate for diabetes and asthma, respectively. See [Table 2](#) for an overview of studies. For blood pressure control, most studies presented results for both systolic and diastolic blood pressure. Since we could enter only one value per study into the meta-analysis, we prioritised systolic blood pressure, as recommended by [Strandberg 2003](#). Similarly, the dyslipidaemia studies reported a range of measures, including total cholesterol, high density lipoproteins (HDL) and low-density lipoproteins (LDL). On the basis of the recognised clinical importance of these measures ([Silverman 2016](#)), we decided to include LDL values in the meta-analysis.

Meta-analyses for intermediate clinical outcomes, including sub-group analysis by condition are shown in [Analysis 1.2](#). Health-promotion interventions probably improve intermediate clinical outcomes slightly in pharmacy users (SMD -0.43, 95% CI -0.65 to -0.21; $I^2 = 90\%$; 20 trials, 3971 participants; moderate-certainty evidence). These findings were also replicated when mean change rather than final scores were used (SMD -0.27, 95% CI -0.38 to -0.17; $I^2 = 0\%$; 7 trials, 1413 participants; moderate-certainty evidence; [Analysis 1.3](#)).

Sub-group analyses separated by condition suggested that interventions probably improve blood pressure in hypertension (SMD -0.34, 95% CI -0.49 to -0.18; $I^2 = 18\%$; 4 trials; 1050 participants; moderate-certainty evidence; [Analysis 1.2](#)). Interventions probably improve blood glucose levels in diabetes (SMD -0.81, 95% CI -1.60 to -0.02; $I^2 = 96\%$; 6 trials; 651 participants; moderate-certainty evidence; [Analysis 1.2](#)), though the high level of heterogeneity is important here. Interventions probably made little or no difference for asthma control (SMD -0.20, 95% CI -0.40 to -0.00; $I^2 = 75\%$; 8 trials, 2220 participants; moderate-certainty evidence; [Analysis 1.2](#)) or for cardiovascular risk (SMD -0.08, 95% CI -0.40 to 0.24; $I^2 = 0\%$; 2 trials, 150 participants; moderate-certainty evidence; [Analysis 1.2](#)). I^2 values were higher for diabetes and asthma than hypertension or cardiovascular risk. This is likely to reflect the greater similarity in outcome measurement and intervention which was more medication focused in the hypertension and cardiovascular risk than asthma and diabetes.

We assessed the certainty of evidence as moderate after downgrading to take into account the high heterogeneity of studies and unclear distribution (possible publication bias) in funnel plots ([GRADE 2013](#)).

2.1.3 Event-based clinical outcomes, e.g. stroke, myocardial infarction (MI)

No study measured event-based clinical outcomes such as mortality, stroke or MI.

2.1.4 Psychological well-being, e.g. anxiety and depression

Two studies; [Crockett 2006](#) and [Fuller 2016](#), measured psychological well-being. [Crockett 2006](#) employed an intervention targeted at depression and measured distress using the K10 ([Kessler 2003](#)), but did not report benefits. [Fuller 2016](#) used the DASS-21 to measure depression, anxiety, and stress ([Norton 2007](#)), and reported improvement in the intervention group compared to controls on some but not all scales. Given the different ways of combining and calculating psychological well-being in each of these studies it was not considered appropriate to conduct meta-analysis, however, overall it appears that psychological well-being was neither improved nor negatively affected by such interventions.

2.1.5 Quality of life

Quality of life was measured in 28 studies as reported [Table 3](#). Fourteen studies used a generic measure, most commonly the SF-36 ([Ware 1992](#)), or EQ-5D ([Herdman 2011](#)). One study used both a generic and an illness-specific quality of life measure, and 14 studies used an illness-specific measure only. We meta-analysed 10 studies [Analysis 1.4](#). As participants should only be included once in the meta-analysis the diabetes specific quality of life scores from [Ali 2012](#) were not included in the overall analysis. Overall, interventions probably improve quality of life slightly (SMD 0.29, 95% CI 0.08 to 0.50; $I^2 = 84%$; 10 trials, 2687 participants; moderate-certainty evidence). For quality of life measured by a generic tool the interventions may make little or no difference (SMD 0.21, 95% CI -0.10 to 0.52; $I^2 = 86%$; 5 trials, 1567 participants; low-certainty evidence). Importantly, however, several studies using a generic quality of life measure were not included in the meta-analysis as data were reported on multiple sub-scales (e.g. [Bond 2007](#), [Cordina 2001](#)). For illness specific quality of life there is probably a slight improvement in favour of the intervention groups (SMD 0.38, 95% CI 0.11 to 0.66; $I^2 = 77%$; 6 trials; 1166 participants; moderate-certainty evidence).

3. Adverse events

No adverse events were reported in any of the studies.

Secondary outcomes

Costs

Seven studies conducted a costs analysis ([Armour 2007](#); [Bond 2007](#); [Burford 2013](#), [Garcia 1998](#); [McLean 2003](#); [Svarstad 2013](#); [Tsuyuki 2002](#)). Five of these found the intervention to be cost-effective relative to usual care, even when accounting for costs of intervention. We did not include these in a meta-analysis because of the heterogeneity of methods used, but the consistency of finding is important. Further studies measured healthcare utilisation, most commonly general practitioner visits or hospitalisation ([Ali 2012](#); [Charrois 2006](#); [Cordina 2001](#); [Mehuys 2008](#); [Petkova 2008](#); [Petkova 2009](#); [Tommelein 2014](#); [Villeneuve 2010](#); [Weinberger 2002](#)), however, these presented mixed findings about whether the intervention group showed improvement relative to controls.

We were not able to conduct the planned sub-group meta-analysis of low- and middle-income countries versus high-income countries, as there was not sufficient homogeneity of outcomes or consistency in reporting across these groups. From visual assessment it does appear that, in general, studies from lower- to middle-

income countries had a higher risk of bias than those in high-income countries. We could not analyse groups at the extremes of health behaviour or cultural/ethnic groups as these data were not reported adequately.

Sensitivity analyses

We repeated meta-analysis for pharmacy user health-related behaviour, intermediate clinical outcomes and quality of life while omitting outliers or any trial with a high risk of bias (e.g. [Park 1996](#)), however, this did not significantly change the outcomes of analyses.

Publication bias

Examination of funnel plots suggested that there was potential publication bias in the community pharmacy user outcomes of quality of life and intermediate clinical outcomes. For these outcomes, fewer smaller non-significant studies were published than small positive studies, however, this effect was not seen for larger studies which contributed greater weight to meta-analysis.

DISCUSSION

Summary of main results

The findings of this review suggest that the community pharmacy is potentially a helpful setting in which to offer behavioural and health-promotion interventions. There is evidence to suggest that such interventions probably slightly improve pharmacy user health-related behaviour, intermediate clinical outcomes - particularly for diabetes and hypertension - and quality of life. Importantly, there is also some indication that these interventions may be cost effective. Although these findings were consistent across conditions and outcomes, it is important to note that there was considerable heterogeneity, as indicated by high I^2 between studies in terms of intervention content and delivery, outcomes measured, and follow-up periods, so we do not have complete certainty in our findings. Nonetheless, the evidence from this review agrees with the current drive in healthcare provision, both within the UK ([NICE 2018](#)), and internationally ([Blouin 2017](#)), to extend the role of the community pharmacy.

In addition to the probable slight effects on pharmacy user outcomes, there is evidence that the professional practice of pharmacy workers is probably influenced positively by the interventions. It is of note, however, that only a minority of studies evaluated pharmacy worker behaviour. Descriptions of the pharmacy worker interventions were often reported more briefly than those of the pharmacy user interventions. Many studies were poor at reporting use of theory. This has important implications for replicability of studies, and also the maximisation of benefits and refinement of interventions. We did not find any studies that measured harms from these interventions. Although adverse effects on pharmacy worker and pharmacy user health-related behaviour, intermediate clinical, quality of life, and cost outcomes were not indicated, more subtle harms - such as disruption to traditional pharmacological services due to a misdirection in the pharmacy workers' time - is possible, and should be investigated in future studies.

Overall completeness and applicability of evidence

This review used stringent inclusion criteria to ensure that only studies of robust quality were included. This led to the exclusion of a significant number of studies from the review, particularly with respect to certain outcomes - for example, lifestyle interventions such as smoking cessation. Smoking cessation interventions are a common health-promotion service for community pharmacies to offer, but trials exploring the effectiveness of these interventions were included less frequently in this review than we anticipated because of our requirement for an objective, clinically verified outcome measure, for example, cotinine levels. The requirement for an objective outcome measure was less of a problem for intermediate clinical outcomes, which typically were objective measurements (e.g. HbA1c). The overall finding of effectiveness for this outcome has more weight for generalisability given the number of studies across different countries and different conditions that contributed to it. This must, however, be balanced against the considerable heterogeneity of trials that makes it difficult to conclude whether specific types, or content, of interventions are more beneficial. It is also important to consider that standardized mean difference (SMD) scores were used in [Analysis 1.1](#) and [Analysis 1.2](#) where the constructs of pharmacy user behaviour and pharmacy user intermediate clinical outcomes were measured across different conditions and different sub-groups e.g. of behaviour. As a result findings may be driven by difference in one sub-group (for example inhaler technique [Analysis 1.1](#)) but not in others. In addition it is not clear to what extent these findings persist after the intervention period since we used the first measurement after intervention completion.

There were insufficient data to conduct a number of our planned subgroup analysis, including whether outcomes varied according to cultural or ethnic group, and the level of health behaviour or theory used, and these remain important questions to answer. Additionally, it was uncommon for studies to report socio-economic status of participants, so the extent to which these interventions reached into populations that are more difficult to access could not be ascertained.

Our original intention was to categorise interventions according to the behaviour-change techniques used, but this was not possible due to the insufficiency of intervention descriptions. In addition, the way in which pharmacy workers were trained to deliver the intervention was poorly reported. We did conduct a higher level coding of interventions according to the theoretical domains framework (see [Characteristics of included studies](#)), which suggested that although studies did frequently involve knowledge and some basic behavioural regulation approaches, they commonly did not explore the more complex elements needed for behaviour change, such as addressing beliefs and emotions. The studies rarely reported being driven by a theoretical model; this is now recommended for development of complex interventions ([Craig 2008](#)), and should apply to the development of future community pharmacy health-promotion interventions.

One issue that is important to consider is the extent to which the studies included in this review were representative of the general community pharmacy population. Studies rarely reported their organisational structure or issues, such as the culture within the practice, which would have aided interpretation of results. In addition, many studies conducted trials in a relatively low number of community pharmacies, which were often close to the research

base. When a larger number of pharmacy sites were recruited, there was variable uptake, often with considerable dropout (e.g. 26% of pharmacists in [Skowron 2011](#)), although this was not always the case (e.g. 0% dropout in [Slater 2013](#)). The importance of this issue was highlighted in [Garcia 2012](#), which reported that over a three-year study period 29% of enrolled pharmacies closed, and the turnover of staff was remarkably high, with 81% of the staff base changing jobs during the study period. This is an important issue to consider when training staff, and suggests that, if interventions are to be supported in the long term, regular and ongoing pharmacy worker training events should be organised.

Certainty of evidence

GRADE assessment suggested that there was moderate certainty for the outcomes evaluated, and, therefore, that the research presented is a good indication of the probable effect. We downgraded the certainty from high to moderate because of the considerable heterogeneity in the studies, and the indication of a level of publication bias. Although our methodology excluded very poor quality designs by virtue of only including randomised trials, there was still a wide range in the quality of the studies included. The inclusion of cluster-randomised trials in this review minimised selection bias and protected against contamination ([Gums 2016](#)), and so was a strength, as was the overall total number of participants included (16,315).

Where participants were individually randomised within pharmacies, this led to a high risk of contamination bias and was a weakness of such studies. Study quality was also threatened in a number of studies due to poor blinding regarding study group. This blinding is particularly difficult to achieve for behavioural interventions, where it is clear there is a change in practice, however, it can be managed by a choice of objective outcomes or by having outcome assessors who are blinded to study group.

Poor reporting of outcomes, or the use of non validated tools, occurred and led to a number of studies being excluded from the meta-analysis (see [Table 2](#), [Table 1](#), [Table 3](#)), which suggests that the results might need to be treated with some caution. Additionally, poor descriptions of some interventions was a significant limitation of many of the studies. The difficulty of reporting behavioural interventions in sufficient detail is a well recognised problem that reporting frameworks, including TiDieR ([Hoffmann 2014](#)), and Wider ([Albrecht 2013](#)), have aimed to address. These frameworks were not readily reported for any of the trials included in this review, but should be included in future trials ([Steed 2017](#)). This will become more feasible with the increase of online supplementary data and open access journals. A final limiting factor concerning the trials was the minimal assessment of fidelity of interventions, which was reported explicitly only by [Svarstad 2013](#), and [Nishita 2013](#). According to [Borrelli 2011](#), this should be assessed at five levels (i.e. study design, training, delivery, receipt, and enactment), but even the most common aspect of fidelity (delivery) that has been measured in other reviews was poorly measured or reported in these trials ([Walton 2017](#)).

Potential biases in the review process

We minimised biases in the review processes by having duplicate screening for full text and extraction, and ensuring reliability of title and abstract screening by using duplicate screening until an excellent level of accuracy was achieved. For several studies,

however, we had difficulty in deciding whether to include them or not, usually because the intervention content had not been reported clearly enough. To ensure consistency and minimise bias, two review authors reviewed all studies and, where there was disagreement, sought discussion with a third author. The study team also met to agree issues such as structure of analysis; and to classify which studies focused on pharmacy workers, pharmacy users or both; and whether the intervention could be considered to be behavioural, was purely medication focused, or involved interaction.

One area of deliberation concerned interventions that were primarily managing disease through altering or promoting medication adherence, but also included some lifestyle advice; this was particularly common in hypertension and dyslipidaemia trials. Typically the extent of lifestyle advice was not well categorised, and this may have caused bias through inclusion of studies that were primarily medication focused. However, we conducted meta-analysis using subgroups with different conditions, and our findings were generally consistent across these subgroups.

The study searches were conducted in February 2018, this may mean some studies have been published since the last search date which could impact on the reliability of the findings.

Agreements and disagreements with other studies or reviews

The findings of this review largely agree with other recent systematic reviews that have looked at the community pharmacy as a context for the delivery of non-pharmacological interventions. [Buss 2018](#) examined a range of clinical services in community pharmacy and concluded that these led to "improved asthma control, detection of diabetes and cardiovascular risk factors, reduction in smoking rates and weight, and identification of drug-related problems". [Brown 2016](#), which evaluated community pharmacy interventions focused on lifestyle behaviours that included smoking cessation, weight management or alcohol use, concluded that smoking cessation services delivered in this context were both effective and cost-effective. Weight management interventions also appeared feasible, but there were insufficient data to permit conclusions to be drawn regarding their effectiveness.

Several reviews have examined community pharmacy-led management of long-term conditions. Their role in control of blood pressure was reported in a review by [Cheema 2014](#), which concluded that community pharmacy-led interventions can significantly reduce both systolic and diastolic blood pressure. Similarly positive effects for diabetes care have been reported in two other reviews that focused on foot care for individuals with type 2 diabetes ([Deters 2018](#); [Soprovich 2019](#)). The [Garcia-Cardenas 2016](#) review reported potential benefit for asthma.

However, the Cochrane Review, [De Barra 2018](#), found less clear results, stating it was unclear whether pharmacist services reduced the percentage of patients with glycosylated haemoglobin levels outside the target range, although it suggested that such services may reduce the percentage of patients whose blood pressure lies outside the target range. The authors concluded there was probably little or no difference in hospital attendance or admissions, adverse drug effects, and mortality, although there was a possibility of improvement in physical functioning. It is

worth noting that the [De Barra 2018](#) review was not specific to community pharmacies as it included pharmacists working in hospital outpatient departments, and those attached to primary care practices. The interventions also included those targeted at improving health through use or stopping of medication and excluded health-promotion interventions. These are important differences that may account for the differences in results between this review and the others previously mentioned, including our review.

A further point of similarity encountered by our review and other reviews is the difficulties surrounding the level of description of interventions and how to code for theory and behaviour-change techniques. [Scott 2016](#) similarly called for a higher level of detail to be provided for descriptions of interventions. Finally, a review of reviews in the community pharmacy context concluded that there were insufficient data to assess the impact of public health interventions in this context on health inequalities ([Thomson 2019](#)).

AUTHORS' CONCLUSIONS

Implications for practice

Community pharmacy interventions probably slightly improve pharmacy users' intermediate clinical, behavioural, and quality of life outcomes, and are also cost-effective, so community pharmacies may be considered as another option for patients in terms of accessing public health services and health promotion. Additionally the potential 'reach' of the community pharmacy network - especially in deprived communities ([Todd 2014](#)) - means that they could offer a platform to people who might not be able to access other public health services. Community pharmacy staff are often more accessible than other healthcare professionals such as General Practitioners ([Todd 2014b](#)), and so may have the opportunity to reduce health inequalities.

Implications for research

This review supports further study of the development of community pharmacy health and health-promotion services. To date there is insufficient evidence to be clear about the reach of these interventions and whether they are moderated by socio-economic status; this is an area that would benefit from clarification through future research, as these interventions have the potential to be an effective means of reducing health inequalities. Additional high-quality studies across countries with different income levels, in different settings - such as rural and urban - or in different populations (for example people who do not speak English), would also be helpful.

Additionally many of the interventions investigated to date are complex in nature and require targeting the pharmacy team and pharmacy environment as a whole ([Steed 2017](#)), as well as pharmacy users. Interventions would benefit from being based upon appropriate theory and using recent approaches to intervention development ([O'Cathain 2019](#)). Interventions would also benefit from being described more clearly, as this would improve both examination and replicability ([Scott 2016](#)). Description of both pharmacy-worker and user-level interventions should follow the guidelines for description of complex behavioural interventions ([Albrecht 2013](#); [Hoffmann 2014](#)). There is also a requirement for greater assessment of fidelity at both the intervention delivery and receipt level.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES
Characteristics of included studies [ordered by study ID]
Adepu 2007

Methods	Design: RT Groups: intervention group (pharmacist counselling); control group (waiting list control)
Participants	Pharmacies: 2 Pharmacy workers: not reported ----- Pharmacy users: 70 people with type 2 diabetes <ul style="list-style-type: none"> • mean age: intervention 51.45 ± 12.27 years; control 53.77 ± 10.35 years • % female: intervention 25.7%; control 37.1% Setting: urban

Adepu 2007 (Continued)

Country: India

Interventions
Pharmacy worker-directed intervention: not reported

Pharmacy worker control: it was unclear whether one pharmacy site acted as a control and the other as the intervention, or whether pharmacists across both sites delivered both counselling to patients receiving the intervention and no treatment to controls

Pharmacy user-directed intervention: patients received counselling and an information leaflet about their disease, diet and lifestyle modifications.

- Delivered by: pharmacists
- Type: behaviour change and education
- Mode of delivery: face-to-face; written materials
- TDF: knowledge
- Duration: not reported
- Follow-up: collected at the final follow-up visit (end of intervention). The duration of intervention delivery was unclear, although the study period was stated as being 6 months.

Pharmacy user control: waiting list

Outcomes
Pharmacy worker: not assessed

Pharmacy user:

- Clinical: random capillary blood glucose levels
- Psychological health: not assessed
- Behavioural: not assessed
- Quality of life: Audit of Diabetes-Dependent Quality of Life (ADDQOL-18) questionnaire
- Process: disease awareness and management using Knowledge, Attitude and Practices (KAP) questionnaire
- Costs/health-care utilisation: not assessed

Notes

Study/intervention name: none given

Funding source: JS Mahavidyapeetha, Mysore

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Baseline outcome measures similar	Unclear risk	Not reported
Baseline characteristics similar	High risk	In the intervention group a higher % of men had a greater range of duration of illness

Adepu 2007 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition was reported, but it was unclear whether this was accounted for in the analysis. Quote: "Out of 70 patients, two expired, four were hospitalized and four did not respond."
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not reported
Protection against contamination	High risk	Patients randomised within pharmacy
Selective reporting (reporting bias)	Low risk	All 3 outcomes mentioned in the Methods were reported.
Other bias	Unclear risk	Not clear whether the 2 participating pharmacies were representative of this area.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported

Ali 2012

Methods	Design: RT Groups: intervention (diabetes education); control (usual care)
Participants	Pharmacies: 2 Pharmacy workers: pharmacists 3 ----- Pharmacy users: 48 people with type 2 diabetes <ul style="list-style-type: none"> • mean age: control 66.8 ± 10.2 years; intervention 66.4 ± 12.7 years • % female: control 43.5%; intervention 56.5% Setting: unsure Country: UK
Interventions	Pharmacy worker-directed intervention: 8-hour training programme involving workshop sessions with a consultant diabetologist and diabetes specialist nurse TDF: knowledge Pharmacy worker control: it appears the same pharmacists delivered both control and intervention treatments ----- Pharmacy user-directed intervention: patients received a programme of education about diabetes, its treatment and associated cardiovascular risk factors. <ul style="list-style-type: none"> • Delivered by: pharmacists • Type: self-management, behaviour change, education materials • Mode of delivery: individual face-to-face

Ali 2012 (Continued)

- TDF: knowledge
- Duration: 6 sessions over 12 months (every month for the first 2 months, and then every 3 months until month 12; a total of six appointments)
- Follow up: 12 months (i.e. end of intervention)

Pharmacy user control: usual care

Outcomes

Pharmacy worker: not assessed

Pharmacy user:

- Clinical: BMI, SBP/DBP, blood glucose, HbA1c, LDL, HDL, triglycerides, total cholesterol
- Psychological health: not assessed
- Behavioural: not assessed
- Quality of life: Diabetes Quality of Life Brief Clinical Inventory (DQOL), Health Status (Short Form-36)
- Process: Satisfaction with Information received about Medicines (SIMS); Patients' concerns and necessities about their medicines (Beliefs about Medication Questionnaire (BMQ); Diabetes Knowledge Test (DKT))
- Costs/resources: emergency hospital visits or admissions (diary)

Notes

Study/intervention name: none reported

Funding source: Department of Health, UK; Merck Sharp, Dohme Ltd

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation conducted by a computer-generated randomised list.
Allocation concealment (selection bias)	Low risk	List held by the researcher at the School of Pharmacy, eliminating the potential influence of pharmacists on the randomisation.
Baseline outcome measures similar	Low risk	No difference in primary outcomes, some secondary outcomes not used in current analysis were significantly different
Baseline characteristics similar	Low risk	No differences
Incomplete outcome data (attrition bias) All outcomes	Low risk	No incomplete data
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Protection against contamination	High risk	Control and intervention participants randomised within same pharmacy
Selective reporting (reporting bias)	Unclear risk	Some selective reporting; assessed questionnaires at 5 months but did not report, data on medication use not included, but no significant differences reported.
Other bias	Low risk	Not reported

Ali 2012 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
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Amariles 2012

Methods	Design: RT Groups: intervention (pharmaceutical care for CVD); control (usual care)
Participants	Pharmacies: not reported Pharmacy workers: 60 community pharmacists invited 40 (66.7%) of whom participated ----- Pharmacy users: 714 patients with a prescription for at least 1 drug indicated for CVD or CV risk factors <ul style="list-style-type: none"> • mean age: control 62.6 (SD 8.0) years, intervention 63.0 (SD 8.3) years • female: control 46.1%, intervention 49.4% Setting: urban Country: Spain
Interventions	Pharmacy worker-directed intervention: 8-hour training-lectures on CVD, CV risk factors, cardiovascular prevention and intervention TDF: knowledge, environment context and resources Pharmacy worker control: it appears the same pharmacists delivered both control and intervention treatments ----- Pharmacy user-directed intervention: the Dader method - patients received verbal and written information regarding CV prevention <ul style="list-style-type: none"> • Delivered by: pharmacists • Type: behaviour change, education materials • Mode of delivery: individual face-to-face • TDF: knowledge, environment context and resources • Duration: 5 sessions over 32 weeks • Follow up: 8 months (end of intervention) Pharmacy user control: usual treatment and written information on CV risk
Outcomes	Pharmacy workers: not assessed. ----- Pharmacy users: <ul style="list-style-type: none"> • Clinical: SBP/DBP, TC, BP/TC • Psychological health: not assessed • Behavioural: not targeted • Quality of life: not targeted • Process: not targeted

Amariles 2012 (Continued)

- Costs: not assessed

Notes

Study/intervention name: Effectiveness of Dader method for pharmaceutical care on control of blood pressure and total cholesterol in outpatients with cardiovascular disease or cardiovascular risk (EM-DADER-CV) study

Funding source: Roche Diagnostics and Stada Laboratory (Spain)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation
Allocation concealment (selection bias)	Low risk	Blinded
Baseline outcome measures similar	Low risk	No significant differences
Baseline characteristics similar	Low risk	No significant differences
Incomplete outcome data (attrition bias) All outcomes	Low risk	Accounted for
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported in paper EMDADER-CV (Efecto del Método Dáder de Seguimiento Farmacoterapéutico en el riesgo cardiovascular de pacientes con factores de riesgo o enfermedad cardiovascular [Effectiveness of Dader Method for Pharmaceutical Care on Control of Blood Pressure and Total Cholesterol in Outpatients with Cardiovascular Disease or Cardiovascular Risk])
Protection against contamination	High risk	Intervention and controls in same pharmacy
Selective reporting (reporting bias)	Low risk	Not noted
Other bias	Low risk	Not noted
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind participants

Armour 2007

Methods

Design: cluster-RT

Groups: intervention (asthma management); control (usual care)

Participants

Pharmacies: invitations to 174 pharmacies, 57 participated (29 intervention and 28 control)

Pharmacy workers: mean number of pharmacists on duty: intervention 2.0 (SD 0.8); control 1.9 (SD 0.7)

Armour 2007 (Continued)

- mean age: intervention 44% ≤ 35 years, 38% = 36-55 years, 19% ≥ 56 years; control 40% ≤ 35 years, 56% = 36-55 years, 4% ≥ 56 years
- % female: intervention 44%; control 56%

Pharmacy users: 396 patients with asthma

- mean age: intervention 47.5 ± 17.1 years; control 50.4 ± 16.1 years
- % female: intervention 67.5%; control 60.5%

Setting: rural and urban

Country: Australia

Interventions

Pharmacy worker-directed intervention: intervention pharmacists received an asthma education manual and were trained on risk assessment, pathophysiology, medications, the National Asthma Campaign (NAC) 6-step asthma management plan, patient education, goal setting, adherence assessment, spirometry and the Pharmacy Asthma Care Program (PACP) protocol. Renumeration per patient

- Delivered by: respiratory scientists and the research team
- Type: education, communication skills
- Mode of delivery: group
- TDF: knowledge
- Duration: 2-day workshop, with ongoing support visits and meetings

Pharmacy worker control: trained on risk assessment, spirometry and the control protocol during a 1-day workshop.

Pharmacy user-directed intervention: patients received education on asthma, assessment, and optimisation of drug therapy by the pharmacist, and referral to a respiratory therapist and/or physician as needed.

- Delivered by: pharmacists, with respiratory therapists and family physicians involved in care as required
- Type: self management, education, disease management
- Mode of delivery: individual face-to-face
- TDF: knowledge, skills, goals
- Duration: 6 sessions
- Length of follow-up: 6 months

Pharmacy user control: usual care

Outcomes

Pharmacy worker:

- Uptake of study - 33%

Pharmacy user:

- Clinical: asthma severity/control (NAC asthma severity assessment table); lung function (FEV1, FEV1/FVC), spirometry; medication profile (dispensed medication history); daily dose of medications (dispensed medication history)
- Psychological health: not assessed
- Behavioural: inhaler technique (inhaler technique checklist); adherence (brief medication questionnaire)
- Quality of life: asthma-related quality of life (asthma-related quality of life questionnaire);

Armour 2007 (Continued)

- Process: perceived control of asthma (perceived control of asthma questionnaire); action plan ownership (self-reported data); asthma knowledge (consumer asthma knowledge questionnaire)
- Costs: cost effectiveness over 5 years (see Gordois 2007 paper listed under [Armour 2007](#))

Notes

Study/intervention name: Pharmacy Asthma Care Program (PACP)

Funding source: Australia Department of Health and Aging. Gordois 2007 paper reported economic outcomes.

 Gordois 2007, Saini 2004 (cited under [Armour 2007](#)) also report on this study.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was accomplished through an internet randomisation service provided by the Epidemiology Coordinating and Research (EPICORE) Centre, and the Centre for Community Pharmacy Research and Interdisciplinary Strategies (COMPRIS) at the University of Alberta. Randomisation was stratified by centre.
Allocation concealment (selection bias)	Low risk	Centralised service, see above
Baseline outcome measures similar	Low risk	Difference in level of control, but accounted for in analysis
Baseline characteristics similar	Low risk	Although differences in smoking, lung disease, and brief medication questionnaire, these were controlled for in the analyses.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Sensitivity analysis conducted
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Protection against contamination	Low risk	Cluster-RT
Selective reporting (reporting bias)	Low risk	Not noted
Other bias	Low risk	Not noted
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Pharmacists not informed regarding allocation to groups

Barbanel 2003

Methods

Design: RT

Groups: intervention (asthma self-management); control (usual care)

Barbanel 2003 (Continued)

Participants	<p>Pharmacies: 1</p> <p>Pharmacy worker: 1 pharmacist</p> <p>-----</p> <p>Pharmacy users: 24 patients with asthma</p> <ul style="list-style-type: none"> • mean age: intervention 45 years (SD 17); control 47 years (SD 17) • % female: intervention 100%; control 71.4% <p>Setting: urban</p> <p>Country: UK</p>
Interventions	<p>Pharmacy worker-directed intervention: a single pharmacist acting as the study intervention attended a 3-day multidisciplinary course on asthma care and self-management.</p> <ul style="list-style-type: none"> • Delivered by: not mentioned, but possibly researchers • Type: education • Mode of delivery: face-to-face • TDF: knowledge, skills • Duration: 3 days <p>Pharmacy worker control: it appears the same pharmacist delivered both control and intervention treatments</p> <p>-----</p> <p>Pharmacy user-directed intervention: self-management advice on asthma</p> <ul style="list-style-type: none"> • Delivered by: pharmacist. • Type: self-management, education • Mode of delivery: individual face-to-face or telephone contact. Took place in pharmacy, or at GP surgeries (although delivered by pharmacist). • TDF: knowledge, skills, goals, environment context and resources, behavioural regulation • Duration: 13 sessions; duration: 1 x 45- to 60-minute session + 12 phone calls • Length of follow-up: 3 months from baseline <p>Pharmacy user control: usual care, no input from pharmacist</p>
Outcomes	<p>Pharmacy worker: not assessed</p> <p>-----</p> <p>Pharmacy user:</p> <ul style="list-style-type: none"> • Clinical: asthma symptom scores (North of England Asthma Symptoms Scale) • Psychological health: not assessed • Behavioural: not assessed • Quality of life: not assessed • Process: not assessed • Costs: not assessed
Notes	<p>Study/intervention name: none given</p> <p>Funding source: not reported</p>

Risk of bias

Barbanel 2003 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised using sealed envelopes
Allocation concealment (selection bias)	Low risk	As above
Baseline outcome measures similar	Low risk	No differences
Baseline characteristics similar	Low risk	No differences
Incomplete outcome data (attrition bias) All outcomes	Low risk	Nothing noted
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Protection against contamination	High risk	intervention and control patients from same pharmacy
Selective reporting (reporting bias)	Low risk	Not noted
Other bias	Unclear risk	Possible recruitment bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information provided

Basheti 2008

Methods	Design: cluster-RT Groups: intervention (asthma inhaler technique); control (usual care)
Participants	Pharmacies: not reported Pharmacy worker: 31 pharmacists (16 intervention; 15 control) of 120 invited ----- Pharmacy user: 97 patients with asthma <ul style="list-style-type: none"> • mean age: intervention group 40.4 ± 10.7 years; control 33.4 ± 9.3 years • % female: intervention group 56.2%; control 33.3% Setting: urban Country: Australia

Basheti 2008 (Continued)

Interventions

Pharmacy worker-directed intervention: pharmacists received general information about asthma, inhaled medications, and peak flow meter technique. They were also trained to assess and teach correct Turbuhaler and Diskus inhaler techniques, asthma management etc. They were reassessed at the end of the workshop and 2 years after.

- Delivered by: specialists
- Type: education
- Mode of delivery: group
- TDF: knowledge, memory, attention and decision making
- Duration: 1 evening workshop for all pharmacists, lasted 3 hours for intervention group, 2 hours for control
- Follow-up: 2 years

Pharmacy worker control: pharmacists received general information about asthma, inhaled medications, and peak flow meter technique.

Pharmacy user-directed intervention: patients' inhaler technique was assessed and then they were educated using a specialised "Show and Tell" inhaler technique counselling service, going through each step on a checklist to describe and demonstrate correct use; had an inhaler technique label placed on their inhaler, which highlighted incorrect steps

- Delivered by: pharmacists
- Type: behaviour change; self-management
- Mode of delivery: individual face-to-face
- TDF: knowledge, skills, environment, context and resources
- Duration: length of intervention: 3 months + extra visit at 6 months
- Length of follow-up: 6 months (end of intervention), and 2 years; follow-ups at baseline, 3 monthly visits + 1 visit 6 months after study began

Pharmacy user control: wait list - inhaler technique assessed and then inhaler technique counselling provided at end of study.

Outcomes

Pharmacy worker:

- Uptake: percentage
- Behavioural: inhaler technique

Pharmacy user:

- Clinical: peak flow variability (Min%Max); categorisation of asthma severity based on the Australian Asthma Management Handbook
- Psychological health: not assessed
- Behavioural: inhaler technique (Mean Inhaler Technique Score)
- Quality of life: Asthma-Related Quality of Life (AQOL)
- Process: Perceived Control of Asthma Questionnaire (PCAQ)
- Costs: not assessed

Notes

Study/intervention name: none given

Funding source: Faculty of Pharmacy, Univeristy of Sydney; placebo inhalers by AstraZeneca and GlaxoSmithKline

Basheti 2007 and Basheti 2009 (both cited under [Basheti 2008](#)) also report on this study

Risk of bias

Basheti 2008 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Pharmacists were allocated randomly by computer-generated list to Active or Control groups."
Allocation concealment (selection bias)	Low risk	By computer
Baseline outcome measures similar	Low risk	Analysis accounted for baseline
Baseline characteristics similar	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Minimal dropouts
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "We blinded pharmacists and patients by teaching both groups how to educate patients in correct peak flow meter technique."
Protection against contamination	Unclear risk	Unclear, as intervention and control pharmacists could work in same pharmacy
Selective reporting (reporting bias)	Low risk	Not noted
Other bias	Unclear risk	Not noted - possible recruitment bias of patients - every second asthma patient
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "pharmacists ... blinded to true nature of intervention"

Bereznicki 2013

Methods	Design: cluster-RT Groups: intervention (asthma education delivered either face to face or by mail); control (usual care)
Participants	Pharmacies: 71 Pharmacy worker: at least 1 per pharmacy ----- Pharmacy users: 1483 patients with asthma <ul style="list-style-type: none"> • mean age: no information given • % female: no information given Setting: unclear Country: Australia (South Australia, Tasmania and Victoria)

Bereznicki 2013 (Continued)

Interventions

Pharmacy worker-directed intervention: education sessions for all participating pharmacists - overview of asthma management in Australia; outline of project's objectives and methods; demonstration of the data-mining software. For pharmacists unable to attend an education session, a personalised one-to-one visit was arranged. Renumeration for training and AUD 200 per pharmacy

- Delivered by: respiratory physician
- Type: education meetings
- Mode of delivery: group; individual face-to-face
- TDF: knowledge, memory, attention decision making, environment context and resources

Pharmacy worker control: received the same education as above. Randomization at pharmacy user level

Pharmacy user-directed intervention: patients received educational material and a referral to their GP for an asthma management review either by mail or a face-to-face intervention

- Delivered by: pharmacists
- Type: behaviour change
- Mode of delivery: individual face-to-face or mailed information
- TDF: knowledge, environment context and resources
- Duration: the intervention period ran for 6 weeks
- Follow-up: post intervention

Pharmacy user control: usual treatment, no intervention pack

Outcomes

Pharmacy worker:

- Uptake: not reported
- Process: satisfaction and perception survey

Pharmacy user:

- Clinical: preventer-to-reliever (P:R) ratio; daily short-acting beta agonist usage; daily inhaled corticosteroid usage.
- Psychological health: not assessed
- Behavioural: not assessed
- Quality of life: not assessed
- Process: not assessed
- Costs: not assessed

Notes

Study/intervention name: none given

Funding source: Australian Government Department of Health and Aging

Bereznicki 2008, 2011 (cited under [Bereznicki 2013](#)) also reported on this study

Risk of bias
Bias
Authors' judgement
Support for judgement

Random sequence generation (selection bias)

Unclear risk

Pharmacies randomly assigned to deliver first type of pharmacist-initiated intervention – mailed or face-to-face, then alternate allocation for remaining pharmacies. First patients within pharmacies randomly allocated to receive intervention or control then alternately allocation.

Bereznicki 2013 (Continued)

Allocation concealment (selection bias)	Low risk	Software allocated
Baseline outcome measures similar	Low risk	No significant differences
Baseline characteristics similar	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Numbers mentioned in paper
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The patient receiving the greatest number of relievers was randomly assigned to the intervention or control group, with subsequent patients being alternately assigned to the control or intervention group."
Protection against contamination	Low risk	Each pharmacy only performed one type of intervention
Selective reporting (reporting bias)	Low risk	Nothing noted
Other bias	Low risk	Nothing noted
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "Pharmacists were blinded to the control patients' identities until the end of the 12-month post-intervention period, with the intention that control patients would receive no intervention other than the pharmacists' usual care until after the post-intervention period."

Bond 2007

Methods	Design: RT Groups: intervention (medicines management for cardiovascular disease); control (usual care)
Participants	Pharmacies: 9 Pharmacy workers: 62 pharmacists ----- Pharmacy user: 1493 patients with CHD <ul style="list-style-type: none"> • mean age: intervention 68.7 ± 9.2 years; control 68.8 ± 9.1 years • % female: intervention 32.6%; control 29.4% Setting: mixed Country: UK
Interventions	Pharmacy worker-directed intervention: pharmacists received training on medicines management, identification of essential information from GP patient records, facilitation of independent studying, communication skills, and action learning. <ul style="list-style-type: none"> • Delivered by: Centre for Pharmacy Post-Graduate Education • Type: medication management, disease management, self management • Mode of delivery: face-to-face, written material, clinical case studies

Community pharmacy interventions for health promotion: effects on professional practice and health outcomes (Review)

Bond 2007 (Continued)

- TDF: knowledge, skills
- Duration: 2-hour launch event, 2.5-hour CHD event, a full day communication event

Pharmacy worker control: it appears the same pharmacists delivered both control and intervention treatments

Pharmacy user-directed intervention: consultations on medicines management delivered, included assessments of the following: therapy, medication compliance, lifestyle and social support

- Delivered by: pharmacists
- Type: self-management; behaviour change; medication management; disease management; education
- Mode of delivery: individual face-to-face
- TDF: knowledge, social support
- Duration: initial meeting then as needed over 12 months
- Follow-up: 12 months (end of intervention period)

Pharmacy user control: usual treatment from GP and community pharmacist

Outcomes

Pharmacy worker: no valid measures

Pharmacy user:

- Clinical: proportion of patients receiving secondary prevention treatment for CHD in accordance with the National Service Framework (2000) (composite of 8 behaviours: aspirin-related management; lipid management; BP management; smoking management; physical activity; diet; alcohol consumption; weight); a cumulative score summarising 'appropriate treatment' and advice; 5-year risk of cardiovascular death
- Psychological health: not assessed
- Behavioural: not assessed
- Quality of life: SF-36, EuroQol
- Process: satisfaction (non validated measure)
- Cost: incremental cost per patient; annual costs of intervention (training and delivery); usual costs of NHS treatment (costs of pharmaceuticals, GP and hospital visits) and costs borne by patients

Notes

Study/intervention name: community pharmacy-led medicines management (MEDMAN)

Funding source: Department of Health England and Wales

Jaffray 2007 and Scott 2007 (cited under [Bond 2007](#)) also reported on this study

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomized in a ratio of 2:1, intervention to control group. This was done independently of the research team using a password protected computer programme in permuted blocks stratified by practice."
Allocation concealment (selection bias)	Low risk	Quote: "Audit clerks performing data extraction were blind to the randomization status of participants, as were the researchers conducting the statistical analyses."
Baseline outcome measures similar	Low risk	Quote: "No substantial differences in the baseline characteristics of the study groups"

Bond 2007 (Continued)

Baseline characteristics similar	Low risk	Quote: "No substantial differences in the baseline characteristics of the study groups"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Missing data was tested, and adjusted for"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Data extraction and analysis were blind,"
Protection against contamination	Unclear risk	Unclear if possible contamination
Selective reporting (reporting bias)	Low risk	Nothing noted
Other bias	Low risk	Nothing noted
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: "Patients could not be blind to trial intervention because of its nature. Community pharmacists were not informed which control patients had nominated their pharmacy."

Burford 2013

Methods	Design: RT Groups: intervention (photo-aging smoking cessation); control group (usual care)
Participants	Pharmacies: 8 Pharmacy worker: not reported ----- Pharmacy users: 160 smokers <ul style="list-style-type: none"> • mean age: intervention 24.2 ± 4.1 years; control 25.1 ± 4.1 years • % female: intervention 68.7%; control 56.2% Setting: urban Country: Perth, Australia
Interventions	Pharmacy worker-directed intervention: not reported ----- Pharmacy user-directed intervention: standard 2-minute smoking cessation advice from the pharmacist plus participants were digitally photo-aged so they could preview images of themselves as a lifelong smoker and as a nonsmoker, and were invited to view the age-processed images, received smoking cessation advice, and were screened for body dysmorphia. <ul style="list-style-type: none"> • Delivered by: unclear whether pharmacist or researcher delivered the intervention • Type: behaviour change/smoking cessation • Mode of delivery: individual face-to-face • TDF: knowledge, beliefs about consequences

Burford 2013 (Continued)

- Duration: unclear – probably a single session with email of image sent to client. Not clear if there was further support from pharmacist.
- Follow-up: 6 months

Pharmacy user control: standard 2-minute smoking cessation advice from the pharmacist.

Outcomes	<p>Pharmacy worker: not assessed</p> <p>-----</p> <p>Pharmacy user:</p> <ul style="list-style-type: none"> • Clinical: carbon monoxide (CO) breath test • Psychological health: not assessed • Behavioural: Fagerström Smoking Dependence scale • Quality of life: not assessed • Process: study designed questions concerning: attitudes toward personal appearance, opinions about health risks associated with smoking, and perceived barriers to quitting smoking; willingness to pay (WTP) for the digital aging service. • Cost: estimated cost per participant; cost-effectiveness
Notes	<p>Study/intervention name: none given</p> <p>Funding source: not reported</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Randomisation by researcher on alternate weeks
Allocation concealment (selection bias)	High risk	Quote: "Allocation to groups was not performed as eligible participants were recruited, but according to the treatment being used at the pharmacy during that week."
Baseline outcome measures similar	Low risk	Quote: "there were no significant differences between the control and intervention group on demographic or smoking dependence at baseline"
Baseline characteristics similar	Unclear risk	There were differences between groups for concern about physical appearance, and the belief that facial wrinkles are associated with smoking.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Few participants lost
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "Because of the nature of the intervention, the participants and researcher could not be blinded to the study group."
Protection against contamination	Unclear risk	Allocation to group dependent on week to avoid contamination, but unclear if successful
Selective reporting (reporting bias)	Low risk	All outcomes appear to have been reported.
Other bias	Unclear risk	Low numbers of control groups self report quit status was verified with objective carbon monoxide measurement

Burford 2013 (Continued)

Blinding of participants and personnel (performance bias)
 All outcomes

High risk

Quote: "Because of the nature of the intervention, the participants and researcher could not be blinded to the study group."

Bynum 2001

Methods

Design: RT

Groups: intervention (telepharmacy counselling); control group (usual care)

Participants

Pharmacies: not reported

Pharmacy worker: 2 pharmacists

Pharmacy user: 49 asthma patients

- mean age (43.4% aged 12-14 years; 50% aged 15-17 years; 6.5% aged 18-19 years)
- % female: 69.4%

Setting: rural

Country: USA

Interventions

Pharmacy worker-directed intervention: not reported

Pharmacy user-directed intervention: pharmacists used interactive compressed video (telepharmacy) to teach metered dose inhaler (MDI) technique to a rural, adolescent asthma population in junior high and high schools.

- Delivered by: pharmacists and other healthcare professionals
- Type: condition management (correct MDI technique).
- Mode of delivery: video/DVD, telemedicine
- TDF: knowledge, skills
- Duration: 3 sessions, 15 minutes, over 3 to 4 weeks
- Follow-up: 2 to 4 weeks

Pharmacy user control: had telepharmacy contact, but not counselling until after study

Outcomes

Pharmacy worker: not assessed

Pharmacy user:

- Clinical: not assessed
- Psychological health: not assessed
- Behavioural: MDI technique checklist; Telepharmacy Metered-Dose Inhaler Technique evaluation
- Quality of life: not assessed
- Process: not assessed
- Costs: not assessed

Notes

Funding source: grant from the Office for the Advancement of Telehealth in the Department of Health Resources and Services Administration

Bynum 2001 (Continued)

Study/intervention name: none given

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number chart
Allocation concealment (selection bias)	Unclear risk	Not specified
Baseline outcome measures similar	Low risk	Reported in text as non significant
Baseline characteristics similar	Low risk	Reported in text as non significant
Incomplete outcome data (attrition bias) All outcomes	High risk	Some loss to follow-up and no reporting of correction for missing data
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not specified
Protection against contamination	Unclear risk	Not clear if control had access to intervention pharmacists
Selective reporting (reporting bias)	Low risk	Seemed to report all planned outcomes.
Other bias	Low risk	Not noted
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear whether pharmacist assessors were aware of grouping

Charrois 2006

Methods	Design: RT Groups: intervention (asthma management); control group (usual care)
Participants	Pharmacies: 5 Pharmacy workers: not reported ----- Pharmacy user: 70 patients with asthma <ul style="list-style-type: none"> • mean age: intervention 35.7 ± 10.2 years; control 38.7 ± 10.7 years • % female: intervention 52.8%; control 52.9% Setting: rural

Charrois 2006 (Continued)

Country: Canada

Interventions

Pharmacy worker-directed intervention: pharmacist trained in an interactive, activity and case-based program which focused on patient assessment, patient interviewing and communication skills

- Delivered by: unclear
- Type: self-management; patient assessment, patient interviewing and communication skills
- Mode of delivery: group
- TDF: knowledge, skills
- Duration: appears to have been a single afternoon with ongoing support visits and meetings as needed.

Pharmacy worker control: the same pharmacists delivered care to both intervention and control groups

Pharmacy user-directed intervention: patients received education on asthma, assessment, and optimisation of drug therapy, with focus on a written asthma plan

- Delivered by: pharmacist and referral to respiratory therapist and/or physician as needed
- Type: self-management; education; medication management; based on clinical practice guidelines
- Mode of delivery: individual face-to-face
- TDF: knowledge, behavioural regulation
- Duration: an initial visit for information/education, referral to physician and pharmacist follow-up: 2 weeks and at 1, 2, 4, and 6 months. Respiratory therapist follow-up: 2 and 6 months
- Follow-up: 6 months (end of intervention)

Pharmacy user control: wait list with asthma education and advice as needed, as well as referral to respiratory therapist

Outcomes

Pharmacy worker: not assessed

Pharmacy user:

- Clinical: inhaled corticosteroid use; number of courses of oral steroid and FEV1
- Psychological health: not assessed
- Behavioural: change in the Asthma Control Questionnaire (ACQ)
- Quality of life: not assessed
- Process: number of emergency room visits and hospitalisations
- Costs/HCU: emergency room visits, hospitalisations

Notes

Study/intervention name: Better Respiratory Education and Asthma Treatment in Hinton and Edson study (BREATHE)

Funding source: Canadian Institutes of Health Research

Charrois 2004 (cited under [Charrois 2006](#)) also referred to this study

Risk of bias
Bias
Authors' judgement
Support for judgement

Random sequence generation (selection bias)

Low risk

Quote: "Randomization was accomplished through an Internet randomization service provided by the Epidemiology Coordinating and Research (EPICORE) Centre and the Centre for Community Pharmacy Research and Interdiscipli-

Charrois 2006 (Continued)

		nary Strategies (COMPRIS) at the University of Alberta. Randomization was stratified by centre."
Allocation concealment (selection bias)	Low risk	Centralised service, see above
Baseline outcome measures similar	Low risk	No differences for main outcomes
Baseline characteristics similar	Low risk	Differences for range characteristics - text reported that this was controlled for in analyses.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Last value of ACQ carried forward where missing
Blinding of outcome assessment (detection bias) All outcomes	High risk	It is possible that assessors were not blinded
Protection against contamination	Low risk	Cluster randomised
Selective reporting (reporting bias)	Unclear risk	Not noted
Other bias	High risk	Quote: "The sites did not apply the intervention uniformly. According to case report forms received, follow-up was poor, few asthma management recommendations were made, and one-quarter of patients in the intervention group never received a written action plan, [which was] the focus of the intervention. The follow-up completed at each site varied, with some sites having less than 30% follow-up at the time of the 6-month visit. The low rate of follow-up leads us to believe that the application of the intervention was also minimal at these sites."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Caregivers/pharmacists involved in the study were not blinded.

Cordina 2001

Methods	Design: cluster-RT Groups: intervention (asthma education and monitoring); control (routine dispensing services)
Participants	Pharmacies: 22 (intervention 11; control 11) Pharmacy worker: not reported ----- Pharmacy user: 152 asthma patients <ul style="list-style-type: none"> • mean age: intervention 41.3 ± 18.35 years; control 45.88 ± 18.11 years • % female: intervention 57%; control 39% Setting: both urban and rural

Cordina 2001 (Continued)

Country: Malta

Interventions
Pharmacy worker-directed intervention:

A manual was prepared in the form of a self-study program with 2 sections: Section 1 dealt with the pathophysiology of asthma and its treatment, including standard intervention instructions; Section 2 provided details of outcome measures and data collection instruments to be used in the study.

- Delivered by: researcher
- Type: education
- Mode of delivery: group
- TDF: knowledge
- Duration: 2 evenings; first evening open only to the intervention group and focused on the intervention, the second evening was open to both groups and focused on study procedures. No other information was provided.

Pharmacy worker control: only attended second evening and received section 2 of manual

Pharmacy user-directed intervention: patients received verbal counselling, an educational video, an information leaflet, and subsequent monitoring with reinforcement.

- Delivered by: pharmacists
- Type: self-management
- Mode of delivery: individual face-to-face; video/DVD; written materials
- TDF: knowledge, skills, behavioural regulation
- Duration: unclear
- Follow up: 12 months (end of intervention)

Pharmacy user control: patients were given their prescribed drugs and informed of the dosage regimen, but received no other assistance.

Outcomes

Pharmacy worker: not assessed

Pharmacy user:

- Clinical: PEFR
- Psychological health: not assessed
- Behavioural: inhaler technique
- Quality of life: patient's health-related quality of life Short Form 36 (SF-36); Living With Asthma Questionnaire (LWAQ) for adults; Childhood Asthma Questionnaire (CAQ) for children aged 14 to 17 years
- Process: patients' subjective opinions of the services provided obtained through a structured patient satisfaction questionnaire
- Costs/HCU: hospitalisations, GP visits, days off work

Notes

Funding source: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not stated.
Allocation concealment (selection bias)	Low risk	Cluster randomised

Cordina 2001 (Continued)

Baseline outcome measures similar	Low risk	Some differences, but adjusted for in analysis.
Baseline characteristics similar	Low risk	Some differences, but adjusted for in analysis.
Incomplete outcome data (attrition bias) All outcomes	High risk	High dropout and unclear how this was adjusted for.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Protection against contamination	Unclear risk	Randomisation by pharmacists, but patients came from same asthma clinic.
Selective reporting (reporting bias)	Low risk	Not noted
Other bias	Unclear risk	Differences in groups at baseline and attrition may have had significant effect.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated

Crockett 2006

Methods	Design: cluster-RT Groups: intervention (depression management); control (usual care)
Participants	Pharmacies: 32 Pharmacy worker: not reported ----- Pharmacy user: 106 patients with depression <ul style="list-style-type: none"> • mean age: intervention 46 (SD: 12 years); control 46 (SD: 15 years) • % female: intervention 76%; control 82% Setting: rural Country: Australia
Interventions	Pharmacy worker-directed intervention: intervention pharmacists were given video-conference training on the nature and management of depression and were asked to dispense medication with extra advice and support. <ul style="list-style-type: none"> • Delivered by: a psychiatrist, psychologist and GP • Type: education; disease management • Mode of delivery: video/DVD (video-conference training) • TDF: knowledge, skills, environment, context and resources • Duration: not reported

Crockett 2006 (Continued)

Pharmacy worker control: usual care

Pharmacy user-directed intervention: education on depression management; patient's psychological well-being monitoring, attitudes towards taking antidepressants, adherence and patient satisfaction with service.

- Delivered by: pharmacists.
- Type: education; disease management.
- Mode of delivery: individual face-to-face; video/DVD; written materials
- TDF: knowledge, emotion
- Duration: variable; an initial visit and then, to quote, "checking 'how they were going' at subsequent visits to the pharmacy".

Follow-up: 3 months

Pharmacy user control: usual care

Outcomes

Pharmacy worker: not assessed

Pharmacy user:

- Clinical: not assessed.
- Psychological health: patients' well-being (K10)
- Behavioural: adherence
- Quality of life: not assessed
- Process: patient satisfaction with service; attitude towards taking antidepressants (using the Drug Attitude Index (DAI)).
- Costs: not assessed.

Notes

Study/intervention name: none given

Funding source: grant from the Rural and Remote Pharmacy Infrastructure Grants scheme

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, but no specific method mentioned.
Allocation concealment (selection bias)	Unclear risk	Not mentioned
Baseline outcome measures similar	Unclear risk	Baseline differences unclear
Baseline characteristics similar	Low risk	No differences in the characteristics reported, but reported adjustment in analyses for baseline differences
Incomplete outcome data (attrition bias) All outcomes	Low risk	Nothing noted
Blinding of outcome assessment (detection bias)	Unclear risk	Not mentioned

Crockett 2006 (Continued)

All outcomes

Protection against contamination	High risk	Randomisation at pharmacist level but four of control pharmacies were delivering similar intervention
Selective reporting (re-reporting bias)	Low risk	Nothing noted.
Other bias	Unclear risk	Assessments may have impacted outcome
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not mentioned

Dhital 2015

Methods	Design: RT Groups: intervention (brief motivational interviewing alcohol intervention); control (leaflet only)
Participants	Pharmacies: 16 Pharmacy worker: not reported ----- Pharmacy user: 407 (205 intervention; 202 control) <ul style="list-style-type: none"> • mean age: intervention 39.6 ± 15.9 years; control 40.5 ± 17.48 years • % female: intervention 47.8%; control 43.6% Setting: urban Country: London, UK
Interventions	<p>Pharmacy worker-directed intervention: Training in motivational and problem solving approach</p> <ul style="list-style-type: none"> • Delivered by: unclear • Type: training workshop • Mode of delivery: possibly face-to-face, but unclear • TDF: knowledge • Duration: 3.5 hour training in motivational interviewing approach + 2 hour additional problem solving session 7 weeks after start of the trial <p>Pharmacy worker control: it appears the same pharmacists saw both intervention and control groups.</p> <p>-----</p> <p>Pharmacy user-directed intervention: structured 10-minute discussion about drinking based on motivational interviewing, also gave participants 'Units and You' booklet and unit/calorie calculator wheel and alcohol services leaflet</p> <ul style="list-style-type: none"> • Delivered by: pharmacist • Type: behaviour change • Mode of delivery: individual, face-to-face; written materials • TDF: knowledge, beliefs about consequences, environment, context, resources

Dhital 2015 (Continued)

- Duration: 10 minutes
- Follow-up: 3 months

Pharmacy user control: given a leaflet called "Alcohol: The Basics"

Outcomes	<p>Pharmacy worker: not assessed</p> <p>-----</p> <p>Pharmacy user:</p> <ul style="list-style-type: none"> • Clinical: not assessed • Psychological health: not assessed • Behavioural: Alcohol Use Disorders Identification Test (AUDIT) • Quality of life: EQ-5D • Process: not assessed • Costs: not assessed
Notes	<p>Study/intervention name: none given</p> <p>Funding source: Pharmacy Practice Research Trust, Royal Pharmaceutical Society of Great Britain, and the Harold and Marjorie Moss Charitable Trust</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Sealed numbered envelopes, monitored for tampering
Allocation concealment (selection bias)	Low risk	Pharmacists not involved in research data collection and allocation after consent
Baseline outcome measures similar	Low risk	Did not differ between the two groups
Baseline characteristics similar	Low risk	No significant differences
Incomplete outcome data (attrition bias) All outcomes	Low risk	Sensitivity analysis and adjustment for attrition
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Researcher blinded to allocation status
Protection against contamination	High risk	Both control and intervention participants within one pharmacy
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias obvious
Blinding of participants and personnel (performance bias)	High risk	Relevant personnel were blinded to randomisation status throughout the trial, but participants not blinded.

Dhital 2015 (Continued)
 All outcomes

Dolovich 2007

Methods	Design: RT Groups: intervention (Asthma Education Program (AEP)); control (usual care-delayed AEP)
Participants	Pharmacies: not reported Pharmacy workers: 64 of 160 approached (40%) <ul style="list-style-type: none"> • mean age: intervention 42.80 ± 13.62 years; control 42.13 ± 9.82 years • % female: intervention 58.1%; control 64.3% ----- Pharmacy user: not targeted Setting: urban Country: Canada
Interventions	Pharmacy worker-directed intervention: volunteer community pharmacists received an asthma education program (AEP) <ul style="list-style-type: none"> • Delivered by: not specified • Type: education: skill building • Mode of delivery: group; individual face-to-face; written materials • TDF: knowledge, skills, environment, context, resources • Duration: one-day workshop; 2 follow-up telephone calls • Follow-up: 3-5 weeks post workshop Pharmacy worker control: delayed AEP ----- Pharmacy user-directed intervention: not targeted
Outcomes	Pharmacy worker: <ul style="list-style-type: none"> • Uptake • Behavioural: providing appropriate action plan, communication skills assessed by simulated patients (mystery shoppers) ----- Pharmacy user: <ul style="list-style-type: none"> • Clinical: not assessed • Psychological health: not assessed • Behavioural: not assessed • Quality of life: not assessed • Process: not assessed • Costs: not assessed
Notes	Study/intervention name: none given

Dolovich 2007 (Continued)

Funding source: Merck Frosst Canada Inc, and in-kind contribution from Agro Health Associates Inc, and the Centre for Evaluation of Medicines

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random numbers table
Allocation concealment (selection bias)	Low risk	Concealed
Baseline outcome measures similar	Unclear risk	Only assessed post workshop
Baseline characteristics similar	Low risk	No reported differences
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low dropout, no patterns identified
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors were blinded to assignment of the pharmacists to intervention or control groups.
Protection against contamination	Unclear risk	Unclear if there was interaction between sites
Selective reporting (reporting bias)	Low risk	Not noted
Other bias	Unclear risk	Possible selection bias - pharmacists volunteers
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded to group allocation

Doucette 2009

Methods	Design: RT Groups: intervention (extended diabetes care); control (usual care)
Participants	Pharmacies: 7 Pharmacy workers: 9 pharmacists ----- Pharmacy user: 78 people with type 2 diabetes <ul style="list-style-type: none"> • Mean age: intervention 58.7 ± 13.3 years; control 61.2 ± 10.9 years • % female: intervention 21%; control 22% Setting: unclear

Doucette 2009 (Continued)

Country: USA

Interventions

Pharmacy worker-directed intervention: participating pharmacists received training in diabetes management and study protocol. Both self-study and live programs included discussion of mock cases. Skills training in monitoring blood pressure, using a blood glucose meter, filling an insulin syringe, and administering an insulin injection

- Delivered by: unclear
- Type: education materials, self-management
- Mode of delivery: self-study and live training
- TDF: knowledge, skills
- Duration: self-study component was 15 hours, but length of live program was not stated.
- Follow-up: not stated

Pharmacy worker control: not applicable as control patients seen by other primary care providers

Pharmacy user-directed intervention: patients had already received 2 diabetes education sessions, then received extended diabetes care, discussed medications, clinical goals, and self-care activities; pharmacists recommended medication changes to physicians when appropriate.

- Delivered by: pharmacists
- Type: self-management; disease management
- Mode of delivery: individual face-to-face
- TDF: knowledge, goals
- Duration: intervention 12 months; number of interventions: up to 4 (quarterly)
- Follow-up: 12 months (end of intervention)

Pharmacy user control: usual diabetes care from their primary care provider

Outcomes

Pharmacy worker: not assessed

Pharmacy user:

- Clinical: HA1c; LDL-C; SBP; DBP; BMI
- Psychological health: not assessed
- Behavioural: The Summary of diabetes self care activities measure (SDSCA)
- Quality of life: not assessed
- Process: not assessed
- Costs: not assessed

Notes

Study/intervention name: none given

Funding source: a grant from the Community Pharmacy Federation

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Unclear, no information provided on method of randomisation
Allocation concealment (selection bias)	Unclear risk	Unclear, not stated

Doucette 2009 (Continued)

Baseline outcome measures similar	Low risk	No differences
Baseline characteristics similar	Low risk	Minimal differences
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No intention-to-treat analysis. Some patients did not present for final data collection, and 2 intervention patients did not meet pharmacist.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Protection against contamination	Unclear risk	Recruitment at patient level, from same centre, unclear if patients attended different pharmacies
Selective reporting (reporting bias)	Low risk	Paper seemed to report all relevant outcomes.
Other bias	Unclear risk	Nothing noted
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded

Fuller 2016

Methods	Design: cluster-RT Groups: intervention (Modified Brief Behavioural Intervention Insomnia (MBBTi)); control (usual care + information leaflet)
Participants	Pharmacies: 12 (7 intervention; 5 control) Pharmacy workers: not reported ----- Pharmacy user: 56 insomniacs (22 intervention; 34 control) <ul style="list-style-type: none"> • mean age: intervention 53.5 ± 21.1 years; control 53.9 ± 6.1 years • % female: intervention 64.7% ; control 78.9% Setting: unclear Country: New South Wales, Australia
Interventions	Pharmacy worker-directed intervention: training on sleep and sleep management through interactive lectures, case study discussions, role play plus manual with details of sleep and MBBTi <ul style="list-style-type: none"> • Delivered by: sleep clinicians • Type: education • Mode of delivery: manual and face-to-face • TDF: knowledge, skills • Duration: workshop 7 hours

Fuller 2016 (Continued)

- Follow-up: 3 months (end of intervention)

Pharmacy worker control: control group manual provided detailed background information on sleep and sleep health, insomnia and its impact, models of insomnia and general insomnia treatment (pharmacological and sleep hygiene methods).

Pharmacy user-directed intervention: standardised education + sleep restriction and/or stimulus control, goal setting, sleep diaries

- Delivered by: pharmacists
- Type: behavioural
- Mode of delivery: face-to-face, workbook
- TDF: knowledge, goals, behavioural regulation
- Duration: 3 visits
- Follow-up: 3 months (end of intervention)

Pharmacy user control: usual care and information sheets on insomnia if needed

Outcomes
Pharmacy worker:

- Behavioural: interventions delivered by pharmacists

Pharmacy user:

- Clinical: Insomnia Severity Score (ISI)
- Psychological health: Depression, Anxiety, Stress Scale (DASS-21)
- Behavioural: not assessed
- Quality of life: not assessed
- Process: participants completed the Dysfunctional Beliefs About Sleep (DBAS-16) questionnaire
- Costs: not assessed

Notes

Funding source: Scholarship Faculty Pharmacy, University of Sydney and CIRUS (Centre for Integrated Research into the Understanding of Sleep)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Used RAND function in Excel for simple randomisation
Allocation concealment (selection bias)	High risk	Incomplete allocation concealment
Baseline outcome measures similar	Low risk	MBBTi and control patients were similar at baseline
Baseline characteristics similar	Low risk	No significant differences between groups in any of the demographics
Incomplete outcome data (attrition bias) All outcomes	Low risk	Alternative analysis performed to allow for all available data to be used

Fuller 2016 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	High risk	Pharmacists undertook data collection, but did not score key outcomes at follow-up.
Protection against contamination	Low risk	Cluster randomised
Selective reporting (reporting bias)	Low risk	Not apparent
Other bias	High risk	Cluster effects not taken into account for all key outcomes other than the ISI.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Pharmacists were aware of participants' groups.

Garcia 1998

Methods	Design: cluster-RT Groups: intervention group (education on sexually transmitted disease (STD) recognition, management, and prevention counselling); control group (usual care)
Participants	Pharmacies: 168 Pharmacy workers: average 1.7 (range 1 to 7) workers per pharmacy <ul style="list-style-type: none"> • mean age: 37.9 years • % female: 60% ----- Pharmacy user: not reported Setting: urban Country: Peru
Interventions	Pharmacy worker-directed intervention: pharmacists and pharmacist technicians received education on STD recognition, management, and prevention counselling, and were visited by standardised simulated patients. <ul style="list-style-type: none"> • Delivered by: intervention team members • Type: education materials, based on clinical practice guidelines; role playing • Mode of delivery: group; individual face-to-face; written materials • TDF: knowledge, skills, environment, context, resources, social support • Duration: 8-hour training course (23%), or a 1.5 to 2-hour on site training using a 32-page revised manual offered at each intervention pharmacy. ----- Pharmacy user-directed intervention: not reported
Outcomes	Pharmacy worker: <ul style="list-style-type: none"> • Behavioural: simulated patients STD management • Costs: cost of treatment

Garcia 1998 (Continued)

Pharmacy user: not assessed

Notes	Study/intervention name: none given Funding source: Fogarty International Center grant NIAID Center for AIDS Research Grant NIH grant, USAID
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Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, but method not mentioned
Allocation concealment (selection bias)	Low risk	By pharmacy
Baseline outcome measures similar	Unclear risk	Overall scores reported, but not comparison between control and intervention
Baseline characteristics similar	Unclear risk	Overall scores reported, but not comparison between control and intervention
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Reported loss to follow-up, but unclear how this was adjusted for
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Simulated patients were blinded
Protection against contamination	Low risk	Pharmacies cluster randomised
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Unclear risk	Not noted
Blinding of participants and personnel (performance bias) All outcomes	High risk	Only intervention group were offered training

Garcia 2003

Methods	Design: cluster-RT Groups: intervention group (management and prevention of STDs); control group (1-day seminar on management of diarrhoea)
Participants	Pharmacies: the 24 districts in Lima that had the lowest socio-economic status were selected and matched in 12 pairs; 7 pairs of districts were chosen randomly to participate in 2 phases reported separately by study:

Garcia 2003 (Continued)

- First phase: a pilot phase:
 - * Intervention: 1 district with 221 pharmacies of which 200 pharmacies received training and 120 pharmacies were randomly selected for evaluation;
 - * Control: 1 district with 159 pharmacies, all invited to seminar and 120 pharmacies were randomly selected for evaluation.
- Second phase: full study phase:
 - * Intervention: 6 districts with 897 pharmacies of which 684 received training and 100 pharmacies were randomly selected for evaluation;
 - * Control: 6 districts with 883 pharmacies, all invited to seminar after which pharmacies were randomly selected for evaluation.

Pharmacy workers: 2223 workers in intervention group participated in at least one seminar, 1872 (84.2%) attended all seminars.

Pharmacy user: not reported

Setting: rural

Country: Peru

Interventions

Pharmacy worker-directed intervention: pharmacies received education on STD recognition, management, and prevention counselling and were visited by standardised simulated patients.

- Delivered by: pharmacist and midwife team
- Type: education materials, based on clinical practice guidelines; education meetings
- Mode of delivery: group; written materials
- TDF: knowledge, skills, environment, context and resources, social support
- Duration: 3 x 90-minute luncheon training seminars on STD/HIV. Monthly follow-up visits to discuss STD/HIV prevention and provide materials.
- Follow-up: 1, 3 and 6 months after training

Pharmacy worker control: invited to a seminar on diarrhoea management

Pharmacy user-directed intervention: not reported

Outcomes

Pharmacy worker:

- Uptake of pharmacies: 884 of 1118 (79%)
- Behavioural: simulated patient management of STD

Pharmacy user: not assessed

Notes

Study/intervention name: none given

Funding source: Wellcome Trust-Burroughs Wellcome Fund Infectious Disease Initiative

Pilot study for 2012 studies

Risk of bias

Bias

Authors' judgement

Support for judgement

Random sequence generation (selection bias)

Low risk

Randomised with table of random numbers.

Garcia 2003 (Continued)

Allocation concealment (selection bias)	Low risk	Adequately concealed - data extraction form
Baseline outcome measures similar	Unclear risk	Preintervention assessments not conducted
Baseline characteristics similar	Unclear risk	Preinterventions assessments not conducted
Incomplete outcome data (attrition bias) All outcomes	Low risk	Minimal attrition
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Standardised simulated patients were blinded to the nature of the training, the randomisation procedure, and the status of districts or pharmacies as intervention or controls.
Protection against contamination	Low risk	Cluster randomised
Selective reporting (reporting bias)	Unclear risk	Findings were presented for the 4 outcomes, but only for selection of pharmacies
Other bias	Low risk	Not noted
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Control pharmacies offered training in diarrhoea to maintain blinding

Garcia 2012

Methods	Design: cluster-RT (by city; n = 20) Groups: intervention group (management and prevention of STDs); control group (standard care)
Participants	Pharmacies: 773 Pharmacy workers: 2292 Median age: 34.6 years % female: 62% ----- Pharmacy user: targeted through pharmacies (data available from 12930 young adults) Setting: urban Country: Peru
Interventions	Pharmacy worker-directed intervention: the intervention comprised 4 modalities: <ul style="list-style-type: none"> • strengthened STD syndromic management by pharmacy workers and clinicians; • mobile-team outreach to female sex workers for sexually transmitted infection screening and pathogen-specific treatment; • periodic presumptive treatment of female sex workers for trichomoniasis; and

Garcia 2012 (Continued)

- condom promotion for female sex workers and the general population.
- Delivered by: pharmacist and midwife team
- Type: education materials, based on clinical practice guidelines; interactive meeting with role play, case studies
- Mode of delivery: group of 8 to 10 pharmacy workers; written materials
- Duration: 4 x 90-minute luncheon training seminars on STD/HIV. Monthly follow-up visits to discuss STD/HIV prevention and provide materials.
- Follow-up: 1, 3 and 6 months after training

Pharmacy worker control: usual treatment

Pharmacy user-directed intervention: not reported

Outcomes	<p>Pharmacy worker:</p> <ul style="list-style-type: none"> • Uptake: not reported • Behavioural: simulated patients for management of STD <p>-----</p> <p>Pharmacy user:</p> <ul style="list-style-type: none"> • Clinical: infection with STD • Psychological health: not assessed • Behavioural: not assessed • Quality of life: not assessed • Process: not assessed • Costs: not assessed
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Notes	<p>Study/intervention name: Peru-PREVEN</p> <p>Funding Source: Wellcome Trust and Burroughs Wellcome Fund, National Institutes of Health, Centre for AIDS Research, CIPRA, and USAID-Peru.</p> <p>Garcia 2012 (cited under Garcia 2012) also reported on this study.</p>
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Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer randomisation
Allocation concealment (selection bias)	High risk	Participants in outcome surveys were recruited after city randomisation, precluding allocation concealment
Baseline outcome measures similar	Low risk	Adjusted for in analysis
Baseline characteristics similar	Low risk	Adjusted for in analysis
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing data replaced with classification of negative composite endpoint

Garcia 2012 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	US and UK investigators masked until testing complete
Protection against contamination	Low risk	Cluster randomised
Selective reporting (reporting bias)	Low risk	Primary and secondary outcomes reported
Other bias	Low risk	Not noted
Blinding of participants and personnel (performance bias) All outcomes	High risk	Fieldworkers and Peruvian study team could not be masked

Garcia-Cardenas 2013

Methods	Design: cluster-RT Groups: intervention group (management of asthma); control group (standard care)
Participants	Pharmacies: 51 (29 intervention; 22 control) Pharmacy workers: 33 pharmacists in intervention group; 32 pharmacists in control group ----- Pharmacy user: 346 patients with asthma (186 intervention; 160 control) <ul style="list-style-type: none"> • mean age: intervention 54.3 ± 19.1 years; control 57.8 ± 19.0 years • % female: intervention 57.9%; control 51.3% Setting: all pharmacies in Malaga and Madrid (urban and rural) Country: Spain
Interventions	<p>Pharmacy worker-directed intervention: 33 pharmacists allocated to the intervention group attended a 1-day workshop. They were trained to provide education on asthma control, medication adherence and inhaler technique and received the Spanish Guide for Asthma Management (GEMA 2009).</p> <ul style="list-style-type: none"> • Delivered by: respiratory physician and a pharmacist educator/researcher • Type: education materials, based on clinical practice guidelines; interactive meeting with role play, case studies • Mode of delivery: group • TDF: knowledge, skills, social support • Duration: 1 day with regular visits to assist delivery <p>Pharmacy worker control: received instructions by phone about study protocol and monitored through 2 visits to the pharmacy</p> <p>-----</p> <p>Pharmacy user-directed intervention: asthma self-management</p> <ul style="list-style-type: none"> • Delivered by: pharmacists

Garcia-Cardenas 2013 (Continued)

- Type: patients were educated using verbal instructions, physical demonstration and written information about turbuhaler use. When appropriate the type of non-adherence (intentional or unintentional) and causes of intentional non-adherence were explored with the Beliefs about Medicines Questionnaire and Health Beliefs Model. Several aspects of asthma control were also covered in each visit. Finally pharmacist and patient jointly agreed goals for the next visit.
- Mode of delivery: individual face-to-face
- TDF: knowledge, skills, beliefs about consequences, goals
- Duration: 3 scheduled visits over 6 months and up to 6 addition visits if needed

Pharmacy user control: usual treatment

Outcomes	<p>Pharmacy worker:</p> <ul style="list-style-type: none"> • Uptake: 51 of 65 pharmacies completed study <p>-----</p> <p>Pharmacy user:</p> <ul style="list-style-type: none"> • Clinical: asthma control via Asthma Control Questionnaire (ACQ) • Psychological health: not assessed • Behavioural: inhaler technique (checklist), adherence to medication (Morisky Adherence scale) • Quality of life: not assessed • Process: not assessed • Costs: not assessed
Notes	<p>Study/intervention name: The AFasma Study</p> <p>Funding Source: AstraZeneca Foundation</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated
Allocation concealment (selection bias)	Low risk	Computer generated
Baseline outcome measures similar	Low risk	Differences adjusted for in analyses
Baseline characteristics similar	Low risk	Differences adjusted for in analyses
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear how missing data were managed
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not clear if assessor blinded
Protection against contamination	Low risk	Cluster randomised

Garcia-Cardenas 2013 (Continued)

Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	None noted
Blinding of participants and personnel (performance bias) All outcomes	High risk	Control group pharmacies were asked not to change care, which suggests that they had knowledge of groups.

Jaffray 2014

Methods	Design: cluster-RT Groups: intervention group (motivational interviewing to improve methadone outcomes); control group (standard practice)
Participants	Pharmacies: 76 of 87 approached were recruited Pharmacy workers: 84 pharmacists of 95 contacted were recruited ----- Pharmacy user: 542 methadone patients (295 intervention; 247 control) <ul style="list-style-type: none"> • mean age: intervention 32.3 ± 7.1 years; control 32.6 ± 7.3 years • % female: intervention 35.9%; control 36.6% Setting: Tayside, Ayrshire, Fort Valley, Lanarkshire, Grampian, Fife Country: Scotland, UK
Interventions	<p>Pharmacy worker-directed intervention: training in motivational interviewing during 4 sessions, the first 2 sessions emphasised techniques and discussion, and subsequent sessions allowed practice of skills. The intervention was also supported by a resource pack.</p> <ul style="list-style-type: none"> • Delivered by: Scottish Training on Drugs and Alcohol (STRADA) accredited motivational interview trainers • Type: education materials; meetings; resource packs • Mode of delivery: group; individual face-to-face; written materials; videotape • TDF: knowledge, skills, memory, attention, decision making, environment, context, resources • Duration: 4 sessions of training <p>Pharmacy worker control: usual practice</p> <p>-----</p> <p>Pharmacy user-directed intervention: motivational interviewing offered at sessions over 6 months</p> <ul style="list-style-type: none"> • Delivered by: pharmacists • Type: motivational interviewing • Mode of delivery: individual face-to-face • Duration: 6 month • Number of sessions: as needed • TDF: this level of intervention not reported • Follow-up: 7 months (end of treatment)

Jaffray 2014 (Continued)

Pharmacy user control: usual treatment

Outcomes

Pharmacy worker:

- Uptake + attendance at training - 60% to 80%
- Behaviour: motivational interview techniques using the Behaviour Change Counseling Index (BECCI)

Pharmacy user:

- Clinical: not assessed
- Psychological health: not assessed
- Behavioural: illicit heroin use
- Quality of life: Maudsley Addition Profile
- Process: interaction with pharmacists
- Costs: not assessed

Notes

Funding source: Chief Scientist Office, Edinburgh, Scotland, UK

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised but method unclear
Allocation concealment (selection bias)	Unclear risk	Unclear method for randomisation
Baseline outcome measures similar	Low risk	Any differences adjusted for in analyses
Baseline characteristics similar	Low risk	Any differences adjusted for in analyses
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Intention-to-treat with imputation for missing values but only for certain variables, others excluded
Blinding of outcome assessment (detection bias) All outcomes	High risk	Assessor aware of groupings
Protection against contamination	High risk	Although cluster randomised, report considerable movement of patients between pharmacies.
Selective reporting (reporting bias)	Low risk	Not noted
Other bias	Unclear risk	Only missing estimates were made for treatment satisfaction, physical and psychological scores.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Patients blinded

Kraemer 2012

Methods	Design: RT Groups: intervention group (pharmacist counselling); control group (printed materials)
Participants	Pharmacies: not reported Pharmacy worker: 22 pharmacists trained ----- Pharmacy user: 67 patients with type 1 or type 2 diabetes mellitus (with insurance from participating employer) <ul style="list-style-type: none"> • mean age: intervention 55.6 ± 6.8 years; control 52.6 ± 9.2 years • % female: intervention 38.89%; control 61.29% Setting: urban Country: USA
Interventions	<p>Pharmacy worker-directed intervention: pharmacists had to demonstrate evidence of prior certification as a diabetes educator or complete 16 hours of online training. All also had to complete 14 hours of didactic and case-based workshops with emphasis on patient education and empowerment, clinical intervention techniques, documentation and billing.</p> <ul style="list-style-type: none"> • TDF: knowledge, skills, environment, context and resources, behavioural regulation <p>Pharmacy worker control: it appears the same pharmacists saw both intervention and control groups.</p> <p>-----</p> <p>Pharmacy user-directed intervention: received waiver of patient out-of-pocket expenses (e.g. co-payments and/or co-insurance) for specified medications and physician visits, plus multiple scheduled education appointments with a pharmacist over a 12-month period.</p> <ul style="list-style-type: none"> • Delivered by: pharmacists • Type: diabetes empowerment • Mode of delivery: individual face-to-face • TDF: knowledge, environment resources and context • Duration: 12 months (end of intervention) • Length of intervention: 12 months; met monthly for the first 3 months and every 1 to 3 months thereafter (less frequently as patient improved on self-management) • Session duration: initial visit was 60 minutes, follow-up visits were 30 minutes <p>Pharmacy user control: printed education materials and the same financial benefits as the intervention group</p>
Outcomes	<p>Pharmacy worker: not reported</p> <p>-----</p> <p>Pharmacy user:</p> <ul style="list-style-type: none"> • Clinical: HbA1c; LDL; HDL; triglycerides; total-to-HDL ratio; and fasting blood glucose; SBP and DBP, weight, waist circumference, and BMI; Diabetes Knowledge Test (DKT) • Psychological health: not assessed • Behavioural: WHO Health and Work Performance Questionnaire (also known as HPQ); Adherence Starts with Knowledge (ASK-20)

Kraemer 2012 (Continued)

- Quality of life: Diabetes Empowerment scale (DES); 4 additional questions from the DES 'Long Form'
- Process: not assessed.
- Costs: insurance claims data

Notes	Study/intervention name: the EMPOWER study Funding source: partial funding for this project was received from the Community Pharmacy Foundation, Sanofi-Avetis, and Lane County Pharmacists Association.
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Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, but methods were not mentioned.
Allocation concealment (selection bias)	Unclear risk	No information provided
Baseline outcome measures similar	Low risk	Any differences accounted for in analyses
Baseline characteristics similar	Low risk	Any differences accounted for in analyses
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not clear how missing data were managed
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is unclear whether the research team conducting follow-up assessments were blind to group.
Protection against contamination	High risk	Participants were known to discuss the study between themselves, so that blinding was broken and risk of contamination was possible.
Selective reporting (reporting bias)	Low risk	No issues noted. Four parameters (cholesterol-to-HDL ratio, weight, waist circumference, and BMI) were not shown due to lack of changes from baseline and difference between groups.
Other bias	Low risk	Not noted
Blinding of participants and personnel (performance bias) All outcomes	High risk	On self-report 54% of control group indicated they were controls while 75% of intervention group were unclear on their grouping. At least some participants discussed the study between themselves, hence blinding was possibly broken.

Krass 2007

Methods	Design: cluster-RT Groups: intervention group (education on diabetes, its management, medicines); control group (standard care)
Participants	Pharmacies: 56 Pharmacy workers: not reported

Krass 2007 (Continued)

Pharmacy user: 289 patients with type 2 diabetes 289

- mean age 62 ± 11 years
- % female 49%

Setting: both rural and urban

Country: Australia

Interventions

Pharmacy worker-directed intervention: all intervention pharmacists received a diabetes education manual for self-directed learning and also attended a 2-day workshop that consisted of lectures, role playing, training on monitors. Pharmacists received reimbursement for patients who completed all study visits.

- Delivered by: unclear
- Type: based on clinical practice guidelines; medication management; disease management, use of relevant devices; role playing
- Mode of delivery: written materials; face to face workshop
- TDF: knowledge, skills, environment, context and resources
- Duration: 2 days

Pharmacy worker control: training on study procedures and payment for every patient that completed both baseline and follow-up assessments

Pharmacy user-directed intervention: patients were given a blood glucose meter, instructed to use it daily. Measurements discussed at each visit to identify other interventions to support patient care (adherence support, medication review, diabetes self-management, lifestyle information etc.)

- Delivered by: pharmacists
- Type: self-management; behaviour change; based on clinical practice guidelines; medication management
- Mode of delivery: individual face-to-face, written materials
- TDF: knowledge, skills, goals, environment resources and context, behavioural regulation
- Duration: 5 meetings over 6 months (baseline, 2 weeks, 1.5 months, 3.5 months, 6 months)
- Follow-up: 6 months (end of intervention)

Pharmacy user control: usual care

Outcomes

Pharmacy worker:

- Uptake: not reported

Pharmacy user:

- Clinical: HbA1c; SBP and DBP, lipid profile and BMI
- Psychological health: not assessed
- Behavioural: not assessed
- Quality of life: EQ-5D
- Process: not assessed
- Costs: not assessed

Notes

Study/intervention name: the Pharmacy Diabetes Care Program

NB This appears to be the same research group as [Armour 2004](#), but this is a more complex study with a separate population.

Krass 2007 (Continued)

Funding source: Australian Government Department of Health and Aging

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The pharmacies identified were located within 300 km of the participating universities. The percentage of pharmacies in each local government area (LGA) was then calculated. To obtain a random stratified sample of 60 pharmacies, the corresponding percentage per LGA was calculated and the required number within each stratum was randomly chosen using Excel.
Allocation concealment (selection bias)	Low risk	As above
Baseline outcome measures similar	Low risk	Any differences controlled for in analyses
Baseline characteristics similar	Low risk	Any differences controlled for in analyses
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comparison was made between completers and non-completers, but unclear how accounted for in analyses
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Objective outcomes
Protection against contamination	Low risk	Cluster-RT
Selective reporting (reporting bias)	Low risk	Not noted
Other bias	Low risk	Not noted
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear whether intervention group participants were aware of grouping

Liambila 2010

Methods	Design: cluster-RT Groups: intervention (training on use of emergency contraceptives); control (standard care)
Participants	Pharmacies: 20 selected from 98 Pharmacy worker: <ul style="list-style-type: none"> • mean age: information not provided • % female: intervention 67.4%; control 50.0% -----

Liambila 2010 (Continued)

Pharmacy user: not reported
 Setting: urban
 Country: Nairobi, Kenya

Interventions

Pharmacy worker-directed intervention: updating the private pharmacy providers on appropriate use of emergency contraceptives, how best to dispense it to users, family planning methods, referral for sexually transmitted infection (STI)/HIV testing and counselling. In-pharmacy information for pharmacy workers and users

- Delivered by: research assistants
- Type: education materials; reminders
- Mode of delivery: individual face-to-face; written materials
- TDF: knowledge, skills, environment, context and resources, behavioural regulation
- Duration: weekly sessions over 2 months
- Follow up: 2 months (end of intervention)

Pharmacy worker control: usual practice

Pharmacy user-directed intervention: advice on emergency contraceptives, family planning and STI management.

- Delivered by: pharmacists
- Type: medication management; information provision, behavioural advice
- Mode of delivery: face-to-face
- Duration: delivered over 3 months

Pharmacy user control: usual treatment

Outcomes
Pharmacy worker:

- Uptake: 20 of 98 pharmacies selected, all of which participated
- Behavioural: mystery clients assessed pharmacist-given information (on emergency contraceptives, offer of regular family planning services, talk about STIs/HIV and offer of STI services)

Pharmacy user: not assessed

Notes

Study/intervention name: none given
 Funding source: William and Flora Hewlett Foundation

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, but method not specified
Allocation concealment (selection bias)	Unclear risk	No information
Baseline outcome measures similar	Low risk	No differences

Liambila 2010 (Continued)

Baseline characteristics similar	Unclear risk	Little information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information on missing data
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not clear if mystery clients were aware of groupings
Protection against contamination	Low risk	Control and intervention in separate geographical areas
Selective reporting (reporting bias)	Unclear risk	Nothing noted
Other bias	High risk	Not all baseline assessments completed before study commenced
Blinding of participants and personnel (performance bias) All outcomes	High risk	Intervention participants must have had awareness of grouping due to materials.

Liekens 2014

Methods	Design: cluster-RT Groups: intervention group (pharmacists received communication skills training related to depression); control group (no intervention)
Participants	Pharmacies: 40 Pharmacy worker: 21 in intervention group; 19 in control group ----- Pharmacy user: not assessed Setting: urban Country: Belgium
Interventions	Pharmacy worker-directed intervention: pharmacists received communication skills training related to depression including role playing with a simulated patient and feedback on their counselling skills. <ul style="list-style-type: none"> • Delivered by: researcher; lecturer in pharmacotherapy/pharmaceutical care; clinical psychologist; consumer educators • Type: education meetings; role-playing with simulated patients; feedback on behaviour • Mode of delivery: group (no more than 10 participants); individual face-to-face • TDF: knowledge, environment, context and resources, behavioural regulation • Duration: 1 day, 3 parts • Follow-up: 'a few weeks later' Pharmacy worker control: not reported -----

Liekens 2014 (Continued)

Pharmacy user-directed intervention: not targeted

Outcomes
Pharmacy worker:

- Uptake: not reported
- Behavioural: simulated patients assessed pharmacists' communication skills. Their interactions were audio-recorded and analysed using Roter Interaction Analysis System (RIAS).

Pharmacy user: not assessed

Notes

Study/intervention name: none given

Funding source: no external funding

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomly ordered list of pharmacy codes
Allocation concealment (selection bias)	Low risk	Researchers blinded to the identity of pharmacies allocated to study groups
Baseline outcome measures similar	Unclear risk	No baseline assessment
Baseline characteristics similar	Unclear risk	No baseline assessment
Incomplete outcome data (attrition bias) All outcomes	Low risk	No reported attrition
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The researchers were blind to the identity of the pharmacies allocated to the study groups." and "The mystery shoppers (MS) were blind to the pharmacy assignment to training or control groups."
Protection against contamination	Unclear risk	All pharmacists from same pharmacy chain
Selective reporting (reporting bias)	Low risk	Not noted
Other bias	Unclear risk	Quote: "limitations of the current study include variable exposure to the intervention as several pharmacists did not complete the role play at the end of the training day. This may have diminished the impact of the intervention for them in terms of patient counselling skills."
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "The researchers were blind to the identity of the pharmacies allocated to the study groups." and "The mystery shoppers (MS) were blind to the pharmacy assignment to training or control groups."

Madurasinghe 2017

Methods	<p>Design: cluster-RT</p> <p>Groups: intervention group (pharmacy workers trained in smoking cessation); control (no treatment)</p>
Participants	<p>Pharmacies: 12 (7 intervention; 5 control)</p> <p>Pharmacy worker: pharmacists and counter assistants</p> <p>Pharmacy user: 621 (302 intervention; 319 control)</p> <ul style="list-style-type: none"> • mean age: 45.2 ± 11.0 years • % female: intervention 73.7%; control 43.8% <p>Setting: urban</p> <p>Country: UK</p>
Interventions	<p>Pharmacy worker-directed intervention: training in communication and behaviour change skills</p> <ul style="list-style-type: none"> • Delivered by: health psychologist and community pharmacist • Type: behaviour change, interactive practice based • Mode of delivery: face-to-face • TDF: knowledge, skills, social/professional role and identity, beliefs about capabilities, • belief about consequences, memory, social support, environment, context and resources, • Duration: 2 x 2.5-hour sessions <p>Pharmacy worker control: no training</p> <p>-----</p> <p>Pharmacy user-directed intervention: optimised smoking cessation programme</p> <ul style="list-style-type: none"> • Delivered by: pharmacy worker • Type: behaviour change (smoking) • Mode of delivery: face-to-face • TDF: knowledge, belief about capability, belief about consequences, goals, environment, context and resources • Duration: 4 sessions of up to 30 minutes <p>Pharmacy user control: Usual care</p>
Outcomes	<p>Pharmacy worker:</p> <ul style="list-style-type: none"> • Uptake: 12 of the 54 pharmacies invited participated • Behaviour: throughput of smokers <p>-----</p> <p>Pharmacy user:</p> <ul style="list-style-type: none"> • Clinical: not assessed • Psychological health: not assessed • Behavioural: quit rate (cotinine); retention • Quality of life: not assessed • Process: not assessed • Costs: not assessed
Notes	<p>Study/intervention name: Smoking Treatment Optimisation in Pharmacy (STOP)</p> <p>Funding source: National Institute of Health Research,UK</p>

Madurasinghe 2017 (Continued)

 Steed 2017 (cited under [Madurasinghe 2017](#)) also refers to this study

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation generated using Stata 12 software.
Allocation concealment (selection bias)	Low risk	Independent statistician generated and administered randomisation list.
Baseline outcome measures similar	Unclear risk	Not reported
Baseline characteristics similar	High risk	Differences in age and % female
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Protection against contamination	Low risk	Cluster randomised
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	High risk	Only 12 of 54 pharmacies participated, no comparison with those who were not recruited
Blinding of participants and personnel (performance bias) All outcomes	High risk	Pharmacy workers were aware of intervention arm.

Maguire 2001

Methods	Design: RT Groups: intervention group (Pharmacists Action on Smoking (PAS)); control group (usual care)
Participants	Pharmacies: 124 (1 pharmacist per site) Pharmacy workers: 124 pharmacists (100 in Northern Ireland, 24 in London) ----- Pharmacy user: 484 smokers • mean age: intervention 42 years; control 38 years • % female: intervention 40.37%; control 43.8% Setting: urban

Community pharmacy interventions for health promotion: effects on professional practice and health outcomes (Review)

Maguire 2001 (Continued)

Country: UK

Interventions

Pharmacy worker-directed intervention: before study, pharmacists were sent the pharmacy-based smoking cessation (PAS model) documentation and literature review and were asked to study it. Attended workshops on epidemiology, smoking statistics, the use of nicotine replacement therapy, the cycle of change model and the PAS model. Researchers visited the pharmacists to provide support and to address any queries they had in implementing the model.

- Delivered by: researcher
- Type: smoking cessation, education
- Mode of delivery: group; individual face-to-face; written materials
- TDF: knowledge, skills, belief about consequences, environment, context and resources, behavioural regulation
- Duration: 1 x 3-hour workshop

Pharmacy worker control: it appears the same pharmacists saw both intervention and control groups.

Pharmacy user-directed intervention: patients received counselling using PAS approach

- Delivered by: pharmacist
- Type: smoking cessation: behaviour change
- Mode of delivery: individual face-to-face; written materials
- TDF: knowledge, reinforcement, goals, environment, context and resources
- Duration: Length of intervention: weekly sessions for 4 weeks, then monthly for 3 months
- Follow-up: 3, 6 and 12 months (intervention ended at 4 months)

Pharmacy user control: usual care including the provision of nicotine replacement therapy as appropriate

Outcomes
Pharmacy worker:

- Uptake: not reported
- Qualitative experience of delivering study

Pharmacy user:

- Clinical: not assessed
- Psychological health: not assessed
- Behavioural: smoking abstinence (cotinine confirmed)
- Quality of life: not assessed
- Process: not assessed
- Costs: not assessed

Notes

Study/intervention name: Pharmacist Action on Smoking (PAS)

Funding source: Medical Research Council and Northern Ireland Department of Health and Social Services

Also informed by Maguire 1996 (additional reference under [Maguire 2001](#))

Risk of bias
Bias

Authors' judgement	Support for judgement
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Maguire 2001 (Continued)

Random sequence generation (selection bias)	Low risk	Randomised using a sealed envelope technique
Allocation concealment (selection bias)	Low risk	Blind to allocation
Baseline outcome measures similar	Low risk	All participants were smokers at baseline.
Baseline characteristics similar	Unclear risk	Differences between groups not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Where data were missing for participants, the participants were assumed to still be smoking.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Objective outcome measure
Protection against contamination	High risk	Within pharmacy randomisation
Selective reporting (reporting bias)	Low risk	Not noted
Other bias	Low risk	Not noted
Blinding of participants and personnel (performance bias) All outcomes	High risk	Pharmacy workers aware of group

Mansell 2016

Methods	Design: cluster-RT Groups: intervention (self-monitoring of blood glucose (SMBG)); control (usual care)
Participants	Pharmacies: 9 (7 intervention; 2 control) Pharmacy worker: 9 (1 pharmacist per pharmacy) ----- Pharmacy user: 36 (26 intervention; 10 control) • mean age: intervention 61 ± 11.8 years; control 65.2 ± 11.8 years • % female: intervention 38%; control 70% Setting: mainly rural Country: Canada
Interventions	Pharmacy worker-directed intervention: provided education on SMBG, the recent Canadian Diabetes Association (now renamed 'Diabetes Canada') recommendations and the study glucose meter • Delivered by: not reported

Mansell 2016 (Continued)

- Type: education
- Mode of delivery: not reported
- TDF: knowledge, environment, context, resources
- Duration: 1 day

Pharmacy worker control: no additional information

Pharmacy user-directed intervention: recommendations for SMBG and behaviours to change

- Delivered by: pharmacist
- Type: self-management
- Mode of delivery: face-to-face
- TDF: knowledge, skills, environmental context, resources, behavioural regulation
- Duration: not reported

Pharmacy user control: usual care

Outcomes	<p>Pharmacy worker:</p> <ul style="list-style-type: none"> • Uptake: 12 of 382 invitees, only 9 recruited participants <p>-----</p> <p>Pharmacy user:</p> <ul style="list-style-type: none"> • Clinical: HbA1c • Psychological health: not assessed • Behavioural: SMBG (study developed) • Quality of life: not assessed • Process: not assessed • Costs: not assessed
Notes	<p>Study/intervention name: none given</p> <p>Funding source: unrestricted research grant from Sanofi, Canada</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	High risk	Blinding not possible
Baseline outcome measures similar	High risk	Considerable missing data for baseline BP
Baseline characteristics similar	High risk	Difference diabetes in age between groups
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition accounted for

Mansell 2016 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data analyst was blind to treatment allocations
Protection against contamination	Low risk	Cluster design
Selective reporting (reporting bias)	Low risk	Not apparent
Other bias	Low risk	Not apparent
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Aware of groups

Mayer 1998

Methods	Design: cluster-RT Groups: intervention group (pharmacist training in skin cancer prevention); control group (usual care)
Participants	Pharmacies 54 (out of 88 sites) Pharmacy worker: pharmacists 147 (out of 178 invited) <ul style="list-style-type: none"> • mean age: intervention 40.52 years; control 41.84 years • % female: intervention 45.1%; control 32.3% ----- Pharmacy user: not targeted Setting: unclear Country: USA
Interventions	<p>Pharmacy worker-directed intervention: training was provided to pharmacists about how to reduce ultraviolet radiation exposure and use sun protection of 15 or higher. A videotape and accompanying print materials were used for 3 weeks, then pharmacists received weekly written feedback on skin cancer prevention counselling performance, plus incentives for the "winning" performance for a further 3 weeks. The 23-minute videotape contained didactic information about skin cancer prevention, a model ("Ask, Advise, and Assist") to help pharmacists give brief counselling to their patients, and 6 brief scenes showing pharmacist-patient interactions.</p> <ul style="list-style-type: none"> • Delivered by: researcher; other pharmacist • Type: education materials • Mode of delivery: video/DVD; written materials; face-to-face feedback • TDF: knowledge, skills, environment, context and resources • Duration: length of intervention: approximately 6 weeks; • Follow-up: 7 weeks after baseline (i.e. end of intervention) <p>Pharmacy worker control: not reported</p> ----- <p>Pharmacy user-directed intervention: not directly targeted</p>

Mayer 1998 (Continued)

Outcomes

Pharmacy worker:

- Uptake: 54 sites selected out of 54; 128 of 178 pharmacists completed pretest survey
- Behavioural: simulated patient - reported the percentage provided with verbal counselling; distribution of brochure and/or sunscreen sample

Pharmacy user: not assessed

Notes

Study/intervention name: Project SUNWISE

Funding source - Grant AR 43025 from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), videotape by Glaxo Wellcome

 Mayer 1998 (cited under [Mayer 1998](#)) also refers to this study

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation method not specified
Allocation concealment (selection bias)	Unclear risk	No information in trial report
Baseline outcome measures similar	Low risk	Although differences at baseline were reported, these were controlled for in analyses
Baseline characteristics similar	Low risk	No significant differences apparent
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Across all observations, 138 pharmacists were observed. Of these, 33 were observed at pretest only, 25 were observed at post-test only, and 80 were observed at both times. Intervention site pharmacists 71; control site pharmacists 67 Not clear how missing data from pre/post-test were handled
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Simulated patients (mystery shoppers) blind to study groups
Protection against contamination	Low risk	Cluster randomisation
Selective reporting (reporting bias)	Unclear risk	Not noted
Other bias	High risk	There appeared to be some discrepancy in figures reported between publications.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Confederates were blinded to pharmacy study conditions, but pharmacists were aware of intervention group.

McDonough 2005

Methods	<p>Design: cluster-RT</p> <p>Groups: intervention group (identification of glucocorticoid-induced osteoporosis risk); control group (usual care)</p>
Participants	<p>Pharmacies 15 (8 intervention; 7 control)</p> <p>Pharmacy worker: pharmacists</p> <p>-----</p> <p>Pharmacy user: patients believed to be at high risk for-developing osteoporosis 96 (70 intervention; 26 control)</p> <ul style="list-style-type: none"> • mean age: not stated • % female: intervention 74.3%; control 57.7% <p>Setting: both urban and rural</p> <p>Country: USA</p>
Interventions	<p>Pharmacy worker-directed intervention: pharmacists received classroom education/training on the pathophysiology and management of glucocorticoid-induced osteoporosis, and were given a packet of articles for independent study.</p> <ul style="list-style-type: none"> • Delivered by: possibly researchers • Type: education; written materials • Mode of delivery: classroom education/training (probably face to face and group, though not specified); written materials • TDF: knowledge, reinforcement, environment, context, resources • Duration: approximately 4 hours • Follow-up: 9 months (end of intervention/monitoring period) <p>Pharmacy worker control: not reported</p> <p>-----</p> <p>Pharmacy user-directed intervention: patients received education; an educational pamphlet about the risks - including behavioural risks - of glucocorticoid-induced osteoporosis; and pharmacists monitored the patients' medical therapy, to identify and address medicine-related problems</p> <ul style="list-style-type: none"> • Delivered by: pharmacists • Type: education; risk management • TDF: knowledge • Mode of delivery: individual face-to-face; written materials • Duration: 9 months of follow-up <p>Pharmacy user control: usual treatment</p>
Outcomes	<p>Pharmacy worker:</p> <ul style="list-style-type: none"> • Behavioural: discussion of osteoporosis risk and bone mineral density testing <p>-----</p> <p>Pharmacy user:</p> <ul style="list-style-type: none"> • Clinical: presence of therapies including biophosphonate therapy, estrogen therapy, calcium supplement • Psychological health: not assessed.

McDonough 2005 (Continued)

- Behavioural: behaviourally modifiable risk factors
- Quality of life: not assessed
- Process: patient awareness and receipt of bone mineral density test
- Costs: not assessed

Notes	Study/intervention name: none given
	Funding source: an unrestricted educational grant from Merck and Co, and by the Center for Improving Medication Use in the Community at the University of Iowa

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation method not specified.
Allocation concealment (selection bias)	Unclear risk	Not stated
Baseline outcome measures similar	High risk	Significant difference by group for alcohol and bisphosphonate therapy at baseline.
Baseline characteristics similar	High risk	Significant difference by group for postmenopausal status at baseline.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Dropouts reported, but unclear how missing data were managed.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessment done by web-based survey, but completed in pharmacy.
Protection against contamination	High risk	Both groups of pharmacists received education on glucocorticoid induced osteoporosis.
Selective reporting (reporting bias)	Low risk	Nothing noted
Other bias	High risk	Insufficient sample size to detect an effect, all pharmacists participated in research and trained in monitoring drug therapies.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	It is likely that pharmacists were aware of grouping.

McLean 2003

Methods	Design: cluster-RT (paired by geographic similarity)
	Groups: intervention group (enhanced pharmaceutical care); control group (usual care)
Participants	Pharmacies: 27

McLean 2003 (Continued)

Pharmacy worker: 33 pharmacists, all of whom had prior training in the pharmaceutical care of asthma

Pharmacy users: 405 (191 enhanced care; 214 usual care)

Setting: unclear

Country: British Columbia, Canada

Interventions

Pharmacy worker-directed intervention: nothing additional to their pre study training in asthma

Pharmacy user-directed intervention: tailored education to patient's readiness to change (intervention only begun once someone in contemplation and strategies applied when in preparation). Taught correct inhaler technique, peak flow monitoring and self-management skills, and enhanced pharmaceutical care

- Delivered by: pharmacist
- Type: asthma self-management, environment, context, resources, behavioural regulation
- Mode of delivery: individual face-to-face
- TDF: knowledge, skills,
- Duration: length of intervention: 6 x 60-minute sessions for a minimum of 9 months. (1 meeting every 2 to 3 weeks for at least 3 appointments then at least every 3 months)
- Follow-up: a minimum of 9 to 12 months from baseline (end of intervention period)

Pharmacy user control: taught inhaler technique and provided a minimum of 9 months usual care after which enhanced care was offered

Outcomes

Pharmacy worker: not assessed

Pharmacy user:

- Clinical: PEFR
- Psychological health: not assessed
- Behavioural: refill prescriptions
- Quality of life: Asthma Quality of Life Questionnaire (AQLQ)
- Process: not assessed
- Costs: health care use and overall health costs

Notes

Study/intervention name: the BC Community Pharmacy Asthma Study

Funding source: Health Transition Fund, Health Canada, and Glaxo-Smith-Kline for educational materials and diaries

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	By coin toss, central randomisation
Allocation concealment (selection bias)	Low risk	By coin toss, central randomisation
Baseline outcome measures similar	Unclear risk	No specific test of baseline similarity, although mean change was used in analysis.

McLean 2003 (Continued)

Baseline characteristics similar	Unclear risk	No specific test of baseline similarity
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Considerable dropout, although numbers reported it was unclear whether this was corrected for.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not clear whether it was the pharmacist or an independent individual who conducted assessment interviews.
Protection against contamination	High risk	11 'grand-fathered' pharmacists appear to have offered both enhanced and usual care.
Selective reporting (reporting bias)	Low risk	Not noted
Other bias	Unclear risk	Although central randomisation used, there were different patient allocation methods which complicated study design. Usual care was also received from highly trained pharmacists which may not be reflective of all practice.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Pharmacists aware of groupings

McLean 2008

Methods	Design: RT Groups: intervention (pharmaceutical care); control (usual care)
Participants	Pharmacies: 14 Pharmacy workers: not reported ----- Pharmacy user: 227 (115 intervention; 112 control) <ul style="list-style-type: none"> • mean age: intervention 66.2 ± 11.3 years, control 61 ± 54.5 years • % female: intervention 25%, control 39% Setting: unclear Country: Alberta, Canada
Interventions	Pharmacy worker-directed intervention: pharmacist training using a combination of an online learning program and a case-based learning session - both based on the Canadian Hypertension Education Program (CHEP) guidelines (www.hypertension.ca) <ul style="list-style-type: none"> • TDF: knowledge, skills Pharmacy worker control: it appears that pharmacists treated both intervention and control groups. ----- Pharmacy user-directed intervention: education about high blood pressure, diabetes and consequences, a focus on potential lifestyle changes, a BP wallet card, fax to GP

McLean 2008 (Continued)

- Delivered by: pharmacist and nurse
- Type: screening, disease management
- Mode of delivery: individual face-to-face
- TDF: knowledge, belief about capabilities, beliefs about consequences, environment, context, resources
- Duration: length of intervention: 6 x 60-minute sessions for a minimum of 9 months (1 meeting every 2 to 3 weeks for at least 3 appointments then at least every 3 months)
- Follow-up: 24 weeks (end of intervention)

Pharmacy user control: a BP wallet card, a pamphlet on diabetes, general diabetes advice, a 12-week follow-up call and usual care

Outcomes

Pharmacy worker: not assessed

Pharmacy user:

- Clinical: DBP,SBP
- Psychological health: not assessed
- Behavioural: not assessed
- Quality of life: not assessed
- Process: not assessed
- Costs: health care use and overall health costs

Notes

Study/intervention name: Study of Cardiovascular Risk Intervention by Pharmacists-Hypertension (SCRIP-HTN)

Funding source - grants from the Canadian Diabetes Association, Heart and Stroke Foundation of Canada, Canadian Council of Cardiovascular Nurses, Alberta Heritage Foundation for Medical Research, and Merck Frosst Canada Ltd

McLean 2006 and Houle 2012 (cited under [McLean 2008](#)) also refer to this study.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was performed centrally to preserve allocation concealment using a computer-generated sequence over a secure internet service at the Epidemiology Coordinating and Research (EPICORE) Centre.
Allocation concealment (selection bias)	Low risk	As above
Baseline outcome measures similar	Low risk	No reported differences
Baseline characteristics similar	Low risk	No reported differences
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up similar in both arms
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Objective measures, although assessors not blinded

McLean 2008 (Continued)

Protection against contamination	High risk	Randomisation at patient level
Selective reporting (reporting bias)	Unclear risk	Not clear
Other bias	Low risk	Not noted
Blinding of participants and personnel (performance bias) All outcomes	High risk	Patients and pharmacists were not blind to group.

Mehuys 2008

Methods	Design: RT Groups: intervention group (asthma self-management); control group (usual care)
Participants	Pharmacies: 66 Pharmacy worker: pharmacists ----- Pharmacy user: 201 patients with asthma (107 intervention; 94 control) <ul style="list-style-type: none"> • mean age: intervention 35.2 (range 19 to 51) years; control 36.3 (range 17 to 51) years • % female: intervention 55%; control 51% Setting: urban Country: Belgium
Interventions	Pharmacy worker-directed intervention: a training session about asthma (pathophysiology), its non-pharmacological and pharmacological treatment (Global Initiative for Asthma (GINA) guidelines), and about the use of the study protocol. <ul style="list-style-type: none"> • Delivered by: unclear • Type: education material; education meeting; based on clinical practice guidelines • Mode of delivery: unclear • TDF: knowledge • Duration: unclear Pharmacy worker control: it appears that pharmacists saw both control and intervention participants. ----- Pharmacy user-directed intervention: intervention focused on ensuring correct use of drug therapy including inhaler use and good adherence <ul style="list-style-type: none"> • Delivered by: pharmacists • Type: asthma self-management; education; based on clinical practice guidelines; medication management • Mode of delivery: individual face-to-face; written materials • TDF: knowledge, skills • Duration: number of sessions: 3 (initial, 1 and 3 month visits with pharmacist)

Mehuys 2008 (Continued)

- Follow-up: 6 months post randomisation (end of intervention period)

Pharmacy user control: usual treatment

Outcomes

Pharmacy worker: not assessed

Pharmacy user:

- Clinical: level of asthma control (Asthma Control Test (ACT)), peak expiratory flow (Mini-Wright Standard Peak Flow Meter); rescue medication use, severe exacerbations
- Psychological health: not assessed
- Behavioural: night-time awakenings due to asthma; inhalation technique (8-point checklist); adherence to controller medication (using 2 validated measures: prescription refill rates and self-reporting), smoking quit rates
- Quality of life: asthma-specific quality of life (Standardised Asthma Quality of Life Questionnaire (AQLQ(S)))
- Process: knowledge about asthma (Knowledge of Asthma and Asthma Medicine questionnaire) and smoking behaviour
- Costs/health care utilisation: not assessed

Notes

Study/intervention name: none given

Funding source: funded by Ghent Unviersity

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Predetermined by the investigators based on a randomisation table. Serially numbered, closed envelopes were made for each participating pharmacy. The envelope with the lowest number was opened by the pharmacist upon inclusion of a new patient.
Allocation concealment (selection bias)	Low risk	See above
Baseline outcome measures similar	Low risk	Baseline variables used as covariates in the analyses
Baseline characteristics similar	Low risk	No significant differences
Incomplete outcome data (attrition bias) All outcomes	Low risk	Linear mixed model used with maximum-likelihood method to handle missing data
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinded assessment at 6 months
Protection against contamination	High risk	Randomisation at patient level, not pharmacy level
Selective reporting (reporting bias)	Low risk	Nothing noted
Other bias	Unclear risk	Potential selection bias, as only regular clients recruited

Mehuys 2008 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Pharmacists aware of patients' groups.
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Mehuys 2011

Methods	Design: cluster-RT	
	Groups: intervention group (self-management of type 2 diabetes); control group (usual care)	

Participants	Pharmacies: 66	
	Pharmacy worker: pharmacists	

	Pharmacy user: 288 patients with type 2 diabetes (153 intervention; 135 control)	
	<ul style="list-style-type: none"> • mean age: intervention 63.0 (range 40 to 84) years; control 62.3 (range 45 to 79) years • % female: intervention 49%; control 46.3% 	
	Setting: urban	
	Country: Belgium	

Interventions	<p>Pharmacy worker-directed intervention: a training session about type 2 diabetes (pathophysiology), its non-pharmacological and pharmacological management (current guidelines), and the study protocol</p> <ul style="list-style-type: none"> • Delivered by: unclear Type: education material; education meeting; based on clinical practice guidelines • Mode of delivery: not clear • TDF: knowledge, skills, behavioural regulation • Duration: unclear <p>Pharmacy worker control: only received training on the study protocol</p>	

	<p>Pharmacy user-directed intervention: patients received protocol-defined intervention at start of the study and at each prescription refill visit (for hypoglycaemic medication) during the course of the study; received education on disease and medication management, lifestyle and annual reviews.</p> <ul style="list-style-type: none"> • Delivered by: pharmacists • Type: self-management; education; based on clinical practice guidelines; medication management; study protocol defined • Mode of delivery: individual face-to-face (unclear) • TDF: knowledge • Duration: the intervention was implemented on each prescription refill visit • Length of follow-up: 6 months (end of intervention period) <p>Pharmacy user control: usual treatment</p>	

Outcomes	<p>Pharmacy worker: not assessed</p> <p>-----</p> <p>Pharmacy user:</p>	
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Mehuys 2011 (Continued)

- Clinical: fasting plasma glucose (FPG); HbA1c
- Psychological health: not assessed
- Behavioural: adherence to treatment (using 2 widely used measures: prescription refill rates and self-report); self-management via validated Dutch translation of the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire
- Quality of life: not assessed
- Process: knowledge about type 2 diabetes (validated Dutch translation of the Brief Diabetes Knowledge Test of the Michigan Diabetes Research and Training Center)
- Costs: not assessed

Notes Study/intervention name: none given
Funding source: Ghent University

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The sequence of allocation to control or intervention group was predetermined by the investigators based on randomisation table generated using SPSS.
Allocation concealment (selection bias)	Low risk	Sequence of allocation predetermined by randomisation table.
Baseline outcome measures similar	Low risk	No differences between groups
Baseline characteristics similar	Low risk	No differences between groups
Incomplete outcome data (attrition bias) All outcomes	Low risk	Minimal attrition
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Objective primary outcome
Protection against contamination	Low risk	Randomisation at pharmacy level
Selective reporting (reporting bias)	Low risk	Nothing noted
Other bias	Unclear risk	Potential selection bias, as only regular clients recruited.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear whether participants or pharmacists were aware of grouping, but likely.

Nishita 2013

Methods Design: RT

Nishita 2013 *(Continued)*

Groups: intervention group (diabetes life-coaching and pharmacist counselling); control group (usual care)

Participants

Pharmacies: 5

Pharmacy worker: 5 licensed pharmacists

Pharmacy user: 190 patients with diabetes

- mean age: intervention 47.59 ± 0.86 years; control 50.26 ± 1.22 years
- % female: intervention 65.63%; control 56.45%

Setting: urban

Country: USA

Interventions

Pharmacy worker-directed intervention: pharmacists received a structured training which covered the 8 behaviours key to motivational interviewing. Additional training was provided on medication management, diabetes education, and diet and exercise support. Life coaches also had project training and diabetes education.

- Delivered by: a registered dietician and certified diabetes educator (CDE) trainer
- Type - pharmacists: education; motivational interviewing; medication management; lifestyle
- Mode of delivery: unclear
- TDF: knowledge, environment, context and resources
- Duration: pharmacists 17 hours training and life coaches 65 hours of training
- Theory: life-coaching, motivational interviewing, self-determination theory

Pharmacy worker control: no training

Pharmacy user-directed intervention: pharmacists supported patients in setting and achieving lifestyle goals using motivational interviewing techniques. Patients also had access to life coaches where conversations could focus on lifestyle changes, diabetes health-related behaviours or employment. In addition, participants were provided with access to additional intervention components that included nutrition and diabetes counselling, diabetes education materials a fitness club membership, and reimbursement for diabetes-related medical expenses.

- Delivered by: pharmacists and life coaches
- Type: self-management; behaviour change; education; motivational interviewing (from pharmacist); medication management
- Mode of delivery: individual face-to-face; written materials
- TDF: knowledge, skills, beliefs about consequences, goals, memory, attention, decision making, environment, context, resources, behavioural regulation
- Duration: patients approached and arranged appointments with both pharmacists and life coaches as they wished
- Length of intervention: 12 months
- Follow-up: 12 months (end of intervention)
- Theory: life coaching and motivational interviewing

Pharmacy user control: no treatment

Outcomes

Pharmacy worker: not accessed

Pharmacy user:

Nishita 2013 (Continued)

- Clinical: glycaemic control (HbA1c), BMI
- Psychological health: not assessed
- Behavioural: not assessed
- Quality of life: quality of life (WHO Quality of Life–Short Form (WHOQOL-BREF)
- Process: diabetes self-efficacy (Diabetes Empowerment Scale–Short Form (DES-SF)
- Costs: not assessed

Notes	Study/intervention name: Hawai'i Demonstration to Maintain Independence and Employment (Hawai'i DMIE) Funding source: Centers for Medicare and Medicaid Services
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Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised blocked design 2:1 allocation intervention:control, sealed envelopes
Allocation concealment (selection bias)	Low risk	As above
Baseline outcome measures similar	Low risk	No significant differences reported at baseline
Baseline characteristics similar	Low risk	No significant differences reported at baseline
Incomplete outcome data (attrition bias) All outcomes	Low risk	Multiple imputation to manage missing data
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Objective primary outcome
Protection against contamination	High risk	Randomisation at pharmacy user level
Selective reporting (reporting bias)	Low risk	Nothing noted
Other bias	Low risk	Nothing noted
Blinding of participants and personnel (performance bias) All outcomes	High risk	Pharmacy workers must have been aware of group allocation.

Nola 2000

Methods	Design: RT Groups: intervention group (lipid management program); control group (usual care)
Participants	Pharmacies: not targeted

Nola 2000 (Continued)

Pharmacy worker: not targeted

Pharmacy user: 51 patients at risk of coronary artery disease (25 intervention; 26 control)

- mean age: intervention 61.1 ± 9.5 years; control 58.4 ± 9.2 years
- % female: intervention 64%; control 53.8%

Setting: urban

Country: USA

Interventions
Pharmacy worker-directed intervention: not reported

Pharmacy user-directed intervention: patients received the lipid management program: diet and exercise evaluation and instruction, monitoring of cholesterol levels, monitoring of drug therapy, collaboration with physicians, education.

- Delivered by: pharmacist
- Type: behaviour change; education; self-management; lifestyle
- Mode of delivery: individual face-to-face
- TDF: knowledge, skills, goals, behavioural regulation
- Duration: 6 months. seen every 1-2 months, average number of visits: 5

Pharmacy user control: usual treatment

Outcomes
Pharmacy worker: not assessed

Pharmacy user:

- Clinical: total cholesterol; LDL-C; HDL-C; triglyceride levels; health-risk appraisal (wellness assessment questionnaire)
- Psychological health: not assessed
- Behavioural: not assessed
- Quality of life: not assessed
- Process: Pharmaceutical Care Satisfaction Questionnaire (PCSQ); Hyperlipidemia-Patient Knowledge evaluation
- Costs: not assessed

Notes

Study/intervention name: none given

Funding source: Pharmacia-Upjohn Corporation and education grant from Novartis and Bristol-Myers Squibb

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A randomization schedule was developed using a computer-generated list of random numbers"
Allocation concealment (selection bias)	Low risk	As above

Nola 2000 (Continued)

Baseline outcome measures similar	Low risk	No significant differences between groups at baseline
Baseline characteristics similar	Low risk	No significant differences between groups at baseline
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not clear how missing data managed
Blinding of outcome assessment (detection bias) All outcomes	Low risk	No information on blinding but objective outcomes
Protection against contamination	High risk	In-pharmacy randomisation
Selective reporting (reporting bias)	Low risk	Nothing noted
Other bias	Unclear risk	Possible that seasonal fluctuations influenced outcomes
Blinding of participants and personnel (performance bias) All outcomes	High risk	Pharmacists must have been aware of group allocation.

Okada 2018

Methods	Design: cluster-RT Groups: intervention group (lifestyle support for blood pressure); control (usual care)
Participants	Pharmacies: 73 (37 intervention; 36 control) Pharmacy worker: pharmacist ----- Pharmacy user: 125 hypertensive patients (64 intervention; 61 control) <ul style="list-style-type: none"> • mean age: intervention 61.6 ± 9.9 years; control 66.6 ± 9.0 years • % female: intervention 40% ; control 35% Setting: unclear Country: Japan
Interventions	Pharmacy worker-directed intervention: training in motivational interviewing-based communication <ul style="list-style-type: none"> • Delivered by: unclear • Type: communication skills • Mode of delivery: unsure whether face-to-face or some other means • TDF: knowledge, skills • Duration: 4 hours

Okada 2018 (Continued)

Pharmacy worker control: not reported

Pharmacy user-directed intervention: home blood pressure monitoring, healthy lifestyle advice using motivational interviewing and brochures

- Delivered by: community pharmacist
- Type: motivational interviewing
- Mode of delivery: face-to-face + leaflets
- TDF: knowledge, skills, goals, environment, context, resources, behavioural regulation
- Duration: 3 visits
- Follow-up: 12 weeks from baseline, 4 weeks from end of intervention

Pharmacy user control: provided with home blood pressure monitor and basic explanation of medications

Outcomes

Pharmacy worker:

- Uptake: 73 pharmacies recruited but 17 did not recruit any patients)
-

Pharmacy user:

- Clinical: SBP/DBP, BMI
- Psychological health: not assessed
- Behavioural: medication adherence (Morisky Scale), International Physical Activity questionnaire, salt intake
- Quality of life: EuroQol
- Process: attitude and knowledge about hypertension
- Costs: not assessed

Notes

Study/intervention name: COMMunity Pharmacists ASSist for Blood Pressure (COMPASS-BP)

Funding source: KAKENHI Grant in Aid

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Central randomisation
Allocation concealment (selection bias)	Low risk	Central randomisation
Baseline outcome measures similar	High risk	Intervention group had lower blood pressure at baseline
Baseline characteristics similar	High risk	Differences on several measurements at baseline
Incomplete outcome data (attrition bias) All outcomes	Low risk	Final analysis used carry forward method to address missing data
Blinding of outcome assessment (detection bias)	Low risk	Outcome assessment was blinded

Okada 2018 (Continued)

All outcomes

Protection against contamination	Low risk	Cluster design
Selective reporting (reporting bias)	Low risk	Not apparent
Other bias	High risk	Only patients who had adhered sufficiently to a strict 2-week run-in monitoring period were recruited so the sample may not be representative of less motivated individuals.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Group not blinded

Park 1996

Methods	Design: RT Groups: intervention group (Pharmaceutical Scare for Hypertension); control group (usual care)
Participants	Pharmacies: 2 Pharmacy worker: pharmacy resident ----- Pharmacy user: 53 hypertensive patients (27 intervention; 26 control) <ul style="list-style-type: none"> • mean age: intervention 57.3 years; control 63 years • % female: intervention 51.8%; control 50% Setting: urban Country: USA
Interventions	Pharmacy worker-directed intervention: not reported ----- Pharmacy user-directed intervention: patients received counselling on lifestyle modifications that would help them manage their condition, and especially their medical treatment. <ul style="list-style-type: none"> • Delivered by: community pharmacy resident • Type: self-management; disease management • Mode of delivery: individual face-to-face; written materials • TDF: knowledge, goals, environment, context, resources • Number of sessions: 4; session duration: 14.6 to 30.7 minutes per visit • Length of follow-up: 4 months (end of intervention) Pharmacy user control: usual treatment
Outcomes	Pharmacy worker: not assessed ----- Pharmacy user:

Park 1996 (Continued)

- Clinical: blood pressure, heart rate
- Psychological health: not assessed
- Behavioural: adherence (pill count)
- Quality of life: Health Status Questionnaire 2.0 (HSQ) - identical to SF-36, but with 4 questions added; Hypertension/Lipid Form 5.1 (HTN; reported as a quality of life measurement)
- Process: not assessed
- Costs: not assessed

Notes Study/intervention name: none given
Funding source: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, but method not specified. Furthermore, article stated "the randomization was not balanced. Far more control patients (26.9%) than study patients (17.4%) had controlled blood pressure, and more study patients (13%) had stage III hypertension at baseline randomization."
Allocation concealment (selection bias)	High risk	Patients were not aware, but the pharmacy residents were aware of the allocation.
Baseline outcome measures similar	High risk	Reported that at baseline there were differences in blood pressure and severity of hypertension
Baseline characteristics similar	High risk	Reported that at baseline there were differences in blood pressure and severity of hypertension
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Dropouts reported, but not clear how managed
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding
Protection against contamination	High risk	Randomisation at patient level
Selective reporting (reporting bias)	High risk	Whilst significance for outcomes was reported, this was only shown in graphs.
Other bias	Unclear risk	Study sample size may have been underpowered.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "A limitation of this study was that it was a Single-blinded study. The pharmacy residents were aware of patient assignment into two different treatment groups, which could have introduced bias."

Patwardhan 2012

Methods Design: cluster-RT

Patwardhan 2012 (Continued)

Groups: intervention group (tobacco cessation counselling); control group (usual care)

Participants

Pharmacies: 16
Pharmacy worker: 32 pharmacists, 48 technicians
• % female: intervention 57%; control 43%

Pharmacy user: not assessed

Setting: urban

Country: USA

Interventions

Pharmacy worker-directed intervention: Ask-Advise-Refer (AAR) tobacco cessation counselling through 30 minutes on-site training, recommendations for integrating AAR in pharmacy work flow, a cessation poster and a support visit that drew on social cognitive theory. Also given the same materials as the control group.

- Delivered by: researcher
- Type: smoking cessation education
- Mode of delivery: face-to-face; video, groups of 2 to 3 people
- TDF: knowledge, skills, beliefs about capability, environment, context, resources, social support
- Duration: 30 minutes

Pharmacy worker control: received quit line cards (a card with the telephone number to access free behavioural support), an informational presentation about the quit line and its services, and enrolment in a free service called Fax-to-Quit (FTQ). FTQ enabled pharmacies to refer tobacco users proactively to the quit line by faxing a signed consent form that allowed the quit line to call users back directly to initiate cessation treatment.

Pharmacy user-directed intervention: AAR tobacco cessation counselling, given quit line cards which have the telephone number of a quit line which provided free counseling and free medication

- Delivered by: pharmacists
- Type: smoking cessation education
- Mode of delivery: face-to-face; written materials
- Duration: single sessions
- Follow-up: 1 month

Pharmacy user control: received quit line cards and FTQ

Outcomes

Pharmacy worker:

- Behavioural: patient referrals to quit line active (quit line records) and passive (quit line cards distributed)

Pharmacy user: not assessed

Notes

Study/intervention name: none given

Funding: Clinical and Translational Science Award, NIH and Wisconsin Department of Health Services and Sonderegger Research Centre

Patwardhan 2009 and Patwardhan 2010 (cited under [Patwardhan 2012](#)) also refer to the same intervention.

Patwardhan 2012 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Block randomisation
Allocation concealment (selection bias)	Low risk	Researchers blinded to study goal
Baseline outcome measures similar	Low risk	No differences reported
Baseline characteristics similar	Low risk	No differences reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data were collected from objective records
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear who collected data
Protection against contamination	Low risk	Cluster design
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Unclear risk	Outcome measures, except for quit line records, were self-report by pharmacists
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Pharmacy staff not informed of the existence of 2 groups and therefore blind

Paulos 2005

Methods	Design: RT Groups: intervention group (pharmaceutical care for dyslipidaemia); control group ('normal counselling')
Participants	Pharmacies: 1 Pharmacy worker: pharmacists ----- Pharmacy user: 42 patients with dyslipidaemia (23 intervention; 19 control) <ul style="list-style-type: none"> • mean age: men 64 ± 10 years; women 66 ± 11 years • % female: 81% Setting: unclear

Paulos 2005 (Continued)

Country: Chile

Interventions
Pharmacy worker-directed intervention: not described

Pharmacy user-directed intervention: patients received education on the role of cholesterol in illness and health, explaining risk factors associated with cardiovascular disease, and providing education/counselling regarding medication.

- Delivered by: pharmacists
- Type: behaviour change and education; medication management
- Mode of delivery: face-to-face; written materials
- TDF: knowledge, environment, context, resources
- Duration: 16 weeks. 5 interviews in the intervention group; Each interview lasted 20 to 25 minutes.
- Follow-up: 16 weeks (end of intervention)

Pharmacy user control: usual treatment (2 interviews)

Outcomes
Pharmacy worker: not assessed

Pharmacy user:

- Clinical: blood cholesterol; triglyceride levels; BMI; body weight
- Psychological health: not assessed
- Behavioural: drug adherence assessed on visual analogue scale (VAS)
- Quality of life: Health Short-Form-36 survey
- Process: not assessed
- Costs: not assessed

Notes

Study/intervention name: none given

Funding source: not reported although Roche Diagnostics provided Accutrend GCT device and strips.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, but specific method not mentioned
Allocation concealment (selection bias)	Unclear risk	Unclear
Baseline outcome measures similar	Unclear risk	Not reported
Baseline characteristics similar	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear
Blinding of outcome assessment (detection bias) All outcomes	Low risk	No blinding, but objective primary outcome

Paulos 2005 (Continued)

Protection against contamination	High risk	Randomisation at client level
Selective reporting (reporting bias)	High risk	No full reporting of all outcomes at all time points
Other bias	Unclear risk	Not noted
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding

Petkova 2008

Methods	Design: RT Groups: intervention group (asthma self-management); control group (usual care)
Participants	Pharmacies: 10 (those pharmacies with the highest number of asthma patients) ----- Pharmacy user: 50 (22 intervention; 28 control) <ul style="list-style-type: none"> • mean age: intervention 35.14 years; control 40.82 years • % female: intervention 41%; control 31% Setting: urban, Sofia Country: Bulgaria
Interventions	Pharmacy worker-directed intervention: not reported ----- Pharmacy user-directed intervention: education program with information on asthma, medication, inhalers, drug reactions, exacerbation and control of asthma attacks and smoking cessation <ul style="list-style-type: none"> • Delivered by: researcher or undergraduate students • Type: education • Mode of delivery: face-to-face, written materials • TDF: knowledge, skills, environment, context, resources • Duration: 4 sessions held monthly • Length of follow-up: at 4 months (post-intervention) Pharmacy user control: usual treatment
Outcomes	Pharmacy worker: not assessed ----- Pharmacy user: <ul style="list-style-type: none"> • Clinical: PEF • Psychological health: not assessed • Behavioural: inhaler technique, asthma self-monitoring • Quality of life: asthma assessment form

Petkova 2008 (Continued)

- Process: patient satisfaction (direct interview)
- Costs: health care utilisation - hospitalisation and GP visits

Notes Study/intervention name: none given
Funding source: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Assigned based on principle of random numbers
Allocation concealment (selection bias)	Unclear risk	No detail provided
Baseline outcome measures similar	Low risk	No differences on outcomes
Baseline characteristics similar	High risk	Differences between groups at the start of the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	No apparent attrition on main outcomes
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear if assessor blind to group
Protection against contamination	High risk	Pharmacies offer both intervention and control
Selective reporting (reporting bias)	Low risk	Not noted
Other bias	Low risk	Not noted
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear if participants aware of grouping

Petkova 2009

Methods Design: RT
Groups: intervention (arthritis management); control (usual care)

Participants Pharmacies: not reported
Pharmacy worker: not targeted

Pharmacy user: 90 (45 intervention; 45 control)

Petkova 2009 (Continued)

- mean age: intervention 45.74 ± 2.72 years; control 44.58 ± 2.61 years
- % female: intervention 67.4%; control 58.1%

Setting: urban, Sofia

Country: Bulgaria

Interventions

Pharmacy worker-directed intervention: 3-day intensive training. Review of disease, pain management, risks, exercise, joint protection, role-play

- Delivered by: rheumatologist, pharmacist and a therapist
- Type: education
- Mode of delivery: face-to-face; written materials
- TDF: knowledge
- Duration: 3 days

Pharmacy worker control: it appears the same pharmacist delivered intervention and control treatment.

Pharmacy user-directed intervention: education program with information on arthritis, heat-cold therapy, physical training, pain management, self-study leaflets

- Delivered by: pharmacist
- Type: education
- Mode of delivery: face-to-face; written materials
- TDF: knowledge, environment, context, resources
- Duration: 4 sessions held monthly
- Length of follow-up: at 4 months (post intervention)

Pharmacy user control: usual treatment

Outcomes

Pharmacy worker: not assessed

Pharmacy user:

- Clinical: frequency of pain
- Psychological health: not assessed
- Behavioural: medication compliance
- Quality of life: pain interference (Brief Pain Inventory)
- Process: patient satisfaction (satisfaction with services questionnaire)
- Costs: healthcare utilisation - GP visits

Notes

Study/intervention name: none given

Funding source: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Used random number generator
Allocation concealment (selection bias)	Unclear risk	Used random number generator

Petkova 2009 (Continued)

Baseline outcome measures similar	High risk	There were differences between the intervention and control groups at baseline for a variety of variables which were not controlled for in analysis.
Baseline characteristics similar	High risk	Differences in age and healthcare use, without evidence that these were controlled for in analyses
Incomplete outcome data (attrition bias) All outcomes	Low risk	Minimal attrition
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear if assessor knew patient grouping
Protection against contamination	High risk	Randomisation at patient level
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	Not noted
Blinding of participants and personnel (performance bias) All outcomes	High risk	Pharmacists must have been aware of group allocation

Planas 2012

Methods	Design: RT Groups: intervention group (diabetes management); control group (standard care)
Participants	Pharmacies: 5 Pharmacy worker: pharmacists ----- Pharmacy user: 65 patients with diabetes and hypertension (38 intervention; 27 control) • mean age: intervention 63.3 ± 10.8 years; control 63.5 ± 14.5 years • % female: intervention 63.2%; control 51.9% Setting: urban Country: USA
Interventions	Pharmacy worker-directed intervention: training on diabetes management, including the most recent treatment guidelines for diabetes, hypertension and dyslipidaemia, and on study procedures. Compensated by pharmacy chain • Delivered by: investigators • Type: education based on clinical practice guidelines, medication management, disease management • Mode of delivery: (assumed to be) face-to-face • TDF: knowledge • Duration: 23.5 hours in total

Planas 2012 (Continued)

Pharmacy worker control: it appears the same pharmacists delivered treatment to both intervention and control groups.

Pharmacy user-directed intervention: patient education and diabetes management services

- Delivered by: pharmacists
- Type: self management, education based on clinical practice guidelines, medication management, other (disease management)
- Mode of delivery: individual face-to-face
- TDF: knowledge, skills, reinforcement, goals, environment, context, resources, behavioural regulation
- Duration: 9 x 1-hour sessions held monthly
- Clinical outcomes collected at baseline, 3, 6, and 9 months
- Length of follow-up: 9 months (end of intervention)

Pharmacy user control: usual treatment

Outcomes

Pharmacy worker: not assessed

Pharmacy user:

- Clinical: HbA1c, blood pressure, LDL cholesterol
- Psychological health: not assessed
- Behavioural: not assessed
- Quality of life: not assessed
- Process: Healthcare Effectiveness Data and Information Set (HEDIS) performance measures
- Costs: not assessed

Notes

Study/intervention name: none given

Funding source: American Society of Health System Pharmacists Research and Education Foundation

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised by previously generated random number list
Allocation concealment (selection bias)	Unclear risk	Unclear if allocation was concealed
Baseline outcome measures similar	Low risk	No differences reported
Baseline characteristics similar	High risk	Difference in BMI
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Reported that used carry forward of missing data, but some exclusions if the 3 month visit was not attended, also significant dropout
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Variable use of objective primary outcome

Planas 2012 (Continued)

Protection against contamination	Unclear risk	Individuals were allowed to choose what intervention to visit, it is possible that pharmacies offered both intervention and control
Selective reporting (reporting bias)	Low risk	Not noted
Other bias	Unclear risk	All pharmacies belonged to the same chain, which is a cause of potential bias. Each participant had to attend the initial 3 month visit to be included in analyses. Participants who dropped out of the study before the 3 month period were excluded from analyses because no effect of intervention on the outcome measures could be determined.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not mentioned - not blinded

Schmiedel 2015

Methods	Design: cluster-RT Groups: intervention group (diabetes prevention); control group (no treatment)
Participants	Pharmacies: 22 (11 intervention; 11 control) Pharmacy worker: pharmacists ----- Pharmacy user: 1092 (565 intervention; 575 control) <ul style="list-style-type: none"> mean age 57.5 ± 11.3 years % female: 68.6% Setting: unclear Country: Germany (Bavaria)
Interventions	Pharmacy worker-directed intervention: half day training on behaviour change + 1 day on how to conduct the trial <ul style="list-style-type: none"> Delivered by: not reported Type: not reported Mode of delivery: not clear TDF: knowledge Duration: half day training on behaviour change Pharmacy worker control: 1 day training on how to conduct the trial ----- Pharmacy user-directed intervention: 3 individual counselling sessions and 5 group lectures covering diabetes and lifestyle issues and personalised goals. Provided written information on healthy diet and physical activity <ul style="list-style-type: none"> Delivered by: pharmacist Type: behaviour change Mode of delivery: face-to-face (individual and group)

Schmiedel 2015 (Continued)

- TDF: knowledge, goals, environment, context, resources, behavioural regulation
- Duration: 3 individual counselling sessions + 5 x 75- to 90-minute lectures
- Follow-up: 12 months (end of intervention)

Pharmacy user control: assessed and informed about their health status but no further counselling.

Outcomes
Pharmacy worker:

- Uptake: not reported, but 2 of 40 dropped out of trial

Pharmacy user:

- Clinical: change in FINDRISC (Finnish Diabetes Risk Score), weight, BP
- Psychological health: not assessed
- Behavioural: physical activity
- Quality of life: SF12
- Process: not assessed
- Costs: not assessed

Notes

Study/intervention name: GLICEMIA (this is the program name not an acronym)

Funding source: Dr August and Dr Anni Lesmuller-Stiftung Foundation, the Bavarian State Ministry of Public Health and Care Services (through the funding and health promotion initiative Gesund Leben Bayern), the Bavarian State Corporate Health Insurers, and the funding initiative for prevention (Forderinitiative Praventio eV).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No method specified
Allocation concealment (selection bias)	Unclear risk	Not reported
Baseline outcome measures similar	Low risk	No significant differences
Baseline characteristics similar	Low risk	No significant differences
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing data imputed
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Protection against contamination	Low risk	Multi-centre cluster-RT
Selective reporting (reporting bias)	Low risk	None noted

Schmiedel 2015 (Continued)

Other bias	Low risk	None noted
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded

Skowron 2011

Methods	Design: cluster-RT Groups: intervention group (pharmaceutical care for hypertension); control group (standard care)
Participants	Pharmacies: 55 (28 intervention; 27 control) Pharmacy worker: 95 pharmacists (44 intervention; 51 control) ----- Pharmacy user: 193 patients with hypertension (70 intervention; 123 control) <ul style="list-style-type: none"> • mean age: 42.9% aged 46 to 60 years, 39.3% aged 61 to 75 years Setting: urban, Krakow Country: Poland
Interventions	<p>Pharmacy worker-directed intervention: training on detection, classification and monitoring of drug-related problems, pathophysiology of hypertension, risk factors and life-style factors influencing the disease, and rules of pharmacotherapy of hypertension</p> <ul style="list-style-type: none"> • Delivered by: researchers (pharmacists) and physicians (specialists in arterial hypertension and cardiology) • Type: education meetings • Mode of delivery: group • TDF: knowledge • Duration: 3 x 5-hour training sessions • Length of follow-up: end of project <p>Pharmacy worker control: wait list; received the same training as the intervention group after final study visit</p> <p>-----</p> <p>Pharmacy user-directed intervention: patients received pharmaceutical care and were educated about pathophysiology, risk factors, treatment and style of life with hypertension, as well as blood pressure measurement, and self-measurement of blood pressure.</p> <ul style="list-style-type: none"> • Delivered by: pharmacist • Type: self-management; behaviour change; education; medication management • Mode of delivery: individual face-to-face • TDF: knowledge • Duration: 12 meetings from November 2004 to January 2006 • Length of follow-up: post intervention (12 months) <p>Pharmacy user control: usual treatment</p>
Outcomes	Pharmacy worker:

Skowron 2011 (Continued)

- Uptake: not reported, but of original 55 pharmacies and 95 pharmacists randomised only 39 pharmacies and 74 pharmacists were retained in study
- Behavioural: not assessed

Pharmacy user:

- Clinical: SBP/DBP
- Psychological health: not assessed
- Behavioural: not assessed
- Quality of life: SF-36
- Process: knowledge about hypertension (not validated)
- Costs/HCU: not assessed

Notes Study/intervention name: none given
 Funding source: no specific grant

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization of community pharmacies to control and study group was done by generation of random numbers by computer software."
Allocation concealment (selection bias)	Low risk	Quote: "Randomization of community pharmacies to control and study group was done by generation of random numbers by computer software."
Baseline outcome measures similar	Unclear risk	Differences in baseline for education, age and place of residence. Unclear if this was accounted for in the analysis.
Baseline characteristics similar	High risk	Differences in education, age and residence
Incomplete outcome data (attrition bias) All outcomes	High risk	Significant number of dropouts from both groups
Blinding of outcome assessment (detection bias) All outcomes	High risk	No information on blinding
Protection against contamination	Low risk	Randomisation by pharmacies
Selective reporting (reporting bias)	High risk	No numerical reporting of quality of life
Other bias	High risk	High number of control pharmacies withdrew
Blinding of participants and personnel (performance bias) All outcomes	High risk	No information about blinding provided

Slater 2013

Methods	Design: cluster-RT Groups: <ul style="list-style-type: none"> • Intervention group 1: pamphlet + education for low back pain (LBP) • Intervention group 2: pamphlet only • Control group (usual care)
Participants	Pharmacy worker: 35 pharmacies (11 in group 1; 11 in group 2; 13 in control) ----- Pharmacy user: <ul style="list-style-type: none"> • 317 patients with low back pain (LBP): <ul style="list-style-type: none"> * 102 in intervention group 1 (pamphlet + education for LBP) * 111 in intervention group 2 (pamphlet only) * 104 in control group • mean age: <ul style="list-style-type: none"> * intervention group 1: 43.3 ± 13.2 years * intervention group 2: 44.2 ± 12.7 years * control group: 44.3 ± 11.8 years • % female: <ul style="list-style-type: none"> * intervention group 1: 55.9% * intervention group 2: 64.9% * control group: 60.6% Setting: urban Country: Australia
Interventions	<p>Pharmacy worker-directed intervention: pharmacist staff allocated to the pamphlet + education intervention were provided with specific training: pretrial workshops by the study team, during which pharmacists were instructed about the key pamphlet messages to reinforce and were advised about the necessity of delivering these messages strictly in accordance with the pamphlet content.</p> <ul style="list-style-type: none"> • Delivered by: researcher • Type: education meetings • Mode of delivery: group • TDF: knowledge, skills • Duration: not stated <p>Pharmacy worker control: not reported</p> <p>-----</p> <p>Pharmacy user-directed intervention:</p> <p>Intervention group 1 (pamphlet + education): in addition to usual care, participants received verbal reinforcement of the pamphlet's content from a trained pharmacy staff member</p> <p>Intervention group 2 (pamphlet only): in addition to usual care, participants were provided with the pamphlet, but without further specific reinforcement of pamphlet content.</p> <ul style="list-style-type: none"> • Delivered by: pharmacist • Type: self-management; education • Mode of delivery: individual face-to-face; written materials • TDF: knowledge, skills, environment, context, resources, behavioural regulation • Duration: 1 session

Slater 2013 (Continued)

- Length of follow-up: 2 weeks and 8 weeks after baseline

Pharmacy user control: no pamphlet at the time of the trial

Outcomes	<p>Pharmacy worker: not assessed</p> <p>-----</p> <p>Pharmacy user:</p> <ul style="list-style-type: none"> • Clinical: average severity of LBP (unsure whether validated) • Psychological health: not assessed • Behavioural: activity impairment (not validated) • Quality of life: not assessed • Process: beliefs about inevitable consequences of future life with LBP (Back Pain Beliefs Questionnaire (BBQ)); fear avoidance beliefs and attitudes related to LBP (Fear Avoidance Beliefs Questionnaire (FABQ)); perceived usefulness of the pamphlet (Global Perceived Impression of Usefulness (GPIU) scale) • Costs: not assessed 	
Notes	<p>Study/intervention name: none given</p> <p>Funding source: grant by Department of Health, Government of Western Australia and Curtin University</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Pharmacies from within each SEIFA block were then randomised (simultaneously)"
Allocation concealment (selection bias)	Low risk	Quote: "Allocation of pharmacies was concealed from the PSWA [Pharmaceutical Society of Western Australia] and the investigator (KW) [Kim Watkins] who provided access to the clusters."
Baseline outcome measures similar	Low risk	Analyses adjusted for baseline scores
Baseline characteristics similar	Low risk	Analyses adjusted for baseline scores
Incomplete outcome data (attrition bias) All outcomes	Low risk	Used likelihood-based estimation procedure for missing data
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Blinding to group allocation included primary investigators, outcome assessors and the statistician."
Protection against contamination	Low risk	Randomisation by pharmacists
Selective reporting (reporting bias)	Low risk	Nothing noted
Other bias	Unclear risk	Possible selection bias

Slater 2013 (Continued)

Blinding of participants and personnel (performance bias)
 All outcomes

High risk

Quote: "Pharmacy staff and consumers were un-blinded."

Smith 2011

Methods

Design: cluster-RT

Groups: intervention group (goal setting for allergic rhinitis); control group (standard pharmacy care)

Participants

Pharmacies: 20 (8 intervention; 12 control)

Pharmacy workers: 38 (22 clinicians; 16 non-clinicians)

Pharmacy user: 150 patients with intermittent allergic rhinitis (IAR) (77 intervention; 77 control)

- mean age: intervention 38 (20 to 79) years; control 38 (21 to 78) years
- % female: intervention 65%; control 68%

Setting: urban

Country: Australia

Interventions

Pharmacy worker-directed intervention: workshop covering the pathophysiology of allergic rhinitis (AR), the current 'Allergic Rhinitis and its Impact on Asthma' (ARIA) guidelines and pharmacotherapy relating to specific AR symptoms. Also training in self-management theory, goal setting and up-skilling in patient counselling

- Delivered by: not stated
- Type: education meetings; based on clinical practice guidelines; role playing
- Mode of delivery: group
- TDF: knowledge, skills, environment resources and context
- Duration: 3-hour workshop for all, with additional component for intervention pharmacists

Pharmacy worker control: only received the workshop covering the pathophysiology of AR, the current ARIA guidelines and pharmacotherapy relating to specific AR symptoms.

Pharmacy user-directed intervention: patients received an informational brochure and received a goals card titled "My Goals and Treatment Card" where two goals were stated: "Eliminate/minimise hay fever symptoms" and "Avoid/minimise hay fever triggers" to record what they experienced. Individually tailored strategies were developed from these data collaboratively between the participant and the pharmacist or assistant, and entered onto the goals card.

- Delivered by: pharmacist; pharmacist assistant
- Type: self-management; goal setting
- Mode of delivery: individual face-to-face; written materials
- TDF: knowledge, skills, goals, environment, context, resources, behavioural regulation
- Duration: length of intervention: 10 days
- Follow-up: 10 days (end of intervention)

Pharmacy user control: usual treatment and a take-home brochure on AR at follow-up visit

Outcomes

Pharmacy worker: not assessed

Smith 2011 (Continued)

Pharmacy user:

- Clinical: AR symptom severity questionnaire (unsure whether validated)
- Psychological health: not assessed
- Behavioural: Medication Adherence Report Scale (MARS); patient self-report of adherence to medication over the 10-day period (not validated)
- Quality of life: Mini Rhinoconjunctivitis Quality of Life Questionnaire (Mini RQLQ)
- Process: generic self-efficacy for chronic disease management questionnaire adapted for its use in the current study (not validated)
- Costs: not assessed

Notes	Study/intervention name: Pharmacy Allergic Rhinitis Intervention Study (PARIS) Funding source: funded by the Australian Government Department of Health and Ageing as part of the Fourth Community Pharmacy Agreement Research & Development Program managed by the Pharmacy Guild of Australia
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Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, but method not specified
Allocation concealment (selection bias)	Unclear risk	Randomised, but method not specified
Baseline outcome measures similar	Low risk	No significant differences between groups
Baseline characteristics similar	Low risk	No significant differences between groups
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information on blinding
Protection against contamination	Low risk	Randomisation by pharmacists
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Unclear risk	Only a small group of pharmacies
Blinding of participants and personnel (performance bias) All outcomes	High risk	Presumably pharmacy workers knew grouping

Svarstad 2013

Methods	<p>Design: cluster-RT</p> <p>Groups: intervention group (hypertension intervention); control group (usual care)</p>
Participants	<p>Pharmacies 28 (14 intervention; 14 control)</p> <p>Pharmacy worker: pharmacist</p> <p>-----</p> <p>Pharmacy user: 576 black patients with hypertension</p> <ul style="list-style-type: none"> • mean age: intervention 53.2 ± 11 years; control 52.8 ± 11.9 years • % female: intervention 64.9%; control 67.3% <p>Setting: urban</p> <p>Country: USA</p>
Interventions	<p>Pharmacy worker-directed intervention: 7 hours of continuing education through an interactive workshop that included a lecture, slides, handouts, a demonstration and practice, role play case studies, and break-out discussions. One additional hour of self-study, clinical guidelines summary, clinical tools e.g. BP monitoring equipment. Also BP clinic hours established.</p> <ul style="list-style-type: none"> • Delivered by: pharmacy and medical educators • Type: interactive education, no monetary incentive • Mode of delivery: unclear • TDF: skills, environment, context, resources • Duration: 7 hours <p>Pharmacy worker control: not reported</p> <p>-----</p> <p>Pharmacy user-directed intervention: patients were sent brochures and received an intervention using scheduled visits, Brief Medication Questionnaires (BMQs), and new toolkits including a pill organizer, BP tracker, pedometer, and tips and goals</p> <ul style="list-style-type: none"> • Delivered by: pharmacist; pharmacist assistant • Type: self-management; behaviour change; education; based on clinical practice guidelines • Mode of delivery: individual face-to-face; telephone contact; written materials • TDF: knowledge, beliefs about consequences, goals, memory, attention, decision making, environment, context, resources, behavioural regulation • Duration: 6 monthly sessions • Length of follow-up: 6 months (end of intervention) and 12 months • Theory: Svarstad and Bultman's Health Collaboration model, Rogers Diffusion of Innovation model <p>Pharmacy user control: received patient information only, including a 14-page guide for lowering BP, pamphlet about hypertension in black people, and cards showing their BP at baseline and follow-up interviews, and instructions on when to seek immediate medical care for high BP.</p>
Outcomes	<p>Pharmacy worker: not assessed</p> <p>-----</p> <p>Pharmacy user:</p> <ul style="list-style-type: none"> • Clinical: SBP/DBP • Psychological health: not assessed • Behavioural: refill adherence (not validated)

Svarstad 2013 (Continued)

- Quality of life: not assessed
- Process: patient perceptions of pharmacist monitoring (not validated)
- Costs: not effectiveness

Notes

Study/intervention name: Team Education and Adherence Monitoring (TEAM)

Funding source: National Heart, Lung and Blood Institute (NHLBI) #R01HL78580

Svarstad 2009 and Shireman 2016 also refer to this study (cited under [Svarstad 2013](#)).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer software for randomisation
Allocation concealment (selection bias)	Low risk	Computer software for randomisation
Baseline outcome measures similar	Low risk	No differences
Baseline characteristics similar	High risk	Difference between groups for physical activity
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear how managed
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinded data collectors
Protection against contamination	Unclear risk	Randomisation by pharmacy
Selective reporting (reporting bias)	Low risk	Not noted
Other bias	Low risk	Not noted
Blinding of participants and personnel (performance bias) All outcomes	High risk	Clients aware of grouping

Tommelein 2014

Methods

Design: RT

Groups: intervention (pharmaceutical care); control (usual care)

Participants

Pharmacies: 22 (11 intervention; 11 control)

Pharmacy workers: 170

Tommelein 2014 (Continued)

Pharmacy user: 734 chronic obstructive pulmonary disease (COPD) patients (371 intervention; 363 control)

- mean age: intervention 68.4 ± 9.6 years; control 68.9 ± 9.4 years
- % female: intervention 36%; control 31%

Setting: unclear

Country: Belgium

Interventions

Pharmacy worker-directed intervention: training session addressing pathophysiology of COPD and its nonpharmacologic and pharmacological treatment

- Delivered by: unclear
- Type: unclear
- Mode of delivery: unclear
- TDF: knowledge
- Duration: unclear

Pharmacy worker control: not clear whether control pharmacists also received the same training session as intervention pharmacists

Pharmacy user-directed intervention: counselling sessions, addressing basic knowledge of COPD, inhalation technique and self-management and lifestyle issues

- Delivered by: pharmacists
- Type: self-management
- Mode of delivery: 1:1, assumed to be face-to-face
- TDF: knowledge, skills, environment, context, resources
- Duration: 2 sessions of 15 to 25 minutes; 1 at start of study and 1 at 1-month follow-up
- Follow-up: 3 months (2 months after end of intervention)

Pharmacy user control: usual treatment

Outcomes

Pharmacy worker:

- Uptake: not reported

Pharmacy user:

- Clinical: dyspnoea (modified Medical Research Council scale (mMRC), COPD Assessment Test (CAT))
- Psychological health: not assessed
- Behavioural: inhalation technique, adherence (medication refill)
- Quality of life: EQ-5D
- Costs: hospitalisations

Notes

Study/intervention name: Pharmaceutical care of patients with COPD (PHARMACOP)

Funding source: Ghent University, Liège University and GlaxoSmithKline (grant protocol number 114684)

Risk of bias

Bias

Authors' judgement

Support for judgement

Tommelein 2014 (Continued)

Random sequence generation (selection bias)	Low risk	Web-based system
Allocation concealment (selection bias)	Low risk	Central system
Baseline outcome measures similar	Low risk	Similar
Baseline characteristics similar	Low risk	Similar
Incomplete outcome data (attrition bias) All outcomes	Low risk	Analysis accounted for missing data
Blinding of outcome assessment (detection bias) All outcomes	High risk	Pharmacists assessed inhalation techniques
Protection against contamination	Unclear risk	Possible due to design
Selective reporting (reporting bias)	Low risk	Not apparent
Other bias	Low risk	Not noted
Blinding of participants and personnel (performance bias) All outcomes	High risk	Pharmacists not blinded, but patients were not told of group assignment

Tsuyuki 2002

Methods	Design: RT Groups: intervention group (cholesterol risk management); control group (usual care)
Participants	Pharmacies: 54 Pharmacy workers: pharmacists ----- Pharmacy user: 675 patients with high risk of vascular events (344 intervention; 331 control) <ul style="list-style-type: none"> • mean age: intervention 64.2 ± 12.2 years; control 64.6 ± 11.3 years • % female: intervention 41%; control 38% Setting: both urban and rural Country: Alberta and Saskatchewan, Canada
Interventions	Pharmacy worker-directed intervention: training sessions to review the management of heart disease risk factors, especially hyperlipidaemia <ul style="list-style-type: none"> • Delivered by: unclear

Tsuyuki 2002 (Continued)

- Type: education
- Mode of delivery: unclear
- TDF: knowledge
- Duration: unclear

Pharmacy worker control: not reported

Pharmacy user-directed intervention: patients received a brochure; pharmacists completed a physician contact form that listed the patient's risk factors, medications and any recommendations; patients were encouraged to contact physician; and also received education about cardiovascular risk factors to reinforce adherence

- Delivered by: pharmacist
- Type: disease-management
- Mode of delivery: individual face-to-face; written materials
- TDF: knowledge, environment, context, resources
- Duration: participants seen at 2, 4, 8, 12, and 16 weeks; 6 sessions
- Length of follow-up: 4 months (post intervention)

Pharmacy user control: patients given a copy of the same brochure and general advice only

Outcomes	<p>Pharmacy worker: not assessed</p> <p>-----</p> <p>Pharmacy user:</p> <ul style="list-style-type: none"> • Clinical: composite of complete lipid panel • Psychological health: not assessed • Behavioural: not assessed • Quality of life: SF-12 • Process: satisfaction with pharmacy services scale • Costs: cost effectiveness
Notes	<p>Study/intervention name: the Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP)</p> <p>Funding source: University of Alberta Hospital Foundation, Merck Frosst Canada Inc, SCRIP study</p> <p>Tsuyuki 1999, Simpson 2001, and Simpson 2004 (cited under Tsuyuki 2002) also refer to this study.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Block randomisation stratified by pharmacy, computer-generated sequence
Allocation concealment (selection bias)	Low risk	Block size for randomisation was not revealed to ensure allocation concealment
Baseline outcome measures similar	Low risk	Baseline scores controlled for in analyses
Baseline characteristics similar	Low risk	Baseline scores controlled for in analyses

Tsuyuki 2002 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition, balanced across groups
Blinding of outcome assessment (detection bias) All outcomes	High risk	Assessed by pharmacist
Protection against contamination	High risk	Patient-level of randomisation
Selective reporting (reporting bias)	Low risk	Not noted
Other bias	Unclear risk	Pharmacies were highly selected
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study

Tsuyuki 2016 - RxACT

Methods	Design: RT Groups: intervention (dyslipidaemia care); control (usual care + pamphlet on CV risk)
Participants	Pharmacies: 14 Pharmacy workers: 22 (intervention 11; control 11) ----- Pharmacy user: uncontrolled dyslipidaemia 99 (intervention 49; control 50) <ul style="list-style-type: none"> mean age: intervention 63 ± 11.91 years; control 63 ± 13.34 years % female: intervention 53%; control 48% Setting: unclear Country: Alberta, Canada
Interventions	Pharmacy worker-directed intervention: not reported ----- Pharmacy user-directed intervention: identification, assessment, care plan development, education/counselling on CV risk, medications and health behaviour. Also prescribing/titration of lipid-lowering medications and close follow-up. <ul style="list-style-type: none"> Delivered by: pharmacist Type: condition management Mode of delivery: face-to-face TDF: knowledge, goals Duration: sessions every 6 weeks for 6 months Length of follow-up: 6 months (end of intervention)

Tsuyuki 2016 - RxACT (Continued)

Pharmacy user control: usual care, lipid results and a pamphlet on CVD

Outcomes

Pharmacy worker: not assessed

Pharmacy user:

- Clinical: proportion achieving dyslipidaemia guidelines, LDL-C levels
- Psychological health: not assessed
- Behavioural: not assessed
- Quality of life: not assessed
- Process: not assessed
- Costs: not assessed

Notes

Study/intervention name: RxACT (no expansion of this name provided)

Funding source: AstraZeneca grant

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Via a secure website
Allocation concealment (selection bias)	Low risk	Central allocation
Baseline outcome measures similar	Low risk	Similar
Baseline characteristics similar	Low risk	Similar
Incomplete outcome data (attrition bias) All outcomes	Low risk	Last value carried forward for missing data
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Objective outcome
Protection against contamination	High risk	Randomisation at patient level
Selective reporting (reporting bias)	Low risk	Not apparent
Other bias	Low risk	None noted
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding not possible

Tsuyuki 2016 - Rx EACH

Methods	Design: RT Groups: intervention (CV risk assessment and education); control (usual care)
Participants	Pharmacies: 56 Pharmacy worker: 723 (370 intervention; 353 control) ----- Pharmacy user: high risk for CVD 723 <ul style="list-style-type: none"> • mean age: intervention 61 ± 12 years; control 62 ± 12 years • % female: intervention 43%; control 42% Setting: unclear Country: Alberta, Canada
Interventions	<p>Pharmacy worker-directed intervention: online modules on case finding, CVD and risk factors, communicating risk, lifestyle behaviours</p> <ul style="list-style-type: none"> • Delivered: online materials as well as access to experts on CVD • Type: condition management • Mode of delivery: online training and face to face • TDF: knowledge, social support • Duration: unclear <p>Pharmacy worker control: it appears all pharmacists had training and saw both intervention and control patients.</p> <p>-----</p> <p>Pharmacy user-directed intervention: medication therapy management assessment, and education including lifestyle</p> <ul style="list-style-type: none"> • Delivered by: pharmacists • Type: condition management • Mode of delivery: face-to-face • TDF: knowledge • Duration: seen every 3 to 4 weeks for 3 months • Length of follow-up: 3 months (end of intervention) <p>Pharmacy user control: usual care with no specific intervention</p>
Outcomes	<p>Pharmacy worker: not assessed</p> <p>-----</p> <p>Pharmacy user:</p> <ul style="list-style-type: none"> • Clinical: cardiovascular risk, BP, LDL-C, HbA1c • Psychological health: not assessed • Behavioural: smoking cessation • Quality of life: not assessed • Process: not assessed • Costs: not assessed
Notes	Study/intervention name: Alberta Vascular Risk Reduction Community Pharmacy Project (Rx EACH)

Tsuyuki 2016 - Rx EACH (Continued)

Funding source: Alberta Health, Merck Canada funds for educational materials

 Al Hamarneh 2017 and Al Hamarneh 2018 (cited under [Tsuyuki 2016 - Rx EACH](#)) also refer to this study.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Central randomisation
Allocation concealment (selection bias)	Low risk	Central randomisation
Baseline outcome measures similar	Low risk	Similar
Baseline characteristics similar	Low risk	Similar
Incomplete outcome data (attrition bias) All outcomes	Low risk	Accounted for in analysis
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Objective outcome
Protection against contamination	High risk	Pharmacists delivered both intervention and control
Selective reporting (reporting bias)	Low risk	Not apparent
Other bias	Low risk	None detected
Blinding of participants and personnel (performance bias) All outcomes	High risk	Pharmacists not blinded

Venkatesan 2012

Methods	Design: RT Groups: intervention group (pharmaceutical care model for diabetes); control group (usual care)
Participants	Pharmacies: 2 Pharmacy worker: pharmacist ----- Pharmacy user: 39 patients with type 2 diabetes (19 intervention; 20 control) <ul style="list-style-type: none"> • mean age: intervention 51.47 ± 9.99 years; control 57.0 ± 12.05 years • % female: intervention 57.8%; control 50%

Venkatesan 2012 (Continued)

Setting: rural

Country: Tamil Nadu, India

Interventions
Pharmacy worker-directed intervention: not targeted

Pharmacy user-directed intervention: patients received diabetic medication counselling, printer educational material and instructions on dietary regulation, exercise and lifestyle modifications.

- Delivered by: pharmacist
- Type: self-management; education; medication management
- Mode of delivery: individual face-to-face
- TDF: knowledge, goals, behavioural regulation
- Duration: 3 sessions over 8 months (at 2, 4 and 8 months)
- Follow-up at 8 months (post intervention)

Pharmacy user control: usual treatment

Outcomes
Pharmacy worker: not targeted

Pharmacy user:

- Clinical: fasting blood glucose; BMI
- Psychological health: not assessed
- Behavioural: not assessed
- Quality of life: Diabetes Care Profile (DCP)
- Process: health status, understanding, control problem and social and personal factors scales
- Costs: not assessed

Notes

Study/intervention name: none given

Funding source: Tamil Nadu Pharmaceutical Sciences Welfare Trust, Chennai, India

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, but method not specified
Allocation concealment (selection bias)	Unclear risk	Unclear
Baseline outcome measures similar	Unclear risk	Not clear if any differences were significant
Baseline characteristics similar	Unclear risk	Not clear if any differences were significant
Incomplete outcome data (attrition bias) All outcomes	Low risk	No attrition reported
Blinding of outcome assessment (detection bias)	Low risk	Unclear if blinded, but objective outcome

Venkatesan 2012 (Continued)

All outcomes

Protection against contamination	High risk	Randomisation at level of patient
Selective reporting (reporting bias)	Low risk	Objective outcomes presented in text
Other bias	Unclear risk	Low power
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information about blinding

Villeneuve 2010

Methods	Design: cluster-RT Groups: intervention group (collaborative dyslipidaemia management); control group (usual care)
Participants	Pharmacies: 15 (from 148 eligible) Personnel: 77 physicians; 108 pharmacists <ul style="list-style-type: none"> • 51 physicians in 18 clinics; % female: intervention 56%; control 42% • 49 pharmacists in 38 pharmacies; % female: intervention 86%; control 57% ----- Pharmacy user: 225 patients with dyslipidaemia (108 intervention; 117 control) <ul style="list-style-type: none"> • mean age: intervention 59.3 ± 9.6 years; control 62.2 ± 12.0 years • % female: intervention 36%; control 40% Setting: unclear Country: Canada
Interventions	<p>Pharmacy worker-directed intervention: pharmacists in the collaborative care group attended a 1-day training workshop. During this workshop, formal lectures, role-playing and interactive exercises were used to present the Canadian treatment recommendations, guidance about the pharmacotherapy, information about the treatment protocol, and communication strategies for optimising adherence + a 2-hour gathering to discuss the intervention after 1 month.</p> <ul style="list-style-type: none"> • Delivered by: pharmacists, family physicians and a cardiologist • Type: education; illness-management • Mode of delivery: group • TDF: knowledge, skills, memory, attention and decision making, environment resources and context • Duration: 1-day workshop <p>Pharmacy worker control: no additional training</p> ----- <p>Pharmacy user-directed intervention: patients received counselling and a treatment plan, which included lifestyle changes and pharmacotherapy.</p> <ul style="list-style-type: none"> • Delivered by: pharmacists

Villeneuve 2010 (Continued)

- Type: behaviour change
- Mode of delivery: individual face-to-face; written materials
- TDF: knowledge
- Duration: possibly 12 months; initial session 30 minutes, 15-minute titration visits at 2-month intervals, adherence visit (30 minutes) if required, follow-up visit (15 minutes) 3 months later
- Length of follow-up: 12 months

Pharmacy user control: usual treatment

Outcomes

Pharmacy worker: not assessed

Pharmacy user:

- Clinical: change in: LDL-C levels; height; weight; waist circumference; SBP; DBP; target lipids; triglycerides; fasting blood glucose; BMI
- Psychological health: not assessed
- Behavioural: not assessed
- Quality of life: not assessed
- Process: not assessed
- Costs: not assessed

Notes

Study/intervention name: Trial to Evaluate an Ambulatory primary care Management program for patients with dyslipidemia (TEAM)

Funding: funded by a grant from the Canadian Institutes of Health Research (grant number 200409MCT-133732-RCT) and unrestricted research grants from AstraZeneca Canada Inc, Merck Frosst Canada Ltd and Pfizer Canada Inc.

Villeneuve 2009 and Villeneuve 2007 (cited under [Villeneuve 2010](#)) also refer to the same study.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "We stratified the randomization by type of medical clinic and number of physicians per cluster. We also blocked the clusters, with two or four clusters per block and balanced randomization within each block"
Allocation concealment (selection bias)	Low risk	Quote: "We stratified the randomization by type of medical clinic and number of physicians per cluster. We also blocked the clusters, with two or four clusters per block and balanced randomization within each block"
Baseline outcome measures similar	Low risk	Adjustment for baseline in analyses
Baseline characteristics similar	Low risk	Adjustment for baseline in analyses
Incomplete outcome data (attrition bias) All outcomes	Low risk	Used last value carried forward approach
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided on blinding

Villeneuve 2010 (Continued)

Protection against contamination	Low risk	Randomisation by pharmacy
Selective reporting (reporting bias)	Unclear risk	Unclear
Other bias	Unclear risk	Only 15 of 148 clusters eligible and agreed to participate
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information on blinding

Weinberger 2002

Methods	Design: cluster-RT Groups: <ul style="list-style-type: none"> • Intervention: pharmaceutical care program (PCP) for asthma or COPD • Control: <ul style="list-style-type: none"> * peak flow monitoring control group (PFMCG) * usual care control group (UCCG)
Participants	Pharmacies: 36 (12 pharmacies per group) Pharmacy worker: ----- Pharmacy user: 1113 patients with asthma or COPD (447 PCP; 363 PFMCG; 303 UCCG) <ul style="list-style-type: none"> • mean age: UCCG: 62.2 ± 11.9 years; PCP: 62.2 ± 11.0 years; PFMCG: 62.9 ± 10.3 years • % female: UCCG: 67.4%; PCP: 63.5%; PFMCG: 66.2% Setting: urban Country: Indianapolis, USA
Interventions	<p>Pharmacy worker-directed intervention: included an overview of pharmaceutical care, orientation to study, interpretation and use of data, measuring PEF, resources.</p> <ul style="list-style-type: none"> • Delivered by: "Investigators representing various backgrounds" • Type: education • Mode of delivery: face-to-face • Duration: unclear <p>Pharmacy worker control: pharmacists received 4-hour training, but were excluded from PCP</p> <p>-----</p> <p>Pharmacy user-directed intervention: patients received individualised handouts based on problems associated with specific clinical data stored on the computer</p> <ul style="list-style-type: none"> • Delivered by: pharmacist • Type: behaviour change • Mode of delivery: individual face-to-face; written materials • TDF: knowledge, environment, context, resources

Weinberger 2002 (Continued)

- Duration: unclear
- Length of follow-up: 1 year (possibly at end of intervention period)

Pharmacy user control: usual care

Outcomes

Pharmacy worker: not assessed

Pharmacy user:

- Clinical: PEFR
- Psychological health: not assessed
- Behavioural: medication compliance
- Quality of life: disease-specific health-related quality of life (HRQOL)
- Process: patient satisfaction (validated)
- Costs: breathing-related emergency department or hospital visits

Notes

Study/intervention name: none given

Funding source: Agency for Healthcare Research and Quality and the Health Services Research and Development Service, Department of Veteran Affairs (grant 5 R01 HS09083)

Weinberger 2001 (cited under [Weinberger 2002](#)) also refers to the same study.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Used random number chart
Allocation concealment (selection bias)	Low risk	Quote: "interviewers, blinded to study group assignment, obtained informed consent and conducted baseline interviews. After completing the interview, the laptop computer used to administer interviews revealed the patient's study group assignment." At that time, interviewers distributed peak flow meters as appropriate.
Baseline outcome measures similar	Low risk	Differences between groups controlled for in analyses
Baseline characteristics similar	Low risk	Differences between groups controlled for in analyses
Incomplete outcome data (attrition bias) All outcomes	High risk	Dropouts had worse breathing problems at 12 months
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Interviewers blinded
Protection against contamination	Low risk	Cluster randomised
Selective reporting (reporting bias)	Low risk	Not noted

Weinberger 2002 (Continued)

Other bias	High risk	Fidelity may have been low, as pharmacists only implemented protocol approximately 50% of the time
Blinding of participants and personnel (performance bias) All outcomes	High risk	Pharmacists aware of groupings

Yuksel 2010

Methods	Design: RT Groups: intervention group (osteoporosis risk management); control group (usual care)
Participants	Pharmacy worker: not targeted ----- Pharmacy user: 262 patients with osteoporosis (129 intervention; 133 control) <ul style="list-style-type: none"> • mean age: intervention 61 years; control 63 years • % female: intervention 62%; control 67% Setting: unclear Country: Canada
Interventions	Pharmacy worker-directed intervention: not reported ----- Pharmacy user-directed intervention: patients received tailored education program on aspects of osteoporosis; including risk factors, bone mineral density testing, lifestyle measures, calcium and vitamin D intake, and medications and written information, and discussion of heel ultrasound <ul style="list-style-type: none"> • Delivered by: pharmacists • Type: behaviour change • Mode of delivery: individual face-to-face; written materials • TDF: knowledge, environment, context, resources • Duration: 30-minute consultation Pharmacy user control: usual treatment and information provided by pharmacy
Outcomes	Pharmacy worker: not assessed ----- Pharmacy user: <ul style="list-style-type: none"> • Clinical: bone mineral density • Psychological health: not assessed • Behavioural: calcium and Vitamin D intake • Quality of life: SF-12 and Osteoporosis Targeted Quality of Life questionnaire (OPTQoL) • Process: not assessed • Costs: not assessed
Notes	Study/intervention name: OSTEOPHARM (no expansion of acronym provided).

Yuksel 2010 (Continued)

By a grant from the Institute of Health Economics (Edmonton) and Faculty Start Up Grant to Nesé Yuksel from the Faculty of Pharmacy and Pharmaceutical Sciences (University of Alberta)

Yuksel 2006 (cited under [Yuksel 2010](#)) also refers to this study.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Internet randomisation
Allocation concealment (selection bias)	Low risk	Internet randomisation
Baseline outcome measures similar	Low risk	Similar
Baseline characteristics similar	Low risk	Similar - control group had higher family history of osteoporosis but unlikely to change result
Incomplete outcome data (attrition bias) All outcomes	Low risk	Used intention-to-treat analysis; similar dropout in both groups
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinded
Protection against contamination	High risk	Both groups were based in the same pharmacies
Selective reporting (reporting bias)	Low risk	Not noted
Other bias	Low risk	Not noted
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded

BMI: body-mass index; **BP:** blood pressure; **cluster-RT:** cluster randomised trial; **COPD:** chronic obstructive pulmonary disease; **CV:** cardiovascular; **CVD:** cardiovascular disease; **DBP:** diastolic blood pressure; **EQ-5D:** Euroqol Measure of quality of life; **FEV1:** forced expiratory volume in 1 second; **FVC:** forced vital capacity; **GP:** general practitioner (family doctor); **HbA1c:** glycosylated haemoglobin; **HCU:** health care utilisation; **HDL:** high-density lipoprotein; **HDL-C:** high-density lipoprotein cholesterol; **LDL:** low-density lipoprotein; **LDL-C:** low-density lipoprotein cholesterol; **NHS:** National Health Service; **PEF:** peak expiratory flow; **PEFR:** peak expiratory flow rate; **RT:** randomised trial; **SBP:** systolic blood pressure; **SD:** standard deviation; **SF-12:** short form-12; **STD:** sexually transmitted disease; **TC:** total cholesterol; **TDF:** theoretical domains framework; **WHO:** World Health Organization

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Ahrens 2003	Compared 2 active intervention groups

Study	Reason for exclusion
Aleo 2014	Inappropriate intervention
Ammari 2013	Compared 2 active intervention groups. Control not randomised or representative
Anderson 1995	Inappropriate design, retrospective controlled study
Anderson 2003	Inappropriate design
Armour 2004	Inappropriate design
Armour 2013	Compared 2 active intervention groups; 3 versus 4 counselling sessions
Basheti 2005	Compared 3 active intervention groups - 3 forms of verbal counselling for turboinhaler device
Bauld 2009	Compared 2 active intervention groups - 1:1 versus group smoking cessation
Bernsten 2001	Inappropriate intervention
Bock 2010	Compared 2 intervention groups; control group not concurrent or randomised
Butt 2016	Not community pharmacy
Chabot 2003	Inappropriate design
Chalker 2002	Unclear intervention - focus primarily on medication, no valid outcomes
Cody 1998	Not community pharmacy
Correr 2009	Inappropriate intervention
Crawford 2013	No validated outcomes, only process-level outcomes (pharmacy support for service)
De Vera 2014	Inappropriate intervention
de Vries 2010	Inappropriate intervention
Denig 2003	Inappropriate intervention
DeRemer 2008	Inappropriate design
DiDonato 2013	Inappropriate design
Ditusa 2001	Not community pharmacy
Ekedahl 2008	Inappropriate intervention
Fera 2008	Inappropriate design
Fikri-Benbrahim 2012	Inappropriate design
Fornos 2006	Inappropriate intervention
Fuller 2007	Inappropriate outcomes
Garcao 2002	Inappropriate intervention

Study	Reason for exclusion
Goeree 2013	Inappropriate intervention
Gorgas 2012	Inappropriate intervention
Grainger-Rousseau 1997	Inppropriate intervention
Green 2008	Not community pharmacy
Haga 2017	Inappropriate intervention
Herborg 2001	Inappropriate design
Kaczorowski 2008	Not community pharmacy
Karwalajtys 2009	Inapppropriate intervention
Kradjan 1999	Inappropriate outcome
Krass 2011	Comparison of 2 active interventions (6 months versus 12 months) and no control group
Kritikos 2007	Inappropriate design
Kumar, 2009	Not community pharmacy
Lalonde 2008 - PRoFIL	Inappropriate intervention
Lugo de Ortellado 2007	Inappropriate intervention
Manfrin 2015	Inappropriate intervention
Mangiapane 2005	Inappropriate design
Marra 2012	The intervention included both education from a pharmacist, exercise from a physiotherapist and referral to a self-management programme. It was not possible to identify the contribution of the pharmacist's intervention.
Marrero 2006	Inappropriate intervention
Meijer 2005	No validated outcome
Michie 2014	No validated outcomes
Michiels 2017a	Inappropriate intervention
Noor 2016	Inappropriate design
O'Dwyer 2016	Inappropriate intervention
Obarcanin 2015	Not community pharmacy
Olivera 2016	Inappropriate intervention
Phimarn 2017	Inappropriate design - comparison of 2 interventions
Podhipak 1993	Inappropriate intervention

Study	Reason for exclusion
Prokhorov 2010	2 active interventions (smoking cessation counselling versus skin cancer prevention counselling); only process outcomes and not validated.
Ratanajamit 2002	Inappropriate intervention
Rickles 2006	Inappropriate intervention
Rouleau 2007	Unable to retrieve
Rubio-Valera 2009	Inappropriate intervention
Saini 2008	Inappropriate design
Saji 2012	Inappropriate setting (clinic and pharmacy)
Santos 2010	Unable to retrieve
Sarayani 2012	3 active interventions (3 different intervention formats) and only process outcomes
Sarkadi 2004	Inappropriate outcomes
Sinclair 1998	No objective outcomes, only self-reported smoking status provided
Sperandio 2012	Inappropriate intervention
Stergachis 2002	Not community pharmacy (< 50% community pharmacy)
Suppakitporn 2005	Not community pharmacy
Taskila 2012	Compared 2 active interventions
Thavorn 2008	Not community pharmacy
Tobari 2010	Not community pharmacy
Tsuyuki 2015	Not clear whether it was community pharmacy
Tumwikirize 2004	Inappropriate intervention
Usami 2009	Unable to retrieve
Van de Steeg-van 2011	Inappropriate intervention
Viens 2007	Inappropriate intervention
Wang 2013	Inappropriate intervention
Watson 2002	Inappropriate design
Westrick 2016	Comparison of 2 interventions, no control group
Wilson 2004	Inappropriate intervention/design
Young 2012	Setting not clearly community pharmacy

Characteristics of ongoing studies [ordered by study ID]

Davis 2016

Trial name or title	Effectiveness of a pharmacist-driven intervention in COPD (EPIC)
Methods	Design: cluster-RT Groups: intervention group (enhanced care for management of COPD); control group (usual care)
Participants	Pharmacies: 20 (10 intervention; 10 control) Pharmacy workers: pharmacists ----- Pharmacy users: 140 patients with COPD Setting: unclear Country: Canada
Interventions	Pharmacy worker-directed intervention: refresher COPD management training, and how to deliver the intervention Pharmacy worker control: training on study protocols ----- Pharmacy user-directed intervention: 7 elements: <ul style="list-style-type: none"> • an education pamphlet: • medication review • patient education • a written COPD action plan provided in collaboration with the family physician (see next point) • patient referral to pulmonary rehabilitation in collaboration with the family physician • provision of, or referral to, smoking cessation counselling (where applicable), and • referral to a community-based chronic disease self-management program Delivered by: pharmacists Type: condition management Mode of delivery: face-to-face Duration: over 1 or 2 visits Pharmacy user control: usual care and a COPD education pamphlet
Outcomes	Pharmacy worker: not targeted ----- Pharmacy user: <ul style="list-style-type: none"> • Clinical: not assessed • Psychological health: not assessed • Behavioural: Adherence Medication Possession Ratio and Morisky scale • Quality of life: St George's Respiratory questionnaire • Process: not assessed • Costs: frequency of physician visits, hospitalisations, emergency department visits
Starting date	May 2016

Davis 2016 *(Continued)*

Contact information emdavis@mun.ca

Notes Funding: Health Research Foundation: Canada

Ekers 2017

Trial name or title Community pHarmacIEs Mood Intervention STudy (CHEMIST)

Methods Design: pilot RT
 Groups: intervention group (enhanced support for depression); control group (usual care)

Participants Pharmacies: 7
 Pharmacy users: 130

 Pharmacy users: patients with sub-threshold depression
 Setting: unclear
 Country: UK

Interventions **Pharmacy worker-directed intervention:** none specific but pharmacists must have experience of extended role or training to Royal Society of Public Health standard (Understanding Health Improvement Level 2).

 Pharmacy user-directed intervention: behavioural activation focused self-help support; proactive follow-up; symptom monitoring; and decision supported signposting

- Delivered by: pharmacists
- Type: condition management
- Mode of delivery: face-to-face
- Duration: 4 to 6 sessions over 4 months

Pharmacy user control: usual care

Outcomes **Pharmacy worker:** not targeted

 Pharmacy user:

- Clinical: not assessed
- Psychological health: depression, anxiety
- Behavioural: participants use of intervention
- Quality of life: SF-12, EQ-5D
- Process: qualitative interviews
- Costs: AD-SUS (Adult Service Use Schedule)

Starting date 13 June 2016

Contact information liz.littlewood@york.ac.uk; david.ekers@york.ac.uk

Ekers 2017 (Continued)

Notes	Funding NIHR
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Michiels 2017

Trial name or title	Impact of a Community Pharmacy-Based Information Program on Type 2 Diabetic Patients' Adherence to Their Oral Treatment: (Iphodia)
Methods	Design: cluster-RT Groups: intervention group (diabetes management); control group (usual care)
Participants	Pharmacies: 182 ----- Pharmacy users: 800 patients with type 2 diabetes (required from sample size calculation) Setting: unclear Country: France
Interventions	Pharmacy worker-directed intervention: not reported ----- Pharmacy user-directed intervention: thematic information on diabetes, namely diet for diabetics, monitoring drug treatment and the complications of diabetes <ul style="list-style-type: none">• Delivered by: pharmacist• Type: self-management• Mode of delivery: face-to-face• Duration: 3 x 30-minute visits over 6 months Pharmacy user control: usual care
Outcomes	Pharmacy worker: unclear ----- Pharmacy user: <ul style="list-style-type: none">• Clinical: HbA1c• Psychological health: not assessed• Behavioural: adherence - Medication Possession Ratio• Quality of life: not assessed• Process: knowledge, satisfaction• Costs: not assessed
Starting date	1 March 2014
Contact information	Dr Yves Michiels
Notes	Funding source: MSG, France

Porteous 2013

Trial name or title	Help for Hayfever
Methods	Design: pilot cluster-RT Groups: intervention group (hay fever management); control group (usual care)
Participants	Pharmacies:12 Pharmacy workers: at least one pharmacist and pharmacy assistant per pharmacy ----- Pharmacy users: 144 patients with allergic rhinitis Setting: unclear Country: Scotland
Interventions	Pharmacy worker-directed intervention: 3-hour training workshop in self-management theory, the use of goal-setting as a behaviour-change technique ----- Pharmacy user-directed intervention: setting and achieving goals that aim to avoid/minimise triggers for, and eliminate/minimise symptoms of allergic rhinitis, including problem solving <ul style="list-style-type: none">• Delivered by: pharmacy workers• Type: behaviour change• Mode of delivery: face-to-face• Duration: unclear Pharmacy user control: usual care
Outcomes	Pharmacy worker: uptake ----- Pharmacy user: <ul style="list-style-type: none">• Clinical: symptom severity• Psychological health: not assessed• Behavioural: medication adherence• Quality of life: mini-rhinoconjunctivitis quality of life questionnaire, EQ-5D• Costs: pharmacy and health service costs, QALYs
Starting date	April 2012
Contact information	t.porteous@abdn.ac.uk
Notes	Funded by the Chief Scientist Office of the Scottish Government.

Spadaro 2010

Trial name or title	GIFT (the Genetic Informatics Trial of Warfarin to Prevent Deep Vein Thrombosis trial)
Methods	Design: RT Groups: intervention group (community pharmacy follow-up); control group (usual care)

Spadaro 2010 (Continued)

Participants	<p>Pharmacy worker: not reported</p> <p>-----</p> <p>Pharmacy users: 220 patients with heart failure</p> <p>Setting: unclear</p> <p>Country: Italy</p>
Interventions	<p>Pharmacy worker-directed intervention: informed about epidemiological relevance of heart failure and therapeutic management</p> <ul style="list-style-type: none"> • Delivered by: unclear • Type: unclear • Mode of delivery: unclear • Duration: 9 meetings <p>Pharmacy worker control: no intervention</p> <p>-----</p> <p>Pharmacy user-directed intervention: patients and relatives receive education in hospital, then community pharmacy follow-up</p> <ul style="list-style-type: none"> • Delivered by: pharmacists • Type: behaviour change • Mode of delivery: individual face-to-face; written materials • Duration: unclear <p>Pharmacy user control: usual care</p>
Outcomes	<p>Pharmacy worker: not assessed</p> <p>-----</p> <p>Pharmacy user:</p> <ul style="list-style-type: none"> • Clinical: not assessed • Psychological health: not assessed • Behavioural: not assessed • Quality of life: SF-12 • Process: not assessed • Costs: not assessed
Starting date	October 2010
Contact information	Francesca Spadaro
Notes	Funding source: unclear

Abbreviations

COPD: chronic obstructive pulmonary disease; **EQ-5D:** EuroQol measure of quality of life; **HbA1c:** glycosylated haemoglobin; **QALY:** quality adjusted life year; **SF-12:** Short Form-12

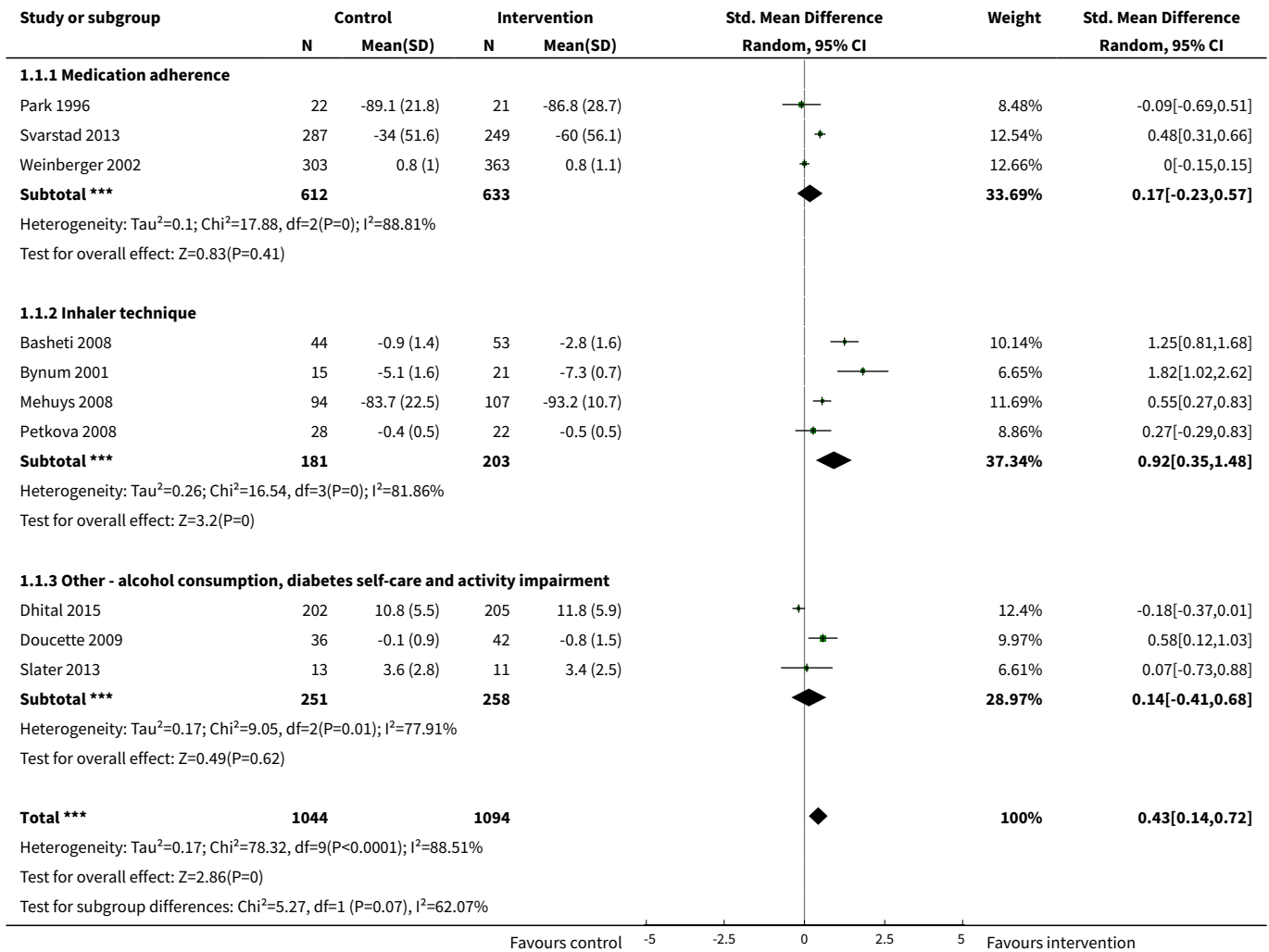
DATA AND ANALYSES

Comparison 1. Community pharmacy user health-promotion intervention versus usual treatment

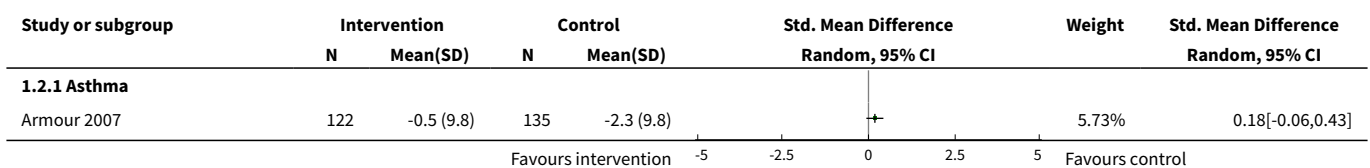
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Health-related behaviour	10	2138	Std. Mean Difference (IV, Random, 95% CI)	0.43 [0.14, 0.72]
1.1 Medication adherence	3	1245	Std. Mean Difference (IV, Random, 95% CI)	0.17 [-0.23, 0.57]
1.2 Inhaler technique	4	384	Std. Mean Difference (IV, Random, 95% CI)	0.92 [0.35, 1.48]
1.3 Other - alcohol consumption, diabetes self-care and activity impairment	3	509	Std. Mean Difference (IV, Random, 95% CI)	0.14 [-0.41, 0.68]
2 Intermediate clinical outcomes (final value scores)	20	3971	Std. Mean Difference (IV, Random, 95% CI)	-0.43 [-0.65, -0.21]
2.1 Asthma	8	2120	Std. Mean Difference (IV, Random, 95% CI)	-0.20 [-0.40, -0.00]
2.2 Diabetes	6	651	Std. Mean Difference (IV, Random, 95% CI)	-0.81 [-1.60, -0.02]
2.3 Hypertension	4	1050	Std. Mean Difference (IV, Random, 95% CI)	-0.34 [-0.49, -0.18]
2.4 CVD/dyslipidaemia	2	150	Std. Mean Difference (IV, Random, 95% CI)	-0.08 [-0.40, 0.24]
3 Intermediate clinical outcome (mean change scores)	7	1413	Std. Mean Difference (IV, Random, 95% CI)	-0.27 [-0.38, -0.17]
3.1 Asthma	2	467	Std. Mean Difference (IV, Random, 95% CI)	-0.14 [-0.32, 0.04]
3.2 Diabetes	2	133	Std. Mean Difference (IV, Random, 95% CI)	-0.30 [-0.64, 0.05]
3.3 Hypertension	1	546	Std. Mean Difference (IV, Random, 95% CI)	-0.36 [-0.53, -0.19]
3.4 Lipids	2	267	Std. Mean Difference (IV, Random, 95% CI)	-0.34 [-0.67, -0.00]
4 Quality of life	10	2733	Std. Mean Difference (IV, Random, 95% CI)	0.30 [0.10, 0.50]
4.1 Generic quality of life	5	1567	Std. Mean Difference (IV, Random, 95% CI)	0.21 [-0.10, 0.52]
4.2 Asthma-specific	5	1120	Std. Mean Difference (IV, Random, 95% CI)	0.38 [0.08, 0.67]

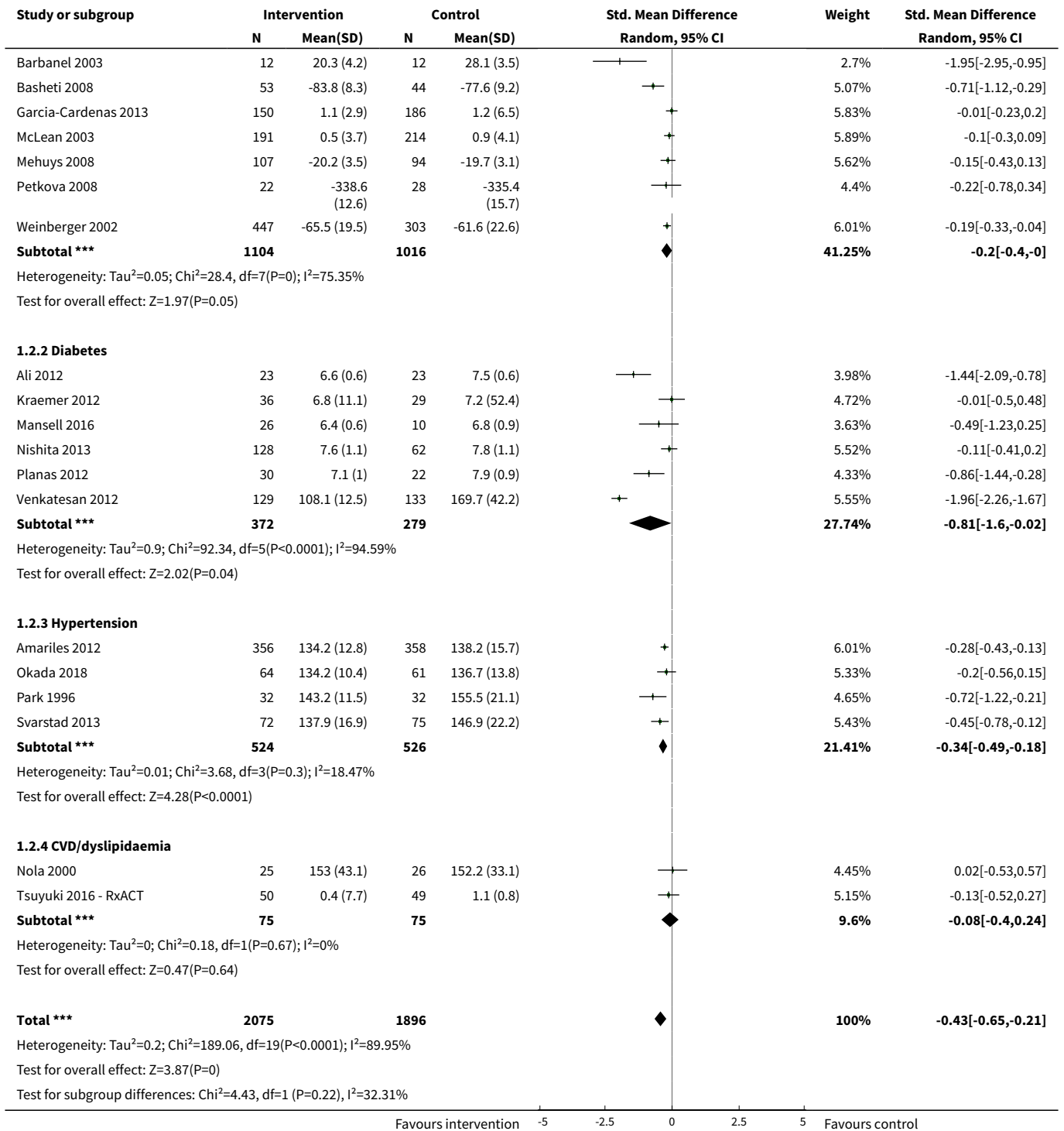
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.3 Diabetes-specific	1	46	Std. Mean Difference (IV, Random, 95% CI)	0.48 [-0.11, 1.06]

Analysis 1.1. Comparison 1 Community pharmacy user health-promotion intervention versus usual treatment, Outcome 1 Health-related behaviour.

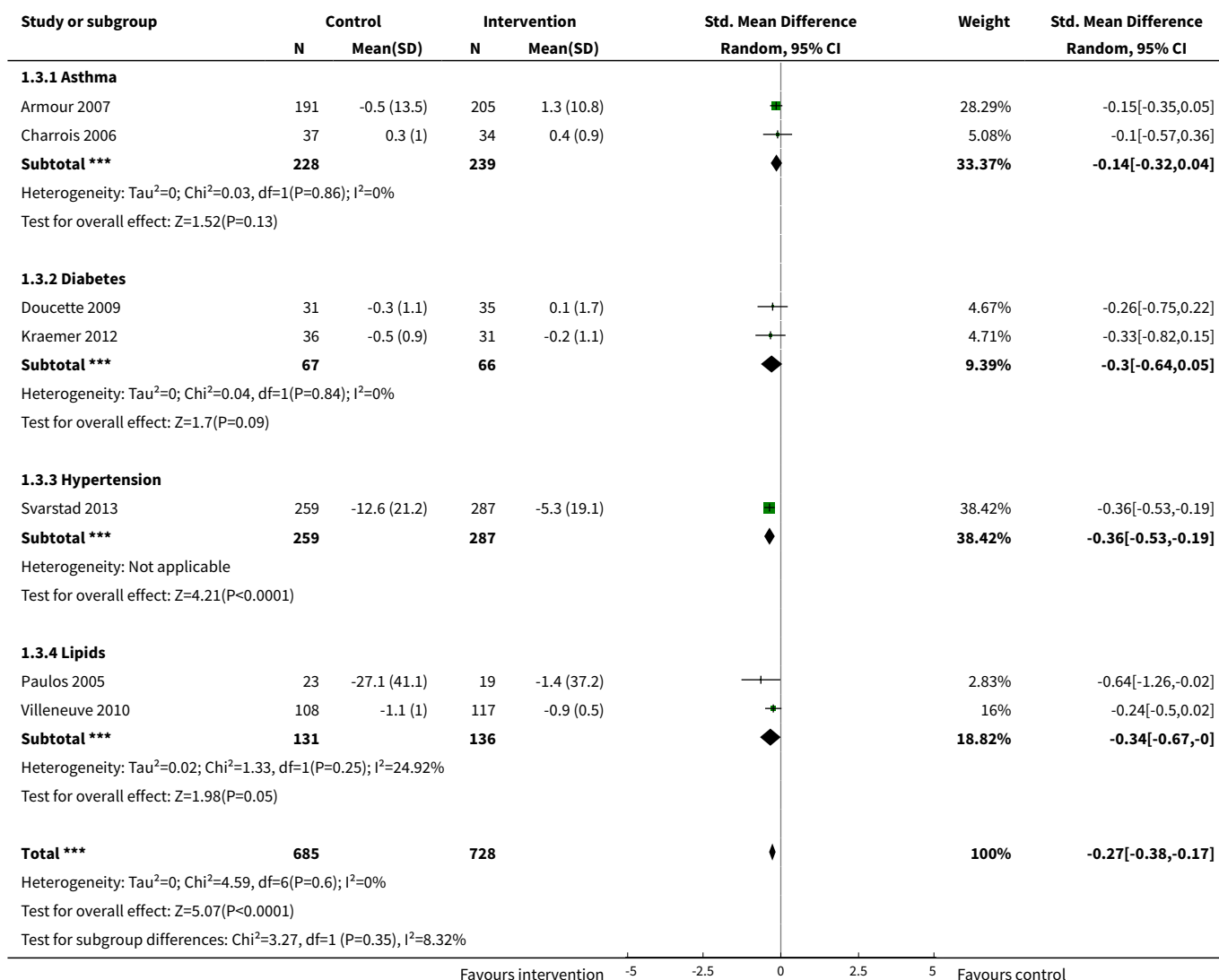


Analysis 1.2. Comparison 1 Community pharmacy user health-promotion intervention versus usual treatment, Outcome 2 Intermediate clinical outcomes (final value scores).

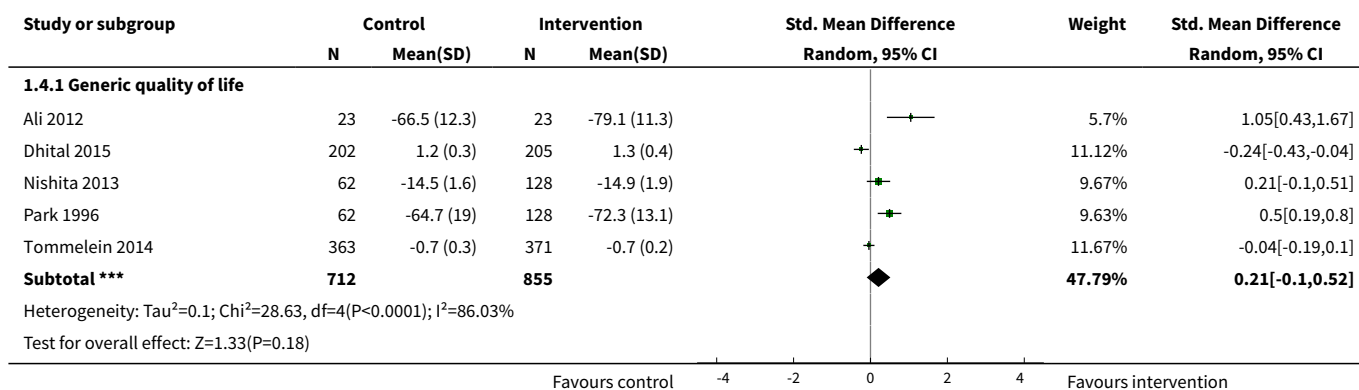


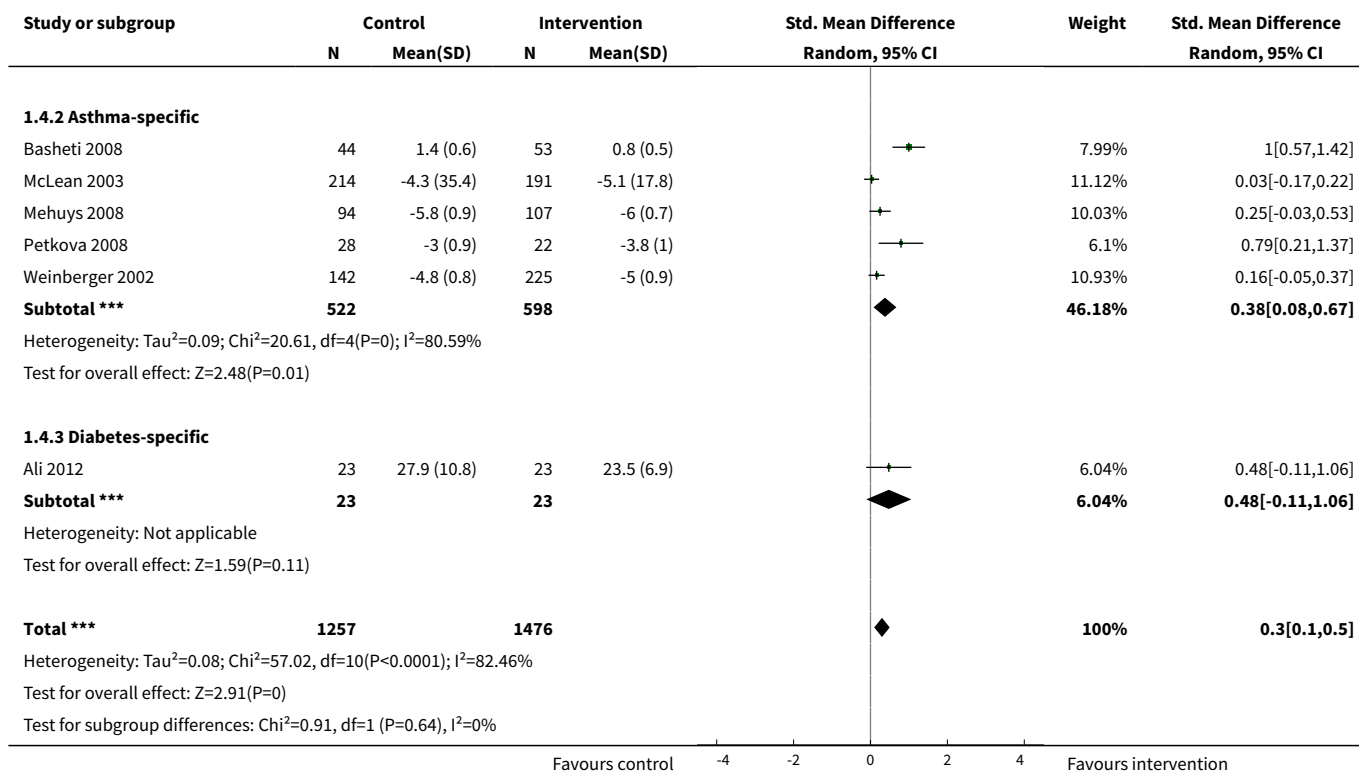


Analysis 1.3. Comparison 1 Community pharmacy user health-promotion intervention versus usual treatment, Outcome 3 Intermediate clinical outcome (mean change scores).



Analysis 1.4. Comparison 1 Community pharmacy user health-promotion intervention versus usual treatment, Outcome 4 Quality of life.





ADDITIONAL TABLES

Table 1. Studies included and excluded from meta-analysis of behavioural outcome

	Adherence	Inhaler technique	Other behaviours
Studies included in the meta-analysis and outcome measure used	<ul style="list-style-type: none"> Pharmacy records: Park 1996; Svarstad 2013; Weinberger 2002 	<ul style="list-style-type: none"> Technique checklist: Basheti 2008; Bynum 2001; Mehuys 2008; Petkova 2008 	<ul style="list-style-type: none"> Diabetes self-care: Doucette 2009 Alcohol consumption: Dhital 2015 Activity impairment: Slater 2013
Studies excluded from the meta-analysis with reasons for exclusion	<ul style="list-style-type: none"> Data poorly presented: Mehuys 2008 Mean change data: Armour 2007; Okada 2018 Median score data: Smith 2011 Dichotomous data: Garcia-Cardenas 2013; Villeneuve 2010 Unvalidated measure: Crockett 2006; Paulos 2005; Petkova 2009 	<ul style="list-style-type: none"> Dichotomous data: Cordina 2001; Garcia-Cardenas 2013; Tommelein 2014 	<ul style="list-style-type: none"> Dichotomous data for: <ul style="list-style-type: none"> * quitting smoking: Burford 2013; Maguire 2001; Madurasinghe 2017 * heroin use: Jaffray 2014 Mean change data for exercise: Okada 2018 Unvalidated measures for: <ul style="list-style-type: none"> * sleep: Fuller 2016 * exercise: Schmiedel 2015; Mansell 2016 * self-monitoring of blood glucose: Mansell 2016

Table 2. Studies included and excluded from meta-analysis of intermediate clinical outcomes

	Asthma	Diabetes	CVD/hypertension	Other conditions
Studies included in the meta-analysis with outcome measure used	<ul style="list-style-type: none"> ACQ/symptoms: Barbanel 2003; Garcia-Cardenas 2013; McLean 2003; Mehuys 2008 FEV: Armour 2007 PEF variability: Basheti 2008; Petkova 2008; Weinberger 2002 	<ul style="list-style-type: none"> HbA1c: Ali 2012; Kraemer 2012; Mehuys 2011; Mansell 2016; Nishita 2013; Planas 2012; Venkatesan 2012 	<ul style="list-style-type: none"> SBP: Amariles 2012; Park 1996; Okada 2018; Svarstad 2013 Lipids-LDL: Nola 2000; Tsuyuki 2016 - RxEACH 	
Studies excluded from the meta-analysis, with reasons for exclusion	<ul style="list-style-type: none"> Data poorly presented: Charrois 2006 	<ul style="list-style-type: none"> Data mean change: Doucette 2009 Data interquartile range: Adepu 2007 Risk of diabetes: Schmiedel 2015 	<ul style="list-style-type: none"> Dichotomous SBP data: Bond 2007; Tsuyuki 2002; Tsuyuki 2016 - RxACT Cluster not accounted for: Skowron 2011 Mean change: Schmiedel 2015 Lipids data mean change: Paulos 2005; Villeneuve 2010 	<ul style="list-style-type: none"> Non valid measure: Smith 2011 - rhinitis; Petkova 2009 - pain; Slater 2013 - pain Interquartile range: Jaffray 2014

Abbreviations

ACQ: Asthma Control Questionnaire; **FEV:** forced expiratory volume ; **HbA1c:** glycosylated haemoglobin; **LDL:** low-density lipoprotein; **PEF:** peak expiratory flow; **SBP:** systolic blood pressure

Table 3. Studies included and excluded from meta-analysis of quality of life

	Generic	Asthma specific	Diabetes specific	Other illness specific
Studies included in the meta-analysis and outcome measure used	<ul style="list-style-type: none"> SF-36: Ali 2012; Park 1996 EQ-5D: Dhital 2015; Tommelein 2014 WhoQol: Nishita 2013 	<ul style="list-style-type: none"> Basheti 2008; McLean 2003; Mehuys 2008; Petkova 2008; Weinberger 2002 		
Studies excluded from the meta-analysis and reasons for exclusion	<ul style="list-style-type: none"> Insufficiently reported: Bond 2007; Cordina 2001; Okada 2018; Paulos 2005; Krass 2007; Skowron 2011; Schmiedel 2015; Tsuyuki 2002; Yuksel 2010 	<ul style="list-style-type: none"> Insufficiently reported: Armour 2007; Barbanel 2003; Cordina 2001 	<ul style="list-style-type: none"> Insufficiently reported: Adepu 2007; Kraemer 2012; Venkatesan 2012 	<ul style="list-style-type: none"> Insufficiently reported: Petkova 2009 - BPI; Jaffray 2014 - MAP; Smith 2011 - RQLQ

Abbreviations

BPI: Back Pain Index; **EQ-5D:** Euroqol quality of life measure; **MAP:** Maudsley Addiction Profile; **RQLQ:** Rhinitis Quality of Life Questionnaire; **SF-36:** Short Form-36;

APPENDICES

Appendix 1. Search Strategies

MEDLINE (OVID)

Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily, Ovid MEDLINE and Versions(R) <1946 to January 31, 2018>

No.	Search terms
1	community pharmacy services/
2	((pharmacy or pharmacist? or pharmacies) adj2 (community or communities)).ti,ab,kf.
3	((pharmacy or pharmacist? or pharmacies) adj2 intervention?).ti,ab,kf.
4	pharmaceutical care.ti,ab,kf.
5	(community or communities).ti,ab,kf.
6	4 and 5
7	or/1-3,6
8	exp randomized controlled trial/
9	controlled clinical trial.pt.
10	randomi#ed.ti,ab.
11	placebo.ab.
12	randomly.ti,ab.
13	Clinical Trials as topic.sh.
14	trial.ti.
15	or/8-14
16	exp animals/ not humans/
17	15 not 16
18	7 and 17

Embase (OVID)

Embase <1974 to 2018 February 05>

No.	Search terms
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(Continued)

1	((pharmacy or pharmacist? or pharmacies) adj2 (community or communities)).ti,ab,kw.
2	((pharmacy or pharmacist? or pharmacies) adj2 intervention?).ti,ab,kw.
3	pharmaceutical care.ti,ab,kw.
4	(community or communities).ti,ab,kw.
5	3 and 4
6	or/1-2,5
7	random*.ti,ab.
8	factorial*.ti,ab.
9	(crossover* or cross over*).ti,ab.
10	((doubl* or singl*) adj blind*).ti,ab.
11	(assign* or allocat* or volunteer* or placebo*).ti,ab.
12	crossover procedure/
13	single blind procedure/
14	randomized controlled trial/
15	double blind procedure/
16	or/7-15
17	exp animal/ not human/
18	16 not 17
19	6 and 18

The Cochrane Library

No.	Search terms
#1	[mh "community pharmacy services"]
#2	((pharmacy or pharmacist? or pharmacies) near/2 (community or communities)):ti,ab
#3	((pharmacy or pharmacist? or pharmacies) near/2 intervention?):ti,ab
#4	(pharmaceutical next care):ti,ab
#5	(community or communities):ti,ab

(Continued)

#6 #4 and #5

#7 {or #1-#3, #6}

PsycINFO (OVID)

PsycINFO <1967 to January Week 5 2018>

No.	Search terms
1	((pharmacy or pharmacist? or pharmacies) adj2 (community or communities)).ti,ab,hw.
2	((pharmacy or pharmacist? or pharmacies) adj2 intervention?).ti,ab,hw.
3	pharmaceutical care.ti,ab,hw.
4	(community or communities).ti,ab,hw.
5	3 and 4
6	or/1-2,5
7	exp clinical trial/
8	random*.ti,ab.
9	((clinical or control*) adj3 trial*).ti,ab.
10	((singl* or doubl* or trebl* or tripl*) adj5 (blind* or mask*)).ti,ab.
11	(volunteer* or control group or controls).ti,ab.
12	placebo/ or placebo*.ti,ab.
13	or/7-12
14	6 and 13

COS Conference Papers Index

ProQuest Dissertations & Theses: UK & Ireland

ProQuest Dissertations & Theses Global

No.	Search terms
1	TI,AB((pharmacy or pharmacist? or pharmacies) NEAR/2 (community or communities)) OR TI,AB((pharmacy or pharmacist? or pharmacies) NEAR/2 intervention?) OR (TI,AB(pharmaceutical care) AND TI,AB(community OR communities))

ClinicalTrials.gov

community pharmacy OR community pharmacist

WHO International Clinical Trials Registry Platform (ICTRP)

community pharmacy OR community pharmacist

OpenGrey

((communit* NEAR/2 pharmac*) OR (intervention* NEAR/2 phramac*))

HISTORY

Protocol first published: Issue 7, 2014

Review first published: Issue 12, 2019

Date	Event	Description
18 August 2014	Amended	Change to author's name

CONTRIBUTIONS OF AUTHORS

Authors LS, RW, and AT have contributed to writing the manuscript.

LS, RS, EE, and CR assisted in data searches and conducted data extraction of studies.

RW assisted in development of the 'Risk of bias' summary tables.

VM provided statistical overview of the analyses.

CR reviewed all quality assessments of studies.

ST and CS provided senior level of guidance and support.

All authors have commented on the manuscript and provided expert advice on the review.

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DECLARATIONS OF INTEREST

LS: is in receipt of grant funding for various projects from the UK National Institutes of Health Research, but has no known conflicts of interest for the current publication

RS: none known

AT: none known

VM: none known

CR: none known

EE: none known

CS: none known

ST: is in receipt of grant funding for various projects from the UK National Institutes of Health Research and (in part) supported by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) North Thames at Bart's Health NHS Trust but has no known conflicts of interest for the current publication.

RW: is in receipt of grant funding for various projects from the UK National Institutes of Health Research. This review was funded by a programme grant for smoking cessation from the National Institute of Health Research in the UK. RW has received consultancy fees from

TTS Pharma and holds shares in this company. He has received royalties from a patent on genetic indicators of tobacco consumption. The Cochrane Funding Arbiter has looked closely into whether his patent constitutes a conflict of interest in this instance, and has decided that it does not.

The authors of the current review were also authors of one included study (Madurasinghe 2017). AT, who was not an author of the study therefore screened for inclusion, extracted, and checked all the data for this study.

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Internal sources

- No sources of support supplied

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Due to the large number of studies that we retrieved and a desire to include only data of the highest quality and utmost relevance to investigate the research question, we made a number of amendments to the review compared to what was stated in the protocol. With regard to inclusion criteria, we decided to exclude studies that compared two or more active interventions without the inclusion of a comparable control group, and to include only randomised controlled studies.

Finally, we decided not to collect data on process variables. This was in response to the level of data available, and the finding that there was high heterogeneity between process outcomes and measures, which meant that synthesis of these data would be unlikely to yield any clear findings.

We did not report data on the behaviour-change techniques of the interventions due to limited resources and poor descriptions in the study reports.

INDEX TERMS

Medical Subject Headings (MeSH)

*Community Health Services [organization & administration]; *Health Promotion; *Pharmaceutical Services [organization & administration]; Chronic Disease [therapy]; Communication; Delivery of Health Care [*methods]; Disease Management; Health Behavior; Outcome and Process Assessment, Health Care; Randomized Controlled Trials as Topic

MeSH check words

Humans