

Document 1

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

Report  
(10<sup>th</sup> September 2008)

## Document 1

## Prevention of cardiovascular disease at population level

[Question 1; phase 1]

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# Document 1

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## West Midlands Health Technology Assessment Collaboration

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

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

### Name of other institution(s) involved

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

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# Contents

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West Midlands Health Technology Assessment Collaboration	v
Name of other institution(s) involved	v
<b>Contents</b>	<b>vi</b>
<b>Executive Summary</b>	<b>viii</b>
Objectives:	viii
Methods:	ix
Conclusions:	ix
<b>1 Introduction</b>	<b>1</b>
1.1 Background	3
1.2 Research Objectives	5
1.3 Structure of report	8
<b>2 Methodology</b>	<b>9</b>
2.1 Identifying potentially relevant studies	9
2.2 Selection of effectiveness studies for inclusion	12
2.3 Data extraction and quality appraisal	19
2.4 Synthesis and formulation of evidence statements	21
<b>3 Effectiveness Findings</b>	<b>22</b>
3.1 Programmes addressing prevention of CVD at population level	23
3.2 Evidence tables	108
3.3 Applicability of the evidence to the UK populations in the scope	129
<b>4 Discussion</b>	<b>130</b>
4.1 Papers included in the review	131
4.2 Programmes overview	132
4.3 Excluded programmes	137
4.4 Emerging themes	138
4.5 Generic evaluation issues	147
4.6 Limitations of the review	149

<b>Appendix 1: Protocol to Address Question 1</b>	<b>156</b>
<b>Appendix 2: Search Strategies</b>	<b>179</b>
<b>Appendix 3: Inclusion/exclusion Checklists for Previous Systematic Reviews</b>	<b>191</b>
<b>Appendix 4: Full Paper Screening Checklists</b>	<b>194</b>
<b>Appendix 5: Excluded Primary Studies by Reason for Exclusion</b>	<b>199</b>
Effectiveness primary studies	199
<b>Appendix 6: Quality Assessment</b>	<b>204</b>
<b>Appendix 7: Example Completed Effectiveness Data Extraction Form</b>	<b>206</b>

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# Executive Summary

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## Objectives:

This report is the first 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 will not address the cost effectiveness aspect of this question and these findings will be detailed in a separate report.

Groups to be covered are 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 in this report 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 specifically focuses on studies identified as included studies in systematic reviews addressing similar questions in the past. In particular, six directly relevant systematic reviews identified from over 3,000 citations were used to identify relevant programmes and their associated publications. Review steps were generally undertaken singly by one of two reviewers. Synthesis was narrative and meta-analysis was not employed.

<b>Evidence statement:</b>
<p>This is an interim statement based on the first part of a 3 stage review.</p> <p>11 directly relevant programmes reported in 41 publications were identified for this report. The majority (9) consider the effectiveness of population programmes using education and mass media. Two others focus on assessing levels of all risk factors and providing advice in general populations. No programmes used legislative or fiscal changes and there were no natural experiments. The education and mass media programmes were generally evaluated using controlled before-after studies with quality gradings ranging from - to +. The "screening" programmes were evaluated using RCTs and were both graded +. For the outcomes of CVD risk factors and behaviours there was a consistent trend in direction of effect in favour of programmes of both types. 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.</p>

## Conclusions:

Provisionally, the first component of this two stage review suggests that there is some support that primary preventative population programmes involving education, mass

media and/or screening for risk factors in members of general populations can be effective in improving CVD risk factors and behaviours. Considerable uncertainty is left about the size of these effects and the effect on health outcomes. Whether the observed findings of the programmes which were conducted many years ago remain generally applicable in the UK at the current time is not clear.

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# 1 Introduction

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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 the first effectiveness review to be delivered to the Programme Development Group (PDG). It represents the initial piece of work (phase 1) addressing question 1 defined in the final scope as:

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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 second report, presenting the second phase of the effectiveness review, was presented to the PDG in October 2008 and 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, was presented to the PDG in January 2009. A review of the qualitative literature was presented at this meeting to address the second question defined in the scope:

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

## 1.1 Background

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

Despite recent improvements, UK death rates from CVD are relatively high

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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 the second and third reports, 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:

<b>POPULATION</b>	
<b>COVERED BY GUIDANCE</b>	<b>NOT COVERED BY GUIDANCE</b>
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

<p>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.</p>	<p>relevance for them. (Individuals at high risk of developing CVD are covered by other NICE guidance, see section 6.)</p>
<b>ACTIVITIES /INTERVENTIONS</b>	
<b>COVERED BY GUIDANCE</b>	<b>NOT COVERED BY GUIDANCE</b>
<p>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:</p> <ul style="list-style-type: none"> <li>• educational/behavioural (including the use of mass media)</li> <li>• fiscal</li> <li>• environmental</li> <li>• legislative</li> </ul>	<p>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.)</p>
<p>OR Programmes that include a pharmacological element alongside a broader, non-pharmacological multiple</p>	<p>OR Interventions which focus on screening for CVD risk factors (for example, cholesterol-level screening)</p>



<p>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.</p>	<p>and do not attempt to modify them</p>
<p>OR Natural experiments, such as changes in the diet of Eastern Europeans brought about by social change, where relevant evidence is available</p>	

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.

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## 2 Methodology

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The protocol governing the conduct of the literature review for both phases of the review addressing question 1 is given in Appendix 1. The methods described in the following sections are the features which particularly apply to phase 1 and 2, that consider 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.

Phase 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).

Phase 1 of the search for primary studies includes 41 primary studies contained in 6 systematic reviews derived from screening of 3,153 reviews.

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

### 2.1.2 Suggestions from experts and PDG

One suggestion was received from the expert group. Input was otherwise limited because the PDG was not fully established during the period when this report was compiled.

### 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

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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. 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 have been used to identify programmes for the current review. Programmes identified from the remaining 8 systematic reviews will be covered in phase 2 of the review process. Only systematic reviews with the specific aim of reviewing programmes aimed at reducing cardiovascular disease were included in phase 1 of this review. Those aiming to address other factors, such as nutrition, obesity or physical activity were retained for

use in phase 2. Table 1 below details systematic reviews that were included in the current report and those identified as 'pending' for use in the phase 2 report.

Systematic reviews included in phase 1
Ketola et al. Effectiveness of individual lifestyle interventions in reducing cardiovascular disease and risk factors <i>Ann Med</i> 2000; 32: 239-251
Ebrahim et al. Multiple risk factor interventions for primary prevention of coronary heart disease <i>Cochrane Database of Systematic Reviews</i> 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? <i>American Journal of Health Promotion</i> 2005; 19(3): 167-193
Nicholson et al. The effect of cardiovascular health promotion on health behaviours in elementary school children: An integrative review. <i>Journal of Pediatric Nursing</i> 2000; 15(6): 343-355
Sellers et al. Understanding the variability in the effectiveness of community heart health programs: A meta-analysis. <i>Soc. Sci. Med.</i> 1997; 44(9): 1325-1339
Krummel et al. Cardiovascular health interventions in women: what works? <i>Journal of Women's Health &amp; Gender-Based Medicine</i> 2001; 10(2): 117-136
Systematic reviews 'pending' for inclusion in phase 2
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. <i>Am J Prev Med</i> 2005; 29(1): 61-70
Finlay et al. Physical activity promotion through the mass media: Inception, production, transmission and consumption. <i>Preventative Medicine</i> 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. <i>Journal of Health Communication</i> 2004; 9: 71-96



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<p>Fogelholm et al. Community health promotion interventions with physical activity: does this approach prevent obesity? <i>Scandinavian Journal of Nutrition</i> 2002; 46(4): 173-177</p> <p>Sowden et al. Community interventions for preventing smoking in young people. <i>Cochrane Database of Systematic Reviews</i> 2003</p> <p>Secker-Walker et al. Community interventions for reducing smoking among adults. <i>Cochrane Database of Systematic Reviews</i> 2002</p> <p>The effectiveness of nutrition education and implications for nutrition education policy programs and research: a review of research. <i>Journal of Nutrition Education</i> 1995; 27(6)</p>
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Table 1 Systematic reviews included for identification of primary studies in the current review and those 'pending' for assessment in phase 2

### 2.2.3 Previous reviews' included study lists' appraisal

A decision was made on whether an included study 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

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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 phase 1 review and 85 programmes were effectively excluded (see appendix 5 for table of excluded programmes).

#### 2.2.4 Reference tracking

It was intended that reference tracking would be used to ensure that most articles representing each of the included programmes were identified, so that as complete published information as possible was available for the data abstraction and quality assessment stages. Reference lists of all included studies were also to have been checked for this purpose. However, because of time constraints this was deferred to the second phase of this review.

#### 2.2.5 Summary of effectiveness studies identified for inclusion

The following programmes were identified for inclusion in the first phase of the review to address question 1. 39 of the 41 related studies are shown by their respective programmes. The 2 remaining studies contain formative data and were only used in the discussion section of this report.

- The Bootheel Project (Brownson 1996)
- The British Family Heart Study (Wood 1994)
- The Danish Municipality Project (Osler 1993)
- The German Cardiovascular Prevention Project (Hoffmeister 1996)
- The Heart to Heart Project (South Carolina Project) (Heath 1995) (Wheeler 1991) (Croft 1994) (Goodman 1994) (Smith 1996)
- The North Karelia Programme (Puska 1979) (Salonen 1981) (Puska 1983 Ten) (Puska 1983 Change) (Puska 1985) (Puska 1989)

- The Norsjo Project (Weinhall 1999)
- The Minnesota Heart Health Programme (Jacobs 1986) (Luepker 1994) (Luepker 1996) (Mittelmark 1986) (Murray 1994) (Kelder 1993) (Perry 1992) (Rissel 1995)
- OXCHECK (Muir 1994) (Imperial Cancer Research Fund OXCHECK Study Group 1995)
- The Pawtucket Heart Health Programme (Elder 1986) (Lefebvre 1987)(Assaf 1987) (Carleton 1995) (Eaton 1999) (Hunt 1990)
- The Stanford Five City Project (Farquhar 1985) (Taylor 1991) (Fortmann 1995) (Fortmann 1993) (Fortmann 1990) (Winkleby 1996) (Farquhar 1990)

The references indicate all the articles identified relating to the programme in question at this stage of the review. Not all of these were used in the data abstraction as they may have provided information available in other publications and/or analysis of sub-projects which were not directly relevant to the research question being addressed in this review.

### 2.2.6 Excluded effectiveness studies

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

<b>Reason for exclusion</b>	<b>Number</b>
Published before 1970	0
Thesis/book chapter	0
Inappropriate setting and population	81
Does not address general purpose (reducing CVD risk)	4
Inappropriate intervention	0
Inappropriate design for effectiveness review	0
No appropriate outcomes	0
Number of articles "included"	41
Number of programmes represented by these articles	11

Table 2 Excluded primary studies obtained from systematic reviews

### 2.2.7 Pending effectiveness papers

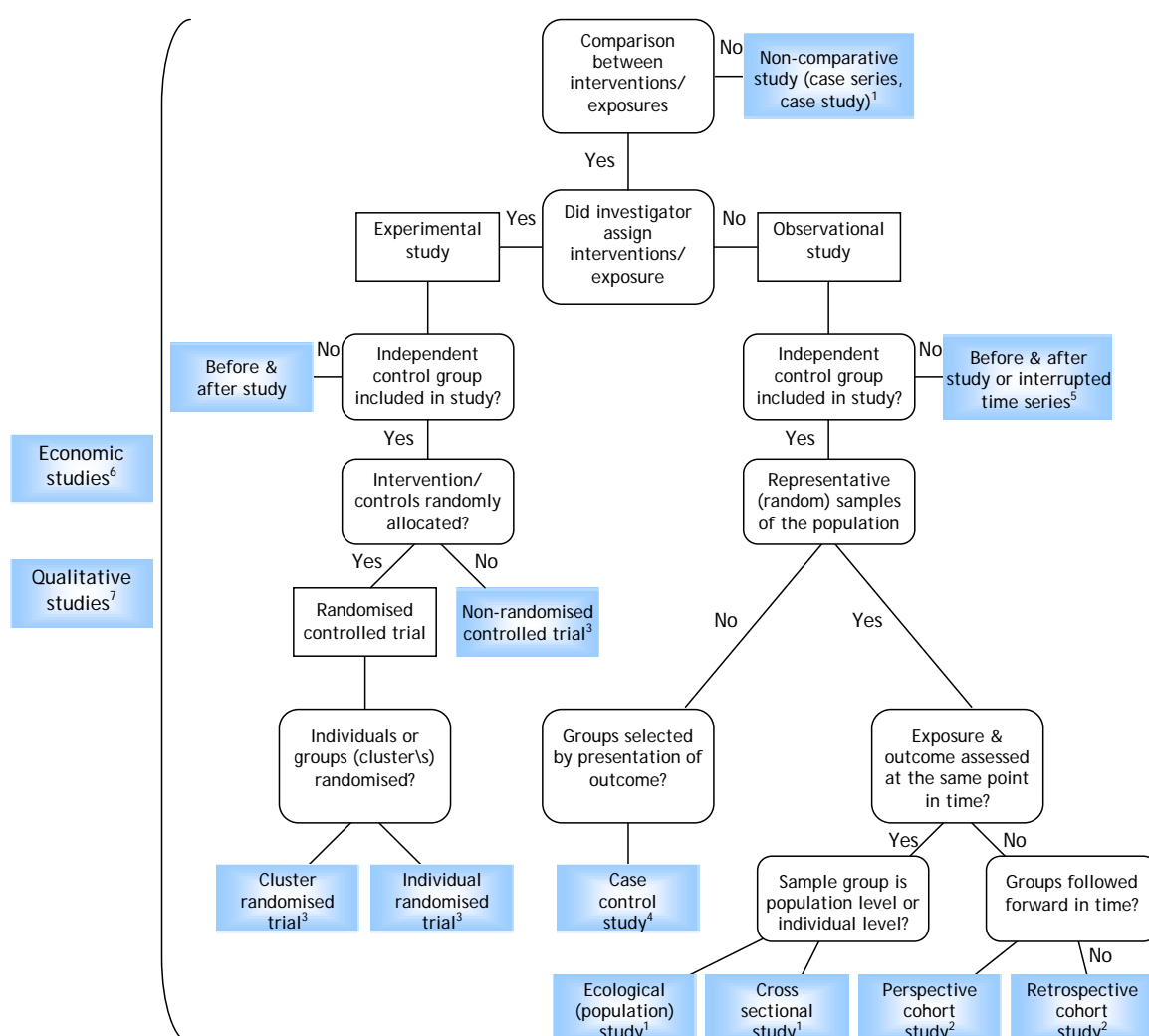
As detailed above, effectiveness papers within systematic reviews allocated to phase 2 are pending inclusion/exclusion.

## 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.

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 and an RCT rated – is still likely to provide more robust data than a before and after study rated ++ because an RCT is an inherently stronger study design.

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. The Appendices provide an example of a completed checklist.

## 2.4 Synthesis and formulation of evidence statements

The results of the data extraction and quality assessment for each programme identified in the included effectiveness studies were presented in a narrative summary and combined in a summary evidence table. An evidence statement, which summarises the evidence of the higher rated studies as well as itemising the evidence from each included study, was then generated. 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.

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## 3 Effectiveness Findings

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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 41 articles (23 identified from previous systematic reviews and 18 from reference tracking and citation checking). 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



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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).

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 The Bootheel Project

The Bootheel Heart Health Project was conducted in the south-eastern part of Missouri, a region with the largest black population in the Missouri district. In 1989 the Bootheel became the target for a state-run (Missouri Department of Health) cardiovascular disease reduction programme. The long-term aim of this intervention was to reduce morbidity and mortality due to cardiovascular disease and the short-term aim was to reduce the major modifiable risk factors for CVD (1).

#### **Target population**

The intervention group consisted of five rural communities in the south-eastern Bootheel region of Missouri: Dunklin, New Madrid, Stoddard, Mississippi and Scott. The control group was also drawn from the Missouri district, from communities where intervention activities had not taken place (sites not stated) (1).

#### **Theory/conceptual model of intervention**

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Initial project development was based on the 'planned approach to community health model' and subsequent implementation used 'social learning theory' and the 'stage theory of innovation' (1). Social learning theory, commonly used for programmes of this type, predicts change in health behaviour on the basis of behavioural spread from person to person. The stage theory of innovation uses staggered, progressive steps of gaining community awareness and input before project implementation. There is an emphasis on leadership from the community and this mode of implementation requires close contact and considerable time investment to fully engage with communities.

### **Intervention description**

During the five months prior to project initiation, local leaders were identified through established agencies such as local government or voluntary agencies, or through word of mouth, and interviewed by the project coordinator. These leaders made up coalition groups responsible for project planning and implementation in different counties. Local sub-coalition groups (about 17 were formed) had the freedom to tailor interventions to the needs of their particular communities. Coalitions were given lists of disease-reduction intervention ideas from which they could select their own priorities. Local health agencies played a supportive role in many areas, giving assistance in blood pressure measurement, screenings, training and providing local funds (1).

Some common project activities were implemented in all intervention counties such as walking clubs, aerobic exercise classes, healthy cooking demonstrations, community blood pressure and cholesterol screenings and CVD education programmes. In tailored projects for individual communities, other projects were run. These were often inventive and their organisation was community involving. For example, an annual heart healthy fitness festival was held involving exercise demonstrations, registration for exercise classes and walking clubs and screenings for hypertension, diabetes and high cholesterol. Another community instituted a "High Blood Pressure Sunday" where heart disease education was incorporated into church sermons, the

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congregations were screened for hypertension and heart healthy dinners were provided at church. Other communities ran poster contests where local schools provided sponsorship and winning entries were featured in local newspapers. A weekly newspaper column, "Heart Healthy Corner" was a feature in one community whilst others made environmental changes such as construction of walking and fitness paths (1).

Many activities were organised, especially those promoting physical activity such as walking club functions (n=4,000) and exercise classes (n=1,275). There were also a high number of blood pressure screenings (n= 2,050) and community events (n=415) as well as cholesterol screenings (n=70), cooking demonstrations (n= 60) and screenings for diabetes (n=30) (1).

### **Accessibility**

The description of the interventions in the Bootheel Project demonstrates that they were offered in a variety of locations including churches, schools and at social events. Interventions were also tailored to meet local priorities and preferences. It is likely that these factors facilitated accessibility. 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. Response rates to the evaluative surveys were lower for younger individuals, males and those with less education which may be an indication that the intervention was less accessible to these sub-groups. However no information is provided on uptake of the intervention by different population sub-groups.

Analysis of sub-groups demonstrated that, although not always significant, the black population showed net improvements in each of the five risk factors studied whereas the white population demonstrated only slight improvements for physical activity and cholesterol screening and showed deterioration in risk for smoking, fruit and vegetable consumption and being overweight. This may be explained by the fact that local coalition groups had the freedom to tailor interventions to the needs of their

particular communities and that, as a result, the intervention was less accessible to the minority, white population.

### **Programme evaluation**

Telephone surveys were conducted at baseline (1990, pre-intervention) and four years into the intervention (1994). These surveys used random digit dialling to select participants who were then asked to answer an 87 question survey relating to cardiovascular risk and socio-demographic details. The main risk factors investigated were low physical activity, smoking, low fruit and vegetable consumption, overweight and attendance at cholesterol screening. No clinical measurements were taken. The same questionnaire was used in the 1994 survey but 30 questions were added to examine exposure to intervention activities as well as health status and quality of life (1).

### ***Participant selection/recruitment***

People over the age of 18 who were not institutionalised were eligible to participate. By definition, participants were required to have household telephones as recruitment and surveys were conducted by phone. This sampling method inevitably resulted in a non-representative sample being drawn and there was a lower percentage of black people compared to census data. Therefore, for the 1994 survey, in order to increase the number of black respondents, one third of the survey calls were made to areas where >20% of the population were black. 1,006 people participated in the baseline survey and 1,510 in the 1994 survey and response rates were 89% and 76% respectively (1).

### **Outcome measures**

Five specific outcome measures were presented (1):

- Percentage of people with no leisure-time physical activity
- Percentage current smokers
- Percentage consuming >5 servings of fruit and vegetables per day

- Percentage overweight
- Percentage having cholesterol screening in past 2 years

## Results

Results were presented as net treatment effects from baseline (1990) to the final survey (1994) in treatment and control areas (difference in absolute change from baseline between intervention and control groups) (1). The relationship between intervention exposure and risk factor prevalence was examined using two separate measures of exposure: the presence of an active coalition in a community and knowledge of the health coalition. Analysis of covariance models were used to adjust for confounders (1).

### 1. Leisure time physical activity

The percentage of respondents reporting that they did no leisure-time physical activity decreased in the treatment areas (-3.0; 95% CI -8.5 to 2.5) and increased in control areas (+3.8; 95% CI -2.9 to 10.5). The net treatment effect was therefore a significant 6.8% improvement ( $p=0.03$ ).

### 2. Smoking

The percentage of respondents reporting that they currently smoked decreased in the treatment areas (-1.3; 95% CI -6.3 to 3.6) but decreased to a greater extent in control areas (-5.0; 95% CI -11.1 to 1.1). The net treatment effect was therefore to slightly increase rates of smoking but this was not significant (net +3.7%;  $p>0.1$ ).

### 3. Diet

The percentage of respondents reporting that they consumed >5 servings of fruit and vegetables per day decreased in the treatment areas (-1.3; 95% CI -5.7 to +3.1) and increased slightly in control areas (+0.9; 95% CI -4.5 to +6.4). However, the net effect was not significant (net treatment effect +2.2;  $p>0.1$ ).

### 4. Overweight

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The percentage of respondents reporting that they were overweight increased in treatment areas (+4.3; 95% CI -0.9 to 9.4) and increased substantially in control areas (+10.2; 95% CI 3.9 to 16.6). Although rates of overweight appeared to rise in both treatment and control areas this may have been slightly attenuated by intervention however the net treatment effect was not significant (net +5.9 p= 0.07).

#### 5. Cholesterol measurement

The percentage of respondents reporting that they had had their cholesterol checked over the last two years increased in the treatment areas (+4.3; 95% CI -1.0 to 9.6) but did not change in control areas (-0.2; 95% CI -6.7 to 6.5). The net treatment effect was therefore a significant 4.5% improvement (p= 0.04).

Analysis of sub-groups demonstrated that although not always significant, the black population showed net improvements in each of the five risk factors studied whereas the white population demonstrated only slight improvements for physical activity and cholesterol screening and deterioration in risk for smoking, fruit and vegetable consumption and overweight.

#### **Limitations of the intervention and its evaluation**

The study was quality assessed and graded 'C'.

##### *Identified by authors:*

The authors identified that this study lacked a proper control group and suffered from the absence of clinical data to validate reported changes in smoking status and measure blood pressure (1).

##### *Identified by reviewer:*

The sole use of telephone surveys introduces the possibility of selection bias. Thirteen percent of households did not have telephones and lower socioeconomic groups were less likely to have been surveyed. Furthermore, the baseline characteristics of the survey respondents were not representative of characteristics of the population.

The selective recruitment of people from higher black population communities in the second survey resulted in the creation of a follow-up group that was different to the baseline group in terms of ethnicity and level of education.

Responses to survey questions may be biased by respondents wanting to give the 'right' answer. In light of health messages received, this may have been an even greater problem in treatment areas resulting in reporting bias.

The group used as a control was unsuitable. It was not distinct from intervention communities and there may have been contamination from intervention activities. The methods used to select control participants were unclear.

### **Applicability**

The Bootheel Heart Health Project was conducted in south-eastern Missouri and was initiated due to high mortality rates for coronary heart disease in the area. Bootheel has a large black population and is described as an underserved rural area with high rates of poverty and low educational levels. Local coalitions were allowed to select their own priorities from a list of possible cardiovascular disease-related interventions. Coalition activities were given financial support but the intervention is described as being modestly resourced. The authors note that 13% of the study sample did not have access to a telephone which may have resulted in exclusion of certain socio-demographic groups from the evaluation.

### **Summary**

Despite failing to properly survey intervention outcomes, the Bootheel Heart Health project generated considerable community enthusiasm and involvement, evidenced by the number and creativity of community initiatives. Although results showing improvements in physical exercise and cholesterol screening may not be wholly reliable, this project may have had some effect to improve community awareness, attitudes and behaviours.

### 3.1.2 The British Family Heart Study

The aim of the British Family Heart Study was to measure the change in cardiovascular disease risk factors achievable in families over one year by a cardiovascular screening and lifestyle intervention in general practice (2).

#### **Target population**

The objective was to identify general practices servicing a variety of different socio-economic groups and 15 British towns, meeting specific demographic criteria, were selected. All practices within those towns, with 4-7 full-time partners, who were willing to take part, were invited to participate. Twenty-eight GP practices in 14 different towns (14 treatment and 14 control practices in the same towns matched for socio-demographic characteristics) were recruited to the study. In the course of the one-year intervention, one general practice was deemed not to have followed proper protocol requirements and, because of doubt in the reliability of the data, this practice and its control practice were excluded from the final analysis. The final study towns were: Bury, Burton on Trent, Carlisle, Bridgend, Darlington, Dunfermline, Gloucester, Huddersfield, Ipswich, Lincoln, Newport, Poole, and Portsmouth. (2).

#### **Theory/conceptual model of intervention**

Not stated.

#### **Intervention description**

The initial screening visit in the intervention group lasted approximately 1.5 hours and consisted of a computer recorded interview to collect demographic and medical information and investigate habitual lifestyle. For control patients, the screening at one year was less intensive and lasted only approximately 45 minutes.

In the screening intervention, measurements of height, weight, blood pressure and carbon monoxide from breath were made and blood samples taken to assess total blood cholesterol and plasma glucose concentration. Some intervention participants



were allocated to not receive blood total cholesterol measurement so that the specific effect of this strategy could be assessed separately (2).

Each intervention participant was given a coronary risk score based on any evidence of CVD risk factors. Participants were told their score and how it compared with average scores in their age bracket. Nurses discussed lifestyle changes relating to smoking, weight, healthy eating, alcohol consumption and exercise with participants and provided pamphlets where appropriate. Negotiated goals for lifestyle change and risk factor score was recorded in a booklet "Your passport to health". Participants in the top quintile of risk scores were offered follow-up every two months, those in the fourth quintile every three months, those in the third quintile every four months, those in the second quintile every six months and those in the bottom quintile only at one year. Participants with high individual risk factors relating to smoking, BMI, blood pressure, cholesterol or plasma glucose were also invited to re-attend every month for up to three months. Participants with plasma glucose  $\geq 10$  mmol/l or diastolic blood pressure  $\geq 115$  mm Hg on any occasion or patients with blood cholesterol  $\geq 6.5$  mmol/l or diastolic blood pressure  $\geq 100$  mmHg sustained for three months, were referred to their GP (2).

### **Accessibility**

The intervention required attendance at health facilities. No information was provided on distance to be travelled or whether participation was affected by distance from facility. Participants were also encouraged to seek help with lifestyle changes by attending groups such as weight watchers, which may limit accessibility on the basis of culture or financial hardship. The intervention relied heavily on written material and there was no discussion of whether materials were adapted for individuals with literacy problems, for those for whom English was not a first language or for those who did not speak English. Similarly, no information is given about whether consideration was given to cultural diversity when recruiting nurses to deliver the intervention.

Lifestyle change was discussed in relation to the results of a CVD risk assessment. Adequate communication of risk to patients requires a level of numeracy which may limit the effectiveness of this approach to certain groups. The intervention was offered to older adults only and therefore assessment cannot be made about its accessibility to younger individuals.

Authors report, from a comparison of those who returned and those who did not return 1 year after the intervention, that non returners had a 'much higher prevalence of smoking' (twice as high) and were a 'slightly higher weight'. No information is provided on uptake of the intervention by different population sub-groups.

### Programme evaluation

The design of the British Family Heart Study is shown in figure 1:

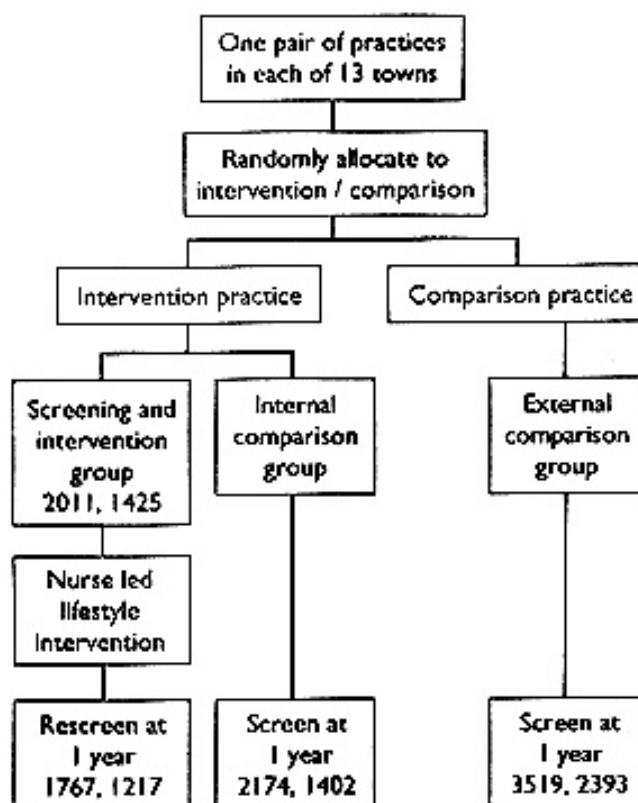


Figure 1 Study design for the British Family Heart Study (2)

This randomised controlled trial compared intervention participants, previously screened one year earlier and receiving tailored nurse led intervention throughout the

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year, with control participants receiving no previous screening. Study outcomes were assessed in all study participants at a final screening session. The intervention group comprised 1,767 men and 1,217 women attending both the initial and final screenings. The internal and external control groups contained 2,174 men/1,404 women and 3,519 men/2,393 women respectively.

### **Participant selection/recruitment**

Families were identified for participation through the male partner. A list of men aged 40-59 in all selected practices was divided into age bands and each age band was randomly divided into two equal groups – one group to be invited as the study group and one to form an internal control. Men on the intervention list, together with their families, were invited to participate at the same rate from each of the five age brackets. Whole families were screened but only the men and their partners were followed up for subsequent study. Families of men on internal control lists (internal control) or attending control practices (external control) were not screened until one year later, coinciding with re-screening of the intervention group (2).

14,086 households were approached and the household response rate was 73% (2). In the intervention group, loss to follow-up was 12% and 15% in men and women respectively (2).

### **Outcome measures**

The main outcomes presented relate to comparisons made for the intervention group versus the external control group. Secondary comparisons were also made for intervention versus internal control groups since these would not be affected by between practice variability.

The principle outcome was the Dundee risk score, an overall measure of CVD risk determined by blood cholesterol concentration, systolic blood pressure and previous and current smoking habit. Prevalence of coronary heart disease, diabetes, high blood pressure and high cholesterol were compared as well as outcomes relating to blood

cholesterol concentration, systolic and diastolic blood pressure, smoking, BMI and random blood glucose (2).

Differences in means for intervention and comparison groups (internal and external) were assessed separately for each treatment town versus its control and these differences were then pooled for all 13 towns (using random effects meta-analysis). Results were compared for men and women and heterogeneity between general practices in treatment/control differences was assessed (2).

## Results

For simplicity, results presented here are for intervention groups compared only to external controls but identical patterns of risk-factor differences were observed with use of internal controls (2).

### 1. Cardiovascular risk score

Dundee risk score was lower in intervention compared to control male (16.1% lower; 95% CI 10.9 to 21.1) and female (15.7% reduction; 95% CI 7.4 to 23.3) patients.

### 2. Smoking

The prevalence of smoking was lower in intervention compared to control male (4.1% lower; SE 1.8) and female (3.5% lower; SE 2.1) patients.

### 3. Cholesterol

Mean blood cholesterol (mmol/l) was lower in intervention compared to control male (0.12 lower; SE 0.06) and female (0.12 lower; SE 0.09) patients and the percentage of patients with blood cholesterol  $\geq 8.0$  mmol/L was less in intervention compared to control males (1.5% lower; SE 0.8) and females (1.1% lower; SE 0.5).

### 4. Blood pressure

Mean systolic and diastolic blood pressure (mm Hg) were lower in intervention compared to control male (systolic: 7.5 lower; SE 1.2, diastolic: 2.5 lower; SE 1.0) and female (systolic: 7.7 lower; SE 1.4, diastolic: 2.5 lower; SE 0.9) patients. The percentage

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of patients with diastolic blood pressure  $\geq 100$  mm Hg was also lower in intervention compared to control males (4.6% lower; SE 1.4) and females (2.2% lower; SE 1.1).

#### 5. Overweight

Mean weight (kg) was lower in intervention compared to control male (1.17 lower; SE 0.36) and female (1.09 lower; SE 0.42) patients. The percentage of obese patients (BMI  $\geq 30$  kg/m<sup>2</sup>) was also lower in intervention compared to control males (1.8% lower; SE 1.3) and females (2.2% lower; SE 1.5).

#### 6. Blood glucose

Differences were not evident for outcomes related to blood glucose. Median random blood glucose (mmol/l) was similar in intervention compared to control male (0.03 lower; SE 0.08) and female patients (0.10 higher; SE 0.09) and the percentage of patients with random blood glucose levels  $\geq 10.0$  mmol/L was also similar for male (0.1% lower; SE 0.4) and female (0.3% higher; SE 0.3) patients.

#### 7. Frequency of disease diagnosis

Due to the intensive screening and follow-up process, substantially greater numbers of intervention compared to control patients were diagnosed with high blood pressure (males: 3.2% more, SE 1.6; females: 4.1% more, SE 2.3) and high cholesterol (males: 4.0% more, SE 1.7; females: 4.0% more; SE 1.2). More people were diagnosed with diabetes for intervention compared to controls but this difference was less substantial (males: 0.6% more; SE 0.5, females: 0.1% more, SE 0.3) and there was no difference between groups for the number of patients diagnosed with CHD (males: 0.6% lower, SE 0.9; females: 0.3% higher, SE 0.4).

#### **Limitations of the study**

The study was quality assessed and graded '+'.

#### *Limitations identified by author*

The study authors stated 12% of males and 15% of females in the intervention group did not return for evaluation the following year and this may have biased results. For

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example, for smoking, for people who dropped out of the study, baseline smoking rates were twice as high as for those who remained until follow-up. Smoking may have been underreported by participants and the confirmation test for smoking cessation, carbon monoxide in breath, may not be a reliable validation measure. Improved blood pressure in intervention compared to control participants may be partly due to people becoming more accustomed to the method of measurement.

#### *Limitations identified by reviewer*

As the authors noted, patients who dropped out of the study intervention group may have been substantially different in terms of CVD risk factors. Since analysis was not done on an intention to treat basis the possibility of bias cannot be discounted.

#### **Applicability**

The British Family Heart Study was conducted in British towns, selected to encompass areas within a broad socio-economic status range, although little data to confirm this claim are reported. However, it is likely that results are applicable to the general UK population but only to those aged 40-59, in whom the study was conducted. The levels of risk in the intervention group at baseline appear similar to those identified in the Health Survey for England (HSE) 2006 e.g. male smoking prevalence 22.2%; female smoking prevalence 19.4%. It was notable that those who did not return for follow-up had higher levels of risk e.g. male smoking prevalence 41.8%; female smoking prevalence 38.9%.

#### **Summary**

The British Family Heart Study shows evidence for a positive effect of screening and follow-up on risk factors for CVD although caution should be taken with estimates from the non-intention to treat analysis. Since a wide range of socio-economic populations were studied, generalisability appears to be high but studies in people of all ages (not only 40-60 years) may be needed to assess whole population applicability. Continuing evaluation is also necessary before the long-term effectiveness of this type of intervention is known.

### 3.1.3 The Danish Municipality Project

The Danish municipality project was part of a larger initiative promoting heart-healthy behaviours in five areas in Denmark: two countries (Vejle and Roskilde) and three municipalities (Copenhagen, Slangerup and Pandrup). The current report gives details for the smaller-scale intervention in only one of these areas, the municipality of Slangerup. The one-year intervention began in 1989 and aimed to draw attention to project issues and activities and to affect the stages of behaviour change in the community (3).

#### **Target population**

Slangerup, a rural town of ~8,000 inhabitants was the intervention community. Helsingør, a town of similar size and demographic features to Slangerup, but with different local media and no ongoing health projects, was chosen as the control (3).

#### **Theory/conceptual model of intervention**

Social learning theory was the primary model used for the basis of intervention activities (3). The rationale is that personal behaviour is learned through social influences and that behaviour is changed as a result of awareness of the need for change, incentives to change and a person's perceived ability to modify their lifestyle. The communication of health messages was guided by the 'diffusion of information' model (3). This describes how information is diffused and predicts lag times between changes in awareness and adoption of new behaviours in different segments of the community. The 'persuasion' model was used to give guidance as to the ways in which people perceive the relevance of health care information and the motivations for change (3). The 'community organisational' model was used to give guidance of the optimal community environment for promoting behavioural change (3).

#### **Intervention description**

A steering committee planned and guided the course of project activities with some members from the Local Health Administration but plans were carried out by a project coordinator, specifically employed for the task. The aim was that activities

should be created and organised by volunteers and these were recruited via personal contacts of members on the steering committee. Twenty five volunteers were recruited and formed six groups, each addressing a different issue relating to CVD. Intervention activities included exercise and smoking cessation programmes, fitness tests, safety education and demonstrations of how to buy healthy foods. Heart-healthy bread and a local recipe cook book were sold in the local supermarket. At six months, there was 'Heart Week', a highly intensive week of lectures, fitness tests and exercise and smoking cessation programmes. More regular activities included group weekly exercise sessions and eating a healthy meal together once a month. There was media involvement with health spots shown during commercials in the local cinema and local radio and newspapers had reports about the campaign (3).

### **Accessibility**

The intervention was implemented using a range of activities in various locations and included fitness tests, exercise, smoking cessation programmes and written education about healthy food. Local media advertised the programme. 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.

Examination of the demographic features of individuals not responding to surveys, show significant non-response amongst younger men (20-24 years) and unmarried or divorced people which are equal in treatment and control group surveys. Similarly, programme awareness in the intervention groups was low amongst 20-24 year olds. This may be an indication of the acceptability of this intervention for these groups. No information is provided on the uptake of the intervention by different population sub-groups.

### **Programme evaluation**

Project assessment was made by means of cross sectional surveys, one taken at baseline and one following a year of intervention. Surveys involved mailed



questionnaires containing 21 questions relating to 1) awareness of, and participation in local health promotion activities; 2) whether programme activities had encouraged changes in health behaviour and 3) changes in health behaviour (3).

#### *Participant selection/recruitment*

Participants of 20-65 years were randomly selected from the local Central Person Register in intervention and control areas and those responding to mailed questionnaires, participated. Baseline surveys were sent to 1,010 and 1,092 adults in treatment and control areas respectively. Response rate was ~51% in both groups and 567 in the treatment group and 629 people in the control group completed the surveys. At one-year, surveys were sent to 1,003 and 1,109 people in each group. Response was slightly higher, 59%, and there were approximately 600 people completing the final survey in each group (NB separate N for each group not stated). Examination of the demographic features of individuals not responding, show significant non-response amongst younger men (20-24 years) and unmarried or divorced people but these differences were equal in treatment and control group surveys (3).

#### *Measured outcomes*

Outcomes related to awareness and participation in local health promotion activities, programme incentives for health behaviour change and changes in health behaviour (3).

#### **Results**

Results are presented for differences between the intervention and control group (3). NB these are not comparisons of differences from baseline.

#### *Primary outcomes*

##### 1. Self-reported smoking cessation

There was no difference in regards to reported smoking cessation, attempted smoking cessation or even consideration of smoking cessation between treatment and control areas and also no differences in extensive sub-group comparisons.

## 2. Diet

Similarly, there was no difference in regards to % reported reduced fat consumption, attempts to consume less fat or consideration of eating less fat between treatment and control areas. There were no differences in demographic sub-groups comparisons except for adults aged 44-54 years who reportedly consumed less fat in the intervention compared to control group (36% verses 47% respectively,  $p < 0.05$ ).

## 3. Physical activity

There was no reported difference in the % of people with increased physical activity, % attempting to increase physical activity or % considering increasing their physical activity between treatment and control areas and also no differences in sub-group comparisons.

### *Secondary outcomes*

## 4. Programme awareness

Post-intervention, there was a high degree of awareness of programme activities with significant differences in % awareness between intervention and control groups (82% verses 67% respectively,  $p < 0.001$ ). This was also true for every demographic sub-group tested except in those aged 20-24 years. Interestingly, in this group of people, despite the one-year intervention, the difference in programme awareness was not significantly different (70% verses 54% for treatment and controls respectively, NS).

### **Limitations of the intervention and its evaluation**

The study was quality assessed and graded '-'.

#### **Identified by authors (3):**

Evaluation strategy was not sensitive enough to detect changes.

Recent migration into the treatment area may have diluted apparent effect.

The programme was not properly integrated into community social organisations and it was therefore difficult to recruit volunteers to project groups. Less than ten people participated in some project activities.

No funds were available for involving the local health services.

The project ultimately consisted of mainly a mass media campaign. This may have raised awareness but have had limited impact on health behaviours.

The project was mainly planned and organised by local volunteers without the skills or understanding of community structure necessary for proper project implementation.

**Identified by reviewer:**

Project implementation may have failed to properly engage with the community. Community volunteers were only drawn from personal project contacts and projects appear to have been planned and set in place by programme organisers without previous community contact or input. This has the feel of a didactic-type programme with the individual volunteers (N=25) taking responsibility for organisation of all programme activities. With the lack of proper community involvement, it is inevitable that capacity was stretched and the programme failed to bring about behavioural change.

Surveys contained questions on awareness of the programme as well as health behaviour change. This may have caused considerable bias in reporting of behaviours.

Results are not reported as changes from baseline but are direct comparisons of control and treatment groups made after intervention. Data for baseline survey results is not reported and results may be unreliable.

**Applicability**

This is a small-scale project set in a rural European town. There maybe reasonable applicability to populations in small, rural UK locations but generalisation to bigger

urban towns is likely to be unsuitable. The 'diffusion of information' model used in this project is unlikely to be appropriate for larger, less homogenised communities.

### **Summary**

The Danish Municipality study was a short-term, but reasonably high profile programme. Failure to show positive intervention effects on behavioural outcomes may be due to ineffective community involvement and inflexible project implementation.

#### **3.1.4 The German Cardiovascular Prevention Project**

The German Cardiovascular Prevention study was a community-orientated, multicentre disease prevention programme conducted over a seven-year period (from 1985 to 1991) in six intervention regions with a total population of more than 1,000,000 scattered throughout the former West Germany. Its main aim was to reduce, by primary prevention, the four cardiovascular risk factors: hypertension, hypercholesterolemia, smoking, and obesity (4).

#### **Target population**

The intervention group comprised six regions of the former West Germany: three city districts (of Berlin, Bremen and Stuttgart), an entire medium sized city (Karlsruhe) with two small neighbouring communities (Bruchsal, Mosbach) and a rural district (Traunstein) (4). When pooled, these regions had a similar demographic and socioeconomic structure to the total West German population. The control group comprised three independent representative samples of the total West German population (4).

#### **Theory/conceptual model of intervention**

The programme aimed to improve health knowledge, awareness, attitudes and behaviour in the population through the implementation of a multifaceted prevention programme. The influence of an underlying theory was not commented on.

**Intervention description**

This was a multifaceted prevention programme. Existing facilities were used and access to health care providers was extended and improved through collaboration with public health services, voluntary welfare federations, institutions for adult education, and sports and consumer associations with the participation of physicians, medical assistants and teachers (4).

Special emphasis was placed on healthy nutrition, increased physical activity, smoking cessation, and the screening for hypertension and hypercholesterolemia (4):

1. Improved nutritional habits were promoted by campaigns at community festivals, public events, restaurants, supermarkets, canteens and schools. Weight reduction courses and seminars on nutritional topics and menus and information about ingredients and food preparation beneficial to cardiovascular health were offered. A healthy diet containing less meat, fat, salt and calories and more vegetables and cereal products was encouraged and the availability of low-salt and low-fat products was increased through co-operation with local food suppliers.
2. Increased physical activity was promoted through the development of recreational sporting events with varying intensity levels, and educational sports circuits were initiated.
3. To discourage smoking, non-smoking areas in public places, anti-smoking campaigns in the local media, an intensive anti-smoking poster campaign, and courses to help smokers to quit were established.
4. To reduce hypertension and hypercholesterolemia, blood screenings were organised at social events and factories in close cooperation with physicians and health insurance companies. A large number of the inhabitants in the intervention areas were screened with the aim of increasing awareness of hypertension and hypercholesterolemia and advice and, if necessary, medical treatment was offered to those participating.

As the mid-survey showed unfavourable trends for cholesterol levels in several regions, an intensified cholesterol-lowering programme focusing on dietary changes was initiated (4).

### **Accessibility**

The intervention included extension of access to healthcare providers by utilising voluntary groups, education facilities, sports facilities, workplaces, industry and pharmacists. The intervention was offered at a range of venues including social events, educational institutions, canteens, restaurants and local food outlets and included local media.

Various modes of delivery were used but there is no information on the accessibility of written and verbal educational materials to those individuals with literacy problems, for those speaking different languages or for those from different cultural backgrounds. Response rates to surveys were between 69 and 75%. No information was provided on evaluation survey response or uptake of the intervention by different population sub-groups.

### **Programme evaluation**

The programme was conducted over a seven year period. Representative, independent samples of the intervention and control populations were used to examine risk factor trends at three time periods. For each intervention region, a sample of about 1,900 men and women aged 25-69 was examined before the intervention (May 1984 to March 1985). At the mid-study (February 1988 to April 1989) and at the end of the intervention (April 1991 to April 1992), surveys of about 1,400 subjects were conducted. National representative reference samples of about 5,000 subjects were examined in almost the same periods (June 1984 to April 1986, Sept 1987 to Oct 1988 and April 1990 to May 1991). Response rates were 74.5%, 73.0% and 71.6% for the intervention samples and 66.7%, 71.4% and 69.0% for the national samples respectively (4).

## Outcome measures

The following outcomes were measured: systolic blood pressure, diastolic blood pressure, total serum cholesterol, smoking and body mass index (4).

## Results

Results were presented for changes from baseline to the end of the intervention and comparisons of those changes made for treatment versus control groups (net changes). No pronounced changes in risk factors were observed in the reference population during the study period, other than an unfavourable rise in serum cholesterol. However, in the pooled intervention population, favourable changes occurred in most risk factors (4):

### 1. Blood pressure

For both systolic and diastolic blood pressure, a statistically significant net decrease in the intervention population in comparison with the control population was seen (net change of approximately 2% for both systolic and diastolic blood pressure). The net decline in systolic and diastolic blood pressure was larger amongst women (systolic -2.4, diastolic -2.3 mm Hg,  $p < 0.001$ ) than men (systolic -1.6, diastolic -1.6 mm Hg,  $p < 0.001$ ). The prevalence of untreated hypertension was significantly reduced amongst the intervention group in comparison with the control group for all participants (net change of -21.1%,  $p < 0.001$ ). However, when divided for gender, although a large reduction was seen for women (net -32.7%,  $p < 0.001$ ) the net change was not significant in men (-12.8, NS).

### 2. Cholesterol

The net decrease in total serum cholesterol was statistically significant when results for all participants were pooled (-1.8%,  $p < 0.001$ ) and changes were almost identical for men and women (-1.9%,  $p < 0.001$  and -1.8%,  $p < 0.05$  respectively).

### 3. Smoking

A significant net decrease in the percentage of smokers in the intervention regions compared with the national trend was observed (-6.7%,  $p < 0.05$ ). However, whilst the reduction was significant amongst men (net -9.7%,  $p < 0.01$ ), the trend was not significant for women (net -1.8%, NS).

#### 4. BMI

No net change in mean values of BMI was observed relative to the national trend. Mean values increased in both intervention and control groups amongst both men and women.

#### **Limitations of the intervention and its evaluation**

The study was quality assessed and graded '+’.

#### *Limitations identified by reviewer*

The non-random allocation of the intervention and control groups raises the possibility of selection bias. Programme influence on the control population (contamination) cannot be discounted although the distribution of the intervention regions across the large control area of the former West Germany may help to reduce any possible spillover effects.

#### **Applicability**

This programme was implemented in West Germany, a European location with demographics that may be generalisable to the UK. There is however limited information in the published report to explore this further. In terms of baseline CVD risk level, these seem slightly higher than currently exist in the UK overall as indicated by the HSE 2006. For instance the average male cholesterol was approximately 6 mmol/L at outset in the German programme, in comparison with the HSE 2006 male average of 5.3 mmol/L.

#### **Summary**



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The results of the German Cardiovascular Prevention programme indicate that a multifaceted strategy aimed at improving health knowledge, awareness, attitudes and behaviour at the population level can effectively reduce CVD risk factors.

### 3.1.5 The Minnesota Heart Health Program

The Minnesota Heart Health Program was a five year community-based educational intervention aimed at achieving reductions in cardiovascular disease risk factors, morbidity and mortality (5). The goal was also to develop and test the strategies being used with the intention that programme methods would continue to be implemented after the official intervention was complete (6).

#### **Target population**

Three communities were assigned (non-randomly) to receive the educational intervention and matched to three allocated control communities with respect to community size, city type (small/large/suburb) and distance of treatment to control city (5).

Treatment communities were:

- 1) Mankato and north Mankato (N=36,000)
- 2) Fargo and Moorhead (N=105,000)
- 3) Bloomington (N=91,000)

Control communities were:

- 1) Winona (N=28,000)
- 2) Sioux falls (N=85,000)
- 3) Roseville, Mayplewood and north St. Paul (N=75,000)

#### **Theory/conceptual model of intervention**

Social learning theory, Persuasion model, Diffusion of innovation, Locality development model and Social Planning model.

### **Intervention description**

A year before the start of the educational intervention, community analysis was undertaken in Mankato; part of one of the treatment communities. The aim was to study existing structures of leadership, local organisations and existing groups active in heart disease health promotion activities so that key people and groups could be identified for involvement in programme activities. After 2-3 years of community intervention in Mankato, educational programmes were introduced into the other treatment areas: Fargo-Moorhead and Bloomington.

A comprehensive description of interventions conducted in the Mankato district has been provided (7) and is described below. Details of interventions in other community areas are given in less detail (6). Although many aspects of the intervention appear to be uniform across treatment communities, some caution may be required in the assumption that interventions detailed below were implemented to the same extent.

The five-year health education was delivered using a number of different strategies: Involvement of community leaders and organisations, mass media, risk factor screening and education, adult education classes, schools-based youth and parent education, education of health professionals and community wide risk factor education campaigns. Interventions were varied in nature and offered at a range of venues (7).

Community leaders in the Mankato district, most interested in being part of the educational effort, were recruited to an advisory board to aid in coordinating community activities and to further recruit other community leaders to contribute to the health programme. From these people, three citizen task forces were set up who were active in developing and conducting annual community-wide educational campaigns in smoking cessation, physical activity and eating behaviour (7).

Local radio, television and newspapers, brochures and posters were used to raise awareness of CVD prevention and to provide information on available programmes and opportunities for involvement (7).

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Early on in the program, a risk factor screening education program was conducted over two years (1981-1983) at the Mankato Heart Health Centre (7). The aim was to provide 60-70% of the eligible population (25-74 year olds) with education related to smoking, cholesterol, hypertension and physical inactivity in relation to CVD. This type of screening programme was also implemented in other treatment communities (6). Systematic recruitment of people from all households was conducted and whole families invited to attend together. Measurements of blood cholesterol, height, weight, blood pressure, habitual physical activity and cigarette smoke exposure were made and, at each assessment station, a short video tape provided information on risk reduction. A discussion with trained staff provided tailored information on the relative risk of each participant and suggestions for health behaviour change (7).

Schools-based and community interventions for youths and parents were included with the rationale that health behaviours and attitudes are learned and developed early on and that youth may also play an important role in motivating and influencing community change (7). Intensive school projects were implemented in all high schools in Mankato aiming to improve knowledge, change behavioural norms, teach health-related skills, reinforce adoption of health behaviours and change expectations of appropriate health behaviour. Smoking prevention programmes were the major part of interventions in high schools whilst elementary schools focussed on diet and exercise programmes to promote behavioural change.

Education of health professionals (doctors, nurses, dentists, dieticians, pharmacists and health educators) was implemented to develop their understanding of CVD risks and the need for preventative practice. Aims were also to promote an attitude of acceptance and support towards their patients and a willingness to participate in the intervention effort (7). Staff were taught concepts, skills, procedures and counselling methods for risk assessment and reduction.

Risk factor campaigns were designed to focus the interest of the community on single risk factors over a defined period of time. This helped to give focus to addressing different areas and also facilitated evaluation of the effectiveness of different strands

of the educational programme. Five two-month campaigns were implemented over one year: general awareness of heart programme goals, smoking cessation, increasing physical activity, blood pressure control and improving diet, and these were recycled the following year to reinforce health messages. To support health-education messages, supermarkets and restaurants added labels to shelves and menus to identify more healthy food alternatives (7).

To achieve long-term community adoption of programme components, following the five-year intervention period, two years of reduced support were planned to implement transfer of resources and responsibilities to community leaders and organisations. The ultimate goal was to incorporate projects as permanent features of community institutions (7).

The appropriateness and effectiveness of particular components of the education programme was evaluated using surveys, focus groups and summative studies (some of which were randomised controlled trials). These gave important feedback to educators and also provided information on program participation rates and general programme awareness (5). Introduction of the educational programme was staggered between the three treatment cities in order to modify existing approaches before they were implemented in other intervention communities (5). Formative evaluation has continued to aid the design of future of heart health programmes and guide their implementation (8,9).

### **Accessibility**

Interventions were varied in nature and offered at a range of venues (for example schools (10,11), churches, work places, social organisations, shops). There is no information on the accessibility of written educational materials for those of low educational attainment or for non-English speaking individuals although non-English speaking individuals were excluded from the programme evaluation. Similarly there is no information on the accessibility of other intervention components (activities and presentations) for individuals from different ethnic backgrounds, non-English

speaking individuals or those for whom English is not a first language. However, from the description of the population it appears homogeneous with respect to ethnic mix.

### **Programme evaluation**

The effectiveness of the Minnesota Heart Health five-year intervention was assessed using annual, independent cross sectional surveys of 300-500 randomly selected participants. In addition, a cohort of individuals were studied at baseline and followed up at three subsequent time points during intervention (7).

Cross sectional surveys covered 37,812, 111,579 and 81,831 participants in community pairs I, II and III and the initial cohorts contained 25,075, 81,343 and 74,731 participants in community pairs I, II and III respectively (7).

Time series analysis was employed with adjustments for confounders (age, sex and educational attainment). Adjustments were also made for within-cluster correlation (6). Risk factors were monitored over a ten-year period, beginning pre-intervention and extending after the intervention period. Due to the staggered introduction of educational programmes in the three treatment cities, some communities provided numerous baseline survey data whilst others provided more post-intervention survey data (7).

### ***Participant selection/recruitment***

Participants aged 25-74 years living in treatment/control areas were eligible to take part in programme surveys (5). A staged neighbourhood cluster design was used to randomly select households for cross sectional survey measurements (6). Identified households were approached using a study invitation letter, subsequently followed up by a visit from a field worker who randomly selected an age-eligible individual. During the home visit, recruited participants underwent a survey to evaluate baseline demographic data as well as information on health beliefs, attitudes and behaviours, medical history and previous exposure to health messages (5). Additional physiological baseline information was subsequently obtained during participant

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visits to a survey centre. Those who spoke no English or were not considered mentally competent were excluded from participation (6). A cohort of participants selected at random from baseline cross sectional surveys, were followed up during the intervention period. Half of the cohort were invited back after two years and half after four years and the whole cohort were invited back at the end of the intervention period (6).

20,184 eligible adults, 87.9% of those selected, completed the home interview of which 18,062 participated in the survey centre protocol giving a total survey response of 78.7%. 300-500 people from each community participated in each population-based survey. 7,097 participants of the baseline cross sectional survey were selected for inclusion in the cohort. 14.9% refused to take part and 67.1% of the original cohort remained for participation for the final cohort survey (6).

### *Outcome measures*

Outcomes are reported as secular trend data for intervention groups versus controls, adjusted for age, gender and educational attainment (5,6). Morbidity and mortality surveillance was carried out on people 30-74 years old whilst other risk factors and related behaviours were measured in all participants (25-74y). Physiological and behavioural outcomes related to blood pressure, cholesterol, physical activity, smoking cessation, diet and CHD risk (constructed from age, systolic blood pressure, total cholesterol and cigarette smoking) were measured (5,6) as well as behavioural intentions, knowledge, attitudes and beliefs related to behaviour change objectives (7). Half of recruited subjects had dietary assessment by 24 hour dietary recall and the other half had physical activity assessment using standardised interview questionnaires (5).

Awareness of the treatment communities to individual educational campaigns was assessed as well as the extent of community leader involvement, extent of mass media coverage and participation rates by health professionals and the general population in educational classes (7).

## Results

Results for all treatment communities and all control communities were pooled (6,12). Regression analysis was used to assess changes in treatment and control groups for each outcome variable with adjustments made for gender, age and educational attainment (6). Results are presented for data obtained from cross-sectional surveys and from the cohort of people monitored during the intervention period.

### *Primary outcomes*

#### 1. Morbidity and mortality from coronary heart disease or stroke

There were no significant differences in treatment/control group changes for morbidity or mortality from coronary heart disease or stroke for cross sectional or cohort data (12).

#### 2. Cholesterol

There were no significant differences in treatment/control group changes for cholesterol levels for cross sectional or cohort data (6).

#### 3. Blood Pressure

There were no significant differences in treatment/control group changes for blood pressure for cross sectional or cohort data (6).

#### 4. BMI

There were no significant differences in treatment/control group changes for BMI for cross sectional or cohort data (6).

#### 5. CHD risk

There were no significant differences in treatment/control group changes for CHD risk for cross sectional or cohort data (6).

#### 6. Smoking

For smoking, there was no evidence of treatment effect in men but, in women, cross sectional data showed a significant net 1.4% per year reduction (CI/p value not

reported). For the cohort, despite reductions in smoking rates in treatment communities, due to concurrent reductions observed in control communities, there was no significant treatment effect in men or women (6).

#### 7. Physical activity

There was an increase in self-reported physical activity in both control and treatment communities but the treatment group appeared to show a greater rise compared to the control for both the cross sectional survey and the cohort (6). However, net differences and p values are not reported.

#### 7. Behavioural intentions, knowledge, attitudes, beliefs and CVD awareness.

Authors state that behavioural intentions, knowledge, attitudes, beliefs and awareness were measured but these are not reported in papers identified for this phase of the review.

#### 8. Community leader involvement

Results for the extent of community leader involvement, extent of mass media coverage and participation rates by health professionals in educational classes are presented for one participating district only, Mankato, comprising 38,000 inhabitants over a period of 3 years (7). 190 community leaders were involved long-term in the project as well as 118 other volunteers. 180,000,500 newspaper inserts and 123 newspaper stories were published. 47 television and radio public service announcements, 13 educational radio programmes and 15 television news stories were broadcast. 135,000 brochures and flyers were distributed.

Sixty five percent of physicians in Mankato attended professional education programmes.

#### **Limitations of the intervention and its evaluation**

The study was quality assessed and graded '-'.

#### *Limitations identified by author*



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Differences between treatment and comparison communities observed in the Minnesota Heart Health study were less than anticipated and generally accepted to be small, short-term and not statistically significant (6). Authors note that, in light of favourable secular trends, changes in treatment communities were not great enough to show an effect. Reasons for no effect offered were (6):

- 1) Outcomes of small, targeted projects did show favourable outcomes for treatment compared to control participants and problems in translation into the community setting may have been the reason for the lack of whole community effect.
- 2) Intervention components did not work
- 3) Intervention contained no effort or ability to change the broader social milieu and, since this has considerable impact on communities and their behaviours, interventions may not have had the required impact.
- 4) Control communities may have been contaminated. Data on exposure to education shows evidence for this since increases in control communities occur in parallel with the treatment group.

*Identified by reviewer*

Contamination is suggested by programme awareness surveys of treatment/control communities. Two years into the Mankato campaign, comparison communities appear to almost match treatment communities for awareness of smoking and physical activity health messages (7).

As for other studies, the use of cross sectional surveys is prone to bias resulting from migration of people into and out of control and treatment communities and the usefulness of cohort data is limited by selection bias and loss to follow-up. Also, as for many of these large population studies, extensive subgroup testing increases the likelihood of random significant results and reduces our confidence in real treatment effect.

Non-English speaking adults were excluded from the programme evaluation which affects the applicability of results to people from different ethnic groups.

Authors report that participants lost to follow-up had higher rates of smoking and lower cholesterol but, for these attributes, there was no evidence of differential attrition between treatment and control communities (6). However, at the final cohort survey those lost to follow-up in treatment communities were slightly leaner than those lost to follow-up in control communities (6).

### **Applicability**

The Minnesota Heart Health Programme was conducted in the USA and the population is described as of Northern European descent. The intervention was offered in a three locations described as economically stable and representing small towns, cities and large metropolitan areas. The description of the population suggests homogeneity with respect to ethnic mix which may limit applicability to the UK.

The programme was supported by dedicated resources during the evaluation phase, following which financial support was reduced and eventually stopped as activities were handed over to local organisations and community leaders. It is unclear what impact this would have on the programme's effectiveness.

### **Summary**

The Minnesota Heart Health Project has been held up as a successful programme on which to model future health promotion activities but there appears to be little evidence of positive health outcomes. Contamination of the comparison community may have reduced observed treatment effects but, given the intensity and duration of programme interventions, the low evidence of effectiveness is disappointing.

#### **3.1.6 The Norsjo Project**

The Norsjo project was launched in 1985 (13). The mortality pattern in Sweden during the 1970s showed that CVD was more common in the north than in the south of Sweden and that the municipality of Norsjo had an excess CVD mortality compared

to regional and national trends. The Norsjo project combined a population-based and individually oriented strategy to develop locally appropriate methods for the prevention of CVD. The risk factors targeted for intervention were mainly those known to have a major negative impact on cardiovascular health: high cholesterol, high blood pressure and smoking (13).

### **Target population**

Norsjo is 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 (13).

### **Theory/conceptual model of intervention**

The Norsjo project combined a population-based and individually oriented strategy to develop locally appropriate methods for the prevention of CVD. The influence of an underlying theory was not commented on.

### **Intervention description**

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 day-care 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. 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 of CVD was given more attention than had previously been given in local political debates. The Norsjo project also received a great deal of publicity in local as well as in national newspapers. On the whole, the preventative work in Norsjo was accomplished within the framework of the existing community organisations and with little additional financial support (13).

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 annually invited to complete a health provider survey focusing on the traditional CVD risk factors. 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 given individual 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 reassess their blood pressure and lipids at the health centre as they desired (13).

### **Accessibility**

The intervention concentrated on messages about lifestyle interventions and was delivered by a range of providers and at a variety of locations including leisure centres, social associations, food retailers, voluntary organisations and workplaces. There is evidence that the intervention was tailored to meet local needs. The intervention is described as including 'less usual' health education such as drama and music but no further information is provided.

There is no information on the accessibility of educational materials for those of low educational attainment, for those speaking different languages or for those with different cultural backgrounds. Participation in the evaluation of the Programme was high (70->90%) but younger men and the less well educated were relatively under-represented. No information is provided on uptake of the intervention by different population sub-groups.

### **Programme evaluation**

Assessment of the community intervention was achieved by a series of annual cross sectional surveys of all the inhabitants of Norsjo aged 30, 40, 50 and 60 years who were invited annually from 1985 to 1992 to take part in a risk factor screening and counselling programme. 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 (13).

Assessment of the risk factor screening and individual counselling programme was achieved by two additional cross sectional surveys of the cohort of individuals invited to participate in the 1986 programme. 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.

The two counties of Norrbotten and Vasterbotten in Northern Sweden served as the reference area. A total of 2,000 inhabitants aged 25-64 years were randomly selected from the population registers in 1986 and 1990 and invited to take part in a screening examination for cardiovascular risk factors (13).

## Results

Compared with the reference population (Northern Sweden MONICA Survey), the initial levels of total cholesterol were significantly higher in the study area for both men and women (13).

Results are shown for risk factor trends measured by cross sectional surveys during the eight years from 1985-92 (NB net significance was only presented for cholesterol. Other changes in treatment and control communities have not been compared and so net effect cannot be deduced) (13):

### 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 kg/m<sup>2</sup> for men ( $p<0.05$ ) and from 25.0 to 25.5 kg/m<sup>2</sup> 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.

### 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.

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.

### **Limitations of the intervention and its evaluation**

The study was quality assessed and graded '+’.

#### *Limitations identified by 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.

The municipality of Norsjo forms part of the wider region of Northern Sweden which served as the control population. Since control and treatment areas were likely to have been in close proximity, it is possible that the programme may have had some spill-over effects into the control area.

### **Applicability**

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 typical CVD risk profile of the UK population.

Cholesterol levels were higher at baseline in this programme (7.1 mmol/L) than currently exist on average in England at present. However, levels of smoking are similar (25% male; 19% female).

### **Summary**

Although net data for control/treatment comparisons is not fully reported, the results of the study indicate that a community CVD intervention that actively involves the

health care sector may have a positive impact on reducing CVD risk factors. Individual counselling appeared to bring about an earlier reduction in some of the risk factors associated with CVD but did not appear to increase the amount of risk reduction overall.

### 3.1.7 The North Karelia Project

The North Karelia project was launched in 1972 in response to a petition from the elected representatives of the local population for urgent help to reduce the high mortality and morbidity from CVD in their county. It had been found that the incidence of CHD was greater in Finland than any other country. Also, within Finland, regional differences had been observed in CVD mortality and morbidity rates, with the highest rates being seen in North Karelia (14).

The North Karelia programme's main objective was to reduce mortality and morbidity rates from CVD amongst the whole population in that area, but particularly in middle-aged men. The main emphasis was on primary prevention through a general reduction in the level of well-established risk factors such as smoking, high serum cholesterol levels and high blood pressure (14).

A baseline survey of the main CVD risk factors was undertaken in 1972 and confirmed a high general level of smoking, cholesterol concentration, and blood pressure in North Karelia. Approximately 52% of men (aged 25-59 years) were current smokers; their mean serum cholesterol was 7.0mmol/l; and mean casual blood pressure was 147/91mmHg (23% had a systolic blood pressure of at least 160mmHg; 34% a diastolic pressure of at least 95mmHg; and in 19% both pressures were above these values) (15).

Given the high general level of the known CHD risk factors and the behavioural and environmental backgrounds of these factors, a community-based programme was felt necessary. The adopted strategy aimed to: 1) influence the combined value of the risk factors in the total population and the whole community; 2) make a 'community



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diagnosis' of the baseline information in order to design appropriate measures of strategic importance; 3) carry out a systematic programme and reallocate the existing service resources to control this modern epidemic; 4) integrate the activities of the existing health and social services in the community and have the full participation of the community; and 5) have a continuous follow-up of progress and feedback to the community (15).

### **Target population**

North Karelia is a large mainly rural county in eastern Finland with a population of approximately 180,000. The county of Kuopio, a neighbouring county in Eastern Finland (population approximately 250,000) was chosen as a control area because of its close similarity to North Karelia in terms of mortality and morbidity from CVD and geographical, occupational, economic and social features (15).

### **Theory/conceptual model of intervention**

PRECEDE model, Social learning theory, Persuasion model, Diffusion of innovation, Belief-attitude model.

### **Intervention description**

A comprehensive programme was integrated into the health and social services of the county drawing on the following elements: 1) Information was given to the public, especially about the practical activities to reduce the risk factors being carried out in the community, by means of newspapers, radio, leaflets, posters, and stickers, and at health education meetings and public campaigns, schools, and workplaces, 2) Organisation of services by systematically integrating the programme into the existing services and creating new services when necessary, for example by making use of basic community health services, special supporting services (i.e. for smoking cessation), and services of other organisations, 3) Training personnel, especially for the practical tasks of the programme. Health personnel, special workers, teachers, voluntary workers, and community leaders received training, 4) Environmental

services were set up to support the desired life style for example with regard to smoking restrictions, the availability of low-fat dairy and meat products, vegetable production, and promotion of sales of health articles in shops and 5) Internal information services to support the practical activities for example by patient cards and files, registers (of hypertension, myocardial infarction and stroke), follow-up surveys and other information (15).

After the initial five years (1977) the project, as a national demonstration programme, became actively involved in national efforts to reduce CVD risk factors. After ten years (1982) the programme was enlarged to include a more integrated prevention of major non-communicable diseases and promotion of health. In 1987, upon completion of the 15 year survey, a decision was made to intensify CHD prevention, focusing particularly on action to reduce cholesterol levels and the incidence of smoking (16).

### **Accessibility**

The intervention was offered at a variety of locations including schools, workplaces and health providers. No information is provided on the accessibility of educational materials for those speaking different languages, for those of low educational attainment or for those with different cultural backgrounds. The intervention was integrated into existing services. Personnel were specially trained to deliver programme components and feedback was given to providers. There are some gender differences in outcomes (cholesterol and smoking prevalence decreased in men but not women) which may be an indicator of the acceptability of the intervention in these population sub-groups. No information is provided on uptake of intervention by different population sub-groups.

### **Programme evaluation**

The effects of the programme on risk factor reduction were assessed by large, independent, cross sectional surveys carried out in North Karelia and the control area (Kuopio) at baseline , pre-intervention (1972) and five (1977), ten (1982) and fifteen

years (1987). A proportion of the baseline survey also participated in the five-year survey. This cohort comprised 339 men and 394 women studied in both 1972 and 1977.

### *Participant selection*

Representative random samples were drawn from the populations of the two counties using the national population register (17). An overview of the number of subjects surveyed in the population age range of 30-59 years and the participation rates in the four main surveys is provided in the table below:

**Table 3 Sample size (n) and participation rates (%) in population surveys (30-59 years old population)**

Year	North Karelia		Kuopio County (control area)		South-west Finland	
	Men n (%)	Women n (%)	Men n (%)	Women n (%)	Men n (%)	Women n (%)
1972	1959 (94)	2056 (96)	2918 (91)	2949 (94)		
1977	2063 (87)	2020 (91)	2933 (89)	2996 (92)		
1982	1599 (77)	1511 (84)	1459 (83)	1143 (88)	1506 (82)	1487 (87)
1987	1521 (79)	1485 (87)	762 (82)	744 (87)	756 (77)	761 (83)

From: Puska et al. (1989) The North Karelia project; 15 years of community-based prevention of coronary heart disease (18)

### *Outcome measures*

Changes in risk factors were examined by deriving the difference in absolute change in baseline to specified follow up between intervention and control groups (net change) with 95% CI. Analyses were adjusted for age, sex and risk factor levels. Outcome measures included CVD morbidity and mortality, the risk factors smoking

prevalence, cholesterol levels, blood pressure and CHD risk based on these 3 risk factors (15).

## Results

### *Primary outcomes*

Cross-sectional surveys:

There were major changes in the levels of the three risk factors in North Karelia during the first ten years (1972-82), and substantial but statistically significantly smaller changes in the control area (19):

#### 1. Smoking

The difference in reported daily smoking from baseline to 1977 was significantly greater in North Karelia in comparison with the control area ( $p < 0.01$ ). The programme net effect was significant for men (difference in absolute change between intervention and control 15%,  $p < 0.01$ ) but not for women (12%, NS). During 1977-82 a further reduction took place amongst men that was greater in North Karelia and the net reduction was 28% ( $p < 0.001$ ). Amongst women, smoking increased during 1977-82 in both areas, but more so in the control area and the net reduction in North Karelia amongst women during 1972-82 was 14% (NS).

#### 2. Cholesterol

The programme effect on reducing mean serum cholesterol concentrations during 1972-77 was significant ( $p < 0.001$ ). Analysed by sex, the net effect was significant amongst men (4%;  $p < 0.001$ ) but not in the whole age range of women (1%; NS). During 1977-82 there was a net reduction of 3% amongst men ( $p < 0.001$ ) and 1% amongst women (NS).

#### 3. Blood pressure

The programme effect on both mean systolic and diastolic blood pressure during 1972-77 was highly significant amongst men and women ( $p < 0.001$ ). The net reduction of systolic blood pressure was 3% amongst men and 5% amongst women, and that of diastolic blood pressure 3% amongst men and 4% amongst women. During 1977-82

the systolic blood pressure levels remained close to those in 1977 amongst both men and women. The mean levels of diastolic blood pressure for men and women were lower in 1982. The net reduction in North Karelia became smaller during 1977-82 but, for the whole period (1972 -82), it remained significant for both sexes ( $p < 0.05$ ).

An overview of the relative net reductions in the risk factor means in North Karelia relative to Kuopio in 1972-77 and 1972-82 is provided in the table below:

**Table 4 Relative net reductions<sup>a</sup> in north Karelia relative to Kuopio in risk factor means in men and women aged 30-59 years in 1972-77 and 1972-82 (values are percentages)**

	Men		Women	
	1972-77	1972-82	1972-77	1972-82
<b>Daily smoking</b>	15 (10)**	28 (11)***	12 (27)	14 (38)
<b>Serum cholesterol</b>	4 (1)***	3 (2)***	1 (2)	1 (2)
<b>Systolic blood pressure</b>	3 (1)***	3 (1)***	5 (1)***	5 (1)***
<b>Diastolic blood pressure</b>	3 (1)***	1 (1)*	4 (1)***	2 (1)*

\* $p < 0.05$ . \*\* $p < 0.01$ . \*\*\* $p < 0.001$ .

<sup>a</sup> $[(\text{North Karelia, 1982/77-1972}) - (\text{Control area, 1982/77-1972})] / \text{North Karelia 1972}$  with 95% CI. Statistical significance based on two way ANCOVA with covariance adjustment for age.

From: Puska et al. (1983) Change in risk factors for coronary heart disease during 10 years of a community intervention programme (North Karelia project) (19)

From 1982-87, the changes in the levels of the three risk factors in North Karelia, Kuopio (control area) and South-West Finland were small. Amongst men, the smoking rates in North Karelia in 1987 were lower than elsewhere but the serum

cholesterol and blood pressure levels were still high and higher than in South-West Finland (17). An overview of the level of risk factors in North Karelia, Kuopio county and South-West Finland is provided in the table below:

**Table 5 Level of risk factors in North Karelia, Kuopio County and South-West Finland from 1972 to 1987 (30-59 years old population)**

	Current smokers			Serum cholesterol			Diastolic blood pressure		
	%			mmol/l			mmHg		
	North Karelia	Kuopio county	South-West Finland	North Karelia	Kuopio county	South-West Finland	North Karelia	Kuopio county	South-West Finland
<b>Men</b>									
1972	52	50		7.09	6.85		92.0	93.3	
1977	44	45		6.68	6.74		88.6	92.6	
1982	36	42	39	6.30	6.26	6.06	86.7	88.9	86.7
1987	36	41	38	6.25	6.20	6.03	88.1	89.1	85.9
<b>Women</b>									
1972	10	11		6.98	6.82		92.4	91.3	
1977	10	12		6.56	6.48		86.3	88.4	
1982	15	15	22	6.11	6.01	5.93	84.5	84.8	81.0
1987	16	15	23	5.98	5.86	5.80	83.2	83.9	81.9

From: Puska et al. (1989) The North Karelia project; 15 years of community-based prevention of coronary heart disease (18)

#### 4. Mortality and morbidity from CHD

Changes in the incidence of disease were assessed in the programme using an analysis of the available mortality and morbidity data from North Karelia, the control area and the whole country (18). The mortality trends were analysed based on national mortality data since 1969 thus three pre-programme years were included. Age adjusted rates for men aged 35-64 were used. Figure 2 illustrates the decline in age-adjusted CHD mortality rates amongst men in North Karelia and the rest of Finland after the three pre-programme years based on means of three consecutive years. The graph indicates mortality rates in North Karelia declined steeply in the latter part of the 1970s and early 1980s.

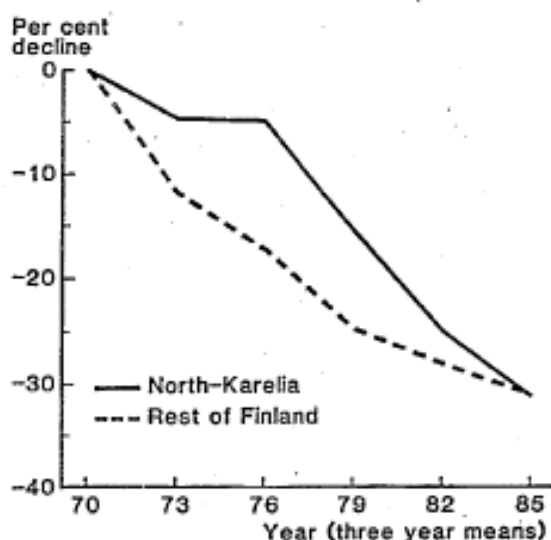


Figure 2 Per cent decline in CHD mortality of 35-64 year old men in North Karelia and rest of Finland

From: Puska et al. (1989) The North Karelia project; 15 years of community-based prevention of coronary heart disease (18)

### Cohort study

In the cohort of subjects surveyed in both 1972 and 1977, there were no major baseline differences in serum cholesterol, systolic or diastolic blood pressure, or in the amount of daily smoking. The 1977 follow-up indicated (14):

1. The mean intra-individual change in daily smoking did not differ significantly between the areas either amongst men or women who were smokers at baseline.
2. The mean serum cholesterol amongst men decreased 3% in the programme area and increased 2% in the control area (net significance not reported). The mean serum cholesterol in women declined in both areas.
3. Systolic blood pressure decreased in the programme area in both men (2%) and women (5%), whereas it increased slightly in the control area in men (1%) and in women (2%). Diastolic blood pressure decreased 1% in men and 5% in women in the programme area but increased 2% in men and fell 1% in women in the control area. The mean intra-individual change differed significantly both by area and by sex.

### **Limitations of the intervention and its evaluation**

The study was quality assessed and graded '+’.

#### *Limitations identified by authors*

The results at five years indicate that, in addition to the observed changes in North Karelia, some favourable changes also occurred in the control area. It is difficult to say whether these changes reflect national trends, whether the programme was already contributing to national trends, or whether the programme in North Karelia had some spill-over effects into the local control community. Certainly after the initial five years (1977) the project, as a national demonstration programme, became actively involved in national efforts to reduce activities that were known risks, thereby influencing the control area population.

#### *Limitations identified by reviewer*

Allocation of the intervention and control populations was not random and there may have been selection bias. However as the control area was more affluent than North Karelia the impact of any possible bias is more likely to negate rather than enhance the effect of the programme.



### **Applicability**

North Karelia is a rural county in eastern Finland which is described as having low socio-economic status, high unemployment, income based on farming and forestry and scarce medical and other services. Risk factors for CVD in the North Karelia population were high at the outset of the programme; for example 52% of men were smokers compared to 24% of males in England (HSE 2006), and the mean serum cholesterol of men was 7.0 mmol/l compared to 5.3 for males in England (HSE 2006). The population of North Karelia was highly motivated and the programme was set up following a petition organised by members of parliament and the local population.

### **Summary**

The North Karelia project shows favourable changes in smoking rates, total cholesterol and blood pressure and may be considered the most successful programme of its type. The high risk community addressed and novelty of intervention may have contributed to effects but efforts to change both environmental and behavioural influences were likely to have played a large part in ultimate project success.

### **3.1.8 OXCHECK**

The OXCHECK project was initiated in 1982 with the aim of using nurse health checks to reduce risk factors for cardiovascular disease.

#### **Target population**

The intervention was carried out in five general practice surgeries in Luton and Dunstable. This area was selected for its mixed urban/suburban setting, presence of heavy/light industry and variation in patient demographics (20). All practices in Luton with greater than 10,000 patients were approached (N=5) and three practices agreed to take part. Two additional practices with approximately 7,500 were then recruited, one in Luton and one in Dunstable (20). No control practices were used.

#### **Theory/conceptual model of intervention**

The intervention was based on a patient-centred communication model (20).

### **Intervention description**

Nurses at participating practices were identified to carry out standard protocol health checks. Study related activities occupied approximately 50 hours of nurse time per week and nurses received specific health check training. They attended a two-day induction course, an annual study day and a monthly evening training session to maintain and develop their skills and knowledge. Nurses were instructed as to the importance of follow-up for patients identified with multiple CVD risk factors and the use of a patient-centred communication model (20).

Health checks included a medical history, lifestyle questionnaire and structured dietary assessment and took approximately 45-60 minutes. The medical history included details of personal and family history of heart disease, stroke, hypertension, diabetes and cancer and the lifestyle questionnaire detailed smoking, exercise rates, alcohol consumption and habitual diet using a food frequency chart. Blood pressure, height and weight were measured and blood was taken for subsequent analysis of blood cholesterol level. Overall risk was assessed by nurses from a chart showing the interactive effect of blood pressure, smoking and blood cholesterol. Patients were given advice on risk factor reduction with the aim of discussing patients' views before negotiating priorities and goals for risk reduction (20).

Where patients showed signs of high blood pressure or hyperlipidaemia, follow-up examinations (taking 10-20 minutes) for repeat measurements were arranged but, otherwise, follow-up was arranged depending on agreement between the nurse and patient. Follow-up visits included re-measurement of height, weight, blood pressure, serum cholesterol and smoking habit (cessation confirmed by serum cotinine concentration) and assessment of dietary fat intake (20).

### **Accessibility**

The intervention was offered in primary care practices and initial health checks took between 45 and 60 minutes, both factors which may limit accessibility. No

information was provided on distance to be travelled or whether participation was affected by distance from facility. Nurses delivering the programme were trained in person-centred counselling but no information is given about whether consideration was given to cultural diversity when recruiting nurses to deliver the intervention. Similarly, there is no information on the accessibility of educational materials for those of low educational attainment, for those speaking different languages or for those with different cultural backgrounds.

Negotiation about lifestyle change was on the basis of a risk assessment. Adequate communication of risk to patients requires a level of numeracy which may limit the effectiveness of this approach to certain groups. Authors report difficulty in recruitment of patients: 'at best 2/3 of the target population received a health check and about half attended for an initial check and the agreed follow up'. Those judged to be at higher risk were less likely to attend and men attended follow ups less frequently than women. No information is given on uptake by other population groups.

### **Programme evaluation**

The OXCHECK study compared changes in patient risk factors between those who had previously attended a health check (treatment group) and those that had not (control group). Comparisons were made for participants at one year and three years after their initial health check. Rechecks for the intervention group were arranged depending on further randomisation. Figure 3 below shows the overall study design and the numbers of participants at each stage in the process:

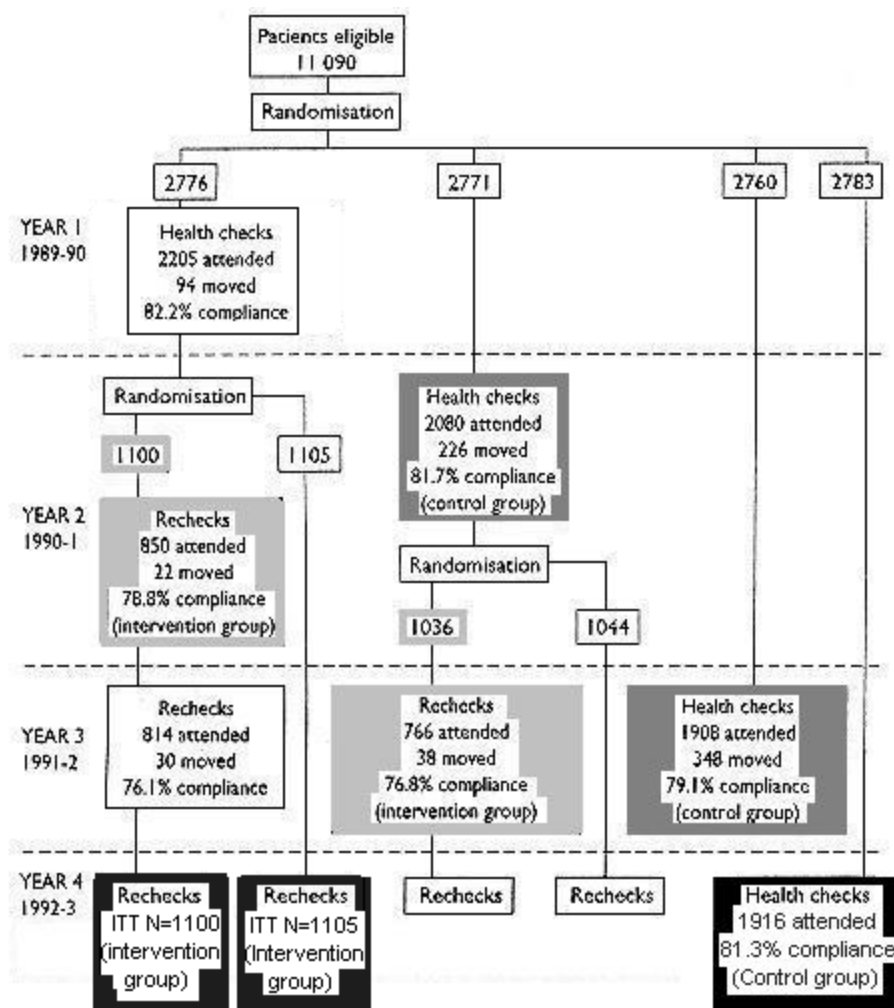


Figure 3 Health checks and rechecks in treatment and control groups in the OXCHECK study (ITT – Intention to treat population) Adapted from (21) and (20)

Interventions appear fairly complex but only two effectiveness comparisons are made:

- 1) One year results: Measurements of patients who had previously undergone one screening (intervention group) compared with patients who had not undergone previous screening (control group) (1). The study groups are highlighted in figure 3 above with the treatment group samples in light grey (■) and the control group samples in darker grey (■). Results from the two treatment groups receiving health checks in year one (N=1,100) and two (N=1,036) are combined to give intervention group N=2,136. Results from the two groups receiving their first health check in year two (N=2,080) and three (N=1,980) were combined to give the control group N=3,988.

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2) End of study results: The results at year four (three years after initial health check) for patients who had undergone previous screening in year one of the study (treatment group) (■ in figure 3) are compared with patients who had received no previous health checks at year 4, (■ in figure 3). Patients in the treatment group may have received rechecks since the initial health check (N=1,100) or have only undergone one previous health check (N=1,105) but were combined to give the final intervention group N=2,205 and compared with the control group (N=1,916).

Analysis was done on an intention to treat basis (ITT). All patients randomised to a particular health check are included in the analysis. Where participants dropped out, their outcome measures were assumed to remain constant from the last time of measurement (20,21).

#### *Participant selection/recruitment*

All patients registered at the five participating GP surgeries aged 35-64 years were identified from a computerised list and sent an initial questionnaire to record demographic data and baseline characteristics. Patients responding were randomised by household in blocks of four to be offered a health check in year one, two, three or four of the study period. All respondents from the same household were allocated health checks in the same year of study (21).

Questionnaires were sent to 17,965 patients of whom 11,090 responded (response rate 80.3% after adjustments). Response rates and rates of drop-out are shown in figure 3.

#### *Outcome measures*

Physiological outcomes of blood cholesterol level, systolic and diastolic blood pressure and BMI were measured as well as behavioural outcomes relating to smoking, physical exercise and dietary habits.

## Results

### *Primary outcomes*

At **year one** of the study, there were a number of significantly favourable outcomes in physiological measurements for the intervention compared to the control group (results shown for intervention versus control groups respectively) (21):

#### 1. Cholesterol

Lower total cholesterol (mmol/l) (6.02 vs. 6.16 respectively, 0.14 difference (95% CI 0.08 to 0.20)) and a lower percentage of patients with total cholesterol  $\geq 8.0$ mmol/l (4.8 vs. 7.6, 2.7 difference (95% CI 0.0 to 1.7)).

#### 2. Blood pressure

Lower systolic and diastolic blood pressure (mmHg) systolic: 124.4 vs. 127.6, 3.2 difference (95% CI 2.2 to 4.3), diastolic: 74.6 vs. 76.4, 1.8 difference (95% CI 1.2 to 2.4) and a lower percentage of patients with diastolic BP  $\geq 100$  mmHg (2.6 vs. 3.4, 0.9 difference (95% CI 0.0 to 1.7)).

#### 3. BMI

Lower BMI (kg/m<sup>2</sup>): 25.68 vs. 25.84, 0.16 difference (95% CI -0.06 to 0.38), and a lower percentage of patients with BMI  $\geq 30$  kg/m<sup>2</sup>: 12.4 vs. 14.0, 1.6 difference (95% CI -0.2 to 3.4).

#### 4. Smoking

Unlike other behavioural outcomes, the intervention did not appear to impact on smoking. The percentage of people smoking any form of tobacco at least daily was similar amongst the intervention and control groups (27.6 vs. 27.2 respectively, 0.5 difference (95% CI -2.8 to 1.9)) and there was no significant difference in the percentage of patients reporting smoking cessation in the previous year amongst the intervention and control groups (4.1 vs. 5.1 respectively, 1.0 difference (95% CI -0.9 to 3.0)).

At year one, the intervention also had a positive impact on behavioural change with significant improvements seen amongst the intervention compared to the control group (21):

#### 5. Physical activity

The percentage of participants exercising vigorously less than once per month was lower in the intervention compared to the control group (65.3 vs. 70.4, 5.1 difference (95% CI 2.7 to 7.6)).

#### 6. Diet

The percentage of participants reporting drinking mainly full cream milk and reporting using mainly butter or hard margarine on bread was lower (milk: -26.3 vs. 38.2, 11.9 difference (95% CI 9.5 to 14.3); butter: -20.3 vs. 31.9, 11.6 difference (95% CI 9.3 to 13.8)) whilst consumption of polyunsaturated fatty acids (PUFA), measured by PUFA score was higher (8.7 vs. 8.3, 0.4 difference (95% CI 0.3 to 0.5)).

At the **final study assessment**, three years after the initial health checks, many of the physiological outcomes continued to be favourable for the intervention. Significantly better outcomes were detected in the intervention compared to the control group (results shown for intervention vs. control groups respectively) (20):

#### 1. Cholesterol

Lower total cholesterol (mmol/l): 5.99 vs. 6.18, 0.19 difference (95% CI 0.12 to 0.26); and a lower percentage of patients with total cholesterol  $\geq 8.0$  mmol/l: 3.9 vs. 7.8, 3.9 difference (95% CI 2.4 to 5.3).

#### 2. Blood pressure

Lower systolic and diastolic blood pressure (mmHg), systolic: 126.5 vs. 129.0, 2.5 difference (95% CI 1.3 to 3.7); and diastolic: 75.7 vs. 77.2, 1.5 difference (95% CI 0.8 to 2.2); and a lower percentage of patients with diastolic BP  $\geq 100$ mmHg (3.4 vs. 4.5, 1.1 difference (95% CI -0.1 to 2.3)).

#### 3. BMI

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Lower BMI (kg/m<sup>2</sup>): 25.88 vs. 26.26, 0.38 difference (95% CI 0.12 to 0.64); and a lower percentage of patients with BMI  $\geq$ 30 kg/m<sup>2</sup> (14.3 vs. 15.9, 1.6 difference (95% CI -0.6 to 3.8)).

#### 4. Smoking

As for assessments for one year following the health check, at three years the intervention did not appear to impact on smoking. The percentage of people smoking any form of tobacco at least daily was not different amongst the intervention and control groups (25.0 vs. 26.4 respectively, 1.4 difference (95% CI -1.3 to 4.1)). Alcohol use (N) was also not different in intervention and control groups (229 vs. 210, 0.6 difference (95% CI -1.3 to 2.5)).

At the final assessment, positive behavioural changes were also maintained, with significant improvements for the intervention compared to the control group (20):

#### 5. Physical activity

The percentage of participants exercising vigorously less than once per month was lower (67.6 verses 70.9; 3.3 difference (95% CI 0.5 to 6.1)).

#### 6. Diet

The percentage of participants reporting drinking mainly full cream milk and reporting using mainly butter or hard margarine on bread was lower (milk- 23.1 verses 30.6; 7.5 difference (95% CI 4.8 to 10.3), Butter- 21.9 verses 30.7; 8.7 difference (95% CI 6.0 to 11.4)).

### **Limitations of the study**

The study was quality assessed and graded '+’.

#### *Limitations identified by author*

The investigators highlight that there may have been contamination amongst the control group. This may have been the case but comparisons between the control group in study one and three show that, at three years, the control group generally had less favourable physiological and behavioural outcomes. These groups contain



different participants so a direct comparison cannot be made but the absence of a more healthy control group to some extent suggests that contamination, if present, was likely to have been minimal.

Another limitation identified by investigators was of the loss of patients to follow-up. Primary analysis (and the results presented here) though was based on data from the intention to treat population and included conservative 'no change' outcomes for patients dropping out of the study.

The authors noted that the improvement in blood pressure in the intervention group may have been due to an "accommodation" effect. The machine used to measure blood pressure may have been daunting to participants resulting in increased rates of blood pressure on first measurement. During subsequent visits "accommodation" may have resulted in participants feeling more comfortable with having their blood pressure checked resulting in the observed lower comparative measurements.

Although the intervention appears to have had short term (3 year) effects, in order to gauge its impact in the longer term (i.e. in terms of reduced CVD morbidity and mortality) follow-up would need to be sustained for several years.

#### *Limitations identified by reviewer*

This was a generally well conducted trial of an applicable intervention. Many issues raised by authors were actually addressed to some degree in the study (e.g. loss to follow-up addressed by use of ITT).

#### **Applicability**

OXCHECK was conducted in Luton and Dunstable, areas selected for their mixed urban/suburban setting, presence of heavy/light industry and variation in patient demographics. Within the limits of the information provided, the results appear generally applicable to the UK population in those aged 35-64 years, although cholesterol levels at baseline and smoking prevalence in the control groups (6.1 mmol/l & 27% respectively) were slightly higher than those indicated by the HSE 2006.

## **Summary**

The OXCHECK programme was well conducted and appears to show modest, positive effects following patient health checks for all outcomes except smoking. Consistency suggests that effects were unlikely to have been due to chance alone and screening may be an influential tool to identify and modify CVD risk factors.

### **3.1.9 The Pawtucket Heart Health Program**

The Pawtucket Heart Health Program aimed to test whether community action via volunteer recruitment and deployment can change CVD knowledge, risk factors and disease related morbidity and mortality (22). This eleven year campaign involved approximately nine years of intervention activities and aimed to produce community change by utilising social networks and person-to-person spread of behavioural change messages.

#### **Target population**

An intervention city was selected from nine cities meeting criteria on size and population stability. The treatment community was Pawtucket in Rhode Island, a city of 71,204 inhabitants. Pawtucket citizens had a median age of 33.6 years, a relatively low average level of education and income, and predominately manufacturing-based employment (23). It was a stable population with 69% of the sampled population being born in Rhode Island. Pawtucket was matched with a control community (name withheld for confidentiality) and, although this was a larger population (n=98,478) there were few demographic or social differences (apart from female smoking rates (24)).

#### **Theory/conceptual model of intervention**

The conceptual model for the Pawtucket Heart Health Program was based on principles of social learning (22), a key theme of this theory being the spread of behavioural change from a person already influenced by programme activities, to other people in their social network. The goal of this approach was that behaviour

change would diffuse throughout the intervention community. Despite this early goal, education strategy somewhat changed during the course of the programme to encompass targeting of the whole community, an approach similar to other Heart Health community approaches documented in this report.

### **Intervention description (22)**

The initial intention was that activities to promote behavioural change were to be implemented primarily through social networks. Programmes and activities were to provide participants with skills for smoking cessation, control of blood pressure, dietary change, weight control, dealing with stress and increasing physical activity. This was done on an individual, small-group and organisational level and participants were encouraged to not only modify their own risk-factor behaviours, but also to encourage a change in behaviours of other people in their social networks.

In the first 11 months of the programme, interventions were focussed on local organisations such as worksites, churches and schools, the rationale being that risk-factor behaviour change would be spread throughout the organisation via social networks. It was also hoped that communication between people in different organisations might draw interest and promote the adoption of programmes in those sites.

However, during this phase of the intervention, it became apparent that the approach was slow and labour intensive with low participation. In the second intervention phase, the decision was therefore made to adopt other whole community interventions such as risk-factor change programmes. Interventions aimed to promote smoking cessation and weight loss. The 'Up In Smoke' programme and community weigh-in, were promoted throughout the community and provided the most successful elements of the programme so far. With the addition of these community activities, participation in organisation-based programmes increased. For activities held in organisations, although the establishment of group risk-factor programmes remained the main focus, other wider projects such as screenings and promotions were offered.

In this second phase it became apparent that public awareness of the Heart Health programme was low and, in order to increase programme visibility, a media campaign using billboards, bumper stickers, placards, mailings, newspaper adverts and public service announcements was introduced. Additionally, continuing risk-factor programmes were also promoted through newspapers, flyers and radio announcements. These activities lead to increasing interest of local organisations and receptivity to Heart Health programme staff for the introduction of new projects. Subsequently, the organisation-based approach became secondary to community-level programmes such as community risk-factor screenings, quit-smoking contests and monthly weigh-ins.

In the third intervention phase new activities focused on community projects such as the 'Heart Check' multiple risk-factor screening campaign. This incorporated direct patient counselling, education and follow-up and was used as a vehicle for recruitment into risk-factor change programmes. During this phase there was increasing interest in Heart Health activities by organisations and individuals and increasing participation in group programmes.

In order to track and monitor programme activities, information regarding intervention activities, participation rates and response to given projects was recorded. This information could be used to modify the direction of the programme and is also useful for future programme implementation.

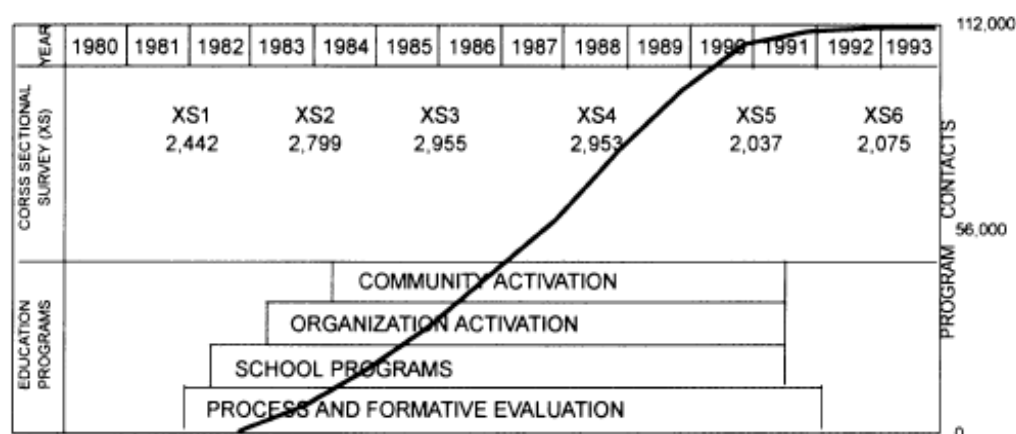
### **Accessibility**

Components of the interventions were delivered in varied settings, (for example schools, churches, work places, social organisations, shops) and local volunteers were recruited to deliver a culturally relevant approach to the programme. Materials and programmes designed for citizens with low literacy skills were emphasised (25). No information is provided on uptake by different population groups but characteristics of survey respondents suggests that they were representative of the target population with respect to country of birth (24,25).

### **Programme evaluation**

Programme evaluation is described as quasi-experimental and comprised six biennial independent random cross sectional surveys at baseline (pre-intervention) and at two year intervals for the next ten years as shown in figure 4 below. Surveys 1 and 2 were used as an estimate of baseline, surveys 4 and 5 to represent the peak of the intervention and survey 6 to represent post-intervention.

Figure 4 Design of the Pawtucket Heart Health Program (25)



Note. The cumulative number of education program-person contacts is shown in the superimposed curve related to the right ordinate.

Additional to the cross-sectional surveys, a cohort of participants were recruited from surveys one and two (58% of survey participants) (24) for re-examination approximately 8.5 years later. A formative and process evaluation system was used to detect confounders operating at local or national level (24).

#### *Participant selection/recruitment*

People aged 18-64 years at the time of first survey contact were eligible to take part. The cross sectional surveys, each with an independent sample, were conducted over a minimum one year time period to minimise confounding by seasonal differences. Batches of six to ten households were selected randomly from a complete list and a single age-eligible resident was selected for recruitment. Interviews were then conducted to establish socio-demographic and health-behavioural information as well as knowledge concerning cardiovascular disease risk. Physiological measurements were made for blood pressure, height and weight.

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Approximately 1,255 people participated in each cross-sectional survey from both the treatment and control sites (total 2,037-2,955 per survey) and the overall average response rate for the six surveys was 68%. The cohort, recruited from the first two cross-sectional surveys, consisted of 2,925 of 5,241 participants (58% follow up) (25).

### *Outcome measures*

For cross sectional surveys, mean values for each survey are compared between control and treatment cities. Also, for both the cross-sectional and cohort samples, changes from baseline for the treatment site were compared to changes from baseline in control communities. Outcome measures were adjusted for differences in age, sex, educational level and place of birth occurring between intervention and control groups and over time using ANOVA. Significance tests were constructed to accommodate the effects of clustering within city and survey. Measurements were made for total cholesterol, systolic and diastolic blood pressure, smoking, BMI, and projected CVD. Sub-group analysis of data was undertaken with regards to sex, age and education (25).

## **Results**

### *Primary outcomes (25)*

#### **Cross sectional surveys**

Results were presented as net differences in absolute change between treatment and control from baseline (surveys 1 and 2) to time of peak intervention (surveys 4 and 5; 7 – 9 years), and from baseline (surveys 1 and 2) to one year post intervention (survey 6; 11 years).

#### **1. Total cholesterol**

Total cholesterol (mg/dl) fell in both treatment and control groups at peak intervention but there was no significant treatment effect (differences in absolute change between treatment and control +0.29; SE 2.08, p=0.890). The same pattern was seen post-intervention, with further total cholesterol reductions in both groups but no

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net treatment effect (differences in absolute change between treatment and control -0.33; SE 2.85,  $p=0.907$ ).

## 2. Blood pressure

At peak intervention, systolic blood pressure (mmHg) increased in the control group and increased to a lesser extent in the treatment group but the between group difference was not significant (differences in absolute change between treatment and control -0.54; SE 1.11,  $p=0.627$ ). At post-intervention, a different pattern was evident, with reductions in both groups but there was no net treatment effect (differences in absolute change between treatment and control -1.39; SE 1.29,  $p=0.281$ ).

At peak intervention, diastolic blood pressure (mmHg) increased in both groups but to a lesser extent following intervention but there was no significant treatment effect (differences in absolute change between treatment and control -1.08; SE 0.81,  $p=0.18$ ). The same pattern was seen post-intervention, but still no net treatment effect was evident (differences in absolute change between treatment and control -0.84; SE 0.94,  $p=0.373$ ).

## 3. Smoking

Rates of smoking (%) fell in both treatment and control groups at peak intervention but there was no significant treatment effect (differences in absolute change between treatment and control +0.34; SE 2.0,  $p=0.867$ ). The same pattern was seen post-intervention, with further reductions in smoking rates in both groups but no net treatment effect (differences in absolute change between treatment and control +2.60; SE 2.58,  $p=0.315$ ).

## 4. BMI

Body mass index ( $\text{kg}/\text{m}^2$ ) increased in both treatment and control groups at peak intervention but there was no significant treatment effect (differences in absolute change between treatment and control -0.11; SE 0.24,  $p=0.645$ ). Post-intervention, there were further reductions in BMI in both groups and, at this time point, there was a net

treatment effect (differences in absolute change between treatment and control -0.62; SE 0.31, p=0.042).

#### 5. Projected CVD rates

Projected rates of CVD (rates/10,000 people within 10 years), calculated from risk factor levels, decreased in both groups at peak intervention but this reduction was greater in the treatment group and approached significance (Risk ratio 0.8; 95% CI 0.63 to 1.00, p=0.052). Post intervention, there were further reductions in the control but not treatment group so that projected CVD rates were similar and there was no net treatment effect (Risk ratio 0.92; CI 0.68 to 1.23, p=0.562).

### **Cohort data**

Results are presented as net (differences in absolute change between treatment and control) differences from baseline to 8.5 years (peak of intervention).

#### 1. Total cholesterol

Total cholesterol (mg/dl) increased in both treatment (+7.4; SD 1.2) and control (+8.1; SD 1.0) groups and there was no significant treatment effect.

#### 2. Blood pressure

Systolic blood pressure (mmHg) increased in both treatment (+6.0; SD 0.4) and control (+5.2; SD 0.4) groups and there was no significant treatment effect.

Diastolic blood pressure (mmHg) increased in both treatment (+2.1; SD 0.3) and control (+1.9; SD 0.3) groups and there was no significant treatment effect.

#### 3. Smoking

Rates of smoking (%) decreased in both treatment (-8.9; SD 1.2) and control (-8.2; SD 1.1) groups but there was no significant treatment effect.

#### 4. Projected CVD rates



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Projected rates of CVD (rates/10,000 people within 10 years) increased dramatically in both treatment (Risk ratio of change 2.79; 95% CI 2.53 to 3.07) and control (Risk ratio of change 2.83; 95% CI 2.57 to 3.11) groups but there was no significant treatment effect.

No significant differences were seen for sex, age or education sub-groups for total cholesterol, blood pressure, smoking or body mass index. Composite CVD risk was significantly lower (0.6 vs. 0.8) in younger intervention group participants.

#### 5. Physical activity

Attempts to increase physical activity generally increased in treatment and control communities (no treatment effect,  $p=0.186$ ) but neither community showed overall changes in physical activity (no treatment effect,  $p=0.146$ ) (26).

#### 6. Knowledge (26)

Knowledge that physical activity prevents CVD increased in treatment and control communities from baseline to peak of intervention but there was no net treatment effect ( $p=0.881$ ).

### **Limitations of the intervention and its evaluation**

The study was quality assessed and graded '-'.

#### *Limitations identified by author*

National education programmes, commercial marketing or other information sources may have created secular trends so that treatment effects were not apparent.

Survey data may possibly be inaccurate.

Working class communities may have been distracted by economic and employment insecurity.

#### *Limitations identified by reviewer*

The project planning was poor with an initially inappropriate expectation of community involvement without first raising awareness.

Throughout the programme there may not be proper community engagement.

The six cross-sectional surveys had response rates of 70%, 67.5%, 68%, 67.5%, 64.5% and 69% respectively. The authors did not offer a reason for the low response rate and did not provide information on non-responders.

### **Applicability**

Participants in the Pawtucket programme had a relatively low average level of education (8.6% college graduates) and income and the area offered predominately manufacturing-based employment (23). The population was relatively stable. 95% of participants were white and 16% were foreign born. 25% of participants spoke a language other than English at home. Single (mother) parent families comprised 10% of households (24). Between 40% and 50% of males (depending on age) in the intervention group were smokers at baseline compared to 24% of men in the HSE (2006). 30%-50% of women in the intervention group were smokers compared to 21% of women in the HSE 2006 (27).

### **Summary**

The Pawtucket Heart Health Programme was a long-term, large-scale intervention but failed to achieve positive behavioural or physiological outcomes in spite of ample funding. Strong secular trends may have played some part but apparent failure over the nine year intervention may be due to poor initial programme implementation and ineffective community involvement.

#### **3.1.10 The Stanford Five City Project**

Implementation of The Stanford Five-city community intervention began in 1979 with the aim of using community health education for the prevention of cardiovascular disease in communities in Northern California (28). The intervention extended the

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scope and objectives of the earlier Stanford Three Community Study and specifically aimed to achieve a 20% reduction in overall risk, 9% reduction in cigarette smoking, 2% relative weight reduction, 7% reduction in systolic blood pressure and 4% reduction in total plasma cholesterol compared to reference communities. The secondary goal of the intervention programme was to create a health promotion structure that would continue to function after the official project end (28).

### **Target population**

The intervention communities were two cities non-randomly allocated to receive treatment: Monterey, with a population of 44,900 and Salinas with a population of 80,500. The control communities were three non-randomly allocated reference communities: Modesto with a population of 132,400, San Luis Obispo with a population of 34,300 and Santa Maria. For Santa Maria only morbidity and mortality events were recorded, and individuals from the other control cities were used for comparison of other outcome variables (28).

For selection of cities to be considered as intervention/control communities, cities had to be: 1) located in northern California; and 2) have populations >30,000. It was also desired that communities had: 3) reasonably similar ethnic, socioeconomic and demographic characteristics; 4) relative independence from other cities; and 5) no shared newspaper or electronic media markets between intervention and control cities. However treatment cities were required to have: 6) shared media markets with each other (to reduce costs); and 7) relative independence of each other (28). Non-random selection of treatment and control cities was therefore inevitable but based on specific project constraints.

### **Theory/conceptual model of intervention**

The rationale for interventions in the Five-City programme was based on a combined theoretic model of both individual learning and community change entitled the "health communication-behaviour change" framework (28). Social learning theory formed the basis for development of educational materials (29).

### **Intervention description**

One of the aims of the Five-City project was to encourage community ownership and sustainability. Therefore, although early in the campaign media materials and community activities were created with programme resources, later the goal was to increase community involvement in production and distribution of media products and organisation of community activities (28). Initially, leaders were recruited and trained and the programme was expanded by obtaining additional external financial support.

The intervention was conducted over a period of six years and consisted of a mass media campaign including television, radio and printed media combined with community programmes that had multiple target audiences and settings. The main risk factors addressed were smoking, low physical exercise, poor diet, obesity and high blood pressure. Interventions aimed to increase awareness, provide information, give skills training, increase motivation and maintain improvements through changes in community organisation (28).

Media programmes, targeting awareness, attitudes and motivation, formed a large proportion of the educational input. Television communications included an hour long "heart health test", providing general information on risk reduction, and short segments of air time (3-5 minutes) covering smoking cessation, cooking, exercise and weight control (approximately 30 nutrition spots (29)). Public service announcements (approximately 100 over the course of the intervention) were used. Radio was used for brief announcements and short radio programmes (5 minutes) and these were mostly in Spanish as radio was an important source of information for the Mexican-American community.

Printed media was used to expand on more simple media approaches, providing skills training and more comprehensive information sources (28). A newspaper column (approximately 20 per year) in English and Spanish was a major element of the programme and booklets containing information on smoking cessation and nutrition were developed. These were distributed through direct mail and organisations such as worksites, libraries and medical care providers. It was

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anticipated that each household would receive more than four pieces of printed media by four years into the intervention period (28). All households were sent a series of eight weekly tip sheets giving brief nutrition information (29).

Community programmes were delivered through health departments, community colleges, schools, voluntary and ad hoc organisations, voluntary health agencies, health professionals, hospitals and other non-profit health service agencies (28).

Classes, school curricula, seminars and workshops were also developed and used. It was estimated that 5% of the population participated in community events associated with an exercise and nutrition programme called 'Healthy Living'. Attempts were also made to make food selections at cafeterias, restaurants and supermarkets more healthy (29).

Formative research was used to obtain information on the relevance of media and community programme approaches. The audience size, comprehension and retention and the degree of impact and behaviour change relating to activities were monitored so that interventions could be tailored appropriately.

### **Accessibility**

The intervention was delivered in a variety of formats and in varied locations such as schools, workplaces, voluntary organisations and healthcare services. Authors made efforts to make written educational materials accessible to both English speaking and Spanish speaking participants, for example by ensuring newspaper articles were printed in both languages. In addition, consideration was given to the media used by different ethnic groups so that, for example, radio production concentrated on Spanish-language programmes as this was identified as a major information source for Mexican Americans (28,30).

### **Programme evaluation**

The Evaluation was described as being of quasi-experimental design (2). Programme effectiveness was assessed using a series of independent cross sectional surveys, a longitudinal cohort, and epidemiologic surveillance. Cohorts were assessed at baseline (pre-intervention) and at three additional time points at two-yearly intervals

over the following six years. Four independent cross-sectional surveys were conducted; one at baseline (pre-intervention) and three during the period of intervention, and epidemiologic surveillance was implemented throughout the study period and for the year following cessation of the intervention (figure 5 (28)).

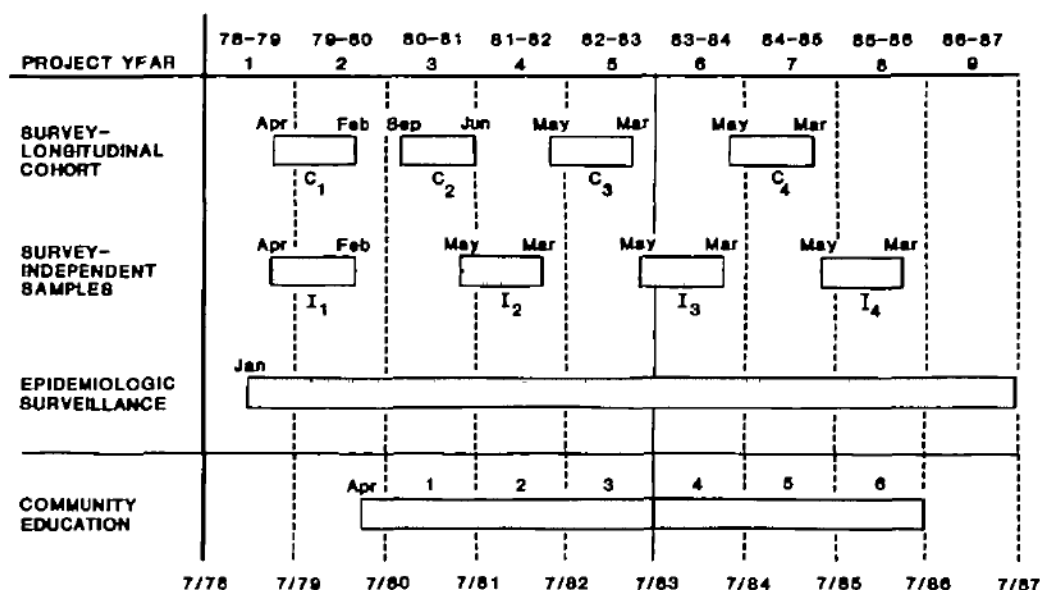


Figure 5 Programme evaluation in the Stanford Five City Project

### *Participant selection/recruitment*

Randomly selected households were identified from city directories and all individuals in those households aged 12-74 were eligible and invited to take part. Households were recruited by receipt of a letter and a subsequent telephone call (28). Included participants in the baseline survey were invited to be part of the cohort and to take part in each two-yearly repeat survey. Each survey consisted of 1,800-2,500 participants. Response rates for the four independent cross sectional surveys were 65%, 70%, 65% and 56% respectively. 743 individuals who participated in the baseline survey participated in the three subsequent follow-up surveys and constituted the cohort (31). Surveys were conducted at centres located in each city and trained health professionals interviewed participants and conducted physiological measurements (29).

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Cohorts were significantly different in terms of baseline BMI and ethnicity. Body mass index was significantly lower and there were significantly more whites (less Hispanics) in the control population (31). Only 743 (39%) people were present for all 4 cohort surveys primarily due to migration out of the area. Dropouts from the cohort were found to be younger, less educated, more likely to be non-white, have higher self-reported BMI and to have greater risk factor levels compared to those remaining in the cohort (31).

Participants in the intervention communities at the baseline cross sectional survey were significantly older, less well educated, less likely to be white, more obese and less knowledgeable about cardiovascular disease than those in control communities (30).

### *Outcome measures*

Numerous study outcomes were assessed. Community surveillance was used to assess total mortality, fatal MI, fatal CHD, non-fatal MI, fatal stroke and non-fatal stroke in all five intervention/control cities. Demographic measures, attitudes, health knowledge, stress, smoking and physical activity levels were measured in questionnaires. Diet was measured in all participants from questions in a general questionnaire and, in 50% of participants, using the 24h dietary recall approach. Physiological measurements (obesity, plasma cholesterol, plasma HDL-C, Plasma thiocyanate, expired air CO, arterial blood pressure, fitness, urinary sodium and potassium) were made at survey centres. Weight and height were used to determine BMI and to assess levels of obesity. Plasma thiocyanate levels and expired carbon monoxide were used to give an indication of smoking cessation (28).

Four years after the end of the intervention, a follow-up cross sectional survey was used to examine the long-term effects of the community intervention (32).

Analysis was performed using ANCOVA models, adjusted for age, sex and education. Covariance analysis was used to investigate whether baseline imbalances in risk factors between treatment and control communities affected outcomes.

Outcomes were expressed as the absolute change from baseline in intervention communities compared to control communities. Changes were assessed from baseline to a point near the end of intervention (approximately 5 years) and at follow-up (4 years after the end of the intervention). At follow-up, results were presented for both men and women separately (33) but, for changes during intervention, average sample results were presented (30,31).

## **Results**

Adjustment for baseline differences by covariance analysis suggested that treatment effects could not be attributed to the initially higher risk status of the treatment group or to the statistical effect of regression to the mean (34).

### *Primary outcomes*

Figure 6 shows the average percentage change in intervention and control cities from baseline. Cohort survey results have been combined at 30 and 51 months (last 2 measures) for comparison with baseline and cross sectional survey results have been combined at 42 and 64 months (last 2 surveys) for comparison with baseline (29).



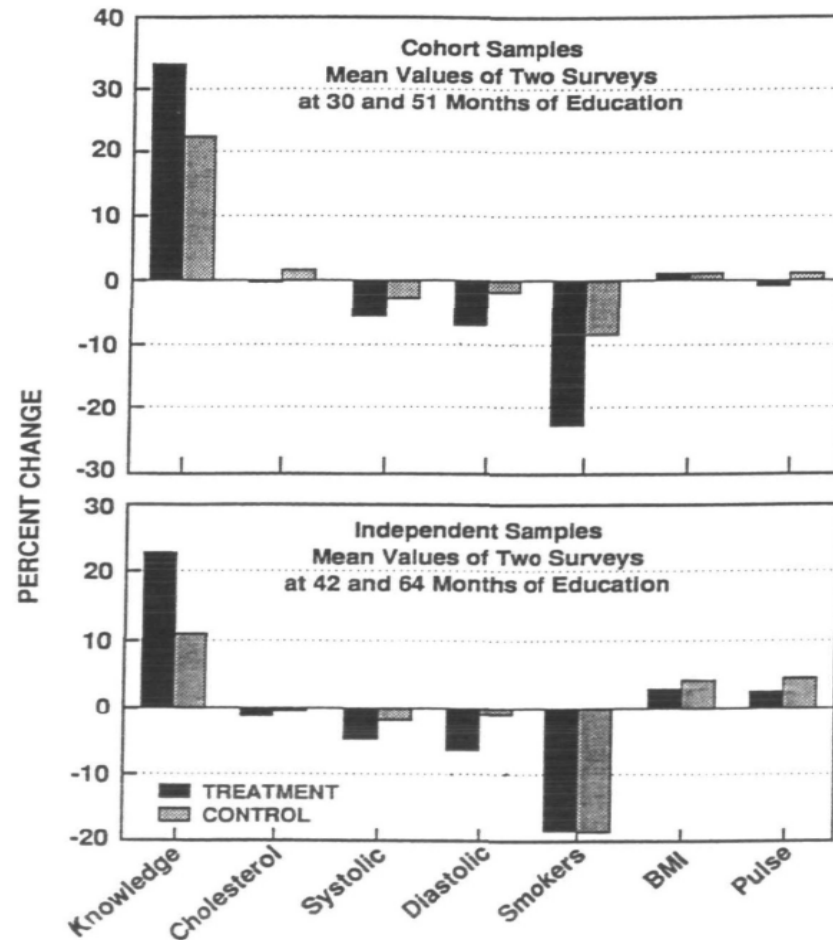


Figure 6 Changes in major outcome variables in the Stanford Five-City Project between the baseline survey and the mean of the last two measures for cohorts (top) and cross sectional surveys (bottom) in treatment and control communities (29)

### 1. All-cause mortality

In control communities, all cause mortality (deaths per 1000 persons in 10 years) increased from the end of intervention to follow-up at four years for men and women. In treatment communities, mortality increased slightly in women but fell in men. However, follow-up changes were not significantly different for men (-1.1 (treatment) vs. +2.0 (control),  $p=0.447$ ) or women (+0.4 (treatment) vs. +0.9 (control),  $p=0.795$ ) (33).

### 2. CVD linked morbidity and mortality

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In men, morbidity and mortality events linked to CVD (events per 1000 persons in 12 years) fell in the follow-up period in control communities with larger reductions seen in the treatment group, but the net treatment effect was not significant (-7.1(treatment) verses -1.5 (control),  $p=0.431$ ). In women, events increased amongst controls but decreased in the treatment group to give a significant net treatment effect (-2.6 (treatment) versus +5.4 (control),  $p=0.034$ ) (33).

### 3. Smoking

Rates of smoking (% smokers) decreased in both treatment and control communities during the intervention period but no significant treatment effect was evidenced in the cross sectional survey. There does appear to have been a significant treatment effect in the cohort (figure 6) but supporting data was not provided in the papers currently obtained. At follow up, smoking rates decreased more in control than treatment communities for men (+3.0% (treatment) vs. -2.8% (control),  $p=0.167$ ) and women (-0.2% (treatment) vs. -4.0% (control),  $p=0.302$ ) but the changes were not significant (33).

### 4. Cholesterol

There was no significant reduction in cholesterol in either intervention city compared to control cities at any time point for the cohort or cross sectional survey (30) and no difference between treatment and control community changes at follow-up (33).

### 5. Blood pressure

Blood pressure decreased in both treatment and control city cohorts and, at the final time point, reductions in systolic (-7.4 vs. -3.6 mmHg,  $p<0.001$ ) and diastolic blood pressure (-5.0 vs. -1.2 mmHg,  $p<0.001$ ) were significantly greater in treatment communities compared to the control communities (32). In the cross sectional surveys, although the decline in blood pressure tended to be greater in treatment compared to control communities, it was not significantly different at the final time point (32). At follow-up there was no difference between treatment and control groups in change

(from the end of intervention) in systolic or diastolic blood pressure in women but there were significant improvements for men in systolic (-0.8 vs. +2.8 mmHg,  $p=0.011$ ) and diastolic (+0.9 vs. +3.9,  $p=0.006$ ) blood pressure for changes in treatment vs. control communities respectively (33).

## 6. BMI

In the cross sectional surveys, BMI rose steadily over time for both the treatment and control areas but was always less in the control cities and there was less weight gain from baseline in treatment cities. At the end of intervention, weight gain was significantly less (0.57 verses 1.25 change in BMI,  $p<0.05$ ) in the treatment compared to the control communities (31). At follow-up, there was no significant difference between control and treatment groups in post-intervention BMI changes for women but, in men, there was a significant net increase compared to control communities (+0.4 verses -0.3,  $p=0.041$ ) (33).

## 7. Knowledge

Nutritional knowledge generally increased in both treatment and control cohorts but only in women was there a net treatment effect (significant difference in absolute change from baseline between intervention and control communities) (no data shown). For the cohort sample, nutrition knowledge increased in treatment and control communities but there was no net treatment effect for men or women (30). In the cohort sample, overall heart disease knowledge increased significantly in treatment compared to control communities (31). At follow-up, the control group had increased their CVD knowledge and showed significantly greater post-intervention changes compared to the treatment group for women (+0.3 (treatment) verses +1.3 (control),  $p<0.01$ ) and men (+0.3 (treatment) verses +1.3 (control),  $p<0.01$ ) (33).

For the cohort data, there were no significant net changes in knowledge, attitude or behaviour variables related to obesity and there were no significant net changes in BMI at any time point between the control and treatment communities (31).

## 8. Intention to lose weight

Intention to lose weight was significantly greater in the treatment compared to the control communities (4.6 versus 4.4 (scale generated by questionnaire),  $p < 0.01$ ) (31).

### **Limitations of the study**

The study was quality assessed and graded '+’.

#### *Limitations identified by authors (33)*

Net effects were only modest and this may have been due to strong secular trends.

More powerful designs for study assessment may be needed to better detect effects e.g. follow-up of high-risk cohort samples and more frequent surveys as well as evaluation of qualitative parameters at the individual, organisational and community level.

More focussed intervention strategies may be necessary including intervention in populations with high levels of risk factors for CVD e.g. lower socio-economic groups.

#### *Limitations identified by reviewer*

Dropouts from the cohort evaluation were significantly more likely to be younger, less educated, non white, smokers and less knowledgeable about cardiovascular disease (34). This would result in a non-representative cohort sample and make applicability of results to whole populations questionable. If drop-outs were different from treatment and control cohorts, this may have led to bias. 66% of cohort drop outs were due to migration (34).

The statistical approach (paired t-test of differences in individuals) assumes random allocation to intervention and control groups and ignores between community variation. In this case though, communities were not matched at baseline for all CVD risk factors. Age and sex specific event rates were measured in order to adjust for demographic differences between intervention and control populations but this

process is not clear in the analysis of results, and adjustments for other baseline differences is not evident.

In the follow-up, effects for different outcomes vary for gender and, with the large number of statistical tests conducted, significant findings for groups of men or women for individual outcome may be artifactual.

### **Applicability**

The Stanford 5 city programme is based in communities in central California with population sizes between 40,600 and 161,600 (31).

The authors note that, due to the characteristics of drop outs from the cohort study, the findings of this aspect of the evaluation are likely only to be generalisable to geographically stable, better educated adults (34).

### **Summary**

The Stanford Five City project appears to have had beneficial community effects on smoking, blood pressure and weight gain and, although net differences are not always large, there is reasonable consistency between cohort and cross-sectional data. The drive for community involvement, delivery through existing organisations and comprehensive programme delivery may have been important factors in achieving community change.

#### **3.1.11 The South Carolina/Heart to Heart Project**

The South Carolina Cardiovascular Disease Prevention Project, otherwise known as the Heart to Heart Program, was initiated in 1987. The long-term goal was the reduction of cardiovascular disease morbidity and mortality and shorter-term goals were to reduce the prevalence or severity of elevated blood cholesterol, high blood pressure and smoking (35). The intervention covered a period of two to three years (36) and this relatively short duration may have been due to the tighter budget constraints imposed for the implementation of this project.

**Target population**

Two rural communities in South Carolina were selected, Florence with an estimated population of 46,227, as the intervention community and Anderson, population 57,246, as the control community. These communities were demographically similar but approximately 200 miles apart (35).

**Theory/ conceptual model of intervention**

The stage theory of innovation was used for project implementation, based on the rationale that any idea or practice that is new to a community must be developed in stages: awareness for a need, search for methods for improvement, select one method from alternatives, gather necessary resources, implement the practice and sustain it (37). Each stage should be community-led and supported by programme organisers through raising awareness, establishing the programme legitimacy and providing and sustaining the necessary infrastructure for community activity. The staged, community involving approach of this model requires sufficient time to develop so that community change can be brought about.

**Intervention description**

Activities in the intervention community of Florence were largely self-established and the project was also known as the 'Florence Heart to Heart Program'. Programme organisers established a community coordinating council which then led the development and implementation of community interventions.

The central programme slogan was "The way you live makes a difference". Existing community organisations such as voluntary and civic agencies, businesses, churches and hospitals were utilised to implement ongoing activities in the community.

Volunteers and facilities were provided to implement programmes and classes.

The other important programme component was a series of risk-factor specific campaigns that were repeated throughout the intervention period. These campaigns were conducted over short periods of time and involved an intensive approach of screening, education for health care professionals, mass-media (newspaper articles,

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community bulletins, live TV and radio discussions), educational programmes, cooking demonstrations, point-of-purchase and restaurant labelling. These activities were coordinated and evaluated by The Heart Health programme (36).

### **Accessibility**

Interventions were varied in nature and offered at a range of venues (for example schools, churches, workplaces, social organisations, and shops). There is no information on the accessibility of written educational materials for those of low educational attainment or for non-English speaking individuals. Similarly, there is no information on the accessibility of other intervention components (activities and presentations) for individuals from different ethnic backgrounds, non-English speaking individuals or those for whom English is not a first language.

### **Programme evaluation**

The evaluation is described as quasi-experimental and takes the form of a controlled before and after design. Data was collected using independent cross sectional surveys conducted at baseline/pre-intervention (1987), during the course of intervention at year one (1988) and two (1989) and a year after intervention was complete (1991). Data collection after the first year of intervention (1988) did not include data for the comparison community (36).

Baseline surveys were large with 2,754 and 2,492 people surveyed in treatment and control communities respectively. Subsequent surveys were smaller with between 1,130 and 1,259 participants for the next three surveys in treatment and control communities. Response rates for treatment/control communities for each of the cross sectional surveys was high, ranging from 78.3-90.2%, and response rates did not systematically change over the course of the intervention period (36).

Analysis of covariance with race, age, and sex as co-variates was used to adjust for baseline differences between intervention and control groups.

### ***Participant selection/recruitment (2)***

Adults over 18 years were eligible for participation. It was estimated that 20% of the treatment and control population did not have telephones in the home. Therefore recruitment was planned so that participants were obtained with and without residential telephone so that a community representative sample could be obtained. For households with telephones, participants were selected using random digit dialling and, for households without telephones, random selection from city directories was used to identify potential recruits.

Interviews were conducted to obtain baseline data on behaviours, programme awareness and participation, knowledge, morbidity, family history and demographic information. For participants with telephones, these interviews were done over the phone but, for those without, household visits were made by locally-based interviewers to obtain baseline information. Physical assessments of all participants were made at specialised clinics where blood pressure, height and weight were measured and blood samples taken for measurement of total cholesterol, blood lipid levels, glycosylated haemoglobin and blood glucose.

During subsequent surveys, behavioural and physiological outcomes were measured as well as knowledge relating to CVD.

### *Outcome measures*

Outcome measures were variables relating to knowledge, preventative behaviour and physiological measures in relation to CVD risk factors. Changes from baseline for the treatment site were compared to changes from baseline in control communities.

## **Results**

Results are presented for changes from baseline to two years (1989) and from baseline to four years (1991) for intervention and control groups.

### *Primary outcomes*

#### 1. Smoking



The prevalence of smoking decreased and rates of physical activity increased in both groups but there were no significant differences between intervention and control groups in the extent of change (37). No significant differences were found according to racial group (38).

## 2. Cholesterol

The percentage of participants with high blood cholesterol rose in both groups but this change was significantly moderated in the treatment group compared to the control group (+0.7% versus +4.5% respectively,  $p=0.006$ ) (37). However, the significant intervention effect was observed in women only (difference in absolute change +5.4%,  $p=0.002$ ) and not men (difference in absolute change -1.2%  $p=0.31$ ). The authors reported that the intervention effect did not differ between black and white respondents.

Self-reported cholesterol screening rates increased from baseline in both groups but this increase was significantly greater in treatment compared to control communities at two years (difference in absolute change 13.3% increase,  $p<0.001$ ) and at four years (difference in absolute change 8.6% increase,  $p<0.001$ ) (36). Although the proportion of those with high blood cholesterol receiving treatment initially increased in both intervention and control communities, it decreased at four years (36).

The number of participants who had been told that their blood cholesterol level was high (by a health professional), increased in both groups and, although the increase was initially greater in the treatment group (2-year difference in absolute change 3.9%,  $p<0.05$ ), this difference was not sustained at four years (36).

## 3. Blood pressure

The intervention appears to have had a negative impact on blood pressure with rises from baseline to four year follow up in the intervention group (+3.0 mmHg) compared to a fall in controls (-3.0 mmHg) and this difference was significant (difference in absolute change +6.0 mmHg,  $p=0.0001$ ). There were no significant differences between

intervention and control groups for any changes in rates of blood pressure treatment (36). The authors did not report differences in blood pressure according to race or age.

#### 4. Weight

The percentage of participants who were overweight increased in both communities from baseline to four year follow up but this increase was less in the treatment compared to control group (difference in absolute change -2.9%,  $p=0.0002$ ) (37). The authors did not report differences in weight according to race or age.

#### 5. Diet

The percentage of participants consuming animal fats decreased in both intervention and control groups. Although intervention/control differences were not significant at two years, at four years this change was greater in the intervention group (-8.9%; 95% CI -11.8 to -5.9) than the control group (-4.0%; 95% CI -6.9 to -1.0,  $p=0.02$ ). A positive effect was also shown for vegetable fat consumption and, although not significant at two years, at four years the increase in the intervention group (+8.4%; 95% CI 5.2 to 11.6) was significantly higher than in controls (+3.6%; 95% CI 0.4 to 6.8,  $p=0.04$ ). There were no significant differences in use of solid vegetable fats or in people not using fat for cooking for intervention compared to control changes from baseline. There were no statistically significant differences in the favourable absolute changes in fat between white and black respondents.

Numbers rarely consuming fat from red meat improved in the intervention but not control communities. Differences were significant at two years (intervention group: +4.4%; 95% CI 1.6 to 7.1, control group -0.2%; 95% CI -3.0 to 2.6,  $p=0.02$ ) and at four years (treatment group: +3.0%; 95% CI 0.2 to 5.8, control group: -1.5%; 95% CI -4.3 to 1.3). No differences between intervention and control communities were shown in consumption of beef, pork and hamburgers or in consumption of fried fish and meats (39).

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An analysis of consumption of high fat foods according to race demonstrated a significantly greater reduction amongst black respondents at four years (-2.0 servings per week; 95%CI-3.0 to -1.1) compared to white respondents (-0.6 servings per week;95%CI -1.6 to 0.3) after adjustment for age, sex, marital status and socio-economic indicators (38).

#### 6. Physical activity

There was a non-significant increase in physical inactivity in both intervention and control groups at 4 years (difference in absolute change -1.0%,  $p=0.2825$ ) (37). The authors did not report differences in physical inactivity according to race or age.

#### 7. Knowledge

Knowledge regarding appropriate blood cholesterol levels increased in both intervention and control communities during the course of intervention.

Improvements though were significantly greater in the treatment group compared to controls at two years (difference in absolute change 7.6%,  $p<0.0001$ ) and this intervention effect was sustained at four years (difference in absolute change 6.4%,  $p<0.001$ ) (36).

Knowledge of participants own blood cholesterol level also improved in both intervention and control communities but this improvement was more marked in the treatment group compared to controls at two years (difference in absolute change 9.4%,  $p<0.0001$ ) and at four years (difference in absolute change 6.0%,  $p<0.001$ ) (36).

Knowledge about the benefits of exercise at four years increased in white and black respondents (absolute increases 18%,  $p<0.001$  and 21%,  $p<0.001$  respectively) but authors reported that prevalence of awareness did not differ significantly between race groups (38).

#### **Limitations of the intervention and its evaluation**

The study was quality assessed and graded ‘-’.

***Limitations identified by authors:***

The major limitation of the study identified by the authors was insufficient intervention time. Community intervention was only implemented for just over two years and, with the selected model of health promotion: stage theory of innovation, this time period was unlikely to be sufficient to raise awareness and allow community selection and development of projects.

***Limitations identified by reviewer:***

A much higher proportion of women than men participated in treatment (64%) and control surveys (62%) (36). If women have a higher participation in community intervention activities this may give a biased impression of intervention effect in favour of the intervention.

Effective management of survey data collection is not clear. No control community measurements were made for the second survey year although measurements were made in the treatment community. In the presentation of cohort data, there appears to be a variable number of study participants giving results for different outcomes. These uncertainties may simply be the result of poor reporting of these studies in the literature but it may undermine the credibility of study outcomes.

The use of cross sectional sampling is prone to bias resulting from migration of people into and out of control and treatment communities.

For this programme, a large quantity of data is presented on outcomes relating to knowledge and behaviours. As for many of these large population studies, extensive subgroup testing may have increased the likelihood of random significant results and may reduce our confidence in real treatment effects.

**Applicability**

The Heart to Heart South Carolina programme was conducted in rural communities in America with a relatively large percentage of African Americans (35% of the

population) and therefore may not be widely demographically applicable to communities in the UK. However, the project was conducted by local public health professionals, with little additional funding and drawing on existing community networks. In this way, the project may be more representative of what can be realistically achieved within existing resources.

### Summary

Despite limited intervention time and possible flaws in survey management, the Heart to Heart/South Carolina Cardiovascular Prevention Project appears to have been effective in developing a high degree of community involvement and there are positive physiological, knowledge and behavioural outcomes. Although this does not necessarily demonstrate long-term change in CVD risk, it provides encouragement for the use of community involving, multi-risk-factor targeting interventions.

Evidence statement for programmes addressing prevention of CVD at population level
<p>This an interim statement based on the first part of a 3 stage review.</p> <p>11 directly relevant programmes reported in 41 publications were identified for this report. The majority, nine consider the effectiveness of population programmes using education and mass media. Two others focus on assessing levels of all risk factors and providing advice in general populations. No programmes used legislative or fiscal changes and there were no natural experiments. The education and mass media programmes were generally evaluated using controlled before-after studies with quality gradings ranging from - to ++. The "screening" programmes were evaluated using RCTs and were graded - or +. The apparently lower grading of the RCTs should not imply that they are more open to bias than the controlled before-after studies. For the outcomes of CVD risk factors and behaviours there was a consistent trend in direction of effect in favour of programmes of both types. 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.</p>

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## 3.2 Evidence tables

Table 3.1: The Bootheel Project.....	109
Table 3.2: The British Family Heart Study .....	110
Table 3.3: The Danish Municipality Project .....	111
Table 3.4: The German Cardiovascular Project .....	113
Table 3.5: The Minnesota Heart Health Program .....	114
Table 3.6: The Norsjo Project .....	116
Table 3.7: The North Karelia Project .....	117
Table 3.8: OXCHECK .....	119
Table 3.9: The Pawtucket Heart Health Program .....	121
Table 3.10: The Stanford Five City Project .....	123
Table 3.11: The South Carolina Cardiovascular Prevention/Heart to Heart Project .....	125

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Table 3.1: The Bootheel Project

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
<p><b>Title:</b> The Bootheel Project</p> <p><b>Relevant papers:</b> Brownson et al. Preventing cardiovascular disease through community-based risk reduction: The Bootheel Heart Health Project. American Journal of Public Health 1996; 86(2): 206-213</p> <p><b>Study designs:</b> Controlled before and after study assessed by cross sectional surveys</p> <p><b>QA Grade:</b> ‘-’</p>	<p><b>Aims:</b> Long-term: to reduce morbidity and mortality due to cardiovascular disease. Short-term: to reduce the major modifiable risk factors for cardiovascular disease. <b>Intervention:</b> Five months prior to start, local leaders identified and formed coalition groups, responsible for planning and implementation in different areas. The groups had freedom to select interventions from own priorities. There was local health agency assistance in BP measurement, screenings, training and the provision of funds. Common project activities were walking clubs, aerobic exercise classes, healthy cooking demonstrations, community blood pressure and cholesterol screenings and CVD education programmes. Tailored individual community projects were a heart healthy fitness festival, “High Blood Pressure Sunday”, poster contests, weekly newspaper column, construction of walking and fitness paths. <b>Comparison:</b> No intervention</p>	<p><b>Intervention group:</b> Six counties in the Bootheel district of Missouri.</p> <p><b>Control group:</b> Districts in Bootheel not undergoing intervention programmes.</p> <p><b>Included participants:</b> Treatment: Those with telephones, randomly selected, aged &gt;18 years Control areas: Those monitored by the state surveillance system, aged &gt;18 years.</p> <p><b>Excluded:</b> Those without phones, the institutionalised.</p> <p><b>Setting:</b> Bootheel area, Missouri, USA.</p>	<p>Five years</p> <p>At baseline, 1,006 people surveyed in treatment communities, number in control group not stated.</p> <p>At four years, 1,510 people surveyed in treatment communities, number for control group not stated.</p> <p>Response rates for treatment group were 89% at baseline and 76% at four years</p>	<p><b>Primary outcomes:</b> % with no leisure-time physical activity % current smokers % consuming &gt;5 servings of fruit and veg. per day % overweight % having cholesterol screening in past 2 years</p> <p><b>Secondary outcomes:</b> None stated</p>	<p><b>Primary:</b> Results presented as changes from baseline to 1994 in treatment versus control areas and the net intervention effect: <b>% reporting did no leisure-time physical activity: treatment -3.0 (95% CI -8.5 to 2.5), control +3.8 (95% CI -2.9 to 10.5), net effect -6.8%; p= 0.03.</b> % reporting currently smoking: treatment -1.3 (95% CI -6.3 to 3.6), control -5.0 (95% CI -11.1 to 1.1), net effect +3.7% (p&gt;0.1). % reporting consuming &gt;5 servings of fruit and vegetables per day: treatment -1.3 (95% CI -6.3 to 3.6) control -5.0 (95% CI -11.1 to 1.1), net effect +2.2 (p&gt;0.1). % reporting overweight: treatment +4.3 (95% CI -0.9 to 9.4) control +10.2 (95% CI 3.9 to 16.6), net +5.9 (p= 0.07). <b>% reporting had blood pressure checked over last two years: treatment +4.3 (95% CI -1.0 to 9.6), control -0.2 (95% CI -6.7 to 6.5), net +4.5% (p= 0.04).</b></p>	<p><b>Identified by author:</b> Lacked proper control group. No clinical data to validate reported smoking changes in status and measure BP.</p> <p><b>Identified by reviewer:</b> Telephone surveys unsuitable: • ~13% without phones. Lower socioeconomic groups less likely to be surveyed, baseline characteristics not representative of population • Selective recruitment of black people in the second survey so changes from baseline compared for differing ethnicity/level of education in groups • Responses may be biased. Respondents want to give ‘right’ answer, especially in treatment areas Unsuitable control group: • Not distinct from intervention communities, may have been contamination • General lack of clarity on control participant selection</p>

Table 3.2: The British Family Heart Study

Program details	Intervention, policy, strategy or programme description	Program/study sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive results)	Confounders and limitations
<p><b>Title:</b> The British Family Heart Study</p> <p><b>Relevant papers:</b> Wood et al. Randomised controlled trial evaluating cardiovascular screening and intervention in general practice: principle results of British family heart study. <i>BMJ</i> 1994; 308: 313-320</p> <p><b>Study design:</b> RCT</p> <p><b>QA Grade:</b> '+'</p>	<p><b>Aims:</b> To measure the change in cardiovascular disease risk factors achievable in families over one year by a cardiovascular screening and lifestyle intervention in general practice</p> <p><b>Intervention:</b> Screening for CVD risk factors, appropriate counselling and negotiated target setting (1.5h session). Follow-up sessions arranged depending on level of risk in quintile 1-5: 5 every two months 4 every three months 3 every four months 2 every six months 1 at one year</p> <p><b>Comparison:</b> No intervention, normal practice.</p>	<p>15 British towns meeting specific demographic criteria were selected. All general practices within those towns, with 4-7 full-time partners, who were willing, were invited to participate.</p> <p><b>Intervention group:</b> 13 GP practices in 13 different towns</p> <p><b>Control group:</b> 13 practices in the same towns matched for socio-demographic characteristics</p> <p><b>Included participants:</b> Men aged 40-59y and their partners.</p> <p><b>Excluded:</b> Families where the male was not aged 40-59y.</p> <p><b>Setting:</b> GP practices located in Bury, Burton on Trent, Carlisle, Bridgend, Darlington, Dunfermline, Gloucester, Huddersfield, Ipswich, Lincoln, Newport, Poole, and Portsmouth.</p>	<p>1 year</p> <p>Participants in intervention group undergo initial screening and follow-up throughout the next year.</p> <p>Outcome measurements for all participants at 1 year.</p> <p>14,086 households approached and household response rate was 73% (1). In the intervention group, loss to follow-up was 12% and 15% in men and women respectively (1).</p>	<p>Results pooled for all intervention /control practices</p> <p><b>Primary outcomes:</b> Dundee risk score, an overall measure of CVD risk determined by blood cholesterol concentration, systolic blood pressure and previous and current smoking habit.</p> <p>Outcomes relating to blood cholesterol concentration, systolic and diastolic blood pressure, smoking, BMI and random blood glucose.</p> <p>Diagnosis of CHD, diabetes, high bp and high cholesterol</p>	<p><b>Primary outcomes:</b> Significant differences favouring intervention for:</p> <p><b>1. Cardiovascular (Dundee) risk score:</b> Men: 16.1% lower; 95% CI 10.9 to 21.1 Women: 15.7% lower; 95% CI 7.4 to 23.3</p> <p><b>2. Smoking prevalence:</b> Men: 4.1% lower; SE 1.8 Women: 3.5% lower; SE 2.1</p> <p><b>3. Mean blood cholesterol (mmol/l):</b> Men: 0.12 lower; SE 0.06 Women: 0.12 lower; SE 0.09</p> <p>Percentage with blood cholesterol <math>\geq 8.0</math> mmol/l: Men: 1.5% lower; SE 0.8 Women: 1.1% lower; SE 0.5</p> <p><b>4. Mean systolic blood pressure (mmHg):</b> Men: 7.5 lower; SE 1.2 Women: 7.7 lower; SE 1.4</p> <p>Mean diastolic blood pressure (mm Hg): Men: 2.5 lower; SE 1.0 Women: 2.5 lower; SE 0.9</p> <p>Percentage with diastolic blood pressure <math>\geq 100</math> mm Hg:</p>	<p><b>Identified by author:</b> Loss to follow-up</p> <p>Under-reporting of smoking and poor reliability of smoking validation measure</p> <p>Acclimatisation to measurement of blood pressure in intervention group</p> <p><b>Identified by reviewer:</b> Analysis not done by intention to treat</p>



Program details	Intervention, policy, strategy or programme description	Program/study sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive results)	Confounders and limitations
					Men: 4.6% lower; SE 1.4 Women: 2.2% lower; SE 1.1. 5. Mean weight (kg): Men: 1.17 lower; SE 0.36 Women: 1.09 lower; SE 0.42 Percentage with BMI $\geq 30$ kg/m <sup>2</sup> : Men: 1.8% lower; SE 1.3 Women: 2.2% lower; SE 1.5	

Table 3.3: The Danish Municipality 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
<p><b>Title:</b> The Danish municipality project 1989</p> <p><b>Relevant papers:</b> Osler et al. The effect of a community-based cardiovascular disease prevention project in a Danish municipality. Dan Med Bull 1993; 40: 485-9.</p> <p><b>Study designs:</b> Controlled before and after study assessed by cross sectional surveys</p> <p><b>QA Grade:</b> '-'</p>	<p><b>Aims:</b> To draw attention to project issues and activities and to affect the stages of behaviour change</p> <p><b>Intervention:</b> Planned and guided by steering committee. 25 volunteers recruited to organise events. Activities included exercise and smoking cessation programmes, fitness tests, safety education and demonstrations of how to buy healthy foods. Heart-healthy bread and a local recipe cook book were sold in the local supermarket. Group weekly exercise sessions and eating a healthy meal together once a month.</p> <p>At six months, there was 'Heart Week', an intensive week of lectures, fitness tests and exercise and smoking</p>	<p><b>Intervention group:</b> Slangerup, a rural municipality with ~8 000 inhabitants</p> <p><b>Control group:</b> Helsinge, similar size and demographic features to Slangerup, but different local media and no ongoing health projects</p> <p><b>Included participants:</b> Adults 20-65 years randomly selected from the local Central Person</p>	<p>1 year intervention period</p> <p>Cross sectional surveys conducted at baseline and after 1 year</p> <p>Baseline survey: 567 and 629 people took part, response rate ~51%</p> <p>One-year survey: ~600</p>	<p><b>Primary outcomes:</b> 1) Changes in health behaviour</p> <p><b>Secondary outcomes:</b> 2) Awareness of, and participation in local health promotion activities 3) Whether programme activities encouraged</p>	<p>Differences are direct treatment/control group comparisons (not changes from baseline)</p> <p><b>Primary outcomes:</b> No difference in reported smoking cessation, attempted smoking cessation or considered smoking cessation for treatment verses controls. No difference in % reporting reduced fat consumption, attempts to consume less fat or consideration of eating less fat. No difference in % reported increased</p>	<p><b>Identified by author:</b> Evaluation strategy not sensitive enough to detect changes. Recent migration into treatment area diluted apparent effect. Programme not properly integrated into community organisations. Low participation rates No funds Mainly mass media, raising awareness but limited health behaviours impact. Planned and organised by local volunteers without the skills or understanding needed.</p>

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
	<p>cessation programmes.</p> <p>Media involvement was health spots, shown during commercials in the local cinema, and campaign reports on local radio and in local newspapers.</p> <p><b>Comparison:</b> No intervention</p> <p><b>Theory/model:</b> Mainly social learning theory 'Diffusion of Information', 'Persuasion and 'Community Organisational' models also used for guidance.</p>	<p>register</p> <p><b>Excluded:</b> People out of the age bracket</p> <p><b>Setting:</b> Communities in Slangerup (treatment) and Helsing (control), Netherlands</p>	<p>people in each group, response rate 59% (NB separate N for each group not stated).</p>	<p>changes in health behaviour</p>	<p>physical activity, attempts to increase physical activity or considered increased physical activity.</p> <p><b>Secondary outcomes:</b> Programme awareness significantly higher in intervention compared to controls (82% vs 67% respectively, <math>p &lt; 0.001</math>).</p>	<p><b>Identified by reviewer:</b> Failed to properly involve, and engage with, the community.</p> <p>Surveys contained questions on programme awareness as well as health behaviour change. May have caused bias in reporting of health behaviours.</p> <p>Results are not reported as changes from baseline.</p>

Table 3.4: The German Cardiovascular 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
<p><b>Title:</b> The German Cardiovascular Project</p> <p><b>Relevant papers:</b> Hoffmeister et al. (1996) Reduction of Coronary Heart Disease Risk Factors in the German Cardiovascular Prevention Study. Preventive Medicine 1996; 25:135-45 (4)</p> <p><b>Study designs:</b> Controlled before and after study</p> <p><b>QA Grade:</b> '+'</p>	<p><b>Aims:</b> To reduce, by primary prevention, the four cardiovascular risk factors: hypertension hypercholesterolemia, smoking and obesity.</p> <p><b>Intervention:</b> This was a multifaceted prevention programme. Existing facilities were used and access to health care providers was extended and improved through collaboration with public health services, voluntary welfare federations, institutions for adult education, and sports and consumer associations. Special emphasis was placed on healthy nutrition, increased physical activity, smoking cessation, the screening for hypertension and hypercholesterolemia:</p> <p><b>Comparison:</b> No intervention</p>	<p><b>Intervention group:</b> Six regions of the former West Germany: three city districts (of Berlin, Bremen and Stuttgart); an entire medium sized city (Karlsruhe) with two small neighbouring communities (Bruchsal, Mosbach); and a rural district (Traunstein). When pooled these regions had a similar demographic and socioeconomic structure to the total West German population.</p> <p><b>Control group:</b> Three independent representative samples of the total west German population.</p> <p><b>Included participants:</b> The community-orientated primary prevention programme was aimed at the whole population.</p> <p><b>Excluded:</b> None</p> <p><b>Setting:</b> Six regions of the former West Germany.</p>	<p>The programme was conducted over a seven year period. Representative, independent samples of the intervention and control populations were used to examine risk factor trends at three time periods.</p> <p>For each intervention region a sample of about 1,900 men and women aged 25-69 was examined before the intervention (May 1984-March 1985). At midstudy (Feb 1988-April 1989), and at the end of the intervention (April 1991-April 1992) surveys of about 1,400 subjects were conducted.</p> <p>National representative reference samples of about 5,000 subjects were examined in almost the same periods (June 1984-April 1986, Sept 1987-Oct 1988, and April 1990 -May 1991). Response rates were 74.5, 73.0, and 71.6% for the intervention samples and 66.7%, 71.4% and 69.0% for the national samples respectively.</p>	<p><b>Primary outcomes:</b> Changes in risk factors associated with CVD specifically: hypertension; hypercholesterolemia; smoking; and obesity.</p> <p><b>Secondary outcomes:</b> No secondary outcomes were listed</p>	<p><b>Primary outcomes:</b> In the pooled intervention regions: Net reduction in mean values of systolic (-2.0%) and diastolic (-2.0%) blood pressure. Decline was significant for both but stronger amongst women (systolic -2.4, diastolic -2.3 mm Hg, p&lt;0.001) than men (systolic -1.6, diastolic -1.6 mm Hg, p&lt;0.001). Net decrease in total serum cholesterol was statistically significant for all participants (-1.8%, p&lt;0.001) and changes were almost identical for men and women (-1.9, p&lt;0.001 and -1.8, p&lt;0.05 respectively). Net decrease in the % of smokers (-6.7%, p&lt;0.05). However, the reduction was only significant amongst men (-9.7%, p&lt;0.01) but not women (-1.8%, NS).</p>	<p><b>Identified by reviewer:</b> The non-random allocation of the intervention and control groups raises the possibility of selection bias.</p> <p>Programme influence on the control population (contamination) cannot be discounted.</p>

Table 3.5: The Minnesota 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 (positive results)	Confounders and limitations
<p><b>Title and start date:</b> The Minnesota Heart Health Program 1980</p> <p><b>Relevant papers:</b> Jacobs et al. Community-wide prevention strategies: Evaluation design of the Minnesota Heart Health Program. <i>J Chron Dis</i> 1986; 39 (10): 775-788 (5)</p> <p>Mittelmark et al. Community-wide prevention of cardiovascular disease: Education strategies of the Minnesota Heart Health Program. <i>Preventative Medicine</i> 1986; 15:1-17 (7)</p> <p>Luepker et al. Community education for cardiovascular disease prevention: Risk factor changes in the Minnesota Heart Health Program. <i>American Journal of Public Health</i> 1994; 84: 1383-1393 (6)</p> <p>Luepker et al. Community education for cardiovascular disease prevention. <i>American Journal of Epidemiology</i> 1996; 144(4): 351-362 (12)</p> <p>Murray et al. Assessing</p>	<p><b>Aims</b></p> <p><b>Primary aim:</b> To achieve reductions in cardiovascular disease risk factors, morbidity and mortality (5).</p> <p><b>Secondary aims:</b> To develop and test education methods used. To promote the continuation of programme implementation after official intervention is complete (6). That the programme will be taken over by communities post-intervention (5).</p> <p><b>Intervention:</b> Involvement of community leaders and organisations, mass media, risk factor screening and education, adult education classes, schools-based youth and parent education, education of health professionals and</p>	<p><b>Intervention group:</b> Non random allocation of 3 intervention communities.</p> <p><b>Control group:</b> 3 non-randomly allocated communities matched to treatment groups for community size, city type (small/large/suburb) and distance of treatment to control city (5).</p> <p><b>Included participants:</b> Participants aged 25-74y living in treatment/control areas (5).</p> <p><b>Excluded:</b> Non-English speakers and those not considered mentally competent (6).</p> <p><b>Setting (5):</b> Treatment communities: 1) Mankato and north Mankato 2) Fargo and Moorhead 3) Bloomington Control communities: 1) Winona 2) Sioux falls 3) Roseville, Mayplewood and</p>	<p>5 year intervention with staggered introduction in 3 treatment cities (5).</p> <p>Risk factors monitored over 10 years beginning pre-intervention and extending after the intervention period. 300-500 people participated in each yearly population-based survey in each treatment/control site (7). Total survey response of 78.7% (6).</p> <p>7,097 participants of baseline cross sectional survey selected for inclusion in a cohort. 14.9% refused to take part. 67.1% of the original cohort</p>	<p><b>Primary outcomes:</b> Presented as net changes relative to control communities. Morbidity and mortality (30-74 year olds) (12). Risk factors and related behaviours (6): Blood pressure, smoking habit, cholesterol, smoking cessation, physical activity, dietary behaviours. Attitudes, risk awareness</p>	<p>Changes from baseline pooled for control/treatment communities.</p> <p><b>Primary outcomes:</b> No significant differences in treatment/control group changes (cross-sectional or cohort data) for morbidity or mortality from coronary heart disease or stroke (12), cholesterol, blood pressure, BMI or CHD risk (6). Smoking: no evidence of treatment effect in men but, in women, cross sectional data showed a 1.4% per year reduction (CI/p value not reported, not significantly different in cohort) (6). Physical activity: Treatment group had</p>	<p><b>Identified by author:</b> The lack of overall apparent effect may have been caused by (6): 1) Poor translation of small targeted projects into the community setting. 1) Intervention components did not work 3) Intervention did not change broader social milieu. 4) Contamination of control communities.</p> <p><b>Identified by reviewer:</b> Extensive subgroup testing increases the likelihood of random significant results. Non-English speaking adults excluded from programme evaluation, reduces applicability of results to people from</p>

Programme details	Intervention, policy, strategy or programme description	Programme/ sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (positive results)	Confounders and limitations
<p>intervention effects in the Minnesota Heart Health Program. American Journal of Epidemiology 1994; 139(1): 91-103 (8)</p> <p>Kelder et al. Community-wide youth exercise promotion: Long-term outcomes of the Minnesota Heart Health Program and the class of 1989 study. Journal of School Health 1993; 63(5): 218-223 (11)</p> <p>Perry et al. Communitywide smoking prevention: Long-term outcomes of the Minnesota Heart Health Program and the class of 1989 study. American Journal of Public Health; 82(9): 1210-1216 (10)</p> <p>Rissel et al. Evaluating quality and sustainability: issues and insights from the Minnesota Heart Health Program. Health Promotion International 1995; 10(5): 199-207 (9)</p> <p><b>Study designs:</b> Controlled before and after study using cross sectional surveys and cohort group data</p> <p><b>QA Grade:</b> '-'</p>	<p>community wide risk factor education campaigns (7).</p> <p><b>Comparison:</b> No intervention</p>	north St. Paul	remained for the final cohort survey (6).		<p>greater rise in physical activity compared to control for both the cohort and cross sectional survey (CI/p value not reported) (6).</p> <p>Behavioural intentions, knowledge, attitudes, beliefs and awareness were measured but these are not reported in papers identified for this phase of the review.</p>	<p>different ethnic groups.</p> <p>At the final cohort survey, those lost to follow-up in treatment communities were slightly leaner than those lost to follow-up in control communities (6).</p>

Table 3.6: The Norsjo Project

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
<p><b>Title:</b> The Norsjo Project</p> <p><b>Relevant papers:</b> Weinehall et al. (1999) Shifting the distribution of risk: results of a community intervention in a Swedish programme for the prevention of cardiovascular disease. J.Epidemiol.Community Health 1999;53:243-50 (13)</p> <p><b>Study designs:</b> Controlled before and after study assessed by cross sectional surveys and follow-up of a cohort</p> <p><b>QA Grade:</b> '+'</p>	<p><b>Aims:</b> 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.</p> <p><b>Intervention:</b> The population based intervention focused on the promotion of health education relating to the lifestyle behaviours (eating habits, alcohol, physical activity etc) felt to influence CVD risk. Information was provided by local associations, sports clubs, media and food retailers and targeted at the whole population. 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.</p>	<p><b>Intervention group:</b> The population of Norsjo (5,500 inhabitants) one of 15 municipalities in the province of Vasterbotten, Northern Sweden.</p> <p><b>Control group:</b> The region of Northern Sweden (510,000 inhabitants).</p> <p><b>Included study participants:</b> 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.</p> <p><b>Excluded:</b> None.</p> <p><b>Setting:</b> The island municipality of Norsjo in Northern Sweden.</p>	<p>The programme was launched in 1985. 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.</p>	<p><b>Primary outcomes:</b> 1) Changes in risk factors associated with CVD specifically: i) cholesterol (mean total serum cholesterol); ii) blood pressure (mean systolic and diastolic blood pressure); iii) body mass index (BMI); iv) smoking (number of smokers. 2) The risk for CVD using the Framington equation.</p> <p><b>Secondary outcomes:</b> No secondary outcomes listed</p>	<p><b>Primary outcomes:</b> NB net treatment vs control effects not reported. In the cross sections during the eight years from 1985-92: i) Mean total cholesterol reduced from 7.09 to 6.27mmol/l for men (p&lt;0.001) and from 7.13 to 5.89mmol/l for women (p&lt;0.001). Significance of the differences in change in cholesterol between intervention and reference population was tested by comparing trends between equivalent years and significant favourable treatment effect observed (p&lt;0.001). ii) Mean systolic blood pressure reduced from 132.2 to 123.7mmHg for men (p&lt;0.05) and from 129.2 to 122.0mmHg for women (p&lt;0.001). iii) BMI increased from 25.6 to 26.2 for men (p&lt;0.05) and from 25.0 to 25.5 for women (NS). iv) The proportion of daily smokers varied between 20% and 25% and no significant smoking cessation trend</p>	<p><b>Identified by reviewer:</b> Changes in outcomes (with the exception of cholesterol) were generally reported separately for the intervention and control groups (not net effects) making it difficult to accurately gauge the treatment effect over time. The non-random allocation of the intervention and control groups raises the possibility of selection bias. As the municipality of Norsjo forms part of the wider region of Northern Sweden which served as the control area it is possible that the programme may have had some</p>

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
	<p>Comparison:</p> <p>No intervention</p>				<p>was seen over time.</p> <p>The cohort data for 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.</p> <p>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).</p>	<p>spillover effects.</p>

Table 3.7: The North Karelia Project

Programme details	Intervention, policy, strategy or programme description	Programme/study sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive results)	Confounders and limitations
<p>Title:</p> <p>The North Karelia</p>	<p>Aim:</p> <p>To carry out a comprehensive CVD</p>	<p>Treatment group:</p> <p>The whole population of</p>	<p>The programme was</p>	<p>Primary outcomes (1):</p>	<p>Primary outcomes:</p> <p>There were major changes in</p>	<p>Identified by author:</p>

project

**Sources:**

Puska et al. Changes in coronary risk factors during comprehensive five-year community programme to control cardiovascular diseases (North Karelia project) *BMJ* 1979; 10:1173-1178 (15)

Salonen et al. Changes in smoking, serum cholesterol and blood pressure levels during a community-based cardiovascular disease prevention program-the North Karelia project. *American Journal of Epidemiology* 1981; 114(1): 81-94 (14)

Puska et al. Ten Years of the North Karelia project: results with community-based prevention of coronary heart disease. *Scand J Soc Med* 1983; 11:65-68 (40)

Puska et al. Change in risk factors for coronary heart

programme within the existing service structure and social organisation of the community. The main emphasis was on primary prevention but the intervention also involved secondary prevention (14).

**Main objective:**

To reduce mortality and morbidity, especially from CVD, with specific reference to middle-aged men (14).

**Intermediate objectives:**

To reduce the levels of the following CVD risk factors: smoking, serum cholesterol and blood pressure (14).

To promote early detection, treatment and rehabilitation in people with severe CVD (14).

**National objective:**

To test the feasibility and effectiveness of this approach and provide tested methods and programmes for nationwide use in the control of CVD and other health problems (14).

**Intervention:**

A comprehensive educational programme integrated within the health and social services of the community utilising the following methods (15):

- 1) general information to the public - especially on practical activities to reduce risk factors (using mass media, health education material and meetings);
- 2) organisation of services - systematically integrating the programme within existing services and creating new services if required;

North Karelia (approximately 180,000) - a geographically large and mainly rural county in Eastern Finland. The choice of programme setting was non-random and in response to a request for national assistance to help reduce the exceptionally high levels of CVD mortality and morbidity in the county (15).

**Control group:**

The county of Kuopio, a neighbouring county in Eastern Finland (population approximately 250,000), was chosen as a control area because of its close similarity to North Karelia (15).

**Included participants:**

The whole population.

**Excluded:**

None

**Setting:**

A comprehensive community-based programme in the county of North Karelia.

launched in 1972. Large cross sectional surveys were carried out in North Karelia and the control area (Kuopio) at baseline (1972), five (1977), ten (1982) and fifteen years (1987).

Large representative random samples (>10,000) were drawn from the population of the two counties using the national population register at baseline and 1977. In the 1982 and 1987 surveys a third survey area in South West Finland was used. The 1982 and 1987 surveys assessed approximately 8,000 and 6,000 subjects respectively (17).

1) Changes in risk factors associated with CVD specifically:

- i) smoking (number of smokers and amount of smoking for each smoker);
  - ii) cholesterol (mean total serum cholesterol levels);
  - iii) blood pressure (mean casual systolic and diastolic blood pressure).
- 2) Changes in CVD mortality and morbidity.

the levels of the three risk factors in North Karelia during the first ten years (1972-82), and substantial but statistically significantly smaller changes in the control area (19). Specifically:

i) The difference in reported daily smoking from baseline to 1977 was significantly greater in North Karelia in comparison with the control area ( $p<0.01$ ). The programme effect was significant for men (15%,  $p<0.01$ ) but not for women (12%, NS). From 1977-82 a further reduction took place amongst men, more so in North Karelia. Thus the net reduction in North Karelia for men during 1972-82 was 28% ( $p<0.001$ ). Amongst women smoking increased from 1977-82 in both areas, but more so in the control area. Thus the net reduction in North Karelia amongst women from 1972-82 was 14% (NS).

ii) The overall programme effect on reducing mean serum cholesterol concentrations from 1972-77 was highly significant ( $p<0.001$ ). Analysed by sex the effect was significant amongst men (4%;  $p<0.001$ ) but not in the whole age range of women (1%). From 1977-82 there was a net reduction of 3% amongst men ( $p<0.001$ ) and 1% amongst women (NS).

iii) The programme effect on both mean systolic and diastolic blood pressure from 1972-77 was highly significant amongst men and women ( $p<0.001$ ). The net reduction of systolic blood

Given the close proximity of the study areas it is possible that the programme in North Karelia had some spill-over effects into the local control community where an albeit smaller level of benefit was reported at five years.

After the initial five years (1977) the project, as a national demonstration programme, became actively involved in national efforts to reduce activities that were known risks, thereby influencing the control area population.

**Identified by the reviewer:**

Given the non-random allocation of the intervention and control populations the possibility of selection bias cannot be discounted. However as the control area was more affluent than North Karelia the impact of any possible bias is



disease during 10 years of a community intervention programme (North Karelia project). BMJ 1983; 287:1840-1844 (19)

Puska et al. The community-based strategy to prevent coronary heart disease: conclusions from the ten years of the North Karelia project. Annual Reviews 1985; 6:147-93 (17)

Puska et al. The North Karelia project; 15 years of community-based prevention of coronary heart disease. Annals of Medicine 1989; 21:169-173 (18)

**Study design:**  
Controlled before and after study.

**QA Grade:** '+'

3) training of personnel - particularly for the practical tasks of the programme;

4) environmental services - to support the desired behaviour (smoking restrictions, provision of healthy food etc);

5) programme information services - to support the practical activities (cards, files, registers, surveys etc).

After the initial five years (1977) the project, as a national demonstration programme, became actively involved in national efforts to reduce activities that were known risks (15).

After ten years (1982) the programme was enlarged to include a more integrated prevention of major non-communicable diseases and promotion of health (15).

In 1987, upon completion of the 15 year survey, a decision was made to intensify CHD prevention, focusing particularly on action to reduce cholesterol levels and the incidence of smoking (15).

**Comparison:**  
No intervention

pressure was 3% amongst men and 5% amongst women, and that of diastolic blood pressure 3% amongst men and 4% amongst women. From 1977-82 the systolic blood pressure levels remained close to those in 1977 amongst both men and women. The mean levels of diastolic blood pressure for men and women were lower in 1982. The net reduction in North Karelia became smaller from 1977-82, but for the whole period 1972-82 it remained significant for both sexes (p<0.05).

From 1982-87, the changes in the levels of the three risk factors in North Karelia, Kuopio (control area) and South-West Finland were small. Amongst men, the smoking rates in North Karelia in 1987 were lower than elsewhere but the serum cholesterol and blood pressure levels were still high and higher than in South-West Finland.

more likely to negate rather than enhance the effect of the programme.

Table 3.8: OXCHECK

Programme	Intervention,	Sample & setting	Duration of	Primary and	Results	Confounders and
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details	policy, strategy or programme description	study and follow-up period/	secondary outcomes	(positive results)	limitations	
<p><b>Title:</b> OXCHECK 1989</p> <p><b>Relevant papers:</b> Muir J et al. Effectiveness of health checks conducted by nurses in primary care: results of the OXCHECK study after one year. BMJ 1994;308:308-12 (21)</p> <p>Imperial Caner Research Fund OXCHECK Study Group. Effectiveness of health checks conducted by nurses in primary care: final results of the OXCHECK study. BMJ 1995; 310: 1099-104 (20)</p> <p><b>Study design:</b> RCT</p> <p><b>QA Grade:</b> '+'</p>	<p><b>Aim:</b> To reduce risk factors for cardiovascular disease</p> <p><b>Intervention:</b> Baseline health check by nurses in general practice identifying risk factors and offering counselling to patients</p> <p><b>Comparison:</b> No health check</p>	<p><b>Intervention group:</b> Patients who had previously undergone one screening health check.</p> <p><b>Control group:</b> Patients who had not received screening/health check.</p> <p><b>Included participants:</b> All registered patients aged 35-64 years in five practices in Luton and Dunstable responding to an initial questionnaire. 17,965 invited 11,090 responded and randomised to receive a health check or act as controls. 80% response rate after adjusting for inaccuracies of registration (21)</p> <p><b>Excluded:</b> Non-responders.</p> <p><b>Setting:</b> General practices in Bedfordshire</p>	<p>Outcome measurements were made one year after the initial health check (for intervention group).</p> <p>Measurements are also made three years after initial health check but groups being compared differ (i.e. participants in OXCHECK three year are not exactly the same as OXCHECK one year) (20)</p>	<p><b>Primary outcomes:</b> Cholesterol, blood pressure, BMI, smoking, physical activity and diet.</p> <p><b>Secondary outcomes:</b> No secondary outcomes listed</p>	<p>Results calculated on an intention to treat basis (non-attendees assumed to have no change).</p> <p><b>Primary outcomes at year one (21):</b> Results presented as intervention vs. control</p> <ul style="list-style-type: none"> <li>• Total cholesterol (mmol/l): 6.02 vs. 6.16, 0.14 lower (95% CI 0.08 to 0.20)</li> <li>• BP systolic (mmHg): 124.4 vs. 127.6, 3.2 lower (95% CI 2.2 to 4.3)</li> <li>• BP diastolic (mmHg): 74.6 vs. 76.4, 1.8 lower (95% CI 1.2 to 2.4)</li> <li>• BMI (kg/m<sup>2</sup>): 25.68 vs. 25.84, 0.16 lower (95% CI -0.06 to 0.38)</li> <li>• Percentage of smokers (smoking any form of tobacco at least daily): 27.6 vs. 27.2, 0.5 higher (95% CI -2.8 to 1.9)</li> <li>• Percentage stopped smoking in previous year: 4.1 vs. 5.1, 1.0 lower (95% CI -0.9 to 3.0)</li> <li>• Percentage diastolic BP ≥100 mmHg: 2.6 vs. 3.4, 0.9 lower (95% CI 0.0 to 1.7)</li> <li>• Total cholesterol ≥ 8.0mmol/l: 4.8 vs. 7.6, 2.7 lower (95% CI 0.0 to 1.7)</li> <li>• BMI ≥30 kg/m<sup>2</sup>: 12.4 vs. 14.0, 1.6 lower (95% CI -0.2 to 3.4)</li> <li>• Percentage exercising vigorously &lt;once/month: 65.3 vs. 70.4; 5.1 lower(95% CI 2.7 to 7.6)</li> <li>• Percentage drinking mainly full cream milk: 26.3 vs. 38.2, 11.9 lower (95% CI 9.5 to 14.3)</li> <li>• Percentage using mainly butter or hard margarine on bread: 20.3 vs. 31.9, 11.6 lower (95% CI 9.3 to 13.8)</li> <li>• Polyunsaturated fatty acid (PUFA) score: 8.7 vs. 8.3, 0.4 higher (95% CI 0.3 to 0.5)</li> </ul> <p><b>Primary outcomes year 3 (20):</b> Results presented as intervention vs. control</p> <ul style="list-style-type: none"> <li>• Total cholesterol (mmol/l): 5.99 vs. 6.18, 0.19 lower (95% CI 0.12 to 0.26)</li> <li>• BP systolic (mmHg): 126.5 vs. 129.0; 2.5 lower (95% CI 1.3 to 3.7)</li> </ul>	<p><b>Identified by author:</b> Possible contamination; similarity between intervention and measurement; patient loss to follow-up; need to sustain follow-up for several years (21). Size of effect on BP noted to be consistent with "accommodation" observed in placebo arms of other trials (21)</p> <p><b>Identified by reviewer:</b> Generally well conducted trial of applicable intervention. Many issues raised by authors were actually addressed to some degree in study e.g. loss to follow-up addressed by use of ITT</p>

- BP diastolic (mmHg): 75.7 vs. 77.2, 1.5 lower (95% CI 0.8 to 2.2)
- BMI (kg/m<sup>2</sup>): 25.88 vs. 26.26, 0.38 lower (95% CI 0.12 to 0.64)
- Percentage of smokers (smoking any form of tobacco at least daily) 25.0 vs. 26.4 respectively, 1.4 higher (95% CI -1.3 to 4.1)
- Percentage diastolic BP  $\geq$ 100 mmHg 3.4 vs. 4.5 1.1 lower; (95% CI -0.1 to 2.3)
- Total cholesterol  $\geq$  8.0 mmol/L 3.9 vs 7.8, 3.9 lower (95% CI 2.4 to 5.3)
- BMI $\geq$ 30 kg/m<sup>2</sup>: 14.3 vs. 15.9, 1.6 lower (95% CI -0.6 to 3.8)
- Percentage exercising vigorously <once/month: 67.6 vs. 70.9, 3.3 lower (95% CI 0.5 to 6.1)
- Percentage drinking mainly full cream milk: 23.1 vs. 30.6, 7.5 lower (95% CI 4.8 to 10.3)
- Percentage using mainly butter or hard margarine on bread: 21.9 vs. 30.7, 8.7 lower (95% CI 6.0 to 11.4)

Table 3.9: The Pawtucket 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
<p><b>Title:</b> The Pawtucket Heart Health Programme</p> <p><b>Relevant papers:</b> Elder et al. Organizational and community approaches to community-wide prevention of heart disease: The first</p>	<p><b>Aims:</b> To test whether community action via volunteer recruitment and deployment can change CVD knowledge, risk factors and disease related morbidity and mortality (22)</p> <p><b>Intervention:</b></p>	<p><b>Intervention group:</b> Pawtucket in Rhode island (n=71,204), median age 33.6 years, relatively low average education level and income, predominately manufacturing-based</p>	<p>10 year study period (-8 year intervention). Cross-sectional surveys (-1,255 participants per survey, per location) conducted at baseline and 2 year intervals for the next ten years. Average</p>	<p><b>Primary outcomes:</b> Total cholesterol, systolic and diastolic blood pressure, smoking, BMI, and projected CVD rate (25)</p> <p>Knowledge and behavioural</p>	<p><b>Primary outcomes (25):</b> Cross sectional surveys Results presented as net (treatment vs control) differences from baseline to time of peak intervention (-7 years) and at 1-2 years follow-up. No net difference in reductions in total cholesterol (mg/dl) at peak intervention (net +0.29; SE 2.08, p=0.890) or follow-up (net -0.33; SE 2.85, p=0.907). No net difference in observed increase in systolic blood pressure (mmHg) at peak intervention (net -0.54; SE 1.11, p=0.627) or for reductions in observed in follow up (net -1.39; SE 1.29, p=0.281).</p>	<p><b>Identified by author:</b> National education programmes, commercial marketing or other information sources created secular trends so treatment effects not apparent. Survey data may</p>

<p>two years of the Pawtucket Heart Health Program. 1986; 15: 107-117 (22)</p> <p>Lefebvre et al. Theory and delivery of health programming in the community: The Pawtucket Heart Health Program. Preventative Medicine 1987; 16:80-95 (23)</p> <p>Assaf et al. The Pawtucket Heart Health Program: II. Evaluation strategies. Rhode Island Medical Journal 1987; 70:541-545 (24)</p> <p>Carleton et al. The Pawtucket Heart Health Program: Community changes in cardiovascular risk factors and projected disease risk. American journal of public health. 1995; 85: 777-785 (25)</p> <p>Eaton et al. Effects of a community-based intervention on physical activity: The Pawtucket Heart Health Program. American journal of Public Health. 1999; 89(11):1741-1744 (26)</p>	<p>Activities initially focussed on local organisations such as worksites, churches and schools with the aim that risk-factor behaviour change would be spread throughout and between organisations via social networks.</p> <p>This approach was slow and labour intensive and, in the second intervention phase, other whole community based interventions were introduced.</p> <p>To increase programme visibility, a media campaign using billboards, bumper stickers, placards, mailings, newspaper adverts and public service announcements was introduced and risk-factor programmes were promoted through newspapers, flyers and radio announcements (22).</p> <p><b>Comparison:</b> No intervention</p>	<p>employment and a stable population (69% born in Rhode island) (23).</p> <p><b>Control group:</b> Name withheld (N=98,478), larger population but few demographic or social differences (23).</p> <p><b>Included participants:</b> People aged 18-64 at the time of fist survey contact.</p> <p><b>Excluded:</b> Not stated</p> <p><b>Setting:</b> Community in Pawtucket and a control community</p>	<p>survey response rate was 68% (25).</p> <p>A cohort of participants were recruited from surveys 1 and 2 for re-examination 8.5 years later (2,925 of 5,241 (58%) follow up). (25).</p>	<p>outcomes relating to physical activity (26)</p>	<p>No net difference in increases in diastolic blood pressure (mmHg) at peak intervention (net -1.08; SE 0.81, p=0.18) or follow-up (net -0.84; SE 0.94, p=0.373).</p> <p>No net difference in the fall in smoking rates (%) at peak intervention (net +0.34; SE 2.0, p=0.867) or follow-up (net +2.60; SE 2.58, p=0.315).</p> <p>No net difference in BMI reductions (kg/m<sup>2</sup>) at peak intervention (net -0.11; SE 0.24, p=0.645) but, at follow-up was a significant treatment effect (net -0.62; SE 0.31, p=0.042).</p> <p>Projected decreases in CVD rates (rates/10,000 people within 10 years) almost significantly greater in treatment group at peak intervention (Risk ratio 0.8; 95% CI 0.63 to 1.00, p=0.052) but not at follow-up (Risk ratio 0.92; CI 0.68 to 1.23, p=0.562).</p> <p><b>Cohort data</b></p> <p>Results are presented as net (treatment vs. control) differences from baseline to time of peak intervention (8-9 years).</p> <p>Total cholesterol (mg/dl) increased in both treatment (+7.4; SD 1.2) and control (8.1; SD 1.0) groups, no significant treatment effect.</p> <p>Systolic blood pressure (mmHg) increased in both treatment (+6.0; SD 0.4) and control (5.2; SD 0.4) groups, no significant treatment effect.</p> <p>Diastolic blood pressure (mmHg) increased in both treatment (+2.1; SD 0.3) and control (1.9; SD 0.3) groups, no significant treatment effect.</p> <p>Rates of smoking (%) decreased in both treatment (-8.9; SD 1.2) and control (-8.2; SD 1.1) groups, no significant treatment effect.</p> <p>Large increase in projected rates of CVD (rates/10,000 people within 10 years) in both treatment (Risk ratio of change 2.79; 95% CI 2.53 to 3.07) and control (Risk ratio of change 2.83; 95% CI 2.57 to 3.11) groups, no significant treatment effect.</p> <p>Knowledge that physical activity prevents CVD improved in treatment and control communities, no net treatment effect (p=0.881) (26).</p> <p>Attempts to increase physical activity generally increased but no treatment effect (p=0.186) and no overall changes in physical activity (no treatment effect, p=0.146).</p>	<p>be inaccurate.</p> <p>Working class communities may have been districted by economic and employment insecurity.</p> <p><b>Identified by reviewer</b></p> <p>Poor project planning with an initially inappropriate expectation of community involvement without first raising awareness.</p> <p>Throughout the programme there does not appear to be proper community engagement.</p>
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Study designs:  
Controlled before  
and after study  
QA Grade: '-'

Table 3.10: The Stanford Five City 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
<p><b>Title:</b> The Stanford Five-City Multifactor Risk Reduction Project</p> <p><b>Relevant papers:</b> Farquhar et al. The Stanford five-city project: Design and methods. American Journal of Epidemiology 1985; 122(2): 323-334 (28)</p> <p>Taylor et al. Effect of long-term community health education on body mass index. American Journal of Epidemiology 1991; 134(3):235-249 (31)</p> <p>Fortmann et al. Community trials: reflections on the Stanford Five-City Project experience. American Journal of</p>	<p><b>Aim:</b> To use community health education for the prevention of cardiovascular disease (extends the scope and objectives of the earlier Stanford Three Community Study) (28)</p> <p><b>Specific aims:</b> 20% reduction in overall CVD risk compared to reference communities; 9% reduction in cigarette smoking; 2% relative weight reduction; 7% reduction in systolic blood pressure; 4% reduction in total plasma cholesterol;</p> <p><b>Secondary goal:</b> To create a health promotion structure that would continue to function after the project ends</p>	<p><b>Intervention group:</b> Non-random allocation of two cities as treatment groups: Monterey (1980 population 44,900) and Salinas (1980 population 80,500)</p> <p><b>Control group:</b> Non-random allocation of three reference communities as comparison groups controls: Modesto (population 132,400), San Luis Obispo (population 34,300) and Santa Maria (only morbidity and mortality events were recorded for this city)</p> <p><b>Included participants:</b></p>	<p>Intervention over 6 years.</p> <p>Cohort measurements taken at baseline and at 3 further time points at 2-yearly intervals during study period.</p> <p>Cross section samples taken at baseline and at 3 further time points at 2-yearly intervals during study period.</p> <p>Cohort study: Baseline measurements in ~625 participants per city. At six years 1,148 of the original cohort remained, primarily due to migration out of the area. 743 people were present for all 4 cohort surveys</p>	<p><b>Primary outcomes:</b> Fatal MI, fatal CHD, non-fatal MI, fatal stroke and non-fatal stroke, smoking, cholesterol, blood pressure, BMI.</p> <p>Attitudes, knowledge, intentions.</p>	<p><b>Primary outcomes:</b> No significant net treatment effects on all-cause mortality (deaths per 1000 persons in 10 years) from end of intervention to follow-up (4 years) for men (-1.1 vs. +2.0 for treatment vs. control, p=0.447) or women (+0.4 vs. +0.9 for treatment vs. control, p=0.795) (33).</p> <p>In women, significant net treatment effect on CVD linked morbidity and mortality (events per 1000 persons in 12 years) (-2.6 vs. +5.4 for treatment vs. control, p=0.034) but not in men (-7.1 vs. -1.5 for treatment vs. control, p=0.431) (33).</p> <p>From baseline to end of intervention, no significant net treatment effect on rates of smoking (% smokers) for the cross sectional survey, but is apparent in the cohort (data not available in papers). At follow up smoking rates decreased but no net treatment effect in men or women (33).</p> <p>No significant reduction in cholesterol for treatment compared to control for</p>	<p><b>Identified by author:</b> A limitation of cross sectional analysis is the possible inclusion of recent migrants into treatment communities not exposed to the intervention (28). Risk factor changes in the cohort may not reflect changes in the whole population as participants may drop out (28). Net effects only modest, may have been due to strong secular trends (33). More powerful designs for study assessment may be needed e.g. follow-up of high-risk cohort, more frequent surveys, evaluation of qualitative parameters at the individual,</p>

<p>Epidemiology 1995; 142(6): 576-586 (29)</p> <p>Fortman et al. Effect of community health education on plasma cholesterol levels and diet: The Stanford Five-City Project. American Journal of Epidemiology 1993; 137(10): 1039-1055 (30)</p> <p>Fortmann et al. Effect of long-term community health education on blood pressure and hypertension control. American Journal of Epidemiology 1990; 132(4): 629-646 (32)</p> <p>Winkleby et al. The Long-term effects of a cardiovascular disease prevention trial: The Stanford Five-City Project. American Journal of Public Health 1996; 86:1773-1779 (33)</p> <p>Farquhar et al. Effects of communitywide education on cardiovascular disease risk factors. JAMA 1990; 264(3): 359-365 (34)</p> <p><b>Study designs:</b> Controlled before and after study</p> <p><b>QA Grade:</b> '-'</p>	<p><b>Intervention:</b> Education programme after completion of baseline population survey.</p> <p><b>Media programs:</b> Education delivered through television and radio.</p> <p>Television - hour long "heart health test" and short segments (3-5 mins) covering smoking cessation, cooking, exercise, weight control. Public service announcements (-100).</p> <p>Radio - Brief announcements and short radio programs (5 mins), mostly in Spanish.</p> <p>Printed media - Weekly newspaper column in English and Spanish. Booklets for smoking cessation, nutrition etc. Distributed through direct mail and organisations such as worksites and medical care providers. Each household to receive &gt;4 printed media by 4 years into intervention</p> <p>Community programmes - Early on, media materials created with program resources. Later the aim was to increase community involvement for collaborative production and distribution of media products and activities.</p> <p>Leaders recruited and trained to introduce the programme. Programme was expanded by recruiting additional organisational sponsors, training a director and obtaining financial</p>	<p>People aged 12-74 living in randomly selected households.</p> <p><b>Excluded:</b> Not stated.</p> <p><b>Setting:</b> Five communities in northern California</p>	<p>(29).</p> <p>Cross sectional surveys: Each survey contained approximately 1,800- 2,500 participants, response rates of 65%, 70%, 65% and 56% (29)</p> <p>A follow-up cross sectional survey was conducted 4 years post-intervention.</p>	<p>the cohort or cross sectional survey at end of intervention (30) or at follow-up (33).</p> <p>At end of intervention, reductions in systolic (-7.4 vs. -3.6 mmHg, <math>p&lt;0.001</math>) and diastolic blood pressure (-5.0 vs. -1.2 mmHg, <math>p&lt;0.001</math>) were significantly greater in treatment compared to control community cohorts but reductions were not significantly greater for cross sectional surveys (32).</p> <p>At follow-up there was no net treatment effect in women but significant net improvements for men in systolic (-0.8 vs. +2.8 mmHg, for treatment vs. control, <math>p=0.011</math>) and diastolic (+0.9 vs. +3.9, for treatment vs. control, <math>p=0.006</math>) blood pressure (33).</p> <p>At the end of intervention weight gain significantly less in treatment compared to the control communities for the cross sectional survey (0.57 vs. 1.25 (change in BMI) <math>p&lt;0.05</math>) but not for the cohort.</p> <p>At follow-up, no significant net treatment effect in women but in men significant net increase in BMI (+0.4 vs. -0.3, for treatment vs. control, <math>p=0.041</math>).</p> <p>In the cohort, during intervention, there were no significant changes in knowledge, attitude or behaviour variables related to obesity (31).</p> <p>Nutritional knowledge increased in both treatment and control cohorts but the net treatment effect was not significantly different (30).</p> <p>At follow-up, knowledge of cardiovascular risk increased in both treatment and control groups but was significantly greater in control compared to treatment cities for women (+0.3 vs. +1.3 for treatment vs. control, <math>p&lt;0.01</math>) and men (+0.3 vs. +1.3 for treatment vs. control, <math>p&lt;0.01</math>) (33).</p>	<p>organisational and community level (33). More focussed intervention strategies may be necessary in high risk factor populations e.g. lower socio-economic groups (33).</p> <p><b>Identified by reviewer:</b></p> <p>Due to selection bias, the cohort may not reflect the population as a whole.</p> <p>Communities were not matched at baseline for all CVD risk factors. Adjustment for differences is stated but is not evident in the analysis of results.</p> <p>Extensive number of outcome variables analysed and further use of sub-group analysis results in possible artifactual statistical significance.</p>
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support.  
**Comparison:**  
 No intervention

**Table 3.11: The South Carolina Cardiovascular Prevention/Heart to Heart Project**

Programme details	Intervention, policy, strategy or programme description	Program/study sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive results)	Confounders and limitations
<p><b>Title:</b>            South Carolina Cardiovascular Disease Prevention /Heart to Heart Project 1987</p> <p><b>Relevant papers:</b>            Heath et al. Changes in blood cholesterol awareness: Final results from the South Carolina Cardiovascular Disease Prevention Project. American Journal of Preventative Medicine 1995; 11(3): 190-196 (36)</p> <p>Wheeler et al. Evaluating South Carolina's cardiovascular disease prevention project. Public health reports 1991, 106(5): 536-543 (35)</p> <p>Croft et al. Community</p>	<p><b>Aims:</b>            To reduce CVD risk factors of elevated blood cholesterol, high blood pressure and smoking (36).</p> <p><b>Intervention:</b>            Community coordinating council established. Existing community organisations used to implement ongoing community activities. Risk-factor specific campaigns that were repeated throughout intervention period involved screening, education for health care professionals, mass-media (newspaper articles, community bulletins, live TV and radio</p>	<p><b>Treatment group:</b>            Florence in South Carolina (N=46,227)</p> <p><b>Control group:</b>            Anderson in South Carolina (N= 57,246)</p> <p><b>Included study participants:</b>            Adults over the age of 18 living in treatment/control communities</p> <p><b>Excluded:</b>            None specified</p> <p><b>Setting:</b>            Florence and Anderson, South Carolina</p>	<p>2-3 year intervention.            At baseline, 2,754 and 2,492 people surveyed in treatment/control communities.</p> <p>1 year, 2 year and 4 year (post-intervention) cross sectional surveys were smaller with 1,130-1,259 participants.</p> <p>Response rates for treatment/control communities for each of the cross sectional surveys was high ranging from 78.3-90.2% (36).</p>	<p><b>Primary outcomes:</b>            Physiological outcomes</p> <p>Outcomes relating to knowledge, preventative behaviour, risk awareness and treatment seeking behaviour</p>	<p>*Cohort data  <b>Primary outcomes (37):</b></p> <ul style="list-style-type: none"> <li>*% increase in no. people with high cholesterol significantly less in treatment (+0.7%) compared to control (+4.5%), p=0.006 but effect only observed in women (difference in absolute change +5.4%, p=0.002) and not men (difference in absolute change -1.2%, p=0.31).</li> <li>*% increase in no. overweight significantly less in treatment (+0.3%) compared to control (+3.2%), p=0.0002.</li> <li>*Changes in smoking and rates of physical activity not different between groups.</li> <li>*Blood pressure increased in the intervention (+3.0 mmHg) but fell in controls (-3.0 mmHg), p=0.0001.</li> <li>% decrease in consumption of animal fats not different at 2 years but was at final survey (-8.9%; 95% CI -11.8 to -5.9 vs -4.0%, 95% CI -6.9 to -1.0, (p=0.02) (39).</li> <li>Significantly greater reduction in high fat foods amongst black respondents at four years (-2.0; 95% CI-3.0 to -1.1) compared to white respondents (-0.6;95%CI -1.6 to 0.3) (38)</li> <li>% increase in vegetable fat consumption not</li> </ul>	<p><b>Identified by author:</b>            Insufficient intervention time for selected model of health promotion (stage theory of innovation).</p> <p><b>Identified by reviewer:</b>            Different baseline demographic features for treatment compared to control.            Higher proportion of women than men participated in cross sectional surveys (-63% women).            Effective management of survey data collection is not clear.</p>

Programme details	Intervention, policy, strategy or programme description	Program/study sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive results)	Confounders and limitations
<p>intervention and trends in dietary fat consumption among black and white adults. Journal of Am Diet Ass 1994; 94(11):1284-1290 (39)</p> <p>Goodman et al. Evaluation of the Heart to Heart Project: Lessons from a community-based chronic disease prevention project. Am J Health Prom 1995, 9(6): 443-455 (37)</p> <p>Smith et al. Changes in cardiovascular disease knowledge and behaviour in a low-education population of African-American and white adults. Ethnicity and Disease 1996; 6:244-254 (5)</p> <p><b>Study designs:</b> Controlled before and after study assessed by cross-sectional survey</p> <p><b>QA Grade:</b> '+'</p>	<p>discussions), educational programmes, cooking demonstrations, point-of-purchase and restaurant labelling (36).</p> <p><b>Comparison:</b> No intervention</p>				<p>different at 2 years but was at final survey (+8.4%; 95% CI 5.2 to 11.6 vs. +3.6%; 95% CI 0.4 to 6.8, p=0.04) (39).</p> <ul style="list-style-type: none"> <li>• No differences in within group changes in solid vegetable fat or cooking fat use (39).</li> <li>• No. people rarely consuming fat from red meat increased in the intervention but not control group. Significant at two years (intervention group: +4.4; 95% CI 1.6 to 7.1, control group: -0.2%; 95% CI -3.0 to 2.6, p=0.02) and at final survey (treatment group: +3.0; 95% CI 0.2 to 5.8, control group: -1.5; 95% CI -4.3 to 1.3) (39).</li> <li>• No differences in within group changes for consumption of beef, pork and hamburgers or in consumption of fried fish and meats (39).</li> <li>• Relative knowledge regarding appropriate cholesterol level greater at 2 years (net 7.6% improvement, p&lt;0.0001) and post-intervention (net 6.4% improvement, p&lt;0.001).</li> <li>• Relative knowledge of own cholesterol level greater at 2 years (net 9.4% improvement, p&lt;0.0001) and at follow-up (net 6.0% improvement, p&lt;0.001).</li> <li>• Self-reported cholesterol screening rates greater at 2 years (net 13.3% increase, p&lt;0.001) and at follow-up (net 8.6% increase, p&lt;0.001).</li> <li>• No. participants told had high cholesterol greater at 2 years (net 3.9% increase, p&lt;0.05) no follow-up difference.</li> <li>• There were no treatment/control differences in changes in rates of blood pressure treatment (36).</li> </ul>	



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Programme details	Intervention, policy, strategy or programme description	Program/study sample & setting	Duration of study and follow-up period/s	Primary and secondary outcomes	Results (significant positive results)	Confounders and limitations
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### 3.3 Applicability of the evidence to the UK populations in the scope

There are no generalisable statements that can be made about the applicability of the evidence to the UK population at this stage beyond the individual comments already made about individual programmes above. It is clear that limited information about the nature of the populations targeted by the programmes considered is a major constraint on judgements about applicability. There are clearly some programmes which seem highly likely to be applicable because they were conducted in the context of the NHS. However, it is also clear that the passage of time is also very important as health care systems evolve and, more importantly, the balance of risk factors faced by the populations does not remain constant. For instance many programmes considered in this report were conducted at a time where smoking prevalence is much higher than currently; a testament to the success of initiatives to reduce smoking in recent decades.

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## 4 Discussion

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The aim of the current report was to form the first part of an effectiveness literature review to address the question:

What multiple risk-factor interventions are effective and cost-effective in the primary prevention of CVD within a given population?

The secondary aim was to report on specific questions identified as potential considerations by the Programme Development Group (Appendix B of the final scope). The following discussion includes:

- Papers included in the current report (4.1)
- An overview of programmes covered in the current report (4.2 Program overview)
- Discussion of the types of interventions/programmes excluded from the review (4.3 Excluded programs)
- A discussion of intervention effectiveness relating to considerations identified by the Programme Development Group (4.4 Emerging themes)
- Generic issues regarding methods used for programme evaluation (4.5 Generic evaluation issues)
- Limitations of the current review (4.6 Limitations of the review)

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## 4.1 Papers included in the review

As already indicated, but repeated here for convenience, the programmes included in this report are:

- The Bootheel Project (Brownson 1996)
- The British Family Heart Study (Wood 1994)
- The Danish Municipality Project (Osler 1993)
- The German Cardiovascular Prevention Project (Hoffmeister 1996)
- The Heart to Heart Project/South Carolina Project (Heath 1995) (Wheeler 1991) (Croft 1994) (Goodman 1994) (Smith 1996)
- The North Karelia Programme (Puska 1979) (Salonen 1981) (Puska 1983 Ten) (Puska 1983 Change) (Puska 1985) (Puska 1989)
- The Norsjo Project (Weinhall 1999)
- The Minnesota Heart Health Programme (Jacobs 1986) (Luepker 1994) (Luepker 1996) (Mittelmark 1986) (Murray 1994) (Kelder 1993) (Perry 1992) (Rissel 1995)
- OXCHECK (Muir 1994) (Imperial Cancer Research Fund OXCHECK Study Group 1995)
- The Pawtucket Heart Health Programme (Elder 1986) (Lefebvre 1987)(Assaf 1987) (Carleton 1995) (Eaton 1999) (Hunt 1990)
- The Stanford Five City Project (Farquhar 1985) (Taylor 1991) (Fortmann 1995) (Fortmann 1993) (Fortmann 1990) (Winkleby 1996) (Farquhar 1990)

## 4.2 Programmes overview

This review evaluates the effectiveness of eleven programmes aimed at improving cardiovascular health. Five of these were very large-scale community intervention programmes and six were smaller scale community interventions.

Of the large-scale interventions, the Finnish **North Karelia project** is generally held as the most successful heart health community programme. Intervention began in 1972 and has been maintained for over twenty years with effective government, industry and community support. Favourable outcomes for smoking rates, total cholesterol and blood pressure have been sustained throughout intervention. This project differs slightly from others in its particular selection of communities with high rates of CVD and this may have been important in the manifest improvements from baseline compared to the lower risk-factor control community. However, net improvements have been sustained throughout the long period of intervention, even after CVD risk factors became comparable with control communities. The novelty of the intervention for the particular time and setting may have contributed to effects, the North Karelian project being the first of its type. The length and sustained effect of intervention though suggest that novelty was not solely responsible for the success of this project. Multi-targeted efforts to change both environmental and behavioural influences were likely to have played a large part in ultimate project success and examination of the particular methods and strategies employed may provide useful insight for future planning of heart health programmes.

Other large-scale projects have been less successful but do provide some encouragement and useful guidance. The **Stanford Five City project** was a six-year intervention, initiated in 1980, in five US cities. Effects appear to have been modest but consistent with improvements in smoking rates, blood pressure and weight gain. The programme used existing organisations as channels for implementation e.g. health departments, community colleges, schools and voluntary and ad hoc organisations. This implementation strategy, putting the emphasis on community

professionals rather than programme providers to deliver the intervention, may have had a positive effect, encouraging responsibility and initiative in the generation of new ideas and activities. The drive for community involvement and comprehensive nature of programme delivery may have been important factors in achieving community change.

The **Minnesota Heart Health Project** shows less evidence of positive health outcomes. This five-year educational programme showed little benefit except for consistent (cross-sectional and cohort data) improvements in physical activity. It is difficult to determine the reason for this particular change in light of the absence of other behavioural and physiological changes. Risk factor campaigns, designed to focus the interest of the community on single CVD risk factors over a defined period of time, were used and it may be that physical activity campaigns were the most effectively communicated or that community programmes encouraging physical activity were higher profile or better organised. Authors suggest that contamination of the comparison community may have had an important role in reducing observed treatment effects. The staggered entry of treatment communities (and their control pairs) into the programme may have increased the risk of contamination but, although this may have played some part, the programme itself must take some responsibility for its failure to bring about community change.

The **Pawtucket Heart Health Programme**, the fourth of the large-scale interventions currently reviewed, also failed to achieve positive behavioural and physiological outcomes. The approach of programme planners may have had detrimental effects on its success. Attempts to involve existing organisations were largely ineffective and planners appear to have taken an inflexible approach to intervention. This may have resulted in lower community enthusiasm and involvement. Authors identify that strong secular trends may have been responsible for lack of observed effect but the nature of intervention and implementation may be largely responsible for the lack of community change.

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The **German Cardiovascular Prevention project**, the fifth of the large-scale interventions currently reviewed, took advantage of existing institutions and facilities for project implementation. Collaboration with many public, voluntary, medical and consumer organisations lead to the implementation of a multifaceted strategy. There was a targeted approach to risk factor reduction over seven years of intervention and the project achieved significant improvements in physiological and behavioural outcomes.

The **Norsjo project** actively involved the health care sector in interventions to reduce risk of CVD and was evaluated over seven years. Results indicate a net reduction in total cholesterol in treatment compared to control communities. For other risk factors, only uncontrolled changes from baseline are presented but, despite this weakness in analysis, there may be positive intervention effects on physiological CVD risk factors. As part of the intervention programme, individual counselling was used and assessed in a separate cohort. There appeared to be an earlier reduction in some of the risk factors associated with CVD but counselling did not act to decrease overall risk.

The South Carolina Cardiovascular Prevention Project, otherwise known as the **Heart to Heart Project**, ran for just over two years and showed beneficial effects on CVD outcomes. Authors cite limited intervention time as reducing program effectiveness but results do appear promising and, although changes are largely behavioural, some physiological improvements were also detected. There may have been flaws in survey management as information on sampling techniques is sometimes unclear but there is no evidence of systematic bias. The Heart to Heart programme appears to have successfully encouraged community involvement with existing community organisations implementing the majority of initiatives, and it provides encouragement that smaller-scale heart health interventions may successfully improve CVD outcomes.

The **Bootheel Heart Health Project** was another smaller-scale programme with intervention occurring over one year. Results for this study may be of less interest as all outcomes were self reported and no physiological measurements were made.



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There were though net improvements in some behavioural outcomes and lower reported weight gain suggesting that the intervention may have had some positive effects. The project appears to have effectively engaged the community, evidenced by the local health agency support and ingenuity of community-led project interventions. Although self-reported results may not be wholly reliable, this project offers a useful model for achieving community engagement in heart health programmes.

The **Danish Municipality study** also involved a one-year community intervention period but showed no positive effects on behavioural or physiological outcomes. There does appear to have been programme awareness, most likely brought about by the media campaign, but other project activities appear small scale with low rates of participation. Initiatives were largely run by social contacts of the steering committee and, with the lack of further community involvement and low attendance levels, the absence of improvement in CVD outcomes does not seem surprising.

The **OXCHECK** programme was based in general practices where participants were randomised to receive health checks or no health checks and followed up after one year and then again at three years. The study was well conducted and appears to show modest, positive, effects for all physiological outcomes except smoking, and a number of behavioural changes, at both one and three years of follow-up. The consistency of changes in a number of risk factors suggests effects were not due to chance and the maintenance of changes at three years suggests that longer-term lifestyle changes were made.

The **British Family Heart Study** also involved general practice-based screening and, in this study, registered males and their partners were given health checks and followed up after one year. Intervention was more intense than for OXCHECK and, throughout the year of study, participants received individual tailored check-ups depending on their level of risk. There was evidence of positive change in numerous physiological outcomes and, although analysis was not done on an intention to treat basis, for those receiving intervention, screening appears to have been highly effective.

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Risk factor changes in OXCHECK and the British Family Heart Study cannot be directly compared with those achieved by the whole community interventions since only the participating part of the population were surveyed (whereas, for community programmes, samples from whole populations were surveyed). OXCHECK and the British Family Heart studies do though provide evidence that screening is a useful tool for modifying CVD risk factors and may be an important component of multiple-strategy community intervention programmes.

Most community intervention programmes were primarily assessed by independent cross-sectional surveys and contemporaneous surveys conducted in control communities and this method of programme evaluation was classed as a controlled before and after study. Additionally, in four of the programmes (Stanford 5 City, Minnesota Heart Health, Pawtucket Heart Health and Norsjo), a cohort of participants from treatment and control communities were followed up for assessment during and after the intervention period. A cohort was also recruited in control communities and differences from baseline were compared for intervention verses control. This method of programme evaluation was therefore also classed as a controlled before and after study. In the Minnesota Heart Health programme, effectiveness was evaluated using the Interrupted Time Series method and classed as such for quality assessment. OXCHECK and The British Family Heart Study both employed a randomised controlled trial design.

The following table gives a summary of the programmes covered in this review. The rating of effectiveness was based on the number of findings of significant improvement in CVD risk factors in treatment compared to control groups. Physiological outcomes were given more weight than behavioural, knowledge or attitude outcomes and negative weighting was given where data analysis was less clear or inappropriate.

Programme	Duration of intervention	Intervention Population size	Effectiveness			Quality score
			Strong	moderate	Weak	
North Karelia	>20 years	~180 000	√			+
Stanford 5 City	6 years	>125 000		√		-
Minnesota	5 years	>230 000			√	-
Pawtucket	11 years	>71 000			√	-
German	7 years	~1 000 000	√			+
Norsjo	~7 years	~5 500		√		+
Heart to Heart	7 years	>46 000	√			-
Bootheel	1 year	Not specified			√	-
Danish	1 year	~ 8 000			√	-
OXCHECK	1 year	~2 200	√			+
British Family	1 year	~ 3 000	√			+

Table 5 Summary of reviewed programmes detailing location, duration, population size, effectiveness and quality

### 4.3 Excluded programmes

Programmes were excluded on the basis of the scope set out by NICE and the NICE approved review protocol, using the checklist detailed in appendix 4. Excluded programmes, with reason for exclusion, are set out in the table in appendix 5 of this report. Most studies were excluded on the basis of the population selected for study since this was the first exclusion criteria applied. The criteria for inclusion was that populations were defined on a geographical basis and, studies where populations were not defined geographically, were excluded. In some cases this resulted in the exclusion of community interventions set in schools or workplaces where interventions did not aim to cover a particular geographical area. However, exclusion of interventions in these types of location was not by design and interventions focusing particularly on schools, workplaces, healthcare settings etc, that were also

defined on a geographical basis, were included e.g. OXCHECK and the British Family Heart Survey.

The second wave of exclusions were programmes involving interventions aimed at high-risk individuals since the aim of this review was not to cover this group. The third wave of exclusions were determined by the intervention aim. Programmes were required to specifically address cardiovascular disease in their project goals and those aiming to address other issues, such as obesity or physical activity, were excluded, even where those programmes covered multiple CVD risk factors. This approach resulted in the exclusion of programmes that may have been effective in reducing a number of CVD risk factors but did not set out to address CVD as a whole. Since the volume of literature in this area is extremely large, it was not within the scale of this review to cover these types of programmes. However, valuable information may be gleaned by analysis of these types of studies and this may be covered by other areas of review.

#### 4.4 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.

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It is difficult to judge cause and effect for questions relating to relative programme effectiveness since a wide range of factors predict intervention effect. The following sections should therefore not be taken to provide evidence of the importance of influencing factors. However, observations made in the course of this review, and discussed in the following sections, are hypothesis generating and may be tested subsequently with data from phase 2 of the review to give a clearer impression of cause and effect.

### **Nature of the target audience**

The effectiveness of heart health programmes to modify CVD risk factors in specific demographic groups may vary. Differences may be due to variations in awareness, knowledge, beliefs and attitudes or due to differences in time and responsibility constraints. From the programmes covered in the current review, there is some information relating the ethnicity of the target audience to programme effectiveness. There is limited information on the impact of age and gender but, where information becomes available, this will be discussed in the second review phase.

### ***Ethnicity***

Programme response may be different in people of different ethnic backgrounds and the Heart to Heart project, conducted in the culturally diverse district of South Carolina, gives some evidence that programme effectiveness varies in people from different ethnic backgrounds. The community programme aimed to reach people of all demographics but it is evident that, over four years of intervention, changes in the black population did not always match changes observed in white people from the same community.

White survey participants showed significant net (treatment compared to control community) improvements from baseline for the % with good cholesterol knowledge (men +8.3%,  $p < 0.05$ , women +8.5%,  $p < 0.01$ ) and in their attendance for cholesterol screenings (men +8.5%,  $p < 0.05$ , women +10.2%,  $p < 0.01$ ). However, there was no significant net improvement in screening rates for black people (men +5.2 NS, women

6.2 NS) and, although black women showed better cholesterol knowledge (+8.6%,  $p < 0.05$ ) black men did not (+7.8%, NS). The same pattern was shown for knowledge of personal cholesterol level. Significant net improvements were evident for white men (+8.5%,  $p < 0.05$ ), white women (+9.3%,  $p < 0.01$ ) and black women (+8.5%,  $p < 0.05$ ) but not for black men, where there was no increase in knowledge (-0.6%, NS) (36).

Cross-racial differences, although important in relation to knowledge and screening behaviour, were not apparent for dietary behaviours. Black and white survey respondents showed very similar improvements in dietary habits (reduction of animal fats and increases in vegetable fats) (39). A possible explanation may be that black women, presumably responsible for a large majority of household cooking, are more responsive to health promotion messages and that, for dietary changes at least, black men receive a positive intervention effect.

There are likely to be cross-cultural differences in the effectiveness of heart health promotion programmes and particular attention may be necessary to reach and relate to black men. Of particular concern may be to ensure that black men receive and act on messages to increase CVD health screening.

### **Intervention theory or conceptual model**

Community health behaviour change is a multi-step process. It requires people to be aware of health risks, be concerned as to their own health status, believe they have the ability to modify risk behaviours, identify the tools with which to make behavioural changes and sustain lifestyle changes into the future. It is logical to conclude that behavioural change will not be achieved with an approach that targets a single stage in this process because, unless other requirements are also met, end-stage lifestyle change will be incomplete, unsustainable or simply not take place.

For the reviewed health promotion programmes, the most common theoretical approach appears to be the Social Learning Theory, used in the North Karelia, Pawtucket, Minnesota, Stanford, Danish and Bootheel programmes. This model utilises the spread of behavioural change from people influenced by programme

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activities to people in their households or other social networks. This is an important aspect of behavioural change that may address many parts of the process. For example, a person influenced by programme activities may raise awareness in their own family, demonstrate the ability to change, give guidance as to practical methods for change and provide ongoing support to others.

Despite the potential in this theory, in practice it may not be sufficient as it relies heavily on individuals and may ignore many of the inhibiting lifestyle factors that impede change. This was demonstrated in the initial implementation of the Pawtucket Heart Health programme. Although social learning principles were first used, there was a failure to fully communicate and raise awareness and the education strategy had to be modified to include concurrent whole community mass media approaches. Other heart health programmes have combined this theory with others (Pawtucket, Minnesota, Stanford) in order to cover each level of change. The 'stage theory of innovation', used in the South Carolina/Heart to Heart and Bootheel projects, also appears to cover different levels, with each stage of health behaviour change being taken into consideration.

Although many different models, with different names and theoretical intricacies, exist, a message that emerges may be that a varied approach, encompassing methods that target each stage of health behaviour change, should be used. It is also important that all those involved in project planning and implementation have a clear understanding of the multi-level, targeted, approach so that all members understand the goals and rationale for decisions making.

### **Status of those implementing the intervention**

Intervention effectiveness may depend on the individuals and organisations responsible for project delivery. This may be important at all levels: management, employed project staff, coordinating bodies and those doing ground level project organisation. From the current review there is insufficient data to comment on

management level implementation but community involvement appears to be vital for engagement and project success.

In the Danish municipality project, activities were organised by volunteers, recruited by social contacts (family and friends) of the steering committee (3). These people were unlikely to have represented a cross-section of the community and may have primarily been from high socio-economic backgrounds. Project activities largely failed, showing low attendance rates, and this programme became a principally mass media campaign, with little community interaction.

In the Pawtucket Heart Health programme, the initial emphasis, aiming to recruit community organisations such as workplaces, churches and schools, failed and organisations showed wariness and even negativity towards activities. Organisations, approached for participation, found the intervention protocol 'cumbersome and rigid' (22). This may demonstrate more about programme coordinators than the organisations themselves. Failure to recognise the need for flexibility and openness of approach led to low interest and participation from community organisations.

Conversely, despite their failings in other respects, the Heart to Heart and Bootheel projects successfully integrated local communities into the planning and organisation of project activities. The lower extent of funding and reduced number of project staff may have necessitated this change but also the 'stage theory of innovation', used to govern both projects, encourages positive community involvement and feedback at every stage. In these programmes, existing organisations were primarily used to implement and sustain community activities and they provide some evidence of changes in health behaviour and physiological outcomes. Although they were shorter and less comprehensive, the degree of community involvement may have been the important factor for community change.

Some degree of pre-intervention community contact may help to form links for future intervention. Most of the big intervention programmes (North Karelia, Pawtucket, Stanford and Minnesota) undertook pre-intervention needs assessment surveys but



these do not necessarily produce community engagement. The Bootheel project allowed a five month period, before the start of intervention activities, to contact and interview local leaders (1) and sufficient pre-intervention contact may help to lay the groundwork for community involvement.

### **Way that the intervention is delivered**

Multiple modes of communication may be essential to affect behaviour change at every level. For example, mass media may be effective in raising awareness but may not give people the belief, skills or tools necessary to make lifestyle changes. Equally, group discussions and counselling may provide guidance and support but, without the awareness of a need for change, these activities will go undersubscribed. From the programmes currently reviewed, there is some evidence as to the importance of certain project activities in heart health programmes.

#### *Mass media*

The Pawtucket Heart Health programme did not use a media campaign in the initial stages of the project but, after a year of intervention, the decision was made to include mailings, newspaper, radio and other forms of media communication (22). It was recognised that media was important in promoting large scale awareness of the campaign and vital for successful implementation of other community projects.

Unlike other programmes though (Stanford, Minnesota, Heart to Heart), Pawtucket did not use television as a mode of media communication. Television looks to have been an important tool in the Stanford Five City project where it was the major channel used for both raising awareness and promoting behavioural change (41). Similarly, in the Heart to Heart project, television was used to host live discussions (36) and evidently provided a more extensive drive to behavioural change than simply raising awareness. Stanford and Heart to Heart projects do appear to have been more effective in improving behavioural and physiological outcomes) than Pawtucket but, it is not possible to infer whether this was due to the use of television.

Television and other media may also be useful in promoting knowledge and understanding of CVD health information. A survey of adults, living in an area of Danish Municipality intervention, reported that television and radio were the primary source of their knowledge relating to cardiovascular health (second was newspapers and magazines) (3). The involvement of some sort of mass media strategy appears to be important in raising community awareness and may also be useful for health education and for encouraging behavioural change.

### *Screening*

Screening sessions may be an effective method to make personal contact with community members. In the Pawtucket Heart Health Program, 55% of programme contacts were made through screening events whereas only 20% were through group programmes (42). The introduction of mass screenings coincided with the biggest rates of new participation and, whether screenings were conducted in community locations or organisational settings, they attracted many new participants (22).

In screenings, participants are counselled and followed up, giving the advantage of not only increasing knowledge of risk, but also giving motivation and provision for change. The effectiveness of screening as a single activity for risk factor change was investigated in two projects described in the current report: OXCHECK and The British Family Heart Survey. Both these projects showed very positive short term effects on physiological and behavioural risk factors, greater than those seen with any of the large community interventions. Effectiveness results cannot be directly compared since community sampling in programme intervention surveys includes both programme participants and non-participants whereas, in the OXCHECK and British family Heart studies, the whole treatment group underwent intervention. However, the high degree of effectiveness in OXCHECK and the British Family Heart Survey suggests potential for screenings to bring about positive lifestyle change.

Most community intervention programmes include a screening component (North Karelia, Bootheel, Minnesota, Pawtucket and Heart to Heart) and, if a high proportion

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of programmes contacts are screened, effects due only to screening may explain a large part of observed treatment effects. Information was not found on the intensity and coverage of screening activities in these programmes but this might provide some insight into the relative effectiveness of different programmes. Whatever the case, screening activities are likely to be an important element for inclusion in heart health programmes.

### *Environmental change*

An important aspect of behavioural change is the creation of an environment that helps to promote, support and sustain change. The North Karelia project may be novel in the extent to which it involved large-scale environmental change including smoking restrictions, the availability of low-fat dairy and meat products, increased vegetable production, and promotion of healthy foods in shops (15). The Stanford Five City programme involved attempts to make food selections at cafeterias, restaurants and supermarkets more healthy (29) and the German Cardiovascular Prevention Project involved increasing availability of low-fat and low salt products and introduced non-smoking areas in public places. North Karelia, the German project, and to some extent Stanford Five City, were effective in improving cardiovascular risk factors compared to other programmes. Although causation cannot be implied until more data is available, there is some suggestion that environmental changes may have an important role in health behaviour change.

### **Duration of intervention**

The duration of intervention may be important for programme effectiveness. Duration varies considerably for the projects currently reviewed: North Karelia > 20 years, Pawtucket Heart Health 9 years, Stanford 5 city 6 years, German Cardiovascular Prevention 6 years, Minnesota Heart Health 5 years, Bootheel ~4 years, Heart to heart just over 2 years and the Danish municipality, OXCHECK and British Family Heart projects 1 year. Although North Karelia, a successful long-term intervention is held as

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a programme to aspire to, is it necessary to have this length programme, or, can shorter interventions be as effective?

Formative data from the Pawtucket Heart Health programme gives information on changes in the numbers of participants in programme activities over time (22). The slow start in programme participation was presumably due to an initial lack of programme awareness (see programme description). The number of new people participating was 253 during phase I of the intervention (11 months), 840 during the second phase (7 months) and increased dramatically to 7,232 during the 8 months of phase III (>80% of all new participants). Although the Pawtucket programme may have had a particularly slow start, this exponential type increase may be common to the way that many programmes develop. If this is the case, a longer project duration, possibly  $\geq 3$  years, may be important to achieve rapid rates of new participation. The Heart to Heart program ran for only ~two years and, although positive changes in risk factors were achieved, these may have been greater had the project duration been extended.

### **Transferability to other settings**

The generalisability of programmes in the current review was discussed previously in the 'applicability' section (section 3.3).

### **Intensity**

For programmes identified in the current review, there is limited evidence for the impact of intervention intensity on relative effectiveness. Some formative data, describing the percentage of time spent on different types of intervention activity, is available (41) but this does not detail the actual number of times each activity was implemented. More data may be available for programmes included in phase 2 of this review and, if this is the case, the phase 2 report will discuss the importance of intervention intensity on programme effectiveness.

### **Availability or accessibility for different population groups**

No information has currently been identified for the availability or accessibility of programmes to people in different population groups but, where information becomes available, it will be discussed in phase 2 of the effectiveness review.

## 4.5 Generic evaluation issues

Community intervention programmes were primarily assessed by independent cross-sectional surveys and cohorts followed up from baseline with comparison with control communities and there are some generic issues related to these methods for programme evaluation.

### *Cross-sectional surveys*

When the aim is to describe simple secular trends, the use of cross sectional surveys is well suited but when the aim is to assess the effects of intervention, it has some limitations. Because the survey participants will be different at each time point, within-person comparisons cannot be made. Changes from baseline may still be a valid method of assessment but the sample size must be large in order to overcome uncertainties due to between-person variation. The size of cross-sectional surveys is therefore important due to the low power associated with the independent measurements. Smaller surveys show higher standard errors and significant findings are harder to detect. This may have been a problem in some of the smaller programme evaluations where sample size may have been restricted.

The other difficulty with the use of cross-sectional surveys in this type of controlled programme evaluation is contamination due to migration in and out of treatment and control communities and this may be a particular problem for programmes operating over a number of years. If people from intervention areas migrate into control community areas, or vice versa, and are included in population surveys, apparent treatment effect may be diluted. The relative locality of treatment and control areas is important in this respect and may have bearing on the apparent effectiveness of different programmes.

Another difficulty with the use of cross-sectional surveys occurs when there are demographic or risk-factor differences between control and intervention communities. Adjustments may be made for baseline differences but the assumption must be made that participants in subsequent surveys are not systematically different to those initially surveyed. This may be a reasonable assumption to make, especially where surveys are large and efforts are made to cover cross sections of the whole community.

### *Nested cohort*

The other study method used in the programmes currently reviewed, the nested cohort design, normally has more power than cross sectional surveys because it makes within-person comparisons. Adjustments can more reliably be made for differences between groups at baseline, especially if there have not been major losses to follow up in treatment or control groups. Cohorts do not suffer from contamination problems of cross-sectional surveys since all of the treatment group will be from the intervention community and all of the control cohort will be from the control community.

A disadvantage of this method is that the cohort may not be representative of the community as a whole. The recruited participants may be systematically different from the whole population because willingness to take part may be associated with a different demographic or risk-factor profile. If cohorts do not represent typical demographic, socioeconomic and risk-factor characteristics, results may not be generalisable to the whole community population.

Drop-out from cohorts is also an important issue, especially where there are differences in the types of people leaving treatment and control groups. There may be systematic differences between participants dropping out of the cohort and those remaining in terms of gender, age, ethnicity, education or other socioeconomic factors. If the type of people leaving the treatment and control cohorts is systematically different, this creates bias and may impact the apparent effectiveness of intervention.

## 4.6 Limitations of the review

The main limitation is that these are the interim results of the full review. We already have indications that there may be a considerable number of additional programmes to consider in the second report. Because we are most likely to have captured older programmes by using existing systematic reviews as the main method of ascertainment it seems likely that the additional programmes will represent newer initiatives operating in populations where the levels and nature of CVD risks in the populations targeted are closer to those existing currently

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 uncovered.

Availability from published reports about important information on the nature of the programmes, the populations targeted and detailed results is also a key limitation. Inability to completely quantify the size of effect is likely to have important implications, particularly identifying whether variation in study results from the included programmes is just due to chance alone. Some of the uncertainty about the nature of the programmes and the populations may become clearer in work to address Question 2.

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## Appendix 1: Protocol to Address Question 1

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### **Primary research questions**

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

### **Secondary research questions**

Any study identified addressing the primary research questions will also be interrogated for information addressing the following potential considerations of the Programme Development Group identified in the final scope (Appendix B):

- The target audience, actions taken and by whom, context, frequency and duration.
- Whether it is based on an underlying theory or conceptual model.
- Whether it is effective and cost effective.
- Critical elements. For example, whether effectiveness and cost effectiveness varies according to:
  - the diversity of the population (for example, in terms of the user's age, gender or ethnicity)

- 
- the status of the person (or organization) delivering it and the way it is delivered
  - its frequency, length and duration, where it takes place and whether it is transferable to other settings
  - its intensity.
  - Any trade offs between equity and efficiency.
  - Any factors that prevent – or support – effective implementation.
  - Any adverse or unintended effects.
  - Current practice.
  - Availability and accessibility for different population groups.

Some of these are implicit in the primary question e.g. bullet 3; others are more relevant to review question 2 e.g. bullet 6 any factors that prevent – or support – effective implementation, covered in a separate protocol.

### **General plan**

The effectiveness part of the research question will be addressed in a single evidence review. In order to provide the information to the PDG in a timely fashion in manageable quanta the evidence review will be delivered in three phases:

- Phase 1 – initial findings, primarily from the included studies of systematic reviews, to be presented at September 2008 PDG meeting.
- Phase 2 – further findings, primarily the included studies of remaining systematic reviews, to be presented at October 2008 PDG meeting.
- Phase 3 – remaining findings, primarily from the search of primary studies, to be presented at December 2008 PDG meeting.

There will be different lead reviewers for the effectiveness and cost-effectiveness reviews and coordination between reviewers when undertaking the work. There will also be co-ordination with the evidence review being undertaken as part of question 2, for which there is a separate protocol. The health economic modellers will be part of the review team addressing question 1, particularly the cost-effectiveness components, which will achieve integration of this part of the programme with the subsequent health economic modelling, which is again not covered directly in this protocol. There will be regular joint meetings of all researchers working on all components of the programme.

### **Search Strategy and Search Protocol**

#### Proposed resources:

##### Phase 1 and 2:

- Primary studies identified in existing systematic reviews relevant to the research question, the systematic reviews being identified from searches of bibliographic databases (see below)

##### Phase 3:

- Additional primary studies identified from searches of bibliographic databases (see below)
- Additional potentially missing studies identified by PDG
- Searches of key UK public health web-sites (see appendix 1.1)
- Checking of bibliographies of included studies



Bibliographic databases:

Given the volume of material in the topic area and the time constraints we feel that concentrating principally on a limited number of electronic databases will be the most appropriate strategy.

Studies for review 2 will therefore be derived from the following bibliographic databases:

Cochrane (CDSR, DARE, HTA, EED, CENTRAL)

MEDLINE

MEDLINE In Process

EMBASE

CINAHL

PsycINFO

HMIC

ASSIA

Searches for cost effectiveness studies will be conducted on NHS EED database (Cochrane Library), ECONLIT, MEDLINE and EMBASE.

Bibliographic database search strategies:

The general approach will be to perform a search which captures all components relevant to the general topic (subject specific search terms) which will be combined with a series of “design filters” focusing on specific sub-types of literature. A review filter will be used to identify reviews for phase 1; a sensitive RCT filter combined with a selected number of other appropriate study design terms will be used to target primary studies providing evidence on effectiveness;

an economic studies filter will be used to target studies providing evidence on cost-effectiveness.

Studies will be limited to those in the English language published since 1970.

Bibliographic database search strategies (content terms):

Scoping searches have been conducted to estimate the nature and volume of the literature. Our initial scoping searches targeted systematic reviews, evidence briefings and guidelines as well as a brief search for primary studies. The key concepts of the search question are 'cardiovascular diseases' (population), 'health promotion' (intervention) and 'nature of the intervention' (focusing on the multiple-risk factor aspect of the intervention).

We submit our search strategy below which combines all three key concepts. The sensitive strategy has been preferred to ensure a comprehensive search and illustrates results for both reviews (line 45) and primary studies (line 55).

Database: Ovid MEDLINE(R) <1950 to June Week 3 2008>

Search Strategy:

- 
- 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)

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- 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 pharmaco-economic\$.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 be 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.



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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

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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

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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.

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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	16 <sup>th</sup> to 20 <sup>th</sup> June	23 <sup>rd</sup> to 27 <sup>th</sup> June	30 <sup>th</sup> June to 4 <sup>th</sup> July	7 <sup>th</sup> to 11 <sup>th</sup> July	14 <sup>th</sup> to 18 <sup>th</sup> July	21 <sup>st</sup> to 25 <sup>th</sup> July	28 <sup>th</sup> July to 1 <sup>st</sup> August	4 <sup>th</sup> to 8 <sup>th</sup> August	11 <sup>th</sup> to 14 August
Protocols & searches signed off by NICE	27 <sup>th</sup> June								
Search and obtain SRs			4 <sup>th</sup> July						
Inclusion / exclusion SR. Characterise SR. Obtain 1y studies				11 <sup>th</sup> July					
Inclusion / Exclusion 1y studies. Pilot data extraction and quality assessment					18 <sup>th</sup> July				
Complete data extraction/quality assessment						1 <sup>st</sup> August			
Synthesize data and prepare draft report for comments								14 <sup>th</sup> 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.

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## Appendix 2: Search Strategies

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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)"



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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)"



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## Appendix 3: Inclusion/exclusion Checklists for Previous Systematic Reviews

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### 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?			
<i>If 'Y' to all, order hard copy of the paper</i>			

### 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?				
<i>If 'Y' to all of section 1 continue. If 'N' to any of section 1 exclude. If '?' to any of section 1 pass to 2<sup>nd</sup> reviewer.</i>				
2.1. Do the review objectives include examination of the effectiveness of interventions targeting $\geq 2$ risk factors for CVD*? (Circle from list below)				
2.2. Do the review inclusion criteria include interventions targeting $\geq 2$ risk factors for CVD*?  (Circle from list below)				
2.3. Does the list / table of included studies include interventions targeting $\geq 2$ risk factors for CVD*?  (Circle from list below)				
<i>If 'N' to 2.3 exclude. If 'Y' to 2.3 continue. If '?' to 2.3 pass to second reviewer</i>				
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?				
<i>If 'N' to 3.3 exclude. If 'Y' to 3.3 continue. If '?' to 3.3 pass to second reviewer</i>				
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?				
<i>If 'N' to 4.3 exclude. IF 'Y' to 4.3 include. If '?' to 4.3 pass to second reviewer.</i>				

\* Risk factors include: smoking, poor diet, insufficient physical activity, high blood pressure, high blood cholesterol, obesity / overweight, diabetes, psychosocial stress, diabetes.

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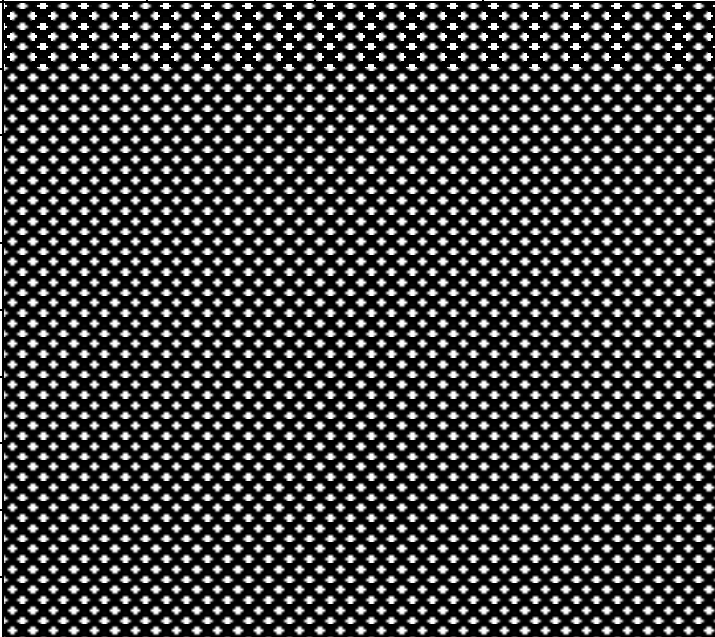
## Appendix 4: Full Paper Screening Checklists

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## Proposed inclusion/exclusion process for selection of primary studies

### Full paper screening checklist

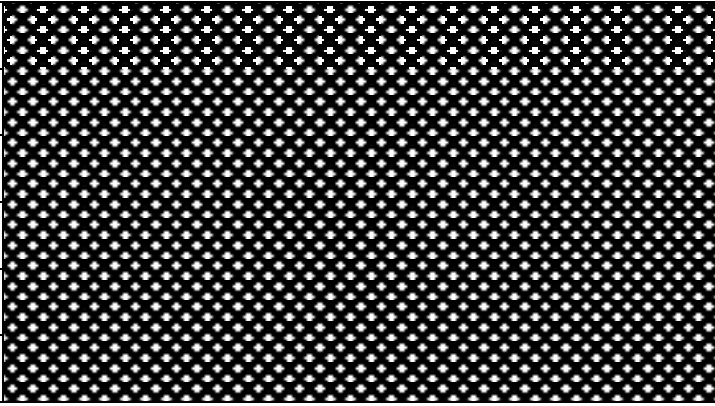
<b>Title:</b>				
<b>Date:</b>		Note: In case of ? use left or right arrow to indicate whether final decision is Y/N		
<b>Ref ID:</b>				
Study feature	Yes	? (Refer to 2 <sup>nd</sup> reviewer)	No	Comments
<b>PUBLICATION TYPE</b>				
Is the study a book, book chapter thesis, dissertation?				
<ul style="list-style-type: none"> <li>• If No continue.</li> <li>• If Yes STOP and exclude study as "INAPPROPRIATE PUBLICATION TYPE"</li> </ul>				
<b>DATE</b>				
Was the paper published after 1970?				
<ul style="list-style-type: none"> <li>• If Yes continue.</li> <li>• If No STOP and exclude study as "PUBLICATION PRIOR TO 1970"</li> </ul>				
<b>GENERAL</b>				
Does the paper broadly consider some sort of change which might affect CVD or CVD risk?				
<ul style="list-style-type: none"> <li>• If Yes continue.</li> <li>• If No STOP and exclude study as "DOES NOT ADDRESS GENERAL PURPOSE"</li> </ul>				
<b>SETTING &amp; POPULATION</b>				
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]				
<ul style="list-style-type: none"> <li>• If Yes to all continue.</li> <li>• If No to any STOP and exclude study as "INAPPROPRIATE SETTING or POPULATION"</li> </ul>				
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		[REDACTED]			
Fiscal					
Environmental					
Legislative					
<ul style="list-style-type: none"> <li>• If Yes to all, continue.</li> <li>• 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.</li> <li>• If No to any and not natural experiment exclude study as “INAPPROPRIATE INTERVENTION”</li> </ul>					
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)?					
<ul style="list-style-type: none"> <li>• If Yes TAG and refer to cost-effectiveness review team. Continue irrespective of Y/N answer.</li> </ul>					
Could this study be of interest in review of qualitative evidence, particularly on barriers and facilitators?					
<ul style="list-style-type: none"> <li>• If Yes TAG and refer to qualitative review team. Continue irrespective of Y/N answer.</li> </ul>					
Is this an evaluative study (RCT;CT;CBA;ITS;BA;Co;C-C) or a natural experiment?					
<ul style="list-style-type: none"> <li>• If Yes, continue.</li> <li>• If No STOP and exclude as “INAPPROPRIATE DESIGN for EFFECTIVENESS REVIEW”</li> </ul>					
OUTCOMES					
Does the study measure 1 or more of the following(tick all those applicable)					

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CVD mortality/morbidity		
Biochemical precursor		
Physiological precursor		
Behavioural change		
Knowledge/attitudes/ intentions		
Adverse events		
<ul style="list-style-type: none"><li>• If Yes, STUDY is INCLUDED.</li><li>• If No STOP and exclude as "NO APPROPRIATE OUTCOMES"</li></ul>		



## Appendix 5: Excluded Primary Studies by Reason for Exclusion

### Effectiveness primary studies

Programme/Study	Reason for exclusion			
	Wrong population (not geographically defined)	High risk group	Intervention not aimed at CVD	Non OECD country
Ebrahim et al. Multiple risk factor interventions for primary prevention of coronary heart disease. Cochrane Database of Systematic Reviews 2008				
Aberg men (Aberg 1989 A)	X			
Aberg women (Aberg 1989 A)	X			
Abingdon (Baron 1990)	X			
Applegate 1992 (Applegate 1992)	X			
Blumenthal 2000 (Blumenthal 2000)	X			
CELL Study (Lindholm 1995)		X		
Change of heart (Hilton 1999)		X		

Connell 1995(Connel 1995)	X			
Faris men (Goble 1997)	X			
Faris women (Goble 1997)	X			
Finnish DPS (Eriksson 1999)	X			
Finnish men (Miettinen 1985)	X			
Given 1984 (Given 1984)	X			
Gothenberg Study (Wilhelmsen 1986)		X		
HDFP trial (Hypertension Detectio and ....group 1979)		X		
Hellenius (Hellenius 1993)	X			
Iso (Iso 1996)		X		
Jalkanen 1991 (Jalkanen 1991)	X			
Johns Hopkins (Morisky 1983)	X			
Lin 1996 (Lin 1997)			X	
Lindahl 1999 (Lindahl 1999)	X			
MRFIT (Multiple Risk...group 1990)	X			
Meland 1997 (Meland 1997)	X			
Nilsson 1992 (Nilsson 1992)	X			
Nilsson 2001 (Nilsson 2001)	X			
Oldroyd (Oldroyd 2001)	X			
Oslo Diet Exercise (Holme 2007)	X			
Perez-Stable no prop (Perez-Stable 1995)	X			
Perez-Stable prop (Perez-Stable 1995)	X			
Stamler 1989 (Stamler 1989)	X			
Stefanick women (Stefanick 1998)	X			

Stefanick men (Stefanick 1998)	X			
Swedish RIS (Agewall 1994)	X			
Take heart (Glasgow 1995)	X			
The Oslo Study (Hjermann 1981)	X			
Tromso men (Knutsen 1991)	X			
Tromso women (Knutsen 1991)	X			
Uusitupa (Laitinen 1993)	X			
WHLP (Kuller 2001 A)	X			
WHO factories (World health organisation...group 1989)	X			
Wing (Wing 1998)	X			
Brunner et al. Can dietary risk interventions change diet and cardiovascular risk factors? A meta-analysis of randomised controlled trials. American Journal of Public Health 1997; 87: 1415-1422				
Baron (Baron 1990)	X			
Beresford (Beresford 1997)	X			
Bloemberg (Bloemberg 1991)	X			
Boyd (Boyd 1996)	X			
Bruno (Bruno 1983)	X			
Crouch (Crouch 1986)	X			
Foreyt (Foreyt 1979)	X			
Hellenius (Hellenius 1995)	X			
Henderson (Henderson 1990)	X			
HTPT (Hypertension prevention trial...group 1990)	X			
Koopman (Koopman 1990)	X			
Monjonier (Monjonier 1980)	X			

Morgan (Morgan 1978)	X			
Schapira (Schapira 1991)	X			
Silman (Silman 1983)	X			
The Treatwell Programme (Sorenson 1992)	X			
TOHP (Trials of hypertension..group 1992)	X			
Ketola et al. Effectiveness of individual lifestyle interventions in reducing cardiovascular disease and risk factors. Ann Med 2000; 32: 239-251 (Only from table of primary prevention studies)				
HBS (Miettinen 1985)	X			
The Tromso Survey (Knutsen 1991)	X			
Meland (Meland 1997)	X			
MRFIT (Multiple Risk...group 1990)	X			
The Oslo Study (Hjermann 1981)	X			
TOHP (Stevens 1993)	X			
WHO (European collaborative.. 1886)	X			
Wood (Wood 1988)	X			
Krummel et al. Cardiovascular health interventions in women: What works? Journal of Women's Health and Gender-Based Medicine. 2001; 10(2): 117-136 (Only from 'targeting multiple risk factors section)				
The Coronary Risk Factor Study (CORIS) (Rossouw 1993)				X
Nicholson. 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				
Heart Smart (Arbeit 1992)	X			
Know your body (Bush 1989)	X			
Cella (Cella 1992)			X	
D'Elia	X			
Duffy (Duffy 1986)	X			

Felton (Felton 1998)	X			
Ferguson (Ferguson 1989)	X			
Ford-Gilboe (Ford-Gilboe 1997)	X			
Project Smart (Hansen 1998)			X	
Howard (Howard 1996)	X			
Murphy (Murphy 1994)			X	
San dieago Family Health Project (Nader 1989)	X			
Go For Health Program (Parcel 1989)	X			
CATCH (Perry 1997)	X			
Petchers (Petchers 1987)	X			
Purath (Purath 1995)	X			
Know Your Body (Walter 1989)	X			
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? Am J Health Promot 2005; 19(3): 167-193 (From section 'Notable Community trials Using Policy and Environmental Interventions to Promote Cardiovascular Health')				
All included				
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				
The Coronary Risk Factor Study (CORIS) (Rossouw 1993)				X

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## Appendix 6: Quality Assessment

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Controlled before and after studies:

	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
Bootheel	Y	Y	NC	Y	N	N	N	N	3	-
Danish	Y	Y	NC	Y	N	Y	N	NA	4	-
German	Y	Y	Y	Y	N	NC	Y	NA	5	+
Minnesota	Y	Y	NC	Y	N	NC	Y	N	4	-
Norsjo	Y	Y	N	Y	N	N	Y	Y	5	+
North Karelia	Y	Y	Y	Y	N	NC	Y	Y	6	+
Pawtucket	Y	Y	N	NC	N	Y	Y	N	4	-
Stanford 5 city	Y	Y	N	Y	N	NC	Y	N	4	-
South Carolina	Y	Y	Y	Y	N	NC	N	NC	4	-

## Randomised controlled trials:

	British Family Heart	OXCHECK
Clear question	Adequately addressed	Adequately addressed
Randomised	Well covered	Well covered
Adequate concealment	Not reported	Not reported
Subjects and investigators 'blind'	Not applicable	Not applicable
Similarity at baseline	Not reported	Adequately addressed
Only difference is intervention	Adequately addressed	Adequately addressed
Validity of outcome measures	Adequately addressed	Well covered
% dropout	Int. 13%, Con. ?	22%
Intention to treat analysis	Not addressed	Well covered
Comparability of intervention sites	Poorly addressed	Not clear
No. well or adequately addressed	5	6
	+	+

++	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.

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## Appendix 7: Example Completed Effectiveness Data Extraction Form

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<b>Data Extraction Form</b>	
<b>Authors/ Title/ Source</b>	
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	
<b>Project:</b> The Norsjo Project	
<b>Data extracted by:</b> Wendy Greenheld	
<b>Date of extraction:</b> 14 <sup>th</sup> August 2008	
<b><u>Aim:</u></b>	
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.	
<b><u>Study design:</u></b>	
Systematic review (including at least one RCT)	<input type="checkbox"/>
Systematic review of experimental studies	<input type="checkbox"/>
Systematic review of observational studies	<input type="checkbox"/>



Randomised controlled trial: Individual	<input type="checkbox"/>
Randomised controlled trial: Cluster	<input type="checkbox"/>
Controlled non-randomised trial	<input type="checkbox"/>
Controlled before-and-after	<input checked="" type="checkbox"/>
Interrupted time series	<input type="checkbox"/>
Before and after study	<input type="checkbox"/>
Case study	<input type="checkbox"/>
Other (please state)	<input type="checkbox"/>
<b><u>Other study parameters:</u></b>	
<b>Setting:</b> The island municipality of Norsjo in Northern Sweden.	
<b>Geographical(city/county):</b> 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.	
<b>Social (school/workplace etc):</b> whole community	
<b>Date of study (to/from):</b> 1985 to 1992	
<b>Funding:</b> Generally, the preventive work in Norsjo was achieved within the framework of the existing community organisations with little additional financial support.	
<b><u>Participants:</u></b>	
<b>Number of participants/organisations etc enrolled:</b> 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.	
<b>Unit of allocation/recruitment:</b> Community	
<b>Sex:</b> Men and Women relative percentages not reported	
<b>Age (range or mean):</b> 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.	
<b>Inclusion criteria:</b> 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<sup>2</sup>), 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<sup>2</sup> 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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Not clear <input type="checkbox"/>
Gender	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Not clear <input type="checkbox"/>
Ethnicity	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Not clear <input type="checkbox"/>
Socio-economic status	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Not clear <input type="checkbox"/>

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?:** Norsjö 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 control area it is possible that the programme may have had some spillover effects.

