A randomized trial to evaluate the effectiveness of dietary advice by practice nurses in lowering diet-related coronary heart disease risk

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SUMMARY

Background. *Dietary factors are an important contribution to the high rates of coronary heart disease in the UK. One approach to achieving change is health-promoting advice in primary care.*

Aim. *To compare the effectiveness of structured dietary advice by practice nurses with standard health education in changing serum cholesterol, weight and diet.*

Method. *Randomized, controlled trial within eight general practices in England and Wales allocated within matched geographical pairs to 'dietary advice' or 'usual care'. Men and women aged 35–59 years, recruited opportunistically by their GPs, underwent health checks. In 'dietary advice' practices, subjects received dietary advice from specially trained nurses based on negotiated change principles, reinforced at follow up. In 'usual care' practices, subjects were only given standard health education materials.*

Results. *A total of 956 patients were recruited: 473 in 'dietary advice' practices and 483 in 'usual care' practices. Compliance with annual follow up was 80%. Compared with 'usual care' practices, there was a mean 0.20 mmol/l lower serum cholesterol (95% CI –0.38 to –0.03 at 1 year) in 'dietary advice' practices. There was a small fall in weight of 0.56 kg (95% CI –1.04 to –0.07) and reductions in total and saturated fat. Factor VII coagulant activity fell by a mean of 6.7% of the standard (95% CI –15.4 to +2.0).*

Conclusion. *Provision of standard health education material alone as part of a health check had no effect on coronary heart disease risk factors. There were modest changes in diet and associated risk factors when a more intensive and individual approach to dietary advice was given by practice nurses. This is, however, probably an ineffective use of resources, except in those at high risk of coronary heart disease. Whole-population strategies to achieve dietary change are required.*

Keywords: diet; practice nurses; coronary risk factors.

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Introduction

THE role of dietary change in reducing the incidence of coronary heart disease (CHD) and other major chronic diseases is well recognized.[1] Dietary guidelines recommend a reduction in total and saturated fat intake and an increased consumption of complex carbohydrates and fruit and vegetables.[2] Such changes would affect important coronary heart disease risk factors, such as serum cholesterol.[3,4] Dietary advice is the mainstay of treatment for moderate hypercholesterolaemia, which is highly prevalent in the UK population. It is an important component, alongside increased exercise, in reversing the rising level of obesity in the population.[5]

Dietary advice in primary care is one potential method by which such change might be achieved. The majority of the population attend their practice regularly, and general practice might be seen as a credible source of health education. There has been a considerable expansion of primary care health promotion, including dietary advice, in which practice nurses have played a central role. It is important to assess the effectiveness and cost-effectiveness of such interventions. However, there have been doubts about the ability of primary care teams to deliver effective dietary counselling.[6] Recent studies have reported modest effects of practice nurse interventions on coronary heart disease risk factors, both at a general population level and in patients identified as being at higher risk of CHD because of hypercholesterolaemia.[7,8,9]

This paper presents the results of a randomized study that aimed to test whether structured dietary advice and follow up by practice nurses was more effective in changing diet, serum cholesterol and weight than provision of standard health education in adults aged 35–59 years recruited opportunistically in primary care. The trial provided an opportunity to study the effect of dietary advice on a recently identified risk factor, factor VII coagulant activity (VIIc), which has been shown to be associated with dietary fat intake.[10,11]

Method

Practice and patient recruitment

This was a randomized, controlled trial in which the unit of randomization was a general practice. Eight practices from the Medical Research Centre's (MRC's) general practice research framework (GPRF) were selected in pairs with one pair from each of four geographical areas – Yorkshire, Midlands, south-east England and South Wales. Practices were randomized to receive either 'dietary advice' or 'usual care' strategies. Patients were recruited opportunistically by their general practitioners (GPs), who were asked to invite all patients aged 35–59 years attending surgery who did not have contra-indications, i.e. known causes of secondary hyperlipidaemia, severe psychiatric illness, pregnancy, terminal illness or those already attending a coronary heart disease health promotion clinic.

Spouses who were in the appropriate age group were encouraged to attend. Patient recruitment was monitored to ensure balanced age and sex distribution within practices.

Baseline measures

Participants completed a questionnaire on sociodemographic details, lifestyle, past medical history and family history of coronary heart disease. It contained a dietary food frequency questionnaire, previously validated against a weighed record method for group estimates on male and female samples in South Wales.[12,13] At a nurse health check, height and weight (without shoes or outdoor clothing using either Seca [in four practices] or balance scales), pulse rate and blood pressure (two readings sitting at rest no more than 5 minutes apart using a random zero sphygmomanometer) were measured, and a non-fasting blood sample was taken for measurement of serum cholesterol. This was analysed by one laboratory using an enzymic method.[14] A sample was spun and plasma separated and sent by post for measurement of factor VII coagulant activity (VIIc) by a one-stage automated clotting assay, and of fibrinogen by the Clauss method.[15,16]

Nurse training

All eight nurses were trained in trial procedures. MRC GPRF regional nurse trainers maintained close contact with all nurses. In the 'dietary advice' practices, nurses were trained by a state registered dietician over a one-and-a-half-day period in diet and its relationship with coronary heart disease, how to use the nutritional tools (including interpretation of the food frequency questionnaire to assess dietary habits), and how to negotiate dietary changes with each patient.

Interventions

All patients received standard health education from the leaflets *Guide to Healthy Eating, Giving up smoking, Look After Your Heart, Heart Disease,* and *Exercise, Why Bother?* This was the only routine intervention in the 'usual care' practices. In the intervention practices, dietary advice was given, based on negotiated change, which aimed for food substitution (i.e. the nurse and patient negotiated and agreed up to five changes) after review of the type, quantity and frequency of key foods consumed. Specially designed dietary sheets were given out according to whether weight loss was required; all foods were classified as 'to eat plentifully', 'in moderation' or 'on special occasions only'. Special leaflets covering, for example, snacking, were given out where appropriate. Patients who were overweight (BMI over 25 kg/m^2) were given special advice, including a self-monitoring chart and a choice of a calorie-restricted diet. Any changes were recorded on an action plan, a copy of which was kept by the nurse.

Follow-up schedule (Figure 1)

In the 'usual care' practices, there was no further follow-up until an annual assessment, except for those with raised baseline serum cholesterol who were asked to return for a fasting repeat that also included measurement of triglyceride and apolipoproteins A and B. If the mean cholesterol was over 7.8 mmol/l, the GP was informed. If the mean was over 6.5 mmol/l, the diet sheet was handed out and a repeat non-fasting blood sample was scheduled at 6 months.

Similar procedures were undertaken for patients with raised cholesterol in the 'dietary advice' practices, except that GPs were only specifically informed of hypercholesterolaemia at 6 months. All patients were asked to return at 4–6 weeks, at which time progress with dietary change was assessed, weight remeasured and further changes agreed if appropriate. Patients who had a high baseline serum cholesterol (over 6.5 mmol/l in men or 7.0 mmol/l in women) or BMI over 27.5 kg/m^2 or two or more other CHD risk factors (male, smokers, hypertensive, family or past history of CHD) were asked to return at 3 and 6 months for further assessment. At the 6-month check, a non-fasting serum cholesterol was repeated and, if it was over 7.8 mmol/l, the patient was referred to the GP. Patients (n=13) with a mean serum cholesterol over 9 mmol/1, or a triglyceride over 11 mmol/l, were excluded and the GP was informed of the result.

Patients with BP over 200/120 were referred to the GP, if 160/95 the measure was repeated and, if it was still raised, they were referred to the GP.

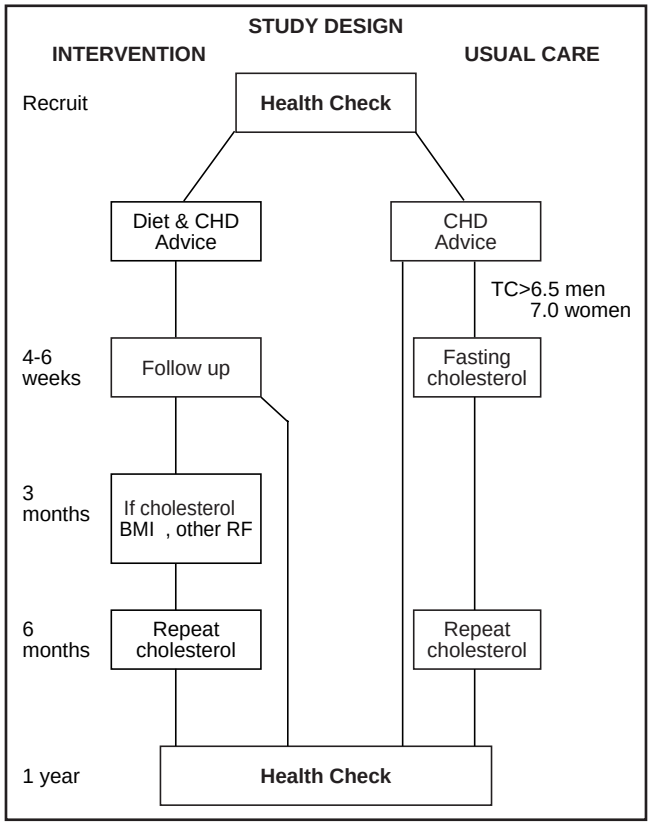

Figure 1. Follow-up schedule.

Annual follow up

At annual follow up, the questionnaire was repeated, weight and blood pressure were measured as at baseline, and venous blood taken for serum cholesterol, fibrinogen and VIIc. Patients who had had a high initial serum cholesterol had a fasting sample to test for serum cholesterol, triglycerides and apolipoproteins A and B. Nurses undertook a note search to document medication and any visits to the GP, hospital referrals or attendance at other health promotion clinics during the course of the follow-up period.

Statistics

The study size calculations were based on the method described by Hsieh[17] for studies that use a cluster, such as a general practice, as the unit of randomization. The study aimed to recruit 1200 patients (150 per practice); this would give 80% power on an intention-to-treat analysis to detect an 8% difference (0.5 mmol/l) in the mean change in serum cholesterol between matched pairs of practices at the 5% level of significance. The estimate was based on a prevalent estimate at the time of the fall in cholesterol that would result from a compliance with national dietary guidelines.[18] Between- and within-practice estimates in serum cholesterol were unpublished estimates derived from the first 20

Table 1. Baseline characteristics of patients recruited into the study.*

Characteristic	'Dietary advice' practices	'Usual care' practices
Number of patients	473	483
Mean age (range)	47.2 (44.3–48.0)	47.4 (46.3–49.4)
Male percentage (range)	48 (36–53)	52 (39–67)
Non-manual percentage (range)	60 (43–75)	49 (23–71)
Car owners percentage (range)	86 (77–99)	82 (53–98)
Accommodation rented percentage (range)	11 (3–24)	25 (3–69)
Mean serum cholesterol (mmol/l) (SD)		
Men	6.20 (1.17)	6.29 (1.08)
Women	5.94 (1.07)	5.95 (1.13)
Percentage over 7.8 (mmol/l)	7.8	7.6
Mean BMI (SD) (kg/m^2)	26.3 (4.4)	25.9 (4.7)
Percentage over 30 kg/m^2	18.4	13.7
Current smokers percentage (range)	26 (11–33)	30 (17–42)
Mean systolic BP (mmHg) (SD)	124.4 (18.0)	125.2 (15.9)
Mean diastolic BP (mmHg) (SD)	77.8 (11.8)	77.1 (11.7)
Percentage of food energy from total fat (SD)	34.3 (6.3)	34.2 (6.7)
Percentage of food energy from saturated fat (SD)	13.7 (3.6)	14.0 (3.9)
Fibre (g/day) (SD)	23.3 (8.0)	23.2 (9.3)
Alcohol (units/ week) (SD)	14.2 (19.1)	15.5 (22.4)

*Range is of practice levels.

practices entering the MRC's Thrombosis Prevention Trial.[19]

The main outcomes were analysed at the level of the general practice as this was the unit of randomization. Between-practice changes were analysed on an intention-to-treat basis weighted for group size.[20] Non-responders were assumed not to have changed their baseline measures.

Ethics

Approval was granted by each of the local research ethics committees concerned.

Results

Study sample

Pairs of practices were selected on the basis of geographical area. The mean (and range) of Jarman scores based on the 1981 census in the practices was 8.3 (–8.6 to 32.2) in the 'dietary advice' group and 9.5 (–7.9 to 40.3) in 'usual care' (which compares with an average Jarman of 6.9 for the 725 practices in the MRC GPRF). The mean list sizes in the two groups were 11500 and 12 100 respectively.

Patient recruitment was undertaken between November 1991 and May 1993. A total of 956 patients entered the study, 473 in 'dietary advice' practices and 483 in 'usual care' practices. Their baseline characteristics are shown in Table 1. The response rate was difficult to determine as it was based on incomplete recording by GPs of the cases invited (65% and 44% 'dietary advice' and 'usual care' practices respectively); the estimated response rate of these cases was 75% in both study arms. The characteristics of non-participants were not available.

The distribution of age and sex was similar in the two study groups. The main differences were the higher percentage of patients who smoked and who were in manual groups in the 'usual care' practices.

Compliance (Figure 2)

The compliance with the yearly follow-up visit was 80% overall;

Table 2. Comparison of non-responders and responders to annual follow up by baseline characteristics

	Dietary advice				Usual care			
	Responders (n = 401)		Non-responders (n = 472)		Responders (n = 352)		Non-responders (n = 131)	
Mean age (SD)	47.5	(7.1)	45.3	(7.5)	47	(7.1)	46.4	(7.2)
Male percentage	47		56		52		53	
Non-manual percentage	60		54		53		38	
Mean serum cholesterol (mmol/l) (SD)	6.08	(1.11)	5.97	(1.18)	6.08	(1.10)	6.26	(1.17)
Body mass index mean (kg/m^2) (SD)	26.2	(4.41)	27.0	(4.04)	25.6	(4.43)	26.7	(5.36)
Current smoker (%)	23		40		25		43	
Percentage of food energy from total fat (SD)	34.4	(6.3)	33.9	(6.2)	33.8	(6.6)	35.2	(6.8)
Percentage of food energy from saturated fat (SD)	13.8	(3.6)	13.5	(3.2)	13.8	(3.9)	14.6	(3.9)
Fibre (g/day) (SD)	23.1	(7.8)	24.3	(9.2)	23.8	(9.7)	21.6	(8.0)
Mean systolic BP (mmHg) (SD)	125.3	(18.4)	119.3	(14.6)	125.0	(16.2)	125.6	(15.2)
Mean diastolic BP (mmHg) (SD)	78.3	(12.1)	75.2	(9.5)	77.4	(11.9)	76.2	(11.1)
Alcohol (units/week) (SD)	13.9	(18.7)	16.3	(21.8)	16.0	(23.0)	14.0	(20.8)

it was higher in 'dietary advice' practices at 86%. Four patients died and nine patients were known to have moved away during the study. Compliance with additional visits was high in the 'dietary advice' practices. In both groups, the non-respondents at 1 year follow up were more likely to be smokers and from manual groups than responders; there was little difference in dietary variables (Table 2).

Changes in nutrient and food intake between practices *(Table 3)*

Dietary advice was associated with a small decrease in the intake of total and saturated fat, a small rise in fibre intake and increases in 'healthy eating' with increased consumption of reduced-fat milk, high-fibre bread, fruit, vegetables and high-fibre cereal.

Changes in coronary heart disease risk factors between practices *(Table 4)*

There was a marginally significant reduction in serum cholesterol in the 'dietary advice' practices of 0.20 mmol/l compared with the 'usual care' practices. This fall was not associated with any increase in prescription of lipid-lowering drugs. These figures were essentially unchanged when on-treatment analysis was performed of only those attending annual follow up. Weight fell, but the mean difference between practices was only 0.56 kg. There was a non-significant reduction in VIIc of 6.7% of the standard. There was little change in smoking prevalence (1.1% mean fall in 'dietary advice' practices, 1.4% in 'usual care' practices, mean between practice difference 0.2%), fibrinogen, the proportion taking vigorous exercise, or blood pressure in either of the two groups.

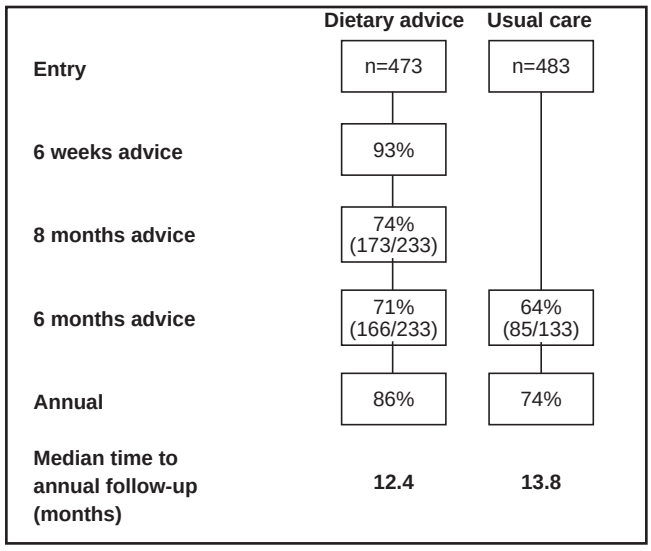

Figure 1. Patient compliance.

Discussion

Standard health education approaches produced little change in diet or related risk factors. More intensive structured dietary advice by trained practice nurses to adults led to moderate changes in diet and in related coronary heart disease risk factors, namely serum cholesterol, weight and VIIc over the 1-year follow up. There was little change in BP or smoking in either group, although neither of these factors was a prime focus for intervention. The serum cholesterol and weight changes accord with other recent studies that have investigated the effectiveness of coronary heart disease prevention in primary care.[7,8] The Oxcheck[7] study found a significant fall in serum cholesterol at 1 year of 0.2 mmol/l or approximately 3%, which would translate into a 6–9% fall in CHD risk.[7] This change was greater in women and it was sustained for 3 years.[21] The Family Heart Study[8] showed a less marked fall in serum cholesterol, despite more intensive intervention. Studies of general practice dietary advice to high-risk groups have also demonstrated modest reductions.[9,22]

Why were the changes we found so modest? Ramsay *et al*[23] has highlighted the fact that marked shifts in dietary habit are required to achieve significant changes in serum cholesterol; this may be hard to achieve in groups not identified as being at 'high risk' of CHD. The negotiated change approach used here may not have produced sufficient alteration in dietary habit to lead to substantial changes in serum cholesterol. It may have been important to consider 'readiness to change', as there is growing

Table 3. Changes in nutrient and food intake in and between practices over one-year follow up.

Nutrient/food	Mean change in 'dietary advice' practices	Mean change in 'usual care' practices	Mean difference within matched pairs between 'dietary advice' and 'usual care' practices (range)	95% CI for this mean difference within matched pairs
Percentage of food energy from total fat	–2.4	–0.9	–1.4 (–2.1 to –0.8)	–2.2 to –0.7
Percentage of food energy from saturated fat	–1.5	–0.6	–0.9 (–1.3 to –0.2)	–1.5 to –0.2
Polyunsaturated–saturated fat ratio	0.078	0.023	0.05 (–0.003 to 0.080)	0.0007 to 0.106
Fibre (g/day)	0.86	–0.19	1.02 (0.11 to 2.09)	–0.20 to 2.23
No. of slices or rolls of wholemeal or brown bread per day	1.17	0.23	0.87 (–0.94 to 1.95)	–0.82 to 2.55
Fruit* (portions/week)	0.76	0.28	0.44 (–0.02 to 1.0)	–0.24 to 1.11
Vegetables** (portions/week)	0.33	–0.25	0.50 (–0.5 to 1.8)	–0.9 to 1.9
High-fibre cereal (portions/week)	0.53	0.2	0.33 (–0.31 to 0.64)	–0.29 to 0.94
Alcohol (units/week)	–0.50	–0.79	0.32 (–1.8 to 1.4)	–1.58 to 2.22

*Apple/orange/banana/canned fruit. **Exclude potatoes, include salad.

Table 4. Changes in practice coronary heart disease risk factors in and between practices over one-year follow up.

Outcome measure	Mean change in 'dietary advice' practices	Mean change in 'usual care' practices	Mean difference within matched pairs between 'dietary advice' and 'usual care' practices (range)	95% CI for this mean difference within matched pairs
Serum cholesterol (mmol/l)				
Total	–0.23	–0.0007	–0.20 (–0.40 to 0.13)	–0.38 to –0.03
Men	–0.26	–0.05	–0.18 (–0.42 to 0.05)	–0.52 to 0.16
Women	–0.20	0.04	–0.25 (–0.40 to 0.04)	–0.53 to 0.02
Weight (kg)				
Total	–0.10	0.44	–0.56(–0.80 to –0.01)	–1.04 to –0.07
Men	–0.29	0.28	–0.44 (–0.88 to 0.14)	–1.20 to 0.30
Women	0.09	0.82	–0.71 (–0.97 to –0.20)	–1.13 to –0.28
Body mass index (kg/m^2)	0.01	0.14	–0.12 (–0.24 to 0.06)	–0.30 to 0.05
Systolic BP (mmHg)	–1.14	–0.39	–0.59 (–2.20 to 0.82)	–2.43 to 1.24
Diastolic BP (mmHg)	–0.19	–0.09	0.09 (–3.1 to 5.2)	–4.9 to 5.0
Factor VIIc (% standard)	–1.63	6.12	–6.7 (–15.5 to 0.3)	–15.4 to 2.0
Fibrinogen (g/l)	–0.024	0.027	–0.047 (–0.018 to 0.009)	–0.21 to 0.11

interest in tailoring intervention to the stages of change, although this requires further evaluation.[24] The dietary advice given may have been inappropriate, although we had specially prepared materials devised in conjunction with dieticians, and changes were recorded in action plans. Our control group had a form of intervention, namely provision of standard health education materials, although there was little change in diet. The analysis used the intention-to-treat principle and assumed that non-responders had not changed any lifestyle factor. This would underestimate effects if there had been some change in the non-responder in the advice group and no change or even a deterioration in the control group. The weight and BMI results include those with weight/BMI in the 'normal range' who would not be advised to reduce weight, hence the estimates underestimate the fall achieved in overweight subjects. However, contrary to these arguments is the fact that despite randomization *between practices*, the 'dietary advice' practices' patients were from higher socioeconomic groups and, hence, more likely to achieve dietary change. Matching of practices or other variables, such as Jarman deprivation index, may have reduced such differences.

To what extent are the results generalizable? Although the practices, GPs and nurses may be atypical as they were part of a research framework, the comparison of the two approaches is based on randomization of practices and should be internally valid (subject to the points raised above). However, it is unlikely, on the whole, that the modest changes seen would be greater in routine practice.

The results were similar to other large studies of primary care health promotion, despite methodological differences between them.[7,8] The Oxcheck[7] study used within-practice design, the study here and the Family Heart study[8] had a between-practice design to overcome potential contamination between groups randomized within practices, although the Family Heart Study internal controls suggested that this effect was negligible.[8] Our study had concurrent controls who were offered an intervention of a health check, whereas the others used recruitment delay to provide controls. The intervention in our study focused largely on diet, although standard health education materials were given out to cover other risk factors, and hypertension was referred for medical care, whereas the other population studies intervened on all risk factors. We recruited opportunistically rather than on invitation from the age–sex register, on the grounds that this reflected how such health promotion would be offered in practice, and the sample might be more representative in terms of social class mix,[25] although Oxcheck[7] shows that a high uptake overcomes this. The sample was chosen from practices geographically and socioeconomically dispersed in the UK. The characteristics of our sample were similar to the 35- to 64-year-old age band in the National 1991 Health Survey in England on serum cholesterol and BMI, although we had fewer smokers, especially women.[5] The nutritional data were based on the food frequency method, which is pragmatic for large studies of this type. It had only been validated on population samples in Wales several years ago, although it has been used in large population surveys.[12,13,26] The baseline total fat intake in this study was lower than in national weighed record surveys.[27]

What are the implications? Although there were positive changes in diet, serum cholesterol, weight and VIIc as a result of nurse advice, which would reduce risk of coronary heart disease and other chronic diseases, these were modest. Taken in conjunction with other recent evidence, it would appear that using practice nurses for one-to-one dietary intervention with all patients is probably an ineffective use of resources.[27] The use of dieticians is unfeasible especially as a large proportion of the population do not meet dietary recommendations for good nutrition. The focus of health professionals should be on those at higher risk in whom any change will lead to greater long-term absolute benefit. Population-based strategies including the use of the media, workplace and other community interventions and a national nutrition policy are all required to improve dietary intake on a population level and therefore ultimately reduce the burden of diet-related chronic disease.

References

1. Department of Health. *Health of the nation. A strategy for health in England.* London: HMSO, 1992.
2. *Nutritional aspects of cardiovascular disease.* Report of the Coronary Review Group of the Committee on Medical Aspects of Food Policy. London: HMSO, 1994.
3. Stamler J, Wentworth D, Neaton JD. Is relationship between serum cholesterol and risk for premature death from coronary heart disease continuous and graded? *JAMA* 1986; **256:** 2823-2828.
4. Shaper G, Pocock JJ, Walker M, *et al.* British Regional Heart Study: cardiovascular risk factors in middle-aged men in 24 towns. *BMJ* 1981; **283:** 179-186.
5. Office of Population and Census Surveys. *Health Survey for England.* London: HMSO, 1991.

6. Francis J, Roche M, Mant D, Jones L, Fullard E. Would primary health care workers give appropriate dietary advice after cholesterol screening? *BMJ* 1989; **298:** 1620-1622.
7. Imperial Cancer Research Fund OXCHECK Study Group. Effectiveness of health checks conducted by nurses in primary care: results of the OXCHECK study after one year. *BMJ* 1994; **309:** 308-312.
8. Family Heart Study Group. Randomised controlled trial evaluating cardiovascular screening and intervention in general practice: principal results of British family heart study. *BMJ* 1994; **308:** 313-320.
9. Lindholm LH, Ekbom T, Dash C, *et al.* The impact of health care advice given in primary care on cardiovascular risk. *BMJ* 1995; **310:** 1105-1108.
10. Meade TW, Brozovic M, Chakrabarti RR *et al.* Haemostatic function and ischaemic heart disease: principal results of the Northwick Park Heart Study. *Lancet* 1986; **ii:** 533-537.
11. Miller GJ, Cruikshank JK, Ellis LJ, *et al.* Fat consumption and factor VII coagulant activity in middle-aged men. An association between a dietary and thrombogenic coronary risk factor. *Atherosclerosis* 1989; **78:** 19-24.
12. Fehily AM, Butland BK, Holliday RM, Yarnell JWG. Dietary studies in the Caerphilly heart disease survey. *Int J Food Sci Nutr* 1988; **42F:** 77-78.
13. Fehily AM, Bird G. A dietary survey of women in Caerphilly: a weighed and photographic method compared. Hum Nutr: *Appl Nutr* 1986; **40A:** 300-307.
14. Siedel J, Schlumberger H, Klose S, *et al.* Improved reagent for the enzymatic determination of serum cholesterol. *J Clin Chem Biochem* 1981; **19:** 838-839.
15. Miller GJ, Stirling Y, Esnouf MP, *et al.* Factor VII – deficient substrate plasmas depleted of protein C raise the sensitivity of the factor VII bio-assay to activated Factor VII an international study. *Thromb Haemost* 1994; **71:** 38-48.
16. von Clauss A. Gerinnungsphysiologische schnellmethode zur bestimmung des fibrinogens. *Acta Haemotol* 1957; **17:** 237-246.
17. Hseih FY. Sample size formulae for intervention studies with cluster as unit of randomisation. *Stat Med* 1988; **8:** 1195-1201.
18. Lewis B, Mann JT, Mancini M. Reducing the risk of coronary heart disease in individuals and in the population. *Lancet* 1986; **I:** 956-959.
19. Meade TW, Wilkes HC, Stirling Y, *et al.* Randomised controlled trial of low dose Warfarin in the primary prevention of ischaemic heart disease in men at high risk: design and pilot study. *Eur Heart J* 1985; **9:** 836-843.
20. Donner A, Klar N. Confidence interval construction for effect measures arising from cluster randomisation trials. *J Clin Epidemiol* 1993; **46:** 123-131.
21. Imperial Cancer Research Fund OXCHECK Study Group. Effectiveness of health checks conducted by nurses in primary care: final results of the OXCHECK study. *BMJ* 1995; **310:** 1099-1104.
22. Neil HAW, Roe L, Godlee RJP, *et al.* Randomised trial of lipid lowering dietary advice in general practice: the effects on serum lipids, lipoproteins, and antioxidants. *BMJ* 1995; **310:** 569-573.
23. Ramsay LE, Yeo WW, Jackson PR. Dietary reduction of serum cholesterol: time to think again. *BMJ* 1991; **303:** 953-957.
24. Pill R, French J, Harding K, Stott N. Invitation to attend a health check in a general practice setting: comparison of attenders and non attenders. *J R Coll Gen Pract* 1988; **38:** 53-56.
25. Prochaska JO, Velicer WF, Rossi JS, *et al.* Stages of change and decisional balance for twelve problem behaviours. *Health Psychol* 1994; **13:** 39-46.
26. Smith WCS, Tunstall-Pedoe H, Crombie IK, Tarendale R. Concomitants of excess coronary events – major risk factor and lifestyle findings from 10,359 men and women in the Scottish Heart Health Study. *Scot Med J* 1989; **34:** 550-555.
27. Office of Population Censuses and Surveys. *The dietary and nutritional survey of British adults.* London: HMSO, 1989.
28. Field K, Thorogood M, Silagy C, *et al.* Strategies for reducing coronary risk factors in primary care: which is most cost effective? *BMJ* 1995; **310:** 1109-1112.

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