National Institute for Health and Care Excellence

Draft

Community pharmacy: Promoting health and wellbeing

Evidence reviews for offering behavioural support to promote health and wellbeing

NICE guideline <number>

Evidence reviews

[January, 2018]

Draft for Consultation

These evidence reviews were developed by the Public Health internal guidelines team

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ISBN:

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Introduction

Community pharmacies are well positioned to promote health and wellbeing to their local community as 90% of people overall, and over 99% of people in the most deprived communities, live within a 20-minute walk of a community pharmacy (The positive pharmacy care law: an area-level analysis of the relationship between community pharmacy distribution, urbanity and social deprivation in England Todd et al. 2014).

Community pharmacies can help raise awareness of health conditions, improve health, and reduce both health inequalities and individual health risks by providing advice and services to everyone entering their premises. This includes people who do not visit GPs or other healthcare services. In addition, they may support other primary care services, such as GP practices.

The risk of many health conditions can be reduced by people adopting healthier behaviours. These include: type 2 diabetes, cardiovascular disease, respiratory diseases such as chronic obstructive pulmonary disease, and conditions related to obesity and smoking.

The aim of this review was to determine which behavioural support interventions are effective and cost-effective for self-care to promote health and wellbeing in community pharmacy and whether behavioural support is acceptable to users of community pharmacy.

This review also aims to explore whether the effectiveness and cost-effectiveness of behavioural support interventions varies by the characteristics of the intervention, the person delivering the intervention, or the person receiving the intervention. It will also explore how behavioural support interventions could be made more acceptable to users of community pharmacy services.

The review focused on identifying studies that fulfilled the criteria specified in Table 1. For full details of the review protocol, see Appendix A.

PICO table

Table 1. PICO table for review questions 3a, 3b and 3c on behavioural support

PICO Element	Details
Population	Anyone who may use community pharmacy services
Intervention	Any intervention delivered by community pharmacy staff that offers behavioural support for self-care to promote health and wellbeing, including: • Brief interventions • Very brief interventions

PICO Element	Details		
	• Extended brief interventions • Motivational interviewing • Motivational enhancement therapy • Any other form of behavioural support, e.g. ask, advise, act		
Comparator	• No intervention • Any intervention provided by community pharmacy staff that provides information • Any information provided by community pharmacy staff that offers advice or education to promote health and wellbeing • Any other behavioural support intervention provided by community pharmacy staff		
Outcomes	*Review question 3a*	*Review question 3b*	*Review question 3c*

	• Clinical measurements of health outcomes
	• Behavioural outcomes
	  ○ Action
	• Modifying factors or determinants of behaviour
	  ○ Intention
	  ○ Attitudes
	  ○ Knowledge
	  ○ Awareness
	• Wellbeing
	• Quality of life
		• Preference and experience of people using the service
		• Qualitative element of quality of life
			• Costs, savings and effectiveness
			  ○ Cost per quality adjusted life year
			  ○ Cost per unit of effect
			  ○ Net benefit

Effectiveness evidence

Included studies

Papers were included if they met the PICO and were:

- Randomised controlled trials, before and after studies, or any other type of comparative study design.
- Systematic reviews of randomised controlled trials or other comparative studies, if the majority of included studies met the PICO. If the majority of studies did not meet the PICO, individual studies included in the systematic review were considered separately for inclusion in this evidence review.
- Conducted in the UK, Australia, Canada, Republic of Ireland, the European Union (including Norway and Switzerland), New Zealand and Chile.
- Published between 1990 and 2016.
- Published in English language.

The health areas of interests included: alcohol use, cancer awareness, prevention of cardiovascular disease, diabetes, substance misuse or falls, mental health and wellbeing, orthopaedic conditions, sexual health, smoking and smokeless tobacco or weight management.

Excluded studies

Papers were excluded if they:

- Did not include comparative data, that is, they did not include data either comparing an intervention to another active intervention or a control intervention, or comparing data before and after an intervention.
- Were related to treatment of diseases and acute medical conditions, such as dispensing, other medicine or device services, self-care to improve the use of medicines or devices, urgent care.
- Were related to vaccinations.
- Only included interventions delivered by distance-selling (online) pharmacies.
- Only looked at the effectiveness of screening, checks and testing, such as blood glucose checks, blood pressure checks, cardiovascular risk assessments, cholesterol checks, medicine use reviews, mole checking services, NHS Health checks.
- Included interventions delivered by people other than community pharmacy staff. Studies that were delivered by a mixture of community pharmacy staff and other healthcare professionals were only included if results for the services provided by community pharmacy staff were reported separately.

See appendix K for full list of excluded studies

Summary of effectiveness studies included in the evidence review

In total 14,652 references were found across the four review questions. Full-text papers of 361 citations seemed potentially relevant. In total 20 primary studies of were included in review 3 (Table 2).

Table 2. Summary of effectiveness evidence for behavioural support

Study	Setting and country	Intervention	Health area	Outcomes
Boardman et al. 2014	Community pharmacies Berkshire, Cornwall, Coventry and Plymouth, UK	Individualised service with calorie restricted diet plans and increased physical activity targets in obese subjects who had at least 1 risk factor for CVD 12 sessions (fortnightly or monthly), length not reported. Pharmacists delivered sessions and were trained on methods to motivate patients to change their behaviour. Face to face, not clear if group or 1 to 1, not clear if written information provided.	Weight management	Blood pressure Waist circumference Weight
Botomino et al 2008	Community pharmacies Switzerland	Intensive counselling with individualised advice on weight reduction, goal setting (e.g. reducing fat intake, eating fruits or vegetables, participating in exercise) in overweight subjects with at least 1 other risk factor for diabetes	Weight management	Body mass index Weight

Study	Setting and country	Intervention	Health area	Outcomes
		Number of sessions not reported Pharmacists trained in 2 evening courses with counselling targeted according to stages of change. Mode of delivery is unclear.		
Bush et al. 2014	Community pharmacies Birmingham, UK	Set weight loss targets, encouraged to keep a food and exercise diary and to modify lifestyle, diet and physical activity in overweight or obese individuals from areas of high socioeconomic deprivation. 12 weekly sessions, duration not reported. 'Trained healthcare workers, e.g. pharmacy assistants' delivered the interventions. Training provided to staff not reported. Face to face and 1 to 1. Written materials provided.	Weight management	Body mass index Waist circumference Weight
Costello et al. 2011	Community pharmacies Ontario, Canada	Brief behavioural counselling session following the brief 5A (Ask, Advise, Assess, Assist, Arrange) model. 5 weeks of nicotine replacement therapy provided Intervention group received 3 sessions, control group received 1 session. Each session was 5 to 10 minutes. Delivered by pharmacists who received up to 5 hours of training. Face to face and 1 to 1. Not clear if written materials provided.	Smoking cessation	Abstinence
Cramp et al. 2007	Community pharmacies Northern Scotland, UK	Counselling, nicotine quiz and 'I quit' contract. Advice on how to deal with situations known to cause relapse. 12 weeks of nicotine replacement therapy provided.	Smoking cessation	Abstinence

Study	Setting and country	Intervention	Health area	Outcomes
		Number and duration of sessions unknown. Duration of intervention unknown. Delivered by pharmacists who received training (duration not reported). Assumed to be face to face. Unclear if 1 to 1 or group sessions. Written materials on nicotine replacement therapy and how to deal with situations known to cause relapse provided.		
Dhital et al. 2015	Community pharmacies London, UK	Participants with AUDIT scores of 8-19 inclusive were encouraged to think about drinking and whether to reduce it. Discussed how to reduce drinking if ready to do so. Included participants evaluating their drinking and associated problems. 1 session of 10 minutes. Delivered by pharmacists who received 3.5 hours of training on counselling approach of motivational interviewing. Face to face and 1 to 1. Written materials provided.	Alcohol use	Alcohol use
Jackson et al. 2008	Community pharmacies Ontario and New Brunswick, Canada	Program based on Transtheoretical Model of Change and the 5As (Ask, Advise, Assess, Assist, Arrange) Model. Nicotine replacement therapy provided. Participants were smokers motivated to quit 7 sessions over 6 months. Duration of sessions not reported. Delivered by pharmacists. No training reported. Face to face initially, then either face to face or by telephone. Assumed to be 1 to	Smoking cessation	Abstinence

Study	Setting and country	Intervention	Health area	Outcomes
		1. Unclear if written materials provided.		
Jolly et al. 2011	Community pharmacies Birmingham, UK	Problem solving approach based on stages of change and motivational interviewing. Sessions focused on goal setting, self-monitoring with food diaries, hunger scale, waist measurements and physical activity. Participants were overweight or obese with a comorbid disorder 12 sessions (frequency not reported). First session was 30 mins, follow up sessions of 15 to 20 mins. 'Staff' delivered the intervention. Attended a 3 day training course. Face to face and 1 to 1. Written resources provided as homework.	Weight management	Body mass index Physical activity Weight
Khan et al. 2013	Community pharmacies London, UK	'Full BI'. Based on the Feedback, Listen, Advice, Goals and Strategies (FLAGS) technique in hazardous drinkers measured by the AUDIT-C score Number and duration of sessions not reported, references Dhital et al. 2015 study so assumed to be 1 session of 10 minutes. Delivered by pharmacists. Attended a 3 day training course. Assumed to be face to face and 1 to 1. Written materials provided.	Alcohol use	Alcohol use
Lalonde et al. 2006	Community pharmacies Montreal, Canada	Action plan for next 3 months, set treatment goals. Participants were on lipid lowering or antihypertensive pharmacotherapy 1 session. Length not reported.	Cardiovascular disease	Alcohol use Blood pressure Body mass index Cardiovascular disease

Study	Setting and country	Intervention	Health area	Outcomes
		Pharmacist delivered the intervention. Training not reported. Face to face and 1 to 1. Written materials, including risk profile or personal worksheet, provided.		Cholesterol Healthy eating Physical activity Smoking cessation Stress Weight
Maguire et al. 2001	Community pharmacies Northern Ireland and London, UK	Pharmacists Action on Smoking model. Interview with contract. Positive approach used to increase confidence and reinforce motivation to stop smoking. Nicotine replacement therapy provided. 7 sessions over 4 months. Duration not reported. Delivered by pharmacists who received 3 hours of training. Face to face and 1 to 1. Written materials on smoking cessation provided.	Smoking cessation	Abstinence
Morrison et al. 2013	Community pharmacies Fife, UK	Prescribed eating plan or goal setting approach, focusing on diet and physical activity in subjects who were overweight or obese with a co-morbidity 1 session a week for 6 weeks (10 to 30 minutes), follow up sessions at 6, 9 and 12 months (duration not reported). Total program time of 130 minutes. Pharmacy assistants and pharmacists delivered the intervention. Received 2x4 hour training sessions. Face to face and assumed to be 1 to 1. Not reported whether written materials were provided.	Weight management	Weight

Study	Setting and country	Intervention	Health area	Outcomes
Narhi et al 2001	Community pharmacies Finland	Asthma self-management, with participant allocated to a pharmacist who taught how to recognise and treat symptoms. Pharmacists trained for 1 day and completed self-study course 1 year interventions with 4 to 8 sessions, lasting 15 to 20 minutes	Asthma	Asthma Knowledge Attitude towards asthma
Neumann et al 2013	Pharmacies Denmark	A smoking cessation program with manual based teaching sessions with nicotine replacement therapy. Subjects were disadvantaged (lower level or education or receiving employment benefits) No information reported on training received by pharmacists 5 session over 6 weeks delivered in either group or individual format	Smoking cessation	Abstinence
Schmiedel et al 2015	Community pharmacies Germany	Written information about healthy diet and exercise and 3 individual counselling sessions provided in subjects with a high risk of diabetes. Goal attainment monitored by pharmacists in 2nd and 3rd session. 5 group based lectures. Group sessions focused on risk factors, health diet, physical activity, psychologic aspects and healthy lifestyle. Group sessions 75-90 minutes Pharmacists received 1 to 1.5 days training	Diabetes	Diabetes risk Weight Arterial blood pressure Physical activity Quality of life
Sinclair et al. 1998	Community pharmacies Grampain region of Scotland, UK	Pharmacy Support Programme based on counselling tailored to current stage of change. Number of sessions and duration not reported. Duration of intervention not reported. Delivered by pharmacists and 'staff'. Received 2 hours of training. Unclear if face to face. Unclear if 1 to 1 or group sessions. Not	Smoking cessation	Abstinence

Study	Setting and country	Intervention	Health area	Outcomes
		reported whether written materials were provided.		
Twigg et al. unpublished	Community pharmacies Northern England, UK	Support for participants to create personalised health goals and agree actions. Initial consultation of 40 minutes then multiple sessions (at least 2 more) over 12 months. Pharmacists and support staff delivered the intervention. Received 1x1 day training session. Face to face and assumed to be 1 to 1. Not reported whether written materials were provided.	General health	Patient activation score Goal achievement
Um et al. 2015	Community pharmacies Sydney, Australia	Targets diet and physical activity in overweight and obese subjects. Counselling tailored to stages of change. Used motivational interviewing strategies to support goal setting and action planning. Encouraged to keep food and physical activity diary. 6 sessions over 3 months. Initial session of 30 to 40 minutes, 15 to 20 minutes in weeks 2 to 8, 20 to 30 minutes in week 12. Pharmacist delivered the intervention. Training with 3 day course, reading, observation of 3 month program. Face to face and 1 to 1 sessions. Not reported whether written materials were provided.	Weight management	Blood pressure Body mass index Healthy eating Physical activity Waist circumference Weight
Winter et al. 2007	Community pharmacies London, UK	Sessions on healthy eating, exercise, shopping, adapting recipes, reading food labels. Subjects were overweight or obese with co-morbidities or a family history of diabetes or heart disease	Weight management	Weight

Study	Setting and country	Intervention	Health area	Outcomes
		At least 12 sessions (additional sessions if requested) over 24 weeks. Duration not reported. Pharmacists delivered the intervention. Training not reported, but PCT provided a list of suggested topics with literature. Face to face, group for weeks 1 to 8 and then group or 1 to 1 from 12 weeks onwards. Not reported whether written materials were provided.		
Zaragoza-Fernandez 2012	Community pharmacies Spain	Sessions on diet, salt intake, alcohol consumption and exercise in hypertensive subjects who were taking anti-hypertensive drugs. Participants telephoned for 3 consecutive weeks and then conducted personal interview in week 4 where intensity of intervention stepped up	Hypertension	Weight Body Mass Index Arterial Blood pressure

See appendix D for full evidence tables.

Synthesis and quality assessment of effectiveness evidence included in the review

Studies included in this review were a mix of experimental and observational study designs. Studies with a control group were assessed for risk of bias using the Cochrane Effective Practice and Organisation of Care (EPOC) checklist as referenced in Appendix H of the NICE methods manual. The Effective Public Health Practice Project (EPHPP) QA Checklist was applied to assess risk of bias in uncontrolled before-and-after studies.

Meta-analysis was undertaken in Cochrane Review Manager (version 5.3). Where data from more than one study were pooled in a meta-analysis, a random effects model was used to account for the different effects anticipated across different study populations and types of intervention, including the mode of delivery.

A general approach was taken to pool data from RCTs with data from observational studies where the same outcome was being investigated under conditions that were considered sufficiently similar. This is because although observational studies may introduce more bias than RCTs, it has been suggested that this issue might be outweighed by the potential benefits of including data from observational studies to improve inferences from RCT trials, particularly where RCT evidence is limited, as the increased sample size may provide

additional evidence to choose a correct intervention for a condition (Shrier et al 2007)[a]. In this review, the pooling of experimental and observational data was undertaken for clinical outcomes (see GRADE profile 2; forest plot figures; ES 3.3, 3.6, 3.10, 3.12). Subgroup analyses were used to determine the impact of study design on the pooled result.

GRADE methodology was used to appraise the evidence across five potential sources of uncertainty: risk of bias, indirectness, inconsistency, imprecision and other issues. Overall ratings start at 'High' where the evidence comes from RCTs, and 'Low' for evidence derived from observational studies. Where RCT and observational studies remained pooled in analyses, a decision was made to start GRADE from 'Low'. Details of how the evidence for each outcome was appraised across each of the quality domains is given below.

Quality domain	Description
Risk of bias	Limitations in study design and implementation may bias the estimates of the treatment effect. Major limitations in studies decrease the confidence in the estimate of the effect. Examples of such limitations are selection bias (often due to poor allocation concealment), performance and detection bias (often due to a lack of blinding of the patient, healthcare professional or assessor) and attrition bias (due to missing data causing systematic bias in the analysis). Where there are no study limitations, evidence is assessed as having 'no serious' risk of bias. Alternatively, evidence may be downgraded one level ('serious' risk of bias) or two levels ('very serious' risk of bias).
Indirectness	Indirectness refers to differences in study population, intervention, comparator and outcomes between the available evidence and the review question. Where the evidence is directly applicable to the PICO, it is assessed as having 'no serious' risk of indirectness. Alternatively, evidence may be downgraded one level ('serious' risk of indirectness) or two levels ('very serious' risk of indirectness).
Inconsistency	Inconsistency refers to an unexplained heterogeneity of effect estimates between studies pooled in the same meta-analysis. The I^2 statistic describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance). The committee agreed that a large amount of clinical and methodological diversity would be expected from pooled analyses of studies in this area. This heterogeneity could be explained by differences in study design, content of interventions and comparators, or differences in clinical risk factors between study populations. In these cases a rigid adherence to cut-offs for downgrading were therefore not applied. A decision was made to downgrade pooled analyses by 1 level (indicating 'serious' inconsistency) when the I^2 statistic was ≥75%. If the I^2 statistic for a pooled analysis was less than 75%, the evidence was not downgraded for inconsistency.
Imprecision	Results are imprecise when studies include relatively few patients and few events (or highly variable measures) and thus have wide confidence intervals around the estimate of the effect relative to clinically important thresholds. 95% confidence intervals denote the possible range of locations of the true population effect at a 95% probability, and so wide confidence intervals may denote a result that is consistent with conflicting interpretations (for example a result may be consistent with both public health benefit AND public health harm) and thus be imprecise. Imprecision was assessed with reference to minimally important difference (MID) thresholds for individual outcomes (smallest change in an outcome that is

[a] Shrier, I., Boivin, J., Steele, R. J. et al. 2007. Should Meta-Analyses of Interventions Include Observational Studies in Addition to Randomized Controlled Trials? A Critical Examination of Underlying Principles. *American Journal of Epidemiology,* 166 (10); 1203-1209.

Quality domain	Description
	considered important by patients or health care professionals). Established MIDs are published in previous literature and seen and accepted in clinical community. For studies on weight reduction a loss of at least 5% was deemed as clinically important. For pooled analyses on absolute weight loss, 70 kg was used as an average indicator of population weight to calculate the MID [ES 3.1-3.3]. For blood pressure changes a reduction of 10mmHg systolic and 5mmHg of diastolic was noted as being clinically important as derived from a recent meta-analysis of 464,000 people, which showed a 22% reduction in coronary heart disease events and a 41% reduction in stroke with these outcomes (11) [ES 3.6-3.7]. It was decided that the point measure would be used to decide whether or not the result was clinically important, and that the 95% confidence intervals would indicate certainty of this importance. Uncertainty is introduced where confidence intervals crossed the MID threshold. If the confidence interval crosses either the lower or upper MID threshold this indicates 'serious' risk of imprecision. Crossing both MID thresholds indicates 'very serious' risk of imprecision in the effect estimate. Default MIDs are used where no established MID's for individual outcomes are found (0.75 and 1.25 for dichotomous outcomes and 0.5 x SD of control group at baseline for continuous outcomes). If the MID could not be calculated (e.g. because standard deviation of outcome measure at baseline was not reported in the paper) then we downgraded by 1 level as it was 'not possible to calculate imprecision from the information reported in the study'. Where data was pooled in analyses, the study with the largest weight was used as the control group for default MID calculations [ES 3.5]. Where the 95% CI does not cross either MID threshold, the evidence is assessed as having 'no serious' risk of imprecision unless the effect estimate is derived on the basis of few events and a small study sample (that is, less than 300 events for dichotomous outcomes or total sample size less than 400 for continuous outcomes). In that case the results were downgraded one level for 'serious' imprecision to reflect uncertainty in the effect estimate.
Other issues	Publication bias is a systematic underestimate or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies. A closely related phenomenon is where some papers fail to report an outcome that is inconclusive, thus leading to an overestimate of the effectiveness of that outcome. Sometimes randomisation may not adequately lead to group equivalence of confounders, and if so this may lead to bias, which should be taken into account. Potential conflicts of interest, often caused by excessive pharmaceutical company involvement in the publication of a study, should also be noted.

Details of how the 4 main quality elements (risk of bias, indirectness, inconsistency and imprecision) were appraised for each outcome are given below in the GRADE tables. Publication or other bias was only taken into consideration in the quality assessment if it was apparent.

GRADE rating	Description
High	Further research is very unlikely to change our confidence in the estimate of effect.

GRADE rating	Description
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very Low	Any estimate of effect is very uncertain.

See Appendix F for full GRADE tables by outcome.

The quality of the evidence for the effectiveness outcomes ranged from moderate to very low, and the majority was very low in quality. This is because most of the included studies had either serious or very serious risk of bias. In addition, many of the effect estimates were imprecise because of small sample sizes and wide confidence intervals.

A summary of the quality of the evidence for each type of outcome is provided in table 3.

Table 3. Summary of the quality of the evidence for each outcome for behavioural support

Outcome		Quality of evidence
Clinical measurements or health outcomes	Weight	Moderate to very low
	Body Mass Index (BMI)	Moderate to very low
	Waist circumference	Very low
	Systolic blood pressure	Moderate to very low
	Diastolic blood pressure	Moderate to very low
	Cardiovascular disease	Very low
	Alcohol use	Moderate to very low
Action	Physical activity	Moderate to very low
	Healthy eating	Very low
	Weight management	Very low
	Mental health and wellbeing	Very low
	Alcohol use	Very low
	Smoking cessation	Moderate to very low
Intention	Physical activity	Very low
	Healthy eating	Very low
	Weight management	Very low
	Mental health and wellbeing	Very low
	Alcohol use	Very low
	Smoking cessation	Very low
	Other	Low
Attitudes	Patient activation measure	Very low
Knowledge	Cardiovascular disease	Very low
	Asthma	Very low
Awareness	Physical activity	Very low
	Healthy eating	Very low
	Weight management	Very low
	Mental health and wellbeing	Very low

Outcome		Quality of evidence
	Alcohol use	Very low
	Smoking cessation	Very low
Wellbeing	No evidence identified	No evidence identified
Quality of life	EQ-5D SF-12	Low Moderate

Acceptability evidence

To assess the acceptability of providing behavioural support interventions in community pharmacy settings, the views and experiences of pharmacy service users were sought from the qualitative literature. Included studies

Studies were included if they sought to determine the acceptability of providing behavioural support to pharmacy users or explored how these types of interventions could be made more acceptable to users of community pharmacy services. Anyone who may use a community pharmacy was eligible for participation and specific types of interventions included brief interventions, motivational interviewing or any form of behavioural support. Outcomes of interest were respondent preferences and experience and also quality of life. Data needed to be collected using either interviews (face to face, telephone, SMS or online) or focus groups. Only studies conducted in the UK, Australia, Canada and the Republic of Ireland were included. See Appendix A for full details of review protocol.

Summary of acceptability studies included in the evidence review

Two studies met the qualitative inclusion criteria. Both assessed the acceptability of alcohol consumption interventions and both were conducted in the UK. Individually the studies met some or most of the items on the quality assessment checklist.

First Author, Year	Design & Analysis	Country	Health Area	Number of Respondents	Outcomes	Quality Rating
Fitzgerald, 2008	Telephone interviews, Thematic analysis	UK	Alcohol consumption	19 pharmacy clients	Experience	+
Quirk, 2016	Semi-structured phone interviews, Framework analysis	UK	Alcohol consumption	24 participants from RCT (Dhital et al 2015)	Behaviour change Knowledge Experience Acceptability	++

See Appendix D for full evidence tables

Fitzgerald (2008[+]) conducted telephone interviews with 19 pharmacy service users (66% female) to evaluate the feasibility and acceptability of providing a brief intervention on alcohol in community pharmacies. Both positive and negative aspects of the experience emerged using thematic analysis.

Quirk (2016[++]) conducted semi-structured telephone interviews with 24 participants enrolled in an RCT that explored participant engagement with the community pharmacist brief intervention. Framework analysis uncovered perception of applicability of findings, pharmacist adherence to protocol, participant knowledge and acceptability of the intervention as key themes.

Quality assessment of acceptability studies included in the evidence review

Included studies were rated individually to indicate their quality, based on assessment using a checklist. The tool used to assess the quality of studies was selected from appendix H in the methods manual. The quality ratings used for included studies are outlined below:

++	All or most of the checklist criteria have been fulfilled, and where they have not been fulfilled the conclusions are Very unlikely to alter.
+	Some of the checklist criteria have been fulfilled, and where they have not been fulfilled, or are not adequately described, the conclusions are unlikely to alter.
-	Few or no checklist criteria have been fulfilled and the conclusions are likely or Very likely to alter.

One study met all the quality criteria on which it was assessed. The other study had deficiencies in reporting how the data was collected, was unclear how rigorous analysis or the data was and the data not being rich.

Economic evidence

Included studies

Papers were included if they met the PICO and were:

- Based on effectiveness and cost data from the UK, Australia, Canada or the Republic of Ireland.
- Published between 1990 and 2016.
- Published in English language.

The health areas of interests included: alcohol use, cancer awareness, prevention of cardiovascular disease, diabetes, substance misuse or falls, mental health and wellbeing, orthopaedic conditions, sexual health, smoking and smokeless tobacco or weight management.

Excluded studies

Papers were excluded if they:

- Were related to treatment of diseases and acute medical conditions, such as dispensing, other medicine or device services, self-care to improve the use of medicines or devices, urgent care.
- Were related to vaccinations.
- Only included interventions delivered by distance-selling (online) pharmacies.
- Only looked at the cost effectiveness of screening, checks and testing, such as blood glucose checks, blood pressure checks, cardiovascular risk assessments, cholesterol checks, medicine use reviews, mole checking services, NHS Health checks.

- Included interventions delivered by people other than community pharmacy staff. Studies that were delivered by a mixture of community pharmacy staff and other healthcare professionals were only included if results for the services provided by community pharmacy staff were reported separately.

See appendix K for full list of excluded studies.

Summary of cost effectiveness studies included in the review

A total of 2 cost effectiveness studies were included in this evidence review. Table 4 provides the details of these studies.

Table 4. Summary of cost effectiveness evidence for behavioural support

Study	Design	Setting and country	Intervention	Health area	Outcomes
Crealey et al. 1998	Cost effectiveness analysis	Community pharmacies Belfast, UK	Pharmacist Action on Smoking	Smoking cessation	Cost per life year saved
Sinclair et al. 1999	Cost effectiveness analysis	Community pharmacies Grampian area of Scotland, UK	Pharmacy Support Programme	Smoking cessation	Cost per quitter Incremental cost per life year

See appendix H for full evidence tables.

Economic model

Due to the lack of published economic evidence on behaviour change interventions in the community pharmacy setting, 2 new economic analyses were undertaken. Existing cost–utility models were identified that were based on, or directly informed, NICE guidance, evaluating smoking cessation (PH10, PH45, GID-PH94) and weight management interventions (CG43). These models were adapted to evaluate behavioural change interventions in these areas, provided in a community pharmacy setting.

The smoking cessation model assessed 4 case studies of interventions that were effective in causing a higher 'quit rate' compared with an alternative strategy (in 3 cases this was usual care, in 1 case a less-intensive intervention). 3 interventions were composed of counselling and nicotine replacement therapy (1 including a leaflet), the other study evaluated the use of photo ageing software. Due to heterogeneity, each case was evaluated separately in the economic model. The model has 3 main health states (current smoker, former smoker and dead), and 6 comorbidity states (e.g. asthma), with former smokers facing a lower comorbidity risk than smokers. Effectiveness was informed by the reported incremental 6-12 month quit rates, with mortality dependent on smoking status. The main health outcome was quality-adjusted life years (QALYs), with health-related quality of life also affected by smoking status and the presence of comorbidities. Costs included delivery of the intervention and NHS costs of managing comorbidities. Outcomes were evaluated over a person's lifetime, and were discounted annually by 3.5% to account for societal time preference.

The model found that all 3 interventions compared with usual care were highly cost effective, producing more QALYs and reducing overall costs, making them 'dominant' strategies. The counselling intervention that was compared with less-intensive counselling was also found to be dominant. QALY gains were largely attributable to the reduced mortality risk in people

who quit smoking, whereas cost reductions were predominantly caused by the reduced incidence of COPD, lung cancer and stroke among former smokers. These findings were robust to a number of scenario and sensitivity analyses, which found that interventions could cost at least 20-times more than their base case estimates and still remain cost-effective. Probabilistic sensitivity analysis was not undertaken, meaning parameter uncertainty was not fully captured in the model, and a cost-effectiveness acceptability analysis could not be undertaken.

The weight management model assessed 4 case studies of behaviour change interventions that were effective in causing a reduction in BMI or body weight compared usual care. Interventions included various components, such as counselling at 1-week to 3-month intervals, diet and exercise planning, and written advice. Due to this heterogeneity, each case was evaluated separately in the economic model. The model has 5 health states: healthy, dead, and 3 chronic comorbidity states (colorectal cancer, congestive heart disease and diabetes). Lower BMI would reduce a person's risk of developing a comorbidity. Effectiveness was informed by the reported 6-12 month BMI reduction, or weight reduction converted to BMI, compared with a background 'natural' BMI increase on the usual care arm. Weight loss was assumed to be temporary, lasting for 1 year then catching up with the usual care arm. Mortality was captured as a function of BMI and age. The main health outcome was QALYs, with health-related quality of life also affected by BMI and the presence of comorbidities. Costs included delivery of the intervention and NHS costs of managing comorbidities. Outcomes were evaluated over a person's lifetime, and were discounted annually by 3.5% to account for societal time preference.

The base case model determined that all 4 interventions are associated with higher total costs, but also improved health (more QALYs), than usual care. Each had an incremental cost-effectiveness ratio (ICER) of less than £20,000 per QALY gained compared with usual care. This means, at an opportunity cost of £20,000 per QALY, each would produce a net gain in health produced by the NHS. The ICERs ranged from £3,309 to £19,845 per QALY gained, such that the least cost-effective option is very close to the opportunity cost value of £20,000. This ICER is for the least effective intervention, which generated a BMI reduction of 0.3 kg/m^2 compared with usual care. Sensitivity analysis results showed the cost-effectiveness of this intervention to be highly uncertain: if baseline BMI is lower than 35 kg/m^2, or the background BMI increase is less than 0.15 kg/m^2 per year, it would no longer be cost-effective. Results for the other 3, more effective interventions (-0.6 to -1.7 kg/m^2) were more robust to sensitivity analysis, however, this range indicates that there is notable uncertainty in the true effect size of weight management interventions, which may be a concern given the borderline cost-effectiveness when a weight loss of 0.3 kg/m^2 is achieved. Additional uncertainty exists regarding the timing of weight loss, with studies reporting a single observation point at 6-12 months after the initial intervention. In reality, weight loss might be expected to occur gradually. Furthermore, a probabilistic analysis was not undertaken, meaning parameter uncertainty was not fully captured in the model, and a cost-effectiveness acceptability analysis could not be undertaken.

Full details of both new economic analyses are provided in Appendix J.

Evidence statements

Clinical measurements or health outcomes

Evidence statement 3.1 – Behavioural support increases the number of participants losing 5%, 10% or more of their body weight [GRADE profile 1].

- Very low quality evidence from 7 studies (1 randomised controlled trial, 5 before and after, 1 retrospective cohort study) with 2171 participants suggests that between 7.9% and

32%[b] of participants lost 5% or more of their body weight at 3 months after behavioural support.

- Very low quality evidence from 2 before and after studies with 711 participants suggests that between 10%[c] and 13.9% (10.7 to 17.7%) of participants lost 5% or more of their body weight at 6 months after behavioural support.
- Very low quality evidence from 1 retrospective cohort study with 183 participants suggests that 22.4%[d] of participants lost 5% or more of their body weight at 9 months after behavioural support.
- Very low quality evidence from 2 studies (1 randomised controlled trial and 1 before and after study) with 500 participants suggests that between 14.3% (7.1 to 24.7%) and 15.9% (12.1 to 20.4%) of participants lost 5% or more of their body weight 1 year after behavioural support.
- Very low quality evidence from 1 before and after study with 60 participants suggests that 3.3%[e] of participants lost 10% or more of their body weight 6 months after behavioural support.

Meta-evidence statement 3.2 – Short term and long term behavioural support reduces absolute weight (in kg) [GRADE profile 2]

- Very low quality evidence from a meta-analysis of 6 studies (2 randomised controlled trials and 4 observational studies) with 1148 participants found a decrease in absolute weight after short term behavioural support of up to 3 months (MD -1.65, 95% CI -2.01 to -1.28), although findings were not clinically important. There were no significant subgroup differences when analysed by type of study (p= 0.49, I^2 = 0%).
- Very low quality evidence from a meta-analysis of 5 studies (2 randomised controlled trials and 3 observational studies) with 1882 participants found a decrease in absolute weight after long term behavioural support of 6 months to one year (MD -1.97, CI -2.07 to -1.88), although findings were not clinically important. There were no significant subgroup differences when analysed by type of study (p= 0.25, I^2=26%).

Evidence statement 3.3 – Behavioural support reduces relative weight [GRADE profile1]

- Very low quality evidence from 3 studies (2 before and after studies and 1 retrospective cohort study) with 327 participants suggests that behavioural support may increase the percentage of weight lost at 3 months although findings were not clinically important (range -1.9% [SD 0.4] to -3.12% [SD 3.34][f]).
- Very low quality evidence from 1 before and after study with 59 participants suggests that behavioural support may increase the percentage of weight loss at 6 months although findings were not clinically important (-4.72% [SD 4.68][g]).
- Very low quality evidence from 1 retrospective cohort study with 183 participants suggests that behavioural support may increase the percentage of weight loss at 9 months although findings were not clinically important (-2.3% [SD 0.6][h]).

Meta-evidence statement 3.4– Short term and long term behavioural support reduces body mass index [GRADE profile 2]

[b] Unable to determine uncertainty in effect estimate.
[c] Unable to determine uncertainty in effect estimate.
[d] Unable to determine uncertainty in effect estimate.
[e] Unable to determine uncertainty in effect estimate.
[f] Unable to determine uncertainty in effect estimate.
[g] Unable to determine uncertainty in effect estimate.
[h] Unable to determine uncertainty in effect estimate.

- Very low quality evidence from a meta-analysis of 4 studies (2 randomised controlled trials and 2 observational studies) with 393 participants found a reduction in BMI after short term behavioural support of up to 3 months (MD -0.71, 95% CI -0.79 to -0.64), although findings were not clinically important. There were no significant subgroup differences when analysed by study type (p= 0.93, I^2= 0%).
- Very low quality evidence from a meta-analysis of 2 studies (1 randomised controlled trial and 1 observational study) with 253 participants found a reduction in BMI after long term behavioural support of 9 months to 1 year (MD -0.54, 95% CI -0.92 to -0.16) although findings were not clinically important. There were significant subgroup differences when analysed by study type (p=0.03, I^2= 79.7%). One moderate quality RCT study found no certain reduction in BMI (MD -0.30, CI -0.65 to 0.05) and 1 very low quality observational study found a non-clinically important reduction in BMI (MD -0.70, CI-0.72 to -0.68).

Meta-evidence statement 3.5 – Short term and long term behavioural support reduces waist circumference (in cm) [GRADE profile 2]

- Very low quality evidence form a meta-analysis of 3 observational studies with 317 participants found a clinically impotent reduction in waist circumference after short term behavioural support of up to 3 months (MD -2.94 CI -4.51 to -1.37).
- Very Low quality evidence from a meta-analysis of 2 observational studies with 238 participants found a clinically important reduction in waist circumference after long term behavioural support of between 6 and 9 months (MD -4.20 CI -4.32 to -4.09).

Meta-evidence statement 3.6 –Mixed evidence for short term and long term behavioural support reducing systolic blood pressure (mmHg) [GRADE profile 2]

- Very low quality evidence from a meta-analysis of 3 studies (1 randomised controlled trial and 2 observational studies) with 236 participants found an uncertain reduction in systolic blood pressure after short term behavioural support of up to 3 months (MD -7.13 CI -19.18 to 4.91). There was uncertainty in the effect estimate as the CI included the MID threshold and therefore clinical importance was undetermined. There were significant subgroup differences when analysed by study type (p< 0.001, I^2= 98.5%). One low quality RCT of 150 participants found a clinically important reduction in systolic blood pressure at 8 weeks (MD-17.90, CI -20.35 to -15.45), whilst very low quality evidence from 2 observational studies of 86 participants found an uncertain reduction in systolic blood pressure at 3 months (MD -1.80, CI -4.80 to 1.20).
- Very low quality evidence from a meta-analysis of 2 studies (1 randomised controlled trial and 1 observational study) with 1173 participants found an uncertain reduction in systolic blood pressure after long term behavioural support of 6 months to one year (MD -3.95 CI -13.58 to 5.68). There was uncertainty in the effect estimate as the CI included the MID threshold and therefore clinical importance was undetermined**.** There were significant subgroup differences when analysed by study type (p= 0.01, I^2= 85.1%). One moderate quality RCT of 1140 participants found no reduction in systolic blood pressure at one year (MD 0.40, CI -1.89 to 2.69), whilst 1 very low quality observational study of 33 participants found a non-clinically important reduction in systolic blood pressure at 6 months (MD -9.50, CI -16.63 to -2.37).

Meta-evidence statement 3.7 – Mixed evidence for short term and long term behavioural support reducing diastolic blood pressure [GRADE profile 2]

- Very low quality evidence from a meta-analysis of 3 studies (1 randomised controlled trial and 2 observational studies) with 236 participants found a non-clinically important

reduction in diastolic blood pressure after short term behavioural support of up to 3 months (MD -4.25, CI -11.74 to -3.23). There were significant subgroup differences when analysed by study type ($p< 0.001$, $I^2= 98\%$). One low quality RCT of 150 participants found a clinically important reduction in diastolic blood pressure at 8 weeks (MD-10.9, CI -12.72 to -9.08), whilst very low quality evidence from 2 observational studies of 86 participants found an uncertain reduction in systolic blood pressure at 3 months (MD -0.78, CI -2.93 to 1.38).

- Very low quality evidence from a meta-analysis of 2 studies (1 randomised controlled trial and 1 observational study) with 1173 participants found an uncertain reduction in diastolic blood pressure after long term behavioural support of 6 months to one year (MD -1.93, CI -6.93 to 3.07). There were significant subgroup differences when analysed by study type ($p< 0.01$, $I^2= 88\%$). One moderate quality RCT of 1140 participants found no reduction in diastolic blood pressure at 12 months (MD 0.42, CI -0.93 to 1.77), whilst 1 very low quality observational study of 33 participants found a non-clinically important reduction in systolic blood pressure at 6 months (MD -4.70, CI -7.89 to -1.51).

Evidence statement 3.8 – Mixed evidence of effectiveness for behavioural support improving cardiovascular disease [GRADE profile 1]

- Very low quality evidence from 1 randomised controlled trial with 26 participants suggests that behavioural support may reduce mean 10 year cardiovascular risk at 3 months (mean reduction of 10.5% [-22.71 to 1.71]). However, very low quality evidence from the same study suggests that behavioural support does not significantly affect mean cardiovascular age at 3 months (mean difference of 0 years [-4.62 to 4.62]).

Evidence statement 3.9 – No evidence of effectiveness for behavioural support for reducing alcohol use (compared to leaflets) [GRADE profile 1]

- Low quality evidence from 1 randomised controlled trial with 407 participants that there is no difference between behavioural support and leaflets at 3 months for the overall AUDIT score (OR 0.87, 95% CI 0.50 to 1.51).
- There is moderate quality evidence from the same study that there is no difference in the consumption subscale of the AUDIT score (between group difference -0.05 [-0.54 to 0.44]) and very low quality evidence that there is no difference in the problem use subscale of the AUDIT score (between group difference -0.13 [-0.66 to 0.41]). Low quality evidence from the same study that leaflets may result in lower scores on the dependence subscale of the AUDIT score compared to behavioural support (between group difference of -0.46 [-0.82 to -0.09]).

Action

Evidence statement 3.10 – Mixed evidence of effectiveness for behavioural support increasing physical activity [GRADE profile 3]

- Very low quality evidence from 1 randomised controlled trial with 23 participants suggests that there is no change in the number of people in the action or maintenance stage of increasing physical activity at 2 weeks after behavioural support (RR 1.63, 95% CI 0.84 to 3.16).
- Very low quality evidence from 1 randomised controlled trial of 70 participants suggests that more calories are used per week 3 months (2720 calories [1790 to 3649]) and 1 year (1473 calories [742 to 2203]) after behavioural support.
- Very low quality evidence from 1 randomised controlled trial of 70 participants suggests that there is no difference in the number of minutes per week spent doing moderate or

vigorous intensity exercise at 3 months (mean difference 73 minutes [51 to 94]) or 1 year (mean difference 27 minutes [3 to 51]) after behavioural support.

- Very low quality evidence from 1 randomised controlled trial of 70 participants suggests that the number of minutes per week spent walking was not different 3 months (1 minute [-11 to 14]) and 1 year (17 minutes [-0.4 to 34]) after behavioural support.
- Very low quality evidence from 1 before and after study with 22 participants suggests that there is no change in the median number of moderate intensity (2.0 to 3.0) or vigorous intensity (0 to 0.5) sessions per week 3 months after behavioural support.
- Very low quality evidence from 1 before and after study with 22 participants suggests that there were more people doing muscle-strengthening activity on 2 or more days per week 3 months after behavioural support (RR 5.00, 95% CI 1.23 to 20.24) although this was not clinically important.
- Very low quality evidence from 1 before and after study with 155 participants suggests that 29% of participants who set goals related to physical activity achieved them by 12 months (45/155).

Evidence statement 3.11 – Behavioural support has a positive effect on action related to healthy eating [GRADE profile 3]

- Very low quality evidence from 1 randomised controlled trial with 23 participants suggests that there is no difference in the number of people in the action or maintenance stage of behaviour change for low fat diet (RR 1.16, 95% CI 0.94 to 1.42) or low salt diet (RR 1.05, 95% CI 0.82 to 1.35) at 2 weeks after behavioural support.
- Very low quality evidence from 1 before and after study with 22 participants suggests that people eat a greater median number of vegetable (1.0 to 3.0, $p<0.05$) and fruit servings per day (1.0 to 2.0, $p<0.05$) and lower number of sweet snack servings per day (1.0 to 0, $p<0.05$) at 3 months after behavioural support.
- Very low quality evidence from 1 before and after study with 77 participants suggests that 31% of participants who set goals related to diet achieved them at 12 months (24/77).

Evidence statement 3.12 – No evidence of effectiveness for behavioural support increasing action related to weight management or mental health and wellbeing [GRADE profile 3]

- Very low quality evidence from 1 randomised controlled trial with 23 participants suggests that there is no difference in the number of participants in the action or maintenance stage of behaviour change for losing weight (RR 1.15, 95% CI 0.88 to 1.51) or reducing stress (RR 1.00, 95% CI 0.71 to 1.41) at 2 weeks after behavioural support.
- Very low quality evidence from 1 before and after study with 43 participants suggests that 19% of participants who set goals related to mental health and wellbeing achieved them at 12 months (8/43).

Evidence statement 3.13 – Behavioural support increases action related to smoking cessation [GRADE profile 3]

- Very low quality evidence from 1 randomised controlled trial with 14 participants suggests that there is no difference in the number of participants in the action or maintenance stage of behavioural change for stopping smoking (RR 1.10, 95% CI 0.72 to 1.69) at 2 weeks after behavioural support.
- Very low quality evidence from 1 before and after study with 177 participants suggests that there is an increase in the number of people abstaining from smoking at 4 weeks (44.6%), 12 weeks (35.0%) and 44 weeks (15.8%) after behavioural support.

- Very low quality evidence from 1 before and after study with 73 participants suggests that there is an increase in the number of people abstaining from smoking at 6 months (38.4%) after behavioural support.
- Very low quality evidence from 1 before and after study with 48 participants suggests that 27% of participants who set goals related to smoking achieved them at 12 months (13/48).
- Low quality evidence from 1 randomised controlled trial with 484 participants suggests that more people abstain from smoking after the Pharmacist Action on Smoking intervention compared to usual care at 12 months (14.3% vs. 2.7%, chi squared=16.2), as well as at 12 weeks (27.5% vs. 11%) and 6 months (18.5% vs. 8.2%).
- Very low quality evidence from 1 randomised controlled trial with 480 participants suggests that there is no difference in the number of people abstaining from smoking after the Pharmacy Support Program intervention compared to usual care at 1 month (mean difference 6.3% [-1.6 to 14.2]), 4 months (mean difference 5.2% [-1.0 to 11.4]) and 9 months (mean difference 4.6% [-0.8 to 10.0]).
- Moderate quality evidence from 1 randomised controlled trial with 6809 participants suggests that there is no difference in the number of participants abstaining from smoking at 12 weeks after 1 counselling session compared to after 3 counselling sessions (OR 0.96, 95% CI 0.86 to 1.08).
- Low quality evidence from 1 cohort study with 5,214 participants found that 28% of individuals had continuous smoking abstinence at 6 months after 5 sessions of smoking cessation program.

Evidence statement 3.14 – No evidence of effectiveness for behavioural support reducing alcohol use [GRADE profile 3]

- Very low quality evidence from 1 randomised controlled trial with 6 participants suggests that there is no change in the number of people in the action or maintenance stage of reducing alcohol consumption 2 weeks after behavioural support (RR 1.00, 95% CI 0.75 to 1.34).
- Very low quality evidence from 1 before and after study of 37 participants suggests that there is no reduction in the number of alcohol units per week 3 months after behavioural support (0.7 units per week [-5.9 to 4.5]).
- Very low quality evidence from 1 before and after study of 36 participants suggests that there is no difference in the median number of drinking days per week (reduction of 1 day) 3 months after behavioural support.
- Very low quality evidence from 1 before and after study of 41 participants suggests that there is no difference in AUDIT-C score 3 months after behavioural support (no change).
- Very low quality evidence from 1 before and after study with 12 participants suggests that 50% of participants who set goals related to alcohol use achieved them at 12 months (6/12).

Intention

Evidence statement 3.15 – No evidence of effectiveness for behavioural support increasing intentions related to physical activity, healthy eating, or mental health and wellbeing [GRADE profile 4]

- Very low quality evidence from 1 before and after study with 23 participants suggests that behavioural support interventions may not affect intention related to physical activity, healthy eating, mental health and wellbeing, or smoking cessation. There is no clinically important difference in the number of participants in the preparation stage of behaviour change for increasing physical activity (RR 0.38, 95% CI 0.11 to 1.24), eating a low fat

diet (RR 0.33, 95% CI 0.04 to 2.97), eating a low salt diet (RR 0.50, 95% CI 0.05 to 5.14), or reducing stress (RR 0.33, 95% CI 0.01 to 7.78) at 2 weeks compared to before the intervention.

Evidence statement 3.16 – Mixed evidence of effectiveness for behavioural support increasing interventions related to smoking cessation [GRADE profile 4]

- Very low quality evidence from 1 before and after study with 23 participants suggests that there is no clinically important difference in the number of participants in the preparation stage of behaviour change for stopping smoking (RR 0.50, 95% CI 0.05 to 4.90) at 2 weeks compared to before the intervention.
- Very low quality evidence from 1 before and after study with 683 participants suggests that behavioural support interventions may increase the number of goals set in relation to smoking cessation (1.1%)[i].
- Low quality evidence from 1 randomised controlled trial with 480 participants suggests that there is an increase in the number of people buying nicotine replacement therapy after the Pharmacy Support Program compared to usual care (data not reported).

Attitudes

Evidence statement 3.17 - Behavioural support has a positive effect on patient activation scores [GRADE profile 5]

- Very low quality evidence from 1 before and after study with 378 participants suggests that there is an increase in the mean patient activation measure score after behavioural support (mean difference 5.39).
- Very low quality evidence from the same study suggests that the number of participants in levels 3 and 4 of patient activation (showing more patient activation) increased after behavioural support [redacted] whereas the number of participants in levels 1 and 2 of patient activation (showing less patient activation) decreased after behavioural support [redacted]

Knowledge

Evidence statement 3.18A – No evidence of effectiveness for behavioural support increasing knowledge of cardiovascular disease [GRADE profile 6]

- Very low quality evidence from 1 randomised controlled trial with 23 participants suggests that there is no difference in the median number of causes of cardiovascular disease listed by participants before and after behavioural support (median number of 3 before and after the intervention[j]).

Evidence statement 3.19B – Behavioural support increases asthma knowledge [GRADE profile 6]

Very low quality evidence from 1 before-after study with 31 participants in Finland found that asthma knowledge increased 12 months after a pharmacist- facilitated asthma self-management program, mean difference 1.00 (95%CI 0.49 to 1.5). The increase in knowledge was still observed at 24 months follow-up, mean difference 0.80 (95%CI 0.27 to 1.33).

[i] Unable to determine uncertainty in effect estimate.
[j] Unable to determine uncertainty in effect estimate.

Awareness

Evidence statement 3.20– No evidence of effectiveness for behavioural support for increasing awareness related to physical activity, healthy eating, weight management, mental health and wellbeing, or smoking cessation. [GRADE profile 7]

- Very low quality evidence from 1 randomised controlled trial with 23 participants suggests that there is no difference in the number of participants in the contemplation and precontemplation stage of behaviour change for increasing physical activity (RR 1.00, 95% CI 0.42 to 2.40), eating a low fat diet (RR 0.33 (95% CI 0.01 to 7.78), eating a low salt diet (RR 1.00, 95% CI 0.15 to 6.51), reducing stress (RR 1.20, 95% CI 0.43 to 3.38) or stopping smoking (RR 1.00, 95% CI 0.16 to 6.14) at 2 weeks after behavioural support.

Wellbeing

Evidence statement 3.21 - No evidence was identified for the effect of behavioural interventions on knowledge. [GRADE profile 8]

- No evidence was identified for the effect of behavioural support on wellbeing.

Quality of life

Evidence statement 3.22 – There is mixed evidence for behavioural support improving quality of life [GRADE profile 9]

- Low quality evidence from 1 randomised controlled trial with 407 participants that suggests that behavioural support interventions for alcohol use may improve quality of life compared to leaflets. The EQ-5D score is higher at 3 months after behavioural support than after leaflets (between group difference 0.09 [0.02 to 0.16]).
- Moderate quality evidence from 1 randomised controlled trial with 1140 participants found that physical aspects of quality of life improved at 1 year after behavioural support (between group Mean difference 2.39 (95%CI 1.43 to 3.34) but mental aspects did not (between group mean difference 1.08 (95%CI -0.21 to 2.37) as measured on the SF-12 quality of life scale (range 0 to 100).

Factors affecting effectiveness

Evidence statement 3.23 – No evidence was identified for what characteristics of the person delivering the intervention affect its effectiveness

No evidence was identified that directly compares interventions delivered by different members of staff working for a community pharmacy.

Evidence statement 3.24 – No evidence was identified for how the way the intervention is delivered affects its effectiveness, except in smoking cessation

No evidence was identified that directly compares interventions delivered in different ways by community pharmacy staff, except for in smoking cessation.

Evidence statement 3.25 – No evidence was identified for what characteristics of the person receiving the intervention affect its effectiveness

No evidence was identified that directly compares different people receiving the same intervention delivered by community pharmacy staff.

Acceptability of intervention evidence statements

Evidence statement 3.26 Pharmacy users were generally receptive to receiving a brief intervention on alcohol consumption in a community pharmacy setting.

Two UK studies [+[6], ++[13]] found that pharmacy service users generally held positive views about receiving alcohol behavioural support interventions in pharmacy and said they thought it was a *"…good idea. Well it's for health reasons as well and I think it tells you if you're a very heavy drinker or a light drinker"[13].* Additionally, perceived familiarity of the community pharmacists, suggest there are parallels with the doctor/ patient model *"He's a very nice chap in there, he's looked after my father over the years and I've come to know him quite well"* [13.] Participants consistently noted it was important for the pharmacists to be understanding, empathic and non-judgemental in delivery of the interventions. Some participants commented on the pharmacist's professional, calm and understanding manner *"I didn't feel like I was under the spotlight, it was a relaxed conversation*".

On the other hand a small number of participants screened as hazardous or harmful drinkers held less favourable views of the intervention *"I would say it would be worthwhile to other people but I didn't really find it worthwhile. I don't feel I've got a problem with alcohol"[6].*

[6.] Fitzgerald 2008 [+]

[13] Quirk 2016 [++]

Evidence statement 3.27 There were mixed reports in terms of whether or not behavioural support in community pharmacy would lead to actual change in volume and pattern of alcohol consumption

One UK study [++[13]] reported that some respondents felt the process of being assessed and provided with individualised results about drinking had little effect as individually they did not think they were consuming too much alcohol *"I don't feel that I've actually got a problem"*. However other participants spoke of being affected by the intervention, sometimes profoundly in one of two ways. First, simply responding to questions about their drinking and the impact it had on their lives, could be surprising in that it made participants aware of how much they were drinking *"I probably drink more than I realised, it's just that you don't think about it until someone asks you to number something and you think God, actually I probably drink two bottles of wine on the weekend".* Second it was being advised that their drinking was unhealthy or excessive that was "*pretty scary"* for some. Other individuals indicated they cut down their drinking as a result of receiving the intervention "*I know that drinking is bad and drinking to excess is bad and I've cut down on my drinking a lot since I first went to the pharmacy and took part in the study. I don't drink half as much as I used to".*

[13] Quirk 2016 [++]

Evidence statement 3.28 Providing behavioural support increases knowledge and awareness regarding safe and high risk alcohol consumption behaviour

One UK study [++[13]] found that many respondents realised they were consuming more alcohol than they thought *"I don't think about it until someone asks you to number something and you think God, actually I probably drink two bottles of wine on the weekend*". In contrast others felt reassured by the communication of recommended levels of consumption and were put at ease *"I was shocked at my result. It was quite good".* The limited effects of the intervention are suggested by the absence of risk or problem identification but one participant went on to articulate something close to the intended intervention effect for those who do not have alcohol problems "*When we started to get into the conversation and taking part and, it sort of opened my eyes to, I'm not a weekly drinker, I'm not an excessive drinker, I don't binge drink, but there was a few little things that came to light that are not a problem. But*

there's times when I could have sort of not drunk but I did drink, if you know what I mean. It's just a little bit of an eye opener really"

However pharmacist must be certain to adhere to the training they receive in providing feedback as there were reports that some went to great pains to reassure participants that their drinking was not excessive thus departing from the intervention protocol *"I thought I was excess. And when he explained to me he said no, you're not excess, you're OK on your drinking wise. He said, your health shouldn't suffer that much. And I thought that was good".* One participant evidently misunderstood his situation, which may have been because it had not been communicated clearly by the pharmacist "*I wasn't told that I was drinking more than the recommended amount because I don't. I'm not a huge drinker though"*

[13] Quirk 2016 [++]

Evidence statement 3.29 Printed information is a valuable and desired component of the behavioural support intervention for alcohol consumption

One study [++] reported that participants who received written information about alcohol consumption still used it even after the study period was over as they found it a useful reference and in fact preferred the written material to a conversation with the pharmacist *"the best thing she gave me was the unit and calorie counter, which I still have on my pin board because it's very interesting".* Additionally some participants also thought that the behavioural intervention was inappropriately targeted and that the printed materials were more useful *"there was a leaflet as well, rather than the conversation. I think the conversation was probably more directed at someone who maybe had experienced issues of severe heavy drinking".*

[13] Quirk 2016 [++]

Cost-effectiveness evidence statements

Evidence statement 3.30 Cost per life-year saved with Pharmacist Action or support on Smoking intervention ranged from £83 to £772.12

- One high quality study with a cost-effectiveness analysis suggests that the cost per life-year saved with the Pharmacist Action on Smoking intervention ranged from £181.35 to £772.12. The cost per life year saved for men was £351.45 if they quit at the age of 35 and £202.22 if they quit at the age of 75. The cost per life year saved for women was £772.12 if they quit at the age of 35 and £181.35 if they quit at the age of 75. Sensitivity analyses based on a 45 year old male smoker (base case cost of £276.67 per life year gained) varied the uptake rate of the intervention by the pharmacies, the number of patients using each pharmacy per year, the success rate of the intervention, natural rate of cessation, lifetime probability of relapse, fixed costs of the intervention, variable costs of the intervention and the discount rate. This resulted in costs per life year saved ranging from £110.75 to £553.14.
- One low quality study with a cost effectiveness analysis suggests that the average cost per quitter with the Pharmacy Support Programme is £572.80 compared to a cost of £742.50 with usual care. There is a gain of 16.6 life years with the Pharmacy Support Programme, resulting in an incremental cost per life year of £83 compared to usual care.

Evidence statement 3.31 Behaviour change interventions for smoking cessation produce QALY gains and reduce overall costs

- One directly applicable cost–utility analysis with potentially serious limitations, developed for this guideline, found behaviour change interventions for smoking cessation to dominate usual care. Incremental QALYs ranged from 0.12 to 0.14, and

incremental costs from -£347 to -£231, per person. More-intensive counselling (3 sessions) was also found to dominate less-intensive counselling (1 session), with 0.05 additional QALYs and -£148 in incremental costs. These results were found to be robust to univariable sensitivity analyses, however probabilistic sensitivity analysis was not undertaken.

Evidence statement 3.32 Behaviour change interventions for weight management produce ICERs of £3,309 to £19,845 per QALY gained

- One directly applicable cost–utility analysis with potentially serious limitations, developed for this guideline, found behaviour change interventions for weight management to have ICERs of less than £20,000 per QALY gained compared with usual care. Incremental QALYs ranged from 0.005 to 0.021, and incremental costs from £70 to £109, per person. These results were found to be highly sensitive to the treatment effect size, with an ICER of £19,845 per QALY gained for the least-effective intervention (Lighten Up, -0.3 kg/m^2) compared with no intervention. At this effect size, the model was also highly sensitive to baseline BMI and natural BMI change over time, though this was not the case at higher effect sizes associated with other interventions (-0.6 to -1.7 kg/m^2). Probabilistic sensitivity analysis was not undertaken.

Recommendations

1.4.1 Offer behavioural support in line with NICE's guidelines on:

- behaviour change: individual approaches (see the recommendations on using proven behaviour change techniques when designing interventions; and on high intensity behaviour change interventions and programmes)
- behaviour change: general approaches (see principles 4 and 5).

1.4.2 Help people to stop smoking by offering behavioural support programmes in line with NICE's guideline on evidence-based stop smoking interventions and services and the recommendation on behavioural support in NICE's guideline on smoking: harm reduction

1.4.3 Help people to manage their weight by offering behavioural support programmes in line with NICE's guidelines on:

- obesity: identification, assessment and management (see the section on behavioural interventions)
- weight management: lifestyle services for overweight or obese adults (see recommendation 11), preventing excess weight gain and obesity prevention.

1.4.4 Consider giving information such as leaflets, or props such as calorie counters or portion size plates, when providing behavioural support.

1.4.5 Consider referring people to other behavioural support services if they are not available in the pharmacy, for example, to voluntary or community services that are part of the local health and care network.

Evidence discussion

Interpreting the evidence

The outcomes that matter most

The committee agreed that clinical measurements or health outcomes and actions were a critical outcome for this review. Nineteen effectiveness studies addressed these outcomes [ES 3.1-3.25]. They agreed that intentions, attitudes, knowledge and awareness were also important outcomes [ES 3.15-3.20], with wellbeing and quality of life being less important outcomes [ES 3.21-3.22].
The committee noted that no evidence was identified for the effect of behavioural support interventions on wellbeing [ES 3.21], or for any variations in effectiveness from the characteristics of the person delivering the intervention [ES 3.23], the person receiving the intervention [ES 3.25] or the way the intervention was delivered [ES 3.24].

Two qualitative studies conducted in the UK assessed the acceptability of providing behavioural support interventions in community pharmacy settings [ES 3.26-3.29]. Furthermore, two studies which investigated the cost-effectiveness of behavioural support programs in relation to smoking cessation were identified in this review [ES 3.30].

The committee acknowledged that some of the studies across the review included members of community pharmacy staff other than pharmacists who delivered the interventions, however outcomes for different staff members were not directly compared within the studies. The committee agreed that as long as appropriate training was in place and staff were competent there was no reason to expect different outcomes from other pharmacy staff delivering interventions.

The committee acknowledged that some of the evidence indicated that behavioural support informed positive effects on clinical outcomes, action, attitudes and knowledge in certain health areas [ES 3.1-3.8, 3.12, 3.18, 3.22, 3.23]. The acceptability evidence also revealed data to support the provision of behavioural support for managing alcohol consumption in community pharmacy settings [ES 3.26-3.29]. However there were concerns with the quality, applicability and generalisability of individual studies which are discussed in further detail below

The quality of the evidence

The committee agreed that there was not enough good quality evidence to make strong recommendations for all health areas investigated. There were 20 studies of effectiveness, of which 11 were conducted in the UK, 1 in Australia, 3 in Canada and 5 in the European Union. The committee noted that few of the included studies considered the same interventions and most had small sample sizes. The committee acknowledged that where possible, pooled analyses of observational and randomised controlled trial (RCT) data were conducted to combine results from different studies and identify patterns among clinical outcomes. Data was pooled from outcomes of absolute weight change, BMI, waist circumference, and blood pressure [ES 3.3, 3.6, 3.8, 3.10, 3.12]. .

The committee noted that the evidence indicated behavioural support increased actions related to smoking cessation at 4 weeks, 12 weeks, 6 months and 12 months follow up [ES 3.18]. There was mixed evidence of effectiveness for behavioural support increasing intentions related to smoking cessation [ES 3.21]. Cost effectiveness evidence also supported the Pharmacists Action on Smoking and the Pharmacy Support Programme [ES 3.34]. Furthermore, the new economic evaluation indicated that behavioural support within this area was cost effective and there was no suggestion that these interventions would cause any harm or disadvantages for participants [ES 3.30, 3.32-3.33]. The committee

agreed that with the addition of the cost-effectiveness evidence this was an area of good evidence and agreed to make recommendations in line with previous NICE guidance on smoking, where recommendations are strong.

The committee noted that very low quality evidence from individual studies suggested that behavioural support increased the number of participants losing 5% or more of their body weight at 3, 6, 9 and 12 months [ES 3.1] and relative weight at 3 and 6 months [ES 3.4]. Very low to moderate quality pooled data from meta-analyses suggested that behavioural support may also reduce absolute weight [ES 3.3], BMI [ES 3.6] and waist circumference [ES 3.8] although not all findings were clinically important. Furthermore, the new economic evaluation indicated that behavioural support within this area was cost effective and there was no suggestion that these interventions would cause any harm or disadvantages for participants [ES 3.30, 3.32-3.33]. The committee agreed that behavioural support for weight loss should be implemented within community pharmacies and delivered in line with relevant NICE guidance which is based on strong recommendations.

The committee considered 3 moderate to very low quality effectiveness studies and 2 high to moderate quality UK acceptability studies on alcohol consumption. There was no evidence of effectiveness for behavioural support reducing alcohol use when compared to leaflets [ES 3.14] and no evidence of effectiveness for behavioural support reducing alcohol use when compared to usual care [ES 3.19]. The committee noted that one study which had 407 participants showed a change in the consumption subscale of the AUDIT score of 0.5, which was not deemed to be clinically significant. The committee also agreed that the short follow-up duration of 3 months did not enable the long-term impact of the intervention to be considered [ES 3.14]. The committee decided that 2 other effectiveness studies (one RCT, one before and after study) were very weak due to small sample sizes and short follow-up periods [ES 3.19]. The committee further noted that 1 of these studies used an AUDIT score of 4 as a cut-off for hazardous drinking. They agreed that this is lower than used in other studies (on review by the technical team a threshold AUDIT-C score of 5 or more may indicate hazardous or harmful drinking).

In contrast, the committee acknowledged that the acceptability evidence in relation to behavioural support for alcohol consumption revealed positive findings. Two high quality studies indicated that pharmacy users were receptive to receiving a brief intervention on alcohol consumption [ES 3.30] and that behavioural support increased knowledge and awareness regarding safe and high risk alcohol consumption [ES 3.32]. Despite this, the committee agreed that recommendations would not be made and that more research which utilises a robust effectiveness assessment of alcohol behaviour change in a pharmacy setting that is appropriately powered and measured over a longer period of time is needed.

The committee noted that there was mixed evidence for behavioural support improving cardiovascular disease outcomes [ES 3.12]. The committee agreed that the number of participants, the follow up period and the intensity of intervention may have not been sufficient to demonstrate any clinical effectiveness. The committee acknowledged that there was some evidence of effect for behavioural support increasing physical activity [ES 3.15] and healthy eating [ES 3.16] although the evidence was considered weak. The committee agreed that information on healthy eating and increased physical activity would be an integral part of obesity and weight management behavioural interventions, therefore recommendations were not required. One very low quality before and after study indicated that there was an increase in patient activation after behavioural support [ES 3.22]. The committee noted that these interventions may be beneficial as they involve the patient setting their own health goals and they may help target those who have lower levels of activation and thus less likely to play an active role in staying healthy. However, due to the paucity of evidence, the committee agreed to make a research recommendation here.

Advantages and disadvantages of behavioural support

The committee agreed with the evidence that behavioural support interventions which support health and wellbeing would be beneficial in community pharmacy settings. It was noted that smoking cessation and weight management were powerful examples of high benefit and low risk health areas where evidence was in favour of pharmacist based interventions. A number of studies found benefits on actions related to smoking cessation such as the number of people abstaining from smoking at 1 month, 3 months, 6 months, 10 months and 12 months [ES 3.13]. Weight management benefits were found in relation to the number of participants losing 5% or more of their body weight at 3, 6, 9 and 12 months [ES 3.1], relative weight at 3 and 6 months [ES 3.4], absolute weight [ES 3.3], BMI [ES 3.6] and waist circumference change [ES 3.8].

The committee agreed that the evidence suggested there were no direct harms or disadvantages of delivering behavioural support within community pharmacy settings. It was further noted that the evidence showed the most beneficial results when the interventions followed the agreed evidence based principles for facilitating behaviour change, therefore it was recommended that behavioural support should be delivered in line with previous NICE guidance on behaviour change individual and general approaches.

Cost effectiveness and resource use

One high quality study with a cost-effectiveness analysis suggested that the cost per life-year saved with the Pharmacist Action on Smoking intervention ranged from £181.35 to £772.12 [ES 3.29]. The cost per life-year saved for men was £351.45 and £202.22 if they stopped smoking at the age of 35 and 75 respectively, whereas for women it was £772.12 and £181.35 if they quit at the age of 35 and 75 respectively. Sensitivity analyses based on a 45-year old male smoker (base-case cost of £276.67 per life year gained) varied according to the uptake rate of the intervention by the pharmacies, the number of people using each pharmacy per year, the success rate of the intervention, the natural rate of cessation, the lifetime probability of relapse, the fixed costs of the intervention, the variable costs of the intervention, and the discount rate. This resulted in costs per life year saved ranging from £110.75 to £553.14.

One low quality study with a cost-effectiveness analysis suggested that the average cost for each person who stopped smoking with the Pharmacy Support Programme is £572.80 compared with £742.50 for usual care. There is a gain of 16.6 life years with the Pharmacy Support Programme, resulting in an incremental cost per life year of £83 compared with usual care [ES 3.29].

A new economic evaluation was performed to assess the cost-effectiveness of behaviour change interventions for smoking cessation in the community pharmacy setting. The model compared 2 counselling interventions and 1 photo ageing software intervention with usual care (no intervention), and 1 counselling intervention with less-intensive counselling (3 sessions versus 1 session). The lifetime model captured 6 comorbidities, with their incidence dependent on smoking status (either current or former), and smoking-related mortality. The main health outcome was QALYs, and costs included delivery of the intervention and management of comorbidities. The model found the 3 interventions compared with usual care to be highly cost effective, producing more QALYs and reducing overall costs. This was also true of the counselling intervention compared with less-intensive counselling. These findings were robust to scenario and sensitivity analyses, however the committee was aware that no probabilistic sensitivity analysis, and consequently no cost-effectiveness acceptability analysis, was undertaken. However, on balance, the committee concluded that behaviour change interventions for smoking cessation are likely to offer good value for money in the community pharmacy setting.

A new economic evaluation was performed to assess the cost-effectiveness of behaviour change interventions for weight management in the community pharmacy setting. The model compared the Counterweight, Lighten Up, My Choice and the Boardman et al. (2014) interventions with usual care (no intervention). These interventions comprised various components, such as counselling at 1-week to 3-month intervals, diet and exercise planning, and written advice. The lifetime model tracked a person's BMI over time, with BMI linked to mortality and the incidence of 3 chronic comorbidities: colorectal cancer, coronary heart disease and diabetes. Weight loss was assumed to be temporary, lasting for 1 year. The main health outcome was QALYs, and costs included delivery of the intervention and management of comorbidities. The model found all 4 interventions to be more effective and more costly than usual care, but each had an ICER below £20,000 per QALY gained (£3,309 to £19,845). A probabilistic analysis was not undertaken, meaning parameter uncertainty was not fully captured in the model, and a cost-effectiveness acceptability analysis could not be undertaken. The cost-effectiveness of the least effective intervention (Lighten Up) was sensitive to small variation in baseline BMI or natural weight gain BMI increase. Results for the other 3, more effective and cost-effective interventions were more robust. However, the range of effect sizes across the 4 studies (-0.3 kg/m^2 to -1.7 kg/m^2) indicates that there is notable uncertainty in the true effect size of weight management interventions, which may be a concern given the borderline cost-effectiveness when a weight loss of 0.3 kg/m^2 is achieved. Additional uncertainty exists regarding the timing of weight loss, with studies reporting a single observation point at 6-12 months after the initial intervention. In reality, weight loss might be expected to occur very gradually. The committee was aware of the uncertainties present in the analysis, but agreed that the base-case model assumptions might in fact be conservative, for example with people returning to the no intervention BMI level after 1 year. On balance, it was felt that there is a reasonable likelihood that behaviour change interventions for weight management are will offer good value for money in the community pharmacy setting.

The committee agreed that the recommendations should reduce variation in current practice and ensure commissioners focus on behavioural support activities that have been shown to be both effective and cost effective, as highlighted in this review. They also agreed that some pharmacy staff may need training in effective behaviour change techniques which may incur some resource costs. Other factors the committee took into account

The committee noted that there is evidence to support the use of behavioural support for some health areas within community pharmacy settings. The committee acknowledged that there were gaps in the evidence in regard to health areas such as cancer awareness, drug misuse prevention, orthopaedic conditions and sexual health. In addition there were no studies which investigated motivational interviewing or motivational enhancement therapy and no studies that directly compared different types of behavioural support, or behavioural support compared to education or brief advice.

Linked expert testimony

No expert testimony was used to inform the recommendations in this review.

Appendices

Appendix A – Review protocols

A number of elements within the protocols are common across two or more of the review questions. To reduce repetition these details have been included below the protocols, and will not be repeated in each protocol.

The elements common across reviews 1 to 4 are:

- Eligibility criteria - population
- Eligibility criteria - interventions
- Eligibility criteria - comparators
- Outcomes and prioritisation
- Eligibility criteria - study design
- Other inclusion or exclusion criteria
- Selection process - duplicate screening
- Data management (software)
- Information sources - databases and dates
- Methods for assessing bias at outcome or study level

See common elements across reviews 1 to 4 for more details.

Review question 3a - Effectiveness of behavioural support

Field	Content
Review question 3a	What types of behavioural support for self-care to promote health behaviour change are effective in community pharmacies? Community pharmacy services related to treating disease and acute medical conditions that do not involve promoting health and wellbeing such as dispensing, other medicine or device services, vaccinations, self-care to improve use of medicines or devices, and urgent care are out of scope.
Type of review question	Intervention
Objective of the review	This review aims to determine which interventions are effective for offering behavioural support for self-care to promote health and wellbeing in community pharmacy. The review will also explore whether effectiveness varies by the characteristics of the intervention, the person delivering the intervention, or the person receiving the intervention.
Eligibility criteria - population	Anyone who may use community pharmacy services See common elements section for further details.
Eligibility criteria - interventions	Any intervention delivered by community pharmacy staff that offers behavioural support for self-care to promote health and wellbeing, including: • Brief interventions • Very brief interventions • Extended brief interventions • Motivational interviewing • Motivational enhancement therapy

Field	Content
	• Any other form of behavioural support, e.g. ask, advise, act Exclusions: • Interventions delivered by anyone who is not working for a community pharmacy • Interventions delivered by distance-selling (online) pharmacies See common elements section for further details
Eligibility criteria - comparators	No intervention. Any intervention provided by community pharmacy staff that provides information. Any intervention provided by community pharmacy staff that offers advice or education to promote health and wellbeing. Any other behavioural support intervention provided by community pharmacy staff. See common elements section for further details.
Outcomes and prioritisation	1 Clinical measurements or health outcomes 2 Behavioural outcomes - Action 3 Modifying factors or determinants of behaviour - Intention - Attitudes - Knowledge - Awareness 4 Wellbeing 5 Quality of life See common elements section for further details.
Eligibility criteria – study design	• Systematic reviews of studies of effectiveness - Studies of effectiveness, including: o Randomised controlled trials o Quasi-experimental studies, such as non-randomised controlled trials and before and after studies See common elements section for further details.
Other inclusion or exclusion criteria	Only papers published in English will be included. Only studies undertaken in the UK, Australia, Canada and Republic of Ireland will be included. See common elements section for further details. March 15, 2017: The committee requested that in addition to the initially agreed 4 countries the effectiveness review be expanded to include studies from the European Union (including Norway and Switzerland), New Zealand and Chile. Change approved by NICE QA on March 28, 2017

Field	Content
Proposed sensitivity or subgroup analysis	Where evidence allows, the review will also answer the following sub questions: I. What characteristics of the person delivering the intervention (for example their job role and competencies, or being a health champion) affect its effectiveness in community pharmacy? II. How does the way the intervention is delivered, for example, the medium used, when, how often, or where the intervention takes place (such as in a consultation room, over the counter, in someone's home, or electronic communication) affect its effectiveness in community pharmacy? III. What characteristics of the people receiving the intervention (for example, age or gender) affect its effectiveness in community pharmacy? Subgroup analysis by the health area (for example, physical activity, smoking cessation) may be undertaken, if appropriate.
Selection process – duplicate screening	See common elements section for details.
Data management (software)	See common elements section for details.
Information sources – databases and dates	See common elements section for details.
Methods for assessing bias at outcome or study level	See common elements section for details.
Criteria for quantitative synthesis	For details please see section 6.4 of Developing NICE guidelines: the manual
Methods for quantitative analysis – combining studies and exploring inconsistency	Data from different studies will be meta-analysed if the studies are similar enough in terms of interventions, comparators and outcomes.
Meta-bias assessment- publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual.
Confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual
Review staff	Rachel Walsh (Technical Analyst) Ella Novakovic (Senior Technical Analyst) Daniel Tuvey (Information Specialist)

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Review question 3b - Acceptability of behavioural support

Field	Content
Review question 3b	Is offering behavioural support acceptable to users of community pharmacy services?
Type of review question	Views and experiences
Objective of the review	The review aims to determine whether offering behavioural support is acceptable to users of community pharmacy services. It will also explore how interventions could be made more acceptable to users of community pharmacy services.
Eligibility criteria - population	Anyone who may use community pharmacy services See common elements section for further details.
Eligibility criteria - interventions	Any intervention delivered by community pharmacy staff that offers behavioural support for self-care to promote health and wellbeing, including: • Brief interventions • Very brief interventions • Extended brief interventions • Motivational interviewing • Motivational enhancement therapy • Any other form of behavioural support, e.g. ask, advise, act Exclusions: • Interventions delivered by anyone who is not working for a community pharmacy • Interventions delivered by distance-selling (online) pharmacies See common elements section for further details.
Eligibility criteria - comparators	No intervention. Any intervention provided by community pharmacy staff that provides information. Any intervention provided by community pharmacy staff that offers advice or education to promote health and wellbeing. Any other behavioural support intervention provided by community pharmacy staff. See common elements section for further details.
Outcomes and prioritisation	Preference and experience of people using the service Quality of life See common elements section for further details.
Eligibility criteria – study design	Interviews – unstructured and semi-structured (face to face, via telephone or SMS, or online). Focus groups. See common elements section for further details.

Other inclusion or exclusion criteria	Only studies undertaken in the UK, Australia, Canada and Republic of Ireland will be included. Only studies published in English will be included. See common elements section for further details.
Proposed sensitivity or subgroup analyses	Where evidence allows, the review will also answer the following sub question: I. How can behavioural support be made more acceptable to users of community pharmacy services? Subgroup analysis by the health area (for example, physical activity, smoking cessation) may be undertaken, if appropriate.
Selection process – duplicate screening	See common elements section for details.
Data management (software)	See common elements section for details.
Information sources – databases and dates	See common elements section for details.
Methods for assessing bias at outcome or study level	See common elements section for details.
Criteria for qualitative synthesis	For details please see section 6.4 of Developing NICE guidelines: the manual
Methods for qualitative analysis – combining studies and exploring inconsistency	Data from different studies will be summarised using narrative synthesis.
Meta-bias assessment-publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual.
Confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual
Review staff	Rachel Walsh (Technical Analyst) Ella Novakovic (Senior Technical Analyst) Daniel Tuvey (Information Specialist)

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Field	Content
Review question 3c	What types of behavioural support for self-care to promote health behaviour change are cost effective in community pharmacies?
Type of review question	Cost effectiveness
Objective of the review	This review aims to determine which interventions are cost effective for offering behavioural support for self-care to promote health and wellbeing in community pharmacy. The review will also explore whether cost effectiveness varies by the characteristics of the intervention, the person delivering the intervention, or the person receiving the intervention.
Eligibility criteria - population	Anyone who may use community pharmacy services See common elements section for further details.
Eligibility criteria - interventions	Any intervention delivered by community pharmacy staff that offers behavioural support for self-care to promote health and wellbeing, including: • Brief interventions • Very brief interventions • Extended brief interventions • Motivational interviewing • Motivational enhancement therapy • Any other form of behavioural support, e.g. ask, advise, act Exclusions: • Interventions delivered by anyone who is not working for a community pharmacy • Interventions delivered by distance-selling (online) pharmacies See common elements section for further details
Eligibility criteria - comparators	No intervention. Any intervention provided by community pharmacy staff that provides information. Any intervention provided by community pharmacy staff that offers advice or education to promote health and wellbeing. Any other behavioural support intervention provided by community pharmacy staff. See common elements section for further details
Outcomes and prioritisation	Costs, savings and effectiveness - Cost per quality adjusted life year - Cost per unit of effect - Net benefit See common elements section for further details
Eligibility criteria – study design	• Systematic reviews of cost-effectiveness studies • Economic evaluations • Cost-utility studies • Cost benefit studies • Cost-effectiveness studies • Cost minimisation studies

Field	Content
	• Cost-consequence studies See common elements section for further details
Other inclusion or exclusion criteria	Only papers published in English will be included. Only studies undertaken in the UK, Australia, Canada and Republic of Ireland will be included. See common elements section for further details
Proposed sensitivity or subgroup analysis	Where evidence allows, the review will also answer the following sub questions: I. What characteristics of the person delivering the intervention (for example their job role and competencies, or being a health champion) affect its cost effectiveness in community pharmacy? II. How does the way the intervention is delivered, for example, the medium used, when, how often, or where the intervention takes place (such as in a consultation room, over the counter, in someone's home, or electronic communication) affect its cost effectiveness in community pharmacy? III. What characteristics of the people receiving the intervention (for example, age or gender) affect its cost effectiveness in community pharmacy? Subgroup analysis by the health area (for example, physical activity, smoking cessation) may be undertaken, if appropriate.
Selection process – duplicate screening	See common elements section for details.
Data management (software)	See common elements section for details.
Information sources – databases and dates	See common elements section for details.
Methods for assessing bias at outcome or study level	See common elements section for details.
Criteria for quantitative synthesis	For details please see section 6.4 of Developing NICE guidelines: the manual
Methods for quantitative analysis – combining studies and exploring inconsistency	Data from different studies will be meta-analysed if the studies are similar enough in terms of interventions, comparators and outcomes.
Meta-bias assessment-publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual.

Field	Content
Confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual
Review staff	Rachel Walsh (Technical Analyst) Ella Novakovic (Senior Technical Analyst) Daniel Tuvey (Information Specialist)

Common elements across reviews 1 to 4

The following aspects are common across two or more of the review questions.

Eligibility criteria - population

Studies of people who have access to or are using community pharmacy services in any setting are included. This means that studies of people using community pharmacy services in commercial settings (such as high streets or supermarkets), healthcare settings (such as general practices), or community settings (such as care homes, places of worship) will be included. Studies of community pharmacy services provided in any area, including healthy new towns, will be included.

Studies of people using community pharmacy services in their own home, for example, if community pharmacy staff deliver medicines to their home, will be included.

Studies of people using distance selling pharmacies (also known as online pharmacies) will be excluded from this review.

Eligibility criteria - interventions

Inclusions

Studies of interventions delivered by community pharmacy staff will be included. This includes studies of interventions provided outside of a community pharmacy premises if the intervention is provided by community pharmacy staff. For example, a study of leaflets provided by community pharmacy staff in a place of worship would be included. Studies of interventions provided by staff who are not community pharmacy staff will be excluded, even if the intervention is delivered in community pharmacy premises. For example, a study of an intervention delivered by a GP that has rented a room in a community pharmacy but is working as an out of hour's service would be excluded. Studies that describe public health interventions provided by a 'clinical pharmacist' will be included if these studies were performed in a community pharmacy setting. Studies of interventions delivered by pharmacy students, within a community pharmacy setting, will be included.

Studies of health promotion campaigns from NHS England and Public Health England (such as Change4Life, One You, Eat well Guide) will be included if they are delivered by community pharmacy staff. Studies of other initiatives, such as Men's Health Week, will be included if they are delivered by community pharmacy staff.

Studies of interventions that provide checks and testing to monitor the outcomes of interventions as part of behavioural support will be included in review 3.

Studies of any type of referral or signposting by community pharmacy staff to other services or support will be included in review 4. This includes:

- studies of referral or signposting to services or support offered by other NHS services, such as NHS stop smoking services
- studies of referral or signposting to services or support offered by non-NHS services, such as those provided by charity organisations
- studies of referral or signposting to other community pharmacies that offer services that are not available at the community pharmacy that the person presented to, such as chlamydia screening

Studies of signposting or referral to any service or support by community pharmacy staff will be included in review 4. This may include:

- disease management programs
- lifestyle weight management programs
- alcohol treatment services
- substance misuse services, including self-help groups
- sexual health services, including STI clinics and services that offer full range of contraceptive methods
- support services for smoking cessation, such as NHS Stop Smoking services
- Social prescribing for debt management, domestic violence helplines, housing support, befriending.

Exclusions

The effectiveness of screening, checks and testing will not be assessed in this review. This includes the effectiveness of:

- blood glucose checks
- blood pressure checks
- cardiovascular risk assessments
- cholesterol checks (including point of care tests)
- medicine use reviews
- mole checking services
- NHS Health Checks

NICE is unable to make recommendations on screening as these are provided by the National Screening Committee. Studies that look at the effectiveness of health promotion information and advice provided during screening (such as lifestyle advice), checks or testing will be included.

Studies of vaccinations will not be included in this review. Recommendations on vaccinations are provided by other NICE guidelines, such as Flu vaccination – increasing uptake (in development) and Immunisations: reducing differences in uptake in under 19s (PH21). Studies that look at the effectiveness of health promotion information and advice provided during a vaccination appointment, such as advice on sunlight exposure for people receiving vaccinations for travel abroad, will be included.

Studies of interventions provided by people who are not community pharmacy staff will be excluded. For example, studies of leaflets provided by district nurses would be excluded. Studies of interventions provided by pharmacy students, outside of the community pharmacy setting will be excluded. For example, an educational seminar led by pharmacy students directed at peers would be excluded.

Studies of interventions that are delivered in part by community pharmacy staff and in part by other healthcare professionals, such as GPs, will only be included if the study reports the results for community pharmacy staff separately. If results are not presented separately for community pharmacy staff then the study will not be included.

Health areas

Studies of interventions in any health area will be included. This includes the following health areas:

- alcohol use, including:
  - alcohol misuse
  - recommended levels of alcohol consumption
- cancer awareness (all cancers), including:
  - risks and benefits of behaviours including:
    - sunlight exposure
    - use of sun care products
    - approaches to protecting skin (clothing, shade and sunscreen)
  - early signs and symptoms of any cancer, such as blood in urine or stools
- cardiovascular disease prevention, including:
  - lifestyle factors
- diabetes prevention, including:
  - lifestyle factors
  - healthy eating
  - physical activity
- substance misuse prevention, including:
  - needle and syringe exchange programmes, including disposal and injecting equipment
  - harm reduction services, including advice on safer injecting practices
  - provision of, or access to services for, blood-borne virus testing, and treatment, including hepatitis B, hepatitis C and HIV
- falls prevention including:
  - correctly fitted footwear
  - using handrails
  - hydration and diet
  - physical activity
- mental health and wellbeing, including
  - getting a good night's sleep
  - physical activity in green spaces, such as how and where to do this locally
- orthopaedic conditions (such as osteoporosis, osteoarthritis and lower back pain), including:
  - physical activity
  - diet
- sexual health, including:
  - emergency contraception
  - safer sex practice, including use of condoms
  - methods of contraception
  - preventing unwanted pregnancies

- pregnancy testing
- sexually transmitted infections, including testing
- information on HIV testing

- smoking and smokeless tobacco, including:
  - stopping use
  - harm reduction
  - nicotine-containing products
  - the importance of smoke free homes
- weight management, including:
  - maintaining a healthy weight
    - why maintaining a healthy weight is beneficial
    - how to maintain a healthy weight
    - checking weight
  - nutrition:
    - healthy eating
    - vitamin D
    - sugar
    - salt
    - saturated fat
    - folic acid
    - child and maternal health
  - physical activity
    - benefits of physical activity
    - appropriate local opportunities to be more active
    - recommended levels of physical activity
  - weight reduction programmes
    - over the counter weight management products
    - healthy eating
    - physical activity

Eligibility criteria - comparators

Studies with comparators provided outside of a community pharmacy premises are to be included only if the comparator is provided by community pharmacy staff. For example, a study that uses leaflets provided by community pharmacy staff in a place of worship as a comparator would be included.

Studies with comparators that are delivered in part by community pharmacy staff and in part by other healthcare professionals, such as GPs, will only be included if the study reports the results for interventions delivered by community pharmacy staff separately. If results are not presented separately for interventions delivered by community pharmacy staff then the study will not be included.

Studies that compare the effectiveness of different types of community pharmacy staff to deliver an intervention will be included. For example, studies that compare leaflets provided by community pharmacy staff who are health champions to leaflets provided by community pharmacy staff who are not health champions.

Studies that compare the way the intervention is delivered will be included. For example, studies that compare face to face with electronic communication, or studies that compare one-off interventions to interventions delivered at every contact with staff, will be included.

Studies that compare the effectiveness of interventions in different groups of people using community pharmacy services will be included. For example, studies comparing the effectiveness of self-help booklets in men and women would be included.

Outcomes and prioritisation

Health outcomes may include clinical measurements, such as physiological and biochemical measures related to risk factors, such as blood pressure, body mass index, or blood glucose levels. It may also include mortality.

Examples of actions include behavioural outcomes such as smoking cessation or changes to levels of physical activity. It can include uptake, continuation and completion of services. 'Action' also includes intermediary steps to enacting a healthier behaviour, such as picking up a leaflet.

Studies may report patient activation, which refers to the knowledge, skills and confidence a person has in managing their own healthcare. Patient activation will be included as an outcome in the existing outcomes listed in the review protocols above.

Outcomes with longer timescales will be prioritised over shorter outcomes, e.g. body mass index at 12 months will be prioritised over body mass index at 3 months.

See table i. for the prioritisation and minimal important differences for each outcome in review questions 1a, 2a, 3a and 4a. These will be used to inform the GRADE profiles.

Table i. Prioritisation and minimal important difference for each outcome

Outcome	Priority	Minimal important difference
Review question 1a (information and awareness raising)		
Action	Critical	25% point change in relative risk
Intention	Important	25% point change in relative risk
Attitudes	Important	25% point change in relative risk
Knowledge	Important	25% point change in relative risk
Awareness	Important	25% point change in relative risk
Review questions 2a (advice or education) and 3a (behavioural support)		
Clinical measurements or health outcomes	Critical	25% point change in relative risk
Action	Critical	25% point change in relative risk
Intention	Important	25% point change in relative risk
Attitudes	Important	25% point change in relative risk
Knowledge	Important	25% point change in relative risk
Awareness	Important	25% point change in relative risk
Wellbeing	Less important	25% point change in relative risk
Quality of life	Less important	25% point change in relative risk
Review question 4a (signposting and referral)		
Uptake of interventions or services to promote, maintain and improve health and wellbeing	Critical	25% point change in relative risk

Eligibility criteria - study design

Systematic reviews will only be included if the review question in the paper matches the review question in the evidence review for the guideline. Systematic reviews that do not answer a review question of interest may be used for citation searching if primary searches

do not yield a substantial amount of evidence. Systematic reviews must have clear inclusion/exclusion criteria and report critical appraisal of included studies to be included.

For review questions 1a, 2a, 3a and 4a (effectiveness) primary studies will only be included if they are comparative. This includes:

- Studies that compare a group that receives an intervention to another group that does not receive an intervention,
- Studies that compare a group that receives an intervention to another group that receives a different intervention,
- Studies that compare the same group before and after an intervention.

Studies that compare the same intervention in different groups will be included to answer the sub question on whether the characteristics of the people receiving an intervention (for example, age or gender) affect its effectiveness.

Qualitative studies that relate to interventions of interest will be included for data on quality of life and preference and experience of people using the services. Only qualitative studies from the UK, Australia, Canada and the Republic of Ireland will be included.

In the event of more evidence being identified than is feasible to consider in the time available, priority will be given to using RCTs and nRCTs to identify data for comparative outcomes.

The following types of papers will not be included:

- Non-systematic literature reviews
- Case-control studies
- Cross-sectional studies
- Quantitative surveys
- Study protocols
- Opinion pieces
- Commentaries
- Editorials
- Letters

Other inclusion or exclusion criteria

The committee agreed that Australia, Canada and the Republic of Ireland, have community pharmacy services that are similar enough to the UK that studies from these countries can be used to make recommendations for UK practice. On March 15, 2017 the committee requested that in addition to the initially agreed 4 countries the effectiveness review be expanded to include studies from the European Union (including Norway and Switzerland), New Zealand and Chile. This change was approved by NICE QA on March 28, 2017. The committee felt that the community pharmacy services in other countries are too dissimilar to the UK to allow evidence from those countries to be used to make recommendations for UK practice.

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Selection process - duplicate screening

10% of the search results will be blind-screened by a second reviewer. Any disagreements will be resolved by the two reviewers, and escalated to a third reviewer if agreement cannot

be reached. If the initial level of agreement is below 90%, a second round of blind-screening will be considered.

All data extraction and critical appraisal will be checked by a second reviewer. Any disagreements will be resolved by the two reviewers, and escalated to a third reviewer if agreement cannot be reached.

In the event of more evidence being identified than is feasible to consider in the time available, priority will be given to:

- evidence with critical or highly important outcomes
- number of participants (n>100) or number of sites in the study.

These criteria were agreed by the committee at the Public Health Advisory Committee (PHAC) 0, however, further discussion of the criteria with PHAC will take place if necessary.

A date cut off of the year 1990 will be used. This is because this is when the National Health Service and Community Care Act 1990 was put in place and health authorities were given responsibility for managing their own budgets. Using 1990 is also consistent with the date that is used in the review question on pharmacists in the Acute Medical Emergencies in adults and young people services guidance that is currently in development by NICE.

Data management (software)

EPPI Reviewer will be used:

- to store lists of citations
- to sift studies based on title and abstract
- to record decisions about full text papers
- to store extracted data.

If meta-analysis is undertaken, Cochrane Review Manager 5 will be used to perform the analysis.

Qualitative data will be analysed using EPPI Reviewer. Qualitative data will be summarised using GRADE-CERQUAL (if appropriate) or narrative synthesis.

Information sources - databases and dates

The following sources will be searched:

- Medline
- Embase
- Cochrane Library
- PsycINFO
- Cinahl
- ASSIA
- EconLit
- EconPapers
- PharmLine
- Health Services Research in Pharmacy Practice

The following grey literature sources will also be searched:

- Social policy and practice
- NIHR journals library

- Academic centres (Pharmacy Schools): Aston, Bath, Birmingham, Bradford, Brighton, Central Lancashire, Sunderland, Durham, De Montfort, East Anglia, Greenwich, Hertfordshire, Huddersfield, Keele, Kingston, Lincoln, Liverpool John Moores, University College London, King's College London, Portsmouth, Reading, Sussex, Manchester, Nottingham, Wolverhampton, Robert Gordon, Strathclyde, Cardiff, Queen's University Belfast, Ulster (Coleraine).
- Healthwatch England
- Community Pharmacy Futures
- Pharmaceutical Services Negotiating Committee
- Centre for Pharmacy Postgraduate Education
- Royal Pharmaceutical Society
- Community Pharmacy Northern Ireland
- Community Pharmacy Scotland
- Community Pharmacy Wales
- Public Health England
- Department of Health
- Welsh Assembly
- Scottish Government
- NHS England

The following limits will be applied to the search:

- Date limit of 1990 to 2016
- English language

A study filter will not be applied.

Citation searching of included studies will be undertaken.

Results will be saved to an EndNote database and de-duplicated. Results will be provided to the Public Health team as RIS files, suitable for import into EPPI Reviewer

A record will be kept of number of records found from each database and of the strategy used in each database. A record will be kept of total number of duplicates found and of total results provided to the Public Health team.

Methods for assessing bias at outcome or study level

Standard study checklists will be used to critically appraise individual studies. For details please see section 6.2 of developing NICE guidelines: the manual

Where appropriate, the risk of bias across all available evidence will be evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/.

Appendix B – Literature search strategies

See separate appendix B document.

Appendix C – Effectiveness and acceptability included evidence

1. Boardman HF and Avery AJ (2014) Effectiveness of a community pharmacy weight management programme. International journal of clinical pharmacy, vol 36(4), p800-6.

2. Botomino A, Bruppacher R, Krahenbuhl S, Hersberger KE (2008) Change of body weight and lifestyle of persons at risk for diabetes after screening and counselling in pharmacies. Pharm World Sci;30:222-22

3. Bush J, Langley C, Mills S et al. (2014) A comparison of the provision of the My Choice Weight Management Programme via general practitioner practices and community pharmacies in the United Kingdom. Clinical obesity, vol 4(2), p91-100.

4. Costello MJ, Sproule B, Victor JC et al. (2011) Effectiveness of pharmacist counselling combined with nicotine replacement therapy: a pragmatic randomized trial with 6,987 smokers. Cancer Causes & Control, 1; 22(2): 167-80

5. Cramp GJ, Mitchell C, Steer C et al. (2007) An evaluation of a rural community pharmacy-based smoking-cessation counselling and nicotine replacement therapy initiative. International Journal of Pharmacy Practice. 1:15 (2), p113-21

6. Dhital R, Norman I, Whittlesea C et al. (2015) The effectiveness of brief alcohol interventions delivered by community pharmacists: randomized controlled trial. Addiction, vol 110 (10), p1586-94

7. Fitzgerald N, McCaig DJ, Watson H et al (2008) Development, implementation and evaluation of a pilot project to deliver interventions on alcohol issues in community pharmacies. Internationl Journal of Pharmacy Practice, 16 (3), 17-22

8. Jackson M, Gaspic-Piskovic M, Cimino S (2008) Description of a Canadian employer-sponsored smoking cessation program utilizing community pharmacy-based cognitive services. Canadian Pharmacists Journal/Revue des Pharmaciens du Canada. 1;141 (4):234-40

9. Jolly K, Lewis A, Beach J et al. (2011) Comparison of range of commercial or primary care led weight reduction programmes with minimal intervention control for weight loss in obesity: lighten Up randomised controlled trial. BMJ vol343, pd6500.

10. Khan N, Norman I, Dhital R et al. (2013) Alcohol brief intervention in community pharmacies: a feasibility study of outcomes and customer experiences. International journal of clinical pharmacy, vol 35(6), p1178-87.

11. Lalonde L, O'Connor AM, Duguay P et al. (2006). Evaluation of a decision aid and a personal risk profile in community pharmacy for patients considering options to improve cardiovascular health: The OPTIONS pilot study. International journal of pharmacy practice, vol 14(1), p51.

12. Maguire TA, McElnay JC, Drummond A (2001) A randomized controlled trial of a smoking cessation intervention based in community pharmacies. Addiction, 1;96 (2), p325-31

13. Morrison D, McLoone P, Brosnahan N et al. (2013). A community pharmacy weight management programme: an evaluation of effectiveness. BMC public health, vol 13, p282.

14. Narhi U, Airaksinen M, Tanskanen P, Enlund H (2001) The effects of a pharmacy-based intervention on the knowledge and attitudes of asthma patients. Patient Education and Counselling, 43:171-177

15. Neumann T, Rasmussen M, Ghith N, Heitmann B (2013) The Gold Standard Programme: smoking cessation interventions for disadvantaged smokers are effective in a real-life setting. Tobacco Control;22:1-8

16. Quirk A, MacNeil V, Dhital R et al (2016) Qualitative process study of community pharmacist brief alcohol intervention effectiveness trial: Can research participation effects explain a null finding? Drug and Alcohol Dependence: 161, 36-41

17. Schmiedel K, Mayr A, Fiebler C et al (2015) Effects of the Lifestyle Intervention Program GLICEMIA in People at Risk for Type 2 Diabetes: A Cluster-Randomized Controlled Trial. Diabetes Care;38:937-939

18. Sinclair HK, Bond CM, Lennox AS et al (1998) Training pharmacists and pharmacy assistant in the stage-of-change model of smoking cessation: randomised controlled trial in Scotland. Tobacco Control, 1;7(3), p253-61

19. Twigg MJ, Wright D, Kirkdale CL, Desborough JA, Thornley T (unpublished) The Pharmacy Care Plan Service: service evaluation and estimate of cost-effectiveness

20. Um IS, Krass I, Armour C et al. (2015) Developing and testing evidence-based weight management in Australian pharmacies: A Healthier Life Program. International journal of clinical pharmacy, vol 37(5), p822-33.

21. Winter H. (2007) Waist management: A pilot scheme using community pharmacists to address the issue of obesity. Pharmacy Management, vol 23 (2), p14-18

22. Zaragoza-Fernandez MP, Gastelurrutia MA, Cardero M, Martinez-Martinez F (2012) Intensive Two-Month Intervention of Diet and Lifestyle in Uncontrolled Hypertensive Patients in a Community Pharmacy. Latin American Journal of Pharmacy;31(5):727-733

Appendix Di – Effectiveness evidence tables

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Boardman HF, Avery AJ (2014) Effectiveness of a community pharmacy weight management programme. Int J Clin Pharm vol 36 p800-806

Quality score
+

Study type
Uncontrolled before and after study

Location and setting
Community pharmacies in England

Aims
To evaluate the effectiveness of a</td>
<td>Health area
Weight management

Number of participants
n=281 participants
34 pharmacies
4 PCTs

Participant characteristics
<table>
<tr><td>Female</td><td>181/234 (77%)</td></tr>
<tr><td>White</td><td>199/271 (73%)</td></tr>
<tr><td>Asian</td><td>18/271 (7%)</td></tr>
<tr><td>Black</td><td>3/271 (1%)</td></tr>
<tr><td>Mixed</td><td>2/271 (1%)</td></tr>
<tr><td>Other</td><td>49/271 (18%)</td></tr>
<tr><td>Mean age</td><td>52.8 years (SD 14.4, range 18 to 79) (n=260)</td></tr>
<tr><td>Mean weight</td><td>96.3kg (SD 15.7), range 64 to 144kg</td></tr>
<tr><td>Mean BMI</td><td>35.5kg/m^2 (SD 4.12, range 30.0 to 49.1) (n=281)</td></tr>
<tr><td>Mean waist circumference</td><td>111cm (SD 11.8, range 85 to 151) (n=271)</td></tr>
<tr><td>Mean hip circumference</td><td>120cm (SD 11.1, range 97 to 156) (n=177)</td></tr>
<tr><td>Mean systolic blood pressure</td><td>128mmHg (SD 17.9, range 91 to 201) (n=238)</td></tr>
<tr><td>Mean diastolic blood pressure</td><td>81mmHg (SD 10.3, range 53 to 114) (n=238)</td></tr>
<tr><td>High blood pressure</td><td>133 (47%)</td></tr>
<tr><td>Heart condition</td><td>91 (32%)</td></tr>
<tr><td>Diabetes:</td><td>104 (37%)</td></tr>
</table>
</td>
<td>Intervention
(n=281)
“Community Pharmacy Weight Management Program”

Number of sessions: 12 (1 initial visit, 11 follow ups every 2 weeks or monthly)

Length of sessions: Not reported

Who performed the sessions: Pharmacist

What was covered in each session: Individualised service with calorie restricted diet plans and increased physical activity targets reviewed at each visit, with other health advice (e.g. smoking cessation) where appropriate. Details of advice provided not available to</td>
<td>Recruitment:
Individual pharmacies within 4 PCTs decided whether or not to participant in the service.

Patients were recruited by pharmacy staff based on use of therapies for conditions associated with obesity, discussion about their weight, or referral by GP practice or self-referral.

Analysis:
Paired t tests used to compare weight and waist circumference. LOCF was used to determine the impact of drop out from the programme on the results.

Records were received for 332 users - 9 patients</td>
<td>LOCF analysis
<table>
<tr><td></td><td>N</td><td>3 months</td><td>6 months</td></tr>
<tr><td>Loss of 5% or more body weight (n, % of participants)</td><td>281</td><td>26 (9%*)
p value not reported</td><td>27 (10%*)
p value not reported</td></tr>
<tr><td>Weight (mean change in kg vs. baseline)</td><td>281</td><td>-1.692 (SD 3.14)
p<0.001</td><td>-1.931 (SD 3.70)
p<0.001</td></tr>
<tr><td>Waist circumference (mean change in cm vs. baseline)</td><td>281</td><td>Not reported
p<0.001</td><td>Not reported
p value not reported</td></tr>
</table>
*Percentage calculated by the NICE technical team and rounded to nearest whole number

Those attending follow up assessments
<table>
<tr><td></td><td colspan="2">3 months</td><td colspan="2">6 months</td></tr>
<tr><td></td><td>N</td><td>Mean change vs. baseline</td><td>N</td><td>Mean change vs. baseline</td></tr>
<tr><td>Weight (kg)</td><td>110</td><td>-3.07 (SD 3.49)
p<0.001</td><td>59</td><td>-4.59 (SD 4.74)
p<0.001</td></tr>
<tr><td>Percentage weight (%)</td><td>110</td><td>-3.12 (SD 3.34)</td><td>59</td><td>-4.72 (SD 4.68)</td></tr>
<tr><td>Waist circumference (cm)</td><td>100</td><td>-3.87 (SD 5.01) (95% CI -2.8759* to -4.8641*)
p<0.001</td><td>55</td><td>-4.79 (SD 5.37) (95% CI -6.2417* to -3.3383*)
p<0.001</td></tr>
<tr><td>Systolic blood pressure (mmHg)</td><td>64</td><td>-0.17 (SD 18.4) (95% CI -4.7662 * to 4.4262*)</td><td>33</td><td>-9.5 (SD 20.1) (95% CI -</td></tr>
</table>
</td>
</tr>
</table>

<table>
<tr>
<td>community pharmacy weight management programme in assisting obese patients to reduce their weight.

Length of follow up
6 months

Source of funding
This study was funded by Alliance Healthcare</td>
<td>
<table>
<tr><td>Family history of obesity or overweight</td><td>127 (45%)</td></tr>
</table>

Pharmacies included independents, small chains and large multiple pharmacies. Mean of 9 patients per pharmacy, range 1 to 21. PCTs were Berkshire West (105 participants [37%]), Cornwall and Isles of Scilly (53 participants [19%]), Coventry (76 participants [27%]), Plymouth (47 participants [17%]).

Inclusion criteria
• 18 years of over
• BMI 30 to 38 kg/m^2 (1 PCT did not have an upper limit)
• At least 1 risk factor for coronary heart disease:
  ○ hypertension,
  ○ hyperlipidaemia (except 1 PCT)
  ○ type 2 diabetes,
  ○ waist circumference of 102cm or more (males, 90cm if Asian) or 88cm or more (females, 80cm if Asian).

Exclusion criteria
Pregnant or breastfeeding women
Considered by pharmacist to be in too poor a state of health
</td>
<td>study authors.
Service provided differed slightly across the 4 PCTs (no further details reported).

Training provided to staff:
Pharmacists were trained on service structure, taking patient measurements and methods to motivate patients to change their behaviour.

Format of intervention: Face to face, not clear if group or 1 to 1, not clear if written information provided.</td>
<td>were excluded as there was no baseline weight or BMI recorded and 42 were excluded because their initial BMI was calculated as less than 30kg/m^2.

Of 281 participants:
54 (19%) did not attend any follow ups,
117 attended at least 1 follow up but dropped out before 3 months.
110 (39%) attended at 3 months
51 dropped out between 3 and 6 months
59 (21%) patients attended at 6 months.</td>
<td>
<table>
<tr><td></td><td></td><td>p=0.941</td><td></td><td>16.6272* to -2.3728* p=0.011</td></tr>
<tr><td>Diastolic blood pressure (mmHg)</td><td>64</td><td>0.42 (SD 11.7) (95% CI -2.5026* to 3.3426*) p=0.774</td><td>33</td><td>-4.7 (SD 9.0) (95% CI -7.8913 to -1.5087*) p=0.006</td></tr>
</table>
*Calculated by NICE technical team

A sensitivity analysis was used to exclude 43 patients with a BMI >38kg/m^2 who had been included in the study by 1 PCT – no change in statistical significance.

At 3 months, 72 (66%) lost less than 5kg, 23 (21%) lost more than 5kg and 15 (14%) gained weight or their weight was unchanged since baseline. At 6 months, 11 (19%) patients gained weight or their weight was unchanged since baseline. Overall 42 (15%) of those who had a baseline assessment were known to have achieved a 5% reduction in weight before leaving the program.

Measurements of cholesterol, random blood glucose and HbA1C were not reported by the study authors due to low numbers.
</td>
</tr>
<tr>
<td colspan="5">Limitations identified by authors
Absence of control group – cannot be confident that intervention caused the weight loss. High loss to follow up (61% at 3 months) – reasons are unknown. LOCF analysis still showed a statistically significant reduction at 3 months but with reduced effect size. Number of participants in some analyses is small (e.g. blood pressure at 6 months)
Limitations identified by review team
No additional limitations identified.
Other comments
Alliance Healthcare provided the service documentation, information about the service and the data for analysis to the authors, but it is stated that they had no influence on the study. No conflicts of interest declared by authors.</td>
</tr>
</table>

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Botomino 2008

Quality score
-
Study type
Controlled before and after study

Location and setting
Community pharmacies in Switzerland

Aims
To investigate the changes of body weight and lifestyle after three different types of counselling provided to persons at risk immediately after screening for type 2 diabetes in</td>
<td>Health area
Weight management

Number of participants
n=1370

Participant characteristics
Standard counselling group:
59.4 years (SD 10.8)
54.9% female
14.4% current smoker
Weight 77.9kg (SD 10.4)
BMI 27.3kg/m2 (SD 2.6)

Intensive counselling group:
58.3 (SD 11.6) years
53.4% female
9.7% current smoker
81.7 (SD 11.2)kg
BMI 28.8kg/m2 (SD 3.2)

No statistically significant differences between groups in age
Statistically significant differences between the groups in gender, smoking, weight and BMI

Inclusion criteria
18 years or older
BMI of 25.0kg/m2 or higher
1 or more additional risk factors:
Age 45 years or older
Low physical activity
Family history of diabetes
Delivery of a baby weight more than 4kg
Hypertension

Exclusion criteria</td>
<td>Pharmacists were trained in 2 compulsory evening courses. Immediately after screening, stage of change were assessed for health enhancing physical activity, reduced fat intake, and consumption of 5 servings of fruits and vegetables per day. Counselling was targeted according to stages of change. Pharmacists could choose to provide either standard counselling or intensive counselling to participants at moderate risk (2 or more risk factors) of diabetes. High risk participants (BMI 25kg/m2 or greater and 1 or more additional risk factors and abnormal blood glucose levels)</td>
<td>Recruitment:
Last questionnaires were sent in August 2003 (for 1 year follow up).
3,800 people were initially contacted and 2,177 returned the first questionnaire.
Participants were recruited from those attending a nationwide diabetes screening campaign in Switzerland.
Three months after screening, a stratified random sample of 3,800 people received a written questionnaire.
Stratified as 1,400 people at moderate risk of type 2 diabetes with standard counselling at the pharmacy, 1,500 people at moderate risk</td>
<td>1,436 (37.8%) of participants returned all three questionnaires. 2,177 returned the first questionnaire and 1,520 returned the second questionnaire. 14 participants were excluded because of wrong data linkage and 52 because of missing self-reported weight data. 1,370 participants in total. Non-responders showed significantly lower mean age and BMI. Subjects at high risk for type 2 diabetes showed a higher dropout rate than those at moderate risk.
All groups showed a significantly lower body weight at 3 months (p<0.001), highest in high risk group, and at 12 months (p<0.001). Slight weight gain in study group as a whole at 6 months, but not statistically significant.
At 1 year, high risk people who had not contacted a physician (n=47) had a weight loss of 1.67%.

Intensive counselling (n=568)
<table>
<tr><th>Outcome</th><th>Baseline</th><th>3 months</th><th>6 months</th><th>1 year</th></tr>
<tr><td>BMI</td><td>28.8 (SD 3.2)</td><td>28.5 (SD 3.3) p<0.001</td><td>28.6 (SD 3.5) p<0.001</td><td>28.4 (SD 3.4) p<0.001</td></tr>
<tr><td>Weight</td><td>81.7 (SD 11.2)</td><td>80.7 (SD 11.4) p<0.001</td><td>80.9 (SD 11.7) p<0.001</td><td>80.4 (SD 11.6) p<0.001</td></tr>
<tr><td>Percentage change of body weight</td><td>-</td><td>-1.20% (p not reported)</td><td>-0.88% (p not reported)</td><td>-1.54% (p not reported)</td></tr>
</table>
P values are vs. baseline
Standard counselling (n=557)
<table>
<tr><th>Outcome</th><th>Baseline</th><th>3 months</th><th>6 months</th><th>1 year</th></tr>
<tr><td>BMI</td><td>27.3 (SD 2.6)</td><td>27.1 (SD 2.7) p<0.001</td><td>27.1 (SD 2.7) p<0.01</td><td>26.9 (SD 2.7) p<0.001</td></tr>
<tr><td>Weight</td><td>77.9 (SD 10.4)</td><td>77.3 (SD 10.6) p<0.001</td><td>77.4 (SD 10.4) p<0.001</td><td>76.8 (SD 10.6) p<0.001</td></tr>
<tr><td>Percentage change of body weight</td><td>-</td><td>-0.67% (p not reported)</td><td>-0.51% (p not reported)</td><td>-1.29% (p not reported)</td></tr>
</table>
P values are vs. baseline
At 3 months, statistically significant differences between all counselling groups (p<0.001) in the number of participants who had lost 5% or more of their initial body weight (7.9% in standard counselling vs. 11.6% in intensive counselling). At</td>
</tr>
</table>

community pharmacies. **Length of follow up** 1 year **Source of funding** Funded by the Swiss Federation of Pharmacists, Health Promotion Switzerland and 5 Swiss health insurances	None stated	were recommended to contact their physician. Intervention Intensive counselling added individual advice on weight reduction and set goals on both nutrition habits (e.g. reduced fat intake and eating 5 fruits or vegetables a day) and physical activity (half an hour of physical activity daily, with at least moderate intensity, or 3 times 20 minutes with vigorous intensity each week). Comparator Standard counselling included unspecified recommendations on physical activity and nutrition.	with intensive counselling, and 900 people at high risk for type 2 diabetes. Data collected 3, 9 and 15 months after screening using anonymous follow up questionnaires. Data files were linked using a 5 digit code, and verified with data for sex and age. The questionnaires included 138 items used by the investigators. **Analysis:** Data sheets were processed electronically and verified visually. Data were deleted when out of a predefined plausibility range (no further details provided). Changes in BMI and weight over time was analysed using	1 year, no statistically significant difference between standard and intensive groups (16.7% vs 17.6%). At 3 months, 67.0% of standard group and 74.1% of intensive group had reported to have changed their physical activity and/or nutrition habits (p<0.001).

			repeated analysis of variance with linear contrasts and with counselling groups as covariates. Subsequent pairwise comparisons were performed using Tukey's-HSD multicomparison test. Different samples and counselling groups were compared using one-way ANOVA with Tukey correction for multiple comparisons, differences in prevalences by Pearson's two-sided chi-square or Fisher's exact test.	
Limitations identified by authors High drop-out rates, particularly in those at high risk Participants who answered all 3 questionnaires were probably more inclined to change their lifestyle Reasons for drop out and changes to lifestyle were not assessed. Self-reported data and uncontrolled study design. Participants were not randomised – pharmacists decided whether to provide intensive or standard counselling. **Limitations identified by review team**				

There were statistically significant differences in outcome measures and important characteristics at baseline between the standard and intensive groups, which were not accounted for in the analysis. It is unclear how many participants contributed to the final data for each group (and conversely, how many participants were excluded/dropped out from each group).

Other comments
Results for high risk participants were also reported in the paper, but as these participants were referred to their GP for advice their results are not reported here.

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Bush J, Langley C, Mills S, Hindle L (2014) A comparison of the provision of the My Choice Weight Management Programme via general practitioner practices and community pharmacies in the United Kingdom. Clinical obesity vol 4 (2), p91-100

Quality score
+

Study type
Non-randomised retrospective observational study

Location and setting
Community pharmacies, Birmingham, UK</td>
<td>Health area
Weight management

Number of participants
451 participants, of which 183 were in community pharmacy and 268 were in GP offices

Participant characteristics
Female: 86% (across GP and pharmacy)
Mean age: 41 years (across GP and pharmacy)

Pharmacy users:
Mean starting weight=86.1kg (SD 17.1)
Mean starting BMI=33.0kg/m^2 (SD 5.6)
Mean starting waist circumference=105.1cm (SD 13.4)

Pharmacy users:
Starting BMI:</td>
<td>Intervention
“My Choice Weight Management Program.”

Number of sessions: 12 (1 per week) and offered 3 follow up appointments for up to 6 months after.

Duration of sessions: Not reported

Who performed the sessions: ‘Trained healthcare workers, e.g. pharmacy assistant’ – other staff types not reported.

What was covered in each session: Set realistic weight loss targets (weekly weight loss of 0.5 to 1.0kg), encouraged to keep a food and exercise diary and to modify lifestyle, diet and physical activity. A different topic was covered at each appointment as follows:

Session 1: Assessment
Session 2: Healthy eating</td>
<td>Recruitment:
12 community pharmacies.

Providers of the program were responsible for recruiting participants.

Analysis:
Primary outcome was weight loss at session 12. Secondary outcomes were weight loss at session 15, proportion of participants losing 5% or more of body weight at sessions 12 and 15 and weight loss (or gain) between sessions 12 and 15.</td>
<td>Outcomes for pharmacy users:
<table>
<tr><th></th><th colspan="2">3 months</th><th colspan="2">9 months</th></tr>
<tr><th></th><th>Completers (n=92)</th><th>LOCF (n=183)</th><th>Completers (n=92)</th><th>LOCF (n=183)</th></tr>
<tr><td>Mean weight loss (kg)</td><td>2.4 (SD 0.6)</td><td>1.6 (SD 0.4)</td><td>3.4 (SD 1.1)</td><td>2.0 (SD 0.5)</td></tr>
<tr><td>Mean percentage weight loss (%)</td><td>2.8 (SD 0.7)</td><td>1.9 (SD 0.4)</td><td>4.0 (SD 1.3)</td><td>2.3 (SD 0.6)</td></tr>
<tr><td>No change in weight</td><td>14 (15.4%)</td><td>55 (30.5%)</td><td>13 (21.7%)</td><td>58 (31.7%)</td></tr>
<tr><td>0.1 to 4.9% weight loss</td><td>56 (61.5%)</td><td>102 (55.7%)</td><td>19 (31.7%)</td><td>84 (45.9%)</td></tr>
<tr><td>5% or greater weight loss</td><td>21 (23.1%)</td><td>26 (14.2%)</td><td>28 (46.7%)</td><td>41 (22.4%)</td></tr>
<tr><td>Mean reduction in BMI (kg/m^2)</td><td>0.9 (SD 0.2)</td><td>0.7 (SD 0.2) (95% CI 0.67* to 0.73*)</td><td>1.3 (SD 0.4)</td><td>0.7 (SD 0.2) (95% CI 0.67* to 0.73*)</td></tr>
<tr><td>Mean reduction in waist circumference (cm)</td><td>4.9 (SD 0.9)</td><td>3.6 (SD 0.7) (95% CI</td><td>6.5 (SD 1.6)</td><td>4.2 (SD 0.8) (95% CI 4.08* to 4.32*)</td></tr>
</table>
</td>
</tr>
</table>

Aims To assess the effectiveness of a novel, community-based weight management programme delivered through general practitioner practices and community pharmacies. **Length of follow up** 9 months **Source of funding** The research was funded by a grant from the commissioning organisation (NHS Heart of Birmingham teaching Primary Care Trust).	<30kg/m^2=52 (28.6%) 30-34kg/m^2=75 (41.2%) 35-39kg/m^2=29 (15.9%) ≥40kg/m^2=26 (14.3%) **Inclusion criteria** Aged 18 years or over BMI greater than 30kg/m^2 (or 25 kg/m^2 if South Asian) or greater than 28 kg/m^2 with one or more of the following: diabetes, hypertension, cardiovascular disease. **Exclusion criteria** None reported	Sessions 3 to 11 covered the following topics in any order (decided by provider and participant): Being more active Coping with slip ups and setbacks Drinks Eating frequency and snacking Hunger and emotional eating Planning ahead Portion control Special occasions Support and rewards Understanding food labels Session 12: maintaining weight loss Training provided to staff: Not reported Format of intervention: Written materials provided. 'Consultations' so assumed 1 to 1 and face to face. Aimed to reduce body weight by 5 to 10%. Targeted at individuals who were 'ready to change' ('preparation' stage).	Data provided for completes and on intention to treat basis with missing values imputed via LOCF. Chi squared test was used for categorical data. Unpaired t-test was used for comparing the means of 2 samples.	<table><tr><td></td><td></td><td>3.48* to 3.70*)</td><td></td><td></td></tr></table> *Calculated by NICE technical team Pharmacy users: Mean weight loss/gain between sessions 12 and 15: 1.2 (SD 0.9) Mean percentage weight loss/gain between sessions 12 and 15: 1.4 (SD 1.1) Pharmacy users: Mean number of sessions attended per participant=7.9 (SD4.5) Number of participants attending session 12=92 (50% of recruited participants) Number of participants attending session 15=60 (33% of recruited participants)
Limitations identified by authors Not a large cohort and follow up period fairly short. Sample bias hasn't been accounted for. Confounding may have occurred. **Limitations identified by review team** No additional limitations identified. **Other comments** Results for GP based programs were also reported in the study but are not presented here. Payment to providers was dependent on the submission of completed data collection forms. The authors declare no personal conflicts of interest.				

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Costello MJ, Sproule B, Victor JC, Leatherdale ST, Zawertailo L, Selby P. Effectiveness of pharmacist counselling combined with nicotine replacement therapy: a pragmatic randomized trial with 6,987 smokers. Cancer Causes & Control. 2011 Feb 1;22(2):167-80.

Quality score
++

Study type
RCT

Location and setting</td>
<td>Health area
Smoking cessation

Number of participants
113 pharmacists from 98 different pharmacies.
6987 participants randomised:
Group A: 3588
Group B: 3399
<u>Follow-up</u>
Group A: 1515
Group B: 1494

Participant characteristics
No significant differences between Group A and B participants except that a slightly larger proportion of Group A participants received a shorter initial session (X^2 =8.4, p=0.015).

<table>
<tr><th></th><th>Group A (%)</th><th>Group B (%)</th></tr>
<tr><td colspan="3">Age</td></tr>
<tr><td>18-24</td><td>7.8</td><td>8.9</td></tr>
<tr><td>25-39</td><td>33.8</td><td>33.3</td></tr>
</table>
</td>
<td>Intervention
Group A: 3, 5-10 minute individual counselling sessions with a pharmacist and 5 weeks of free NRT, given out as 1 weeks' worth in the first session and the remaining 4 weeks' worth given out at the subsequent 2 sessions.

Group B: 1 5-10 minute individual counselling session with a pharmacist and 5 weeks of free NRT, all given in the first session.

The counselling session was identical for both groups following the 5-A model for brief behavioural counselling. Additional sessions for Group A</td>
<td>Recruitment:
Pharmacists were recruited from invitations sent to members of the Ontario Pharmacists Association. Recruited pharmacists were trained in the methodology during a 5-hour face to face session or a 3-hour online session plus a 1-hour teleconference.

Ontario residents were notified by 2 media events and print materials distributed by pharmacists to enrol.

Methods:
At enrolment, eligible participants were randomised to one of 2 intervention conditions and instructed to visit 1 of the participating</td>
<td>Among group A participants, 49.7% (n=1783) completed all 3-sessions. A greater proportion of non-completers were younger (X^2 =48.6, p<0.001), received a shorter initial session (X^2 =15.8, p<0.001) and were provided with inhalers (X^2 =156.3, p<0.001) compared to completers.
A greater proportion of group A completers than group B participants were older (X^2 =21.5, p<0.001) and provided with patches or multiple forms of NRT (X^2 =83.4, p<0.001).

Abstinence rates:
There was no difference in abstinence between Group A and B, however, a greater proportion of Group A 3-session completers were abstinent compared to Group B (X^2 =33.4, p<0.001; ITT: X^2 =63.4, p<0.001).

Only including survey responders, n=3006:
<table>
<tr><th>Intervention group</th><th>n quit</th><th>% Quit</th><th>X^2</th><th>p value</th></tr>
<tr><td>Pharmacy (assigned)</td><td></td><td></td><td>0.0</td><td>ns</td></tr>
<tr><td>Group A, 3 session</td><td>612</td><td>40.5</td><td></td><td></td></tr>
<tr><td>Group B, 1 session</td><td>604</td><td>40.4</td><td></td><td></td></tr>
<tr><td>Pharmacy (observed)</td><td></td><td></td><td>137.8</td><td><0.001</td></tr>
<tr><td>Group A, 3 session (completer)</td><td>478</td><td>52.5</td><td></td><td></td></tr>
<tr><td>Group A, 3 session (non-completer)</td><td>134</td><td>22.3</td><td></td><td></td></tr>
<tr><td>Group B, 1 session</td><td>604</td><td>40.4</td><td></td><td></td></tr>
</table>
Including non-responders as still smoking, n=6853:
<table>
<tr><th>Intervention group</th><th>n</th><th>% Quit</th><th>X^2</th><th>p value</th></tr>
<tr><td>Pharmacy (assigned)</td><td></td><td></td><td>0.4</td><td>ns</td></tr>
<tr><td>Group A, 3 session</td><td>612</td><td>17.5</td><td></td><td></td></tr>
<tr><td>Group B, 1 session</td><td>604</td><td>18.0</td><td></td><td></td></tr>
<tr><td>Pharmacy (observed)</td><td></td><td></td><td>244.0</td><td><0.001</td></tr>
<tr><td>Group A, 3 session (completer)</td><td>478</td><td>27.7</td><td></td><td></td></tr>
</table>
</td>
</tr>
</table>

Community pharmacies throughout Ontario, Canada. **Aims** To evaluate the effectiveness of two models of smoking cessation support provided by community pharmacists that included NRT. **Length of follow up** 5-12 weeks **Source of funding** The STOP study was funded by the Ontario Ministry of Health Promotion. (Author funding [conflicts of interest] includes: Health Canada, the	40-54	40.8	40.1	followed a similar protocol. Participants who missed scheduled sessions were contacted by the pharmacist up to 3 times to reschedule. 1 weeks of NRT (for either group) consisted of 7 Nicoderm Patches (21mg, 14mg or 7mg), 32 (starter) or 48 (refill) cartridges of Nicorette Inhalers (10mg) or 48 pieces of Nicorette Gum (2mg). Type and dosage of NRT was determined collaboratively based on pharmacist recommendation and participant preference. **Comparator** Group A compared to Group B	pharmacies to receive the intervention. 5 weeks post intervention start date, participants were contacted by email and asked to complete a brief online questionnaire. Non-responders were re-contacted by phone up to 2 times and asked to complete the survey over the phone. Abstinence at end of treatment was determined by self-reported, 7-day point prevalence defined as having smoked no cigarettes –'not even a puff' – in the previous 7 days. **Analysis:** Frequency distributions and chi-square tests of association were used to compare the characteristics and abstinence rates of Groups A	Group A, 3 session (non-completer)	134	7.5		
	55+	17.6	17.7			Group B, 1 session	604	18.0		
	Female	54.4	54.9							
	Employment status									
	Not employed	33.9	33.1							
	Employed	63.1	63.6							
	Missing	3.0	3.3							
	Education level									
	HS uncompleted	23.9	23.0							
	HS completed	23.5	24.7							
	University/college	51.8	51.7							
	Missing	0.7	0.6							
	Heaviness of smoking index									
	0-2 (mild)	8.2	8.6							
	3-4 (moderate)	51.1	51.3							
	5-6 (high)	40.7	40.1							

Hierarchical analysis showed no significant between-pharmacy random variation for self-reported abstinence [$\sigma^2_{\mu 0}$ =0.011 (0.106, p=0.330)]. Pharmacy-level differences accounted for 0.33% of the variability in the odds of a participant being abstinent.
Intention to treat analysis showed significant between-pharmacy variation for self-reported abstinence [$\sigma^2_{\mu 0}$ =0.078 (0.280), p<0.001)]. Pharmacy-level differences accounted for 2.3% of the variability in the odds of a participant being abstinent.

Among survey responders (model 1), participants assigned to group A were no more likely than group B to be abstinent [OR=1.00 (95% CI: 0.88, 1.15)], controlling for potential confounders, covariates and pharmacy level clustering effects.

Abstinence rates (7-day point prevalence) by intervention group (observed) and covariates using survey responders

	Group A, 3 session completer			**Group A, 3 session non-completer**			**Group B, 1 session**		
	% quit	**X^2**	**p value**	**% quit**	**X^2**	**p value**	**% quit**	**X^2**	**p value**
Age									
18-24	50.0	12.4	0.006	25.6	0.8	0.859	42.0	6.6	0.087
25-39	60.9			23.5			42.4		
40-54	49.5			21.2			36.5		
55+	46.5			20.8			44.5		
Female	50.3	2.2	0.142	20.8	1.0	0.305	39.7	0.4	0.503
Male	55.2			24.4			41.4		
Not employed	44.6	14.2	<0.001	20.4	0.7	0.405	37.4	3.4	0.064
Employed	57.8			23.5			42.4		
Education									
HS non-completer	51.8	1.9	0.385	24.0	1.0	0.595	40.6	3.0	0.218

Canadian Institutes of Health Research, Canadian Tobacco Control Research Initiative and the Whitaker Foundation, National Institute on Drug Abuse and Ontario Ministry of Health Promotion).

Made quit attempt in last 12 months		
Yes	53.1	53.2

Inclusion criteria
Ontario resident; 18yrs +, self-report current daily smokers of 10 or more cigarettes/day, willing to make a quit attempt within the next 30 days, reported no labelled contraindications for using NRT, and had not taken varenicline within the past 7 days.

Exclusion criteria
Participants who returned the completed survey after the 12 week follow-up period were excluded from analysis.

and B participants. Chi-square analyses were used to examine differences in abstinence between groups A+B as a function of possible confounders and known covariates. Two hierarchical logistic regression models were performed to examine the between-pharmacy variation abstinence: Model 1 - with only follow up survey responders and Model 2 - with intent to treat where all non-responders at follow up were considered to still be smoking. Pharmacy level variance terms were used to calculate the intraclass correlation for binary outcomes. Generalised estimating equations was used to account for pharmacy-level

HS completer	49.0			24.8			36.6		
College/university	54.6			20.9			42.0		
HSI									
0-2 (mild)	63.7			33.3			48.0		
3-4 (moderate)	53.5	7.6	0.022	25.7	11.7	0.003	42.2	9.7	0.008
5-6 (high)	47.9			15.6			35.7		
Had past quit attempt	52.1	0.1	0.813	24.1	1.5	0.219	41.7	1.1	0.300
No past quit attempt	52.9			19.8			39.0		
No current mental health disorder	55.3	11.1	0.001	25.5	12.4	<0.001	42.3	8.1	0.005
Current mental health disorder	41.6			11.4			33.4		
Length of session									
<5 mins	60.8			18.3			49.0		
5-10 mins	52.9	3.7	0.154	23.2	1.2	0.559	38.8	5.5	0.064
>10 mins	50.1			22.9			40.2		

HSI = heaviness of smoking index (combines measures of cigarettes per day and time of first cigarette after waking; higher scores indicate more cigarettes per day and a quicker time to smoking after waking).

Smoking abstinence by intervention group (assigned) controlling for covariates

	Model 1: Responders (n=2989)	**Model 2: ITT (n=6809)**

			variance when testing the main effects of both interventions on 7-day point prevalence for Model 1 and Model 2 while adjusting for other covariates. This was repeated using a modified intervention group variable where 3 interventions groups were compared (Group A 3 session completer, Group A 3 session non-completer and Group B) for only follow up survey responders and ITT with non-responders considered to still be smoking.		**OR [95% CI]**	**p value**	**OR [95% CI]**	**p value**
				Intervention group				
				Group B, 1 session	1.00 [Ref]	-	1.00 [Ref]	-
				Group A, 3 sessions	1.00 [0.88-1.15]	0.950	0.96 [0.86-1.08]	0.503
				Age				
				18-24	1.00 [Ref]	-	1.00 [Ref]	-
				25-39	1.16 [0.85-1.58]	0.345	1.52 [1.19-1.95]	0.001
				40-54	0.96 [0.68-1.36]	0.819	1.35 [1.01-1.81]	0.042
				55+	1.13 [0.82-1.57]	0.454	1.66 [1.23-2.24]	0.001
				Female	1.00 [Ref]	-	1.00 [Ref]	-
				Male	1.20 [1.05-1.37]	0.009	1.01 [0.89-1.15]	0.866
				Education				
				HS non-completer	1.00 [Ref]	-	1.00 [Ref]	-
				HS completer	0.88 [0.70-1.10]	0.268	1.00 [0.82-1.22]	0.993
				College/university	0.98 [0.78-1.22]	0.824	1.32 [1.09-1.59]	0.004
				HSI				
				0-2 (mild)	1.00 [Ref]	-	1.00 [Ref]	-
				3-4 (moderate)	0.73 [0.54-0.98]	0.034	0.71 [0.58-0.88]	0.002
				5-6 (high)	0.53 [0.40-0.69]	<0.001	0.50 [0.41-0.61]	<0.001
				Had past quit attempt	1.03 [0.87-1.22]	0.730	1.01 [0.89-1.16]	0.834
				No past quit attempt	1.00 [Ref]	-	1.00 [Ref]	-
				No current mental health disorder	1.00 [Ref]	-	1.00 [Ref]	-
				Current mental health disorder	0.64 [0.52-0.79]	<0.001	0.68 [0.57-0.81]	<0.001
				Length of session				

				<5 mins	1.00 [Ref]	-	1.00 [Ref]	-
				5-10 mins	0.81 [0.63-1.05]	0.113	0.84 [0.66-1.07]	0.156
				>10 mins	0.88 [0.70-1.11]	0.292	0.93 [0.72-1.20]	0.558

Limitations identified by authors

Relies on short term (5-12 week) reported outcomes and relapse beyond end of treatment is common; outcomes were self-reported without biochemical confirmation; in some cases the 1st pharmacy session was not necessarily the participants quit date; the time it took to contact the participants resulted in 7-day point prevalence rates that spanned 5-12 weeks over the follow-up period; participant recruitment may have been biased due to the reliance on electronic processes for enrolment and follow-up data collection (although ¾ of smokers in the region reported being Internet users in 2007); recruitment may also have been biased as those enrolling could only take part if there was a participating pharmacy feasibly located; representation within many communities was absent; unknown if low abstinence rates in the 3 session non-completers was due to having fewer counselling sessions or less NRT compared to those who completed all sessions.

Limitations identified by review team

'ITT' analysis compared to 'responders only' analysis is missing data comparing rates of abstinence in employed and unemployed participants

Other comments

The data presented were derived from a larger host study called the STOP Study (Smoking Treatment for Ontario Patients). This was a large multiphase smoking cessation study implemented from 2005 onwards in Ontario, Canada. This study reports on the community pharmacy arm of this study.

Also included in this study is report of the effectiveness of a mail-out intervention in comparison to the CP intervention, but this data is outside of the protocol for this guideline and not reported here.

Correlation of effect reported in study but not reported here (OR reported in its place).

Effect comparing region and type or NRT reported but not included here as deemed not-applicable for this review.

Smoking abstinence by intervention group controlling for covariates (observed) was also reported (as oppose to the assigned group reported here). This was not reported here as the assigned groups were deemed to be more applicable to the real world effectiveness of an assigned intervention.

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Cramp GJ, Mitchell C, Steer C, Pfleger S. An evaluation of a rural community pharmacy-based smoking-cessation counselling and nicotine replacement therapy initiative. International Journal of Pharmacy Practice. 2007 Jun 1;15(2):113-21.

Quality score
-

Study type
Before and after

Location and setting
Community pharmacies in NHS Highland in Northern Scotland.

Aims
To undertake an evaluation of the effectiveness and efficiency of a smoking cessation service which aimed to help smokers to stop or reduce smoking; provide</td>
<td>Health area
Smoking cessation

Number of participants
177
105 (59.3%) successful follow-up

Participant characteristics
Male: 54.2%
Age: 18-78yrs; mean 42yrs; 15.8% between 40-44yrs

Participants came from areas of poor access to services.

Mean number of pack-years smoked – 34 (range: 1-174) (Average number cigarettes per day/ 20 * number years smoked)

73.3% of participants main preference was for cigarettes only.

No inclusion or exclusion criteria were used.</td>
<td>Intervention
(Sep 2001-July 2003)

Participants undertook a nicotine quiz and signed an ‘I quit’ contract. Written advice material about NRT was supplied along with further information describing strategies to deal with situations known to lead to relapse. NRT was prescribed over a 12-week period, adjusted at 2-4 week intervals with counselling as appropriate. NRT was given mainly as patches (75%), lozenges (9%), gum (4%) and inhalator and microtab (1%).</td>
<td>Recruitment:
Referral to CP was provided by GPs, and some participants were recruited directly at the CP. All clients who attended the service were recruited.

Method:
Pharmacists underwent training to become familiar with written material and counselling and to develop an understanding of the stage-of-change model to ensure the selection of clients that were at a stage where they were likely to stop.

Participant records were completed by pharmacists throughout each session attendance and analysed. Questionnaires were sent to each client and combined with client record data in a Microsoft Access Database and transferred to Excel for analysis.

Smoking history, self-reported outcomes and outcomes reported by the pharmacist, NRT usage</td>
<td>Primary outcomes:
N=177
<table>
<tr><th></th><th>Abstinence week 0</th><th>Abstinence end of 4th week</th><th>Abstinence end of 12th week</th><th>Abstinence for 44 weeks</th></tr>
<tr><td>Number (%)</td><td>0 (0%)</td><td>79 (44.6)</td><td>62 (35.0)</td><td>28 (15.8)</td></tr>
</table>
Relapse rate between week 4 and week 12 when participants were attending the service was 47.0%.
Between the time when participants left the initiative and completed the questionnaire, the relapse rate was 54.8%.

Acceptability:
96/105 (91.4% of those returning the survey) claimed the pharmacy advice was helpful.
78/105 (74.3%) considered written material helpful for reducing smoking.

Participants were very positive about access to the service and the availability of NRT stating:
“Very happy with the service, easy and convenient.”
“I think that giving free NRT to any smoker that wants it is a good idea.”

Cost-effectiveness:
Cost of the initiative totalled £14684.50, amounting to £524.45 cost per quitter.</td>
</tr>
</table>

readily available ongoing smoking cessation advice and target areas of known inequality in the region. **Length of follow up** Up to 2 years **Source of funding** GPs' prescribing budget to fund NRT and the regional Health Improvement Fund.		Many pharmacists did not formally counsel the client on the first contact but provided information and invited them back. **Comparator** Smoking rate before intervention = 100%	and views on the acceptability and accessibility of the service were collected. A cost-effectiveness analysis was undertaken by determining the total costs of the scheme, enabling the cost per quitter to be calculated. When no result was recorded or those who did not respond to the questionnaire were assumed to be continuing to smoke.	
Limitations identified by authors The client group in the evaluation has been subject to a selection bias since pharmacists actually asked people to go home and think about giving up and their return was considered an indicator of commitment. The questionnaire was undertaken retrospectively, in some cases with a time delay of 2 years before completion, thus recall bias and data inaccuracy may have occurred. It was not possible to calculate the quit-rate at 1 year – this was substituted with the average length of time abstinence had been maintained. Quit-rates were self-reported and no attempt was made to substitute claims by carbon monoxide testing. The rates reported assume clients who did not respond to the questionnaire, or who were not recorded in the client record, were still smoking. **Limitations identified by review team** Unclear how long the intervention was conducted, and over how many sessions. Unclear what the length of follow-up was, although a max follow-up of 2 years was reported. Unclear how many participants were offered the intervention but declined. Selection bias introduced by community pharmacy staff who asked participants to go home and think about giving up before returning to the pharmacy to receive the intervention. Characteristics of participants who did not complete follow up were not reported. **Other comments** Pharmacists were remunerated £20 per participant irrespective of outcome or time taken with the client.				

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Dhital R, Norman I, Whittlesea C, Murrells T, McCambridge J. The effectiveness of brief alcohol interventions delivered by community pharmacists: randomized controlled trial. Addiction. 2015 Oct 1;110(10):1586-94.

Quality score
+

Study type
Randomised controlled trial

Location and setting
Community pharmacies within the London borough of Hammersmith and Fulham, UK

Aims</td>
<td>Health area
Alcohol misuse

Number of participants
n=407 participants
16 community pharmacies

Participant characteristics
Characteristics of those followed up:
<table>
<tr><th></th><th>Intervention</th><th>Control</th></tr>
<tr><td>Mean age (years, range)</td><td>41.1 (18 to 74)</td><td>43.2 (18 to 92)</td></tr>
<tr><td>Female</td><td>81</td><td>63</td></tr>
<tr><td>Male</td><td>87</td><td>95</td></tr>
<tr><td>White British, white Irish or any other white background</td><td>124 (73.8%)</td><td>116 (73.4%)</td></tr>
<tr><td>Asian British</td><td>7 (4.2%)</td><td>11 (7%)</td></tr>
<tr><td>Black British</td><td>15 (9%)</td><td>17 (10.7%)</td></tr>
<tr><td>Mixed</td><td>5 (3%)</td><td>5 (3.1%)</td></tr>
<tr><td>Chinese</td><td>4 (2.4%)</td><td>0</td></tr>
<tr><td>Any other ethnic group</td><td>2 (1.2%)</td><td>0</td></tr>
<tr><td>Post-16 education</td><td>129 (76.7%)</td><td>119 (75.3%)</td></tr>
</table>
Statistical significance of differences in baseline characteristics not reported

10 pharmacies were independent chemists and 6 were multiple chemists. 11 on a high streets, 1 on housing</td>
<td>Intervention (n=205)
Brief intervention.

Pharmacist discussion lasting up to 10 minutes. Encouraged to think about their drinking and whether they should reduce it and discuss if they were ready to do so.

Structured intervention protocol aimed to build a rapport and encourage informal chat; encourage participants to talk about how drinking fits into their lives; explore ambivalence towards drinking and evaluate drinking, including any problems.

Given ‘Units and You’ booklet, a ‘Unit/Calorie</td>
<td>Recruitment:
May 2012 to May 2013. 2361 participants were approached, 561 (24%) were interested in participating of whom 549 passed the first stage single question screen. 94 (17%) were excluded for AUDIT score of 7 or lower, 38 (7%) for AUDIT score 20 or more, 2 (0.4%) had incomplete data recorded by pharmacist.

Customers were invited to be screened for eligibility if they were: viewing study posters and flyers; making a general health enquiry or seeking advice linked to alcohol use; purchasing pharmacy over the counter products for smoking cessation, gastrointestinal remedies, sleep aids and central nervous system depressants; receiving any of the following services: smoking cessation, medication review, health check or emergency hormonal contraception; presenting prescriptions for medications for any of the following conditions: CVD, depression or anxiety, diabetes or gastric problems</td>
<td>Primary outcomes:
Overall AUDIT score
<table>
<tr><th></th><th>Baseline</th><th>Follow up</th><th>Baseline vs. follow up</th></tr>
<tr><td>Intervention group</td><td>11.93 (SD 3.24)</td><td>11.80 (SD 5.88)</td><td>-0.11 (-0.82 to 0.61) p=0.76</td></tr>
<tr><td>Control group</td><td>11.53 (SD 3.19)</td><td>10.77 (SD 5.54)</td><td>-0.74 (-1.47 to 0.00) p=0.049</td></tr>
</table>
Between group differences in overall AUDIT score
<table>
<tr><th></th><th>Complete cases</th><th>BOCF</th></tr>
<tr><td>Adjusted for baseline score</td><td>-0.63 (-1.69 to 0.43) p=0.24</td><td>0.49 (-1.33 to 0.36) p value not statistically significant</td></tr>
<tr><td>Adjusted for baseline score, gender, age, ethnicity and education</td><td>-0.57 (-1.59 to 0.45) p=0.28</td><td>-0.37 (-1.18 to 0.45) p value not statistically significant</td></tr>
</table>
Overall score of less than 8 at follow up: Intervention= 38 (22.6%), control= 42 (26.6%).

Odds ratio for between group differences from baseline to follow up:
Unadjusted= 0.80 (0.48 to 1.34), p=0.40
Adjusted for gender, age, ethnicity and education= 0.87 (0.50 to 1.51), p=0.61 (None of the prognostic variables used in the adjusted model had any moderating effect on total AUDIT score at follow up [p=0.22 to 0.46].)

Secondary outcomes:
AUDIT score - Consumption subscale
<table>
<tr><th></th><th>Baseline</th><th>Follow up</th><th>Baseline vs. follow up</th></tr>
<tr><td>Intervention group</td><td>8.29 (SD 1.55)</td><td>7.58</td><td>-0.75 (-1.08 to -0.41)</td></tr>
</table>
</td>
</tr>
</table>

<table>
<tr>
<td>To evaluate the effectiveness of a brief intervention delivered by community pharmacists to reduce hazardous or harmful drinking

Length of follow up
3 months

Source of funding
See ‘other comments’ below.</td>
<td>estate, 3 in shopping centre and 1 in doctor’s surgery.

Inclusion criteria
• 18 years or over
• Accessed services within the 16 participating pharmacies
• AUDIT score of 8 to 19 inclusive
• Contactable by phone during the study
• Home address in UK
• Able to speak, read and write in English
• Able to give informed consent
Pharmacies:
Consultation room at the pharmacy

Exclusion criteria
• In treatment for alcohol problems
• Involved in other alcohol research
• Employee of pharmacy in trial</td>
<td>Calculator Wheel’ and alcohol services leaflet.

Pharmacists trained over 3.5 hours, influenced by counselling approach of motivational interviewing. 10/17 pharmacists attended 2 hour follow up training session at 7 weeks.

Comparator (n=202)
Control group – not provided with brief intervention. Given leaflet ‘Alcohol: the basics’.</td>
<td>Allocation by computerised random number generator in clusters within each pharmacy. Data collection personnel blinded to randomisation throughout.

Analysis:
Sample size calculation showed need for 139 participants for power of 80% and significant level of 5%.
Complete cases only used in primary analysis, with sensitivity analysis of ITT with BOCF. 326 had outcomes collected – 168 in intervention; 156 in control (83 (20%) lost to follow up). Loss to follow up was similar in control and intervention groups (p=0.39), but non-responders significantly younger (p<0.001) and lower AUDIT score (p=0.001).</td>
<td>
<table>
<tr><td></td><td></td><td>(SD 2.31)</td><td>p<0.001</td></tr>
<tr><td>Control group</td><td>8.02 (SD 1.53)</td><td>7.37 (SD 2.52)</td><td>-0.69 (-1.03 to -0.35) p<0.001</td></tr>
</table>
AUDIT score - Dependence subscale
<table>
<tr><td></td><td>Baseline</td><td>Follow up</td><td>Baseline vs. follow up</td></tr>
<tr><td>Intervention group</td><td>1.04 (SD 1.35)</td><td>1.23 (SD 2.13)</td><td>0.22 (-0.05 to 0.50) p=0.11</td></tr>
<tr><td>Control group</td><td>1.05 (SD 1.34)</td><td>0.75 (SD 1.54)</td><td>-0.29 (-0.57 to -0.01) p=0.041</td></tr>
</table>
AUDIT score - Problem use subscale
<table>
<tr><td></td><td>Baseline</td><td>Follow up</td><td>Baseline vs. follow up</td></tr>
<tr><td>Intervention group</td><td>2.60 (SD 2.14)</td><td>2.99 (SD 2.82)</td><td>0.42 (0.03 to 0.80) p=0.033</td></tr>
<tr><td>Control group</td><td>2.46 (SD 2.19)</td><td>2.65 (SD 2.97)</td><td>0.26 (-0.13 to 0.65) p=0.20</td></tr>
</table>
General health (EQ-5D)
Not reported at baseline. 1.28 (SD 0.35) in intervention group and 1.20 (SD 0.32) in control group at follow up.

Between group differences in secondary outcomes (complete cases only)
<table>
<tr><td></td><td>Adjusted for baseline score</td><td>Adjusted for baseline score, gender, age, ethnicity and education</td></tr>
<tr><td>Consumption subscale</td><td>-0.05 (-0.53 to 0.43) p=0.84</td><td>-0.05 (-0.54 to 0.44) p=0.85</td></tr>
<tr><td>Dependence subscale</td><td>-0.51 (-0.89 to -0.13) p=0.008</td><td>-0.46 (-0.82 to -0.09) p=0.014</td></tr>
</table>
</td>
</tr>
</table>

				Problem use subscale	-0.18 (-0.72 to 0.36) p=0.52	-0.13 (-0.66 to 0.41) p=0.64
				EQ-5D	-0.09 (-0.16 to -0.01) p=0.019	-0.09 (-0.16 to -0.02) p=0.013

Limitations identified by authors
Blinding of participants to group allocation not possible and all gave informed consent; this raises the possibility of some heightened potential for performance bias. All participants received AUDIT score feedback, indicating they were hazardous or harmful drinkers for eligibility purposes, so raises the possibility of behaviour change in response to feedback. Whilst BI followed a structured protocol, some variability between pharmacists in their skills in engaging with participants should be expected (though no differences were observed). It is highly likely that the pharmacists were under trained in BI, and the naturalistic context precluded audio-recording, meaning this couldn't be observed and recorded.
Limitations identified by review team
The statistical significance of differences between groups for characteristics and outcome measurements at baseline was not reported. Allocation was not clustered by pharmacy and so contamination may have occurred.
Other comments
The brief intervention tool is included as part of the supplementary information reported with the study paper but is not presented here. The research costs for this study were funded through the Hugh Linstead Fellowship Award by the Pharmacy Practice Research Trust, Royal Pharmaceutical Society of Great Britain and the Harold and Marjorie Moss Charitable Trust PhD award, both made to Ranjita Dhital. Jim McCambridge was supported by a Welcome Trust Research Career Development fellowship in Basic Biomedical Science (WT086516MA). This study was awarded Service Support Payment by North West London CLRN (UKCRN number 11920).

Study details	Population	Intervention and comparator	Methods and analysis	Results
Reference Jackson M, Gaspic-Piskovic M, Cimino S. Description of a Canadian employer-sponsored smoking cessation program utilizing community pharmacy-based cognitive services. Canadian Pharmacists Journal/Revue des Pharmaciens du	**Health area** Smoking cessation **Number of participants** Material was sent to 46,000 with information for participation 180 individuals completed registration 81 participants attended a pharmacy for assessment of eligibility 80 participants were at the preparation stage of	**Intervention** Smoking cessation programme for General Motors Canada Limited, based on the Transtheoretical Model of Change and the 5 A's (Ask, Advise, Assess, Assist and Arrange) Model described in the US Public Health Service Clinical Practice Guidelines for treating tobacco use and dependence. This programme added NRT to the existing benefits package in conjunction	**Recruitment:** Pharmacies that submitted 10 or more prescription drug claims between August 1-June 30 2006 for GMCL employees retirees or their spouses and dependents were sent a recruitment letter. Pharmacists were accepted based on their familiarity with the 5A's Model and Stages of Change Model through prior experience with a smoking cessation educational program.	**Primary outcomes:** 91.3% of participants used NRT *7.5% of participants used bupropion* *1.3% of participants quit 'cold turkey'* *- results for groups in italics are reported together, and are excluded due to use of bupropion as part of the intervention* Number of patients: 73 Number relapsed/ withdrawn: 45 Number quit: 28 % quit: 38.4

Canada. 2008 Jul 1;141(4):234-40. **Quality score** **-** **Study type** Designed as non-comparative but can be analysed as before and after **Location and setting** Community pharmacies in Ontario and New Brunswick, Canada **Aims** To describe and assess the effectiveness of a smoking cessation program using community pharmacists to provide behavioural support to smokers motivated to quit. **Length of follow up** 6 months **Source of funding** Unknown	behaviour change model and included in the intervention. 23 participants were lost to follow up *6 participants used bupropion and are excluded from analysis.* *1 quit 'cold turkey' and results cannot be disaggregated from bupropion quitters.* Before the start of the intervention, 212 pharmacies had been recruited, with 217 recruited by the end of patient enrolment. 47 pharmacies were utilised by participants. **Participant characteristics** <u>80 included participants</u> General Motors Canada Limited active employees, retirees, their spouses and dependents. Average age 49.8; range 20-67. **Inclusion criteria** Employees, retirees, their spouses and dependents of General Motors Canada Limited.	with pharmacy based behavioural support as part of GMCL's existing wellness initiatives. The programme included a 'Quit and Win' contest that offered a C$300 prize to a selected successful quitter. The quit attempt was to occur between Nov 4 2006 and Dec 17 2006. The pharmacist delivered intervention consisted of an initial assessment (face to face) and 6 month follow up appointments (either face to face or by telephone at the discretion of the pharmacist and participant), for a total of 7 contacts. Follow up contacts were to occur on or around days 3-5, days 7-10, days 14-21, day 28, day 56, day 84 and day 180 (to be more heavily weighted to the beginning of therapy). Participants wishing to use bupropion or quit cold turkey were eligible for additional pharmacist support. Informed consent was obtained for participation in the programme. Any participants identified by the pharmacist as being in the 'preparation' or 'action' stage of the Stages of Change Model was automatically made eligible for NRT through employee benefits.	**Methods:** Those who completed registration received more detailed packages containing supportive reading material on smoking cessation and a listing of pharmacies that had indicated some level of training in smoking cessation and a willingness to participate in the program. It was participant's responsibility to seek out a pharmacist of their choice in order to continue in the program. ID numbers were assigned to each participant and used by participating pharmacies to indicate the patient's stage of change at the time of the initial assessment by the pharmacist as well as the quit/withdrawal status for each follow-up. Prescription claims data generated by the assessment and follow-up claims was used to collect data on the NRT and pharmacotherapy used. Self-reported quit rates were captured based on the submission by pharmacies. **Analysis:** Descriptive statistics were used in describing demographics and quit rates. Patients who were lost to follow up were assumed to have relapsed. Quit rates were calculated as the percentage of patients reporting continued abstinence after 6 months.	Before intervention 73 participants were smokers with 0% quit rate

	Exclusion criteria Those identified as being in the contemplative stage of change.	**Comparator** Smoking rate before intervention = 100%	Fisher exact test were administered to determine statistical significance.	

Limitations identified by authors
Possible that participants were very highly motivated to quit as they self-referred to a pharmacy after signing consent. Those not highly motivated to quit would be unlikely to make an assessment appointment with their pharmacist. This is supported by the fact that 80/81 of the participants initially assessed for the program were found to be in the preparation stage of the Stages of Change Model.
A high number of participants were lost to follow up
There was a suspicion of pharmacy non-compliance with the follow up schedule as 18 patients had no follow up claims, although this could have been true loss to follow up.
The integrity of the information taken from claims databases is dependent on the accuracy of the information contained within the claims. The data of pharmacological support participants were on, relied on this data set.
The study relied on self-reported 6 month quit rates and was not assessed by biochemical methods.
The inclusion of the Quit and Win program could affect the self-reported quit rate in this study. Non-smokers may have also claimed to be smokers and participated in order to enter the contest.

Limitations identified by review team
Consistency of the intervention not reported. Follow up appointments over the 6 month intervention period were made by telephone or by face to face interactions – it is unknown how many participants chose each option, and whether there was any difference in success rates due to differences in the intervention.
The inclusion of the Quit and Win campaign as part of the intervention makes it unclear if the behavioural support given by the pharmacist or the Quit and Win campaign were responsible for the successful quits.
The pharmacy was reimbursed for each patient contact – up to C$115 if all patient follow ups were made
Analysis performed on 80 participants who were successfully recruited, but excludes those who did not respond to invitation to participate or the 180 individuals who requested more information but did not present to a pharmacy to receive the intervention.
No characteristics of withdrawals/drop outs reported. High loss to follow up (23/80). Possibility of pharmacy non-compliance with intervention protocol.

Other comments
None

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Jolly K, Lewis A, Beach J et al. (2011) Comparison of range of commercial or primary care led weight reduction programmes with minimal intervention control for weight loss in obesity: Lighten Up randomised controlled trial. BMJ 343:d6500

Quality score
++

Study type
Randomised controlled trial

Location and setting
Primary care trust in Birmingham, UK

Aims</td>
<td>Health area
Weight management

Number of participants
Total in trial n=740
N in pharmacy arm=70

17 pharmacies took part

Participant characteristics
For pharmacy arm:
Male=19 (27%)
Mean age=48.94 years (SD 15.82)

Ethnicity:
White British/Irish=61 (87%)
South Asian=0
Black British/Caribbean/African=6 (9%)
Mixed and other=3 (4%)

Starting BMI:
<30 =9 (13%)
30 to 34=35 (50%)
35 to 39=20 (29%)
≥40=3 (4%)

Median physical activity (kcals/week)= 457 (IQR 0 to 1481)
Median moderate/vigorous physical activity (minutes per week)= 0 (IQR 0 to 60)

Weight loss drug at baseline= 3 (4%)

Participants lost to follow up tended to be younger, but were similar in all other characteristics to those who were followed up.</td>
<td>Intervention
Based on a problem solving approach using stages of change and motivational interviewing. Predominant behaviour change strategies included goal setting, self monitoring with food diaries, hunger scale, waist measurements, and physical activity. Participants encouraged to reward themselves for success

Number of sessions: 12

Duration of sessions: First session was 30 minutes. Follow up session of 15 to 20 minutes.

Who performed the sessions: Pharmacists.

What was covered in each session: weight and dieting history, exploration of goals and expectations of</td>
<td>Recruitment:
January to May 2009

Call centre nurses randomised patients to trial arm. Independent statistician prepared randomisation sequences. Allocations were place in opaque, consecutively numbered envelopes, which the nurses used in order.

Patients randomised in blocks of 35 (from practices with personnel trained to provide the practice based weight management program, n=7) or 13 (other practices, n=10). Block sizes determined to achieve allocation ratio of 1 to 0.7 compared to other groups (due to limited spaces).

A trained practice nurse, health trainer or researcher blinded to the allocation group did the 1 year assessment at the participant's general practice or home.

Power analysis showed that 70 participants were needed in each group for 90% power and 5% significance level, assuming a 20% loss to follow up. This did not take account of adjustments for multiple comparisons. Bonferroni correction applied to each pairwise comparison to adjust for multiple analyses.

Analysis:</td>
<td>Primary outcome:
<table>
<tr><th>Outcome</th><th>Baseline observation carried forward</th><th>Last observation carried forward</th><th>Complete cases only</th></tr>
<tr><td>Weight loss at 3 months (kg)</td><td>2.11 (1.0 to 3.2), p≤0.001 vs. baseline</td><td>2.80 (1.4 to 4.2), p≤0.001 vs. baseline</td><td>2.14 (1.0 to 3.2), p≤0.001 vs. baseline</td></tr>
</table>
Secondary outcomes:
<table>
<tr><th>Outcome</th><th>Baseline observation carried forward</th><th>Last observation carried forward</th><th>Complete cases only</th></tr>
<tr><td>Weight loss at 1 year (kg)</td><td>0.66 (-0.4 to 1.7), not statistically significant (p value not reported)</td><td>1.19 (-0.7 to 3.1), not statistically significant (p value not reported)</td><td>1.85 (0.5 to 3.2), p<0.05 vs. baseline</td></tr>
</table>
<table>
<tr><th>Outcome</th><th>Baseline observation carried forward</th><th>Complete cases only</th></tr>
<tr><td>Change in physical activity (kcal/week) at 3 months</td><td>2720 (1790 to 3649), p≤0.001 vs. baseline</td><td>2885 (1912 to 3857), p≤0.001 vs. baseline</td></tr>
<tr><td>Change in physical activity (kcal/week) at 1 year</td><td>1473 (742 to 2203), p≤0.001 vs. baseline</td><td>1562 (792 to 2332), p≤0.001 vs. baseline</td></tr>
</table>
</td>
</tr>
</table>

To assess the effectiveness of a range of weight management programmes in terms of weight loss
 	
Length of follow up
12 months
 	
Source of funding
See 'other comments' below.
	Inclusion criteria
	• Registered with general practice in South Birmingham Primary Care Trust
	• At least 18 years old
	• Raised body mass index in previous 15 months:
	  ○ Not South Asian with no comorbidities BMI≥30 or with comorbidities BMI≥28
	  ○ South Asian with no comorbidities BMI≥25 or with comorbidities BMI≥23
	• No medical contraindications
	
	Exclusion criteria
	Unable to understand English
	Pregnant
		patients, the eatwell plate, setting goals to reduce calorie intake and increase physical activity, planning strategies to deal with challenging situations, use of food diaries, and maintaining weight loss.
		
		Training provided to staff: 3 day training course on weight management in adults, delivered by dieticians.
		
		Format of intervention: 1 to 1 and face to face. Written materials provided as homework.
			A researcher contacted participants who did not attend their first session to obtain a weight and height measurement. Other data at baseline were collected by nurses at the call centre, before randomisation. People no longer attending program at the end of the study were offered follow up at convenient location. If declined, asked to self-report weight.
			
			Over 50% attended less than 25% (3) pharmacy sessions, around 20% attended 25 to 49% (3 to 5) sessions and over 20% attended 50% or more (6 to 12) sessions.*
				Body mass index reduction at 1 year (kg/m^2): 0.31 (0.0 to 0.7), not statistically significant (p value not reported); 0.73 (-0.1 to 1.6), not statistically significant (p value not reported)
				
				Baseline observation carried forward:
				Change in moderate and vigorous physical activity at 3 months (mins/week): 73 (51 to 94), not statistically significant (p value not reported)
				Changes in moderate and vigorous physical activity at 1 year (mins/week): 27 (3 to 51), not statistically significant (p value not reported)
				Changes in walking at 3 months (mins/week): 1 (-11 to 14), not statistically significant (p value not reported)
				Changes in walking at 1 year (mins/week): 17 (-0.4 to 34), not statistically significant (p value not reported)
				Participants achieving 5% loss in body weight at 3 months: 21.4% (12.5 to 32.9)
				Participants achieving 5% loss in body weight at 1 year: 14.3% (7.1 to 24.7)

Limitations identified by authors
Powered only to compare individual programmes with the comparator group, not to make head to head comparisons [note: this is not a limitation when looking at before and after data]. Self-report of weight from some participants may have introduced measurement error. Self reported physical activity seems high and may be an over report. Response rate to invitation was 11.5% and is likely to be people who were most motivated to change. Attendance data could not be independently validated and may be subject to some errors.
Limitations identified by review team
*Attendance numbers were reported in a graph and could not be accurately interpreted.
Unclear how allocation sequence was generated – "an independent statistician prepared 2 separate randomisation sequences". Not clear whether outcome assessors at 3 months were blinded to allocation.
Other comments
This was an RCT with 8 arms. Included 7 interventions in addition to 1 to 1 support from a pharmacist: Weight Watchers (commercial), Slimming World (commercial), Rosemary Conley (commercial), Size Down (NHS group weight loss program), nurse led 1 to 1 support in general practice (NHS), an intervention arm allowed people to choose which

intervention they wanted, and a minimal intervention arm (12 vouchers enabling free entrance to a local leisure centre). Further details of the other interventions are provided in the paper but are not reported here and they did not include community pharmacy staff. Funded by NHS South Birmingham. PA supported by a NIHR career scientist award. AD supported by a senior research fellowship award from the NIHR. KJ part funded by NIHR through Collaborations for Leadership in Applied Health Research and Care for Birmingham and Black Country programme. PA and AL received hospitality from Weight Watchers on one occasion. JD and JB were employed by the funding organisation and managed the service.

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Khan Natasha S, Norman Ian J, Dhital Ranjita, McCrone Paul, Milligan Peter, and Whittlesea Cate M (2013) Alcohol brief intervention in community pharmacies: a feasibility study of outcomes and customer experiences. International journal of clinical pharmacy 35(6), 1178-87

Quality score
-

Study type
Uncontrolled before and after

Location and setting
Community pharmacies in Lambeth, London, UK

Aims
To assess customer progression through the community pharmacy alcohol BI service; to establish post-BI changes in alcohol consumption</td>
<td>Health area
Alcohol

Number of participants
26 pharmacies

-927 approached
-663 eligible
-125 successfully received intervention
-105 were eligible for follow-up
-61 completed follow-up (41 hazardous drinkers; 20 low-risk drinkers)

78/141 participants responded to service feedback forms

Participant characteristics
<table>
<tr><th></th><th>N</th><th>%</th></tr>
<tr><td>Male</td><td>80</td><td>64</td></tr>
<tr><td>Female</td><td>45</td><td>36</td></tr>
<tr><td>18-25yrs</td><td>11</td><td>9</td></tr>
<tr><td>25-44 yrs</td><td>53</td><td>42</td></tr>
<tr><td>45-64 yrs</td><td>47</td><td>38</td></tr>
<tr><td>65+ yrs</td><td>12</td><td>10</td></tr>
<tr><td>White</td><td>81</td><td>65</td></tr>
<tr><td>Black/ African/ Caribbean/ Black British</td><td>30</td><td>24</td></tr>
<tr><td>Asian/ Asian British</td><td>3</td><td>2</td></tr>
<tr><td>Mixed</td><td>8</td><td>6</td></tr>
<tr><td>Other</td><td>3</td><td>2</td></tr>
</table>
</td>
<td>Intervention
Alcohol Brief Advice (BI):
A paper based screening pack containing AUDIT-C and a Drinking Diary was administered by the pharmacist in a confidential consultation room.

Identified <u>hazardous drinkers</u> received a full BI from the pharmacist based upon the Feedback, Listen, Advice, Goals and Strategies technique. Average length of BI was 18 minutes.

<u>Low risk drinkers</u> received feedback on their status, without advice,</td>
<td>Recruitment:
Pharmacists proactively offered the service to all customers visiting the pharmacy for alcohol related advice and/or the purchase of over-the-counter products for symptoms which may be related to alcohol use.

Customers could also refer themselves after reading information posters and leaflets placed in the pharmacy.

Methods:
Alcohol Use Disorders Identification Test-Consumption (AUDIT-C) measured alcohol use risk level and informed pharmacist feedback and type of intervention. The validated scale comprises 3 alcohol consumption questions derived from the 10-item AUDIT. A retrospective 7 day Drinking Diary was used to calculate an overall week alcohol unit total and number of drinking days for each BI recipient and also structured pharmacist feedback and advice. An alcohol unit total for each day was calculated and summed to give the overall week alcohol unit total. A drinking day was defined as at least 1 unit of alcohol consumed during that particular day.

<u>Follow up:</u>
Hazardous or low risk drinkers were followed up by telephone interview 3 months after intervention where the AUDIT-C and Drinking Diary were administered. Questionnaire with closed-format responses and open-ended responses was used to assess the acceptability of the</td>
<td>Primary outcomes:
<u>Low risk drinkers outcomes:</u>
<table>
<tr><th></th><th>Before</th><th>Follow-up</th><th>Change</th><th>P</th></tr>
<tr><td>Alcohol units - geometric mean * (CI) (n=20)</td><td>0.9 (0.2, 4.9)</td><td>0.4 (0.1, 2.9)</td><td>54% (-135, 91%)</td><td>ns</td></tr>
<tr><td>Alcohol units – arithmetic mean * (CI) (n=20)</td><td>5.3 (2.7, 8.0)</td><td>5.7 (2.4, 8.9)</td><td>-0.4 (-2.1, 1.4)</td><td>ns</td></tr>
<tr><td>Median drinking days* (Q1, Q3) (n=22)</td><td>2 (1,3)</td><td>1 (1,1)</td><td>0 (0, 1)</td><td>ns</td></tr>
<tr><td>AUDIT-C (Q1, Q3) (n=20)</td><td>3.7 (2.0, 5.0)</td><td>4.4 (3.0, 6.0)</td><td>-0.5 (-3.0, 0.8)</td><td>ns</td></tr>
</table>
*alcohol units and median drinking days within a 7 day period

<u>Hazardous drinkers outcomes:</u>
<table>
<tr><th></th><th>Before</th><th>Follow-up</th><th>Change</th><th>P</th></tr>
<tr><td>Alcohol units - geometric mean * (CI) (n=37)</td><td>6.7 (3.1, 19.5)</td><td>1.1 (0.3, 4.6)</td><td>84% (48, 95%)</td><td>0.004</td></tr>
<tr><td>Alcohol units – arithmetic mean * (CI) (n=37)</td><td>14.5 (10.4, 18.7)</td><td>15.2 (9.2, 21.3)</td><td>-0.7 (-5.9, 4.5)</td><td>ns</td></tr>
<tr><td>Median drinking days* (Q1, Q3) (n=36)</td><td>3 (1, 5)</td><td>2 (0, 4)</td><td>1 (0, 2)</td><td>0.05</td></tr>
<tr><td>AUDIT-C (Q1, Q3) (n=41)</td><td>6.6 (5.0, 8.0)</td><td>6.8 (5.0, 8.5)</td><td>0.0 (-2.0, 1.5)</td><td>ns</td></tr>
</table>
*alcohol units and median drinking days within a 7 day period</td>
</tr>
</table>

for non-dependent hazardous drinkers; to investigate the acceptability of the service to customers who receive it; to establish whether the pharmacy based alcohol BI service is cost-effective

Length of follow up
3 months

Source of funding
New Services and Innovations in Healthcare grant (Guy's and St Thomas' Charity)

Employed	67	54
Unemployed	27	22
Economically inactive	25	20

(2 and 6 respondents didn't record their age and ethnic group respectively)

Inclusion criteria
- Aged 18 years or over
- Contactable by telephone or a UK postal address for the following 3 months

Exclusion criteria
- Customers who were not currently drinking
- Anyone currently in alcohol misuse treatment
- Anyone who had received alcohol BI elsewhere in the past 3 months

goals or strategies.

All participants received an alcohol unit wheel calculator, a 'Units and You' booklet and contact details of local and national specialist alcohol service.

intervention, which was completed directly after the intervention, before follow up.

Analysis:
Hazardous drinkers were identified via an AUDIT-C score of 4 (men) or 3 (women). Low risk drinkers were identified by a score of </= 3 (men) or 2 (women). AUDIT-C results were verified for accuracy. Two-tailed paired t-tests examined differenced in the pre- and post-BI weekly alcohol unit scores, and two-tailed Wilcoxon sign tests examined AUDIT-C and drinking day scores. Alcohol unit data was log-transformed to approach nearer to symmetry as alcohol unit data was heavily skewed, with some quite heavy drinkers classified as hazardous drinkers.

58% of participants had follow up data. Only results for participants with follow up data was reported.

Secondary outcomes:
Acceptability of intervention:

Closed-ended responses	
Rated privacy as good	74%
Rated confidentiality as good	77%
Rated quietness as good	70%
Would recommend to others	77%
Open-ended responses	
General service satisfaction expressed	22%
'Like having increased alcohol awareness'	23%
'Like the informative written information'	18%
'Like opportunity to ask questions'	15%
'Service was ineffective'	9%
'Dislike amount of paperwork'	5%
'Felt embarrassed'	4%
'Need to increase awareness of service'	15%
Participant recommendations	
Advertising service further	9%
Reduce length of consultation	8%
Add more information	5%

Limitations identified by authors
Small sample size; no control group; not possible to identify the number of individuals who could potentially have been approached; self-reported alcohol consumption is susceptible to social desirability responding, leading to underreporting of actual drinking patterns.

Limitations identified by review team
Missing data from the group of participants identified as harmful/possibly dependent drinkers – only 58% participants had follow up data. Follow up interviews conducted by a 'member of the project team' – not clear if team member was blind to baseline outcome measure of participants.

Other comments
£10 gift voucher given to participants who completed the follow up interviews; pharmacists remunerated £10 for each AUDIT-C and BI completed.

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Lalonde L, O'Connor AM, Duguay P, et al. (2006) Evaluation of a decision air and a personal risk profile in community pharmacy for patients considering options to improve cardiovascular health: the OPTIONS pilot study. International Journal of Pharmacy Practice, vol 14 (1), p51

Quality score
+

Study type
Randomised controlled trial

Location and setting
Community pharmacies in Montreal

Aims</td>
<td>Health area
Cardiovascular disease

Number of participants
N=26 patients
42 eligible patients were approached. 10 refused, 1 was involved in another study, 2 had discontinued treatment and 3 did not send medical report to research nurse. 26 (62%) were recruited. 10 out of 13 pharmacies approached agreed to take part, 8 recruited participants.

Participant characteristics
<table>
<tr><th></th><th>Decision aid</th><th>Personal risk profile</th></tr>
<tr><td>N</td><td>13</td><td>13</td></tr>
<tr><td>Male</td><td>7 (54 %)</td><td>5 (39 %)</td></tr>
<tr><td>Median age</td><td>55 years</td><td>57 years</td></tr>
<tr><td>BMI >27kg/m^2</td><td>7 (54 %)</td><td>10 (77 %)</td></tr>
</table>
</td>
<td>Personal worksheet including an action plan for next 3 months and defining treatment goals.

1 session with pharmacist, duration not reported. Training of pharmacists not reported, although likely CV disease is included in their education

Face to face and 1 to 1, written material including risk profile and personal worksheet provided.

Intervention
Consultation with a decision aid - general information on CVD, risk factors, effects of lifestyle change or</td>
<td>Recruitment:
Pharmacists identified participants. Randomly assigned by research nurse to decision aid or personal risk profile, stratified by pharmacy. Pharmacists received educational tools.

Patients interviewed over the phone at start of study, 2 weeks and 3 months after pharmacist consultation.

Analysis:
Before and after the intervention compared using Wilcoxon</td>
<td>Primary outcomes:
Similar CVD knowledge and risk perception before and after the intervention was observed in both groups, so the groups were combined. There was no change in the median number of causes cited after the intervention (median= 3).

Increasing physical activity (complete cases only)
<table>
<tr><th>Stage of change</th><th>Baseline (n=23)</th><th>2 weeks (n=23)</th><th>Relative risk*</th></tr>
<tr><td>Precontemplation – contemplation</td><td>7 (30.4%)</td><td>7 (30.4%)</td><td>1.00 (0.42 to 2.40)</td></tr>
<tr><td>Preparation</td><td>8 (34.8%)</td><td>3 (13.0%)</td><td>0.38 (0.11 to 1.24)</td></tr>
<tr><td>Action - maintenance</td><td>8 (34.8%)</td><td>13 (56.5%)</td><td>1.63 (0.84 to 3.16)</td></tr>
</table>
Low-fat diet (complete cases only)
<table>
<tr><th>Stage of change</th><th>Baseline (n=23)</th><th>2 weeks (n=23)</th><th>Relative risk*</th></tr>
<tr><td>Precontemplation – contemplation</td><td>1 (4.3%)</td><td>0</td><td>0.33 (0.01 to 7.78)</td></tr>
<tr><td>Preparation</td><td>3 (13.0%)</td><td>1 (4.3%)</td><td>0.33 (0.04 to 2.97)</td></tr>
<tr><td>Action - maintenance</td><td>19 (82.6%)</td><td>22 (95.6%)</td><td>1.16 (0.94 to 1.42)</td></tr>
</table>
Losing weight (only patients with BMI>27kg/m^2 included) (complete cases only)
<table>
<tr><th>Stage of change</th><th>Baseline (n=16)</th><th>2 weeks (n=16)</th><th>Relative risk*</th></tr>
<tr><td>Precontemplation – contemplation</td><td>3 (18.8%)</td><td>1 (6.3%)</td><td>0.33 (0.04 to 2.87)</td></tr>
<tr><td>Preparation</td><td>0</td><td>0</td><td>Not estimable</td></tr>
<tr><td>Action - maintenance</td><td>13 (81.3%)</td><td>15 (93.8%)</td><td>1.15 (0.88 to 1.51)</td></tr>
</table>
Low-salt diet (complete cases only)
<table>
<tr><th>Stage of change</th><th>Baseline (n=23)</th><th>2 weeks (n=23)</th><th>Relative risk*</th></tr>
<tr><td>Precontemplation – contemplation</td><td>2 (8.7%)</td><td>2 (8.7%)</td><td>1.00 (0.15 to 6.51)</td></tr>
<tr><td>Preparation</td><td>2 (8.7%)</td><td>1 (4.3%)</td><td>0.50 (0.05 to 5.14)</td></tr>
<tr><td>Action - maintenance</td><td>19 (82.6%)</td><td>20 (86.9%)</td><td>1.05 (0.82 to 1.35)</td></tr>
</table>
Reducing stress (complete cases only)
<table>
<tr><th>Stage of change</th><th>Baseline (n=23)</th><th>2 weeks (n=23)</th><th>Relative risk*</th></tr>
</table>
</td>
</tr>
</table>

To assess the feasibility and relevance of providing pharmacist collaboration supplemented by a decision aid or a personal risk profile to community patients initiating or already receiving pharmacotherapy for hypertension or dyslipidaemia.

Length of follow up
3 months

Source of funding
See 'other comments' below.

Previous cardiovascular disease	2 (15 %)	4 (31 %)
Median 10 year cardiovascular risk	16 %	34 %
Median cardiovascular age	54 years	59 years

Statistical significance of differences between the groups not reported

15 people recruited at the initiation of lipid-lowering treatment. 8 people already on lipid-lowering medication when started the study.

Inclusion criteria
Aged 30 to 74 years
Understood English or French
Started lipid-lowering or antihypertensive pharmacotherapy in previous 12 months

Exclusion criteria
None reported

medication. Examples of patients who come to different treatment decisions.

Comparator
Consultation with a personal risk profile e.g. diagnosis of CVD, high cholesterol. Bar chart with estimated actual 10 year CVD risk and estimated risk assuming specific changes to risk factors. General information on CVD, CVD risk-factors and recommended lifestyle changes.

test for paired data.

24 patients (12 in each group) from 8 pharmacies completed the 2 week post-intervention interview. 23 completed the 3 month post-intervention interview.

Precontemplation – contemplation	5 (21.7%)	6 (26.0%)	1.20 (0.43 to 3.38)
Preparation	1 (4.3%)	0	0.33 (0.01 to 7.78)
Action - maintenance	17 (73.9%)	17 (73.9%)	1.00 (0.71 to 1.41)

Reducing alcohol consumption (only patients who report consuming [or in past] regularly at least 2 bottles of beer of 2 glasses of wine or 2 ounces of hard liquor per day) (complete cases only)

Stage of change	**Baseline (n=6)**	**2 weeks (n=6)**	**Relative risk***
Precontemplation – contemplation	0	0	Not estimable
Preparation	0	0	Not estimable
Action - maintenance	6 (100%)	6 (100%)	1.00 (0.71 to 1.41)

Stopping smoking (only former and current smokers included) (complete cases only)

Stage of change	**Baseline (n=14)**	**2 weeks (n=14)**	**Relative risk***
Precontemplation – contemplation	2 (14.3%)	2 (14.3%)	1.00 (0.16 to 6.14)
Preparation	2 (14.3%)	1 (7.1%)	0.50 (0.05 to 4.90)
Action - maintenance	10 (71.4%)	11 (78.6%)	1.10 (0.72 to 1.69)

Changes in CVD risk factors over time

Stage of change	**Baseline (n=26)**	**3 months (n=23)**	**Mean difference**
Mean BMI	28.8 (SD 5.6)	27.1 (SD 8.8)	-1.70* (-5.89 to 2.49) p=0.025
Mean 10 year cardiovascular risk	30% (SD 23.7)	19.5% (SD 19.9)	-10.50* (-22.71 to 1.71) p=0.013
Mean cardiovascular age	57.1 years (SD 8.9)	57.1 years (SD 7.6)	0* (-4.62 to 4.62) p=0.076

Secondary outcomes:
Personal risk profile participants appreciated the graphics used in presenting the information. Decision aid patients appreciated the patient examples at the end of the booklet, the use of colour, and the illustrations.

*indicates calculated by NICE technical team
Limitations identified by authors

Pharmacists were not formally trained in how to use the tool and only delivered it to a small number of participants. Pharmacists only met participants once – meeting more than once would have allowed the information to be better assimilated over time.

Limitations identified by review team

The method of generating the allocation sequence was not reported. The baseline outcome measurements and characteristics appear to be fairly similar between the groups, however, the statistical significance of any differences it not reported. Missing outcome data were not addressed – data were only included from people who provided data at both time points. Outcomes were not blindly assessed.

Other comments

Pharmacists received a total of CAD$45 per patient recruited in partial compensation for their time. CVD risks reported in the tools are estimated using the validated Cardiovascular Life Expectancy Model. The estimated CVD age is the average age of Canadians of the same sex who have a similar CVD risk. Changes in lipid levels and blood pressure are also reported in the study, but as participants had recently started lipid lowering treatment those results are not reported here. Estimations by participants of their 10 year CVD risk, CVD risk category, HDL-C, LDL-C, blood pressure and BMI are also presented in the study but are not reported here. Supported financially by a research grant from the Canadian Stroke Network. LL is supported by the Fonds de la recherché en santé du Quebec. AC holds a Tier 1, Canada Research Chair in Health Care Consumer Decision Support. AK was supported by the APOTEX-P.A.C.E. 2002-2003 grant in pharmaceutical practice research.

Study details

Reference
Maguire TA, McElnay JC, Drummond A. A randomized controlled trial of a smoking cessation intervention based in community pharmacies. Addiction. 2001 Feb 1;96(2):325-31.

Quality score
+

Study type
RCT

Location and setting

Population

Health area
Smoking cessation

Number of participants
124 pharmacies
484 participants across those pharmacies
Intervention: 265
Control: 219

Failure to follow-up 10.2% (27) of intervention group and 14.2% (31) of the control groups at 3, 6 and 12 months.

Participant characteristics

Variable	PAS	Non-PAS
Female	107	96
Male	158	123

Intervention and comparator

Intervention
Study ran from March 1996-May 1998.
Each study site pharmacist was given a copy of the PAS (Pharmacists' Action on Smoking) model documentation and written literature on smoking cessation.
Pharmacists attended a 3hr local workshop on smoking cessation, providing information on epidemiology, smoking statistics, the use of NRT, the cycle of change model and the PAS model. A researcher visited the pharmacies to provide support and address any queries.

PAS intervention
An initial 1:1 interview lasted between 10-30 minutes, taking place in a quiet area within the

Methods and analysis

Recruitment:
Pharmacy recruitment via mailing and via an advertisement in the pharmaceutical press.
To recruit participants, pharmacies were asked to display a poster in their window, display leaflets and the project was given local media attention with television, radio and newspaper coverage to advertise the project to the public. Those reporting and asking for advice at pharmacies on minor ailments or those being dispensed medicines were asked about smoking and told about the programme.

Methods:
Each participant gave written informed consent (for follow up and urine sample testing).

Results

All participants who claimed to have stopped smoking at 12 months had cotinine concentration below the cut off for a positive smoking status, and therefore confirmed the self-reported abstinence.

Of the intervention group, 141 participants were followed up at week 1, 98 for 2 weeks, 86 for 3 weeks and 46 for 4 weeks.
None of the pharmacists reported follow-up consultations with participants beyond 4 weeks other than for the supply of NRT.

	PAS	Non-PAS	p value	chi-squared
Total number	265	219	NA	NA
Number abstained for 12 months (%)	38 (14.3)	6 (2.7)	<0.001	16.2

Community pharmacies in Northern Ireland and London

Aims
To evaluate if a structured community pharmacy-based smoking cessation programme (the PAS model) would give rise to a higher smoking cessation rate compared with *ad hoc* advice from pharmacists.

Length of follow up
12 months

Source of funding
Medical Research Council and N. Ireland Department of Health and Social Services.

Age (yrs)		
Average	42	38
Youngest	17	25
Oldest	69	72
Cigarettes per day		
1-10	14	26
10-20	197	121
20-30	29	33
>30	13	20
No information	12	19

Inclusion criteria
18+ years of age
Individual expressing an interest to stop smoking.

Exclusion criteria
Pregnant women

pharmacy or in a private consultation room.
A contract was agreed verbally between the smoker and the pharmacist and a positive approach was used by the pharmacist to increase the smokers confidence and reinforce the smokers own motivation to stop. The indication for NRT was assessed and if deemed appropriate it was offered. If accepted, NRT was paid for at full retail price by the client (87% of participants started NRT). A leaflet on smoking cessation was also provided. Participants were asked to return to the pharmacy for follow-up advice at weekly intervals for 4 weeks, then monthly for 3 months. The pharmacist recorded the action taken at each follow-up visit.

Comparator
'Usual care':
Normal pharmaceutical service provided, including provision of NRT were appropriate (84% of participants started NRT). Smokers were not counselled using the PAS flip-chart, they were not given a PAS leaflet and they were not asked to attend for follow-up interviews. Demographic details were collected from this group as for the PAS group.

An initial interview was conducted to collect demographic data and participants were randomly assigned to receive the PAS model or usual care, using the sealed envelope technique.

All enrolled smokers were contacted in the pharmacy or by telephone at 3 months and asked if they had stopped smoking. Those who claimed to have quit were followed up again at 6 months, and again at 12 months if they had reported a quit. Smoking status was determined by the question "Are you currently smoking cigarettes?" (Yes/No). Those who answered "No" were asked: "Have you stayed stopped since entering the programme?" (Yes/No). Those who had reported not smoking since the intervention at 3, 6 and 12 months were asked to provide a urine sample for confirmation. If participants did not report to the pharmacy for this sample, they were mailed a sample kit and failing return on this, were contacted at their home in person.

Analysis:
Any participants lost to follow up were considered to still be smokers.

Number abstained for 6 months (%)	49 (18.5)	18 (8.2)	-	-
Number abstained for 3 months (%)	73 (27.5)	24 (11)	-	-

Secondary outcomes:
Pharmacy type and size had no impact on the 12 month smoking cessation rates. Neither gender nor age of the pharmacist involved in the study influenced the smoking cessation rates at 12 months.

Limitations identified by authors

Only a minority of pharmacists who expressed an initial interest in the study were motivated to take part and many were not able to recruit patients at the desired rate.
Limitations identified by review team
Pharmacists were paid £15 for each smoker enrolled and followed up to 12 months.
Indication from discussions with pharmacists that not all follow-ups were recorded formally indicating inconsistency in data reporting.

Other comments
Qualitative research on the pharmacists views on the intervention was included in this study, but did not include views of participants and was therefore deemed outside the scope of this review.
Linked to Crealey 1998

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Morrison D, McLoone P, Brosnahan N, et al. (2013) A community pharmacy weight management programme: an evaluation of effectiveness. BMC Public Health vol 23 p282

Quality score
+

Study type
Uncontrolled before and after study

Location and setting
Community pharmacies in Fife, Scotland

Aims
To evaluate the effectiveness of the Counterweight Programme delivered within community pharmacies, using a primary outcome of clinically significant weight change at 12 months.

Length of follow up
12 months

Source of funding
LM and NB are employees and shareholders of Counterweight Ltd. The</td>
<td>Health area
Weight management

Number of participants
N=458 patients

16 community pharmacies -12 in small urban settlements and 4 in small towns.

Participant characteristics
74.7% (n=342) female
Mean age: 54.0 years (SD 7.4)
Mean weight: 96.4 kg (SD 18.3)
Mean BMI: 36.0kg/m^2 (SD 5.9)

BMI:
<30=9.8% (n=45)
30 to 34=43.9% (n=201)
35 to 39=23.8% (n=109)
>40=21.2% (n=97)
No recorded=1.3% (n=6)

14.4% (n=66) reported smoking (18.8% [n=86] not recorded)

11.6% (n=53) reported diabetes (15.7% [n=72] not recorded)

Sex, age and BMI were not reported for 2 (0.4%), 12 (2.6%) and 6 (1.3%) of patients respectively.</td>
<td>Intervention
Counterweight Programme

Pharmacy staff were trained by specialist dieticians – 2 4-hour training sessions and a further 3 hours after 6 months. Specialist dieticians also provided mentoring to all pharmacies.

Most trained staff were pharmacy assistants rather than pharmacists.

Pharmacy staff agreed not to sell over the counter weight loss medications to patients enrolled in the programme.

Pharmacy staff delivered patient education by discussing weight management, and communicating information on behaviour change strategies. Initial interventions involved a prescribed eating plan or a goal-setting approach. The aim was to achieve an energy deficit of 500-600kcal a day. As patients progressed through the program, emphasis was increasingly directed to weight loss maintenance and the prevention of weight regain.

Patients were asked to commit to 9 appointments in 12 months following the initial screening visit. This included 6 initial appointments of 10 to 30 mins each, with follow up visits at 6, 9 and 12 months. The total time for 1 patient to be taken</td>
<td>Recruitment:
March 2009 to July 2012

Pharmacies were paid a single commitment fee of £100 to take part, plus a payment per patient (£30 to £64 for 1-3 appointments, £24 to £40 for 4 or more appointments) and payments for the provision of replacement staff while staff were being trained.

Analysis:
Data were entered into a database, which was sent to an independent team at set time points.

Kruskal-Wallis one way analysis of variane, chi-square test for differences in proportions, and logistic regression.

Attendance declined from 56.0% at 3 months to 24.5% at 12 months. A higher percentage of men than women attended at 12 months. Attendance increased with age and decreased with BMI, but these trends were not statistically significant.</td>
<td>56.0% (241/430) attended at 3 months, 33.7% (133/395) attended at 6 months, and 24.5% (77/314) attended at 12 months.

Weight loss (mean kg) vs. baseline
<table>
<tr><th></th><th>3 months</th><th>6 months</th><th>12 months</th></tr>
<tr><td>Attending patients</td><td>2.4 (2.02 to 2.70)</td><td>3.5 (2.66 to 4.25)</td><td>4.1 (2.83 to 5.41)</td></tr>
<tr><td>BOCF</td><td>1.3 (1.10 to 1.54)</td><td>1.2 (0.85 to 1.58)</td><td>1.0 (0.64 to 1.38)</td></tr>
<tr><td>LOCF</td><td>1.3 (1.10 to 1.54)</td><td>1.6 (1.25 to 1.89)</td><td>1.7 (1.31 to 2.14)</td></tr>
</table>
>5% weight loss (percentage of patients) vs. baseline
<table>
<tr><th></th><th>3 months</th><th>6 months</th><th>12 months</th></tr>
<tr><td>Attending patients</td><td>17.0 (12.5 to 22.4)</td><td>34.6 (26.6 to 43.3)</td><td>41.6 (30.4 to 53.4)</td></tr>
<tr><td>BOCF</td><td>9.5 (6.9 to 12.7)</td><td>11.6 (8.7 to 15.2)</td><td>10.2 (7.1 to 14.1)</td></tr>
<tr><td>LOCF</td><td>9.5 (6.9 to 12.7)</td><td>13.9 (10.7 to 17.7)</td><td>15.9 (12.1 to 20.4)</td></tr>
</table>
Statistically significant differences were not found when weight loss was modelled by sex (p=0.66), age (p=0.66) and BMI (p=0.21) individually or in combination.

Percentage achieving ≥5% weight loss did not show statistically significant associations with sex (p=0.78), age (p=0.86) or BMI (p=0.86).</td>
</tr>
</table>

other authors have no competing interests. DM and PM were responsible for the statistical analyses and drafting and writing the manuscript. AS, JG, LM and NB arranged and coordinated pharmacy involvement, data acquisition and contributed to the drafting of the paper. The intervention was conducted during the Scottish Government Health Department funding of the Counterweight weight management programme in primary care. The pharmacy delivery of the Counterweight Programme was funded through the NHS Fife keep well project.	Inclusion criteria BMI≥30kg/m^2 or ≥28kg/m^2 with a comorbidity Assessed as motivated to lose weight Pharmacies were required to have a private consultation room and time to deliver the intervention. **Exclusion criteria** None stated.	through the full programme was estimated at 130 minutes. **Comparator** None		Of 314 patients enrolled for at least 12 months, 32 (10.2%) had achieved the target weight loss of ≥5%. At 12 months, 57 (74% of patients who attended, 18% of all patients) had lost some weight, 15 patients (19% of patients who attended, 5% of all patients) had gained weight, and 5 (6% of patients who attended, 2% of all patients) had no appreciable change in weight since baseline (absolute change ≤250g). Maximum weight loss was 27kg and maximum weight gain was 4.6kg at 12 months.
Limitations identified by authors Possible unrepresentativeness of the patients or pharmacies – study population was composed mainly of people from disadvantaged backgrounds. Lack of detailed information about other social and clinical factors that may have influenced patients' attendance and weight loss. No comparison group. **Limitations identified by review team** Only 25% of participants attended at 12 months. It is not clear how many participants attended more than 1 sessions and/or how many session were needed to ensure that the intervention was delivered. The consistency of the intervention between pharmacies, pharmacy staff and participants was not measured. **Other comments** No additional comments.				

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Narhi et al. 2001

Quality score
+

Study type
Before and after study

Location and setting
Community pharmacies in Finland

Aims
To assess the effects of enhanced education, counselling and outcomes monitoring by community pharmacists on knowledge about and attitudes of asthma patients towards asthma as a disease and its medication</td>
<td>Health area
Asthma

Number of participants
n=31 patients
n=4 pharmacies

Participant characteristics
28 participants in total
Male: 7/28 (25%)

Age: 41.3 years (SD 12.2), range 23 to 56

At baseline, all participants were receiving some kind of anti-inflammatory asthma medication (beclomethasone, budesonide, fluticasone or nedocromil).

27/28 participants also had a prescription for an inhaled short acting beta$_2$ sympathomimetic: salbutamol or terbutaline.

7/28 had a prescription for an inhaled long acting beta$_2$ sympathomimetic.

Inclusion criteria
20 to 64 years
Asthma diagnosis
Perceived problems in management of asthma (i.e. patients not compliant or were compliant by still had asthma symptoms or had perceived problems with disease)
Willingness to participate</td>
<td>Intervention
Modified from the Danish version of the TOM concept. Patients were encouraged to practice asthma self-management. Each patient was allocated to a named pharmacist who taught the patient to recognise and treat asthma symptoms, measured outcomes and documented the progress according to instructions.

Pharmacists participated in a 1 day training course. Also completed self-study programmes on the</td>
<td>Recruitment:
Patients were recruited by general practitioners and specialist physicians in 2 community pharmacies and by general practitioners, specialist physicians and pharmacists in the other 2 pharmacies. 21 patients were recruited by physicians and 7 by pharmacists.

Analysis:
Pharmacists posted or gave the questionnaires to participants in the pharmacy, asked them to complete them at home, and return them to the pharmacy (at baseline) or university (at 12 months</td>
<td>3 patients withdrew (reasons not provided), leaving 28 participants.

Disease-related knowledge
<table>
<tr><th rowspan="2">Statement</th><th colspan="3">Percentage of participants providing correct answer</th></tr>
<tr><th>Baseline (n=28)</th><th>12 months (n=26)</th><th>24 months (n=27)</th></tr>
<tr><td>The bronchi are distended during the asthma attack (N)</td><td>89%</td><td>100%</td><td>96%</td></tr>
<tr><td>Asthma symptoms are caused by drying in lung mucous membrane (N)</td><td>79%</td><td>100%</td><td>85%</td></tr>
<tr><td>The peak expiratory flow meter is used to measure respiration (Y)</td><td>89%</td><td>96%</td><td>100%</td></tr>
<tr><td>If peak expiratory flow values fall below half of normal, you have to contact the doctor (Y)</td><td>75%</td><td>100%
p<0.05 vs. baseline</td><td>100%
p<0.05 vs. baseline</td></tr>
<tr><td>There are no disadvantages for asthma patients for keeping cats or dogs inside (N)</td><td>96%</td><td>92%</td><td>100%</td></tr>
<tr><td>Asthma attacks can be affected also by breathing technique (Y)</td><td>86%</td><td>88%</td><td>93%</td></tr>
<tr><td>Asthma attacks can be anticipated according to peak expiratory flow value measurements (Y)</td><td>71%</td><td>100%
p<0.05 vs. baseline</td><td>89%</td></tr>
</table>
<table>
<tr><th rowspan="2"></th><th colspan="3">Mean score (possible scores 0 to 7)</th></tr>
<tr><th>Baseline (n=28)</th><th>12 months (n=26)</th><th>24 months (n=27)</th></tr>
<tr><td>Knowledge about asthma as a disease</td><td>5.8 (SD 1.3)</td><td>6.8 (SD 0.4)
p=0.003 vs. baseline</td><td>6.6 (SD 0.6)
p=0.045 vs. baseline</td></tr>
</table>
</td>
</tr>
</table>

<table>
<tr>
<td>using the TOM concept.

Length of follow up
24 months

Source of funding
This study was supported by the Finnish Cultural Foundation – Elli Turunen Fund, the Association of Finnish Pharmacies, and the Association of the Pulmonary Disabled.</td>
<td>Exclusion criteria
None reported</td>
<td>management of asthma. Encouraged to change their focus from dispensing to individual care and problem solving.

1 year intervention with 4 to 8 (average 5.2) sessions with the pharmacist, each session lasting from 15 to 120 minutes.

Comparator
Pre-intervention</td>
<td>and 24 months).

Data were analysed using Friedman two-way analysis of variance for repeated measures. Measurements between baseline, 12 months and 24 months were compared with each other by the Wilcoxon rank sum test. Bonferroni’s correct was applied.</td>
<td>For assessing patients’ knowledge, a 10 item questionnaire used in the local hospital was taken as a basis and complemented with questions 3, 6 and 7. It was pretested with 4 patients in 2 of the study pharmacies and commented by the representatives of the Association of the Pulmonary Disabled. Answers could be ‘yes’, ‘no’, or ‘do not know’. ‘Do not know’ answers were recorded as wrong answers, scoring 0 points. Each correct answer yielded 1 point for a score from 0 to 7.

The questionnaire also included ‘asthma symptoms are caused by inflammation in bronchi’ but at baseline all patients answered this question correctly so it was dropped from further analysis.

Attitudes to disease
<table>
<tr><th rowspan="2">Statement</th><th colspan="3">Mean score (possible scores 1 to 4, with 4 being most positive attitude)</th></tr>
<tr><th>Baseline (n=28)</th><th>12 months (n=26)</th><th>24 months (n=27)</th></tr>
<tr><td>I enjoy my life even though I have asthma</td><td>3.4 (SD 0.7)</td><td>3.6 (SD 0.6)</td><td>3.5 (SD 0.7)</td></tr>
<tr><td>Asthma symptoms affect my mood</td><td>1.8 (SD 0.8)</td><td>2.0 (SD 1.0)</td><td>1.9 (SD 0.7)</td></tr>
<tr><td>I do everything I want not considering its effects on my asthma</td><td>2.0 (SD 1.0)</td><td>2.1 (SD 1.0)</td><td>2.1 (SD 1.0)</td></tr>
<tr><td>Without asthma symptoms I am still worried about asthma attacks</td><td>2.8 (SD 1.1)</td><td>3.2 (SD 0.8)</td><td>3.1 (SD 0.9)</td></tr>
<tr><td>I think I need more information about asthma and its management</td><td>1.8 (SD 0.9)</td><td>2.6 (SD 1.1) p<0.001 vs. baseline</td><td>2.8 (SD 1.0) p<0.001 vs. baseline</td></tr>
<tr><td>There are no problems with my</td><td>2.5 (SD 0.8)</td><td>3.4 (SD 0.6) p<0.001 vs. baseline</td><td>3.2 (SD 0.8) p<0.01 vs. baseline</td></tr>
</table>
</td>
</tr>
</table>

asthma management				
I consider my asthma symptoms as being serious	2.5 (DS 0.9)	3.1 (SD 0.8) p<0.01 vs. baseline	3.0 (SD 0.9)	

	Mean score (1 to 4, with 4 being most positive attitude)		
	Baseline (n=28)	12 months (n=26)	24 months (n=27)
Attitudes towards asthma as a disease	2.4 (SD 0.5)	2.8 (SD 0.4) p<0.001 vs. baseline	2.8 (SD 0.5) p<0.001 vs. baseline

Disease-related attitude statements had an internal consistency reliability coefficient of 0.69. 2 of the statements decreased Cronbach's alpha by 0.03 or more and so were omitted from further analyses – 'Asthma does not disturb my social relationships' and 'I avoid telling people that I am suffering from asthma'.

Limitations identified by authors
Small convenience sample with no control group – limits generalisability and interpretation of results.
Voluntary enrolment – participants may have had more positive health attitudes than average patients. May have been more compliant and active in self management.
Asthma status was measured subjectively but not verified from medical records.
Cannot be sure if improvements in knowledge and attitudes exclusively due to counselling by the pharmacists due to pre/post design of the study.

Limitations identified by review team
Knowledge statements were tested by a small group of patients and commented on by an appropriate organisation, however, it's not clear what the results of this testing/commenting were.
Reasons for withdrawal of participants were not reported. It is not clear how missing data were accounted for.

Other comments
Questionnaire also included questions on asthma medication, but these are not presented here as they are not relevant to the review question.

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Neumann 2013

Quality score
+

Study type
Observational prospective cohort study

Location and setting
Denmark, Pharmacies

Aims
To identify the program, setting, payment, modality and geographic region with the highest rates of continuous smoking abstinence in disadvantaged patients

Length of follow up
6 months

Source of funding
Danish National Board of Hand; Danish Ministry of Interior and Health</td>
<td>Health area
Smoking
Number of participants
Participants obtained from a national Smoking Cessation registry.
N=5,214 treated in pharmacy (All smokers at baseline)

Pharmacy Participant characteristics
<table>
<tr><td></td><td>N=5,214</td></tr>
<tr><td>Education
Low

High</td><td>
1677 (32%)
3537 (68%)</td></tr>
</table>
Inclusion criteria
Individuals who registered in the Smoking Cessation registry, at least 18 years old and participated in the GSP in Denmark.

Exclusion criteria
Patients with <7 month follow-up and those attending interventions other than the GSP were excluded.</td>
<td>Intervention
The Gold Standard Program (GSP) has been the standard intervention in Denmark since 2001. Developed with guidance for the National Cancer Institute, which trained the Stop Smoking Centre.
It consists of manual-based teaching sessions along with nicotine replacement therapy. There are 5 meetings over 6 weeks, with clearly structured patient education program, including motivational interviewing at the beginning, reflections on benefits and costs of continuous smoking versus cessation, date of cessation, teaching and training about risk situations and relapse prevention, withdrawal symptoms and medical support and planning for the future. Nicotine replacement provided and adjusted to smoking severity, according to the Fagerstrom test score, the number of cigarettes and patient preferences. A hotline was available during daytime hours on working days. GSP delivered either in group or individual format. Group sizes varied with a median of 12 (range 2-26).</td>
<td>Recruitment:
Overall 29,805 smoking cessation interventions were considered. (Note some of these happened in other settings such as hospital, county or municipality and are not included in the evidence table). Allocation of patient to group or individual program at the discretion of the smoking cessation units or the instructors.

Overall 21,516/ 29,805 (72%) included in study

16,377/21,516 (76%) available for 6 month follow-up

Analysis:
Chi-square or exact methods used in the analysis of categorical data. Two-sided p-value of <0.05 was regarded as significant. Non-parametric Mann-Whitney U for comparison of continuous or almost continuous variables. Non-responders at follow-up assumed to have relapsed and were continuing to smoke</td>
<td>Primary outcomes:
<u>Continuous Abstinence (</u>defined as not smoking from end of intervention to the 6 month follow-up as reported in a phone interview after 6 months ± 1 months)
<table>
<tr><td></td><td>Continuous Abstinence</td></tr>
<tr><td></td><td>All</td></tr>
<tr><td>Pharmacy</td><td>1463/ 5214 (28%)*</td></tr>
</table>
*Calculated by NICE Technical team (proportion from the low and high education group combined to provide overall abstinence rate)</td>
</tr>
</table>

		Program was usually free of charge. Of the 20588 patients in all settings who received treatment, 93% did not pay. Some patients received free medication while other had to pay themselves. **Comparator** None		
Limitations identified by authors Patients who participated in a program with an individual format showed favourable outcome. It is unclear if this finding is primarily related to patient preferences or staff competencies. Other factors not addressed such as comorbidity, patient resources or motivation or the patients ability to recall events in the past such as health professionals recommendation to quit might be important in the context of continuous abstinence. Patients with lower education were under-represented **Limitations identified by review team** Unclear if interventions delivered were all in community pharmacies as the authors have not explicitly stated community pharmacy as the setting. Assuming interventions occurred in a community pharmacy it is unclear which member of the pharmacy team delivered the intervention. Unclear which patients received group or individual treatment. Other comments Overall aim of this study was to evaluate effectiveness of the GSP for smoking cessation. No information has been provided about the pharmacy settings and its inclusion is tangential rather than a main aim of the study. This was a well designed study but there was no reporting on factors relevant to community pharmacy.				

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Schmiedel et al. 2015

Quality score
+

Study type
Randomised controlled trial

Location and setting
Community pharmacies in Germany

Aims
To assess the efficacy of a 12 month prevention program conducted in 42 community pharmacies in reducing the risk of diabetes

Length of follow up
12 months

Source of funding
This work was supported by the Dr August and Dr Anni</td>
<td>Health area
Diabetes

Number of participants
n=1140 participants
42 community pharmacies

Participant characteristics
68.6% were female (n=749)
Mean age=57.5 years (SD 11.3)

Statistically significant differences between intervention and comparator groups for age, BMI, FINDRISC, physical activity, physical quality of life, sex, family status and employment.

Inclusion criteria
Increased risk for diabetes according to a German Finnish Diabetes Risk Score of 7 or more
35 years or older

Exclusion criteria
Pregnant women
People with diabetes
People with cancer
People who had participated in a clinical trial 30 days prior to enrolment.</td>
<td>All participants received written information about a healthy diet and physical activity.

Pharmacists in both intervention and comparator arms received 1 day training on how to conduct study. Intervention pharmacies received an additional 0.5 days of training on counselling for behaviour changes.

Intervention
(n=565)
3 individual counselling sessions and 5 group-based lectures (program GLICEMIA)
Diet and physical activity were discussed and recorded in an individual prevention journal in the individual sessions.
Goal attainment was monitored by</td>
<td>Recruitment:
October 2012 to January 2014

Community pharmacies were randomly assigned 1:1 to intervention or control

Analysis:
The pharmacists were not blinded to allocation. All participants were informed that the study aimed to prevent diabetes, but they did not know what the outcome measures were.

Intention to treat analysis used, with last observation carried forward for missing data. Participants were excluded from the analysis if they did not fulfil the inclusion criteria of the pharmacy became insolvent.</td>
<td>40 of the 42 pharmacies completed the trial – 2 pharmacies in the intervention group dropped out due to insolvency and illness. Dropout rate for participants was 13.0% (n=148). Final participant numbers were 530 in the intervention group and 562 in the control group. Missing end points were imputed using LOCF for 115 (10.5%) participants.

Primary outcomes:
Change in FINDRISC after 12 months
<table>
<tr><th>Intervention (n=530)</th><th>Control group (n=562)</th><th>Adjusted effect size</th></tr>
<tr><td>-0.55 (SD 1.84)</td><td>0.17 (SD 1.64)</td><td>-0.74 (-1.04 to -0.42)</td></tr>
</table>
Effect sizes adjusted for cluster structure and differences in sex, age, BMI, employment and level of education at baseline

FINDRISC is a “self-developed demographic and behaviour questionnaire”. Acronym stands for the German Finnish Diabetes Risk Score.

Secondary outcomes:
<table>
<tr><th></th><th>Intervention (n=530)</th><th>Control (n=562)</th><th>Adjusted effect size</th></tr>
<tr><td>Mean weight change (kg)</td><td>-1.52 (SD 3.84)</td><td>0.11 (SD 3.58)</td><td>-1.57 (-2.23 to -0.90)</td></tr>
<tr><td>Change in systolic blood pressure (mmHg)</td><td>-3.23 (SD 13.01)</td><td>-3.61 (SD 14.62)</td><td>0.40 (-1.88 to 2.71)</td></tr>
<tr><td>Change in diastolic blood pressure (mmHg)</td><td>-0.91 (SD 8.42)</td><td>-1.50 (SD 9.25)</td><td>0.42 (-0.93 to 1.77)</td></tr>
<tr><td>Change in physical activity (hours per week)</td><td>0.31 (SD 1.63)</td><td>-0.23 (SD 1.72)</td><td>0.52 (0.32 to 073)</td></tr>
</table>
</td>
</tr>
</table>

Lesmuller-Siftung 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 Pravention e.V.).		the pharmacists in the 2nd and 3rd sessions. Group based lectures were 75 to 90 mins each, covering diabetes and risk factors, healthy diet, physical activity, psychological aspects of behaviour change, and maintenance of a healthy lifestyle. **Comparator** (n=575) Assessment and information about health status, but no further counselling.		<table><tr><td>Change in SF-12 physical component summary</td><td>1.74 (SD 8.05)</td><td>-0.73 (SD 7.34)</td><td>2.39 (1.43 to 3.34)</td></tr><tr><td>Change in SF-12 mental component summary</td><td>1.29 (SD 9.90)</td><td>0.37 (SD 8.62)</td><td>1.08 (-0.21 to 2.37)</td></tr></table> Effect sizes all adjusted for cluster structure and differences in sex, age, BMI, employment and level of education at baseline The sensitivity analysis led to similar results as the intention to treat analysis.
Limitations identified by authors None reported **Limitations identified by review team** It is unclear how the allocation sequence was generated. Pharmacies were not blinded to which group they were allocated to. Outcomes were not blindly assessed. There were significant differences between the groups in FINDRISC at baseline, however, this was not adjusted for in the analysis.				

Study details	**Population**	**Intervention and comparator**	**Methods and analysis**	**Results**
Reference Sinclair HK, Bond CM, Lennox AS, Silcock J, Winfield AJ,	**Health area** Smoking cessation **Number of participants** 62 pharmacies recruited (81.6% recruitment rate)	**Intervention** <u>Pharmacist training:</u> A 2hr training package based on the stage of change model of smoking	**Recruitment:** (began Sep 1994) 76 non-city pharmacies were invited to participate. Non-responders were followed-up for 6 weeks. Participants were recruited over 12 months. All smokers who sought advice on smoking	**Primary outcomes:** <u>Smoking cessation point prevalence rates at 1, 4 and 9 month follow up:</u> <table><tr><td></td><td></td><td>1 mo.</td><td>4 mo.</td><td>9 mo.</td></tr><tr><td rowspan="2">Inter-vention</td><td>%</td><td>29.9</td><td>16.1</td><td>12.0</td></tr><tr><td>n</td><td>66</td><td>35</td><td>26</td></tr></table>

Donnan PT. Training pharmacists and pharmacy assistants in the stage-of-change model of smoking cessation: a randomised controlled trial in Scotland. Tobacco Control. 1998 Sep 1;7(3):253-61.

Quality score
++

Study type
cRCT

Location and setting
Community pharmacies throughout the Grampian region of Scotland, UK.

Aims
To develop and evaluate

31 intervention and 29 control pharmacies participated throughout study

492 participants recruited (63.5% recruitment rate)
224 intervention and 268 control
159 intervention (73.3%) and 188 control (73.2%) participants continued through to 9 month follow up

Participant characteristics
Pharmacy characteristics:
Rural, urban, single outlet, small multiple and large multiples were all equally represented across control and intervention groups.
54 assistants – all female
40 pharmacists – 25 female; 15 male

There were no significant differences between the characteristics of the intervention and control customers:

Variable	Inter-vention (%)	Control (%)
Gender		
Male	38.8	37.3
Female	61.2	62.7
Age (yrs)		
Range	17-74	17-77
Mean	41.7	41.5
SE	1.12	0.98
Socio- economic status*		
Range	1-7	1-7
Mean	3.0	3.4
SE	0.13	0.12

cessation was delivered to pharmacy staff who were routinely involved in giving anti-smoking advice or selling NRT.
Training included specific content and recommendations pertaining to preparation, action, maintenance and relapse and aimed to give an understanding of the stages in the stage of change model and focussed on brief questioning which could enable counsellors to assess the stage of individual customers and increase frequency and effectiveness of counselling support by tailoring their advice. It included case studies of pharmacy customers and focused on communication skills for negotiating change and providing on-going support and encouragement. It did not focus on

cessation or those buying over the counter anti-smoking products were offered an information sheet, specific to their intervention/control group, informing them of the research and inviting participation. Willing participants joined either the control or intervention group depending on which pharmacy they had presented at.
Recruitment for the qualitative research was conducted by asking customers completing the 1 month follow-up questionnaire if they were willing to participate, confirmed by the provision of their phone number. A sub-sample of 25 intervention and 25 control interviewees were selected, through stratification by group and ranking by date of recruitment, then every 4th subject was selected for interview.
Methods:
The training was piloted on a cross section of pharmacy personnel from outside the study sample.
Pharmacies were stratified by type (chain/non-chain) and ranked according to the date their willingness to participate was received. They were then randomised to either intervention or control groups by sequential allocation and intervention staff were invited to training, at a convenient time, date and place.
Pharmacy staff maintained a confidential client record with participant's permission.
Questionnaires to determine self-reported quit (at 1, 4 and 9 months) were used. At each of the 3 data collection time points, 2 postal reminders and duplicate questionnaires were sent to non-responders. The 1 month questionnaire also recorded demographics data.
Qualitative data was collected by telephone interview. A semi-structured interview schedule was piloted on 2 intervention and 2 control

	total n	221	217	217
Control	**%**	23.6	10.9	7.4
	n	61	28	19
	total n	259	257	257
Diff-erence	**%**	6.3	5.2	4.6
	95% CI	-1.6 to 14.2	-1.0 to 11.4	-0.8 to 10.0
	p	0.12	0.094	0.089

Secondary outcomes:
Intervention subjects were significantly more likely to make an NRT purchase (p=0.0085).

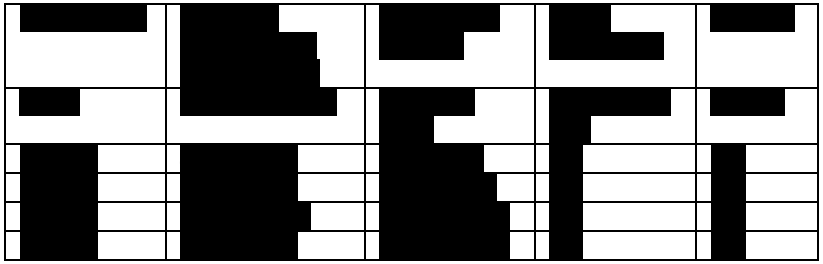
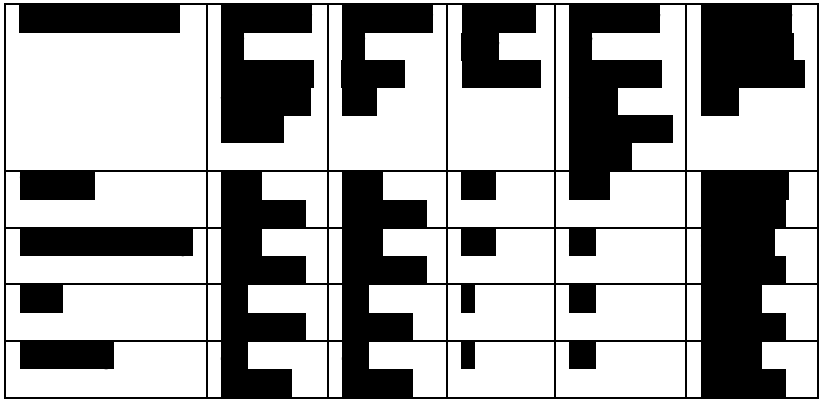
The potential confounders of age, sex, socioeconomic status and nicotine dependence showed no differences between intervention and controls.
Estimates for intra-cluster correlation for the outcomes at each time point were calculated, as less than 0.0001.

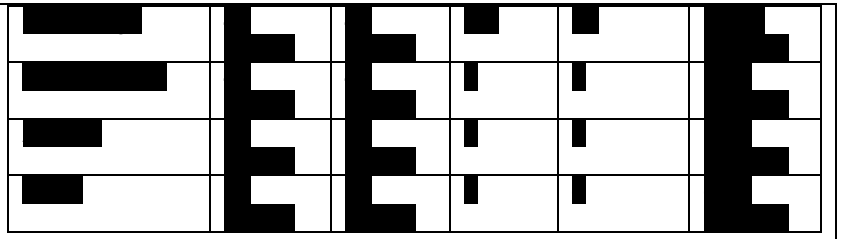
<table>
<tr>
<td>an interactive training workshop for community pharmacists and their staff based on the stage-of-change model.
Length of follow up
9 months
Source of funding
Scottish Office, Department of Health. No pharmaceutical company support was received.</td>
<td>
<table>
<tr><td>FTND**</td><td></td><td></td></tr>
<tr><td>Range</td><td>0-10</td><td>0-10</td></tr>
<tr><td>Mean</td><td>5.2</td><td>5.2</td></tr>
<tr><td>SE</td><td>0.2</td><td>0.2</td></tr>
</table>
* Carstairs Morris deprivation score (1992), where 1 is affluent and 7 is deprived
** Fagerstöm test for nicotine dependence

Inclusion criteria
None specified

Exclusion criteria
City pharmacies were excluded to prevent contamination with a similar concurrent training initiative for other primary care professionals.
No participant exclusion criteria were specified
</td>
<td>smoking cessation products.
<u>Behavioural support:</u>
Participants were offered the Pharmacy Support Programme, which involved client registration, counselling and record keeping.

Comparator
Control group participants assessed for eligibility, were asked to register and then continued to be provided with standard professional support.</td>
<td>customers; no major amendments were required.
Analysis:
Statistical software SPSS was used to store and analyse questionnaire data, to calculate descriptive statistics and to demonstrate differences between intervention and control groups using parametric tests (t tests for quantitative variables) and non-parametric tests (Mann-Whitney tests for quantitative and X^2 for association for qualitative variables). Multiple logistic regression was carried out for binary outcomes and to assess the effect of potential confounders.
Intra-cluster correlation was used to assess the effect of cluster randomisation. Regression techniques, adding the pharmacy as a random factor nested within the treatment groups, to other fixed effect factors were considered leading to a generalised linear mixed model approach.
Power calculations estimated 538 subjects needed to be recruited to each group for 80% chance of detecting 5% difference in smoking cessation rates, statistically significant at the 5% level.</td>
<td></td>
</tr>
<tr>
<td colspan="5">Limitations identified by authors
Pharmacies were aware as to which group they had been allocated; it was not a practical option to blind because of the training aspect of the intervention
Pharmacy staff expected follow-up which may have impacted performance. However, control pharmacy staff also knew they were being monitored.
Generalisability was compromised by the need to exclude city pharmacies. Comparisons with national data highlighted under-representation of urban pharmacies and a higher proportion of single outlets and fewer large multiple in the study population.
The study failed to reach its recruitment target.
Bias may have resulted from customer self-selection and selective recruitment of customers by pharmacy personnel; however, analysis showed that the 2 arms of the study were well balanced in terms of potential confounders.
Limitations identified by review team
Relies on self-reported quit rates (however, no reason that quit rates should differ between control and intervention group).
Other comments
Qualitative evidence regarding pharmacists views were reported in the study, but not reported here as this is outside the protocol for this review.</td>
</tr>
</table>

Study details	Population	Intervention and comparator	Methods and analysis	Results
Reference Twigg MJ, Wright D, Kirkdale CL, Desborough JA, Thornley T. (unpublished) The Pharmacy Care Plan Service: service evaluation and estimate of cost-effectiveness **Quality score** **Study type** Before and after **Location and setting** Community pharmacies in Northern England, UK **Aims** To evaluate the pharmacy care plan service and estimate cost-effectiveness. **Length of follow up** 12 months **Source of funding**	**Health area** General health **Number of participants** n=700 patients 38 pharmacies **Participant characteristics** Mean age= 68 (SD 8.1) years Female= 212 (56.1%) White= 371 (98.1%) Baseline patient activation (PAM) score for those completing 12 months (n=378): Mean= 60.3 (SD 14.2) Level 1=46 (12.7%) Level 2=92 (24.3%) Level 3=181 (47.9%) Level 4=57 (15.1%) Baseline patient activation (PAM) score for all those receiving service (n=700): Mean= 59.1 (SD 14.3) Level 1=98 (14.0%) Level 2=182 (26.0%) Level 3=321 (45.9%) Level 4=99 (14.1%) Particpants who left the service before the 12 month consultation were similar for most clinical and process measures with the exception that they had a significantly higher BMI, lower patient activation, lower adherence to	**Intervention** "Pharmacy Care Plan service" Support for patients to create personalised health goals and agree actions. Number of sessions: 'multiple sessions' with the pharmacist over the course of 12 months (at least baseline, 6 months and 12 months). Initial consultation consisted of medication review, cardiovascular risk assessment, adherence advice including inhaler technique, personalised care plan with agreed goals, referral to GP, referral to other services (e.g. smoking cessation, weight loss). At subsequent consultations, discussed	**Recruitment:** February 2015 to June 2016 Identification was via the pharmacy medication record or referral from the GP. **Analysis:** Anonymised data were assessed for accuracy via visual, range and logic checks by the implementation team. Anonymised data were transferred to the research team for analysis. Paired samples t-test was performed if change in clinical measure was normally distributed. Where 2 independent groups were compared, an independent samples t-test or Mann-Whitney U test were performed depending on the nature of the data.	Patient activation (PAM) scores were derived from 10 questions of the instrument, resulting in a score of 0 to 100, with a higher score denoting greater activation. Depending on the score, patients were then assigned a PAM level from 1 (low activation) to 4 (high activation). 700 participants attended the initial consultation. At month 12, 378 (54%) remained in the service and had a complete set of clinical data. Reasons for drop-out collected from 220 patients – [redacted]  NA Not applicable, NR Not reported 

Study design and implementation funded by the Community Pharmacy Future group. CPF group also paid a consultancy fee to the team at UEA to provide advice on service design, to support training, and to undertaken the evaluation for this service. The CPF research team (CLK and TT) are both employees receiving salaries from Boots UK.	medicines and lower quality of life. **Inclusion criteria** • 50 years or older • Prescribed medication for at least 1 long term condition, including 1 or more drugs from the British National Formulary chapter 2 (cardiovascular) or 6.1 (diabetes) • Consent to participate **Exclusion criteria** Previously experienced a myocardial infarction, transient ischaemic attacks, angina or stroke.	progress with goals and made further recommendations. Length of session: 40 minutes initially, follow up sessions of unknown length Who performed the sessions: Pharmacist or member of support team Training provided to staff: All community pharmacists and a member of their support team completed a 1 day training session. Format of intervention: Face to face, assumed to be 1 to 1, not clear if written information provided.		

Limitations identified by authors
Before and after study with no control group – changes in outcome measures cannot be attributed directly to the intervention. 50% of patients who started the service did not remain until the end – affects generalisability of the results as patients dropping out were less activated, less likely to take their medicines and had a lower quality of life. Questionnaires measuring activation were self report, and patients were unblinded to the intervention.
Limitations identified by review team
The number of participants who were selected to participate but refused is not reported. The validity and reliability of the PAM tool was not reported. Only 54% of participants completed the 12 month intervention. The consistency of the intervention was not reported.
Other comments

As the intervention included a medication review and adherence advice, outcomes affected by these components of the intervention are not reported here (e.g. weight, BMI, blood pressure, cholesterol levels, cardiovascular risk score). Cost effectiveness data were also reported for this intervention, but as this included a medication review and adherence advice, the data could not be included in the current review. Competing interests declared – MT, DW and GB were paid a consultancy fee to provide advice, training and evaluation of the service by the Community Pharmacy Future group. The CPF group designed and implemented the service and had sight and approved the submission to the journal. CLK and TT are employees of Boots UK (and part of CPF group) and were part of the evaluation team who were involved in the study design, data collection and analysis, decision to publish, and preparation of the manuscript. Further details of methods taken from Twigg MJ, Wright D, Kirkdale CL et al. (unpublished). The UK Pharmacy Care Plan service: description, recruitment and initial views on a new community pharmacy intervention. [manuscript received from the authors prior to publication] where necessary.

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Um IS, Krass I, Armour C, et al. (2015) Developing and testing evidence-based weight management in Australian pharmacies: a Healthier Life Program. Int J Clin Pharm, vol 37, p822-833

Quality score
+

Study type
Uncontrolled before and after

Location and setting
Community pharmacies in Sydney, Australia

Aims
To develop and evaluate a pharmacist-delivered,</td>
<td>Health area
Weight management

Number of participants
n=34

Participant characteristics
Age: 50.7 years (SD 15.7)
Female: 24 (71%)
Weight: 93.1kg (SD 17.1)
Waist: 108.0cm (SD 15.8)
BMI: 34.3 kg/m^2 (SD 5.3)
Systolic BP: 127.1mmHg (16.2)
Diastolic BP: 81.9mmHg (12.1)

No significant difference in characteristics of completers and non-completers (p value not reported). 65% participants completed the final session.

Inclusion criteria
Aged 18 years or over
BMI 25 kg/m^2 or greater
Able to take part in moderate physical</td>
<td>Intervention
A Healthier Life Program targeting diet, physical activity and behaviour change.

6 sessions with pharmacist: 30-40 mins for initial session, 15-20 mins in weeks 2, 4, 6 and 8, 20-30 mins in week 12.

Initial session assessed readiness to change, goal setting and action planning, tailored counselling about diet and physical activity. Follow up sessions evaluated progress and discussed strategies to overcome barriers, review and modify action plans, tailored counselling on diet and physical activity. Final session evaluated and discussed overall progress and outcomes, weight maintenance and relapse prevention strategies.

Diet - strategies for controlling or reducing portion sizes, reducing intake of foods that are high in energy, increasing intake of foods that are low in energy but rich in other nutrients. Physical activity - 150-300 min moderate</td>
<td>Recruitment:
Recruited through databases of prescription clients (for obesity-related comorbidities), engaging people purchasing weight-loss products, and client initiated enquiries triggered by promotional materials in the pharmacy.

Analysis:
A sample size of 33 people was needed to detect a 3.8kg weight loss with 90% power and 5% significance.

22 out of 34 participants completed the program.

LOCF used for program completers.

9 out of the 12 people that</td>
<td>Weight and waist circumference
<table>
<tr><th>Week</th><th>Weight (kg, SD, n=22)</th><th>Waist (cm, SD, n=22)</th></tr>
<tr><td>0</td><td>93.2 (15.6)</td><td>108.3 (16.8)</td></tr>
<tr><td>2</td><td>92.2 (14.7)</td><td>108.1 (16.7)</td></tr>
<tr><td>4</td><td>92.6 (14.4)</td><td>107.8 (16.4)</td></tr>
<tr><td>6</td><td>92.0 (13.7)</td><td>107.3 (16.4)</td></tr>
<tr><td>8</td><td>91.2 (14.0)</td><td>107.1 (16.5)</td></tr>
<tr><td>12</td><td>89.7 (13.8)</td><td>106.2 (16.8)</td></tr>
</table>
Statistically significant reduction in program-completer's mean weight ($p<0.05$) and mean waist circumference ($p<0.05$) over the six time points.

Mean change in weight, BMI, waist circumference and blood pressure
<table>
<tr><th></th><th>Last observation carried forward (n=34)</th><th>Program completers (n=22)</th></tr>
<tr><td>Weight</td><td>-2.5kg (-3.5 to -1.6)</td><td>-3.5kg (-4.8 to -2.2)</td></tr>
<tr><td>BMI</td><td>-1.0kg/m^2 (-1.3 to -0.6)</td><td>-1.3kg/m^2 (-1.8 to -0.8)</td></tr>
<tr><td>Waist circumference</td><td>-1.4cm (-2.0 to -0.9)</td><td>-2.0cm (-2.8 to -1.3)</td></tr>
<tr><td>Systolic blood pressure</td><td>Not reported</td><td>-3.0mmHg (-7.0 to 0.9)</td></tr>
<tr><td>Diastolic blood pressure</td><td>Not reported</td><td>1.2mmHg (-2.0 to 4.4)</td></tr>
</table>
Mean difference in weight, BMI and waist circumference at program completion was statistically significant vs. baseline ($p<0.05$)
Mean weight loss as absolute percentage of baseline weight for program completers was 3.6% (SD 2.5). Seven participants (32%) achieved a weight loss of 5% or greater. Mean weight loss with LOCF was 2.6% (SD 2.6).
No significant difference was observed in mean systolic or diastolic blood pressure at program completion compared with baseline.

Lifestyle outcomes (n=22 program completers)
<table>
<tr><th></th><th>Baseline median (IQR)</th><th>Final median (IQR)</th></tr>
<tr><td>Vegetable serves per day</td><td>1.0 (1.0 to 2.0)</td><td>3.0 (2.0 to 3.0)</td></tr>
<tr><td>Fruit serves per day</td><td>1.0 (1.0 to 2.0)</td><td>2.0 (2.0 to 2.0)</td></tr>
<tr><td>Sweet snack serves per day</td><td>1.0 (1.0 to 2.0)</td><td>0 (0)</td></tr>
<tr><td>Moderate physical activity of 30 mins or more (sessions per week)</td><td>2.0 (0 to 3.0)</td><td>3.0 (3.0 to 5.0)</td></tr>
</table>
</td>
</tr>
</table>

<table>
<tr>
<td>non-product-centred weight management service for community pharmacy in Australia

Length of follow up
12 weeks

Source of funding
Authors declare that no external funding was obtained for this study.</td>
<td>activity (medical clearance from GP)

Eligible pharmacies needed to have a private counselling room or screened area and pharmacy staff members able and willing to recruit potential participants.

Exclusion criteria
• Accessing any other weight management program
• Use of medicines associated with weight gain or loss of 5% or greater
• Serious psychiatric illness or uncontrolled depressed</td>
<td>intensity physical exercise or 75-150 min vigorous physical activity or a combination of both, each week, plus muscle strengthening activities at least 2 days a week. Discussions on reducing sedentary behaviours and increasing amount of incidental activity.

Training provided to staff: extensive reading, completion of a 3 day course from specialised dieticians, observation of a 3 month multidisciplinary weight management program.

Format of intervention: 1 to 1 and face to face. Provision of written materials not reported.</td>
<td>dropped out
dropped out after initial session. Seven participants who dropped out were interviewed. Reasons for dropping out included: dissatisfied with intervention and preferred product based program (n=3), difficulty attending follow up sessions (n=2), and moved away (n=2).</td>
<td>
<table>
<tr><td>Vigorous physical activity of 20 mins or more (sessions per week)</td><td>0 (0)</td><td>0.5 (0 to 2.0)</td></tr>
</table>
Significant increases in self-reported consumption of vegetables and fruit (p<0.05) and significant decrease in self-reported consumption of sweet snacks (p<0.05) at program completion vs. baseline. Changes in physical activity were not statistically significant. At completion, 10 (45.5%) people reported engaging in muscle-strengthening activity on 2 or more days a week, compared to 2 people at baseline.

Thematic analysis of interviews with 19 program completers:
• Easily accessible and convenient setting
• “Very comfortable” speaking to the pharmacist about weight, compared with general practitioner, which was perceived as being serious
• It is “within sphere of daily life” compared with making specific appointment to go see a dietician or join a commercial weight loss group
• More appealing [than product centred programs] as it is based on gaining knowledge and adopting lifestyle changes, which is more sustainable
• Convincing as sceptical about ‘‘quick fixes’’ and product-centred weight loss programs
• All participants had a positive experience and were highly satisfied
• Appreciated pharmacist’s support and motivation
• Some preferred prescribed diet plans, some preferred group-based while others favoured the privacy and personalised interaction of one-on-one
• Some suggested utilising technologies such as mobile phone and Internet to gain access to resources. Some suggested using a smart phone application for reminder functions and recording rather than a paper diary system
• Single session worth the same value as a consultation with the general practitioner
• Some suggested having an upfront payment would increase commitment. Willing to pay AU$8 to 40 per session or depending on affordability.
</td>
</tr>
<tr>
<td colspan="5">Limitations identified by authors
Single group intervention design with no control group. Small scale study with small numbers of participants and high attrition. Limited follow up data prevented comparison of completers and non-completers.
Limitations identified by review team
No additional limitations identified.
Other comments
Pilot study.</td>
</tr>
</table>

Study details	Population	Intervention and comparator	Methods and analysis	Results
Reference Winter H. (2007) Waist Management: A pilot scheme using community pharmacists to address the issue of obesity. Pharmacy Management vol 23 (2), p14-18. **Quality score** - **Study type** Before and after **Location and setting** Community pharmacies, London, UK. **Aims** To promote and deliver a weight management service for patients from community pharmacies.	**Health area** Weight management **Number of participants** n=60 2 pharmacies **Participant characteristics** Not reported **Inclusion criteria** BMI>28 with no comorbidities or BMI>27 with comorbidities or familial history of diabetes or heart disease. In the 'action' stage in the cycle of change. **Exclusion criteria** None reported	**Intervention** "Waist management programme" Number of sessions: At least 12 (additional sessions provided in same time frame if requested by patient) Length of sessions: Not reported Who performed the sessions: Pharmacists What was covered in each session: Week 1 to 8 topics such as healthy eating, exercise, shopping tips, adapting recipes, reading food labels. Weeks 12, 16, 20 and 24: not reported. Training provided to staff: Not reported. PCT provided a list of suggested topics for group sessions with literature for each one, but pharmacists were free to use alternative topics or speakers if they wished. Format of intervention: Face to face, group for weeks 1 to 8 and then group or 1 to 1 from 12 weeks onwards. Written materials and exercise passes (valid for 8 weeks) for local leisure centres provided.	**Recruitment:** Referral from GP or self-referral. If patients failed to attend 2 meetings then their space was reallocated to another patient (n not reported). **Analysis:** Method of analysis not reported. Not clear how missing data were accounted for.	42 (70%) participants dropped out before 24 weeks. Average weight loss was 1.82kg per patient. 10 (16.7%) patients reached target of reducing weight loss by 5% at week 12, and 2 (3.3%) achieved a 10% reduction by week 24. Seemed to be poor weight loss in participants with BMI>35. Most weight loss occurred between weeks 1 and 8. After week 8, weight loss slowed and some patients started to gain weight. "Patient feedback indicated that pharmacists are having difficulty in getting the health lifestyle messages across to motivate patients to lose weight." "Patient surveys have indicated that they were satisfied overall with the availability and access to the service, especially as it was free." "Patients felt that although the meetings were interesting, their needs (e.g. tackling their emotional relationship with food) were not addressed." "Exercise passes were considered an excellent opportunity to give patients a chance to sample various forms of exercise." [not clear if this is a pharmacist or patient view] [Note: the study paper refers to results in table 1, however, table 1 was not available with the study paper. It is likely there are results from this study that are not reported here]

Length of follow up 24 weeks **Source of funding** None reported				

Limitations identified by authors
None reported.

Limitations identified by review team
70% of participants dropped out before the end of the study.
Participant characteristics at baseline were not reported.
It is not clear if the intervention was delivered consistently – 2 different pharmacies delivered the intervention, and it is not clear how many different pharmacists were involved.
Staff were not trained to deliver the intervention.

Other comments
Pharmacies received £200 per patient during the pilot scheme - £100 after first consultation, £50 at week 8 and £50 at week 24 if patient continued to attend.

Study details	Population	Intervention and comparator	Methods and analysis	Results

Reference
Zaragoza Fernandez et al. (2012)

Quality score
+

Study type
Randomised controlled trial

Location and setting
Community pharmacies in Spain

Aims
To assess the impact of an intensive intervention in community pharmacies (involving diet, salt intake, alcohol and regular physical exercise) on blood pressure in hypertensive, treatment-compliant patients who are not controlled with antihypertensive agents

Health area
Hypertension

Number of participants
n=150
3 community pharmacies

Participant characteristics
Male= 56 (37.3%)

	Intervention	Control
Mean age	67.4 years (SD 9.7)	69.3 years (SD 11.4)
Smoker	19 (25.0%)	13 (17.6%)
Diabetes	19 (25.0%)	21 (28.4%)
Hypercholesterol	49 (64.5%)	56 (75.7%)
CVD antecedents	25 (32.9%)	19 (25.7%)
Physical exercise	43 (56.6%)	40 (54.1%)
Weight	78.3kg (SD 14.4)	74.9kg (SD 12.4)
BMI	30.8 (SD 3.9)	30.0 (SD 4.1)

Inclusion criteria
Over the age of 18
Taking medication for hypertension
Treatment-compliant
Blood pressure of 140/90mmHg or higher, or 130/80mmHg or higher with other risk factors (e.g. smoking, diabetes, hypercholesterolaemia), previous cardiovascular accident or stroke.

Exclusion criteria

Intervention (n=76)
Patients were given a sheet with changes to be made to their diet and lifestyle in order to control their blood pressure. Four factors were stressed: diet, salt intake, alcohol intake, and exercise.

Participants were telephoned on the same day of the week for 3 consecutive weeks. Given an appointment for a personal interview in week 4, where the intervention was stepped up in intensity and participants were asked what changes they had made and any problems they had encountered. Their blood pressure was taken again.

In week 8, participants were

Recruitment:
Participants collecting antihypertensive drugs at the pharmacies were offered the opportunity to participate, in consecutive order.

50 participants were recruited from each participating pharmacy

Participants were randomised once sample size was reached.

Analysis:
Appropriate sample size of 143 patients was calculated with a power of 80% and a significance of 5%, allowing 10% for loss to follow up.

7 drop outs during the study

Mean weight

	Intervention	Control
Baseline	78.3kg (SD 14.4)	74.9kg (SD 12.4)
8 weeks	77.6kg (SD 14.8)	74.3kg (SD 12.2)

Mean BMI

	Intervention	Control
Baseline	30.8 (SD 3.9)	30.0 (SD 4.1)
8 weeks	30.4 (SD 4.0)	29.8 (SD 4.1)

Mean systolic blood pressure

	Intervention	Control
Baseline	147.3 (SD 15.1)	140.1 (SD 9.4)
8 weeks	131.6 (SD 13.3)	142.0 (SD 10.5)
Difference vs. baseline	-16.08 (SD 9.46)	1.79 (SD 5.12)

Mean diastolic blood pressure

	Intervention	Control
Baseline	91.4 (SD 8.0)	86.3 (SD 6.5)
8 weeks	81.4 (SD 8.5)	87.1 (SD 6.2)
Difference vs. baseline	-9.95 (SD 7.46)	0.95 (SD 3.37)

Group membership (intervention or control), sex and being aged under/over 60 was statistically significantly associated with mean systolic blood pressure at baseline and at week 8 ($p<0.05$). The same was true for diastolic blood pressure, except the association with sex was not statistically significant.

Length of follow up 8 weeks Source of funding None reported.	Aged under 18 years Pregnant women Those who did not agree to participate Non-compliant patients in the intervention group who remained non-compliant after the pharmacist intervention	interviewed and their blood pressure recorded again. Comparator (n=74) No details provided.		
Limitations identified by authors Presents self-report measures. Limitations identified by review team Other comments No additional comments.				

Appendix Dii – Acceptability evidence tables

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
Author name and year Fitzgerald 2008 **Quality score** + **Study type** Qualitative **Aim of the study** To evaluate the feasibility and acceptability of the provision of brief	**Intervention** Two day training course for pharmacists to prepared them to screen clients for hazardous drinking using brief intervention framework. This covered problem alcohol use, attitudes to alcohol use, drinking guidelines, screening tools, motivational interviewing and brief intervention, how and where to refer clients and	**Inclusion** Targeted groups of clients seeking information on the following: 1. Emergency hormonal contraception 2. Advice or products to address sleep difficulties 3. Advice or products to address fatigue/ lethargy or feeling 'run-down'	**Target health area** Alcohol consumption **Study population** 9 Pharmacists and 13 Medicine counter assistants trained Pharmacists recruited were urban, rural, independent and multiples *Clients* 70 recruited (n=46, 66% female) Of 70 clients: - 19 (27%) seeking smoking cessation advice	Pharmacists results not reported (out of scope) <u>*Clients Responses*</u> Experience/ Acceptability POSITIVE ASPECTS - Most happy to have taken part and generally positive about experience. Also found it valuable as not previously aware of sensible drinking guidelines *"…I'm not a great drinker, well I wouldn't think so anyway, maybe a bottle of wine at the weekend…that would last me the whole night and that would be me once a week. But I found it really interesting when she said that was actually coming under hazardous drinking*"

<table>
<tr><th>Study details</th><th>Research Parameters</th><th>Inclusion/ Exclusion criteria</th><th>Population</th><th>Results</th></tr>
<tr>
<td>interventions on alcohol in community pharmacies.

Location and setting
Glasgow, Scotland Community Pharmacies

Source of funding
Alcohol Education and Research Council</td>
<td>the study protocol. Counter assistants received One day training to enable correct identification of possible clients for referral to pharmacists. Clients screen clients using FAST (Fast Alcohol Screening Tool).

Average times per consultation were 9 minutes with clients in the non-hazardous/harmful category (n=29) and 12 minutes with those in the hazardous/harmful drinking category (n=30). Average for clients in harmful drinking category was 16 minutes (n=7)

Sampling Frame
All pharmacies in Greater Glasgow (n=222) informed of study. 17 interested and a purposive sample of eight selected on basis of availability for training and maximum variation

Data collection
Clients recruited July-Oct 2005 by pharmacy staff as well as through</td>
<td>4. Advice or products for smoking cessation/reduction
Exclusion
Pharmacies without a “counselling area” (a separate enclosed space or room dedicated to client consultations)</td>
<td>- 13 (19%) asked about posters/ displays
- 12 (17%) feeling run-down/ tired/ lethargic
- 4 (6%) seeking sleep aids
- 2 (3%) emergency hormonal contraception
- 20 (29%) Not recorded</td>
<td>- Liked the non-judgemental style of pharmacists and knowing the pharmacists made participation easier (No quotations provided)
- Clear explanations given and the importance of privacy referred to my multiple clients (No quotations provided)

NEGATIVE ASPECTS
- Small number expressed less-positive reactions. Note all these were initially screened as hazardous or harmful drinkers
-
“I would say it would be worthwhile to other people but I didn’t really find it worthwhile. I don’t feel I’ve got a problem with alcohol”

Number of clients screened as hazardous/harmful drinkers and interventions delivered by pharmacists
<table>
<tr><th>Intervention</th><th>Hazardous (n=30) N (%)</th><th>Harmful (n=7) N (%)</th></tr>
<tr><td>Feedback on screening and risks to health</td><td>22 (73)</td><td>5 (71)</td></tr>
<tr><td>Explanation of sensible drinking and units in clients preferred drinks</td><td>25 (83)</td><td>5 (71)</td></tr>
<tr><td>Discuss pros/ cons of current drinking pattern and link with presenting issue</td><td>18 (60)</td><td>5 (71)</td></tr>
<tr><td>Discuss options for cutting down</td><td>16 (53)</td><td>5 (71)</td></tr>
<tr><td>Recommend to seek further advice</td><td>0</td><td>1 (14)</td></tr>
<tr><td>Literature: unit calculator wheel</td><td>18 (60)</td><td>2 (29)</td></tr>
<tr><td>Literature: Alcofacts leaflet</td><td>12 (40)</td><td>1 (14)</td></tr>
<tr><td>Literature: So you Want to Cut Down book</td><td>15 (50)</td><td>4 (57)</td></tr>
<tr><td>Literature: Alcohol Support Services contacts</td><td>1 (3)</td><td>0</td></tr>
<tr><td>No intervention recorded</td><td>3 (10)</td><td>1 (14)</td></tr>
</table>
</td>
</tr>
</table>

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
	posters inviting public to enquire about alcohol issues highlighting the expertise available in the pharmacy. Two group interviews and a 1-to-1 interview with six pharmacists. 1-to1 phone interviews with 19 clients agreed for follow-up **Method of analysis** Thematic analysis using the framework approach as the research started deductively from pre-set objectives and more structured data generation. Analysis undertaken by one author, and all emerging themes and illustrative quotes discussed and finalised by two researchers			
Notes **Limitations identified by author** Generalisability of results based on pharmacies selected called into question. Selection bias possible as pharmacists who took part were really interested in this area of study and therefore more likely to recruit clients. Feasibility study and requires more work to determine the best way to approach clients if to be implemented on a large scale **Limitations identified by review team** Only two quotes from participants provided				

<table>
<tr><th>Study details</th><th>Research Parameters</th><th>Inclusion/ Exclusion criteria</th><th>Population</th><th>Results</th></tr>
<tr>
<td>Author name and year
Quirk et al. 2016

Quality score
++

Study type
Qualitative process study

Aim of the study
To explore participants' engagement with a randomised control trial (Dhital et al. 2013) evaluating community pharmacist brief alcohol intervention delivery to identify whether research participation effects may explain why the brief intervention was not found to be effective.

Location and setting
London, UK

Source of funding
The research costs for this study is funded through the</td>
<td>Intervention
Brief intervention on alcohol use, as described in Dhital et al. 2015

Data collection
Participants were asked if they were interested in participating in a further telephone call to explore experiences of participant in the trial. 24 participants (12 from each condition) were 'randomly selected' (no further details provided) to participate in the process study out of 291 participants who were followed up. All 24 accepted.

Participants were contacted approximately 1 month after the 3 month trial follow up call for a 20 minute discussion on the phone with the researcher.

Semi structured topic guide was used to provide the basis for a</td>
<td>24 participants followed up from Dhital et al. 2013 study.</td>
<td>n=24
<table><tr><th></th><th>Intervention (n=12)</th><th>Control (n=12)</th><th>Total</th></tr><tr><td>Mean age (SD, range)</td><td>36.0 (14.2, 22 to 69)</td><td>41.4 (17.9, 19 to 67)</td><td>38.5 (16.0, 19 to 69)</td></tr><tr><td>Female</td><td>7 (58.3%)</td><td>4 (33.3%)</td><td>11 (45.8%)</td></tr><tr><td>White British</td><td>10 (83.3%)</td><td>6 (50.0%)</td><td>16 (66.7%)</td></tr><tr><td>Continued education after 16</td><td>8 (66.7%)</td><td>10 (83.3%)</td><td>18 (75.0%)</td></tr></table></td>
<td>Intervention and control participants were coded using I and C followed by unique number.

Recruitment to the trial and reasons for participation

A quarter of the people we interviewed said that they had taken part because they wanted to find out "where [they] stand" as a drinker:

I wanted to find out a bit more about what the alcohol study was about, whether it was going to moderate my drinking, or how much I was drinking was affecting my health and my emotional well-being, if I'm being honest. I24

A few interviewees gave just one single reason for participating in the trial but more identified a range of factors as having influenced their decision. Two-thirds cited altruism:

It's good to take part in these sort of things because I mean I'm not saying it wasn't beneficial to me, don't get me wrong, but if you don't help with these sort of things then you're not going to help find a process or get a cure or help people if you don't help the research. I13

A recurrent theme was the importance of a trusting, pre-existing relationship between participant and pharmacist. The perceived familiarity of the community pharmacist, suggest there are parallels with the doctor/patient model in this regard:

He's a very nice chap in there, he's looked after my father over the years and I've come to know him quite well. I21

In addition, pharmacists' friendly manner, and the perception that it was a place where "you probably wouldn't feel judged", contributed to pharmacy customers agreeing to take part:

The pharmacist who served me told me about the study and was very friendly in the way that she did so, which definitely encouraged me. I14

Screening/assessment</td>
</tr>
</table>

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
Hugh Linstead Fellowship Award by the Pharmacy Research UK, Royal Pharmaceutical Society and the Harold and Marjorie Moss Charitable Trust PhD award, both made to Ranjita Dhital. Jim McCambridge and Virginia MacNeill were supported by a Welcome Trust Research Career Development fellowship in Basic Biomedical Science (WT086516MA). This study was awarded Service Support Payment by North West London CLRN (UKCRN number 11920).	chronological account of study participation. **Method of analysis** Telephone discussion was digitally recorded and transcribed verbatim. Transcripts were imported into NVivo10 for qualitative analysis. Framework Analysis was used to systematically code and analyse the data, using a matrix to summarise and compare the transcripts by participant and theme. Themes were partly drawn from topic guide and were later refined to include emerging and unexpected material in the data. Data initially identified and coded by VM, then reviewed by AQ and JM and the same three authors discussed and agreed how the data should be interpreted. AQ led the writing of			The process of being assessed and fed back the results reportedly had little effect on about half of all participants, some of whom invoked ideas about problem drinking: *I don't feel that I've actually got a problem with alcohol that I drink excessively. I13* *I know a lot of heavy drinkers, in the building game there is a lot of heavy drinkers, and maybe I was one a few years ago, but I've never got up in the morning and been dependent on a drink, even when I was drinking heavily. C07* However, other participants spoke of being affected by assessment, sometimes profoundly, in one of two ways. First, simply responding to questions about their drinking and the impact it has on their lives, could be surprising in that it made participants aware they were drinking "more than I realised": *Some of the questions that were put before me, I was quite shocked in some of my own replies. I13* *I probably drink more than I realised, it's just that you don't think about it until someone asks you to number something and you think God, actually I probably drink two bottles of wine on the weekend.I23* Second, it was being advised that their drinking was unhealthy or excessive that was "pretty scary" for this participant with an AUDIT score of 19: *She said that I was close to the mark. I think I was one point away from where she would have had to refer me to a GP for alcohol treatment. So that was pretty scary. I16* In contrast, others felt reassured by the communication of their eligibility because they thought their drinking would have been classified as "much worse than that" and it made had them realise it was actually "not that much": *On the whole I was quite shocked at my result. It was quite good. I thought it would be worse than that C03*

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
	results after the first draft prepared by VM.			*It made me realise that I don't drink so much, so I did feel better about myself…because the way the questions were asked made me think about when I drink, and how frequently I drink, and made me realise that it's not that much. C02* The AUDIT identifies risky but not necessarily problematic drinking and the pharmacists had been trained to feed back the results in a dispassionate and non-judgemental way. But this did not always happen, indicating some implementation failure. Several participants reported that the pharmacist had been at pains to reassure them that their drinking was not excessive, thus departing from the study protocol: *I thought I was excess. And when he explained to me, he said, no, you're not excess, you're OK on your drinking wise. He said, your health shouldn't suffer that much. And I thought that was good.C01* One participant evidently misunderstood his situation, which may have been because it had not been communicated clearly by the pharmacist: *I wasn't told that I was drinking more than the recommended amount because I don't. I'm not a huge drinker though. C05* **The brief intervention** All 12 intervention participants we interviewed said that their pharmacist had been understanding or empathic, as they were meant to have been with this group: *I didn't feel like I was under the spotlight, it was, more a relaxed conversation, like what I'm having with you now. It just didn't feel like any pressure to me, anyway, as I say I've not got a problem. Someone with a problem might not want to talk about it, I don't know, denial and all that malarkey. But I felt quite at ease and quite happy to speak to him. I13.* The limited effects of the intervention are suggested by the absence of risk or problem identification in the quotation above. This participant, however, went on to articulate something close to the intended prevention effects for those

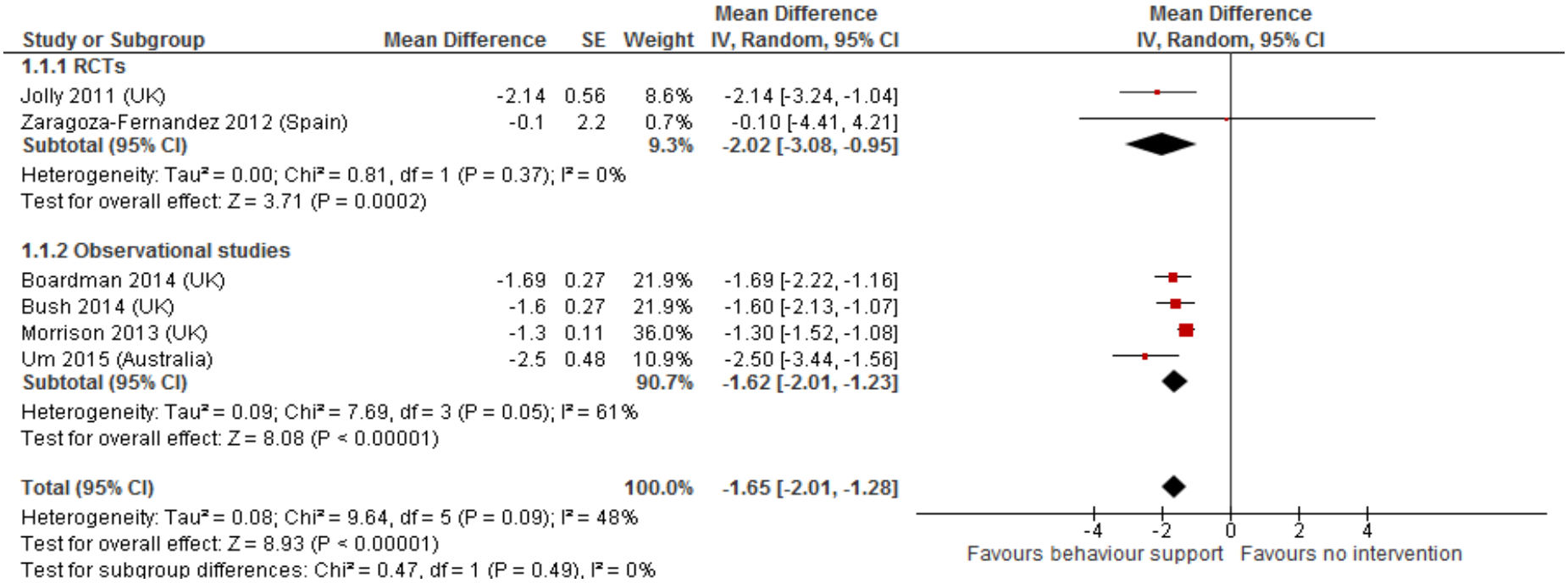
Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
				who do not have alcohol problems (the intended effects for those who do have current problems would be to help reduce them): *When we started to get into the conversation and taking part and, it sort of opened my eyes to, I'm not a weekly drinker, I'm not an excessive drinker, I don't binge drink, but there was a few little things that came to light that are not a problem. But there's times when I could have sort of not drunk but I did drink, if you know what I mean. It's just a little bit of an eye opener really. I13* **Printed information** After the ten minute discussion, the intervention group was given the "Units and You" booklet, a "Unit/Calorie Calculator Wheel" and an alcohol services leaflet to take away. This additional intervention component was valued, especially the information about unit recommendations and calorific information: *The best thing that she gave me was the unit and calorie counter, which I still have actually on my pin board because it's very, very interesting. I was sort of on a mission to, as I continue to be, to lose some weight. So if anything, that was very beneficial to provide for me. I22* Another participant thought that the discussion (BI) was inappropriately targeted at her and that she found the printed material more useful: *It was more the wheel, there was a leaflet as well, rather than the conversation. I think the conversation was probably more directed at someone who maybe had experienced issues of severe, heavy drinking and things or other social issues around it. I19* Some participants said they still looked at it from time to time because the information was very useful while another said he had not read any of the material as he preferred the discussion with the pharmacist. Participants allocated to the control condition were not explicitly informed that they were control participants and were given a leaflet entitled "Alcohol: The Basics", the content of which was not expected to be effective at promoting behaviour change. Again there were protocol departures:

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
				I didn't read it all because he also gave a talk about it, the units and everything else so really for what I read is what he was explaining to me. I wouldn't say I sat down and read it indoors because he was explaining everything for you. C01 Others said they found the information useful and that it had had an impact on their thinking and behaviour: *The leaflet made me think about things…and in this case thinking about my drinking meant I drank slightly less. C05* The pharmacists undertook a half-day training course on skilful listening and communication skills in preparation for brief intervention delivery in the trial. However, approximately half of the information leaflet-only control participants commented on the pharmacists' professional, calm and understanding manner, which suggests that the pharmacists were using similar empathic communication skills with both groups. In trials terms, this is contamination, with the control group being exposed to an integral component of the intervention being evaluated. **Perceived impact of participation** About half of the intervention group said that taking part had not changed their thinking or their drinking, because they did not perceive them-selves to have a problem anyway. Others said that it had "got them thinking" about their behaviour, which is what the intervention had been designed to do: *I think what was quite powerful is that when I spoke to the pharmacist then it got me thinking about actually the things I have done at university, and how I was different now, and how I'd changed a little bit and how my drinking at university was clearly to excess, and now how I wanted to regulate and stop that. I20.* Others went further and said they had "cut down" their drinking: *I know that drinking is bad and drinking to excess is bad and I've cut down on my drinking a lot since I first went to the pharmacy and took part in the study. I don't drink half as much as I used to.I16*

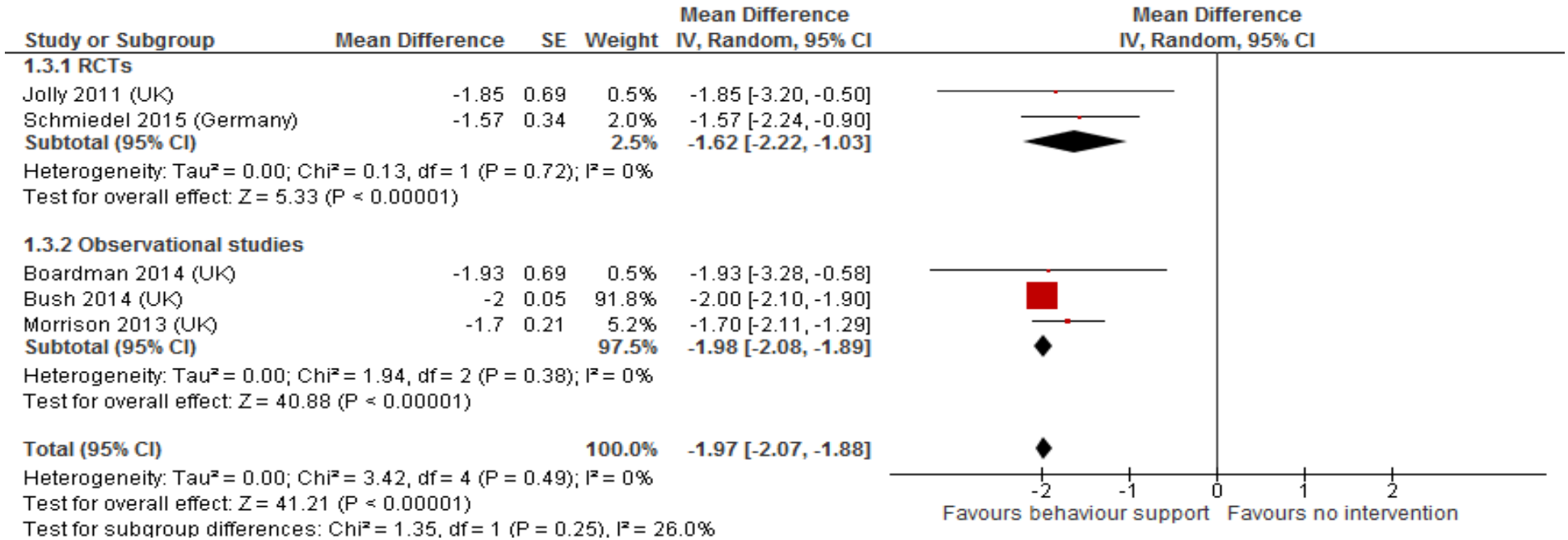
Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
				What it did do…I didn't drink for the whole of January for various reasons, because I just wanted to see if I could do it, and I did. But also for me who is someone that has given up smoking and continues to battle with that on a social level, it really highlighted to me that in my head smoking and drinking go together, so the less I do it the better. I22 As with the intervention group, around half of the control group said that that taking part had not changed their thinking or their drinking. The others said that talking to the pharmacist during assessment or reading the leaflet had made a difference to how they thought about their drinking, and in a few cases they had made a change to their behaviour: *I've eased up on it, instead of drinking three cans of beers, just drinking probably two. C11*
Notes This study was nested within the RCT by Dhital et al. (2013) on a brief intervention for alcohol use. **Limitations identified by author** Separation of interviewer and interviewee on the phone can present challenges for interpersonal communication, specifically in the formation of trust and with interviewees typically providing relatively less detail and elaboration than in face to face interviewing. Authors acknowledge limited depth of understanding expected from short telephone interviews. **Limitations identified by review team** No additional limitations identified.				

Appendix E – Forest plots

Short term weight change (in kg) < 6 months [ES

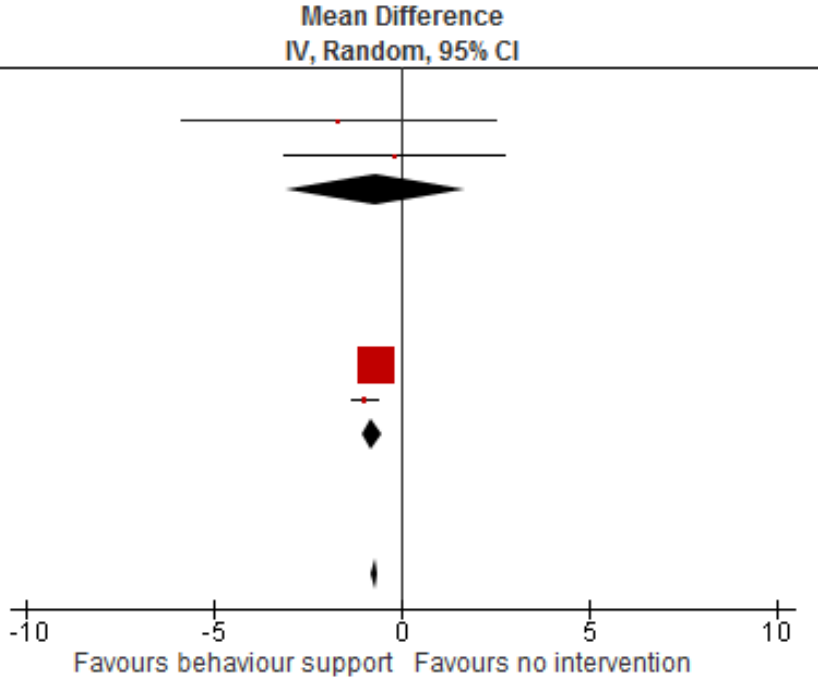


Long term weight change (in kg) ≥ 6 months

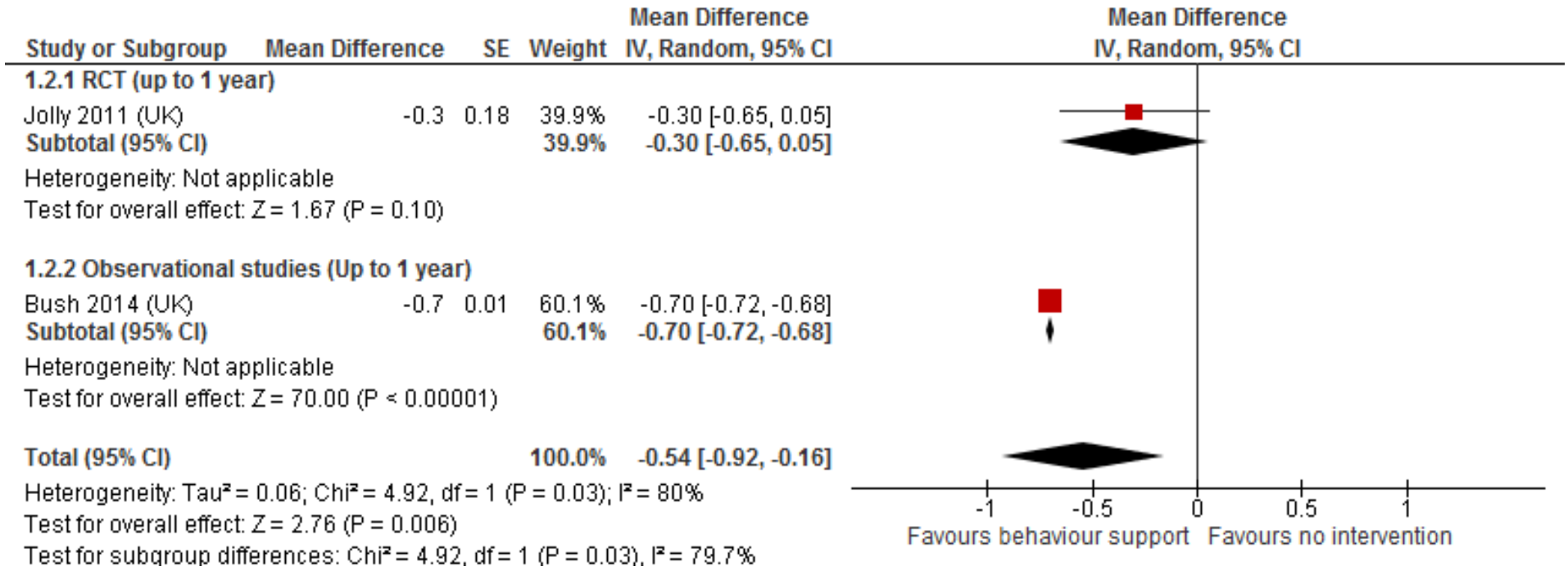


Short term BMI change < 6 months

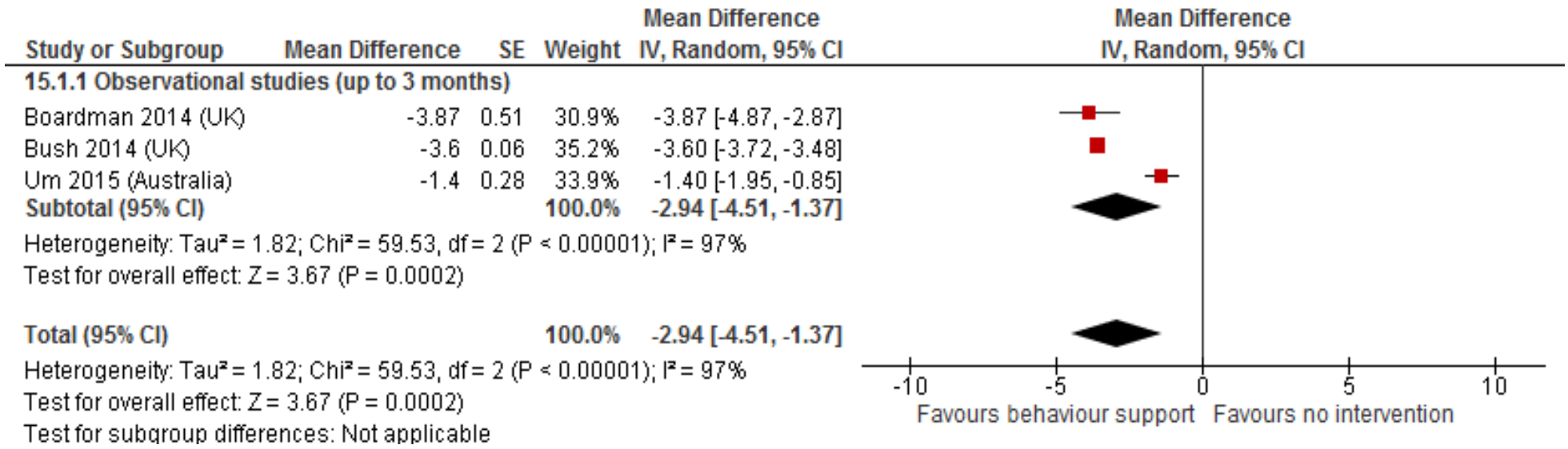
Study or Subgroup	Mean Difference	SE	Weight	Mean Difference IV, Random, 95% CI
1.4.1 RCTs (up to 3 months)				
Lalonde 2006 (Canada)	-1.7	2.14	0.0%	-1.70 [-5.89, 2.49]
Zaragoza-Fernandez 2012 (Spain)	-0.2	1.5	0.1%	-0.20 [-3.14, 2.74]
Subtotal (95% CI)			**0.1%**	**-0.69 [-3.10, 1.71]**
Heterogeneity: Tau² = 0.00; Chi² = 0.33, df = 1 (P = 0.57); I² = 0%				
Test for overall effect: Z = 0.57 (P = 0.57)				
1.4.2 Observational studies (up to 3 months)				
Bush 2014 (UK)	-0.7	0.02	95.4%	-0.70 [-0.74, -0.66]
Um 2015 (Australia)	-1	0.18	4.5%	-1.00 [-1.35, -0.65]
Subtotal (95% CI)			**99.9%**	**-0.80 [-1.07, -0.52]**
Heterogeneity: Tau² = 0.03; Chi² = 2.74, df = 1 (P = 0.10); I² = 64%				
Test for overall effect: Z = 5.68 (P < 0.00001)				
Total (95% CI)			**100.0%**	**-0.71 [-0.79, -0.64]**
Heterogeneity: Tau² = 0.00; Chi² = 3.07, df = 3 (P = 0.38); I² = 2%				
Test for overall effect: Z = 18.38 (P < 0.00001)				
Test for subgroup differences: Chi² = 0.01, df = 1 (P = 0.93), I² = 0%				



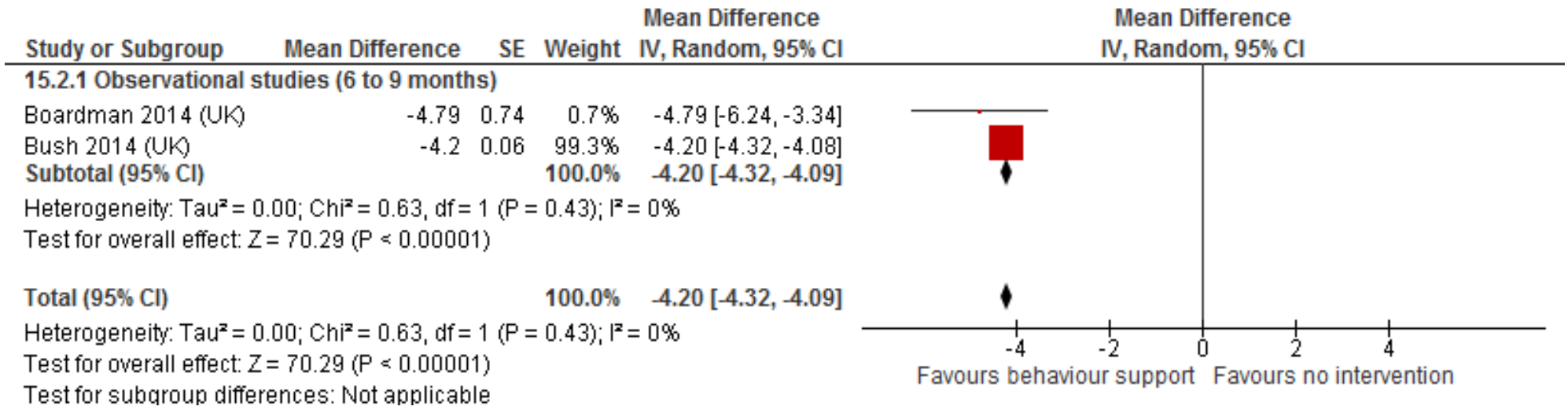
Long term BMI change ≥ 6 months



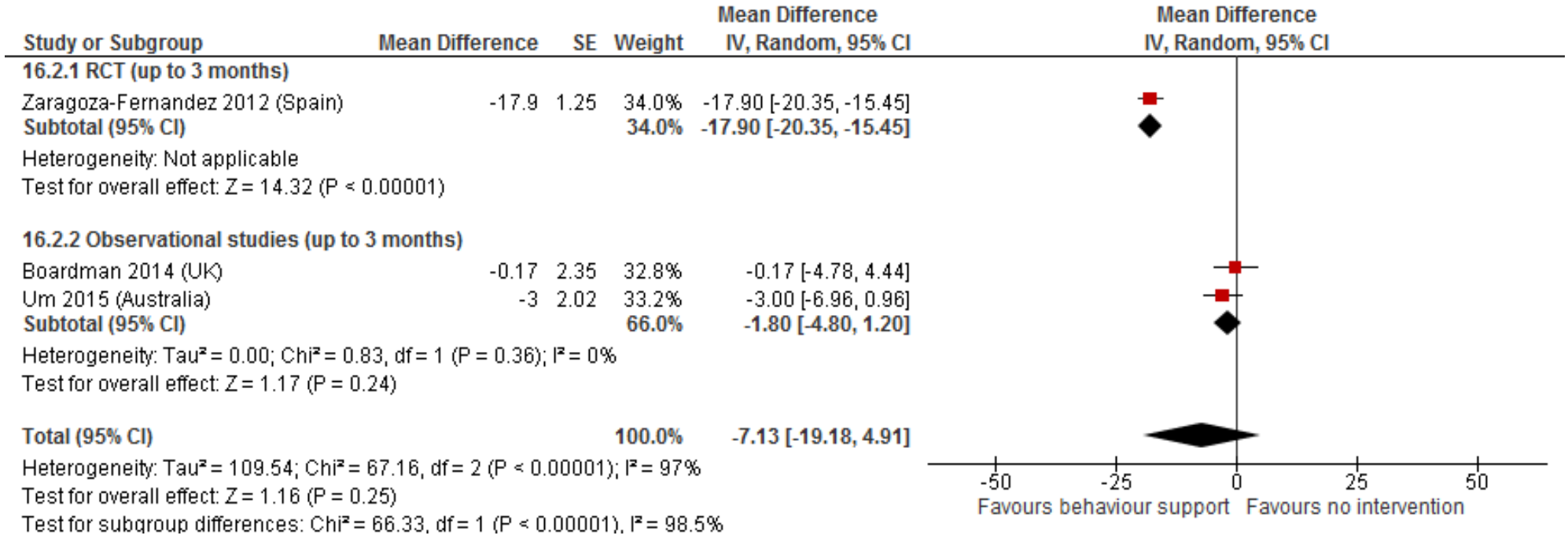
Short term Waist circumference (in cm) < 6 months



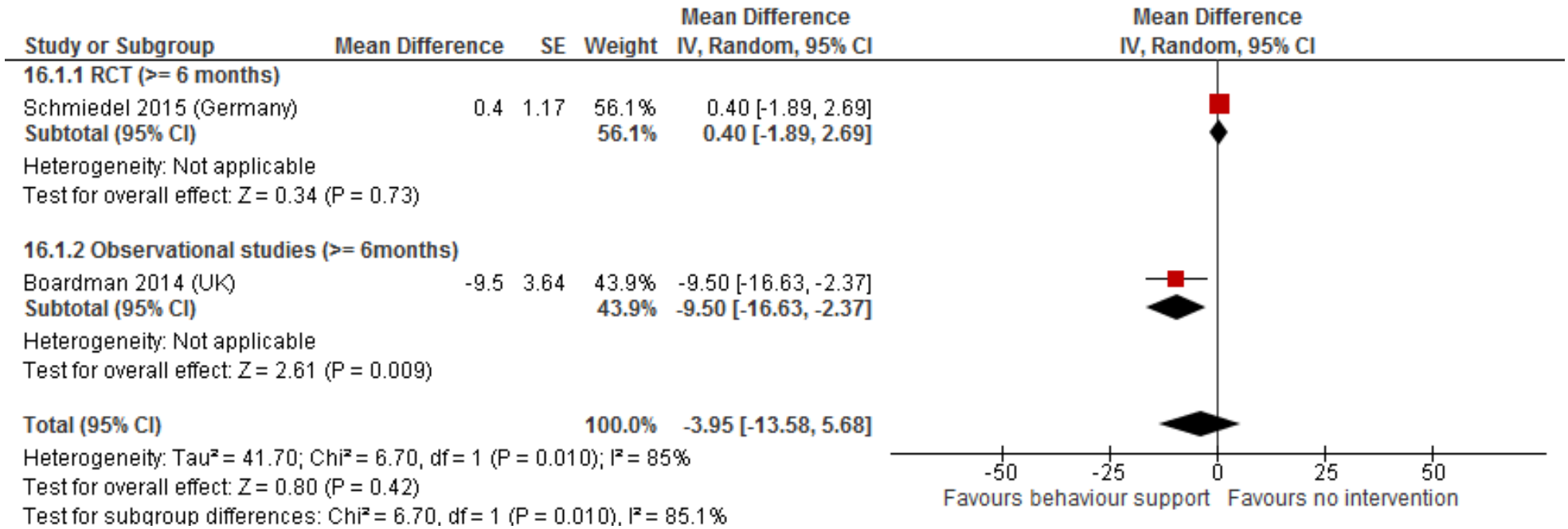
Long term waist circumference (in cm) ≥ 6 months



Short term systolic blood pressure < 6 months

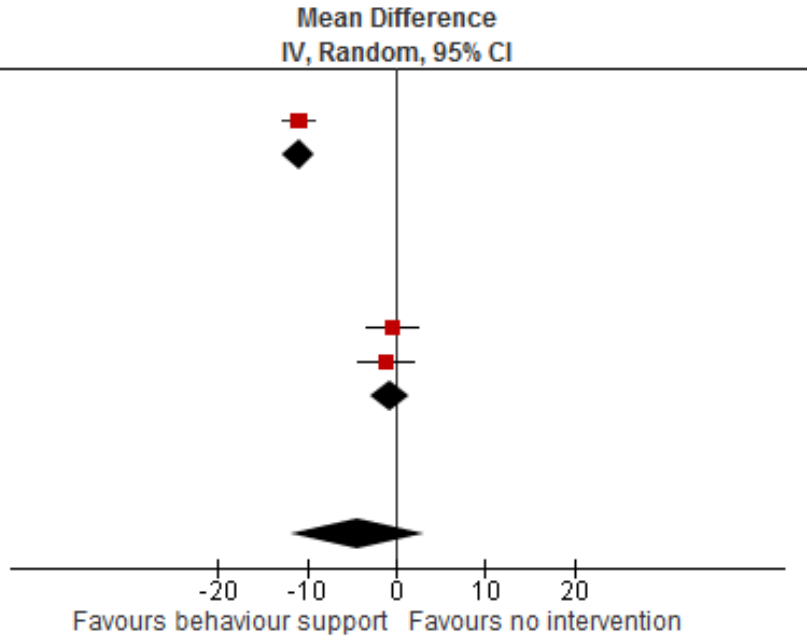


Long term systolic blood pressure ≥6 months

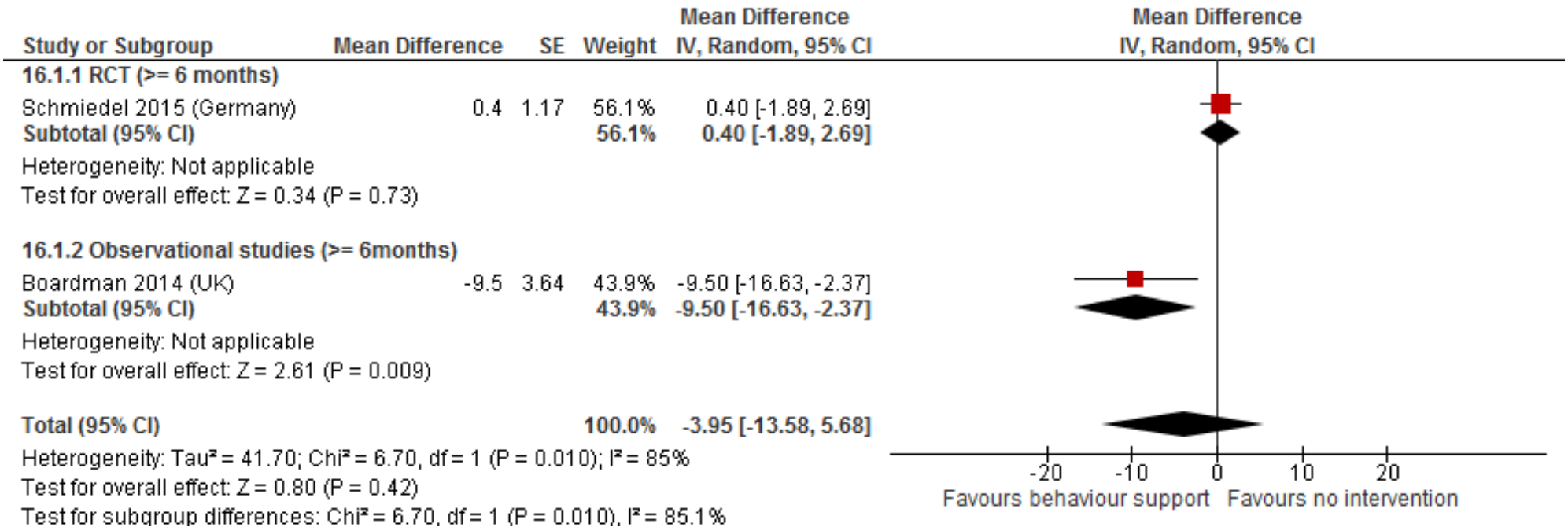


Short term diastolic blood pressure < 6 months

Study or Subgroup	Mean Difference	SE	Weight	Mean Difference IV, Random, 95% CI
17.1.1 RCT				
Zaragoza-Fernandez 2012 (Spain)	-10.9	0.93	34.1%	-10.90 [-12.72, -9.08]
Subtotal (95% CI)			**34.1%**	**-10.90 [-12.72, -9.08]**
Heterogeneity: Not applicable				
Test for overall effect: Z = 11.72 (P < 0.00001)				
17.1.2 Observational studies				
Boardman 2014 (UK)	-0.42	1.49	33.1%	-0.42 [-3.34, 2.50]
Um 2015 (Australia)	-1.2	1.63	32.8%	-1.20 [-4.39, 1.99]
Subtotal (95% CI)			**65.9%**	**-0.78 [-2.93, 1.38]**
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.12$, df = 1 (P = 0.72); $I^2 = 0\%$				
Test for overall effect: Z = 0.70 (P = 0.48)				
Total (95% CI)			**100.0%**	**-4.25 [-11.74, 3.23]**
Heterogeneity: $Tau^2 = 41.88$; $Chi^2 = 49.54$, df = 2 (P < 0.00001); $I^2 = 96\%$				
Test for overall effect: Z = 1.11 (P = 0.27)				
Test for subgroup differences: $Chi^2 = 49.42$, df = 1 (P < 0.00001), $I^2 = 98.0\%$				



Long term diastolic blood pressure ≥ 6 months



Appendix F – GRADE tables

GRADE profile 1: Outcome: Clinical measurements or health outcomes

Quality assessment										
No. of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	No. of participants	Effect	Quality of evidence for outcome	Importance of outcome
Loss of 5% or more of body weight (percentage of participants)										
Baseline vs. 3 months [ES3.1]										
1[1]	Randomised controlled trial	No serious	Not applicable	No serious	Very serious[b]	Yes[a]	70	21.4%[c] (12.5 to 32.9) p value not reported	Very low	Critical
1[2]	Before and after	No serious	Not applicable	No serious	Very serious[b]	No	22	32%[d] (CI not reported) p value not reported	Very low	Critical
1[3]	Before and after	Very serious[r]	Not applicable	No serious	Very serious[b]	No	60	16.7%[s] (CI not reported) p value not reported	Very low	Critical
1[4]	Retrospective cohort study	No serious	Not applicable	No serious	Very serious[b]	No[e]	183	14.2%[f] (CI not reported) p value not reported	Very low	Critical
1[5]	Before and after	Serious[g]	Not applicable	No serious	Very serious[b]	No	430	9.5%[f] (6.9 to 12.7) p value not reported	Very low	Critical
1[6]	Before and after	No serious	Not applicable	No serious	Very serious[b]	No	281	9%[f] (CI not reported) p value not reported	Very low	Critical
1[11]	Controlled before after	Very Serious	Not applicable	No serious	No serious	No	1125	7.9%standard counselling vs. 11.6% counselling, p-value not reported	Very low	Critical
Baseline vs. 6 months [ES 3.1]										
1[4]	Before and after	Serious[g]	Not applicable	No serious	Very serious[b]	No	430	13.9%[f] (10.7 to 17.7) p value not reported	Very low	Critical
1[6]	Before and after	No serious	Not applicable	No serious	Very serious[b]	No	281	10%[f] (CI not reported) p value not reported	Very low	Critical
Baseline vs. 9 months [ES 3.1]										
1[4]	Retrospective cohort study	No serious	Not applicable	No serious	Very serious[b]	No[e]	183	22.4%[f] (CI not reported) p value not reported	Very low	Critical
Baseline vs. 1 year [ES 3.1]										
1[1]	Randomised controlled trial	No serious	Not applicable	No serious	Very serious[b]	Yes[a]	70	14.3%[c] (7.1 to 24.7) p value not reported	Very low	Critical
1[5]	Before and after	Serious[g]	Not applicable	No serious	Very serious[b]	No	430	15.9%[f] (12.1 to 20.4) p value not reported	Very low	Critical
Loss of 10% or more of body weight (percentage of participants)										
Baseline vs. 6 months [ES 3.1]										
1[3]	Before and after	Very serious[r]	Not applicable	No serious	Very serious[b]	No	60	3.3%[s] (CI not reported)	Very low	Critical

								p value not reported		
Weight change (%)										
Baseline vs. 3 months [ES 3.3]										
1[2]	Before and after	No serious	Not applicable	No serious	Very serious[b]	No	34	-2.6%[f] (SD 2.6) p value not reported	Very low	Critical
1[6]	Before and after	No serious	Not applicable	No serious	Very serious[b]	No	110	-3.12%[d] (SD 3.34) p value not reported	Very low	Critical
1[4]	Retrospective cohort study	No serious	Not applicable	No serious	Very serious[b]	No[e]	183	-1.9%[f] (SD 0.4) p value not reported	Very low	Critical
1[11]	Controlled before after	Very Serious	Not applicable	No serious	No serious	No	1125	-0.53kg% p-value not reported	Very low	Critical
Baseline vs. 6 months [ES 3.3]										
1[5]	Before and after	No serious	Not applicable	No serious	Very serious[b]	No	59	-4.72%[d] (SD 4.68) p value not reported	Very low	Critical
1[11]	Controlled before after	Very Serious	Not applicable	No serious	No serious	No	1125	-0.37%kg%, p-value not reported	Very low	Critical
Baseline vs. 9 months [ES 3.3]										
1[4]	Retrospective cohort study	No serious	Not applicable	No serious	Very serious[b]	No[e]	183	-0.25kg% p value not reported	Very low	Critical
Baseline vs. 1 year [ES3.3]										
1[11]	Controlled before after	Very Serious	Not applicable	No serious	No serious	No	1125	-1.54%kg intensive counselling vs. -1.29%kg standard counselling, p-value not reported	Very low	Critical
Cardiovascular disease										
Baseline vs. 3 months [ES 3.8]										
1[7]	Randomised controlled trial	Serious[o]	Not applicable	Serious[j]	Very serious[b]	Yes[l]	26	Mean 10 year cardiovascular risk Mean difference of -10.5[d] (-22.71 to 1.71) p=0.013	Very low	Critical
1[7]	Randomised controlled trial	Serious[o]	Not applicable	Serious[j]	Very serious[b]	Yes[l]	26	Mean cardiovascular age Mean difference of 0[d] (-4.62 to 4.62) p=0.076	Very low	Critical
Alcohol use										
Behavioural support vs. leaflets at 3 months [ES 3.9]										
1[8]	Randomised controlled trial	Serious[p]	Not applicable	No serious	Serious[m]	No	407	Overall AUDIT score OR 0.87 [c,n] (0.50 to 1.51) favouring leaflets	Low	Critical
1[8]	Randomised controlled trial	Serious[p]	Not applicable	No serious	No serious	No	407	AUDIT score – consumption subscale Between group difference -0.05[d,q] (-0.54 to 0.44) favouring behavioural support, p=0.85	Moderate	Critical

1[8]	Randomised controlled trial	Serious[p]	Not applicable	No serious	Serious[m]	No	407	AUDIT score – dependence subscale Between group difference -0.46[d,q] (-0.82 to -0.09) favouring leaflets, p=0.014	Low	Critical
1[8]	Randomised controlled trial	Serious[p]	Not applicable	No serious	No serious	No	407	AUDIT score – problem use subscale Between group difference -0.13[d,q] (-0.66 to 0.41) favouring behavioural support, p=0.64	Very low	Critical

Data from multiple studies could not be meta-analysed as either none of the studies, or only 1 of the studies, reported the statistics needed to meta-analyse the data.
CI confidence intervals

1. Jolly et al. 2011
2. Um et al. 2015
3. Winter et al. 2007
4. Bush et al. 2014
5. Morrison et al. 2013
6. Boardman et al. 2014
7. Lalonde et al. 2006
8. Dhital et al. 2015
9. Zaragoza-Fernandez et al 2012
10. Schmiedel et al 2015
11. Botomino et al 2008

[a] Overall quality started at 'low' because although this was a randomised controlled trial, only 1 arm took place in a community pharmacy and so before and after data for this arm is presented here.
[b] Downgraded 2 levels - not possible to calculate imprecision from the information reported in the study and number of events is less than 300 (if a dichotomous outcome) or total sample size is less than 400 (if a continuous outcome).
[c] Based on intention to treat analysis using baseline observation carried forward. Overall quality not downgraded.
[d] Based on data only from people who completed all follow up sessions (intention to treat analysis not reported). Overall quality not downgraded.
[e] This study compared two interventions, however, only 1 intervention took place in a community pharmacy and so before and after data for this group are presented here. Overall quality not downgraded.
[f] Based on intention to treat analysis using last observation carried forward. Overall quality not downgraded.
[g] Downgraded 1 level. Only 25% of participants attended at 12 months. It is not clear how many participants attended more than 1 sessions and/or how many session were needed to ensure that the intervention was delivered. The consistency of the intervention between pharmacies, pharmacy staff and participants was not measured.
[h] Downgraded 1 level as number of events is less than 300 (if a dichotomous outcome) or total sample size is less than 400 (if a continuous outcome).
[i] Downgraded 2 levels as confidence intervals cross the minimally important difference (0.75 and 1.25 for dichotomous outcomes, 0.5*SD of control group at baseline for continuous outcomes) and number of events is less than 300 (if a dichotomous outcome) or total sample size is less than 400 (if a continuous outcome).
[j] Downgraded 1 level as all participants were on antihypertensive or lipid lowering treatment.
[k] Unclear if based on intention to treat analysis or data only from people who completed all follow up sessions. Overall quality not downgraded.
[l] Overall quality started at 'low' because although the original study design was an RCT, the study authors combined the results for the 2 interventions as the results were similar and only reported before and after data.
[m] Downgraded 1 level as confidence intervals cross the minimally important difference (0.75 and 1.25 for dichotomous outcomes, 0.5*SD of control group at baseline for continuous outcomes).
[n] Adjusted for gender, age, ethnicity and education. Overall quality not downgraded.
[o] Downgraded 1 level. The method of generating the allocation sequence was not reported. The baseline outcome measurements and characteristics appear to be fairly similar between the groups, however, the statistical significance of any differences it not reported. Missing outcome data were not addressed – for some outcomes, data were only included from people who provided data at both time points. Outcomes were not blindly assessed.
[p] Downgraded 1 level. The statistical significance of differences between groups for characteristics and outcome measurements at baseline was not reported. Allocation was not clustered by pharmacy and so contamination may have occurred.

[q] Adjusted for baseline score, gender, age, ethnicity and education. Overall quality not downgraded.
[r] Downgraded 2 levels. 70% of participants dropped out before the end of the study. Participant characteristics at baseline were not reported. It is not clear if the intervention was delivered consistently – 2 different pharmacies delivered the intervention, and it is not clear how many different pharmacists were involved. Staff were not trained to deliver the intervention.
[s] Based on intention to treat data, but it is not clear how missing data were accounted for. Overall quality not downgraded.
t. Downgrade 1 level as allocation generation and sequence unclear and no baseline mesures provided
u. Downgrade 1 level as outcome was self reported

GRADE profile 2: Pooled Data: Clinical outcomes

Quality assessment										
No. of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**No. of participants**	**Effect**	**Quality of evidence for outcome**	**Importance of outcome**
Absolute weight change (in kg) [ES 3.2]										
Baseline vs. < 6 months										
6	RCT/Observational[1]	Serious[a]	No serious	No serious	No serious	No	1148	MD -1.65, CI -2.01 to -1.28	Very Low	Critical
2	RCTs	Serioius[b]	No serious	No serious	Serious[l]	No	220	MD -2.02, CI -3.08 to -0.95	Low	Critical
4	Observational	Serious[c]	No serious	No serious	No serious	No	928	MD -1.62, CI -2.01 to -1.23	Very Low	Critical
Baseline vs. ≥ 6 months										
5	RCT/Observational[2]	Serious[e]	No serious	No serious	No serious	No	1882	MD -1.97, CI -2.07 to -1.88	Very Low	Critical
2	RCTs	Serious[f]	No serious	No serious	No serious	No	1210	MD -1.62, CI -2.22 to -1.03	Moderate	Critical
3	Observational	Serious[c]	No serious	No serious	No serious	No	672	MD -1.98, CI -2.08 to -1.89.	Very low	Critical
BMI [ES 3.4]										
Baseline vs. < 6 months										
4	RCT/Observational[3]	Serious[f]	No serious	No serious	Serious[m]	No	393	MD -0.71, CI -0.79 to -0.64	Very Low	Critical
2	RCTs	Serious[f]	No serious	No serious	Very serious[k]	No	176	MD -0.69, CI -3.10 to 1.71	Very Low	Critical
2	Observational	Not serious	No serious	No serious	Serious[g]	No	217	MD -0.80, CI -1.07 to -0.52	Very Low	Critical
Baseline vs. ≥ 6 months										
2	RCT/Observational[4]	No serious	Serious[c]	No serious	Serious[l]	No	253	MD -0.54, CI -0.92 to -0.16	Very Low	Critical
1	RCT	No serious	Not applicable	No serious	Serious[f]	No	70	MD -0.30, CI -0.65 to 0.05	Moderate	Critical
1	Observational	No serious	Not applicable	No serious	Serious[l]	No	183	MD -0.70, CI -0.72 to -0.68	Very Low	Critical
Waist circumference (in cm) [ES 3.5]										
Baseline vs. < 6 months										
3	Observational[5]	No serious	Serious[c]	No serious	Serious[g]	No	317	MD -2.94, CI -4.51 to -1.37	Very Low	Critical
Baseline vs. ≥ 6 months										

2	Observational[6]	No serious	Not serious	No serious	Serious[l]	No	238	MD -4.20, CI -4.32 to -4.09	Very Low	Critical
Systolic blood pressure [ES 3.6]										
Baseline vs. < 6 months										
3	RCT/Observational[7]	Serious[h]	Serious[c]	No serious	Serious[f]	No	236	MD -7.13, CI -19.18 to 4.91	Very Low	Critical
1	RCT	Serious[h]	Not applicable	No serious	Serious[l]	No	150	MD -17.90, CI -20.35 to -15.45	Low	Critical
2	Observational	No serious	Not serious	No serious	Serious[m]	No	86	MD -1.80, CI -4.80 to 1.20	Very Low	Critical
Baseline vs. ≥ 6 months										
2	RCT/Observational[8]	Serious[f]	Serious[c]	No serious	Serious[g]	No	1173	MD -3.95, CI -13.58 to 5.68	Very Low	Critical
1	RCT	Serious[f]	Not applicable	No serious	Not serious	No	1140	MD 0.40, CI -1.89 to 2.69	Moderate	Critical
1	Observational	No serious	Not applicable	No serious	Serious[g]	No	33	MD -9.50, CI -16.63 to -2.37	Very Low	Critical
Diastolic blood pressure [ES 3.7]										
Baseline vs < 6 months										
3	RCT/Observational[9]	Serious[i]	Serious[c]	No serious	Serious[l]	No	236	MD -4.25, CI -11.74 to 3.23	Very Low	Critical
1	RCT	Serious[j]	Not applicable	No serious	Serious[l]	No	150	MD -10.90, CI -12.72 to -9.08	Low	Critical
2	Observational	No serious	Not serious	No serious	Serious[m]	No	86	MD -0.78, CI -2.93 to 1.38	Very Low	Critical
Baseline vs ≥ 6 months										
2	RCT/Observational[10]	Serious[f]	Serious[c]	No serious	Not serious	No	1173	MD -0.36, CI -1.60 to 0.89	Very Low	Critical
1	RCT	Serious[k]	Not applicable	No serious	Not serious	No	1140	MD 0.42, CI -0.93 to 1.77	Moderate	Critical
1	Observational	No serious	Not applicable	No serious	Serious[f]	No	33	MD -4.70, CI -7.89 to -1.51	Very Low	Critical

CI confidence intervals
Note: Where RCT and observational studies are pooled in analyses, a decision was made to start GRADE from 'Low'

1. Jolly et al. 2011, Um et al. 2015, Bush et al. 2014, Morrison et al. 2013, Boardman et al. 2014, Zaragoza-Fernandez et al 2012,
2. Morrison et al. 2013, Boardman et al 2014, Jolly et al. 2011, Bush et al. 2014, Schmiedel et al 2015
3. Lalonde et al. 2006, Zaragoza-Fernandez et al 2012, Um et al. 2015, Bush et al. 2014
4. Jolly et al. 2011, Bush et al. 2014
5. Boardman et al 2014, Um et al. 2015, Bush et al. 2014
6. Boardman et al 2014, Um et al. 2015
7. Zaragoza-Fernandez et al 2012, Boardman et al 2014, Um et al. 2015
8. Schmiedel et al 2015, Boardman et al 2014
9. Zaragoza-Fernandez et al 2012, Boardman et al 2014, Um et al. 2015
10. Schmiedel et al 2015, Boardman et al 2014

a) Downgraded 1 level as follow up period varied across studies, missing or in-complete data and consistency of intervention not measured in one study, allocation generation/sequence unclear in one study
b) Downgraded 1 level as follow up period varied across studies allocation sequence method unclear and outcomes not blindly assessed in one study
c) Downgraded 1 level as $I^2 > 75\%$, indicating hetereogeneity.
d) Downgraded 1 level as follow up period varied across studies, missing or incomplete data in two studies, allocation sequence method unclear and outcomes not blindly assessed in one study
e) Downgraded 1 level as follow up period varied across studies, method of generating allocation sequence not reported, missing outcome data not addressed and outcomes ot blindly assessed in one RCT study
f) Downgraded 1 level as one 95% confidence interval crosses the MID threshold

g) Downgraded 1 level as follow up periods varied across studies, allocation generation/sequence unclear and no baselinemeasures reported in one study, method of allocation sequence not reported and outcomes not blinded in one study
h) Downgraded 1 level as follow up periods varied across studies, missing or in-complete data and consistency of intervention not measured in one study
i) Downgraded 1 level as missing or in-complete data and consistency of intervention not measured in one study
j) Downgraded 1 level as method of generating allocation sequence not reported, missing outcome data not addressed and outcomes ot blindly assessed in one RCT study
k) Downgraded 2 levels as both 95% confidence intervals cross upper and lower MID thresholds
l) Downgraded 1 level as small study sample (total sample size less than 400 for continuous outcomes)

GRADE profile 3: Outcome: Action

Quality assessment								Effect	Quality of evidence for outcome	Importance of outcome
No. of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	No. of participants			
Physical activity										
Baseline vs. 2 weeks [ES 3.10]										
1[1]	Randomised controlled trial	Serious[b]	Not applicable	No serious	Very serious[c]	Yes[a]	23	Action/maintenance stage for increasing physical activity RR 1.63[e] (0.84 to 3.16)	Very low	Critical
Baseline vs. 3 months [ES 3.10]										
1[2]	Before and after	No serious	Not applicable	No serious	Very serious[d]	No	22	Moderate intensity sessions/week[e] Median 2.0 (0 to 3.0) to 3.0 (3.0 to 5.0) Not statistically significant, p value not reported	Very low	Critical
1[2]	Before and after	No serious	Not applicable	No serious	Very serious[d]	No	22	Vigorous intensity sessions/week[e] Median 0 (0) to 0.5 (0 to 2.0) Not statistically significant, p value not reported	Very low	Critical
1[3]	Randomised controlled trial	No serious	Not applicable	No serious	Very serious[d]	Yes[f]	70	Mean difference in moderate and vigorous intensity minutes/week[g] 73 (51 to 94) Not statistically significant, p value not reported	Very low	Critical
1[3]	Randomised controlled trial	No serious	Not applicable	No serious	Very serious[d]	Yes[f]	70	Mean difference in calories used per week[g] 2720 (1790 to 3649) p≤0.001	Very low	Critical
1[3]	Randomised controlled trial	No serious	Not applicable	No serious	Very serious[d]	Yes[f]	70	Mean difference in walking minutes/week[g] 1 (-11 to 14) Not statistically significant, p value not reported	Very low	Critical

1[2]	Before and after	No serious	Not applicable	No serious	Very serious[c]	No	22	Muscle-strengthening activity on 2 or more days/week RR 5.00[e] (1.23 to 20.24)	Very low	Critical
Baseline vs. 1 year [ES 3.10]										
1[3]	Randomised controlled trial	No serious	Not applicable	No serious	Very serious[d]	Yes[f]	70	Mean difference in moderate and vigorous intensity minutes/week 27[g] (3 to 51) Not statistically significant, p value not reported	Very low	Critical
1[3]	Randomised controlled trial	No serious	Not applicable	No serious	Very serious[d]	Yes[f]	70	Mean difference in calories used per week 1473[g] (742 to 2203) p≤0.001	Very low	Critical
1[3]	Randomised controlled trial	No serious	Not applicable	No serious	Very serious[d]	Yes[f]	70	Mean difference in walking 17 minutes/week[g] (-0.4 to 34) Not statistically significant, p value not reported	Very low	Critical
1[10]	Before and after	Very serious[t]	Not applicable	No serious	Very serious[q]	No	155	45 (29%) patients who set goals achieved them	Very low	Critical
1[10]	Randomised controlled trial	Serious[o]	Not applicable	No serious	No serious	No	1140	Mean difference 0.52 (0.32 to 0.73), p<0.001	Moderate	Critical
Healthy eating										
Baseline vs. 2 weeks, low fat diet [ES 3.11]										
1[1]	Randomised controlled trial	Serious[b]	Not applicable	No serious	Very serious[c]	Yes[a]	23	Action/maintenance stage of behaviour change for low fat diet RR 1.16[e] (0.94 to 1.42)	Very low	Critical
Baseline vs. 2 weeks, low salt diet [ES 3.11]										
1[1]	Randomised controlled trial	Serious[b]	Not applicable	No serious	Very serious[c]	Yes[a]	23	Action/maintenance stage of behaviour change for low salt diet RR 1.05[e] (0.82 to 1.35)	Very low	Critical
Baseline vs. 3 months [ES 3.11]										
1[2]	Before and after	No serious	Not applicable	No serious	Very serious[d]	No	22	**Vegetable servings per day[e]** **Median 1.0 (1.0 to 2.0) to 3.0 (2.0 to 3.0)** **p<0.05**	Very low	Critical
1[2]	Before and after	No serious	Not applicable	No serious	Very serious[d]	No	22	**Fruit servings per day[e]** **Median 1.0 (1.0 to 2.0) to 2.0 (2.0 to 2.0)** **p<0.05**	Very low	Critical
1[2]	Before and after	No serious	Not applicable	No serious	Very serious[d]	No	22	**Sweet snack servings per day[e]** **Median 1.0 (1.0 to 2.0) to 0 (0)** **p<0.05**	Very low	Critical
Baseline vs. 12 months [ES 3.11]										

1[10]	Before and after	Very serious[t]	Not applicable	No serious	Very serious[q]	No	77	24 (31%) patients who set goals achieved them	Very low	Critical
Weight management										
Baseline vs. 2 weeks [ES 3.12]										
1[1]	Randomised controlled trial	Serious[b]	Not applicable	No serious	Very serious[c]	Yes[a,h]	16	Action/maintenance stage for losing weight RR 1.15[e] (0.88 to 1.51)	Very low	Critical
Mental health and wellbeing										
Baseline vs. 2 weeks [ES 3.12]										
1[1]	Randomised controlled trial	Serious[b]	Not applicable	No serious	Very serious[c]	Yes[a]	23	Action/maintenance stage for reducing stress RR 1.00[e] (0.71 to 1.41)	Very low	Critical
Baseline vs. 12 months [ES 3.12]										
1[10]	Before and after	Very serious[t]	Not applicable	No serious	Very serious[q]	No	43	8 (19%) patients who set goals achieved them	Very low	Critical
Alcohol use										
Baseline vs. 2 weeks [ES 3.14]										
1[1]	Randomised controlled trial	Serious[b]	Not applicable	No serious	Very serious[c]	Yes[a, i]	6	Action/maintenance stage for reducing alcohol consumption RR 1.00[e] (0.75 to 1.34)	Very low	Critical
Baseline vs. 3 months [ES 3.14]										
1[4]	Before and after	Very serious[k]	Not applicable	Serious[l]	Very serious[d]	No	37	84% (48 to 95%) reduction in alcohol units per week [geometric mean] p=0.004 0.7 (-5.9 to 4.5) increase in alcohol units per week [arithmetic mean] P value not significant	Very low	Critical
1[4]	Before and after	Very serious[k]	Not applicable	Serious[l]	Very serious[d]	No	36	Reduction of 1 (0 to 2) in median drinking days per week P value not significant	Very low	Critical
1[4]	Before and after	Very serious[k]	Not applicable	Serious[l]	Very serious[d]	No	41	No change (-2.0 to 1.5) in AUDIT-C score P value not significant	Very low	Critical
Baseline vs. 12 months [ES 3.14]										
1[10]	Before and after	Very serious[t]	Not applicable	No serious	Very serious[q]	No	12	6 (50%) patients who set goals achieved them	Very low	Critical
Smoking cessation										
Baseline vs. 2 weeks [ES 3.13]										
1[1]	Randomised controlled trial	Serious[b]	Not applicable	No serious	Very serious[c]	Yes[a, j]	14	Action/maintenance stage for stopping smoking RR 1.10[e] (0.72 to 1.69)	Very low	Critical
Baseline vs. 4 weeks [ES 3.13]										

1[5]	Before and after	Very serious[m]	Not applicable	No serious	Very serious[n]	No	177	Abstinence at 4 weeks 0% vs. 44.6%, p value not reported	Very low	Critical
Baseline vs. 12 weeks [ES 3.13]										
1[5]	Before and after	Very serious[m]	Not applicable	No serious	Very serious[n]	No	177	Abstinence at 12 weeks 0% vs. 35.0%, p value not reported	Very low	Critical
Baseline vs. 6 months [ES 3.13]										
1[6]	Before and after	Very serious[o]	Not applicable	No serious	Very serious[n]	No	73	Abstinence at 6 months 0% vs. 38.4%, p value not reported	Very low	Critical
Baseline vs. 44 weeks [ES 3.13]										
1[5]	Before and after	Very serious[m]	Not applicable	No serious	Very serious[n]	No	177	Abstinence at 44 weeks 0% vs. 15.8%, p value not reported	Very low	Critical
Baseline vs. 12 months [ES 3.13]										
1[10]	Before and after	Very serious[t]	Not applicable	No serious	Very serious[q]	No	48	13 (27%) patients who set goals achieved them	Very low	Critical
Pharmacist Action on Smoking vs. usual care [ES 3.13]										
1[7]	Randomised controlled trial	Serious[p]	Not applicable	No serious	Serious[q]	No	484	Abstinence at 12 weeks 27.5% vs. 11%, p value not reported	Low	Critical
1[7]	Randomised controlled trial	Serious[p]	Not applicable	No serious	Serious[q]	No	484	Abstinence at 6 months 18.5% vs. 8.2%, p value not reported	Low	Critical
1[7]	Randomised controlled trial	Serious[p]	Not applicable	No serious	Serious[q]	No	484	Abstinence at 12 months 14.3% vs. 2.7%, p<0.001	Low	Critical
Pharmacy Support Program vs. usual care [ES 3.13]										
1[8]	Randomised controlled trial	Serious[s]	Not applicable	No serious	Serious[q]	Yes[r]	480	Abstinence at 1 month Mean difference of 6.3% (-1.6 to 14.2), p=0.12	Very low	Critical
1[8]	Randomised controlled trial	Serious[s]	Not applicable	No serious	Serious[q]	Yes[r]	480	Abstinence at 4 months Mean difference of 5.2% (-1.0 to 11.4), p=0.09	Very low	Critical
1[8]	Randomised controlled trial	Serious[s]	Not applicable	No serious	Serious[q]	Yes[r]	480	Abstinence at 9 months Mean difference of 4.6% (-0.8 to 10.0), p=0.09	Very low	Critical
1 counselling session with NRT vs. 3 counselling sessions with NRT [ES 3.13]										
1[9]	Randomised controlled trial	Serious[s]	Not applicable	No serious	No serious	No	6809	Abstinence at 12 weeks OR 0.96[g] (0.86 to 1.08)	Moderate	Critical
5 sessions of National Gold standard smoking cessation program [ES3.13]										
1[11]	Cohort study	Serious	Not applicalble	No serious	No serious	Yes	5214	Abstinece at 6 months 28%, p-value not reported	Low	Critical

1. Lalonde et al. 2006
2. Um et al. 2015
3. Jolly et al. 2011
4. Khan et al. 2013
5. Cramp et al. 2007
6. Jackson et al. 2008
7. Maguire et al. 2001

8. Sinclair et al. 1998
9. Costello et al. 2011
10. Twigg et al. unpublished
11. Neumann et al 2013
12.Schmiedel et al 2015

[a] Overall quality started at 'low' because although the original study design was an RCT, the study authors combined the results for the 2 interventions as the results were similar and only reported before and after data.
[b] Downgraded 1 level. The method of generating the allocation sequence was not reported. The baseline outcome measurements and characteristics appear to be fairly similar between the groups, however, the statistical significance of any differences it not reported. Missing outcome data were not addressed – for some outcomes, data were only included from people who provided data at both time points. Outcomes were not blindly assessed.
[c] Downgraded 2 levels as confidence intervals cross the minimally important difference (0.75 and 1.25) and number of events is less than 300.
[d] Downgraded 2 levels as imprecision could not be calculated and total sample size is less than 400.
[e] Based on data only from people who completed all follow up sessions (intention to treat analysis not reported). Overall quality not downgraded.
[f] Overall quality started at 'low' because although this was a randomised controlled trial, however, only 1 arm took place in a community pharmacy and so before and after data for this arm is presented here.
[g] Based on intention to treat analysis using baseline observation carried forward. Overall quality not downgraded.
[h] Only includes participants with a baseline BMI of 27kg/m^2 or greater. Overall quality not downgraded.
[i] Only includes participants who were drinking 2 or more alcoholic drinks per day at baseline. Overall quality not downgraded.
[j] Only includes participants who were 'former or current' smokers at baseline. Overall quality not downgraded.
[k] Downgraded 2 levels. Missing data from the group of participants identified as harmful/possibly dependent drinkers – only 58% participants had follow up data. Follow up interviews conducted by a 'member of the project team' – not clear if team member was blind to baseline outcome measure of participants.
[l] Downgraded 1 level as this only included hazardous drinkers (AUDIT-C score of 4 for men or 3 for women).
[m] Downgraded 2 levels. Unclear how long the intervention was conducted, and over how many sessions. Unclear how many participants were offered the intervention but declined. Selection bias introduced by community pharmacy staff who asked participants to go home and think about giving up before returning to the pharmacy to receive the intervention. Characteristics of participants who did not complete follow up were not reported. Abstinence was self reported.
[n] Downgraded 2 levels as imprecision cannot be calculated and number of events is less than 300.
[o] Downgraded 2 levels as no characteristics of withdrawals/drop outs reported. Additional intervention of competition entry if a successful quit was reported and quitting was self-reported – open to bias. High loss to follow up (23/80). Consistency of the intervention not measured – important as some interventions were on the phone and some were face to face. Possibility of pharmacy non-compliance with intervention protocol. Abstinence was self reported.
[p] Downgraded 1 level as not all follow-ups were recorded formally indicating inconsistency in data reporting. Not clear if allocation was given to all participants prior to the intervention period
[q] Downgraded 2 levels as number of events less than 300 and imprecision cannot be calculated.
[r] Downgraded 1 level as number and duration of sessions unknown, and length of intervention unknown.
[s] Downgraded 1 level as outcome was self reported.
[t] Downgraded 2 levels. The number of participants who were selected to participate but refused is not reported. The validity and reliability of the PAM tool was not reported. Only 54% of participants completed the 12 month intervention. The intervention was delivered by different pharmacists in different locations and the consistency of it was not reported.

GRADE profile 4: Outcome: Intention

Quality assessment								Effect	Quality of evidence for outcome	Importance of outcome
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	No. of participants	Relative risk (95% CI) or Mean difference (95% CI)		
Physical activity										
Baseline vs. 2 weeks [ES 3.15]										
1[1]	Randomised controlled trial	Serious[a]	Not applicable	Serious[b]	Very serious[c]	Yes[d]	23	Preparation stage for increasing physical activity RR 0.38[f] (95% CI 0.11 to 1.24)	Very low	Important
Healthy eating										
Baseline vs. 2 weeks, low fat diet [ES 3.15]										
1[1]	Randomised controlled trial	Serious[a]	Not applicable	Serious[b]	Very serious[c]	Yes[d]	23	Preparation stage for low fat diet RR 0.33[f] (95% CI 0.04 to 2.97)	Very low	Important
Baseline vs. 2 weeks, low salt diet [ES 3.15]										
1[1]	Randomised controlled trial	Serious[a]	Not applicable	Serious[b]	Very serious[c]	Yes[d]	23	Preparation stage for low salt diet RR 0.50[f] (95% CI 0.05 to 5.14)	Very low	Important
Weight management										
Baseline vs. 2 weeks [ES 3.15]										
1[1]	Randomised controlled trial	Serious[a]	Not applicable	Serious[b]	Very serious[c]	Yes[d, e]	16	Preparation stage for losing weight No events in either arm[i] RR not estimable	Very low	Important
Mental health and wellbeing										
Baseline vs. 2 weeks [ES 3.15]										
1[1]	Randomised controlled trial	Serious[a]	Not applicable	Serious[b]	Very serious[c]	Yes[d]	23	Preparation stage for reducing stress RR 0.33[f] (95% CI 0.01 to 7.78)	Very low	Important
Alcohol use										
Baseline vs. 2 weeks [ES 3.15]										
1[1]	Randomised controlled trial	Serious[a]	Not applicable	Serious[b]	Very serious[c]	Yes[d, g]	6	Preparation stage for reducing alcohol use No events in either arm[f] RR not estimable	Very low	Important
Smoking cessation										
Baseline vs. 2 weeks [ES 3.16]										
1[1]	Randomised controlled trial	Serious[a]	Not applicable	Serious[b]	Very serious[c]	Yes[d,h]	14	Preparation stage for stopping smoking RR 0.50[f] (95% CI 0.05 to 4.90)	Very low	Important
Pharmacy Support Program vs. usual care [ES 3.16]										
1[2]	Randomised controlled trial	No serious	Not applicable	No serious	Serious[i]	Yes[j]	480	Intervention group more likely to purchase nicotine replacement therapy (data not reported, p=0.009)	Low	Important

CI Confidence intervals
1. Lalonde et al. (2006)
2. Sinclair et al. (1998)
[a] Downgraded by 1 level. The method of generating the allocation sequence was not reported. The baseline outcome measurements and characteristics appear to be fairly similar between the groups, however, the statistical significance of any differences it not reported. Missing outcome data were not addressed – for some outcomes, data were only included from people who provided data at both time points. Outcomes were not blindly assessed.
[b] Downgraded by 1 level as participants in the preparation stage of behaviour change could already be taking some action towards their goals.
[c] Downgraded by 2 levels as number of events is less than 300 and confidence intervals cross either 1 or both thresholds for determining a minimal important difference (0.75 and 1.25).
[d] Overall quality started at 'low' because although the original study design was an RCT, the study authors combined the results for the 2 interventions as the results were similar and only reported before and after data.
[e] Only includes participants with a baseline BMI of 27kg/m^2 or greater. Overall quality not downgraded.
[f] Based on data only from people who completed all follow up sessions (intention to treat analysis not reported). Overall quality not downgraded.
[g] Only includes participants who were drinking 2 or more alcoholic drinks per day at baseline. Overall quality not downgraded.
[h] Only includes participants who were 'former or current' smokers at baseline. Overall quality not downgraded.
[i] Downgraded by 1 level as imprecision cannot be calculated.
[j] Downgraded 1 level as number and duration of session unknown, and length of intervention unknown.

GRADE profile 5: Outcome: Attitudes

Quality assessment								Effect	Quality of evidence for outcome	Importance of outcome
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	No. of participants	Relative risk (95% CI) or Mean difference (95% CI)		
Patient activation measure										
Baseline vs. 12 months [ES 3.17]										
1[1]	Before and after	Very serious[a]	Not applicable	No serious	Serious[b]	No	378	[redacted]	Very low	Important
1[1]	Before and after	Very serious[a]	Not applicable	No serious	Very serious[d]	No	378	[redacted]	Very low	Important
1[1]	Before and after	Very serious[a]	Not applicable	No serious	Very serious[d]	No	378	[redacted]	Very low	Important
1[1]	Before and after	Very serious[a]	Not applicable	No serious	Very serious[d]	No	378	[redacted]	Very low	Important
1[1]	Before and after	Very serious[a]	Not applicable	No serious	Very serious[d]	No	378	[redacted]	Very low	Important

1. Twigg et al. Unpublished

[a] Dowgraded 2 levels. The number of participants who were selected to participate but refused is not reported. The validity and reliability of the PAM tool was not reported. Only 54% of participants completed the 12 month intervention. The intervention was delivered by different pharmacists in different locations and the consistency of it was not reported.
[b] Downgraded 1 level as total sample size is less than 400
[c] Based on data only from people who completed all follow up sessions (intention to treat analysis not reported). Overall quality not downgraded.
[d] Downgraded 2 levels as total number of events less than 300 and imprecision could not be calculated.

GRADE profile 6: Outcome: Knowledge

Quality assessment								Effect	Quality of evidence for outcome	Importance of outcome
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	No. of participants	Relative risk (95% CI) or Mean difference (95% CI)		
Cardiovascular disease										
Baseline vs. 2 weeks [ES 3.18]										
1[1]	Randomised controlled trial	Very serious[b]	Not applicable	No serious	Very serious[c]	Yes[a]	23	No change in median number of causes of CVD listed by participants[d] P value not reported	Very low	Important
Asthma (possible score 0 to 7)										
Baseline vs. 12 months [ES 3.18B]										
1[2]	Before-After study	Serious[e]	Not applicable	Serious[f]	Serious[g]	No	31	Mean difference 1.00 (95%CI 0.49-1.5),p=0.003	Very low	Important
Baseline vs. 24 months [ES 3.18B]										
1[2]	Before-After study	Serious[e]	Not applicable	Serious[f]	Serious[g]	No	31	Mean difference 0.80 (95%CI 0.27-1.33), p=0.045	Very low	Important

1. Lalonde et al. (2006)
2. Narhi et al 2001

[a] Overall quality started at 'low' because although the original study design was an RCT, the study authors combined the results for the 2 interventions as the results were similar and only reported before and after data.
[b] Downgraded 2 levels. The method of generating the allocation sequence was not reported. The baseline outcome measurements and characteristics appear to be fairly similar between the groups, however, the statistical significance of any differences is not reported. Missing outcome data were not addressed – for some outcomes, data were only included from people who provided data at both time points. Outcomes were not blindly assessed.
[c] Downgraded 2 levels as total sample size is less than 400 and imprecision cannot be calculated.
[d] Based on data only from people who completed all follow up sessions (intention to treat analysis not reported). Overall quality not downgraded
e.Downgrade 1 level due to small sample size and convenience sample.
f. Downgrade 1 level measure used to test knowledge not validated in a large sample
g.Downgrade 2 level due as total sample size less than 300 and imprecision cannot be calculated

GRADE profile 7: Outcome: Awareness

Quality assessment								Effect	Quality of evidence for outcome	Importance of outcome
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	No. of participants	Relative risk (95% CI) or Mean difference (95% CI)		
Physical activity										
Baseline vs. 2 weeks [ES 3.19]										
1[1]	Randomised controlled trial	Serious[b]	Not applicable	Serious[c]	Very serious[d]	Yes[a]	23	Pre/contemplation stage for increasing physical activity	Very low	Important

								RR 1.00[e] (95% CI 0.42 to 2.40)		
Healthy eating										
Baseline vs. 2 weeks, low fat diet [ES 3.19]										
1[1]	Randomised controlled trial	Serious[b]	Not applicable	Serious[c]	Very serious[d]	Yes[a]	23	Pre/contemplation stage for low fat diet RR 0.33[e] (95% CI 0.01 to 7.78)	Very low	Important
Baseline vs. 2 weeks, low salt diet [ES 3.19]										
1[1]	Randomised controlled trial	Serious[b]	Not applicable	Serious[c]	Very serious[d]	Yes[a]	23	Pre/contemplation stage for low salt diet RR 1.00[e] (95% CI 0.15 to 6.51)	Very low	Important
Weight management										
Baseline vs. 2 weeks [ES 3.19]										
1[1]	Randomised controlled trial	Serious[b]	Not applicable	Serious[c]	Very serious[d]	Yes[a, f]	23	Pre/contemplation stage for losing weight RR 0.33[e] (95% CI 0.04 to 2.87)	Very low	Important
Mental health and wellbeing										
Baseline vs. 2 weeks [ES 3.19]										
1[1]	Randomised controlled trial	Serious[b]	Not applicable	Serious[c]	Very serious[d]	Yes[a]	23	Pre/contemplation stage for reducing stress RR 1.20[e] (95% CI 0.43 to 3.38)	Very low	Important
Alcohol use										
Baseline vs. 2 weeks [ES 3.19]										
1[1]	Randomised controlled trial	Serious[b]	Not applicable	Serious[c]	Very serious[d]	Yes[a, g]	6	Pre/contemplation stage for reducing alcohol use No events in either arm[e] RR not estimable	Very low	Important
Smoking cessation										
Baseline vs. 2 weeks [ES 3.18]										
1[1]	Randomised controlled trial	Serious[b]	Not applicable	Serious[c]	Very serious[d]	Yes[a, h]	14	Pre/contemplation stage for stopping smoking RR 1.00[e] (95% CI 0.16 to 6.14)	Very low	Important

CI Confidence intervals
1. Lalonde et al. (2006)
[a] Overall quality started at 'low' because although the original study design was an RCT, the study authors combined the results for the 2 interventions as the results were similar and only reported before and after data.
[b] Downgraded 1 level. The method of generating the allocation sequence was not reported. The baseline outcome measurements and characteristics appear to be fairly similar between the groups, however, the statistical significance of any differences it not reported. Missing outcome data were not addressed – for some outcomes, data were only included from people who provided data at both time points. Outcomes were not blindly assessed.
[c] Downgraded 1 level as includes participants who were in the precontemplation stage of behaviour change. These participants may not have had awareness.
[d] Downgraded 2 levels as number of events is less than 300 and confidence intervals cross either 1 or both thresholds for determining a minimal important difference (0.75 and 1.25).
[e] Based on data only from people who completed all follow up sessions (intention to treat analysis not reported). Overall quality not downgraded.
[f] Only includes participants with a baseline BMI of 27kg/m^2 or greater. Overall quality not downgraded.
[g] Only includes participants who were drinking 2 or more alcoholic drinks per day at baseline. Overall quality not downgraded.
[h] Only includes participants who were 'former or current' smokers at baseline. Overall quality not downgraded.

GRADE profile 8: Outcome: Wellbeing

No evidence was identified [ES 3.20].

GRADE profile 9: Outcome: Quality of life

Quality assessment								Effect	Quality of evidence for outcome	Importance of outcome
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	No. of participants			
Alcohol										
Leaflets vs. behavioural support for alcohol use at 3 months, EQ-5D [ES 3.21]										
1[1]	Randomised controlled trial	Serious[a]	Not applicable	No serious	Serious[b]	No	407	Mean difference of 0.09[c,d] (0.02 to 0.16) p=0.013 favouring behavioural support	Low	Less important
Diabetes										
Counselling and group lectures vs. information at 1 year; SF-12- physical component (score range 0-100, 0-lowest level of health, 100 best level of health) [ES3.21]										
1[2]	Randomised controlled trial	Serious[o]	Not applicable	No serious	No serious	No	1140	Mean difference 2.39 (95%CI 1.43 to 3.34), p<0.001	Moderate	Less important
Counselling and group lectures vs. information; at 1 year; SF-12- mental component (score range 0-100, 0-lowest level of health, 100 best level of health)[ES 3.21]										
1[2]	Randomised controlled trial	Serious[o]	Not applicable	No serious	No serious	No	1140	Mean difference 1.08 (95%CI -0.21 to 2.37), p=0.10	Moderate	Less important

1. Dhital et al. (2015)
2. Schmiedel et al (2015)

[a] Downgraded by 1 level. The statistical significance of differences between groups for characteristics and outcome measurements at baseline was not reported. Allocation was not clustered by pharmacy and so contamination may have occurred.
[b] Downgraded by 1 level as imprecision cannot be calculated.
[c] Based on data only from people who completed all follow up sessions (intention to treat analysis not reported). Overall quality not downgraded.
[d] Adjusted for baseline score, gender, age, ethnicity and education. Overall quality not downgraded.

Appendix G – Economic evidence study selection

1. Crealey GE, McElnay JC, Maguire TA et al. (1998) Costs and effects associated with a community pharmacy-based smoking-cessation programme. Pharmacoeconomics, Sep 1;14(3):323-33.
2. Sinclair HK, Silcock J, Bond CM et al. (1999) The cost-effectiveness of intensive pharmaceutical intervention in assisting people to stop smoking. International Journal of Pharmacy Practice, Jun 1;7(2):107-12.

Appendix H – Economic evidence tables

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Crealey GE, McElnay JC, Maguire TA, O'Neill C. Costs and effects associated with a community pharmacy-based smoking-cessation programme. Pharmacoeconomics. 1998 Sep 1;14(3):323-33.

Quality score
++

Study type
Cost-effectiveness analysis

Location and setting
2 Belfast pharmacies

Aims
To determine the costs and effects associated with a community pharmacy based smoking cessation programme in Northern Ireland, using the perspective of the payer in the main analysis.</td>
<td>Health area
Smoking cessation

In original pilot study:
Number of participants
100:
52 - intervention group
48 - bought nicotine gum only (control)

Participant characteristics
None specified

Inclusion criteria
None specified

Exclusion criteria
None specified</td>
<td>Intervention
Pharmacist Action on Smoking (PAS) service:
6 month intervention involving the use of a flip chart, visual aids and 1-to-1 counselling, in 4 stages:
- Stage 1: promotion of smoking cessation to all customers through leaflets, posters, window displays
- Stage 2: pharmacist identification of smokers an discussion of the service. An individual will either enter stage 3 or leave the programme here, but may re-enter again at stage 2.
- Stage 3: pharmacist conducts an interview with the patient to establish a formal commitment to stop smoking. Information on the benefits and effects of withdrawal is given. A stop date is agreed upon and a</td>
<td>Cost-effectiveness was defined in terms of direct costs only of the intervention, with indirect costs (eg time taken off work and travel costs) not included. The costs per successful intervention was based on the assumptions in the below table:

<table>
<tr><th>Variable</th><th>Baseline assumption (range for sensitivity analysis)</th></tr>
<tr><td>Uptake rate of PAS by pharmacies, % (n=519)</td><td>100 (75-50)</td></tr>
<tr><td>Number of patients/ pharmacy/year</td><td>20 (10-30)</td></tr>
<tr><td>Success rate[a], %</td><td>10 (5-25)</td></tr>
<tr><td>Annual rate of cessation in absence of PAS, %</td><td>1 (0-2)</td></tr>
<tr><td>Lifetime relapse rate, %</td><td>10 (0-15)</td></tr>
<tr><td>Fixed costs of PAS, £[b]</td><td>55,000 (40,000-70,000)</td></tr>
<tr><td>Variable costs/patient, £[b]</td><td>30 (15-45)</td></tr>
<tr><td>Discount rate of PAS, %</td><td>4 (3-5)</td></tr>
</table>
[a]Patients entering stage 3 of the PAS programme who remain abstinent at 12 months.
[b]Pounds sterling, 1997 values

Results expressed in terms of cost per (discounted) life-year saved, from the perspective of the payer (NHS). Data from a pilot study was used to inform the analysis,</td>
<td>Pilot study effectiveness outcomes:
Abstinence rates, %:
<table>
<tr><th></th><th>Intervention</th><th>Control</th></tr>
<tr><td>3 months</td><td>56</td><td>16</td></tr>
<tr><td>6 months</td><td>46</td><td>6</td></tr>
</table>
A statistically significant difference (p<0.01) was found in cessation rates between intervention and control patients.

Cost-effectiveness outcomes:
<table>
<tr><th rowspan="2">Age at quitting (years)</th><th colspan="2">Cost[a] per life-year saved (£)</th></tr>
<tr><th>Men</th><th>Women</th></tr>
<tr><td>35</td><td>351.45</td><td>772.12</td></tr>
<tr><td>40</td><td>310.73</td><td>661.82</td></tr>
<tr><td>45</td><td>276.96</td><td>525.36</td></tr>
<tr><td>50</td><td>242.67</td><td>447.02</td></tr>
<tr><td>55</td><td>222.53</td><td>392.00</td></tr>
<tr><td>60</td><td>222.53</td><td>320.50</td></tr>
<tr><td>65</td><td>196.76</td><td>233.76</td></tr>
<tr><td>70</td><td>201.42</td><td>202.22</td></tr>
<tr><td>75</td><td>202.22</td><td>181.35</td></tr>
</table>
[a]Costs and benefits were discounted at an annual rate of 4% and reflect 1997 values, in pounds sterling.

Sensitivity analysis:

<table>
<tr><th>Variable</th><th>Cost per life-year saved per successful intervention[a]</th></tr>
<tr><td>Uptake rate of PAS by pharmacies (50-75%)</td><td>227.78-276.65</td></tr>
<tr><td>Number of patients/ pharmacy/year (10-30/year)</td><td>318.09-262.97</td></tr>
<tr><td>Success rate of PAS (5-25%)</td><td>553.14-110.75</td></tr>
</table>
</td>
</tr>
</table>

Length of follow up 12 months **Source of funding** Unknown		written contract is drawn up between the patient and the pharmacist. - Stage 4: pharmacist arranges multiple meetings to reinforce abstinence: an initial 10 min meeting, followed by subsequent 5 min meetings over 6 months, to motivate and provide support. **Comparator** Normal, ad hoc, non-formalised advice that is currently given in community pharmacies.	including the difference in the percentage of patients who stop smoking if counselled under PAS and the percentage who would be expected to stop without the intervention For intervention patients, the percentage who stopped smoking was estimated as the number who stopped smoking out of the number who entered stage 3 of the PAS programme. For control patients, the percentage was estimated as the number who stopped smoking out of those who enrolled to stop smoking. The cost-effectiveness of the PAS model was therefore measured in terms of cost per life-year gained for all patients who enter stage 3 of the PAS programme. To calculate life expectancy associated with smoking cessation, life expectancy of a former smoker for each age and gender was analysed. Annual probabilities of survival derived from mortality rates were then applied to the life expectancies. It was assumed that the life expectancy gained among patients who received intervention occurred after the life expectancy of the patients who did not receive intervention. Therefore, a discount of 4% annually was applied to additional years of life expectancy. This follows a common methods to allow for the benefits of the program not being accrued fully until some time in the future. Analysis was conducted on the assumption that no additional lifetime expenditures were incurred for successful patients.	<table><tr><td>Natural rate of cessation (0-2% annually)</td><td>213.20-364.04</td></tr><tr><td>Lifetime probability of relapse (0-15%)</td><td>249.22-293.27</td></tr><tr><td>Fixed costs of PAS (£40,000 -70,000)</td><td>265.62-288.29</td></tr><tr><td>Variable costs (£15-45/patient)</td><td>159.26-394.65</td></tr><tr><td>Discount rate (3-5%)</td><td>213.22-361.42</td></tr></table> [a]Costs and benefits were discounted at an annual rate of 4% and reflect 1997 values, in pounds sterling. Results based on a 45-year old male smoker
Limitations identified by authors Life expectancies for smokers were derived from estimates in a Northern Ireland population, whereas the probability of survival among former smokers was based on estimates from a US population (as no values for Northern Ireland are available). However, life expectancy values for current smokers and people who have never smoked in both populations are practically identical and follow the same pattern.				

It was assumed that all pharmacies offered the PAS programme (uptake rate of 100%). However, it may be the case that only a proportion of pharmacies will offer the programme routinely. **Limitations identified by review team** NRT was optional throughout the PAS programme, with 35/52 of the intervention group using nicotine gum. **Other comments** Linked to Maguire 2001

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Sinclair HK, Silcock J, Bond CM, Lennox AS, Winfield AJ. The cost-effectiveness of intensive pharmaceutical intervention in assisting people to stop smoking. International Journal of Pharmacy Practice. 1999 Jun 1;7(2):107-12.

Quality score
-

Study type
Cost-effectiveness

Location and setting
Community pharmacies across</td>
<td>Health area
Smoking cessation

Number of participants
62 pharmacies were recruited; after some drop out, 31 intervention and 29 control pharmacies participated.

492 clients recruited (224 intervention; 268 control). At 9 months follow-up, 474 clients were available (217 intervention; 257 control).

Participant characteristics

Inclusion criteria</td>
<td>Intervention
Staff from pharmacies attended health promotion workshops held to explain the stages of change model, delivered by health promoters from Grampian Health Promotions.

Intervention pharmacists tailored their advice to match the client's stage of change in respect to smoking cessation and NRTs.

Comparator
Control pharmacies gave standard advice and</td>
<td>Both control and intervention pharmacies recruited smokers on an opportunistic basis.

Pharmacies were randomised to control or intervention group.

For cost effectiveness analysis, the alternatives considered were: advice to stop smoking given by pharmacy personnel trained in the stage of change model or advice to stop smoking given by personnel who have no had this training. Outcome measures used are the number of quitters (continuous cessation) at 9 months and an estimate, based on previous studies of the life years gained by smoking cessation. Incremental cost effectiveness ratios for the intervention were calculated, looking at the cost of producing one additional unit of effectiveness (eg quitter or life year gained) by using intensive rather than standard pharmaceutical support.

Assessment of cost effectiveness took a wider societal perspective. Costs to the NHS arose from organisation of the training sessions and trainees out of pocket expenses (including staff costs and travel). Any NRT purchased was a cost of the intervention to the client. The cost of the health promotion materials and pharmacy client documentation would not ultimately be a cost for the NHS and was a research cost only.

Lost working time was values at the participants wage rate for the 2 hour workshop and travel time was valued at 0.4 times their wage rate. Lost leisure time was valued at 0.4 times the wage rate.</td>
<td>
<table>
<tr><td>Training costs:</td><td>Cost (£) 1995 prices</td></tr>
<tr><td>Invitation letters</td><td>10.00</td></tr>
<tr><td>Postage</td><td>34.00</td></tr>
<tr><td>Telephone</td><td>5.00</td></tr>
<tr><td>Health promotions consultancy fee</td><td>1260.00</td></tr>
<tr><td>Trainer travel expenses</td><td>79.00</td></tr>
<tr><td>Training materials</td><td>30.00</td></tr>
<tr><td>Refreshments</td><td>67.00</td></tr>
<tr><td>Car @33p per mile</td><td>393.08</td></tr>
<tr><td>Private bus hire</td><td>80.00</td></tr>
<tr><td>Public bus fare</td><td>0.50</td></tr>
<tr><td colspan="2">Lost working time (2hr daytime sessions)</td></tr>
<tr><td>9 pharmacists @£9.93/hr x 1</td><td>178.74</td></tr>
<tr><td>7 assistants @£3.19/hr x1</td><td>44.66</td></tr>
<tr><td colspan="2">Lost leisure time (2hr evening sessions)</td></tr>
<tr><td>31 pharmacists @£9.93/hr x0.4</td><td>246.26</td></tr>
<tr><td>47 assistants @£3.19/hr x0.4</td><td>119.94</td></tr>
<tr><td colspan="2">Travel time (average 1.3hrs)</td></tr>
<tr><td>40 pharmacists @£9.93/hr x0.4</td><td>206.54</td></tr>
<tr><td>54 assistants @£3.19/hr x0.4</td><td>89.58</td></tr>
<tr><td>Total</td><td>2844.30</td></tr>
</table>

<u>NRT and counselling costs:</u>
212 intervention clients (97.7%) purchased NRT. Total cost to the intervention clients for NRT was £10,076.57: £47.53 per NRT user.
238 control clients (92.6%) purchased NRT. Total cost to the control clients for NRT was £12463.50: £52.37 per NRT user.
<table>
<tr><th>Costs in intervention group</th><th colspan="3">Costs (£) 1995 prices</th></tr>
<tr><th>Details</th><th>NHS</th><th>Pharmacy</th><th>Customer</th></tr>
</table>
</td>
</tr>
</table>

Grampian, Scotland, UK **Aims** To assess the cost-effectiveness of intensive pharmaceutical intervention in assisting people to stop smoking. **Length of follow up** 9 months **Source of funding** Scottish Office and health services and public health research grant.	Smokers either asking for advice on smoking cessation or buying an over the counter anti-smoking product for their own use. **Exclusion criteria** Pharmacies within the city of Aberdeen	support with respect to smoking cessation and NRTs.	Discounting was not performed (deemed that all costs and benefits discussed fall in 1 year). <u>Training costs:</u> An opportunity costs questionnaire was developed to collect information on the costs of attending the training workshop: alternative activity, lost income, means of travel and travel time. A pharmacy expense claim form was devised to gather data on the full financial costs incurred by each pharmacy: staff costs, travel, lost income and miscellaneous costs. <u>NRT and counselling costs:</u> A customer registration postcard and one-month customer questionnaire monitored which product (if any) had been purchased. Retail price, excluding VAT was used to cost all NRT supplies. Duration of product use was also monitored by questionnaires at 4 and 9 month follow up. Semi-structured telephone interviews with 20 intervention pharmacy personnel and 50 clients (25 control, 25 intervention) gave information on duration of initial and subsequent consultations. Pharmacy personnel were selected to reflect job title, shop ownership, age, gender and smoking status. Data was not collected on the cost to clients of travelling to the pharmacy as this was assumed to be the same for control and intervention participants.	

Organising and operating costs	1485.00	-	-
Pharmacy travel expenses	473.58	-	-
Pharmacy training time	-	885.72	-
Anti-smoking products	-	-	10076.57
Promotional material and client documentation	617.00	-	-
Customer counselling time	-	-	770.43
Pharmacy counselling time	-	607.46	-
Sub-totals	2575.58	1493.18	10847.00
Grand total	**14915.76**		

Costs in control group	**Costs (£) 1995 prices**	
Details	**Pharmacy**	**Customer**
Anti-smoking products	-	12463.50
Customer counselling time	-	926.85
Pharmacy counselling time	730.78	-
Sub-totals	730.78	13390.35
Grand total	**14121.13**	

Quit rates at 9 months and costs:

Group	**Cost/100 (£)**	**Quitters at 9 mo. /100**	**Average cost/ quitter (£)**
Control	5494.6	7.4	742.5
Intervention	6873.6	12	572.8
p		<0.089	

Incremental analysis:

Group	**Extra cost (£)**	**Extra quitters**	**Incremental cost/quitter (£)**	**Extra life yrs**	**Incremental cost/life yr (£)**
Intervention	1378	4.6	300	16.6	83

Limitations identified by authors
The need to randomise at the level of pharmacy rather than the individual client had the potential to confound the analysis. Detailed statistics show that the cluster design had a negligible effect on the magnitude of the outcomes
Larger studies needed to confirm the trend towards effectiveness in the intervention group.
Limitations identified by review team
It is not clear if discounting has been applied to the benefits. No time horizon analysed, which is likely to miss important differences in costs and outcomes, such as relapse rate, life years gained at the end of life and change in quality of life. No quality of life measure made.
Other comments

Linked to Sinclair 1998 – cost effectiveness analysis of the same intervention.

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
New economic evaluation for this guideline (1)

Quality score
++

Study type
Cost-utility analysis

Location and setting
NHS

Aims
To determine the costs and effects associated with 4 community pharmacy based smoking cessation programmes identified in the evidence review.

Length of follow up
Lifetime model

Source of funding
N/A</td>
<td>Health area
Smoking cessation

Number of participants
N/A (modelling study)

Participant characteristics
From each study for relative effects. Age-weighted to reflect UK population.

Inclusion criteria
As per evidence review

Exclusion criteria
As per evidence review</td>
<td><u>Intervention vs. usual care (no intervention)</u>
Intervention
• Leaflet + counselling + NRT (Maguire et al. 2001)
• Counselling + NRT (Cramp et al. 2007)
• Photoageing software (Burford et al. 2013)
Comparator
Usual care (e.g. brief advice, normal services, with/without NRT).

<u>Intervention vs. intervention</u>
Intervention
3x 5-10 minute counselling sessions + NRT.
Comparator
1x 5-10 minute counselling sessions + NRT.
.</td>
<td>Lifetime cost–utility model developed composed of smoking status health states, 6 smoking-related comorbidities, and death. Model closely based on the model used for NICE GID-PH94 (itself based on PH10 & PH45).

Effectiveness was informed by incremental 6-12 month quit rates identified in the evidence review. Comorbidity and mortality risk dependent on smoking status. Quality of life dependent on smoking status and presence of comorbidity. Costs composed of interventions and management of comorbidities.

Results expressed in terms of discounted QALYs and costs (discount rate 3.5% per year), from the perspective of the NHS/PSS, and the resulting ICER.

.</td>
<td>Counselling 1 (Maguire et al.):
<table>
<tr><th>Strategy</th><th>QALYs</th><th>Costs (£)</th><th>ICER (£)</th></tr>
<tr><td>Intervention</td><td>16.61</td><td>10,360</td><td>Dominant</td></tr>
<tr><td>Usual care</td><td>16.50</td><td>10,667</td><td></td></tr>
</table>
Counselling 2 (Cramp et al.):
<table>
<tr><th>Strategy</th><th>QALYs</th><th>Costs (£)</th><th>ICER (£)</th></tr>
<tr><td>Intervention</td><td>16.63</td><td>10,447</td><td>Dominant</td></tr>
<tr><td>Usual care</td><td>16.49</td><td>10,679</td><td></td></tr>
</table>
Photoageing software intervention:
<table>
<tr><th>Strategy</th><th>QALYs</th><th>Costs (£)</th><th>ICER (£)</th></tr>
<tr><td>Intervention</td><td>16.61</td><td>10,345</td><td>Dominant</td></tr>
<tr><td>Usual care</td><td>16.49</td><td>10,692</td><td></td></tr>
</table>
High-intensity counselling:
<table>
<tr><th>Strategy</th><th>QALYs</th><th>Costs (£)</th><th>ICER (£)</th></tr>
<tr><td>3 sessions</td><td>16.93</td><td>9,485</td><td>Dominant</td></tr>
<tr><td>1 session</td><td>16.87</td><td>9,633</td><td></td></tr>
</table>
Sensitivity analysis:
Results determined to be highly robust to univariable sensitivity analysis. Each intervention cost can be over 20-times its base case level and still have an ICER under £20,000 per QALY gained.
Probabilistic sensitivity analysis not undertaken.</td>
</tr>
<tr><td colspan="5">Limitations identified by authors
Substantial heterogeneity between studies precludes the development of a meaningful pooled analysis. Limited to separate comparisons for each study.
Model does not capture secondary quit attempts or relapse.</td></tr>
</table>

Probabilistic sensitivity analysis was not undertaken as this functionality was not possible using the original model (developed for NICE GID-PH94).
Other comments
Linked to Burford et al. (2013), Costello et al. (2011) Cramp et al. (2007) and Maguire et al. (2001)

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
New economic evaluation for this guideline (2)

Quality score
++

Study type
Cost-utility analysis

Location and setting
NHS

Aims
To determine the costs and effects associated with 4 community pharmacy based weight management programmes identified in the evidence review.

Length of follow up
Lifetime model

Source of funding
N/A</td>
<td>Health area
Weight management

Number of participants
N/A (modelling study)

Participant characteristics
From each study for relative effects. Age-weighted to reflect UK population.

Inclusion criteria
As per evidence review

Exclusion criteria
As per evidence review</td>
<td>Intervention
• 12x counselling visits with diet and exercise reviews (Boardman et al. 2014)
• Counterweight (Morrison et al. 2011)
• Lighten Up (Jolly et al. 2013)
• My Choice (Bush et al. 2014)
Comparator
Usual care (normal services).</td>
<td>Lifetime cost–utility model developed composed of 5 health states: ‘healthy’, ‘dead, and 3 weight-related chronic comorbidities (colorectal cancer, congestive heart disease, diabetes). Model closely based on the model used for NICE CG43.

Effectiveness was informed by incremental 6-12 month reductions in BMI or weight (converted to BMI) identified in the evidence review. Effect assumed to last for 1 year, then BMI reverts to same level as the usual care arm. Usual care arm has natural BMI growth in the UK (0.16 kg/m^2 per year). Comorbidity and mortality risk dependent on BMI. Quality of life dependent on BMI and presence of comorbidity. Costs composed of interventions and management of comorbidities.

Results expressed in terms of discounted QALYs and costs (discount rate 3.5% per year), from the perspective of the NHS/PSS, and the resulting ICER.

.</td>
<td>Counselling intervention (Boardman et al.):
<table>
<tr><th>Strategy</th><th>QALYs</th><th>Costs (£)</th><th>ICER (£)</th></tr>
<tr><td>Usual care</td><td>12.45</td><td>11,477</td><td></td></tr>
<tr><td>Intervention</td><td>12.47</td><td>11,547</td><td>3,309</td></tr>
</table>
Couterweight:
<table>
<tr><th>Strategy</th><th>QALYs</th><th>Costs (£)</th><th>ICER (£)</th></tr>
<tr><td>Usual care</td><td>12.45</td><td>11,477</td><td></td></tr>
<tr><td>Intervention</td><td>12.46</td><td>11,585</td><td>11,668</td></tr>
</table>
Lighten Up:
<table>
<tr><th>Strategy</th><th>QALYs</th><th>Costs (£)</th><th>ICER (£)</th></tr>
<tr><td>Usual care</td><td>12.45</td><td>11,477</td><td></td></tr>
<tr><td>Intervention</td><td>12.46</td><td>11,586</td><td>19,845</td></tr>
</table>
My Choice:
<table>
<tr><th>Strategy</th><th>QALYs</th><th>Costs (£)</th><th>ICER (£)</th></tr>
<tr><td>Usual care</td><td>12.45</td><td>11,477</td><td></td></tr>
<tr><td>Intervention</td><td>12.46</td><td>11,572</td><td>7,723</td></tr>
</table>
Sensitivity analysis:
Results for Boardman et al., Counterweight and My Choice interventions determined to be robust to univariable sensitivity analysis. Results for Lighten Up (the least effective intervention) are highly sensitive to its effect size, baseline BMI and natural change in BMI. Probabilistic sensitivity analysis not undertaken.</td>
</tr>
<tr><td colspan="5">Limitations identified by authors</td></tr>
</table>

Substantial heterogeneity between studies precludes the development of a meaningful pooled analysis. Limited to separate comparisons for each study. Probabilistic sensitivity analysis was not undertaken as this functionality was not possible using the original model (developed for NICE GID-PH94). **Other comments** Linked to Boardman et al. (2014), Bush et al. (2014) Jolly et al. (2013) and Morrison et al. (2011)

Appendix I – Health economic evidence profiles

[To be presented by Economic Modelling Unit, the results will be available in a separate modelling report]

Appendix J – Health economic analysis

[To be presented by Economic Modelling Unit, the results will be available in a separate modelling report]

Appendix K – Excluded studies

See separate appendix K document.

Appendix L – Research recommendations

How effective and cost effective is advice, education or behavioural support, offered by community pharmacy teams to improve patient activation particularly in areas where activation levels are lower? What are the different approaches used (for example, are there regular meetings between the person and their pharmacist to monitor and set personal health goals)?

Rationale

Interventions that involve people setting their own health goals may help those who are less likely to play an active role in staying healthy. For example, highly activated people may be more likely to adopt healthy behaviour, to have better clinical and overall outcomes and lower rates of hospitalisation, and to be more satisfied with services. People with low activation levels may be more likely to attend accident and emergency departments, and to be hospitalised or re-admitted to hospital after being discharged.

Currently there is limited evidence on how interventions delivered in community pharmacies may improve patient activation scores.

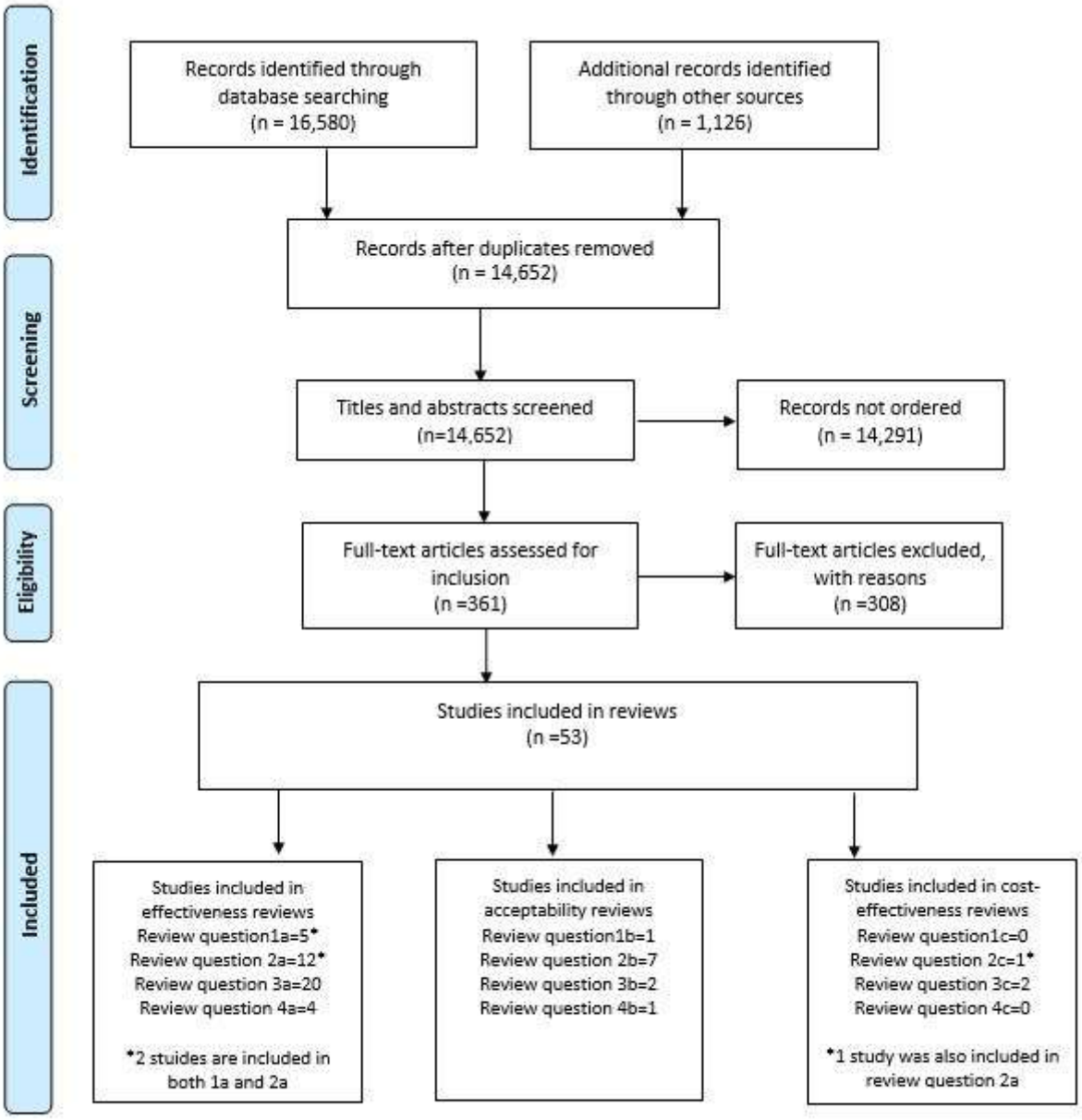
Criterion	Explanation
Population	General population (primary prevention) and high risk groups (secondary prevention)
Intervention	Delivering health and wellbeing interventions to improve patient activation measures. This may involve interventions based on delivering advice, education or behavioural support.

Comparators	Comparative effectiveness of other interventions in the network such as usual care (that is the same or alternative interventions delivered elsewhere in the network) No intervention
Outcomes	Patient activation measures Costs, savings and effectiveness
Study design	Study designs could include cost-effectiveness studies and RCTs of specific interventions or other types of evaluation with the purpose of ascertaining what interventions are effective at improving patient activation measures, specifically within a UK context. It will also be important to gain public and staff feedback as part of any studies so a mixed methods approach to include qualitative elements may also be appropriate.
Timeframe	Studies would require sufficient follow up time to capture impacts on health and wellbeing

Appendix M – Expert testimony

See separate appendix M document

Appendix N – PRISMA diagram



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.