Document 1

Prevention of cardiovascular disease at population level [Question 1; phase 3]

Report (20th November 2008)

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Prevention of cardiovascular disease at population level

[Question 1; phase 3]

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Published by:

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West Midlands Health Technology Assessment Collaboration

The West Midlands Health Technology Assessment Collaboration (WMHTAC) is an organisation involving several universities and academic groups who collaboratively undertake research synthesis to produce health technology assessments. Most of our members are based in the Department of Public Health & Epidemiology, University of Birmingham, however other members are drawn from a wide field of expertise including economists and mathematical modellers from the Health Economics Facility, University of Birmingham.

WMHTAC produce systematic reviews, health technology assessments and economic evaluations for NHS R&D HTA programme (NCCHTA), the National Institute for Health and Clinical Excellence (NICE), and for the health service in the West Midlands. WMHTAC also undertakes methodological research on research synthesis, and provides training in systematic reviews and health technology assessment.

Name of other institution(s) involved

WMHTAC work in close collaboration with the Peninsula Technology Appraisal Group (PenTAG) with respect to providing support to the CPHE. They were not however involved in this report.

Contents

Executive Summary

Objectives:

This report is the final of three effectiveness reports which together address:

Which multiple risk-factor interventions are effective and cost effective in the primary prevention of CVD within a given population? Where the data allows, how does the effectiveness and cost effectiveness of interventions vary between different population groups?

The three effectiveness reports do not address the cost effectiveness aspect of this question and these findings will be detailed in a separate report.

Groups to be covered were populations defined on a geographical basis

The interventions included were multiple risk-factor approaches to preventing CVD among a given population. These included addressing two or more risk factors through one or more of the following types of intervention:

- educational/behavioural (including the use of mass media)
- fiscal
- environmental
- legislative

The expected outcomes of interest were population changes in: rates or levels of CVD mortality or morbidity; the biochemical or physiological precursors of CVD; behaviour associated with the risk of developing CVD.

Methods:

Working to a pre-determined protocol, a systematic review was conducted. The main component of the search addressing the review question was 8 major bibliographic databases. These were searched from 1970 to August 2008 for evaluative studies addressing the review question and published in the English language. Previous reports (phase 1 and 2) focused on studies identified from systematic reviews and this report (phase 3) focused on studies identified from a search of the primary literature. Directly relevant publications (21) were identified from over 36,000 citations relating to 16 programmes. Synthesis was narrative and meta-analysis was not employed.

Evidence statements are given below. The first broad statement summarises evidence from the current report (phase III of review 1) and more detailed evidence statements are then used to summarise available evidence from both the current and previous reports (phase I, II and III of review 1).

Evidence statement for programmes addressing prevention of CVD at population level (phase III of review 1)
This is an interim statement based on the third part of a 3 stage review. 16 directly relevant programmes reported in 21 publications were identified for this report. The majority (11) consider the effectiveness of population programmes using education and/or mass media and other programmes (5) focus on assessing levels of CVD risk factors with screening and providing advice in general populations. No programmes used legislative or fiscal changes and there were no natural experiments. The education and mass media programmes were generally evaluated using controlled before-after studies with quality gradings ranging from – to +. The "screening" programmes were evaluated using RCTs and were graded from – to +.

Evidence statements for programmes addressing prevention of CVD at population level (phase I, II and III of review 1)

These are statements based on the combined data from the all 3 parts of the 3 stage review.

Introduction. Thirty eight directly relevant programmes reported in 90 publications have been identified in this review of effectiveness. The majority of programmes (31) are concerned with the effectiveness of population programmes using education and mass media and were generally evaluated using controlled before-after studies (CBA studies), with quality grading from – to +. Seven screening programmes have been evaluated using RCTs and were quality graded from – to +. No programmes using legislative or fiscal changes have been identified.

Due to limitations in reporting, statistical significance has not been considered when commenting on the direction of effect of programmes on CVD outcomes and it has not been possible to quantify the overall size of effects across all programmes. The effect of programmes on CVD outcomes is described as mixed where the direction of effect is conflicting across programmes. In addition, a distinction is made between outcomes where the majority of programmes demonstrate a beneficial effect, outcomes where the majority of programmes demonstrate a disbeneficial effect and outcomes where programmes are balanced with respect to beneficial and disbeneficial effects. Programmes described as demonstrating 'inconclusive' effects provide more than one effect estimate which are conflicting e.g. one beneficial and one disbeneficial. Programmes demonstrating inconclusive or no effects have not been considered when distinguishing between outcomes with broadly beneficial, disbeneficial or balanced effects.

1) Are population level multiple risk factor interventions (MRFI) effective in the primary prevention of CVD?

E.1.a. CVD mortality and morbidity. Limited evidence from 3/38 programme evaluations using different summary effect measures demonstrate a mixed effect of MRFI on CVD mortality (the majority of programmes beneficial) with 2 CBA studies (-[27] and +[28]) demonstrating a net decrease in CVD mortality and one RCT (+[36]) demonstrating no net change. Limited evidence from 4/38 programme evaluations, using different summary effect measures, demonstrate a mixed effect of MRFI on CVD morbidity (the majority disbeneficial) with 1 CBA study (-[27]) and 1 RCT (-[38]) demonstrating a net increase in morbidity and 1 RCT (+[36]) demonstrating no net change in morbidity. The effect of one programme (CBA study -[29]) on morbidity and mortality is unclear.

E.1.b. Blood cholesterol. A large body of evidence from 15 CBA studies (10-, 5+) and 5 RCTs (2-, 3+) demonstrates a mixed direction of effect (majority of programmes beneficial) of MRFI programmes on blood cholesterol. Fourteen studies (9 CBA (5-[30,17,16,10a,9a], 4+ [6,22a,5a,4]) and 5 RCTs (2-[37,38], 3+[8,34,2]) demonstrate a beneficial net effect, 4 CBA studies (3-[20,27,19], 1+[15a]) demonstrate no net effect or inconclusive net effects and 2 CBA studies (2-[7,14]) demonstrate a disbeneficial net effect. The most optimistic result was from a CBA study (+[6]), reporting a 0.7mmol/l net reduction in blood cholesterol. The least optimistic result was from a CBA study (-[14]), reporting a +0.5mmol/l net increase in blood cholesterol.

E.1.c. Diastolic and systolic blood pressure. A large body of evidence demonstrates a mixed direction of effect (majority of programmes beneficial) in favour of MRFI programmes on diastolic and systolic blood pressure.

Fourteen CBA studies (10-, 4+) and 5 RCTs (2-, 3+) demonstrate a mixed direction of effect (majority of programmes beneficial) on diastolic blood pressure. Twelve studies (7 CBA studies (4-[30,16,9a,14],3+[15a,5a,4]) and 5 RCTs (2-[37,38]3+[2,8,34])) demonstrate a beneficial net effect, 5 CBA studies (4-[10a,27,7,17], 1+[6]) demonstrate no net effect or inconclusive net effects and 2 CBA studies (2-[19,20]) demonstrate a disbeneficial net effect. The most optimistic result was from a CBA study (-[30]), reporting a 5.5mm Hg net reduction in diastolic blood pressure. The least optimistic result was from a CBA study (-[19]), reporting a 6mmHg net increase in diastolic blood pressure.

Fourteen CBA studies (9-, 5+) and 5 RCTs (2-, 3+) demonstrate a mixed effect (majority of programmes beneficial) on systolic blood pressure. Ten studies (5 CBA studies (1-[16], 4+[22a,15a,5a,4]) and 5 RCTs (2-[38,37] 3+[2,8,34]) demonstrate a beneficial net effect, 5 CBA studies (4-[10a,19,9a,27], 1+[6]) demonstrate no net effect or inconclusive net effects and 4 CBA studies (4-[17,7,14,20]) demonstrate a disbeneficial net effect. The most optimistic result was from a CBA study (+[22a]), reporting an 11.8 mmHg net reduction in systolic blood pressure. The least optimistic result was from a CBA study (-[20]), reporting a 5mmHg net increase in systolic blood pressure.

E.1.d. Smoking. A large body of evidence from twenty CBA studies (17-, 3+) and four RCTs (2-, 2+) demonstrate a mixed effect of MRFI on smoking prevalence (the majority of programmes beneficial). Twelve studies (9 CBA studies (7-[21,12a/b,20,16,7,25,11a], 2+[4,5a]) and 3 RCTs (2-[37,38], 1+[2])) demonstrate a beneficial net effect, 7 studies (6 CBA studies (6-[17,14,13,19,10a,9a]) and 1 RCT (+[8])) demonstrate no net effect or inconclusive net effects and 5 CBA studies (4-[18,3,1,27], 1+[6]) demonstrate a disbeneficial net effect. The most optimistic result was from a CBA study (-[21]), reporting an 18.6% net reduction in smoking prevalence. The least optimistic result was from a CBA study (-[27]), reporting a 12.8 % net increase in smoking prevalence.

E.1.e. BMI. A large body of evidence from fourteen CBA studies (11-, 3+) and 3 RCTs (1-, 2+) demonstrate a mixed effect of MRFI programmes on BMI (the majority of programmes beneficial). Ten studies (7 CBA studies (6-[17,19,14,7,13,25], 1+[15a]) and 3 RCTs (1-[37], 2+[34,8])) demonstrate a beneficial net effect, 4 CBA studies (3-[9a,10a,27], 1+[4]) demonstrate no net effect or inconclusive net effects and 3 CBA studies (2-[16,20], 1+[6]) demonstrate a disbeneficial net effect. The most optimistic result was from a CBA study (-[17]), reporting a 1.3kg/m^2 net reduction in BMI. The least optimistic result was from a CBA study (+[6]), reporting a 0.7kg/m^2 net increase in BMI.

E.1.f. Blood glucose. Limited evidence from 3/38 programme evaluations, using different summary effect measures, demonstrate a mixed effect of MRFI on blood glucose. One RCT (+[2]) and 1 CBA study (-[14]) report mixed results: net decreases in men and net increases in women, whilst 1 CBA study (-[15a]) demonstrates no net effect.

E.1g. Triglyceride levels, HDL/LDL ratio or lipid levels. No evidence has been identified on the effects of MRFI programmes on triglyceride levels, HDL/LDL ratio or lipid levels.

E.1.h. Dietary change: low versus high fat spreads. Five CBA studies (4-, 1+) and one RCT (+) demonstrate a mixed effect of MRFI programmes on consumption or low versus high fat spreads (the majority of programmes beneficial). Four studies (3 CBA studies (2-[17,18], 1+[5b]) and 1 RCT (+[8]))

demonstrate a beneficial net effect, 1 CBA study (-[16]) demonstrates an inconclusive net effect and 1 CBA study (-[12a/b]) demonstrates an unfavourable net effect. The most optimistic result was from a CBA study (+[5b]), reporting a 24% net reduction in the number of people with high consumption of fat spread on bread. The least optimistic result was from a CBA study (-[16]), reporting a 3.3% net decrease in the use of unsaturated spreading fats.

E.1.i. Dietary change: vegetable versus animal fats for cooking. Four CBA studies (3-, 1+) demonstrate a mixed effect of MRFI programmes on the use of vegetable versus animal fat for cooking (the majority of programmes beneficial). Three CBA studies (2-[16,17], 1+[5b]) demonstrate a beneficial net effect and 1 CBA study (-[11b]) demonstrates an inconclusive net effect. The most optimistic result was from a CBA study (-[16]), reporting a 6% net increase in the use of unsaturated fats for cooking. The least optimistic result was from a CBA study (-[11b]), reporting a 2% net decrease in the use of vegetable fats for cooking.

E.1.j. Dietary change: low versus high fat milk. Five CBA studies (4-, 1+) and 1 RCT (+) demonstrate a mixed effect of MRFI programmes on the consumption of low versus high fat milk (the majority of programmes beneficial). Three CBA studies (2-[17,12a/b], 1+[5b]) and 1 RCT (+[8]) demonstrate a beneficial net effect and 2 CBA studies (2-[16,18]) demonstrate an inconclusive net effect. The most optimistic result was from a CBA study (-[17]), reporting a 9% net increase in the use of low fat milk in men. The least optimistic result was from a CBA study (-[16]), reporting a 1% net decrease in the use of low fat milk in women.

E.1.k. Dietary change: consumption high fat foods. Six CBA studies (4-, 2+) demonstrate a mixed effect of MRFI programmes on the percentage of high fat foods in the diet (the majority of programmes beneficial). Three CBA studies (1-[10b], 2+[22a,5b]) demonstrate a beneficial net effect, 2 CBA studies (2-[13,11b]) demonstrate no net effect or inconclusive net effects and 1 CBA study (-[18]) demonstrates a dis-beneficial net effect. The most optimistic result was from a CBA study (+[22a]), reporting a 24% net decrease in saturated fat intake. The least optimistic result was from a CBA study (-[13]), reporting a 3.4% net increase in high fat/junk food consumption.

E.1.l. Dietary change: consumption of fruit and vegetables and wholemeal bread. Limited evidence is available on the effects of MRFI programmes on the consumption of fruit and vegetables and wholemeal bread (the majority of programmes beneficial). Three CBA studies (3-) demonstrate a mixed effect of MRFI programmes on the consumption of fruit and vegetables. Two CBA studies (2-[25,1]) demonstrate a beneficial net effect and 1 CBA study (1-[18]) demonstrates an inconclusive net effect. The most optimistic result is from a CBA study (-[25]), reporting a 9% net increase in the number of people consuming five portions of fruit and vegetables per day. The least optimistic result is from a CBA study (-[18]), reporting a 0.2% net decrease in fruit consumption.

Two CBA studies (2-) demonstrate a mixed effect on the consumption of wholemeal bread. One CBA study[18] demonstrates a beneficial net effect and one CBA study[12a/b] demonstrates an inconclusive effect. The most optimistic result is from a CBA study (-[12b]), reporting a 3% increase in children. The least optimistic result is from the same CBA study (-[12a]), reporting a 0.3% net decrease in adults.

E.1.m. Dietary change: salt intake. Two CBA studies (+ and -) provide mixed results for the effects of MRFI programmes on salt intake. One CBA study (-[10b]) demonstrates a beneficial net treatment effect and 1 CBA (+[5c]) demonstrates an inconclusive net treatment effect.

E.1.n. Physical activity. Evidence from 11 CBA studies (10-, 1+) and 1 RCT (+) provide a mixed pattern for the effect of MRFI programmes on physical activity (the majority of studies are dis-beneficial). Three CBA studies (3-[27,17,12a/b]) and 2 RCTs (-[37], +[8]) demonstrate a favourable net effect, 3 CBA studies (3-[21,16,3]) demonstrate inconclusive net effects and 4 CBA studies (3-[7,18,25], 1+[15c]) demonstrate a dis-beneficial net effect. The most optimistic result is from a CBA study (-[21]), reporting an 11.5% net increase in the number of people doing strenuous physical activity >3 times per week. The least optimistic result is from a CBA study (-[7]), reporting a 6% net decrease in the number of people who were physically active.

E.1.o. Attitudes, knowledge and intentions relating to CVD risk factors. Limited evidence is available on the effects of MRFI programmes on CVD risk factor attitudes, knowledge and intention to change. One CBA study (-[10a/b]) and one uncontrolled before-after study (-[23]) suggest beneficial changes in CVD knowledge following MRFI programmes and one of these studies (-[10c]) showed a net increase in the number of individuals intending to lose weight. No evidence has been identified on the effects of MRFI programmes on CVD risk factor attitudes.

2) How does the effectiveness of interventions for the primary prevention of CVD vary between different population groups, for example, groups that differ in terms of age, gender and ethnicity?

E.2.a. General. Evidence for variation in effectiveness in sub-groups of the population is limited and inconsistently reported across included programmes. There is no clear pattern with respect to gender, age, ethnicity or measures of deprivation which may be the result of the limited information available, confounding and selective reporting.

E.2.b. Ethnicity. Three programmes report the results of sub-group analysis of effectiveness according to ethnicity. One uncontrolled before after study (-[23]) reports lower effectiveness in ethnic minorities in acquisition of CVD knowledge, one CBA study (-[1]) reports lower effectiveness in ethnic minority groups for reducing smoking prevalence, reducing BMI and increasing fruit and vegetable intake and one CBA study (-[11a]) reports no difference in effectiveness according to ethnic group.

E.2.c. Age. Six programmes report results of sub-group analysis according to age. Two uncontrolled before-after studies (2-[23,24]) report a reduction in effectiveness in acquisition of CVD knowledge in younger participants and one uncontrolled before-after study (-[24]) reports a reduction in effectiveness in reducing salt intake in younger participants. One CBA study (-[13]) reports a reduction in effectiveness in promoting CVD awareness in older participants. Two CBA studies (2-[12a/b,11a]) report no differences in effectiveness according to age.

E.2.d. Gender. Seven programmes report results of sub-group analysis according to gender. Four programmes report a reduction in effectiveness in women compared to men. One RCT (-[35]) reports a reduction in effectiveness in increasing physical activity in women compared to men. One uncontrolled before after study (-[24]) and 2 CBA studies (-[12a/b], +[5a]) report a reduction in effectiveness in reducing smoking prevalence in women compared to men. One CBA study (+[5a])

reports a reduction in effectiveness in reducing cholesterol in women compared to men. One CBA study (-[12a]) reports a reduction in effectiveness in drinking low fat compared to high fat milk in women compared to men.

Two programmes report a reduction in effectiveness in men compared to women. Two CBA studies (2-[10a,13]) report a reduction in effectiveness in promoting CVD awareness and acquisition of CVD knowledge in men compared to women and one CBA (-[10a]) study reports a reduction in effectiveness in reducing CVD morbidity and mortality in men compared to women. One CBA study (-[14]) reports no differences in effectiveness according to gender.

E.2.e. Social class. Two programmes report results of sub-group analysis according to social class. One CBA study (-[19]) reports a reduction in effectiveness in reducing smoking in lower social classes compared to higher social classes. One CBA study (+[15a]) reports no differences in effectiveness according to social class.

E.2.f. Level of education. One programme reports results of sub-group analysis according to level of education. One CBA study (-[13]) reports a reduction in effectiveness in CVD awareness in those relatively more educated.

3) How does the effectiveness of interventions for the primary prevention of CVD vary according to the nature of the intervention, whether the intervention is based on an underlying theory or conceptual model, the status of the organisation or person delivering the intervention, the context in which the intervention takes place, the intensity and duration of the intervention?

E.3.a. Nature of the interventions. 31 programmes were concerned with the effectiveness of population programmes using education and mass media, and seven with screening programmes directed at large populations in the community or primary care. However, 16 of the education and mass media programmes contained screening components. Counselling was a key process in many programmes, undertaken individually in 24 programmes and amongst groups in 16 programmes.

The 38 programmes varied in many other ways. Programme length ranged from one to >20 years. The size of the population addressed ranged from approximately 2,500 to over 1,000,000. 14 of the programmes implemented changes to the environment. Health departments (n=23), local health committees (n=12), voluntary organisations (n=11) and community volunteers (n=9) had roles in programme delivery. Programmes were delivered in a variety of settings including workplaces (n=12) and schools (n=18).

E.3.b. Education & mass media based programmes compared to screening based. As indicated this was the most marked contrast between the programmes. However comparing the effectiveness of the two groups is complicated by:

- Many of the education and mass media based programmes containing elements of screening.
- There are many CVD screening programmes, particularly focused on moderate or high risk populations which are not included in this review.

- The comparison between the two groups being likely to be confounded by other factors, a very important one of which is that CBA studies are used to evaluate most of the education and mass media based programmes, and RCTs all the screening based programmes.

With these provisos and reference to pages 127 to 131 in report 3, the pattern of results for the risk factors of cholesterol, BP, smoking and BMI in the two different groups of programmes are summarised in the table below:

Programme type (n=38)	**Programme result, based on direction of effect**			
	Beneficial	**Inconclusive**	**Disbenefical**	**No data**
Net change in mean total cholesterol in mmol/L				
Educ & MM	9[6,30,22a,5a,4,17,16,10a,9a]	4[20,15a,27,19]	2[7,14]	16
Screening	5[8,34,2,37,38]	0	0	2
Net change in systolic BP in mmHg				
Educ & MM	6[22a,15a,5a,4,16,10a]	4[19,9a,6,27]	4[17,7,14,20]	17
Screening	5[2,8,38,34,37]	0	0	2
Net change in diastolic BP in mmHg				
Educ & MM	7[15a,30,16,10a,5a,4,9a]	5[6,14,27,7,17]	2[20,19]	17
Screening	5[2,8,37,34,38]	0	0	2
Net change in BMI in kg/m^2				
Educ & MM	8[17,19,14,7,15a,10a,13,25]	3[9a,27,4]	3[16,20,6]	17
Screening	3[34,8,37]	0	0	4
Net change in smoking prevalence in %				
Educ & MM	9[21,12a,20,16,4,7,25,5a,11a]	6[17,14,13,19,10a,9a]	5[18,3,6,1,27]	11
Screening	3[2,37,38]	1[8]	0	3

Although the results are similar, there does appear to be a more consistent pattern of benefit in the programmes focusing on screening. As well as the provisos mentioned above, the following also need to be borne in mind when taking this observation at face value:

- Whether this difference could be accounted for by chance alone.

- Whether the difference would persist if the size of the effects could be taken into account.

- Vote counting as a method of summarising the results in a systematic review is recognised to be the weakest approach.

E.3.c. Possible variations in effectiveness by other aspects of the nature of the intervention. Over the three reports, many other plausible reasons for the noted variation in effectiveness have been identified. These include:

- Duration of programme

- Intensity of programme

- Use of an underlying theoretical model to inform the design of the programme

- Pre-programme investigation of particular risk factors operating in a population

- Community involvement in planning and/or design of programme

- Adaptability of the programme as new challenges emerge

- Level of integration of the separate components of the programme

- Inclusion of environmental changes as part of the programme

Whether any of these factors account for differences in effectiveness which could not arise by chance alone has not been fully explored, and their potential importance can neither be confirmed nor refuted. Unfortunately, the extent to which the differences could ever be satisfactorily explored using the results from these evaluations is debatable given noted limitations in the reporting of the precise differences in nature of the programmes and the amount of statistical information available.

4) Do multiple risk factor interventions for the primary prevention of CVD have any adverse or unintended effects?

E.4.a. There is no evidence for adverse or unintended effects from multiple risk factor interventions for the primary prevention of CVD from the 90 publications covering 38 programmes scrutinised for the effectiveness review.

5) What is the accessibility of multiple risk factor interventions for the primary prevention of CVD for different population groups?

E.5.a. General. Few programmes reported initiatives in accessing hard to reach groups: different cultural factors were addressed by seven programmes, attempts to overcome barriers resulting from different language were considered in three programmes, and the problem of poor literacy was also addressed in three programmes. E.5.b. to E.5.h document characteristics of non-participants in programme interventions and/or programme evaluation surveys where they are reported in studies scrutinised for this review.

E.5.b. Gender. Twelve programmes report participation in programme interventions and/or programme evaluation surveys according to gender. One uncontrolled before-after study (-[26]), 7

CBA studies (6-[1,12a,13,14,25,27], 1+[6]) and 2 RCTS (2+[8,34]) report lower participation in evaluation surveys or programme interventions by males whilst two programmes, 1 CBA study (-[30]) and 1 RCT (+[36]), report no gender differences in participation rates.

E.5.c. Age. Fifteen programmes report participation in programme interventions and/or programme evaluation surveys according to age. One uncontrolled before-after study (-[26]) and 13 CBA studies (11-[1,3,10a,12a,13,14,17,16,25,27,29], 2+[6,15a]) report lower participation in evaluation surveys or programme interventions by those of younger age whilst 1 CBA study (+[28]) reports no difference in participation according to age.

E.5.d. Level of education. Seven programmes report participation in programme interventions and/or programme evaluation surveys according to level of education. Six CBA studies (4-[1,10a,21,27], 2+[6,15a]) report lower participation by those relatively less well educated whilst 1 CBA study (-[13]) reports lower participation by those relatively better educated.

E.5.e. Social class. Three programmes report participation in programme interventions and/or programme evaluation surveys according to social class. One CBA study (-[29]) and 2 RCTs (-[38], +[36]) report lower participation by those of lower social class.

E.5.f. Ethnicity. Three programmes report participation in programme interventions and/or programme evaluation surveys according to ethnicity. Two CBA studies (2-[10a,20]) and 1 RCT (+[36]) report lower participation by ethnic minority groups.

E.5.g. Marital status. Three programmes report participation in programme interventions and/or programme evaluation surveys according to marital status. Two CBA studies (2-[3,21]) and 1 RCT (+[36]) report lower participation by those unmarried or divorced.

E.5.h. CVD risk. Twelve programmes report participation in programme interventions and/or programme evaluation surveys according to CVD risk. One uncontrolled before-after study (-[26]), six CBA studies (5-[7,10a,17,16,29], 1+[22a]) and 3 RCTs (1-[35], 2+[2,8]) report lower participation by individuals at relatively higher CVD risk whilst 1 RCT (+[34]) reports relatively lower participation by individuals at relatively lower CVD risk.

E.6. How applicable are the findings from the 38 programme evaluations to the UK?

E.6.a. Applicability related nature of programmes. 5 of the programmes included in this review were conducted in the UK, 17 in Europe, 15 in North America and 1 in Australia. The programmes identified were initiated across a wide time period: 8 in the 1970s, 16 in the 1980s, 13 in the 1990s and 1 in 2000. They covered a wide range of community settings: 15 general, 12 urban, 1 suburban, and 10 mixed. Twelve of the 38 included programmes were undertaken in areas of low socioeconomic status, 10 in areas considered to be 'high risk' for CVD and 8 in communities with both these characteristics.

E.6.b. Constraints on judgements about applicability. Even for those interventions considered applicable in setting and place, the passage of time is very important. Healthcare systems evolve, the nature of interventions change, the balance of CVD risk factors faced by the population alters and the population knowledge of CVD risk factors develops. These considerations undermine the applicability of all the programmes as the most recent programme is over 8 years old.

Consideration of the applicability of the included programmes to the UK populations is also constrained by the limited information provided by virtually all studies on the socio-demographic characteristics of the target populations and/or the population actually reached by the interventions. Possible selection bias and substantial losses to follow-up in the evaluated populations in some studies further challenges judgements about applicability.

More complexity is introduced by the possibility that general populations in past years, when risk factors like smoking levels were more common, although not applicable to current day general populations, may remain applicable to current day high risk populations. Finally, both average risk and high risk populations may be of interest in the context of the guidance.

E.6.c. Conclusions on applicability. Given the noted constraints, it was felt that judgements about applicability were too subjective to assign individual applicability ratings as encouraged in the NICE Public Health methods guidance.

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	10b	Fortmann SP, Taylor CB, Flora JA, Winkleby MA: Effect of community health education on plasma cholesterol levels and diet: the Stanford Five-City Project. *American Journal of Epidemiology* 137:1039-1055, 1993
	10c	Taylor CB, Fortmann SP, Flora J, Kayman S, Barrett DC, Jatulis D, Farquhar JW: Effect of long-term community health education on body mass index. The Stanford Five-City Project. *American Journal of Epidemiology* 134:235-249, 1991
South Carolina	11a	Goodman RM, Wheeler FC, Lee PR: Evaluation of the Heart To Heart Project: lessons from a community-based chronic disease prevention project. *American Journal of Health Promotion* 9:443-455, 1995
	11b	Croft JB, Temple SP, Lankenau B, Heath GW, Macera CA, Eaker ED, Wheeler FC: Community intervention and trends in dietary fat consumption among black and white adults. *J Am Diet Assoc* 94:1284-1290, 1994
	11c	Smith NL, Croft JB, Heath GW, Cokkinides V: Changes in cardiovascular disease knowledge and behaviour in a low-education population of African-American and white adults. *Ethnicity & Disease* 6:244-254, 1996
Action Heart	12a	Baxter T, Milner P, Wilson K, Leaf M, Nicholl J, Freeman J, Cooper N: A cost effective, community based heart health promotion project in England: prospective comparative

		study. *BMJ (Clinical research ed)* 315:582-585, 1997
	12b	Baxter AP, Milner PC, Hawkins S, Leaf M, Simpson C, Wilson KV, Owen T, Higginbottom G, Nicholl J, Cooper N: The impact of heart health promotion on coronary heart disease lifestyle risk factors in schoolchildren: lessons learnt from a community-based project. *Public Health* 111:231-237, 1997
Coeur En Santé	13	O'Loughlin JL, Paradis G, Gray-Donald K, Renaud L: The impact of a community-based heart disease prevention program in a low-income, inner-city neighborhood. *American Journal of Public Health* 89:1819-1826, 1999
Di.S.Co	14	Giampaoli S, Poce A, Sciarra F, Lo NC, Dima F, Minoprio A, Santaquilani A, Caiola De SP, Volpe R, Menditto A, Menotti A, Urbinati GC: Change in cardiovascular risk factors during a 10-year community intervention program. *Acta Cardiologica* 52:411-422, 1997
Dutch Heart Health	15a	Schuit AJ, Wendel-Vos GC, Verschuren WM, Ronckers ET, Ament A, van AP, van RJ, Ruland EC: Effect of 5-year community intervention Hartslag Limburg on cardiovascular risk factors. *Am J Prev Med* 30:237-242, 2006
	15b	Ronda G, van AP, Candel M, Ruland E, Steenbakkers M, van RJ, Brug J: The Dutch Heart Health Community Intervention 'Hartslag Limburg': effects on smoking behaviour. *European Journal of Public Health* 14:191-193, 2004
	15c	Ronda G, van AP, Candel M, Ruland E, Steenbakkers M, van RJ, Brug J: The Dutch Heart Health community intervention 'Hartslag Limburg': results of an effect study at individual level. *Health Promotion International* 19:21-31, 2004
Finnmark Båtsfjord	16	Lupton BS, nneb V, gaard AJ: The Finnmark Intervention Study: is it possible to change CVD risk factors by community-based intervention in an Arctic village in crisis? *Scandinavian Journal of Public Health* 31:178-186, 2003
Finnmark North Cape	17	Lupton BS, nneb V, gaard AJ: The Finnmark Intervention Study: is it possible to change CVD risk factors by community-based intervention in an Arctic village in crisis? *Scandinavian Journal of Public Health* 31:178-186, 2003
Heartbeat Wales	18	Tudor-Smith C, Nutbeam D, Moore L, Catford J: Effects of the Heartbeat Wales programme over five years on behavioural risks for cardiovascular disease: quasi-experimental comparison of results from Wales and a matched reference area. *BMJ* 316:818-822, 1998
Kilkenny Health	19	Shelley E, Daly L, Collins C, Christie M, Conroy R, Gibney M, Hickey N, Kelleher C, Kilcoyne D, Lee P, .: Cardiovascular risk factor changes in the Kilkenny Health Project. A community health promotion programme. *Eur Heart J* 16:752-760, 1995
National Research Programme	20	Gutzwiller F, Nater B, Martin J: Community-based primary prevention of cardiovascular disease in Switzerland: methods and results of the National Research Program (NRP 1A). *Preventive Medicine* 14:482-491, 1985
Otsego-Schoharie Healthy Heart	21	Nafziger AN, Erb TA, Jenkins PL, Lewis C, Pearson TA: The Otsego-Schoharie healthy heart program: prevention of cardiovascular disease in the rural US. *Scandinavian Journal*

		*of Public Health*21-32, 2001
Stanford 3 community	22a	Farquhar JW, Maccoby N, Wood PD, Alexander JK, Breitrose H, Brown BW, Haskell WL, McAlister AL, Meyer AJ, Nash JD, Stern MP: Community education for cardiovascular health. *Lancet* 1:1192-1195, 1977
	22b	Maccoby N, Farquhar JW, Wood PD, Alexander J: Reducing the risk of cardiovascular disease: effects of a community-based campaign on knowledge and behaviour. *Journal of Community Health* 3:100-114, 1977
American Heart Association Campaign for Women	23	Christian AH, Rosamond W, White AR, Mosca L: Nine-year trends and racial and ethnic disparities in women's awareness of heart disease and stroke: An American Heart Association national study. *Journal of Women's Health* 16:68-81, 2007
ATS Sardegna	24	Muntoni S, Stabilini L, Stabilini M: Results of a five-year community-based programme for cardiovascular disease prevention: the ATS-Sardegna Campaign. *European Journal of Epidemiology* 15:29-34, 1999
CardioVision 2020	25	Kottke TE, Thomas RJ, Lopez-Jimenez F, Brekke LN, Brekke MJ, Aase LA, Deboer SW, Hayes SN, Hoffman RS, Mangan MA, Menzel PA: CardioVision 2020: program acceptance and progress after 4 years. *Am J Prev Med* 30:137-143, 2006
German CINDI	26	Wiesemann A, Metz JN: Four years of practice-based and exercise-supported behavioural medicine in one community of the German CINDI area. Countrywide Integrated Non-Communicable Diseases Intervention. *International Journal of Sports Medicine* 18:308-315, 1997
Coalfields Healthy Heartbeat	27	Higginbotham N, Heading G, McElduff P, Dobson A, Heller R: Reducing coronary heart disease in the Australian Coalfields: evaluation of a 10-year community intervention. *Soc Sci Med* 48:683-692, 1999
Franklin Cardiovascular Health	28	Record NB, Harris DE, Record SS, Gilbert-Arcari J, DeSisto M, Bunnell S: Mortality impact of an integrated community cardiovascular health program. *American Journal of Preventive Medicine* 19:30-38, 2000
Have a Heart Paisley	29	Blamey, Avril, Ayana, M, Lawson, L, Mackinnon, J, Paterson, I, and Judge, K. Final report of the independent evaluation of Have a Heat Paisley. 1-136. 2004. The University of Glasgow.
Olöfstrom	30	Isacsson A, Lindholm LH, Schersten B, Eklund E, Bjorkman S, Jarhult B, Asp NG, Lanke J: Community intervention against non-insulin dependent diabetes mellitus (NIDDM) and cardiovascular disease: A study based on Swedish health care. *Cardiovascular Risk Factors* 6:164-171, 1996
Quebec Heart Health: Rural	31	Huot I, Paradis G, Ledoux M, Quebec Heart Health Demonstration Project Research Group.: Effects of the Quebec Heart Health Demonstration Project on adult dietary behaviours. *Preventive Medicine* 38:137-148, 2004
Quebec Heart Health: Suburban	32	Huot I, Paradis G, Ledoux M, Quebec Heart Health Demonstration Project Research Group.: Effects of the Quebec Heart Health Demonstration Project on adult

		dietary behaviours. *Preventive Medicine* 38:137-148, 2004
Quebec Heart Health: Urban	33	Huot I, Paradis G, Ledoux M, Quebec Heart Health Demonstration Project Research Group.: Effects of the Quebec Heart Health Demonstration Project on adult dietary behaviours. *Preventive Medicine* 38:137-148, 2004
Ebeltoft	34	Engberg M, Christensen B, Karlsmose B, Lous J, Lauritzen T: General health screenings to improve cardiovascular risk profiles: a randomized controlled trial in general practice with 5-year follow-up. *The Journal of Family Practice* 51:546-552, 2002
Inter99	35	Von Huth SL, Ladelund S, Borch-Johnsen K, Jorgensen T: A randomized multifactorial intervention study for prevention of ischaemic heart disease (Inter99): the long-term effect on physical activity. *Scand J Public Health* 36:380-388, 2008
The Malmö Preventative Project	36	Berglund G, Nilsson P, Eriksson KF, Nilsson JA, Hedblad B, Kristenson H, Lindgarde F: Long-term outcome of the Malmo preventive project: mortality and cardiovascular morbidity.[see comment]. *Journal of Internal Medicine* 247:19-29, 2000
Minnesota Heart Health Screening	37	Murray DM, Luepker RV, Pirie PL, Grimm RH, Bloom E, Davis MA, Blackburn H: Systematic risk factor screening and education: a community-wide approach to prevention of coronary heart disease. *Preventive Medicine* 15:661-672, 1986
The multifactor primary prevention trial: Göteborg	38	Wilhelmsen L, Berglund G, Elmfeldt D, Tibblin G, Wedel H, Pennert K, Vedin A, Wilhelmsson C, Werkö L: The multifactor primary prevention trial in Göteborg, Sweden. *European Heart Journal* 7:279-288, 1986

Conclusions:

This review suggests that there is some support that primary preventative population programmes involving education, mass media and screening in members of general populations can be effective in improving some CVD risk factors and behaviours. Considerable uncertainty is left about the size of these effects and the effect on health outcomes summarised across all programmes. It is not possible, on the basis of available evidence, to comment on whether characteristics of programmes or target populations may mediate programme effectiveness. Whether the observed findings of the programmes that were conducted many years ago remain generally applicable in the UK at the current time is not clear.

1 Introduction

The National Institute for Health and Clinical Excellence ('NICE' or 'the Institute') has been asked by the Department of Health (DH) to develop guidance on a public health programme aimed at preventing cardiovascular disease (CVD) in different populations.

NICE public health programme guidance supports implementation of the preventive aspects of national service frameworks (NSFs) where a framework has been published. The statements in each NSF reflect the evidence that was used at the time the framework was prepared. The public health guidance published by the Institute after an NSF has been issued will have the effect of updating the framework. Specifically, in this case, the guidance will support NSFs on the following: cancer, coronary heart disease (including obesity), diabetes, and older adults (including stroke services) (DH 2000a; DH 2000b; DH 2001a; DH 2001b).

This guidance will support a number of related policy documents including:

- 'Delivering choosing health: making healthier choices easier' (DH 2005a)
- 'Health challenge England – next steps for choosing health' (DH 2006a)
- 'National stroke strategy' (DH 2007)
- 'Our health, our care, our say' (DH 2006b)
- 'Tackling health inequalities: what works' (DH 2005b)

- 'The NHS in England: the operating framework for 2006/7' (DH 2006c)
- 'Wanless report: securing good health for the whole population' (Wanless 2004).
- 'Tackling Health Inequalities – A Programme for Action' (DH 2003)
- 'Tackling Health Inequalities: 2007 Status Report on the Programme for Action' (DH 2008)
- Commissioning framework for health and well-being (DH 2007)
- 'The NHS in England: The operating framework for 2008/9' (DH 2007)
- 'Healthy Weight, Healthy Lives: A Cross Government Strategy for England' (DH 2008)
- 'Putting prevention first – vascular checks: risk assessment and management' (DH 2008a)

This guidance will provide recommendations for good practice, based on the best available evidence of effectiveness, including cost effectiveness. It is aimed at professionals, commissioners and managers with public health as part of their remit working within the NHS, local authorities and the wider public, private, voluntary and community sectors. It may also be of interest to members of the public.

The guidance will complement and support NICE guidance on alcohol, CVD risk assessment, obesity, physical activity and smoking cessation.

This report is part of the effectiveness review to be delivered to the Programme Development Group (PDG). It is the final of three reports addressing question 1 defined in the final scope as:

Which multiple risk-factor interventions are effective and cost effective in the primary prevention of CVD within a given population? Where the data allows, how does the effectiveness and cost effectiveness of interventions vary between different population groups?

A subsequent report, presenting findings for cost effectiveness, was presented to the PDG in January 2009. A review of the qualitative literature will also be presented at this meeting to address the second question defined in the scope:

What barriers and facilitators influence the effectiveness of multiple risk-factor programmes aimed at reducing CVD (or the risk factors associated with CVD) among a given population (including sub-groups experiencing health inequalities where the data allows)?

1.1 Background

A large number of preventable illnesses and deaths are associated with CVD (CVD includes coronary heart disease [CHD], heart failure, stroke and peripheral arterial disease). In 2005, there were 171,021 deaths from circulatory diseases in England, including 45,620 from CHD and 18,013 from stroke (Health Survey for England 2005, cited in Allender et al. 2007). In that year, over 40% of deaths in the UK were caused by CVD. More than 4 million UK patients are currently affected and it costs the UK approximately £30 billion annually. A large proportion of the risk of a first heart attack (over 90%) comes from nine easily or potentially modifiable risk factors (Yusuf et al. 2004).

Despite recent improvements, UK death rates from CVD are relatively high compared with other developed countries (only Ireland and Finland have higher rates). There is also considerable variation within the UK itself – geographically, ethnically and socially. For instance, premature CVD death rates are three times

higher among lower socioeconomic groups than among more affluent groups – and death rates from CVD are approximately 50% higher than average among South Asian groups (Allender et al. 2007). Circulatory disease makes a substantial contribution to the gap in life expectancy between the Spearhead areas (the areas with the worst health and deprivation indicators) and England generally. For males, 35% of the gap is due to differences in circulatory diseases (70% of this being due to CHD), and for females the figure is 30% of the gap (63% of this being due to CHD) (DH 2008b).

CVD is influenced by a variety of 'upstream' factors (such as access to a safe environment for physical activity and a person's educational level) and 'downstream' behavioural issues (such as diet and smoking). The British Heart Foundation identifies nine key risk factors that can be modified: smoking/tobacco use, poor diet, insufficient physical activity, high blood pressure, obesity/overweight, diabetes, psychosocial stress (linked to people's ability to influence the potentially stressful environments in which they live), high alcohol consumption and high blood cholesterol. Other factors, such as maternal nutrition and air pollution may also be linked to the disease (Allender et al. 2007). Changes in risk factors, such as a reduction in cholesterol or blood pressure, or quitting using tobacco, can rapidly reduce the risk of developing CVD.

Evaluating complex changes between populations is problematic for a number of reasons, for example: it's difficult to design studies which evaluate entire cities, regions or countries; control sites can become 'contaminated' (that is, if the intervention affects people living in the control area); unreasonable expectations about the speed of effect; and failure to address 'upstream' influences such as policy or manufacturing practices. Some population programmes have been

accompanied by a substantial reduction in the rate of CVD deaths. However, the degree to which these are attributable to the programme is debatable.

1.2 Research Objectives

This report, together with two others, addresses the question:
Which multiple risk-factor interventions are effective and cost effective in the primary prevention of CVD within a given population? Where the data allows, how does the effectiveness and cost effectiveness of interventions vary between different population groups?

The expected outcomes are population changes in: rates or levels of CVD mortality or morbidity; the biochemical or physiological precursors of CVD; behaviour associated with the risk of developing CVD.

The precise nature of the populations and interventions to be covered, and those which are not included are defined in the final scope as follows:

POPULATION	
COVERED BY GUIDANCE	**NOT COVERED BY GUIDANCE**
Groups to be covered are populations defined on a geographical basis. The area will usually be at least a region of a country (such as Merseyside) or an urban or rural area (such as Paisley and Nottingham or New Forest). In the UK, the geographical area would not be less than what is currently covered by a Primary Care Trust. A population could	The guidance will not focus on individuals who are clinically diagnosed as being at high risk of developing – or who have already been diagnosed with – CVD. However, as populations include people at different stages of disease, it will have some relevance for them. (Individuals at high risk of developing CVD are covered by

also be made up of people living in a designated geographical area that fulfils the criteria above who also share a specific characteristic, such as all South Asian men over 50 who live in Sheffield. Populations will include both adults and children.	other NICE guidance, see section 6.)
ACTIVITIES /INTERVENTIONS	
COVERED BY GUIDANCE	**NOT COVERED BY GUIDANCE**
Multiple risk-factor approaches to preventing CVD among a given population. These include addressing two or more risk factors through one or more of the following types of intervention: • educational/behavioural (including the use of mass media) • fiscal • environmental • legislative	Secondary prevention activities and those aimed only at people who are at high risk of developing CVD. (If an intervention covers both primary and secondary prevention, it will only be included if the primary component is sufficiently disaggregated and can be reported separately.)
OR Programmes that include a pharmacological element alongside a broader, non-pharmacological multiple risk-factor approach (as indicated in 4.2.1a) will be included when they	OR Interventions which focus on screening for CVD risk factors (for example, cholesterol-level screening) and do not attempt to modify them

involve a primary prevention element and where data can be disaggregated to allow consideration of the impact of the non-pharmacological elements.	
OR Natural experiments, such as changes in the diet of Eastern Europeans brought about by social change, where relevant evidence is available	

A number of secondary questions were posed should sufficient data be available:

- The target audience, actions taken and by whom, context, frequency and duration.
- Whether it is based on an underlying theory or conceptual model.
- Whether it is effective and cost effective.
- Critical elements. For example, whether effectiveness and cost effectiveness varies according to:
  - the diversity of the population (for example, in terms of the user's age, gender or ethnicity)
  - the status of the person (or organization) delivering it and the way it is delivered
  - its frequency, length and duration, where it takes place and whether it is transferable to other settings
  - its intensity.

- Any trade offs between equity and efficiency.
- Any factors that prevent – or support – effective implementation.
- Any adverse or unintended effects.
- Current practice.
- Availability and accessibility for different population groups.

The study designs of particular interest for effectiveness were: RCT, Controlled before and after, Cohort, Case control, Before and after and Interrupted time series.

1.3 Structure of report

The structure of this report is as follows:

■ Chapter 2 discusses how the literature search was conducted, the retrieval of papers, the selection of studies for inclusion, data extraction and quality assessment.
■ Chapter 3 presents the effectiveness findings.
■ Chapter 4 discusses the review findings, highlighting their applicability, limitations and any gaps.

Appendices present supporting documents such as protocol, example search strategies, inclusion/exclusion checklists, quality assessment tools and data extraction sheets.

2 Methodology

The protocol governing the conduct of the literature review for all three phases of the review addressing question 1 is given in Appendix 1. The methods described in the following sections are the features which particularly apply to phase 3, which considers relevant material, identified in the primary studies search, used for the current report. There were no major departures from the stated protocol.

2.1 Identifying potentially relevant studies

2.1.1 Effectiveness literature searches

The search strategy was developed by the information specialists at WMHTAC in consultation with CPHE who signed off the final version before implementation.

Resources for locating primary studies

Initial scoping searches, to estimate the nature and volume of the literature targeted systematic reviews, evidence briefings and guidelines, following the recommendations of the ARIF search protocol (see appendix 1.2 of Appendix 1), as well as a brief search of bibliographic databases for primary studies. Given the volume of literature likely to be generated by this topic it was decided to run the search strategy for locating primary studies in three phases according to resources in which the studies were to be located.

Phases 1 and 2:

- Primary studies identified via existing systematic reviews relevant to the research question, these reviews being located using the same bibliographic databases selected for the searches for primary studies (see below) plus additional sources recommended in the ARIF search protocol (see appendix 1.2 of appendix 1)

Phase 3:

- Additional primary studies identified from searches of bibliographic databases specifically targeting primary studies (listed below)
- Additional potentially missing studies identified by PDG
- Searches of key UK public health web-sites (see list in protocol appendix 1)
- Checking of bibliographies of included studies

The key components of the search question - 'cardiovascular diseases' (population), 'health promotion' (intervention) and thirdly the concept of 'Programmes tackling at least two CVD risk factors' (focus of the intervention) - were combined, ready to be used with the appropriate study design terms. The main focus of the searches in phase 1 and 2 is on existing relevant systematic reviews. Therefore, where possible, a systematic reviews filter (e.g. the Haynes "Reviews – specificity" in-built filter on Ovid) or otherwise appropriate textwords were used in combination with the subject search terms to identify reviews for this phase of the search.

Databases

After consultation with NICE it was decided that the following bibliographic databases would be searched:

■ Cochrane Library (Wiley) (CDSR, DARE, HTA databases)

■ MEDLINE

■ MEDLINE In Process

■ EMBASE

■ CINAHL (Cumulative Index of Nursing and Allied Health Literature)

■ PsycINFO

■ HMIC (Health Management Information Consortium DH-Data & King's Fund Database, plusHELMIS)

■ ASSIA (Applied Social Science Index and Abstracts)

Websites

The following websites were also searched for relevant reviews:

■ Centre for the Evaluation of Public Health Interventions London School of Hygiene & Tropical Medicine http://www.lshtm.ac.uk/cephi/

■ Cochrane Public Health Group http://www.ph.cochrane.org/en/index.html

■ The Campbell Collaboration http://www.campbellcollaboration.org/

■ The Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre Social Science Research Unit Institute of Education, University of London http://eppi.ioe.ac.uk/cms/

■ Health evidence.ca http://health-evidence.ca/

Limits

The following limits were placed on the search strategy:

■ Published from 1970 onwards

■ In English language only

Any studies undertaken in populations from non-developed or non-OECD countries were also to be excluded. Due to concerns about the effectiveness of trying to incorporate this aspect into the search strategy this exclusion criterion was to be applied by reviewers at a later stage.

The following were excluded: books; book chapters; thesis; dissertations; studies which describe the relationship between health and ill/health and CVD risk factors (i.e. correlates studies or non-evaluative studies).

The search process has been clearly documented to ensure there is a transparent and repeatable audit trail. For all search strategies used in phase 1/2 of the searches see appendix 2.

2.1.2 Suggestions from experts and PDG

Six primary studies were received from the expert group and were considered for inclusion in phase 3 together with studies identified from the primary studies literature search.

2.1.3 Additional web-site searches

No additional web-site searches were undertaken beyond those described in section 2.1.1

2.2 Selection of effectiveness studies for inclusion

2.2.1 Review title and abstract appraisal

Primary studies were identified as being possibly relevant to this review by screening retrieved titles/abstracts from the primary studies search. 36,622 citations were examined for inclusion and 127 potentially relevant studies were ordered for assessment of their full text. The process was undertaken by one of four reviewers (MP, WG, CD, CH). There was no double-checking of decisions.

2.2.2 Review full text appraisal

Using hard copies identified in 2.2.1 as the starting point, full text assessment was undertaken using the full paper inclusion checklist for inclusion/exclusion of primary studies (appendix 4). This form was developed by the review group and signed off by the CPHE. This focused on the nature of the study and whether the activity aimed to address CVD, targeted multiple risk factors, targeted a population and was mainly aimed at primary prevention. Of the 127 hard-copy primary studies, 21 were identified for inclusion in the current report.

The process was undertaken by one of two reviewers (MP, WG). Where inclusion/exclusion was unclear, decisions were discussed with a third reviewer. The reasons for exclusion of studies/programmes were recorded according to the categories identified in the in/exclusion list.

16 programmes, represented by 21 publications, were included in the current report.

2.2.3 Reference tracking

Due to time constraints, reference tracking was not undertaken for all programmes in the current report. However, where there was suggestion or evidence of related publications, these were sought. Additionally, the comprehensive literature search (>36,000 references) was expected to retrieve most relevant primary studies.

2.2.4 Summary of effectiveness studies identified for inclusion

The following programmes were identified for inclusion in this second phase to address question 1 and 21 related publications are shown by their respective programmes.

- The American Heart Association campaign for women (Christian 2007) (Mosca 2004) (Robertson 2001) (Mosca 2000)
- The ATS-Sardegna Campaign (Muntoni 1999)
- CardioVision 2020 (Kottke 2000) (Kottke 2006)
- The German CINDI (Wiesemann 1997) (Wiesemann 2004)
- Coalfields Healthy Heartbeat (Higginbotham 1999)
- The Franklin Cardiovascular Health Program (Burgess 2000)

- Have a Heart Paisley (Independent evaluation report 2005)
- The Olöfstrom community intervention (Isacsson 1996)
- The Quebec Heart Health Demonstration Project – Rural (Huot 2004)
- The Quebec Heart Health Demonstration Project – Suburban (Huot 2004)
- The Quebec Heart Health Demonstration Project – Urban (Huot 2004)

- The Ebeltoft screening and counseling intervention (Engberg 2002)
- The Inter99 study (Von Huth Smith 2008) (Pisinger 2005a) (Pisinger 2005b)
- The Malmö Preventative Project (Berglund 2000)
- The Minnesota Heart Health community screening and education (Murray 1986)
- The Multifactor Primary Prevention Trial, Göteborg (Wilhelmsen 1986)

2.2.5 Excluded effectiveness studies

A summary of the reasons for exclusion of studies from the hard-copy stage of phase 3 of the review is given in table 2 below:

Reason for exclusion	**Number**
Published before 1970	0
Thesis/book chapter	0
Not English language	4
Inappropriate setting and population	66
Does not address general purpose (reducing CVD risk)	4
Inappropriate intervention	13
Inappropriate design for effectiveness review	9
No appropriate outcomes	31
Number of articles "included"	21
Number of programmes represented by these articles	16

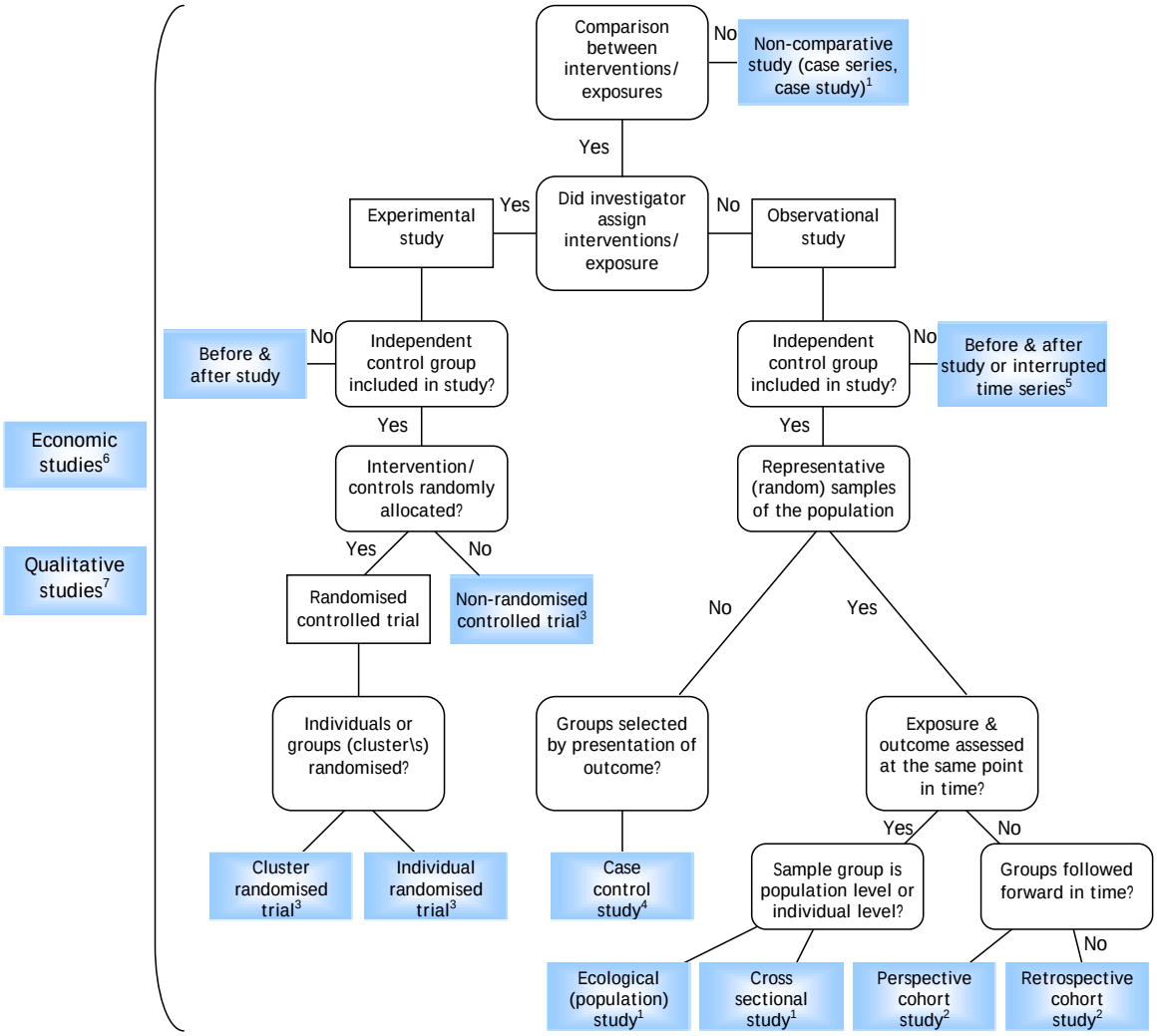
Table 2 Excluded primary studies obtained from screening of hard-copy studies in phase 3

2.3 Data extraction and quality appraisal

2.3.1 Data extraction

The study type of each included effectiveness paper was identified using the following algorithm which was adapted from *Methods for development of NICE public health guidance.*

Figure 2.1: Algorithm for classifying primary study designs about effectiveness *(Adapt or delete as appropriate)*



Source:

The effectiveness data extraction form contained in the *Methods for development of NICE public health guidance* was adapted to reflect the parameters of this review – please see Appendices for an example of a completed form. One reviewer extracted

data for each full paper using this form. A second independent reviewer checked the data extraction, and any differences were resolved by discussion with a third reviewer. In a slight departure from the original protocol this was only done for a random 10% sample of the data items. Following feedback on the first report, a separate table focussing on the precise nature of the intervention has been included (Section 5.2).

For the cost effectiveness review, the data extraction form contained in the *Methods for development of NICE public health guidance* was adapted to reflect the parameters of this review and supplemented with questions from the Drummond checklist (Guidelines for authors and peer reviewers of economic submissions to the BMJ, M F Drummond, 1996, on behalf of the BMJ Economic Evaluation Working Party).

2.3.2 Quality assessment for effectiveness primary studies

Quality appraisal was conducted based on the NICE CPHE forms. These forms provide criteria for rating a study based on how robust an example it is of that particular study design. For example, a randomised control trial (RCT) was rated on how well it meets the defined standards for a robust RCT. Different criteria exist for each type of study design. This means that the quality rating for studies of the same design can be compared with each other (*i.e.* an RCT rated ++ is more robust than an RCT rated +). However, quality ratings for different study designs cannot be compared.

Two independent reviewers assessed the quality of each included study. Any differences in quality assessment were resolved by discussion with a third reviewer or, if agreement could not be reached, details were reported in the review. Appendix 5 provides details of quality assessment results for each of the programmes in the current review.

2.4 Synthesis and formulation of evidence statements

The results of the data extraction and quality assessment for each programme identified in the included effectiveness studies were presented in a narrative summary and combined in a summary evidence table. An evidence statement was then generated for programmes relating to this report as well as statements consolidating evidence from all three phases of the review process. In addition, graphical representation of the best available nominal data was explored for the main physiological outcomes: blood pressure, smoking, cholesterol and BMI and behavioural outcomes of diet and physical activity. The aim was to help identify patterns in direction of effect across the included programmes and to explore the possibility of formal meta-analysis.

Chapter three of the report presents the synthesis of data and evidence statements for the included effectiveness studies.

.

3 Effectiveness Findings

A total of 16 programmes addressing prevention of CVD at a population level were identified in the third phase of the review for the current report. Two main types of community intervention were found:

- Media and education community programmes (n=11) (section 3.1)
- Screening and advice programmes aimed at the population level (n=5) (section 3.2)

For clarity, these programmes are described in separate sections. Programmes are given in alphabetical order.

Each programme is first described paying particular attention to some of the issues raised by the PDG such as:

- Nature of the target population, particularly diversity in terms of age, gender and ethnicity
- Whether intervention is based on an underlying theory or conceptual model.
- Precise nature of the intervention including :
  - status of the person (or organization) delivering it and the way it is delivered
  - its frequency, length and duration, where it takes place and whether it is transferable to other settings

- its intensity
- factors with a bearing on the availability or accessibility for different population groups.

Its results are then reported taking each of the targeted outcomes in turn (primary outcomes: CVD mortality; CVD morbidity; biochemical precursors of CVD including lipid levels, HDL/LDL ratio, triglyceride levels; physiological precursors of CVD including blood pressure and the metabolic syndrome; behaviours associated with the risk of CVD including use of tobacco, diet, physical activity, alcohol consumption; secondary outcomes: knowledge, attitudes and intentions with regard to behaviours related to CVD; adverse events). All available results have been reported. Where results are not given for outcomes, this was due to their absence in the identified studies.

Finally, the limitations of the study are then described based on the quality assessment and issues of applicability.

The information is also presented in a series of summary tables in section 3.4.

3.1 Media and education community programmes addressing prevention of CVD at population level

3.1.1 The American Heart Association campaign for women (1)

From 1979-2001, rates of CVD-related death in the United States were decreasing in men but, in women, were stable or increasing. In 1997, the American Heart Association initiated a national campaign aimed at reducing rates of cardiovascular

disease in women. The aim of the study was to track trends over this period of time with particular attention to trends in women of different race/ethnicity and age.

Target population

The whole of the United States is the target for the intervention campaign. No control group has been used for evaluation.

Theory/conceptual model of intervention

None stated

Intervention description

The American Heart association national campaign for women started with 'Take Wellness to Heart' in 1997. More recently, the 'Go Red for Women' movement was launched (2004) and is currently running across the US. This campaign aims to promote a positive, proactive approach to tackling the risks of CVD in women and "celebrates the energy passion and power that we have as women to band together to wipe out heart disease and stroke". The website is the major source of campaign information (http://www.goredforwomen .org/).

Risk factor screening is promoted and a 'National ware red day' used to raise awareness of the risks of CVD. The website gives details of Go Red events held in each area including a twelve week physical activity programme, 'choose to move', Go Red luncheons and community events held in hespanic communities. Nutrition tips are available and stories from people who have changed their lives and risks of CVD. Online specialists are available to answer questions relating to heart disease and educational materials are provided.

The campaign has been supported by many companies and, in 2007, >5 000 showed their support by conducting fundraising events where employees wore something red to raise awareness of the risks of CVD. In early 2008, cities across the country went red

by illuminating monumental buildings to raise awareness of the risks of heart disease in women.

Accessibility:

Limited information is provided about the nature of the intervention. The intervention was initiated by the American Heart Association and comprised a national media campaign, educational materials and conferences, programs to address behaviour change and 'grassroots initiatives'. No information is provided to indicate the intensity of the intervention or the range of venues used. Similarly, no information is provided on whether education materials were made accessible for non native language speakers, those from different cultural backgrounds or for those with low literacy levels.

The evaluation of the intervention is described as being based on a nationally representative sample of women. However, the authors themselves note that interviews conducted in the English Language from a random digit dialling sample limit the generalisability of findings for women in households without telephones or those who do not speak English. The evaluation identified that healthcare providers were cited as a source of information about CVD by a minority of respondents in comparison to mass media. Ethnic differences existed in how comfortable women felt about talking to a doctor (Hispanic< Black+White). In addition, > 50% of women stated that the media had caused them confusion regarding CVD risk factors. Several ethnic, socio-economic and age related differences in CVD awareness and knowledge were noted which may be a reflection of the accessibility of the intervention to these population sub-groups:

-Black and Hispanic women were significantly less likely to identify CVD as the leading cause of death in women compared to white women

-Younger women (<35) were significantly less likely to identify CVD as the leading cause of death in women compared to older women

-Ethnic differences in knowledge about CVD and CVD prevention were evident (Black and Hispanic knowledge< White).

Evaluation

Cross sectional surveys of US women were taken in 1997, 2000, 2003 and 2006.

Participant selection/recruitment

In 2006, women aged ≥25 years were contacted through random digit dialling and one female respondent was interviewed per household. 870 respondents were successfully recruited and, to ensure an adequate sample of Hespanic and black women were recruited, additional random digit dialling was conducted in these groups. The final sample comprised 1,005 women (71% white non-Hispanic, 12% black non-Hispanic, 12% Hispanic and 6% other ethnicities).

Similar surveys had previously been conducted in 1997 (n=1,000) (21), 2000 (n=1,004) (2) and 2003 (n=1,024) (3).

Outcome measures

The following questions were asked about knowledge and awareness of CVD and its risk factors:

- What is the leading cause of death in women?
- What is the greatest health problem facing women?
- How well informed are you about heart disease?
- How well informed are you about stroke?
- Is there anything you can do to prevent getting heart disease?
- When you think of heart disease, do you think of someone having a heart attack and dying quickly?
- When you think of stroke, do you most often think about someone having a long-term disease that will reduce the quality of life?

- Are you comfortable talking to your doctor about prevention and treatment options regarding your health?
- Is it easy to find accurate and easy to understand information about heart disease and stroke in women?
- Do you think that you are at low risk for a heart attack or stroke for a woman of your age?
- Do you think that taking hormone therapy can help reduce your risk for heart disease? (together with 4 more questions relating to the use of hormone therapy).
- What are the symptoms of heart attack and stroke?
- What are strategies to prevent heart disease?
- What are the areas of confusion regarding CVD from messages in the media?

Results were also examined according to ethnicity (white/black/hespanic) and age (25-34, 35-64, ≥65).

Statistical methods

Responses to cross sectional surveys were weighted to obtain nationally representative samples matched to the 2005 Current Population Survey for region of the country, age, race/ethnicity, income and household size. Univariate relationships of responses between each ethnic and age group were analysed using t tests and logistic regression models were used to evaluate the effect of race/ethnicity, age and education on awareness of CVD. Trend analysis was conducted using linear regression to evaluate women's attitudes across all survey years. No adjustments were made for multiple comparisons and statistical tests.

Results

Only results from a portion of the survey questions were reported in the text of the study report and a selection of results are reported here.

Primary outcomes

1. Knowledge of CVD: What is the leading cause of death?

The proportion of all females who correctly identified CVD as the leading cause of death in 2006 was 57% and this was significantly higher than the proportion in 2003 (46%, $p<0.001$), 2000 (34%, $p<0.001$) and 1997 (30%, $p<0.001$) and there was a significant positive trend in knowledge ($p=0.02$).

When respondents were sub-divided by racial/ethnic group, the positive trend remained for knowledge and was significant for white ($p=0.02$) and black ($p=0.05$) respondents and neared significance for Hispanic respondents ($p=0.07$). However, the gap between awareness of different ethnic groups had not narrowed over time and, in 2006 there were still differences between women of different ethnicities. In 2006, white women were significantly more likely to identify CVD as the leading cause of death compared to black women (68% versus 31% respectively, $p<0.05$) and hespanic women (29%, $p<0.05$) and these observations held in a multivariable regression model adjusting for age and education ($p<0.05$).

In 2006, women aged 45-64 years were more likely to identify heart disease as the leading cause of death than those aged 25-34 years (61% versus 48% respectively, $p<0.05$).

2. Knowledge of CVD: What is the greatest health problem facing women?

In 2006, 21% of women correctly identified heart disease as the greatest health problem, a significant increase from the proportion in 2003 (13%, $p<0.05$), 2000 (8%, $p<0.05$) and 1997 (7%, $p<0.05$). In 2006, the proportion correctly identifying heart disease as the greatest health problem was significantly lower in black (15%) and Hespanic (6%) women compared to white women (21%, $p<0.05$). Younger women (25-44 years) were significantly more likely to cite breast cancer as the greatest health problem compared to older women ($\geq$65 years) (32% versus 37% respectively, $p<0.05$).

3. Knowledge of CVD: Do you consider yourself to be very well/well informed about CVD?

In 2006, 42% of women considered themselves to be very well or well informed about heart disease, higher than the 34% in 1997. Hespanic women were more likely than black women to consider themselves to be not at all informed about heart disease (17% versus 6%, $p<0.05$).

4. Knowledge of CVD: Is there anything that can be done to prevent CVD?

In 2006, 14% of women thought that there was nothing that they could do to help prevent heart disease and this was similar to findings in previous years. Hespanic women more often strongly/somewhat agreed that there was nothing they could do to prevent CVD compared to white women (22% versus 11% respectively, $p<0.05$) and women aged 25-34 and $\geq$65 years were more likely than women aged 35-64 years to strongly/somewhat agree that there was nothing they could do to prevent CVD.

5. Knowledge of CVD: Can you reduce your risk of heart disease by taking hormone therapy?

In 2006, fewer women agreed that by taking hormone therapy they could reduce their risk of heart disease (41%) compared to 2003 (46%), 2000 (63%) and 1997 (56%). Younger women (25-34 and 35-44 years) were more likely to strongly or somewhat agree that hormone therapy can help reduce their risk for heart disease compared with women $\geq$65 years (47% and 43% versus 32%, $p<0.05$).

6. Knowledge of CVD: What are strategies to prevent heart disease?

In 2006, most women recognised that maintaining a healthy blood pressure (97%), maintaining healthy cholesterol (96%), exercise (96%), loosing weight (96%), reducing stress (96%), quitting smoking (95%), reducing dietary cholesterol (93%) and reducing dietary salt (90%) were important methods for preventing heart disease, similar to proportions observed in previous survey years.

7. Knowledge of CVD: What are areas of confusion relating to media messages about CVD?

In 2006, the three most commonly cited areas of confusion were 1) what type of diet is best to protect the heart? (69%), 2) how can weight be controlled? (66%) and 3) how does stress/depression affect the heart? (66%).

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors

Results may not be generalisable as the survey was only conducted in those women that had household telephones and were English speaking.

There may have been response bias with women giving better self-reported measures.

Power to detect differences between ethnic minorities was limited because of the small sample size.

Limitations identified by reviewer

A large amount of outcome variables were measured and it seems likely that a vast number of statistical tests were conducted. However, no adjustments were made for multiple comparisons and this increases the level of uncertainty about the significance of results.

Respondents to questionnaires may have been people who were more likely to be well informed about cardiovascular disease.

Summary

Knowledge of cardiovascular disease in US women appears to have increased since 1997. The American Heart Association 'Take Wellness to Heart' campaign and more recent 'Go Red for Women' movement may have played an import role in mediating change but, without comparison with trends in a control population, causality cannot be inferred.

3.1.2 The ATS-Sardegna Campaign (4)

The ATS-Sardegna Campaign began in 1990 on the Italian island of Sardinia. Specific aims of the CVD prevention and health promotion programme were to reduce cholesterol through changes in diet, prevent/reduce high blood pressure, reduce smoking and promote cessation, control body weight and increase physical activity.

Target population

Sardinia (n=1,645,000), an island off the coast of Italy, was targeted and intervention also extended to Sardinians migrating away from the area (n=~500,000). No control area was used for evaluation of the programme.

Theory/conceptual model of intervention

Not stated

Intervention description

In the years before implementation of programme activities, observational studies and intervention trials were conducted in Sardinia to investigate risk factors and test the effect of intervention. Subsequently, intervention in Sardinia had two main components: an individual (high risk) strategy and a population strategy. Due to irregular funding, intervention occurred in cycles and was maintained for five years until 1995. The high risk strategy, targeted at individuals, was managed by the Sardinian Association of General Practitioners. This was sustained until 1993 but then funding was terminated when new leadership came into place.

The community strategy largely consisted of a media campaign. An educational booklet: 'The Human Machine', was widely distributed covering 80% of Sardinian households and was also placed in pharmacies and given to people attending programme activities. A cartoon on CVD risk factors was broadcast 2,355 times on regional television. Messages were published in local newspapers and posters (~5,000) were put up in public places in all municipalities in Sardinia.

Sardinian migrants were also targeted by dispatching educational material to 152 Sardinian clubs over the world.

Accessibility:

The intervention comprised mass media education using a variety of outlets including delivery of a booklet to all households, television broadcasts, newspaper coverage and posters. The intervention was aimed at the adult population of Sardinia but no information is provided on the ethnic, socio-economic or educational profile of the target population. No information is provided on whether education materials were made accessible for non native language speakers, those with low literacy levels or those from different cultural backgrounds.

Evaluation survey samples are described as two random samples of the urban and rural populations aged 20-59 years and sexes are equally represented. Response rates varied between 60 and 66% but no information is provided on non-responders. The evaluation revealed that 80% of respondents were aware of the booklet delivered to households.

Effectiveness of the intervention varied in certain population sub-groups which may be an indicator of the acceptability of the intervention to these sub-groups:

-more men than women quit smoking (non significant)

-young people were less likely to have reduced their salt intake or to know their cholesterol (significance not reported).

Evaluation

There were two modes of programme evaluation, none of which used reference populations as a control:

a) Repeated cross sectional surveys conducted before (1978 and 1984) during (1992) and after (1995) the period of intervention, assessed changes in risk factor levels and eating habits.

b) Retrospective individual household interviews were made at the end of the campaign (1995-1996) to assess the programme.

Participant selection/recruitment

a) Cross sectional surveys of adults aged 20-59 years were conducted in 1978, 1984, 1992 and 1995 with equal male and female representation. Levels of the main CVD risk factors were measured and questionnaires included a food frequency questionnaire to assess dietary habits and questions relating to the use of lipid, blood glucose and blood pressure lowing drugs.

The 1978 survey contained 384 male and 409 female participants (response rate 66%), the 1984 survey contained 315 males and 349 females (response rate 55%), the 1992 survey contained 305 males and 324 females (response rate 60.2%) and the 1995 survey contained 200 males and 206 females (response rate 59.3%).

b) Retrospective door to door interviews were made in urban (Cagliari) and rural (Sinnai) areas with a total of 1 486 participants (1,053 urban and 433 rural). Participants were questioned about changes in knowledge and dietary habits.

Outcome measures

a) Cross sectional surveys in 1978, 1984, 1992 and 1995

Total cholesterol, triglycerides, systolic and diastolic blood pressure, BMI and prevalence of smoking. Dietary habits: Scores from food frequency questionnaire for consumption of foods rich in saturated fat, traditional foods, butter, olive oil, corn oil and lard.

b) Retrospective survey

Reported changes over intervention period in smoking, use of fats, use of alcohol, degree of physical activity, awareness of own cholesterol and blood pressure levels.

Statistical methods

Standardisation was made for age using the Italian population 10-year distribution groups as the reference population. Unpaired t tests were used. It appears that differences between sample means for each survey were compared with those of the previous survey but this is not fully clear from the study description. The prevalence of smoking was tested by the test of proportions.

Results

Primary outcomes

a) Cross sectional surveys

Results for the changes in risk factors between 1984 and 1992 surveys and 1992 and 1995 surveys are discussed below (intervention period was 1990-1995).

1. Total cholesterol

There was a significant increase in total cholesterol in men from 1984 (206 mg/dl; SE 2.5) to 1992 (215 mg/dl; SE 2.3, p=0.0001) and a subsequent non-significant decrease in 1995 (209 mg/dl; 2.5, p=NS). In women, the same pattern was observed with a significant increase from 1984 (197 mg/dl; SE 1.9) to 1992 (212 mg/dl; SE 2.2, p=0.0001) and a non-significant decrease in 1995 (210 mg/dl; SE 2.4, p=NS).

2. Triglycerides

There were non-significant increases in triglyceride levels in men (118 mg/dl; SE 3.5 to 1992: 122 mg/dl; SE 5.8, p=NS) and women (1984: 94 mg/dl; SE 2.7 to 1992: 96 mg/dl; SE 3.9, p=NS) from 1984-1992 but little change to 1995 for men (120 mg/dl; SE 6.2, p=NS) or women (96 mg/dl; SE 4.5, p=NS).

3. Blood pressure

There was no change in systolic blood pressure from 1984 to 1992 in men (1984: 130 mmHg; SE 0.9 to 1992: 129 mmHg; SE 1.0, p=NS) or women (1984: 129 mmHg; SE 1.1

to 1992: 128 mmHg; SE 0.9, p=NS). However, there were significant reductions in 1995 in both men (125 mmHg; SE 1.4, p=0.05) and women (124 mmHg; SE 1.1, p=0.05).

Diastolic blood pressure increased significantly from 1984 to 1992 in men (1984: 81 mmHg; SE 0.6 to 1992: 83 mmHg; SE 0.6, p=0.0001) and women (1984: 81 mmHg; SE 0.7 to 1992: 85 mmHg; 0.6, p=0.0001) and reduced significantly in 1995 in men (80 mmHg; SE 0.9, p=0.004) and women (82 mmHg; SE 0.9, p=0.004).

4. BMI

In men, BMI showed a non-significant increase from 1984 to 1992 (1984: 25.6 kg/m^2; SE 0.2 to 1992: 26.0 kg/m^2; SE 0.3, p=NS) and a non-significant decrease in 1995 (25.7 kg/m^2; SE 0.4, p=NS). In women, BMI rose significantly from 1984 to 1992 (1984: 25.3 kg/m^2; SE 0.2 to 1992: 26.4 kg/m^2; SE 0.3, p=0.0001) and showed a non-significant decrease in 1995 (25.9 kg/m^2; SE 0.4, p=NS).

5. Smoking

From 1984 to 1992, the proportion of current smokers decreased significantly in men (1984: 49%; SE 2.7 to 1992: 43%; SE 2.7, p=0.05) but increased significantly in women (1984: 22%; SE 0.8 to 1992: 28%; SE 2.1, p=0.004). In 1995, the proportion of smokers showed a non-significant decrease in men (41%; SE 2.9, p=NS) and a non-significant increase in women (31%; SE 2.4, p=NS).

6. Diet scores (Results for 1992 not detailed in the paper)

There were no significant changes from 1984 to 1995 for men or women in intake of foods rich in saturated fat, traditional foods, butter or olive oil. Consumption of corn oil increased significantly in men (1984: 0.8; SE 0.0 to 1995: 1.4; SE 0.1, p=0.0001) but not women. Consumption of lard decreased significantly in men (1984: 0.8; SE 0.0 to 1995: 0.6; SE 0.0, p=0.0001) and women (1984: 0.8; SE 0.0 to 1995: 0.6; SE 0.0, p=0.0001).

b) Retrospective survey

Results are reported separately for men, women and children in urban and rural areas. Although data is given for the % of people reporting change in different dietary and knowledge factors, no statistical analysis appears to have been conducted on the retrospective survey.

The percentage of smokers remained high in both urban and rural areas, especially in women. Almost two thirds of participants reported a reduction in total fat intake and most reported an increased preference for olive oil. Decreases in alcohol consumption and in salt intake were reported by ~30% of participants and increased attention to body weight and increased physical activity was reported by 40-60% of participants.

There appears to be a trend for higher reported change in urban compared to rural participants and in men compared to women but this cannot be properly ascertained from the information provided.

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors

The programme was begun only one year after a natural fall in heart disease mortality in Sardinia.

Limitations identified by reviewer

Trends for physiological and dietary risk factor changes obtained from the four population surveys cannot be separated from secular trends since no control group was used.

Incomplete data is reported for diet from the food frequency questionnaires (Measured in 1992 but not reported).

The retrospective survey was likely to be biased: programme staff asked respondents about lifestyle change in the context of the CVD programme. The retrospective survey is also uncontrolled and results are badly reported with no statistical analysis.

The reporting of p values in the paper is misleading: * is used to signify p=0.0001 whilst **** is used to signify p=0.05.

Summary

The absence of a control group and generally poor methods of program evaluation makes it impossible to judge with any certainty the effectiveness of the ATS-Sardegna Campaign. The particular attention given to urban versus rural differences in programme effect may have been an interesting factor for study but caution should be taken in interpretation as results may not be reliable.

3.1.3 CardioVision 2020 (5)(6)

CardioVision 2020 was introduced in 1999 with the ambitious goal of making Olmsted County the healthiest county in the United States by the year 2020. The main areas targeted were tobacco, nutrition and physical activity with goals set for both individuals and the community.

Target population

The county of Olmsted, Minnesota (n=87,685) was the site for intervention. The whole of Minnesota and the US population were used as control groups for comparison of some programme outcomes (changes in other risk factors were simply assessed as trends over time).

Theory/conceptual model of intervention

Social Modelling and Diffusion of Innovation were the primary models for programme implementation. The rational for intervention was that both stimulation of individuals to attempt behavioural change and the provision of physical and social

environments amenable to change, are necessary for sustained lifestyle improvements to take place.

Intervention description

Intervention activities included a media campaign with television programmes, radio interviews and features in newspapers. "Behavioural journalism" was used; publicising healthy behaviours of real people living in the community. Contests and competitions for smoking cessation, physical activity and weight control were set up to encourage proactive lifestyle changes.

A large emphasis was put on environmental changes to make provision for behavioural change. The aim was to provide a public environment that was free of smoke, free of promotion of tobacco products and to stop the sale of tobacco to youth. Nutritious, clearly labelled, foods and opportunities for physical activity were to be readily available and widely promoted.

Smoke free restaurants used menu labelling to identify low salt, low saturated fat and low calorie foods. Labelling was also used in cafeterias and by suppliers of ready-to-eat foods. The construction of walking/cycling trails was advocated to increase opportunities for physical activity.

Individuals were encouraged to take on their own individual goals, similar to those of the CardioVision community strategy. Personal goals related to smoking cessation, fruit and vegetable/low fat meat/fat free dairy product consumption, cholesterol and lipid levels, systolic and diastolic blood pressure and physical activity. The aim of CardioVsion was also to work towards improved clinical care systems for the secondary prevention and treatment of elevated CVD risk factors.

Accessibility:

The intervention included media coverage, environmental improvement programmes, written educational materials and competitions. The intervention was aimed at adults 20 years and older but no further information is provided on the ethnic, socio-

economic or educational profile of the target population, the range or number of venues used to deliver intervention components or whether materials were made accessible for non-native language speakers, those from different cultural backgrounds or for those with low literacy levels.

Younger men were under-represented in the survey evaluations which may be a reflection of the accessibility of the intervention to this population sub-group. Participation rates are reported for a small number of intervention components and range between 0.6 and 5% of the eligible population (eg 5% of smokers). After 4 years of delivery, 20% of respondents were aware of the intervention. No information is provided on participant rates in sub-groups of the population.

Evaluation

The programme was evaluated using four independent cross sectional surveys undertaken at baseline (1999) and in 2000, 2001 and 2003 to measure intentions and behavioural outcomes (telephone interviews and mailed surveys). Mayo clinic records were used to obtain information on blood pressure and blood lipids.

National and Minnesota state data (to act as controls) was obtained from the Behavioural Risk Factor Surveillance System (BRFSS).

Participant selection/recruitment

Participants ≥20 years were recruited for cross sectional surveys using age and gender stratified random digit dialling. Uptake and participation numbers were similar for surveys in 1999 (n=1,232), 2000 (n=1,224), 2001 (n=1,210) and 2003 (n=1,229). Respondents were given telephone interviews to assess the majority of self-reported outcomes. Participants were also sent mailed questionnaires for more detailed dietary assessment of fat and total calorie intake. Responses were reasonable but diminished over the four survey years: 1999 n= 732 (59%), 2000 n=688 (56%), 2001 n=590 (49%) and 2003 n=436 (35%).

Outcome measures

The proportion of participants reporting: behavioural change as a result of CardioVision 2020, doing something to try to lower cholesterol, reducing fat in diet/watching diet/eating a balanced diet/eating better to lower cholesterol, trying to increase exercise level, participation in any physical activity during past month and not being a current smoker.

The reported average number of fruit and vegetables eaten per day, average minutes of physical activity per week and BMI (from reported height and weight).

Percentage of participants reaching CardioVision personal goals: zero tobacco use, zero exposure to environmental tobacco smoke, eating 5 servings of fruit and/or vegetables per day, cholesterol <200 mg/dl, systolic blood pressure <130 mmHg, diastolic blood pressure <85 mmHg and does some form of physical activity every day.

Statistical methods

Survey data was weighted to reflect the US census estimates of the 2000 Olmsted population and Minnesota and national data were also weighted to the age-gender Olmsted population. Trends for Olmsted were compared to those of Minnesota and national trends using logistic regression for dichotomous variables and regression for continuous variables. Regression models included terms for year, area and year x area.

Results

Positive significant trends are shown for the proportions of participants reporting: behaviour change as a result of CardioVision, doing something to quit smoking, doing something to lower cholesterol and reducing fat in diet/watching diet/eating a balanced diet/eating better to lower cholesterol and for the percentage meeting CardioVision personal goals: zero exposure to environmental tobacco smoke, eating five servings of fruit and vegetables per day, cholesterol <200 mg/dl, systolic blood pressure <130 mmHg, diastolic blood pressure <85 mmHg and doing some physical

activity every day. However, these outcomes were not assessed against a control group. Outcomes that were compared with national and Minnesota state trends are presented in more detail bellow.

Primary outcomes

1. Smoking

The proportion of respondents reporting that they were not current smokers was stable in Olmsted (1999: 84%, 2000: 83%, 2001: 84%, 2003: 84%), Minnesota (1999: 80%, 2000: 83%, 2001: 79%, 2002: 79% and 2003: 78%) and the whole country (77% at each time point) and there were no significant differences in linear trends for Olmsted versus Minnesota or national trends.

2. BMI

BMI (kg/m^2) tended to increase slightly in Olmsted (1999: 26.43, 2000: 26.25, 2001: 26.19, 2003: 27.04), Minnesota (1999: 26.01, 2000: 26.20, 2001: 26.80, 2002: 26.80, 2003: 26 72) and nationally (1999: 26.36, 2000: 26.53, 2001: 26.74, 2002: 26.79, 2003: 26.87) and there were no significant differences in linear trends for Olmsted versus Minnesota or national trends.

3. Physical exercise

The proportion of respondents reporting doing physical exercise such as running, calisthenics, golf, gardening, walking for exercise etc during the past month was reasonably stable in Olmsted (1999: 82%, 2000: 86%, 2001: 85%, 2003: 84%) and nationally (2000: 73%, 2001: 74%, 2002: 75% and 2003: 75%) but increased in Minnesota (2000: 73%, 2001: 80%, 2002: 83%, 2003: 85%). Linear trends were significantly more positive for Minnesota ($p<0.001$) and nationally ($p=0.028$) compared to Olmsted.

4. Diet (fruit and vegetable intake)

The number of respondents reporting eating five servings of fruit and vegetables per day tended to increase in Olmsted (1999: 27%, 2000: 30%, 2001: 31%, 2003: 32%), but

tended to decrease slightly in Minnesota (2000: 34%, 2002: 23%, 2003: 27%) and nationally (2000: 25%, 2002: 24%, 2003: 23%) and the linear trend was more positive for Olmsted compared to national trends (p=0.078, NS) and significantly more positive for Olmsted compared to Minnesota (p=0.012).

The reported number of portions of fruit and vegetables eaten per day (mean) tended to increase in Olmsted (1999: 4.03, 2000: 4.09, 2001: 4.15, 2003: 4.18) but tended to decrease in Minnesota (2000: 4.23, 2002: 3.70, 2003: 3.97) and nationally (2000: 3.93, 2002: 3.84, 2003: 3.76) and there were significantly more positive trends for Olmsted compared to Minnesota (p=0.027) and to national trends (p=0.011).

These patterns were similar when the number of portions of fruit and vegetables eaten per day were assessed separately but findings were more favourable for fruit than vegetables:

The reported number of portions of fruit per day (mean) increased in Olmsted (1999: 1.74, 2000: 1.80, 2001: 1.82, 2003: 1.84) but tended to decrease in Minnesota (2000: 1.85, 2002: 1.51, 2003: 1.63) and nationally (2000: 1.55, 2002: 1.52, 2003: 1.47) and there were significantly more positive trends for Olmsted compared to Minnesota (p=0.008) and national trends (p=0.033).

The reported number of portions of vegetables per day (mean) increased in Olmsted (1999: 2.29, 2000: 2.30, 2001: 2.32, 2003: 2.34) but tended to decrease in Minnesota (2000: 2.38, 2002: 2.19, 2003: 2.34) and nationally (2000: 2.37, 2002: 2.32, 2003: 2.28) and there were significantly more positive trends for Olmsted compared to national trends (p=0.038) but not to Minnesota (p=0.397, NS).

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors

Self-reported data may be biased.

A similar county to Olmsted was not used as a control group.

Positive changes were not solely due to the project achievements. The implementation of smoke-free restaurants resulted from the work of many individuals and organisations and the meeting of blood pressure and cholesterol goals was likely to be due to the efforts of community physicians who organised their practices to achieve these goals.

Limitations identified by reviewer

Although data from four survey years was used to calculate trends for Olmsted, there were less data points available to determine National and Minnesota trends.

Although response rates for telephone questionnaires were stable, response rates declined for postal surveys over the four survey years. In later years, greater response of 'healthy' individuals or those adopting healthier lifestyles, compared to earlier surveys, would tend to result in positive trends for outcome measures and may have acted to favourably bias results. It is not clear whether outcomes assessed against Minnesota and national trends were obtained from telephone or mailed questionnaires.

Summary

CardioVision 2020 was a heart health programme with a strong emphasis on environmental change and increased availability of fruit and vegetables may have contributed to favourable effects on fruit and vegetable consumption compared to state and national trends. The programme may have had positive effects on physiological CVD risk factors but the absence of a suitable control group for these outcomes makes it difficult to assign causality.

3.1.4 The German CINDI (7)(8)

The Countrywide Integrated Non-communicable Diseases Intervention Programme of the WHO (CINDI) aimed to improve cardiovascular health by reducing rates of

smoking, hypertension, obesity, hypercholesterolaemia and sedentary lifestyle. In 1992, the 'Three-level-strategy" intervention began in Oestringen, Germany.

Target population

Intervention was conducted in the small provincial town of Oestringen (n= 12,500) and no control group was used for programme evaluation.

Theory/conceptual model of intervention

None stated

Intervention description

The major setting for intervention was primary care with a large emphasis on individual risk factor counselling. Intervention was named "The Three-level-strategy" and consisted of:

1) Individual counselling from primary care physicians to give information on cardiovascular risks and advice on healthy lifestyle behaviours.

2) Group counselling, given by physicians to patients in their practice in specialised programmes e.g. smoking cessation, hypertension prevention etc.

3) Community-based counselling courses and health promoting activities e.g. exercise-based courses and health promoting activities in nurseries, worksites, sports clubs and schools. A work group was assigned the task of ensuring cooperation between local health professionals to develop health-promoting activities in the community.

There was an emphasis on increasing rates of physical exercise and primary and secondary CVD intervention measures were offered in combination with promotion of exercise-based groups. These groups were small (8-20 people) but numerous (n=600) and included many different types of activities e.g. jogging and stress

management, gymnastics and stress management, physical activity and dietary counselling for the elderly and swimming and dietary counselling.

Activity groups were 'prescribed' in the same way as medications by general practitioners and costs of the exercise programmes were covered in part by health insurance companies and municipal institutions.

Accessibility:

The intervention had 3 main levels with the main location for activities being healthcare facilities. It is unclear how varied the venues were in the level three intervention or how far individuals had to travel to participate. Levels one and two of the intervention were offered in the general practice setting (individual consultations and GP referral to group education programme requiring participation for 1-2 evenings per week over 16 weeks).

Authors state that, 6 years after the start of the intervention, on-going educational groups continued to have a 300-400 participants, representing 2-3% of the community population. Level three comprised of counselling courses with a focus on exercise taking place in the community (typically 1 hour per week) and on health promoting activities in educational establishments, industry and social venues. Counselling courses at level three were subsidised by local industry and public services but required a prescription by an individual's GP. It is not clear how much participants had to contribute to the cost of these activities or if cost was a barrier to participation in such events.

A local health guide was made available on the internet and newspaper articles are mentioned as a communication medium. There is no information on whether written materials were made accessible for those of low literacy levels, those from different cultural backgrounds or for non native language speakers. No information is provided on access to the internet in the population.

Relevant data from participants in the programme evaluation (10% random sample of GP attendees and 50% of those attending educational courses in primary care) which may indicate the accessibility of the intervention includes:

-53% of the population were familiar with the intervention
- no information is provided on distance to travel to GP surgeries but 2% of evaluation participants stated distance to place of exercise was a barrier to participation
-27% stated lack of time was a barrier to participation
-8% stated that caring for dependents was a barrier to participation
-men, younger people and high risk individuals were less likely to attend level three community based interventions

Evaluation

Programme effectiveness was evaluated from data collected during medical examinations by primary care physicians in seven Oestringen practices.

Participant selection/recruitment

Random independent samples of patients aged ≥16 years were assessed each year (1992, 1993, 1994, 1995) and the presence of CVD risk factors recorded. Similar numbers of men and women took part and the size of samples was similar in 1992 (n=1,176), 1993 (n=1,057), 1994 (n=1,381) and 1995 (n=1,267).

Outcome measures

The occurrence of CVD risk factors of smoking, hypercholesterolaemia, obesity and hypertension.

Statistical methods

Data for patients from different practices were pooled for each year. The occurrence of risk factors were compared for differences using X^2.

Results

Results are presented as trends over time but do not show net intervention effect (no control group was used). Risk factor levels in intervention years are compared with levels at baseline for outcomes of smoking and hypertension whereas, for hypercholesterolaemia and BMI, levels are compared with measurements from the last survey year. Data pooled for men and women is presented but similar trends were observed in both.

Primary outcomes

1. Smoking

The prevalence of smoking decreased from baseline (1992: 20.8%; CI ±2.3) and was significantly lower in 1993 (16.0%; CI ±2.2, $p<0.01$), 1994 (16.8%; CI ±2.0, $p<0.01$) and 1995 (17.1%; CI ±2.1, $p<0.05$) (differences are for comparisons with baseline).

2. Hypertension

The prevalence of hypertension decreased from baseline (1992: 28.5%; CI ±2.6) and was significantly lower in 1993 (19.0%; CI ±2.4, $p<0.01$), 1994 (21.6%; CI ±2.2, $p<0.01$) and 1995 (19.5%; CI ±2.3, $p<0.01$) (differences are for comparisons with baseline).

3. Hypercholesterolaemia

The prevalence of hypercholesterolaemia increased and then stabilised during the intervention period: Baseline (21.8%; CI ±2.4), 1993 (31.3%; CI ±2.9, $p<0.01$), 1994 (31.0%; CI ±2.5, p=NS) and 1995 (28.3%; CI ±2.7, p=NS) (differences from previous survey year assessed for significance).

4. BMI

The proportion of participants with BMI$\geq$30 increased and then stabilised during the intervention period: Baseline (17.4%; CI ±2.2), 1993 (18.8%; CI ±2.4, p=NS), 1994

(18.8%; CI ±2.1, p=NS) and 1995 (18.7%; CI ±2.2, p=NS) (differences from previous survey year assessed for significance).

Outcomes are also detailed specifically for participants of the exercise-based groups but these results are not presented in the current report.

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors

An absence of an effect on BMI may be due to people giving up smoking and eating more in compensation.

Limitations identified by reviewer

Participants of the evaluation surveys were people attending their GP and ~75% were 40 years or older. This is not a community representative sample and, when assessing the effect of intervention on a whole community level, this should be taken into account.

Significance testing was done for differences from baseline for the prevalence of smoking and hypertension but, for the prevalence of hypercholesterolaemia and obesity, differences from the last survey year were assessed. This is misleading and, had differences for hypercholesterolaemia and obesity been assessed from baseline, it may be that significant increases would have been reported.

Summary

The highly structured, physical activity-driven, German CINDI intervention resulted in reductions in the prevalence of smoking and hypertension but apparent increases in the prevalence of hypercholesterolaemia and obesity. However, the un-controlled method of programme evaluation and inconsistency of methods for significance testing makes it difficult to interpret programme effectiveness.

3.1.5 Coalfields Healthy Heartbeat (9)

In the mining community of the Hunter region, New South Wales, Australia, the Coalfields Healthy Heartbeat coalition was introduced to address high prevailing rates of death from heart disease. The programme was set up in 1990, following on from a previous community awareness programme, the Healthy Heart support group, and aimed to prevent heart disease through community activation.

Target population

The Coalfields district (n= 46,520) in the Hunter region was the site for intervention. This area was a centre for coal mining and initially drew a large population of migrants from northern England and Wales, UK. The Anglo-Celtic heritage remained, with a large proportion of the population being descended from the UK migrants. Within the mining community, a culture of independence developed and their lifestyle was sometimes considered 'uncouth' by outsides. The development of poor relations with people from other communities led to a high degree of suspicion of outsides and there was wariness towards messages of health promotion.

Other areas in the Hunter region acted as the control for programme evaluation: Newcastle, Lake Macquarie, Maitland and Port Stephens (N not given).

Theory/conceptual model of intervention

Intervention was based on the idea of 'community activation', encouraging community empowerment, democracy and self-sustainment.

Intervention description

Activities to raise awareness of CVD risk had previously begun in 1986, run by a local healthy heart support group. In 1990, the more intense Coalfields Healthy Heartbeat community action programme began and programme activities were merged. A coalition of community members, local government officers and councillors, health

workers and a research group at the University of Newcastle came together to plan programme activities.

Early in programme development, a needs assessment survey was mailed out to a random sample of 919 community residents to identify areas on concern. Of these, 435 people responded and surveys, together with a subsequent health ideology questionnaire and input from local leaders and community health workers, were used to inform and guide project implementation.

In 1990, University researchers and the project coordinator organised two public meetings to announce the initiative, identify interested local leaders and gain consensus on targets and strategies for change. These meetings were widely publicised and lead to the development of a steering committee that met monthly with the project coordinator. The project coordinator supported the steering committee in the development and implementation of activities and raised local awareness of the problem of heart disease and raised funds for project implementation.

Initially, the project coordinator delivered presentations to local organisations such as schools, workplaces, social clubs and women's groups to raise awareness of CVD and the community programme. Although the goal had been to promote community involvement, in practice mobilisation was difficult and most activities were implemented by the project coordinator.

Interventions included a media campaign (with continuing radio broadcasts), public displays, guest speakers at clubs, schools and worksites and heart health promotions such as 'Heart Week', a community fun run and a motorcycle race. A rehabilitation exercise program was also put in place and counsellors were trained to give advice over the telephone. Many activities targeted nutrition, exercise and smoking and included cooking classes, cooking demonstrations, supermarket tours, weight control classes, exercise classes, publishing of a walking trails book and anti-smoking programs aimed at adolescents and adults. There was environmental and institutional

development in schools, restaurants, retailers and fast food outlets and other programmes were initiated by industry.

Accessibility:

The intervention was designed following community consultation on needs and priorities. Interventions were offered at a range of venues including schools, workplaces, social clubs and food outlets. Interventions included written and oral education provided in a variety of formats including presentations, classes and media coverage; screening activities; competitions; support groups and social activities.

No information is provided on the ethnic, socioeconomic or educational profile of the population but the community is described as a coal mining community with a strong Anglo-Celtic heritage. No information is provided on whether materials were made accessible for non native language speakers, those from different cultural backgrounds or for those with low literacy levels.

Males and people of younger ages and lower educational attainment were under represented in the needs assessment exercise which may be an indicator of the accessibility of the programme to these population sub-groups.

Response to evaluation surveys was between 60 and 70% over 9 years although 'extensive systems of reminders and follow up were used'. Attempts to engage community support are described as 'disappointing' and difficulty was experienced in 'mobilising the community in general'. This led to narrowing of the range of initially planned interventions to focus on activities aimed at interested sub-groups (described as not necessarily those at most risk) in the population.

Intervention uptake was predominantly by schools and those with pre-existing CVD. Information on uptake of individual activities is poorly reported and numbers, rather than rates, are provided. However, where reported, uptake of primary prevention activities aimed at adults (35-64) is less than 1% of the total population. No further information is provided on uptake of interventions by sub-groups of the population.

Evaluation

The programme was evaluated using data obtained by the MONICA surveillance project that monitored trends for non-fatal MI and coronary death over the period 1984-1994. Three independent cross-sectional surveys were used to determine risk factor changes during the course of intervention.

Participant selection/recruitment

Independent cross sectional surveys were conducted in 1983, 1988-1989 and 1994 in adults aged 35-64 years. Stratified samples of the population were selected from the electoral role and those identified were invited to attend study centres to complete a self-administered questionnaire and physical examination. Extensive reminders were used to maximise participation and response rates were 70% and 68% in 1983, 63% and 60% in 1988-1989 and 63% and 62% in 1994 (in treatment and control areas respectively).

Outcome measures

Rates of non-fatal MI, coronary death, case-fatality (calculated by dividing no. deaths/no. events), BMI, diastolic and systolic blood pressure, cholesterol and proportion with no physical activity.

Statistical methods

Age standardised rates of coronary events per 100,000 were calculated for the period 1991-1993 separately for men and women. Trends in event rates from 1985 to 1993 were estimated using weighted Poisson regression. Case fatality was calculated by dividing the number of deaths by the total number of events. Trends in case fatality were estimated by logistic regression with year of onset as the exploratory variable. The weights used for all analysis were the estimated 1991 Hunter region population figures from the 1991 census.

For risk factor variables, means, percentages and standard errors were standardised for age using the 1991 population census. Annual changes in risk factor levels were estimated using linear regression with year as the exploratory variable and risk factor as the outcome variable.

Results

Results are presented as annual changes i.e. the average increase or decrease per year estimated by linear regression.

Primary outcomes

1. Fatal coronary event

The rate of fatal coronary events (rate per 100,000) decreased over time in Coalfields men (-10.9; CI -18.2 to -3.6) to a greater extent than control men (-7.0; CI -9.3 to -4.7) but this was not significant. In women, fatal coronary events also fell more in the Coalfields area (-14.2; CI -26.0 to -2.4) than the control (-7.8; CI -12.8 to -2.9) but again, this was not significant.

2. Non-fatal MI

Rates of non-fatal MI (rate per 100,000) increased over time in Coalfields men (+3.2; CI -0.6 to 7.0) although it decreased in control men (-2.5; CI -4.5 to -0.5) and the difference between regions was nearly significant. In women, non-fatal MI also increased in the Coalfields (+1.7; CI -4.4 to +7.9) and reduced in the control (-3.6; CI -7.0 to -0.2) but the difference was not significant.

3. Case fatality

Case fatality (fraction of those experiencing MI that subsequently died) decreased over time to a greater extent in Coalfields men (-17.2%; CI -25.1 to -9.3) than in control men (-5.1%; CI -7.8 to -2.4) and the difference between areas was significant. In women, case fatality decreased over time to a greater extent in the Coalfields (-16.9%;

CI -30.1 to -3.7) than in control areas (-4.5%; CI -9.0 to -0.1) but the difference between areas was not significant.

4. Smoking

For smoking, in men, there were reductions in smoking rates in the Coalfields (-0.45%; CI -1.82 to 0.9) but greater reductions in the control (-1.27%; CI -1.68 to -0.86) although the area difference was not significant. For women, there was an increase in smoking rates in the Coalfields (+0.49%; CI -0.59 to +1.56) that was significantly different from the decrease observed in controls (-0.66%; CI -1.01 to -0.30).

5. Physical activity

The proportion of people reporting doing no physical activity decreased in men in the Coalfields (-1.14%; CI -2.91 to +0.63) and increased in control males (+0.42%; CI -0.04 to 0.88) (no significant difference). In women, the same pattern was observed, with a reduction in the Coalfields (-1.08; CI -2.99 to +0.83) but an increase in controls (+0.21; CI -0.37 to 0.79) (no significant difference).

6. Other risk factors

BMI tended to increase whilst levels of other risk factors tended to decrease over time and changes in BMI, diastolic and systolic blood pressure and cholesterol were similar in the Coalfields and control areas.

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors

There was no clear pattern of changes in risk factor levels or reductions in non-fatal MI and apparent treatment effect on case fatality was probably due to the very efficient transport of people with MI to hospital (the Coalfields had developed a very good system).

CVD risk factors were higher in the Coalfields compared to the control and it may be that risk factor levels would have continued to worsen naturally in the Coalfields. Positive intervention effects may therefore not have been recognised as the programme may have been acting just to prevent further disparity between the Coalfield and control communities.

Limitations identified by reviewer

The Coalfields population may have been different to the control population in many respects such as socioeconomic status, ethnicity and provision of healthcare.

Although the programme only began in 1990, trends from 1983/4 to 1994 were used to inform results.

Summary

The Coalfields Healthy Heartbeat programme tackled a difficult population where, in this independent community, scepticism was high and project organisers were likely to have faced many barriers to implementation. The programme may have succeeded in preventing development of further health disparities but it seems likely that the absence of effect was also due to a failure of the programme to produce behavioural change.

3.1.6 The Franklin Cardiovascular Health Program (10)

The Franklin Cardiovascular Health Program was initiated in 1974, around the time of the National High Blood Pressure Education Program, the National Cholesterol Education Program and the formation of the Rural Health Associates corporation (a community-based, non-profit health care corporation). Initiatives aimed to reduce risk factors for CVD via a range of intervention activities and intervention stretched over more than 20 years.

Target population

Intervention covered the county of Franklin, a population of 29,645 people spread between 23 predominately rural communities. Control sites, Oxford and Somerset, were larger (n=53,000 and 51,000 respectively) but similar in respect to demographic features and risk factor profiles. The whole of the state of Maine (n=1,240,280), of which Franklin, Oxford and Somerset are part, was also used as a control population.

Theory/conceptual model of intervention

Not stated

Intervention description

The programme used a multifaceted approach including media campaigns, environmental modifications and group education. Training was given to local personnel and education was provided for healthcare professionals. Interventions were delivered via community organisations, school and worksites and interventions also took place in supermarkets, restaurants and medical settings.

There was collaboration with health care agencies and a high degree of emphasis was put on risk factor screening and follow up of individuals. Professional nurses and physicians were involved and reciprocal referrals were made between medical and programme staff. Individuals screened for CVD risk were given personal counselling and provided with a copy of their results. Screenings were publicised by employers and followed up with mailed reminders for repeat visits.

Accessibility:

The individualised component of the intervention was offered at clinics in healthcare facilities, workplaces, schools and food outlets. No further information is provided on how education was delivered. The ethnic, socio-economic and education profile of the target community is not described. Education is described as having a low-literacy emphasis but no information is provided on whether materials were made accessible for non-native language speakers or those from different cultural backgrounds. The ethnic, socio-economic and education profile of the target community is not described.

It is estimated that the programme reached >50% of adults in the target population. Males were slightly under-represented (42%) but there is no clear difference in participation by age. No information is provided on participation according to ethnic group.

Evaluation

Evaluation was made over different time periods:

RHA – The years 1970-1973, before the start of the intervention programme but when the Rural Health Associates corporation was in place.

Program – The time period from 1974-1994, when the intervention programme was active.

Growth – The time period from 1974-1980 and 1986-1989, when the programme was considered to be in stages of growth.

Decline – The time period from 1981-1985 and 1990-1994, when the programme was considered to be in stages of decline.

HBP – The period in which the National High Blood Pressure Education Program was conducted (1974-1985).

CHOL – The period in which the National Cholesterol Education Program was conducted (1986-1994).

Comparisons in mean death rates over time periods were made between Franklin and the control communities and with Maine, the whole state population.

Participant selection/recruitment

Data was provided by the Maine Office of Data, Research and Vital Statistics and Maine's Bureau of Health and Departments of Education, Human Services and Labour.

Outcome measures

Rates of death from heart disease, coronary heart disease and stroke.

Statistical methods

The data provided was determined using direct methods to calculate annual age adjusted mortality rates (per 1000,000 population) with the US population as standard. Relative rate (rate in Franklin/rate in control) was then calculated for Franklin compared to Maine and the control counties.

Results

Primary outcomes

1. Heart disease-related death rate

Figure 3.1 shows heart disease-related death rates over the different periods of study for Franklin and the control counties relative to the whole state of Maine:

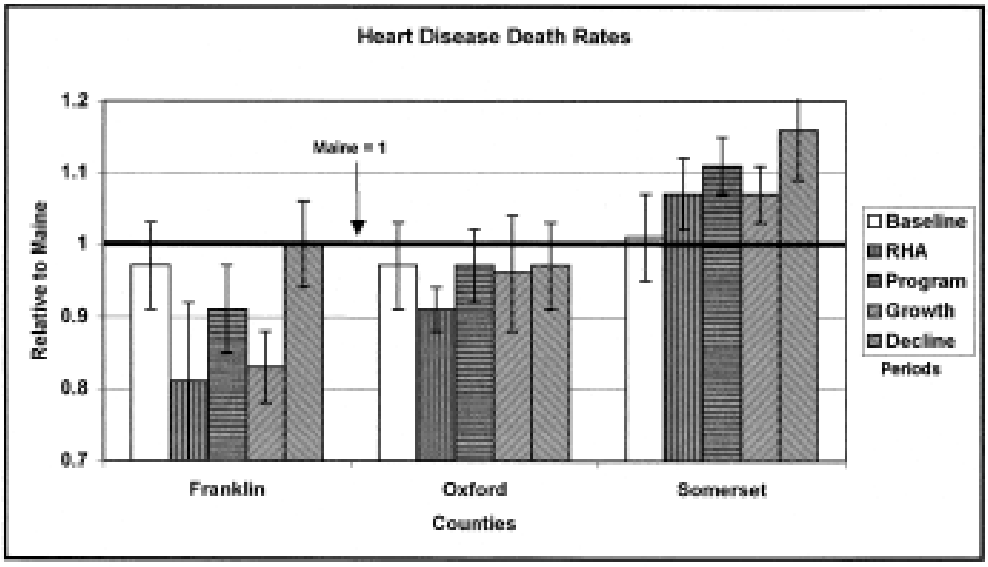


Figure 3.1 Heart disease death rate, mean values relative to Maine, for Franklin and control counties for each study period: baseline 1960-1969, RHA 1970-1973, Program 1974-1994, Program growth 1974-1980 and 1986-1989 and Program decline 1981-1985 and 1990-1994.

During the years of program implementation, rates of heart disease-related death were lower in Franklin than in Maine, Oxford or Somerset. The rate of death from heart disease was significantly lower when calculated relative to Maine (RR 0.91, CI 0.06, p<0.05) and Somerset (RR 0.82, CI 0.06, p<0.05) but not significantly lower relative to Oxford (0.96, CI 0.09, p=NS).

2. Coronary heart disease-related death rate

During the years of program implementation, rates of coronary heart disease-related death were lower in Franklin than in Maine, Oxford or Somerset. The rate of death from coronary heart disease was significantly lower when calculated relative to Maine (RR 0.91, CI 0.06, p<0.05) and Somerset (RR 0.82, CI 0.06, p<0.05) but not significantly lower relative to Oxford (0.96, CI 0.1, p=NS).

3. Stroke-related death rate

During the years of program implementation, rates of stroke-related death were lower in Franklin than in Maine, Oxford or Somerset. However, this was not significant for Maine (RR 0.90, CI 0.10, p=NS), Somerset (RR 0.94, CI 0.16, p=NS) or Oxford (RR 0.89, CI 0.12, p=NS).

Limitations of the study

The study was quality assessed and graded '+'.

Limitations identified by authors

This is only an observational, retrospective study and associations do not prove cause and effect.

Observations may reflect undetected secular trends specific to the county of Franklin.

In the early stages, effects brought about by institution of the Regional Health Associates could not be separated from the effect of the programme.

Mortality rates were based on death certificates which may or may not be fully reliable reflections of death from CVD. Awareness of physicians to the programme objectives may have influenced the coding of causes of death. However, this would not affect total death rates and, since findings for death from heart disease, coronary heart disease and stroke were consistent with those for total death rate, this suggests a lack of systematic bias.

Limitations identified by reviewer

The national blood pressure and cholesterol education campaigns were also likely to have positive effects since there may have been a large number of screenings and follow-up of individuals.

Summary

Retrospective evaluation of the Franklin Cardiovascular Health Program suggests that community heart health intervention may be effective in reducing rates of CVD related death. The high degree of health service integration in this long-term programme may have contributed to programme success but the presence of concurrent public health initiatives may have also been important in producing apparent effect.

3.1.7 Have a Heart Paisley (11)

Have a Heart Paisley (HaHP) began in 2000 as a demonstration project for community heart health intervention. The intervention aimed to reduce the total burden of CVD and to specifically address levels of health inequality using strategies for both primary and secondary prevention.

Target population

HaHP covered the town of Paisley, shown to have many areas with high levels of deprivation. Not only was deprivation higher than the Scottish national average, there were high levels of inequality in health status. The control population, Inverclyde,

was served by the same NHS board (Argyll and Clyde) and had a similar socioeconomic profile and similar levels of CVD.

Theory/conceptual model of intervention

Project organisers were encouraged to discuss their ideas for intervention and to identify their rational for how these activities would combine to result in effective project implementation and positive behavioural change. This method is known as 'theory of change' and implementers are required to record the methods they propose with an explicit logic pathway so that these theories may be modified in the planning stage and during the course of intervention.

Intervention description

http://www.healthscotland.com/resources/networks/HHN-HaHP1.aspx#nhs

The programme was implemented via community groups and the local authority. A steering group guided project direction whilst a management group provided ongoing project coordination and delivery in three main areas: smoking, healthy eating and physical activity. Intervention was delivered in combination with voluntary organisations and the local community and covered a wide range of activities.

Intervention targeted various groups in the community. For people receiving community care, the 'HEAL' project aimed to improve the quality of diets, influence food choices and increase opportunities for physical activity.

Programmes targeting the workforce, particularly manual workers were implemented. The 'Healthy at Work – Healthy for Life' project targeted employees of Renfrewshire council. Intervention was also based in schools and the Health Promoting School Project consisted of education and promotion activities in nursery, primary and secondary schools. Increased physical activity was promoted through the 'Healthercise' project. Exercise was encouraged, particularly in areas where people were thought to have low levels of physical activity.

Several strategies were used within the health service. Training was given to NHS staff to encourage them to feel confident in broadening their roles to encompass project activities. A register of CHD (the Central Data Repository) was developed. This held information on patient's risk of CHD and was used to calculate risk factors and to help in the clinical audit of patients with CHD. The 'Improving the patient pathway' project aimed to improve awareness and community links and to streamline the continuum from primary to secondary to tertiary care. The goal was to develop a 'Health Promoting Health Service' and training was provided to NHS staff to develop their public health roles. There was also specific support given to projects with that aimed to reduce morbidity and mortality in patients with diagnosis of CVD.

Accessibility:

The intervention consisted of 15 linked work strands covering primary and secondary prevention activities and involving the NHS, local authorities and community and voluntary organisations. Involvement of NHS organisations appears to have been largely limited to secondary prevention activities.

The primary prevention aspect of the intervention covered a range of CVD risk factors and activities were offered in the community, schools, workplaces and local authority care. No further information is provided with respect to the intensity of the intervention (frequency or range of venues) or whether efforts were made to make intervention components accessible to those with low literacy levels (Paisley is a town with high deprivation levels), those from different cultural backgrounds or for non-native language speakers.

With respect to participation in elements of the intervention, information was not collected to allow an assessment of the quality or reach of interventions.

The evaluation survey had a low response rate (28%) and younger, less affluent individuals and smokers were under-represented. This may be an indication of the acceptability of the intervention to these population sub-groups.

Evaluation

Population surveys were conducted with the initial aim of evaluating both physiological and behavioural intervention effects. A cross-sectional survey was conducted at baseline and participants were followed up 2.5 years later to evaluate changes in the cohort during the course of intervention.

Participant selection/recruitment

Samples of participants were drawn from three different neighbourhood areas, intended to give a range of participants from locations with different levels of deprivation. A random sample of potential recruits were sent a baseline questionnaire along with a card to record their willingness to take part. Due to issues of confidentiality, this card had to first be returned to the NHS board before study organisers could contact participants directly. Participants were given the option of whether to only complete the questionnaire or whether they were also willing to undergo a medical examination. If they were willing to attend a medical, they were asked to bring health questionnaires along with them so that they could receive guidance, if necessary, on completing the form. Those declining the medical examination, but accepting questionnaire-only participation, were asked to return the questionnaire by post.

At baseline, initial study invites were sent to 2,720 people (1,377 in Paisley, 1,343 in Inverclyde), of which 432 and 398 respectively were willing to participate (response rates Paisley 31%, Inverclyde 30%). Some people subsequently declined participation and a total of 743 returned questionnaires that were suitable for inclusion (response rates of 27% and 28% for Paisley and Inverclyde respectively). The majority of participants were also willing to undergo a medical examination and medical information was gathered on 724 participants.

After ~2.5 years a second evaluation was conducted with 556 participants from the original cohort: 276 Paisley 280 Inverclyde (response rate ~75%). Although the initial

intention was to repeat clinical investigations in the cohort of participants followed up over the intervention period, it was decided that this was not possible and the final survey consisted only of questionnaires, shortened from the baseline questionnaire, to focus on areas where change was thought most likely to occur (evidenced by ongoing formative evaluation). Final survey evaluation therefore only covered self reported measures of physical health, behaviour, knowledge and attitudes.

Drop-outs from baseline to follow-up were significantly younger ($p>0.001$) and more likely to be from lower socioeconomic groupings ($p=0.05$) but there was no evident gender bias. Those dropping out were more likely to be smokers ($p=0.001$). They were also more likely to have assessed their own health status as not good whilst those remaining in the study were more likely to self-assess their health as fair or good ($p=0.031$).

Outcome measures

Overall project outcomes are described in the independent evaluation report:

http://www.healthscotland.com/documents/1781.aspx

Self-reported measures were made of:

Self-assessed health, presence of high blood pressure, taking medication for high blood pressure, diabetes, high cholesterol, current smoking status, number of cigarettes smoked, changes in tobacco use within last 6 months, smoking cessation, levels of physical activity, changes in eating habits, current weight, type of spread used on bread, type of milk used for drinks and cereals, number of portions of fruit eaten per day, number of portions vegetables eaten per day.

Survey participants were also asked whether they had had any of the following: angina, coronary artery bypass, coronary angiogram, coronary angioplasty, myocardial infarction, heart failure and stroke and participants were asked to rank themselves on a scale of hopelessness.

Their knowledge was tested regarding the importance of avoidance of passive smoking, limiting tea and coffee intake, avoiding food additives, eating oily fish, having regular blood pressure checks, having regular chest x-rays in relation to CVD, having regular medical check-ups, reducing cholesterol levels and taking medication to keep blood pressure down. Their knowledge was also tested regarding the level of physical activity needed and the number of fruit and vegetables/salad that should be eaten to stay healthy.

'Learning outcomes' are also given for various projects implemented during programme intervention:

http://www.healthscotland.com/resources/networks/HHN-HaHP1.aspx#local

These evaluations describe project activities and give statements summarising areas of success or failure for specific projects. Results are not detailed in the current report.

Results

Results are described for self-reported outcomes for the number of people increasing/not changing/decreasing from baseline to follow-up. For clarity, an example of the format of results is shown below. For each participant, changes from baseline have been graded as positive, stable or negative. Significance is tested on the difference between the intervention and control areas:

e.g. self-assessed health

	Positive	Stable	Negative	N	Significance
Paisley	45 (16.6%)	194 (71.6%)	32 (11.8%)	271	p=0.71
Inverclyde	53 (19.1%)	190 (68.6%)	34 (12.3%)	277	

Statistical methods

Chi squared analysis was used to assess differences in changes in the intervention versus control population.

Primary outcomes

There were no significant differences for any of the self-reported physiological, behavioural or knowledge outcome measures (36 outcomes assessed) except for correct knowledge of the number of portions of fruit/vegetables/salad that should be eaten per day:

	Positive	Stable	Negative	N	Significance
Paisley	50 (18.1%)	213 (77.2%)	13 (4.7%)	276	p=0.005
Inverclyde	82 (29.7%)	184 (66.7%)	10 (3.6%)	276	

Knowledge increased in both groups but there were larger changes in the control compared to the intervention area with a significant trend in favour of the control (p=0.005).

Assessment was then made within the Paisley survey participants, comparing those who had taken part in project activities with those who had not. The same 36 outcomes were assessed and there was a significant positive intervention effect only for the reported number of fruit and vegetables eaten per day (p=0.01):

	Positive	Stable	Negative	N	Significance
Paisley	32 (14.5%)	164 (74.2%)	25 (11.3%)	273	p=0.01
Inverclyde	16 (30.8%)	34 (65.4%)	2 (3.8%)	279	

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors

Poor survey response rates reduced the power of evaluation and increased the possibility that effects of intervention were not detected. The survey may not have been fully representative of the socioeconomic, age and sex demographics of the Paisley and may not have reflected risk factors and behaviours of the whole intervention area.

There may have been contamination from treatment to reference area because they were in close locations.

The timescale of evaluation may have been too short to allow changes influenced by policies and agendas (e.g. workplace smoking and nutrition policies).

Limitations identified by reviewer

The final questionnaire was modified to focus on areas where change was thought most likely to occur from previous formative evaluation. This change was likely to increase the likelihood of detecting positive intervention effect since it allowed pre-selection of factors most likely to show positive outcome measures.

There is no reported adjustment in significance testing despite multiple outcomes being tested. Significant findings may have resulted from chance since, with 36 associations tested, two significant findings would be expected by chance alone.

Summary

Despite the specific primary and secondary prevention goals for CVD, Have a Heart Paisley appears to have had little intervention effect. There may have been insufficient time for implementation of environmental changes and contamination of the control area may have contributed to the lack of programme effectiveness.

3.1.8 The Olöfstrom community intervention (12)

In 1988, a community intervention targeting primary prevention of cardiovascular disease and non-insulin dependent diabetes mellitus (NIDDM) began in the municipality of Olofström. The overall project aim was to improve the health of the community by reducing the incidence of CVD and NIDDM and to prevent/postpone associated complications.

Target population

Olofström (n=15,000), in the county of Blekinge, southern Sweden, was the target for intervention. Olofström had a large manufacturing industry with 54% blue collar workers and 38% white collar workers and, in comparison with other southern Swedish communities, a relatively high rate of CVD mortality had been observed. Reference is made to results from the MONICA surveillance survey (for adults aged 30-64 years) in northern Sweden as the control group.

Theory/conceptual model of intervention

None stated

Intervention description

A steering committee, with representatives from Blekinge county council, Olofström politicians, manufacturing industries and the University Health Science Centre led the intervention and a local working group, coordinated by a registered nurse, were responsible for organising and supervising project activities. The working group was made up of members from primary health care, the school board and other local agencies and they cooperated with organisations such as the local food industry, sports clubs and schools to disseminate information and implement educational programmes.

Meetings were held in ten community locations to inform residents of the local incidence of CVD and diabetes and to relate diseases to lifestyle factors such as

smoking, high cholesterol and high blood pressure. A local physician or nurse was present at each meeting to answer any health questions and screenings were offered to all attendees (~90% accepted). Members of each local household were invited to attend, leaflets were distributed by local sports clubs and meetings were advertised in local newspapers. The risk factor talk was supported by a short video and those attending were advised to participate in the locally organised 'easy exercise' programme.

The Olofström health centre played a major role in programme activities and, before the start of intervention, district physicians, nurses and other medical staff were given educational training relating to nutrition, diet and prevention of CVD, diabetes and other metabolic disorders. A screening programme was designed to identify individuals in the community with elevated CVD risk factors. Anyone aged 30-64 years visiting the health centre for any reason was offered a screening examination and, after two years, those revisiting the health centre were invited back for another screening. Dietary advice/printed information/referral to a district physician was given depending on the level of CVD risk and those with high cholesterol/blood pressure/blood glucose were directed to special programmes for lipid reduction/hypertension/diabetes run by staff from the health centre.

The programme also took a wider role to encompass school-based and environmental interventions. In one primary school, an education program was led by the school physician and nurse with class education for children aged 7-13 years. There was also one-to-one discussion with those aged 15-18 years relating to their lifestyles and behavioural risk factors of diet, smoking and alcohol. Recipes for low fat/low saturated fat/high fibre meals were distributed in supermarkets and worksites and at the library, pharmacy and health centre. Discount campaigns for low fat and high fibre foods were implemented by stores.

There was a large programme emphasis on education and nutrition teaching was offered to employees of supermarkets, restaurants and cafes. Information meetings

were also arranged with business associations in the food sector. Advanced educational programmes were provided for dieticians, teachers of domestic science and managers of worksites, school canteens and supermarkets to inform of CVD risks and prevention. Lectures were also given to key groups such as school teachers, sports and exercise instructors, union members and representatives of voluntary organisations.

Media was used to communicate campaign messages. A magazine was distributed to each household giving information about the benefits of a healthy lifestyle and detailing baseline risk factors in Olofström. Numerous articles were displayed in local newspapers and broadcasts of lectures and programme activities were made by the local radio station.

Accessibility:

The intervention comprised opportunistic screening in the single healthcare facility serving the community. In addition, educational meetings using oral, written and video materials were offered twice over a period of 2 years in each of 10 local areas following advertisements in newspapers and leaflet distribution and health screening was offered to those attending meetings. An easy exercise programme was promoted but it is unclear whether this was offered at more than one location in the community. It is also unclear how far individuals had to travel to access intervention activities.

School based interventions seem to have been restricted to a single school expressing a particular interest in the project. Healthy recipes were distributed through food outlets, libraries, pharmacies, larger workplaces and health centres. Local media and radio were used to advertise events and educational purposes. Immigrants (born outside Sweden) made up 15% of the population but it is not clear whether materials were made accessible for non native language speakers, those from different cultural backgrounds or for those with low literacy levels. Respondents to evaluation surveys were balanced with respect to gender with a mean age of 47-49 years. Participation in

educational meetings represented ~28% of the working population. No further information is given on the uptake of intervention components.

Evaluation

The programme was evaluated via three semi-independent cross sectional surveys undertaken at baseline (1989), 1991 and 1993.

Participant selection/recruitment

Random samples of adults aged 30-64 years were drawn from population registries. At baseline, those born on the first or second day of each month were invited to participate, in 1991, those born on the second or third day were invited and, in 1993, those born in on the third or forth day of each month were invited. Samples were therefore made up with approximately 50% participants who had undergone the previous survey and 50% new participants.

Identified individuals were invited by letter to examinations at the health centre (separate from screening activities). Response rates and numbers of participants were reasonably similar in all three surveys: 1989 n=347 (79%), 1991 n=312 (70%) and 1993 n=325 (74%). In examinations, measurements were made for BMI, cholesterol, non-fasting blood glucose and blood pressure and participants were asked about their smoking habits and general health.

Outcome measures

BMI, cholesterol, diastolic and systolic blood pressure, smoking (smoker/non-smoker/ex-smoker ($\geq$6 months)) and non-fasting blood glucose.

Statistical methods

Continuous variables were compared using two-tailed t tests and differences between those measured on nominal or ordinal scales were tested by X^2.

Results

Results are presented as changes from baseline to intervention year two (1991) and four (1993) and do not show net intervention effects. The MONICA survey was used to assess concurrent secular trends as a control but results were only presented for levels in 1986 (pre-baseline) and 1991 (two years into intervention).

Primary outcomes

1. Cholesterol

In men, total cholesterol decreased from baseline (5.65 mmol/l; SE 0.07) and was significantly lower after two (5.25 mmol/l; SE 0.07, $p<0.001$) and four years (5.26 mmol/l; SE 0.07, $p<0.001$). The same pattern was observed in women, showing significant changes from baseline (5.73 mmol/l; SE 0.09) to two (5.35 mmol/l; SE 0.09, $p<0.01$) and four years (5.43 mmol/l; SE 0.09, $p<0.05$).

In the Monica survey, in men, there were no significant changes in cholesterol level from 1986 (6.25 mmol/l) to 1991 (6.41 mmol/l) and, in women, there was also no significant change from 1986 (6.18 mmol/l) to 1991 (6.25 mmol/l).

2. Blood pressure

In men, systolic blood pressure decreased from baseline (137.4 mmHg; SE 1.2) and was significantly lower after two (130.7 mmHg; SE 1.3, $p<0.001$) and four years (131.5 mmHg; SE 1.3, $p<0.001$). In women, significant changes from baseline (133.0 mmHg; SE 1.2) were observed after to two (127.2 mmHg; SE 1.4, $p<0.01$) but not four years (130.1 mmHg; SE 1.6, p=NS).

In men, diastolic blood pressure decreased from baseline (85.0 mmHg; SE 0.6) and was significantly lower after two (80.5 mmHg; SE 0.7, $p<0.001$) and four years (80.4 mmHg; SE 0.8, $p<0.001$). In women, significant changes from baseline (82.0 mmHg; SE 0.7) were observed after to two (77.8 mmHg; SE 0.7, $p<0.001$) and four years (78.7 mmHg; SE 0.8, $p<0.01$).

In the MONICA survey, diastolic blood pressure increased slightly in men (1986: 82.6 mmHg to 1991: 83.5 mmHg) and women (1986: 79.8 mmHg to 1991: 79.3 mmHg) (NS). Not information is given for MONICA survey systolic blood pressure results.

3. BMI

In men, BMI increased from baseline (25.9 kg/m^2; SE 0.23) to two (26.3 kg/m^2; SE 0.26) and four years (26.4 kg/m^2; SE 0.27) but differences were not significant. In women, BMI increased from baseline (25.3 kg/m^2; SE 0.33) to two (25.4 kg/m^2; SE 0.35) and four years (25.1 kg/m^2; SE 0.30) but, again, differences were not significant.

Although data on BMI is presumably obtainable from the MONICA survey, it is not reported in the results of this study.

4. Non-fasting blood glucose

In men, non-fasting glucose decreased significantly from baseline (5.40 mmol/l; SE 0.08) after two years (5.17 mmol/l; SE 0.09, $p<0.05$) and four years (5.10 mmol/l; SE 0.09, $p<0.01$) of intervention. In women, non-fasting glucose also decreased significantly from baseline (5.75 mmol/l; SE 0.07) to two (5.33 mmol/l; SE 0.08, $p<0.001$) and four years (5.29 mmol/l; SE 0.09, $p<0.001$) of intervention.

No details of blood glucose were given in the MONICA report.

5. Smoking

The prevalence of smoking increased throughout intervention years from baseline (26.2%) to two years (27.6%) and four years (28.6%) but increases were not significant.

Although data on smoking is presumably obtainable from the MONICA survey, it is not reported in the results of this study.

Analysis was also done separately on cohorts of individuals that were measured in 1989 and 1991 and those that were measured in 1991 and 1993 and cross sectional

changes in cholesterol, blood pressure and non-fasting glucose level were supported by results observed in the cohorts.

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors

None

Limitations identified by reviewer

The MONICA study in northern Sweden was used to provide control group data. Although MONICA results for cholesterol and diastolic blood pressure are presented, they are not given for systolic blood pressure, BMI or rates of smoking.

Control changes in MONICA are not used to calculate net intervention effect or even presented in the results section. Since it appears that the same positive trends were not observed in the MONICA population, it may be likely that net positive intervention effects would be found and this would have added strength to claims of an intervention effect.

Summary

In the Olofström area of Southern Sweden, community intervention coincided with positive trends in physiological risk factors. The lack of concurrent change in the northern Swedish MONICA population in cholesterol and diastolic blood pressure suggests that intervention may have been beneficial in these areas. However, the absence of control information on other risk factors makes it difficult to attribute change in these variables to intervention activities.

3.1.9 The Quebec Heart Health Demonstration Project – Rural (13)

The Quebec Heart Health Demonstration Project was part of the Canadian Heart Health Initiative: a fifteen year scheme designed to build the capacity of the public

health system and to develop, implement and evaluate heart health programmes across Canada. Quebec Heart Health was a five year intervention that covered three public health departments implementing independent health promotion programmes.

These programmes were in different settings (urban/suburban/rural) and used different modes of intervention. In the literature, these three interventions are described under the label of one programme (Huot 2004): Quebec Heart Health, with comparisons made between interventions for the effect of geographical setting. However, these comparisons are likely to be unwarranted given the difference in programme delivery and the nature and intensity of intervention. Therefore, in the current report, for clarity, programmes are discussed separately. This is a summary of the rural part of the intervention.

Target population

Ten municipalities in the rural area of Rivière-du-Loup (n=90,000), located 500km east of the city of Montreal, were chosen for intervention.

Nine control municipalities (locations not stated) were selected on the basis of criteria of sufficient geographical distance (to prevent contamination), the absence of community heart health initiatives in the previous year and a comparable size to intervention communities. On average, these communities had similar mean age and socioeconomic status to intervention communities.

Theory/conceptual model of intervention

Strategies of Community Development and the Social Planning Theory were used as the basis for intervention.

Intervention description

Freedom was given to the local Public Health Department to determine the objectives, target population and intervention strategies that best suited their needs and requirements.

Ten groups of local volunteers developed and implemented the community programme. They were offered a 21 hour course on health promotion, developed specifically for the project at a local college. Educational tools were developed by the local health department for use by the volunteers including pamphlets, a video, tips for restaurant choices, games and posters.

The most commonly implemented projects were screening sessions for hypertension and hypercholesterolemia, supermarket tours, distribution of healthy recipe books, healthy food tastings, cooking classes, walking clubs and conferences. Social support groups were created for people with hypercholesterolemia and for patients with ischemic heart disease.

Accessibility:

The interventions were planned to meet the needs and priorities of the local community and included screening, written educational materials, development of social support groups, media coverage and physical activities. It is unclear how many activities took place or the range of venues used. Community volunteers were trained to deliver the intervention.

The target population is described as highly homogeneous, French speaking, low income, of low educational attainment, with high unemployment and with a low rate of mobility. No information is provided on whether materials were made accessible for non native language speakers, those from different cultural backgrounds or for those with low literacy levels. Evaluation questionnaires in English and French were sent via children to all parents in the intervention and control communities.

Response rates were greater than 65% but not precisely reported. The respondents to the survey are described as 'not representative of all adults in the intervention community' but further information is not provided. This pattern of response rates may be an indicator of the accessibility of the intervention to certain sub-groups of the population.

Evaluation

Schools in the intervention and control areas were used to survey children and to contact adult participants for programme evaluation (number of schools not detailed). Surveys were conducted via all community schools and taken at baseline (1993) and four years into intervention (1997). In the literature, only results for adult participants are presented.

Participant selection/recruitment

All children in grades 4-6 of each school completed classroom questionnaires with the aid of two trained research assistants. Children were given questionnaires along with information about the project and consent forms for each of their parents to complete.

Questionnaires collected information on socio-demographics as well as health status and health behaviours and intentions. Dietary behaviours were assessed with a validated food frequency questionnaire, used to generate a 'Global Dietary Index', 'Meat Consumption Index', 'Dairy Consumption Index' and 'Fat Consumption Index'.

In 1993, there were 780 adult participants from the intervention community and 634 from the control. In 1997, there were 1,187 adult participants from the intervention community and 747 from the control. Response rates are not detailed.

Outcome measures

Global Dietary Index, Dairy Consumption Index, Meat Consumption Index, Fat Consumption Index and intentions to change dietary behaviours: increasing consumption of low fat meats, increasing skimmed milk consumption, increasing low fat processed meat consumption.

Statistical methods

Baseline differences were assessed by Chi-square tests. Analysis of Variance was used to assess the impact of the programme on dietary behaviours with individual as the unit of analysis. Baseline variables of age, BMI, education level, smoking status,

duration of residence in the community, physical activity level and reported risk factors (diabetes, elevated cholesterol, hypertension and heart problems) were included in models to control for potential confounding.

Results

Primary outcomes

Results are given for parents of children attending schools in intervention/control areas. Lower values for dietary indexes indicate more favourable diets.

1. Global Dietary Index

In men, Global Dietary Index increased in the intervention group (1993: 0.85; SD 0.19 to 1997: 0.88; SD 0.20) and the control (1993: 0.87; SD 0.20 to 1997: 0.91; SD 0.21) and there was no significant difference between the size of group changes. In women, Global Dietary Index increased in the intervention group (1993: 0.74 SD 0.18 to 1997: 0.77; SD 0.20) and the control (1993: 0.76; SD 0.19 to 1997: 0.80; SD 0.20) and there was no significant difference between the size of group changes.

2. Dairy Consumption Index

In men, Dairy Consumption Index increased in the intervention group (1993: 1.1; SD 0.35 to 1997: 1.11; SD 0.35) and the control (1993: 1.1; SD 0.35 to 1997: 1.18; SD 0.36) and there was no significant difference between the size of group changes. In women, Dairy Consumption Index increased in the intervention group (1993: 0.99 SD 0.36 to 1997: 1.02; SD 0.36) and in the control (1993: 1.01; SD 0.34 to 1997: 1.09; SD 0.36) and there was no significant difference between the size of group changes.

3. Meat Consumption Index

In men, Meat Consumption Index decreased in the intervention group (1993: 0.80; SD 0.26 to 1997: 0.63; SD 0.22) and the control (1993: 0.81; SD 0.27 to 1997: 0.64; SD 0.22) and there was no significant difference between the size of group changes. In women, Meat Consumption Index increased in the intervention group (1993: 0.66 SD 0.23 to

1997: 0.68; SD 0.24) and the control (1993: 0.69; SD 0.24 to 1997: 0.71; SD 0.25), no significant difference between the size of group changes.

4. Fat Consumption Index

In men, Fat Consumption Index increased in the intervention group (1993: 0.63; SD 0.32 to 1997: 0.68; SD 0.36) and the control (1993: 0.67; SD 0.34 to 1997: 0.70; SD 0.37) and there was no significant difference between the size of group changes. In women, Fat Consumption Index increased in the intervention group (1993: 0.53 SD 0.31 to 1997: 0.58; SD 0.35) and stayed the same in the control (1993: 0.56; SD 0.33 to 1997: 0.61; SD 0.36), no significant difference between the size of group changes.

5. Health-related behaviours and intentions

Data not presented except to comment that, in intervention men, there was increased consumption of low fat processed meats (p=0.02). Whether this change was significantly different in intervention and control communities is not stated.

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors

Strong secular trends may have masked intervention effects.

Programme messages may have been too general and not sufficiently practical to induce changes.

The cross sectional method of assessment may not have been powerful enough to detect change (less powerful than cohort).

There may have been cross community contamination: 19% of residents in intervention compared to 15% of residents in control areas participated in heart health activities.

The adult sample was not representative of the community adult population as it only contained parents of children attending intervention/control schools.

Food frequency questionnaires may have be subject to reporting bias.

The low-intensity intervention may have had a bigger impact if it had been delivered to a larger segment of the community.

Limitations identified by reviewer

Response rates for parents participating in surveys were not detailed and participants may not have been a typical representation of all parents (or indeed the true adult population). Those that were healthier, or who had made behavioural modifications since the last survey, may have been more likely to take part.

Summary

In the rural arm of the Quebec Heart Health project, although intervention was delivered by community volunteers and appears to have been reasonably wide ranging, there is no evidence for positive effects on the dietary habits of parents. There may have been insufficient programme reach and project focus may have been too weak to bring about dietary change.

3.1.10 The Quebec Heart Health Demonstration Project – Suburban (13)

The Quebec Heart Health Demonstration Project was part of the Canadian Heart Health Initiative; a fifteen year scheme designed to build the capacity of the public health system and to develop, implement and evaluate heart health programmes across Canada. Quebec Heart Health was a five year intervention by three public health departments in different settings (urban/suburban/rural) and this section details intervention in the suburban community.

Target population

Intervention was conducted in the suburban area of Fabreville (n=35,216); located in North Montreal. Two control communities (location and size not stated) were selected, with a similar distribution of age and income to Fabreville.

Theory/conceptual model of intervention

Social learning theory, the Precede-Proceed model, Social Marketing, Persuasive communication and diffusion of innovation were used to plan intervention activities with the aim of community mobilisation and local development.

Intervention description

Freedom was given to the local Public Health Department to determine the objectives, target population and intervention strategies that best suited their needs and requirements. Intervention was community based and activities largely related to nutrition and physical activity.

Articles were put in local newspapers and there were nutrition related activities such as taste-testing sessions. Conferences and workshops on healthy eating were run as well as games on heart health in local shops. Activities for increasing physical activity were also implemented such as a walking club and physical activity projects in local parks.

Accessibility:

Interventions were planned to meet the needs and priorities of local communities. Activities were aimed at adults (an estimated 20% of the population over 18 were reached). Activities were varied and included written educational materials, physical activities and media coverage. It is unclear how many activities took place or the range of venues used. Community volunteers were trained to deliver the intervention. No details about the ethnic or socio-economic make-up of the target community is provided. No information is provided on whether materials were made accessible for non native language speakers, those from different cultural backgrounds or for those with low literacy levels.

Evaluation questionnaires in French and English were sent via children to all parents in the intervention and control communities. Response rates were above 65% but not given precisely. The respondents to the survey are described as 'not representative of all adults in the intervention community' but further information is not provided. Authors state that educational meetings were cancelled due to lack of participation and awareness and participation in the intervention in individuals aged 18 and over was only 12% and 4% respectively. These rates may be a reflection of the accessibility of the intervention.

Evaluation

Schools in the intervention and control areas were used to survey children and to contact adult participants for programme evaluation (number of schools not detailed). Surveys were conducted via all community schools and taken at baseline (1993) and four years into intervention (1997). In the literature, only results for adult participants are presented.

Participant selection/recruitment

All children in grades 4-6 of each school completed classroom questionnaires with the aid of two trained research assistants. Children were given questionnaires along with information about the project and consent forms for each of their parents to complete.

Questionnaires collected information on socio-demographics as well as health status and health behaviours and intentions. Dietary behaviours were assessed with a validated food frequency questionnaire, used to generate a 'Global Dietary Index', 'Meat Consumption Index', 'Dairy Consumption Index' and 'Fat Consumption Index'.

In 1993, there were 571 adult participants from the intervention community and 564 from the control. In 1997, there were 621 adult participants from the intervention community and 1,127 from the control. Response rates are not detailed.

Outcome measures

Global Dietary Index, Dairy Consumption Index, Meat Consumption Index, Fat Consumption Index and intentions to change dietary behaviours: increasing consumption of low fat meats, increasing skimmed milk consumption, increasing low fat processed meat consumption.

Statistical methods

Baseline differences were assessed by Chi-square tests. Analysis of Variance was used to assess the impact of the programme on dietary behaviours with individual as the unit of analysis. Baseline variables of age, BMI, education level, smoking status, duration of residence in the community, physical activity level and reported risk factors (diabetes, elevated cholesterol, hypertension and heart problems) were included in models to control for potential confounding.

Results

Primary outcomes

Results are given for parents of children attending schools in intervention/control areas. Lower values for dietary indexes indicate more favourable diets.

1. Global Dietary Index

In men, Global Dietary Index decreased in the intervention group (1993: 0.82; SD 0.20 to 1997: 0.80; SD 0.20) and the control (1993: 0.81; SD 0.20 to 1997: 0.80; SD 0.20) and there was no significant difference between the size of group changes. In women, Global Dietary Index decreased in the intervention group (1993: 0.71 SD 0.20 to 1997: 0.68; SD 0.19) and remained constant in the control (1993: 0.69; SD 0.18 to 1997: 0.69; SD 0.19) and there was no significant difference between the size of group changes.

2. Dairy Consumption Index

In men, Dairy Consumption Index decreased in the intervention group (1993: 1.03; SD 0.35 to 1997: 1.01; SD 0.35) and the control (1993: 1.05; SD 0.34 to 1997: 1.0; SD 0.34) and there was no significant difference between the size of group changes. In women,

Dairy Consumption Index decreased in the intervention group (1993: 0.92 SD 0.37 to 1997: 0.90; SD 0.36) and in the control (1993: 0.94; SD 0.35 to 1997: 0.91; SD 0.36) and there was no significant difference between the size of group changes.

3. Meat Consumption Index

In men, Meat Consumption Index decreased in the intervention group (1993: 0.80; SD 0.25 to 1997: 0.76; SD 0.24) and stayed the same in the control (1993: 0.77; SD 0.24 to 1997: 0.77; SD 0.25) and there was no significant difference between the size of group changes. In women, Meat Consumption Index decreased in the intervention group (1993: 0.69 SD 0.24 to 1997: 0.63; SD 0.22) and the control (1993: 0.66; SD 0.24 to 1997: 0.64; SD 0.22), no significant difference between the size of group changes.

4. Fat Consumption Index

In men, Fat Consumption Index increased in the intervention group (1993: 0.53; SD 0.35 to 1997: 0.54; SD 0.35) and the control (1993: 0.54; SD 0.34 to 1997: 0.56; SD 0.34) and there was no significant difference between the size of group changes. In women, Fat Consumption Index decreased in the intervention group (1993: 0.44 SD 0.31 to 1997: 0.43; SD 0.31) and increased in the control (1993: 0.38; SD 0.27 to 1997: 0.43; SD 0.29), no significant difference between the size of group changes.

5. Health-related behaviours and intentions

Data not presented except to comment that, in intervention men, there was increased consumption of low fat meats (p=0.02) and, in intervention women, there was increased consumption of low fat milk (p=0.04) and low fat processed meats (p=0.04). Whether these changes were significantly different in intervention and control communities is not stated.

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors

Strong secular trends may have masked intervention effects.

Participation in intervention activities was low e.g. 10 nutrition meetings were cancelled on the basis of poor participation and the one session that was held drew only 15 participants.

Programme messages may have been too general and not sufficiently practical to induce changes.

The cross sectional method of assessment may not have been powerful enough to detect change (less powerful than cohort).

The adult sample was not representative of the community adult population as it only contained parents of children attending intervention/control schools.

Food frequency questionnaires may have be subject to reporting bias.

The low-intensity intervention may have had a bigger impact if it had been delivered to a larger segment of the community.

Limitations identified by reviewer

Response rates for parents participating in surveys were not detailed and participants may not have been a typical representation of all parents (or indeed the true adult population). Those that were healthier, or who had made behavioural modifications since the last survey, may have been more likely to take part.

Summary

Community intervention in the suburban arm of the Quebec Heart Health project showed no impact on the dietary habits of parents. Activities were small scale with poor rates of participation and resulted in an unsurprising lack of behavioural change.

3.1.11 The Quebec Heart Health Demonstration Project – Urban (13)

The Quebec Heart Health Demonstration Project was part of the Canadian Heart Health Initiative; a fifteen year scheme designed to build the capacity of the public

health system and to develop, implement and evaluate heart health programmes across Canada. Quebec Heart Health was a five year intervention by three public health departments in different settings (urban/suburban/rural) and this section details intervention in the urban community.

Target population

Intervention took place in St-Louis-du-Parc (n=41,625); an urban, multiethnic, low socioeconomic status neighbourhood in south-central Montreal. This was a diverse population with a range of principle languages spoken: 49% French, 34% English, and 34% other. There tended to be low educational achievement and 31% of women and 27% of men had not been educated past the 9th grade (~15 years old). Intervention was mainly conducted in the eight community elementary schools (normally 4-11 years old).

The location and size of control communities is not stated. Sixteen schools in the control community acted as the control group and were selected to be of similar socioeconomic status, language spoken at home and geographical location.

Theory/conceptual model of intervention

Social learning theory, the Precede-Proceed model and the Azjen and Fishbein theory of planned behaviour were used as the basis for intervention. Although the major focus of intervention was directed towards school children, it was anticipated that adults would be reached by diffusion of information.

Intervention description

For the urban arm of the Quebec Heart Health Demonstration Project, as with the other intervention sites, freedom was given to the local Public Health Department to determine the objectives, target population and intervention strategies that best suited their needs and requirements. Intervention was delivered through all of the eight elementary schools in the area and through activities aimed at parents and the wider community.

In schools, twenty hours of curriculum teaching was given annually covering nutrition, physical activity and prevention of smoking. Among the nutrition activities, children were taught how to select a healthy meal using the four food groups of the Canadian food guide and to choose or prepare healthy foods and snacks.

Parents were invited to participate in schools and community-based activities that aimed to improve their ability to choose and prepare healthy foods. Healthy food tasting sessions were organised with the aid of a dietician, open to parents and all school personnel.

Accessibility:

Interventions were planned to meet the needs and priorities of local communities. The intervention was offered in schools as part of the curriculum. School based and community education activities for parents also took place but it is unclear how many of these activities were offered or whether they were offered at venues other than school.

The urban area is described as multi-ethnic, low income and the rural community as highly homogeneous, French speaking, low income, low educational attainment and high unemployment with a low rate of mobility. However, no information is provided on whether materials were made accessible for non native language speakers, those from different cultural backgrounds or for those with low literacy levels.

Evaluation questionnaires were sent via children to all parents in the intervention and control communities. Evaluation questionnaires were available in French and English. The response rate was 65% and the low rate is explained on the basis that 34% of the intervention population speak languages other than French and English. The respondents to the survey are described as 'not representative of all adults in the intervention community' but further information is not provided. Participation in parental activities is also described as low. The low response rates to the evaluation

and low uptake of interventions by parents may be a reflection of the accessibility of the intervention to adults.

Evaluation

Eight schools in the intervention area and sixteen schools in the control area were used to survey children and to contact adult participants for programme evaluation. Surveys were taken at baseline (1993) and four years into intervention (1997). In the literature, only results for adult participants are presented.

Participant selection/recruitment

All children in grades 4-6 of each school completed classroom questionnaires with the aid of two trained research assistants. Children were given questionnaires along with information about the project and consent forms for each of their parents to complete.

Questionnaires collected information on socio-demographics as well as health status and health behaviours and intentions. Dietary behaviours were assessed with a validated food frequency questionnaire, used to generate a 'Global Dietary Index', 'Meat Consumption Index', 'Dairy Consumption Index' and 'Fat Consumption Index'.

In 1993, there were 619 adult participants from the intervention community and 1,692 from the control. In 1997, there were 602 adult participants from the intervention community and 979 from the control. Response rates are not detailed.

Outcome measures

Global Dietary Index, Dairy Consumption Index, Meat Consumption Index, Fat Consumption Index and intentions to change dietary behaviours: increasing consumption of low fat meats, increasing skimmed milk consumption, increasing low fat processed meat consumption.

Statistical methods

Baseline differences were assessed by Chi-square tests. Analysis of Variance was used to assess the impact of the programme on dietary behaviours with individual as the unit of analysis. Baseline variables of age, BMI, education level, smoking status, duration of residence in the community, physical activity level and reported risk factors (diabetes, elevated cholesterol, hypertension and heart problems) were included in models to control for potential confounding.

Results

Primary outcomes

Results are given for parents of children attending intervention/control schools. Lower values for dietary indexes indicate more favourable diets.

1. Global Dietary Index

In men, Global Dietary Index decreased in the intervention group (1993: 0.71; SD 0.19 to 1997: 0.70; SD 0.20) and the control (1993: 0.75; SD 0.20 to 1997: 0.71; SD 0.20) and there was no significant difference between the size of group changes. In women, Global Dietary Index decreased in the intervention group (1993: 0.68 SD 0.18 to 1997: 0.66; SD 0.18) and remained constant in the control (1993: 0.69; SD 0.18 to 1997: 0.69; SD 0.19) and there was no significant difference between the size of group changes.

2. Dairy Consumption Index

In men, Dairy Consumption Index decreased in the intervention group (1993: 1.0; SD 0.32 to 1997: 0.99; SD 0.34) and the control (1993: 1.04; SD 0.35 to 1997: 0.98; SD 0.33) and there was no significant difference between the size of group changes. In women, Dairy Consumption Index decreased in the intervention group (1993: 1.0 SD 0.33 to 1997: 0.99; SD 0.35) and in the control (1993: 1.02; SD 0.35 to 1997: 0.99; SD 0.34) and there was no significant difference between the size of group changes.

3. Meat Consumption Index

In men, Meat Consumption Index decreased in the intervention group (1993: 0.69; SD 0.25 to 1997: 0.66; SD 0.25) and the control (1993: 0.73; SD 0.26 to 1997: 0.69; SD 0.25) and there was no significant difference between the size of group changes. In women, Meat Consumption Index decreased in the intervention group (1993: 0.62 SD 0.24 to 1997: 0.61; SD 0.24) and stayed the same in the control (1993: 0.65; SD 0.23 to 1997: 0.65; SD 0.23), no significant difference between the size of group changes.

4. Fat Consumption Index

In men, Fat Consumption Index decreased in the intervention group (1993: 0.43; SD 0.33 to 1997: 0.39; SD 0.34) and the control (1993: 0.46; SD 0.35 to 1997: 0.43; SD 0.34) and there was no significant difference between the size of group changes. In women, Fat Consumption Index decreased in the intervention group (1993: 0.40 SD 0.32 to 1997: 0.36; SD 0.29) and stayed the same in the control (1993: 0.41; SD 0.32 to 1997: 0.41; SD 0.31), no significant difference between the size of group changes.

5. Health-related behaviours and intentions

Data not presented

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors

Strong secular trends may have masked intervention effects.

There was a social and cultural gap between parents and schools and participation of parents in intervention activities was low.

Programme messages may have been too general and not sufficiently practical to induce changes.

The cross sectional method of assessment may not have been powerful enough to detect change (less powerful than cohort). The urban setting intervention may have been particularly affected by cross community contamination.

The adult sample was not representative of the community adult population as it only contained parents of children attending intervention/control schools.

Food frequency questionnaires may have be subject to reporting bias.

The low-intensity intervention may have had a bigger impact if it had been delivered to a larger segment of the community.

Limitations identified by reviewer

Response rates for parents participating in surveys were not detailed and participants may not have been a typical representation of all parents (or indeed the true adult population). Those that were healthier, or who had made behavioural modifications since the last survey, may have been more likely to take part.

Summary

The urban setting Quebec Heart Health schools-based intervention appears to have had no impact on the dietary habits of parents. There was poor participation of adults in programme activities and effective transfer of heart health messages from child to parent seems unlikely given the lack of behavioural change and low community involvement.

3.2 Screening and education programmes addressing prevention of CVD at population level

3.2.1 Ebeltoft screening and counselling (14)

In 1991, a general health screening and follow-up intervention was initiated in Ebeltoft, Denmark with the aim of reducing rates of risk factors for CVD.

Target population

Ebeltoft, Aarhus county, Denmark was a rural area with approximately 13,000 inhabitants. Patients registered at all of the nine general practitioners were the target for intervention and other patients acted as controls.

Theory/conceptual model of intervention

None stated

Intervention description

Before the start of intervention, all GPs took part in four meetings aimed to increase their knowledge of the prevention of heart and lung disease and to provide teaching on giving appropriate dietary advice and engaging in patient health discussions. Intervention consisted of health screening with or without additional health counselling with their GP.

Baseline health screenings took place in a central clinic in Ebeltoft town and included an assessment of total cholesterol, blood pressure, BMI and tobacco use. A cardiovascular disease risk score was calculated for each participant based on these measures and on their sex and family history of CVD. A few weeks following the health screening, participants received written feedback from their GPs with results and, where appropriate, advice relating primarily to lifestyle change. All participants with high cardiovascular risk scores were encouraged to visit their GPs and all received a pamphlet on how to lead a healthy lifestyle.

A 45 minute GP consultation was offered to those randomised to receive additional health counselling (half of the intervention group). Before consultation, participants completed a questionnaire to identify appropriate topics for discussion. After the consultation, health-related lifestyle goals were set through GP/patient discussion (maximum of 3) for the following year.

A year later, the same procedure was undertaken: participants received a questionnaire and were invited for a health screening. Those in the additional health counselling group were also offered GP consultations every year until the final evaluation (5 years from baseline).

Accessibility:

Invitation to attend for screening at one of 9 health centres was by letter. No information is given on distance to travel for participants. Screening was followed by personalised, written feedback which included an assessment of CVD risk and written health education. Individuals with an elevated risk and those in one of the 2 randomised intervention groups were also invited for annual consultations with their GP where lifestyle modifications were jointly agreed. Adequate communication of risk to patients requires a level of numeracy which may limit the effectiveness of this approach to certain groups. The ethnic, socio-economic and education profile of the target community is not described and no information is given on whether written materials were made accessible for those of low literacy levels, those from different cultural backgrounds or for non native language speakers.

Participation rate in the screening component of the intervention was 75%. Non-participants in the screening component of the intervention were more likely to be men which may be an indicator of the acceptability of this component of the intervention in this population sub-group but no other details are provided for this group. Participation in the first GP consultation was 88% and in jointly agreed lifestyle change plans was 61%. Non-participants in the GP consultations were significantly less likely to have been advised of an elevated CVD risk score. No further information is given on non-participants. Participation in subsequent annual GP consultations declined to 45% at two

years and 18% at three years. However, no information is provided on the demographic CVD profile of those who dropped out.

Evaluation

Participant selection/recruitment

In Elbeltoft, 3,464 people aged 30-49 years were registered with one of the local GPs (87% of people in this age group). Of these, a random sample of 2,000 were invited to participate in the study. Potential recruits received an invitation along with a general demographic/lifestyle questionnaire and those agreeing to participate received a more detailed questionnaire evaluating health, lifestyle, psychosocial status and psychosocial life events.

Participants were randomised to one of three groups by proportional, stratified, randomisation based on GP with whom they were registered, sex, age, cohabitation status and BMI:

1) Health screenings
2) Health screenings with follow-up health consultations with their GP
3) No intervention (control group)

Of those invited to take part (n= 2,000), 1,507 (75%) agreed to participate and, after randomisation, there were no significant differences between groups in age, gender, % cohabiting, BMI or % smokers (control n= 501, Health screening 502, Health screening + discussion 504). Of those randomised to the screening + discussion group, 88.9% received at lease one health discussion, 45.2% at least two, and 18.1% at least three.

Data from questionnaires was used to assess baseline similarity and a follow-up physiological evaluation in intervention and control groups took place five years after the initial screening. At the final evaluation five years later, rates of follow-up were

similar in control (73.7%, n=369), screening (75.3%, n=378) and screening + discussion (68.7%, n=346) groups.

Outcome measures

Cardiovascular risk score, total cholesterol, BMI, diastolic and systolic blood pressure.

Statistical methods

Differences between groups were calculated by X^2 for categorical variables, by t test for means and by non-parametric tests for non-parametric data and relative risks were calculated. All participants in randomised groups were compared regardless of whether they had complied with the intervention programme (NB Authors state that this was intention to treat but this does not appear to be the case - those lost to follow-up were not included in the final analysis).

Results

Results for the two intervention groups (health screening and health screening + counselling) were pooled for comparison with the control (authors state that this was because no significant differences were noted between intervention groups in any of the measures).

Primary outcomes

1. Cardiovascular risk score

Cardiovasclular risk score was significantly lower in the intervention (5.69; SD 3.05) compared to the control (6.25; SD 3.47) group ($p<0.01$).

2. Total cholesterol

Total serum cholesterol was significantly lower in intervention (5.54 mmol/l; SD 1.03) compared to the control (5.68mmol/l; SD1.06) group ($p<0.05$).

3. BMI

BMI was significantly lower in the intervention (25.9kg/m^2; SD 4.1) compared to the control (26.5 kg/m^2; SD 4.4) group ($p<0.05$).

4. Blood pressure

Systolic blood pressure was slightly lower in the intervention (130.9 mmHg; SD 18.2) compared to the control (132.6 mmHg; SD 19.9) but the difference was not significant.

Diastolic blood pressure was slightly lower in the intervention (79.8 mmHg; SD 10.5) compared to the control (81.0 mmHg; SD 11.7) but the difference was not significant.

Subgroup analysis was also done for smokers and overweight participants but full results will not be detailed in the current report. In smokers, significant positive intervention effects were noted for cardiovascular risk score ($p<0.05$) and systolic ($p<0.01$) and diastolic ($p<0.01$) blood pressure. In overweight participants, significant positive intervention effects were noted for cardiovascular risk score ($p<0.01$), BMI ($p<0.05$), total cholesterol ($p<0.05$) and systolic ($p<0.05$) and diastolic ($p<0.01$) blood pressure.

Limitations of the study

The study was quality assessed and graded '+'.

Limitations identified by authors

For ethical reasons, all intervention participants with elevated risk factors were offered a consultation with their GP regardless of whether they were in the screening or screening + consultation group. This may have been responsible for the lack of difference observed between these two groups.

The low rate of participation in GP health discussions may have weakened the strength of intervention in the screening + consultation group.

The baseline questionnaire and contact between intervention and control participants within clinics may have induced change in the control group.

Limitations identified by reviewer

Despite claims by authors, analysis does not appear to truly have been done on an intention to treat basis.

Baseline comparisons are presented for age, gender, % cohabiting, BMI and % smokers but not for other physiological variables. This is an inevitable difficulty in studies of this type where screening acts as both the intervention and also the baseline measure in the intervention group. Since the control group are not to receive the screening intervention, baseline data on many outcome measures is not available and comparisons cannot be made.

Summary

The screening and health counselling programme in Ebeltoft resulted in reductions in cardiovascular risk score, total cholesterol and BMI. The extent to which counselling was an important feature is difficult to assess but it appears that screening may have a positive intervention effect on some physiological risk factors for CVD.

3.2.2 The Inter 99 Study

The Inter99 study was a large (n=18,280), Danish, randomised multifactorial intervention study. It commenced in 1999 with the aim of reducing ischaemic heart disease (IHD) in the general population by promoting increased physical activity, better dietary habits and smoking cessation (15).

Target population

The study population comprised all 61,301 individuals born in 1939-40, 1944-45, 1949-50, 1954-55, 1959-60, 1964-65 and 1969-70 living in 11 municipalities in the south-western part of Copenhagen County (15).

Theory/conceptual model of intervention

The intervention utilized the Health Belief Model, Social Cognitive Theory, and the Transtheoretical Model. It focused on participants' perceptions of their health risk, along with their perceived benefits and barriers, their self-efficacy, and their readiness in relation to changing health-related behaviours (15).

Intervention description

Of those in the intervention sample, 90% (group A) were randomised to receive a high-intensity intervention and 10% (group B) were randomised to receive a low-intensity intervention.

The baseline intervention was conducted from 1999 to 2001 at the Research Centre for Prevention and Health. All those in groups A and B underwent a health examination, an assessment of their risk of developing IHD and individual lifestyle counselling.

The Copenhagen Risk Score was used to estimate the participants' absolute risk of developing IHD within the next 10 years and they were classified as high-risk if they were in the upper quintile of the distribution stratified according to sex and age, or if they had one or more of the following risk factors: being a smoker, systolic blood pressure ≥160mmHg, total cholesterol ≥7.5mmol/l, body mass index ≥30kg/m^2, diabetes, or impaired glucose tolerance.

The individual lifestyle counselling was based on the participant's personal risk estimate and focused on physical activity, diet, smoking and alcohol. Counselling lasting 15-45 minutes was provided by a trained nurse, dietitian or doctor trained in Motivational Interviewing. Participants were advised to aim for 4 hours of moderate physical activity per week in line with the Danish recommendations. All daily smokers (smokers of at least 1g of tobacco daily) received a personalised smoking consultation depending on their motivation to quit.

In addition to individualised lifestyle counselling, participants at high risk in group A were offered group counselling on diet/physical activity and/or smoking cessation or reduction. High-risk participants in group B were referred to their GP for usual care.

The diet/physical activity groups were led by a nurse or dietitian and comprised 15-20 participants who met 6 times for 2 hours over a 6-month period. Group counselling focused on information regarding healthy diet and the benefits of physical activity. Together with staff, participants set specific goals for behaviour change aiming to make small positive changes in physical activity in their everyday lives (15). All smokers in group A were additionally offered participation in a smoking cessation group or smoking reduction group (16).

After 12 months, the high-risk participants in both groups A and B were sent a questionnaire, invited for a further health examination and again offered individualised lifestyle counselling. Participants still at high risk in group A were again offered group counselling and those still at high risk in group B were once more referred to their GP. Low-risk participants in both groups A and B and the control group (group C) were sent a questionnaire only at 12 months. At 36 months after the baseline examination, a further questionnaire was mailed to all participants in groups A, B and C (15).

Accessibility:

Individuals were invited to attend for a health examination, CVD risk assessment and individual counselling. High risk individuals in one intervention arm were also offered group based counselling which required attendance for 2 hours, 6 times over a 6 month period. This process was repeated after 12 months for high risk individuals.

The method of invitation to screening was written but no information is provided on how screening results were communicated to participants. The ethnic, socio-economic and education profile of the target community is not described. There is no information on whether written materials were made accessible for those of low literacy levels, those from different cultural backgrounds or for non native language speakers.

No information is provided on the location of health examinations and counselling or distance to travel for participants. Uptake of the screening invitation and individualised counselling was 53% and non-responders had significantly higher admissions to hospital for CVD and diabetes. Uptake of group counselling was 48% but no information is provided for non-responders. Between 20% and 25% of participants in the evaluation across 2 intervention and 1 control arms were lost to follow up over a 36 month period but no information is provided for those lost to follow up. The intervention was effective in increasing physical activity in men in the short-term but not women which may indicate variation in acceptability of the intervention by gender.

Programme evaluation

Participant selection/recruitment

Intervention groups: An age and sex stratified random sample of 13,016 individuals was drawn from the study population of those living in the south-western part of Copenhagen County (n=61,301). Before intervention, the sample was randomised into group A (90%, high-intensity intervention) and group B (10%, low-intensity intervention). The intervention included a questionnaire to be answered in advance. Of those invited (n=13,016), 82 had died or could not be traced and, of the remaining 12,934, a total of 6,906 (53.4%) participated. Finally, a further 122 of the 6,906 participants were excluded because of alcoholism, drug abuse, or linguistic barriers, leaving 6,784 (52.5%) for analyses (3,482 women, 51.3%)(15). A total of 2,408 daily smokers were included at baseline: 2,168 in group A and 240 in group B (16).

Control group: A random sample of 5,264 individuals was drawn from the remaining 48,285 individuals in the study population (group C) and, of these, 3,324 (61.1%) answered a postal questionnaire (1,756 women, 52.8%). The age distribution in this group was different from group A and B.

Women in group B had a higher baseline physical activity level when compared with group A and group C. With this exception, physical activity was similar in both group and sex comparisons. In group C, more men and women ate an unhealthy diet and more men were smokers, but there was no significant difference in alcohol consumption between the groups. Compared with non-respondents, respondents in group A+B had significantly fewer admissions to hospital due to IHD, CVD and diabetes. However, there was no difference in admissions due to all causes. In group C there was no difference between respondents and non-respondents in admissions due to all causes or diabetes. Female respondents in group C had fewer admissions due to IHD and CVD (15). A total of 1,276 daily smokers were identified from information provided in the baseline questionnaires completed by those in the control group (16).

Outcome measures

Although the intervention was aimed at physical activity, better dietary habits and smoking cessation (15) only outcome data on its effectiveness on physical activity (15) and smoking cessation/reduction (16,17) has been identified.

1. Physical activity

Physical activity was measured by self-administered questionnaire at baseline, 12 and 36-month follow-up and based on two questions: 1) in your leisure time how many hours a week are you physically active (including walking, cycling, gardening but excluding transportation to and from work) and 2) how much time do you spend walking, cycling, or running on your way to and from work? The amount of physical activity undertaken was converted into minutes per week using a 5-day working week and variable physical activity was calculated by summing responses to the two questions. For stratified analyses, baseline physical activity level was dichotomized using 3.5 hours/week as the cut-off point.

Statistical methods

Data were analysed using a longitudinal linear regression model with random effects. All analyses were stratified on sex. The outcome was change in physical activity (min/week) from baseline to 12 and 36-month follow-up. Change in physical activity was examined by including an interaction term between intervention group and time. The model used information about baseline, 12 and 36-month physical activity and made it possible to include those who only reported physical activity in one or two of the investigations. The models were adjusted for baseline age, diet, smoking, alcohol intake, self-rated health, being limited in climbing stairs, living with partner, vocational education, and employment as these factors were associated with missing physical activity values due to dropout or non-response at 12-month and/or 36-month follow-up. Four separate models were developed: 1) restricted to those with a low baseline physical activity level (<3.5 hours/week, n=3,662), 2) restricted to those with a high baseline physical activity level (≥3.5 hours/week, n=6,051), 3) restricted to those at high risk of developing IHD at baseline due to factors other than smoking (group A: n=2,134, group B: n=248), and 4) including all participants regardless of their baseline physical activity level. The participation rate at 12-month/36-month follow-up was 74.7%/74.9% in group A, 77.2%/75.0% in group B, and 83.6%/80.4% in group C. The total model sample size in the longitudinal analyses was 30,324 observations coming from 10,108 subjects at baseline, 12 and 36-month follow-up. Missing information on physical activity in one or more of the three investigations reduced the sample size to 24,090 observations coming from 9,824 subjects, and missing information on covariates reduced the sample size further, leaving 20,661 observations from 8,282 subjects for analyses in multi-adjusted models (15).

2. Smoking

For the assessment of smoking reduction in the group of identified smokers, two variables of tobacco reduction were defined: 1) a minimum 5g/day reduction(because for many smokers this was an obtainable goal) and 2) a minimum 50% reduction (because this has been used in several studies measuring health improvement) (16).

Statistical methods

In the assessments of smoking reduction changes in tobacco consumption after 1 year were tested with Wilcoxons Signed Rank Test. Logistic regression analysis was used to predict successful reduction in the study population (Groups A+B) in comparison with the control population (Group C) (16). In the assessments of smoking cessation, categorical data were tested by Pearson chi-square test, and continuous and ordinal data were tested by independent samples *t* test. Logistic regression analysis was used to analyse the likelihood of cessation among smokers in the high intensity intervention group A compared with the low intensity group B and background population group C, adjusted for sex, age, socioeconomic status, and motivational level at baseline.

Results

Primary outcomes:

1) Physical activity

Amongst those with a low baseline physical activity level, there were no significant differences between the groups at 12 months however all groups increased their physical activity levels during this period (approximate increases of 75min/week and 80min/week amongst men and women respectively– figures read from graphs). At 36 months, men in group A and in group B increased their activity by 22min/week (p=0.019) and 44min/week (p=0.018) more than men in group C. There was no significant difference between group A and B (p=0.221). Amongst women, there were no significant differences (15).

Amongst those with a high baseline physical activity level, the decrease in physical activity was 23min/week less amongst men in group A (p=0.009) and 39min/week less amongst women in group A (p=0.023) when compared with group C at 12 months. Physical activity levels decreased amongst all groups over the 12-month period (by approximately 40-60 min/week and 40-80 min/week amongst men and

women respectively – figures read from graphs). At 36-months follow-up, the decrease in physical activity was 24min/week less in group A than in group C amongst men (p=0.005) but there was no significant difference between groups A and B (p=0.908). Amongst women, there were no significant differences between the groups at 36-month follow-up (15).

Amongst high risk participants, for men in group A, physical activity increased by 11min/week at 12-months follow-up (p=0.048), but there was no significant change from baseline to 36-month follow-up (p=0.571). There was no significant change in physical activity from baseline to 12 or 36-months follow-up amongst men in group B (12 months: p=0.4147; 36 month: p=0.5644) or for women in group A (12 months: p=0.354; 36 months: p=0.861) or group B (12 months: p=0.428; 36 months: p=0.304) (15).

In analyses including all participants, physical activity decreased from baseline to 12 and 36-month follow-up amongst men and women in all three groups. Amongst men, the decrease in physical activity was 13min/week less in group A than in group C after 12 months (p=0.27) and 25min/week less after 36 months (p<0.0001). The decrease in physical activity was 30min/week less in group B than in group C after 36 months (p=0.006), but there was no significant difference between group A and B (p=0.664). Amongst women, physical activity decreased 30min/week more in group B than in group C after 12 months (p=0.004) but there was no significant difference after 36 months (p=0.398). There were no significant differences between group A and group C in the decrease in physical activity after 12 months (p=0.167) or after 36 months (p=0.636) (15).

Women in group B had a higher baseline physical activity level when compared with group A and group C. With this exception, physical activity was about the same in the three groups and amongst men and women. In the control group, more men and women ate an unhealthy diet and more men were smokers, but there was no significant difference in alcohol consumption between the groups. Compared with responders, male non-responders at 12-month follow-up in group A and C were less

physically active at baseline, whereas those in group B were more physically active. Female non-responders at 12-month follow-up in group A were less active than responders. Both male and female non-responders at 36-month follow-up were less physically active than responders (15).

2) Smoking

In those who smoked at baseline, changes in tobacco consumption and smoking cessation were ascertained at 1-year follow-up:

Changes in smoking consumption were based on participants self reports. The mean reduction in tobacco consumption in the study group AB was 1.4g (SD±6.3) amongst those with both baseline and 1-year data compared with 0.03g (SD±6.1) in the control population ($p<0.001$). The mean achieved reduction amongst those who reduced by at least 5g/day was 9.2g (SD±7.5; range 60). Amongst those who achieved a 50% reduction it was 13.5g (SD±10.8; range 63). A total of 245 (11.4%) smokers achieved a minimum 5g reduction and 89 (4.2%) reduced consumption by 50% or more. Less than 2% of those in the high intensity group attended the smoking reduction groups (16).

For smoking cessation, the validated abstinence rate at 1-year follow-up was 16.3% in the high intensity group and 12.7% in the low intensity group compared with a self-reported abstinence rate of 7.3% in the control group. Validated abstinence in the high intensity group A was not significantly higher than in the low intensity group B (OR=1.4; CI 0.8-2.3). The adjusted odds ratio of abstinence in the high intervention group was significantly higher (OR=2.2; CI 1.6-3.0) than in the control group and the intention to treat analyses reflected a similar significant trend (OR=1.5; CI 1.1-2.0). (17).

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors

Losses to follow-up of 20-25% across the two intervention and one control arms raise the possibility of selection bias. However the use of longitudinal linear regression models with random effects in the analysis of physical activity levels help take account of loss to follow-up under the assumption of missing at random (15).

Limitations identified by reviewer

Low uptake (53%) of the invitation for screening and individual counselling calls into question the extent to which those receiving the intervention adequately reflect the study population. Two separate samples were drawn from the study population to form the intervention group (which was then randomised to two groups: high or low-intensity intervention) and the control group. This led to some baseline differences between the intervention and control groups. However, in their analyses the authors made adjustments to take account of differences in baseline age, diet, smoking, alcohol intake, self-rated health, being limited in climbing stairs, living with partner, vocational education, and employment.

Summary

The study indicated that, for men, both high and low-intensity multifactorial interventions for the prevention of IHD may have a beneficial impact on physical activity over a 36-month period, regardless of baseline physical activity levels. However, the additional group counselling provided to those at high IHD risk in the high-intensity intervention group did not provide any additional improvement in physical activity levels in comparison with the standard GP consultation offered to those at high IHD risk in the low-intensity intervention group. The intervention did not benefit the development of physical activity amongst women. The intervention in smokers was also seen to have a favourable impact on both smoking cessation and smoking reduction. However, whilst the high level additional group intervention appeared to confer some additional benefits in smoking cessation, its uptake amongst participants attempting to reduce tobacco consumption was negligible (16).

3.2.3 The Malmö Preventative Project (18)

The Malmö Preventative Project began in 1974 and aimed to examine the effect of preventative intervention on total mortality and cardiovascular mortality, alcohol abuse and breast cancer.

Target population

The city of Malmö (n=250,000) was the site for intervention, and it was implemented via the Section of Preventative Medicine at Malmo University Hospital. Males born in the years 1927, 1928, 1929, 1944, 1946 and 1948 and females born in 1928, 1930 and 1938 were invited to take part whilst males born in the years 1925, 1943, 1945 and 1947 and females born in 1927, 1929 and 1939 acted as controls.

Theory/conceptual model of intervention

None stated

Intervention description

Men and women born between 1921 and 1949 were recruited to a large scale programme for risk factor screening and lifestyle modification. At the screening, assessment of BMI, blood pressure and pulse rate was made and blood samples were taken for total cholesterol, triglycerides and fasting blood glucose. Questionnaires were administered to obtain details of family history of CVD, hypertension and diabetes, smoking and dietary habits, alcohol consumption, work and leisure time physical activity, previous weight gain and any signs or symptoms of CVD or alcohol abuse.

Participants with risk factors for cardiovascular disease were identified and treated accordingly:

1) Hypertension: systolic blood pressure >160mm Hg and/or diastolic blood pressure >100 mmHg or those currently taking anti-hypertension therapy. These participants

were referred to their usual physician if they had one, or to a specially created outpatient clinic.

2) Hyerlipideamia: total cholesterol ≥6.5 mmol/l and/or triglycerides >2.3 mmol/l or those taking already receiving ongoing lipid therapy. Referrals were made to a lipid outpatient clinic.

3) Diabetes/glucose intolerance: fasting blood glucose or 2h post oral glucose (30g/body surface area m2) ≥7 mmol/l. Participants with elevated glucose levels were referred to a special outpatient clinic. Treatment was mainly non-pharmacological (presumably dietary counselling) and continued during the majority of follow up.

4) Smokers were given antismoking advice.

5) Participants who were overweight/obese were given dietary advice and, where appropriate, referred to weight reduction groups.

4) High alcohol intake: in the highest decentile of the GGT distribution as assessed by the screening questionnaire. These participants were referred to a special outpatient clinic for treatment.

5) Screening for breast cancer was also conducted and suspected cases referred to the hospital department of surgery.

Accessibility:

The intervention comprised screening and subsequent management in primary and secondary care dependent on CVD risk. Screening took place in one healthcare facility covering a population of 250,000. No information is provided on distance to travel for participants. The method of invitation to screening was written but no information is provided on how screening results were communicated to participants. The ethnic, socio-economic and education profile of the target community is not described. There is no information on whether written materials were made accessible for those of low

literacy levels, those from different cultural backgrounds or for non native language speakers.

Uptake of screening was 75% and non-participants were more likely to be non-native, single or divorced, of lower socio-economic status and with lower educational attainment. This may be an indication of the accessibility of the intervention in these population groups. No clear gender differences were noted between participants and non-participants. Men who refused screening were observed to have a higher incidence of fatal CVD events and women who refused screening had higher incidence of fatal CVD and stoke events.

Evaluation

The project was evaluated by monitoring rates of mortality and morbidity from the start of the recruitment period (1974) until 1995 in those that had and had not been invited to participate in screenings.

Participant selection/recruitment

At baseline, males born in the years 1927, 1928, 1929, 1944, 1946 and 1948 and females born in 1928, 1930 and 1938 were invited to take part in the intervention. Recruitment began in 1974 and continued until 1992. 21,911 men and 8,676 women participated in the screening programme with an overall response rate of 71.2% (range between different years 64-78%). Men were mostly recruited in the first half of the recruitment period (1974-82) whilst women were mostly recruited in the second half (1981-92). Since follow-up assessment was made until 1995 for all, there were differences in the length of follow up for men and women.

A control group had not initially been planned but, on later reflection, males born in the years 1925, 1943, 1945 and 1947 and females born in 1927, 1929 and 1939 who had not been invited to screenings were selected to act as controls.

Follow up was done until 1995 and data for all people who had been contacted for initial screening (regardless of whether they had participated in the intervention or

declined) was compared with data from those who had not been contacted (control group). Follow-up started at the same age in both treatment and control groups (age not stated) so that there was minimal age difference between groups. National registries were used to assess comparative rates of total mortality, cause-specific mortality, nonfatal ischemic heart disease and nonfatal stroke.

Outcome measures

Total mortality, cause-specific mortality, nonfatal myocardial infarction and nonfatal stroke.

Statistical methods

The Cox proportional model was used to test the mortality rates in those invited compared to those not invited for the whole group and then for subgroups divided according to age. When calculating incidence rates and relative risks in the total male intervention and control group, numbers were weighted according the relative amount of 'younger' and 'older' men.

Results

Results are presented as relative risks i.e. the relative risk of incidence of the outcome from 1974-95 in the intervention group compared to that in the control group for men and women.

Primary outcomes

1. Total deaths

For men, death rates over follow up were, on average, lower in the intervention (49 per 10,000 person years) compared to the control (54 per 10,000 person years) but the relative risk of treatment effect was not significant (RR 0.94; CI 0.85-1.05, p=0.089). For women, there was no difference between death rates for the intervention (55 per 10,000 person years) compared to the control (55 per 10,000 person years) group (RR 1.0; CI 0.9-1.2, p=0.954).

2. Death from ischemic heart disease

For men, the incidence of death from ischemic heart disease was similar over follow up in the intervention (14 per 10,000 person years) and control (12 per 10,000 person years) and there was no significant difference between groups (RR 1.1; CI 0.9-1.4, p=0.435). Similarly, for women, there was no difference in the incidence of death from ischemic heart disease between intervention (8 per 10,000 person years) and control (7 per 10,000 person years) groups (RR 1.1; CI 0.7 to 1.7, p=0.586).

3. Deaths from stroke

The incidence of death from stroke in men was similar in the intervention (2 per 10,000 person years) and control (2 per 10,000 person years) group (RR 0.9; CI 0.5-1.7, p=0.757). For women, incidence of death from stroke was also similar in intervention (3 per 10,000 person years) and control (4 per 10,000 person years) groups (RR 0.9; CI 0.5-1.7, p=0.811).

4. Total CVD deaths

Total incidence of CVD death in men was similar in intervention (18 per 10,000 person years) and control (17 per 10,000 person years) groups (RR 1.0; CI 0.8-1.2, p=0.811). In women, incidence of CVD was also similar in the intervention (15 per 10,000 person years) and control (14 per 10,000 person years) group (1.1; CI 0.8-1.5, p=0.576).

5. Death from cancer

Incidence of death from cancer was similar in intervention (13 per 10,000 person years) and control (14 per 10,000 person years) men (RR 0.9; CI 0.8-1.2, p=0.632) and in intervention (23 per 10,000 person years) and control (27 per 10,000 person years) women (RR 0.8; CI 0.7-1.1, p=0.142).

6. Death from other causes

In men, incidence of death from other causes was lower in the intervention (18 per 10,000 person years) than the control (23 per 10,000 person years) group and the

relative risk of death from other causes was significant (RR 0.8; CI 0.6-0.9, p=0.012). In women, incidence of death from other causes was slightly higher in the intervention (17 per 10,000 person years) compared to the control (14 per 10,000 person years) group but not significantly so (RR 1.2; CI 0.9-1.6, p=0.224).

7. Non fatal MI

The incidence of non fatal myocardial infarction was similar in intervention (28 per 10,000 person years) and control (29 per 10,000 person years) men (RR 1.0; CI 0.8-1.1, p=0.734) and in intervention (28 per 10,000 person years) and control (26 per 10,000 person years) women (RR 1.1; CI 0.9-1.3, p=0.539).

8. Non fatal stroke

The incidence of non fatal stroke was similar in intervention (12 per 10,000 person years) and control (12 per 10,000 person years) men (RR 1.0; CI 0.8-1.3, p=0.932) and slightly higher in intervention (18 per 10,000 person years) compared to control (14 per 10,000 person years) women (RR 1.2; CI 0.9-1.6, p=0.178).

Sub group analysis was also done for younger and older men and women. This analysis showed some significant differences in certain outcomes (although 24 tests were conducted and at lease 1 significant result would be expected by chance):

- Fewer deaths in young intervention compared to young control men (p=0.015).

- Fewer deaths from other causes in young intervention compared to young control men (p=0.0230).

- Fewer deaths in young intervention compared to young control women (RR 0.7; CI 0.5-0.9, p=0.018).

- Fewer deaths from cancer in young intervention compared to young control women (RR 0.6; CI 0.4-0.98, p=0.042).

Analysis was also done for people participating in the screening intervention compared to those who did not participate. However, this analysis compares those that that participated with those that declined participation (not with controls) and groups were significantly different regarding marital status, education level, socio economic grouping, housing and ethnic origin. Therefore, results for this analysis are not presented.

Limitations of the study

The study was quality assessed and graded '+'.

Limitations identified by authors

Only 30-35% of participants in the screening subsequently entered intervention programmes. As the overall attendance rate was 71%, only 25% of all people invited to take part were in a post-screening programme and this may have been too small a proportion for effects to be seen.

Secular trends may have diminished the power to detect positive effects.

Limitations identified by reviewer

It is unclear whether intervention and control groups were similar in terms of age and gender as these characteristics are not presented at baseline.

Recruitment of men and women occurred in different years and, since men were mostly recruited in the first half of the recruitment period (1974-82) and females in the second half (1981-1992) there were differences in the average length of follow up for men and women. Control group men and women were recruited during similar time periods to intervention men and women and therefore bias may not have been introduced. However, this limits making comparisons between men and women in observed effect.

Comparisons are made between participants and invited non participants (not included in this report). There were between-group differences in socioeconomic and

demographic characteristics and presentation of favourable findings from this analysis may mislead readers.

Subgroup analysis of younger and older men and women was done post hoc, without a preformed hypothesis. The large number of tests performed was likely to have contributed to the finding of significant results.

Summary

The Malmö Preventative project was an intervention employing screening and follow up but was unsuccessful in reducing rates of total or CVD-linked mortality. Only a quarter of those invited were involved in a follow-up programme and this dilution may have masked intervention effects.

3.2.4 The Minnesota Heart Health community screening and education (19)

Within the activities of the Minnesota Heart Health (MHH) programme (report 1), a one year screening and education programme (1982-83) was conducted with the aim of modifying health behaviours and reducing risk factor levels for CVD.

Target population

The screening programme took place in one of the key MHH sites: Mankato (n=35,000), a primarily agricultural community. Mankato acted as the initial test area for MHH activities with subsequent further intervention in other locations. The screening programme targeted half of Mankato residents, randomised to the intervention group, and the other half of the community were randomised to the control.

Theory/conceptual model of intervention

None stated

Intervention description

The screening intervention consisted of an initial examination at the Heart Health Centre where total cholesterol, height, weight, blood pressure and expired air carbon monoxide were assessed at different measurement stations. At these stations, participants received health education messages using videos and/or printed material.

Health messages focussed on healthy eating, increasing physical activity and smoking cessation and aimed to teach participants how to change their behaviour rather than presenting factual information. Eating pattern messages, centred on saturated fat, cholesterol and sodium were given and strategies were suggested to gradually reduce intake whilst increasing consumption of complex carbohydrates, lean meat, poultry, fish and low fat dairy products. There was guidance on how to read and interpret food labels for fat and salt content and how to prepare low fat, low salt foods. Participants were encouraged to undertake vigorous physical activity for 30 min more than three times a week. Smokers were encouraged to quit and non-smokers given advice on how to help others to quit.

Participants were given colour coded risk factor cards that recorded each person's risk factor level and provided with a message tailored to their risk. During the visit, results were returned and each family spent twenty minutes with a health educator to review their test results. The health educator reinforced previous messages on modifying diets, increasing levels of physical activity, having blood pressure checked regularly, taking blood pressure medication if prescribed and quitting smoking. The discussion centred on any risk factors present in family members and little time was spent discussing less relevant risk factors. Participants were advised about upcoming MHH events and encouraged to take part.

Accessibility:

The central component of the intervention being evaluated was a screening and education programme conducted at one clinic site. Individuals randomised to intervention were invited for screening by telephone, door to door contact and written invitation to ensure access for households without a telephone. The distance to travel for participants is not

given. Following screening results, individuals received health education via printed materials, video recordings and a face to face interview with a health educator.

The ethnic, socio-economic and education profile of the target community is not described and there is no information on whether health education was made accessible for those of low literacy levels, those from different cultural backgrounds or for non native language speakers.

Participation in screening was 50% of those invited. In addition, 13% of the intervention group were lost to follow up. Individuals who declined to attend were similar with respect to cardiovascular risk factors but were more likely to already be engaging in health promoting behaviours. No data is presented on the demographic comparability of participants and non participants. Individuals lost to follow up were demographically similar to individuals who were not lost to follow up but were more likely to be smokers which may be an indication of the accessibility of the intervention to this population sub-group.

Evaluation

In the intervention group, the initial screening intervention (1982) acted as the baseline evaluation and evaluation was also made a year after intervention (1983). In the control group, no baseline assessment was done and a single risk factor screening was conducted in 1983 for comparison with the intervention group.

Participant selection/recruitment

All households in Mankato (n=2,323) were randomised to the intervention (n=1,156) or control (n=1,167) group. At baseline (1982), intervention households were contacted primarily by telephone but, where phone contact could not be made, door to door contact was used. Up to six attempts were made to contact each household and, where contact failed, a written invitation was left at the home. All residents in contacted households were encouraged to attend the health centre and one person, aged 25-74, was selected at random to participate in the evaluation. A year later, in

1983, intervention subjects, who had participated in the initial evaluation were invited back for a follow up examination.

Households randomised to the control were not contacted at baseline but, in 1983, they underwent the same recruitment and intervention process as those in the intervention group. Results from this screening were used for comparison with the intervention group.

The participation rate in first screening for intervention (1982) and control (1983) groups was 50.6% and, of the intervention group, 88.6% returned for rescreening (1983). There were 379 and 468 participants in the intervention and control groups respectively.

Outcome measures

Total cholesterol, BMI, diastolic and systolic blood pressure, expired air carbon monoxide and reported current smoking. A computerised test was used to determine physical activity and estimated weekly kilocalorie expenditure from leisure time physical activity.

Statistical methods

Intervention subjects who moved out of the area between baseline and follow-up assessment (7%) were excluded from the analysis although those remaining in the area, but choosing not to return (n=49), were retained in the analysis. Data from their initial visit were used again as follow-up measurements.

Intervention and control group measurements were compared at baseline using data from the initial intervention group screening (1982) and control group screening one year later (1983). The z test for independent proportions was used for categorical variables and analysis of variance and covariance techniques were used for continuous variables.

Within-group analysis was conducted for the intervention group. Changes from baseline to follow-up were assessed using McNemar's test for symmetry for categorical variables and repeated measures analysis of variance for continuous variables.

The 1983 data for intervention and control groups was also compared using similar methods. All tests for risk factor and behavioural changes were one-tailed (demographic comparisons were two-tailed).

Results

Comparisons are presented for baseline intervention versus intervention follow-up data and for endpoint intervention verses control data. Because baseline similarity for intervention and control groups cannot be judged with any certainty, where differences between baseline and follow-up in the intervention group and differences between end-point intervention versus control measures are not concurrently present, caution should be taken in the interpretation of significant results.

Primary outcomes

1. Total cholesterol

Total cholesterol decreased significantly in the intervention group from baseline (1982: 207.7 mg/dl, 1983: 201.0 mg/dl, $t=5.25$, $p<0.0001$) and was significantly lower than the control group (205.1 mg/dl) at follow-up ($t=1.69$, $p<0.05$).

2. Blood pressure

Diastolic blood pressure did not change from baseline in the intervention group (1982: 73.3 mg/dl, 1983: 73.0 mg/dl, p=NS) but was significantly lower than the control group (74.4 mg/dl) at follow-up ($t=2.02$, $p<0.05$).

Systolic blood pressure decreased significantly from baseline in the intervention group (1982: 120.4 mg/dl, 1983: 118.7 mg/dl, $t=2.95$, $p<0.01$) but was not significantly

lower than the control group (119.0 mg/dl) at follow-up (p=NS) (the treatment group had slightly higher systolic blood pressure at baseline, t=1.72, p<0.1).

3. BMI

BMI showed a small but significant increase from baseline in the intervention group (1982: 25.3 kg/m^2, 1983: 25.4 kg/m^2, t=2.44, p<0.01) but was not significantly different to the control group (25.5 kg/m^2) at follow-up (p=NS).

4. Smoking

The amount of expired air carbon monoxide did not change from baseline in the intervention group (1982: 30.0 ppm, 1983: 30.7 ppm, p=NS) but was significantly lower than the control group (34.8 ppm) at follow-up (t=1.97, p<0.05) (treatment and control groups differed significantly at baseline, t=2.37, p<0.05).

Reported prevalence of smoking did not change from baseline in the intervention group (1982: 24.9 %, 1983: 24.8 %, p=NS) and was not significantly different to the control group (27.9 %) at follow-up (p=NS).

5. Physical activity

The proportion of participants that were very active increased from baseline in the intervention group (1982: 23.8 %, 1983: 32.9 %, X^2=19.16, p<0.005) and was significantly higher than the control group (26.3 %) at follow-up (t=2.13, p<0.05).

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors

None given

Limitations identified by reviewer

All tests for risk factor and behavioural changes were one-tailed.

It is difficult to make comparisons for intervention and control groups at baseline since measurements were made a year later in the control group. The concurrent MHH programme might be expected to produce changes over time and it may not be valid to make comparisons between 1983 control group data with 1982 data for the intervention group. It is therefore difficult to assess whether groups were comparable at baseline.

Summary

The screening and education project of the Minnesota Heart Health programme may have had a positive impact on levels of total cholesterol and physical activity. Although changes in other risk factors are less clear (due to the uncertainty of baseline control data), there appears to be some evidence for the effectiveness of this type of intervention.

3.2.5 The Multifactor Primary Prevention Trial, Göteborg (20)

The Mutifactor primary preventative trial in Göteborg aimed to examine whether multifactoral intervention could reduce rates of CVD, stroke and total mortality and change risk factors for CVD. The trial began in 1970 and intervention took place over four years, involving screening and treatment of risk factors.

Target population

Intervention took place in Göteborg, Sweden and men born from 1915-1922 and 1924-1925 were identified for recruitment into both intervention and control groups.

Theory/conceptual model of intervention

None stated

Intervention description

The intervention group (and 2% of the control group) were sent a postal questionnaire and those that accepted attended a screening examination. Based on the screening,

intervention (but not control) men were treated for risk factors of elevated cholesterol and blood pressure and smoking.

Men were allocated to risk groups for hypertension (SBP≥175 or DBP≥115 mmHg), hypercholesterolaemia (cholesterol ≥7.8 mmol/l) and smoking (≥15 cigarettes per day). Risk factors in the newly diagnosed and those with risk factors already diagnosed, were treated in special outpatient clinics. Physicians were responsible for treating risk factors and also for giving advice on diet, smoking cessation etc.

Those allocated to the hypertension risk group attended a hypertension clinic. Those with high cholesterol were given individual dietary advice or advice in a small-group (7-10 men) with a physician and dietician and their wives were also invited to attend. Heavy smokers were invited to an anti-smoking clinic conducted by a physician and psychologist. The first meeting was large (~40 men) and information was given with a short talk on the health consequences of smoking and this lead into a group discussion. Subsequent group sessions were smaller (7-10 men), held at one week intervals, and gave further information about the smoking cessation programme and Nicotine chewing gum was distributed to some participants. Additionally, the 'anti-smoking club' met every second week to act as a social support group.

Treatment was also given to participants with 'borderline' risk factors. Those with systolic blood pressure 160-174 mmHg or diastolic blood pressure 95-114 mmHg were regularly checked (every year or second year depending on BP). Those with moderate levels of cholesterol (6.8-7.7 mmol/l) were invited to dietary advice counselling sessions (as for the high risk group). Those considered to be more moderate smokers were given brief printed information in a letter with the advantages of quitting smoking and methods recommended for cessation.

Four years after the initial screening, subjects in the intervention group and an 11% random sample from the control group were invited to a second screening session for reassessment and continued referral to treatment groups.

Accessibility:

The target population was a representative random sample of men aged 47-55 years from Göteborg, Sweden. The intervention comprised screening by postal questionnaire and face-face interview and examination followed by intervention for elevated or borderline risk factors in out-patient clinics. Treatment included lifestyle advice, pharmacological treatment and oral and written educational materials. There is no information on whether written materials were made accessible for those of low literacy levels, those from different cultural backgrounds or for non native language speakers. The number of clinics or distance to travel for participants is not given.

Frequency of attendance at hypertension and cholesterol management groups is not reported; the smoking group required attendance every 2 weeks. Participation in the screening examinations was 75%. Non-responders were more likely to suffer from a chronic disease; to be of lower social class and were observed to have higher mortality over the course of the evaluation compared to responders. This may be a reflection of the accessibility of the intervention in these population sub-groups. Participation in the hypertensive management group was reported as 90%. Participation rates in other management groups (elevated cholesterol and smoking) are not reported.

Evaluation

Evaluation was made at baseline and after ten years of intervention.

Participant selection/recruitment

All men born from 1915-1922 and from 1924-1925 living in Göteborg were invited to participate. These men were aged 47-55 years when the study began (mean 51 years) and 57-65 years at the final evaluation (mean 61 years). Before contact was made, men were randomised to the intervention group or to one of two control groups (control group 1 and 2) and each group comprised ~10,000 men.

Questionnaires were sent to all men in the treatment group and to a 2% random sample of those in control group 1 (none in control group 2 received the

questionnaire). Questionnaires detailed CVD family history, the subjects own heart health, the presence of stress and behaviours relating to smoking and physical exercise. Subjects (intervention and 2% of control group 1) were invited to a medical examination where height, weight, cholesterol, blood pressure, ECG and interview responses were recorded.

Out of 10,004 men in the intervention group invited to the initial screening, 8,393 (84%) responded to the postal questionnaire and 7 495 (75%) attended the first screening examination.

Ten years after the initial screening, a new 20% random sample of the whole intervention group and control group 1 were invited for assessment. Of those invited, 1,473 in the intervention group and 1,404 in the control took part in the final evaluation.

Copies of all death certificates were collected to record total death rates and the Swedish national cause specific death register was matched against the file for all 30,000 men in the trial. CVD Morbidity was assessed using data from the Myocardial Infarction Register and Stroke Register.

Outcome measures

Total, CHD and stroke related mortality, non-fatal CHD and stroke, mean levels of blood pressure, cholesterol and body weight.

Proportion of participants reporting never smoking, smoking cessation or smoking 1-14, 15-24 or $\geq$25 cigarettes per day.

Statistical methods

Methods for between-group statistical testing are not detailed and results for statistical tests are not presented for the majority of intervention versus control comparisons. However, a multiple logistic function: predicted mortality risk and predicted CHD incidence, was used to predict the average effect on the three main

risk factors: cholesterol, tobacco smoking and systolic blood pressure. The calculation of β-vectors for total predicted mortality risk and predicted CHD incidence is described in the report of the trial.

Results

Differences between independent baseline and post-intervention surveys are compared (~75% of the intervention group took part at baseline and a new 20% random sample was taken for the final evaluation).

Primary outcomes

1. Total CHD/Stroke

Incidence of CHD/Stroke was very similar in intervention and control groups over the study period. CHD and stroke events occurred in 8.36% and 2.11% of those in the intervention group compared to 8.35% and 1.96% in the control.

2. Cholesterol

Total cholesterol decreased similarly from baseline (6.46 mmol/l) to 6.04 mmol/l in the intervention and 6.05 mmol/l in the control. The proportion of participants with cholesterol >6.8 mmol/l also decreased from baseline (33.3%) to 19.7% in the intervention group and 20.6% in the control.

3. Blood pressure

Average systolic blood pressure decreased from baseline (149 mmHg) to 143 mmHg in the intervention and 145 mmHg in the control group and diastolic blood pressure similarly declined from baseline (95 mmHg) to 85 mmHg in the intervention and 86 mmHg in the control. The proportion of men with systolic blood pressure >180 mmHg decreased from baseline (8.0%) to 3.3% in the intervention and 4.6% in the control group.

4. Body weight

Body weight increased from baseline (78.9 kg) to follow up in both groups: intervention 80.3 kg and control 80.5 kg.

5. Smoking

The proportion of men who smoked decreased from baseline (50.7%) to 32.5% in the intervention and 35.4% in the control group.

6. Total predicted mortality

Predicted mortality risk (obtained from risk factor levels, see statistical analysis above) was 9.74% at baseline and, following intervention, decreased to 8.08% in the intervention and 8.34% in the control group (17% and 14.3% reductions respectively) (p of treatment versus control difference=0.034).

7. Predicted incidence of CHD

The predicted incidence of CHD decreased from baseline (7.33%) to 5.14% in the intervention and 5.36 in the control group (29.8% and 26.9% reductions respectively) (NS difference for treatment versus control).

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors

The intervention was mainly directed towards high risk groups. It was likely to have only impacted the upper end of the tail of risk distribution and therefore may not have affected mean risk factor levels to any great extent.

The inclusion of non-participants (25%) in the intervention group was likely to have diluted the apparent intervention effect as these people had higher rates of morbidity and mortality.

The approach to CVD prevention was not as personal as in other screening programmes and a more aggressive approach may have had more impact on rates of CVD morbidity and it's risk factors.

Limitations identified by reviewer

No results for statistical tests of between group comparisons are presented. Although it appears likely that this is due to no significant effects being detected, this is not made explicit.

No information is given about the uptake of risk factor counselling groups. Poor attendance and low motivation might explain the lack of intervention effect.

Summary

There appears to be little positive intervention effect of the Göteborg screening trial and this may be surprising in light of the direct mode of intervention. Dilution of participates by those not undergoing screening may have reduced apparent effect but, since a range of demographic/socioeconomic status participants were also present in the control group, this cannot be given sole blame and poor programme uptake and acceptance may have played some role in reducing programme success.

3.3 Summary of the evidence

Evidence for the current review is summarised in four parts:

1) Outcome graphs

2) Outcome tables

3) Programme summary tables

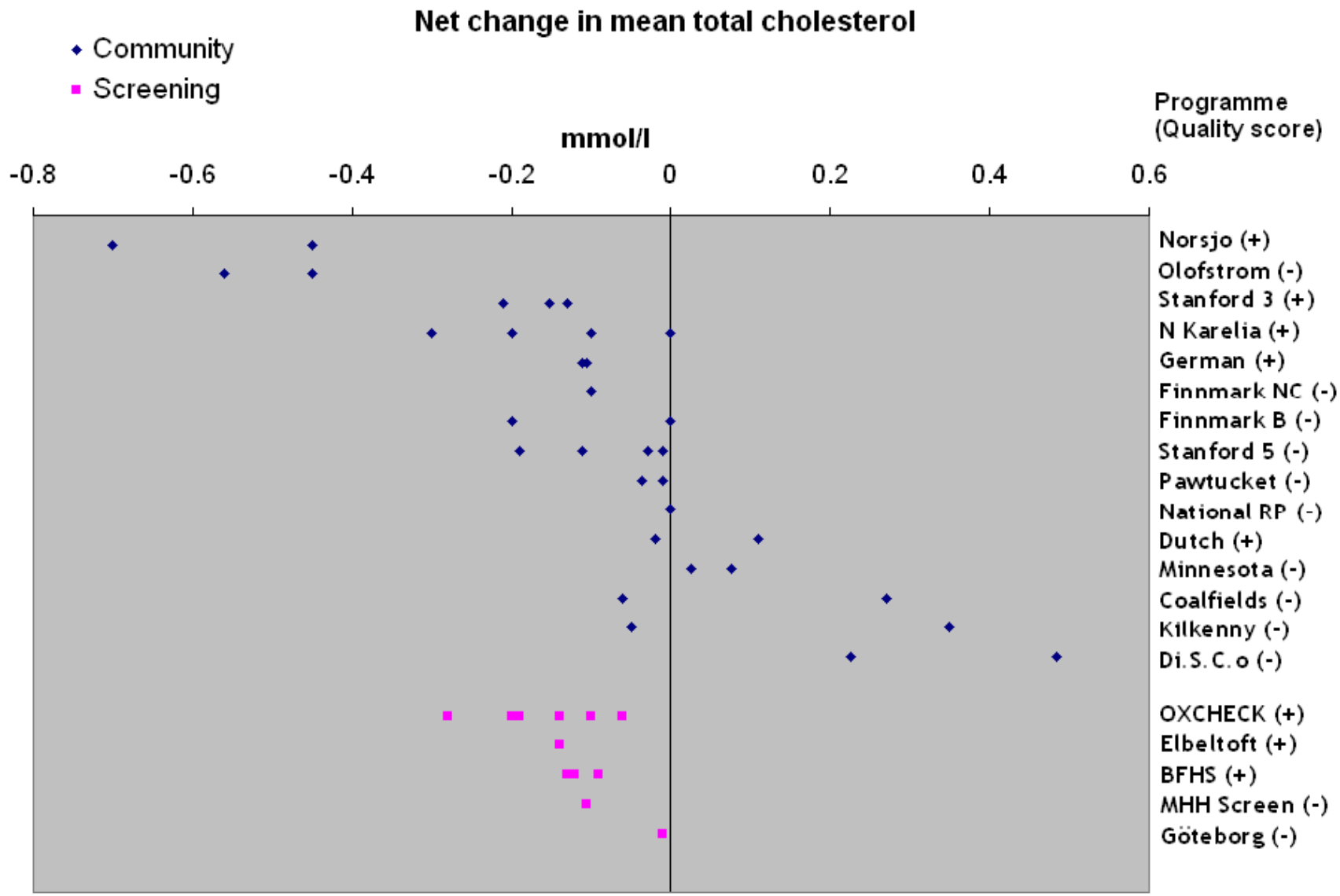
4) Evidence statements

1) Graphical representations summarising net changes in outcomes of total blood cholesterol (mmol/l), diastolic and systolic blood pressure (mm/Hg), BMI (kg/m^2), prevalence of smoking (%), dietary variables and physical activity for each programme are displayed below (negative values indicate that the programme was advantageous). It was not possible to indicate confidence intervals for point estimates since, for the majority of programmes, this data was not available. Where point estimates are not displayed, this is because results were not reported for that outcome or they were only reported as dichotomous variables. Programmes are divided into sub-categories of 'screening' (screening and advice aimed at the population level) and 'community' (media and education community programmes) for clear presentation. Programmes are ranked by effectiveness of the particular outcome presented with scores for the quality of programme evaluation indicated. Only continuous variables are represented graphically but data from dichotomous variables was examined and contributed to the formulation of evidence statements.

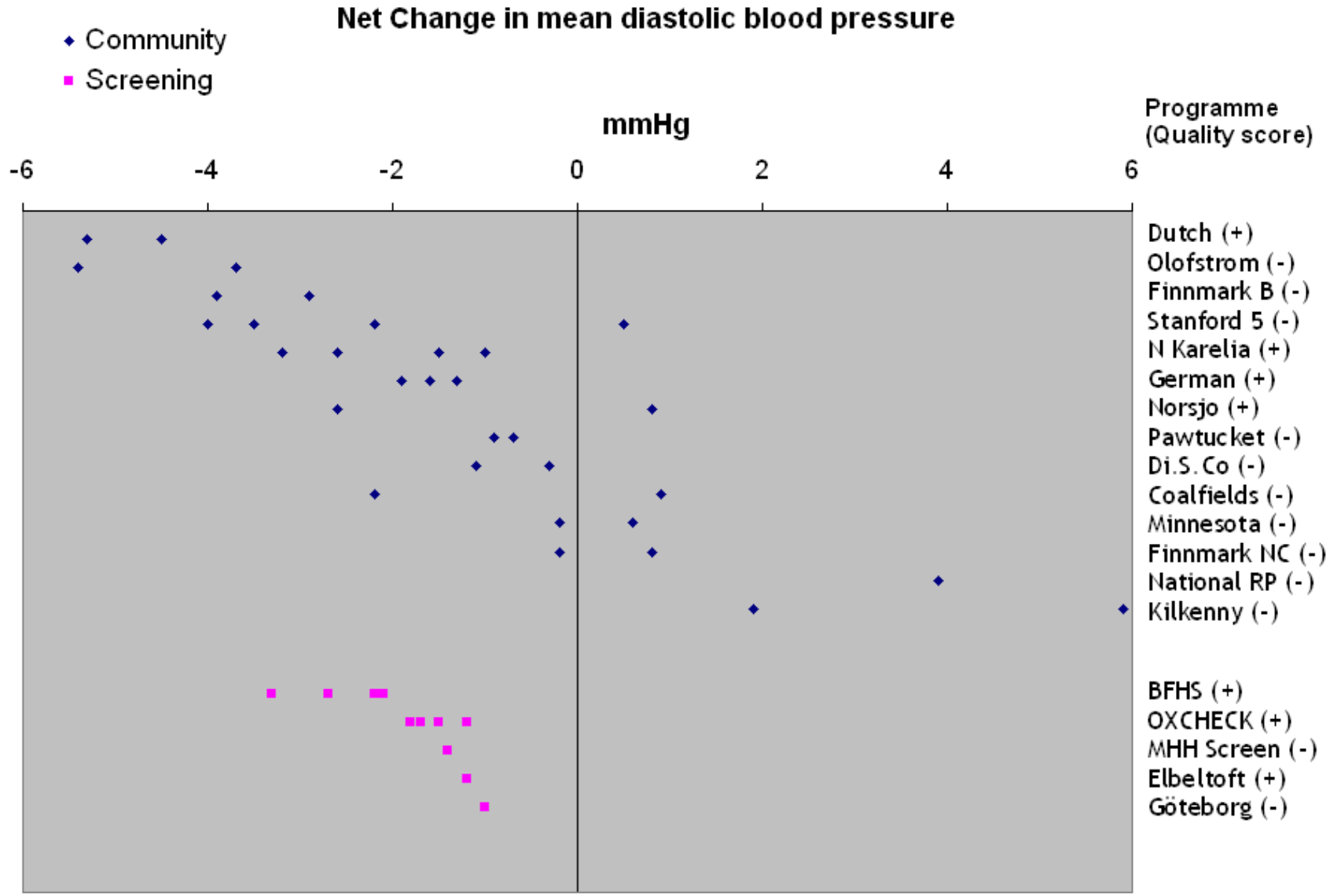
2) For outcome variables without sufficient data for graphical representation, tables are given detailing the specific outcomes assessed and net changes. Tables are provided for outcomes of morbidity/mortality, blood glucose concentration, knowledge/attitudes relating to CVD and salt intake. Negative net changes have been used to indicate where programmes were advantageous.

3) Programme summary tables have been constructed to provide clear information about the components of each programme: their target audience, underlying theories, pre-planning, nature of intervention, accessibility and mode of implementation (Table 3.7 below). Tables constructed for the programmes identified in the first and second review are also provided (Table 3.5 and 3.6 below).

4) Evidence statements, based on outcome measures and the nature of programmes, are then given. The first broad statement summarises evidence from the current report (phase III of review 1) and more detailed evidence statements are then used to summarise available evidence from both the current and previous report (phase I, II and III of review 1).

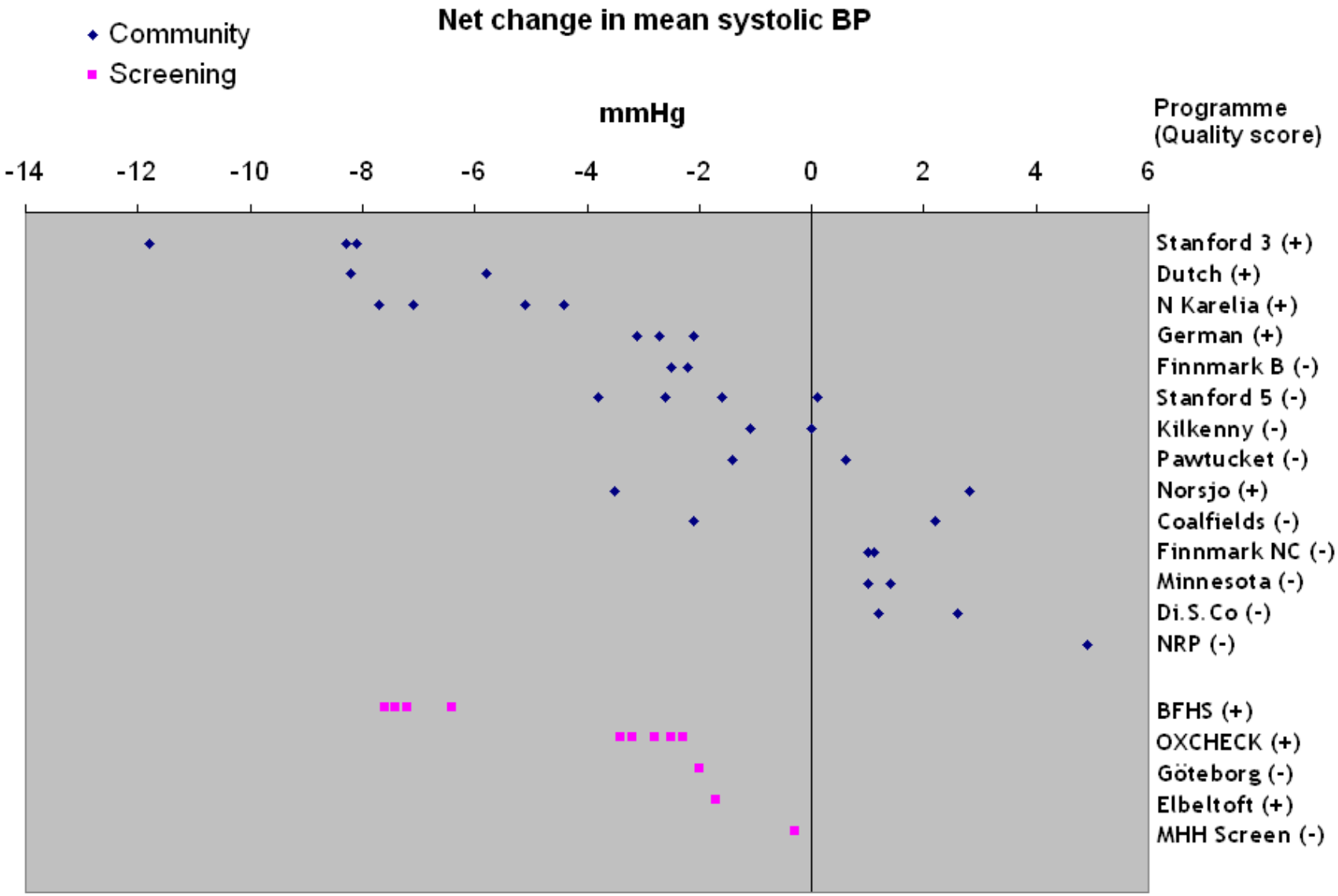


Programmes are ranked by average effectiveness, negative values indicating where programmes are advantageous. Points on the same line indicate multiple measurements for the same programme e.g. for male/female/cross section/cohort groups. The graph contains data only from programmes where it was available. No cholesterol data was available for:
Danish, Boothheel, S Carolina, Action Heart, Heartbeat Wales, Otsego, Coeur, US Heart Association, ATS-Sardegna, Cardiovision, CINDI, Franklin, HH Paisley, Quebec Urban Rural and Suburban, Malmo, Inter99



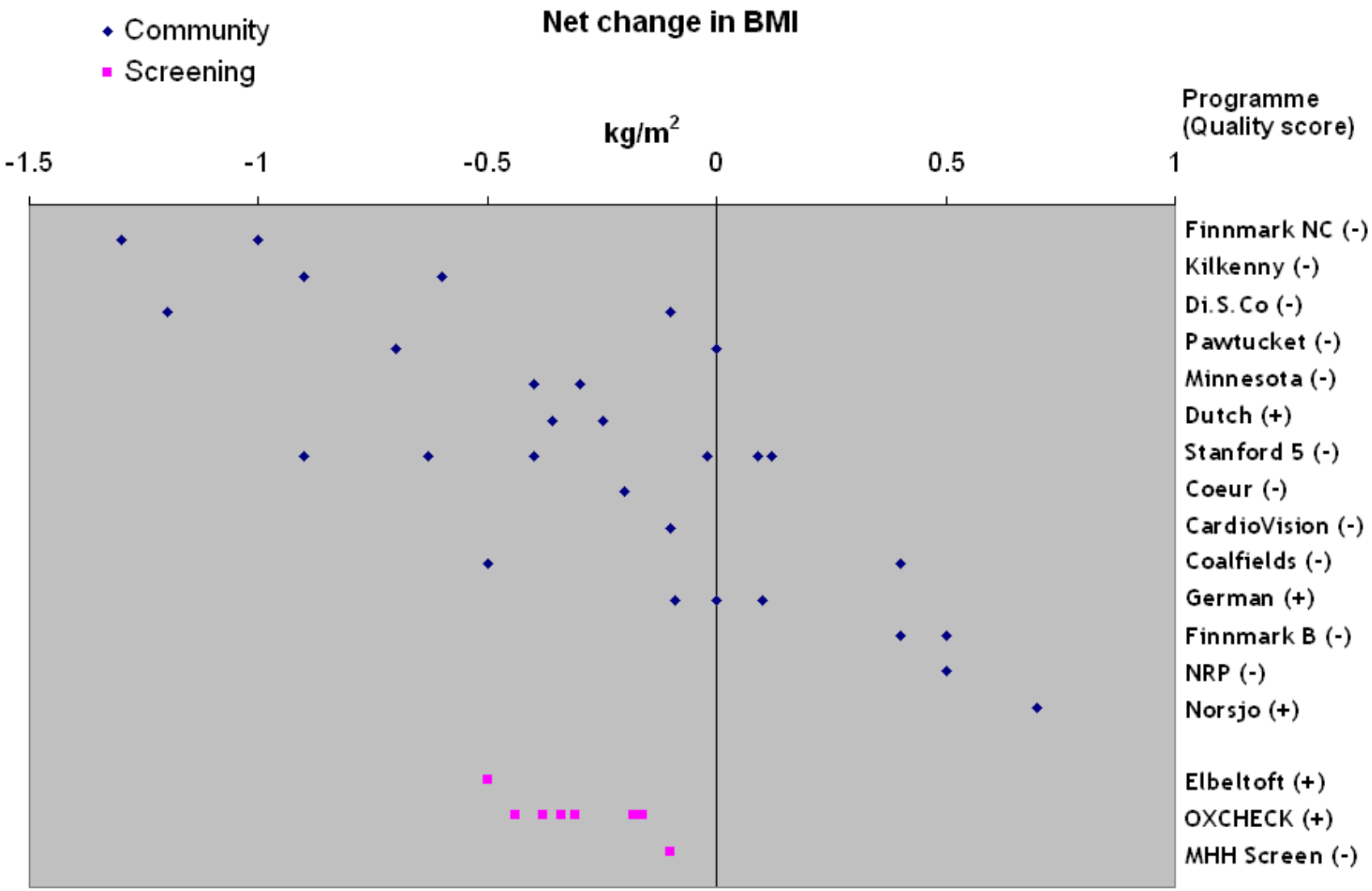
Programmes are ranked by average effectiveness, negative values indicating where programmes are advantageous. Points on the same line indicate multiple measurements for the same programme e.g. for male/female/cross section/cohort groups. The graph contains data only from programmes where it was available. No diastolic blood pressure data was available for:

Danish, Stanford 3, Boothheel, S Carolina, Action Heart, Heartbeat Wales, Otsego, Coeur, US Heart Association, ATS-Sardegna, Cardiovision, CINDI, Franklin, HH Paisley, Quebec Urban Rural and Suburban, Malmo, Inter99



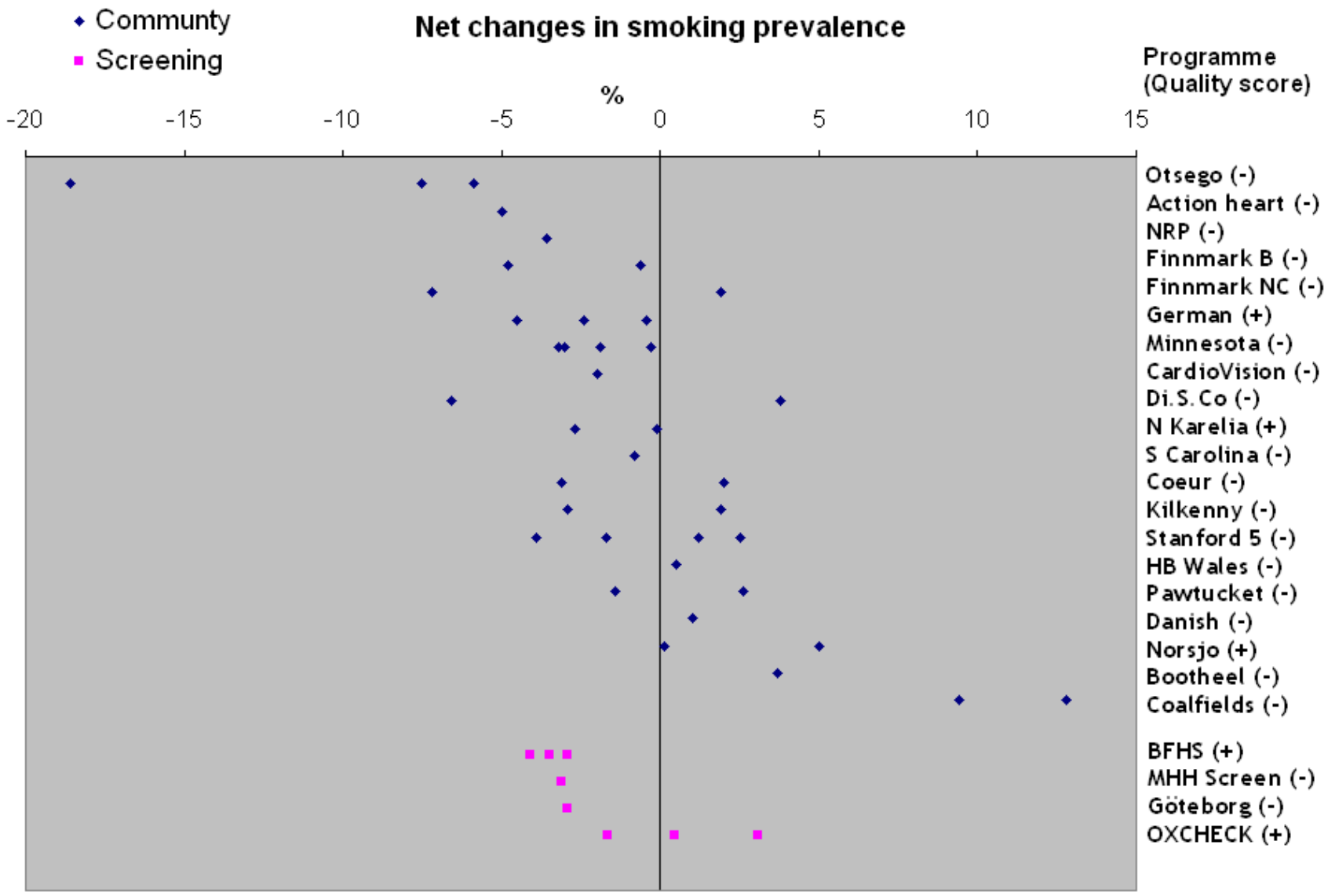
Programmes are ranked by average effectiveness, negative values indicating where programmes are advantageous. Points on the same line indicate multiple measurements for the same programme e.g. for male/female/cross section/cohort groups. The graph contains data only from programmes where it was available. No systolic blood pressure data was available for:

Danish, Boothheel, S Carolina, Action Heart, Heartbeat Wales, Otsego, Coeur, Olofstrom, US Heart Association, ATS-Sardegna, Cardiovision, CINDI, Franklin, HH Paisley, Quebec Urban Rural and Suburban, Malmo, Inter99



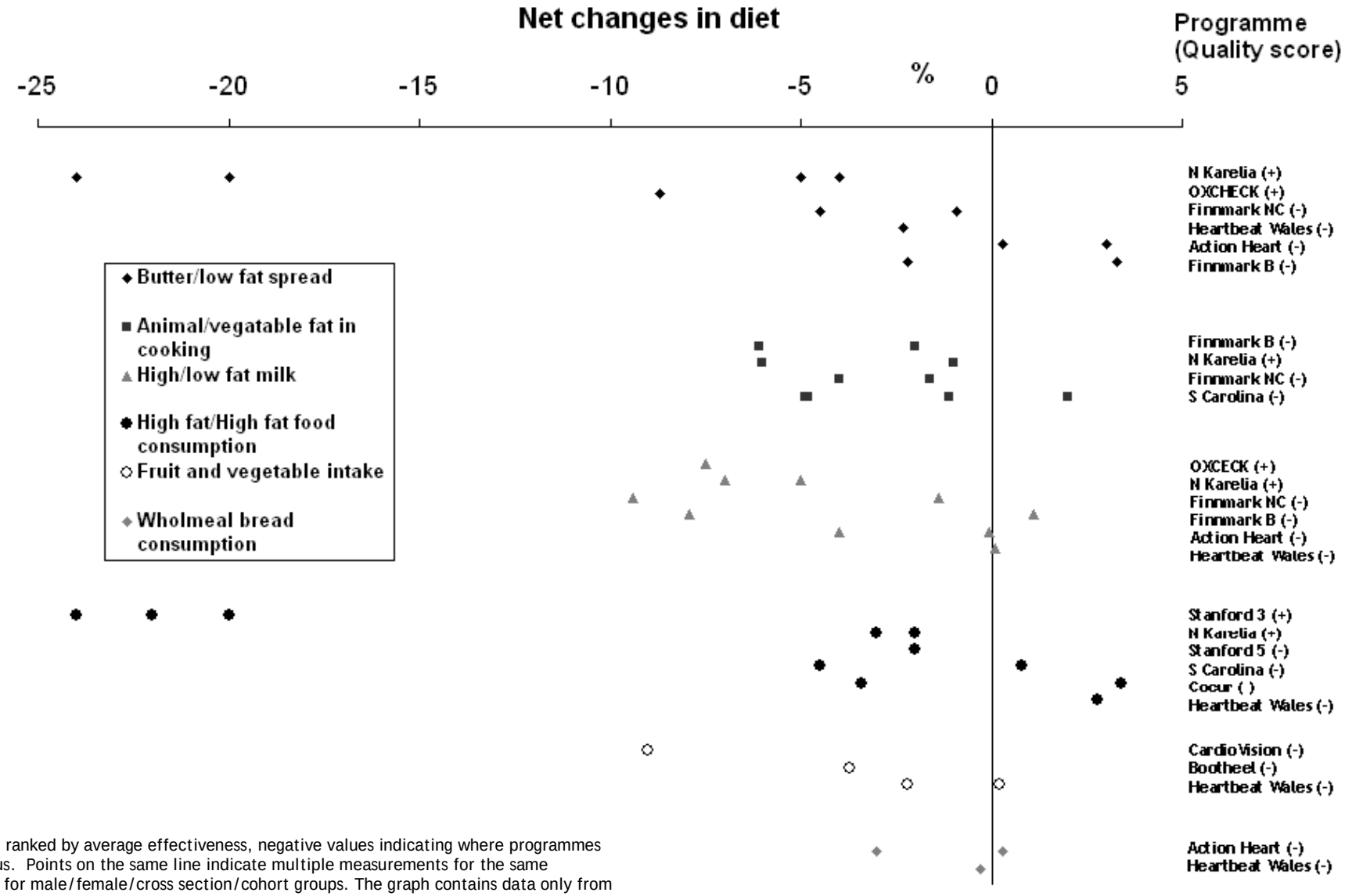
Programmes are ranked by average effectiveness, negative values indicating where programmes are advantageous. Points on the same line indicate multiple measurements for the same programme e.g. for male/female/cross section/cohort groups. The graph contains data only from programmes where it was available. No BMI data was available for:

Danish, Boothheel, N Karelia, S Carolina, Stanford 3, Action Heart, Heartbeat Wales, Otsego, Olofstrom, US Heart Association, ATS-Sardegna, CINDI, Franklin, HH Paisley, Quebec Urban Rural and Suburban, BFHS, Göteborg, Malmo, Inter99



Programmes are ranked by average effectiveness, negative values indicating where programmes are advantageous. Points on the same line indicate multiple measurements for the same programme e.g. for male/female/cross section/cohort groups. The graph contains data only from programmes where it was available. No smoking prevalence data was available for:

Stanford 3, Dutch, Olofstrom, US Heart Association, ATS-Sardegna, CINDI, Franklin, HH Paisley, Quebec Urban Rural and Suburban, Elbeltoft, Malmo, Inter99

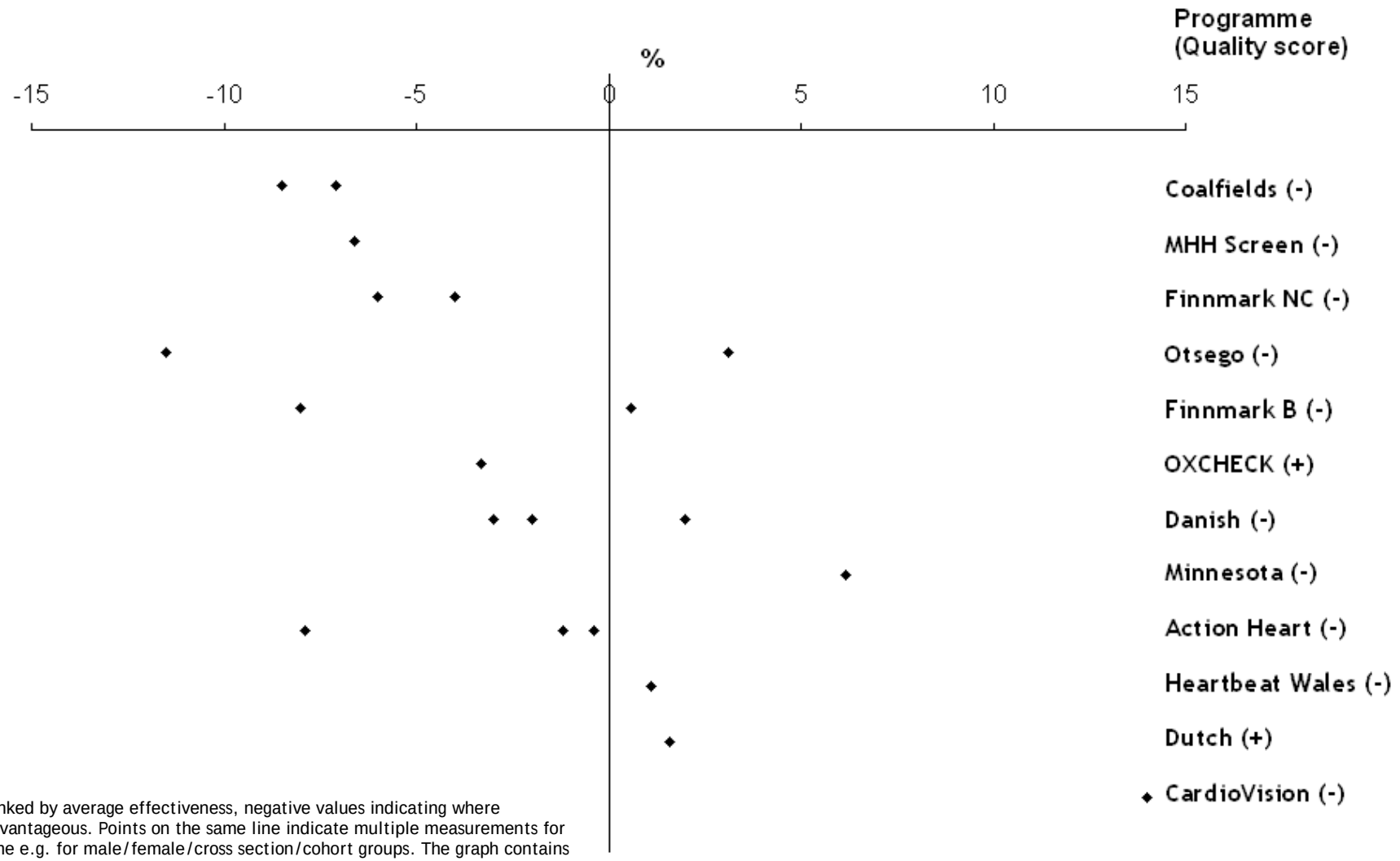


Programmes are ranked by average effectiveness, negative values indicating where programmes are advantageous. Points on the same line indicate multiple measurements for the same programme e.g. for male/female/cross section/cohort groups. The graph contains data only from programmes where it was available. No dietary data was available for:

Bootheel, BFHS, Danish, German, Norsjo, Minnesota, Pawtucket, Di.S.Co, Dutch, Kilkenny, NRP, Otsego, US Heart Association, ATS-Sardegna, CINDI, Coalfields, Franklin, HH Paisley, Olöfstrom, Quebec Urban Rural and Suburban, Ebeltoft, Inter99, Malmö, MHH Screening, Göteborg

NB graph contains data for both community programmes and the only screening programme with dietary data (OXCHECK).

Net change in variables of physical actvity



Programmes are ranked by average effectiveness, negative values indicating where programmes are advantageous. Points on the same line indicate multiple measurements for the same programme e.g. for male/female/cross section/cohort groups. The graph contains data only from programmes where it was available. No physical activity data was available for:

Bootheel, BFHS, German, S Carolina, N Karelia, Norsjo, Pawtucket, Stanford 5, Coeur, Di.S.Co, Kilkenny, NRP, Stanford 3, US Heart Association, ATS-Sardegna, CINDI, Franklin, HH Paisley, Olöfstrom, Quebec Urban Rural and Suburban, Ebeltoft, Inter99, Malmö, Göteborg

NB graph contains data for both community programmes and screening programmes with physical activity data (MHH screening and OXCHECK).

Table 3.1 Mortality and morbidity

		Treatment	Control	Net treatment effect (nega indicates programme advar
Stanford 5 city men	All cause mortality (deaths/1000 persons in 10 years)	-1.1	+2.0	-3.1 (p=0.447)
Stanford 5 city Women	All cause mortality (deaths/1000 persons in 10 years)	+0.4	+0.9	-0.5 (p=0.795)
Coalfieds Men	Annual change in CVD mortality (deaths per 100 000 per year)	-10.9 (CI -18.2 to -3.6)	-7.0 (CI -9.3 to -4.7)	-3.9
Coalfields Women	Annual change in CVD mortality (deaths per 100 000 per year)	-14.2 (CI -26.0 to -2.4)	-7.8 (CI -12.8 to -2.9)	-6.4
Coalfields Men	Annual change in non-fatal MI (events/1000 persons per year)	+3.2 (CI -0.6 to 7.0)	-2.5 (CI -4.5 to -0.5)	+5.7
Coalfields women	Annual change in non-fatal MI (events/1000 persons per year)	+1.7 (CI -4.4 to +7.9)	-3.6 (CI -7.0 to -0.2)	+5.3
Franklin CH (relative to the state of Maine)	Rate of death from heart disease (deaths/100 000 persons in 10 years)			RR 0.91 (CI 0.06, p<0.05)
	Rate of death from CHD (deaths/100 000 persons in 10 years)			RR 0.91 (CI 0.06, p<0.05)
	Rate of death from stroke (deaths/100 000 persons in 10 years)			RR 0.90 (CI 0.10, p=NS)
Have a Heart Paisley	Rates of MI	Stable 98.7% Negative 1.3%	Stable 98.8% Negative 0.8%	

	Rates of stroke	Stable 99.6% Negative 0.4%	Stable 98.8% Negative 1.2%	
Malmo	Men Total mortality (per 10 000 person years over 21y)	49	54	RR 0.94 (CI 0.85-1.05, p=0.089)
	Women Total mortality (per 10 000 person years 0ver 21y)	55	55	RR 1.0 (CI 0.9-1.2, p=0.954)
	Men CVD mortality (per 10 000 person years over 21y)	18	17	RR 1.0 (CI 0.8-1.2, p=0.811)
	Women CVD mortality (per 10 000 person years over 21y)	15	14	RR 1.1 (CI 0.8-1.5, p=0.576)
	Men non-fatal MI (per 10 000 person years over 21y)	28	29	RR 1.0 (CI 0.8-1.1, p=0.734)
	Women non-fatal MI (per 10 000 person years over 21y)	28	26	RR 1.1 (CI 0.9-1.3, p=0.539)
Göteborg	Proportion with CHD event during 10y intervention	8.36%	8.35%	+0.01%
	Proportion with stroke during 10 intervention	2.11%	1.96%	+0.15%
	Predicted mortality risk after intervention	8.08% (17% reduction from baseline)	8.34% (14.3% reduction from baseline)	-0.26% (p=0.034 for differen reductions)
	Predicted incidence of CHD after intervention	5.14% (29.8% reduction from baseline)	5.36% (26.9% reduction from baseline)	-0.22% (p=NS for difference reductions)

Table 3.2 Blood glucose

		Treatment	Control	Net treatment effect (negative indicates programme advantageous)
BFH Men	Median blood glucose (mmol/l)			-0.03 (SE 0.08)
	% with random BG >=10 mmol/l			-0.1% (SE 0.4)
BFH women	Median blood glucose (mmol/l)			+0.1 (SE 0.09)
	% with random BG >=10 mmol/			+0.3%, SE 0.3
Di.S.Co Men	Fasting glucose levels (mg/dl)	-5.2	-1.8	-3.4 (CI -6.7 to -0.1)
Di.S.Co Women	Fasting glucose levels (mg/dl)	-2.0	-7.0	+5.0 (CI +0.8 to +9.2)
Dutch (Main cohort)	Plasma glucose (mmol/l)			-0.17 (SE 0.1) (NS)

Table 3.3 Salt

Programme	Outcome	Treatment	Control	Net treatment effect (negative indicates programme advantageous)
Stanford 5 city	% change in use of table salt	-27.2	-20.0	-7.2 ($p<0.05$)
	% change in use of cooking salt	-17.0	-9.7	-7.3 (NS)
North Karelia	Salt intake men (calculated from Na excretion) (g) 1979-1982	12.9 (CI 12.4-13.5) to 13.9 (CI 13.2-14.5)	13.1 (CI 12.6-13.7) to 12.9 (CI 12.2-13.6)	+1.2
	Salt intake women (calculated from Na excretion) (g) 1979-1982	10.4 (CI 9.9-10.9) to 9.9 (CI 9.4-10.4)	10.4 (CI 10.0-10.9) to 10.3 (CI 9.8-10.7)	-0.4

	Salt intake men (calculated from Na excretion) (g) 1979-1987	12.9 (CI 12.4-13.5) to 12.0 (CI 11.2-12.7)	13.1 (CI 12.6-13.7) to 12.0 (CI 11.3-12.6)	+0.2
	Salt intake women (calculated from Na excretion) (g) 1979-1987	10.4 (CI 9.9-10.9) to 8.8 (CI 8.3-9.2)	10.4 (CI 10.0-10.9) to 9.5 (CI 9.0-10.0)	-0.7

Table 3.4 Knowledge/Attitudes/Intentions relating to CVD or CVD risk factors

		Treatment	**Control**	**Net treatment effect (negative indicates programme advantageous)**
Stanford 5 city men	Nutrition knowledge score (cross section)	+7.1	+4.3	-2.8 (NS)
	Nutrition knowledge (cohort)	+9.6	+6.0	-3.6 (NS)
	CVD knowledge score (cross section)	+1.5	+0.8	-0.7
Stanford 5 city Women	Nutrition knowledge (cross section)	+7.8	+3.1	-4.7 (p<0.003)
	Nutrition knowledge (cohort)	+10.5	+7.4	-3.1 (NS)
	CVD knowledge score (cross section)	+1.8	+1.1	-0.7
Stanford 5 city All	Intention to loose weight score (cross section)	+0.6	+0.5	-0.1
	Intention to loose weight score (cohort)	+0.3	0	-0.3
	CVD knowledge score (cross section)	+1.61 (SE 0.16)	+0.97 (SE 0.17)	-0.64 (p<0.005)
	CVD knowledge score (cohort)	+2.31 (SE 0.12)	+1.72 (SE 0.12)	-0.59 (p<0.001)
The American Heart Association	What is the leading cause of death? (1997 to 2006 change in % correct)	+27%, p<0.001		
	What is the greatest health problem facing women? (1997 to 2006 change in % correct)	+14%, p<0.05		
	Do you consider yourself to be very well/well informed	+8%		

	about CVD? (1997 to 2006 change in % correct)			
	Is there anything that can be done to prevent CVD? (1997 to 2006 change in % correct)	No change		
	Can you reduce your risk of heart disease by taking hormone therapy? (1997 to 2006 change in % correct)	-15%		

Table 3.5: Review 1 Summary

Programme		Bootheel	British Family	Danish Municipality	German CV Prevention	Minnesota	Norsjo	North Karelia	OXCHECK	Pawtucket	Stanford 5 City	South Carolina
Target audience	Rural/Urban	R	R/U	R	R/U	R/U	R	R	U	U	U	R
	Low socioeconomic status	√	—	—	—	—	—	—	—	—	—	√
	High risk	√	—	—	—	—	√	√	—	—	—	—
	Size		~3 000	~8 000	~1 000 000	232 000	5 500	180 000	22 000	71 000	126 000	46 000
Date		1989	1994	1989	1985	1980	1985	1972	1982	1982	1979	1987
Duration		1y	1y	1y	7y	5y	7y	>20y	1y	9y	6y	2y
Theory		PACH, SL, STI	—	SL	—	SL, PM, DI, LD, SP	—	SL, DI, PM, BA	PCC	SL	HCBC, SL	STI
Pre planning	Key informants	√	—	—	—	√	—	—	—	—	—	—
	Community involvement	—	—	—	—	—	—	—	—	—	—	—
Intervention	Flexible/community choice	√	—	—	—	—	√	—	—	—	√	—
	Media	—	—	√	√	√	√	√	—	√	√	√
	Printed material	—	—	—	√	√	—	√	—	√	√	—
	Group counselling	—	—	—	√	√	—	—	—	√	—	√
	Individual counselling	—	√	—	√	√	√	—	√	√	—	√
	Screening	√	√	—	√	√	√	—	√	√	—	√
	Environmental change	—	—	—	√	—	√	√	—	—	√	√
Effectiveness		X	√√	X	√√	X	√	√√	√√	X	√	√√

Table 3.5 continued: Review 1 summary

		Bootheel	British Family	Danish Municipality	German CV Prevention	Minnesota	Norsjo	North Karelia	OXCHECK	Pawtucket	Stanford 5 City	South Carolina
Accessibility	Range of venues	√√	X	√	√√	√√	√√	√√	X	√√	√√	√√
	Language	X	X	X	X	X	X	X	X	X	√	X
	Literacy	X	X	X	X	X	X	X	X	√	X	X
	Cultural factors	√	X	X	X	X	X	X	X	√	√	X
	Variation uptake / awareness	√	√	√	__	√	√	__	√	__	√	__
	Variation effectiveness	√	X	X	X	X	X	√	√	X	√	X
Delivered by	Local health committee	√	__	√	__	√	√	__	__	__	__	√
	Project staff	√	√	√	√	√	√	__	√	√	√	√
	Voluntary organisations	__	__	__	√	√	√	√	__	__	√	√
	Health departments	√	√	__	√	__	√	√	√	__	√	√
	Community volunteers	√	__	__	__	__	__	√	__	__	__	√
	Schools	√	__	__	√	√	__	√	__	√	√	√
	Workplaces	__	__	__	__	√	__	√	__	√	__	√
Effectiveness		X	√√	X	√√	X	√	√√	√√	X	√	√√

Table 3.6: Review 2 Summary

Programme		Action Heart	Coeur En Sante	Dutch Heart Health	Heartbeat Wales	Kilkenny	Otesego	Finnmark Båtsfjord	Finnmark Cape North	Di.S.Co	Stanford 3 community	National Research Program
Target audience	Rural/Urban	U	U	U	R/U	R/U	R	R	R	R	R	U
	Low socioeconomic status	√	√	√	__	__	√	√	√	__	__	__
	High risk	√	__	__	__	__	√	√	√	__	__	__
	Size	~22 000	~25 000	180 000	All Wales	73 000	~100 000	2 500	4 000	~26 000	~42 000	28 000
Date		1991	1992	1998	1985	1985	1989	1988	1988	1982	1972	1978
Duration		4y	3.5y	>6y	>5y	5y	5y	3y	10y	3y	3y	3y
Theory		__	SL, RA, PP	Mix	SL, SM, DI	SL, HCBC, DT, CO	___	CE	LE	__	SL BSC	__
Pre planning	Key informants	__	__	√	√	√	√	√	__	__	__	__
	Community involvement	__	__	__	__	√	__	√	__	__	__	__
Intervention	Flexible/community choice	__	__	√	__	__	√	√	√	__	__	__
	Media	__	√	√	√	√	√	√	__	√	√	√
	Printed material	√	__	√	√	√	√	__	__	√	√	√
	Group counselling	√	√	__	__	__	__	__	__	__	√	√
	Individual counselling	√	__	__	__	√	√	√	√	__	√	√
	Screening	√	√	__	__	__	√	√	__	√	√	__
	Environmental change	__	__	√	√	__	__	√	√	__	__	√
Effectiveness		X	X	√√	X	X	√	√	√	X	√√	X

NB For Stanford 3 community, details in this table and results in the outcomes graphs have been updated. Results for all participants (media campaign) replace data for high risk participants given in the previous report.

Table 3.6 continued: Review 2 Summary

		Action Heart	Coeur En Sante	Dutch Heart Health	Heartbeat Wales	Kilkenny	Otesego	Finnmark Båtsfjord	Finnmark Cape North	Di.S.Co	Stanford 3 community	National Research Program
Accessibility	Range of venues	√	√√	√√	√√	__	√√	√√	√√	√√	√	√
	Language	X	√	X	X	X	X	X	X	X	√	X
	Literacy	X	√	X	X	X	√	X	X	X	X	X
	Cultural factors	X	√	X	X	√	X	√	X	X	√	X
	Variation uptake / awareness	√	√	√	__	√	√	√	√	√	√	√
	Variation effectiveness	√	X	X	X	√	X	X	X	√	X	X
Delivered by	Local health committee	__	__	√	__	__	√	__	__	__	__	√
	Project staff	√	__	√	√	√	√	√	√	√	√	√
	Voluntary organisations	__	√	__	√	__	__	√	__	__	__	__
	Health departments	__	√	__	√	√	__	√	√	__	__	__
	Community volunteers	√	__	__	√	__	√	__	__	__	__	__
	Schools	√	√	__	√	√	√	__	__	√	__	__
	Workplaces	__	__	__	√	__	__	√	√	√	__	__
Effectiveness		X	X	√√	X	X	√	√	√	X	√√	X

NB For Stanford 3 community, details in this table and results in the outcomes graphs have been updated. Results for all participants (media campaign) replace data for high risk participants given in the previous report.

Table 3.7: Review 3 Summary

Programme		ATS Sardegna	Cardio-vision	Coalfields	Ebeltoft	Olofström	Franklin	CINDI	Goteburg	HH Paisley	Quebec rural	Quebec suburban	Quebec urban	Malmo	MHH screen	Inter 99	US Heart
Target audience	Rural /Urban	Mix	Mix	R	R	U	R	Mix	U	U	R	Suburban	U	U	R	Mix	Mix
	Low socio-economic status	_	_	√	_	√	_	_	_	√	_	_	√	_	_	_	_
	High risk	_	_	√	_	√	_	_	_	√	_	_	_	_	_	_	_
	Size	1 645 000	87 685	46 520	13 000	15 000	29 645	12 500	10 004	74 170	90 000	35 216	41 625	250 000	379	13 016	US
Date		1990	1999	1990	1991	1988	1974	1992	1973	2000	1992	1992	1992	1974	1982	1999	1997
Duration		5y	4y	10y	5y	5y	20y	3y	10y	2.5y	5y	5y	5y	~12y	1y	5y	9y
Theory		_	SMod, DI	CA	_	_	_	_	_	TC	CD SP	SL, PP, SM, PC, DI	SL, PP, AF	_	_	_	_
Pre planning	Key informants	_	_	√	_	_	_	_	_	√	_	_	_	_	_	_	_
	Community involvement	_	_	√	_	_	_	_	_	_	_	_	_	_	_	_	_
Intervention	Flexible/ community choice	_	_	√	_	_	_	_	_	_	√	√	√	_	_	_	_
	Media	√	√	√	_	√	√	_	_	√	_	√	_	_	_	_	√
	Printed material	√	√	_	_	√	_	_	_	_	_	_	_	_	√	_	√
	Group counselling	_	_	√	_	_	√	√	√	_	√	_	_	√	_	√	√
	Individual counselling	√	_	√	√	√	√	√	√	_	_	_	_	√	√	√	_
	Screening	_	_	_	√	√	√	√	√	_	√	_	_	√	√	√	√
	Environmental change	_	√	√	_	√	√	_	_	_	_	_	_	_	_	_	_
Effectiveness			X	X	√√	√	√		X	X	X	X	X	X	√	√	

NB no effectiveness grade could be assigned to uncontrolled studies

Table 3.7 continued: Review summary 3

Programme		ATS Sardegna	Cardiovision 2020	Coalfields	Ebeltoft	Olofström	Franklin	CINDI	Goteburg	HH Paisley	Quebec rural	Quebec suburban	Quebec Urban	Malmo	MHH screen	Inter 99	US Heart
Accessibility	Range of venues	√	_	√√	X	X	√	X	X	√√	_	_	_	X	X	X	_
	Language	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
	Literacy	_	_	_	_	_	√	_	_	_	_	_	_	_	_	_	_
	Cultural factors	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
	Variation uptake / awareness	_	√	√	√	_	X	√	√	√	√	√	√	√	√	√	_
	Variation effectiveness	√	_	_	_	_	_	_	_	_	_	_	_	√	_	√	√
Delivered by	Local health committee	_	_	√	_	√	_	√	_	_	√	_	_	_	_	_	_
	Project staff	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
	Voluntary organisations	_	_	_	_	_	√	_	_	√	_	_	_	_	_	_	_
	Health departments	√	_	_	√	√	√	√	_	√	√	√	√	√	_	_	_
	Community volunteers	_	_	_	_	_	_	_	_	√	√	_	_	_	_	_	√
	Schools	_	_	√	_	√	√	_	_	√	_	_	√	_	_	_	_
	Workplaces	_	_	√	_	_	√	_	_	√	_	_	_	_	_	_	√
Effectiveness			X	X	√√	√	√		X	X	X	X	X	X	√	√	

NB no effectiveness grade could be assigned to uncontrolled studies

Notes to tables 3.5, 3.6 and 3.7

Information is given where available from identified published literature. Where a particular target/method/component was not used or where no information was available, programmes are marked as –.

Accessibility:

Venues: Was the intervention delivered at a wide range of venues?
Language: Is the intervention tailored to meet the needs of those speaking different languages?
Literacy: Is the intervention tailored to meet the needs of those with low literacy levels?
Cultural factors: Is there any indication that the intervention was tailored to be sensitive to the needs of the predominant cultural group√ or a diversity of cultural groups√√?
Variation uptake: is there variation in uptake of intervention, variation in awareness of programme or variation in evaluation survey response by sub-groups of the population?
Variation Effectiveness: is there variation in magnitude of effectiveness by sub-groups of the population?

Theory: SL=Social Learning, RA=Reasoned Action, PP=Precede-proceed, SM=Social Marketing, DI=Diffusion of Innovation, HCBC=Health Communication-behavior Change, DT=Diffusion theory, Community Organisation for Health, CE=Community Empowerment, LE=Local Empowerment, BSC=Behavioral Self-control, PACH= planned approach to community health, STI=Stage Theory of Innovation, PM=Persuasion model, LD=Locality Development, SP=Social Planning, P=Precede, BA=Belief-attitude, PCC=Patient-centred Communication, HCBC=Health Communication-behaviour Change, SMod=social modelling, CA=community activation, TC=Theory of change, CD community development, SP= social planning, PC=Persuasive communication, AF=Azjen and Fishbein theory of planned behaviour

Effectiveness:

√√ - Strong intervention effect, √ - Moderate intervention effect, X – Weak intervention effect

NB These grades are indications of the apparent strength of effect on the outcome measures provided and are not based on direct outcome comparisons between programmes.

Evidence statement for programmes addressing prevention of CVD at population level

(phase III of review 1)

This is an interim statement based on the third part of a 3 stage review.

16 directly relevant programmes reported in 21 publications were identified for this report. The majority (11) consider the effectiveness of population programmes using education and/or mass media and other programmes (5) focus on assessing levels of CVD risk factors with screening and providing advice in general populations. No programmes used legislative or fiscal changes and there were no natural experiments. The education and mass media programmes were generally evaluated using controlled before-after studies with quality gradings ranging from – to +. The "screening" programmes were evaluated using RCTs and were graded from – to +.

Evidence statements for programmes addressing prevention of CVD at population level (phase I, II and III of review 1)

These are statements based on the combined data from the all 3 parts of the 3 stage review.

Introduction. Thirty eight directly relevant programmes reported in 90 publications have been identified in this review of effectiveness. The majority of programmes (31) are concerned with the effectiveness of population programmes using education and mass media and were generally evaluated using controlled before-after studies (CBA studies), with quality grading from – to +. Seven screening programmes have been evaluated using RCTs and were quality graded from – to +. No programmes using legislative or fiscal changes have been identified.

Due to limitations in reporting, statistical significance has not been considered when commenting on the direction of effect of programmes on CVD outcomes and it has not been possible to quantify the overall size of effects across all programmes. The effect of programmes on CVD outcomes is described as mixed where the direction of effect is conflicting across programmes. In addition, a distinction is made between outcomes where the majority of programmes demonstrate a beneficial effect, outcomes where the majority of programmes demonstrate a disbeneficial effect and outcomes where programmes are balanced with respect to beneficial and disbeneficial effects. Programmes described as demonstrating 'inconclusive' effects provide more than one effect estimate which are conflicting e.g. one beneficial and one disbeneficial. Programmes demonstrating inconclusive or no effects have not been considered when distinguishing between outcomes with broadly beneficial, disbeneficial or balanced effects.

1) Are population level multiple risk factor interventions (MRFI) effective in the primary prevention of CVD?

E.1.a. CVD mortality and morbidity. Limited evidence from 3/38 programme evaluations using different summary effect measures demonstrate a mixed effect of MRFI on CVD mortality (the

majority of programmes beneficial) with 2 CBA studies (-[27] and +[28]) demonstrating a net decrease in CVD mortality and one RCT (+[36]) demonstrating no net change. Limited evidence from 4/38 programme evaluations, using different summary effect measures, demonstrate a mixed effect of MRFI on CVD morbidity (the majority disbeneficial) with 1 CBA study (-[27]) and 1 RCT (-[38]) demonstrating a net increase in morbidity and 1 RCT (+[36]) demonstrating no net change in morbidity. The effect of one programme (CBA study -[29]) on morbidity and mortality is unclear.

E.1.b. Blood cholesterol. A large body of evidence from 15 CBA studies (10-, 5+) and 5 RCTs (2-, 3+) demonstrates a mixed direction of effect (majority of programmes beneficial) of MRFI programmes on blood cholesterol. Fourteen studies (9 CBA (5-[30,17,16,10a,9a], 4+ [6,22a,5a,4]) and 5 RCTs (2-[37,38], 3+[8,34,2]) demonstrate a beneficial net effect, 4 CBA studies (3-[20,27,19], 1+[15a]) demonstrate no net effect or inconclusive net effects and 2 CBA studies (2-[7,14]) demonstrate a disbeneficial net effect. The most optimistic result was from a CBA study (+[6]), reporting a 0.7mmol/l net reduction in blood cholesterol. The least optimistic result was from a CBA study (-[14]), reporting a +0.5mmol/l net increase in blood cholesterol.

E.1.c. Diastolic and systolic blood pressure. A large body of evidence demonstrates a mixed direction of effect (majority of programmes beneficial) in favour of MRFI programmes on diastolic and systolic blood pressure.

Fourteen CBA studies (10-, 4+) and 5 RCTs (2-, 3+) demonstrate a mixed direction of effect (majority of programmes beneficial) on diastolic blood pressure. Twelve studies (7 CBA studies (4-[30,16,9a,14],3+[15a,5a,4]) and 5 RCTs (2-[37,38]3+[2,8,34])) demonstrate a beneficial net effect, 5 CBA studies (4-[10a,27,7,17], 1+[6]) demonstrate no net effect or inconclusive net effects and 2 CBA studies (2-[19,20]) demonstrate a disbeneficial net effect. The most optimistic result was from a CBA study (-[30]), reporting a 5.5mm Hg net reduction in diastolic blood pressure. The least optimistic result was from a CBA study (-[19]), reporting a 6mmHg net increase in diastolic blood pressure.

Fourteen CBA studies (9-, 5+) and 5 RCTs (2-, 3+) demonstrate a mixed effect (majority of programmes beneficial) on systolic blood pressure. Ten studies (5 CBA studies (1-[16], 4+[22a,15a,5a,4]) and 5 RCTs (2-[38,37] 3+[2,8,34]) demonstrate a beneficial net effect, 5 CBA studies (4-[10a,19,9a,27], 1+[6]) demonstrate no net effect or inconclusive net effects and 4 CBA studies (4-[17,7,14,20]) demonstrate a disbeneficial net effect. The most optimistic result was from a CBA study (+[22a]), reporting an 11.8 mmHg net reduction in systolic blood pressure. The least optimistic result was from a CBA study (-[20]), reporting a 5mmHg net increase in systolic blood pressure.

E.1.d. Smoking. A large body of evidence from twenty CBA studies (17-, 3+) and four RCTs (2-, 2+) demonstrate a mixed effect of MRFI on smoking prevalence (the majority of programmes beneficial). Twelve studies (9 CBA studies (7-[21,12a/b,20,16,7,25,11a], 2+[4,5a]) and 3 RCTs (2-[37,38], 1+[2])) demonstrate a beneficial net effect, 7 studies (6 CBA studies (6-[17,14,13,19,10a,9a]) and 1 RCT (+[8])) demonstrate no net effect or inconclusive net effects and 5 CBA studies (4-[18,3,1,27], 1+[6]) demonstrate a disbeneficial net effect. The most optimistic result was from a CBA study (-[21]), reporting an 18.6% net reduction in smoking prevalence. The least optimistic result was from a CBA study (-[27]), reporting a 12.8 % net increase in smoking prevalence.

E.1.e. BMI. A large body of evidence from fourteen CBA studies (11-, 3+) and 3 RCTs (1-, 2+) demonstrate a mixed effect of MRFI programmes on BMI (the majority of programmes beneficial). Ten studies (7 CBA studies (6-[17,19,14,7,13,25], 1+[15a]) and 3 RCTs (1-[37], 2+[34,8])) demonstrate a beneficial

net effect, 4 CBA studies (3-[9a,10a,27], 1+[4]) demonstrate no net effect or inconclusive net effects and 3 CBA studies (2-[16,20], 1+[6]) demonstrate a disbeneficial net effect. The most optimistic result was from a CBA study (-[17]), reporting a 1.3kg/m^2 net reduction in BMI. The least optimistic result was from a CBA study (+[6]), reporting a 0.7kg/m^2 net increase in BMI.

E.1.f. Blood glucose. Limited evidence from 3/38 programme evaluations, using different summary effect measures, demonstrate a mixed effect of MRFI on blood glucose. One RCT (+[2]) and 1 CBA study (-[14]) report mixed results: net decreases in men and net increases in women, whilst 1 CBA study (-[15a]) demonstrates no net effect.

E.1g. Triglyceride levels, HDL/LDL ratio or lipid levels. No evidence has been identified on the effects of MRFI programmes on triglyceride levels, HDL/LDL ratio or lipid levels.

E.1.h. Dietary change: low versus high fat spreads. Five CBA studies (4-, 1+) and one RCT (+) demonstrate a mixed effect of MRFI programmes on consumption or low versus high fat spreads (the majority of programmes beneficial). Four studies (3 CBA studies (2-[17,18], 1+[5b]) and 1 RCT (+[8])) demonstrate a beneficial net effect, 1 CBA study (-[16]) demonstrates an inconclusive net effect and 1 CBA study (-[12a/b]) demonstrates an unfavourable net effect. The most optimistic result was from a CBA study (+[5b]), reporting a 24% net reduction in the number of people with high consumption of fat spread on bread. The least optimistic result was from a CBA study (-[16]), reporting a 3.3% net decrease in the use of unsaturated spreading fats.

E.1.i. Dietary change: vegetable versus animal fats for cooking. Four CBA studies (3-, 1+) demonstrate a mixed effect of MRFI programmes on the use of vegetable versus animal fat for cooking (the majority of programmes beneficial). Three CBA studies (2-[16,17], 1+[5b]) demonstrate a beneficial net effect and 1 CBA study (-[11b]) demonstrates an inconclusive net effect. The most optimistic result was from a CBA study (-[16]), reporting a 6% net increase in the use of unsaturated fats for cooking. The least optimistic result was from a CBA study (-[11b]), reporting a 2% net decrease in the use of vegetable fats for cooking.

E.1.j. Dietary change: low versus high fat milk. Five CBA studies (4-, 1+) and 1 RCT (+) demonstrate a mixed effect of MRFI programmes on the consumption of low versus high fat milk (the majority of programmes beneficial). Three CBA studies (2-[17,12a/b], 1+[5b]) and 1 RCT (+[8]) demonstrate a beneficial net effect and 2 CBA studies (2-[16,18]) demonstrate an inconclusive net effect. The most optimistic result was from a CBA study (-[17]), reporting a 9% net increase in the use of low fat milk in men. The least optimistic result was from a CBA study (-[16]), reporting a 1% net decrease in the use of low fat milk in women.

E.1.k. Dietary change: consumption high fat foods. Six CBA studies (4-, 2+) demonstrate a mixed effect of MRFI programmes on the percentage of high fat foods in the diet (the majority of programmes beneficial). Three CBA studies (1-[10b], 2+[22a,5b]) demonstrate a beneficial net effect, 2 CBA studies (2-[13,11b]) demonstrate no net effect or inconclusive net effects and 1 CBA study (-[18]) demonstrates a dis-beneficial net effect. The most optimistic result was from a CBA study (+[22a]), reporting a 24% net decrease in saturated fat intake. The least optimistic result was from a CBA study (-[13]), reporting a 3.4% net increase in high fat/junk food consumption.

E.1.l. Dietary change: consumption of fruit and vegetables and wholemeal bread. Limited evidence is available on the effects of MRFI programmes on the consumption of fruit and

vegetables and wholemeal bread (the majority of programmes beneficial). Three CBA studies (3-) demonstrate a mixed effect of MRFI programmes on the consumption of fruit and vegetables. Two CBA studies (2-[25,1]) demonstrate a beneficial net effect and 1 CBA study (1-[18]) demonstrates an inconclusive net effect. The most optimistic result is from a CBA study (-[25]), reporting a 9% net increase in the number of people consuming five portions of fruit and vegetables per day. The least optimistic result is from a CBA study (-[18]), reporting a 0.2% net decrease in fruit consumption.

Two CBA studies (2-) demonstrate a mixed effect on the consumption of wholemeal bread. One CBA study[18] demonstrates a beneficial net effect and one CBA study[12a/b] demonstrates an inconclusive effect. The most optimistic result is from a CBA study (-[12b]), reporting a 3% increase in children. The least optimistic result is from the same CBA study (-[12a]), reporting a 0.3% net decrease in adults.

E.1.m. Dietary change: salt intake. Two CBA studies (+ and -) provide mixed results for the effects of MRFI programmes on salt intake. One CBA study (-[10b]) demonstrates a beneficial net treatment effect and 1 CBA (+[5c]) demonstrates an inconclusive net treatment effect.

E.1.n. Physical activity. Evidence from 11 CBA studies (10-, 1+) and 1 RCT (+) provide a mixed pattern for the effect of MRFI programmes on physical activity (the majority of studies are dis-beneficial). Three CBA studies (3-[27,17,12a/b]) and 2 RCTs (-[37], +[8]) demonstrate a favourable net effect, 3 CBA studies (3-[21,16,3]) demonstrate inconclusive net effects and 4 CBA studies (3-[7,18,25], 1+[15c]) demonstrate a dis-beneficial net effect. The most optimistic result is from a CBA study (-[21]), reporting an 11.5% net increase in the number of people doing strenuous physical activity >3 times per week. The least optimistic result is from a CBA study (-[7]), reporting a 6% net decrease in the number of people who were physically active.

E.1.o. Attitudes, knowledge and intentions relating to CVD risk factors. Limited evidence is available on the effects of MRFI programmes on CVD risk factor attitudes, knowledge and intention to change. One CBA study (-[10a/b]) and one uncontrolled before-after study (-[23]) suggest beneficial changes in CVD knowledge following MRFI programmes and one of these studies (-[10c]) showed a net increase in the number of individuals intending to lose weight. No evidence has been identified on the effects of MRFI programmes on CVD risk factor attitudes.

2) How does the effectiveness of interventions for the primary prevention of CVD vary between different population groups, for example, groups that differ in terms of age, gender and ethnicity?

E.2.a. General. Evidence for variation in effectiveness in sub-groups of the population is limited and inconsistently reported across included programmes. There is no clear pattern with respect to gender, age, ethnicity or measures of deprivation which may be the result of the limited information available, confounding and selective reporting.

E.2.b. Ethnicity. Three programmes report the results of sub-group analysis of effectiveness according to ethnicity. One uncontrolled before after study (-[23]) reports lower effectiveness in ethnic minorities in acquisition of CVD knowledge, one CBA study (-[1]) reports lower effectiveness in ethnic minority groups for reducing smoking prevalence, reducing BMI and increasing fruit and

vegetable intake and one CBA study (-[11a]) reports no difference in effectiveness according to ethnic group.

E.2.c. Age. Six programmes report results of sub-group analysis according to age. Two uncontrolled before-after studies (2-[23,24]) report a reduction in effectiveness in acquisition of CVD knowledge in younger participants and one uncontrolled before-after study (-[24]) reports a reduction in effectiveness in reducing salt intake in younger participants. One CBA study (-[13]) reports a reduction in effectiveness in promoting CVD awareness in older participants. Two CBA studies (2-[12a/b,11a]) report no differences in effectiveness according to age.

E.2.d. Gender. Seven programmes report results of sub-group analysis according to gender. Four programmes report a reduction in effectiveness in women compared to men. One RCT (-[35]) reports a reduction in effectiveness in increasing physical activity in women compared to men. One uncontrolled before after study (-[24]) and 2 CBA studies (-[12a/b], +[5a]) report a reduction in effectiveness in reducing smoking prevalence in women compared to men. One CBA study (+[5a]) reports a reduction in effectiveness in reducing cholesterol in women compared to men. One CBA study (-[12a]) reports a reduction in effectiveness in drinking low fat compared to high fat milk in women compared to men.

Two programmes report a reduction in effectiveness in men compared to women. Two CBA studies (2-[10a,13]) report a reduction in effectiveness in promoting CVD awareness and acquisition of CVD knowledge in men compared to women and one CBA (-[10a]) study reports a reduction in effectiveness in reducing CVD morbidity and mortality in men compared to women. One CBA study (-[14]) reports no differences in effectiveness according to gender.

E.2.e. Social class. Two programmes report results of sub-group analysis according to social class. One CBA study (-[19]) reports a reduction in effectiveness in reducing smoking in lower social classes compared to higher social classes. One CBA study (+[15a]) reports no differences in effectiveness according to social class.

E.2.f. Level of education. One programme reports results of sub-group analysis according to level of education. One CBA study (-[13]) reports a reduction in effectiveness in CVD awareness in those relatively more educated.

3) How does the effectiveness of interventions for the primary prevention of CVD vary according to the nature of the intervention, whether the intervention is based on an underlying theory or conceptual model, the status of the organisation or person delivering the intervention, the context in which the intervention takes place, the intensity and duration of the intervention?

E.3.a. Nature of the interventions. 31 programmes were concerned with the effectiveness of population programmes using education and mass media, and seven with screening programmes directed at large populations in the community or primary care. However, 16 of the education and mass media programmes contained screening components. Counselling was a key process in many programmes, undertaken individually in 24 programmes and amongst groups in 16 programmes.

The 38 programmes varied in many other ways. Programme length ranged from one to >20 years. The size of the population addressed ranged from approximately 2,500 to over 1,000,000. 14 of

the programmes implemented changes to the environment. Health departments (n=23), local health committees (n=12), voluntary organisations (n=11) and community volunteers (n=9) had roles in programme delivery. Programmes were delivered in a variety of settings including workplaces (n=12) and schools (n=18).

E.3.b. Education & mass media based programmes compared to screening based. As indicated this was the most marked contrast between the programmes. However comparing the effectiveness of the two groups is complicated by:

- Many of the education and mass media based programmes containing elements of screening.
- There are many CVD screening programmes, particularly focused on moderate or high risk populations which are not included in this review.
- The comparison between the two groups being likely to be confounded by other factors, a very important one of which is that CBA studies are used to evaluate most of the education and mass media based programmes, and RCTs all the screening based programmes.

Programme type (n=38)	**Programme result, based on direction of effect**			
	Beneficial	**Inconclusive**	**Disbenefical**	**No data**
Net change in mean total cholesterol in mmol/L				
Educ & MM	9[6,30,22a,5a,4,17,16,10a,9a]	4[20,15a,27,19]	2[7,14]	16
Screening	5[8,34,2,37,38]	0	0	2
Net change in systolic BP in mmHg				
Educ & MM	6[22a,15a,5a,4,16,10a]	4[19,9a,6,27]	4[17,7,14,20]	17
Screening	5[2,8,38,34,37]	0	0	2
Net change in diastolic BP in mmHg				
Educ & MM	7[15a,30,16,10a,5a,4,9a]	5[6,14,27,7,17]	2[20,19]	17
Screening	5[2,8,37,34,38]	0	0	2
Net change in BMI in kg/m^2				
Educ & MM	8[17,19,14,7,15a,10a,13,25]	3[9a,27,4]	3[16,20,6]	17

Screening	3[34,8,37]	0	0	4
Net change in smoking prevalence in %				
Educ & MM	9[21,12a,20,16,4,7,25,5a,11a]	6[17,14,13,19,10a,9a]	5[18,3,6,1,27]	11
Screening	3[2,37,38]	1[8]	0	3

With these provisos and reference to pages 127 to 131 in report 3, the pattern of results for the risk factors of cholesterol, BP, smoking and BMI in the two different groups of programmes are summarised in the table below:

Although the results are similar, there does appear to be a more consistent pattern of benefit in the programmes focusing on screening. As well as the provisos mentioned above, the following also need to be borne in mind when taking this observation at face value:

- Whether this difference could be accounted for by chance alone.
- Whether the difference would persist if the size of the effects could be taken into account.
- Vote counting as a method of summarising the results in a systematic review is recognised to be the weakest approach.

E.3.c. Possible variations in effectiveness by other aspects of the nature of the intervention. Over the three reports, many other plausible reasons for the noted variation in effectiveness have been identified. These include:

- Duration of programme
- Intensity of programme
- Use of an underlying theoretical model to inform the design of the programme
- Pre-programme investigation of particular risk factors operating in a population
- Community involvement in planning and/or design of programme
- Adaptability of the programme as new challenges emerge
- Level of integration of the separate components of the programme
- Inclusion of environmental changes as part of the programme

Whether any of these factors account for differences in effectiveness which could not arise by chance alone has not been fully explored, and their potential importance can neither be confirmed nor refuted. Unfortunately, the extent to which the differences could ever be satisfactorily explored using the results from these evaluations is debatable given noted limitations in the reporting of the precise differences in nature of the programmes and the amount of statistical information available.

4) Do multiple risk factor interventions for the primary prevention of CVD have any adverse or unintended effects?

E.4.a. There is no evidence for adverse or unintended effects from multiple risk factor interventions for the primary prevention of CVD from the 90 publications covering 38 programmes scrutinised for the effectiveness review.

5) What is the accessibility of multiple risk factor interventions for the primary prevention of CVD for different population groups?

E.5.a. General. Few programmes reported initiatives in accessing hard to reach groups: different cultural factors were addressed by seven programmes, attempts to overcome barriers resulting from different language were considered in three programmes, and the problem of poor literacy was also addressed in three programmes. E.5.b. to E.5.h document characteristics of non-participants in programme interventions and/or programme evaluation surveys where they are reported in studies scrutinised for this review.

E.5.b. Gender. Twelve programmes report participation in programme interventions and/or programme evaluation surveys according to gender. One uncontrolled before-after study (-[26]), 7 CBA studies (6-[1,12a,13,14,25,27], 1+[6]) and 2 RCTS (2+[8,34]) report lower participation in evaluation surveys or programme interventions by males whilst two programmes, 1 CBA study (-[30]) and 1 RCT (+[36]), report no gender differences in participation rates.

E.5.c. Age. Fifteen programmes report participation in programme interventions and/or programme evaluation surveys according to age. One uncontrolled before-after study (-[26]) and 13 CBA studies (11-[1,3,10a,12a,13,14,17,16,25,27,29], 2+[6,15a]) report lower participation in evaluation surveys or programme interventions by those of younger age whilst 1 CBA study (+[28]) reports no difference in participation according to age.

E.5.d. Level of education. Seven programmes report participation in programme interventions and/or programme evaluation surveys according to level of education. Six CBA studies (4-[1,10a,21,27], 2+[6,15a]) report lower participation by those relatively less well educated whilst 1 CBA study (-[13]) reports lower participation by those relatively better educated.

E.5.e. Social class. Three programmes report participation in programme interventions and/or programme evaluation surveys according to social class. One CBA study (-[29]) and 2 RCTs (-[38], +[36]) report lower participation by those of lower social class.

E.5.f. Ethnicity. Three programmes report participation in programme interventions and/or programme evaluation surveys according to ethnicity. Two CBA studies (2-[10a,20]) and 1 RCT (+[36]) report lower participation by ethnic minority groups.

E.5.g. Marital status. Three programmes report participation in programme interventions and/or programme evaluation surveys according to marital status. Two CBA studies (2-[3,21]) and 1 RCT (+[36]) report lower participation by those unmarried or divorced.

E.5.h. CVD risk. Twelve programmes report participation in programme interventions and/or programme evaluation surveys according to CVD risk. One uncontrolled before-after study (-[26]), six CBA studies (5-[7,10a,17,16,29], 1+[22a]) and 3 RCTs (1-[35], 2+[2,8]) report lower participation by individuals at

relatively higher CVD risk whilst 1 RCT (+[34]) reports relatively lower participation by individuals at relatively lower CVD risk.

E.6. How applicable are the findings from the 38 programme evaluations to the UK?

E.6.a. Applicability related nature of programmes. 5 of the programmes included in this review were conducted in the UK, 17 in Europe, 15 in North America and 1 in Australia. The programmes identified were initiated across a wide time period: 8 in the 1970s, 16 in the 1980s, 13 in the 1990s and 1 in 2000. They covered a wide range of community settings: 15 general, 12 urban, 1 suburban, and 10 mixed. Twelve of the 38 included programmes were undertaken in areas of low socioeconomic status, 10 in areas considered to be 'high risk' for CVD and 8 in communities with both these characteristics.

E.6.b. Constraints on judgements about applicability. Even for those interventions considered applicable in setting and place, the passage of time is very important. Healthcare systems evolve, the nature of interventions change, the balance of CVD risk factors faced by the population alters and the population knowledge of CVD risk factors develops. These considerations undermine the applicability of all the programmes as the most recent programme is over 8 years old.

Consideration of the applicability of the included programmes to the UK populations is also constrained by the limited information provided by virtually all studies on the socio-demographic characteristics of the target populations and/or the population actually reached by the interventions. Possible selection bias and substantial losses to follow-up in the evaluated populations in some studies further challenges judgements about applicability.

More complexity is introduced by the possibility that general populations in past years, when risk factors like smoking levels were more common, although not applicable to current day general populations, may remain applicable to current day high risk populations. Finally, both average risk and high risk populations may be of interest in the context of the guidance.

E.6.c. Conclusions on applicability. Given the noted constraints, it was felt that judgements about applicability were too subjective to assign individual applicability ratings as encouraged in the NICE Public Health methods guidance.

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Have a Heart Paisley	29	Blamey, Avril, Ayana, M, Lawson, L, Mackinnon, J, Paterson, I, and Judge, K. Final report of the independent evaluation of Have a Heat Paisley. 1-136. 2004. The University of Glasgow.
Olöfstrom	30	Isacsson A, Lindholm LH, Schersten B, Eklund E, Bjorkman S, Jarhult B, Asp NG, Lanke J: Community intervention against non-insulin dependent diabetes mellitus (NIDDM) and cardiovascular disease: A study based on Swedish health care. *Cardiovascular Risk Factors* 6:164-171, 1996
Quebec Heart Health: Rural	31	Huot I, Paradis G, Ledoux M, Quebec Heart Health Demonstration Project Research Group.: Effects of the Quebec Heart Health Demonstration Project on adult dietary behaviours. *Preventive Medicine* 38:137-148, 2004
Quebec Heart Health: Suburban	32	Huot I, Paradis G, Ledoux M, Quebec Heart Health Demonstration Project Research Group.: Effects of the Quebec Heart Health Demonstration Project on adult dietary behaviours. *Preventive Medicine* 38:137-148, 2004
Quebec Heart Health: Urban	33	Huot I, Paradis G, Ledoux M, Quebec Heart Health Demonstration Project Research Group.: Effects of the Quebec Heart Health Demonstration Project on adult dietary behaviours. *Preventive Medicine* 38:137-148, 2004
Ebeltoft	34	Engberg M, Christensen B, Karlsmose B, Lous J, Lauritzen T: General health screenings to improve cardiovascular risk profiles: a randomized controlled trial in general practice with 5-year follow-up. *The Journal of Family Practice* 51:546-552, 2002
Inter99	35	Von Huth SL, Ladelund S, Borch-Johnsen K, Jorgensen T: A randomized multifactorial intervention study for prevention of ischaemic heart disease (Inter99): the long-term effect on physical activity. *Scand J Public Health* 36:380-388, 2008
The Malmö Preventative Project	36	Berglund G, Nilsson P, Eriksson KF, Nilsson JA, Hedblad B, Kristenson H, Lindgarde F: Long-term outcome of the Malmo preventive project: mortality and cardiovascular morbidity.[see comment]. *Journal of Internal Medicine* 247:19-29, 2000
Minnesota Heart Health Screening	37	Murray DM, Luepker RV, Pirie PL, Grimm RH, Bloom E, Davis MA, Blackburn H: Systematic risk factor screening and education: a community-wide approach to prevention of coronary heart disease. *Preventive Medicine* 15:661-672, 1986
The multifactor primary prevention trial: Göteborg	38	Wilhelmsen L, Berglund G, Elmfeldt D, Tibblin G, Wedel H, Pennert K, Vedin A, Wilhelmsson C, Werkö L: The multifactor primary prevention trial in Göteborg, Sweden. *European Heart Journal* 7:279-288, 1986

3.4 Evidence Tables

Table 3.1: The American Heart Association Campaign for Women

Programme details	Intervention, policy, strategy or programme description	Programme/sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive results)	Confounders and limitations
Title: American Heart Association campaign for women **Relevant papers:** Christian et al. Nine-years trends and racial and ethnic disparities in women's awareness of heart disease and stroke: An American Heart Association national study. Journal of Woman's Health 2007; 16 (1): 68-81 (1) Mosca et al. Tracking women's awareness of heart disease: an American Heart Association national study. Circulation 2004; 109: 573-579 (3) Robertson. Women and cardiovascular disease: The risks of misperception and the need for action. Circulation 2001; 103: 2318-2320 (2)	**Aim:** National campaigns aimed at reducing rates of cardiovascular disease in women (1). **Intervention:** The American Heart association national campaign for women started with 'Take Wellness to Heart' in 1997. More recently, the 'Go Red for Women' movement was launched (2004) and is currently running across the US. The website is the major source of campaign information (http://www.goredforwomen.org/). Risk factor screening is promoted and a 'National ware red day' used to raise awareness of the risks of CVD. The website gives details of Go Red events held in each area including a twelve week physical activity programme, 'choose to move', Go Red luncheons and community events held in hespanic communities. Nutrition tips are available and stories from people who have changed their lives and risks of CVD. Online specialists are available to answer questions relating to heart disease and educational materials are provided. The campaign has been supported by many companies and, in 2007,	**Intervention group:** The whole of the United States **Control group:** No control group **Included participants:** Women ≥25 years **Excluded:** None **Setting:** United States	9 years (1997-2006) Four independent cross sectional surveys in 1997, 2000, 2003 and 2006 1997 (n=1,000) (21), 2000 (n=1,004) (2), 2003 (n=1,024) (3), 2006 n=1,005 (1)	**Primary outcomes** (1)**:** Knowledge relating CVD	**Primary outcomes** (1)**:** Knowledge was assessed with questions: 1. What is the leading cause of death (LCOD)? Proportion of all females correctly identifying CVD as the LCOD in 2006 was 57%, significantly higher than in 2003 (46%, p<0.001), 2000 (34%, p<0.001) and 1997 (30%, p<0.001) and significant positive trend in knowledge (p=0.02). Awareness gap between ethnic groups did not narrow over time. In 2006, white women significantly more likely to identify CVD as LCOD compared to black (68% versus 31% respectively, p<0.05) and hespanic women (29%, p<0.05). In 2006, women aged 45-64 years more likely to identify heart disease as the LCOD than those aged 25-34 years (61% versus 48% respectively, p<0.05). 2. Do you consider yourself very well/well informed? In 2006, 42% of women considered themselves to be very well/well informed about heart disease, higher than the 34% in 1997. Hespanic women more likely than black women to consider themselves to be not at all informed about heart disease (17% versus 6%, p<0.05). 3. What are strategies to prevent heart disease? In 2006, most women recognised that	**Identified by author** (1) Results may not be generalisable as the survey was only conducted in those women that had household telephones and were English speaking. There may have been response bias with women giving better self-reported measures. Power to detect differences between ethnic minorities was limited because of the small sample size. **Identified by reviewer:** A large amount of outcome variables were measured and it seems likely that a vast number of statistical tests were conducted. However, no adjustments were made for multiple comparisons and this increases the level of uncertainty about the significance of results. Respondents to questionnaires may have been people who were more likely to be well informed about cardiovascular disease.

Mosca et al. Awareness, perception and knowledge of heart disease risk and prevention among women in the United States. Archives of Family Medicine 2000; 9: 506-515 (21) **Study design:** Cross sectional surveys **QA Grades: '-'**	>5,000 showed their support by conducting fundraising events where employers wore something red to raise awareness of the risks of CVD. In early 2008, cities across the country went red by illuminating monumental buildings in red to raise awareness of women and heart disease (1). **Comparison:** No intervention				maintaining a healthy blood pressure (97%), maintaining healthy cholesterol (96%), exercise (96%), loosing weight (96%), reducing stress (96%), quitting smoking (95%), reducing dietary cholesterol (93%) and reducing dietary salt (90%) were important methods for preventing heart disease, similar to proportions observed in previous survey years.	

Table 3.2: The ATS-Sardegna Campaign

Programme details	Intervention, policy, strategy or programme description	Programme/sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive net results)	Confounders and limitations
Title: The ATS-Sardegna Campaign **Relevant papers:** Muntoni et al. Results of a five-year community-based programme for cardiovascular disease	**Aims:** Reduce cholesterol through changes in diet, prevent/reduce high blood pressure, reduce smoking and promote cessation, control body weight and increase physical activity. **Intervention:** Two main components: an individual (high risk) strategy and a population strategy.	**Intervention group:** Sardinia (n=1 645,000), an island off the coast of Italy **Control group:** No control area used for programme evaluation **Included**	5 years (1990-1995) Cross sectional surveys: conducted in 1978 (384 males, 409 females, response rate 66%), 1984 (315 males, 349 females, response rate 55%), 1992 (305 males and 324 females, response rate 60.2%) and 1995	**Primary outcomes:** From cross sectional surveys in 1978, 1984, 1992 and 1995: Total cholesterol, triglycerides, Systolic and diastolic blood pressure, BMI and prevalence of smoking. Dietary habits: Scores from food frequency questionnaire for consumption of foods rich in saturated fat, traditional foods,	**Primary outcomes:** a) Repeated cross sectional surveys 1. Total cholesterol In men significant increase from 1984 (206 mg/dl; SE 2.5) to 1992 (215 mg/dl; SE 2.3, p=0.0001) and non-significant decrease in 1995 (209 mg/dl; 2.5, p=NS). In women, significant increase from 1984 (197 mg/dl; SE 1.9) to 1992 (212 mg/dl; SE 2.2, p=0.0001) and a non-significant decrease in 1995 (210 mg/dl; SE 2.4, p=NS). 2. Triglycerides Non-significant rises in triglyceride levels from 1984 to 1992 in men (1984: 118 mg/dl; SE 3.5 to 1992: 122 mg/dl; SE 5.8, p=NS) and women (1984: 94	**Identified by author** The programme was begun only one year after the natural fall in heart disease mortality in Sardinia. **Identified by reviewer:** Data for physiological and dietary risk factors obtained from the four population surveys cannot be separated from secular trends since no control group

prevention: The ATS-Sardegna Campaign. European Journal of Epidemiology 1999; 15: 29-34 (4)

Study designs:

Uncontrolled cross sectional surveys and retrospective survey

QA Grade:'-'

Due to irregular funding, intervention occurred in cycles.

High risk strategy: targeted at individuals, managed by the Sardinian Association of General Practitioners, sustained until 993 when funding was terminated by new leadership.

The community strategy: largely a media campaign. Educational booklet 'The Human Machine' widely distributed covering 80% of households and also placed in pharmacies and given to people attending programme activities. Cartoon on CVD risk factors broadcast 2,355 times on regional television. Messages published in local newspapers and posters (~5,000) put up in public places in all municipalities in Sardinia.

Sardinian migrants also targeted by dispatching educational material to 152 Sardinian clubs over the world.

Comparison:

No intervention

participants:

Cross sectional surveys: Adults aged 20-59y

Retrospective survey: Adults and children, ages not specified.

Excluded:

Not stated

Setting:

Sardinia

(200 males and 206 females, response rate 59.3%).

Retrospective survey in 1995: total of 1,486 participants (1,053 urban and 433 rural).

butter, olive oil, corn oil and lard.

From retrospective 1995 survey: Reported changes over intervention period in smoking, use of fats, use of alcohol, degree of physical activity, awareness of own cholesterol and blood pressure levels.

mg/dl; SE 2.7 to 1992: 96 mg/dl; SE 3.9, p=NS) and little change to 1995 for men (120 mg/dl; SE 6.2, p=NS) or women (96 mg/dl; SE 4.5, p=NS).

3. Blood pressure

Systolic blood pressure: No change from 1984 to 1992 in men (1984: 130 mmHg; SE 0.9 to 1992: 129 mmHg; SE 1.0, p=NS) or women (1984: 129 mmHg; SE 1.1 to 1992: 128 mmHg; SE 0.9, p=NS). Significant reduction in 1995 in men (125 mmHg; SE 1.4, p=0.05) and women (124 mmHg; SE 1.1, p=0.05).

Diastolic blood pressure: Significant increase from 1984 to 1992 in men (1984: 81 mmHg; SE 0.6 to 1992: 83 mmHg; SE 0.6, p=0.0001) and women (1984: 81 mmHg; SE 0.7 to 1992: 85 mmHg; 0.6, p=0.0001) and significant decrease in 1995 in men (80 mmHg; SE 0.9, p=0.004) and women (82 mmHg; SE 0.9, p=0.004).

4. BMI

In men, non-significant increase from 1984 to 1992 (1984: 25.6 kg/m^2; SE 0.2 to 1992: 26.0 kg/m^2; SE 0.3, p=NS) and a non-significant decrease in 1995 (25.7 kg/m^2; SE 0.4, p=NS). In women, significant rise from 1984 to 1992 (1984: 25.3 kg/m^2; SE 0.2 to 1992: 26.4 kg/m^2; SE 0.3, p=0.0001) and a non-significant decrease in 1995 (25.9 kg/m^2; SE 0.4, p=NS).

5. % current smokers

Decreased significantly from 1984 to 1992 in men (1984: 49%; SE 2.7 to 1992: 43%; SE 2.7, p=0.05) and increased significantly in women (1984: 22%; SE 0.8 to 1992: 28%; SE 2.1, p=0.004). In 1995, non-significant decrease in men (41%; SE 2.9, p=NS) and a non-significant increase in women (31%; SE 2.4, p=NS).

6. Diet scores (Results for 1992 not given)

No significant changes from 1984 to 1995 for men or women in intake of foods rich in saturated fat, traditional foods, butter or olive oil. Consumption of corn oil increased significantly in men (1984: 0.8; SE 0.0 to 1995: 1.4; SE 0.1, p=0.0001) but not women. Consumption of lard decreased significantly in men (1984: 0.8; SE 0.0 to 1995: 0.6; SE 0.0, p=0.0001) and women (1984: 0.8; SE 0.0 to

was used.

Incomplete data is reported for diet from the food frequency questionnaires (Measured in 1992 but not reported).

Retrospective survey is likely to be biased: programme staff asked respondents about lifestyle change in the context of the CVD programme. Retrospective survey is also uncontrolled and results are badly reported with no statistical analysis.

The reporting of p values in the study is misleading: * is used to signify p=0.0001 whilst **** is used to signify p=0.05.

1995: 0.6; SE 0.0, p=0.0001).

b) Retrospective survey

No statistical analysis.

Possible trend for higher reported change in urban than rural participants and in men compared to women.

Table 3.3: Cardiovision 2020

Programme details	Intervention, policy, strategy or programme description	Programme/sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive results)	Confounders and limitations
Title: CardioVision 2020 **Relevant papers:** Kottke et al. CardioVision 2020 Program acceptance and progress after 4 years. American journal of Preventive Medicine 2006; 30 (2): 137-143 (6) Kottke et al. The CardioVision 2020 baseline community report card. Mayo Clin Proc. 2000; 75: 1153-1159 (5)	**Aim:** To make Olmsted county the healthiest county in the United States by the year 2020. **Intervention:** Media campaign including television programmes, radio interviews and features in newspapers. "Behavioural journalism"; publicising healthy behaviours of real people living in the community. Contests and competitions for smoking cessation, physical activity and weight control. Emphasis on environmental changes. Aims: Public environment free of smoke, free of promotion of tobacco products and to stop the sale of tobacco to youth. Nutritious foods, clearly labelled, readily available and widely promoted. Opportunities for physical activity, widespread and widely	**Intervention group:** The county of Olmsted in Minnesota (n=87,685). **Control group:** The whole of Minnesota and the US population were used as control groups for comparison of some programme outcomes although changes in other risk factors were just assessed as trends over time. **Included participants:** ≥20 years **Excluded:** None	4 years (1999-2004) Four independent cross sectional surveys at baseline (1999) and in 2000, 2001 and 2003 National and Minnesota state data (for the control) was obtained from the Behavioural Risk Factor Surveillance System (BRFSS).	**Primary outcomes:** The proportion of participants reporting: behavioural change as a result of CardioVision 2020, doing something to try to lower cholesterol, reducing fat in diet/watching diet/eating a balanced diet/eating better to lower cholesterol, trying to increase exercise level, participation in any physical activity during past month and not being a current smoker. The reported average number of fruit and vegetables eaten per day, average minutes of physical activity per week and BMI (from reported height	**Primary outcomes:** 1. Smoking: Proportion reporting not current smokers stable in Olmsted (1999: 84%, 2000: 83%, 2001: 84%, 2003: 84%), Minnesota (1999: 80%, 2000: 83%, 2001: 79%, 2002: 79% and 2003: 78%) and the whole country (77% at each time point), no significant differences in linear trends for Olmsted versus Minnesota or national trends. 2. BMI (kg/m^2): tended to increase in Olmsted (1999: 26.43, 2000: 26.25, 2001: 26.19, 2003: 27.04), Minnesota (1999: 26.01, 2000: 26.20, 2001: 26.80, 2002: 26.80, 2003: 26 72) and nationally (1999: 26.36, 2000: 26.53, 2001: 26.74, 2002: 26.79, 2003: 26.87), no significant differences in linear trends for Olmsted versus Minnesota or national trends. 3. Physical exercise: Proportion reporting physical exercise during past month stable in Olmsted (1999: 82%, 2000: 86%, 2001: 85%, 2003: 84%) and Minnesota (2000: 73%, 2001: 74%, 2002: 75% and	**Identified by author** Self-reported data may be biased. A similar county to Olmsted was not used as a control group. Positive changes were not solely due to the project achievements. The implementation of smoke-free restaurants resulted from the work of many individuals and organisations and the meeting of blood pressure and cholesterol goals was likely to be due to the efforts of community physicians who organised their practices to achieve these goals. **Identified by reviewer:** Although data from four survey years was used to calculate trends for Olmsted, there were less data points available to determine National and Minnesota trends. Response rates for telephone

Study design: Time series (cross sectional method of data collection), controlled with population surveillance data **QA Grade: '-'**	promoted. Smoke free restaurants used menu labelling to identify low salt, low saturated fat and low calorie foods. Labelling was also used in cafeterias and by suppliers of ready-to-eat foods. The construction of walking/cycling trails advocated to increase opportunities for physical activity. Individuals encouraged to make their own goals, similar to those of the CardioVision community strategy. Personal goals related to smoking cessation, fruit and vegetable intake, low fat meat and fat free dairy product consumption, cholesterol and lipid levels, systolic and diastolic blood pressure and physical activity. The aim of CardioVsion was also to work towards improved clinical care systems for the secondary prevention and treatment of elevated CVD risk factors. **Comparison:** No intervention	**Setting:** Olmsted, Minnesota, US	and weight). Percentage of participants reaching CardioVision personal goals: zero tobacco use, zero exposure to environmental tobacco smoke, eating 5 servings of fruits and/or vegetables per day, cholesterol <200 mg/dl, systolic blood pressure <130 mmHg, diastolic blood pressure <85 mmHg and does some form of physical activity every day.	2003: 75%) and increased nationally (2000: 73%, 2001: 80%, 2002: 83%, 2003: 85%). Linear trends significantly more positive for Minnesota (p=0.028) and nationally (p<0.001) compared to Olmsted. 4. Fruit and vegetable intake: Proportion reporting eating five servings of fruit and vegetables per day increased in Olmsted (1999: 27%, 2000: 30%, 2001: 31%, 2003: 32%), but decreased in Minnesota (2000: 34%, 2002: 23%, 2003: 27%) and nationally (2000: 25%, 2002: 24%, 2003: 23%), linear trend was more positive for Olmsted compared to national trends (p=0.078, NS) and significantly more positive for Olmsted compared to Minnesota (p=0.012). Number of portions of fruit and vegetables eaten per day (mean) increased in Olmsted (1999: 4.03, 2000: 4.09, 2001: 4.15, 2003: 4.18) but decreased in Minnesota (2000: 4.23, 2002: 3.70, 2003: 3.97) and nationally (2000: 3.93, 2002: 3.84, 2003: 3.76), significantly more positive trends for Olmsted compared to Minnesota (p=0.027) and national trends (p=0.011).	questionnaires were stable but response rates declined for postal surveys over the four survey years. In later years, greater response of 'healthy' individuals or those adopting healthier lifestyles, compared to earlier surveys, would tend to result in positive trends for outcome measures and may have acted to favourably bias results. It is not clear whether outcomes assessed against Minnesota and national trends were obtained from telephone or mailed questionnaires.

Table 3.4: The German CINDI

Programme details	Intervention, policy, strategy or programme description	Programme/sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive results)	Confounders and limitations
Title: The German CINDI **Relevant papers:** Wiesemann et al. Four years of practice-based and exercise-supported behavioural medicine in one community of the German CINDI area. Orthopedics and Clinical Science 1997; 18: 308-315 (7) Wiesemann et al. Cardiovascular risk factors and motivation for a healthy life-style in a German community – results of the GP-based Oestringen study. Patient Education and Counseling 2004; 55: 40-47 (8) **Study design:** Cross sectional surveys,	**Aim:** To improve cardiovascular health by reducing rates of smoking, hypertension, obesity, hypercholesterolaemia and sedentary lifestyle. **Intervention:** The "Three-level-strategy" consisted of: 1) Individual counselling from primary care physicians to give information on cardiovascular risks and advice on healthy lifestyle behaviours. 2) Group counselling, given by physicians to patients in their practice in specialised programmes e.g. smoking cessation, hypertension prevention etc. 3) Community-based counselling courses and health promoting activities e.g. exercise-based courses and health promoting activities in nurseries, worksites, sports clubs and schools. Emphasis on increasing rates of physical exercise. Exercise-based groups were 'prescribed' by GPs e.g. jogging and stress management, swimming and	**Intervention group:** Oestringen (n= 12,500), small provincial town. **Control group:** No control group used **Included participants:** ≥16 years **Excluded:** None **Setting:** Oestringen, Germany	3 years (1992-1995) Evaluated from data collected during medical examinations by GPs in 7 practices Random independent samples of patients assessed each year: 1992 (n= 1,176) 1993 (n=1,057) 1994 (n=1,381) 1995 (n=1,267)	**Primary outcomes:** Smoking, hyper-cholesterolaemia, obesity and hypertension.	Results presented as trends over time but do not show net intervention effect (no control group was used). **Primary outcomes:** 1. Smoking: Prevalence decreased from baseline (1992: 20.8%; CI ±2.3) and was significantly lower in 1993 (16.0%; CI ±2.2, p<0.01), 1994 (16.8%; CI ±2.0, p<0.01) and 1995 (17.1%; CI ±2.1, p<0.05) (differences are for comparisons with baseline). 2. Hypertension: Prevalence decreased from baseline (1992: 28.5%; CI ±2.6) and was significantly lower in 1993 (19.0%; CI ±2.4, p<0.01), 1994 (21.6%; CI ±2.2, p<0.01) and 1995 (19.5%; CI ±2.3, p<0.01) (differences are for comparisons with baseline). 3. Hypercholesterolaemia: Prevalence increased and then stabilised during the intervention period: Baseline (21.8%; CI ±2.4), 1993 (31.3%; CI ±2.9, p<0.01), 1994 (31.0%; CI ±2.5, p=NS) and 1995 (28.3%; CI ±2.7, p=NS) (differences from previous survey year assessed for significance). 4. BMI: Prevalence of obesity increased and then stabilised during the intervention period: Baseline (17.4%; CI ±2.2), 1993 (18.8%; CI ±2.4, p=NS), 1994 (18.8%; CI ±2.1, p=NS) and 1995 (18.7%; CI ±2.2, p=NS) (differences from previous survey year assessed for	**Identified by author** An absence of an effect on BMI may be due to people giving up smoking and eating more in compensation. **Identified by reviewer:** Participants of the evaluation surveys were people attending their GP and ~75% were 40 years or older. This is not a community representative sample and, when assessing the effect of intervention on the whole community level, this should be taken into account. Significance testing was done for differences from baseline for the prevalence of smoking and hypertension but, for the prevalence of hypercholesterolaemia and obesity, differences from the last survey year were assessed. This is misleading and, had differences for hypercholesterolaemia and obesity been assessed from baseline it may be that significant increases would have been reported.

uncontrolled **QA Grades: '-'**	dietary counselling etc. **Comparison:** No intervention				significance).	

Table 3.5: Coalfields Healthy Heartbeat

Programme details	**Intervention, policy, strategy or programme description**	**Programme/sample & setting**	**Duration of study and follow-up period/s**	**Primary and secondary outcomes**	**Results (significant positive results)**	**Confounders and limitations**
Title: Coalfields Healthy Heartbeat **Relevant papers:** Higginbotham et al. Reducing coronary heart disease in the Australian Coalfields: evaluation of a 10-year community intervention. Social science & Medicine 1999; 48: 683-692 (9) **Study design:** Controlled population census, controlled cross sectional surveys. **QA Grades: '-'**	**Aim:** To prevent heart disease through community activation **Intervention:** Initially project coordinator delivered presentations to schools, workplaces, social clubs, women's groups etc to raise awareness of CVD and the programme. Although the goal was to promote community involvement, in practice mobilisation was difficult and most activities implemented by the project coordinator. Interventions included a media campaign (with continuing radio broadcasts), public displays, guest speakers at clubs, schools and worksites, heart health promotions such as 'Heart Week', a community fun run and a motorcycle race, a rehabilitation exercise program and telephone counsellors were trained. Many activities targeted	**Intervention group:** Coalfields district (n= 46,520) in the Hunter region. Centre for coal mining with large population of migrants from northern England and Wales, UK. **Control group:** Other areas in the Hunter region: Newcastle, Lake Macquarie, Maitland and Port Stephens (N not given). **Included participants:** 35-64 years **Excluded:** None **Setting:** Coalfields, Hunter	10 year intervention began in 1990, evaluation of trends from 1984-1994 Data obtained from the MONICA surveillance project, monitored trends in non-fatal MI and coronary death. 3 independent cross-sectional surveys used to determine risk factors. Response rates were 70% and 68% in 1983, 63% and 60% in 1988-1989 and 63% and 62% in 1994 in treatment and control areas	**Primary outcomes:** Rates of non-fatal MI, coronary death, case-fatality (calculated by dividing no. deaths/no. events), BMI, diastolic and systolic blood pressure, cholesterol and proportion with no physical activity.	**Primary outcomes:** Results are presented as annual changes. 1. Fatal coronary event (rate per 100,000): decreased in Coalfields men (-10.9; CI -18.2 to -3.6) to a greater extent than control men (-7.0; CI -9.3 to -4.7), NS. In women, fell more in the Coalfields area (-14.2; CI -26.0 to -2.4) than the control (-7.8; CI -12.8 to -2.9), NS. 2. Non-fatal MI (rate per 100,000): increased in Coalfields men (+3.2; CI -0.6 to 7.0) but decreased in control men (-2.5; CI -4.5 to -0.5), difference nearly significant. In women, increased in Coalfields (+1.7; CI -4.4 to +7.9) and decreased in control (-3.6; CI -7.0 to -0.2), NS. 3. Case fatality: decreased in Coalfields men (-17.2%; CI -25.1 to -9.3) and control men (-5.1%; CI -7.8 to -2.4) difference between areas significant. In women, decreased in Coalfields (-16.9%; CI -30.1 to -3.7) and control (-4.5%; CI -9.0 to -0.1), NS. 4. Smoking rates: decreased in Coalfields men (-0.45%; CI -1.82 to 0.9) and control (-1.27%; CI -1.68 to -0.86), NS. Increase in Coalfields women	**Identified by author** No clear pattern of changes in risk factor levels or reductions in non-fatal MI. Apparent treatment effect on case fatality was probably due to the very efficient transportation of people with MI to hospital in the Coalfields. CVD risk factors were higher in the Coalfields than the control areas and it may be that risk factor levels would have continued to worsen naturally. Positive intervention effects may not have been recognised as the programme may have been acting just to prevent further disparity between the Coalfield and control communities. **Identified by reviewer:** The Coalfields population may have been different to the control population in many respects such as socioeconomic status,

	nutrition, exercise and smoking: cooking classes, cooking demonstrations, supermarket tours, weight control classes, exercise classes, publishing of a walking trails book and anti-smoking programs aimed at adolescents and adults. There was environmental and institutional development in schools, restaurants, retailers, fast food outlets and projects were initiated by industry. **Comparison:** No intervention	region, New South Wales, Australia	respectively.		(+0.49%; CI -0.59 to +1.56), significantly different to decrease in controls (-0.66%; CI -1.01 to -0.30). 5. Proportion of people reporting no physical activity: decreased in Coalfields men (-1.14%; CI -2.91 to +0.63) and increased in control men (+0.42%; CI -0.04 to 0.88), NS. Decreased in Coalfields women (-1.08; CI -2.99 to +0.83) but increased in controls (+0.21; CI -0.37 to 0.79), NS. 6. Other risk factors: BMI increased whilst levels of other risk factors tended to decrease over time and changes in BMI, diastolic and systolic blood pressure and cholesterol were similar both areas.	ethnicity and provision of healthcare. Although the programme only began in 1990, trends from 1983/4 to 1994 were used to inform results.

Table 3.6: The Franklin Cardiovascular Health Program

Programme details	**Intervention, policy, strategy or programme description**	**Programme/sample & setting**	**Duration of study and follow-up period/s**	**Primary and secondary outcomes**	**Results (significant positive results)**	**Confounders and limitations**
Title: The Franklin Cardiovascular Health Program **Relevant papers:** Burgess et al. Mortality impact of an integrated community cardiovascular health program. American Journal of Preventative Medicine 2000; 19(1): 30-38 (10)	**Aim:** To reduce risk factors for CVD **Intervention:** Media campaigns, environmental modifications, group education, training given to local personnel, education provided for healthcare professionals. Interventions delivered via community organisations, school and worksites and interventions also took place in supermarkets, restaurants and medical settings.	**Intervention group:** Franklin (n=29,645), 23 predominately rural communities. **Control group:** Oxford and Somerset, (n=53,000 and 51,000 respectively), similar in demographic and risk factor profiles. Whole of the state	20 years (1974-1994) Data from the Maine Office of Data, Research and Vital Statistics and Maine's Bureau of Health and Departments of Education, Human Services and Labour. Mortality rates over period of programme	**Primary outcomes:** Rates of death from heart disease, coronary heart disease and stroke	**Primary outcomes:** Relative rates (RR) are given for death rates relative to control communities 1. Heart disease-related death rate Rate of death from heart disease in Franklin significantly lower relative to Maine (RR 0.91, CI 0.06, p<0.05) and Somerset (RR 0.82, CI 0.06, p<0.05) but not significantly lower relative to Oxford (0.96, CI 0.09, p=NS). 2. Coronary heart disease-related death rate	**Identified by author** Only an observational, retrospective study, associations do not prove cause and effect. Observations may reflect undetected secular trends specific to the county of Franklin. In the early stages, effects brought about by institution of the Regional Health Associates could not be separated from the effect of the programme. Mortality rates based on death certificates may or may not be fully reliable. Awareness of physicians to the programme

Study design: Controlled population census **QA Grades: '+'**	Collaboration with health care agencies and with emphasis on risk factor screening and follow up. Professional nurses and physicians involved, reciprocal referrals made between medical and programme staff. Individuals screened for CVD risk given personal counselling and provided with a copy of their results. Screenings publicised by employers, followed up with mailed reminders for repeat visits. **Comparison:** No intervention	of Maine (n=1,240,280), also used as control. **Included participants:** Whole population **Excluded:** None **Setting:** Franklin, Maine, US	implementation compared for intervention and control areas.	Rate of death from coronary heart disease in Franklin significantly lower relative to Maine (RR 0.91, CI 0.06, p<0.05) and Somerset (RR 0.82, CI 0.06, p<0.05) but not significantly lower relative to Oxford (0.96, CI 0.1, p=NS). 3. Stroke-related death rate Rates of stroke-related death lower in Franklin than in controls but not significant for Maine (RR 0.90, CI 0.10, p=NS), Somerset (RR 0.94, CI 0.16, p=NS) or Oxford (RR 0.89, CI 0.12, p=NS).	objectives may have influenced coding of causes of death. However, this would not affect total death rates and, since findings for death from heart disease, coronary heart disease and stroke were consistent with those for total death rate, this suggests lack of systematic bias. **Identified by reviewer:** The national blood pressure and cholesterol education campaigns were likely to have positive effects and there may have been a large number of screenings and follow-up of individuals.

Table 3.7: Have a Heart Paisley

Programme details	Intervention, policy, strategy or programme description	Programme/sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive results)	Confounders and limitations
Title: Have a Heart Paisley **Relevant papers:** Evaluation report: http://www.healthscotland.com/documents/1781.aspx (11) **Study designs:** Controlled before and after study (cohort method of data	**Aim:** To reduce the total burden of CVD and to specifically address levels of health inequality using strategies for both primary and secondary prevention **Intervention:** Programme implemented via community groups and the local authority and targeted primary and secondary CVD prevention. A steering group guided project direction whilst a management group provided ongoing project coordination and delivery in three main areas: smoking,	**Intervention group:** Paisley, shown to have many areas with high levels of deprivation and high levels of inequality in health status. **Control group:** Inverclyde, served by the same NHS board (Argyll and Clyde), and had similar	2.5 years Baseline and 2.5 year surveys in cohort of participants: 556 participants completed both questionnaires: 276 Paisley 280 Inverclyde (response rate ~75%).	**Primary outcomes:** All outcome measures were self reported: Self-assessed health, presence of high blood pressure, taking medication for high blood pressure, diabetes, high cholesterol, current smoking status, number of cigarettes smoked, changes in tobacco use within last 6 months, smoking cessation, levels of physical activity, changes in eating habits, current weight, type of spread used on bread, type of milk used for drinks and	**Primary outcomes:** No significant intervention effect for any outcome variable except for correct knowledge of the number of portions of fruit/vegetables/ salad that should be eaten per day. Knowledge increased in both groups but change was larger in the control and showed a significant	**Identified by author** Poor survey response rates reduced the power of evaluation and increased the possibility that effects of intervention were not detected. The survey may not have been fully representative of the socioeconomic, age and sex demographics of Paisley and may not have reflected risk factors and behaviours of the whole intervention area. There may have been contamination from treatment to reference area

collection) **QA Grades: '-'**	healthy eating and physical activity. The 'HEAL' project aimed to improve the quality of diets, influence food choices and increase opportunities for physical activity in people receiving community care. The 'Healthy at Work – Healthy for Life' project targeted employees of Renfrewshire council. The Health Promoting School Project consisted of education and promotion activities in nursery, primary and secondary schools. Increased physical activity was encouraged through the 'Healthercise' project. Strategies used within the health service: training given to NHS staff, Central Data Repository register developed to help in the clinical audit of patients with CHD. The 'Improving the patient pathway' project aimed to improve awareness, better community links and streamlining the continuum from primary/ secondary/tertiary care. Specific support given to a project with the aim of reducing morbidity and mortality in patients with diagnosis of CVD. **Comparison:** No intervention	socioeconomic profile and similar levels of CVD. **Included participants:** Adults aged 20-69 years **Excluded:** Not stated **Setting:** Paisley, Scotland	cereals, number of portions of fruit eaten per day, number of portions vegetables eaten per day. Presence of: angina, coronary artery bypass, coronary angiogram, coronary angioplasty, myocardial infarction, heart failure, stroke and asked to rank themselves on a scale of hopelessness. Knowledge: the importance of avoidance of passive smoking, limiting tea and coffee intake, avoiding food additives, eating oily fish, having regular blood pressure checks, having regular chest x-rays in relation to CVD, having regular medical check-ups, reducing cholesterol levels, taking medication to keep blood pressure down. Their knowledge was also tested regarding the level of physical activity needed and the number of fruit and vegetables/salad that should be eaten to stay healthy.	trend in favour of the control (p=0.005).	because they were in close proximity. The timescale of evaluation may have been too short to provide changes influenced by policies and agendas (e.g. workplace smoking and nutrition policies). **Identified by reviewer:** The final questionnaire was modified to focus on areas where change was thought most likely to occur from previous formative evaluation. This change from the initial protocol was likely to increase the likelihood of detecting positive intervention effect since it allowed pre-selection of factors most likely to show positive outcome measures. There is no reported adjustment in significance testing despite multiple outcomes testing.

Table 3.8: The Olofström community intervention programme

Programme details	Intervention, policy, strategy or programme description	Programme/sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive results)	Confounders and limitations
Title: The Olofström community intervention programme **Relevant papers:** Isacsson et al. Community intervention against non-insulin dependent diabetes mellitus (NIDDM) and cardiovascular disease: A study based on Swedish health care. Cardiovascular Risk Factors 1996; 6(3): 164-171 (12) **Study design:** Observational semi-independent cross sectional surveys **QA Grades: '-'**	**Aim:** To improve the health of the community by reducing the incidence of CVD and NIDDM and to prevent/postpone associated complications. **Intervention:** A steering committee led the intervention and a local working group, coordinated by a registered nurse was responsible for organising and supervising activities. Meetings were held to inform residents of the local incidence of CVD and diabetes and to relate diseases to lifestyle factors. A local physician or nurse was present to answer questions and screenings were offered to all attendees. Screening: Adults 30-64y visiting the health centre invited. Dietary advice/printed information/referral to a district physician given depending on the level of CVD risk. Those with high cholesterol/blood pressure/blood glucose directed to special programmes for lipid reduction/hypertension/ diabetes. Schools: In a primary school, education program led by the school physician and nurse, class education for children	**Intervention group:** Olofström (n=15,000), in the county of Blekinge, southern Sweden. Large manufacturing industry: 54% blue collar workers, 38% white collar workers. A relatively high rate of CVD mortality observed compared to other southern Swedish communities. **Control group:** The MONICA survey in northern Sweden. **Included participants:** Adults 30-64y **Excluded:** None **Setting:** Olofström, Blekinge, southern Sweden	Studied over 4 years (1989-1993) Cross sectional surveys at baseline (1989), 1991 and 1993. Samples were approximately 50% participants who had undergone the previous survey and 50% new participants. Response rates and numbers of participants: 1989 n=347 (79%), 1991 n=312 (70%) and 1993 n=325 (74%).	**Primary outcomes:** BMI, cholesterol, diastolic and systolic blood pressure, smoking and non-fasting blood glucose	**Primary outcomes:** No control group used so results simply show changes from baseline to intervention years 2 (1991) and 4 (1993) 1. Cholesterol In men, total cholesterol decreased from baseline (5.65 mmol/l; SE 0.07), significantly lower after two (5.25 mmol/l; SE 0.07, p<0.001) and four years (5.26 mmol/l; SE 0.07, p<0.001). In women, significant changes from baseline (5.73 mmol/l; SE 0.09) to two (5.35 mmol/l; SE 0.09, p<0.01) and four years (5.43 mmol/l; SE 0.09, p<0.05). In the Monica survey (control), in men, no significant change in cholesterol level from 1986 (6.25 mmol/l) to 1991 (6.41 mmol/l) and, in women, no significant change from 1986 (6.18 mmol/l) to 1991 (6.25 mmol/l). 2. Blood pressure In men, systolic blood pressure decreased from baseline (137.4 mmHg; SE 1.2), significantly lower after two (130.7 mmHg; SE 1.3, p<0.001) and four years (131.5 mmHg; SE 1.3, p<0.001). In women, decreases from baseline (133.0 mmHg; SE 1.2) significant after to two (127.2 mmHg; SE 1.4, p<0.01) but not four years (130.1 mmHg; SE 1.6, p=NS). In men, diastolic blood pressure decreased from baseline (85.0 mmHg; SE 0.6), significantly lower after two (80.5 mmHg; SE 0.7, p<0.001) and four years (80.4 mmHg; SE 0.8, p<0.001). In women, significant changes from baseline (82.0 mmHg; SE 0.7) after two (77.8 mmHg; SE 0.7, p<0.001) and four years (78.7 mmHg;	**Identified by author** None given **Identified by reviewer:** The MONICA survey in northern Sweden was used to provide control group data. Although MONICA reports results for cholesterol and diastolic blood pressure they are not given for systolic blood pressure, BMI or rates of smoking. Control changes in MONICA are not used to calculate net intervention effect or even presented in the results section. Since it appears that the same positive trends were not observed in the MONICA population, it may be likely that net positive intervention effects would be found and this would have added strength to claims of an intervention effect.

aged 7-13 years and one-to-one discussion with those aged 15-18 years.

Environmental: Recipes for low fat/low saturated fat/high fibre meals distributed in supermarkets and worksites and at the library, pharmacy and health centre. Discount campaigns for low fat and high fibre foods were implemented by stores.

Education: Nutrition teaching offered to employees of supermarkets, restaurants and cafes, information meetings arranged with food sector business associations. Advanced educational programmes provided for dieticians, teachers of domestic science and managers of worksites, school canteens and supermarkets. Lectures given to school teachers, sports and exercise instructors, union members and voluntary organisations.

Media: magazine distributed to each household, articles displayed in local newspapers, broadcasts of lectures and programme activities made by the local radio station.

Comparison:

No intervention

SE 0.8, p<0.01).

In the MONICA survey (control), diastolic blood pressure increased slightly in men (1986: 82.6 mmHg to 1991: 83.5 mmHg) and women (1986: 79.8 mmHg to 1991: 79.3 mmHg) (NS). Not information in MONICA for systolic blood pressure results.

3. BMI

In men, BMI increased from baseline (25.9 kg/m^2; SE 0.23) to two (26.3 kg/m^2; SE 0.26) and four years (26.4 kg/m^2; SE 0.27), differences NS. In women, BMI increased from baseline (25.3 kg/m^2; SE 0.33) to two (25.4 kg/m^2; SE 0.35) and four years (25.1 kg/m^2; SE 0.30), differences NS.

Data from MONICA survey not reported in results.

4. Non-fasting blood glucose

In men, non-fasting glucose decreased significantly from baseline (5.40 mmol/l; SE 0.08) after two (5.17 mmol/l; SE 0.09, p<0.05) and four years (5.10 mmol/l; SE 0.09, p<0.01). In women, non-fasting glucose decreased significantly from baseline (5.75 mmol/l; SE 0.07) after two (5.33 mmol/l; SE 0.08, p<0.001) and four years (5.29 mmol/l; SE 0.09, p<0.001).

No details of blood glucose given in the MONICA report.

5. Smoking

Prevalence of smoking increased throughout intervention years from baseline (26.2%) to two (27.6%) and four years (28.6%), differences NS.

Data from MONICA survey not reported in results.

Table 3.9: The Quebec Heart Health Demonstration Project - Rural

Programme details	Intervention, policy, strategy or programme description	Programme/sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive results)	Confounders and limitations
Title: The Quebec Heart Health Demonstration Project - Rural **Relevant papers:** Huot et al. Effects of the Quebec Heart Health Demonstration Project on adult dietary behaviours. Preventative Medicine 2004; 38: 137-148 (13) **Study design:** Controlled cross sectional surveys **QA Grades: '-'**	**Aim:** To reduce risk factors for CVD **Intervention:** Freedom given to the local Public Health Department to determine objectives, target population, intervention strategies and method for evaluation. Ten groups of local volunteers developed and implemented the community programme. They were offered a 21 hour course on health promotion, developed specifically for the project at a local college. Educational tools were developed by the local health department for use by the volunteers including pamphlets, a video, tips for restaurant choices, games and posters. The most commonly implemented projects were screening sessions for hypertension and hypercholesterolemia, supermarket tours, distribution of healthy recipe books, healthy food tastings, cooking classes,	**Intervention group:** 10 municipalities in the rural area of Rivière-du-Loup (n=90,000), located 500km east of the city of Montral. **Control group:** 9 control municipalities (location not stated), selected on the basis of criteria of sufficient geographical distance (to prevent contamination), the absence of community heart health initiatives in previous year, similar size to intervention communities. On average, communities had similar mean age and socioeconomic status to intervention communities. **Included participants:** Children in grades 4-6 and their parents **Excluded:** None **Setting:** Rivière-du-Loup,	Five year intervention. Surveys were taken at baseline (1993) and four years into intervention (1997). 1993: 780 adult participants from the intervention community and 634 from the control. 1997: 1,187 adult participants from the intervention community and 747 from the control.	**Primary outcomes:** Global Dietary Index, Dairy Consumption Index, Meat Consumption Index, Fat Consumption Index, intentions to change dietary behaviours: increasing consumption of low fat meats, increasing skimmed milk consumption, increasing low fat processed meat consumption.	**Primary outcomes:** Results are given for parents of children attending schools in intervention/control areas. Lower values for dietary indexes indicate more favourable diets. 1. Global Dietary Index In men, Global Dietary index increased in the intervention group (1993: 0.85; SD 0.19 to 1997: 0.88; SD 0.20) and the control (1993: 0.87; SD 0.20 to 1997: 0.91; SD 0.21), no significant difference between the size of group changes. In women, Global Dietary Index increased in the intervention group (1993: 0.74 SD 0.18 to 1997: 0.77; SD 0.20) and the control (1993: 0.76; SD 0.19 to 1997: 0.80; SD 0.20), no significant difference between the size of group changes. 2. Dairy Consumption Index In men, Dairy Consumption Index increased in the intervention group (1993: 1.1; SD 0.35 to 1997: 1.11; SD 0.35) and the control (1993: 1.1; SD 0.35 to 1997: 1.18; SD 0.36), no significant difference between the size of group changes. In women, Dairy Consumption Index increased in the intervention group (1993: 0.99 SD 0.36 to 1997: 1.02; SD 0.36) and in the control (1993: 1.01; SD 0.34 to 1997: 1.09; SD 0.36), no significant difference between the size of group changes. 3. Meat Consumption Index In men, Meat Consumption Index	**Identified by author** Strong secular trends may have masked intervention effects. Programme messages may have been too general and not sufficiently practical to induce changes. The cross sectional method of assessment may not have been powerful enough to detect change (less powerful than cohort). There may have been cross community contamination: 19% of residents in intervention compared to 15% of residents in control areas participated in heart health activities. The adult sample was not representative of the community adult population as it only contained parents of children attending intervention/control schools. Food frequency questionnaires may have been subject to reporting bias. The low-intensity intervention may have had a bigger impact if it had been delivered to a larger segment of the community. **Identified by reviewer:** Response rates for parents participating in surveys were not detailed and participants may not have been a typical

walking clubs and conferences. Social support groups were created for people with hypercholesterolemia and for patients with ischemic heart disease. **Comparison:** No intervention	Quebec, Canada		decreased in the intervention group (1993: 0.80; SD 0.26 to 1997: 0.63; SD 0.22) and the control (1993: 0.81; SD 0.27 to 1997: 0.64; SD 0.22), no significant difference between the size of group changes. In women, Meat Consumption Index increased in the intervention group (1993: 0.66 SD 0.23 to 1997: 0.68; SD 0.24) and the control (1993: 0.69; SD 0.24 to 1997: 0.71; SD 0.25), no significant difference between the size of group changes. 4. Fat Consumption Index In men, Fat Consumption Index increased in the intervention group (1993: 0.63; SD 0.32 to 1997: 0.68; SD 0.36) and the control (1993: 0.67; SD 0.34 to 1997: 0.70; SD 0.37), no significant difference between the size of group changes. In women, Fat Consumption Index increased in the intervention group (1993: 0.53 SD 0.31 to 1997: 0.58; SD 0.35) and stayed the same in the control (1993: 0.56; SD 0.33 to 1997: 0.61; SD 0.36), no significant difference between the size of group changes. 5. Health-related behaviours and intentions Data not presented except to comment that, in intervention men, there was increased consumption of low fat processed meats (p=0.02). Whether this change was significantly different in intervention and control communities is not stated.	representation of all parents (or indeed the true adult population). Those that were healthier, or who had made behavioural modifications since the last survey, may have been more likely to take part.

Table 3.10: The Quebec Heart Health Demonstration Project - Suburban

Programme details	Intervention, policy, strategy or programme description	Programme/sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive results)	Confounders and limitations
Title: The Quebec Heart Health Demonstration Project - Suburban **Relevant papers:** Huot et al. Effects of the Quebec Heart Health Demonstration Project on adult dietary behaviours. Preventative Medicine 2004; 38: 137-148 (13) **Study design:** Controlled cross sectional surveys **QA Grades: '-'**	**Aim:** To reduce risk factors for CVD **Intervention:** Freedom given to the local Public Health Department to determine objectives, target population, intervention strategies and method for evaluation. Intervention was community based and activities largely related to nutrition and physical activity. Articles were put in local newspapers and there were nutrition related activities such as taste-testing sessions. Conferences and workshops on healthy eating were run as well as games on heart health in local shops. Activities for increasing physical activity were also implemented such as a walking club and physical activity projects in local parks. **Comparison:** No intervention	**Intervention group:** Fabreville (n=35,216), suburban area in North Montreal. **Control group:** Two control communities (location and size not stated) were selected with a similar distribution of age and income to Fabreville. **Included participants:** Children in grades 4-6 and their parents **Excluded:** None **Setting:** Fabreville, Quebec, Canada	Five year intervention. Surveys were taken at baseline (1993) and four years into intervention (1997). 1993: 571 adult participants from intervention community and 564 from control. 1997: 621 adult participants from intervention community and 1,27 from control.	**Primary outcomes:** Global Dietary Index, Dairy Consumption Index, Meat Consumption Index, Fat Consumption Index and intentions to change dietary behaviours: increasing consumption of low fat meats, increasing skimmed milk consumption, increasing low fat processed meat consumption.	**Primary outcomes:** Results are given for parents of children attending schools in intervention/control areas. Lower values for dietary indexes indicate more favourable diets. 1. Global Dietary Index In men, Global Dietary index decreased in the intervention group (1993: 0.82; SD 0.20 to 1997: 0.80; SD 0.20) and the control (1993: 0.81; SD 0.20 to 1997: 0.80; SD 0.20), no significant difference between the size of group changes. In women, Global Dietary Index decreased in the intervention group (1993: 0.71 SD 0.20 to 1997: 0.68; SD 0.19) and remained constant in the control (1993: 0.69; SD 0.18 to 1997: 0.69; SD 0.19), no significant difference between the size of group changes. 2. Dairy Consumption Index In men, Dairy Consumption Index decreased in the intervention group (1993: 1.03; SD 0.35 to 1997: 1.01; SD 0.35) and the control (1993: 1.05; SD 0.34 to 1997: 1.0; SD 0.34), no significant difference between the size of group changes. In women, Dairy Consumption Index decreased in the intervention group (1993: 0.92 SD 0.37 to 1997: 0.90; SD 0.36) and in the control (1993: 0.94; SD 0.35 to 1997: 0.91; SD 0.36), no significant difference between the size of group changes. 3. Meat Consumption Index In men, Meat Consumption Index decreased in the intervention group (1993: 0.80; SD 0.25 to 1997: 0.76; SD	**Identified by author** Strong secular trends may have masked intervention effects. Participation in intervention activities was low e.g. 10 nutrition meetings were cancelled on the basis of poor participation and the one session that was held drew only 15 participants. Programme messages may have been too general and not sufficiently practical to induce changes. The cross sectional method of assessment may not have been powerful enough to detect change (less powerful than cohort). The adult sample was not representative of the community adult population as it only contained parents of children attending intervention/control schools. Food frequency questionnaires may have been subject to reporting bias. The low-intensity intervention may have had a bigger impact if it had been delivered to a larger segment of the community. **Identified by reviewer:** Response rates for parents participating in surveys were

0.24) and stayed the same in the control (1993: 0.77; SD 0.24 to 1997: 0.77; SD 0.25), no significant difference between the size of group changes. In women, Meat Consumption Index decreased in the intervention group (1993: 0.69 SD 0.24 to 1997: 0.63; SD 0.22) and the control (1993: 0.66; SD 0.24 to 1997: 0.64; SD 0.22), no significant difference between the size of group changes.

4. Fat Consumption Index

In men, Fat Consumption Index increased in the intervention group (1993: 0.53; SD 0.35 to 1997: 0.54; SD 0.35) and the control (1993: 0.54; SD 0.34 to 1997: 0.56; SD 0.34), no significant difference between the size of group changes. In women, Fat Consumption Index decreased in the intervention group (1993: 0.44 SD 0.31 to 1997: 0.43; SD 0.31) and increased in the control (1993: 0.38; SD 0.27 to 1997: 0.43; SD 0.29), no significant difference between the size of group changes.

5. Health-related behaviours and intentions

Data not presented except to comment that, in intervention men, there was increased consumption of low fat meats (p=0.02) and, in intervention women, there was increased consumption of low fat milk (p=0.04) and low fat processed meats (p=0.04). Whether these changes were significantly different in intervention and control communities is not stated.

not detailed and participants may not have been a typical representation of all parents (or indeed the true adult population). Those that were healthier, or who had made behavioural modifications since the last survey, may have been more likely to take part.

Table 3.11: The Quebec Heart Health Demonstration Project - Urban

Programme details	Intervention, policy, strategy or programme description	Programme/sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive results)	Confounders and limitations
Title: The Quebec Heart Health Demonstration Project - Urban **Relevant papers:** Huot et al. Effects of the Quebec Heart Health Demonstration Project on adult dietary behaviours. Preventative Medicine 2004; 38: 137-148 (13) **Study design:** Controlled cross sectional surveys **QA Grades: '-'**	**Aim:** To reduce risk factors for CVD **Intervention:** Freedom given to the local Public Health Department to determine objectives, target population, intervention strategies and method for evaluation. Intervention delivered through all of the eight community elementary schools and through activities aimed at parents and the wider community. In schools, twenty hours of curriculum teaching given annually covering nutrition, physical activity and prevention of smoking. Among the nutrition activities, children were taught how to select a healthy meal using the four food groups of the Canadian food guide and to choose or prepare healthy foods and snacks. Parents were invited to participate in schools and community-based activities that aimed to improve their ability to choose and prepare healthy foods. Healthy food tasting sessions were	**Intervention group:** Urban population, St-Louis-du-Parc (n=41,625); a multiethnic, low socioeconomic status neighbourhood in south-central Montreal. Diverse population with a range of principle languages spoken: 49% French, 34% English, 34% other. High presence of low educational achievement. **Control group:** Control communities not stated. Sixteen schools in the control community selected for evaluation, similar socioeconomic status, language spoken at home and geographical location **Included participants:** Children in grades 4-6 and their parents **Excluded:** None	Five year intervention. Surveys were taken at baseline (1993) and four years into intervention (1997). 1993: 619 adult participants in intervention community and 1,692 in control. 1997: 602 adult participants in intervention community and 979 in control.	**Primary outcomes:** Global Dietary Index, Dairy Consumption Index, Meat Consumption Index, Fat Consumption Index, intentions to change dietary behaviours: increasing consumption of low fat meats, increasing skimmed milk consumption, increasing low fat processed meat consumption.	**Primary outcomes:** Results are for parents of children attending intervention/control schools. Lower values for dietary indexes indicate more favourable diets. 1. Global Dietary Index In men, Global Dietary index decreased in the intervention (1993: 0.71; SD 0.19 to 1997: 0.70; SD 0.20) and the control (1993: 0.75; SD 0.20 to 1997: 0.71; SD 0.20), no significant difference between the size of group changes. In women, Global Dietary Index decreased in the intervention (1993: 0.68 SD 0.18 to 1997: 0.66; SD 0.18) and remained constant in the control (1993: 0.69; SD 0.18 to 1997: 0.69; SD 0.19), no significant difference between the size of group changes. 2. Dairy Consumption Index In men, Dairy Consumption Index decreased in the intervention (1993: 1.0; SD 0.32 to 1997: 0.99; SD 0.34) and the control (1993: 1.04; SD 0.35 to 1997: 0.98; SD 0.33), no significant difference between the size of group changes. In women, Dairy Consumption Index decreased in the intervention (1993: 1.0 SD 0.33 to 1997: 0.99; SD 0.35) and in the control (1993: 1.02; SD 0.35 to 1997: 0.99; SD 0.34), no significant difference between the size of group changes. 3. Meat Consumption Index In men, Meat Consumption Index decreased in the intervention (1993: 0.69; SD 0.25 to 1997: 0.66; SD 0.25) and the control (1993: 0.73; SD 0.26 to 1997: 0.69; SD 0.25), no significant difference	**Identified by author** Strong secular trends may have masked intervention effects. There was a social and cultural gap between parents and schools and participation of parents in intervention activities was low. Programme messages may have been too general and not sufficiently practical to induce changes. Cross sectional method of assessment may not have been powerful enough to detect change (less powerful than cohort). The urban setting intervention may have been particularly affected by cross community contamination. Adult sample was not representative of the adult population as it only contained parents of children attending intervention/control schools. Food frequency questionnaires may have been subject to reporting bias. Low-intensity intervention may have had larger impact if delivered to a larger segment of the community. **Identified by reviewer:** Response rates for parents participating in surveys were not detailed and participants

organised with the aid of a dietician, open to parents and all school personnel. **Comparison:** No intervention	**Setting:** St-Louis-du-Parc, Quebec, Canada				between the size of group changes. In women, Meat Consumption Index decreased in the intervention (1993: 0.62 SD 0.24 to 1997: 0.61; SD 0.24) and stayed the same in the control (1993: 0.65; SD 0.23 to 1997: 0.65; SD 0.23), no significant difference between the size of group changes. 4. Fat Consumption Index In men, Fat Consumption Index decreased in the intervention (1993: 0.43; SD 0.33 to 1997: 0.39; SD 0.34) and the control (1993: 0.46; SD 0.35 to 1997: 0.43; SD 0.34), no significant difference between the size of group changes. In women, Fat Consumption Index decreased in the intervention (1993: 0.40 SD 0.32 to 1997: 0.36; SD 0.29) and stayed the same in the control (1993: 0.41; SD 0.32 to 1997: 0.41; SD 0.31), no significant difference between the size of group changes. 5. Health-related behaviours and intentions Data not presented	may not have been a typical representation of all parents (or indeed the true adult population). Those that were healthier, or who had made behavioural modifications since the last survey, may have been more likely to take part.

Table 3.12: The Ebeltoft screening and counselling study

Programme details	Intervention, policy, strategy or programme description	Programme/sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive results)	Confounders and limitations
Title: The Ebeltoft screening and counselling study **Relevant papers:** Engberg et al. General health	**Aim:** To reduce rates of risk factors for CVD. **Intervention:** Initially, all GPs took part in meetings to increase their knowledge and to learn how to give appropriate dietary advice and engage in patient discussions.	**Intervention group:** Patients at GPs in Ebeltoft, Aarhus county, Denmark, a rural area (n~13,000) **Control group:** Patients in	5 years (1991-96) Random sample of 2,000 in GP registries invited to participate. Of those invited, 1,507 (75%) agreed to take part. Randomised to:	**Primary outcomes:** Cardiovascular risk score, total cholesterol, BMI, diastolic and systolic blood pressure.	**Primary outcomes:** 1. Cardiovascular risk score Significantly lower in the intervention (5.69; SD 3.05) compared to the control (6.25; SD 3.47) group (p<0.01). 2. Total cholesterol Significantly lower in intervention (5.54 mmol/l; SD 1.03) compared	**Identified by author** All intervention participants with elevated risk factors were offered consultation with a GP regardless of whether in screening or screening + consultation group. This may have been responsible for lack of difference observed between

screenings to improve cardiovascular risk profiles: A randomised controlled trial in general practice with 5-year follow-up. The Journal of Family Practice 2002; 51 (6): 546-552 (14) **Study design:** Randomised controlled trial **QA Grades: '+'**	Intervention consisted of health screenings with or without additional GP health counselling. Baseline health screenings included assessment of total cholesterol, blood pressure, BMI and tobacco use. A cardiovascular disease risk score was calculated based on these measures and on gender and family history of CVD. A few weeks later, participants received written feedback from their GPs with results and, where appropriate, lifestyle change recommendations. All participants with high cardiovascular risk scores encouraged to visit their GPs, all received a pamphlet on how to lead a healthy lifestyle. A 45 minute GP consultation was offered to those randomised to receive additional health counselling (half the intervention group). After the consultation, health-related lifestyle goals set through GP/patient discussion (maximum of 3) for the following year. A year later, participants received another questionnaire and invited to a health screening. Those in the additional health counselling group were offered GP consultations every year until the final evaluation (5 years from baseline). **Comparison:** No intervention	Ebeltoft **Included participants:** Patients aged 30-49 years registered at any of the nine general practitioners randomised to intervention or control. **Excluded:** None **Setting:** Ebeltoft, Aarhus county, Denmark	1) Health screenings 2) Health screenings + consultations with their GP 3) No intervention (control group) At the final 5y physiological evaluation, follow-up rates similar in control (73.7%, n=369), screening (75.3%, n=378) and screening + discussion (68.7%, n=346) groups.	to the control (5.68mmol/l; SD1.06) group ($p<0.05$). 3. BMI Significantly lower in the intervention (25.9kg/m^2; SD 4.1) compared to the control (26.5 kg/m^2; SD 4.4) group ($p<0.05$). 4. Blood pressure Systolic blood pressure was slightly lower in the intervention (130.9 mmHg; SD 18.2) compared to the control (132.6 mmHg; SD 19.9) but the difference was not significant. Diastolic blood pressure was slightly lower in the intervention (79.8 mmHg; SD 10.5) compared to the control (81.0 mmHg; SD 11.7) but the difference was not significant.	these groups. Low rate of participation in GP health discussions may have weakened the strength of intervention. The baseline questionnaire and contact between intervention and control participants may have induced change in the control group. **Identified by reviewer:** Despite claims by authors, analysis does not appear to truly have been done on an intention to treat basis. Baseline comparisons are not presented for most physiological variables. This is a difficulty in studies of this type where screening acts as both the intervention and also the baseline measure in the intervention group. Since the control group are not to receive the screening intervention, complete baseline data is not available and comparisons cannot be made.

Table 3.13: The Inter99 Study

Programme details	Intervention, policy, strategy or programme description	Programme sample and setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results	Confounders and limitations
Title: The Inter99 study **Relevant papers:** Von Huth Smith et al. A randomised multifactorial intervention study for prevention of ischaemic heart disease (Inter99): The long-term effect on physical activity. Scandinavian Journal of Public Health 2008; 36: 380-88 (15) Pisinger et al. Smoking reduction intervention in a large population-based study. The Inter99 study. Preventive Medicine 2005; 40: 112-18 (16) Pisinger et al. Smoking cessation intervention in a large randomised population-based study. The Inter99study. Preventive Medicine 2005; 40: 285-92 (17) **Study design:** RCT	**Aims:** To reduce ischaemic heart disease (IHD) in the general population by promoting increased physical activity, better dietary habits and smoking cessation (15). **Intervention:** Participants were randomised to receive either a high-intensity intervention (group A) or a low-intensity intervention (group B). Participants in both groups underwent a health examination, an assessment of their risk of developing IHD and individual lifestyle counselling that focused on physical activity, diet, smoking and alcohol. In addition to individualised lifestyle counselling, participants at high risk in group A were offered group counselling on diet/physical activity and/or smoking cessation or reduction. High-risk participants in group B were referred to their GP for usual care. After 12 months, the high-risk participants in both groups A and B were sent a questionnaire, invited for a further health examination and again offered individualised lifestyle counselling. Participants still at high risk in group A were again offered group counselling and those still at high risk in group B	**Intervention group** An age and sex stratified random sample of 13,016 individuals drawn from the study population of those living in the south-western part of Copenhagen County (n=61,301). Before intervention the sample was randomised into group A (90%, high-intensity intervention) and group B (10%, low-intensity intervention). **Control group** A random sample of 5,264 individuals was drawn from the remaining 48,285 individuals in the study population. **Included:** Individuals born in 1939-40, 1944-45, 1949-50, 1954-55, 1959-60, 1964-65 and 1969-70 living in 11 municipalities in the south-western part of	3 years. Assessments were undertaken at baseline, 12 and 36-months follow-up.	**Primary outcomes:** Increased physical activity, better dietary habits and smoking cessation (15).	**Primary outcomes:** Only outcome data on the effectiveness of the intervention on physical activity (15) and smoking cessation/reduction (16) has been identified. 1. Physical activity In analyses including all participants, physical activity decreased from baseline to 12 and 36-month follow-up amongst men and women in all three groups. Amongst men, the decrease in physical activity was 13min/week (p=0.27) less in group A than in group C after 12 months and 25min/week (p<0.0001) less after 36 months. The decrease in physical activity was 30min/week (p=0.006) less in group B than in group C after 36 months, but there was no significant difference between groups A and B (p=0.664). Amongst women, physical activity decreased 30min/week (p=0.004) more in group B than in group C after 12 months but there was no significant difference (0.398) after 36 months. There were no significant differences between group A and C in the decrease in physical activity after 12 months (p=0.167) or 36 months	**Identified by author:** Losses to follow-up of 20% to 25% across the two intervention and one control arms raise the possibility of selection bias. However, the use of longitudinal linear regression models with random effects in the analysis of physical activity levels help take account of loss to follow-up under the assumption of missing at random (15). **Identified by reviewers:** Low uptake (53%) of the invitation for screening and individual counselling calls into question the extent to which those receiving the intervention adequately reflect the study population. Two separate samples were drawn from the study population to form the intervention group (which was then randomised to two groups: high or low-intensity intervention) and the control group. This led to some baseline differences between the intervention and control groups. However, in their analyses the authors made adjustments to take account

Programme details	Intervention, policy, strategy or programme description	Programme sample and setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results	Confounders and limitations
QA Grade: '-'	were once more referred to their GP. Low-risk participants in both groups A and B and the control group (group C) were sent a questionnaire only at 12 months. **Comparison:** No intervention (group C).	Copenhagen County. **Excluded:** Those not born in the years specified above. **Setting:** 11 municipalities in the south-western part of Copenhagen County (15).			(p=0.636) (15). 2.1 Smoking reduction The mean reduction in tobacco consumption in the study group AB was 1.4g (SD±6.3) amongst those with both baseline and 1-year data compared with 0.03g (SD±6.1) in the control population (p<0.001 (16). 2.2 Smoking cessation The validated abstinence rate at 1-year was 16.3% in the high intensity group and 12.7% in the low intensity group compared with a self-reported abstinence rate of 7.3% in the control. Validated abstinence in the high intensity group A was not significantly higher than in the low intensity group B (OR=1.4; CI 0.8-2.3). The adjusted odds ratio of abstinence in the high intensity group was significantly higher (OR=2.2 CI 1.6-3.0) than in the control group, and the intention to treat analyses reflected a similar significant trend (OR=1.5 CI 1.1-2.0) (17).	of differences in baseline age, diet, smoking, alcohol intake, self-rated health, being limited in climbing stairs, living with partner, vocational education, and employment.

Table 3.14: The Malmö Preventative Project

Programme details	Intervention, policy, strategy or programme description	Programme/sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive results)	Confounders and limitations
Title:	**Aim:**	**Intervention**		**Primary**	**Primary outcomes:**	**Identified by author**

The Malmö Preventative Project **Relevant papers:** Berglund et al. Long-term outcome of the Malmö Preventative Project: mortality and cardiovascular mortality. Journal of Internal Medicine 2000; 247: 19-29 (18) **Study design:** Follow up prevalence data **QA Grades: '+'**	To examine the effect of preventative intervention on total mortality and cardiovascular mortality, alcohol abuse and breast cancer. **Intervention:** Men and women born between 1921 and 1949 were recruited to a large scale programme for risk factor screening and lifestyle modification. At the screening, assessment of BMI, blood pressure and pulse rate was made and blood samples were taken for total cholesterol, triglycerides and fasting blood glucose. Questionnaires were administered to obtain details of family history of CVD, hypertension and diabetes, smoking and dietary habits, alcohol consumption, work and leisure time physical activity, previous weight gain and any signs or symptoms of CVD or alcohol abuse. Participants with risk factors for cardiovascular disease were identified and treated by GPs or in specially created clinics for hypertension, hyperlipideamia, diabetes/glucose intolerance, smoking, overweight/obesity, high alcohol intake and females were screened for breast	**group:** Malmö city (n=250,000) **Control group:** Malmö city (n=250,000) **Included participants:** Intervention: Males born in the years 1927, 1928, 1929, 1944, 1946 and 1948 and females born in 1928, 1930 and 1938. Control: Males born in the years 1925, 1943, 1945 and 1947 and females born in 1927, 1929 and 1939. **Excluded:** None **Setting:** Malmö, Sweden	Recruitment began in 1974 and continued until 1992. 21,911 men and 8,676 women participated in the screening programme, overall response rate 71.2% (range 64-78% for different years). Follow up in national registries until 1995 for all people who had been contacted for initial screening (regardless of whether they had participated in the intervention) and non contacted control.	**outcomes:** Incidence rates of total mortality, cause-specific mortality, nonfatal ischemic heart disease and nonfatal stroke.	1. Total deaths: For men, lower in intervention (49 per 10,000 person years) compared to control (54 per 10,000 person years) but NS (RR 0.94; CI 0.85-1.05, p=0.089). For women, similar in intervention (55 per 10,000 person years) and control (55 per 10,000 person years) (RR 1.0; CI 0.9-1.2, p=0.954). 2. Death from ischemic heart disease: for men similar in intervention (14 per 10,000 person years) and control (12 per 10,000 person years), NS (RR 1.1; CI 0.9-1.4, p=0.435). For women, similar in intervention (8 per 10,000 person years) and control (7 per 10,000 person years) (RR 1.1; CI 0.7 to 1.7, p=0.586). 3. Deaths from stroke: For men, similar in intervention (2 per 10,000 person years) and control (2 per 10,000 person years) (RR 0.9; CI 0.5-1.7, p=0.757). For women, similar in intervention (3 per 10,000 person years) and control (4 per 10,000 person years) (RR 0.9; CI 0.5-1.7, p=0.811). 4. Total CVD deaths: For men, similar in intervention (18 per 10,000 person years) and control (17 per 10,000 person years) (RR 1.0; CI 0.8-1.2, p=0.811). In women, similar in the intervention (15 per 10,000 person years) and control (14 per 10,000 person years) (1.1; CI 0.8-1.5, p=0.576). 5. Death from cancer: In men, similar in intervention (13 per 10,000 person years) and control (14 per 10,000 person years) (RR 0.9; CI 0.8-1.2). In women, slightly lower in intervention (23 per 10,000 person years) and control (27 per 10,000 person years) (RR 0.8; CI 0.7-1.1, p=0.142). 6. Death from other causes: In men, lower in the intervention (18 per 10,000 person years) than the control (23 per 10,000 person years) (RR 0.8; CI 0.6-0.9, p=0.012). In women, slightly higher in the intervention (17 per 10,000 person years)	Only 30-35% of participants in the screening subsequently entered intervention programmes. As the overall attendance rate was 71%, only 25% of all people invited to take part were in a post-screening programme and this may have been too small a proportion for effects to be seen. Secular trends may have diminished the power to detect positive effects. **Identified by reviewer:** It is unclear whether intervention and control groups were similar in terms of age and gender as these characteristics are not presented at baseline. Recruitment of men and women occurred in different years and, since men were mostly recruited in the first half of the recruitment period (1974-82) and females in the second half (1981-1992) there were differences in the average length of follow up for men and women. Control group men and women were recruited during similar time periods to intervention men and women and therefore bias may not have been introduced. However, this limits making comparisons between men and women in observed effect. Comparisons are made between participants and invited non participants (not

cancer. **Comparison:** No intervention				compared to the control (14 per 10,000 person years) NS (RR 1.2; CI 0.9-1.6, p=0.224). 7. Non fatal MI: In men, similar in intervention (28 per 10,000 person years) and control (29 per 10,000 person years) (RR 1.0; CI 0.8-1.1, p=0.734). In women, similar in intervention (28 per 10,000 person years) and control (26 per 10,000 person years) (RR 1.1; CI 0.9-1.3, p=0.539). 8. Non fatal stroke: In men, similar in intervention (12 per 10,000 person years) and control (12 per 10,000 person years) (RR 1.0; CI 0.8-1.3, p=0.932). In women, slightly higher in intervention (18 per 10,000 person years) compared to control (14 per 10,000 person years) (RR 1.2; CI 0.9-1.6, p=0.178).	included in this report). There were between-group differences in socioeconomic and demographic characteristics and presentation of favourable findings from this analysis may mislead readers. Subgroup analysis of younger and older men and women was done post hoc, without a preformed hypothesis. The large number of tests performed was likely to have contributed to the finding of significant results.

Table 3.15: The Minnesota Heart Health screening and education

Programme details	Intervention, policy, strategy or programme description	Programme/sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive results)	Confounders and limitations
Title: The Minnesota Heart Health screening and education **Relevant papers:** Murray et al. Systematic risk factor screening and education: A community-wide approach	**Aim:** To modify health behaviours and reduce risk factor levels for CVD. **Intervention:** Initial examination at the Heart Health Centre, physiological risk factors assessed at different measurement stations. At these stations, participants received health education messages using videos and/or printed material. Messages focussed on healthy eating, increasing physical activity	**Intervention group:** Mankato (n=35,000), a primarily agricultural community. Mankato acted as the initial test area for Minnesota Heart Health (MHH) activities. **Control group:**	1 year (1982-83) All households in Mankato (n=2,323) randomised to intervention (n=1,156) or control (n=1,167). All residents in contacted households encouraged to attend the	**Primary outcomes:** Total cholesterol, BMI, diastolic and systolic blood pressure, expired air carbon monoxide, reported current smoking. A computerised test was used to	**Primary outcomes:** Changes only marked as significant where there was both a significant change from baseline and a follow-up difference between intervention and control groups. 1. Total cholesterol: decreased significantly in the intervention group from baseline (1982: 207.7 mg/dl, 1983: 201.0 mg/dl, t=5.25, p<0.0001) and was significantly lower than the control group (205.1 mg/dl) at follow-up (t=1.69, p<0.05). 2. Blood pressure: Diastolic blood pressure did not change from baseline in the intervention group (1982: 73.3 mg/dl,	**Identified by author** None given **Identified by reviewer:** All tests for risk factor and behavioural changes were one-tailed. It is difficult to make comparisons for intervention and control groups at baseline since measurements were made a year later in the

to prevention of coronary heart disease. Preventive Medicine 1986; 15: 661-672 (19) **Study design:** Randomised controlled trial **QA Grades: '-'**	and smoking cessation. Strategies advised gradual reduction of saturated fat, cholesterol and sodium intake whilst increasing consumption of complex carbohydrates, lean meat, poultry, fish and low fat dairy products. Guidance given for reading and interpreting food labels for fat and salt content and for preparing low fat, low salt foods. Encouraged to undertake vigorous physical activity for 30 min >3 times a week. Smokers encouraged to quit, non-smokers given advice on how to help others to quit. Participants given colour coded risk factor cards that recorded each person's risk factor level and provided a tailored message. During the visit, results returned and each family spent 20 minutes with a health educator to review results. Previous messages reinforced: modifying diets, increasing levels of physical activity, having blood pressure checked regularly, taking blood pressure medication if prescribed and quitting smoking. Discussion centred on any risk factors present in family members. Participants advised of upcoming MHH events and encouraged to take part. **Comparison:** No intervention	Mankato (n=35,000) **Included participants:** All residents in contacted households encouraged to attend the health centre and one per household, randomly assigned, aged 25-74, took part in evaluation **Excluded:** None **Setting:** Mankato, Minnesota, US	health centre and one participant, aged 25-74 years, selected at random for programme evaluation. Baseline (1982) and follow-up (1983) measurements in intervention group. Only final measurements in control (1983). Participation rate in first screening for intervention (1982) and control (1983) was 50.6%. Follow up in the intervention group (1983) was 88.6%. There were 379 and 468 participants in the intervention and control groups respectively.	determine physical activity and estimated weekly kilocalorie expenditure from leisure time physical activity.	1983: 73.0 mg/dl, p=NS) but was significantly lower than the control group (74.4 mg/dl) at follow-up (t=2.02, p<0.05). Systolic blood pressure decreased significantly from baseline in the intervention group (1982: 120.4 mg/dl, 1983: 118.7 mg/dl, t=2.95, p<0.01) but was not significantly lower than the control group (119.0 mg/dl) at follow-up (p=NS) (the treatment group had slightly higher systolic blood pressure at baseline, t=1.72, p<0.1). 3. BMI: small but significant increase from baseline in the intervention group (1982: 25.3 kg/m^2, 1983: 25.4 kg/m^2, t=2.44, p<0.01) but was not significantly different to the control group (25.5 kg/m^2) at follow-up (p=NS). 4. Smoking: expired air carbon monoxide did not change from baseline in the intervention group (1982: 30.0 ppm, 1983: 30.7 ppm, p=NS) but was significantly lower than the control group (34.8 ppm) at follow-up (t=1.97, p<0.05) (treatment and control groups differed significantly at baseline, t=2.37, p<0.05). Reported prevalence of smoking did not change from baseline in the intervention group (1982: 24.9 %, 1983: 24.8 %, p=NS) and was not significantly different to the control group (27.9 %) at follow-up (p=NS). 5. Physical activity: proportion of participants that were very active increased from baseline in the intervention group (1982: 23.8 %, 1983: 32.9 %, X^2=19.16, p<0.005) and was significantly higher than the control group (26.3 %) at follow-up (t=2.13, p<0.05).	control group. The concurrent MHH programme might be expected to produce changes over time and it may not be valid to make comparisons between 1983 control group data with 1982 data for the intervention group. It is therefore difficult to assess whether groups were comparable at baseline.

Table 3.16: The Multifactor Primary Prevention Trial, Göteborg

Programme details	Intervention, policy, strategy or programme description	Programme/sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive results)	Confounders and limitations
Title: The multifactor primary prevention trial, Göteborg **Relevant papers:** Wilhelmsen et al. The multifactor primary prevention trial in Göteborg European Heart Journal 1986; 7: 279-288 **Study design:** Randomised controlled trial **QA Grades: '-'**	**Aim:** To examine whether multifactoral intervention could reduce rates of CVD, stroke and total mortality and change risk factors for CVD. **Intervention:** Postal questionnaire and screening examination in intervention group. Based on the screening, intervention men treated for risk factors. Allocated to risk groups for hypertension (SBP≥175 or DBP≥115 mmHg), hypercholesterolaemia (cholesterol ≥7.8 mmol/l) and smoking (≥15 cigarettes per day). Those allocated to the hypertension risk group attended a hypertension clinic. Those with high cholesterol given individual dietary advice or advice in a small-group (7-10 men) with a physician and dietician, wives also invited. Heavy smokers invited to anti-smoking clinic conducted by physician and psychologist. Initial meeting large (~40 men), information given, short talk on health consequences of smoking, group discussion. Subsequent group sessions smaller (7-10 men), held at one week intervals. The 'anti-smoking club' met every second week to act as a social support group. Treatment also given to 'borderline' risk factor participants. Those with	**Intervention group:** Men in Göteborg, Sweden **Control group:** Men in Göteborg, Sweden **Included participants:** Men born from 1915-1922 and 1924-1925 (~51 years at first screening) **Excluded:** None **Setting:** Göteborg, Sweden	10 years (began 1970) All men in age range randomised to intervention or one of two control groups, each group comprised ~10,000 men. Questionnaires and screening for all intervention men and 2% random sample of control group. 8,393 (84%) intervention men responded to the postal questionnaire and 7,495 (75%) attended first screening. Rescreening 10 years later, new 20% random sample of whole intervention group and control group 1 invited for assessment.	**Primary outcomes:** Total, CHD and stroke related mortality, non-fatal CHD and stroke, mean levels of blood pressure, cholesterol and body weight. Proportion of participants reporting never smoking, smoking cessation or smoking 1-14, 15-24 or ≥25 cigarettes per day.	**Primary outcomes:** 1. Incidence of CHD/Stroke: very similar in intervention and control groups over the study period. CHD and stroke events occurred in 8.36% and 2.11% of those in the intervention group compared to 8.35% and 1.96% in the control. 2. Cholesterol: decreased similarly from baseline (6.46 mmol/l) to 6.04 mmol/l in the intervention and 6.05 mmol/l in the control. The proportion of participants with cholesterol >6.8 mmol/l also decreased from baseline (33.3%) to 19.7% in the intervention group and 20.6% in the control. 3. Blood pressure: systolic bp decreased from baseline (149 mmHg) to 143 mmHg in the intervention and 145 mmHg in the control group and diastolic bp declined from baseline (95 mmHg) to 85 mmHg in the intervention and 86 mmHg in the control. The proportion of men with systolic bp >180 mmHg decreased from baseline (8.0%) to 3.3% in the intervention and 4.6% in the control group. 4. Body weight: increased from baseline (78.9 kg) in both groups: intervention 80.3 kg and control 80.5 kg. 5. Smoking: proportion	**Identified by author** The intervention was mainly directed towards high risk groups. It was likely to have only impacted the upper end of the tail of risk distribution and therefore may not have affected mean risk factor levels to any great extent. The inclusion of non-participants (25%) in the intervention group was likely to have diluted the apparent intervention effect as these people had higher rates of morbidity and mortality. The approach to CVD prevention was not as personal as in other screening programmes and a more aggressive approach may have had more impact on rates of CVD morbidity and it's risk factors. **Identified by reviewer:** No results for statistical tests of between group comparisons are presented. Although it appears likely that this is due to no significant effects being detected, this is not made explicit. No information is given about the uptake of risk factor

systolic blood pressure 160-174 mmHg or diastolic blood pressure 95-114 mmHg regularly checked (every year or second year depending on BP). Those with moderate levels of cholesterol (6.8-7.7 mmol/l) invited to dietary advice counselling sessions (as for high risk group). Moderate smokers given brief printed information with the advantages of quitting smoking and methods recommended for cessation. Four years after the initial screening, subjects in the intervention group were invited to a second screening session for reassessment and continued referral to treatment groups. **Comparison:** 2% of control group received initial postal questionnaire and screening, 11% had four-year screening.	1,473 in the intervention and 1,404 in the control.	decreased from baseline (50.7%) to 32.5% in the intervention and 35.4% in the control group. 6. Total predicted mortality: 9.74% at baseline and, following intervention decreased to 8.08% in the intervention and 8.34% in the control group (17% and 14.3% reductions respectively, p of treatment versus control difference=0.034). 7. Predicted incidence of CHD: decreased from baseline (7.33%) to 5.14% in the intervention and 5.36% in the control group (29.8% and 26.9% reductions respectively, NS).	counselling groups. Poor attendance and low motivations might explain the lack of intervention effect.

4 Discussion

The aim of the current report was to form the third part of an effectiveness literature review to address the question:

What multiple risk-factor interventions are effective and cost-effective in the primary prevention of CVD within a given population?

The secondary aim was to report on specific questions identified as potential considerations by the Programme Development Group (Appendix B of the final scope). The following discussion includes:

- Papers included in the current report (4.1)
- An overview of programmes covered in the current report (4.2 Program overview)
- A discussion of general trends in physiological, behavioural and other outcome measures (4.3 Outcomes)
- A discussion of intervention effectiveness relating to considerations identified by the Programme Development Group (4.4 Emerging themes)
- Limitations of the current review (4.5 Limitations of the review)

4.1 Papers included in the review

Two main types of community intervention were found in the literature review for the current report: media and education community programmes (section 3.1) and screening and advice programmes aimed at the population level (section 3.2).

Media and education community programmes included in this report are:

- The American Heart Association campaign for women (Christian 2007) (Mosca 2004) (Robertson 2001) (Mosca 2000)
- The ATS-Sardegna Campaign (Muntoni 1999)
- CardioVision 2020 (Kottke 2000) (Kottke 2006)
- The German CINDI (Wiesemann 1997) (Wiesemann 2004)
- Coalfields Healthy Heartbeat (Higginbotham 1999)
- The Franklin Cardiovascular Health Program (Burgess 2000)
- Have a Heart Paisley (Independent evaluation report 2005)
- The Olöfstrom community intervention (Isacsson 1996)
- The Quebec Heart Health Demonstration Project – Rural (Huot 2004)
- The Quebec Heart Health Demonstration Project – Suburban (Huot 2004)
- The Quebec Heart Health Demonstration Project – Urban (Huot 2004)

Screening and advice programmes included in this report are:

- The Ebeltoft screening and counseling intervention (Engberg 2002)
- The Inter99 study (Von Huth Smith 2008) (Pisinger 2005a) (Pisinger 2005b)
- The Malmö Preventative Project (Berglund 2000)
- The Minnesota Heart Health community screening and education (Murray 1986)

- The Multifactor Primary Prevention Trial, Göteborg (Wilhelmsen 1986)

4.2 Programmes overview

The media and education community programmes covered in the current report tended to be of lower quality than those previously reviewed and some had a poor control groups or no control group comparison.

The absence of a control group in the **ATS-Sardegna** Campaign made effectiveness of intervention difficult to judge. In the **American Heart Association Campaign for Women,** although knowledge of CVD appeared to increase over time, without comparison with trends in a control population, causality could not be inferred. Also, the **German CINDI** intervention resulted in some positive changes but the un-controlled method of programme evaluation makes it difficult to interpret programme effectiveness.

The heart health intervention in **Olofström** provided information for a control (the northern Swedish MONICA survey) for some outcomes but not others. Intervention coincided with positive trends in physiological risk factors and, although control information suggests the intervention had an effect on cholesterol and diastolic blood pressure, the absence of control information on other risk factors makes it impossible to attribute change in these variables to intervention activities.

In **CardioVision 2020,** the absence of a control group for physiological outcomes made it difficult to assign causality to change. However, national and state data acted as a control for other outcomes and there appears to have been favourable net effects on fruit and vegetable consumption.

Other community programmes were generally higher in quality and used control groups (although most were still graded '-', see appendix 5). However, the quality of programme evaluation and the success of the intervention are different issues and many

of the programmes covered in this review, even where the quality of programme was better, may still have failed to achieve targets for intervention.

There were likely to have been many barriers to implementation of the **Coalfields Healthy Heartbeat** programme; set in an independent community where there was a high degree of scepticism of outside intervention. Programme effectiveness was not evident in any outcome and, although intervention may have acted to prevent development of further health disparities, it seems likely that the programme failed to bring about behavioural change. The **Have a heart Paisley** intervention also appeared to have had no effect on behavioural CVD risk factors. There may have been insufficient time for implementation of environmental changes and contamination of the control area may have contributed to the lack of apparent programme effectiveness.

In the **Quebec Heart Health project** the **rural, Suburban and urban** arms of the intervention showed little positive change in dietary variables. Poor reach of activities and low participation rates may have been responsible but the apparent lack of community involvement in all of these programmes may have impacted programme effectiveness.

The **Franklin Cardiovascular Health Program** does appear to show positive effects of intervention on rates of CVD related death. The high degree of health service integration in this long-term programme may have contributed to programme success but the presence of concurrent public health initiatives may have also been important in producing apparent effect.

Effectiveness findings for screening and education programmes generally appeared to be more favourable. The programme in **Ebeltoft** resulted in reductions in cardiovascular risk score, total cholesterol and BMI. The extent to which counselling was an important feature is difficult to assess but it appears that screening may have a positive intervention effect on some physiological risk factors for CVD.

The **screening** and education project of the **Minnesota Heart Health** programme may have had a positive impact on levels of total cholesterol and physical activity. Although changes in other risk factors are less clear, there appears to be some evidence for the effectiveness of this type of intervention. The **Inter99** screening study also appeared to have a beneficial impact on physical activity in some groups.

Some screening interventions however appeared to be less successful. The **Malmö** Preventative project did not reduce rates of total or CVD-linked mortality and the **Göteborg** screening trial did not appear to produce any sizable intervention effects.

4.3 Outcomes

The graphs in section 3.2 show net changes in the major physiological outcomes and changes in dietary variables and physical activity for all programmes (from reports 1-3) where data is available. There appears to be a general trend for positive intervention effect with modest effect in total cholesterol, diastolic and systolic blood pressure, BMI and smoking.

Although there is little evidence of an intervention effect on rates of physical activity, there appears to be consistent positive changes in some dietary variables. Reductions in BMI associated with programmes may be attributable to dietary changes rather than changes in levels of physical activity. However, causality cannot be inferred since, even where programmes show concurrent reductions in BMI and improved dietary habits, it is impossible to tell whether changes occurred in the same individuals.

On these graphs, quality scores have been inserted beside each of the programme names. It appears that the quality of programme evaluation was not related to the degree of effectiveness for these outcomes and this is shown more clearly where the graphs have been ranked by quality of programme evaluation (see appendix 7). This may contradict work done by previous investigators who, from meta-regression of heart health

programmes, found that the biggest predictor of programme effectiveness was the characteristics of programme evaluation (22).

Tabulated results for outcomes of mortality and morbidity (table 3.1) show a mixed pattern of effect. With the assumption that changes in physiological risk factors for CVD result in changing rates of CVD morbidity/mortality, this may suggest that community heart health programmes fail to bring about physiological changes large enough to result in changes in morbidity/mortality rates. Duration of programme implementation and/or evaluation may be an important factor in this respect. It may be argued that more sustained intervention and evaluation over a longer period of time might reveal positive programme effects.

There is limited data for the effect of programmes on blood glucose level (table 3.2). There appears to be little positive programme effect but more information is required to make any judgment on the likely impact of intervention on glycaemic control. Similarly, there is limited information on the impact of programmes on salt consumption. Only two appear to have measured salt intake (table 3.3) and, although the Stanford five city project showed positive programme effect, without further data, it is difficult to generalise about the feasibility of reducing salt intake with this type of approach.

There is little information of the effect of intervention on knowledge, attitudes and intentions relating to CVD (table 3.4). Again, the Stanford five city project appears to have had positive effects on knowledge and intentions but further evidence may be required to infer that all programmes of this type will result in changes in CVD knowledge, attitudes or intentions.

4.4 Emerging themes

Limitations of approach

In order to assign programmes an 'effectiveness grade', results were examined to see the general direction of effect and the size of risk factor changes. This has inevitable

flaws since programmes measure different outcome variables and there may be selective reporting of outcomes in some programmes.

The type of outcome measure is likely to affect the apparent size of effect. For example, large changes in lifestyle covering whole communities may be required to bring about changes in morbidity or mortality whereas, to change general intentions towards CVD risk factors, only modest intervention may be required.

The second important consideration is the possibility of selective reporting by investigators. In several cases, outcomes are not reported where data covering those measures might be expected. For example, for Stanford 3 community, there is an absence of data for whole community diastolic blood pressure (although there is data for systolic blood pressure) and, for North Karelia, data for BMI is not reported despite survey measurements of height and weight. Where numerous statistical testing has been conducted in subgroups, this may also impact apparent programme effect. If investigators have selectively reported outcomes or subgroups with favorable effects this may give a disproportionate impression of the effectiveness of intervention.

With these issues in mind, topics raised for consideration by the Programme Development Group were examined in light of apparent programme effectiveness. The issues for consideration identified by the PDG were:

- Nature of the target audience, particularly diversity in terms of age, gender and ethnicity
- Whether intervention is based on an underlying theory or conceptual model.
- Precise nature of the intervention including :
  - status of the person (or organization) delivering it and the way it is delivered
  - its frequency, length and duration, where it takes place and whether it is transferable to other settings

- its intensity
- factors with a bearing on the availability or accessibility for different population groups.

Overall, half of the programmes were graded as low effectiveness (18) and half were graded as medium/high effectiveness (17) (3 could not be graded since they were uncontrolled studies).

Nature of the target audience

CVD Risk

As discussed in report 2 of this review, the degree of CVD risk in the intervention community may impact the effectiveness of the implemented programme. Three of the programmes in review 3, four in review 2 and three from review 1 targeted communities considered to be at high risk of CVD (Review 1: Bootheel, Norsjo, North Karelia; Review 2: Action Heart, Otesego, Finnmark Båtsfjord, Finnmark North Cape; Review 3: Coalfields, Olofström, HH Paisley). Of these programmes, four had low effectiveness and seven had high/medium effectiveness.

The addition of studies in the current report to previous findings weakens the suggestion that interventions aiming to improve physiological and behavioural CVD risk factors may be more successful in high risk groups. High risk groups may be an effective option for intervention but the current data do not strongly support this hypothesis and further research may be necessary to assess the benefits of intervention in high-risk communities.

Setting

The role of site of intervention was discussed previously in report 2, examining whether intervention in urban versus rural settings had some influence on programme

effectiveness. Five of the programmes in review 3, five of the programmes in review 2 and five programmes from review 1 targeted rural communities (the others were in urban or mixed areas) (Review 1: Bootheel, Danish, Norsjo, North Karelia, South Carolina; Review 2: Otesego, Finnmark Båtsfjord, Finnmark North Cape, Di.S.Co, Stanford 3 community; Review 3: Coalfileds, Ebeltoft, Franklin, Quebec rural, MHH screening). Of these programmes, five had low effectiveness and ten had high/medium effectiveness.

With inclusion of the final set of programmes, there still appears to be some suggestion that rural communities are more amenable to heart health intervention compared to those set in urban locations. However, this hypothesis may require further investigation and research before a causal link can be inferred.

Intervention theory or conceptual model

The role of the theory of intervention/conceptual model has been discussed previously in reports 1 and 2, particularly in relation to the use of Social Learning Theory. With the addition of programmes from the current report, of the twelve programmes using Social Learning as the theory for intervention (on its own or in combination with others), three had high/medium effectiveness whilst the remaining nine were graded as low effectiveness. The two programmes reporting using only Social Learning as the basis for intervention, both achieved low effectiveness.

As previously discussed, this may suggest that caution should be taken with the reliance on person-to-person communication for the spread of information (utilised in Social Learning Theory) and that other methods of communication and motivation may be necessary to influence behavioural change.

Nature of the intervention

Environmental change

Four of the programmes in review 3, five of the programmes in review 2 and five from review 1 implemented environmental changes (Review 1: German, Norsjo, North

Karelia, Stanford 5 City, South Carolina; Review 2: Dutch, Heartbeat Wales, Finnmark Båtsfjord, Finnmark North Cape, National Research Progamme; Review 3: CardioVision, Coalfields, Olöfstrom, Franklin). Of these programmes, four had low effectiveness and ten had high/medium effectiveness.

With the addition of the third set of programmes, environmental change still generally appears to have been implemented by effective community programmes. This may be an important part of large scale heart health interventions but this hypothesis should be tested on an independent data set or new research conducted in order to further investigate causality.

Flexibility of intervention/community input

In the previous report (report 2), data suggested that there may be a relationship between the flexibility of project organisers to input by community members and the effectiveness of intervention. With the addition of programmes from the third phase of this review, this suggestion is weaker. Four of the programmes in review 3, four from review 2 and three programmes from review 1 allowed communities to have input into the types of activities chosen for implementation (Review 1: Bootheel, Norsjo, Stanford 5 City; Review 2: Dutch, Otesego, Finnmark Båtsfjord, Finnmark North Cape; Review 3: Coalfields and Quebec rural, suburban and urban). Since none of these programmes added from report 3 were rated as effective, little pattern has remained and, of all these programmes, five had low effectiveness and six had high/medium effectiveness.

When reviewing the literature for the current review, ascertainment of true community input from publications was difficult. Unlike more categorical components of the programmes e.g. whether screening or environmental changes took place, assessment of real community involvement is difficult to prove or disprove. The inclusion of community members in a superficial role and the allocation of real, decision making powers are very different in practice but, in reported publications, it may be difficult to differentiate between these types of approach. The current review does not appear to suggest any influence of community empowerment. However, this does not mean that

this is not an important factor and difficulties in assessing real community empowerment and the large number of other variables involved in community programmes may have masked any effect on outcomes. Although research in this area is likely to be difficult due to difficulties in ascertaining the true extent of community involvement, this may remain and important point for consideration in project planning.

Group counselling

Group counselling (not previously discussed) was utilised in many programmes from the current review. Seven programmes from review 3, two from review 2 and three from review 1 implemented counseling courses for groups (Review 1: German, Minnesota, Pawtucket; Review 2: Action Heart, National Research Programme; Review 3: Coalfields, Franklin, CINDI, Goteborg, Quebec rural, Malmo, Inter99, American Heart association). These included nutrition education, support groups for smoking cessation and groups to promote physical activity. Of these programmes, three had high/medium effectiveness whilst the other nine had low effectiveness.

Although poor participation may be a problem for achieving behavioural change via group discussion, it may also be the case that group counseling is in itself ineffective. Society in the UK may be increasingly individualistic and people may be closed and unwilling to be accountable to others in a group situation. The current review does not indicate that group counseling is necessarily ineffective but suggests that it may not be an essential part of community heart health programmes.

Screening

Screening and mass media interventions may be considered to take very different approaches to intervention. Screening and counselling may concentrate on raising individual awareness and promoting the belief that lifestyle can impact cardiovascular risk whereas a media, community orientated approach may raise general awareness without the implication of an individuals own specific risk and need for change.

The potential importance of screening activities in heart health programmes was discussed previously (report 1). Screening was conducted in twenty three programmes (Review 1: Bootheel, British Family Heart, German, Minnesota, OXCHECK, Pawtucket, Norsjo, South Carolina; Review 2: Action Heart, Coeur en Sante, Otsego, Finnmark Basford, Di.S.Co Stanford Three Community; Review 3: Ebeltoft, Olöfstrom, Franklin, Goteburg, Quebec rural, Malmo, MHH screening, Inter99, American Heart Association). Of these programmes, thirteen had high/medium effectiveness and eleven had low effectiveness.

From an overview of all the programmes the current review, there appears to be no pattern as to the importance of screening to programme effectiveness. However, from the graphs illustrating change in physiological CVD risk factors (section 3.3), there does seem to be a trend to positive intervention effect in the group of programmes that particularly focused on screening and individual lifestyle couselling.

Some caution should be taken in the interpretation of results of screening studies in comparison with the media and education programmes due to the difference in the method of evaluation. From the outcomes graphs, programmes implementing only screening and advice may appear to show more consistent trends for programme effectiveness. However, in the majority of screening studies, only participants who took part in the screening intervention are assessed by the programme evaluation. This is different to evaluation of the community based programmes where cross sections of the whole community are assessed, whether or not they have specifically participated in any intervention activities or come into contact with media messages. Effects in community-based evaluations will therefore be diluted in comparison with screening type studies.

Community programmes in the current review may appear to compare reasonably with screening and counseling interventions. Despite considerable 'dilution' effect, there is evidence of some positive risk factor change. Some investigators have tried to directly compare the effectiveness of screening intervention and whole community intervention using data from the Norsjo project (implemented screening and whole community

activities) and a screening project (Stroruman), implemented in the same area (23). Although not significantly so, the whole community plus screening approach showed more favorable outcomes compared to the only screening approach and whole community activities may have an important function in heart health interventions.

Screening and counseling interventions may achieve positive changes in physiological risk factors but their importance to the success of heart health programmes and the relative effectiveness of pure screening interventions in comparison with a multi-factorial approach is unclear.

Provider of intervention

The status of the people delivering an intervention may mediate its effectiveness as attitudes and beliefs may depend on an individuals or communities perception of the provider. From the current programmes, there is no apparent pattern for whether provider status affects programme effectiveness. Almost all programmes appear to have been implemented with project staff, likely to be necessary for efficient delivery of the intervention. The importance of the involvement of community volunteers, community organisations, public health departments and guidance from locally formed steering committees is unclear. However, the lack of emerging themes in this respect is unlikely to mean that intervention provider is not important.

As discussed previously (report 1), the community may have an important role to play in planning and implementation of programme activities. The involvement of community organisations and committees formed from key community members may intuitively be anticipated to benefit programme delivery and acceptance but, whether this is also associated with improved programme effectiveness is not clear. A higher degree of programme acceptance does not necessarily translate into greater changes in lifestyle and the qualitative report, addressing question 2 of this review, may shed more light on the affecters of behavioural change.

It might be anticipated that delivery via public health departments may benefit response to intervention. Doctors, nurses and other medical staff may bring with them profession-linked status and respect for their knowledge and expertise may give a bigger incentive for behavioural change. In the medically advised exercise programme of the German CINDI intervention, 86% of participants reported that they felt strongly that GP examination at the start and end of courses enabled them to better judge their personal health status and 81% stated that it made them feel secure and always well advised (7).

However, in the Ebeltoft screening programme, there was no difference in physiological changes between intervention groups receiving screening with or without a GP discussion and attendance rates at scheduled annual GP consultations declined throughout the course of intervention (14). The presence of other life responsibilities and strains may provide barriers to attending health discussions. If these barriers are too great they may impede the course of behavioural change despite the willingness of clinicians to provide help.

The appropriateness of medical staff involvement may also depend on provisions of time and resources. Overstretched doctors and nurses, if given responsibilities additional to their day-to-day workload may find intervention infeasible and unmanageable.

From the programmes currently reviewed, the role of public health departments is unclear. Further examination of qualitative material may provide information about the perception of medical personnel in relation to programme acceptance and behavioural change.

The nature and delivery of heart health programmes has been discussed in terms of possible influences on programme effectiveness. Although patterns have emerged from comparisons between programmes, the evidence provided by this review is not sufficient to interpret cause and effect. These elements may be important for consideration in project planning but the current data only supports the interpretation

that heart health community programme may be generally effective. Considerable uncertainty is left as to the determinants of programme reach and success and the qualitative report, investigating barriers and facilitators to change, may shed further light on the affecters of behavioural change.

4.5 Limitations of the review

The systematic review of the effectiveness of population level programmes to prevent cardiovascular disease described in the three reports presented to the first three meetings of the PDG is a truly systematic review in most respects. In particular we have worked to a pre-agreed protocol, the search strategies have been as comprehensive as possible and key steps such as inclusion/exclusion, data extraction and quality assessment of included studies have been done in a manner which should reduce bias. The review has been conducted by a multi-disciplinary team with both expertise in systematic review methods and experience in general public health. This has been further augmented by input from experts at the CPHE and, in the case of the second and third reports, experts in the PDG itself.

Inevitably, there are limitations arising from the review process. Foremost of these is that the review only contains the information as it is reported in the publications representing the identified programmes. In consequence, information regarding the nature of the programmes, the populations targeted, the studies conducted and detailed results are often lacking, which in turn limits the review. Selective reporting of the more optimistic outcomes of sub-group analyses with statistically significant differences is an increasingly widely recognised phenomenon and is likely to be operating in the included studies in this review. In some systematic reviews, there is capacity to approach investigators directly to provide clarification or missing information. This has not been possible in the current review. Some additional detail of the nature of the programmes and the populations they target may arise in work to address question 2 concerning barriers and facilitators of population level programmes to prevent CVD (to be provided in reports to the fourth and fifth meetings of the PDG).

The difficulty in defining concepts such "population level" and "high CVD risk focused" approaches and the degree to which these can truly be separated in integrated programmes also needs to be taken into account. Concerning screening approaches, it should be noted that all programmes which have evaluated screening have not been considered, just those that have targeted and covered sufficiently large populations of a defined nature to be considered "population level".

The best available quality assessment tools for the main study design encountered in this review (controlled before-after studies) do not appear to be particularly sensitive, raising the possibility that important differences in study quality have not been highlighted. The lack of any empirical evidence identifying the most influential aspects of quality (which has been accumulated for RCTs) is a handicap in this respect.

Some constraints have also arisen from the obvious need to adapt the timing of the reviews to the NICE PH guidance process. Splitting the review into three separate sub-reports is not ideal, but was inevitable in order to maximise the use of time by the PDG early in the guidance development process. In addition, the time from the availability of the scope to the final date for circulation of the material for the third PDG meeting, approximately 6 months, is limited relative to that which would normally be available for a review of this scope and scale. The degree to which we have been able to interrogate sources of grey literature may have been compromised to some degree by this. However, an area where this has had a particular impact is the degree to which synthesis, synopsis and exploration of the findings from the included studies has been possible. Reduced availability of statistical information about the results of the included studies is a limitation already mentioned, but it is possible that with greater time there may have been ways to overcome this and provide quantification of the overall size of the effects of the programmes, how they might vary between studies and whether the differences observed were more or less than could be observed by chance alone. This in turn would have allowed a more rigorous investigation of whether any differences in effect on CVD risk factors could be reliably attributed to any of the many potentially

important differences that are observed between the nature of the programmes, the populations they target and the quality of evaluations of effectiveness.

A related issue, where more time might have allowed a better solution, is the possibility of summarising small effects of several different risk factors into a single measure. This might provide a single indicator of the likelihood of a statistically significant, clinically important, impact on CVD morbidity and mortality.

Capturing the effects of changes in behaviours and risk factors for CVD that have impacts on other diseases e.g. simultaneous effect of smoking reduction on cancer, is a further problem which the review has not been able to address, but would probably not have been solved by greater time available. We have also not been able to investigate the possibility of publication bias, which may be important because of the observed lack of opportunity to fully search grey literature sources.

Finally, although not strictly a limitation of the review, it has emerged that the interventions considered in the review did not cover all those considered to be of importance to this guidance. Further evidence on initiatives addressing single risk factors, as opposed to multiple risk factors, are being sought outside of this review to address these concerns.

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Appendix 1: Protocol to Address Question 1

Primary research questions

What multiple risk-factor interventions are effective and cost-effective in the primary prevention of CVD within a given population? Where the data allows, how does the effectiveness and cost-effectiveness of interventions vary between different population groups?

Secondary research questions

Any study identified addressing the primary research questions will also be interrogated for information addressing the following potential considerations of the Programme Development Group identified in the final scope (Appendix B):

- The target audience, actions taken and by whom, context, frequency and duration.
- Whether it is based on an underlying theory or conceptual model.
- Whether it is effective and cost effective.
- Critical elements. For example, whether effectiveness and cost effectiveness varies according to:
    - the diversity of the population (for example, in terms of the user's age, gender or ethnicity)
    - the status of the person (or organization) delivering it and the way it is delivered
    - its frequency, length and duration, where it takes place and whether it is transferable to other settings

  - its intensity.
- Any trade offs between equity and efficiency.
- Any factors that prevent – or support – effective implementation.
- Any adverse or unintended effects.
- Current practice.
- Availability and accessibility for different population groups.

Some of these are implicit in the primary question e.g. bullet 3; others are more relevant to review question 2 e.g. bullet 6 any factors that prevent – or support – effective implementation, covered in a separate protocol.

General plan

The effectiveness part of the research question will be addressed in a single evidence review. In order to provide the information to the PDG in a timely fashion in manageable quanta the evidence review will be delivered in three phases:

- Phase 1 – initial findings, primarily from the included studies of systematic reviews, to be presented at September 2008 PDG meeting.
- Phase 2 – further findings, primarily the included studies of remaining systematic reviews, to be presented at October 2008 PDG meeting.
- Phase 3 – remaining findings, primarily from the search of primary studies, to be presented at December 2008 PDG meeting.

There will be different lead reviewers for the effectiveness and cost-effectiveness reviews and coordination between reviewers when undertaking the work. There will also be co-ordination with the evidence review being undertaken as part of question 2, for which there is a separate protocol. The health economic modellers will be part of the review team addressing question 1, particularly the cost-effectiveness components, which will achieve integration of this part of the programme with the subsequent health economic modelling, which is again not covered

directly in this protocol. There will be regular joint meetings of all researchers working on all components of the programme.

Search Strategy and Search Protocol

Proposed resources:

Phase 1 and 2:

- Primary studies identified in existing systematic reviews relevant to the research question, the systematic reviews being identified from searches of bibliographic databases (see below)

Phase 3:

- Additional primary studies identified from searches of bibliographic databases (see below)
- Additional potentially missing studies identified by PDG
- Searches of key UK public health web-sites (see appendix 1.1)
- Checking of bibliographies of included studies

Bibliographic databases:
Given the volume of material in the topic area and the time constraints we feel that concentrating principally on a limited number of electronic databases will be the most appropriate strategy.

Studies for review 2 will therefore be derived from the following bibliographic databases:

Cochrane (CDSR, DARE, HTA, EED, CENTRAL)
MEDLINE
MEDLINE In Process
EMBASE
CINAHL
PsycINFO
HMIC
ASSIA

Searches for cost effectiveness studies will be conducted on NHS EED database (Cochrane Library), ECONLIT, MEDLINE and EMBASE.

Bibliographic database search strategies:
The general approach will be to perform a search which captures all components relevant to the general topic (subject specific search terms) which will be combined with a series of

"design filters" focusing on specific sub-types of literature. A review filter will be used to identify reviews for phase 1; a sensitive RCT filter combined with a selected number of other appropriate study design terms will be used to target primary studies providing evidence on effectiveness; an economic studies filter will be used to target studies providing evidence on cost-effectiveness.

Studies will be limited to those in the English language published since 1970.

Bibliographic database search strategies (content terms):
Scoping searches have been conducted to estimate the nature and volume of the literature. Our initial scoping searches targeted systematic reviews, evidence briefings and guidelines as well as a brief search for primary studies. The key concepts of the search question are 'cardiovascular diseases' (population), 'health promotion' (intervention) and 'nature of the intervention' (focusing on the multiple-risk factor aspect of the intervention).

We submit our search strategy below which combines all three key concepts. The sensitive strategy has been preferred to ensure a comprehensive search and illustrates results for both reviews (line 45) and primary studies (line 55).

Database: Ovid MEDLINE(R) <1950 to June Week 3 2008>
Search Strategy:
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1 cardiovascular disease$.mp. or exp Cardiovascular Diseases/ (1484533)
2 CVD.mp. (6382)
3 coronary disease$.mp. (122405)
4 heart disease$.mp. (140976)
5 atherosclerosis.mp. (56204)
6 arteriosclerosis.mp. (65345)
7 hypertension.mp. (275687)
8 blood pressure.mp. (286797)
9 exp Hyperlipidemias/ or hyperlipidaemia$.mp. (47567)
10 hyperlipidemia$.mp. (26227)
11 exp Cholesterol/ or cholesterol.mp. (166774)
12 exp Stroke/ or stroke$.mp. (125458)
13 peripheral vascular disease$.mp. (12988)
14 peripheral arterial disease$.mp. (3132)
15 hypercholesterol$.mp. (29117)
16 hyperlipid$.mp. (28816)
17 or/1-16 (1837113)
18 health education.mp. or exp Health Education/ (112537)
19 health promotion.mp. or exp Health Promotion/ (38318)
20 primary prevention.mp. or exp Primary Prevention/ (96681)
21 campaign$.mp. (15632)

22 media.mp. or exp Mass Media/ (279445)
23 exp Counseling/ or advice$.mp. (43805)
24 counsel$.mp. (60062)
25 program$.mp. (426510)
26 (policy or policies).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (134656)
27 or/18-26 (1057511)
28 exp Smoking/ or smoking.mp. (135469)
29 exp Tobacco/ or tobacco.mp. (56047)
30 exp Diet/ or diet.mp. (248737)
31 exercise.mp. or exp Exercise/ (159441)
32 obesity.mp. or exp Obesity/ (109574)
33 diabetes.mp. or exp Diabetes Mellitus/ (287258)
34 stress.mp. or exp Stress/ (341439)
35 exp Cholesterol/ or cholesterol.mp. (166774)
36 exp Hypertension/ or hypertension.mp. (275687)
37 blood pressure.mp. or exp Blood Pressure/ (294128)
38 alcohol$.mp. (220914)
39 drinking.mp. or exp Alcohol Drinking/ (86568)
40 (cardiovascular adj3 risk$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (34276)
41 multiple risk$.mp. (2128)
42 or/28-41 (1836612)
43 17 and 27 and 42 (43707)
44 limit 43 to (english language and humans and yr="1970 - 2008") (33237)
45 limit 44 to "reviews (specificity)" (577)
46 limit 44 to "therapy (sensitivity)" (13483)
47 epidemiologic studies/ (4126)
48 longitudinal studies/ (52280)
49 (control$ before and after).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (1064)
50 cohort.mp. (150206)
51 case control.mp. (113097)
52 interrupted time series.mp. (362)
53 or/47-52 (299591)
54 44 and 53 (3403)
55 46 or 54 (15574)

Bibliographic database search strategies (study design filters):

Searches for systematic reviews will be based on Evidence Based resources and specific sources of Health Technology Assessments as recommended in the ARIF search protocol (see appendix 1.2), including bibliographic databases.

All study designs will be included, however, searches for primary studies will focus in the first instance on RCTs by using specialist search filters. A broad filter (the Haynes “Therapy –

sensitive" in-built filter on Ovid) should capture a wider range of study designs beyond RCTs with the addition of selected terms to capture other appropriate study designs

A study design filter based on the CRD model will be used when searching for studies relevant to cost-effectiveness (illustrated below)

Database: Ovid MEDLINE(R) <1950 to June Week 3 2008>
Search Strategy:
---
1 cardiovascular disease$.mp. or exp Cardiovascular Diseases/ (1484533)
2 CVD.mp. (6382)
3 coronary disease$.mp. (122405)
4 heart disease$.mp. (140976)
5 atherosclerosis.mp. (56204)
6 arteriosclerosis.mp. (65345)
7 hypertension.mp. (275687)
8 blood pressure.mp. (286797)
9 exp Hyperlipidemias/ or hyperlipidaemia$.mp. (47567)
10 hyperlipidemia$.mp. (26227)
11 exp Cholesterol/ or cholesterol.mp. (166774)
12 exp Stroke/ or stroke$.mp. (125458)
13 peripheral vascular disease$.mp. (12988)
14 peripheral arterial disease$.mp. (3132)
15 hypercholesterol$.mp. (29117)
16 hyperlipid$.mp. (28816)
17 or/1-16 (1837113)
18 health education.mp. or exp Health Education/ (112537)
19 health promotion.mp. or exp Health Promotion/ (38318)
20 primary prevention.mp. or exp Primary Prevention/ (96681)
21 campaign$.mp. (15632)
22 media.mp. or exp Mass Media/ (279445)
23 exp Counseling/ or advice$.mp. (43805)
24 counsel$.mp. (60062)
25 program$.mp. (426510)
26 (policy or policies).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (134656)
27 or/18-26 (1057511)
28 exp Smoking/ or smoking.mp. (135469)
29 exp Tobacco/ or tobacco.mp. (56047)
30 exp Diet/ or diet.mp. (248737)
31 exercise.mp. or exp Exercise/ (159441)
32 obesity.mp. or exp Obesity/ (109574)
33 diabetes.mp. or exp Diabetes Mellitus/ (287258)
34 stress.mp. or exp Stress/ (341439)
35 exp Cholesterol/ or cholesterol.mp. (166774)
36 exp Hypertension/ or hypertension.mp. (275687)
37 blood pressure.mp. or exp Blood Pressure/ (294128)
38 alcohol$.mp. (220914)

39 drinking.mp. or exp Alcohol Drinking/ (86568)
40 (cardiovascular adj3 risk$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (34276)
41 multiple risk$.mp. (2128)
42 or/28-41 (1836612)
43 17 and 27 and 42 (43707)
44 limit 43 to (english language and humans and yr="1970 - 2008") (33237)
45 economics/ (25685)
46 exp "costs and cost analysis"/ (138513)
47 cost of illness/ (10679)
48 exp health care costs/ (31269)
49 economic value of life/ (5041)
50 exp economics medical/ (11755)
51 exp economics hospital/ (15540)
52 economics pharmaceutical/ (1933)
53 exp "fees and charges"/ (23893)
54 (econom$ or cost or costs or costly or costing or price or pricing or pharmacoeconomic$).tw. (271202)
55 (expenditure$ not energy).tw. (11542)
56 (value adj1 money).tw. (11)
57 budget$.tw. (11609)
58 quality of life/ (69271)
59 life style/ (29162)
60 health status/ (38738)
61 health status indicators/ (12882)
62 quality-adjusted life years/ (3488)
63 "Value of Life"/ (5041)
64 SF$.mp. (37692)
65 EQ-5D.mp. (776)
66 TTO.mp. (291)
67 Time trade off.mp. (406)
68 HUI$.mp. (3820)
69 health utilit$.tw. (501)
70 cost utilit$.tw. (1207)
71 or/45-70 (545016)
72 44 and 71 (5779)

Documentation:
The search process will be clearly documented (databases searched, date searched, time span searched, results of individual searches) to ensure it is transparent and repeatable.

Search results will be saved as textfiles and also stored in a Reference Manager database which will be managed by the reviewers.

Inclusion / Exclusion criteria
Inclusion criteria will be developed mirroring the research question elements detailed in the final scope. In general, inclusion/exclusion decisions will be made in two stages; step 1

decisions on studies sufficiently likely to included on the basis of title +/- abstract for the full copy of the paper to be ordered; step 2 final decisions based on the full text of the potentially included study. Only a sub-set of the complete inclusion criteria will be used to make the step 1 decisions. Inclusion decisions at each step will be operationalised as checklists which will be piloted and discussed with CPHE prior to final use. Slightly different criteria may be required for the inclusion/exclusion of systematic reviews from which primary studies will be identified in phase 1 from the criteria used to identify primary studies in phase 2. In both cases, the final criteria will be agreed with CPHE.

Population:

Populations including children and adults from developed / OECD countries or a WHO region. Populations may be defined geographically (local, regional or national) with a minimum size no less than that covered by a Primary Care Trust in the UK, or according to other characteristics such as workplace, age, sex, social class, ethnicity. Studies confined to populations clinically diagnosed as being at high risk of CVD or diagnosed with CVD will not be included.

Intervention:

Multiple risk factor intervention programmes that include primary prevention strategies to tackle at least two of the following CVD risk factors: Smoking, poor diet, insufficient physical activity, high blood pressure, high blood cholesterol, obesity/overweight, diabetes, psychosocial stress (linked to an individual's ability to influence the potentially stressful environments in which they live) and high alcohol consumption. Intervention programmes should specifically aim to address CVD with the goal of reducing morbidity/mortality from CVD or reducing CVD risk factors. Interventions may include one or more of: educational/behavioural approaches, fiscal changes, environmental changes, legislative changes. Interventions that include a pharmacological component and/or a secondary prevention component will only be included where data can be disaggregated to allow consideration of the impact of primary prevention and non-pharmacological elements. Interventions including screening for CVD risk factors will only be included if accompanied by interventions to modify these risk factors.

Outcomes:

- Primary outcomes:

CVD mortality

CVD morbidity
Biochemical precursors of CVD including lipid levels, HDL/LDL ratio, triglyceride levels.
Physiological precursors of CVD including blood pressure and the metabolic syndrome.
Behaviours associated with the risk of CVD including use of tobacco, diet, physical activity and alcohol consumption.

- Secondary outcomes:
Knowledge, attitudes and intentions with regard to behaviours related to CVD.
Adverse events

Study designs:

Effectiveness: RCT; Controlled before and after; Cohort; Case control; Before and after; Interrupted time series;
Cost effectiveness: Cost benefit analysis; Cost effectiveness analyses; Cost utility analyses

Systematic reviews will be considered as a source of primary studies only.

The following will be excluded: books, book chapters, thesis, dissertations, studies which describe the relationship between health and ill/health and CVD risk factors (i.e. correlates studies or non-evaluative studies). Any studies undertaken in non-developed or non-OECD countries will also be excluded.

Inclusion decisions will be made by one reviewer from the review team, with reference to a co-reviewer in the case of uncertainty (in step 2 decisions in particular). Uncertainty about a decision concerning inclusion of a study relevant to cost-effectiveness will always be referred to one of the review team members with experience in reviewing and appraising economic evaluations. A final list of included studies after phase 2 will be sent to the PDG to offer an opportunity for them to suggest possible omissions to the included studies before completion of the evidence review for question 1. Lists of studies excluded at the retrieval of hard copy stage will also be compiled with reasons for exclusion and made available to the PDG.

As part of the inclusion/exclusion process, we will also tag studies of potential relevance to other parts of the programme particularly:

- Studies relevant to the evidence review for question 2 on enhancers or barriers to CVD risk reduction population programmes. There will be liaison with researchers working on question 2 advising on the precise nature of the studies of potential relevance.
- Studies which contain costs and consequences data but are neither comparative economic evaluations, as defined above in the included economic primary studies, or effectiveness studies, as defined in above included effectiveness primary studies, which may be potentially relevant for supporting modelling work.

Data extraction and quality assessment

Data extraction of included studies will be performed directly into evidence tables, based on the proforma outlined in appendix D of the Methods for development of NICE public health guidance 2006. The final format will be agreed with CPHE prior to implementation. Key data, particularly study results, will be checked for accuracy by a second reviewer, any differences being resolved by consensus and any irresolvable items being arbitrated by a third reviewer.

Quality assessment of included studies will be undertaken based on relevant checklists provided in appendix A of the Methods for development of NICE public health guidance 2006 and, where an appropriate checklist is not provided in the NICE guidance form, other sources such as the Cochrane collaboration and NHS CRD will be used. Checklists will be modified for the topic area where necessary and approved by CPHE team prior to use. Study quality information will be extracted by two reviewers independently, differences being resolved by consensus and any irresolvable items being arbitrated by a third reviewer.

External validity (i.e. applicability) of each included intervention will be assessed according to the 'Methods for development of NICE public health guidance'.

During data extraction, particular attention will be paid to aspects raised by the secondary research questions:

- Nature of the target audience, particularly diversity in terms of age, gender and ethnicity
- Whether intervention is based on an underlying theory or conceptual model.

- Precise nature of the intervention including :
  - status of the person (or organization) delivering it and the way it is delivered
  - its frequency, length and duration, where it takes place and whether it is transferable to other settings
  - its intensity
  - factors with a bearing on the availability or accessibility for different population groups.

Concerning studies pertinent to cost-effectiveness, particular attention will be focused on results suggesting trade offs between equity and efficiency.

Data synthesis

A narrative synthesis, based on tabulated study characteristics and results, will be undertaken and, if appropriate, data synthesis will proceed to meta-analysis. Data synthesis will culminate in evidence statements constructed as outlined in the Methods for development of NICE public health guidance 2006.

Further development of protocol

The protocol may be further finessed in the light of feedback from NICE. Experience during phase 1 and feedback from the PDG may also result in modifications to the conduct of phase 2. Any modifications will be agreed with NICE and a record of changes kept and reported in the methods of the full review presented in the October 2008 PDG meeting.

Review timetable and milestones for phase 1 of evidence review to address question 1

TASK NAME	16th to 20th June	23rd to 27th June	30th June to 4th July	7th to 11th July	14th to 18th July	21st to 25th July	28th July to 1st August	4th to 8th August	11th to 14 August
Protocols & searches signed off by NICE	27th June								
Search and obtain SRs			4th July						
Inclusion / exclusion SR. Characterise SR. Obtain 1y studies				11th July					
Inclusion / Exclusion 1y studies. Pilot data extraction and quality assessment					18th July				
Complete data extraction/quality assessment						1st August			
Synthesize data and prepare draft report for comments								14th August	

Appendix 1.1
Public Health websites

Centre for the Evaluation of Public Health Interventions London School of Hygiene & Tropical Medicine http://www.lshtm.ac.uk/cephi/

Cochrane Public Health Group http://www.ph.cochrane.org/en/index.html

The Campbell Collaboration http://www.campbellcollaboration.org/

The Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre Social Science Research Unit Institute of Education, University of London http://eppi.ioe.ac.uk/cms/

The Trials Register of Promoting Health Interventions (TRoPHI) http://eppi.ioe.ac.uk/webdatabases/Intro.aspx?ID=5

List on heart disease http://eppi.ioe.ac.uk/webdatabases/SearchHistory.aspx

Public Health Specialist Library http://www.library.nhs.uk/publichealth/

Faculty of Public Health http://www.fphm.org.uk/

NICE public health guidance http://www.nice.org.uk/guidance/index.jsp?action=byType&type=5

Health evidence.ca http://health-evidence.ca/

DoH Public Health http://www.dh.gov.uk/en/Publichealth/index.htm

UK Public Health Association http://www.ukpha.org.uk/

Association of Public Health Observatories http://www.apho.org.uk/

Appendix 1.2

SEARCH PROTOCOL FOR ARIF ENQUIRIES (October 2007)

In the first instance the focus of ARIF's response to requests is to identify systematic reviews of research. The following will generally be searched, with the addition of any specialist sources as appropriate to the request.

1. Cochrane Library

- Cochrane Reviews
- Database of Abstracts of Reviews of Effects (DARE)
- Cochrane Central Register of Controlled Trials (CENTRAL)
- Health Technology Assessment (HTA) database

2. ARIF Database

An in-house database of reviews compiled by scanning current journals and appropriate WWW sites. Many reviews produced by the organisations listed below are included.

3. NHS CRD

- DARE
- Health Technology Assessment Database
- Completed and ongoing CRD reviews

4. Health Technology Assessments

- NICE guidance (all programmes)
- West Midlands Health Technology Assessment Collaboration
- Evidence Based Commissioning Collaboration (Trent R & D Support Unit). Links to Trent Purchasing Consortia reports and Wessex DEC reports (both no longer published)
- SBU – Swedish Council on Technology Assessment in Health Care
- NHS Coordinating Centre for Health Technology Assessments
- Canadian Agency for Drugs and Technologies in Health
- New Zealand Health Technology Assessment
- Agency for Healthcare Research and Quality (AHRQ)
- Alberta Heritage Foundation

- McGill Medicine Technology Assessment Unit of MUHC (McGill University Health Centre)
- Monash reports – Centre for Clinical Effectiveness, Monash University
- US Department of Veterans Affairs
- NHS QIS (Quality Improvement Scotland)
- SIGN (Scottish Intercollegiate Guidelines Network)

5. Clinical Evidence

6. Bandolier

7. National Horizon Scanning Centre

8. TRIP Database

9. Bibliographic Databases

- Medline – systematic reviews
- Embase – systematic reviews
- Other specialist databases

10. Contacts

- Cochrane Collaboration (via Cochrane Library)
- Regional experts, especially Pharmacy Prescribing Unit, Keele University (& MTRAC) and West Midlands Drug Information Service for any enquiry involving drug products.

Appendix 2: Search Strategies

This search was used to obtain primary studies for inclusion in the current report; phases 3 of the literature review.

Primary studies

Database: PsycINFO (Ovid) 1967 to July Week 3 2008
Search Strategy:

1 exp Cardiovascular Disorders/ or cardiovascular disease$.mp.
2 cvd.mp.
3 heart disease$.mp.
4 coronary disease$.mp.
5 atherosclerosis.mp. or exp ATHEROSCLEROSIS/
6 exp ARTERIOSCLEROSIS/ or arteriosclerosis.mp.
7 exp HYPERTENSION/ or hypertension.mp.
8 blood pressure.mp.
9 hyperlipid$.tw.
10 cholesterol.mp. or exp CHOLESTEROL/
11 exp Cerebrovascular Accidents/ or stroke.mp.
12 peripheral arterial disease$.mp.
13 peripheral vascular disease$.mp.
14 hypercholesterol$.mp.
15 or/1-14
16 health education.mp. or exp Health Education/
17 health promotion.mp. or exp Health Promotion/
18 primary prevention.mp.
19 campaign$.mp.
20 exp MASS MEDIA/ or media.mp.
21 advice.mp.
22 exp Counseling/ or counsel$.mp.
23 program$.mp.

24 (policy or policies).mp.
25 or/16-24
26 smoking.mp. or exp TOBACCO SMOKING/
27 tobacco.mp.
28 diet.mp.
29 exp EXERCISE/ or exercise.mp.
30 exp OBESITY/ or obesity.mp.
31 diabetes.mp. or exp DIABETES MELLITUS/
32 exp STRESS/ or stress.mp.
33 cholesterol.mp. or exp CHOLESTEROL/
34 exp HYPERTENSION/ or hypertension.mp.
35 blood pressure.mp. or exp Blood Pressure/
36 alcohol$.mp.
37 exp DRINKING BEHAVIOR/ or drinking.mp.
38 (cardiovascular adj3 risk$).mp.
39 exp Risk Factors/ or multiple risk$.mp.
40 or/26-39
41 15 and 25 and 40
42 limit 41 to (human and english language and yr="1970 - 2008")
43 limit 42 to "treatment (high sensitivity)"
44 limit 42 to "0450 longitudinal study"
45 (control$ before and after).mp.
46 cohort.mp.
47 case control.mp.
48 interrupted time series.mp.
49 or/45-48
50 42 and 49
51 43 or 44 or 50

ASSIA Applied Social Sciences Index and Abstracts 1970-2008 searched 18/7/2008

Search strategy:

(coronary disease* or heart disease* or cardiovascular disease* or cvd) and (health education or health promotion or primary prevention or policy or policies or program*) and (risk* or diet* or smoking or tobacco or stress or obesity or diabetes or alcohol* or blood pressure or exercise or hypertension or cholesterol) and (review* or meta-analysis)

493 refs no study design filter

Database: (DH-Data & King's Fund Database 2008/05,HELMIS 1984-1998) (ERL WebSPIRS) searched 18/7/2008

Search strategy:

(cardiovascular disease* or heart disease* or coronary disease* or cvd or stroke or hypertension or blood pressure or hyperlipid* or atherosclerosis or arteriosclerosis or hypercholesterol*) and (public health or health promotion or primary prevention or campaign* or media or advice or counsel* or program* or policy or policies) and (smok* or tobacco or diet* or exercise or obesity or diabetes or stress or cholesterol or hypertension or blood pressure or alcohol* or drinking or risk) in all fields

1438 hits

Database: EMBASE (Ovid) 1980 to 2008 Week 28
Search Strategy:

1 cardiovascular disease$.mp. or exp Cardiovascular Disease/
2 cvd.mp.
3 coronary disease$.mp. or exp Coronary Artery Disease/
4 heart disease$.mp. or exp Heart Disease/
5 atherosclerosis.mp. or exp ATHEROSCLEROSIS/
6 arteriosclerosis.mp. or exp ARTERIOSCLEROSIS/
7 exp HYPERTENSION/ or hypertension.mp.
8 blood pressure.mp. or exp Blood Pressure/
9 hyperlipidaemia$.mp. or exp Hyperlipidemia/
10 hyperlipidaemia$.mp.
11 cholesterol.mp. or exp CHOLESTEROL/
12 exp STROKE/ or stroke.mp.
13 peripheral vascular disease$.mp. or exp Peripheral Vascular Disease/
14 peripheral arterial disease$.mp. or exp Artery Disease/
15 exp Hypercholesterolemia/ or hypercholesterol$.mp.
16 hyperlipid$.mp.
17 or/1-16
18 health education.mp. or exp Health Education/
19 health promotion.mp. or exp Health Promotion/
20 primary prevention.mp. or exp Primary Prevention/
21 campaign$.mp.
22 media.mp.
23 exp Mass Medium/
24 advice.mp.
25 counsel$.mp.
26 exp COUNSELING/
27 program$.mp.
28 (policy or policies).mp.
29 or/18-28
30 exp SMOKING/ or smoking.mp.
31 tobacco.mp. or exp TOBACCO/

32 exp DIET/ or diet.mp.
33 exercise.mp. or exp EXERCISE/
34 exp OBESITY/ or obesity.mp.
35 diabetes.mp. or exp Diabetes Mellitus/
36 exp STRESS/ or stress.mp.
37 cholesterol.mp. or exp CHOLESTEROL/
38 exp HYPERTENSION/ or hypertension.mp.
39 blood pressure.mp.
40 alcohol$.mp.
41 drinking.mp.
42 exp Drinking Behavior/
43 (cardiovascular adj3 risk$).mp.
44 multiple risk$.mp.
45 or/30-44
46 17 and 29 and 45
47 limit 46 to (human and english language and yr="1974 - 2008")
48 limit 47 to "treatment (2 or more terms high sensitivity)"
49 exp Longitudinal Study/
50 (epidemiologic$ adj stud$).mp.
51 (control$ before and after).mp.
52 cohort.mp.
53 case control.mp.
54 interrupted time series.mp.
55 or/49-54
56 47 and 55
57 48 or 56

Database: MEDLINE(Ovid) 1950 to July Week 2 2008
Search Strategy:

1 cardiovascular disease$.mp. or exp Cardiovascular Diseases/
2 CVD.mp.
3 coronary disease$.mp.
4 heart disease$.mp.
5 atherosclerosis.mp.
6 arteriosclerosis.mp.
7 hypertension.mp.
8 blood pressure.mp.
9 exp Hyperlipidemias/ or hyperlipidaemia$.mp.
10 hyperlipidemia$.mp.
11 exp Cholesterol/ or cholesterol.mp.
12 exp Stroke/ or stroke$.mp.
13 peripheral vascular disease$.mp.
14 peripheral arterial disease$.mp.

15 hypercholesterol$.mp.
16 hyperlipid$.mp.
17 or/1-16
18 health education.mp. or exp Health Education/
19 health promotion.mp. or exp Health Promotion/
20 primary prevention.mp. or exp Primary Prevention/
21 campaign$.mp.
22 media.mp. or exp Mass Media/
23 exp Counseling/ or advice$.mp.
24 counsel$.mp.
25 program$.mp.
26 (policy or policies).mp.
27 or/18-26
28 exp Smoking/ or smoking.mp.
29 exp Tobacco/ or tobacco.mp.
30 exp Diet/ or diet.mp.
31 exercise.mp. or exp Exercise/
32 obesity.mp. or exp Obesity/
33 diabetes.mp. or exp Diabetes Mellitus/
34 stress.mp. or exp Stress/
35 exp Cholesterol/ or cholesterol.mp.
36 exp Hypertension/ or hypertension.mp.
37 blood pressure.mp. or exp Blood Pressure/
38 alcohol$.mp.
39 drinking.mp. or exp Alcohol Drinking/
40 (cardiovascular adj3 risk$).mp.
41 multiple risk$.mp.
42 or/28-41
43 17 and 27 and 42
44 limit 43 to (english language and humans and yr="1970 - 2008")
45 limit 44 to "therapy (sensitivity)"
46 epidemiologic studies/
47 longitudinal studies/
48 (control$ before and after).mp.
49 cohort.mp.
50 case control.mp.
51 interrupted time series.mp.
52 or/46-51
53 44 and 52
54 45 or 53

Database: MEDLINE(Ovid) In-Process & Other Non-Indexed Citations <July 10, 2008>
Search Strategy:

1 cardiovascular disease$.tw.
2 cvd.tw.
3 coronary disease$.tw.
4 heart disease$.tw.
5 atherosclerosis.tw.
6 arteriosclerosis.tw.
7 hypertension.tw.
8 blood pressure.tw.
9 hyperlipidaemia$.tw.
10 hyperlipidemia$.tw.
11 cholesterol.tw.
12 stroke$.tw.
13 peripheral vascular disease$.tw.
14 peripheral arterial disease$.tw.
15 hypercholesterol$.tw.
16 hyperlipid$.tw.
17 or/1-16
18 health education.tw.
19 health promotion.tw.
20 primary prevention.tw.
21 campaign$.tw.
22 media.tw.
23 advice.tw.
24 counsel$.tw.
25 program$.tw.
26 policy.mp. or policies.tw.
27 or/18-26
28 smoking.tw.
29 tobacco.tw.
30 diet.tw.
31 exercise.tw.
32 obesity.tw.
33 diabetes.tw.
34 stress.tw.
35 cholesterol.tw.
36 hypertension.tw.
37 blood pressure.tw.
38 alcohol$.tw.
39 drinking.tw.
40 (cardiovascular adj3 risk$).tw.
41 multiple risk$.tw.
42 or/28-41
43 epidemiologic studies.tw.
44 longitudinal studies.tw.

45 control$ before and after.tw.
46 cohort.tw.
47 case control.tw.
48 interrupted time series.tw.
49 (random$ adj3 trial$).tw.
50 or/43-49
51 42 and 27 and 17
52 50 and 51
53 limit 52 to english language
54 limit 53 to yr="1970 - 2008"

Database: CINAHL (R) - 1982 to date (DIALOG Datastar Web Version)
Run: 20/07/2008
Search strategy:

1. Cardiovascular-Diseases#.DE.
2. (cardiovascular ADJ disease$2).TI,AB. OR (cardiovascular ADJ disease$2).DE.
3. CVD.TI,AB,DE.
4. (coronary ADJ disease$2).TI,AB,DE.
5. (heart ADJ disease$2).TI,AB,DE.
6. atherosclerosis.TI,AB,DE.
7. arteriosclerosis.TI,AB,DE.
8. hypertension.TI,AB,DE.
9. (blood ADJ pressure).TI,AB,DE.
10. Hyperlipidemia#.W..DE.
11. hyperlipidaemia$2.TI,AB,DE.
12. hyperlipidemia$2.TI,AB,DE.
13. Cholesterol#.W..DE. OR cholesterol$2.TI,AB,DE.
14. stroke$2.TI,AB,DE.
15. Cerebral-Vascular-Accident#.DE.
16. (peripheral ADJ vascular ADJ disease$3).TI,AB,DE.
17. (peripheral ADJ arterial ADJ disease$2).TI,AB,DE.
18. hypercholesterol$2.TI,AB,DE.
19. hyperlipid$5.TI,AB,DE.
20. 1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19

21. (health ADJ education).TI,AB,DE. OR Health-Education#.DE.
22. (health ADJ promotion).TI,AB,DE. OR Health-Promotion#.DE.
23. (primary ADJ prevention).TI,AB,DE. OR Preventive-Health-Care#.DE.
24. campaign$2.TI,AB,DE.
25. Communications-Media#.DE. OR media.TI,AB,DE.
26. Counseling.TI,AB,DE. OR advice.TI,AB,DE.
27. Counseling#.W..DE.
28. program$2.TI,AB,DE.
29. polic$5.TI,AB,DE.
30. 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29
31. Smoking#.W..DE. OR smoking.TI,AB,DE.
32. Tobacco#.W..DE. OR tobacco.TI,AB,DE.
33. Diet#.W..DE. OR diet.TI,AB,DE.
34. exercise.TI,AB,DE. OR Exercise#.W..DE.
35. obesity.TI,AB,DE. OR Obesity#.W..DE.
36. Diabetes-Mellitus#.DE. OR diabete$2.TI,AB,DE.
37. Stress.TI,AB,DE. OR Stress#.W..DE.
38. cholesterol$2.TI,AB,DE. OR Cholesterol#.W..DE.
39. Hypertension#.W..DE. OR Hypertension.TI,AB,DE.
40. Blood-Pressure#.DE. OR (Blood ADJ Pressure).TI,AB,DE.
41. alcohol$4.TI,AB,DE.
42. drinking.TI,AB,DE.
43. Alcohol-Drinking#.DE.
44. (cardiovascular NEAR risk$4).TI,AB,DE.
45. (multiple ADJ risk$4).TI,AB,DE.
46. 31 OR 32 OR 33 OR 34 OR 35 OR 36 OR 37 OR 38 OR 39 OR 40 OR 41 OR 42 OR 43 OR 44 OR 45
47. 20 AND 30 AND 46

48. 47 AND LG=EN
49. clinical.TI,AB. AND trial.TI,AB.
50. random.TI,AB.
51. PT=CLINICAL-TRIAL

52. Clinical-Trials#.DE.
53. 49 OR 50 OR 51 OR 52
54. Epidemiological-Research#.DE.
55. Prospective-Studies#.DE.
56. (control$3 ADJ before).TI,AB,DE. AND after.TI,AB,DE.
57. cohort.TI,AB,DE.
58. (case ADJ control).TI,AB,DE.
59. (interrupted ADJ time ADJ series).TI,AB,DE.
60. 54 OR 55 OR 56 OR 57 OR 58 OR 59
61. 53 OR 60
62. 48 AND 61

Appendix 3: Inclusion/exclusion Checklists for Previous Systematic Reviews

Step 1 inclusion /exclusion process
for selection of reviews as a source of primary studies

Starting point: titles and abstracts from bibliographic database searches

Item	Y	N	Comments
1.1 Is the review described as a systematic review or a meta-analysis in the title or abstract OR 1.2 Is there an identifiable search strategy in the abstract			
2.1 Is there reference to prevention of CVD OR risk reduction in CVD in the title or abstract?			
If 'Y' to all, order hard copy of the paper			

Step 2 inclusion /exclusion process
for selection of reviews as a source of primary studies

Starting point: hard copies of possible systematic reviews addressing review question based on information of title and abstract in step 1

Item	Y	N	?	Comments
1.1 Is the review systematic? -Is there an identifiable search strategy AND -Are there inclusion and exclusion criteria AND -Was quality assessment of primary studies performed				
1.2. Is there a list / table of included studies?				
If 'Y' to all of section 1 continue. If 'N' to any of section 1 exclude. If '?' to any of				

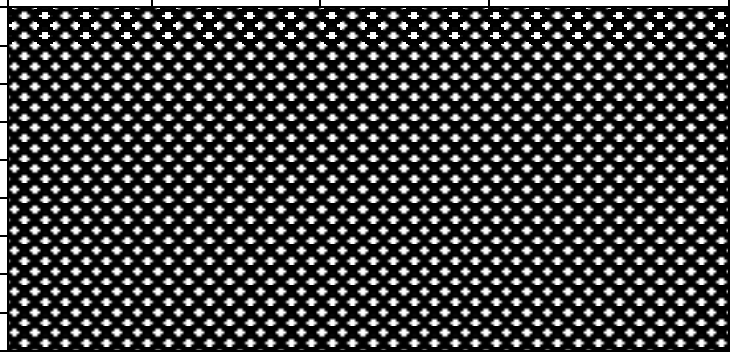
section 1 pass to 2nd reviewer.				
2.1. Do the review objectives include examination of the effectiveness of interventions targeting ≥ 2 risk factors for CVD*? (Circle from list below)				
2.2. Do the review inclusion criteria include interventions targeting ≥ 2 risk factors for CVD*? (Circle from list below)				
2.3. Does the list / table of included studies include interventions targeting ≥ 2 risk factors for CVD*? (Circle from list below)				
If 'N' to 2.3 exclude. If 'Y' to 2.3 continue. If '?' to 2.3 pass to second reviewer				
3.1. Do the review objectives include examination of the effectiveness of interventions targeting populations?				
3.2. Do the review inclusion criteria include studies examining the effectiveness of interventions targeting populations?				
3.3. Does the list / table of included studies include studies examining the effectiveness of interventions targeting populations?				
If 'N' to 3.3 exclude. If 'Y' to 3.3 continue. If '?' to 3.3 pass to second reviewer				
4.1. Do the review objectives include examination of the effectiveness of primary prevention interventions?				
4.2. Do the review inclusion criteria include studies examining the effectiveness of primary prevention interventions?				
4.3. Does the list / table of included studies include studies examining the effectiveness of primary prevention interventions?				
If 'N' to 4.3 exclude. IF 'Y' to 4.3 include. If '?' to 4.3 pass to second reviewer.				

* Risk factors include: smoking, poor diet, insufficient physical activity, high blood pressure, high blood cholesterol, obesity / overweight, diabetes, psychosocial stress, diabetes.

Appendix 4: Full Paper Screening Checklist

Proposed inclusion/exclusion process for selection of primary studies
Full paper screening checklist

Title:				
Date: **Ref ID:**		Note: In case of ? use left or right arrow to indicate whether final decision is Y/N		
Study feature	Yes	? (Refer to 2nd reviewer)	No	Comments
PUBLICATION TYPE				
Is the study a book, book chapter thesis, dissertation?				
• If No continue. • If Yes STOP and exclude study as "INAPPROPRIATE PUBLICATION TYPE"				
DATE				
Was the paper published after 1970?				
• If Yes continue. • If No STOP and exclude study as "PUBLICATION PRIOR TO 1970"				
GENERAL				
Does the paper broadly consider some sort of change which might affect CVD or CVD risk?				
• If Yes continue. • If No STOP and exclude study as "DOES NOT ADDRESS GENERAL PURPOSE"				
SETTING & POPULATION				
Is the study set in a developed/OECD country				
Does the approximate target population exceed 100,000 (or similar to a PCT) or does the study involve a population living within a certain geographical area (which should not be smaller than primary care trust)?				
Are the vast majority of participants likely to have low or minimal risk of CVD. [Answer NO if clear study focus is on participants with clinical diagnosis of CVD or diagnosed high risk of CVD]				
• If Yes to all continue. • If No to any STOP and exclude study as "INAPPROPRIATE SETTING or POPULATION"				
INTERVENTION or PROGRAMME				
Is the primary aim of any intervention to address CVD?				
Does the intervention or programme tackle 2 or more of the risk factors below (tick those applicable)				
Smoking				
Poor diet				
Insufficient physical activity				
High blood pressure				
High cholesterol				
Obesity/overweight				
Diabetes				
Psychosocial stress				
High alcohol consumption				



Proposed inclusion/exclusion process for selection of primary studies –page 2

INTERVENTION (continued)					
Could the intervention or programme be considered as one or more of the following (tick all those applicable)					
Educational/behavioural including use of mass media					
Fiscal					
Environmental					
Legislative					
• If Yes to all, continue. • If No to any, could any intervention be considered a "NATURAL EXPERIMENT" which might affect a CVD risk factor. If it could be a NATURAL EXPERIMENT, clearly circle this phrase. • If No to any and not natural experiment exclude study as "INAPPROPRIATE INTERVENTION"					
DESIGN					
Does the study contain any economic evaluation data (such as cost-effectiveness, cost benefit, cost utility, cost consequence, cost minimization or net monetary [cost] benefit)?					
• If Yes TAG and refer to cost-effectiveness review team. Continue irrespective of Y/N answer.					
Could this study be of interest in review of qualitative evidence, particularly on barriers and facilitators?					
• If Yes TAG and refer to qualitative review team. Continue irrespective of Y/N answer.					
Is this an evaluative study (RCT;CT;CBA;ITS;BA;Co;C-C) or a natural experiment?					
• If Yes, continue. • If No STOP and exclude as "INAPPROPRIATE DESIGN for EFFECTIVENESS REVIEW"					
OUTCOMES					
Does the study measure 1 or more of the following(tick all those applicable)					
CVD mortality/morbidity					
Biochemical precursor					
Physiological precursor					
Behavioural change					
Knowledge/attitudes/ intentions					
Adverse events					
• If Yes, STUDY is INCLUDED. • If No STOP and exclude as "NO APPROPRIATE OUTCOMES"					

Appendix 5: Quality Assessment

	Contemporaneous data collection	Appropriate choice of control site	Similarity of baseline measures	Similarity of study/control providers	Blinded outcome assessment	Protection against contamination	Reliability of outcome measures	Follow-up of individuals	Total no. Y	Quality rating
American Heart Association	NA	N	Y	N	N	NA	N	NA	1	-
ATS-Sardegna	NA	N	Y	N	N	NA	D	NA	2	-
Cardiovision	Y	Y	NC	Y	N	NC	N	NA	3	-
German CINDI	NA	N	Y	N	N	NA	Y	NA	2	-
Coalfields	Y	Y	NC	Y	N	N	Y	NA	4	-
Franklin	Y	Y	Y	Y	N	NC	Y	Y	6	+
Have a Heart Paisley	Y	Y	NC	Y	N	NC	N	N	3	-
Olofström	N	Y	NC	NC	N	NC	Y	NC	2	-
Quebec rural	Y	Y	NC	Y	N	NC	N	NA	3	-
Quebec suburban	Y	Y	NC	Y	N	NC	N	NA	3	-
Quebec Urban	Y	Y	NC	Y	N	NC	N	NA	3	-

Randomised controlled trials	Ebeltoft	Malmö	Inter99	MHH screening	Götenborg
Clear question	Well covered	Well covered	Well covered	Well covered	Well covered
Randomised	Well covered	Poorly addressed	Adequately addressed	Poorly addressed	Poorly addressed
Adequate concealment	Adequately addressed	Not reported	Not reported	Not reported	Not reported
Subjects and investigators 'blind'	NA	NA	NA	NA	NA
Similarity at baseline	Poorly addressed	Poorly addressed	Poorly addressed	Poorly addressed	Poorly addressed
Only difference is intervention	Adequately addressed	Adequately addressed	Adequately addressed	Adequately addressed	Not addressed
Validity of outcome measures	Well covered	Well covered	Well covered	Well covered	Adequately addressed
% dropout	I 24.7%, C 26.3%	NA – none	I 42%, C 21%	I 11.4%	NA – none
Intention to treat analysis	Poorly addressed	Well covered	Poorly addressed	Poorly addressed	Well covered
Comparability of intervention sites	Not clear	NA	Not reported	NA	NA
No. well or adequately addressed	5	5	4	4	4
	+	+	-	-	-

++	All or most of the criteria have been fulfilled. Where they have not been fulfilled the conclusions of the study or review are thought very unlikely to alter.
+	Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.
−	Few or no criteria fulfilled The conclusions of the study are thought likely or very likely to alter.

Appendix 6: Example Completed Effectiveness Data Extraction form

Data Extraction Form

Authors/ Title/ Source

Weinehall L, Westman G, Hellsten G, Boman K, Hallmans G, Pearson TA, Wall S. Shifting the distribution of risk: results of a community intervention in a Swedish programme for the prevention of cardiovascular disease. Journal of Epidemiology and Community Health 1999;53:243-50

Project: The Norsjo Project

Data extracted by: Wendy Greenheld
Date of extraction: 14th August 2008

Aim:

To examine the impact of systematic risk factor screening and counselling carried out by family physicians and nurses within the larger framework of a community intervention programme for the prevention of CVD.

To assess whether the health provider survey afforded risk factor improvements in addition to those of the population-based intervention.

Study design:

Systematic review (including at least one RCT)		☐
Systematic review of experimental studies		☐
Systematic review of observational studies	☐	
Randomised controlled trial: Individual		☐
Randomised controlled trial: Cluster	☐	
Controlled non-randomised trial		☐
Controlled before-and-after		☐
Interrupted time series	☐	
Before and after study		☐
Case study		☐
Other (please state)		☐

Other study parameters:

Setting: The island municipality of Norsjo in Northern Sweden.

Geographical(city/county): Norsjo - a rural island municipality in the province of Vasterbotten, in Northern Sweden, with a population of approximately 5,500. The population in MONICA (Multinational monitoring of Trends and Determinants in Cardiovascular Diseases) Northern Sweden, with a population of approximately 510,000, was used as a control area.

Social (school/workplace etc): whole community

Date of study (to/from): 1985 to 1992

Funding: Generally, the preventive work in Norsjo was achieved within the framework of the existing community organisations with little additional financial support.

Participants:

Number of participants/organisations etc enrolled: The main community based intervention was targeted at the whole population of Norsjo (approx 5,500). The risk factor screening and counselling 'sub-programme' was targeted at a cohort of all inhabitants aged 30, 40, 50 and 60 who took part in the 1986 risk factor screening and counselling programme.

Unit of allocation/recruitment: Community
Sex: Men and Women relative percentages not reported
Age (range or mean): A whole population approach. But age range of those assessed was 30 to 60 years in the intervention group and 25 to 64 years in the control group.
Inclusion criteria: The main community based intervention was targeted at the whole population of Norsjo. The risk factor screening and counselling 'sub-programme' was targeted at a cohort of all inhabitants aged 30, 40, 50 and 60 who took part in the 1986 risk factor screening and counselling programme.

Exclusion criteria: None

Intervention:

Description of the intervention: To meet expressed public expectations and demands questions on nutrition received a great deal of attention. At the beginning of 1987 a food labelling system was introduced in the grocery shops in Norsjo (foods with a low fat and/or high fibre content were marked with a special heart symbol). The use of novel health education activities and methods such as drama, music, and informal meetings were encouraged. Prevention was given more attention than previously in local political debates. The Norsjo project also received a great deal of publicity in local as well as in national newspapers.

Within the community programme a risk factor screening and counselling programme was undertaken. Information was provided by family physicians and nurses and targeted at the individuals screened. The individual strategy focused on traditional risk factors (plasma lipids, blood pressure, glucose tolerance, smoking and body mass index in age defined groups. All people of 30, 40, 50 and 60 years of age, were invited annually to a health provider survey focusing on the traditional risk factors CVD. As the health examination was intended to be an integral part of

the community based activities it was decided that the individual counselling performed by family health practitioners should include all age eligible participants and not only those at high risk of CVD. Therefore all participants were individually given verbal information about their test results and provided with appropriate medical counselling. All participants in the health provider survey were encouraged to participate in the community intervention and could, at their own initiative reassess their blood pressure and lipids at the health centre.

Description of the comparator(s): No intervention, but also assessed the effects of individual counselling as a supplement to the population level initiatives.
Was there an underlying theoretical model? None stated

Method of delivery (for example, peer education): Providers/deliverers of the intervention (including organisations involved): The programme was co-ordinated by a local collaborative committee, representing voluntary organisations as well as the Norsjo municipality executive board and Norsjo Primary Health Care. Co-operation between the local authorities and the general public was reinforced by the local working committee's emphasis on an open dialogue. From the start of the Norsjo project the primary health care organisation played a key role. The dental services expanded their intervention activities to include schools and daycare centres. The staff of the occupational health services co-operated with primary health care groups in implementing health surveys and other public health activities, such as educational programmes. The health examination was an integral part of the community-based activities. The municipality of Norsjo, which was responsible for environmental protection, leisure time activities and social welfare also extended its network of contacts among adult education organisations, clubs and other local organisations and the general public.
Length, duration and intensity of the intervention: >7 years

Time to follow-up (average/median): ~7 years

How many (n/%) participants completed the intervention? All 30, 40, 50 and 60 year old inhabitants were invited to take part in a health provider survey each year from 1985 to 1992. The survey focused on the traditional risk factors associated with CVD. Of the 2,046 eligible participants 1,893 (92.5%) participated forming eight independent cross sections.

The cohort of subjects assessed in 1986 was re-surveyed in 1988 and 1991 forming a panel which was used to evaluate the long term effects of individual counselling as a supplement to the population level initiatives.
For non-completers, were the reasons for non-completion described? No

Outcomes:
Primary outcomes: Cholesterol, blood pressure, BMI, smoking, CVD risk
Describe outcome measures: Net changes from baseline to follow-up in intervention group vs. controls : Cholesterol (mmol/l), blood pressure (mmHg), BMI (kg/m^2), smoking (% daily smokers), CVD risk (using Framingham equation).
Were baseline measurements of outcomes assessed?
Yes ☒ No ☐
Were outcome measure(s) validated?
Yes ☐ No ☐ Not clear ☒
If yes, how?
Secondary outcomes: N/A
Describe outcome measures

Were baseline measurements of outcomes assessed?
Yes ☐ No ☐
Were the outcome measure(s) validated?
Yes ☐ No ☐ Not clear ☐
If yes, how?

Analyses:

Data collection methods used: cross sectional surveys during the eight years from 1985-92 (see above).

Describe methods used (intention to treat, descriptive statistics, qualitative analysis etc): To account for aging over time in the cohort panels and differences in age distribution in the cross sectional surveys and the reference population individual measures were expressed as standard deviation z scores based on age and sex specific averages from the MONICA 1986 surveys. An individual or mean z value of 0 would thus correspond to the reference value after age and sex standardisation. Changes in outcome measures within the cohort panel were assessed using ANOVA for repeated measurements. Time trends between the different cross sectional surveys were in each study assessed by linear regression, while the significance of the differences in change between the studies were assessed by ANOVA. To evaluate the difference between participants and non-participants in the Panel, and for differences between 1986 and 1990 in the reference area, Student's t test was used for categorical variables and X^2 test for differences between the distributions. A value of $p<0.05$ was regarded as statistically significant.

Unit of analysis: individual
Power:
Was a power calculation presented?
Yes ☐ No ☐
If yes, describe:
Was the study powered to detect an effect if one exists?
Yes ☐ No ☐ Not clear ☐

Results:

1. Cholesterol

Mean total cholesterol was reduced from 7.09 to 6.27mmol/l for men ($p<0.001$) and from 7.13 to 5.89mmol/l for women ($p<0.001$). The significance of the differences in change in cholesterol between intervention and reference population was tested by comparing trends between equivalent years and a significant favourable reduction was observed in the intervention area ($p<0.001$).

2. Blood pressure

Mean systolic blood pressure was reduced from 132.2 to 123.7mmHg for men ($p<0.05$) and from 129.2 to 122.0mmHg for women ($p<0.001$). No net difference presented.

3. BMI

BMI increased from 25.6 to 26.2 for men ($p<0.05$) and from 25.0 to 25.5 for women

(NS). No net difference presented.

4. Smoking

The proportion of daily smokers varied between 20% and 25% and no significant smoking cessation trend was seen over time. No net difference presented.

The cohort data for the years 1986-91 highlighted corresponding reductions in cholesterol and blood pressure whilst BMI was unchanged. The proportion of smokers decreased non-significantly. The individual attention and evaluation afforded by the health provider survey seemed to accelerate but not increase the amount of risk reduction.

5. CVD risk

The risk for CVD using the Framingham equation was estimated to be reduced overall by 19% (p=0.0021) when comparing early cross sections (1985/86) with later cross sections (1990/91). No net difference presented.

Does the paper address or offer any evidence of effect according to any of the following individual/population characteristics? If so, please ensure that evidence is presented in results above.

Older people	Yes ☐	No ☒	Not clear ☐
Gender	Yes ☒	No ☐	Not clear ☐
Ethnicity	Yes ☐	No ☒	Not clear ☐
Socio-economic status	Yes ☐	No ☒	Not clear ☐

Other (please specify):

Does the paper demonstrate any evidence of harms or adverse effects associated with the intervention? No

In your opinion, are the results generalisable to the UK?

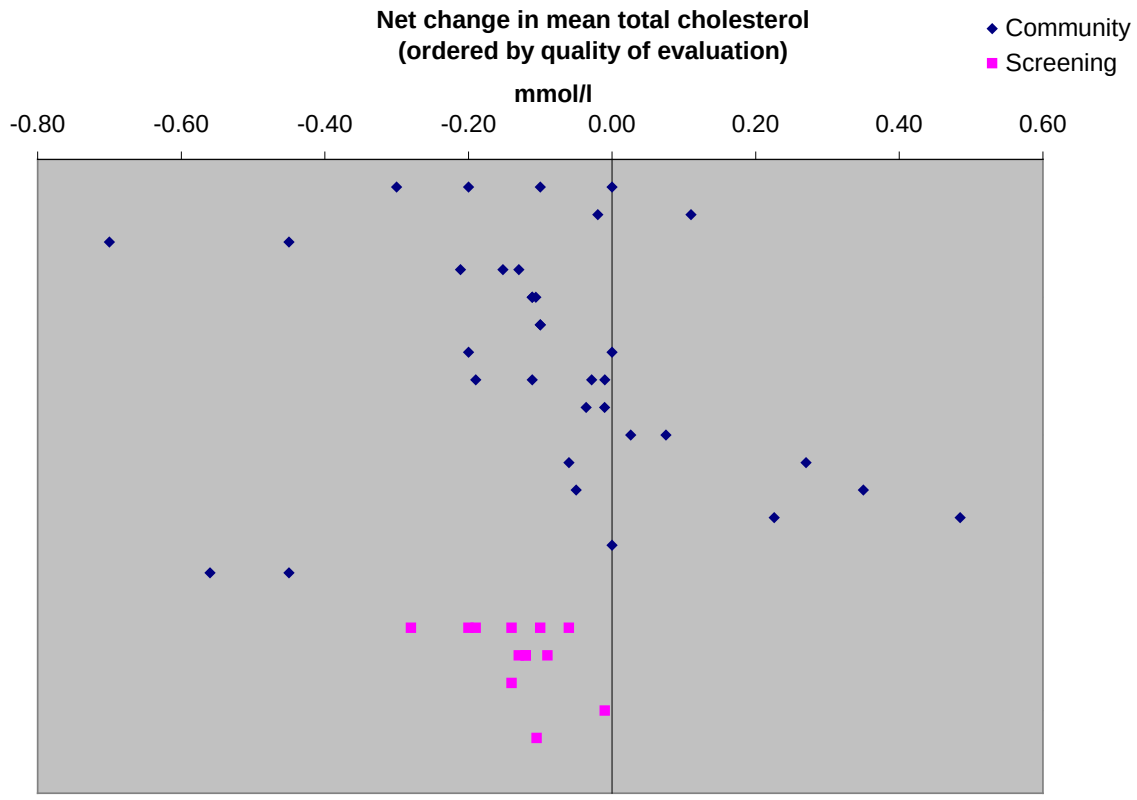
Yes ☐ No ☐ Not clear ☒

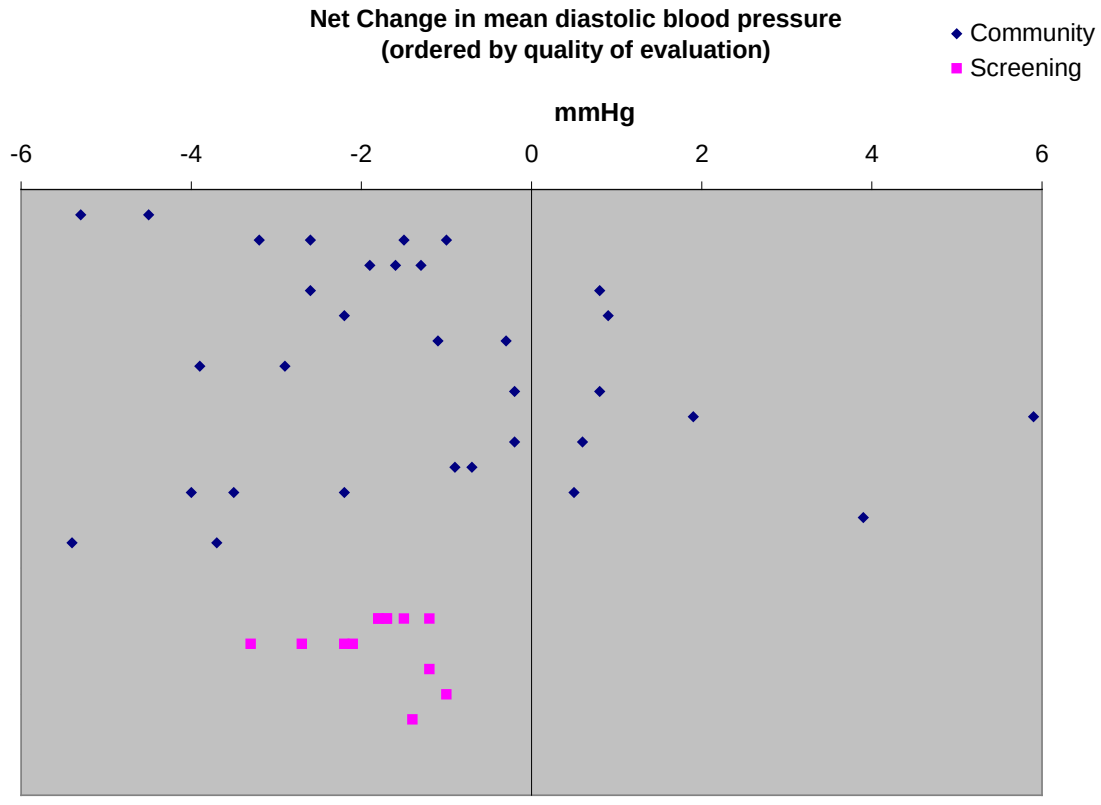
Why?: Norsjo is a small (approximately 5,500 inhabitants) rural municipality in Northern Sweden and at the programme outset had high rates of CVD in comparison to the rest of Sweden. Although possibly applicable in similar rural settings, the programme may not be as relevant to the different demographics of the UK as a whole.

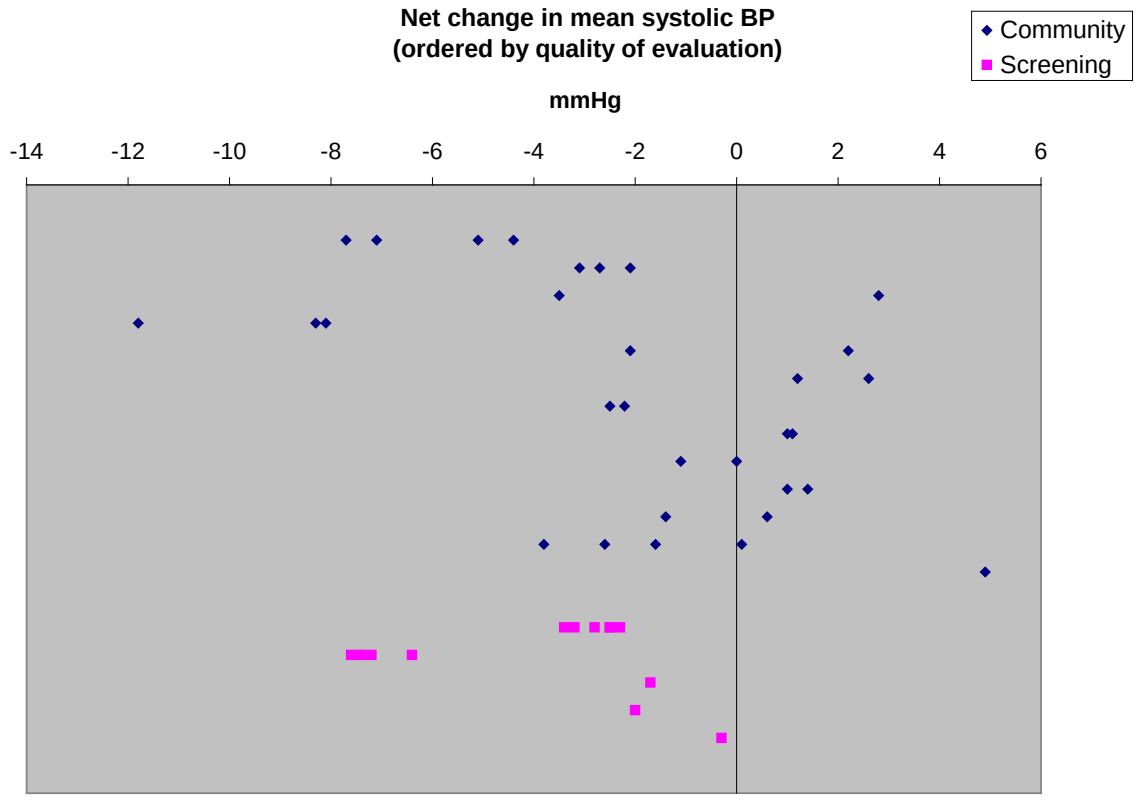
Confounders and limitations of the study results:
Identified by the study author(s): -

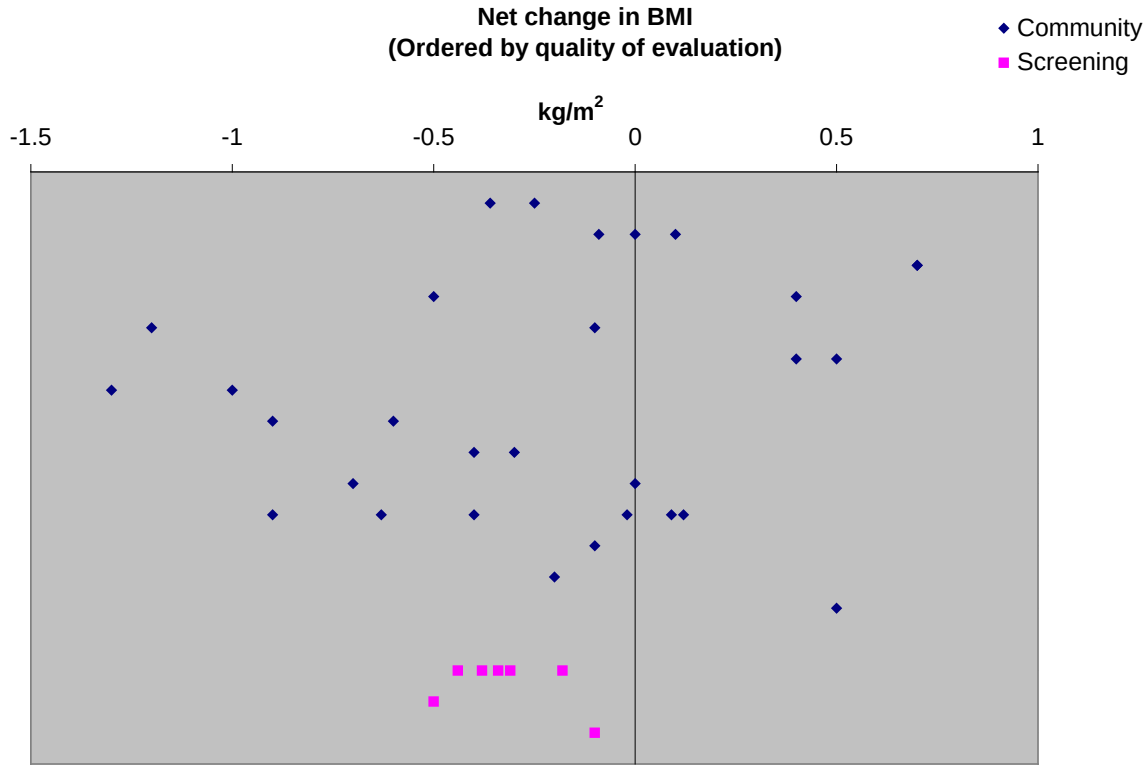
Identified by the reviewer: Changes in outcomes (with the exception of cholesterol) were generally reported separately for the intervention and control groups. Since net intervention effects are not given, it difficult to accurately gauge the treatment effect over time for most outcome measures. Given the non-random allocation of the intervention and control groups the possibility of selection bias cannot be discounted. Furthermore, as the municipality of Norsjo forms part of the wider region of Northern Sweden which served as the contol area it is possible that the programme may have had some spillover effects.

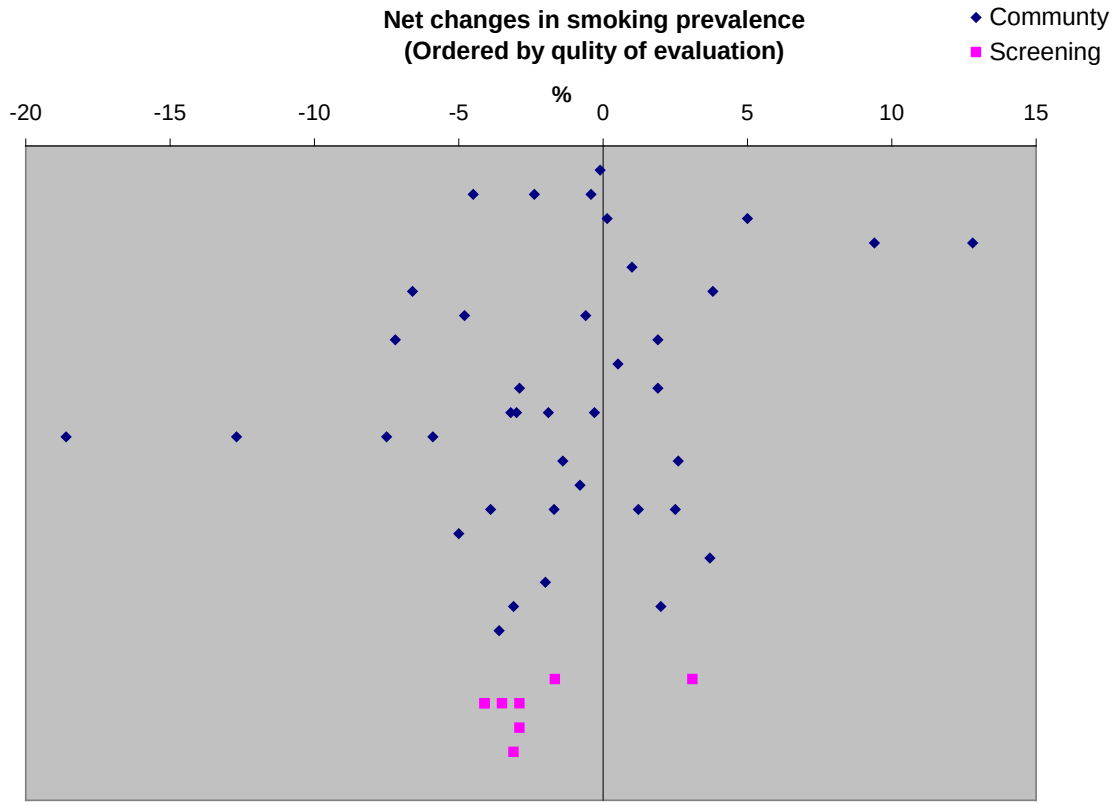
Appendix 7: Outcome graphs ranked by quality of programme evaluation

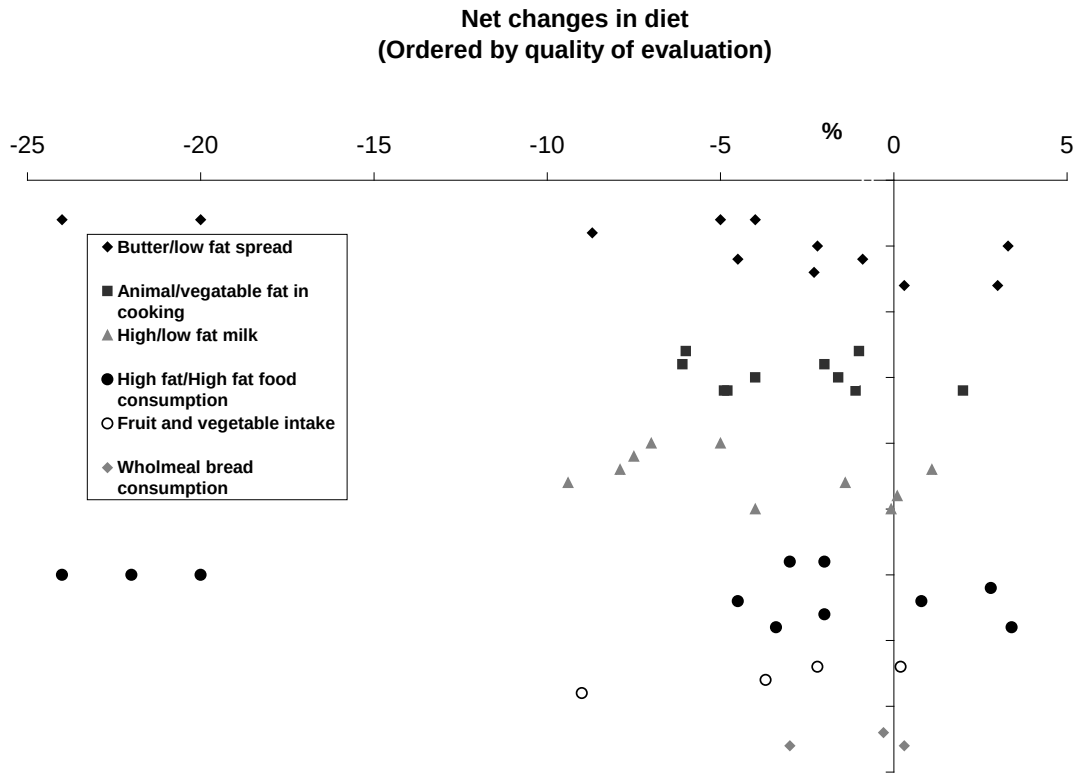

Net change in mean total cholesterol
(ordered by quality of evaluation)
Community
Screening
mmol/l
-0.80
-0.60
-0.40
-0.20
0.00
0.20
0.40
0.60

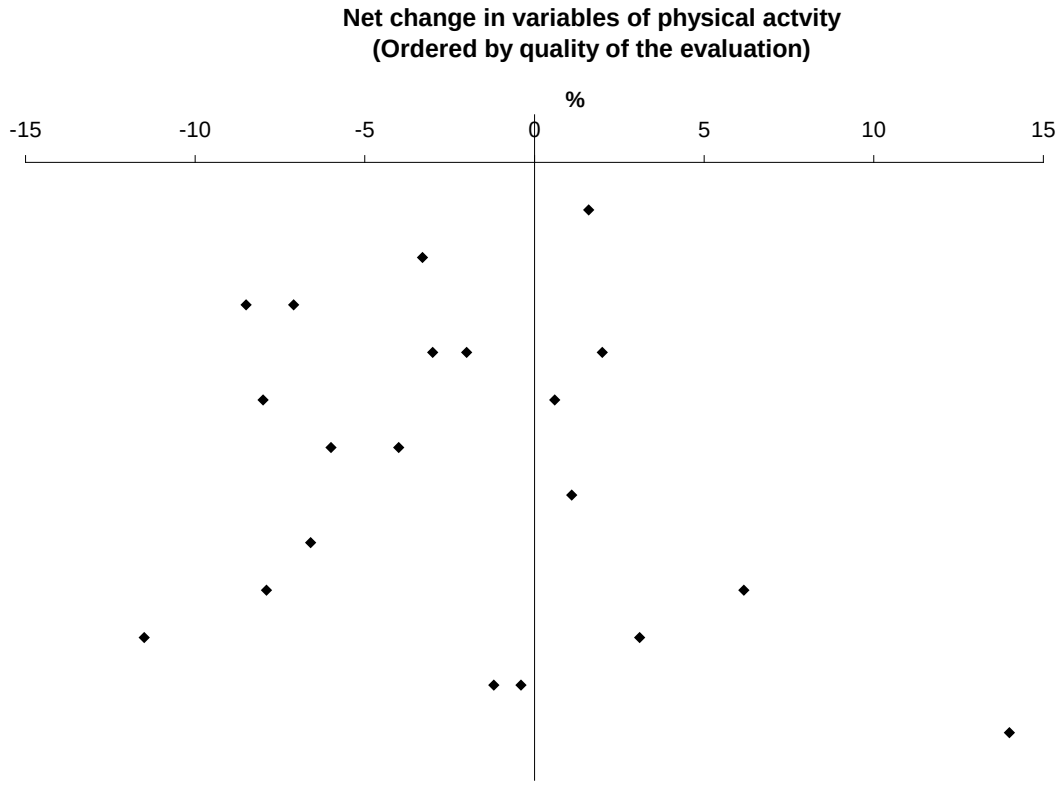

Net Change in mean diastolic blood pressure
(ordered by quality of evaluation)
Community
Screening
mmHg
-6
-4
-2
0
2
4
6


Net change in mean systolic BP
(ordered by quality of evaluation)
Community
Screening
mmHg
-14
-12
-10
-8
-6
-4
-2
0
2
4
6


Net change in BMI
(Ordered by quality of evaluation)
Community
Screening
kg/m2
-1.5
-1
-0.5
0
0.5
1


Net changes in smoking prevalence
(Ordered by qulity of evaluation)
Communty
Screening
%
-20
-15
-10
-5
0
5
10
15


Net changes in diet
(Ordered by quality of evaluation)
%
-25
-20
-15
-10
-5
0
5
Butter/low fat spread
Animal/vegatable fat in cooking
High/low fat milk
High fat/High fat food consumption
Fruit and vegetable intake
Wholmeal bread consumption


Net change in variables of physical actvity
(Ordered by quality of the evaluation)
%
-15
-10
-5
0
5
10
15