Behavioural components associated with increased uptake and effectiveness of screening programmes for coronary heart disease and diabetes: A systematic review.

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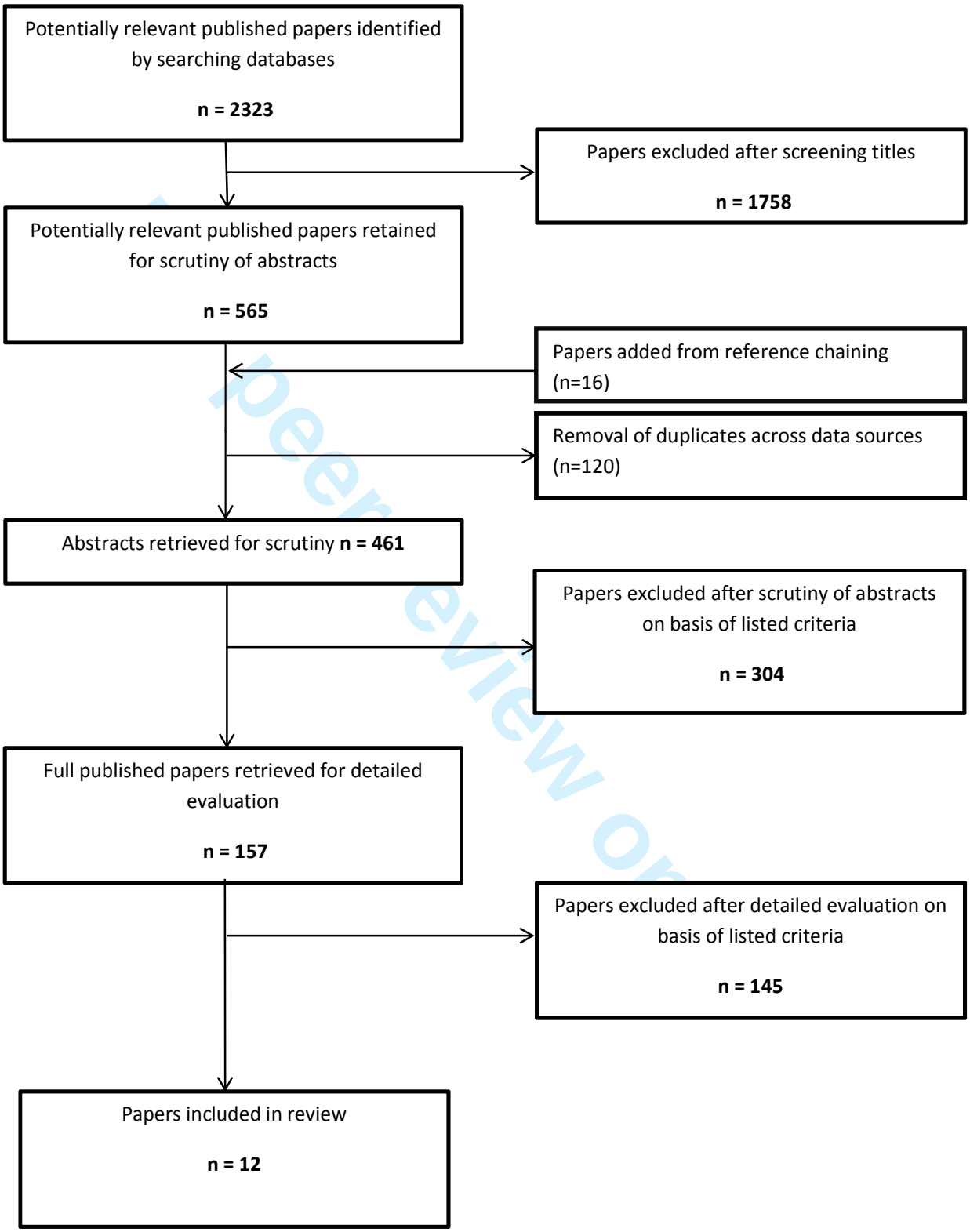
Figure 1 Flow chart of intervention studies included and excluded from this review



PRISMA checklist

Table 1

Checklist of items to include when reporting a systematic review or meta-analysis

Section/topic	Item No	Checklist item	Reported on page No
Title **Behavioural components associated with increased uptake and effectiveness of screening programmes for coronary heart disease and diabetes: A systematic review.**			
Title	1	Identify the report as a systematic review, meta-analysis, or both	2
Abstract			
Structured summary	2	Provide a structured summary including, as applicable, background, objectives, data sources, study eligibility criteria, participants, interventions, study appraisal and synthesis methods, results, limitations, conclusions and implications of key findings, systematic review registration number	2-3
Introduction			
Rationale	3	Describe the rationale for the review in the context of what is already known	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS)	5
Methods			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (such as web address), and, if available, provide registration information including registration number	N/A

Section/topic	Item No	Checklist item	Reported on page No
Eligibility criteria	6	Specify study characteristics (such as PICOS, length of follow-up) and report characteristics (such as years considered, language, publication status) used as criteria for eligibility, giving rationale	5
Information sources	7	Describe all information sources (such as databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated	Appendix 1, p36
Study selection	9	State the process for selecting studies (that is, screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis)	6
Data collection process	10	Describe method of data extraction from reports (such as piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators	6
Data items	11	List and define all variables for which data were sought (such as PICOS, funding sources) and any assumptions and simplifications made	6-7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis	7
Summary measures	13	State the principal summary measures (such as risk ratio, difference in means).	Table 32-34
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (such as I^2 statistic) for each meta-analysis	N/A
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (such as publication bias, selective reporting within studies)	7

Section/topic	Item No	Checklist item	Reported on page No
Additional analyses	16	Describe methods of additional analyses (such as sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified	N/A
Results			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram	6, flow diagram in this supplementary file
Study characteristics	18	For each study, present characteristics for which data were extracted (such as study size, PICOS, follow-up period) and provide the citations	Table 1, pages 32-34
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome-level assessment (see item 12).	Included in SIGN 50, see Table 1.
Results of individual studies	20	For all outcomes considered (benefits or harms), present for each study (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a forest plot	Table 1, 32-34, main findings presented, but standard summary data not possible
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see item 15)	22
Additional analysis	23	Give results of additional analyses, if done (such as sensitivity or subgroup analyses, meta-regression) (see item 16)	N/A
Discussion			
Summary of	24	Summarise the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (such as health care	Summary boxes PP15, 20,

Section/topic	Item No	Checklist item	Reported on page No
evidence		providers, users, and policy makers)	24, policy implications, p23
Limitations	25	Discuss limitations at study and outcome level (such as risk of bias), and at review level (such as incomplete retrieval of identified research, reporting bias)	22
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research	23
Funding			
Funding	27	Describe sources of funding for the systematic review and other support (such as supply of data) and role of funders for the systematic review	25

Effectiveness and uptake of screening programmes for coronary heart disease and diabetes: A realist review of design components used in interventions.

Short title: Effectiveness and uptake of screening programmes

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1 Table

Abstract

Objective

To evaluate behavioural components and strategies associated with increased uptake and effectiveness of screening for coronary heart disease (CHD) and diabetes, with an implementation science focus.

Design

Realist review.

Data sources

PubMed, Web of Knowledge, Cochrane Database of Systematic Reviews, Cochrane Controlled Trials Register and reference chaining. Searches limited to English language studies published since 1990.

Eligibility criteria

Eligible studies evaluated interventions designed to increase uptake of CVD and diabetes screening and examined behavioural and/or strategic designs. Studies were excluded if they evaluated changes in risk factors or cost-effectiveness only.

Results

In 12 eligible studies, several different intervention designs and evidence based strategies were evaluated. Salient themes were effects of feedback on behaviour change, or benefits of health dialogues over simple feedback. Studies provide mixed evidence about benefits of these intervention constituents which are suggested to be

situation and design specific, broadly supporting their use, but highlighting concerns about fidelity of intervention delivery, raising implementation science issues.[1,2] Three studies examined effects of informed choice, or loss versus gain frame invitations, finding no effect on screening uptake, but highlighting opportunistic screening as more successful for recruiting higher CVD and diabetes risk patients than invitation letter, with no differences in outcomes once recruited. Two studies examined differences between attenders and non-attenders, finding higher risk factors amongst non-attenders, and higher diagnosed CVD and diabetes amongst those who later dropped out of longitudinal studies.

Conclusions

If risk and prevalence of these diseases are to be reduced, interventions must take into account what we know about effective health behaviour change mechanisms, monitor delivery by trained professionals, and examine the possibility of tailoring programmes according to contexts such as risk level to reach those most in need. Further research is needed to determine the best strategies for lifelong approaches to screening.

Article Summary

- 1) Article Focus: The primary objective of this realist review was to evaluate the impact on health and attendance outcomes of theoretically supported behaviour change features embedded within intervention designs of screening programmes targeting CHD and diabetes.

- A secondary objective was to evaluate factors predicting attendance and attrition from these programmes and appraise their impact, with implications for design in specific contexts.

2) Key Messages

- The benefits of a structured, motivational health dialogue, with feedback, are supported over simple screening and advice, where outcomes are measured long term. Structure of motivational health dialogues and the terms over which they are most successful needs further research

- However, the issue of intervention fidelity (adherence to intervention protocol by those delivering) has potential to differentiate between programmes that are or are not successful in getting patients to change health behaviour and as such represents a key implementation science component of the review.

- This review highlights the need for a more systematic approach to using the evidence base for strategic design, conduct and analysis of health interventions

by taking into account the complex interactions between design, delivery, attrition, context and health outcomes.

3) Strengths and Limitations.

Strengths:

- The study's strength is its focus on what contributes to success and reach of screening plus intervention studies, based on health psychology evidence.
- Its evaluation of the degree and fidelity with which evidenced health behaviour strategies are used has important implications for practitioners managing screening and intervention programmes.
- Evaluation of opportunistic screening confirms previous work showing that it reaches people with higher CVD risk factors than reached using standard invitations, but additionally demonstrates that people screened opportunistically show very similar improvements in assessed risk factors and behaviours to people invited in other ways.

Limitations:

- This review raised two key challenges. First, many studies do not analyse behavioural components of the intervention design discretely, making it impossible to discern which factors are at work in producing the observed effects. Second, the heterogeneity of outcome measures precludes statistical evaluations using meta-analysis.

- Publication or outcome bias may have affected our results, though not all included studies found significant reductions in assessed risk or differences in outcomes between intervention and control groups.

- Several potentially relevant studies focusing on design of screening interventions were excluded because they were not delivered in healthcare settings.

- Well-known selective drop out ("selective attrition") biases are confirmed in these studies, whereby people with more lifestyle risk factors (smoking, higher alcohol consumption, overweight) are more likely to fail to return for follow-up appointments. Careful methodological and statistical controls are needed to reduce resultant effects on findings, but few studies employ these.

- As a realist review, this document examines outcomes which may be situation specific. The acknowledgement that some findings that may be situation specific is important in generalisation of results.

Introduction

Previous reviews of multiple risk factor interventions for primary prevention of coronary heart disease (CHD) and diabetes often conclude that interventions have no overall effect on mortality.[3] Nevertheless, CHD deaths have halved in the UK and other developed countries in the last 30 years.[4] Unal et al[5] compared targeted interventions and general population screening. They estimated the proportion of reduced deaths from CHD in England and Wales between 1981 and 2000 that were attributable to changes in risk factors in patients with CHD or changes in cardiovascular risk factors in the general population, and found both approaches beneficial. These authors calculated that reductions in risk factors (such as smoking, high blood pressure) in the general population account for 50-75% of the fall in cardiac deaths, and pharmacological and surgical treatments for diagnosed CHD patients account for 25-50%.[5] However, that benefit was greater when individuals without CHD were screened: results indicated an additional 21 years of life for each death prevented in those with no CHD diagnosis compared to 7.5 years for those with CHD.

Public health campaigns to reduce these conditions usually involve: government-sponsored programmes at the population level or changes in policy (such as food labelling legislation); targeted interventions for those at heightened risk (for example, moderate-intensity, low-impact exercise for those very overweight or with chronic conditions); or general population screening and intervention to reduce risk development in the healthy population and identify high risk people leading to specific referral for detected or previously untreated symptoms (for example, current NHS Health Check[6] programme).

This review focuses on quantitative evaluations of screening plus intervention programmes that target the general population to reduce incidence of CHD and diabetes. These conditions were selected because they are the focus of screening programmes in many countries and the negative outcomes of these conditions can be ameliorated by lifestyle behaviour change. Previous reviews have focussed on reductions in risk measurements, cost effectiveness, or years of life added.[3] In contrast, the primary objective of this review was to examine use of behaviour change features embedded within intervention designs of screening programmes targeting CHD and diabetes, and their impact on health outcomes. A secondary objective was to evaluate the factors predicting attendance and attrition from these programmes.

These objectives are not well-suited to systematic review and meta-analysis approaches, where the aim is to synthesise results across contexts to gain a sense of the pattern of results for studies conducted using similar methodologies. In contrast, the present paper is focused on questions around “how” and “why” behavioural features are incorporated into interventions, and how these features can contribute to the success of interventions. Therefore, we adopted a realist review, also called a meta-narrative approach. This approach was adopted to gain insights into the direction the evidence is pointing and the underlying theoretically driven concepts, behaviour change mechanisms, and barriers, that may combine to contribute to outcomes in population screening for CHD and diabetes.[7] Focus on the mechanisms and use of evidence based behaviour change strategies locate the review within an implementation science approach, given that “one of the most consistent findings from clinical and health services research is the failure to translate research into practice and policy” p1.[2]

A realist methodology[8] is suited to areas where there is a diverse literature, which may have a variety of methods, components and outcomes. This methodology is concerned with explaining more fully the processes of interventions within the complexity of their contexts, rather than focussing on simple cause and effect deterministic theories. Realist reviews can "contribute to programme understandings even when the outcomes are not rigidly defined at the outset of the review and have been characterised as a theory-driven and interpretive approach to systematic reviews to answer questions about what works, for whom and in what circumstances" p4.[9]

Inclusion of studies in a realist review is intended to be less proscribed than in a systematic review to allow for a mix of methods and outcomes to be included, ensuring that underlying theories and approaches can be evaluated rather than a focus on specific measured outcomes.[8] Inclusion criteria in this review of screening plus intervention studies were generated using guidance from systematic reviews on screening (PRISMA), [10] but were further generated iteratively using the themes that emerged. The flowchart and checklist are available as supplementary material.

Data sources

Web of Knowledge, PubMed, Cochrane Database of Systematic Reviews, Cochrane Controlled Trials Register restricted to English language and published post 1990. Reference chaining of identified studies was then conducted.

Search strategy

Search terms were adapted from previous Cochrane reviews of screening plus uptake studies.[11,12] The full strategy is available in Appendix 1. The search was first carried out in July 2010 and updated in March 2013.

Study selection

The initial inclusion criteria were: studies that tested interventions designed to increase uptake of CHD and diabetes screening programmes, or to increase early detection and prevention of these conditions *and* examined the behavioural and/or strategic design of the intervention tested. Studies which only reported on changes in risk factors or cost-effectiveness were excluded.

The initial search elicited 2323 relevant published papers. Retrieved papers were screened according to the inclusion criteria. Details of screening and exclusion stages are detailed in Figure 1 in the supplementary material.

Following screening of titles, 565 relevant papers remained. Reference lists and citations of these papers were searched (using Pubmed and Web of Knowledge) specifically to identify studies that evaluated behavioural aspects of interventions tested; a pragmatic approach was taken to ensure that articles which may not have been found using such traditional chaining were not missed, in that new keywords elicited from themes of identified articles were added to the search, notably on specific behavioural approaches. An example was “informed choice invitation”. This process identified a further 16 articles. Following removal of duplicates across sources (120), and removal after abstract screening (304), two authors (CH, YC) independently reviewed 157 full text papers, and further excluded studies which only evaluated changes in risk factors

or cost-effectiveness. Further exclusions at abstract and full text stages were guided by framing of the interventions into their constituent components using PICO(T) categories (Population, Intervention, Comparison, Outcome and Type of study design). The review was concerned with general population (adult) screening, and so interventions that considered only those already identified as at high risk of CVD/Diabetes or already receiving treatment, younger or specific age or disease limited groups, were excluded. Although initial reading included interventions in a variety of settings, the selection of the final set of papers restricted inclusion to studies set in primary health care in line with the aim of this review being to inform primary health care based interventions. Comparison with a control group of some nature was necessary for inclusion, and although most of the identified studies did consist of Randomised or Cluster Randomised Control Trials, other designs were not excluded, and the relevant quality appraisal criteria for the different designs were used as appropriate (See Table 1). Although most of the studies examined outcomes in terms of successful or unsuccessful lowering of CVD or diabetic risk, the intention of this review was to determine “how, why and what works” or what may prevent it working[8], so outcome type was not restricted.

Preliminary examination of studies sought to extract dominant themes reflecting the behavioural features of the “how and why” such interventions succeed or fail in reducing CVD or Diabetic risk. Most studies examined the effect of a multi-component intervention, in which key features were engaging populations in screening, providing screened populations with feedback about risk status, a health dialogue (defined as counselling that includes aspects of shared decision making such as goal setting or intention formation, and is not just information giving or psychological support),

information about the impact of risk factors on illness development, counselling, motivational interviewing, referral, and pharmacological treatment. The impact of feedback and health dialogue on health outcomes was reported but due to the multiple constituents of interventions, isolating the effects of any one feature is often difficult. Search for studies that focused on explicitly examining such features therefore developed. Twelve studies were left that fulfilled this requirement and met inclusion criteria. Details of the components covered by these papers, year of publication, details of the samples recruited, populations studied and main findings are presented in Table 1. The selection process is summarized in a PRISMA flow diagram (supplementary materials).

Data extraction

Two reviewers (CH and YC) independently extracted information from each article, and one author (CH) reviewed all studies. Data were extracted on study authors, geographical location, year of publication, study cohort characteristics, behavioural design features of the intervention, and outcome measures (see Table 1).

Results

Study characteristics and quality

The SIGN 50 assessment of quality of studies included is summarised in Table 1. Two authors (CH and RC) independently rated each included study for quality using the SIGN 50 guidelines,[13] with each study rated as either ++ = high quality, + = acceptable quality or 0 = low quality. After independent ratings the authors met to discuss their ratings. All disagreements were resolved via discussion. Seven studies were of

acceptable quality and five were high quality studies. The key elements of the studies were summarised into Table 1, so that key themes and evidence from the papers could be identified and extracted for examination.

The review of included papers begins by describing studies that addressed the question of what impact behaviour change features embedded within intervention designs of CVD and diabetes screening programmes have on health outcomes. The review then proceeds to cover literature that evaluates the factors predicting attendance and attrition from screening and intervention programmes.

Impact of feedback on behaviour change

Providing people with feedback on their behaviour can prompt behaviour change,[14,15] and has been recognised as an effective behaviour change technique in Abraham and Michie's behaviour change taxonomy.[16,17] In general, there are two types of feedback: informing patients about their risk status, e.g. of CVD; and giving patients behaviour-specific feedback, e.g. discussion related to detailed dietary analysis[18], with a key point of contention being the effectiveness and practicalities of these two approaches Two studies examined the impact of feedback on behaviour change.

Aubin et al[19] investigated whether knowledge of blood cholesterol level affected intention to adopt a low fat diet. The study was conducted in hospital-based family medical centres in Quebec, Canada. Participants were randomly assigned to complete a questionnaire about CVD risk profile, intention to adopt a low fat diet, and dietary fat

intake either before or after receiving their screening results, i.e. one group knew their results, and one did not at the time of completing the questionnaire. Patients who were aware of their blood screening results before they completed the questionnaire showed a significantly higher intention to adopt a lower fat diet than patients who were not ($F_{1,417}$ = 5.4, p<0.02). In addition, in those who had received their results, intention tended to rise with blood cholesterol level (non-significant, $F_{5,413}$= 2.0, p<0.08).

Three months after screening, participants' dietary fat intake and changes in eating habits were assessed by comparing diet with that reported at baseline. Data for 391 participants (mean age = 35 years) were analysed. Mean dietary fat intake significantly reduced from 48.5g per day at baseline, to 37.7g per day at three month follow-up for the participant group as a whole. After three months, patients who had abnormal cholesterol levels had a significantly greater reduction in dietary fat intake than patients with normal cholesterol results ($F_{(2,388)}$ = 3.6, p = 0.03); correlational analysis showed a highly significant link between reduction in fat intake and reduction in blood cholesterol (the researchers report an R^2 of 0.5, p=0.001, but confirmed by email that a Pearson's correlation was intended). This shows that patients who had higher blood cholesterol were more likely to make dietary changes. Although the method and analysis did not separate out people who were aware of their cholesterol levels in the longitudinal comparisons, the authors concluded that informing patients of their blood cholesterol levels effects an immediate change in dietary habits, and that over all, the change in dietary habits effects a reduction in fat intake and lower CVD risk.

Elton et al[20] used a workplace screening and intervention trial in Manchester, UK to examine if knowledge of cholesterol level led to a reduction in cholesterol over a thirteen week period. Participants were randomly allocated to either an intervention group that received information on their current cholesterol level, or to a control group where this information was not provided. Then all participants attended a health education session about diet. The results demonstrated that the reduction in cholesterol measurements thirteen weeks after baseline was greater in intervention participants with initially high (>6.5mmol/l) serum cholesterol than in matched control participants (change of -0.29 for intervention participants, 95% CI -0.48 to -0.11, but only a change of -0.01, 95% CI -0.16 to +0.15 for controls, difference between groups reached significance at p<0.024). A key difference between this and an earlier study[18] which had not shown an effect of informing participants of their cholesterol level was that the interventions specifically focussed on diet here, whereas the earlier study delivered a general health education package.

Impact of health dialogue on behaviour change

Five studies examined the role of health dialogue in influencing health outcomes of screening interventions.[21-25] Färnkvist et al[21] investigated the extent to which health screening with or without health dialogue influenced self-reported CVD and diabetes morbidity 11 years post-screening. Participants were men aged 35-55 years in Härnösand, Sweden. Screening included objective measurements (e.g. blood pressure), a self-report questionnaire, and health counselling provided by nurses. Although described alternately as health dialogue and counselling in this study, it did actually consist of a structured motivational dialogue that included discussion of the

individual's CVD risk, and possible lifestyle changes, and hence fulfils our definition of a health dialogue. Other healthcare providers in the same community (mainly occupational health services; OHS) carried out the same screening but without the health dialogue.

Eleven years later participants were asked to complete a questionnaire including questions about smoking, alcohol, physical activity, height, weight, fat intake and the presence of CVD and/or diabetes. There was no significant decline in health during the 11 years for those participants who received the screening plus health dialogue (8.2% incidence of CVD and/or diabetes), in stark contrast to those who received screening only (22.6% incidence) or no screening (19.2%). The odds ratios (OR) of developing CVD or diabetes over the 11 years was 2.5 for those who had screening with no health dialogue, and 3.0 for those who had not participated in either the original screening or the dialogue, as compared with the dialogue group. That is, the risk was more than doubled for any group who had not received the dialogue. The authors concluded that screening that includes a structured, motivational health dialogue is more effective than screening without this dialogue.

Engberg et al[22] conducted a RCT in Denmark investigating the impact of general health screening versus screening plus GP-patient discussions about CVD risk profile. Randomly selected men aged 30-50 from several GP practices were sent an invitation letter and postal questionnaire about lifestyle. Those who agreed to take part completed a second questionnaire asking about their health, lifestyle, psychosocial status and life

events. Participants were randomised to a control group (questionnaire only, no screening) or one of two intervention groups: screening only and screening plus health discussions (time points not given). Participants in the health screening plus discussion group were offered a 45-minute consultation with their GP to discuss their results and how to adapt to a healthier lifestyle. They were encouraged to set their own topics for discussion and to set health-related lifestyle goals to achieve within the next year. These participants were offered further discussions annually for five years. Randomisation to groups was stratified based on the GP to whom they were registered, age, sex, BMI and "cohabitation status". All screened participants received personal written feedback from their GPs, including advice on lifestyle change (where necessary) and information leaflets about a healthy lifestyle. All participants were followed up at 1 and 5 years.

At the 5 year follow-up, there were no significant differences in measures of CVD risk factors between the two intervention groups (screening only versus screening plus discussion). Taken together, however, these two intervention groups had a much lower proportion of patients with elevated CVD risk scores than the control group, whose prevalence of elevated CVD risk was approximately twice that of the intervention groups (RR = 0.54, 95% CI = 0.40-0.73). However, there were no significant differences between the control and intervention groups for blood pressure, and no effects on smoking. The authors concluded that though the intervention as a whole had a marked effect on CVD risk, the discussions did not improve the cardiovascular health of participants over and above the improvement shown from screening with feedback.

Rubak et al[23] examined the difference in patient outcomes (improved metabolic status in patients with diabetes) between those whose GPs had received training in motivational interviewing and those whose GPs had been allocated to a control group. Both groups of GPs received training in intensive treatment of Type 2 Diabetes. The study found that patients with GPs in both groups showed significant improvements, with no difference between the groups at one year follow-up. One explanation for the lack of difference found is that GPs in the motivational interview group had used an average of less than 2 of the 3 motivational interview sessions allocated to them. The authors suggest that some contamination of effect may have occurred, in that the control group GPs also became aware of MI, and that the GPs in the motivational interview group did not use it as much as had been recommended.

Koelewijn-van Loon et al[24] investigated differences between participants who had a structured dialogue with a trained nurse (including risk assessment, risk communication, motivational interview and a patient "decision support tool") and patients who received usual care. Outcome measures were self-reported lifestyle behaviours, diet, exercise, smoking and alcohol use, which were measured 12 weeks after baseline to assess change. 522 patients completed the follow-up measures. The authors concluded that the results showed an improvement in lifestyle in both groups; there were no differences between groups in terms of effects.

Craigie et al[25] examined the impact of a personalised lifestyle programme (HealthForce) aimed at promoting lifestyle behaviour change and based specifically on health behaviour change theory. HealthForce targeted motivational elements to create intentions to change behaviour and volitional elements, focussing on translating

intentions into planned behaviours. It involved patients attending three face-to-face sessions with a trained lifestyle counsellor, plus other materials, with topics being activity, diet and weight management. The outcome assessments all showed significant positive changes for the intervention group (all $p<0.01$), with no positive, but some negative changes for the control group. Consumption of 5 portions of fruit and vegetables a day went from 56% to 85% for the intervention group; weight was down by an average of 1.1kg, BMI went from a mean of 26.7 to 26.2kg/m^2 (with increases, rather than decreases, for the control group, $p<0.01$) and waist circumference went from 87.3 to 84.0cm (no significant change for control group).

The contrast between these five similar studies is striking; Färnkvist et al and Craigie et al's analyses supported the impact of health dialogue, Engberg et al found that screening plus verbal health dialogue was not superior to screening that included a written dialogue, while Rubak et al and Koelewijn-van Loon et al found no effect. However, the outcome measures, and time between measurements, vary across studies; Färnkvist et al compared risk of CVD and diabetes diagnosis over 11 years, Engberg et al assessed differences between groups in risk factors five years after initial screening, Rubak et al tested metabolic status in patients with diabetes after one year, Koelewijn-van Loon et al compared self-reports of lifestyle behaviours 12 weeks after the intervention, and Craigie et al compared anthropometric and health behaviour changes12 weeks later. This raises a number of issues. First, endpoint diagnosis is the most objective measure of the impact of intervention, and the strongest evidence of efficacy. Second, in general, longer-term follow-ups are preferable, however selective attrition could be a greater issue for longer-term follow-ups, biasing the sample.

Conversely, shorter-term follow-ups may not allow enough time for change to happen. Finally, these studies, though conducted with similar samples, were run in four different countries with subsequent differences in healthcare services and risk levels at baseline, and so conclusions need to take into account the healthcare context when assessing the mechanisms and outcomes.[8]

Of particular interest were the two studies (Craigie et al and Koelewijn-van Loon et al) which both used self-reported behavioural outcomes and a 12 week follow-up and yet had contradictory results. Both included face to face counselling on more than one occasion, telephone support sessions, and motivational interview plus decision support or goal setting. The most obvious difference is that patients in Craigie et al's study were all pre-selected as high risk (but not on statins), whereas only 28% of those in Koelewijn-van Loon et al's study were designated as high CVD risk. Indeed the latter study did find a difference between intervention and control groups in fruit and vegetable consumption when only those with diagnosed diabetes were included. As in previous analyses, the difference seems to be due to the finding that those with higher perceived risk are more likely to make appropriate changes to their health behaviour. Again context is highlighted, but here in terms of the individuals one is trying to influence.

Key points:

Providing patients with feedback on screened measurements can promote changes in behavioural intentions and actual health behaviour change.

The benefits of a structured, motivational health dialogue are supported over simple screening where outcomes are measured long term, but the actual structure of such dialogues has not been directly analysed in the literature.

The comparison of similar studies highlights the need for a set of basic standardised measures.

Comparisons suggest that longer term influences on disease occurrence need assessing.

Patients informed they are at high risk tend to make the most lifestyle changes and achieve the most positive outcomes

Factors predicting uptake, attendance and attrition from screening programmes

Uptake and invitation

For screening programmes to be cost-effective it is essential to maintain high levels of uptake, attendance and avoid excessive attrition. Research[21] has demonstrated that some groups, for example, the less healthy, are less likely to participate in screening programmes, and more likely to drop out if they do commence participation. Attempts have been made to encourage uptake of screening by manipulating the method of invitation: three studies examined the effect of invitation style on uptake and health outcome.[27-29]

Marteau et al[27] hypothesised that providing an informed choice leaflet lower attendance relative to standard invitations, because individuals receiving the leaflet would see that screening is unlikely to provide individual benefits. The authors found no difference in attendance rates between individuals who received an informed choice letter versus a standard letter, but they did replicate previous studies in finding that attendance fell with increasing social deprivation. There was no interaction between social deprivation and invitation type, however, the authors concluded that the ethical advantage gained in informed choice invitations did not outweigh the attendance benefit of standard invitations.

Park et al[28] investigated the effects of loss- and gain-framed messages in an invitation to screen for Type 2 diabetes. The loss frame message ("If you have diabetes but are not detected early, your diabetes may lead to more complications") highlights the possible losses due to not attending; the gain frame message ("If your diabetes is detected early, you can receive early and more effective treatment") emphasises the possible gains of attending. Participants, aged 40-69 years, were randomly selected from two GP practices in Cambridgeshire, England. Fifty-nine patients were randomised to receive the loss-framed invitation and 57 the gain-frame. All invitations included a neutral framed message ("A simple blood test is the best way to detect diabetes").

There were no significant differences in attendance rates between groups (loss-frame = 81% vs gain-frame = 82%). Overall, results show that how information was framed made little difference to attendance rates. There was, however, a significant interaction effect between sex and invitation frame; attendance was higher in men invited using the loss-frame (89%) compared to the gain-frame (77%), and higher in women invited using the gain-frame (94%) compared to the loss-frame (68%). Although this result should be viewed with caution because of the small numbers, it does suggest potential for using different frames for different patient groups.

In addition to investigating the content and format of invitation letters, researchers have also examined the potential of opportunistic screening that is asking patients to complete screening while they are attending a healthcare setting for another purpose, such as collecting medication. Hellénius et al[29] investigated opportunistic screening on visits to a healthcare centre for other purposes in a suburban area of Sweden

(Sollentuna). Male and female adults under the age of 60 who visited health centres were opportunistically invited to screening. This group was compared with a group who were invited by letter. 59% of those invited by letter participated (249 people) compared to 15% of the men and 20% of the women who were invited when they visited their health centres (4655 people, the opportunistic sample). Frequency of hypertension, high cholesterol, high triglycerides were greater in the opportunistic sample than the letter-invited sample, but there were no differences in smoking or likelihood of being overweight. Outcomes of the intervention showed significant blood pressure, cholesterol, and triglyceride reductions, but no differences in the level of reductions in risk factors between opportunistic and letter-invited participants. The authors concluded that the integration of a large scale CVD risk screening programme into a regular primary healthcare system was successful, and that, taking into account low uptake, opportunistically screening patients was successful in identifying those with high CVD risk factors whose risk factor level could be reduced.

Difference between attenders and non-attenders

It has been noted that differences exist between individuals who attend screening and those who do not[26] and our search strategy identified two papers on this topic. Jones et al[30] recruited 3800 patients (aged 25-55 years) across six GP practices in Wales who were invited for a CHD risk factor screening programme. 2402 (63.2%) attended for screening, 1389 (36.8%) did not attend. A 1 in 10 random sample of 140 non-attenders was obtained, using a further letter offering them a medical "MOT" with specific reference made to heart disease and asking them to make an appointment any morning or afternoon. (MOT is an annual car maintenance test which is legally required by the

Ministry of Transport for cars on UK public roads, a term which is very familiar in the UK.) After three weeks any persisting non-respondents were sent another letter including a specific appointment time, asking them to contact the surgery if this was not convenient. A final contact was made by telephone after a further three weeks, and the nurse visited the home for the appointment if necessary. This approach resulted in 98 (70.0%) of the original non-attenders being screened. They were asked to indicate reasons for their initial non-attendance. Reasons (in order of frequency) were: invitation letter not received (36.7%); 'practical reasons' (26.5%); felt screening was unnecessary because they were feeling well (18.4%); already under medical care for CHD related issues (12.2%); already aware of having risk factors and so felt screening was unnecessary (10.2%); felt apathetic about screening (10.2%); afraid of screening (7.1%); forgot to attend appointment (4.1%).

Non-attenders were significantly older than attenders (mean age 42.6 years and 39.4 years respectively; $p<0.001$, 95% CI of difference 1.50, 4.88). They were more likely to have lower SES than attenders and more likely to have a personal history of CHD (12% versus 5.7%, $p<0.05$). In addition, mean BMI ($p<0.01$; 95% CI 0.84, 2.58), cholesterol ($p<0.01$, 95% CI 0.26, 0.74), and blood pressure (systolic $p<0.001$; 95% CI 9.57,15.86; diastolic $p<0.01$; 95% CI 1.63, 5.82) were significantly higher for non-attenders than attenders. These results show that those people most in need of healthcare are less likely to access it. However, it is also clear that approximately 22% of non-attenders did not attend because they were already under medical care for CHD issues or were already aware of their risk factors (no data for attenders), possibly influencing the

outcome differences between attenders and non-attenders, and potentially reducing the likelihood of these individuals responding to an invitation to screening.

A further issue of non-attendance is that of differences between people who continue in a programme once started, and those who drop out. Thomas et al[31] examined the characteristics of attenders and non-attenders at the 20-year follow-up screening in the British Regional Heart Study. The non-attenders referred to here were all people who had attended originally, but failed to return for re-assessment, i.e. had dropped out. A total of 7735 men took part in the original screening, and 4252 (77%) attended the follow-up. There were no significant differences at baseline in age, BMI and cholesterol between those who attended those who did not attend at the follow-up, but non-attenders at follow-up had higher baseline blood pressure. Questionnaire data on the non-attenders was available from 2-4 years before the invitation to the follow-up health check. This showed that they were more likely to have suffered stroke, peripheral vascular disease and bronchitis and that they were twice as likely to smoke cigarettes. Attenders were significantly more likely to be married, to own their own home, to have access to a car, and to be educated past the age of 16.

Mortality rates within one year of follow-up were significantly higher among non-attenders than attenders (6.2% vs. 1.7%), though the majority of deaths were non CVD-related. Non-attenders who self-reported having poor or fair health and a disability were significantly less likely to attend for follow-up, as were participants who reported using four or more medications regularly. Furthermore non-attenders were shown to be taking multiple prescribed medications, report more disabling conditions, and had a high early mortality rate.

Key points:

Informed choice invitations are preferable ethically and do not appear to reduce screening uptake

Framing of invitations to screen may affect attendance rates for men and women; where a screening invitation is gender specific, targeting may benefit from framing

Opportunistic screening at visits to GP surgeries for other purposes is shown to be effective

- Evaluation of opportunistic screening confirms that it reaches people with higher CVD risk factors than reached using standard invitations.
- People screened opportunistically showed very similar improvements in assessed risk factors to people invited in other ways

People who do not attend or who drop out at later stages may be different.

- Differences between people who respond to invitations for screening and who do not are difficult to ascertain, but evidence suggests non-attenders have higher CVD risk factors.
- Selective drop out ("selective attrition") biases longitudinal studies in that inevitably people who are less healthy, less well educated, of lower socio-economic status or with more lifestyle risk factors (smoking, higher alcohol consumption, overweight) are more likely to fail to return for follow-up appointments.
- Selective attrition may result in outcomes in longitudinal studies appearing more positive (overestimate of effect) because people who remain in the study are the healthier people
- Careful methodological and statistical controls are needed to reduce resultant effects on findings.

Discussion

This realist review focussed on use of evidence based design features of interventions which aimed to increase uptake of CVD and diabetes screening with a view to increasing early detection and reduction of risk factors for these diseases. Only 12 studies were identified that critically examined the intervention design and tested the efficacy of health behaviour change components, such as feedback, against health outcomes. Key findings include the following: health-related feedback or health dialogue can be effective, but in order to enable specific analyses, a working definition of what

this communication entails is required; whether individuals are invited for screening or are screened opportunistically may influence the nature of participants recruited, with those at higher risk less likely to respond to an invitation; and selective attrition of those at higher risk may be skewing results of longitudinal studies because it is the healthier, lower risk patients who are most likely to attend for follow-up.

Impact of behavioural features on quality and outcome of interventions

It is clear from the studies reviewed that consideration of evidenced behavioural features of interventions is limited; in particular, several large UK studies[26,32,33] were excluded from the review at an early stage in the search process because they did not examine any design, behavioural or psychological features of screening or intervention. Nevertheless, the studies included in the review indicate several strategies that could be usefully employed to reduce risk in high risk and general population targets, such as providing opportunistic screening. There was a lack of evidence that intervention design was based on health psychology theory (e.g., Ajzen's theory of planned behaviour,[34] despite research showing that such theories can predict screening attendance,[35] and lifestyle behaviours that are the target of screening interventions,.[36] Even studies that claimed to be based on theories and target motivation[25] failed to specify the theory base for their intervention. This lack of emphasis on health psychology theories suggests a greater focus on the outcome of the intervention (i.e., did people change their behaviour?) rather than a focus on the motivations and perspectives of the individuals invited to screen. This 'one-size fits all' approach to intervention design is unlikely to yield success as research shows that even in a sample of 10 participants not all of them respond positively to the same interventions.[37] Although there was limited use of

health psychology theories in the design of the interventions included in this review, several interventions included elements such as the influence of health dialogue, goal setting and feedback, which have been shown to promote health behaviour change,[38,39] although much of this research has been conducted outside of primary care settings. Therefore, it was encouraging to find that goal setting promoted changes in outcomes in Craigie et al and that feedback was helpful in Aubin et al and Elton et al. These elements require further examination with reference to a behaviour change taxonomy e.g., Abraham and Michie's,[16] to determine whether they are effective within the context of CVD and diabetes screening programmes. Relatedly, an issue highlighted by our evaluation of a CVD screening intervention in the UK,[40] is the extent to which healthcare practitioners use the strategies and tools with which they have been provided in the health dialogues they have with their patients. This issue of intervention fidelity has the potential to differentiate between programmes that are successful in getting patients to change their behaviour and programmes that are not,[41] and is evident in Rubak et al[23] who found that GPs failed to deliver, on average, more than one session of motivational interview to patients, when they were facilitated to deliver three. CERAG's definition of implementation research: "the scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices in routine practice, and hence to improve the quality (effectiveness, reliability, safety, appropriateness, equity, efficiency) of healthcare" (cited in Eccles et al.[1]) sets this study firmly in the context of implementation science.

Study limitations

This review raised two key challenges. First, studies rarely analyse behavioural components of the intervention design discretely, making it impossible to discern which factors are at work in producing the observed effects. Second, the heterogeneity of outcome measures precludes statistical evaluations using meta-analysis. Publication or outcome bias may have affected our results, though not all included studies found significant reductions in assessed risk or differences in outcomes between intervention and control groups. Several potentially relevant studies that focus on the design of screening interventions were excluded because they were not delivered in healthcare settings. The reviewed studies also highlight the disadvantages of Intention-To-Treat analyses, which are better suited for assessing the efficacy of an intervention in practice as opposed to understanding "how" and "why" and intervention works, and the need to control for selective attrition either by use of features which reduce drop out or by statistical control for known differences between returners and non-returners, but few studies employ this. As a realist review, this document examines outcomes which may be situation specific. The acknowledgement that some findings that may be situation or population specific is important in generalisation of results.

Conclusions and policy implications

This review highlights the need for a more systematic approach to the strategic design, conduct and analysis of health interventions by taking into account the complex interactions between design, delivery, attrition and health outcomes. It is recommended that insights from health psychology should be incorporated in the design of interventions aimed at increasing screening uptake, as well as involving cross-disciplinary specialist areas such as physical activity and nutrition to promote lifestyle

behaviour change alongside pharmacological treatment. Furthermore, to control the effects of selective attrition, there is a need to perform sensitivity analyses in order to monitor the make-up of the sample and perhaps some purposive sampling to protect against biasing the sample toward a healthier baseline and therefore reduced effect at follow-up, particularly in longitudinal studies. It is anticipated that such carefully designed interventions would result in health behaviour change that provide as much benefit to the wider population as they do for those with heightened risk, resulting in better overall population outcomes.

What is already known on this topic

Previous reviews have raised concerns about the cost effectiveness of CVD and diabetes screening interventions.

- Some researchers have instead recommended replacement of screening programmes with pharmacological interventions alone, (e.g. prescription of statins to everyone aged 55 or older[42]).
- Other work has illustrated that health behaviour change and intervention effectiveness can significantly reduce CVD risk, controlling for effects of pharmacological intervention.
- Some features of intervention style, and of populations, often result in less than optimum risk reduction.

What this study adds

- **The study confirms the need for and success of strategies that encourage higher risk patients to become and stay involved in screening and intervention programmes, such as opportunistic screening.**
-
- Careful training and monitoring of the use of evidenced behaviour change strategies in improving the reach and success of interventions is needed.
- Ethically supported invitation styles such as fully informed choice do not reduce participation or effect outcome.
- Clear feedback and targeted intervention on specific risk factors or behaviours is supported, whereas general lifestyle advice is less effective.
- Structure of motivational health dialogues and the terms over which they are most successful needs further research.

Contributorship statement:

CH, RS, HP, and RC were responsible for the conception and design of the study. YC had principal responsibility for search and sourcing of articles and initial data extraction, and RC contributed to reference chaining. Two authors (CH, YC) independently reviewed the157 full text papers retrieved, and further excluded studies which only evaluated changes in risk factors or cost-effectiveness. CH and RC assigned quality scores to each included full-text article based on the Scottish Intercollegiate Guidelines Network (SIGN 50) quality assessment instruments. CH had principal responsibility for data extraction, analysis and interpretation of the data and for drafting the article,

revisions, and final approval. RS, HP, and RC contributed to interpretation of the data, revisions and final article approval. CH and RC are the guarantors.

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Competing interest statement

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work other than that outlined under "Funding" above; no other financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years ; no other relationships or activities that could appear to have influenced the submitted work .

Ethical approval: Not required.

Data sharing: No additional data available.

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Table 1. Included Studies

Study	Country	Sample	N	Design	Intervention Component	Main findings	Quality
Aubin 1998[14]	Canada	58% female, mean age 35 years	391	RCT, controls completed questionnaire on intention to eat a low fat diet before they received results of cholesterol screening, intervention participants completed it after	Impact of feedback on behaviour change	Intervention participants were more likely to intend to adopt a low fat diet than controls. Patients with abnormally high cholesterol(≥ 6.3mmol/L) showed a greater reduction in dietary fat intake than those who had a normal cholesterol (<5.2mmol/L)	+
Elton 1994[15]	England	44% female, mean age 37.9 years	469	Prospective, blinded RCT, Intervention participants knew their cholesterol level before the health education	Impact of feedback on behaviour change	Participants whose initial serum cholesterol was ≥ 6.5mmol/L and who had been informed of this, showed a significantly greater	++

				and diet session, control participants did not.		reduction in serum cholesterol than control participants in the same high cholesterol group who had not been informed. All participants received the same dietary advice.	
Färnkvist 2008[16]	Sweden	100% male, age stratified, aged 66, 56 and 46 years.	817	Cross-sectional study. Screening only, Screening plus health dialogue by trained professionals, and non-participants compared.	Benefits of health dialogue over simple feedback	Odds ratios of developing diabetes or CVD over 11 years were 2.5 for those had received screening with no health dialogue and 3.0 for those who had not participated in the original screening, as compared with those who had received screening plus a structured, motivational health dialogue.	+

Engberg 2002[17]	Denmark	52% female, Mean age 40.4 years	150 7	RCT, Screening, screening plus health dialogue compared with normal care control group.	Benefits of health dialogue over simple feedback	After 5 years there were no differences between the two intervention groups Total intervention/control Risk Ratio was 0.54. Absolute risk reduction 8.6%.	++
Rubak 2011[18]	Denmark	42% female, Mean age 61 years. Patients with screen detected type 2 diabetes	628	Cluster RCT, Intervention and control groups received training in intensive treatment of Diabetes, intervention group GPs additionally received training in Motivational Interviewing (MI) and instructed to use it.	Benefits of health dialogue over simple feedback	No effect of motivational interview on medication adherence or metabolic status in relative to control group. Medication adherence across both groups almost 100%, both groups showed significant improvements in all risk measures. Key issues were lower than planned use of motivational interview by intervention group GPs, and contamination of	++

						methods and training into control group GPs.	
Koelewijn-van Loon 2010[19]	Netherlands	55% female, Mean age 57 years	615	Cluster RCT, Intervention nurses received training to use risk assessment, communication, a decision support tool and MI. Control group nurses received training on risk assessment and applied usual care.	Benefits of health dialogue over simple feedback	Outcome measures were self-reported lifestyle measures. No differences between control and intervention groups noted at 12 week follow up, but overall both groups showed improvements.	+
Craigie 2011[20]	Scotland	72% female, Mean age 54.5 years, high risk but not on statins.	75	RCT, Intervention – motivational interview and volitional aspects to change planned behaviour, Control group usual care.	Benefits of health dialogue over simple feedback	Percentage achieving 5 portions of fruit and vegetables a day, and weight maintenance or loss indicators were significantly better in the intervention group over the 12 week follow up. Control group	+

						made no positive change.	
Marteau 2010[22]	England	47.6 % female, mean age 57.4 years	1272	RCT, informed choice invitation compared with standard invitation.	Impact of type of invitation on uptake and outcome	Primary outcome of attendance did not differ between groups Secondary outcome of intention to change health behaviour was unaffected by invitation type.	++
Park 2010[23]	England	66.6% male, Mean age 58 years	116	RCT, loss frame compared with gain frame invitation.	Impact of type of invitation on uptake and outcome	Primary outcome of attendance did not differ between groups (invitation types). Secondary outcome measures of anxiety, self-perceived health and Illness representation also did not differ between groups.	++
Hellénius 1998[24]	Sweden	65% female, age range 20-60 years	4904	Observational Cross sectional study, those screened as a result of	Impact of type of invitation on	Opportunistically screened participants showed higher CVD risk factors than letter invited	+

				opportunistic invitations compared with those responding to a letter invitation.	uptake and outcome	participants at baseline. Effectiveness of screening in lowering risk factors did not differ between the two groups.	
Jones 1993[25]	Wales	53.4% female, mean age 42.5 years	2542	Observational cross-sectional study, those not responding to initial invitations to screenings compared with those who did.	Differences between attenders and non-attenders	Non-attenders showed more risk factors than attenders.	+
Thomas 2002[26]	England	100% male, Mean age 69.1 years,	5655	Observational cross sectional study, Health characteristics of those who attended and did not attend a 20 year follow-up were compared.	Differences between attenders and non-attenders	Despite no differences at baseline in BMI and cholesterol, those who later dropped out of a longitudinal study had higher blood pressure at baseline and greater number of CVD and bronchial diagnoses, and	+

						adverse lifestyle factors (e.g. OR of smoking in non-attenders 2.33).	

Note. SIGN 50 cohort checklist used to assess study quality. ++ = High quality study, + = Acceptable, 0 = Unacceptable.

Appendix 1. Search terms used in search strategy

The following terms were used in all data sources: (cardiovascular OR vascular OR CVD OR “chronic heart disease” OR “coronary heart disease” OR CHD OR diabetes) AND (“mass screening” OR surveillance*) AND (letter OR mail* OR phone OR telephone OR “reminder system*” OR “videotape recording*” OR “audiotape recording*” OR questionnaire* OR strateg* OR alert* OR hotline OR community OR media) AND (intervention* OR goal OR “behav* change” OR “implementation intention*” OR plans OR planned OR planning OR plan OR educat* OR campaign* OR barriers OR intention* OR “behav* outcome” OR outcome OR “lifestyle change” OR longitudinal OR “follow up” OR motivation*) AND (satisf* OR dropout* OR “drop out” OR attrition OR uptak* OR adher* OR compliance OR complie* OR comply* OR “patient acceptance of health care” OR encourag* OR improve* OR improving OR increas* OR promot* OR particip* OR nonattend* OR “non attend” OR accept* OR attend* OR attitud* OR utilisation OR utilization OR refus* OR respond* OR respons* OR reluctan* OR nonrespon* OR “non respon*” OR incidence OR prevalence OR prevelence OR satisfaction OR cooperat* OR “co operat*”) AND (findings OR interview* OR qualitative OR experienc* OR RCT OR “randomised controlled trial” OR trial).

BMJ open

Effectiveness and uptake of screening programmes for coronary heart disease and diabetes: A realist review of design components used in interventions.

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Manuscript ID:	bmjopen-2013-003428.R1
Article Type:	Research
Date Submitted by the Author:	27-Sep-2013
Complete List of Authors:	Holland, Carol; Aston University, Psychology Cooper, Yvonne; Aston University, Psychology Shaw, Rachel; Aston University, Pattison, Helen; Aston University, Psychology; Aston University, Health Sciences Cooke, Richard; Aston University, Psychology
Primary Subject Heading:	Public health
Secondary Subject Heading:	Cardiovascular medicine, Diabetes and endocrinology, Evidence based practice
Keywords:	PRIMARY CARE, PREVENTIVE MEDICINE, General diabetes < DIABETES & ENDOCRINOLOGY, Coronary heart disease < CARDIOLOGY

Effectiveness and uptake of screening programmes for coronary heart disease and diabetes: A realist review of design components used in interventions.

Short title: Effectiveness and uptake of screening programmes

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1 Table

Abstract

Objective

To evaluate behavioural components and strategies associated with increased uptake and effectiveness of screening for coronary heart disease (CHD) and diabetes, with an implementation science focus.

Design

Realist review.

Data sources

PubMed, Web of Knowledge, Cochrane Database of Systematic Reviews, Cochrane Controlled Trials Register and reference chaining. Searches limited to English language studies published since 1990.

Eligibility criteria

Eligible studies evaluated interventions designed to increase uptake of CVD and diabetes screening and examined behavioural and/or strategic designs. Studies were excluded if they evaluated changes in risk factors or cost-effectiveness only.

Results

In 12 eligible studies, several different intervention designs and evidence based strategies were evaluated. Salient themes were effects of feedback on behaviour change, or benefits of health dialogues over simple feedback. Studies provide mixed evidence about benefits of these intervention constituents which are suggested to be

situation and design specific, broadly supporting their use, but highlighting concerns about fidelity of intervention delivery, raising implementation science issues.[1,2] Three studies examined effects of informed choice, or loss versus gain frame invitations, finding no effect on screening uptake, but highlighting opportunistic screening as more successful for recruiting higher CVD and diabetes risk patients than invitation letter, with no differences in outcomes once recruited. Two studies examined differences between attenders and non-attenders, finding higher risk factors amongst non-attenders, and higher diagnosed CVD and diabetes amongst those who later dropped out of longitudinal studies.

Conclusions

If risk and prevalence of these diseases are to be reduced, interventions must take into account what we know about effective health behaviour change mechanisms, monitor delivery by trained professionals, and examine the possibility of tailoring programmes according to contexts such as risk level to reach those most in need. Further research is needed to determine the best strategies for lifelong approaches to screening.

Article Summary

- 1) Article Focus: The primary objective of this realist review was to evaluate the impact on health and attendance outcomes of theoretically supported behaviour change features embedded within intervention designs of screening programmes targeting CHD and diabetes.

- A secondary objective was to evaluate factors predicting attendance and attrition from these programmes and appraise their impact, with implications for design in specific contexts.

2) Key Messages

- The benefits of a structured, motivational health dialogue, with feedback, are supported over simple screening and advice, where outcomes are measured long term. Structure of motivational health dialogues and the terms over which they are most successful needs further research

- However, the issue of intervention fidelity (adherence to intervention protocol by those delivering) has potential to differentiate between programmes that are or are not successful in getting patients to change health behaviour and as such represents a key implementation science component of the review.

- This review highlights the need for a more systematic approach to using the evidence base for strategic design, conduct and analysis of health interventions

by taking into account the complex interactions between design, delivery, attrition, context and health outcomes.

3) Strengths and Limitations.

Strengths:

- The study's strength is its focus on what contributes to success and reach of screening plus intervention studies, based on health psychology evidence.
- Its evaluation of the degree and fidelity with which evidenced health behaviour strategies are used has important implications for practitioners managing screening and intervention programmes.
- Evaluation of opportunistic screening confirms previous work showing that it reaches people with higher CVD risk factors than reached using standard invitations, but additionally demonstrates that people screened opportunistically show very similar improvements in assessed risk factors and behaviours to people invited in other ways.

Limitations:

- This review raised two key challenges. First, many studies do not analyse behavioural components of the intervention design discretely, making it impossible to discern which factors are at work in producing the observed effects. Second, the heterogeneity of outcome measures precludes statistical evaluations using meta-analysis.

- Publication or outcome bias may have affected our results, though not all included studies found significant reductions in assessed risk or differences in outcomes between intervention and control groups.

- Several potentially relevant studies focusing on design of screening interventions were excluded because they were not delivered in healthcare settings.

- Well-known selective drop out ("selective attrition") biases are confirmed in these studies, whereby people with more lifestyle risk factors (smoking, higher alcohol consumption, overweight) are more likely to fail to return for follow-up appointments. Careful methodological and statistical controls are needed to reduce resultant effects on findings, but few studies employ these.

- As a realist review, this document examines outcomes which may be situation specific. The acknowledgement that some findings that may be situation specific is important in generalisation of results.

Introduction

Previous reviews of multiple risk factor interventions for primary prevention of coronary heart disease (CHD) and diabetes often conclude that interventions have no overall effect on mortality.[3] Nevertheless, CHD deaths have halved in the UK and other developed countries in the last 30 years.[4] Unal et al[5] compared targeted interventions and general population screening. They estimated the proportion of reduced deaths from CHD in England and Wales between 1981 and 2000 that were attributable to changes in risk factors in patients with CHD or changes in cardiovascular risk factors in the general population, and found both approaches beneficial. These authors calculated that reductions in risk factors (such as smoking, high blood pressure) in the general population account for 50-75% of the fall in cardiac deaths, and pharmacological and surgical treatments for diagnosed CHD patients account for 25-50%.[5] However, that benefit was greater when individuals without CHD were screened: results indicated an additional 21 years of life for each death prevented in those with no CHD diagnosis compared to 7.5 years for those with CHD.

Public health campaigns to reduce these conditions usually involve: government-sponsored programmes at the population level or changes in policy (such as food labelling legislation); targeted interventions for those at heightened risk (for example, moderate-intensity, low-impact exercise for those very overweight or with chronic conditions); or general population screening and intervention to reduce risk development in the healthy population and identify high risk people leading to specific referral for detected or previously untreated symptoms (for example, current NHS Health Check[6] programme).

This review focuses on quantitative evaluations of screening plus intervention programmes that target the general population to reduce incidence of CHD and diabetes. These conditions were selected because they are the focus of screening programmes in many countries and the negative outcomes of these conditions can be ameliorated by lifestyle behaviour change. Previous reviews have focussed on reductions in risk measurements, cost effectiveness, or years of life added.[3] In contrast, the primary objective of this review was to examine use of behaviour change features embedded within intervention designs of screening programmes targeting CHD and diabetes, and their impact on health outcomes. A secondary objective was to evaluate the factors predicting attendance and attrition from these programmes.

These objectives are not well-suited to systematic review and meta-analysis approaches, where the aim is to synthesise results across contexts to gain a sense of the pattern of results for studies conducted using similar methodologies. In contrast, the present paper is focused on questions around "how" and "why" behavioural features are incorporated into interventions, and how these features can contribute to the success of interventions. Therefore, we adopted a realist review, also called a meta-narrative approach. This approach was adopted to gain insights into the direction the evidence is pointing and the underlying theoretically driven concepts, behaviour change mechanisms, and barriers, that may combine to contribute to outcomes in population screening for CHD and diabetes.[7] Focus on the mechanisms and use of evidence based behaviour change strategies locate the review within an implementation science approach, given that "one of the most consistent findings from clinical and health services research is the failure to translate research into practice and policy" p1.[2]

A realist methodology[8] is suited to areas where there is a diverse literature, which may have a variety of methods, components and outcomes. This methodology is concerned with explaining more fully the processes of interventions within the complexity of their contexts, rather than focussing on simple cause and effect deterministic theories. Realist reviews can "contribute to programme understandings even when the outcomes are not rigidly defined at the outset of the review and have been characterised as a theory-driven and interpretive approach to systematic reviews to answer questions about what works, for whom and in what circumstances" p4.[9]

Inclusion of studies in a realist review is intended to be less proscribed than in a systematic review to allow for a mix of methods and outcomes to be included, ensuring that underlying theories and approaches can be evaluated rather than a focus on specific measured outcomes.[8] Inclusion criteria in this review of screening plus intervention studies were generated using guidance from systematic reviews on screening (PRISMA), [10] but were further generated iteratively using the themes that emerged. The flowchart and checklist are available as supplementary material.

Data sources

Web of Knowledge, PubMed, Cochrane Database of Systematic Reviews, Cochrane Controlled Trials Register restricted to English language and published post 1990. Reference chaining of identified studies was then conducted.

Search strategy

Search terms were adapted from previous Cochrane reviews of screening plus uptake studies.[11,12] The full strategy is available in Appendix 1. The search was first carried out in July 2010 and updated in March 2013.

Study selection

The initial inclusion criteria were: studies that tested interventions designed to increase uptake of CHD and diabetes screening programmes, or to increase early detection and prevention of these conditions *and* examined the behavioural and/or strategic design of the intervention tested. Studies which only reported on changes in risk factors or cost-effectiveness were excluded.

The initial search elicited 2323 relevant published papers. Retrieved papers were screened according to the inclusion criteria. Details of screening and exclusion stages are detailed in Figure 1 in the supplementary material.

Following screening of titles, 565 relevant papers remained. Reference lists and citations of these papers were searched (using Pubmed and Web of Knowledge) specifically to identify studies that evaluated behavioural aspects of interventions tested; a pragmatic approach was taken to ensure that articles which may not have been found using such traditional chaining were not missed, in that new keywords elicited from themes of identified articles were added to the search, notably on specific behavioural approaches. An example was “informed choice invitation”. This process identified a further 16 articles. Following removal of duplicates across sources (120), and removal after abstract screening (304), two authors (CH, YC) independently reviewed 157 full text papers, and further excluded studies which only evaluated changes in risk factors

or cost-effectiveness. Further exclusions at abstract and full text stages were guided by framing of the interventions into their constituent components using PICO(T) categories (Population, Intervention, Comparison, Outcome and Type of study design). The review was concerned with general population (adult) screening, and so interventions that considered only those already identified as at high risk of CVD/Diabetes or already receiving treatment, younger or specific age or disease limited groups, were excluded. Although initial reading included interventions in a variety of settings, the selection of the final set of papers restricted inclusion to studies set in primary health care in line with the aim of this review being to inform primary health care based interventions. Comparison with a control group of some nature was necessary for inclusion, and although most of the identified studies did consist of Randomised or Cluster Randomised Control Trials, other designs were not excluded, and the relevant quality appraisal criteria for the different designs were used as appropriate (See Table 1). Although most of the studies examined outcomes in terms of successful or unsuccessful lowering of CVD or diabetic risk, the intention of this review was to determine “how, why and what works” or what may prevent it working[8], so outcome type was not restricted.

Preliminary examination of studies sought to extract dominant themes reflecting the behavioural features of the “how and why” such interventions succeed or fail in reducing CVD or Diabetic risk. Most studies examined the effect of a multi-component intervention, in which key features were engaging populations in screening, providing screened populations with feedback about risk status, a health dialogue (defined as counselling that includes aspects of shared decision making such as goal setting or intention formation, and is not just information giving or psychological support),

information about the impact of risk factors on illness development, counselling, motivational interviewing, referral, and pharmacological treatment. The impact of feedback and health dialogue on health outcomes was reported but due to the multiple constituents of interventions, isolating the effects of any one feature is often difficult. Search for studies that focused on explicitly examining such features therefore developed. Twelve studies were left that fulfilled this requirement and met inclusion criteria. Details of the components covered by these papers, year of publication, details of the samples recruited, populations studied and main findings are presented in Table 1. The selection process is summarized in a PRISMA flow diagram (supplementary materials).

Data extraction

Two reviewers (CH and YC) independently extracted information from each article, and one author (CH) reviewed all studies. Data were extracted on study authors, geographical location, year of publication, study cohort characteristics, behavioural design features of the intervention, and outcome measures (see Table 1).

Results

Study characteristics and quality

~~Most of the studies examined the effect of a multi-component intervention, in which key features were engaging populations in screening, providing screened populations with feedback about risk status, a health dialogue (defined as counselling that includes aspects of shared decision making such as goal setting or intention formation, and is not just information giving or psychological support), information about the impact of risk factors on illness development, counselling, motivational interviewing, referral,~~

~~and pharmacological treatment. The impact of feedback and health dialogue on health outcomes was reported but due to the multiple constituents of interventions, isolating the effects of any one feature is often difficult.~~

The SIGN 50 assessment of quality of studies included is summarised in Table 1. Two authors (CH and RC) independently rated each included study for quality using the SIGN 50 guidelines,[13] with each study rated as either ++ = high quality, + = acceptable quality or 0 = low quality. After independent ratings the authors met to discuss their ratings. All disagreements were resolved via discussion. Seven studies were of acceptable quality and five were high quality studies. The key elements of the studies were summarised into Table 1, so that key themes and evidence from the papers could be identified and extracted for examination.

The review of included papers begins by describing studies that addressed the question of what impact behaviour change features embedded within intervention designs of CVD and diabetes screening programmes have on health outcomes. The review then proceeds to cover literature that evaluates the factors predicting attendance and attrition from screening and intervention programmes.

Impact of feedback on behaviour change

Providing people with feedback on their behaviour can prompt behaviour change,[14,15] and has been recognised as an effective behaviour change technique in Abraham and Michie's behaviour change taxonomy.[16,17] In general, there are two types of feedback: informing patients about their risk status, e.g. of CVD; and giving patients behaviour-specific feedback, e.g. discussion related to detailed dietary analysis[18], with a key point

of contention being the effectiveness and practicalities of these two approaches Two studies examined the impact of feedback on behaviour change.

Aubin et al[19] investigated whether knowledge of blood cholesterol level affected intention to adopt a low fat diet. The study was conducted in hospital-based family medical centres in Quebec, Canada. Participants were randomly assigned to complete a questionnaire about CVD risk profile, intention to adopt a low fat diet, and dietary fat intake either before or after receiving their screening results, i.e. one group knew their results, and one did not at the time of completing the questionnaire. Patients who were aware of their blood screening results before they completed the questionnaire showed a significantly higher intention to adopt a lower fat diet than patients who were not ($F_{1,417}$ = 5.4, p<0.02). In addition, in those who had received their results, intention tended to rise with blood cholesterol level (non-significant, $F_{5,413}$= 2.0, p<0.08).

Three months after screening, participants' dietary fat intake and changes in eating habits were assessed by comparing diet with that reported at baseline. Data for 391 participants (mean age = 35 years) were analysed. Mean dietary fat intake significantly reduced from 48.5g per day at baseline, to 37.7g per day at three month follow-up for the participant group as a whole. After three months, patients who had abnormal cholesterol levels had a significantly greater reduction in dietary fat intake than patients with normal cholesterol results ($F_{(2,388)}$ = 3.6, p = 0.03); correlational analysis showed a highly significant link between reduction in fat intake and reduction in blood cholesterol (the researchers report an R^2 of 0.5, p=0.001, but confirmed by email that a Pearson's

correlation was intended). This shows that patients who had higher blood cholesterol were more likely to make dietary changes. Although the method and analysis did not separate out people who were aware of their cholesterol levels in the longitudinal comparisons, the authors concluded that informing patients of their blood cholesterol levels effects an immediate change in dietary habits, and that over all, the change in dietary habits effects a reduction in fat intake and lower CVD risk.

Elton et al[20] used a workplace screening and intervention trial in Manchester, UK to examine if knowledge of cholesterol level led to a reduction in cholesterol over a thirteen week period. Participants were randomly allocated to either an intervention group that received information on their current cholesterol level, or to a control group where this information was not provided. Then all participants attended a health education session about diet. The results demonstrated that the reduction in cholesterol measurements thirteen weeks after baseline was greater in intervention participants with initially high (>6.5mmol/l) serum cholesterol than in matched control participants (change of -0.29 for intervention participants, 95% CI -0.48 to -0.11, but only a change of -0.01, 95% CI -0.16 to +0.15 for controls, difference between groups reached significance at $p<0.024$). A key difference between this and an earlier study[18] which had not shown an effect of informing participants of their cholesterol level was that the interventions specifically focussed on diet here, whereas the earlier study delivered a general health education package.

Impact of health dialogue on behaviour change

Five studies examined the role of health dialogue in influencing health outcomes of screening interventions.[21-25] Färnkvist et al[21] investigated the extent to which health screening with or without health dialogue influenced self-reported CVD and diabetes morbidity 11 years post-screening. Participants were men aged 35-55 years in Härnösand, Sweden. Screening included objective measurements (e.g. blood pressure), a self-report questionnaire, and health counselling provided by nurses. Although described alternately as health dialogue and counselling in this study, it did actually consist of a structured motivational dialogue that included discussion of the individual's CVD risk, and possible lifestyle changes, and hence fulfils our definition of a health dialogue. Other healthcare providers in the same community (mainly occupational health services; OHS) carried out the same screening but without the health dialogue.

Eleven years later participants were asked to complete a questionnaire including questions about smoking, alcohol, physical activity, height, weight, fat intake and the presence of CVD and/or diabetes. There was no significant decline in health during the 11 years for those participants who received the screening plus health dialogue (8.2% incidence of CVD and/or diabetes), in stark contrast to those who received screening only (22.6% incidence) or no screening (19.2%). The odds ratios (OR) of developing CVD or diabetes over the 11 years was 2.5 for those who had screening with no health dialogue, and 3.0 for those who had not participated in either the original screening or the dialogue, as compared with the dialogue group. That is, the risk was more than doubled for any group who had not received the dialogue. The authors concluded that

screening that includes a structured, motivational health dialogue is more effective than screening without this dialogue.

Engberg et al[22] conducted a RCT in Denmark investigating the impact of general health screening versus screening plus GP-patient discussions about CVD risk profile. Randomly selected men aged 30-50 from several GP practices were sent an invitation letter and postal questionnaire about lifestyle. Those who agreed to take part completed a second questionnaire asking about their health, lifestyle, psychosocial status and life events. Participants were randomised to a control group (questionnaire only, no screening) or one of two intervention groups: screening only and screening plus health discussions (time points not given). Participants in the health screening plus discussion group were offered a 45-minute consultation with their GP to discuss their results and how to adapt to a healthier lifestyle. They were encouraged to set their own topics for discussion and to set health-related lifestyle goals to achieve within the next year. These participants were offered further discussions annually for five years. Randomisation to groups was stratified based on the GP to whom they were registered, age, sex, BMI and "cohabitation status". All screened participants received personal written feedback from their GPs, including advice on lifestyle change (where necessary) and information leaflets about a healthy lifestyle. All participants were followed up at 1 and 5 years.

At the 5 year follow-up, there were no significant differences in measures of CVD risk factors between the two intervention groups (screening only versus screening plus discussion). Taken together, however, these two intervention groups had a much lower

proportion of patients with elevated CVD risk scores than the control group, whose prevalence of elevated CVD risk was approximately twice that of the intervention groups (RR = 0.54, 95% CI = 0.40-0.73). However, there were no significant differences between the control and intervention groups for blood pressure, and no effects on smoking. The authors concluded that though the intervention as a whole had a marked effect on CVD risk, the discussions did not improve the cardiovascular health of participants over and above the improvement shown from screening with feedback.

Rubak et al[23] examined the difference in patient outcomes (improved metabolic status in patients with diabetes) between those whose GPs had received training in motivational interviewing and those whose GPs had been allocated to a control group. Both groups of GPs received training in intensive treatment of Type 2 Diabetes. The study found that patients with GPs in both groups showed significant improvements, with no difference between the groups at one year follow-up. One explanation for the lack of difference found is that GPs in the motivational interview group had used an average of less than 2 of the 3 motivational interview sessions allocated to them. The authors suggest that some contamination of effect may have occurred, in that the control group GPs also became aware of MI, and that the GPs in the motivational interview group did not use it as much as had been recommended.

Koelewijn-van Loon et al[24] investigated differences between participants who had a structured dialogue with a trained nurse (including risk assessment, risk communication, motivational interview and a patient “decision support tool”) and patients who received usual care. Outcome measures were self-reported lifestyle behaviours, diet, exercise, smoking and alcohol use, which were measured 12 weeks after baseline to assess

change. 522 patients completed the follow-up measures. The authors concluded that the results showed an improvement in lifestyle in both groups; there were no differences between groups in terms of effects.

Craigie et al[25] examined the impact of a personalised lifestyle programme (HealthForce) aimed at promoting lifestyle behaviour change and based specifically on health behaviour change theory. HealthForce targeted motivational elements to create intentions to change behaviour and volitional elements, focussing on translating intentions into planned behaviours. It involved patients attending three face-to-face sessions with a trained lifestyle counsellor, plus other materials, with topics being activity, diet and weight management. The outcome assessments all showed significant positive changes for the intervention group (all $p<0.01$), with no positive, but some negative changes for the control group. Consumption of 5 portions of fruit and vegetables a day went from 56% to 85% for the intervention group; weight was down by an average of 1.1kg, BMI went from a mean of 26.7 to 26.2kg/m^2 (with increases, rather than decreases, for the control group, $p<0.01$) and waist circumference went from 87.3 to 84.0cm (no significant change for control group).

The contrast between these five similar studies is striking; Färnkvist et al and Craigie et al's analyses supported the impact of health dialogue, Engberg et al found that screening plus verbal health dialogue was not superior to screening that included a written dialogue, while Rubak et al and Koelewijn-van Loon et al found no effect. However, the outcome measures, and time between measurements, vary across studies; Färnkvist et al compared risk of CVD and diabetes diagnosis over 11 years, Engberg et al assessed differences between groups in risk factors five years after initial

screening, Rubak et al tested metabolic status in patients with diabetes after one year, Koelewijn-van Loon et al compared self-reports of lifestyle behaviours 12 weeks after the intervention, and Craigie et al compared anthropometric and health behaviour changes12 weeks later. This raises a number of issues. First, endpoint diagnosis is the most objective measure of the impact of intervention, and the strongest evidence of efficacy. Second, in general, longer-term follow-ups are preferable, however selective attrition could be a greater issue for longer-term follow-ups, biasing the sample. Conversely, shorter-term follow-ups may not allow enough time for change to happen. Finally, these studies, though conducted with similar samples, were run in four different countries with subsequent differences in healthcare services and risk levels at baseline, and so conclusions need to take into account the healthcare context when assessing the mechanisms and outcomes.[8]

Of particular interest were the two studies (Craigie et al and Koelewijn-van Loon et al) which both used self-reported behavioural outcomes and a 12 week follow-up and yet had contradictory results. Both included face to face counselling on more than one occasion, telephone support sessions, and motivational interview plus decision support or goal setting. The most obvious difference is that patients in Craigie et al's study were all pre-selected as high risk (but not on statins), whereas only 28% of those in Koelewijn-van Loon et al's study were designated as high CVD risk. Indeed the latter study did find a difference between intervention and control groups in fruit and vegetable consumption when only those with diagnosed diabetes were included. As in previous analyses, the difference seems to be due to the finding that those with higher perceived risk are more likely to make appropriate changes to their health behaviour.

Again context is highlighted, but here in terms of the individuals one is trying to influence.

Key points:

Providing patients with feedback on screened measurements can promote changes in behavioural intentions and actual health behaviour change.

The benefits of a structured, motivational health dialogue are supported over simple screening where outcomes are measured long term, but the actual structure of such dialogues has not been directly analysed in the literature.

The comparison of similar studies highlights the need for a set of basic standardised measures.

Comparisons suggest that longer term influences on disease occurrence need assessing.

Patients informed they are at high risk tend to make the most lifestyle changes and achieve the most positive outcomes

Factors predicting uptake, attendance and attrition from screening programmes

Uptake and invitation

For screening programmes to be cost-effective it is essential to maintain high levels of uptake, attendance and avoid excessive attrition. Research[21] has demonstrated that some groups, for example, the less healthy, are less likely to participate in screening programmes, and more likely to drop out if they do commence participation. Attempts have been made to encourage uptake of screening by manipulating the method of invitation: three studies examined the effect of invitation style on uptake and health outcome.[27-29]

Marteau et al[27] hypothesised that providing an informed choice leaflet lower attendance relative to standard invitations, because individuals receiving the leaflet would see that screening is unlikely to provide individual benefits. The authors found no difference in attendance rates between individuals who received an informed choice letter versus a

standard letter, but they did replicate previous studies in finding that attendance fell with increasing social deprivation. There was no interaction between social deprivation and invitation type, however, the authors concluded that the ethical advantage gained in informed choice invitations did not outweigh the attendance benefit of standard invitations.

Park et al[28] investigated the effects of loss- and gain-framed messages in an invitation to screen for Type 2 diabetes. The loss frame message ("If you have diabetes but are not detected early, your diabetes may lead to more complications") highlights the possible losses due to not attending; the gain frame message ("If your diabetes is detected early, you can receive early and more effective treatment") emphasises the possible gains of attending. Participants, aged 40-69 years, were randomly selected from two GP practices in Cambridgeshire, England. Fifty-nine patients were randomised to receive the loss-framed invitation and 57 the gain-frame. All invitations included a neutral framed message ("A simple blood test is the best way to detect diabetes").

There were no significant differences in attendance rates between groups (loss-frame = 81% vs gain-frame = 82%). Overall, results show that how information was framed made little difference to attendance rates. There was, however, a significant interaction effect between sex and invitation frame; attendance was higher in men invited using the loss-frame (89%) compared to the gain-frame (77%), and higher in women invited using the gain-frame (94%) compared to the loss-frame (68%). Although this result should be

viewed with caution because of the small numbers, it does suggest potential for using different frames for different patient groups.

In addition to investigating the content and format of invitation letters, researchers have also examined the potential of opportunistic screening that is asking patients to complete screening while they are attending a healthcare setting for another purpose, such as collecting medication. Hellénius et al[29] investigated opportunistic screening on visits to a healthcare centre for other purposes in a suburban area of Sweden (Sollentuna). Male and female adults under the age of 60 who visited health centres were opportunistically invited to screening. This group was compared with a group who were invited by letter. 59% of those invited by letter participated (249 people) compared to 15% of the men and 20% of the women who were invited when they visited their health centres (4655 people, the opportunistic sample). Frequency of hypertension, high cholesterol, high triglycerides were greater in the opportunistic sample than the letter-invited sample, but there were no differences in smoking or likelihood of being overweight. Outcomes of the intervention showed significant blood pressure, cholesterol, and triglyceride reductions, but no differences in the level of reductions in risk factors between opportunistic and letter-invited participants. The authors concluded that the integration of a large scale CVD risk screening programme into a regular primary healthcare system was successful, and that, taking into account low uptake, opportunistically screening patients was successful in identifying those with high CVD risk factors whose risk factor level could be reduced.

Difference between attenders and non-attenders

It has been noted that differences exist between individuals who attend screening and those who do not[26] and our search strategy identified two papers on this topic. Jones et al[30] recruited 3800 patients (aged 25-55 years) across six GP practices in Wales who were invited for a CHD risk factor screening programme. 2402 (63.2%) attended for screening, 1389 (36.8%) did not attend. A 1 in 10 random sample of 140 non-attenders was obtained, using a further letter offering them a medical "MOT" with specific reference made to heart disease and asking them to make an appointment any morning or afternoon. (MOT is an annual car maintenance test which is legally required by the Ministry of Transport for cars on UK public roads, a term which is very familiar in the UK.) After three weeks any persisting non-respondents were sent another letter including a specific appointment time, asking them to contact the surgery if this was not convenient. A final contact was made by telephone after a further three weeks, and the nurse visited the home for the appointment if necessary. This approach resulted in 98 (70.0%) of the original non-attenders being screened. They were asked to indicate reasons for their initial non-attendance. Reasons (in order of frequency) were: invitation letter not received (36.7%); 'practical reasons' (26.5%); felt screening was unnecessary because they were feeling well (18.4%); already under medical care for CHD related issues (12.2%); already aware of having risk factors and so felt screening was unnecessary (10.2%); felt apathetic about screening (10.2%); afraid of screening (7.1%); forgot to attend appointment (4.1%).

Non-attenders were significantly older than attenders (mean age 42.6 years and 39.4 years respectively; $p<0.001$, 95% CI of difference 1.50, 4.88). They were more likely to have lower SES than attenders and more likely to have a personal history of CHD (12%

versus 5.7%, p<0.05). In addition, mean BMI (p<0.01; 95% CI 0.84, 2.58), cholesterol (p<0.01, 95% CI 0.26, 0.74), and blood pressure (systolic p<0.001; 95% CI 9.57,15.86; diastolic p<0.01; 95% CI 1.63, 5.82) were significantly higher for non-attenders than attenders. These results show that those people most in need of healthcare are less likely to access it. However, it is also clear that approximately 22% of non-attenders did not attend because they were already under medical care for CHD issues or were already aware of their risk factors (no data for attenders), possibly influencing the outcome differences between attenders and non-attenders, and potentially reducing the likelihood of these individuals responding to an invitation to screening.

A further issue of non-attendance is that of differences between people who continue in a programme once started, and those who drop out. Thomas et al[31] examined the characteristics of attenders and non-attenders at the 20-year follow-up screening in the British Regional Heart Study. The non-attenders referred to here were all people who had attended originally, but failed to return for re-assessment, i.e. had dropped out. A total of 7735 men took part in the original screening, and 4252 (77%) attended the follow-up. There were no significant differences at baseline in age, BMI and cholesterol between those who attended those who did not attend at the follow-up, but non-attenders at follow-up had higher baseline blood pressure. Questionnaire data on the non-attenders was available from 2-4 years before the invitation to the follow-up health check. This showed that they were more likely to have suffered stroke, peripheral vascular disease and bronchitis and that they were twice as likely to smoke cigarettes. Attenders were significantly more likely to be married, to own their own home, to have access to a car, and to be educated past the age of 16.

Mortality rates within one year of follow-up were significantly higher among non-attenders than attenders (6.2% vs. 1.7%), though the majority of deaths were non CVD-related. Non-attenders who self-reported having poor or fair health and a disability were significantly less likely to attend for follow-up, as were participants who reported using four or more medications regularly. Furthermore non-attenders were shown to be taking multiple prescribed medications, report more disabling conditions, and had a high early mortality rate.

Key points:

Informed choice invitations are preferable ethically and do not appear to reduce screening uptake

Framing of invitations to screen may affect attendance rates for men and women; where a screening invitation is gender specific, targeting may benefit from framing

Opportunistic screening at visits to GP surgeries for other purposes is shown to be effective

- Evaluation of opportunistic screening confirms that it reaches people with higher CVD risk factors than reached using standard invitations.
- People screened opportunistically showed very similar improvements in assessed risk factors to people invited in other ways

People who do not attend or who drop out at later stages may be different.

- Differences between people who respond to invitations for screening and who do not are difficult to ascertain, but evidence suggests non-attenders have higher CVD risk factors.
- Selective drop out ("selective attrition") biases longitudinal studies in that inevitably people who are less healthy, less well educated, of lower socio-economic status or with more lifestyle risk factors (smoking, higher alcohol consumption, overweight) are more likely to fail to return for follow-up appointments.
- Selective attrition may result in outcomes in longitudinal studies appearing more positive (overestimate of effect) because people who remain in the study are the healthier people
- Careful methodological and statistical controls are needed to reduce resultant effects on findings.

Discussion

This realist review focussed on use of evidence based design features of interventions which aimed to increase uptake of CVD and diabetes screening with a view to increasing early detection and reduction of risk factors for these diseases. Only 12 studies were identified that critically examined the intervention design and tested the efficacy of health behaviour change components, such as feedback, against health outcomes. Key findings include the following: health-related feedback or health dialogue can be effective, but in order to enable specific analyses, a working definition of what this communication entails is required; whether individuals are invited for screening or are screened opportunistically may influence the nature of participants recruited, with those at higher risk less likely to respond to an invitation; and selective attrition of those at higher risk may be skewing results of longitudinal studies because it is the healthier, lower risk patients who are most likely to attend for follow-up.

Impact of behavioural features on quality and outcome of interventions

It is clear from the studies reviewed that consideration of evidenced behavioural features of interventions is limited; in particular, several large UK studies[26,32,33] were excluded from the review at an early stage in the search process because they did not examine any design, behavioural or psychological features of screening or intervention. Nevertheless, the studies included in the review indicate several strategies that could be usefully employed to reduce risk in high risk and general population targets, such as providing opportunistic screening. There was a lack of evidence that intervention design was based on health psychology theory (e.g., Ajzen's theory of planned behaviour,[34] despite research showing that such theories can predict screening attendance,[35] and lifestyle behaviours that are the target of screening interventions,.[36] Even studies that

claimed to be based on theories and target motivation[25] failed to specify the theory base for their intervention. This lack of emphasis on health psychology theories suggests a greater focus on the outcome of the intervention (i.e., did people change their behaviour?) rather than a focus on the motivations and perspectives of the individuals invited to screen. This 'one-size fits all' approach to intervention design is unlikely to yield success as research shows that even in a sample of 10 participants not all of them respond positively to the same interventions.[37] Although there was limited use of health psychology theories in the design of the interventions included in this review, several interventions included elements such as the influence of health dialogue, goal setting and feedback, which have been shown to promote health behaviour change,[38,39] although much of this research has been conducted outside of primary care settings. Therefore, it was encouraging to find that goal setting promoted changes in outcomes in Craigie et al and that feedback was helpful in Aubin et al and Elton et al. These elements require further examination with reference to a behaviour change taxonomy e.g., Abraham and Michie's,[16] to determine whether they are effective within the context of CVD and diabetes screening programmes. Relatedly, an issue highlighted by our evaluation of a CVD screening intervention in the UK,[40] is the extent to which healthcare practitioners use the strategies and tools with which they have been provided in the health dialogues they have with their patients. This issue of intervention fidelity has the potential to differentiate between programmes that are successful in getting patients to change their behaviour and programmes that are not,[41] and is evident in Rubak et al[23] who found that GPs failed to deliver, on average, more than one session of motivational interview to patients, when they were facilitated to deliver three. CERAG's definition of

implementation research: “the scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices in routine practice, and hence to improve the quality (effectiveness, reliability, safety, appropriateness, equity, efficiency) of healthcare” (cited in Eccles et al.[1]) sets this study firmly in the context of implementation science.

Study limitations

This review raised two key challenges. First, studies rarely analyse behavioural components of the intervention design discretely, making it impossible to discern which factors are at work in producing the observed effects. Second, the heterogeneity of outcome measures precludes statistical evaluations using meta-analysis. Publication or outcome bias may have affected our results, though not all included studies found significant reductions in assessed risk or differences in outcomes between intervention and control groups. Several potentially relevant studies that focus on the design of screening interventions were excluded because they were not delivered in healthcare settings. The reviewed studies also highlight the disadvantages of Intention-To-Treat analyses, which are better suited for assessing the efficacy of an intervention in practice as opposed to understanding “how” and “why” and intervention works, and the need to control for selective attrition either by use of features which reduce drop out or by statistical control for known differences between returners and non-returners, but few studies employ this. As a realist review, this document examines outcomes which may be situation specific. The acknowledgement that some findings that may be situation or population specific is important in generalisation of results.

Conclusions and policy implications

This review highlights the need for a more systematic approach to the strategic design, conduct and analysis of health interventions by taking into account the complex interactions between design, delivery, attrition and health outcomes. It is recommended that insights from health psychology should be incorporated in the design of interventions aimed at increasing screening uptake, as well as involving cross-disciplinary specialist areas such as physical activity and nutrition to promote lifestyle behaviour change alongside pharmacological treatment. Furthermore, to control the effects of selective attrition, there is a need to perform sensitivity analyses in order to monitor the make-up of the sample and perhaps some purposive sampling to protect against biasing the sample toward a healthier baseline and therefore reduced effect at follow-up, particularly in longitudinal studies. It is anticipated that such carefully designed interventions would result in health behaviour change that provide as much benefit to the wider population as they do for those with heightened risk, resulting in better overall population outcomes.

What is already known on this topic

Previous reviews have raised concerns about the cost effectiveness of CVD and diabetes screening interventions.

- Some researchers have instead recommended replacement of screening programmes with pharmacological interventions alone, (e.g. prescription of statins to everyone aged 55 or older[42]).
- Other work has illustrated that health behaviour change and intervention effectiveness can significantly reduce CVD risk, controlling for effects of pharmacological intervention.
- Some features of intervention style, and of populations, often result in less than optimum risk reduction.

What this study adds

- **The study confirms the need for and success of strategies that encourage higher risk patients to become and stay involved in screening and intervention programmes, such as opportunistic screening.**
-
- Careful training and monitoring of the use of evidenced behaviour change strategies in improving the reach and success of interventions is needed.
- Ethically supported invitation styles such as fully informed choice do not reduce participation or effect outcome.
- Clear feedback and targeted intervention on specific risk factors or behaviours is supported, whereas general lifestyle advice is less effective.
- Structure of motivational health dialogues and the terms over which they are most successful needs further research.

Contributorship statement:

CH, RS, HP, and RC were responsible for the conception and design of the study. YC had principal responsibility for search and sourcing of articles and initial data extraction, and RC contributed to reference chaining. Two authors (CH, YC) independently reviewed the157 full text papers retrieved, and further excluded studies which only evaluated changes in risk factors or cost-effectiveness. CH and RC assigned quality scores to each included full-text article based on the Scottish Intercollegiate Guidelines Network (SIGN 50) quality assessment instruments. CH had principal responsibility for data extraction, analysis and interpretation of the data and for drafting the article,

revisions, and final approval. RS, HP, and RC contributed to interpretation of the data, revisions and final article approval. CH and RC are the guarantors.

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Competing interest statement

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work other than that outlined under "Funding" above; no other financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years ; no other relationships or activities that could appear to have influenced the submitted work .

Ethical approval: Not required.

Data sharing: No additional data available.

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Table 1. Included Studies

Study	Country	Sample	N	Design	Intervention Component	Main findings	Quality
Aubin 1998[14]	Canada	58% female, mean age 35 years	391	RCT, controls completed questionnaire on intention to eat a low fat diet before they received results of cholesterol screening, intervention participants completed it after	Impact of feedback on behaviour change	Intervention participants were more likely to intend to adopt a low fat diet than controls. Patients with abnormally high cholesterol(≥ 6.3mmol/L) showed a greater reduction in dietary fat intake than those who had a normal cholesterol (<5.2mmol/L)	+
Elton 1994[15]	England	44% female, mean age 37.9 years	469	Prospective, blinded RCT, Intervention participants knew their cholesterol level before the health education	Impact of feedback on behaviour change	Participants whose initial serum cholesterol was ≥ 6.5mmol/L and who had been informed of this, showed a significantly greater	++

				and diet session, control participants did not.		reduction in serum cholesterol than control participants in the same high cholesterol group who had not been informed. All participants received the same dietary advice.	
Färnkvist 2008[16]	Sweden	100% male, age stratified, aged 66, 56 and 46 years.	817	Cross-sectional study. Screening only, Screening plus health dialogue by trained professionals, and non-participants compared.	Benefits of health dialogue over simple feedback	Odds ratios of developing diabetes or CVD over 11 years were 2.5 for those had received screening with no health dialogue and 3.0 for those who had not participated in the original screening, as compared with those who had received screening plus a structured, motivational health dialogue.	+

Engberg 2002[17]	Denmark	52% female, Mean age 40.4 years	1507	RCT, Screening, screening plus health dialogue compared with normal care control group.	Benefits of health dialogue over simple feedback	After 5 years there were no differences between the two intervention groups Total intervention/control Risk Ratio was 0.54. Absolute risk reduction 8.6%.	++
Rubak 2011[18]	Denmark	42% female, Mean age 61 years. Patients with screen detected type 2 diabetes	628	Cluster RCT, Intervention and control groups received training in intensive treatment of Diabetes, intervention group GPs additionally received training in Motivational Interviewing (MI) and instructed to use it.	Benefits of health dialogue over simple feedback	No effect of motivational interview on medication adherence or metabolic status in relative to control group. Medication adherence across both groups almost 100%, both groups showed significant improvements in all risk measures. Key issues were lower than planned use of motivational interview by intervention group GPs, and contamination of	++

						methods and training into control group GPs.	
Koelewijn-van Loon 2010[19]	Netherlands	55% female, Mean age 57 years	615	Cluster RCT, Intervention nurses received training to use risk assessment, communication, a decision support tool and MI. Control group nurses received training on risk assessment and applied usual care.	Benefits of health dialogue over simple feedback	Outcome measures were self-reported lifestyle measures. No differences between control and intervention groups noted at 12 week follow up, but overall both groups showed improvements.	+
Craigie 2011[20]	Scotland	72% female, Mean age 54.5 years, high risk but not on statins.	75	RCT, Intervention – motivational interview and volitional aspects to change planned behaviour, Control group usual care.	Benefits of health dialogue over simple feedback	Percentage achieving 5 portions of fruit and vegetables a day, and weight maintenance or loss indicators were significantly better in the intervention group over the 12 week follow up. Control group	+

						made no positive change.	
Marteau 2010[22]	England	47.6 % female, mean age 57.4 years	1272	RCT, informed choice invitation compared with standard invitation.	Impact of type of invitation on uptake and outcome	Primary outcome of attendance did not differ between groups Secondary outcome of intention to change health behaviour was unaffected by invitation type.	++
Park 2010[23]	England	66.6% male, Mean age 58 years	116	RCT, loss frame compared with gain frame invitation.	Impact of type of invitation on uptake and outcome	Primary outcome of attendance did not differ between groups (invitation types). Secondary outcome measures of anxiety, self-perceived health and Illness representation also did not differ between groups.	++
Hellénius 1998[24]	Sweden	65% female, age range 20-60 years	4904	Observational Cross sectional study, those screened as a result of	Impact of type of invitation on	Opportunistically screened participants showed higher CVD risk factors than letter invited	+

				opportunistic invitations compared with those responding to a letter invitation.	uptake and outcome	participants at baseline. Effectiveness of screening in lowering risk factors did not differ between the two groups.	
Jones 1993[25]	Wales	53.4% female, mean age 42.5 years	2542	Observational cross-sectional study, those not responding to initial invitations to screenings compared with those who did.	Differences between attenders and non-attenders	Non-attenders showed more risk factors than attenders.	+
Thomas 2002[26]	England	100% male, Mean age 69.1 years,	5655	Observational cross sectional study, Health characteristics of those who attended and did not attend a 20 year follow-up were compared.	Differences between attenders and non-attenders	Despite no differences at baseline in BMI and cholesterol, those who later dropped out of a longitudinal study had higher blood pressure at baseline and greater number of CVD and bronchial diagnoses, and	+

						adverse lifestyle factors (e.g. OR of smoking in non-attenders 2.33).	

Note. SIGN 50 cohort checklist used to assess study quality. ++ = High quality study, + = Acceptable, 0 = Unacceptable.

Appendix 1. Search terms used in search strategy

The following terms were used in all data sources: (cardiovascular OR vascular OR CVD OR “chronic heart disease” OR “coronary heart disease” OR CHD OR diabetes) AND (“mass screening” OR surveillance*) AND (letter OR mail* OR phone OR telephone OR “reminder system*” OR “videotape recording*” OR “audiotape recording*” OR questionnaire* OR strateg* OR alert* OR hotline OR community OR media) AND (intervention* OR goal OR “behav* change” OR “implementation intention*” OR plans OR planned OR planning OR plan OR educat* OR campaign* OR barriers OR intention* OR “behav* outcome” OR outcome OR “lifestyle change” OR longitudinal OR “follow up” OR motivation*) AND (satisf* OR dropout* OR “drop out” OR attrition OR uptak* OR adher* OR compliance OR complie* OR comply* OR “patient acceptance of health care” OR encourag* OR improve* OR improving OR increas* OR promot* OR particip* OR nonattend* OR “non attend” OR accept* OR attend* OR attitud* OR utilisation OR utilization OR refus* OR respond* OR respons* OR reluctan* OR nonrespon* OR “non respon*” OR incidence OR prevalence OR prevelence OR satisfaction OR cooperat* OR “co operat*”) AND (findings OR interview* OR qualitative OR experienc* OR RCT OR “randomised controlled trial” OR trial).

PRISMA checklist

Table 1

Checklist of items to include when reporting a systematic review or meta-analysis

Section/topic	Item No	Checklist item	Reported on page No
Title **Effectiveness and uptake of screening programmes for coronary heart disease and diabetes: A realist review of design components used in interventions**			
Title	1	Identify the report as a systematic review, meta-analysis, or both	Realist review, P2
Abstract			
Structured summary	2	Provide a structured summary including, as applicable, background, objectives, data sources, study eligibility criteria, participants, interventions, study appraisal and synthesis methods, results, limitations, conclusions and implications of key findings, systematic review registration number	2-3
Introduction			
Rationale	3	Describe the rationale for the review in the context of what is already known	7-8
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS)	8
Methods			
Protocol and	5	Indicate if a review protocol exists, if and where it can be accessed (such as web address), and, if available, provide registration information including	N/A

Section/topic	Item No	Checklist item	Reported on page No
registration		registration number	
Eligibility criteria	6	Specify study characteristics (such as PICOS, length of follow-up) and report characteristics (such as years considered, language, publication status) used as criteria for eligibility, giving rationale	10-11
Information sources	7	Describe all information sources (such as databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched	9-10
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated	Appendix 1, p46
Study selection	9	State the process for selecting studies (that is, screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis)	10-11
Data collection process	10	Describe method of data extraction from reports (such as piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators	11-13
Data items	11	List and define all variables for which data were sought (such as PICOS, funding sources) and any assumptions and simplifications made	11-13
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis	13
Summary measures	13	State the principal summary measures (such as risk ratio, difference in means).	Table 39-43
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (such as I^2 statistic) for each meta-analysis	N/A

Section/topic	Item No	Checklist item	Reported on page No
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (such as publication bias, selective reporting within studies)	13
Additional analyses	16	Describe methods of additional analyses (such as sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified	N/A
Results			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram	10, flow diagram in this supplementary file
Study characteristics	18	For each study, present characteristics for which data were extracted (such as study size, PICOS, follow-up period) and provide the citations	Table 1, pages 39-43
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome-level assessment (see item 12).	Included in SIGN 50, see Table 1.
Results of individual studies	20	For all outcomes considered (benefits or harms), present for each study (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a forest plot	Table 1, 39-43, main findings presented, but standard summary data not possible
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see item 15)	29
Additional analysis	23	Give results of additional analyses, if done (such as sensitivity or subgroup analyses, meta-regression) (see item 16)	N/A

Section/topic	Item No	Checklist item	Reported on page No
Discussion			
Summary of evidence	24	Summarise the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (such as health care providers, users, and policy makers)	Summary boxes pp21,26,31 policy implications, p23
Limitations	25	Discuss limitations at study and outcome level (such as risk of bias), and at review level (such as incomplete retrieval of identified research, reporting bias)	5-6, 29
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research	30
Funding			
Funding	27	Describe sources of funding for the systematic review and other support (such as supply of data) and role of funders for the systematic review	32

Effectiveness and uptake of screening programmes for coronary heart disease and diabetes: A realist review of design components used in interventions.

Short title: Effectiveness and uptake of screening programmes

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Word count (excl. abstract, summary, refs, table, boxes) (5938)

1 Table

Abstract

Objective

To evaluate behavioural components and strategies associated with increased uptake and effectiveness of screening for coronary heart disease (CHD) and diabetes, with an implementation science focus.

Design

Realist review.

Data sources

PubMed, Web of Knowledge, Cochrane Database of Systematic Reviews, Cochrane Controlled Trials Register and reference chaining. Searches limited to English language studies published since 1990.

Eligibility criteria

Eligible studies evaluated interventions designed to increase uptake of CVD and diabetes screening and examined behavioural and/or strategic designs. Studies were excluded if they evaluated changes in risk factors or cost-effectiveness only.

Results

In 12 eligible studies, several different intervention designs and evidence based strategies were evaluated. Salient themes were effects of feedback on behaviour change, or benefits of health dialogues over simple feedback. Studies provide mixed evidence about benefits of these intervention constituents which are suggested to be

situation and design specific, broadly supporting their use, but highlighting concerns about fidelity of intervention delivery, raising implementation science issues.[1,2] Three studies examined effects of informed choice, or loss versus gain frame invitations, finding no effect on screening uptake, but highlighting opportunistic screening as more successful for recruiting higher CVD and diabetes risk patients than invitation letter, with no differences in outcomes once recruited. Two studies examined differences between attenders and non-attenders, finding higher risk factors amongst non-attenders, and higher diagnosed CVD and diabetes amongst those who later dropped out of longitudinal studies.

Conclusions

If risk and prevalence of these diseases are to be reduced, interventions must take into account what we know about effective health behaviour change mechanisms, monitor delivery by trained professionals, and examine the possibility of tailoring programmes according to contexts such as risk level to reach those most in need. Further research is needed to determine the best strategies for lifelong approaches to screening.

Article Summary

- 1) Article Focus: The primary objective of this realist review was to evaluate the impact on health and attendance outcomes of theoretically supported behaviour change features embedded within intervention designs of screening programmes targeting CHD and diabetes.

- A secondary objective was to evaluate factors predicting attendance and attrition from these programmes and appraise their impact, with implications for design in specific contexts.

2) Key Messages

- The benefits of a structured, motivational health dialogue, with feedback, are supported over simple screening and advice, where outcomes are measured long term. Structure of motivational health dialogues and the terms over which they are most successful needs further research

- However, the issue of intervention fidelity (adherence to intervention protocol by those delivering) has potential to differentiate between programmes that are or are not successful in getting patients to change health behaviour and as such represents a key implementation science component of the review.

- This review highlights the need for a more systematic approach to using the evidence base for strategic design, conduct and analysis of health interventions

by taking into account the complex interactions between design, delivery, attrition, context and health outcomes.

3) Strengths and Limitations.

Strengths:

- The study's strength is its focus on what contributes to success and reach of screening plus intervention studies, based on health psychology evidence.
- Its evaluation of the degree and fidelity with which evidenced health behaviour strategies are used has important implications for practitioners managing screening and intervention programmes.
- Evaluation of opportunistic screening confirms previous work showing that it reaches people with higher CVD risk factors than reached using standard invitations, but additionally demonstrates that people screened opportunistically show very similar improvements in assessed risk factors and behaviours to people invited in other ways.

Limitations:

- This review raised two key challenges. First, many studies do not analyse behavioural components of the intervention design discretely, making it impossible to discern which factors are at work in producing the observed effects. Second, the heterogeneity of outcome measures precludes statistical evaluations using meta-analysis.

- Publication or outcome bias may have affected our results, though not all included studies found significant reductions in assessed risk or differences in outcomes between intervention and control groups.

- Several potentially relevant studies focusing on design of screening interventions were excluded because they were not delivered in healthcare settings.

- Well-known selective drop out ("selective attrition") biases are confirmed in these studies, whereby people with more lifestyle risk factors (smoking, higher alcohol consumption, overweight) are more likely to fail to return for follow-up appointments. Careful methodological and statistical controls are needed to reduce resultant effects on findings, but few studies employ these.

- As a realist review, this document examines outcomes which may be situation specific. The acknowledgement that some findings that may be situation specific is important in generalisation of results.

Introduction

Previous reviews of multiple risk factor interventions for primary prevention of coronary heart disease (CHD) and diabetes often conclude that interventions have no overall effect on mortality.[3] Nevertheless, CHD deaths have halved in the UK and other developed countries in the last 30 years.[4] Unal et al[5] compared targeted interventions and general population screening. They estimated the proportion of reduced deaths from CHD in England and Wales between 1981 and 2000 that were attributable to changes in risk factors in patients with CHD or changes in cardiovascular risk factors in the general population, and found both approaches beneficial. These authors calculated that reductions in risk factors (such as smoking, high blood pressure) in the general population account for 50-75% of the fall in cardiac deaths, and pharmacological and surgical treatments for diagnosed CHD patients account for 25-50%.[5] However, that benefit was greater when individuals without CHD were screened: results indicated an additional 21 years of life for each death prevented in those with no CHD diagnosis compared to 7.5 years for those with CHD.

Public health campaigns to reduce these conditions usually involve: government-sponsored programmes at the population level or changes in policy (such as food labelling legislation); targeted interventions for those at heightened risk (for example, moderate-intensity, low-impact exercise for those very overweight or with chronic conditions); or general population screening and intervention to reduce risk development in the healthy population and identify high risk people leading to specific referral for detected or previously untreated symptoms (for example, current NHS Health Check[6] programme).

This review focuses on quantitative evaluations of screening plus intervention programmes that target the general population to reduce incidence of CHD and diabetes. These conditions were selected because they are the focus of screening programmes in many countries and the negative outcomes of these conditions can be ameliorated by lifestyle behaviour change. Previous reviews have focussed on reductions in risk measurements, cost effectiveness, or years of life added.[3] In contrast, the primary objective of this review was to examine use of behaviour change features embedded within intervention designs of screening programmes targeting CHD and diabetes, and their impact on health outcomes. A secondary objective was to evaluate the factors predicting attendance and attrition from these programmes.

These objectives are not well-suited to systematic review and meta-analysis approaches, where the aim is to synthesise results across contexts to gain a sense of the pattern of results for studies conducted using similar methodologies. In contrast, the present paper is focused on questions around “how” and “why” behavioural features are incorporated into interventions, and how these features can contribute to the success of interventions. Therefore, we adopted a realist review, also called a meta-narrative approach. This approach was adopted to gain insights into the direction the evidence is pointing and the underlying theoretically driven concepts, behaviour change mechanisms, and barriers, that may combine to contribute to outcomes in population screening for CHD and diabetes.[7] Focus on the mechanisms and use of evidence based behaviour change strategies locate the review within an implementation science approach, given that “one of the most consistent findings from clinical and health services research is the failure to translate research into practice and policy” p1.[2]

A realist methodology[8] is suited to areas where there is a diverse literature, which may have a variety of methods, components and outcomes. This methodology is concerned with explaining more fully the processes of interventions within the complexity of their contexts, rather than focussing on simple cause and effect deterministic theories. Realist reviews can "contribute to programme understandings even when the outcomes are not rigidly defined at the outset of the review and have been characterised as a theory-driven and interpretive approach to systematic reviews to answer questions about what works, for whom and in what circumstances" p4.[9]

Inclusion of studies in a realist review is intended to be less proscribed than in a systematic review to allow for a mix of methods and outcomes to be included, ensuring that underlying theories and approaches can be evaluated rather than a focus on specific measured outcomes.[8] Inclusion criteria in this review of screening plus intervention studies were generated using guidance from systematic reviews on screening (PRISMA), [10] but were further generated iteratively using the themes that emerged. The flowchart and checklist are available as supplementary material.

Data sources

Web of Knowledge, PubMed, Cochrane Database of Systematic Reviews, Cochrane Controlled Trials Register restricted to English language and published post 1990. Reference chaining of identified studies was then conducted.

Search strategy

Search terms were adapted from previous Cochrane reviews of screening plus uptake studies.[11,12] The full strategy is available in Appendix 1. The search was first carried out in July 2010 and updated in March 2013.

Study selection

The initial inclusion criteria were: studies that tested interventions designed to increase uptake of CHD and diabetes screening programmes, or to increase early detection and prevention of these conditions *and* examined the behavioural and/or strategic design of the intervention tested. Studies which only reported on changes in risk factors or cost-effectiveness were excluded.

The initial search elicited 2323 relevant published papers. Retrieved papers were screened according to the inclusion criteria. Details of screening and exclusion stages are detailed in Figure 1 in the supplementary material.

Following screening of titles, 565 relevant papers remained. Reference lists and citations of these papers were searched (using Pubmed and Web of Knowledge) specifically to identify studies that evaluated behavioural aspects of interventions tested; a pragmatic approach was taken to ensure that articles which may not have been found using such traditional chaining were not missed, in that new keywords elicited from themes of identified articles were added to the search, notably on specific behavioural approaches. An example was “informed choice invitation”. This process identified a further 16 articles. Following removal of duplicates across sources (120), and removal after abstract screening (304), two authors (CH, YC) independently reviewed 157 full text papers, and further excluded studies which only evaluated changes in risk factors

or cost-effectiveness. Further exclusions at abstract and full text stages were guided by framing of the interventions into their constituent components using PICO(T) categories (Population, Intervention, Comparison, Outcome and Type of study design). The review was concerned with general population (adult) screening, and so interventions that considered only those already identified as at high risk of CVD/Diabetes or already receiving treatment, younger or specific age or disease limited groups, were excluded. Although initial reading included interventions in a variety of settings, the selection of the final set of papers restricted inclusion to studies set in primary health care in line with the aim of this review being to inform primary health care based interventions. Comparison with a control group of some nature was necessary for inclusion, and although most of the identified studies did consist of Randomised or Cluster Randomised Control Trials, other designs were not excluded, and the relevant quality appraisal criteria for the different designs were used as appropriate (See Table 1). Although most of the studies examined outcomes in terms of successful or unsuccessful lowering of CVD or diabetic risk, the intention of this review was to determine “how, why and what works” or what may prevent it working[8], so outcome type was not restricted.

Preliminary examination of studies sought to extract dominant themes reflecting the behavioural features of the “how and why” such interventions succeed or fail in reducing CVD or Diabetic risk. Most studies examined the effect of a multi-component intervention, in which key features were engaging populations in screening, providing screened populations with feedback about risk status, a health dialogue (defined as counselling that includes aspects of shared decision making such as goal setting or intention formation, and is not just information giving or psychological support),

information about the impact of risk factors on illness development, counselling, motivational interviewing, referral, and pharmacological treatment. The impact of feedback and health dialogue on health outcomes was reported but due to the multiple constituents of interventions, isolating the effects of any one feature is often difficult. Search for studies that focused on explicitly examining such features therefore developed. Twelve studies were left that fulfilled this requirement and met inclusion criteria. Details of the components covered by these papers, year of publication, details of the samples recruited, populations studied and main findings are presented in Table 1. The selection process is summarized in a PRISMA flow diagram (supplementary materials).

Data extraction

Two reviewers (CH and YC) independently extracted information from each article, and one author (CH) reviewed all studies. Data were extracted on study authors, geographical location, year of publication, study cohort characteristics, behavioural design features of the intervention, and outcome measures (see Table 1).

Results

Study characteristics and quality

The SIGN 50 assessment of quality of studies included is summarised in Table 1. Two authors (CH and RC) independently rated each included study for quality using the SIGN 50 guidelines,[13] with each study rated as either ++ = high quality, + = acceptable quality or 0 = low quality. After independent ratings the authors met to discuss their ratings. All disagreements were resolved via discussion. Seven studies were of

acceptable quality and five were high quality studies. The key elements of the studies were summarised into Table 1, so that key themes and evidence from the papers could be identified and extracted for examination.

The review of included papers begins by describing studies that addressed the question of what impact behaviour change features embedded within intervention designs of CVD and diabetes screening programmes have on health outcomes. The review then proceeds to cover literature that evaluates the factors predicting attendance and attrition from screening and intervention programmes.

Impact of feedback on behaviour change

Providing people with feedback on their behaviour can prompt behaviour change,[14,15] and has been recognised as an effective behaviour change technique in Abraham and Michie's behaviour change taxonomy.[16,17] In general, there are two types of feedback: informing patients about their risk status, e.g. of CVD; and giving patients behaviour-specific feedback, e.g. discussion related to detailed dietary analysis[18], with a key point of contention being the effectiveness and practicalities of these two approaches Two studies examined the impact of feedback on behaviour change.

Aubin et al[19] investigated whether knowledge of blood cholesterol level affected intention to adopt a low fat diet. The study was conducted in hospital-based family medical centres in Quebec, Canada. Participants were randomly assigned to complete a questionnaire about CVD risk profile, intention to adopt a low fat diet, and dietary fat

intake either before or after receiving their screening results, i.e. one group knew their results, and one did not at the time of completing the questionnaire. Patients who were aware of their blood screening results before they completed the questionnaire showed a significantly higher intention to adopt a lower fat diet than patients who were not ($F_{1,417}$ = 5.4, p<0.02). In addition, in those who had received their results, intention tended to rise with blood cholesterol level (non-significant, $F_{5,413}$= 2.0, p<0.08).

Three months after screening, participants' dietary fat intake and changes in eating habits were assessed by comparing diet with that reported at baseline. Data for 391 participants (mean age = 35 years) were analysed. Mean dietary fat intake significantly reduced from 48.5g per day at baseline, to 37.7g per day at three month follow-up for the participant group as a whole. After three months, patients who had abnormal cholesterol levels had a significantly greater reduction in dietary fat intake than patients with normal cholesterol results ($F_{(2,388)}$ = 3.6, p = 0.03); correlational analysis showed a highly significant link between reduction in fat intake and reduction in blood cholesterol (the researchers report an R^2 of 0.5, p=0.001, but confirmed by email that a Pearson's correlation was intended). This shows that patients who had higher blood cholesterol were more likely to make dietary changes. Although the method and analysis did not separate out people who were aware of their cholesterol levels in the longitudinal comparisons, the authors concluded that informing patients of their blood cholesterol levels effects an immediate change in dietary habits, and that over all, the change in dietary habits effects a reduction in fat intake and lower CVD risk.

Elton et al[20] used a workplace screening and intervention trial in Manchester, UK to examine if knowledge of cholesterol level led to a reduction in cholesterol over a thirteen week period. Participants were randomly allocated to either an intervention group that received information on their current cholesterol level, or to a control group where this information was not provided. Then all participants attended a health education session about diet. The results demonstrated that the reduction in cholesterol measurements thirteen weeks after baseline was greater in intervention participants with initially high (>6.5mmol/l) serum cholesterol than in matched control participants (change of -0.29 for intervention participants, 95% CI -0.48 to -0.11, but only a change of -0.01, 95% CI -0.16 to +0.15 for controls, difference between groups reached significance at $p<0.024$). A key difference between this and an earlier study[18] which had not shown an effect of informing participants of their cholesterol level was that the interventions specifically focussed on diet here, whereas the earlier study delivered a general health education package.

Impact of health dialogue on behaviour change

Five studies examined the role of health dialogue in influencing health outcomes of screening interventions.[21-25] Färnkvist et al[21] investigated the extent to which health screening with or without health dialogue influenced self-reported CVD and diabetes morbidity 11 years post-screening. Participants were men aged 35-55 years in Härnösand, Sweden. Screening included objective measurements (e.g. blood pressure), a self-report questionnaire, and health counselling provided by nurses. Although described alternately as health dialogue and counselling in this study, it did actually consist of a structured motivational dialogue that included discussion of the

individual's CVD risk, and possible lifestyle changes, and hence fulfils our definition of a health dialogue. Other healthcare providers in the same community (mainly occupational health services; OHS) carried out the same screening but without the health dialogue.

Eleven years later participants were asked to complete a questionnaire including questions about smoking, alcohol, physical activity, height, weight, fat intake and the presence of CVD and/or diabetes. There was no significant decline in health during the 11 years for those participants who received the screening plus health dialogue (8.2% incidence of CVD and/or diabetes), in stark contrast to those who received screening only (22.6% incidence) or no screening (19.2%). The odds ratios (OR) of developing CVD or diabetes over the 11 years was 2.5 for those who had screening with no health dialogue, and 3.0 for those who had not participated in either the original screening or the dialogue, as compared with the dialogue group. That is, the risk was more than doubled for any group who had not received the dialogue. The authors concluded that screening that includes a structured, motivational health dialogue is more effective than screening without this dialogue.

Engberg et al[22] conducted a RCT in Denmark investigating the impact of general health screening versus screening plus GP-patient discussions about CVD risk profile. Randomly selected men aged 30-50 from several GP practices were sent an invitation letter and postal questionnaire about lifestyle. Those who agreed to take part completed a second questionnaire asking about their health, lifestyle, psychosocial status and life

events. Participants were randomised to a control group (questionnaire only, no screening) or one of two intervention groups: screening only and screening plus health discussions (time points not given). Participants in the health screening plus discussion group were offered a 45-minute consultation with their GP to discuss their results and how to adapt to a healthier lifestyle. They were encouraged to set their own topics for discussion and to set health-related lifestyle goals to achieve within the next year. These participants were offered further discussions annually for five years. Randomisation to groups was stratified based on the GP to whom they were registered, age, sex, BMI and "cohabitation status". All screened participants received personal written feedback from their GPs, including advice on lifestyle change (where necessary) and information leaflets about a healthy lifestyle. All participants were followed up at 1 and 5 years.

At the 5 year follow-up, there were no significant differences in measures of CVD risk factors between the two intervention groups (screening only versus screening plus discussion). Taken together, however, these two intervention groups had a much lower proportion of patients with elevated CVD risk scores than the control group, whose prevalence of elevated CVD risk was approximately twice that of the intervention groups (RR = 0.54, 95% CI = 0.40-0.73). However, there were no significant differences between the control and intervention groups for blood pressure, and no effects on smoking. The authors concluded that though the intervention as a whole had a marked effect on CVD risk, the discussions did not improve the cardiovascular health of participants over and above the improvement shown from screening with feedback.

Rubak et al[23] examined the difference in patient outcomes (improved metabolic status in patients with diabetes) between those whose GPs had received training in motivational interviewing and those whose GPs had been allocated to a control group. Both groups of GPs received training in intensive treatment of Type 2 Diabetes. The study found that patients with GPs in both groups showed significant improvements, with no difference between the groups at one year follow-up. One explanation for the lack of difference found is that GPs in the motivational interview group had used an average of less than 2 of the 3 motivational interview sessions allocated to them. The authors suggest that some contamination of effect may have occurred, in that the control group GPs also became aware of MI, and that the GPs in the motivational interview group did not use it as much as had been recommended.

Koelewijn-van Loon et al[24] investigated differences between participants who had a structured dialogue with a trained nurse (including risk assessment, risk communication, motivational interview and a patient "decision support tool") and patients who received usual care. Outcome measures were self-reported lifestyle behaviours, diet, exercise, smoking and alcohol use, which were measured 12 weeks after baseline to assess change. 522 patients completed the follow-up measures. The authors concluded that the results showed an improvement in lifestyle in both groups; there were no differences between groups in terms of effects.

Craigie et al[25] examined the impact of a personalised lifestyle programme (HealthForce) aimed at promoting lifestyle behaviour change and based specifically on health behaviour change theory. HealthForce targeted motivational elements to create intentions to change behaviour and volitional elements, focussing on translating

intentions into planned behaviours. It involved patients attending three face-to-face sessions with a trained lifestyle counsellor, plus other materials, with topics being activity, diet and weight management. The outcome assessments all showed significant positive changes for the intervention group (all $p<0.01$), with no positive, but some negative changes for the control group. Consumption of 5 portions of fruit and vegetables a day went from 56% to 85% for the intervention group; weight was down by an average of 1.1kg, BMI went from a mean of 26.7 to 26.2kg/m^2 (with increases, rather than decreases, for the control group, $p<0.01$) and waist circumference went from 87.3 to 84.0cm (no significant change for control group).

The contrast between these five similar studies is striking; Färnkvist et al and Craigie et al's analyses supported the impact of health dialogue, Engberg et al found that screening plus verbal health dialogue was not superior to screening that included a written dialogue, while Rubak et al and Koelewijn-van Loon et al found no effect. However, the outcome measures, and time between measurements, vary across studies; Färnkvist et al compared risk of CVD and diabetes diagnosis over 11 years, Engberg et al assessed differences between groups in risk factors five years after initial screening, Rubak et al tested metabolic status in patients with diabetes after one year, Koelewijn-van Loon et al compared self-reports of lifestyle behaviours 12 weeks after the intervention, and Craigie et al compared anthropometric and health behaviour changes12 weeks later. This raises a number of issues. First, endpoint diagnosis is the most objective measure of the impact of intervention, and the strongest evidence of efficacy. Second, in general, longer-term follow-ups are preferable, however selective attrition could be a greater issue for longer-term follow-ups, biasing the sample.

Conversely, shorter-term follow-ups may not allow enough time for change to happen. Finally, these studies, though conducted with similar samples, were run in four different countries with subsequent differences in healthcare services and risk levels at baseline, and so conclusions need to take into account the healthcare context when assessing the mechanisms and outcomes.[8]

Of particular interest were the two studies (Craigie et al and Koelewijn-van Loon et al) which both used self-reported behavioural outcomes and a 12 week follow-up and yet had contradictory results. Both included face to face counselling on more than one occasion, telephone support sessions, and motivational interview plus decision support or goal setting. The most obvious difference is that patients in Craigie et al's study were all pre-selected as high risk (but not on statins), whereas only 28% of those in Koelewijn-van Loon et al's study were designated as high CVD risk. Indeed the latter study did find a difference between intervention and control groups in fruit and vegetable consumption when only those with diagnosed diabetes were included. As in previous analyses, the difference seems to be due to the finding that those with higher perceived risk are more likely to make appropriate changes to their health behaviour. Again context is highlighted, but here in terms of the individuals one is trying to influence.

Key points:

Providing patients with feedback on screened measurements can promote changes in behavioural intentions and actual health behaviour change.

The benefits of a structured, motivational health dialogue are supported over simple screening where outcomes are measured long term, but the actual structure of such dialogues has not been directly analysed in the literature.

The comparison of similar studies highlights the need for a set of basic standardised measures.

Comparisons suggest that longer term influences on disease occurrence need assessing.

Patients informed they are at high risk tend to make the most lifestyle changes and achieve the most positive outcomes

Factors predicting uptake, attendance and attrition from screening programmes

Uptake and invitation

For screening programmes to be cost-effective it is essential to maintain high levels of uptake, attendance and avoid excessive attrition. Research[21] has demonstrated that some groups, for example, the less healthy, are less likely to participate in screening programmes, and more likely to drop out if they do commence participation. Attempts have been made to encourage uptake of screening by manipulating the method of invitation: three studies examined the effect of invitation style on uptake and health outcome.[27-29]

Marteau et al[27] hypothesised that providing an informed choice leaflet lower attendance relative to standard invitations, because individuals receiving the leaflet would see that screening is unlikely to provide individual benefits. The authors found no difference in attendance rates between individuals who received an informed choice letter versus a standard letter, but they did replicate previous studies in finding that attendance fell with increasing social deprivation. There was no interaction between social deprivation and invitation type, however, the authors concluded that the ethical advantage gained in informed choice invitations did not outweigh the attendance benefit of standard invitations.

Park et al[28] investigated the effects of loss- and gain-framed messages in an invitation to screen for Type 2 diabetes. The loss frame message ("If you have diabetes but are not detected early, your diabetes may lead to more complications") highlights the possible losses due to not attending; the gain frame message ("If your diabetes is detected early, you can receive early and more effective treatment") emphasises the possible gains of attending. Participants, aged 40-69 years, were randomly selected from two GP practices in Cambridgeshire, England. Fifty-nine patients were randomised to receive the loss-framed invitation and 57 the gain-frame. All invitations included a neutral framed message ("A simple blood test is the best way to detect diabetes").

There were no significant differences in attendance rates between groups (loss-frame = 81% vs gain-frame = 82%). Overall, results show that how information was framed made little difference to attendance rates. There was, however, a significant interaction effect between sex and invitation frame; attendance was higher in men invited using the loss-frame (89%) compared to the gain-frame (77%), and higher in women invited using the gain-frame (94%) compared to the loss-frame (68%). Although this result should be viewed with caution because of the small numbers, it does suggest potential for using different frames for different patient groups.

In addition to investigating the content and format of invitation letters, researchers have also examined the potential of opportunistic screening that is asking patients to complete screening while they are attending a healthcare setting for another purpose, such as collecting medication. Hellénius et al[29] investigated opportunistic screening on visits to a healthcare centre for other purposes in a suburban area of Sweden

(Sollentuna). Male and female adults under the age of 60 who visited health centres were opportunistically invited to screening. This group was compared with a group who were invited by letter. 59% of those invited by letter participated (249 people) compared to 15% of the men and 20% of the women who were invited when they visited their health centres (4655 people, the opportunistic sample). Frequency of hypertension, high cholesterol, high triglycerides were greater in the opportunistic sample than the letter-invited sample, but there were no differences in smoking or likelihood of being overweight. Outcomes of the intervention showed significant blood pressure, cholesterol, and triglyceride reductions, but no differences in the level of reductions in risk factors between opportunistic and letter-invited participants. The authors concluded that the integration of a large scale CVD risk screening programme into a regular primary healthcare system was successful, and that, taking into account low uptake, opportunistically screening patients was successful in identifying those with high CVD risk factors whose risk factor level could be reduced.

Difference between attenders and non-attenders

It has been noted that differences exist between individuals who attend screening and those who do not[26] and our search strategy identified two papers on this topic. Jones et al[30] recruited 3800 patients (aged 25-55 years) across six GP practices in Wales who were invited for a CHD risk factor screening programme. 2402 (63.2%) attended for screening, 1389 (36.8%) did not attend. A 1 in 10 random sample of 140 non-attenders was obtained, using a further letter offering them a medical “MOT” with specific reference made to heart disease and asking them to make an appointment any morning or afternoon. (MOT is an annual car maintenance test which is legally required by the

Ministry of Transport for cars on UK public roads, a term which is very familiar in the UK.) After three weeks any persisting non-respondents were sent another letter including a specific appointment time, asking them to contact the surgery if this was not convenient. A final contact was made by telephone after a further three weeks, and the nurse visited the home for the appointment if necessary. This approach resulted in 98 (70.0%) of the original non-attenders being screened. They were asked to indicate reasons for their initial non-attendance. Reasons (in order of frequency) were: invitation letter not received (36.7%); 'practical reasons' (26.5%); felt screening was unnecessary because they were feeling well (18.4%); already under medical care for CHD related issues (12.2%); already aware of having risk factors and so felt screening was unnecessary (10.2%); felt apathetic about screening (10.2%); afraid of screening (7.1%); forgot to attend appointment (4.1%).

Non-attenders were significantly older than attenders (mean age 42.6 years and 39.4 years respectively; $p<0.001$, 95% CI of difference 1.50, 4.88). They were more likely to have lower SES than attenders and more likely to have a personal history of CHD (12% versus 5.7%, $p<0.05$). In addition, mean BMI ($p<0.01$; 95% CI 0.84, 2.58), cholesterol ($p<0.01$, 95% CI 0.26, 0.74), and blood pressure (systolic $p<0.001$; 95% CI 9.57,15.86; diastolic $p<0.01$; 95% CI 1.63, 5.82) were significantly higher for non-attenders than attenders. These results show that those people most in need of healthcare are less likely to access it. However, it is also clear that approximately 22% of non-attenders did not attend because they were already under medical care for CHD issues or were already aware of their risk factors (no data for attenders), possibly influencing the

outcome differences between attenders and non-attenders, and potentially reducing the likelihood of these individuals responding to an invitation to screening.

A further issue of non-attendance is that of differences between people who continue in a programme once started, and those who drop out. Thomas et al[31] examined the characteristics of attenders and non-attenders at the 20-year follow-up screening in the British Regional Heart Study. The non-attenders referred to here were all people who had attended originally, but failed to return for re-assessment, i.e. had dropped out. A total of 7735 men took part in the original screening, and 4252 (77%) attended the follow-up. There were no significant differences at baseline in age, BMI and cholesterol between those who attended those who did not attend at the follow-up, but non-attenders at follow-up had higher baseline blood pressure. Questionnaire data on the non-attenders was available from 2-4 years before the invitation to the follow-up health check. This showed that they were more likely to have suffered stroke, peripheral vascular disease and bronchitis and that they were twice as likely to smoke cigarettes. Attenders were significantly more likely to be married, to own their own home, to have access to a car, and to be educated past the age of 16.

Mortality rates within one year of follow-up were significantly higher among non-attenders than attenders (6.2% vs. 1.7%), though the majority of deaths were non CVD-related. Non-attenders who self-reported having poor or fair health and a disability were significantly less likely to attend for follow-up, as were participants who reported using four or more medications regularly. Furthermore non-attenders were shown to be taking multiple prescribed medications, report more disabling conditions, and had a high early mortality rate.

Key points:

Informed choice invitations are preferable ethically and do not appear to reduce screening uptake

Framing of invitations to screen may affect attendance rates for men and women; where a screening invitation is gender specific, targeting may benefit from framing

Opportunistic screening at visits to GP surgeries for other purposes is shown to be effective

- Evaluation of opportunistic screening confirms that it reaches people with higher CVD risk factors than reached using standard invitations.
- People screened opportunistically showed very similar improvements in assessed risk factors to people invited in other ways

People who do not attend or who drop out at later stages may be different.

- Differences between people who respond to invitations for screening and who do not are difficult to ascertain, but evidence suggests non-attenders have higher CVD risk factors.
- Selective drop out ("selective attrition") biases longitudinal studies in that inevitably people who are less healthy, less well educated, of lower socio-economic status or with more lifestyle risk factors (smoking, higher alcohol consumption, overweight) are more likely to fail to return for follow-up appointments.
- Selective attrition may result in outcomes in longitudinal studies appearing more positive (overestimate of effect) because people who remain in the study are the healthier people
- Careful methodological and statistical controls are needed to reduce resultant effects on findings.

Discussion

This realist review focussed on use of evidence based design features of interventions which aimed to increase uptake of CVD and diabetes screening with a view to increasing early detection and reduction of risk factors for these diseases. Only 12 studies were identified that critically examined the intervention design and tested the efficacy of health behaviour change components, such as feedback, against health outcomes. Key findings include the following: health-related feedback or health dialogue can be effective, but in order to enable specific analyses, a working definition of what

this communication entails is required; whether individuals are invited for screening or are screened opportunistically may influence the nature of participants recruited, with those at higher risk less likely to respond to an invitation; and selective attrition of those at higher risk may be skewing results of longitudinal studies because it is the healthier, lower risk patients who are most likely to attend for follow-up.

Impact of behavioural features on quality and outcome of interventions

It is clear from the studies reviewed that consideration of evidenced behavioural features of interventions is limited; in particular, several large UK studies[26,32,33] were excluded from the review at an early stage in the search process because they did not examine any design, behavioural or psychological features of screening or intervention. Nevertheless, the studies included in the review indicate several strategies that could be usefully employed to reduce risk in high risk and general population targets, such as providing opportunistic screening. There was a lack of evidence that intervention design was based on health psychology theory (e.g., Ajzen's theory of planned behaviour,[34] despite research showing that such theories can predict screening attendance,[35] and lifestyle behaviours that are the target of screening interventions,.[36] Even studies that claimed to be based on theories and target motivation[25] failed to specify the theory base for their intervention. This lack of emphasis on health psychology theories suggests a greater focus on the outcome of the intervention (i.e., did people change their behaviour?) rather than a focus on the motivations and perspectives of the individuals invited to screen. This 'one-size fits all' approach to intervention design is unlikely to yield success as research shows that even in a sample of 10 participants not all of them respond positively to the same interventions.[37] Although there was limited use of

health psychology theories in the design of the interventions included in this review, several interventions included elements such as the influence of health dialogue, goal setting and feedback, which have been shown to promote health behaviour change,[38,39] although much of this research has been conducted outside of primary care settings. Therefore, it was encouraging to find that goal setting promoted changes in outcomes in Craigie et al and that feedback was helpful in Aubin et al and Elton et al. These elements require further examination with reference to a behaviour change taxonomy e.g., Abraham and Michie's,[16] to determine whether they are effective within the context of CVD and diabetes screening programmes. Relatedly, an issue highlighted by our evaluation of a CVD screening intervention in the UK,[40] is the extent to which healthcare practitioners use the strategies and tools with which they have been provided in the health dialogues they have with their patients. This issue of intervention fidelity has the potential to differentiate between programmes that are successful in getting patients to change their behaviour and programmes that are not,[41] and is evident in Rubak et al[23] who found that GPs failed to deliver, on average, more than one session of motivational interview to patients, when they were facilitated to deliver three. CERAG's definition of implementation research: "the scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices in routine practice, and hence to improve the quality (effectiveness, reliability, safety, appropriateness, equity, efficiency) of healthcare" (cited in Eccles et al.[1]) sets this study firmly in the context of implementation science.

Study limitations

This review raised two key challenges. First, studies rarely analyse behavioural components of the intervention design discretely, making it impossible to discern which factors are at work in producing the observed effects. Second, the heterogeneity of outcome measures precludes statistical evaluations using meta-analysis. Publication or outcome bias may have affected our results, though not all included studies found significant reductions in assessed risk or differences in outcomes between intervention and control groups. Several potentially relevant studies that focus on the design of screening interventions were excluded because they were not delivered in healthcare settings. The reviewed studies also highlight the disadvantages of Intention-To-Treat analyses, which are better suited for assessing the efficacy of an intervention in practice as opposed to understanding "how" and "why" and intervention works, and the need to control for selective attrition either by use of features which reduce drop out or by statistical control for known differences between returners and non-returners, but few studies employ this. As a realist review, this document examines outcomes which may be situation specific. The acknowledgement that some findings that may be situation or population specific is important in generalisation of results.

Conclusions and policy implications

This review highlights the need for a more systematic approach to the strategic design, conduct and analysis of health interventions by taking into account the complex interactions between design, delivery, attrition and health outcomes. It is recommended that insights from health psychology should be incorporated in the design of interventions aimed at increasing screening uptake, as well as involving cross-disciplinary specialist areas such as physical activity and nutrition to promote lifestyle

behaviour change alongside pharmacological treatment. Furthermore, to control the effects of selective attrition, there is a need to perform sensitivity analyses in order to monitor the make-up of the sample and perhaps some purposive sampling to protect against biasing the sample toward a healthier baseline and therefore reduced effect at follow-up, particularly in longitudinal studies. It is anticipated that such carefully designed interventions would result in health behaviour change that provide as much benefit to the wider population as they do for those with heightened risk, resulting in better overall population outcomes.

What is already known on this topic

Previous reviews have raised concerns about the cost effectiveness of CVD and diabetes screening interventions.

- Some researchers have instead recommended replacement of screening programmes with pharmacological interventions alone, (e.g. prescription of statins to everyone aged 55 or older[42]).
- Other work has illustrated that health behaviour change and intervention effectiveness can significantly reduce CVD risk, controlling for effects of pharmacological intervention.
- Some features of intervention style, and of populations, often result in less than optimum risk reduction.

What this study adds

- **The study confirms the need for and success of strategies that encourage higher risk patients to become and stay involved in screening and intervention programmes, such as opportunistic screening.**
-
- Careful training and monitoring of the use of evidenced behaviour change strategies in improving the reach and success of interventions is needed.
- Ethically supported invitation styles such as fully informed choice do not reduce participation or effect outcome.
- Clear feedback and targeted intervention on specific risk factors or behaviours is supported, whereas general lifestyle advice is less effective.
- Structure of motivational health dialogues and the terms over which they are most successful needs further research.

Contributorship statement:

CH, RS, HP, and RC were responsible for the conception and design of the study. YC had principal responsibility for search and sourcing of articles and initial data extraction, and RC contributed to reference chaining. Two authors (CH, YC) independently reviewed the157 full text papers retrieved, and further excluded studies which only evaluated changes in risk factors or cost-effectiveness. CH and RC assigned quality scores to each included full-text article based on the Scottish Intercollegiate Guidelines Network (SIGN 50) quality assessment instruments. CH had principal responsibility for data extraction, analysis and interpretation of the data and for drafting the article,

revisions, and final approval. RS, HP, and RC contributed to interpretation of the data, revisions and final article approval. CH and RC are the guarantors.

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Competing interest statement

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work other than that outlined under "Funding" above; no other financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years ; no other relationships or activities that could appear to have influenced the submitted work .

Ethical approval: Not required.

Data sharing: No additional data available.

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Table 1. Included Studies

Study	Country	Sample	N	Design	Intervention Component	Main findings	Quality
Aubin 1998[14]	Canada	58% female, mean age 35 years	391	RCT, controls completed questionnaire on intention to eat a low fat diet before they received results of cholesterol screening, intervention participants completed it after	Impact of feedback on behaviour change	Intervention participants were more likely to intend to adopt a low fat diet than controls. Patients with abnormally high cholesterol(≥ 6.3mmol/L) showed a greater reduction in dietary fat intake than those who had a normal cholesterol (<5.2mmol/L)	+
Elton 1994[15]	England	44% female, mean age 37.9 years	469	Prospective, blinded RCT, Intervention participants knew their cholesterol level before the health education	Impact of feedback on behaviour change	Participants whose initial serum cholesterol was ≥ 6.5mmol/L and who had been informed of this, showed a significantly greater	++

				and diet session, control participants did not.		reduction in serum cholesterol than control participants in the same high cholesterol group who had not been informed. All participants received the same dietary advice.	
Färnkvist 2008[16]	Sweden	100% male, age stratified, aged 66, 56 and 46 years.	817	Cross-sectional study. Screening only, Screening plus health dialogue by trained professionals, and non-participants compared.	Benefits of health dialogue over simple feedback	Odds ratios of developing diabetes or CVD over 11 years were 2.5 for those had received screening with no health dialogue and 3.0 for those who had not participated in the original screening, as compared with those who had received screening plus a structured, motivational health dialogue.	+

Engberg 2002[17]	Denmark	52% female, Mean age 40.4 years	150 7	RCT, Screening, screening plus health dialogue compared with normal care control group.	Benefits of health dialogue over simple feedback	After 5 years there were no differences between the two intervention groups Total intervention/control Risk Ratio was 0.54. Absolute risk reduction 8.6%.	++
Rubak 2011[18]	Denmark	42% female, Mean age 61 years. Patients with screen detected type 2 diabetes	628	Cluster RCT, Intervention and control groups received training in intensive treatment of Diabetes, intervention group GPs additionally received training in Motivational Interviewing (MI) and instructed to use it.	Benefits of health dialogue over simple feedback	No effect of motivational interview on medication adherence or metabolic status in relative to control group. Medication adherence across both groups almost 100%, both groups showed significant improvements in all risk measures. Key issues were lower than planned use of motivational interview by intervention group GPs, and contamination of	++

						methods and training into control group GPs.	
Koelewijn-van Loon 2010[19]	Netherlands	55% female, Mean age 57 years	615	Cluster RCT, Intervention nurses received training to use risk assessment, communication, a decision support tool and MI. Control group nurses received training on risk assessment and applied usual care.	Benefits of health dialogue over simple feedback	Outcome measures were self-reported lifestyle measures. No differences between control and intervention groups noted at 12 week follow up, but overall both groups showed improvements.	+
Craigie 2011[20]	Scotland	72% female, Mean age 54.5 years, high risk but not on statins.	75	RCT, Intervention – motivational interview and volitional aspects to change planned behaviour, Control group usual care.	Benefits of health dialogue over simple feedback	Percentage achieving 5 portions of fruit and vegetables a day, and weight maintenance or loss indicators were significantly better in the intervention group over the 12 week follow up. Control group	+

						made no positive change.	
Marteau 2010[22]	England	47.6 % female, mean age 57.4 years	1272	RCT, informed choice invitation compared with standard invitation.	Impact of type of invitation on uptake and outcome	Primary outcome of attendance did not differ between groups Secondary outcome of intention to change health behaviour was unaffected by invitation type.	++
Park 2010[23]	England	66.6% male, Mean age 58 years	116	RCT, loss frame compared with gain frame invitation.	Impact of type of invitation on uptake and outcome	Primary outcome of attendance did not differ between groups (invitation types). Secondary outcome measures of anxiety, self-perceived health and Illness representation also did not differ between groups.	++
Hellénius 1998[24]	Sweden	65% female, age range 20-60 years	4904	Observational Cross sectional study, those screened as a result of	Impact of type of invitation on	Opportunistically screened participants showed higher CVD risk factors than letter invited	+

				opportunistic invitations compared with those responding to a letter invitation.	uptake and outcome	participants at baseline. Effectiveness of screening in lowering risk factors did not differ between the two groups.	
Jones 1993[25]	Wales	53.4% female, mean age 42.5 years	2542	Observational cross-sectional study, those not responding to initial invitations to screenings compared with those who did.	Differences between attenders and non-attenders	Non-attenders showed more risk factors than attenders.	+
Thomas 2002[26]	England	100% male, Mean age 69.1 years,	5655	Observational cross sectional study, Health characteristics of those who attended and did not attend a 20 year follow-up were compared.	Differences between attenders and non-attenders	Despite no differences at baseline in BMI and cholesterol, those who later dropped out of a longitudinal study had higher blood pressure at baseline and greater number of CVD and bronchial diagnoses, and	+

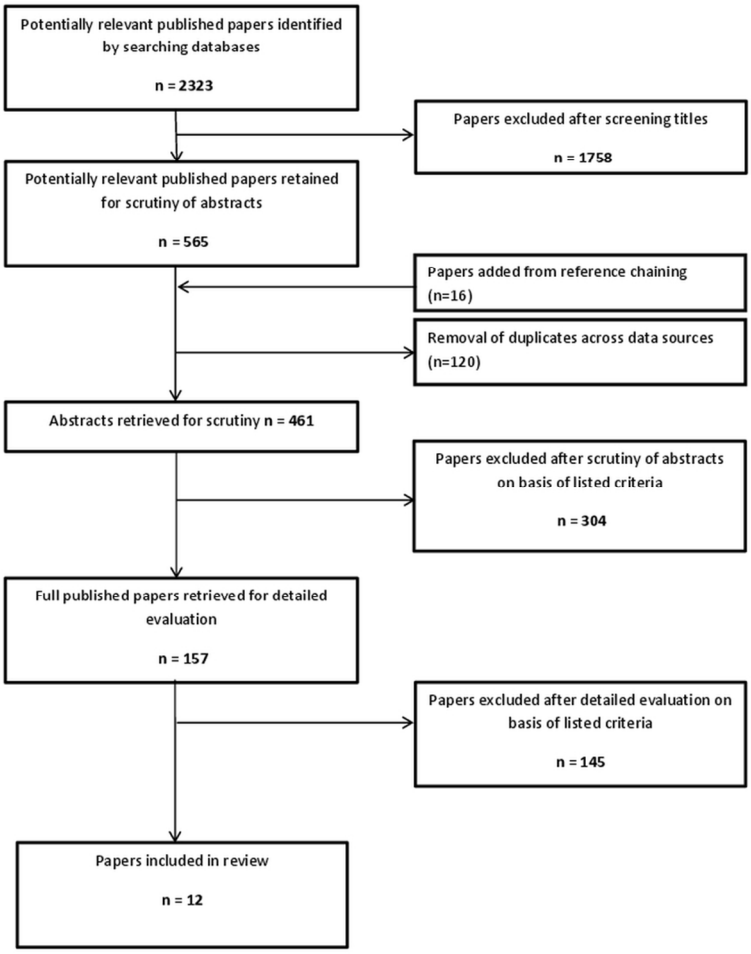
						adverse lifestyle factors (e.g. OR of smoking in non-attenders 2.33).	

Note. SIGN 50 cohort checklist used to assess study quality. ++ = High quality study, + = Acceptable, 0 = Unacceptable.

Appendix 1. Search terms used in search strategy

The following terms were used in all data sources: (cardiovascular OR vascular OR CVD OR “chronic heart disease” OR “coronary heart disease” OR CHD OR diabetes) AND (“mass screening” OR surveillance*) AND (letter OR mail* OR phone OR telephone OR “reminder system*” OR “videotape recording*” OR “audiotape recording*” OR questionnaire* OR strateg* OR alert* OR hotline OR community OR media) AND (intervention* OR goal OR “behav* change” OR “implementation intention*” OR plans OR planned OR planning OR plan OR educat* OR campaign* OR barriers OR intention* OR “behav* outcome” OR outcome OR “lifestyle change” OR longitudinal OR “follow up” OR motivation*) AND (satisf* OR dropout* OR “drop out” OR attrition OR uptak* OR adher* OR compliance OR complie* OR comply* OR “patient acceptance of health care” OR encourag* OR improve* OR improving OR increas* OR promot* OR particip* OR nonattend* OR “non attend” OR accept* OR attend* OR attitud* OR utilisation OR utilization OR refus* OR respond* OR respons* OR reluctan* OR nonrespon* OR “non respon*” OR incidence OR prevalence OR prevelence OR satisfaction OR cooperat* OR “co operat*”) AND (findings OR interview* OR qualitative OR experienc* OR RCT OR “randomised controlled trial” OR trial).

Figure 1 Flow chart of intervention studies included and excluded from this review



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