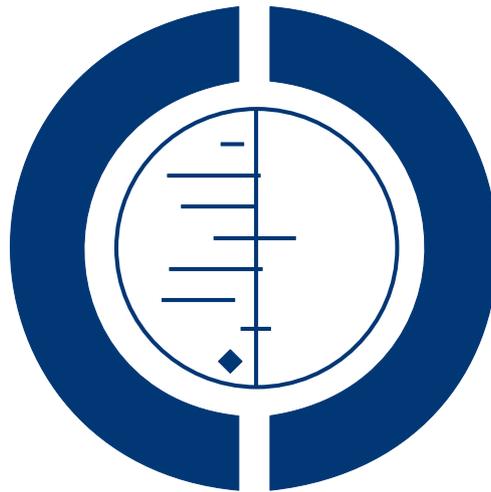


Community pharmacy interventions for health promotion: effects on professional practice and health outcomes (Protocol)

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[Intervention Protocol]

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

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

Primary objective

To assess the effectiveness of health promotion interventions in community pharmacy practice settings on pharmacy workers and pharmacy clients (including diagnosed patients) when compared to

- i) No treatment controls
- ii) Usual treatment controls
- iii) Other active intervention

Secondary objectives

To assess whether there are differences in effectiveness of health promotion interventions in community pharmacy practice settings on

- i) Pharmacy worker
- ii) Client (patient)

with regard to:

- i) Ethnicity of patients

- ii) Country income level ([World Bank Group 2009](#))
- iii) Extent of adverse health behaviour (defined according to national guidelines where available)
- iv) Type of pharmacy worker delivering the intervention (e.g. pharmacist versus pharmacist technician)
- v) Theoretical constructs/components and behaviour change techniques employed in the intervention
- vi) Costs of health care

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 have been identified as an easily accessible and cost-effective platform for delivering health care worldwide ([DOH 2005](#); [WHO 1998](#)). For example, in England there are over 12,000 community pharmacies; crucially, 99% of the population - even those living in deprived areas - can access a pharmacy within a 20 minute drive ([DOH 2008](#)). In Australia, over 90% of the population visit a pharmacist over the course of a year ([Benrimoj 2004](#)). Similarly, in low- and middle-income countries pharmacies are often seen as 'a first point of call' for advice on symptoms and for early diagnosis of illness ([Smith 2009](#)).

In view of the wide accessibility of community pharmacists, the role has undergone rapid expansion in recent years ([WHO 2006](#)). In addition to dispensing and medication-linked services, pharmacies 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 ([DOH 2005](#)). Smoking cessation was one of the earlier behaviour change tasks given to pharmacists in the UK, and now others have been added such as improving general lifestyle behaviours, increasing uptake of screening and giving sexual health advice ([RPSGB 1996](#)). To address the needs of this changing role and to maintain high standards, international guidance for good pharmacy practice has been published which stresses health promotion as one of six components which contribute to the health improvement of individuals that access community pharmacy services ([WHO 2011](#)).

However, despite this potential, the evidence base underpinning these wider health promotion tasks is currently relatively poor, both for effective methods of changing professional practice and to evaluate the health gains that could result from these changes. Research evidence suggests that whilst pharmacists and consumers hold positive attitudes to pharmacist involvement in public health, pharmacist confidence is currently low and additional training needs are perceived ([Eades 2011](#)).

Systematic reviews examining behaviour change interventions by clinical topic have thus far been limited by small numbers of poor quality studies ([Gordon 2011](#); [Sinclair 2004](#); [Watson 2006](#)), suggesting that a broad overview of studies of health promotion interventions in pharmacies is needed both to inform current pharmacy practice and to identify areas for future research.

Description of the intervention

The World Health Organization defines health promotion as "the process of enabling people to increase control over, and to improve, their health". The idea of health promotion moves 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 cessation, or that address wider aspects of clinical management, such as overweight and obesity or type 2 diabetes mellitus, therefore fall within this definition.

Interventions to address these broad health promotion and behaviour change tasks amongst people attending community pharmacies may be directed at pharmacy staff, their clients (or patients), or at both groups. The types of intervention may vary from educational programmes ([Sarayani 2012](#)), to specific training in particular behavioural issues, such as readiness to change behaviour ([Sinclair 1998](#)). Other interventions target management of medical conditions by patients, for example monitoring blood pressure ([Fikri-Benbrahim 2012](#)) or managing asthma ([Armour 2007](#)). These types of interventions go well beyond the traditional remit of pharmacy workers, which conventionally focused on the dispensing and management of medicines.

Previous Cochrane reviews ([Nkansah 2010](#); [Pande 2013](#)) have examined non-dispensing services in pharmacies; however, these have still had a strong focus on medications, including 'medication reviews' or medication therapy management interventions. Such interventions provide person-centred care and consider the medication regimen, including issues of adherence. To avoid overlap with previous work, we will exclude any purely medication-related interventions in this review. We will also exclude studies that only use behavioural techniques to address adherence to medication.

How the intervention might work

The way in which health promotion and behaviour change interventions work within community pharmacy is likely to be dependent on the theoretical basis for the intervention and the behaviour change techniques they use (Michie 2008). For example, interventions may aim to increase self efficacy in performing a behaviour that promotes health, or may 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, will be important in designing more effective interventions, both for existing clinical areas and to support the expansion of the role of the pharmacist in the future.

The current review will therefore seek to identify which underpinning theories and behaviour change techniques are most effective in achieving health behaviour change in a community pharmacy setting. We aim to identify generic methods that could be used to inform development of any health promotion intervention in a community pharmacy setting.

Most interventions involve training the pharmacist or pharmacy worker; however, evidence is sparse regarding the best methods of training pharmacists in health behaviour change techniques. Even if pharmacists and pharmacy staff can be trained effectively and can deliver the intervention with fidelity, there still remains the question of whether clients (or patients) follow the given advice and, further, whether this results in meaningful improvements in health and well-being. There has been no previous comprehensive review of the effectiveness of community pharmacy staff as agents for health behaviour change (Anderson 2003). It is important to consider the complete pathway from intervention to effects on health outcomes. Hence we will examine study outcomes related both to the professional behaviour of pharmacy staff and to health promotion in their clients.

Why it is important to do this review

This review is important because pharmacists worldwide are increasingly taking on health promotion as part of their rapidly expanding role in delivery of primary health care. However research evidence supporting the use of pharmacists as agents for changing health behaviours is sparse, and thus the best ways of enabling pharmacists to perform this new role and the magnitude of the health benefits that might accrue for their patients are both uncertain. Similar uncertainty surrounds the optimum structure of pharmacy-based health promotion interventions and their costs. This review aims to address gaps in existing knowledge, highlighting ways in which current clinical practice can be improved and suggesting areas where further research is needed.

We will examine all relevant studies where pharmacists or pharmacy staff (pharmacy technicians, pharmacy assistants) deliver an intervention to improve the health behaviour of people attending community pharmacies. The review will study the impact of the intervention on changing professional practice and effecting health behaviour change in patients or members of the public (collectively called 'clients (patients)' here). We shall also collate evidence on the methods of training pharmacists and pharmacy staff and will consider whether any specific approaches are associated with greater effectiveness in changing professional behaviour or patient-based outcomes.

The review will include high-, middle- and low-income country settings and will consider whether effectiveness differs by country income group. Pharmacies provide an existing health infrastructure with a client base, supply chains and trained health professionals in countries where other forms of primary care are poorly developed. Evidence to support expansion of their clinical role in low- and middle-income countries could be important in planning use of healthcare resources globally.

The review will also evaluate whether effectiveness of interventions varies by ethnicity or by the extent of the adverse health behaviour (e.g. number of cigarettes smoked per day), as it is important to understand whether a 'one size fits all' approach is effective, or whether there is evidence of differential effectiveness of the intervention in people with particular characteristics. For example, in asthma self management there is evidence that culturally specific interventions for different ethnic groups are more effective than generic programmes (Bailey 2009). Thus, this review will consider whether there is likely to be a benefit in stratifying people for targeted health promotion interventions in a community pharmacy setting.

The review will also evaluate whether the type of pharmacy worker delivering the intervention has an impact on the effectiveness of the intervention (e.g. pharmacist versus pharmacist assistant). A previous review has stressed the importance of training of facilitators for the effectiveness of self-management education programmes for chronic conditions (Foster 2007). Thus the current review will evaluate whether the level of qualification and experience of the pharmacy worker has an impact on the effectiveness of the intervention on clients'/patients' behaviour change and health outcomes.

OBJECTIVES

Primary objective

To assess the effectiveness of health promotion interventions in community pharmacy practice settings on pharmacy workers and pharmacy clients (including diagnosed patients) when compared to

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Secondary objectives

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with regard to:

- i) Ethnicity of patients
- ii) Country income level ([World Bank Group 2009](#))
- iii) Extent of adverse health behaviour (defined according to national guidelines where available)
- iv) Type of pharmacy worker delivering the intervention (e.g. pharmacist versus pharmacist technician)
- v) Theoretical constructs/components and behaviour change techniques employed in the intervention
- vi) Costs of health care

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) and cluster-RCTs comparing the intervention to usual practice or to control intervention(s). We will also include non-randomised controlled trials, controlled before-after (CBA) studies and interrupted time series (ITS) studies, in line with Cochrane Effective Practice and Organisation of Care (EPOC) group recommendations ([EPOC Guidance on Study Designs](#)), and as it is expected that a number of studies will have utilised these designs. In line with EPOC recommendations ([EPOC Guidance on Study Designs](#)), cluster-RCTs and CBA studies will only be eligible if there are at least two intervention sites and two control sites. ITS studies will only be eligible if there is a clearly defined point in time when the intervention occurred and at least three data points before and three after the intervention. Publication status of study (i.e. abstract, full text, unpublished data) will not be a bar to inclusion ([Chandler 2013](#)).

Types of participants

Participants in this review will be workers within community pharmacy settings, defined as regulated outlets outside a secondary healthcare setting, which are under the direction of a pharmacist. We will include interventions directed at any worker within the pharmacy including pharmacists and other workers such as pharmacy technicians and assistants. We will exclude studies where participants are from a hospital or non-community-based pharmacy, e.g. outpatient clinic setting. Where studies have mixed settings we will only include them if the majority of pharmacy staff took part in a community setting or if the community subset was analysed independently. Similarly, where the intervention is multidisciplinary we will only include studies if i) the majority of the intervention was delivered in community pharmacy, or ii) the community pharmacy aspect of the intervention was evaluated separately, e.g. change in community pharmacists behaviour.

Types of interventions

We will include any health promotion intervention targeted at, or delivered by, community pharmacy staff with the aim of improving health behaviours of individuals attending the pharmacy.

We will exclude studies if the intervention is solely focused on medication. This includes those interventions only concerned with prescriptions of medication, medication review, or adherence to medication. Where medication management is only one component of an intervention and other behavioural aspects (e.g. diet or exercise) are targeted, then we will include these interventions. We will exclude studies in which interventions do not involve active interaction between pharmacy staff and their clients (e.g. displays of leaflets/posters on lifestyle in the pharmacy).

We will describe 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 intervention delivered); incentives and/or reimbursement of pharmacy staff;
- Theoretical basis as classified by the Theoretical Domains Framework ([Cane 2012](#)) and defined by [Michie 2010](#), and behaviour change techniques - classified using the 93-item Behaviour Change Taxonomy (v1) ([Michie 2012](#));
- Content (e.g. smoking cessation, lifestyle recommendations, condition management, pharmaceutical prescription/no medication)

We will also document the intervention fidelity where this was assessed. Where necessary, we will contact authors of studies to obtain additional details of interventions and training of pharmacy staff.

Comparison interventions will be those where i) no treatment is received, ii) usual treatment but not the intervention is received,

or iii) where another active intervention is received, for example comparison of small-group education versus large-group education.

Types of outcome measures

Primary outcomes

To assess the effects of community pharmacy interventions on health promotion by pharmacy staff, we will look at three categories of outcomes:

1) Professional practice outcomes, 2) Client (patient) outcomes, 3) Adverse effects.

1. Professional practice outcomes will primarily be behavioural and will include:

- Uptake of intervention by pharmacy staff, adherence to the intervention (e.g. number of clients asked about smoking status), change in behaviour, e.g. inhaler technique.
- Social-cognitive process outcomes such as pharmacists' knowledge of the subject area.

2. Client (patient) outcomes will include assessment of:

- Health status and well-being, including i) intermediate outcomes, e.g. cholesterol, glycated haemoglobin, ii) clinical outcomes, e.g. stroke, myocardial infarction, iii) psychological health, e.g. anxiety and depression, iv) psychosocial outcomes, e.g. quality of life.
- Health behaviours, e.g. smoking, exercise, inhaler technique.
- Socio-cognitive process outcomes such as knowledge, satisfaction.

3. Adverse effects which will include any adverse events defined as such by the included studies, either at the professional or participant level.

In line with EPOC recommendations (EPOC 2002), we will only include studies where at least one outcome is assessed using an objective or validated tool. For assessment of pharmacist behaviour simulated patients are considered a recognised and objective measurement tool and will therefore be included (Watson 2006; Xu 2012).

Secondary outcomes

We will include costs, as reported in primary studies, as a secondary outcome. This will include direct and indirect healthcare costs including scheduled and unscheduled visits to other healthcare providers.

Search methods for identification of studies

Electronic searches

The Effective Practice and Organisation of Care (EPOC) Trials Search Co-ordinator (TSC) will write the search strategies in consultation with the authors. The TSC will search the Cochrane Database of Systematic Reviews and the Database of Abstracts of Reviews of Effects (DARE) for related systematic reviews, and will search the following databases for primary studies.

- Cochrane Central Register of Controlled Trials (CENTRAL)
- Health Technology Assessment Database, Cochrane Library
- NHS Economic Evaluation Database, Cochrane Library, Issue
- MEDLINE, 1950-, In-process and other non-indexed citations, OvidSP
- EMBASE, 1947- , OvidSP
- PsycINFO, 1950-
- EPOC Group, Specialised Register

A draft search strategy for MEDLINE is provided in Appendix 1. We will test this strategy by screening selected citations for relevance, and will validate it using a selection of exemplar papers on the topic of this review. We will present the finalised strategy in the review. We will modify the MEDLINE strategy for other databases using appropriate syntax and vocabulary for those databases. We will limit results by two methodological filters: the Cochrane Highly Sensitive Search Strategy (sensitivity- and precision-maximising version - 2008 revision) to identify randomised trials, and an EPOC methodology filter to identify non-RCT designs. We will apply no limits by date or language.

Searching other resources

We will conduct a grey literature search to identify studies not indexed in the databases listed above. Sources will include the sites listed below. We will document additional sources, if any, in the review.

- Open Grey (www.opengrey.eu)
- ProQuest Dissertations & Theses Full Text
- ProQuest Dissertations & Theses: UK & Ireland

Trial Registries

We will search the following Registries:

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 will also:

- Review reference lists of all included studies, relevant systematic reviews/primary studies/other publications.

- Contact authors of relevant studies or reviews to clarify reported published information/seek unpublished results/data.
- Conduct cited reference searches for all included studies in citations indexes.

Data collection and analysis

Selection of studies

We will import results of each search into the reference management software package [Endnote 2013](#). One review author will remove duplicates and screen titles and abstracts for obvious irrelevance to the review, e.g. not intervention study. A second review author will complete sequential 10% checks of titles and abstracts until we achieve an inter-rater reliability of 0.75 or greater (excellent agreement ([Orwin 1994](#))). The emphasis will be on over-inclusion at this stage. We will then retrieve potentially relevant papers and two review authors will screen all of these against the inclusion criteria. We will present any studies excluded at this stage in a 'Characteristics of excluded studies' table, with reasons for exclusion given. We will resolve any disagreements through discussion, referring where necessary to a third review author for arbitration. We will treat multiple publications from a single study as a single intervention evaluation.

We will document the full screening process in a PRISMA flowchart, presenting details of initial hits, hits following de-duplication, studies excluded at title abstract screening stage, studies excluded at full-text screening stage and final included studies.

Data extraction and management

We will extract data from eligible studies using a tailored extraction form based on the generic Cochrane Effective Practice and Organisation of Care (EPOC) Review Group data collection checklist ([EPOC 2002](#)) and including the following data:

- Study details: Author, year, research question, country where research was carried out; inclusion and exclusion criteria; study design (RCT, cluster-RCT, controlled before-after study (CBA), interrupted time series (ITS)); recruitment method (e.g. self referral, advertisement); description of usual care.
- Intervention details: Intervention target (pharmacy staff and/or clients), behavioural target (smoking, diet, exercise, etc); health condition targeted, intervention description (mode of delivery; theoretical basis; behaviour change techniques (Using 93-item BCT taxonomy ([Michie 2012](#)))).
- Pharmacy worker details: number, age, socioeconomic status, ethnicity, gender, time since qualification.
- Client/Patient details: number, age, socioeconomic status, ethnicity, gender, time since diagnosis (where applicable).
- Quality Criteria (in line with EPOC recommendations [EPOC Guidance on Risk of Bias](#)).

- Results in primary and secondary outcomes.

Two review authors will independently and in duplicate extract key information (inclusion criteria, e.g. design, participants, interventions and outcomes, quality criteria and results) from each included paper. One review author will extract other data and another will check them. We will resolve any errors or disagreements through discussion, with recourse to a third review author for arbitration, and if necessary by discussion among the full author group. One review author will enter data into Review Manager 5 ([RevMan 2012](#)), and a second review author will check them.

Assessment of risk of bias in included studies

We will assess the risk of bias in accordance with the Cochrane Collaboration's 'Risk of bias' assessment tool ([Higgins 2011a](#)) and in line with the EPOC groups 'suggested risk of bias criteria for EPOC reviews' ([EPOC Guidance on Risk of Bias](#)). There are nine standard criteria for all RCTs, non-RCTs and CBA studies, which relate to the following questions:

- 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?

For interrupted time series (ITS) studies we will use seven criteria. These include items vi) - ix) above, as well as three further questions:

- Was the intervention independent of other changes?
- Was the shape of the intervention effect prespecified?
- Was the intervention unlikely to affect data collection?

We will score each study as being at low, high or unclear risk (if not specified in the paper). For some studies it may not have been possible to blind participants to the intervention, e.g. an exercise intervention, but we will still record this in the quality assessment. Two review authors will assess each study's quality, comparing results and resolving discrepancies by discussion and by recourse to a third review author if necessary. We will measure inter-rater agreement using Cohen's kappa coefficient ([Uebersax 1987](#)). We will present the results both graphically and in a 'Risk of bias' table.

Measures of treatment effect

For continuous data we will estimate treatment effect sizes as standardised mean differences (SMDs) for each outcome, or weighted mean difference if studies have a common outcome measure. We will treat available data as continuous unless there is a defensible cut-point available by which it may be considered dichotomous.

Where dichotomous data are available, we will estimate the relative risk (RR) and the 95% confidence interval (CI) for all point estimates. For CBA studies, in order to maximise data from individual studies we will extract the baseline and final measurements as well as the change scores with associated standard deviations for continuous outcomes. Where dichotomous data are reported we will extract the relative risk as available. Where adjusted estimates are reported, we will also extract the factors being adjusted for. For ITS studies, we will extract and report immediate change in level/trend and associated standard deviation estimates. We will include change in level estimates in any subsequent meta-analysis. We will prefer final value scores to change scores where both are presented.

Unit of analysis issues

Where cluster-randomised trials are included we will consider whether any unit of analysis errors are made. Where such errors are identified we will perform a re-analysis using the information on the size or number of clusters and the value of the intra-cluster correlation coefficient (ICC) where the information is available. When ITS studies are analysed using inappropriate statistical methods or statistical analysis is not performed, we will re-analyse the results (where possible). For re-analysis we will extract data on individual observations over time from tables of results or graphs presented in the original study. We will use time series regression to re-analyse the results from each study. We will use model specification $\text{Outcome} = \text{constant} + \beta_1 \text{time period} + \beta_2 \text{phase} + \beta_3 \text{time period} * \text{phase}$, using Stata version 12.1 (Higgins 2011b). Thus it may be possible to perform an approximately correct analysis.

Dealing with missing data

Where a study has missing data we will in the first instance contact the authors and request any additional data they may have, including on training and content of interventions. If missing data are still present we will calculate standard deviations for changes, where possible. When there is insufficient information available to calculate the standard deviations, we will impute missing standard deviations for changes from baseline using other information available (e.g. correlation coefficients) (Higgins 2011b).

For dichotomous data where possible we will derive missing treatment estimates and standard errors from the number of participants included/randomised and the numbers with outcomes. Where possible, we will use confidence intervals to derive missing standard error estimates.

Assessment of heterogeneity

Given the diverse nature that behavioural interventions can take, we anticipate some heterogeneity between studies. We will assess

this both qualitatively (for example, examining intervention characteristics, study populations, context, etc) as well as quantitatively. We will investigate non-statistical heterogeneity by inspecting forest plots for poorly overlapping confidence intervals of the results of individual studies. We will discuss possible reasons for heterogeneity and will assess the influence of those identified individual studies in sensitivity analyses.

We will formally assess the extent of statistical heterogeneity using the Cochran's Q statistic and corresponding Chi² and I² statistics. This latter describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance) (Higgins 2003).

Assessment of reporting biases

To test for publication bias we will draw funnel plots, assuming that standard errors and a unitary measure of effect can be produced, if more than 10 studies are identified for a given outcome. We will visually inspect funnel plot asymmetry and will discuss possible reasons.

Data synthesis

We will give details of all included studies in a 'Characteristics of included studies' table, irrespective of whether measured outcome data are reported in a useable way.

For the main analysis, we will split outcomes into those examining the effect on pharmacy staff and those examining the effect on clients (patients).

In the first instance, we will consider the suitability of studies for meta-analysis. If there is evidence of heterogeneity, it may be misleading to conduct a meta-analysis. In that case we will conduct a narrative synthesis of studies and will present descriptive and summary data of interventions.

Where meta-analysis is deemed appropriate, given there is likely to be heterogeneity in terms of intervention, setting, and population, we will adopt the more conservative random-effects model, unless there is little suggestion of heterogeneity, when we would use a fixed-effect model. If an outcome was measured at different times in the same study, we will select the value nearest the endpoint of the intervention period. When there are related outcomes from the same study we will use the outcome most consistent across studies (e.g. SF-36 above condition-specific measures) or the most clinically rigorous measure (e.g. HbA1c above fasting blood glucose). In this way we will pool only a single effect size for each study. We will use Review Manager 5 software (RevMan 2012) to collate data and perform calculations.

For each main comparison we will prepare a 'Summary of findings' table. We will use EPOC worksheets 1 - 4 to define the most important outcomes and use the GRADE approach to assess quality for each included outcome.

Subgroup analysis and investigation of heterogeneity

We will conduct subgroup analyses in RevMan. We will consider whether there are different effects from studies conducted within low- and middle-income countries (LMICs) compared with high-income countries (HMICs). We will also examine whether people from particular ethnic groups and those at extremes of adverse health behaviour (e.g. heavy smokers) are more likely to respond to pharmacy-based interventions. If there are sufficient studies we will also explore whether theory-based interventions are more effective than those not based on theory, and whether a financial incentive influences effectiveness.

Meta regression

We will perform meta-regression where there are an adequate amount of data, using Stata 12.1. This will consider which features of interventions are more likely to be successful and will examine: 1) How the intervention is delivered (e.g. single brief consultation, several brief consultations plus follow-up telephone contact, extended consultation); 2) Behaviour change techniques (Michie 2012) and underpinning behaviour change theory where this is stated (or the likely under-

pinning behaviour change theory where this is not explicitly stated (Michie 2010)).

Sensitivity analysis

We will conduct sensitivity analyses by excluding studies assessed as being at high risk of bias, where standard deviations are imputed, or by varying the ICC for re-analysis of data from cluster-randomised trials. We will also exclude studies contributing to non-statistical heterogeneity, i.e. studies with poorly overlapping confidence intervals for their results. This will involve undertaking the meta-analysis twice, both with and without the studies in question. We will examine Individual forest plots, but presentation of sensitivity analyses will be in terms of a summary table.

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* Indicates the major publication for the study

APPENDICES**Appendix I. Medline Search Strategy**

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>

-
- 1 Community Pharmacy Services/ [Combine with Filters & Screen all] (2660)
 - 2 ((pharmacy or pharmacist? or pharmacies) adj3 (community or counsel\$ or advice or care)).ti. (2221)
 - 3 (pharmacist? adj3 (front line or “one to one” or face to face)).ti,ab. (34)
 - 4 (community adj2 pharmacist?).ab. (1256)
 - 5 or/1-4 [**Community Pharmacist**] (4320)
 - 6 Pharmacy/ or Pharmacists’ Aides/ or Pharmacists/ (17979)
 - 7 (pharmacist? or pharmacy or pharmacies).ti. (21057)
 - 8 (pharmacist? or (pharmacy adj3 (aide or aides or assistant? or staff))).ab. (15609)
 - 9 or/6-8 [**Pharmacists/Pharmacies**] (37873)
 - 10 Community Health Services/ or Community Mental Health Services/ or Community networks/ or exp Counseling/ or Family Planning Services/ (99363)
 - 11 exp Maternal Health Services/ [part of Community Health Services] (33717)
 - 12 schools/ or students/ (49141)
 - 13 (community or communities).ti. (100290)
 - 14 (community adj3 (care or healthcare or health care or service or services)).ab. (17873)
 - 15 or/10-14 [**community**] (270495)
 - 16 Patient Education as Topic/ or exp health education/ or consumer health information/ or health fairs/ (132424)
 - 17 “tobacco use cessation”/ or smoking cessation/ (19729)

18 self care/ or blood glucose self-monitoring/ (26231)
 19 health promotion/ or healthy people programs/ or weight reduction programs/ (51960)
 20 exp Mass Screening/ (97458)
 21 (smoking cessation or (quit\$ adj2 smok\$)).ti,ab. (17945)
 22 patient care.ti,ab. (37361)
 23 (patient? adj3 (educat\$ or counsel\$ or helping or advising or directing or caring or assist? or assisting or assistance or teaching or learning or promoting)).ti,ab. (50821)
 24 (patient? adj2 (advice or counsel\$ or program? or programme or programmes or workshop? or session?)).ti,ab. (16803)
 25 (consumer? adj3 (advice or educat\$ or counsel\$ or helping or advising or directing or caring or care or assist? or assisting or assistance or teaching or learning or promoting)).ti,ab. (2983)
 26 (health adj2 (improv\$ or promotion)).ti,ab. (43998)
 27 partner\$.ti,ab. (100595)
 28 ((weight gain or weight loss or (weight adj2 (losing or gaining)) or obesity or obese or addicted or addiction? or smoking or lifestyle or blood pressure or self-care) adj3 (educat\$ or counsel\$ or helping or advising or directing or caring or assist? or assisting or assistance or teaching or learning or promoting)).ti,ab. (10046)
 29 deleted line
 30 ((cholesterol or blood pressure or blood sugar or glyc?em\$ or asthma\$ or eating or diet or inhaler? or diabet\$ or immuni?ation? or vaccination? or screening or self-manag\$ or hypertension) adj3 (control\$ or counsel\$ or manage\$ or education\$)).ti,ab. (123593)
 31 or/16-28,30 [**Patient Ed, Health Promotion--proxy terms for interventions conducted in community pharmacy settings**] (615267)
 32 deleted line
 33 Professional Role/ (7926)
 34 ((role or roles) adj2 (chang\$ or new or pharmacy or pharmacies or pharmacist?)).ti,ab. (12440)
 35 or/33-34 [**Professional Role**] (19902)
 36 (9 and 15) not 5 [Pharmacists/Pharmacies & Community] (1012)
 37 (9 and 31) not (or/5,36) [Pharmacists/Pharmacies & Patient Ed] (3905)
 38 (and/9,35) not (or/5,36-37) [Pharmacists & Role] (1313)
 39 (randomized controlled trial or controlled clinical trial).pt. or randomized.ab. or placebo.ab. or clinical trials as topic.sh. or randomly.ab. or trial.ti. (872795)
 40 exp animals/ not humans.sh. (3869593)
 41 39 not 40 [Cochrane RCT Filter 6.4.d Sens/Precision Maximizing] (805144)
 42 5 and 41 [RCT Community Pharmacy MeSH Set 1] (452)
 43 36 and 41 [Pharmacists/Pharmacies & Community & RCT: Set 2] (97)
 44 37 and 41 [Pharmacists/Pharmacies & Patient Ed & RCT : Set 3] (399)
 45 38 and 41 [Pharmacists & Role & RCT: Set 4] (58)
 46 intervention?.ti. or (intervention? adj6 (clinician? or collaborat\$ or community or complex or DESIGN\$ or doctor? or educational or family doctor? or family physician? or family practitioner? or financial or GP or general practice? or hospital? or impact? or improv\$ or individuali?e? or individuali?ing or interdisciplin\$ or multicomponent or multi-component or multidisciplin\$ or multi-disciplin\$ or multifacet\$ or multi-facet\$ or multimodal\$ or multi-modal\$ or personali?e? or personali?ing or pharmacies or pharmacist? or pharmacy or physician? or practitioner? or prescrib\$ or prescription? or primary care or professional\$ or provider? or regulatory or regulatory or tailor\$ or target\$ or team\$ or usual care)).ab. (153300)
 47 (pre-intervention? or preintervention? or “pre intervention?” or post-intervention? or postintervention? or “post intervention?”).ti,ab. [added 2.4] (9542)
 48 (hospital\$ or patient?).hw. and (study or studies or care or health\$ or practitioner? or provider? or physician? or nurse? or nursing or doctor?).ti,hw. (698954)
 49 demonstration project?.ti,ab. (1913)
 50 (pre-post or “pre test\$” or pretest\$ or posttest\$ or “post test\$” or (pre adj5 post)).ti,ab. (62958)
 51 (pre-workshop or post-workshop or (before adj3 workshop) or (after adj3 workshop)).ti,ab. (582)
 52 trial.ti. or ((study adj3 aim?) or “our study”).ab. (600821)
 53 (before adj10 (after or during)).ti,ab. (347556)
 54 (“quasi-experiment\$” or quasiexperiment\$ or “quasi random\$” or quasirandom\$ or “quasi control\$” or quasicontrol\$ or ((quasi\$ or experimental) adj3 (method\$ or study or trial or design\$))).ti,ab,hw. (98088)
 55 (“time series” adj2 interrupt\$).ti,ab,hw. (962)

56 (time points adj3 (over or multiple or three or four or five or six or seven or eight or nine or ten or eleven or twelve or month\$ or hour? or day? or “more than”).ab. (8547)

57 pilot.ti. (38095)

58 Pilot projects/ (79317)

59 (clinical trial or controlled clinical trial or multicenter study).pt. (611602)

60 (multicentre or multicenter or multi-centre or multi-center).ti. (27823)

61 random\$.ti,ab. or controlled.ti. (726448)

62 (control adj3 (area or cohort? or compare? or condition or design or group? or intervention? or participant? or study)).ab. not (controlled clinical trial or randomized controlled trial).pt. (395608)

63 (control year? or experimental year? or (control period? or experimental period?)).ti,ab. [Added May 30-2013] (13197)

64 evaluation studies as topic/ or prospective studies/ or retrospective studies/ [Added Jan 2013] (923092)

65 (utili?ation or programme or programmes).ti. [Added Jan 2013] (53169)

66 (during adj5 period).ti,ab. [Added Jan 2013] (291762)

67 ((strategy or strategies) adj2 (improv\$ or education\$)).ti,ab. [Added Jan 2013] (17390)

68 (purpose adj3 study).ab. (217816)

69 “comment on”.cm. or review.pt. or (review not “peer review\$”).ti. or randomized controlled trial.pt. [Changed Jan 2013] (2828940)

70 (rat or rats or cow or cows or chicken? or horse or horses or mice or mouse or bovine or animal?).ti,hw. or veterinar\$.ti,ab,hw. [Edited May 2013] (5333261)

71 exp animals/ not humans.sh. (3869593)

72 (or/46-68) not (or/69-71) [EPOC Methods Filter 2.6] (2743232)

Results to Export--EPOC Filter

73 (5 and 72) not (or/42-45) [Community Pharmacy MeSH: EPOC Set 1] (1768)

74 (36 and 72) not (or/42-45) [Pharmacists/Pharmacies & Community & EPOC Set 6] (418)

75 (37 and 72) not (or/42-45) [Pharmacists/Pharmacies & Patient Ed & EPOC : Set 7] (1737)

76 (38 and 72) not (or/42-45) [Pharmacists & Role & EPOC: Set 8] (429)

Results to Export--RCT Filter

77 or/42-45 [RCT Export] (1006)

78 remove duplicates from 77 (1004)

79 (9 and (primary adj2 care).ti. and (or/41,72)) not (or/73-77) (89)

80 remove duplicates from 79 (89) [Primary Care & Pharmacist/Pharmacy & Filters--Exported]

WHAT'S NEW

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

CONTRIBUTIONS OF AUTHORS

Authors LS, AK, RW have contributed to writing the protocol. VM has provided statistical contribution to the manuscript. All other authors have commented on the manuscript and provided general advice on the review.

DECLARATIONS OF INTEREST

No potential conflict of interest

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