Document 1

Prevention of cardiovascular disease
at population level
[Question 1; phase 2]

Report
(21st October 2008)

Document 1

Prevention of cardiovascular disease at population level

[Question 1; phase 2]

Mary Pennant, Wendy Greenheld, Anne Fry-Smith, Sue Bayliss, Clare Davenport, Chris Hyde.

WMHTAC

West Midlands HTA Collaboration

Document 1

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 second of three effectiveness reports which together will 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. This report, together with our first report, specifically focuses on studies identified as included studies in systematic reviews addressing similar questions in the past. Directly relevant systematic reviews (14) were identified from over 3,000 citations and, for this report, 8 were used to identify relevant programmes and their associated publications (the other 6 were used for the previous report). Review steps were generally undertaken singly by one of two reviewers. 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 II of review 1) and more detailed evidence statements are then used to summarise available evidence from both the current and previous report (phase I and II of review 1).

Evidence statement for programmes addressing prevention of CVD at population level (phase II of review 1)

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

11 directly relevant programmes reported in 28 publications were identified for this report. All publications are concerned with the effectiveness of population programmes using education and mass media although programmes vary according to the relative contribution of these two components. No programmes used legislative or fiscal changes and there were no natural experiments. Programmes were generally evaluated using controlled before-after studies with

---

quality gradings ranging from – to +. For CVD risk factor physiological and behavioural outcomes, there was a mixed pattern across studies with some outcomes demonstrating no obvious direction of effect and other outcomes demonstrating a direction of effect in favour of programmes. The size of these effects could not be quantified. There was little useful information on the effect of the programmes on CVD morbidity and mortality.

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

These are interim statements based on the combined data from the first and second parts of a 3 stage review.

22 directly relevant programmes reported in 69 publications have been identified across phases I and II of this review of effectiveness. The majority of publications are concerned with the effectiveness of population programmes using education and mass media and were generally evaluated using controlled before-after studies with quality gradings ranging from – to +. Two screening programmes have been evaluated using RCTs and were both quality graded +. No programmes have used legislative or fiscal changes and no natural experiments have been identified. It is not possible to quantify the size of these effects across all programmes.

Evidence statements relate to 1) the effectiveness of programmes to reduce physiological and behavioural risk factors for CVD and 2) the nature of community programmes i.e. setting, target audience, intervention strategies etc. However, the extent to which the nature of community programmes might influence programme effectiveness has not been addressed as there is inadequate evidence to support evidence statements of this kind.

Evidence statements for outcomes

- There is currently little useful information on the effect of the programmes on **CVD morbidity** and **mortality**.

- For the CVD risk factor **cholesterol** a moderate trend in direction of effect in favour of programmes is observed.

- For the CVD risk factors **diastolic and systolic blood pressure** a moderate trend in direction of effect in favour of programmes is observed.

- For the CVD risk factor **smoking** a moderate trend in direction of effect in favour of programmes is observed.

- For the CVD risk factor **BMI** a strong trend in direction of effect in favour of programmes is observed.

- For the CVD risk factor **blood glucose** there is a mixed pattern across studies with no clear direction of effect.

- There is currently no evidence on the effect of the programmes on **triglyceride levels, HDL/LDL ratio or lipid levels**.

- There is currently no evidence of **adverse events** associated with these types of programmes.

- For CVD risk factors of **dietary change** a strong trend in direction of effect in favour of programmes is observed.

- There is currently no evidence of the effect of programmes on the CVD risk factor **salt intake**.

- For the CVD risk factor **physical activity** there is a mixed pattern across studies with no clear direction of effect.

- There is limited evidence of the effect of programmes on **attitudes, knowledge and intentions relating to CVD risk factors**.

- Additional outcomes to those specified in the protocol have been reported in some programmes but with little consistency across programmes limiting their usefulness.

Evidence statements for the nature of programmes

The 22 programmes identified targeted a variety of audiences, utilized various modes of delivery and drew on the skills and resources of a range of different personnel.

- The programmes identified were initiated across a wide time period from 1972 to 1998.

- Programme length ranged from one to >twenty years.

- Community settings were rural (n=10), urban (n=7), or mixed (n=5).

- The size of the target audience varied: ranging from approximately 2,500 to over 1,000,000.

- Additional consideration was given to groups of a low socioeconomic status in eight of the programmes.

- Communities considered to be at high risk of developing CVD were targeted in eight of the programmes.

- The majority of the programmes (n=17) relied heavily on mass media.

- Counselling was a key process in many programmes; undertaken individually (n=14) and amongst groups (n=8).

- Fourteen of the programmes utilized screening.

- Ten of the programmes implemented changes to the environment.

- Personnel delivering the intervention were generally drawn from staff associated with the respective projects (n=20).

- Health departments (n=13), local health committees (n=8), voluntary organisations (n=9) and community volunteers (n=6) had roles in programme delivery.

- Programmes were delivered in a variety of settings including workplaces (n=8) and schools (n=13).

- For programme accessibility, a consistent observation was a relatively lower response from males, those of younger age, those relatively less educated and those at higher risk of CVD. However, response rates are usually only provided for evaluation surveys and information is generally not available on uptake of intervention activities.

- 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 assessed in three programmes.

Conclusions:

Provisionally, the first and second components of this three stage review suggest 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. 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 second 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 third report, presenting the third phase of the review, was presented to the PDG in November 2008. A subsequent report, presenting findings for cost effectiveness, will be 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 final scope as:

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	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

than what is currently covered by a Primary Care Trust. A population could 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.	relevance for them. (Individuals at high risk of developing CVD are covered by 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	OR Interventions which focus on screening for CVD risk factors (for example, cholesterol-level screening)

risk-factor approach (as indicated in 4.2.1a) will be included when they involve a primary prevention element and where data can be disaggregated to allow consideration of the impact of the non-pharmacological elements.	and do not attempt to modify them
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 phases 1 and 2, which considers relevant original ("primary") studies identified in existing systematic reviews addressing an identical or similar question to the research objective above. 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

A number of suggestions were received from the expert group: two systematic reviews and six primary studies. Primary studies will be considered for inclusion in phase 3, together with studies identified from the primary studies literature search. Specific inclusion/exclusion criteria was applied to the systematic reviews.

2.1.3   Additional web-site searches

No additional web-site searches were undertaken at this stage of the review beyond those described in section 2.1.1

2.2   Selection of effectiveness studies for inclusion

2.2.1   Review title and abstract appraisal

Previous systematic reviews, most likely to have included primary studies relevant to this review, were identified from the results of the searches using the first part of the form provided in Appendix 3. This focused on the nature of the review and whether the review addressed CVD risk. The form was developed by the review group and signed off by the CPHE. 3153 citations were examined for systematic reviews to inform this report and the first report. 622 potentially relevant reviews were ordered for assessment based on their full text. The process was undertaken by one of three reviewers (MP, WG, CD). 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, previous systematic reviews most likely to have included primary studies relevant to this review were identified using the second part of the form provided in Appendix 3. This focused on the nature

of the review, particularly whether there was a clearly identified list of included

studies, whether the activity targeted multiple risk factors, whether the activity

targeted a population and whether the activity was mainly targeted on primary

prevention. The form was developed by the review group and signed off by CPHE. Of

the 622 hard-copy systematic reviews, 572 were excluded as they failed to meet the

main inclusion criteria and 50 were retained for detailed scrutiny of their list of

included studies. 36 were effectively excluded leaving 14 'included' systematic

reviews. Brief details were kept of reasons for exclusion and are held on a reference

management database held by the review team. Due to the volume of excluded

studies these details are not provided in this report but are available on request. The

process was undertaken by one of two reviewers (MP, WG). There was no double-

checking of decisions.

Of the 14 systematic reviews identified for primary study identification, 6 were used

to identify programmes for the first report. Programmes identified from the

remaining 8 systematic reviews are covered in this report. Table 1 below details

systematic reviews that were included in the earlier report and those used for the

current work.

Systematic reviews used for report 1 (previous report)
Ketola et al. Effectiveness of individual lifestyle interventions in reducing cardiovascular disease and risk factors Ann Med 2000; 32: 239-251
Ebrahim et al. Multiple risk factor interventions for primary prevention of coronary heart disease Cochrane Database of Systematic Reviews 2006, 4
Matson-Koffman et al. A site-specific literature review of policy and environmental interventions that promote physical activity and nutrition for cardiovascular health: What works? American Journal of Health Promotion 2005; 19(3): 167-193
Nicholson et al. The effect of cardiovascular health promotion on health behaviours in elementary school children: An integrative review. Journal of Pediatric Nursing 2000; 15(6): 343-355

Sellers et al. Understanding the variability in the effectiveness of community heart health programs: A meta-analysis. Soc. Sci. Med. 1997; 44(9): 1325-1339 Krummel et al. Cardiovascular health interventions in women: what works? Journal of Women's Health & Gender-Based Medicine 2001; 10(2): 117-136
Systematic reviews used for report 2 (current report)
Shiell et al. A systematic review of the effectiveness of population health interventions for the prevention of type II diabetes. Report from the Population Health Intervention Research Centre 2008 Engbers et al. Worksite health promotion programs with environmental changes. Am J Prev Med 2005; 29(1): 61-70 Finlay et al. Physical activity promotion through the mass media: Inception, production, transmission and consumption. Preventative Medicine 2004; 40: 121-130 Snyder et al. A meta-analysis of the effect of mediated health communication campaigns on behaviour change in the United States. Journal of Health Communication 2004; 9: 71-96 Fogelholm et al. Community health promotion interventions with physical activity: does this approach prevent obesity? Scandinavian Journal of Nutrition 2002; 46(4): 173-177 Sowden et al. Community interventions for preventing smoking in young people. Cochrane Database of Systematic Reviews 2003 Secker-Walker et al. Community interventions for reducing smoking among adults. Cochrane Database of Systematic Reviews 2002 The effectiveness of nutrition education and implications for nutrition education policy programs and research: a review of research. Journal of Nutrition Education 1995; 27(6)

Table 1 Systematic reviews included for identification of primary studies in the first two reports addressing question 1.

2.2.3   Previous reviews' included study lists' appraisal

A decision was made on whether a study described in any particular "included" systematic review would be included in the current review using the checklist given

in Appendix 4. With the exception of the ability to disaggregate components of mixed studies, all aspects of the general nature of the study, target population, activities/intervention or programme, study designs and desired outcomes as indicated in 1.2 above were captured. The form was developed and piloted by the review group and commented on and signed off by CPHE.

The reasons for exclusion of studies/programmes were recorded according to the categories identified in the in/exclusion list.

The in/exclusion process was undertaken by one of two reviewers (MP, WG). There was no double-checking of decisions. Because of the inclusion criteria used to identify what was considered a "systematic review", most decisions on whether a study or programme was to be included/excluded in the current review could be made using the information in the tables of included study characteristics. Where this was not possible the full text of the article in question was ordered.

11 programmes, represented by 41 articles, were included in the first report and 11 programmes, represented by 28 articles, were included in the current report.

2.2.4 Reference tracking

Reference tracking was used to ensure that most articles representing each of the included programmes were identified. Textwords, titles and abstracts were searched in Medline for each programme name or variations on programme name (see appendix 2). Reference tracking identified 133 primary studies, most of which were related to the 11 included programmes. Of the primary studies identified from reference tracking and those previously found in systematic reviews, 28 were identified as useful for data extraction and quality assessment. Reference lists of all included studies were not checked for further primary studies because of time constraints.

2.2.5 Summary of effectiveness studies identified for inclusion

The following programmes were identified for inclusion in this second phase to address question 1. 28 related studies are shown by their respective programmes.

- Action Heart (Baxter,T. 1997) (Baxter,A.P. 1997)

- Coeur en santé St-Henri (O'Loughlin 1995) (Paradis 1995) (O'Loughlin 1999)

- Di.S.Co – Sezze District Community Control – project (Giampaoli 1991) (Giampaoli 1997)

- The Dutch Heart Health Community Intervention/Harslag limburg (Ronda 2004 a) (Schuit 2006) (Ronda 2004 b) (Ronda 2004 c) (Ronda 2005)

- The Health and Inequality in Finnmark programme – Båtsfjord (Lupton 2003)

- The Health and Inequality in Finnmark programme – North Cape (Lupton 2002)

- Heartbeat Wales (Parish 1987) (Smail 1989) (Tudor-Smith 1998) (Nutbeam 1993)

- The Kilkenny Health Project (Shelley 1991) (Shelley 1995) (Collins 1993)

- The National Research Programme (Gutzwiller 1985)

- The Otsego-Schoharie Healthy Heart (Nafziger 2001) (Barthold 1993)

- The Stanford Three Community Study (Maccoby 1977) (Farquhar 1977) (Leventhal 1980) (Meyer 1980)

2.2.6 Excluded effectiveness studies

A summary of the reasons for exclusion of studies from phase 2 is given in table 2 below:

Reason for exclusion	Number
Published before 1970	0
Thesis/book chapter	0
Inappropriate setting and population	38
Does not address general purpose (reducing CVD risk)	87
Inappropriate intervention	0
Inappropriate design for effectiveness review	0
No appropriate outcomes	0
Number of articles "included"	28
Number of programmes represented by these articles	11

Table 2 Excluded primary studies obtained from systematic reviews in phase 2

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)*
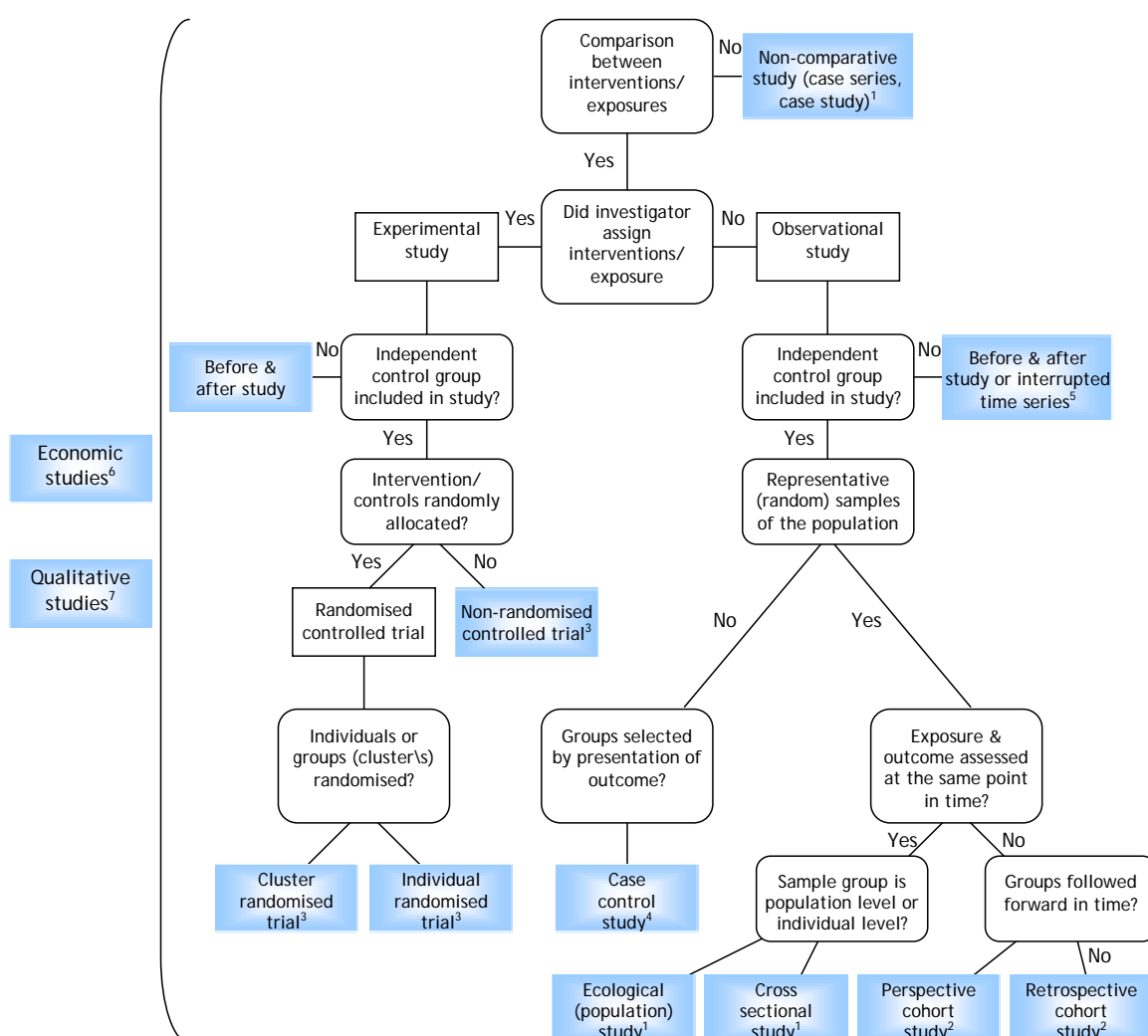
Source:

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 was included (Section 5.2).

For the cost effectiveness review, the data extraction form contained in the *Methods for development of NICE public health guidance* would have been 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). However, in the event there were no included cost-effectiveness studies.

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

2.4.1   Effectiveness studies

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. This statement was compared for consistency and inconsistency with the statement generated for the first report. In addition, graphical representation of the best available nominal data was explored for the main physiological outcomes: blood pressure, smoking, cholesterol and BMI. 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 11 programmes addressing prevention of CVD at population level were identified in the first phase of the review. These were described in 28 articles. The programmes are described 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.

Then its results are 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 3.2.

3.1 Programmes addressing prevention of CVD at population level

3.1.1   Action Heart

The four-year Action Heart intervention began in 1991 with the aim of producing lifestyle changes to slow the development of coronary heart disease (1).

Target population

Intervention was conducted in two communities in Rotherham: Swinton and Wath, chosen for their high incidence of coronary heart disease. The control area, Maltby had a similar socio-economic profile and presence of CVD risk factors and was considered far enough from the intervention region to minimise the risk of contamination (1).

Theory/conceptual model of intervention

None stated

Intervention description

Action heart was managed by an executive group comprised of representatives from the Rotherham Health Authority, Rotherham Priority Health Services Trust, general practice, Rockingham College of Further education and a senior registrar in public health medicine (2).

The programme ran courses, such as 'Look After Yourself' and stop smoking support groups. These were designed to give information and explore values and attitudes related to CVD and develop skills required for healthy living. Programme activities also included medical interventions such as blood pressure screening, Action Heart body check ups, weight control clinics and a nicotine patch scheme.

Printed information leaflets were used to convey programme messages and library resources were available. Institutional Action Heart Charters were set up with the aim of implementing physical and social environmental changes.

An important component of the Action Heart programme was schools-based health promotion activities. This work was supported by health promotion officers, health visitors, project staff, dieticians and school nurses together with school staff. Schools-based intervention was conducted over three years, from 1991 to 1994 (2) (main community intervention lasted four years).

Most interventions were targeted at secondary schools and aimed to promote behavioural change in individuals and also to influence the school environment in which they studied. The 'My Body' project was run in primary schools, with particular emphasis on the effects of smoking on health. In secondary schools, interventions involved healthy eating days, no smoking school policies and an Action Heart lunch time club. In one secondary school, a training programme was run for students who subsequently ran 'health days' for other students. Some schools provided training for staff involved in health education and most schools reported the

inclusion of heart health topics in the teaching curriculum. Leaflets, T-shirts, posters and other promotional materials were used to support events and local press were contacted to cover activities (2).

Across the whole community, the "Wake up to semi-skimmed milk" promotion took place in the last year of intervention and involved delivery of leaflets, promoting low fat milk, to 13,000 households (1).

Accessibility:

It is not clear whether the community aspects of the intervention required attendance at health facilities and no information is provided on distance to be travelled or whether participation was affected by distance from facility. Written educational materials were made available, for example from libraries, but were not delivered directly to homes. No indication is given of whether materials were adapted for those with low levels of literacy, for those speaking different languages of for those from different cultural backgrounds.

Response rates to the programme evaluation surveys in adults were high (>80%) but varied in population sub-groups: the authors report a relatively lower response rate in younger men. Some sex differences in outcomes were noted (less favourable results for smoking prevalence and drinking low fat milk in women compared to men) but no differences noted according to age. These observations may be a reflection of the accessibility of the intervention in these population sub-groups. Response rates in the school surveys were high (85-95%) but questionnaires were administered by teachers and this is therefore not likely to be a reflection of the accessibility of the intervention. No information is provided on uptake of the intervention in adults or children.

Programme evaluation

Programme effectiveness was assessed separately in adults and children.

Adults (1): Two independent surveys were conducted, one at baseline (July 1991) and one four years later (June 1995). At baseline, the proportions of questionnaires mailed

to subgroups of men and women aged 18-40 or 41-64 years were the same in both intervention and control areas. In the four year survey, the proportions of surveys sent out to each group were adjusted to try to achieve equal numbers of respondents in each of the subgroups based on the baseline survey response rates. Although this gave better estimates for the prevalence of risk factors in different subgroups, the proportions in each group for baseline and four-year surveys was different to those measured by census data and statistical adjustment was required (see below).

Children (2): There were three secondary schools in the intervention area and one in the control area and all four agreed to participate in evaluation surveys. A questionnaire was first piloted in each of the schools before use. Results from questionnaires were analysed using cohort and cross sectional analysis. For the cohort, results for children aged 11 years in the first survey were compared with results from the same children aged 14 years in the post-intervention survey. For the cross sectional analysis, results for children aged 11 and 14 years were examined in both surveys.

Participant selection/recruitment

Adults: Questionnaires were sent by mail to a sample of adults, randomly selected from the Rotherham Family Health Services Authority population age-sex register. Response rates for the baseline and four-year surveys ranged from 82 to 86%.

Children: Questionnaires were sent to schools and administered by teaching staff at the beginning of the school year in 1991 (baseline) and in 1994 (post schools-based intervention) and response rates ranged from 85-95%.

Outcome measures

All outcome measures were self reported.

Adults: Prevalence of active smoking, passive smoking, consumption of wholemeal bread, use of low fat spreads, use of low fat milk, exercise ≥3 times per week, obesity or overweight, blood pressure and cholesterol measurement.

Children: Prevalence of active smoking, passive smoking, wholemeal bread consumption, low fat spread consumption, low fat milk consumption and exercise ≥3 times per week.

Statistical methods

Adults (1): Univariate analysis was used to compare the prevalence of risk factors between intervention and control groups from baseline to four years with responses weighted so that they were directly proportional to the corresponding subgroups in the Office of Population Census survey populations.

Multiple logistic regression was used to assess the effect of intervention on lifestyle behaviours to model the proportion with a particular behaviour in the treatment community as a function of age group (18-40 or 41-64 years), sex, year of observation and area (intervention or control). The effect of intervention was then measured by comparing the change in the proportion showing a particular behaviour from baseline to post-intervention in the treatment compared to the control area, the test being based on the interaction between year and area. Whether intervention effect differed for age group and sex was also investigated.

Children (2): Analyses used logistic regression models to make cross sectional comparisons. The prevalence of each behavioural outcome was first modelled for sex, school and year separately for 11 and 14 year olds. Intervention effect was then measured by comparing the difference in behaviour proportion from pre to post intervention between treatment and control schools.

Results

Programme results are reported separately for children (2) and for adults (1).

Primary outcomes

Adults: Outcomes from the univariate analysis are presented as the estimated % intervention effect. Outcome from the multiple logistic regression analysis are

presented as odds ratios of change in prevalence from baseline to post-intervention for intervention and control communities. These ratios were then compared (using X^2) to test if there was a significant treatment effect.

For the univariate and multiple logistic regression analysis, there was no significant estimated intervention effect for any outcome variable except for reported smoking and consumption of low fat milk.

1. Smoking

Univariate analysis: The prevalence of reported smoking decreased from 32.3% to 28.8% in the intervention group and increased from 36.4% to 38.0% in the control group (estimated net effect -24.5%; CI -39.4 to -6.1).

Multiple logistic regression: The odds ratio for pre to post-intervention change in reported smoking prevalence was 0.83 in the intervention area (CI 0.71-0.97) and 1.1 in the control area (CI 0.95-1.29) and difference in odds ratios was statistically significant (X^2=6.4, p=0.01). Intervention effect held for all age groups but there was weak evidence that intervention effect was greater in women (X^2=2.6, p=0.11).

2. Low fat milk consumption

Univariate analysis: The prevalence of low fat milk consumption increased from 48.2% to 71.0% in the intervention group but from 53.6% to only 68.8% in the control group (estimated net effect +42.5%; CI 14.8 to 77.0).

Multiple logistic regression: The odds ratio for pre to post-intervention change in prevalence of low fat milk consumption was 2.58 in the intervention area (CI 2.22-3.01) and 1.81 in the control area (CI 1.55-2.11) and the difference in odds ratios was statistically significant (X^2=10.3, p<0.001).

Children:

Cohort: Outcomes are presented separately as changes from baseline in boys and girls in intervention and control schools. Some positive changes are noted in intervention

and control schools but, since no intervention/control school comparisons are made, net intervention effect cannot be assessed. The absence of these comparisons in this study has been interpreted to show the absence of net significant treatment effects in the cohort.

Cross sectional surveys: The odds ratio for each risk factor is presented for post-intervention compared to baseline for children aged 11 and 14 years in intervention and control schools. Positive intervention effects were detected for exercise and wholemeal bread consumption but for none of the other risk factors.

1. Physical activity

The prevalence of children exercising ≥3 times a week increased from baseline to 3 years in the intervention 11 year olds (odds ratio 1.76) but decreased in 14 year olds (odds ratio 0.65). In control schools, it decreased in 11 year olds (odds ratio 0.41) and increased slightly in 14 year olds (odds ratio 1.1). Although there was a significant overall net improvement for treatment compared to control schools (X^2=11.4, p<0.01), authors state that the opposite direction of effect in different age groups may suggest that this finding is not due to a direct intervention effect.

2. Diet

Wholemeal bread consumption increased from baseline in intervention 11 year olds (odds ratio 1.3) and decreased slightly in 14 year olds (odds ratio 0.79). For controls, consumption decreased in both age groups (odds ratios: 11y 0.84, 14y 0.23). For all children, there was a significant net improvement in treatment compared to control schools (X^2=7.1, p<0.01).

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors (Schools-based (2)

It may not be possible to produce lifestyle changes within a school setting in this short period of time as other influences may be too important.

There were very limited resources for health promotion in schools.

Work was not informed with a systematic review of the evidence of the effectiveness of health promotion interventions.

Tobacco industry marketing was great in comparison with government spending on smoking prevention activities.

Limitations identified by reviewer

There was a greater fall in unemployment rate in the intervention compared to the control area during the period of study. This has been identified by other reviewers as a potentially important confounder at it is suggested that this factor may have influenced the observed treatment effect on smoking in adults.

All outcomes are self-reported and, since smoking may be particularly at risk from reporting bias, this outcome may not be fully reliable.

The questionnaire that was used to evaluate intervention effects in school children was first piloted in the schools that it was later used to assess.

Summary

The Action Heart programme appears to have been ineffective in producing behavioural change in schools or the wider community. The self-reported mode of programme evaluation may be evidence of poor project funding and the low intensity, small scale nature of intervention may have been responsible for the lack of effect.

3.1.2   Coeur en Santé St-Henri

St-Henri, a low income, low education, urban neighbourhood in west-central Montreal, was the setting for the Coeur en Santé St-Henri heart health promotion

programme that began in 1992. St-Henri, predominately French-speaking, is one of the most disadvantaged urban communities in Canada and this intervention programme specifically aimed to address the needs of this low socio-economic status population. The three and a half-year multi-factorial community intervention was modelled on earlier heart health initiatives: North Karelia, Stanford Five City, Minnesota and Pawtucket, with the goal of promoting heart healthy behaviours, particularly in those aged 18-65 years (3).

Target population

Intervention took place in St-Henri, a community of ~25,000 people. The control community, Centre-Sud was matched to St-Henri on size, geographic location, language spoken at home, level of education, income sufficiency and CVD mortality. These communities were close geographically and shared a common media market and therefore received equivalent exposure to any national or provincial heart health promotional activities (3).

Theory/conceptual model of intervention

The major underlying strategies for programme implementation were social leaning theory, the reasoned action model and the precede-proceed model (4). Central to this was the idea that behaviour change was determined by factors within an individual – their knowledge and beliefs conferring favourable attitudes and higher perceived self-efficacy to make behavioural change. In combination with this, a perception of 'healthy behaviour' social norms is important and social class, employment status and cultural values are influencers in the decision making process. Regulatory policy, legislation and favourable environments are believed to facilitate decisions for change and social support is thought to be a key factor in sustaining newly acquired modifications in behaviour (5).

Intervention activities were planned in each of the five axis of the Ottawa charter describing principles of strengthened community action, supportive environments,

building good public health policy, developing personal skills and re-orientating health services (5).

Intervention description

The programme was implemented by the public health department (4) and all interventions were planned and implemented in close collaboration with local community groups (3). Intervention activities included school-based smoking prevention programmes for youth, adult smoking cessation courses, a smoking cessation contest, a heart healthy recipe contest, nutrition courses, a supermarket nutrition campaign, heart healthy menus in local restaurants, a walking club, cholesterol and blood pressure screening events, distribution of heart health videos and a weekly heart health column in the local press (3).

Interventions appear to be small scale compared to bigger heart health programmes. This may be due to the more limited funding but activities were particularly tailored to the low-income, low education population (3).

Accessibility:

The intervention specifically targeted a low education, low income urban community. Educational materials were refined with the help of local community leaders and the intended audience since part of the aim was to be responsive to local needs. For example, educational videos were available free of charge and depicted examples of low income families and individuals making lifestyle changes. Interventions were varied and offered at a variety of locations (health services, schools, social clubs, food retailers and delivered directly to the home).

Written materials were adapted for those with low level literacy skills and were bilingual (English and French) but no provision was made for those speaking other languages. No mention is made of provision for those with different cultural backgrounds. Those not speaking French or English were also excluded from the programme evaluation.

Participation in the programme evaluation was >80% in the intervention community. Awareness of the programme in the intervention community was > 60% and participation varied between 21 and 34% over time. It was noted that participation and awareness was greater for interventions that were 'easily accessible' for example newspaper coverage or that were available in the context of other community events. Multi-variate analysis also suggested that awareness and participation were greater among females, those aged between 45 and 65, those with a lower education and those who had been resident in the community for >5 years.

Programme evaluation

Evaluation was conducted at baseline (1992) and after intervention in treatment and comparison communities (3). This included independent cross sectional surveys at baseline and three years into intervention (1995) and a cohort of participants was also surveyed after five years (1997), 18 months after the end of intervention activities. The same baseline survey acted as the pre-intervention measure for both independent cross sectional and cohort samples (4).

Formative evaluation was conducted using three independent sample surveys to assess awareness of, and participation in, programme activities after one, two and three years of intervention (3). Details of findings from this evaluation are given (4) but not described in the current report.

Participant selection/recruitment

A random selection of 1,422 households in St Henri and 1,454 in the control area were identified from telephone directory lists of residential subscribers (lists included ~85-90% of populations). These households were sent a letter to relay information about the study and to inform them that a telephone call would be made by programme coordinators within the next two weeks. Coordinators randomly selected one member of each household, aged 18-65 years, for interview. Interviews lasted approximately 35 minutes and were conducted in French or English and collected data on socio-

demographic features as well as risk factor behavioural variables such as past and current use of tobacco, behaviours relating to blood pressure and cholesterol control, physical activity and dietary fat. A 'junk food' score was obtained from scores from a number of diet-related questions. Information was also collected on psychosocial variables such as behaviour specific measures of attitude, perceived self-efficacy, knowledge of community resources, social support for positive behaviour change, perceived barriers to physical activity and intentions to undertake risk reducing behaviours (3).

In the baseline survey, of the households primarily contacted, 849 in St Henri and 825 in the control region took part, representing response rates of 79.3% and 77.8% respectively (of those who could be contacted) (3,4). Response rates for the independent cross-sectional survey three years later were lower: 70.6% and 67.2% in treatment and control communities respectively.

For the cohort, to minimise attrition, two re-contact surveys were scheduled in the intervening period, between baseline and five years, that updated participant contact details (3). Approximately 50% of participants of the baseline cross sectional survey took part in the cohort survey at five years (423 in St Henri and 396 in the control) and subjects lost to follow-up were younger, more were male and more had completed secondary school (4).

Statistical methods

For the independent cross-sectional surveys, data from the baseline and 3-year survey were used to compare unadjusted prevalence's of behavioural CVD risk factors between intervention and control communities over time in univariate analyses. The proportion of subjects with a specific risk factor was then modelled as a function of year in each community separately and controlled for sex, age group (18-34y, 35-65y), language, education and no. in household to give an odds ratio. Odds ratios were compared for communities using X^2 and analysis was repeated for each sex

separately, for the two age groups and by level of education (less than high school, high school or more) (4).

For the longitudinal cohort survey, repeated-measures analysis of variance was used to study programme impact on continuous outcome variables with community and time as independent variables. A community x time interaction term at $p \leq 0.05$ was taken to imply significant programme impact. For dichotomous outcomes, multiple logistic regression analysis was used. Follow-up (5-year) values were modelled as a function of community, with baseline value included in the model as an independent variable. The odds ratio for community (St Henri subjects relative to control subjects) was used to interpret significance of programme effect. If the 95% CI for the odds ratio did not include 1 then this was classed a significant finding. Baseline age group, sex, language, education and no. in household were included in models to control for potential confounding. Analysis for each outcome was repeated separately for each sex, for the two age groups and by level of education (4).

Individual based analysis was to be used to assess intervention effect. Intraclass correlation coefficients (23 variables, estimated from the Minnesota programme) were used to obtain estimates of standard errors (3).

Outcome measures

Reported measures relating to smoking, cholesterol, blood pressure, BMI, physical activity and fat intake (4).

Results

Primary outcomes (4)

Outcomes are detailed for independent and cohort samples (some additional outcomes were reported for cohort samples). Where percentage changes are shown, these are percentage changes from baseline:

1. Reported Smoking

For independent cross-sections surveys, the percentage of respondents reporting that they smoked daily increased in both intervention (+0.5%) and control (+3.6%) groups and there was no difference between groups in the baseline relative to 3-year adjusted odds ratios (intervention 1.2; CI 0.9-1.5, control 1.2; CI 0.9-1.6, p=0.550). There was also no difference between intervention and control group odds ratios for the percentage smoking $\geq$ 25 cigarettes per day (intervention 0.8; CI 0.5-1.2, control 1.1; CI 0.7-1.8).

Conversely, in the longitudinal cohort, percentage of respondents reporting that they smoked daily, reported no. cigarettes per day, percentage smoking $\geq$ 25 cigarettes per day and the number attempting to quit, decreased at follow-up compared to baseline in treatment and control communities. There were no significant differences between communities in the reported smoking habits or intentions but group differences in the percentage of smoking $\geq$25 per day neared significance (treatment -23.1%, control -5.3%, odds ratio 0.5; CI 0.3-1.1).

2. Physical activity

For independent cross-sectional surveys, the percentage of respondents with infrequent leisure time physical activity (LTPA) increased substantially in both groups from baseline to 3 years (intervention +52%, control +104%) but the difference in adjusted odds ratios was not different between groups (intervention 1.9; CI 1.4-2.6, control 2.8; CI 2.0-4.0, p=0.063).

Similarly, in the cohort, the percentage of respondents with infrequent LTPA increased in both groups (intervention +85%, control +101%) but with no significant between-group difference (odds ratio 1.0; CI 0.7-1.3). However, the percentage describing themselves as 'more active', increased in the intervention (+5.5%) and decreased in the control (-1.6%) group and the adjusted odds ratio for the difference between groups was just significant (1.3; CI 1.0-1.8).

3. Body mass index

The percentage of respondents reporting BMI (from reported height and weight) $\geq$27 kg/m^2 was reasonably stable between baseline and 3-year independent cross-sectional surveys and there was no difference between groups for adjusted odds ratio (intervention 1.1; CI 0.8-1.6, control 1.0; CI 0.6-1.5, p=0.466).

In the cohort, both groups reported a similar increase in BMI (intervention +51%, control +53%) and there was no between-group difference (odds ratio 1.0; CI 0.7-1.6).

4. Diagnosed high blood pressure

In the independent cross-sectional surveys, the percentage of people being told that their blood pressure was high decreased in both intervention and control groups and there was no between group difference in the change.

In the cohort sample, a decrease was also observed in both groups and there was also no significant difference between communities in respect to change. However, the percentage of people with blood pressure checked in the past year increased in both groups and the change appears to be greater in the treatment compared to control group (treatment +5.7%, control +2.6%, odds ratio 1.3; CI 1.0-1.9).

5. Diagnosed high cholesterol

For the independent cross sectional samples, the percentage of respondents reporting that they had been told that they had high cholesterol decreased slightly in both groups and there was no significant difference between groups in the size of change.

For the cohort, there was an increase in the treatment group (+17.6%) but a decrease in the control group (-8.5%) and the difference was significant (odds ratio 1.6; CI 1.1-2.6). This corresponded to a significantly greater baseline to five-year increase in the percentage having their cholesterol checked in the past year in the intervention compared to the control group (intervention +19.7%, control +3.2%, odds ratio 1.4; CI 1.1-1.9).

6. Diet

For the independent cross sectional samples, the percentage of responders reporting frequently consuming high fat/junk foods increased in both treatment and control groups and there was no significant difference between groups in the size of change. For the cohort, the percentage also increased slightly in both groups and there was no difference in the size of changes between the groups.

In subgroup analysis of the independent cross-sectional surveys, only one subgroup provided a statistically significant finding. For smokers with less than a high school education, the odds ratio for the percentage reporting heavy smoking ($\geq$25 cigarettes per day) in the intervention group (0.5; CI 0.2-1.2) was significantly different to that for the control group (4.4; CI 1.4-13.7) (X^2=9.3, p=0.002).

Data for subgroup analysis for the cohort is not shown but authors report that changes occurred primarily among females, younger subjects (18-34 years) and those with higher education (high school or more).

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors (4)

There were consistently low levels of participation in programme activities.

Intervention components may not have been sufficiently intense or effective to bring about behavioural change.

Methodological problems such as reliance on self-reported behaviour, use of telephone surveys, loss to follow-up in the cohort and contamination of the comparison community may have limited ability to detect an intervention effect.

Limitations identified by reviewer

There were large differences between groups in baseline measures, particularly for reported rates of smoking.

Summary

The Coeur en Santé St-Henri programme showed no positive effects on behavioural change when assessed by independent cross-sectional surveys. Although some positive findings were detected in the cohort analysis, the high attrition (~50%), self-reported nature of outcomes and low consistency with cross-sectional findings, may limit the reliability and generalisability of these results.

3.1.3   The Di.S.Co (Sezze District Community Control) Project

The Di.S.Co – Sezze District Community Control project began in 1982 in a rural area located south-east of Rome. The project's objective was to reduce the morbidity and mortality associated with some non-communicable diseases through community medicine-based actions: modifying the risk factors for chronic diseases in a general population, identifying and treating high-risk subjects, re-orienting health services toward prevention and creating a reproducible model for low-cost community intervention.

One sector of the Di.S.Co. project was directed to the control and prevention of cardiovascular diseases. Its main ten-year objectives were to decrease the prevalence of smoking by 20%, mean diastolic blood pressure by 3mmHg, and total cholesterol by 5% in the treatment area (in comparison with the designated control area) by following suggestions of the Countrywide Integrated Non-Communicable Diseases Intervention Programme (CINDI) of the WHO.

Target population

Two rural areas in central Italy were involved in the study: one for intervention (the treatment area), corresponding to the Sezze Health District and including the municipalities of Sezze, Roccagorga and Bassiano (total population 25,706) and one for reference (the control area), corresponding to the municipality of Priverno (total population 12,655). Both areas were located in the province of Latina, about 100km south-east of Rome.

Theory/conceptual model of intervention

The influence of an underlying theory on this programme was not commented on.

Intervention description

Between 1983 and 1993 several intervention activities based on community medicine were carried out in the treatment area. They were based on interaction with the local socio-sanitary institutions and the school system with the aim of influencing individuals, small groups and the whole community. The intervention programmes included: mass health education; community checks on arterial hypertension; information on diet; anti-smoking propaganda; and a campaign to promote regular physical activity. General health education was carried out at all levels with special attention to schools and workplaces.

Among younger generations, preventive activity largely took place in school with the aim of engaging the interest of children and adolescents as a way of reaching the whole family. Interventions involved the following activities: preparation and distribution of printed material; setting up consulting rooms; organisation of lectures and exhibitions; and theoretical and practical courses for teachers and health care personnel (6).

Accessibility:

The intervention was varied in nature and included written and verbal health education, screening and mass media (television, radio and newspaper) campaigns. The health education components of the intervention were delivered through schools, workplaces, churches, health services, sports and leisure centres and specially organised lectures / seminars. Screening was undertaken in dedicated clinics in existing health services following a letter of invitation. No indication is given of whether materials were adapted for those with low levels of literacy, for those speaking different languages of for those from different cultural backgrounds.

Response rates to evaluation surveys were lower at follow up than at baseline in both intervention and control populations. However response rates were higher at both time points and in both intervention and control populations in females compared to males and in older compared to younger individuals. No information is provided on uptake of intervention components.

Outcomes at three years were generally more favourable in women compared to men in the intervention population. A proposed explanation for this observation according to the researchers is that it is more difficult to involve men than women in health programmes. At ten years follow up, generally no differences in outcomes were observed in different population sub-groups.

Programme evaluation

Participant selection/recruitment

Samples of men and women aged 20-69 years (randomly drawn from the electoral rolls) were screened and the main risk factors for cardiovascular diseases assessed. At baseline (1983), 739 men and 958 women in the treatment area and 942 men and 1,045 women in the control area were examined.

In 1986 a second screening was conducted on the same sample assessed in 1983 (350 men and 443 women in the treatment area, and 512 men and 553 women in the control area). Also, a new independent sample was enrolled in involving 570 men and 648 women in the treatment area and 553 men and 725 women in the control area.

In 1993-96 a new independent sample was examined including 307 men and 305 women in the treatment area and 704 men and 748 women in the control area.

Outcome measures

Participants were invited by letter to come to an examination centre where blood samples for lipid tests (total and HDL cholesterol) and fasting blood glucose levels were obtained, systolic and diastolic blood pressure were assessed, and height and

weight were measured to allow calculation of BMI. Smoking habits and the use of antihypertensive drugs were evaluated with a questionnaire (6).

Results

Primary outcomes:

The main results presented are those at ten year follow-up which use samples from two independent sets of cross-sectional surveys in the intervention and reference communities (undertaken in 1983 and 1993-96) to compare changes in the following outcomes (7). Net changes are expressed as age-adjusted mean differences between 1983 and 1993:

1.   Cholesterol

For men, HDL cholesterol decreased more in the control area (-1.4mg/dl (treatment) vs. -1.8mg/dl (control), net difference: +0.4mg/dl). Serum cholesterol decreased more in the control area (-1.6mg/dl (treatment) vs. -10.4mg/dl (control), net difference: +8.8mg/dl). The prevalence of hypercholesterolaemia decreased more in the control area (0% (treatment) vs. -9.8% (control), net difference: +9.8%).

For women, HDL cholesterol increased less in the control area (+1.9mg/dl (treatment) vs. +1.7mg/dl (control), net difference: -0.2mg/dl). Serum cholesterol increased in the treatment area and decreased in the control area (+13.0mg/dl (treatment) vs. -5.9mg/dl (controls), net difference: +18.9mg/dl). The prevalence of hypercholesterolaemia increased in the treatment area and decreased in the control area (+9.4% (treatment) vs. -3.4% (control), net difference: +12.8%).

2.   Blood pressure

For men, systolic blood pressure increased more in the treatment area (+3.9mmHg (treatment) vs. +1.3mmHg (control), net difference: +2.6mmHg). Diastolic blood pressure decreased more in the treatment area (-1.9mmHg (treatment) vs. -0.8mmHg (control), net difference: -1.1mmHg). The prevalence of hypertension increased more

in the treatment area (+5.2% (treatment) vs. +1.3% (control), net difference: +3.9%). The prevalence of people with hypertension under treatment increased more in the treatment area (+22.2% (treatment) vs. +6.6% (control), net difference: +15.6%).

For women, systolic blood pressure increased more in the treatment area (+3.9mmHg (treatment) vs. +2.7mmHg (control), net difference: +1.2mmHg). Diastolic blood pressure decreased more in the treatment area (-0.8mmHg (treatment) vs. -0.6mmHg (control), net difference: -0.2mmHg). The prevalence of hypertension increased more in the treatment area (+3.7% (treatment) vs. +2.3% (control), net difference: +1.7 %). The prevalence of people with hypertension under treatment increased more in the treatment area (+6.5% (treatment) vs. +1.5% (control), net difference: +5.0%).

3. Smoking

For men, the prevalence of smokers decreased more in the control area (-11.5% (treatment) vs.-15.3% (control), net difference: +3.8%). For women, the prevalence of smokers decreased in the treatment are and increased in the control area (-3.9% (treatment) vs. +2.7% (control), net difference: -6.6%).

4. BMI

For men, BMI increased slightly more in the control area (+0.4kg/m^2 (treatment) vs. +0.5 kg/m^2 (control), net difference: -0.1 kg/m^2). For women, BMI decreased in the treatment area and increased in the control area (-0.8kg/m^2 (treatment) vs. +0.4 kg/m^2 (control), net difference: -1.2 kg/m^2)-net changes of the differences in the treatment area compared with the control area showed a significant benefit in favour of treatment (p<0.002).

5. Fasting blood glucose levels

For men, fasting blood glucose levels decreased more in the treatment area (-5.2mg/dl (treatment) vs. -1.8mg/dl (control), net difference: -3.4mg/dl).)-net changes of the differences in the treatment area compared with the control area showed a significant benefit in favour of treatment (p<0.05). For women, fasting blood glucose levels

decreased more in the control area (-2.0mg/dl (treatment) vs. -7.0mg/dl (control), net difference: +5.0mg/dl).

NB. At ten years the only statistically significant improvements amongst the treatment group in comparison with the control group were the reductions in fasting blood glucose amongst men ($p<0.05$) and BMI amongst women ($p<0.002$).

The ten year results were not as positive as expected from the preliminary findings after the first three years (6) which had reported the following net percentage differences in the treatment versus control areas: in men, BMI: -1.3% and number of cigarettes smoked per day: -5.1%; in women, systolic blood pressure: -2.1%, BMI: -3.2% and number of cigarettes smoked per day: -34.4%.

Limitations of the study

The study was quality assessed and graded '- '.

Limitations identified by authors

The study was carried out in too small an area to adequately capture the programme effects. The treatment and control communities were geographically too close (in the same province) to prevent the possibility of the control area being contaminated by the effects of the intervention programme.

Limitations identified by reviewer

The use of different population samples to assess trends over the ten-year period raises doubts about the extent to which the later samples represent the same population as the initial ones due to migratory effects.

Summary

The Di.S.Co project, despite continued intervention over a ten year period, failed to reach the targets set at outset. The close proximity of control and treatment populations may have been an important contributor to lack of findings but the

programme seems to have been implemented with a 'top-down' mode of delivery with little community involvement and this may have impacted it's ability to influence change.

3.1.4   The Dutch Heart Health Community Intervention

The Dutch Heart Health community Intervention, also known as 'Harslag Limburg' (Heatbeat Limburg), began in 1998 and intervention has continued for more than six years. The aim of this project was to reduce CVD risk by achieving a reduction in fat intake, an increase in physical activity and a reduction in the prevalence of smoking in the general population and to specifically target groups of low socio-economic status (8).

Target population

Intervention took place in the Maastrict region (n= 180,000). This consisted of the capital, Limburg (n= 120,000) and four smaller municipalities (n= 12,000 to 21,000). The control region (location not stated) was six municipalities (total n~130,000) (9).

Intervention had two targets: 1) The whole population and specifically those of low-socio-economic status, 2) Individuals with CVD or with multiple risk factors for CVD (10).

Theory/conceptual model of intervention

The intervention was designed using a combination of planning and evaluation models. The model used assumed that a reduction in CVD could be achieved via a reduction in risk related behaviours and behavioural change could be brought about via changes in awareness, attitudes, social influences and self-efficacy expectations. It was anticipated that, for changes to take place, there had to be sufficient programme activities tailored to changing these factors that effectively reached the target population (8).

Intervention description

Community-based principles were used as the basis for project implementation. Initial community analysis preceded the creation of nine intersectoral local health committees that collaborated with experts in the planning and implementation of programme activities. Each committee was allocated a social worker, civil servant and a neighbourhood assistant as well as a health educator who specifically assisted the committee in selecting programme activities from a suggested pool and in the development of their own ideas for implementation (8).

About 50% of programme activities took place in areas of low socio-economic status and interventions were aimed at improving diet, increasing physical activity and achieving smoking cessation. Computer tailored nutrition education, supermarket nutrition education tours, television programmes, food labelling and collaborations with the retail sector were used to encourage healthy eating. Increased physical activity was encouraged with the creation of walking and cycling clubs and implementation of walking and cycling campaigns. Activities to promote smoking cessation were fewer in comparison but included a stop smoking campaign and the provision of smoke-free areas. The media was utilised and there were commercials on local television, radio and newspaper articles and the distribution of printed material (10).

Project implementation was evaluated at all stages including the number and effect of activities, strategies used, participation rates and sustainability of projects (8).

Accessibility:

Interventions were varied in nature and delivered by a range of organisations including health and social services, local business' and social organisations at a variety of venues. Activities were 'tailored to various target groups'. There is no discussion of whether materials were adapted for individuals with literacy problems, for those speaking different languages or for those with different cultural backgrounds. A specific aim of the programme was to target low socio-economic

groups and the magnitude of changes in risk factors was similar in low socio-economic groups compared to moderate and high socioeconomic groups.

Attrition in the programme evaluation was noted to be greater for younger participants and those who were less educated in the intervention population. Only 42% of smokers in the intervention region were aware of the smoking campaign three years after the intervention began. These factors may be an indication of the acceptability of the intervention in these population sub-groups. No information is provided on uptake of the intervention in different population sub-groups.

Programme evaluation

The effect of intervention was investigated using a cohort design (10). Net differences were assessed i.e. changes observed in reference population and those observed in the treatment population were compared. A group of subjects who smoked were also specifically recruited in treatment and control communities to assess treatment effects on smoking over the intervention period (11) (smoking cohort) and another cohort was recruited to evaluate the effect of programme activities on physical activity and fat intake (12).

Participant selection/recruitment

Main cohort:

Men and women were identified for recruitment to control and treatment groups through two previous monitoring studies conducted by the Dutch National Institute for Public Health and the Environment. These adults were aged 20-59 years at the time of the previous monitoring study.

The source population from these studies was 13,184 in the intervention region and, of this group, 4,500 participants were selected for potential recruitment. Of these individuals, 441 had migrated to another region and the remaining 4,059 were invited to participate. 80% agreed to take part (3,232 people) but, since the aim was only to

recruit 3,000 participants, 3,000 of these were invited to take part. Of these, 2,414 (81%) participated in the main follow-up measurements five years later (10).

In the control region, there was only a source population of 1,115 from the previous monitoring study. Therefore, all of these people were invited to take part. 895 subjects agreed to participate (80%) in the baseline survey and, of these, 758 (85%) were retained for five-year follow-up (10).

The age range in the intervention and control groups differed and, in order to standardise age, participants ≤30 years (58 subjects) were excluded from the final analysis (numbers in treatment verses control groups not stated). The age of the final study cohort was therefore 31-70 years (10).

All participants were invited to the Regional Public Health Institute where they underwent a physical examination and a self-administered questionnaire (10). Participants also received surveys by mail to obtain information on physical activity and dietary fat intake (12). Validated dietary and physical activity questionnaires were used that generated a 'fat consumption score' and a 'physical activity score' and single questions were also posed that evaluated intervention effects on attitudes, intended behavioural change and other mediating variables (11).

Smoking cohort (11):

A sample of 6,500 inhabitants from each of the treatment and control areas were identified using random stratified sampling from the five municipalities (based on relative population sizes) using computerised telephone registries. 4,242 and 4,697 inhabitants, over the age of 18, were reached by telephone in treatment and control areas respectively. Subjects were asked whether they had smoked in the last 7 days and, of the current smokers (34.6%), 21.6% refused the telephone interview (19.1% for treatment and 24.0% for control).

Participants underwent baseline, 2-year and 3-year questionnaires to assess smoking habits, attitudes, attempts to quit and familiarity with smoking cessation campaigns.

There was 18.7% dropout from the baseline to the 3-year survey and, overall, 772 treatment and 736 control participants completed all three questionnaires. Attrition did not differ between groups and there were no significant differences between dropouts and participants with respect to age, gender and education.

Physical activity/diet cohort (12):

A third cohort was recruited with the specific aim of assessing intervention effects on physical activity and fat intake. Stratified, random samples of 1,450 and 1,200 inhabitants from treatment and control communities respectively, aged $\geq$14, were selected from population registries. Participants underwent baseline, 2-year and 3-year surveys to assess physical activity and dietary variables. Response rate to baseline surveys was 57.5% (n=820) in the treatment group and 52.9% (n=624) in the control. Due to dropouts, undeliverable questionnaires and incomplete data, net dropout from baseline to the final 3-year survey was 31.5%. 505 treatment and 392 control participants completed all three questionnaires and, although attrition did not differ between regions, dropouts tended to be younger and less well educated.

Outcome measures

Main cohort: At the physical examination, systolic and diastolic blood pressure, height, weight and waist circumference were measured using standardised techniques and a blood sample was taken for total cholesterol and non-fasting glucose (10).

Smoking cohort: Smoking behaviour, attitudes and intentions (11).

Physical activity/diet cohort: Physical activity, fat intake and their psychosocial determinants (12).

Statistical methods

Mean values were calculated for men and women separately. Effectiveness was assessed by comparing change in risk factors between the intervention and control

group using regression analysis, with risk factor as the dependent variable and group status (intervention/control) as the independent variable. Net adjusted differences are presented as changes in the treatment group from baseline to post-five year intervention minus the changes in the control group. Adjustments were made for the mean of the individual pre and post-intervention values for the outcome measure under study (to reduce possible effects of regression to the mean), age and smoking. For analysis of blood pressure and cholesterol, adjustments were also made for use of medication (10).

For the smoking cohort, multiple logistic regression analysis was conducted to identify potential dropout bias with attendance verses dropout as the dependent variable and baseline values for gender, age, education and condition as the independent variables. Further multiple logistic regression analysis was used to identify potential baseline differences between the treatment and control region and the independent variables in this analysis were the baseline values for gender, age and education. Multilevel regression analysis was used to assess post-test treatment versus control group changes, except where individuals within municipalities could be regarded as independent and, in these cases, ordinary regression analysis was used. The main independent variable included in all effect analysis was condition. In addition, the pre-intervention score of the outcome variable, gender, age and education were included as independent variables in all analysis (11).

For assessment of physical activity and dietary variables, a pre-test-post-test control group design was used where post-tests were two and three years after the start of the intervention. Multiple logistic regression was used to identify potential dropout bias with attendance versus dropout as the dependent variable and independent variables of (baseline) gender, age, education, fat consumption, physical activity level and condition. Potential baseline differences between regions were also identified using multiple logistic regression with study region as the dependent variable and (baseline) gender, age, education, fat consumption and physical activity level as independent variables (12).

Results

Primary outcomes

Five-year post-intervention main cohort (10):

1. Cholesterol

Cholesterol levels generally decreased during the intervention period and there was no significant difference between changes in intervention and control communities for men (net difference -0.02 mmol/L; SE 0.06, NS). For women, a slight increase in total cholesterol in the treatment community and a decrease in the control community actually resulted in a significant net worsening for the treatment compared to control group (net difference 0.11 mmol/L; SE 0.05, p<0.05).

2. Blood pressure

Systolic and diastolic blood pressure increased in treatment and control communities in both men and women during the intervention period but the magnitude of increase was significantly less in the treatment group for systolic (men net difference -7.8 mmHg; SE 1.0, p<0.05, women net difference -5.5 mmHg; SE 1.0, p<0.05) and diastolic (men net difference -5.1 mmHg; SE 0.7, p<0.05, women net difference -4.4 mmHg; SE 0.6, p<0.05) blood pressure.

3. BMI

Body mass index increased in men and women in both the treatment and control areas during the intervention period but this change was significantly less in treatment compared to control communities (men net difference -0.36 kg/m^2; SE 0.09, p<0.05, women net difference -0.25 kg/m^2; SE 0.10, p<0.05).

4. Glucose

Plasma glucose levels changed little over the intervention period in men from treatment or control communities and there was no difference between groups (net

difference -0.17 mmol/L; SE0.10). For women, a decrease in the treatment community and an increase in the control community resulted in a significant net treatment effect (net difference -0.23 mmol/L; SE 0.07, p<0.05).

Three year post-intervention smoking cohort (11):

5. Smoking

In the cohort specifically recruited to assess effects on smoking behaviour, rates of smoking decreased in both treatment and control groups. However, there was no difference between treatment and control community changes in smoking behaviour, attitudes or intentions.

Three year post-intervention physical activity/diet cohort (12):

6. Physical activity

There were no overall treatment effects on physical activity or its determinants.

7. Fat intake

Fat intake score (derived from self-reported fat intake) decreased in both treatment and control cohorts over time and linear regression estimates showed reductions in intake to be significantly greater in the treatment compared to the control cohort (-0.666 (no units given), p=0.000). Further statistical investigation showed that reductions in fat score were fully attributable to changes in the younger half (<49y) of the cohort.

Secondary outcomes

The effect of socio-economic status and age were investigated by assessing intervention effects separately in those with moderate/high compared to low socio-economic status and those aged 31-50y compared to 51-70y over 5 years of intervention. In all cases, risk factor changes were similar and socio-economic status and age did not appear to impact intervention effectiveness (10). In these analyses,

adjustments were made for gender, age, smoking and mean of the individual pre- and post-intervention measurements of the variable under study.

Limitations of the study

The study was quality assessed and graded '+'.

Limitations identified by authors

The unit of randomisation was the community, not the individual and net differences between groups may have been due to other external factors (10).

Participants were recruited via a previous study and may have been more health conscious than the general population. However, since this was the case for both intervention and control groups, it was not anticipated to result in study bias (10).

Height was found to reduce in the control area and this contributed to the net treatment effect on BMI. However, the net difference in BMI remained when subjects showing a >2cm reduction in height were excluded from the analysis (10).

The national smoking cessation campaign and associated secular decreases in rates of smoking may have made intervention effects on smoking behaviour undetectable (11).

Limitations identified by reviewer

Although follow-up for the main cohort and smoking cohort was good, there were large numbers of dropouts from physical activity/diet cohort. Dropouts tended to be younger and less well educated. High attrition in this cohort may make findings not applicable to the main study population. However, since attrition was good for the main cohort and smoking cohort, the majority of findings may be generalisable to the whole population.

Summary

Hartslag Limburg was a small community-based intervention specifically targeting smoking, nutrition and physical activity. Unlike most community programmes, there was no screening intervention and this may have had some role in the absence of treatment effect in total cholesterol. However, the programme showed significant net changes in other physiological and behavioural risk factors suggesting positive intervention effect.

3.1.5   Health and Inequality in Finnmark: Båtsfjord

In 1988, in response to observations of high rates of CVD linked mortality, the Norwegian government introduced the 'Health and Inequality in Finnmark' programme. The costal communities had the highest mortality rates from CVD and intervention was particularly aimed at this area. The current report describes intervention in two different areas of Finnmark: Båtsfjord and the North Cape. Although both were part of the wider Health and Inequality programme, they were set up with different aims, different methods of intervention and separate evaluations were made. Therefore, in the current report, these interventions are described separately as Båtsfjord and the North Cape (see next section).

The aim of intervention in Båtsfjord was to influence the intervention population to be more health conscious, to motivate health promoting activities and to change environmental factors influencing health (13).

Target population

Båtsfjord, a fishing community in the Norwegian arctic (n= ~2,500), was the site for intervention, selected on the basis of local initiative for intervention. Three costal communities: Loppa, Gamvik and Måsøy (together n= 5,000) acted as control areas and had similar age distribution, ethnic background and also relied on the fishing industry. Communities were separated by deep fjords, presumably reducing intervention/control community interaction (13).

Theory/conceptual model of intervention

Community empowerment was used as the basis for intervention, using local community members to generate intervention ideas and implement programme activities (13).

Intervention description (13)

"Health and Well being" began in 1988 and ran for three years. Around the time of the start of intervention, a major crisis in fish supplies had a severe impact on coastal communities (14) impacting local employment, income and morale.

Before the start of intervention, voluntary organisations were invited to attend a workshop to identify barriers to good health. These organisations collected information from local schools, a factory, other voluntary organisations and the local public health administration to produce a manual detailing suggestions for health promotion improvements (~270 individuals contributed). This information was discussed and projects identified for implementation.

Interventions related to wider issues such as employment and road safety as well as CVD-linked activities but, in the current report, only CVD-related interventions will be discussed. Many of the interventions were given to voluntary organisations working in a relevant field. Others were implemented by a local teacher who was the designated project manager and worked closely with the local medical officer. A public health fair was organised where organisations could present their intervention activities.

Many projects that were implemented related to physical activity and included ladies aerobics classes, exercise training for people with CHD, adult badminton clubs, organised hikes and cycle trails and ski tracks were also created. A body coordinating sport in workplaces was re-established (The Factory Sports Clubs Association) and arranged volleyball and football tournaments. For older people, dances were

organised and swimming and physiotherapist guided training was available throughout the whole intervention period.

Programme organisers joined with the national cholesterol campaign to introduce screenings. Cholesterol was measured in local supermarkets (510 people tested), healthy recipes and menus were provided and evening cookery classes were introduced (~40 participants). Low-fat meals were produced, suitable for fishermen to prepare on board ship and healthy foods were promoted through the 'Healthy food at sea is safe' initiative by The Norwegian fishermen's union.

The long-term aim of the Municipality of Båtsfjord was to achieve smoke-free public buildings by 2002. Work began in health centres, schools and nurseries and, by the end of intervention, smoking was confined to designated rooms in these institutions.

Local newspaper, radio and television were used widely as a means of communication. Local television and radio covered only the intervention area but local newspapers were also distributed to one of the control communities.

Guidelines on individual counselling for smoking cessation, heart-healthy diets and increasing physical exercise were established for use in local GPs. Individual counselling was given to those identified as high risk (100 people, ~10% of households) but this was also undertaken in the control communities.

Accessibility:

The intervention was designed by local inhabitants and voluntary organisations and managed by a local public sector employee. The intervention was varied in nature and offered in a variety of locations (schools, workplaces, voluntary agencies and the local public administration organisation) and at varied times to meet the needs of different population sub-groups. For example, physical activities were tailored according to gender, age, presence of existing disease and common workplace and written materials promoting healthy eating were based on local food traditions. In addition, the local media supported the project. There is no discussion of whether materials

were adapted for individuals with literacy problems, for those speaking different languages or for those with different cultural backgrounds.

The participation rate in the evaluation survey was 61% and non-attendees were significantly younger and smoked more than attendees which may be an indication of the accessibility of the programme in certain sub-groups. No information is given on uptake of intervention components.

Programme evaluation (13)

A survey was conducted at baseline (1987) and a cohort of participants was followed up six years later (1993), two years post-intervention.

Participant selection/recruitment

All residents aged 40-62 years and a 15% random sample of those aged 20-39 years, were invited to participate in the baseline survey (total of 2,435 people in all communities). In 1993, 1,957 participants of the initial survey were still alive and had not migrated out of the area and, of these, 1,324 (68%) completed the follow-up survey (follow up from baseline 54%). The age and level of education did not differ between control and intervention communities but there were significantly less males of Sami origin in Båtsfjord compared to the control community (4.8% versus 11.2% of participating males).

At both time points, participants underwent a physical examination and answered two questionnaires (an additional one was used at baseline but not in further investigation). Neither questionnaire was administered by project staff but one was completed and brought to the clinical examination and the second was given out during the examination and returned by mail. Questionnaires related mostly to demographic and social factors including lifestyle, well-being and social networks and also detailed medications and health service contact. At the physical examination, blood pressure, lipid levels, weight and height were measured.

Outcome measures

Blood pressure, cholesterol and BMI as well as dichotomous variables relating to physical activity, smoking and diet.

Statistical methods

Sex-specific comparisons using analysis of variance were made between mean individual change in the intervention compared to the control community (3 control community results combined). For the dichotomous variables, the mean value of individual change represented the group's net proportional change. Continuous variables were adjusted for baseline values but no adjustments were made for age and education since there were no intervention/control baseline differences.

Results (13)

Changes are presented as the mean changes (value or %) in intervention and control communities and the changes in intervention and control communities are compared.

Primary outcomes

1. Cholesterol

Total cholesterol level decreased in intervention (males -0.04 mmol/L, women -0.1 mmol/L) and control communities (men -0.2 mmol/L, women -0.1 mmol/L) but the net difference between community changes was not significant (men $p=0.704$, women $p=0.446$).

2. Blood pressure

Diastolic blood pressure fell in the intervention community (men -2.1 mmHg, women -2.1 mmHg) but increased in the control (men +0.8 mmHg, women 1.8 mmHg) and the difference between community changes was significant for men and women ($p<0.0001$ for both). Systolic blood pressure was stable in intervention men (-0.01 mmHg) but increased in intervention women (+2.1 mmHg) and increased in control groups of both gender (men +2.2 mmHg, women +4.6 mmHg). The difference in

intervention/control group changes was significant for men (p=0.002) and women (p=0.024).

3. BMI

BMI increased in both intervention (men +1.5 kg/m^2, women +1.9 kg/m^2) and control (men +1.1 kg/m^2, women +1.4 kg/m^2) groups but increases in the intervention groups were in fact significantly greater than increases in the control group (men p=0.002, women p=0.001).

4. Smoking

In men, reported daily smoking fell in both intervention (-7.5%) and control (-2.7%) communities but the difference only neared significance (p=0.091). For women, reported smoking increased (intervention +0.6%, control +1.2%) and there was no difference between control and intervention community changes (p=0.793).

5. Physical activity

The percentage of respondents reporting that they were physically active increased slightly in women from both communities (intervention +0.6%, control +1.2%) but there was no difference between community changes (p=0.793). However, for men, intervention group changes were greater and intervention/control group changes were significantly different (intervention +8.6%, control +0.6%, p of difference=0.047).

6. Diet

There tended to be positive trends in dietary habits with increased use of unsaturated cooking fats in men (intervention +14.0%, control +7.9%, p=0.163) and women (intervention +14.0%, control +12.0%, p=0.619) and use of unsaturated spreading fats in men (intervention +2.7%, control +6.0%, p=0.30) and women (intervention +5.1%, control +2.9%, p=0.514). However, the only dietary change that showed a significant difference between intervention and control group changes was the use of low fat

milk that was different for women (intervention +11.2%, control +3.3%, p=0.046) but not for men (intervention +0.0%, control +1.1%, p=0.793).

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors (13)

Baseline differences were only adjusted for continuous variables (cholesterol, blood pressure and BMI) but difference in lifestyle factors were not adjusted for in the analysis of dichotomous lifestyle variables.

The questionnaire assessing lifestyle may have been too simplistic and may not have included enough questions to properly describe lifestyle outcomes.

The duration of intervention may have been too short to detect lifestyle changes.

The sample size may have been too small to detect differences in lifestyle variables but large enough to detect effects in physiological outcomes.

Limitations identified by reviewer

There may have been some contamination of control populations as individual counselling was given in the control as well as intervention areas and a local newspaper was also distributed to one of the control communities.

Unlike most programmes of this type (that also use independent cross sectional surveys), evaluation was only done in a cohort of people before and after intervention. The rate of follow-up appears to be low (~68% of those still alive and living in intervention/control areas) and this may to some extent explain positive changes in both intervention and control groups. Attendance for both surveys was significantly lower in intervention (61%) compared to control (70%) communities and this may have influenced study findings. If more 'unhealthy lifestyle' people dropped

out from the intervention group this might bias results in favour of intervention as a greater proportion of 'Healthy lifestyle' people would remain.

Summary

The three year 'Health and Inequality' programme in Båtsfjord appeared to achieve reductions in blood pressure and some lifestyle changes and this may be commendable considering the concurrent community stresses of unemployment and economic insecurity. Although programme interventions brought about some positive change, differences in intervention/control community follow up may also have had an impact and a more moderate interpretation may be appropriate.

3.1.6   Health and Inequality in Finnmark: North Cape

The Finnmark intervention in North Cape, part of the Norwegian government 'Health and Inequality in Finnmark' programme, was introduced in 1988 and continued for ten years. The main aims of intervention were to reduce accidents and improve working conditions in the fishing industry and to reduce the MI risk score by 25% (14).

Target population

Intervention was conducted in the costal community of North Cape (n ~4,000) and, for the control region, the same communities were used as for the study in Båtsfjord (see previous section): Loppa, Gamvik and Måsøy (together n= 5,000).

Theory/conceptual model of intervention

Local empowerment, emphasising the role of the individual and the community to take responsibility for decision making, make priorities and determine their own lifestyle, was used as the theoretical basis for intervention (14).

Intervention description (14)

The major crisis in fish resources in the first two years of the Båtsfjord intervention also very much affected the North Cape community. Programme organisers recognised that, for many people, distractions of work and home life were likely to be too great to warrant interventions aimed at lifestyle change in individuals. Initial activities therefore concentrated on environmental changes.

In the first two years of intervention, the "North Cape Occupational Health Services" programme focused on improving working conditions and available health services. Safety at work programmes and occupational health services were established in cooperation with trade unions and integrated into the public health division of the primary care services.

Subsequently, there was a much stronger emphasis on individual counselling. Advice was given on diet, smoking and physical activity as part of routine consultations with GPs, public health nurses and occupational health services. Those people identified with a high risk of MI in the initial 1987 health survey, were given additional individual counselling.

Throughout the intervention, the project leader communicated with fishery workers, conducting and videotaping interviews to define problems associated with programme activities and determine future direction.

Accessibility:

The intervention was aimed at fisherman and workers in the fishing industry and was delivered by newly established occupational health services and the public health division of primary care services. The eligible population were invited to screening examinations by personal invitation. Mobile teams visited localities in order to screen the eligible population. Lifestyle change was negotiated with participants on the basis of CVD risk. Adequate communication of risk to patients requires a level of numeracy which may limit the effectiveness of this approach to certain groups. Educational

material to support lifestyle change outside of the screening consultation appears largely to have been in written format.

Health education activities also took place in venues other than the work place including schools, clubs and voluntary health care organisations and was supported by the local media but the nature of this additional health education is not clear. There is no discussion of whether materials were adapted for individuals with literacy problems, for those speaking different languages or for those with different cultural backgrounds. The intervention was delivered to a 'small and close–knit community' which is likely to have favoured the tailoring of the programme to ensure accessibility.

The response rate to screening was 70%; non–responders were reported to be younger and to smoke more than responders which may be an indication of the accessibility of the programme in certain sub-groups. No information is given on uptake of intervention components.

Programme evaluation (14)

The ten year programme was evaluated after six years of intervention. A baseline survey was conducted in 1987 and a cohort of participants was followed up six years later (1993), two years post-intervention.

Participant selection/recruitment

All residents aged 40-62 years and a 15% random sample of those aged 20-39 years, were invited to participate in the baseline survey (n not given). In 1993, 2,404 participants of the initial survey were still alive and had not migrated out of the area and, of these, 1,685 (70%) completed the follow-up survey.

At both time points, participants underwent a physical examination and answered two questionnaires (an additional questionnaire was given at baseline but not in further investigation). Neither questionnaire was administered by project staff but one was completed and brought to the examination whilst the second was given out

during the examination and returned by mail. Questions related mostly to demographic and social factors including lifestyle, well-being and social networks and also detailed medications and health service contact. At the physical examination blood pressure, lipid levels, weight and height were measured.

Outcome measures

Blood pressure, cholesterol, MI risk score (calculated on the basis of gender, BP, cholesterol and smoking habits) and BMI, as well as dichotomous variables relating to physical activity, smoking and diet.

Statistical methods

Sex-specific comparisons using analysis of variance were made between mean individual change in the intervention compared to the control community (3 control community results combined). For the dichotomous variables, the mean value of individual change represented the group's net proportional change and adjustment was made for age. Continuous variables were adjusted for baseline values and age.

Results (14)

Changes are presented as the mean changes (value or %) in intervention and control communities and the changes in intervention and control communities are compared.

Primary outcomes

1. Cholesterol

Total cholesterol level decreased in intervention (males -0.3 mmol/L, women -0.2 mmol/L) and control communities (men -0.2 mmol/L, women -0.1 mmol/L) and the age/baseline adjusted net difference between community changes was significant (positive intervention effect, men $p<0.01$, women $p=0.05$).

2. Blood pressure

Diastolic blood pressure increased to the same extent in intervention (+1.6 mmHg) and control (+0.8 mmHg) community men with no significant differences between groups. Diastolic blood pressure also increased in women with a greater, statistically significant, increase amongst the control group (+1.8 mmHg) in comparison with the intervention group (+1.6 mmHg), $p < 0.05$, after age/baseline adjustments.

Systolic blood pressure increased in both communities in men (intervention +3.2 mmHg, control +2.2 mmHg) and women (intervention +5.7 mmHg, control +4.6 mmHg) and there were no significant differences in the size of change.

3. BMI

In men, BMI decreased slightly for the intervention community (-0.2 kg/m²) but increased in the control (+1.1 kg/m²) and the difference in group changes was significant (positive net intervention effect, $p < 0.001$). For women, BMI increased in the intervention community (+0.4 kg/m²) but the increase was significantly greater in the control communities (+1.4 kg/m², positive net intervention effect, $p < 0.001$).

4. MI risk score

MI risk score decreased in men to a greater extent in the intervention (-3.4) compared to the control group (-1.4) and the difference in community changes neared significance ($p = 0.055$). For women, risk score increased slightly in the intervention community (+0.1) but to a greater extent in controls (+0.6) and there was a positive net intervention effect ($p < 0.05$).

5. Smoking

In men, reported daily smoking fell slightly in the intervention group (-0.8%) but to a greater extent in controls (-2.7%) but the difference in change was not significant. For women, reported smoking decreased in the intervention (-5.9%) but increased in the control (+1.3%) group and there was a significant difference between control and intervention community changes (positive net intervention effect, $p < 0.01$).

6. Physical activity

The percentage of respondents reporting that they were physically active increased in intervention men (+6.6%) and women (+6.1%) and to a lesser extent in control men (+0.6%) and women (+2.1%) but there was no significant differences in the size of community changes in either sex (men p=0.077, women p=NS).

7. Diet

There tended to be positive trends in dietary habits with increased use of unsaturated cooking fats in men (intervention +12.0%, control +8.0%, p=NS) and women (intervention +13.5%, control +11.9%, p=NS) and use of unsaturated spreading fats in men (intervention +6.9%, control +6.0%, p=NS) and women (intervention +7.4%, control +2.9%, p= 0.072). However, the only dietary factor that showed a significant difference between intervention and control group changes was the use of low fat milk that was different for men (intervention +10.5%, control +1.1%, p<0.01) but not for women (intervention +4.7%, control +3.3%, p=NS).

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors (14)

As MI risk score increases with age, in a longitudinal cohort, the apparent intervention effect will be less.

Limitations identified by reviewer

Baseline differences in % smoking daily and % with physically active lifestyle were not adjusted for in the analysis of lifestyle variables.

Summary

Intervention in the North Cape appears to have achieved positive changes in physiological risk factors. Although positive changes were also observed in the

Båtsfjord arm of the Finnmark intervention, these were in different outcome variables. Although random variation is likely to play a part, this may highlight the possibility that mode of intervention affects the type of risk factor change.

3.1.7   Heartbeat Wales

Heartbeat Wales, or the Welsh Heart Programme, was launched on St David's day in 1985 to promote good health and reduce the risk of cardiovascular disease in Wales. Wales was chosen as the location for the demonstration project because of its strong regional identity, existing networks and the particularly high prevalence of coronary heart disease (15).

Target population

The whole of Wales, covered by nine Welsh district health authorities, was the target for intervention and the north east of England (Tyne and Wear, Cleveland, Durham and North Yorkshire) was selected as a control area. This area was chosen since, at the 1981 census, it was the location most similar in socio-demographic profile and health status (16).

Theory/conceptual model of intervention

The mode of intervention resulted from a number of theories/models: Social learning, Social marketing and Diffusion of innovation. The rational relied on the premise that new attitudes and behaviours are taken up by opinion leaders and spill over into other groups of society (15).

Intervention description

A major goal of Heartbeat Wales was to keep the programme in the public eye and, in the first year, the emphasis was on creating a climate of interest and positive opinion. Mass media coverage was utilised with a major television series ('Don't break your Heart') shown at peak viewing times, regular press articles and news coverage. Presentations were held at national exhibitions and agricultural shows and

information leaflets and health kits were produced and distributed. A newspaper insert was distributed in the major regional press and, by the third issue, was read by almost a third of the Welsh population. The next year another television series was produced and broadcast. By the mid-point of this healthy eating show, it was estimated that 37% of the Welsh population had watched at least one programme (15,17).

In the early months of the development of Heartbeat Wales, key individuals and agencies were visited to plan activities and formulate a programme strategy. A population approach was emphasised, with the desire to involve the community and specific project aims were: collaboration with health authorities to develop district policies, support for voluntary local community action, schools and youth initiatives, initiatives in primary care, promotion of workplace innovations and support for local health authority schemes. Change was also to be addressed at a macro level, with the involvement of commerce and industry in the provision of goods and services (17).

The programme aimed to change dietary habits in Wales and substantial environmental changes were implemented to improve community nutrition. A supermarket chain modified many own-brand products and introduced a food-labelling scheme as well as running in-store health education programmes. Approved catering establishments could display a 'Heartbeat Award' certificate. Welsh farmers were encouraged to switch to rearing low-fat breeds and a lean-meat butchery scheme was introduced. Food and health policies were developed by every health and education authority in Wales and supported by many voluntary organisations (15).

Smoking cessation was promoted via a National No-Smoking Day, linked to workplace smoking policies developed by Health authorities, trade unions and the British Institute of Management. 'Heartbeat Ways' were constructed to promote increased physical exercise, implemented in conjunction, among other projects, with the Sports Council for Wales (15).

Policies were developed for health in the workplace and an award was instituted for the most health-promoting employers in Wales (15). Occupational health nurses received special training and a mobile screening service was offered to offices and factories on request. Materials and professional support were provided to school teachers and a heart club for young people was started. Fun runs took place in many primary schools with support from prominent Welsh sports personalities.

Primary health care practitioners were encouraged to engage with programme ideals by the provision of an Open University Course, fully designated to the extension of coronary heart disease knowledge. A paper was published by the Welsh council of the RCGP called 'Stitches in time' that emphasised the importance of general practitioners in primary prevention and encouraged the reorganisation of preventative health care (15).

Accessibility:

Interventions were varied in nature (the use of mass media, food labelling and nutrition education, restaurant and canteen schemes to increase the availability of healthy food choices, environmental changes, mobile screening services and a worksite health promotion programme), offered at a variety of venues (workplaces, schools, leisure facilities, healthcare premises) and involved industry, health services, local authority and community organisations. There is no discussion of whether materials were adapted for individuals with literacy problems, for those speaking different languages or for those with different cultural backgrounds. No information is given on uptake of intervention components. Response rates to the programme evaluation surveys varied between 61% - 88%. No information is reported on non-respondents.

Programme evaluation

Programme evaluation was conducted by two independent cross sectional surveys, one at baseline and one at five years into intervention in Wales and the reference area

(16). Formative evaluation was conducted to track programme activities in Wales and in the reference community (18).

Participant selection/recruitment

A random sample of 21,000 households in Wales, comprising 32,000 people aged 12-64 years (eligible), was selected from the electoral register using a multistage cluster sampling design (numbers for reference area not given). Households were visited in person and, after a short doorstep interview, respondents were given a questionnaire to return by mail.

In Wales, response for the doorstep interview was 88% and 67% of eligible participants returned the postal survey (n=18,538). In the reference community, responses were 84% and 64% for the household and mailed survey respectively (n=1,483) (16,17).

In Wales, a sub-sample of 2,000 participants were also recruited to a clinical survey where they underwent a medical examination at a local health centre. These results were used to validate self-reported behaviours and provide information on CVD risk factors (17).

Five years later, in 1990, the repeat survey showed slightly reduced doorstep response rates of 79% and 77% for Wales and the reference areas respectively and response to returned postal questionnaires were 61% in both areas (Wales n=13,045, reference n=4,534) (16).

Outcome measures (16)

Key behavioural measures relating to diet, smoking, exercise and overweight were assessed. These were either health enhancing behaviours:

Consume chicken or other poultry $\geq$2 days/week, consume fish $\geq$2 days/week, consume fresh frit >4 days/week, consume green vegetables or salad $\geq$4 days/week, mainly use skimmed or semi-skimmed milk, mainly use wholemeal bread, smokers

who agree present level of smoking is harmful to health, smokers with serious attempt to quit in last 12 months, daily smokers visiting GP in last 12 months and advised to quit or cut down, engage in moderate or strenuous activity $\geq$2 times/week for>20 minutes.

Or health compromising behaviours:

Mainly use butter on bread, consume fried food cooked in solid fat >2 days/week at home, smoke daily, mean no cigarettes/day, BMI (kg/m^2) $\geq$24 for women or $\geq$25 for men.

Results for clinical measures in the small (n=2,000) sub-sample are not presented.

Statistical methods (16)

Fifteen measures were selected as outcomes for analysis. Analyses were undertaken at both the individual and community level.

For individual level analysis, standard errors of survey estimates and 95% CIs were estimated on weighted data from questionnaires. The statistical package used utilises the Taylor series linearisation method to calculate standard errors, taking into account the effects of stratification and clustering on the precision of survey estimates. For each measure, percentage point changes between baseline and 5 year measures were calculated.

For the community level analysis, the 9 Welsh district health authorities and the 4 counties in the reference area were used as the units for analysis. For each unit, the prevalence of binary outcomes was calculated for baseline and 5 year data and the mean number of cigarettes per day for smokers was calculated for each unit. The logarithm of intervention effect ratio was estimated by fitting to a model (detailed in Tudor-Smith et al. 1998(16)) and weighted least squares regression models were fitted for each outcome, weighted by the mean sample size in each unit over the two surveys. Subgroup analysis was also conducted for separate sub-groups: men,

women, 3 age groups (18-34, 34-49 and 50-64 years) and people in households where head of the household was in manual/non-manual employment.

Results

Primary outcomes (16)

In the individual-level analysis, in Wales, 14 of the 15 behavioural measures showed positive changes (all except proportion overweight) and 13 of these were significant changes from baseline. In the reference community positive changes were also observed in 13 of the outcomes and 9 of these were significant changes from baseline. However, net changes i.e. the difference between changes in intervention and reference groups, are not presented.

In the community-level analysis, no significant intervention effects were found when results from all participants were pooled. For the subgroup analysis, there was a general net improvement for the treatment compared to reference area for consumption of fried food and daily smoking. This showed a consistent positive trend in each sub-group tested but consumption of fried food was only significant in one subgroup (aged 50-64y) and no subgroup was significant for daily smoking. The control area showed an improvement over the intervention area for the tried to stop smoking outcome but the net effect was only significant for men.

NB changes reported in the text of this paper (16) differ to those displayed in the table of results. In the current report, table results are given.

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors (16)

The baseline sample size in the reference area was too small to give sufficient statistical power for detection of a net intervention effect.

There was contamination of the reference area with diffusion of projects and programmes from Wales, the initiation of the 'Look After Your Heart' project (launched in 1987 over the whole of England) and the Heartbeat Yorkshire programme (conducted in the reference area from 1988).

Limitations identified by reviewer

Net results for individual level analysis are not given. Results are presented in a slightly misleading way although authors do conclude that there are no clear net intervention effects.

Summary

The Heartbeat Wales programme implemented an array of high profile media activities as well as policy changes and numerous community projects. The failure to show net intervention effects may be due to ineffective transition from awareness to behavioural change. However, reference area contamination appears to have been a major contributor and may have been responsible for masking intervention effect.

3.1.8   The Kilkenny Health Project

The Kilkenny Health Project was an Irish cardiovascular disease prevention programme with the main aim of reducing mortality linked to cardiovascular disease and cerebrovascular disease by 20% over ten years in those aged 35 to 64 years and the secondary aim of reducing all-cause mortality rates by 15%. Intervention began in 1985 and spanned a period of five years to the end of 1990 (19).

Target population

The county of Kilkenny (n=73,186 in 1986), in south east Ireland, was selected for intervention. Kilkenny contains a mixture of urban (45%) and rural (55%) communities and has a history of community development and county pride. Approximately one quarter of residents live in Kilkenny City whilst others live in one

of the four large towns (n=1,000 to 1,5000), nine smaller towns (n=500 to 1,000) or seven villages (n<500).

Offaly (n not stated) was chosen as the reference area and had similar characteristics to Kilkenny (19).

Theory/conceptual model of intervention

The theoretical framework for project implementation was developed from theories of learning, health communication-behavioural change, diffusion theory and community organisation for health (19).

Intervention description (19)

Early in the community programme, project staff became familiar with the area of intervention to assess the extent of existing resources and facilities. Links were made with those working in the media and in the local education and health services. Community meetings were held to discuss strategies for prevention of heart disease.

An awareness programme was used to introduce the project and to inform about the importance of CHD as a cause of morbidity and mortality. Training was given to people involved in education, health and catering. A working party was set up with the role of supporting health promotion in secondary schools and a health assessment programme was established in collaboration with the Kilkenny Faculty of the Irish College of General Practitioners. A nutrition counselling service was provided by the project dietician and an oral health project was developed in conjunction with Kilkenny dental practitioners.

Programmes and events were supported by the local media with newspaper and radio coverage and educational materials were reviewed to produce leaflets for distribution. Other events were also organised, such as a yearly Quit Smoking competition and a 10K run.

Accessibility:

The intervention included use of mass media; written and verbal heath education, educational meetings and social activities. These education materials are described as 'appropriate to the Irish context' but no further information is given. In terms of accessibility, for example, for those with low levels of literacy, those speaking different languages or those from different cultural backgrounds . Although it is clear that health services and education services were involved in planning and delivery, little information is provided about venues that were used for dissemination.

Response to evaluation surveys was 70-75% but no information is provided on non-responders. Awareness of the intervention after 5 years was high (>90%) with the exception of those in lower social classes and those not in work where awareness was between 76% and 89%. Evaluation of intervention penetration suggests that television and radio were more effective at reaching lower social class groups compared to printed media. Socio-economic differences were also noted for smoking prevalence as an outcome (a greater decline in smoking prevalence was observed in skilled manual and non manual workers compared to unskilled manual workers). However these differences were not restricted to the intervention population and were observed nationally across Ireland. No information is provided on the uptake of intervention components.

Programme evaluation

The project was evaluated using independent cross sectional surveys conducted at baseline and after the five year intervention period. In Kilkenny, the baseline survey took place in 1995 whilst, in the reference community, baseline measurement was undertaken in 1986 (complete year later) and final surveys were taken five years after baseline in each community (20).

Process evaluation was used to gain information on project awareness and participation, health related attitudes and behaviour, strengths and weaknesses of activities and perceived effectiveness. Feedback was sought from participants, professionals and project committees (19,21).

Participant selection/recruitment

An independent, geographically clustered, stratified random sample of names and addresses was taken from the Register of Electors for each survey. 2,000-3,000 names of people aged 35-64 years were selected and contacted by field interviewers. Where contact could not be made, postal invitations were sent. Response rates ranged from 70-75% and, in the first survey, there were 792 and 604 participants from intervention and reference communities respectively. In the final survey, there were 802 participants from the intervention community and 631 participants from the reference community. Each participant attended an interview where a questionnaire was administered by a survey nurse and physiological measurements were made (20).

Outcome measures

Smoking (assessed via questionnaire), BMI, systolic and diastolic blood pressure, total serum cholesterol and predicted five year risk of a CHD event (predicted from the UK Heart Disease Prevention Project logistic function) (20).

Statistical methods

Changes from baseline in the treatment community were compared with changes from baseline in the control community (net changes). For categorical variables, net changes in percentages were calculated as absolute, and not relative changes. Analysis is based on individuals and assumes a randomised design (although people in treatment/control communities would tend to be more similar than with true randomisation).

For continuous variables, analysis of variance was used with the significance of baseline differences between communities, change over time within communities and net change determined using linear contrasts. For categorical variables, a linear model was used that allowed for direct estimation of the significance of net change.

Results

Primary outcomes (20)

Changes from baseline to five years are presented separately for males and females.

1. Cholesterol

Cholesterol levels decreased in both intervention and control communities in men and women. For women, changes were similar in both groups (intervention -0.36 mmol/L, control -0.31 mmol/L) but, in men, this change was greater in the control community (control -0.44 mmol/L, intervention -0.09 mmol/L) and there was a significant net difference in favour of the control community (-0.35 mmol/L, p<0.01).

In men and women of both communities, the percentage of participants with serum cholesterol <6.5 mmol/L increased, the percentage with serum cholesterol 6.5-7.7 mmol/L decreased and the percentage with >7.8 mmol/L decreased. There were however no significant differences between treatment and control community changes showing an absence of net treatment effect.

2. Blood pressure

Systolic blood pressure fell in both men and women in intervention and control communities but there was no significant net difference between community changes.

Diastolic blood pressure fell in women of both communities (no net difference) and in control men but increased slightly in men from the intervention community. Intervention and control changes in men were significantly different and there was a net difference in favour of the control community (intervention +0.5mmHg, control -5.4mmHg, net difference -5.9 favouring control, p<0.05).

The prevalence of hypertension decreased in men from both communities and in women from the intervention community. There was a slight increase in the prevalence of hypertension in woman from the control community but no significant net difference between communities.

There were no net differences between intervention and control community changes regarding the use of medications in people with hypertension.

3. BMI

BMI increased in men and women from both communities during the intervention period. Although increases in BMI tended to be greater in control communities for men (intervention +0.4, control +1.0 kg/m^2) and women (intervention +0.4, control +1.3 kg/m^2), there was no significant net intervention effect.

The percentage of participants with BMI <25 kg/m^2, decreased in men from both communities and in women from the control community. For women in the intervention area, there was a small positive improvement in the percentage with BMI <25 kg/m^2 and the net community difference was significant (intervention +0.4%, control -13.0%, net difference +13.4% for treatment, p not stated) (NB reported as significant in text but not in the table of results).

The percentage overweight increased in intervention men and decreased in intervention women whilst it decreased in control men and increased in control women. No net differences were significant.

The percentage obese increased in men and women from both communities but to a larger extent in controls. Net difference was not significant for men or women (as stated in the text of the paper but significance is marked in the table of results for women: intervention +3.6%, control +5.7%, net difference -2.1% for intervention, p<0.05).

4. Smoking

The percentage of people smoking decreased in men and women from intervention and control communities during the study period but there was no significant net difference in community changes.

5. Dundee risk score

There was a reduction in Dundee risk score in men and women from intervention and control communities but there was no significant net difference in community changes.

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors (20)

The establishment of the intervention programme may be a symptom of increased interest in CVD prevention and healthy lifestyles and secular change may have made intervention effects difficult to detect.

People from the reference community participating in surveys may feel a greater impetus for change than the average population because they are participating in a reference study.

There was contamination of the reference community through the media and population surveys and through contacts between health professionals in the two counties.

There were important attitudinal barriers to behavioural change. There was a low level of awareness of CHD as an important cause of morbidity and mortality and a disbelief that behavioural change would result in risk reduction.

The short-term nature of the project made it difficult to implement environmental changes.

Limitations identified by reviewer

Data collection was not contemporaneous and baseline and five year surveys were conducted one year later in control compared to intervention communities.

Summary

The Kilkenny Health Project showed little intervention effect and the reference group appear to show more net improvements than the treatment community during the intervention period. Authors highlight prevailing attitudes as important inhibitors of behavioural change and these, together with the presence of strong secular trends, may have prevented lifestyle change and the detection of any intervention effect.

3.1.9   The National Research Programme

The National Research Program 1A on Primary Prevention of Cardiovascular Disease in Switzerland was undertaken from 1978 to 1981. The programme was designed to determine whether community health education could reduce CVD risk factors in whole populations and provide tested, cost-effective methods for nationwide use in the future control of CVD.

Target population

Two intervention towns and two reference towns were chosen on the basis of similar quantitative and qualitative criteria; one pair (16,000 inhabitants each) in the German-speaking, and one pair (12,000 inhabitants each) in the French–speaking part of Switzerland were selected. The populations of Aarau (German speaking) and Nyon (French speaking) were selected to receive the intervention, and those of Solothurn (German speaking) and Vevey (French speaking) were selected to act as controls.

Theory/conceptual model of intervention

The influence of an underlying theory was not commented on.

Intervention description

This community based multifaceted health education programme sought to: 1) engage the active participation of the population, 2) mobilise personal and community resources and 3) achieve integration within existing local health and social services. Responsibility for these three main functions was assumed by a local action committee and its co-ordinator. The main tasks included the conceptualisation, planning, and implementation of the various components of the intervention both in

the community as a whole and amongst specified high-risk groups. Specialised inputs from outside the community in the domains of conceptualisation (i.e. non-smoking sessions) and implementation (i.e. advertising campaigns) were used to the extent to which this was felt possible to implement in future programmes.

Efforts directed towards individual action were supplemented by interventions designed to reach the whole of the community with all media included as an integral part of the intervention strategy. Also, environmental changes were promoted (with efforts made to reach distributors and producers of food products, advertisers, cafeteria and restaurant chefs). Finally, attempts were made to motivate the whole population to adopt a healthier lifestyle.

In dietary education, mass-media campaigns were combined with the regular appearance of health information in local newspaper promotions, including new types of lunch dishes and similar menus that were offered at competitive prices in the most frequented restaurants. In participating restaurants, additional educational materials were used and special menu cards provided information on the dietary energy intake of the items listed. Special exhibitions in marketplace centres, where information could be obtained, also promoted healthier eating. An automatic telephone service, with recorded messages, helped families devise new menus. At an individual level, activities were offered including individual dietary counselling, cooking courses and self help groups to lose weight.

Accessibility:

The intervention was varied in nature and included media involvement (mass media campaigns and regular newspaper promotions), food labelling in restaurants, telephone advice lines, cooking courses, individuals counselling and self-help groups. No further information is provided regarding venues for delivery or whether educational materials were adapted for those with low levels of literacy, those speaking different languages or those from different cultural backgrounds.

Response to evaluation surveys was low (34%) and non-respondents were more likely to be foreign residents or living in French-speaking Switzerland. This may be a reflection of differences in accessibility of the intervention in these population sub-groups and indeed the authors suggest attitudes to prevention may be different in different cultures. No information is provided on the uptake of intervention components.

Programme evaluation

Participant selection/recruitment

Based on their population registries, stratified random samples of the four populations were drawn, with 30 individuals allocated to each stratum according to the following variables: nationality, age, sex, date of arrival in the town (for persons living alone), and nationality, average age of the couple, date of arrival in the town, and number of children (for married persons).

An initial health examination was organised during 1977-78 in the four towns. A further health examination was carried out amongst the subjects in the four cohorts during 1980-81.

Outcome measures

Risk factors associated with CVD: smoking, plasma cholesterol, blood pressure, and BMI.

Results

Primary outcomes

Net changes in exposure to risk factors in the intervention towns in comparison with controls were obtained (see Table 3.1 below).

Table 3.1 Risk factor changes (random population sample 16 to 69 years) standardised by age and sex

	Intervention towns (n=848)		Reference towns (n=1,358)			
	1977-1978 (1)	1980-1981 (2)	1977-1978 (3)	1980-1981 (4)	Difference (5)	P
Regular smokers	32.8	27.4	37.1	35.3	-3.6	<0.05
Amount of tobacco (g/day)	5.0	4.2	6.7	6.3	-0.4	NS
Plasma cholesterol (mmol/l)	5.58	5.43	5.55	5.4	-0	NS
Systolic blood pressure (mmHg)	123.1	125.5	124.7	122.2	+4.9	<0.001
Diastolic blood pressure (mmHg)	76.4	80.1	76.6	76.4	+3.9	<0.001
Weight (kg)	66.4	67.3	67.5	67.7	+0.7	<0.001
Body mass index (kg/m²)	23.4	23.8	24.1	24.0	+0.44	<0.001

Note. (5) = [(2)-(1)] − [(4)–(3)]

From: Gutzwiller et al. Community-based primary prevention of cardiovascular disease in Switzerland: methods and results of the National Research Program (NRP 1A). Preventive Medicine 1985;14:482-91 (22)

Reduction in the prevalence of regular smokers was significantly greater in the intervention areas. However, only a small non-significant reduction in the amount of tobacco smoked was observed in the intervention compared with the reference areas.

Changes in blood cholesterol levels were comparable in the intervention and reference areas. However, the analysis of a sub-group of Swiss women showed that, in both intervention towns, women who had participated in preventive activities reduced their cholesterol level significantly more than those who had not.

Both systolic and diastolic blood pressure measurements were significantly improved in the reference area in comparison with the treatment area. However, the proportion of hypertensives under control was significantly higher in the intervention towns.

A comparison of the changes in weight and BMI also revealed a disadvantage in the intervention area with a small but statistically significant improvement seen amongst the reference population.

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by reviewer

Bias may have been created by the high losses to follow-up.

Summary

The National Research Programme utilised a range of intervention activities but it failed to show positive treatment effects. Given the programmes extensive and innovative involvement of a diverse range of community groups, it's small and sometimes absent treatment effect appears disappointing. Secular trends may have had some influence to mask intervention effects.

3.1.10 **The Otsego-Schoharie Healthy Heart Program**

The main aim of the Otsego-Schoharie project was to provide health education to isolated villages and populations. The five year intervention began in 1989 and was

delivered in an area demonstrated to have a high level of poverty and mortality from CVD. There was an emphasis on rural communities, where rates of CHD mortality were highest and access to adequate economic and medical resources were considered to be poor (23).

Target population

Intervention took place in the counties of Otsego and Schoharie in the state of New York with Herkimer, also located in New York state, as the control community (n~158,000 for all areas). The intervention and control communities were similar with respect to demographic characteristics but geographically isolated and relied on different sources of mass media (23).

The intervention population was predominately white (98%) with low average educational attainment (19% did not finish high school). In these areas, there were low income rates, high poverty rates (11-16% of the population lived below the poverty level) and moderate levels of unemployment.

Theory/conceptual model of intervention

None stated

Intervention description (24) (23)

The Otsego-Schoharie Healthy Heart Program was modelled on larger programmes such as Stanford Five City, Minnesota and Pawtucket but differed in that the Otsego-Schoharie population was scattered over a sparsely populated rural area and had a particularly low socioeconomic status. Funding was far lower than for many of the large programmes and the emphasis was therefore put on adaption of existing strategies and materials, rather than on the development of new ones.

In the year before programme implementation, a face to face questionnaire was conducted with organisational leaders from businesses, churches, educational establishments, and government offices to assess the extent of current heart health

initiatives and to investigate the needs and concerns of each organisation. An important finding was that people might not be willing to travel to participate in project activities but, if brought to their place of work or home area, they would support and attend. This process also helped to forge links between project staff and community establishments and led to the development of a programme strategy.

Community leaders formed Healthy Heart advisory committees to provide programme direction and special task forces were brought together to address specific CVD risk factors. A full-time, and a part-time community organiser, a health educator, exercise physiologist and media expert were hired to implement programme activities and a large number of volunteers became involved, taking direction from programme staff. Interventions were aimed at the micro level, as well as the macro level, utilising different approaches to access the whole population as well as targeting small rural areas.

Micro level intervention: Healthy Heart Hometowns was a small-scale initiative implemented separately in each town/village. Specific concerns were addressed by giving local health committees the option to choose particular interventions and project staff provided assistance (for screenings, media support etc) in implementation of activities. Healthy-heart foods and recipes were promoted, fitness activities organised and printed information was provided at heart-healthy events. Funding for events was provided by many communities through donations or community events.

Macro level intervention: Other activities were implemented across all intervention areas. Walking programmes were introduced and promoted in the community and risk factor screenings were conducted in neighbourhoods and workplaces. Screening activities covered a large proportion of the working population (offered at all workplaces ≥ 25 staff) and were followed up with recommendations for behavioural change. Media was used with radio and newspaper articles geared to the rural population. One-page brochures were produced to give clear health messages on one

CVD risk factor and these were designed to be understood by low literacy readers. They were distributed through schools, with work paychecks and posted on notice boards in workplaces, community agencies, schools and doctors and dental surgeries.

Schools were particularly used as a channel for communication and there were assemblies and class room presentations in schools in all districts. Presentation material was adapted from existing resources and presentations were planned to coincide with community-wide events. Three cartoon characters were designed for the programme (made by a local artist/designer) and parents, teachers and students from schools prepared and gave presentations. Walking programmes and tobacco education programs were also implemented and shops were encouraged to enforce the restriction of cigarettes to people >18 years.

Accessibility:

The intervention was planned and delivered following an assessment of community needs. Interventions were varied (written and verbal education, screening and activities such as creation of walking groups) and supported by local business, schools, churches, local government and the local media. They were offered in a variety of settings including workplaces, schools, restaurants, local health fairs, supermarkets, directly to the home and to health services.

Written verbal education was tailored for low-literacy audiences. The majority of the community are described as speaking English but no mention is made of provision for those speaking other languages or those from other cultural backgrounds. Interventions were offered free with the support of community fund-raising.

Participation in the two cross sectional surveys was 62% at baseline and 45% at 5 years. Participants in the survey evaluations were more likely to be married and to have higher educational attainment compared to non-participants which may be an indication of the accessibility of the intervention for these population sub-groups. No information is given on the uptake of intervention components.

Programme evaluation

Independent cross sectional surveys in the two intervention and one control region were taken at baseline (1989-1990) and after the five year intervention (1994-1996). A cohort of participants from the baseline survey was also followed up and surveyed after the intervention period (1994-1995).

Participant selection/recruitment

Cross sectional surveys selected a random sample of adults using a three-stage cluster design with random digit dialling and a Kish selection table. Adults aged 20-69 years, who had lived in the area for more than six months, were eligible to take part and were recruited into 10-year age and sex strata. Institutionalised adults and, for the second cross sectional survey, those that had participated at baseline, were not eligible for participation.

A telephone questionnaire was administered by trained interviewers to assess self-reported CVD risk factors and participants were then invited to a free clinical examination. Those with history of myocardial infarction, major surgery or who had been pregnant in the previous six months were excluded from the clinical examination. Participants attended a clinic or, where this was not possible, visits to homes or workplaces were made to conduct examinations. Blood pressure, exhaled carbon monoxide, height, weight and waist and hip circumference were measured and a blood sample taken for lipid profiles, serum glucose and total cholesterol.

The cohort survey included adults that had participated in the baseline cross-sectional survey. All participants that had undergone telephone and clinic interviews at baseline were contacted for restudy.

In the baseline survey, of those eligible to take part, 911 (response rate 85.1%) participated in the telephone interview and 628 (response rate 61.8%) participated in the clinical examination. In the independent cross sectional survey five years later, 1,035 (response rate 77.4%) participated in the telephone interview and 548 (response

rate 45.0%) participated in the clinical examination. In the cohort, of the original clinical survey participants, 494 (78.7%) took part in the telephone interview and 424 (67.5%) took part in a second clinical examination. The primary cause for loss to follow up was migration or death (19.4%). There were no significant demographic differences between intervention and control regions for any of the population surveys.

Outcome measures

Smoking (classified as reported current smoking or exhaled carbon monoxide $\geq$8ppm), sedentary (strenuous physical activity <3 times per week), systolic and diastolic blood pressure, total serum cholesterol (23).

Statistical methods (23)

Comparison of pre to post intervention changes in intervention verses control areas was done for the serial cross sectional studies using 2 x 2 randomised block ANOVA. The same comparisons were made for the cohort study using a 2 x 2 mixed ANOVA. In this second model, comparison of pre to post changes and the pre verses post changes by intervention versus reference group were within-subject effects.

The F test was used to test the interaction of the treatment group and the pre verses post condition (tests interaction effect). Secular trends over time were also tested by the pooled main effect for the pre verses post condition.

For the cohort study, comparisons were made of the changes in the prevalence of dichotomous outcomes between intervention and reference communities using the extension of the McNemar test with variables of diabetes, hypertension, sedentary lifestyle and smoking considered.

For the serial cross sectional data, comparison of the reduction in smoking prevalence was inferred by comparing the results of the test of two independent binomials done separately for the intervention and reference populations.

Results

Primary outcomes (23)

1. Smoking

Cohort: The prevalence of self reported smoking decreased in both intervention (27.9% to 17.6%) and control (24.4% to 21.6%) areas but the greater change in the intervention group resulted in a significant net treatment effect ($p<0.001$). The same pattern was also shown when cigarette smoking was defined by exhaled carbon monoxide $\geq$8ppm. Smoking prevalence decreased in the intervention region to a greater extent (30.3% to 21.9%) than the control region (23.6% to 21.1%) and the net treatment effect was significant ($p<0.01$). The amount of exhaled carbon monoxide, as a continuous variable (inferring the amount of cigarettes smoked), also decreased in the intervention (10.2±11.6 ppm to 8.1±10.2) but not in the control (8.4±9.7 ppm to 8.7±11.2 ppm) group and the net treatment effect was significant ($p<0.01$).

Cross sectional: The prevalence of self-reported smoking decreased in the intervention area (27.9% to 19.0%) but increased in the control (24.4% to 28.2) and there was a significant net improvement with intervention (p value not given). For carbon monoxide assessed cigarette smoking, the prevalence also decreased in the intervention (30.3% to 19.0%) and increased in the control (23.6% to 30.9%) and the net treatment effect was significant (p value not given). The amount of exhaled carbon monoxide decreased in the intervention (10.2±11.6 ppm to 7.7±11.4 ppm) but not in the control (8.4±9.7 ppm to 10.0±13.0 ppm) group and the net treatment effect was significant ($p<0.01$).

NB there is inconsistency between the results table and the text of this paper. For the cross sectional data, only one of the smoking variables is marked in the table as showing a net treatment effect.

2. Cholesterol

There were no significant changes in intervention or control groups assessed in the cohort or cross sectional surveys for total cholesterol level and no significant net effects were detected.

3. Blood pressure

For systolic blood pressure, there were significant reductions in both intervention and control groups for both cohort and cross sectional surveys but no significant net treatment effects.

For diastolic blood pressure, in the cohort, there were no significant changes in intervention or control groups. In the cross sectional surveys, there were significant reductions in both the intervention and the control group but no significant net treatment effect.

4. Physical activity

There were no significant changes in intervention or control groups assessed in the cohort or cross sectional surveys in regard to sedentary lifestyle and no significant net effects were detected.

5. Plasma glucose

There were no significant changes in intervention or control groups assessed in the cohort or cross sectional surveys for plasma glucose level and no significant net effects were detected.

6. BMI

For the cohort, BMI increased significantly in both the intervention and control areas (results not reported in the table). Results for the cross sectional surveys are not discussed.

Limitations of the study

The study was quality assessed and graded '-'.

Limitations identified by authors (23)

The sample size may have been too small to detect intervention effects.

Limitations identified by reviewer

Those in the baseline survey were told that they would be invited to participate in another survey five years later (cohort study). This may have influenced lifestyle changes in those receiving intervention messages, particularly just before the second survey. Positive smoking results for the cohort may, to some extent, result from short term changes and may not be representative of whole intervention community change.

Summary

The Otsego-Schoharie Healthy Heart Program provided comprehensive, varied promotion of risk factor reduction but did not show positive changes in most physiological risk factors. However, the consistent beneficial programme effect on rates of smoking, assessed by different methodological (reported rates, expired CO) and evaluation (cohort and cross sectional samples) measures, provides evidence for some positive intervention effect.

3.1.11 The Stanford Three Community Study

The Stanford Three Community Study, also known as the Stanford Heart Disease Prevention Program, was launched in 1972. A multimedia campaign was conducted for two years in two Californian communities (Watsonville and Gilroy), one of which

(Watsonville) implemented an additional by an intensive face-to-face instruction programme with high-risk subjects. During the third and final year of the campaign the intensity of the media effort was reduced to about half its former level and virtually no face-to-face contact was maintained. The campaigns were designed to increase participants' knowledge of the risk factors associated with cardiovascular disease and to change risk-producing behaviour such as smoking and poor diet (i.e. reduce high intakes of calories, salt, sugar, saturated fat and cholesterol)(25,26) .

Target population

Three roughly comparable communities in northern California were selected for study: Watsonville (14,569 inhabitants), Gilroy (12,665 inhabitants) and Tracy (14,724 inhabitants). These towns were semi-rural with mainly agricultural economies. Tracy was selected as a control as it was relatively distant and isolated from the media in the other communities. Gilroy and Watsonville shared some media channels (television and radio) but each town had its own newspaper (25) (26).

Theory/conceptual model of intervention

The programme comprised a previously untested combination of extensive mass media and face-to-face instruction aimed at reducing CVD risk through the simultaneous modification of smoking, exercise and dietary behaviour. The face-to-face component drew on treatment techniques derived from social learning theory and behavioural self-control principles such as self-observation, modelling, and token reinforcement (27).

Intervention description

The mass media and counselling campaigns were designed to produce awareness of the probable causes of CVD and of the specific measures which might reduce risk and to provide the knowledge and skills necessary to accomplish and maintain behavioural change. Dietary habits recommended for all participants were those which, if followed, would lead to substantial reductions in intakes of saturated fat,

cholesterol, salt, sugar, and alcohol. Weight loss was also promoted through recommendations to reduce the number of calories consumed and increase the amount of exercise taken. Smokers were educated on the need and methods for quitting or counselled to reduce the number of cigarettes smoked (25).

The media campaign in Gilroy and Watsonville comprised about 50 television spots, three hours of television programming, over 100 radio spots, several hours of radio programming, weekly newspaper columns, newspaper advertisements and stories, billboards, posters, and printed material posted to participants. A campaign was also created for the large population of Spanish speakers in the communities. The media campaign started two months after the initial survey and continued for nine months in 1973. It was withheld for three months during the second survey and then re-instated for a further nine months in 1974 (25).

Two-thirds (113) of the Watsonville participants identified as being in the top quartile of risk of coronary heart disease were randomly selected for counselling. 107 attended counselling sessions and 77 high-risk individuals and 34 spouses completed all three interviews and examinations. These individuals, and their physicians, were informed by letter of their relatively high risk of coronary heart disease (the letter was regarded as part of the treatment). They and their spouses were invited to take part in an instruction programme that was launched six months after the first baseline survey and was conducted intensively over a ten-week period through group classes and home counselling sessions. In the summer months of the second year, at a less intensive level, individuals were counselled about special problems (i.e. smoking and weight-loss) and encouraged to maintain previous changes. The counsellors were graduate students in communication, physicians, and specialist health educators trained in behaviour modification techniques. The intensive instruction was designed to achieve the same changes that were advocated in the media campaign. The strategy was to present information about the behaviour which influences risk of coronary heart disease, to stimulate personal analysis of existing behaviour, to demonstrate

desired skills (i.e. food selection and preparation), and to guide the individual through practice of those skills and gradually withdraw instructor participation (25).

Accessibility:

The mass media component of the intervention included television, radio and newspaper coverage, billboards and written materials delivered to homes. Materials were made available for 'the sizeable' number of Spanish speaking individuals within the intervention population but no mention is made of provision for those with low levels of literacy, those speaking other languages or those from other cultural backgrounds.

The counselling component of the intervention was offered using a letter of invitation to those identified as high risk for CVD. The communication of an individual's risk by letter was considered an integral part of the intervention but no information is provided on how this information was communicated. Adequate communication of risk to patients requires a level of numeracy which may limit the effectiveness of this approach to certain groups.

Counselling took place weekly either in group sessions or in homes. Group sessions were run at two local churches but the distance needed to travel to group sessions is not clear. Counselling was available in English and Spanish and authors describe the Spanish instruction as being 'carefully tailored to the information–seeking habits of the Spanish speaking community'. Counselling sessions lasted between 2 and 3 hours and a considerable amount of homework was required.

Although initial response rates to evaluation surveys were >95%, drop-out rates in follow up surveys were 25-26% in mass media only intervention populations and 33% in mass media plus counselling intervention populations. This latter figure represents the drop out rate from the counselling intervention. Within the counselling group those with a higher risk of CVD at baseline were significantly more likely to drop out. This drop-out may be a reflection of the accessibility of the intervention for these

population sub-groups. No further information is provided on uptake of intervention. No difference in outcomes according to population sub-groups is reported.

Programme evaluation

As the media campaigns were targeted at the whole community, the random assignment of individuals to treatment or control conditions was not possible. Furthermore, the alternative of treating large numbers of populations as single units and randomly assigning them to treatment or control conditions would have been prohibitively expensive. Therefore a quasi-experimental research design (controlled before and after study) using on small number of experimental units was adopted.

Participant selection/recruitment

To assess the effects of intervention, sample surveys were conducted to obtain baseline and yearly follow-up data from a random sample of adults aged 35-59 years in all three towns. The first survey (S_b) took place just prior to the first campaign year in 1972. Follow-up surveys of the cohorts were then undertaken at the end of each of the two main campaign years in 1973 (S_1) and 1974 (S_2).

In an attempt to account for the impact of the measurement process on future risk-related behaviour an additional, 'after-only', sample was surveyed in each town at the end of the first year.

Baseline survey data were combined into a multiple logistic function of the overall risk of coronary heart disease developing within 12 years and high-risk subjects (in the top quartile) were selected for special study. In Watsonville, a random subset of two-thirds of these high-risk people and their spouses were randomised to receive face-to-face intensive instruction (designated W-I.I.) and the remaining subjects were observed as controls (designated W-RC). High-risk sub-groups in Gilroy (receiving the mass media programme only) and Tracy (receiving no additional attention other than their identification) were also followed up.

Overall, there were 12 partially overlapping study groups (see Table 3.2): 'total

participants', a 'high-risk' group, and an 'after-only' sample in each of the three

communities; within Watsonville, the intensive-instruction sub-sample (W-I.I.) and

the control high-risk group (W-RC) and the spouses of those in the instruction groups

were also observed. Also, in Watsonville, a 'reconstituted' (with W.I.I. subjects

replaced) sample of total participants (W-R) was observed.

Table 3.2 Composition and treatment of 12 participant groups in three communities

Participant group	N	Data collected at	Treatment given
Tracy (T)			
Total participants	384	S_b S_1 S_2	No intervention
High-risk	95	S_b S_1 S_2	No intervention
After-only	107	S_1	No intervention
Gilroy (G)			
Total participants	397	S_b S_1 S_2	Mass-media campaign
High-risk	94	S_b S_1 S_2	Mass-media campaign
After-only	102	S_1	Mass-media campaign
Watsonville (W)			
Total participants	423	S_b S_1 S_2	Mass-media campaign for all with additional intensive instruction for high risk participants
Reconstituted (W-R)	423	S_b S_1 S_2	Mass-media campaign
High risk participants:			
Intensive instruction (W-I.I)	77	S_b S_1 S_2	Mass-media campaign & intensive instruction
Randomised control (W-RC)	40	S_b S_1 S_2	Mass-media campaign
W-I.I. spouses (I.I.-	34	S_b S_1 S_2	Mass-media campaign & intensive

spouse)			instruction
After-only	100	S$_1$	Mass-media campaign

S$_b$ = baseline survey; S$_1$ = first annual follow-up survey; S$_2$ = second follow-up survey

From: Maccoby et al. Reducing the risk of cardiovascular disease: effects of a community-based campaign on knowledge and behaviour. Journal of Community Health 1977;3(2):100-14 (26)

A final survey was undertaken at the end of year three (1975) during which time the intensity of the media campaign was greatly reduced and virtually no face-to-face contact was maintained.

Outcome measures

Each survey included a behavioural interview and a medical examination of each subject. The behavioural survey covered the subject's knowledge about CVD risk factors and their attitude towards CVD and towards modifying risk-promoting behaviour in the area of diet, weight, smoking and exercise. The medical examination included measures of plasma cholesterol and triglyceride concentrations, blood pressure and relative weight and electrocardiograms. These data were combined into a multiple logistic function of risk (based on that developed for the Framingham study) {Truet 1967} which yield a prediction of the subject developing CVD within 12 years (26).

Results

The results presented relate to the total number of participants (both high-risk and non high-risk) in the three communities of Tracy, Gilroy and Watsonville. They reflect changes in the participants' knowledge about risk factors, changes in risk-related behaviours (saturated fat intake and number of cigarettes smoked/day), changes in physiological indicators of risk (total plasma cholesterol, systolic blood pressure and relative weight), and changes in risk-score. Regrettably, the data reported lack numerical precision as the results are presented in charts with poorly delineated

scales. The charts provide absolute baseline values and indicate percentage changes in selected variables after two years in the control (Tracy) and treatment (Gilroy: mass-media, Watsonville: mass-media for general population with additional intensive instruction for high-risk participants and Watsonville reconstituted: a reconstructed group in which the high-risk sub sample receiving intensive instruction were replaced) groups (25).

Primary outcomes

1. CVD risk score

Changes in the multiple logistic function of risk help to predict changes in the risk of developing CVD and thus provide a useful benchmark in the absence of long-term follow-up data on cardiovascular morbidity and mortality.

At baseline, there were no significant differences in CVD risk score between the control and intervention groups. CVD risk score increased in the Tracy control group (by approximately 7%) after two years but decreased in the Gilroy, Watsonville and Watsonville reconstituted treatment groups (by approximately 17, 20 and 16% respectively). Results read from charts indicated significant ($p < 0.05$) net reductions in the overall risk of developing CVD within 12 years amongst the Gilroy, Watsonville and Watsonville reconstituted treatment groups in comparison with the Tracy control group (of approximately 24, 27 and 23% respectively). However there were no significant differences between the media only (Gilroy) and media plus intensive instruction (Watsonville) group (25).

2. Total plasma cholesterol

At baseline, total plasma cholesterol levels for the Tracy control group and Gilroy, Watsonville and Watsonville reconstituted intervention groups were 209, 212, 213 and 212 mg/dl respectively, with no significant differences between the groups. Total plasma cholesterol increased in the Tracy control group (by approximately 0.8%) after two years but decreased in the Gilroy, Watsonville and Watsonville reconstituted

treatment groups (by approximately 3.1, 2 and 1.6% respectively). Results read from charts indicated significant (p<0.05) net reductions in total plasma cholesterol amongst the Gilroy, Watsonville and Watsonville reconstituted treatment groups in comparison with the Tracy control group (of approximately 3.9, 2.8 and 2.4% respectively). This translates to net reductions of 8.2, 5.9 and 5.1mg/dl amongst the respective Gilroy, Watsonville and Watsonville reconstituted intervention groups in comparison with the Tracy control group. There were no significant differences between the media only (Gilroy) and media plus intensive instruction (Watsonville) group (25).

3. Systolic blood pressure

At baseline, systolic blood pressure levels for the Tracy control group and the Gilroy, Watsonville and Watsonville reconstituted intervention groups were 129, 132, 133 and 133 mmHg respectively. Systolic blood pressure increased in the Tracy control group (by approximately 1.5%) after two years but decreased in the Gilroy, Watsonville and Watsonville reconstituted treatment groups (by approximately 7.5, 4.8 and 4.7% respectively). Results read from charts indicated significant (p<0.05) net reductions in systolic blood pressure amongst the Gilroy, Watsonville and Watsonville reconstituted treatment groups in comparison with the Tracy control group (of approximately 9, 6.3 and 6.2% respectively). This translates to net reductions of 11.8, 8.3 and 8.2 mmHg amongst the respective Gilroy, Watsonville and Watsonville reconstituted groups in comparison with the Tracy control group. A significantly greater reduction (p<0.05) in systolic blood pressure was seen in the media only (Gilroy) group in comparison with the media plus intensive instruction (Watsonville) group (25).

4. Relative weight

Relative weight was defined as actual/'ideal' weight. At baseline, relative weight ratios for the Tracy control group and Gilroy, Watsonville and Watsonville reconstituted intervention groups were 1.26, 1.24, 1.21 and 1.22 respectively. The

relative weight ratio for Watsonville was significantly lower at baseline than those for the Tracy, Gilroy and Watsonville reconstituted groups. Small decreases of 0.4, 0.9, 0.4 and 0.2% were evidenced over two years amongst the Tracy control and Gilroy, Watsonville and Watsonville reconstituted intervention groups respectively. There were no significant differences between the control and treatment groups and no significant differences between the media and media plus intensive instruction treatment groups (25).

5. Dietary modification – saturated fat intake

At baseline saturated fat intakes for the Tracy control group and Gilroy, Watsonville and Watsonville reconstituted groups were 34, 38, 36 and 36gm/day respectively. Saturated fat intake at baseline was significantly higher in the Gilroy intervention group than in the Tracy control group and Watsonville and Watsonville reconstituted intervention groups. Saturated fat intake decreased in the Tracy control group (by approximately 4%) after two years but decreased to a significantly greater extent in the Gilroy, Watsonville and Watsonville reconstituted treatment groups (by approximately 26, 28 and 24% respectively). Results read from charts indicated significant ($p<0.05$) net reductions in saturated fat intake amongst the Gilroy, Watsonville and Watsonville reconstituted treatment groups in comparison with the Tracy control group (of approximately 22, 24 and 20% respectively). This translates to net reductions of 8.5, 8.7 and 7.2 gm/day amongst the respective Gilroy, Watsonville and Watsonville reconstituted intervention groups in comparison with the Tracy control group. There were no significant differences between the media only (Gilroy) and media plus intensive instruction (Watsonville) groups (25).

6. Smoking

Information is provided on the number of cigarettes smoked per day. This appears to reflect an average across the respective groups taking account of both smokers and non-smokers however the text does not make this explicit. At baseline the number of cigarettes smoked per day for the Tracy control group and Gilroy, Watsonville and

Watsonville reconstituted intervention groups were 6.9, 6.8, 7.2 and 6.8 respectively. There were no significant differences between the groups. Results read from charts indicated the number of cigarettes smoked per day decreased in the Tracy control group by approximately 3% and decreased in the Gilroy, Watsonville and Watsonville reconstituted intervention groups by approximately 6, 22 and 13% respectively after two years. In comparison with Tracy there was a net, non-significant decrease of 3% in Gilroy, a significant ($p<0.5$) net decrease of 19% in Watsonville, and a significant ($p<0.5$) net decrease of 10% in the Watsonville reconstituted group. Comparisons between media only (Gilroy) and media plus intensive instruction (Watsonville) indicate significant reductions in the Watsonville group (25).

7. Knowledge of risk factors

Twenty-five items were used to test participants' knowledge about CVD and its risk factors: 14 items assessed the role of diet, three were concerned with smoking, four with physical activity, two with body weight, and two with general information. There were no significant differences between the control and intervention groups at baseline. After two years knowledge of risk factors increased in the Tracy control group by approximately 8% but increased to a significantly greater extent in the Gilroy, Watsonville and Watsonville reconstituted groups (approximately 27, 41 and 39% respectively). Results read from charts indicated significant ($p<0.5$) net increases of 19, 33 and 31% in comparison with Tracy for the respective Gilroy, Watsonville and Watsonville reconstituted intervention groups. Those in the media plus intensive instruction group (Watsonville) also increased knowledge of risk factors to a significantly greater extent than those in the media only (Gilroy) group (25).

Limitations of the study

The study was quality assessed and graded '+'.

Limitations identified by authors

Knowledge of a forthcoming appointment, with the expectation of a series of physiological measurements, may promote temporary compliance amongst subjects in the treatment group.

The link between increased knowledge, subsequent changes in behaviour and reductions in physiological risk factors is not fully proven. The presence of a heart disease control programme may create a more proactive local healthcare system with increased screening for, and medical treatment of, the risk factors associated with CVD.

Limitations identified by reviewer

Estimates of relative effectiveness have been made from information presented in graphs with poorly delineated scales and therefore lack precision.

Summary

One of the earliest programmes of its type, the intervention comprised a previously untested combination of extensive mass media and face-to-face instruction aimed at reducing CVD risk through the simultaneous modification of smoking, exercise and dietary behaviour. The study findings indicate that multimedia campaigns in isolation may favourably influence the risk of CVD and some of the behaviours felt to impact on it and, for some risk factors, the addition of face-to-face instruction amongst selected high-risk participants may increase the magnitude of effect amongst the population as a whole.

3.2 Summary of the evidence

Graphical representations summarising net changes in outcomes of total blood cholesterol (mmol/l), diastolic and systolic blood pressure (mm/Hg), BMI (kg/m^2) and prevalence of smoking (%) for each programme are displayed below. 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 reported as dichotomous variables. Only continuous variables are represented graphically but data from dichotomous variables was examined and contributed to the formulation of evidence statements.

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

Mean total blood cholesterol

Effect as mean difference in mmol/L
(negative value indicates programme advantageous)
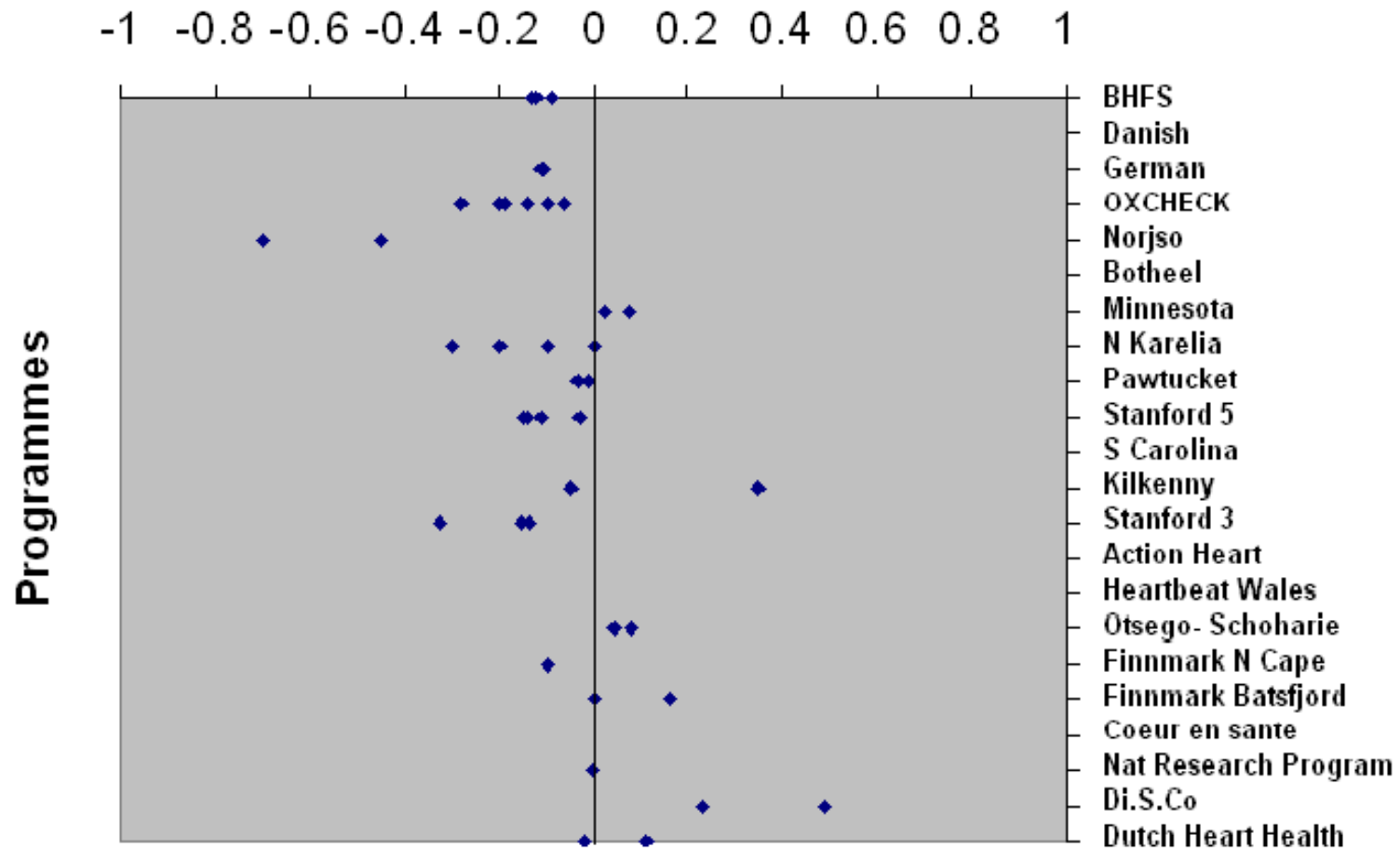
Mean diastolic blood pressure

Effect as mean difference in mm Hg
(negative value indicates programme advantageous)
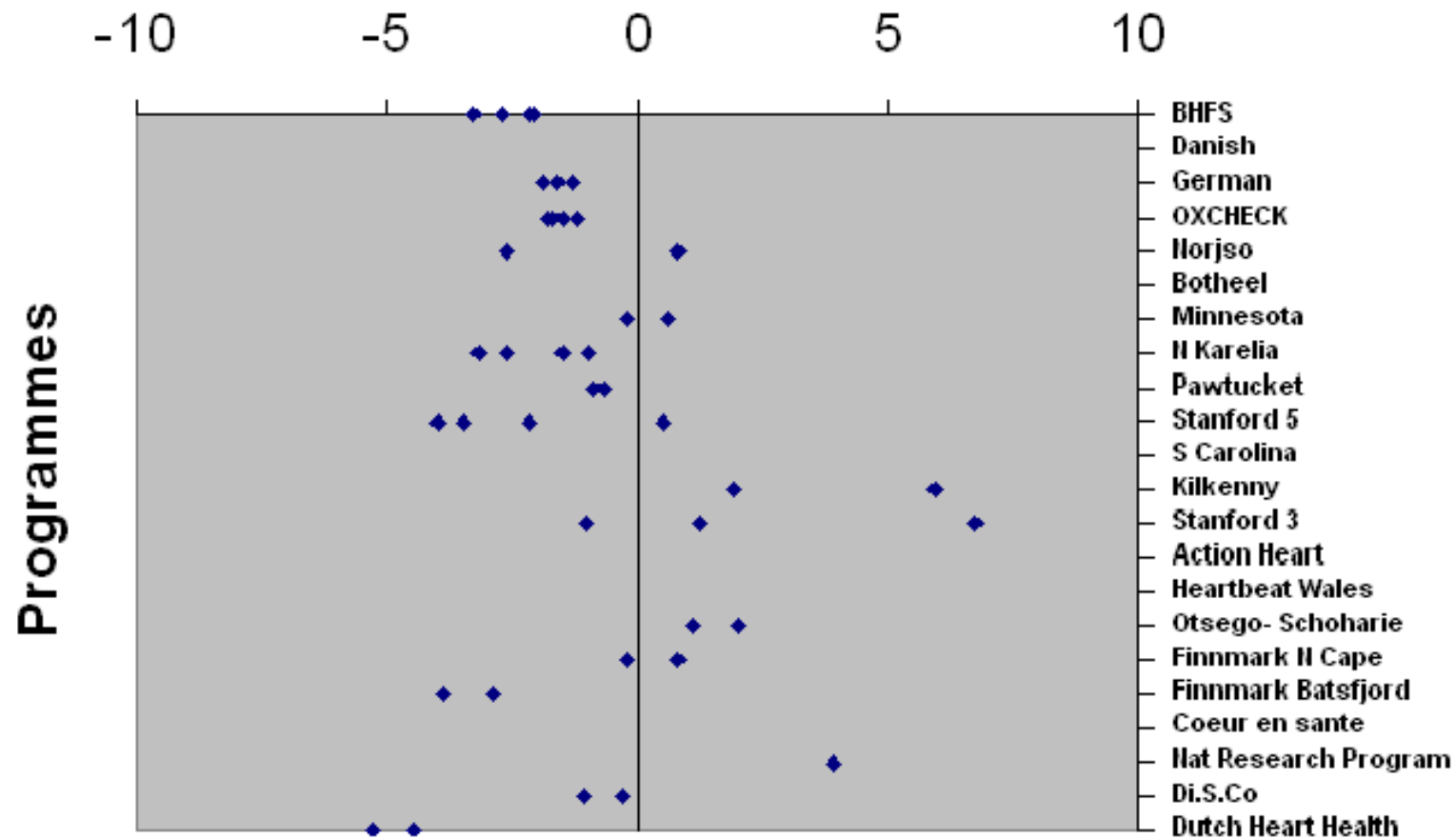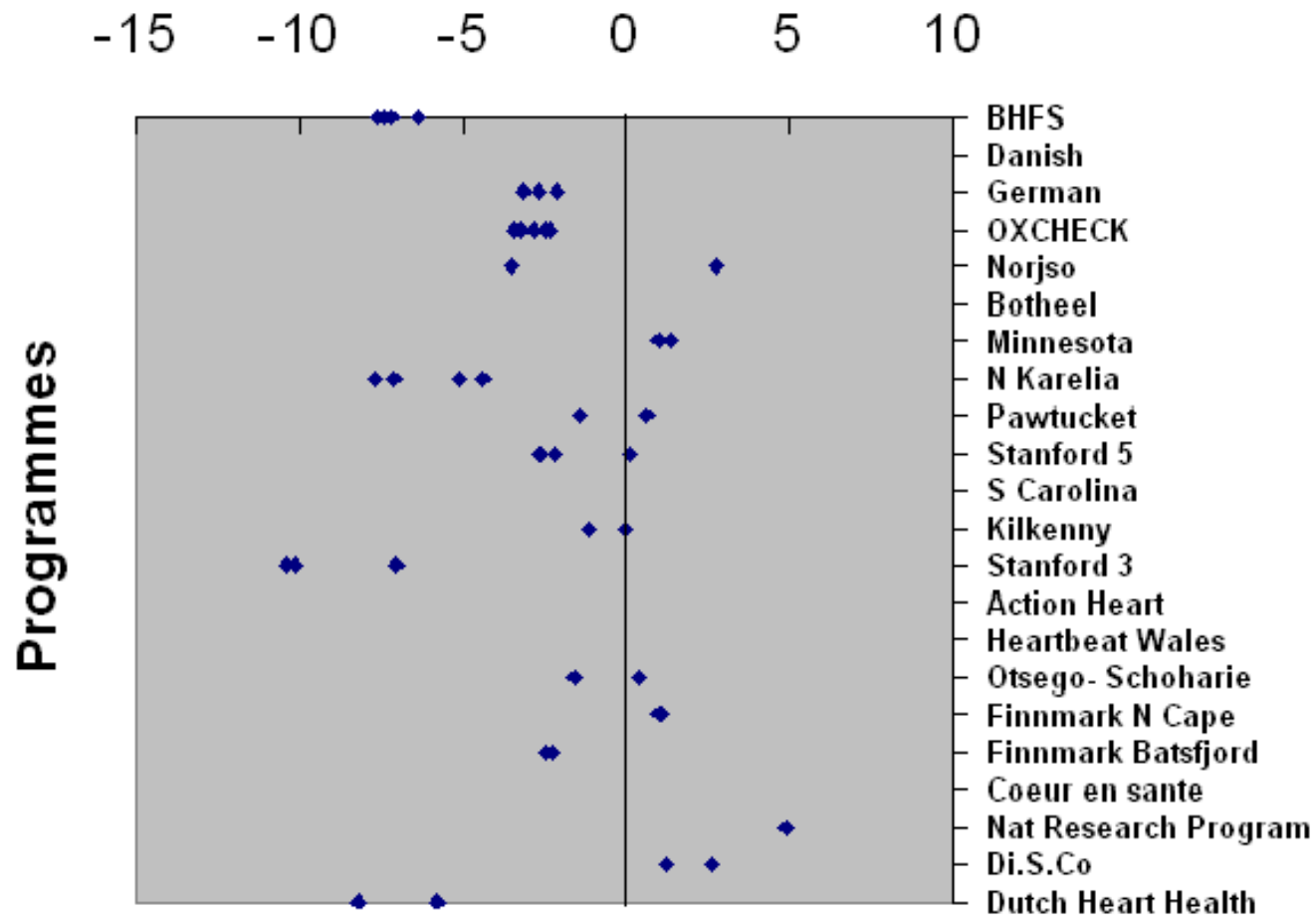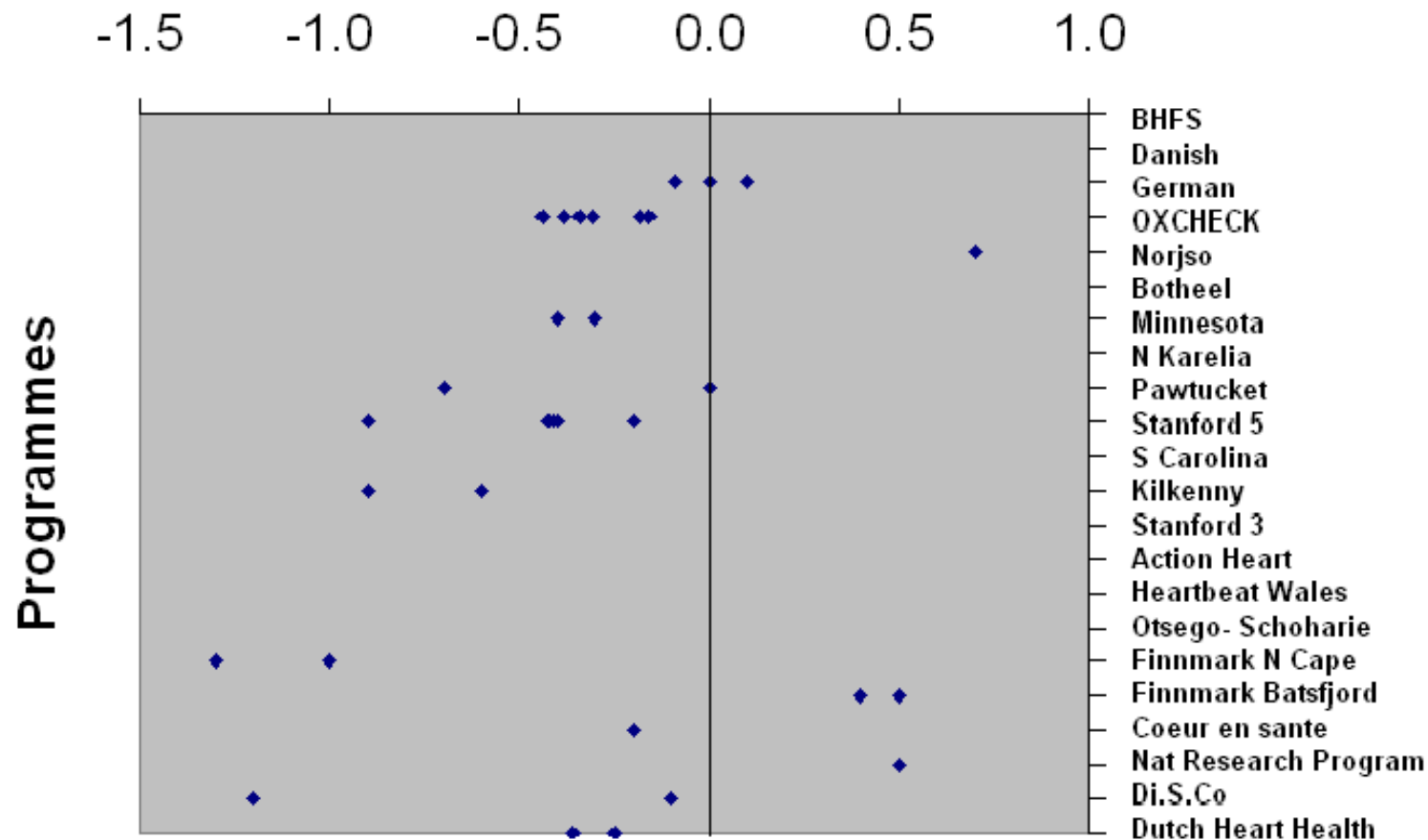
Mean systolic blood pressure

Effect as mean difference in mm Hg
(negative value indicates programme advantageous)
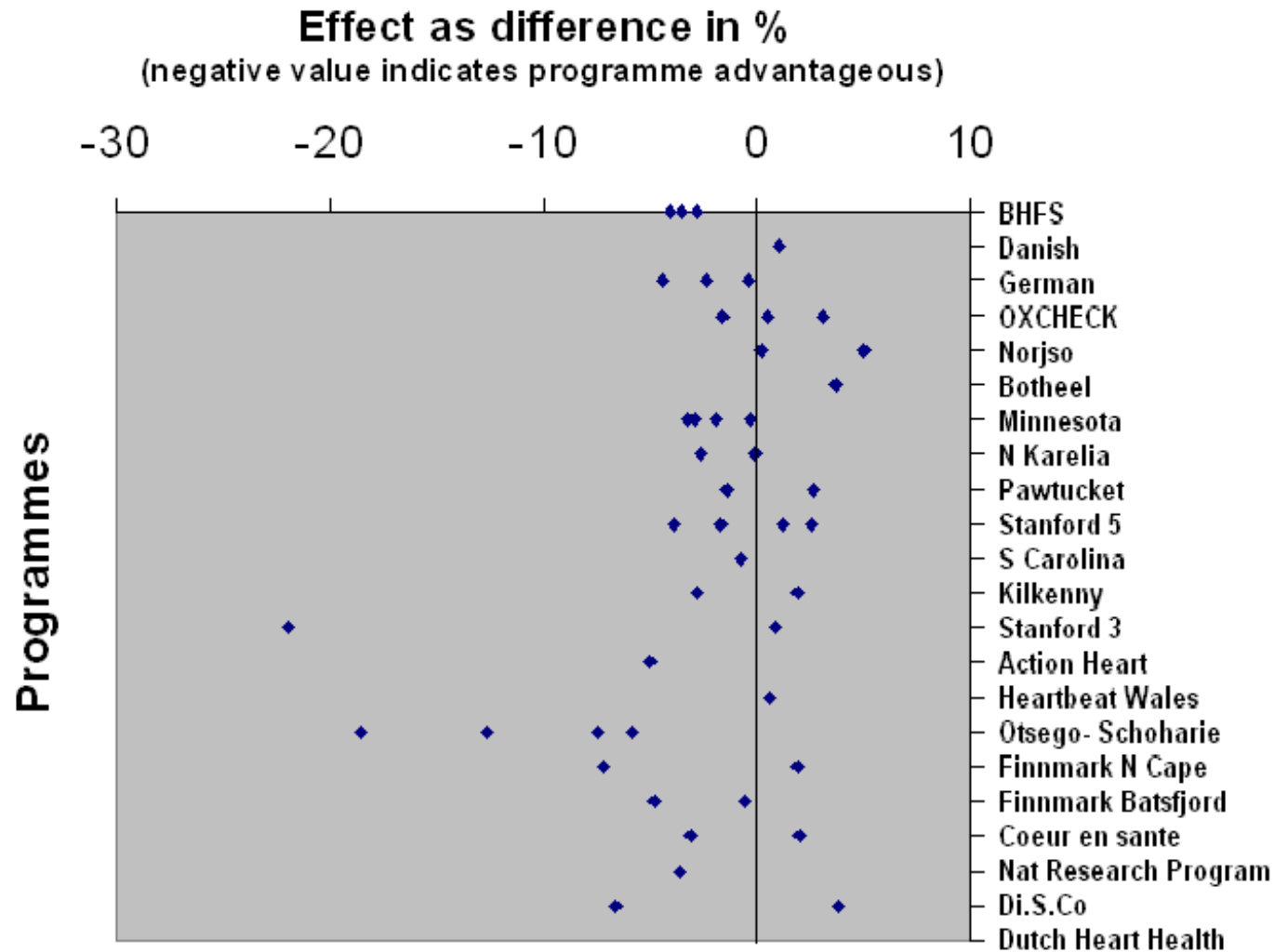
Mean body mass index (BMI)

Effect as mean difference in kg/m^2
(negative value indicates programmes advantageous)

Percentage smokers

Effect as difference in %
(negative value indicates programme advantageous)

Evidence statement for programmes addressing prevention of CVD at population level (phase II of review 1)

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

11 directly relevant programmes reported in 28 publications were identified for this report. All publications are concerned with the effectiveness of population programmes using education and mass media although programmes vary according to the relative contribution of these two components. No programmes used legislative or fiscal changes and there were no natural experiments. Programmes were generally evaluated using controlled before-after studies with quality gradings ranging from – to +. For CVD risk factor physiological and behavioural outcomes, there was a mixed pattern across studies with some outcomes demonstrating no obvious direction of effect and other outcomes demonstrating a direction of effect in favour of programmes. The size of these effects could not be quantified. There was little useful information on the effect of the programmes on CVD morbidity and mortality.

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

These are interim statements based on the combined data from the first and second parts of a 3 stage review.

22 directly relevant programmes reported in 69 publications have been identified across phases I and II of this review of effectiveness. The majority of publications are concerned with the effectiveness of population programmes using education and mass media and were generally evaluated using controlled before-after studies with quality gradings ranging from – to +. Two screening programmes have been evaluated using RCTs and were both quality graded +. No programmes have used legislative or fiscal changes and no natural experiments have been identified. It is not possible to quantify the size of these effects across all programmes.

Evidence statements relate to 1) the effectiveness of programmes to reduce physiological and behavioural risk factors for CVD and 2) the nature of community programmes i.e. setting, target audience, intervention strategies etc. However, the extent to which the nature of community programmes might influence programme effectiveness has not been addressed as there is inadequate evidence to support evidence statements of this kind.

Evidence statements for outcomes

- There is currently little useful information on the effect of the programmes on **CVD morbidity** and **mortality**.

- For the CVD risk factor **cholesterol** a moderate trend in direction of effect in favour of programmes is observed.

- For the CVD risk factors **diastolic and systolic blood pressure** a moderate trend in direction of effect in favour of programmes is observed.

- For the CVD risk factor **smoking** a moderate trend in direction of effect in favour of programmes is observed.

- For the CVD risk factor **BMI** a strong trend in direction of effect in favour of programmes is observed.

- For the CVD risk factor **blood glucose** there is a mixed pattern across studies with no clear direction of effect.

- There is currently no evidence on the effect of the programmes on **triglyceride levels, HDL/LDL ratio or lipid levels**.

- There is currently no evidence of **adverse events** associated with these types of programmes.

- For CVD risk factors of **dietary change** a strong trend in direction of effect in favour of programmes is observed.

- There is currently no evidence of the effect of programmes on the CVD risk factor **salt intake**.

- For the CVD risk factor **physical activity** there is a mixed pattern across studies with no clear direction of effect.

- There is limited evidence of the effect of programmes on **attitudes, knowledge and intentions relating to CVD risk factors**.

- Additional outcomes to those specified in the protocol have been reported in some programmes but with little consistency across programmes limiting their usefulness.

Evidence statements for the nature of programmes

The 22 programmes identified targeted a variety of audiences, utilized various modes of delivery and drew on the skills and resources of a range of different personnel.

- The programmes identified were initiated across a wide time period from 1972 to 1998.

- Programme length ranged from one to >twenty years.

- Community settings were rural (n=10), urban (n=7), or mixed (n=5).

- The size of the target audience varied; ranging from approximately 2,500 to over 1,000,000.

- Intervention targeted communities of a low socioeconomic status in eight of the programmes.

- Communities considered to be at high risk of developing CVD were targeted in eight of the programmes.

- The majority of the programmes (n=17) relied heavily on mass media.

- Counselling was a key element of many programmes; undertaken individually (n=14) and amongst groups (n=8).

- Fourteen of the programmes utilized screening.

- Ten of the programmes implemented changes to the environment.

- Personnel delivering the intervention were generally drawn from staff associated with the respective projects (n=20).

- Health departments (n=13), local health committees (n=8), voluntary organisations (n=9) and community volunteers (n=6) had roles in programme delivery.

- Programmes were delivered in a variety of settings including workplaces (n=8) and schools (n=13).

- For programme accessibility, a consistent observation was a relatively lower response from males, those of younger age, those relatively less educated and those at higher risk of CVD. However, response rates are usually only provided for evaluation surveys and information is generally not available on uptake of intervention activities.

- 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 assessed in three programmes.

3.3 Evidence Tables

Table 3.1: Action Heart

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: Action Heart **Relevant papers:** Baxter et al. A cost effective, community based heart health promotion project in England: prospective comparative study. BMJ 1997; 315: 582-585 {Baxter,T. 1997} Baxter et al. The impact of heart health promotion on coronary heart disease lifestyle risk factors in schoolchildren: lessons learnt from a community-based project. Public Health 1997; 111: 231-237 {Baxter,A.P. 1997} **Study designs:** Controlled before and after study (cross sectional and cohort method of data collection) **QA Grade: '-'**	**Aim:** To produce lifestyle changes that affect the development of coronary heart disease (1) **Intervention:** Schools-based activities: 'My Body' project run in primary schools, particular emphasis on the effects of smoking on health. In secondary schools, interventions included healthy eating days, no smoking school policies, an Action Heart lunch time club and a training programme for students who subsequently ran 'health days' for peers. Some schools trained staff and most included heart health topics in their curriculum. Leaflets, T-shirts, posters and other promotional materials were used to support events and local press contacted to cover activities (2). Whole community: "Wake up to semi-skimmed milk" promotion, took place in the final year of intervention and involved delivery of leaflets to 13,000 households (1). Full details of the main	**Intervention group:** Swinton and Wath in Rotherham, chosen for their high incidence of coronary heart disease (1). **Control group:** Maltby, similar socio-economic profile and presence of CVD risk factors, considered far enough from intervention region to minimise risk of contamination (1). **Included participants:** Adults aged 18-64y Children aged 11 and 14y **Excluded:** Not stated **Setting:** North England	4 years (community intervention) and 3 years (schools-based intervention) Adults: Baseline and 4 year (post intervention) cross sectional surveys with response rates ranging from 82 to 86%. Children: Baseline and 3 year (post intervention) surveys with response rates ranging from 85-95%. Cohort analysis used for children aged 11y at baseline (14y post-intervention). Cross sectional analysis of children aged 11 and 14y in each survey.	**Primary outcomes:** All outcome measures were self reported **Adults**: Prevalence of active smoking, passive smoking, consumption of wholemeal bread, use of low fat spreads, use of low fat milk, exercise ≥ 3 times per week, obesity or overweight, blood pressure and cholesterol. **Children**: Prevalence of active smoking, passive smoking, wholemeal bread consumption, low fat spread consumption, low fat milk consumption and exercise ≥ 3 times per week.	**Primary outcomes** **Adults (1):** No significant intervention effect for any outcome variable except: 1. Smoking Prevalence decreased from 32.3% to 28.8% in intervention group and increased from 36.4% to 38.0% in control group (estimated net effect -24.5%; CI -39.4 to -6.1). 2. Low fat milk consumption: Prevalence increased from 48.2% to 71.0% in the intervention group but from 53.6% to only 68.8% in the control group (estimated net effect +42.5%; CI 14.8 to 77.0). **Children (2):** Cohort: No intervention/control school comparisons are made and so net intervention effect cannot be assessed. Cross sectional surveys: No significant intervention effect for any outcome variable except: 1. Exercise Prevalence of children exercising ≥ 3 times a week increased in the intervention 11 year olds (odds ratio 1.76) but decreased in 14 year olds (odds ratio 0.65). In control	**Identified by author** It may not be possible to produce lifestyle changes within the school setting in this short period of time as other influences may be too important. There were very limited resources for health promotion in schools. Work was not informed on a systematic review of the evidence of the effectiveness of health promotion interventions. Tobacco industry marketing was great in comparison with government spending on smoking prevention activities. **Identified by reviewer:** There was a greater fall in unemployment rate in the intervention compared to the control area during the period of study. This has been identified by other reviewers as a potentially important confounder and suggested that this

community intervention are not described.

Comparison:

No intervention

schools, it decreased in 11 year olds (odds ratio 0.41) and increased slightly in 14 year olds (odds ratio 1.1). Significant combined ages net treatment improvement (X^2=11.4, p<0.01).

2. Diet

Wholemeal bread consumption increased in intervention 11 year olds (odds ratio 1.3) and decreased slightly in 14 year olds (odds ratio 0.79). For controls, consumption decreased in both age groups (odds ratios: 11y 0.84, 14y 0.23). Significant combined ages net treatment effect (X^2=7.1, p<0.01).

may have caused observed treatment effect on adult smoking {Davey Smith 1998}.

All outcomes are self-reported and, since smoking may be particularly at risk from reporting bias, this outcome may not be fully reliable.

The questionnaire that was used to evaluate intervention effects in school children was first piloted in the schools that it was later used to assess.

Table 3.2: Coeur en Santé St-Henri

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: Coeur en Santé St-Henri **Relevant papers:** O'Loughlin et al. Coeur en Santé St-Henri – a heart health promotion programme in Montreal, Canada; design and methods for evaluation. Journal of Epidemiology and	**Aim:** To promote heart healthy behaviours, particularly in those aged 18-65 years **Intervention:** Implemented by public health department (3) in close collaboration with local community groups (3). Activities included school-based smoking prevention	**Intervention group:** St-Henri (n=~25,000) (3) **Control group:** The control community, Centre-Sud was matched to St-Henri on size, geographic location, language spoken at home, level of education, income sufficiency and CVD	3.5 years 849 treatment and 825 control participants in baseline survey (79.3% and 77.8% response rates) (3,4). Cross-sectional surveys: In the final (3 year) independent cross sectional survey,	**Primary outcomes:** Reported measures relating to smoking, cholesterol, blood pressure, BMI, physical activity and fat intake. **Secondary**	**Primary outcomes** (4): Reported % smoking: no significant treatment effect in independent surveys or cohort. Reported physical activity: no significant difference for independent samples. For the cohort no difference in outcomes apart from % describing themselves as 'more active'. This increased in the intervention (+5.5%) and decreased in the control (-1.6%) group, significant adjusted odds ratio for the difference between	**Identified by author**(4): Consistently low levels of participation in programme activities. Intervention components may not have been sufficiently intense or effective to bring about behavioural change. Methodological problems such as

Community Health 1995; 49: 495-502 (3)

Paradis et al. Coeur en Santé St-Henri – a heart health promotion programme in a low income, low education neighbourhood in Montreal, Canada: theoretical model and early field experience. Journal of epidemiology and community health 1995; 49: 503-512 (5)

O'Loughlin et al. The impact of a community-based heart disease prevention program in a low-income, inner-city neighbourhood. American journal of Public Health 1999; 89(12):1819-1826 (4)

Study designs:

Controlled before and after study (cross sectional and cohort method of data collection)

QA Grade: '-'

programmes for youth, adult smoking cessation courses, a smoking cessation contest, a heart healthy recipe contest, nutrition courses, a supermarket nutrition campaign, heart healthy menus in local restaurants, a walking club, cholesterol and blood pressure screening events, distribution of heart health videos and a weekly heart health column in the local press (3).

Comparison:

No intervention

mortality (3).

Included participants:

18-65 years, French or English speaking

Excluded:

Not stated

Setting:

Communities in Montreal, Quebec

response rates were 70.6% and 67.2% respectively.

Cohort survey: 5-year follow-up. Used same baseline as the cross-sectional survey. ~50% dropout to follow-up (n=423 in treatment and n=396 in control) (4).

outcomes:

groups (1.3; CI 1.0-1.8).

Reported BMI: no significant treatment effect in independent surveys or cohort.

Diagnosed high blood pressure: no significant difference for independent samples. For the cohort, % with blood pressure checked in past year increased significantly in treatment compared to control group (treatment +5.7%, control +2.6%, odds ratio of difference 1.3; CI 1.0-1.9).

Diagnosed high cholesterol: no significant difference for independent samples. For the cohort, changes in the % of participants reporting that they had been told they had high cholesterol were significantly different (treatment +17.6%, control -8.5%, odds ratio of difference 1.6; CI 1.1-2.6). This corresponded to a significantly greater change in the percentage having their cholesterol checked (intervention +19.7%, control +3.2%, odds ratio 1.4; CI 1.1-1.9).

Diet: no significant treatment effect in independent surveys or cohort on the percentage of responders reporting frequent consumption of high fat/junk foods.

reliance on self-reported behaviour, use of telephone surveys, loss to follow-up in the cohort and contamination of the comparison community may have limited ability to detect an intervention effect.

Identified by reviewer:

Large differences between groups in baseline measures, particularly for reported rates of smoking.

Table 3.3: Di.S.Co

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 Di.S.Co (Sezze District Community Control) Project **Relevant papers:** Giampaoli et al. Short term chhanges in cardiovascular risk factors in th Di.S.Co. intervention project. Eur. J. Epidemiol 1991;7(4):372-9 (6) Giampaoli et al. Change in cardiovascular risk factors during a 10-year community intervention program. Acta Cardiologica 1997;5:411-22 (7) **Study design:** Controlled before and after study (cohort and cross sectional method of data collection)	**Aims:** To reduce cardiovascular risk factors through action based on community intervention directed toward modifying levels of risk factors for chronic diseases in the general population, identifying and treating high-risk subjects and re-orienting health services toward prevention. **Intervention:** A ten-year community intervention programme was conducted in a rural area of central Italy. **Comparison:** No intervention.	**Intervention group:** A rural area of central Italy corresponding to the Sezze Health District and including the municipalities of Sezze, Roccagorga and Bassiano (total population 25,706), located in the province of Latina, about 100km south-east of Rome. **Control group:** A rural area corresponding to the municipality of Priverno (total population 12,655), also located in the province of Latina. **Included participants:** The whole population **Excluded participants:** None. **Setting:** Two areas in the province of Latina, about 100km south-east of Rome.	The programme was launched in 1983. Samples of men and women aged 20-69 years (statistically drawn from the electoral rolls) were screened and the main risk factors for cardiovascular diseases assessed. 739 men, and 958 women in the treatment area and 942 men and 1,045 women in the control area were examined. In 1986, a second screening was conducted on the same sample assessed in 1983 (350 men and 443 women in the treatment area, and 512 men and 553 women in the control area). Also, a new independent sample was enrolled in 1986 involving 570 men and 648 women in the treatment area and 553 men and 725 women in the control area. In 1993-96, a new independent sample was examined including 307 men and 305 women in the treatment area and 704 men and 748 women in the control area.	**Primary outcomes:** Risk factors associated with CVD: total and HDL cholesterol, fasting blood glucose, systolic and diastolic blood pressure, BMI, and smoking. **Secondary outcomes:** None stated.	**Primary outcomes:** Main results are at ten years follow-up from cross-sectional surveys (7): Cholesterol: For men, HDL cholesterol decreased more in the control area (-1.4mg/dl (treatment) vs. -1.8mg/dl (control), net difference: +0.4mg/dl). Serum cholesterol decreased more in the control area (-1.6mg/dl (treatment) vs. -10.4mg/dl (control), net difference: +8.8mg/dl). The prevalence of hypercholesterolaemia decreased more in the control area (0% (treatment) vs. -9.8% (control), net difference: +9.8%). For women, HDL cholesterol increased less in the control area (+1.9mg/dl (treatment) vs. +1.7mg/dl (control), net difference: -0.2mg/dl). Serum cholesterol increased in the treatment area and decreased in the control area (+13.0mg/dl (treatment) vs. -5.9mg/dl (controls), net difference: +18.9mg/dl). The prevalence of hypercholesterolaemia increased in the treatment area and decreased in the control area (+9.4% (treatment) vs. -3.4% (control), net difference: +12.8%). Blood pressure: For men, systolic blood pressure increased more in the treatment area (+3.9mmHg (treatment) vs. +1.3mmHg (control), net difference: +2.6mmHg). Diastolic blood pressure decreased more in the treatment area (-1.9mmHg (treatment) vs. -0.8mmHg (control), net difference: -1.1mmHg). The prevalence of hypertensives increased more in the treatment area (+5.2% (treatment) vs. +1.3% (control), net difference: +3.9%). The prevalence of hypertensives under treatment increased more in the treatment area (+22.2% (treatment) vs. +6.6% (control), net difference: +15.6%).	**Identified by author:** The study was carried out in too small an area to adequately capture the programme effects. The treatment and control communities were geographically too close (in the same province) to prevent the possibility of the control area being contaminated by the effects of the intervention programme. **Identified by reviewers:** The use of different population samples to assess trends over the ten-year period raises doubts about the extent

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: '-'					For women, systolic blood pressure increased more in the treatment area (+3.9mmHg (treatment) vs. +2.7mmHg (control), net difference: +1.2mmHg). Diastolic blood pressure decreased more in the treatment area (-0.8mmHg (treatment) vs. -0.6mmHg (control), net difference: -0.2mmHg). The prevalence of hypertensives increased more in the treatment area (+3.7% (treatment) vs. +2.3% (control), net difference: +1.7 %). The prevalence of hypertensives under treatment increased more in the treatment area (+6.5% (treatment) vs. +1.5% (control), net difference: +5.0%). Smoking: For men, the prevalence of smokers decreased more in the control area (-11.5% (treatment) vs.-15.3% (control), net difference: +3.8%. For women, the prevalence of smokers decreased in the treatment area and increased in the control area (-3.9% (treatment) vs. +2.7% (control), net difference: -6.6%). BMI: For men, BMI increased slightly more in the control area (+0.4kg/m^2 (treatment) vs. +0.5 kg/m^2 (control), net difference: -0.1 kg/m^2). For women, BMI decreased in the treatment area and increased in the control area (-0.8kg/m^2 (treatment) vs. +0.4 kg/m^2 (control), net difference: -1.2 kg/m^2). Net changes of the differences in the treatment area compared with the control area showed a significant benefit in treatment for BMI. Fasting blood glucose: For men, fasting blood glucose levels decreased more in the treatment area (-5.2mg/dl (treatment) vs. -1.8mg/dl (control), net difference: -3.4mg/dl). Net changes of the differences in the treatment area compared with the control area showed a significant benefit in treatment for fasting blood glucose levels. For women, fasting blood glucose levels decreased more in the control area (-2.0mg/dl (treatment) vs. -7.0mg/dl (control), net difference: +5.0mg/dl).	to which the later sample represents the same population as the initial one due to migratory effects.

Table 3.4: The Dutch Heart Health Community Intervention

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 Dutch Heart Health Community Intervention **Relevant papers:** Ronda et al. The Dutch Heart Health Community Intervention 'Hartslag Limbury': design and results of a process study. Health Education Research 2004; 19(5): 596-607 (8) Schuit et al. Effect of 5-year community intervention Hartslag Limbury on cardiovascular risk factors. American Journal of Preventative Medicine 2006; 30(3): 237-242 (10) Ronda et al. The Dutch Heart Health Community Intervention 'Hartslag Limburg': Effects on smoking behaviour. European Journal of Public Health 2004;14(2): 191-193 (11) Ronda et al. The Dutch Heart Healthy Community	**Aim:** To reduce CVD by encouraging a reduction in fat intake, an increase in physical activity and a decrease in rates of smoking (8). **Intervention** (10): Delivered via 9 intersectoral local health committees. Almost half of interventions conducted in low-income areas, focussed on nutrition, physical activity and smoking cessation. Nutrition: nutrition education, nutrition education tours in supermarkets and food labelling. Smoking: large stop smoking campaign using radio commercials, adverts in newspapers and on billboards, posters and postcards in waiting rooms/public buildings, introduction of smoke-free areas. Physical activity: walking and bicycling clubs and physical activity campaigns. Television programmes, local TV commercials, radio, newspaper articles and pamphlet distribution used to support and promote risk	**Intervention group:** Non-random allocation. The city of Maastricht (~120,000 inhabitants) and 4 smaller adjacent municipalities (12,000-21,000 inhabitants each). **Control group:** Non-random allocation. Six municipalities (location not specified) with ~130,000 inhabitants in total (9). **Included participants:** Main cohort: People aged 31-70y having taken part in previous monitoring study. Smoking cohort: People aged $\geq$18 identified from computerised telephone registries (12). Physical activity/diet cohort: People aged $\geq$14 identified from computerised	Intervention over >5 years. Main cohort: 2414 treatment (81% dropout) and 758 control (85% dropout) participated in main follow-up at 5y (10). Smoking cohort: 772 treatment (dropout ~82%) and 736 control (~84% dropout) participated in baseline, 2y and 3y questionnaires (11). Physical activity/diet cohort: 505 treatment (dropout 61.6%) and 392 control (dropout 62.8%) participants participated in baseline, 2y and 3y questionnaires 4).	**Primary outcomes:** Smoking, cholesterol, blood pressure, BMI, plasma glucose, physical activity, saturated fat intake, adverse events. **Secondary outcomes:** Attitudes, knowledge, intentions relating to smoking, physical activity and diet.	**Primary outcomes:** Cholesterol: For men decreased in both groups and no significant treatment effect (net difference -0.02 mmol/L; SE 0.06, NS). For women, slight increase in treatment community and decrease in control community, significant net worsening for treatment compared to control group (net difference +0.11 mmol/L; SE 0.05, p<0.05) (10). Blood pressure: Increased in treatment and control groups in men and women but size of increase was significantly less in the treatment group for systolic (men net difference -7.8 mmHg; SE 1.0, p<0.05, women net difference -5.5 mmHg; SE 1.0, p<0.05) and diastolic (men net difference -5.1 mmHg; SE 0.7, p<0.05, women net difference -4.4 mmHg; SE 0.6, p<0.05) blood pressure (10). BMI: Increased in men and women in treatment and control groups but change was significantly less in treatment compared to control communities (men net difference -0.36 kg/m^2; SE 0.09, p<0.05, women net difference -0.25 kg/m^2; SE 0.10, p<0.05) (10). Plasma glucose: Changed little in men for treatment or control group, no difference between groups (net difference -0.17 mmol/L; SE 0.10). For women, decrease in the treatment group and increase control group resulted in significant net treatment effect (net difference -0.23 mmol/L; SE 0.07, p<0.05) (10).	**Identified by author:** Unit of randomisation was the community, not the individual and net differences between groups may have been due to other external factors (10). Participants were recruited via a previous study, may have been more health conscious than the general population. Since this was the case for both intervention and control groups, not anticipated to result in study bias (10). Height reduced in control area and contributed to the net treatment effect on BMI. However, net difference in BMI remained when subjects with >2cm reduction were excluded from analysis (10). National smoking cessation campaign and associated secular decreases in smoking rates may have made intervention effects

Intervention 'Hartslag Limburg': results of an effect study at individual level. Health Promotion International 2004; 19(1): 21-31 (12)

Ronda et al. The Dutch Heart Health Community Intervention 'Hartslag Limburg': results of an effect study at an organisational level. Public Health 2005; 119: 353-360 (9)

Study designs:

Controlled before and after study (cohort method of data collection)

QA Grade: '+'

factor campaigns.

Comparison:

No intervention

telephone registries (12).

Excluded:

Not stated.

Setting:

Community in Maastrict region and control area

Smoking rates: decreased in both treatment and control groups (smoking cohort) but no difference in smoking behaviour, attitudes or intentions (11).

Physical activity: No overall treatment effects on physical activity or its determinants (physical activity/diet cohort) (12).

Fat intake score decreased in treatment and control groups over time but to a significantly greater extent in treatment group (-0.666 (no units given), p=0.000). Reductions in fat score fully attributable to changes in younger half (<49y) of the cohort (12).

undetectable (11).

Identified by reviewer:

Attrition for the main cohort was low but there were large dropouts from the physical activity/diet cohort, may make findings from that cohort not applicable to the main study population.

Table 3.5: Health and Equality in Finnmark: Batsfjord

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: Health and Inequality in Finnmark: Båtsfjord **Relevant papers:** Lupton et al. The Finnmark	**Aim:** To influence the whole intervention population to be more health conscious, to motivate health promoting activities and to change environmental factors influencing health.	**Intervention group:** Båtsfjord, a fishing community in the Norwegian arctic (n= ~2,500) **Control group:**	Intervention began in 1988, ran for three years Survey at baseline (1987) and cohort of participants followed up two	**Primary outcomes:** Blood pressure, cholesterol and BMI and dichotomous variables relating to	**Primary outcomes** Cholesterol: decreased in intervention (men -0.04 mmol/L, women -0.1 mmol/L) and control (men -0.2 mmol/L, women -0.1 mmol/L) communities but net difference between community changes not significant (men	**Identified by author** Baseline differences were only adjusted for continuous variables (cholesterol, blood pressure and BMI), but difference in lifestyle factors were not adjusted for in the

Intervention Study: is it possible to change CVD risk factors by community-based intervention in an Arctic village in crisis? Scand J Public Health 2003; 31: 178-186 (13)

Study designs:

Controlled before and after study (cohort method of data collection)

QA Grade: '-'

Intervention:

Before the start, voluntary organisations produced a manual with suggestions (~270 individuals contributed) and projects identified for implementation.

Physical activity: ladies aerobics classes, exercise training for people with CHD, adult badminton clubs, organised hikes, cycle trails and ski tracks. 'The Factory Sports Clubs Association' was re-established, arranged volleyball and football tournaments. Dances organised, swimming and physiotherapist guided training available for older people.

Diet: healthy recipes and menus, evening cookery classes (~40 participants), low-fat meals produced to be suitable for fishermen to take on board ship.

Smoking: Smoking confined to designated rooms in health centres, schools and nurseries.

Other: Cholesterol screenings in local supermarkets (510 people tested). Guidelines on individual counselling for smoking cessation, heart-healthy diets and increasing physical exercise were established for use in local GPs. Individual counselling was given to those identified

Three costal communities: Loppa, Gamvik and Måsøy (together n= 5,000). Similar age distribution, ethnic background and also relied on the fishing industry.

Included participants:

All residents aged 40-62 years invited and 15% random sample of those aged 20-39 years

Excluded:

Not stated

Setting:

Costal communities in Norwegian arctic. Around start of intervention major crisis in fish supplies had severe impact on local employment, income and moral.

years after end of intervention (1993).

1,957 participants of the initial survey still alive and not migrated, of these, 1,324 (68%) completed the follow-up survey (total follow up 54%).

physical activity, smoking and diet.

p=0.704, women p=0.446).

Blood pressure: diastolic blood pressure fell in intervention community (men -2.1 mmHg, women -2.1 mmHg) but increased in control (men +0.8 mmHg, women 1.8 mmHg), between community changes significant for men and women (p<0.0001 for both).

Systolic blood pressure stable in intervention men (-0.01 mmHg) but increased in intervention women (+2.1 mmHg). Increased in control groups of both gender (men +2.2 mmHg, women +4.6 mmHg). Difference in intervention/control group changes significant for men (p=0.002) and women (p=0.024).

BMI: increased in both intervention (men+1.5 kg/m^2, women +1.9 kg/m^2) and control (men +1.1 kg/m^2, women +1.4 kg/m^2) groups, increases in intervention significantly greater than increases in control groups (men p=0.002, women p=0.001).

Reported smoking: in men, fell in intervention (-7.5%) and control (-2.7%) communities, difference not significant (p=0.091). In women, increased (intervention +0.6%, control +1.2%), no difference between control and intervention community changes (p=0.793).

Reported physically active: increased slightly in women (intervention +0.6%, control +1.2%), no difference between community changes (p=0.793). For men, intervention/control group changes were significantly different (intervention +8.6%, control 0.6%, p of

analysis of dichotomous lifestyle variables.

Questionnaire assessing lifestyle may have been too simplistic and not included enough questions to properly describe lifestyle outcomes.

The duration of intervention may have been too short to detect lifestyle changes.

The sample size may have been too small to detect differences in lifestyle variables but large enough to detect effects in physiological outcomes.

Identified by reviewer:

May have been some contamination of control populations as individual counselling given to both areas and a local newspaper was also distributed to one control community.

Evaluation was only done in cohort of people. Follow-up rate appears to be low (~68% of those still alive and living in area). Dropouts may have had less healthy lifestyles. Attendance for both surveys was significantly lower in intervention (61%) compared to control

as high risk (100 people, ~10% of households).

Local newspaper, radio and television were used widely as a means of communication.

Comparison:

No intervention

difference=0.047).

Diet: positive trends, increased use of unsaturated cooking fats in men (intervention +14.0%, control +7.9%, p=0.163) and women (intervention +14.0%, control +12.0%, p=0.619) and increased use of unsaturated spreading fats in men (intervention +2.7%, control +6.0%, p=0.30) and women (intervention +5.1%, control (intervention 5.1%, control 2.9%, 0.514). Use of low fat milk showed significant difference in intervention versus control group changes for women (intervention +11.2%, control +3.3%), p=0.046) but not for men (intervention +0.0%, control +1.1%, p=0.793).

(70%) communities and may have caused bias. If more 'unhealthy lifestyle' people dropped out from the intervention group a greater proportion of 'Healthy lifestyle' people would remain.

Table 3.6: Health and Inequality in Finnmark: North Cape

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: Health and Inequality in Finnmark: North Cape **Relevant papers:** Lupton et al. The Finnmark Intervention Study: Better health for the fishery population in an Arctic village in	**Aim:** To reduce accidents and improve working conditions in the fishing industry and to reduce the MI risk score by 25% **Intervention:** Initial activities concentrated on environmental changes. Focused on improving working conditions and available health services.	**Intervention group:** North Cape, a fishing community in the Norwegian arctic (n= ~4,000) **Control group:** Three costal communities: Loppa, Gamvik and Måsøy (together n= 5,000). Similar age distribution and	Intervention began in 1988, ran for ten years Survey at baseline (1987) and cohort of participants followed up after six years of intervention (1993). In 1993, 2,404 participants of the	**Primary outcomes:** Blood pressure, cholesterol and BMI and dichotomous variables relating to physical activity, smoking and diet.	**Primary outcomes** Cholesterol: decreased in intervention (males -0.3 mmol/L, women -0.2 mmol/L) and control (men -0.2 mmol/L, women -0.1 mmol/L) and net difference between community changes was significant (men p<0.01, women p=0.05). Blood pressure: diastolic bp increased in intervention (+1.6 mmHg) and control (+0.8 mmHg) men. Diastolic bp increased in intervention women (+1.6 mmHg) but to a greater extent in control women (+1.8 mmHg, p=NS).	**Identified by author** As MI risk score increases with age, in a longitudinal cohort, the apparent intervention effect will be less. **Identified by reviewer:** Baseline differences in % smoking daily and % with physically active lifestyle were not adjusted for in the analysis of lifestyle

North Norway 2002; 20: 213-218 (14)

Study designs:

Controlled before and after study (cohort method of data collection)

QA Grade: '-'

Safety at work programmes and occupational health services established in cooperation with trade unions and integrated into the public health division of the primary care services.

Subsequently, much stronger emphasis on individual counselling. Advice given on diet, smoking and physical activity as part of routine consultations with GPs, public health nurses and occupational health services. People identified with a high risk of MI in the initial 1987 health survey, were given additional individual counselling.

Throughout intervention, the project leader communicated with fishery workers, conducting and videotaping interviews to define problems associated with programme activities and determine future direction.

Comparison:

No intervention

ethnic background and also relied on the fishing industry.

Included participants:

All residents aged 40-62 years invited. 15% random sample of those aged 20-39 years invited

Excluded:

Not stated

Setting:

Costal communities in Norwegian arctic. Around start of intervention major crisis in fish supplies had severe impact on local employment, income and morale.

initial survey were still alive and had not migrated out of the area and, of these, 1,685 (70%) completed the follow-up survey.

Systolic bp increased in men (intervention +3.2 mmHg, control +2.2 mmHg) and women (intervention +5.7 mmHg, control +4.6 mmHg), no significant differences in size of change.

BMI: in men, decreased slightly for the intervention (-0.2 kg/m^2) but increased in control (+1.1 kg/m^2), difference in group changes significant (positive net intervention effect, $p<0.001$). In women, increased in intervention (+0.4 kg/m^2) but increased significantly more in control (+1.4 kg/m^2, positive net intervention effect, $p<0.001$).

MI risk score: decreased in men to greater extent in intervention (-3.4) compared to control (-1.4), difference in community changes neared significance ($p=0.055$). For women, increased slightly in intervention (+0.1) but to greater extent in control (+0.6), positive net intervention effect ($p<0.05$).

Reported daily smoking: in men, fell slightly in intervention (-0.8%) but to greater extent in control (-2.7%), difference in change not significant. For women, decreased in intervention (-5.9%) but increased in control (+1.3%), significant difference between changes (positive net intervention effect, $p<0.01$).

% reporting physically active: increased in intervention men (6.6%) and women (6.1%) but to lesser extent in control men (+0.6%) and women (+2.1%), no significant difference in changes (men $p=0.077$, women p=NS).

Diet: increased use of unsaturated cooking fats in men (intervention +12.0%, control +8.0%, p=NS) and women (intervention +13.5%, control +11.9%, p=NS). Increased use of unsaturated spreading fats in men

variables.

(intervention +6.9%, control +6.0%, p=NS) and women (intervention +7.4%, control +2.9%, p= 0.072). Increased use of low fat milk in men (intervention +10.5%, control +1.1%, net significant positive intervention effect, p<0.01) and women (intervention +4.7%, control +3.3%, p=NS).

Table 3.7: Heartbeat Wales

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: Heartbeat Wales **Relevant papers:** Parish et al. Breathing life into Wales: Progress in the Welsh Heart programme. Health Trends 1987; 19: 2327 (17) Smail et al. Heartbeat Wales – a community programme. The Practitioner 1989: 233: 343-347 (15) Tudor-Smith et al. Effects of the Heartbeat Wales programme over five years on behavioural risks for cardiovascular disease: quasi-experimental comparison of results from Wales and a	**Aim:** To promote good health and reduce the risk of cardiovascular disease **Intervention** (15,17): Mass media: major television series ('Don't break your Heart' and a healthy eating show), regular press articles, news coverage, presentations at national exhibitions/agricultural shows, information leaflets and health kits. Diet related: Supermarket modified own-brand products, introduced food-labelling scheme, ran in-store health education programmes. Approved catering establishments could display 'Heartbeat Award' certificate. Farmers encouraged to rear low-fat breeds, lean-meat butchery scheme introduced. Food	**Intervention group:** The whole of Wales, covered by nine Welsh district health authorities **Control group:** North east of England (Tyne and Wear, Cleveland, Durham and North Yorkshire) **Included participants:** Random sample, aged 12-64 years **Excluded:** Not stated **Setting:** Wales and north-east England	5 years (16,17) Households visited in person with doorstep interview followed by questionnaire to return by mail. At baseline, response for the postal survey was 67% in the treatment (n=18 538) and 64% in the control (n=1 483). At five years, response for the postal questionnaire was 61% in both areas (Wales n=13 045, reference n=4 534).	**Primary outcomes:** Consume chicken or other poultry ≥2 days/week Consume fish ≥2 days/week Consume fresh fruit ≥4 days/week Consume green vegetables or salad ≥4 days/week Mainly use skimmed or semi-skimmed milk Mainly use wholemeal bread Smokers who agree present level of smoking is harmful to health Smokers with serious attempt to quit in last 12 months Daily smokers visiting GP in last 12 months and advised to quit or cut	**Primary outcomes** Individual-level analysis: net changes are not presented. Community-level analysis: no significant net intervention effects when results from all participants pooled. For subgroup analysis, net treatment improvement for consumption of fried food in all subgroups but only significant in one (aged 50-64y). Control area showed significant net improvement for the tried to stop smoking variable in men.	**Identified by author (16)** Baseline sample size in reference area was too small to give statistical power for detection of net intervention effect. Contamination of the reference area - diffusion of projects and programmes from Wales, the initiation of the 'Look After Your Heart' project (launched 1987 over all England) and the Heartbeat Yorkshire programme (conducted from 1988). **Identified by reviewer:** Net results for individual level analysis are not given. Results are presented in a slightly misleading way although authors do conclude that there are no clear net intervention effects.

match reference area. BMJ 1998; 316: 818-822 (16)

Nutbeam et al. Maintaining evaluation designs in long term community based health promotion programmes: Heartbeat Wales case study. Journal of Epidemiology and Community Health 1993; 47: 127-133 (18)

Study designs:

Controlled before and after study (cross sectional method of data collection)

QA Grade: '-'

and health policies developed by every health and education authority, supported by voluntary organisations.

Smoking related: National No-Smoking Day, workplace smoking policies.

Physical activity: 'Heartbeat Ways' constructed, other projects implemented by the Sports Council for Wales.

Workplace/schools: Policies developed, award instituted for most health-promoting employers, occupational health nurses trained, mobile screening service offered to offices and factories. Materials and professional support for school teachers, heart club for young people, school fun runs with support from prominent Welsh sports personalities.

Primary health care: Practitioners encouraged to engage, provision of CHD Open University Course, paper published - 'Stitches in time' to emphasise importance of GPs in primary prevention.

Comparison:

No intervention

down

Engage in moderate or strenuous activity ≥ 2 times/week for >20 minutes

Mainly use butter on bread

Consume fried food cooked in solid fat >2 days/week at home

Smoke daily

Mean no cigarettes/day

BMI (kg/m^2) ≥ 24 for women or ≥ 25 for men

Table 3.8: The Kilkenny Health 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: The Kilkenny Health Project **Relevant papers:** Shelley et al. The Kilkenny Health Project: A community research and demonstration cardiovascular health programme. Irish Journal of Medical Science 1991; 160 suppl. 9:10-16 (19) Shelley et al. Cardiovascular risk factor changes in the Kilkenny Health Project: A community health promotion programme. European Heart Journal 1995; 16: 752-760 (20) Collins et al. Penetration of the Kilkenny Health Project education programme. Hygie 1993; 12: 11-14 (21) **Study designs:** Controlled before and after study (cross sectional	**Aim** (19): To reduce mortality linked to cardiovascular disease and cerebrovascular disease by 20% over ten years. Second goal, to reduce all-cause mortality rates by 15% over ten years in those aged 35-64 years. **Intervention** (19): Pre-intervention: Project staff assessed extent of existing resources and facilities, made links with those working in the media and in the local education and health services. Community meetings held to discuss strategies for prevention of heart disease. Activities: Awareness programme used to introduce the project and inform about the importance of CHD as a cause of morbidity and mortality. Training given to people involved in education, health and catering. Working party set up to support health promotion in secondary schools and health assessment programme established. Nutrition	**Intervention group:** Kilkenny (n=73,186 in 1986), mixture of urban (45%) and rural (55%) communities (19) **Control group:** Offaly (n not stated) chosen as the reference area, similar characteristics to Kilkenny (19). **Included participants:** Adults aged 35-64y **Excluded:** Not stated **Setting:** South East Ireland	5 years (1985 to 1990) Baseline and 5 year independent cross sectional surveys in treatment and control communities. Response rates 70-75%. N=792 (treatment) and 604 (control) in the first survey. N= 802 (treatment) and 631 (control) in the final survey.	**Primary outcomes:** Smoking (assessed via questionnaire), BMI, systolic and diastolic blood pressure, total serum cholesterol and Dundee risk score (20).	**Primary outcomes:** 1. Cholesterol: decreased in intervention and control groups in men and women. No significant net difference in women but significant net difference in favour of the control community in men (control -0.44 mmol/L, intervention -0.09 mmol/L, net difference -0.35 mmol/L for control, p<0.01). In men and women of both communities, % with serum cholesterol <6.5 mmol/L increased, % 6.5-7.7 mmol/L decreased and % >7.8 mmol/L decreased but no significant net differences. 2. Blood pressure: Systolic blood pressure fell in men and women in intervention and control groups but no significant net difference. Diastolic blood pressure fell in women of both groups (no net difference). In men, significant net difference in favour of control community (intervention +0.5mmHg, control -5.4mmHg, net difference -5.9 for control, p<0.05). No significant net differences in % with hypertension or the use of medications in people with hypertension. 3. BMI: Increased in men	**Identified by author (20)** Secular change may have made intervention effects difficult to detect. Survey participants from reference community may have felt greater impetus for change than average population because participating in a study. Contamination of the reference community through the media and population surveys and through contacts between health professionals in the two counties. Important attitudinal barriers to behavioural change - low level of awareness of CHD as an important cause of morbidity and mortality and a disbelief that behavioural change would result in risk reduction. Short-term nature of the project made it difficult to implement environmental

method of data collection)

QA Grade: '-'

counselling service provided by project dietician and oral health project developed in conjunction with Kilkenny dental practitioners.

Media: Programmes and events supported by local media with newspaper and radio coverage. Educational materials reviewed to produce leaflets for distribution.

Other events: Yearly Quit Smoking competition and a 10K run.

Comparison:

No intervention

(intervention +0.4, control +1.0 kg/m^2) and women (intervention +0.4, control +1.3 kg/m^2) from both communities but no significant net intervention effect.

% BMI <25 kg/m^2, decreased in men from both communities and in women from control community. For women in the intervention area, there was a small positive improvement in % with BMI <25 kg/m^2 and net community difference was significant (intervention +0.4%, control -13.0%, net difference +13.4% for treatment, p not stated) (NB reported as significant in text but not in table of results).

No significant net differences in the percentage overweight or obese.

4. Smoking: % smokers decreased in men and women from both groups but no significant net community difference.

5. Dundee risk score: Reduction in men and women from intervention and control communities but no significant net difference.

changes.

Identified by reviewer:

Data collection was not contemporaneous and baseline and five year surveys were conducted one year later in control compared to intervention communities.

Table 3.9: The National Research Program

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

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 National Research Program 1A on Primary Prevention of Cardiovascular Disease in Switzerland **Relevant papers:** Gutzwiller et al. Community-based primary prevention of cardiovascular disease in Switzerland: methods and results of the National Research Program (NRP 1A). Preventive Medicine 1985;14:482-91 (22) **Study design:** Controlled before and after study (cohort method of data collection) **QA Grade: '-'**	**Aims:** To evaluate ways to reduce known CVD risk factors among the local populations of two intervention towns. To provide tested, cost-effective methods for nationwide use in the future control of CVD. **Intervention:** A community based multifaceted health education programme that sought to engage the active participation of the population; mobilise personal and community resources; and achieve integration within existing local health and social services. **Comparison:** No intervention.	**Intervention group:** Two towns in the German-speaking (Aarau: population approx 16,000) and French-speaking (Nyon: population approx 12,000) parts of Switzerland. **Control group:** Two towns in the German-speaking (Solothurn: population approx 16,000) and French-speaking (Vevey: population approx 12,000) parts of Switzerland. **Included participants:** The whole population. **Excluded participants:** None. **Setting:** Two intervention towns and two reference towns chosen on the basis of similar quantitative and qualitative criteria; one pair (16,000 inhabitants each) in the German-speaking, and one pair (12,000 inhabitants each) in the French –speaking part of Switzerland.	An initial health examination was organised during 1977-78 in the four towns. A further health examination was carried out amongst the subjects in the four cohorts during 1980-81.	**Primary outcomes:** Risk factors associated with CVD: smoking, plasma cholesterol, blood pressure, and BMI.	**Primary outcomes:** Net changes in exposure to risk factors in the intervention towns in comparison with controls were obtained. Smoking: Reduction in the prevalence of regular smokers was significantly greater in the intervention areas. However only a small non-significant reduction in the amount of tobacco smoked was observed in the intervention compared with the reference areas. Cholesterol: Changes in blood cholesterol levels were comparable in the intervention and reference areas. However the analysis of a sub-group of Swiss women showed that in both intervention towns women who had participated in preventive activities reduced their cholesterol level significantly more than those who had not. Blood pressure: Both systolic and diastolic blood pressure measurements were significantly improved in the reference area in comparison with the treatment area. BMI: There was a disadvantage in the intervention area with a small but statistically significant improvement seen amongst the reference population.	**Identified by reviewers:** Bias may have been created by the high losses to follow-up.

Table 3.10: The Otsego-Schoharie Heart 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 Otsego-Schoharie Heart Health Program **Relevant papers:** Nafziger et al. The Otsego-Schoharie healthy heart program: prevention of cardiovascular disease in the rural US. Scand J Public Health 2001; 29 (suppl 56): 21-32 (23) Barthold et al. A cardiovascular health education program for rural schools. Journal of School Health 1993; 63 (7): 298-301 (24) **Study designs:** Controlled before and after study (cross sectional and cohort methods of data collection) **QA Grades: '-'**	**Aim** (23): To provide health education to isolated rural villages and populations **Intervention** (23,24): Community leaders formed Healthy Heart advisory committees to work with employed project staff (full-time and a part-time community organiser, health educator, exercise physiologist and media expert) and volunteers. Macro and micro level interventions: Micro intervention: Healthy Heart Hometowns was small-scale initiative implemented separately in each town/village. Local health committees given choice of intervention activities. Healthy-heart foods and recipes were promoted, fitness activities organised, printed information was provided at heart-healthy events. Macro intervention: Walking programmes, risk factor screenings in neighbourhoods and workplaces, mass media with radio and newspaper articles geared to the rural population. One-page brochures designed for low literacy readers distributed	**Intervention group:** Otsego and Schoharie in New York state **Control group:** Herkimer, New York state (n=~158,00 for intervention and control areas) **Included participants:** Adults aged 20-69y, lived in area for >6 months **Excluded:** Institutionalised and (for the second cross sectional survey) those that participated in the baseline survey **Setting:** Rural, low socioeconomic status communities in New York State	5 years (1990 to 1995) Baseline and 5 year independent cross sectional surveys in treatment and control communities. First survey n= 628 (response rate 61.8%) for treatment and control. Final survey n= 548 (response rate 45.0%) for treatment and control. Cohort of participants followed up from baseline cross sectional survey at 5 years. n= 424 (response rate 67.5%) for treatment and control.	**Primary outcomes:** Smoking (classified as reported current smoking or exhaled carbon monoxide $\geq$8ppm), sedentary (strenuous physical activity <3 times per week), systolic and diastolic blood pressure, total cholesterol (23).	Net treatment effect refers to the difference in changes from baseline to post-intervention in intervention compared to control groups. **Primary outcomes** (23): 1. Smoking: For the cohort, significant net intervention effects on: self reported smoking prevalence (intervention change 27.9% to 17.6%, control change 24.4% to 21.6%, sig. net treatment effect p<0.001), Cigarette smoking defined by exhaled carbon monoxide $\geq$8ppm (intervention change 30.3% to 21.9%, control change 23.6% to 21.1%, sig. net treatment effect p<0.01) Amount of exhaled carbon monoxide (intervention 10.2±11.6ppm to 8.1±10.2ppm, control 8.4±9.7ppm to 8.7±11.2ppm, sig. net treatment effect p<0.01). For cross sectional surveys, no significant net intervention effect on prevalence of self-reported smoking or carbon monoxide $\geq$8ppm but amount of exhaled carbon monoxide showed significant net treatment effect (intervention 10.2±11.6ppm to 7.7±11.4ppm, control 8.4±9.7ppm to 10.0±13.0ppm, net treatment effect p<0.01). NB there is inconsistency between	**Identified by author** Sample size may have been too small to detect intervention effects (23). **Identified by reviewer:** Those in the baseline survey were told that they would be invited to participate in another survey five years later (cohort study). This may have influenced lifestyle changes in those receiving intervention messages, particularly just before the second survey. Positive smoking results for the cohort may, to some extent, result from short term changes and may not be representative of whole intervention community change.

through schools, with paychecks, posted on notice boards in workplaces, community agencies, schools and doctors and dental surgeries.

Schools and youth: Assemblies and class room presentations in all districts. Presentation material adapted from existing resources and planned and given by parents, teachers and students. Walking programmes and tobacco education programs implemented, shops encouraged to uphold the restriction of cigarettes to people <18 years.

Comparison:

No intervention

the results table and the text of this paper.

2. Cholesterol: No significant net intervention effects detected.

3. Blood pressure: No significant net intervention effects detected for systolic or diastolic blood pressure.

4. Sedentary lifestyle: No significant net intervention effects detected.

5. Plasma glucose: No significant net intervention effects detected.

Table 3.11: The Stanford Three Community 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 (significant positive results)	Confounders and limitations
Title: The Stanford Three Community Study **Relevant papers:** Maccoby et al. Reducing the risk of cardiovascular disease: effects of a community-based campaign on knowledge and	**Aims:** To increase participants' knowledge of the risk factors associated with CVD and change risk-producing behaviour such as smoking and poor diet (i.e. reduce intake of calories, salt, sugar, saturated fat and cholesterol).	**Intervention group:** The towns of Watsonville (14,569 inhabitants) and Gilroy (12,665 inhabitants). **Control group:** The town of Tracy (14,724	The programme was launched in 1972. Data were collected from a random (multi-stage probability) sample of adults aged 35-59 years in all three towns. The first survey took place just prior to the first campaign year (1972). The cohorts identified at baseline were then surveyed at the	**Primary outcomes:** Risk factors associated with CVD: poor diet, relative weight (actual/ideal), smoking, low levels of physical activity, high cholesterol and blood pressure	**Primary outcomes:** After two years: Cholesterol: significant net reductions in total plasma cholesterol amongst the Gilroy, Watsonville and Watsonville reconstituted treatment groups in comparison with the Tracy control group. No significant differences between media only (Gilroy) and media plus intensive instruction (Watsonville) group (25).	**Identified by author:** Given the non-random allocation of the intervention and control populations the possibility of selection bias cannot be discounted. The methods used to obtain information may impact on future behaviour. Measurement may

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 (significant positive results)	Confounders and limitations
behaviour. Journal of Community Health 1977;3(2):100-14 (26) Farquhar et al. Community education for cardiovascular health. Lancet 1977;June 4:1192-95 (25) Leventhal et al. Cardiovascular risk modification by community-based programs for life-style change: comments on the Stanford Study. Journal of Consulting and Clinical Psychology 1980;48(2):150-8 (28) Meyer et al. Skills training in a cardiovascular health education campaign. Journal of Consulting and Clinical Psychology 1980;48(2):129-42 (27) **Study design:** Controlled before and after study (cohort methods of data collection) **QA Grade: '+'**	**Intervention:** An intensive multimedia cardiovascular health education campaign was conducted for two years in two California communities (Watsonville and Gilroy), in one of which (Watsonville) this was supplemented by an intensive, face-to-face, instruction programme with high-risk subjects. During the third final year of the campaign the intensity of the media effort was reduced to about half its former level. **Comparison:** No intervention.	inhabitants). **Included:** The main mass media health education campaign was targeted at the whole Watsonville and Gilroy communities. The intensive instruction programme was directed at a subset of the random sample of participants (and their spouses) in the Watsonville community, assessed as being at high-risk using information provided in the baseline survey. **Excluded:** None. **Setting:** Three communities in northern California: Watsonville, Gilroy, and Tracy.	end of each of the two main campaign years (1973 & 1974). In an attempt to account for the impact of the measurement process on future risk-related behaviour an additional sample (an 'after-only' sample) was surveyed in each town at the end of the first year. Baseline survey data were combined into a multiple logistic function of the overall risk of coronary heart disease developing within 12 years, and high-risk subjects (in the top quartile) were selected for special study. In Watsonville, a random subset of two-thirds of these high-risk people and their spouses were randomised to receive face-to-face intensive instruction and the remaining subjects were observed as controls. High-risk groups in Gilroy (receiving the mass media programme only) and Tracy (receiving no additional attention other than their identification) were also followed up. A final survey was undertaken at the end of year three (1975) during which time the intensity of the media campaign was greatly reduced and virtually no face-to-face contact was maintained.	levels. The overall risk of coronary heart disease developing within twelve years. **Secondary outcomes:** Knowledge of the risk factors associated with CVD. Attitudes towards CVD and towards modifying risk-promoting behaviour in the areas of diet, weight, smoking, and exercise.	Systolic blood pressure: significant net reductions amongst the Gilroy, Watsonville and Watsonville reconstituted groups in comparison with the Tracy control group. A significantly greater reduction in systolic blood pressure was seen in the media only (Gilroy) group in comparison with the media plus intensive instruction (Watsonville) group (25). Relative weight: small decreases in relative weight seen in the control and intervention groups. No significant differences between the control and treatment groups and no significant differences between the media and media plus intensive instruction groups (25). Dietary modification – saturated fat intake: significant net reductions amongst the Gilroy, Watsonville and Watsonville reconstituted groups in comparison with the Tracy control group (25). Smoking: In comparison with Tracy a net, non-significant decrease in Gilroy, and significant net decreases in Watsonville, and the Watsonville reconstituted groups in the no of cigarettes smoked were seen. Comparisons between media only (Gilroy) and media plus intensive instruction (Watsonville and Watsonville reconstituted) indicate significant reductions in the Watsonville group and non-significant reductions in the Watsonville	unwittingly create a treatment effect amongst those examined as controls. Equally the knowledge of a forthcoming appointment with the expectation of a series of physiological measurements may promote temporary compliance amongst subjects in the treatment group (28). **Identified by reviewers:** Estimates of relative effectiveness at 2-years have been made from graphs with poorly delineated scales and therefore lack precision. As an intention to treat analysis does not appear to have been undertaken the possibility of bias needs to be taken into 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 (significant positive results)	Confounders and limitations
					reconstituted group (25).	
					CVD risk score: significant net reductions in overall risk of developing CVD within 12 years amongst the Gilroy, Watsonville and Watsonville reconstituted treatment groups in comparison with the Tracy control group. No significant differences between the media only (Gilroy) and media plus intensive instruction (Watsonville) group (25).	
					Knowledge of risk factors increased in the Tracy control group but increased to a significantly greater extent in the Gilroy, Watsonville and Watsonville reconstituted groups. The media plus intensive instruction groups (Watsonville and Watsonville reconstituted) also increased their knowledge of risk factors to a significantly greater extent than the media only (Gilroy) intervention group (25).	

4 Discussion

The aim of the current report was to form the second half 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 intervention effectiveness relating to considerations identified by the Programme Development Group (4.3 Emerging themes)

- Generic issues relating to programmes (4.4 Generic issues)

Limitations of the current review (4.5 Limitations of the review)

4.1 Papers included in the review

Programmes included in this report are:

- Action Heart (Baxter,T. 1997) (Baxter,A.P. 1997)

- Coeur en santé St-Henri (O'Loughlin 1995) (Paradis 1995) (O'Loughlin 1999)

- Di.S.Co – Sezze District Community Control – project (Giampaoli 1991)
 (Giampaoli 1997)

- The Dutch Heart Health Community Intervention/Harslag limburg (Ronda 2004 a)
 (Schuit 2006) (Ronda 2004 b) (Ronda 2004 c) (Ronda 2005)

- The Health and Inequality in Finnmark programme – Båtsfjord (Lupton 2003)

- The Health and Inequality in Finnmark programme – North Cape (Lupton 2002)

- Heartbeat Wales (Parish 1987) (Smail 1989) (Tudor-Smith 1998) (Nutbeam 1993)

- The Kilkenny Health Project (Shelley 1991) (Shelley 1995) (Collins 1993)

- The National Research Programme (Gutzwiller 1985)

- The Otsego-Schoharie Healthy Heart (Nafziger 2001) (Barthold 1993)

- The Stanford Three Community Study (Maccoby 1977) (Farquhar 1977) (Leventhal
 1980) (Meyer 1980)

4.2 Programmes overview

The earliest programme described in the current review, the **Stanford Three
Community** intervention comprised extensive mass media coverage for all those in
the Gilroy and Watsonville intervention communities and additional individual
counselling for those considered to be at high risk of CVD in the Watsonville
community. Findings indicated multimedia campaigns in isolation may favourably
influence the risk of CVD and the addition of face-to-face instruction amongst

selected high-risk participants may increase the magnitude of effect amongst the population as a whole.

The **National Research Programme**, another early community intervention, utilised a range of intervention activities but it failed to show positive treatment effects. Given the programmes extensive and innovative involvement of a diverse range of community groups, it's small and sometimes absent treatment effect appears disappointing. Secular trends may have had some influence to mask intervention effects.

The **Di.S.Co** project, despite continued intervention over a ten year period, failed to reach the targets set at outset. The close proximity of control and treatment populations may have been an important contributor to lack of findings but the programme seems to have been implemented with a 'top-down' mode of delivery with little community involvement and this may have impacted its ability to influence change.

The **Kilkenny Health Project** also showed little intervention effect and the reference group often showed net improvements compared to the treatment community. Authors highlight prevailing attitudes as important inhibitors of behavioural change and these, together with the presence of strong secular trends, may have prevented changes in lifestyle and the detection of any intervention effect.

Heartbeat Wales was an extensive programme with a range of high profile media activities as well as policy changes and numerous community projects. The failure to show net intervention effects may be due to ineffective transition from awareness to behavioural change. However, reference area contamination appears to have been a major contributor in programme evaluation and may have been responsible for masking positive intervention effects.

The '**Health and Inequality in Finnmark**' programme was set up to tackle high rates of CVD in the costal areas of Finnmark. Programme initiation coincided with a major crisis in fish supplies had impacts local employment, income and moral. The three year intervention in **Båtsfjord** appeared to achieve reductions in blood pressure and some lifestyle changes and this may be commendable considering concurrent community stresses and economic insecurity.

Intervention in the **North Cape** also appeared to bring about positive changes. There was a positive treatment effect on cholesterol and BMI with intervention, primarily using existing medical health services to implement programme delivery. The difference in risk factor changes in Båtsfjord and North Cape regions, brought about by very different styles of intervention, suggests that intervention type may affect the type of risk factor change observed.

The **Otsego-Schoharie Healthy Heart** Program was aimed at a particularly poor rural community within the New York state and, despite a comprehensive, varied promotion of risk factor reduction, it did not show positive changes in most physiological risk factors. However, the consistent beneficial programme effect on rates of smoking, assessed by different methodological (reported rates, expired CO) and evaluation (cohort and cross sectional samples) measures, provided evidence for some positive intervention effect.

The **Action Heart** programme, the first of those implemented in the 1990's, appears to have been ineffective in producing behavioural change in schools or in the wider community. The self-reported mode of programme evaluation may be evidence of poor project funding and the low intensity, small scale nature of intervention may have been responsible for lack of effect.

The **Coeur en Santé St-Henri** programme, initiated around the same time, showed no positive behavioural effects when assessed by independent cross-sectional

surveys. Although some positive findings were detected in the cohort analysis, the high attrition (~50%), self-reported nature of outcomes and low consistency with cross-sectional findings, may limit the reliability and generalisability of these results.

The **Dutch Heart Health Community Intervention (Hartslag Limburg)** is the most recent of the programmes reviewed in the current report. Initiated in 1998, it was a small, community-based intervention specifically targeting smoking, nutrition and physical activity. Unlike most community programmes, there was no screening intervention and this may have been responsible for the absence of treatment effect in total cholesterol. However, the programme showed significant net changes in other CVD risk factors suggesting a positive programme impact.

A programme summary table has 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 5.2 below). A table has also been constructed for the programmes identified in the first review and is provided (Table 5.1 below). Where patterns have been identified, these have been commented on. However, these comments should be regarded as ideas for reflection and will be added to by evidence generated by stage 3 of the review process. Programmes are described as having low or medium/high effectiveness and, since there are approximately equal numbers of programmes falling into low or medium/high categories, these categories were used for comparison.

Table 5.1: 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 5.1 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 5.2: 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

Table 5.2 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

Notes to tables 5.1 and 5.2

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

Effectiveness:

√√ - Strong intervention effect, √ - Moderate intervention effect, X – Weak intervention effect (relative to other programme

4.3 Emerging themes

The issues for consideration identified by the Programme Development Group 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.

Nature of the target audience

CVD Risk

Four of the programmes in review 2 and three programmes 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). Of these programmes, two had low effectiveness and five had high/medium effectiveness.

A consideration in the interpretation of this type of effect is the phenomena of regression to the mean, discussed later in section 5.4. Programmes in the current review predominantly selected high risk areas on the basis of ongoing surveillance and not using single baseline measurements. Since elevated rates of CVD in these populations were unlikely to result from random variation, apparent treatment effects in these populations may be real and not symptoms of regression to the mean.

The current work therefore suggests that interventions aiming to improve physiological and behavioural CVD risk factors may be more successful in high risk groups. People with a greater risk of developing CVD, once made aware, may be more motivated to behavioural change. However, confounding from other factors, such as socioeconomic status and location, cannot be ruled out. People with high levels of CVD risk factors may tend to be in low socioeconomic groups or may tend to live in particular areas (urban/rural) and these factors may affect programme effectiveness. Although caution in interpretation is necessary, high risk groups may be an effective and attractive option for intervention; achieving population risk factor reduction in those with the greatest need for change.

Setting

Programmes described in the current review have been conducted in both urban and rural settings and there may be some influence of location on programme effectiveness. This may relate to the ability of channelled education to reach the targeted population, the receptiveness of the population to educational messages, the degree of community involvement and the spread of information within that population.

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). Of these programmes, three had low effectiveness and seven had high/medium effectiveness.

Culture may, to a large extent, determine community involvement and proactively. The work ethic and busy lifestyle associated with urban environments may act to undermine programme activities, where life stresses may have a detrimental impact on community lifestyle change. Rurally located communities, where there is often a steadier pace of life, may be more inclined to participate in, and connect with, programme activities. Indeed, the majority of programmes where independent members of the community appear to

have been actively involved in project implementation, appear to have taken place in rural settings.

Intervention theory or conceptual model

There appears to be little pattern in the choice of theoretical basis for intervention activities and it seems unlikely that any particular theory will emerge as the key to project planning and implementation. However, these programmes may show some evidence of the balance necessary to achieve programme success. The Social Learning theory has been used by many programme implementers and relies on the spread of knowledge and attitudes between people within family and social networks. As discussed in review 1, this mode of implementation may rely too heavily on the individual for the spread of behavioural change.

The programme summary tables shows that, of the ten 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 seven were graded as low effectiveness. The two programmes reporting using only Social Learning as the basis for intervention both achieved low effectiveness.

This by no means proves Social Learning to be an ineffective intervention strategy but it may suggest caution with the reliance on person-to-person communication for the spread of information. The addition of other modes of knowledge spread and other influencers of awareness, attitudes and motivation may be important. A broad approach appears necessary, where all aspects of behavioural change are addressed.

Nature of the intervention

Environmental change

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). Of these programmes, two had low effectiveness and eight had

high/medium effectiveness. Programmes used interventions such as smoking restrictions, availability of low-fat/low salt products, increased vegetable production, promotion of healthy foods at supermarkets and restaurants, construction of walking/cycling/skiing tracks, food labelling and collaborations with the retail sector.

One of the programmes showing the largest environmental changes, Heartbeat Wales, did not show positive intervention effects despite an array of environmental changes. As well as the more common modifications introduced by other programmes, Heartbeat Wales achieved the development of food and health policies by every health and education authority in Wales and the development of workplace policies by trade unions and the British Institute of Management. Concurrent heart health initiatives in the reference area were likely to have been an important factor, contributing to the lack of apparent treatment effect in Wales. However, the success of project staff to bring about these environmental changes may be a testament to the potential for heart health programmes to implement considerable high-level intervention.

The other programme with promotion of environmental change that showed low effectiveness, The National Research Programme, seems to have been small in scale. Although "efforts were made to reach distributors and producers of food products…", success is not reported and it is difficult to determine the extent of these changes.

Environmental change generally appears to have been implemented by effective community programmes and may be an important part of large scale heart health interventions.

Flexibility of intervention/community input

Four of the programmes in review 2 and three programmes from review 1 were flexible in their methods of intervention and 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). Of these programmes, one had low effectiveness and six had high/medium effectiveness.

Opportunity for community members to take part in the decision making process may be an important factor in determining attitudes to programme intervention. If a non-negotiable approach is taken, communities may respond with low enthusiasm and scepticism. Alternatively, an open approach may promote enthusiastic community participation.

Programmes that were flexible as to the type of intervention activities may have incorporated less conventional methods. For example, in the Otsego-Schoharie community, locally-designed puppets were used for presentations in school assemblies, in Båtsfjord (Finnmark), volleyball and football tournaments were organised and activities run specifically for older people and, in Norsjo, drama and music were employed for health education and informal meetings were used. Despite the less traditional methods used, these programmes showed some success and the type of intervention may be of less importance than the provision of open discussion and the role of community members in implementing their own ideas.

However correct or evidence based decisions are for the mode of project implementation, detachment of community members from the programme, it's aims and ideals, may inhibit effective behavioural change. In the Di.S.Co, National Research, Minnesota and Pawtucket programmes, established methods of community health promotion were used. Screenings and individual counseling; media campaigns, group counselling and courses for health professionals, teachers, parents and youth were implemented but all interventions failed to produce much positive risk factor change. These programmes may have suffered from a lack of community engagement so that, despite the use of sensible, established modes of health promotion, behavioural changes were not observed. Empowered involvement may be necessary to promote individual change and enthusiasm of those involved may also encourage the spread of attitudes and behaviours between community members.

The practicality of an open approach however depends on the scale of the intervention area and duration of intervention. In large scale, national programmes, run over a

number of years, this may be difficult to organise, especially where activities are directed from a single central project coordinating body. Also, some projects with a less flexible approach have been effective (Stanford 3 community, BFH, German, North Karelia, OXCHECK, South Carolina) suggesting that, where communities are amenable, didactic project implementation can be effective.

5.2.3 Generic issues

Regression to the mean

Regression to the mean may be an important phenomena for consideration where high-risk groups are targeted for intervention. If a group with apparently elevated risk factor levels is selected from a one-off measurement of many population groups, because that observation may have been due to random variation over time, subsequent measurements in that group will naturally tend to decrease (regress to the mean). However, in the case of the current programmes targeting high-risk populations, areas have largely been selected on the basis of ongoing surveillance and the observation of elevated CVD is unlikely to result solely from random variation.

Since CVD is a slowly progressing, long term disease, rates are likely to be reasonably stable and subject to smaller changes in natural variation. Regression to the mean may become more of an issue when CVD risk factor changes are measured since these may show bigger natural variation over time. Generally, when elevated baseline risk factors are used as the criteria for intervention, the method of ascertainment (i.e. if there was ongoing surveillance or a one-off measurement was made) should be examined in order to avoid spurious interpretations resulting from regression to the mean.

Risk factor interaction

In the review of programmes for the current and previous report, there is some indication that net improvements in smoking rates i.e. reduced smoking prevalence, is associated with adverse changes in BMI. Out of six programmes showing significant net reductions in prevalence of smoking (Otsego, National Research Programme, German,

North Karelia, Finnmark North Cape, Stanford 3 Community), only one also showed a net decrease in BMI (Women, Finnmark North Cape). Three showed concurrent net increases in BMI compared to the control community (German, Stanford 3 Community, National Research Programme) and this was significant for one programme (The National Research Programme).

For the remaining two interventions showing significant increases in rates of smoking, results for BMI are not reported. In the Otsego programme, although height and weight measurements were made, results are not detailed, except to say that "BMI increased significantly in both reference and treatment populations" (net difference not reported). For North Karelia, results for BMI are also not reported at five, ten or fifteen years despite clinical evaluation of height and weight at each survey. Although it is impossible to infer that these results would have shown negative treatment effects on BMI, it seems likely that, for these studies, there was certainly no positive treatment effect on weight status.

In the German intervention, there was only an 8% reduction in smoking prevalence (although net change significant) but, in the Stanford 3 community (Watsonville intensive) and Otsego programmes, there were 50% and ~35% reductions respectively. These programmes were conducted some time ago (initiated in 1985, 1972 and 1989) and these large reductions in smoking prevalence may not be replicated in modern day interventions since, in most countries, current rates of cigarette smoking are lower than in previous decades. However, if there is an interaction between reductions in smoking and BMI, even smaller changes may potentially inhibit intervention targeted weight loss.

There is also the possibility that there are negative/positive interactions between changes in other risk factors. For example, increases in physical activity, if resulting in concurrent over-compensations in eating, might lead to increases in BMI. Beneficial changes in blood cholesterol, if brought about via reductions in saturated fat intake, might result in weight loss if total calorie intake was also reduced.

The presence of possible risk factor interactions may be an important consideration for programme planning and implementation. If interventions aimed at one risk factor can potentially cause adverse changes in another, priorities may be required (considering the relative impact of risk factors on CVD) to optimise the overall programme effect on cardiovascular health.

4.4 Limitations of the review

The main limitation of this review is that these are the interim results of the full review. Because we are most likely to have captured older programmes in the first two review phases (by using existing systematic reviews as the main method of ascertainment), it seems likely that additional programmes will represent newer initiatives, operating in populations where the levels and nature of CVD risks are closer to those that currently exist.

We may also identify further publications reporting evaluation of the programmes considered in this report. We do not expect this to have major consequences, but we do expect some health economic evaluations on the programmes discussed in this report to be identified.

The poor availability in the literature of important information regarding the nature of the programmes, the populations targeted and detailed results is also a key limitation of this review. Inability to completely quantify the size of effect is likely to have important implications, particularly in identifying whether variation in study results from the included programmes is just due to chance alone. Some detail of the nature of programmes and the populations they target may become clearer in work to address Question 2 (Qualitative review).

References

1. 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

2. 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

3. O'Loughlin J, Paradis G, Kishchuk N, Gray-Donald K, Renaud L, Fines P, Barnett T: Coeur en sante St-Henri--a heart health promotion programme in Montreal, Canada: design and methods for evaluation. *Journal of Epidemiology & Community Health* 49:495-502, 1995

4. 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

5. Paradis G, O'Loughlin J, Elliott M, Masson P, et al.: Coeur en sante St-Henri: A heart health promotion programme in a low income, low education neighbourhood in Montreal, Canada: Theoretical model and early field experience. *Journal of Epidemiology & Community Health* 49:Oct-512, 1995

6. Giampaoli S, Urbinati GC, Menotti A, Ricci G: Short term changes in cardiovascular risk factors in the Di.S.Co. Intervention Project. Research Group of the DI.S.Co. Project. *Eur J Epidemiol* 7:372-379, 1991

7. 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 Cardiol* 52:411-422, 1997

8. Ronda G, van AP, Ruland E, Steenbakkers M, Brug J: The Dutch Heart Health Community Intervention 'Hartslag Limburg': Design and results of a process study. *Health Education Research 19(5)()(pp 596-607), 2004 Date of Publication: Oct 2004*596-607, 2004

9. Ronda G, van AP, Ruland E, Steenbakkers M, van RJ, Brug J: The Dutch heart health community intervention 'Hartslag Limburg': results of an effect study at organizational level. *Public Health* 119:353-360, 2005

10. 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

11. 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. *Eur J Public Health* 14:191-193, 2004

12. 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

13. Lupton BS, Fonnebo V, Sogaard 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

14. Lupton BS, Fonnebo V, Sogaard AJ, Langfeldt E, Lupton BS, Fonnebo V, Sogaard AJ, Langfeldt E: The Finnmark Intervention Study. Better health for the fishery population in an Arctic village in North Norway. *Scandinavian Journal of Primary Health Care* 20:213-218, 2002

15. Smail S, Parish R: Heartbeat Wales--a community programme. *Practitioner* 233:343-347, 1989

16. 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. *British Medical Journal* 316:818-820, 821, 1998

17. Parish R, Catford J, Nutbeam D: Breathing life into Wales: progress in the Welsh Heart Programme. *Health Trends* 1987

18. Nutbeam D, Smith C, Murphy S, Catford J: Maintaining evaluation designs in long term community based health promotion programmes: Heartbeat Wales case study. *J Epidemiol Community Health* 47:127-133, 1993

19. Shelley E, Daly L, Graham I, Beirne A, Conroy R, Gibney M, Hickey N, Kilcoyne D, Lee B, O'Dwyer T, .: The Kilkenny Health Project: a community research and demonstration cardiovascular health programme. *Ir J Med Sci* 160 Suppl 9:10-16, 1991

20. 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

21. Collins C, Daly L, Shelley E: Penetration of the Kilkenny Health Project Education Programme. *Hygie* 12:11-14, 1993

22. 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

23. 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

24. Barthold J, Pearson J, Ellsworth A, Mason C, Hohensee T, McLaud B, Lewis C: A cardiovascular health education program for rural schools. *Journal of School Health* 63:298-301, 1993

25. 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

26. Maccoby N, Farquhar JW, Wood PD, Alexander J: Reducing the risk of cardiovascular disease: effects of a community-based campaign on knowledge and behavior. *J Community Health* 3:100-114, 1977

27. Meyer AJ, Nash JD, McAlister AL: Skills training in a cardiovascular health education campaign. *Journal of Consulting & Clinical Psychology* 48:129-142, 1980

28. Leventhal H, Safer MA, Cleary PD, Gutmann M: Cardiovascular risk modification by community-based programs for life-style change: comments on the Stanford study. *J Consult Clin Psychol* 48:150-158, 1980

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.

<u>Bibliographic database search strategies (content terms):</u>
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:
----
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 systematic reviews containing primary studies for inclusion in phases 1 and 2 of the review.

Reviews

Database: Ovid MEDLINE(R) 1950 to June Week 4 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 "reviews (specificity)"

Database: Ovid MEDLINE(R) In Process and Other Non-Indexed Citations at 3 July 2008
Search Strategy:

1   cardiovascular disease$.mp.
2   CVD.mp.
3   coronary disease$.mp.
4   heart disease$.mp.
5   atherosclerosis.mp.
6   arteriosclerosis.mp.
7   hypertension.mp.
8   blood pressure.mp.
9   hyperlipidaemia$.mp.
10   hyperlipidemia$.mp.
11   cholesterol.mp.
12   stroke$.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.

19   health promotion.mp.
20   primary prevention.mp.
21   campaign$.mp.
22   media.mp.
23   advice$.mp.
24   counsel$.mp.
25   program$.mp.
26   (policy or policies).mp.
27   or/18-26
28   smoking.mp.
29   tobacco.mp.
30   diet.mp.
31   exercise.mp.
32   obesity.mp.
33   diabetes.mp.
34   stress.mp.
35   cholesterol.mp.
36   hypertension.mp.
37   blood pressure.mp.
38   alcohol$.mp.
39   drinking.mp.
40   (cardiovascular adj3 risk$).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 "reviews (specificity)"

Database: Cochrane Library (Wiley) 2008 Issue 2 *(CDSR DARE and HTA)*
Search Strategy

#1   cardiovascular next disease*
#2   cvd
#3   coronary next disease*
#4   MeSH descriptor Cardiovascular Diseases explode all trees
#5   heart next disease*
#6   atherosclerosis
#7   arteriosclerosis
#8   hypertension
#9   blood next pressure
#10   hyperlipidaemia*
#11   hyperlipidemia*
#12   MeSH descriptor Hyperlipidemias explode all trees
#13   cholesterol

#14   MeSH descriptor Cholesterol explode all trees
#15   stroke*
#16   MeSH descriptor Stroke explode all trees
#17   "peripheral vascular disease*"
#18   "peripheral arterial disease*"
#19   hypercholesterol*
#20   hyperlipid*
#21   (#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 OR #20)
#22   health next education
#23   MeSH descriptor Health Education explode all trees
#24   health next promotion
#25   MeSH descriptor Health Promotion explode all trees
#26   primary next prevention
#27   MeSH descriptor Primary Prevention explode all trees
#28   campaign*
#29   media
#30   MeSH descriptor Mass Media explode all trees
#31   advice
#32   counsel*
#33   MeSH descriptor Counseling explode all trees
#34   program*
#35   policy
#36   policies
#37   (#22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32
OR #33 OR #34 OR #35 OR #36)
#38   smoking
#39   MeSH descriptor Smoking explode all trees
#40   tobacco
#41   MeSH descriptor Tobacco explode all trees
#42   diet
#43   MeSH descriptor Diet explode all trees
#44   exercise
#45   MeSH descriptor Exercise explode all trees
#46   obesity
#47   MeSH descriptor Obesity explode all trees
#48   diabetes
#49   MeSH descriptor Diabetes Mellitus explode all trees
#50   stress
#51   MeSH descriptor Stress explode all trees
#52   cholesterol
#53   MeSH descriptor Cholesterol explode all trees
#54   hypertension
#55   MeSH descriptor Hypertension explode all trees

#56   blood next pressure

#57   MeSH descriptor Blood Pressure explode all trees

#58   alcohol*

#59   drinking

#60   MeSH descriptor Alcohol Drinking explode all trees

#61   cardiovascular near/3 risk*

#62   multiple next risk*

#63   (#38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58 OR #59 OR #60 OR #61 OR #62)

#64   (#21 AND #37 AND #63)

#65   <nothing>, from 1970 to 2008

#66   (#64 AND #65)

Database: EMBASE 1980 to 2008 Week 26

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 "reviews (1 term high specificity)"

Database: ASSIA Applied Social Sciences Index and Abstracts 1970-2008 searched 7/7/2008
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)

11 refs

Database: HMIC (DH-Data & King's Fund Database 2008/05, HELMIS 1984-1998) (ERL WebSPIRS) searched 8/7/2008
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

Plus Limits (systematic review* or meta-analysis) no date limits poss

46 refs

Database: PsycINFO 1967 to July Week 1 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 "reviews (high specificity)"

Reference tracking search strategies 21 August 2008

Database: MEDLINE(Ovid) 1950 to August Week 1 2008
Search Strategy:

1   norsjo.mp.

Database: MEDLINE(Ovid) 1950 to August Week 1 2008
Search Strategy:

1   minnesota heart health.mp.
2   minnesota heart.mp.
3   1 or 2

Database: MEDLINE(Ovid) 1950 to August Week 1 2008
Search Strategy:

1   oxcheck.mp.

Database: MEDLINE(Ovid) 1950 to August Week 1 2008
Search Strategy:

1   BFHS.mp.
2   British Family Heart.mp.
3   1 or 2

Database: MEDLINE(Ovid) 1950 to August Week 2 2008
Search Strategy:

1   bootheel.mp.

Database: MEDLINE(Ovid) 1950 to August Week 2 2008
Search Strategy:

1   danish municipality.mp.
2   slangerup.mp.
3   1 or 2

Database: MEDLINE(Ovid) 1950 to August Week 2 2008
Search Strategy:

1   german cardiovascular prevention study.mp.

Database: MEDLINE(Ovid) 1950 to August Week 2 2008
Search Strategy:

1   stanford five city.mp.

Database: MEDLINE(Ovid) 1950 to August Week 2 2008
Search Strategy:
1   pawtucket heart.mp.

Database: MEDLINE(Ovid) 1950 to August Week 2 2008
Search Strategy:

1   north karelia project.mp.
2   north Karelia.mp.

Database: MEDLINE(Ovid) 1950 to August Week 2 2008
Search Strategy:

1   heart to heart.mp.
2   south carolina cardiovascular disease prevention project.mp.
3   1 or 2

Database: MEDLINE(Ovid) 1950 to August Week 3 2008
Search Strategy:

1   (stanford adj2 community).mp.
2   stanford 3.mp.
3   stanford three.mp.)
4   or/1-3

Database: MEDLINE(Ovid) 1950 to August Week 3 2008
Search Strategy:

1   heartbeat wales.mp.

Database: MEDLINE(Ovid) 1950 to August Week 3 2008
Search Strategy:

1   action heart.mp.

Database: MEDLINE(Ovid) 1950 to August Week 3 2008
Search Strategy:

1   epernon town.mp.
2   epernon.mp.
3   or/1-2

Database: MEDLINE(Ovid) 1950 to August Week 3 2008
Search Strategy:

1   sezze.mp.

Database: MEDLINE(Ovid) 1950 to August Week 3 2008
Search Strategy:

1   national research program.mp.
2   nrp 1A.mp.
3   swiss.mp.
4   switzerland.mp.
5   or/3-4
6   1 and 5
7   2 or 6

Database: MEDLINE(Ovid) 1950 to August Week 3 2008
Search Strategy:

1   schleiz.mp.

Database: MEDLINE(Ovid) 1950 to August Week 3 2008
Search Strategy:

1   finnmark.mp.
2   cape.mp.
3   1 and 2
4   cardiovascular.mp.
5   1 and 4
6   5 and 2
7   batsfjord.mp.
8   7 and 5
9   3 or 5 or 6 or 8

Database: MEDLINE(Ovid) 1950 to August Week 3 2008
Search Strategy:

1   a su salud.mp.

Database: MEDLINE(Ovid) 1950 to August Week 3 2008
Search Strategy:

1   coeur en sante.mp.

Database: MEDLINE(Ovid) 1950 to August Week 3 2008
Search Strategy:

1   kilkenny.mp.
2   kilkenny health project.mp.

Database: MEDLINE(Ovid) 1950 to August Week 3 2008
Search Strategy:

1   otsego.mp.
2   (otsego adj schoharie).mp.

Database: MEDLINE(Ovid) 1950 to August Week 3 2008
Search Strategy:

1   dutch heart health.mp.

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.
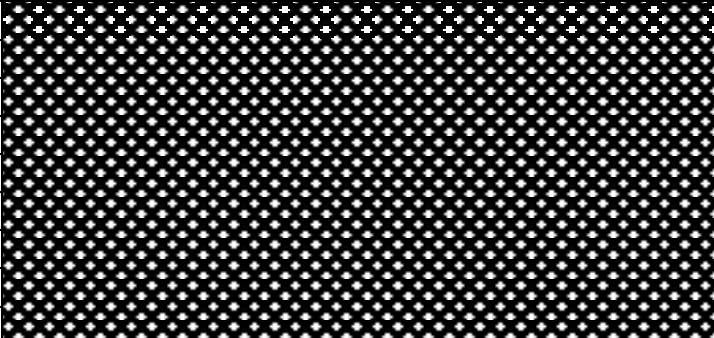
Appendix 4: Full Paper Screening Checklist

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
Action Heart	Y	Y	N	Y	N	NC	N	NA	3	-
Coeur en santé	Y	Y	N	Y	N	N	N	N	3	-
Heartbeat	Y	Y	Y	Y	N	N	N	NA	4	-
National RP	Y	Y	NC	NC	N	NC	Y	NC	3	-
Di.S.Co	Y	Y	NC	Y	N	NC	Y	NC	4	-
Dutch	Y	Y	Y	Y	N	NC	Y	Y	6	+
Otsego	Y	Y	NC	Y	N	NC	Y	N	4	-
Kilkeny	N	Y	Y	Y	N	NC	Y	NA	4	-
Båtsfjord	Y	Y	N	Y	N	NC	Y	N	4	-
North Cape	Y	Y	N	Y	N	NC	Y	N	4	-
Stanford 3	Y	Y	Y	Y	N	NC	Y	NC	5	+

++	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

<table>
<tr><td colspan="3">

Data Extraction Form

</td></tr>
<tr><td colspan="3">

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

</td></tr>
<tr><td colspan="3">

Project: The Norsjo Project

</td></tr>
<tr><td colspan="3">

Data extracted by: Wendy Greenheld
Date of extraction: 14th August 2008

</td></tr>
<tr><td colspan="3">

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.

</td></tr>
<tr><td colspan="3">

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)		☐

</td></tr>
<tr><td colspan="3">

Other study parameters:

Setting: The island municipality of Norsjo in Northern Sweden.

</td></tr>
</table>

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.