Randomised controlled trial evaluating cardiovascular screening and intervention in general practice: principal results of British family heart study

Family Heart Study Group

Abstract

***Objective*—To measure the change in cardiovascular risk factors achievable in families over one year by a cardiovascular screening and lifestyle intervention in general practice.**

***Design*—Randomised controlled trial in 26 general practices in 13 towns in Britain.**

***Subjects*—12 472 men aged 40-59 and their partners (7460 men and 5012 women) identified by household.**

***Intervention*—Nurse led programme using a family centred approach with follow up according to degree of risk.**

***Main outcome measures*—After one year the pairs of practices were compared for differences in (*a*) total coronary (Dundee) risk score and (*b*) cigarette smoking, weight, blood pressure, and random blood cholesterol and glucose concentrations.**

***Results*—In men the overall reduction in coronary risk score was 16% (95% confidence interval 11% to 21%) in the intervention practices at one year. This was partitioned between systolic pressure (7%), smoking (5%), and cholesterol concentration (4%). The reduction for women was similar. For both sexes reported cigarette smoking at one year was lower by about 4%, systolic pressure by 7 mm Hg, diastolic pressure by 3 mm Hg, weight by 1 kg, and cholesterol concentration by 0·1 mmol/l, but there was no shift in glucose concentration. Weight, blood pressure, and cholesterol concentration showed the greatest difference at the top of the distribution. If maintained long term the differences in risk factors achieved would mean only a 12% reduction in risk of coronary events.**

***Conclusions*—As most general practices are not using such an intensive programme the changes in coronary risk factors achieved by the voluntary health promotion package for primary care are likely to be even smaller. The government's screening policy cannot be justified by these results.**

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Introduction

The prevention of coronary heart disease and stroke is a priority for the government in the *Health of the Nation*.[1] Targets have been set for the major cardiovascular risk factors—smoking, diet in relation to obesity, and blood pressure—and a voluntary health promotion package for primary care aimed at modifying these factors, among both high risk groups and the population as a whole, is now being put in place.[2] Though practice teams can ascertain cardiovascular risk factors in their population,[3] the important question is whether intervention will result in a reduction in these risk factors.

The only randomised controlled trial of multifactorial screening reported from general practice showed no significant changes in morbidity or mortality during a nine year follow up of those screened compared with those offered conventional medical care.[4] Controlled trials of unifactorial interventions are scarce in general practice and restricted to smoking, blood pressure, and diabetes. Trials of smoking cessation among unselected cigarette smokers in general practice have consistently reported a higher rate of stopping in the intervention group,[5] particularly for an intensive programme led by general practitioners.[6] More recently nicotine patches in motivated heavy cigarette smokers have proved to be an effective aid to stopping smoking.[7,8] The Medical Research Council's mild to moderate hypertension trial showed a significant reduction in the incidence of stroke, although not coronary heart disease, in those taking antihypertensive drugs[9]; but retrospective reviews of general practice records to assess the detection and management of hypertension have shown that patients who have their blood pressure measured are not necessarily investigated, followed up, and treated.[10-12] In a randomised comparison of care of patients with non-insulin dependent diabetes in hospital and general practice the group being cared for by their general practitioner had less regular follow up and higher glycated haemoglobin concentrations than those who attended hospital clinics.[13] So although intensive smoking interventions may lead to reduced cigarette consumption, little or no evidence from intervention studies supports the efficacy of the government's current health promotion package for primary care based on multifactorial risk factor assessment and lifestyle intervention.

The British family heart study addressed this issue in a randomised controlled trial of nurse led screening for cardiovascular risk factors and lifestyle intervention in families in general practices in towns throughout Britain.[14] The overall aim of the trial was to estimate the size of the change in cardiovascular risk factors in men and women that could be achieved by such a practice based strategy in one year. Specifically, the main objectives were to measure the effect of one year's intervention on (*a*) total coronary risk score assessed with the Dundee risk score[15] for three modifiable risk factors (cigarette smoking, blood pressure, and cholesterol concentration) and (*b*) the prevalence of cigarette smoking and the distribution of weight, blood pressure, and random blood cholesterol and glucose concentrations in the population.

Subjects and methods

DESIGN

The study design has already been described[14] and is summarised in figure 1. Fifteen towns were selected which met specific demographic criteria. Within each town all general practices with 4-7 full time partners were surveyed and a pair of willing practices in each town with similar sociodemographic characteristics was randomised to either arm of the study. Such a pair was successfully identified in 14 towns and the two practices in each town were then randomly allocated to either intervention or external comparison groups.

Research nurses were recruited locally and trained centrally in the Department of Clinical Epidemiology at the National Heart and Lung Institute, London. Training comprised questionnaire interviews on a lap top computer, measurement of risk factors, quality

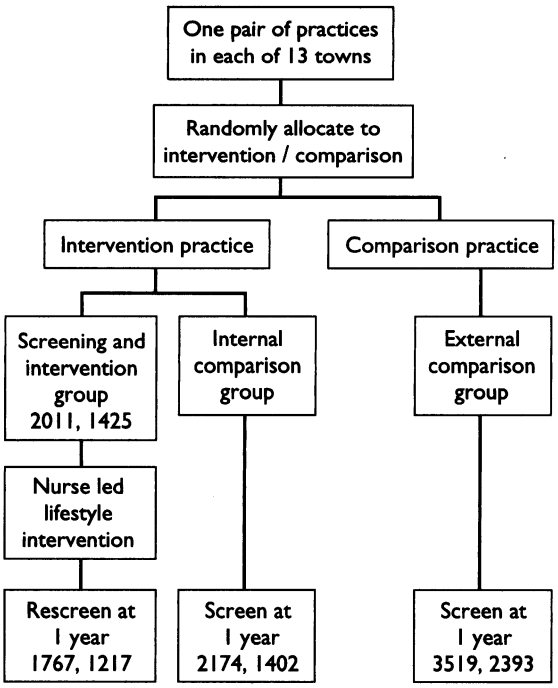

FIG 1—*Design of British family heart study showing numbers of men (first) and women seen at baseline and one year in the intervention group and at one year in the internal and external comparison groups*

assurance and follow up, and client centred counselling about lifestyle within families.

Identification of families suitable for recruitment to the study was by household through the male partner. The entire list of men aged 40-59 in each of the intervention and comparison practices was randomly ordered within five year age bands. In intervention practices each five year age band was randomly divided into two equal size groups: an intervention and internal comparison group. In the intervention group men and their families were approached in order (and at the same rate within each five year age band) by the nurses. Families were screened, offered risk related lifestyle intervention and follow up, and then rescreened after one year. Families in the internal or external comparison groups, although identified at the same time as those in the intervention groups, were first screened at one year at the same time as the intervention group was being rescreened.

SCREENING

Appointments were made by the nurses for each man and his family by telephoning the household. All family members attending were screened but only men and their partners were followed up. The initial screening interview for an adult couple in the intervention group lasted on average one and a half hours and for comparison families about half this time, the lifestyle intervention being less intensive. During the interview demographic, lifestyle, and medical information was recorded on computer and the following measurements were made: height and weight (Seca digital model 707 with telescopic measuring rod), body mass index (weight/height^2), carbon monoxide concentration in breath (Smokerlyzer), blood pressure (Takeda UA731 automatic digital sphygmomanometer), and random blood concentration of total cholesterol and glucose in a finger prick sample (Reflotron, Boehringer Mannheim); quality assurance was organised by the Wolfson Research Laboratories, Birmingham. In five practices cholesterol concentration was measured only in a random three quarters of families, as a substudy to evaluate the impact of cholesterol testing. Families allocated to no measurement of cholesterol do not appear in the results presented here. The results for this substudy will be reported separately.

LIFESTYLE COUNSELLING AND FOLLOW UP IN INTERVENTION GROUP

By means of a coronary risk score[16] derived from the intermediate score of the British regional heart study[17] based on both modifiable and unmodifiable risk factors, subjects were told which decile of the distribution of risk for coronary heart disease they were in relative to other men (or women) of the same age. Those who reported a history of coronary heart disease or chest pain on exercise were automatically placed in the top decile of risk. The risk score was recorded in a booklet, "Your passport to health," in which personally negotiated lifestyle changes in relation to smoking, weight, healthy eating, alcohol consumption, and exercise could be documented. When appropriate, Health Education Authority pamphlets on each of these subjects were provided. The frequency of follow up visits was determined by both the coronary risk score and individual risk factors. Adults (either partner) in the top quintile of the risk distribution 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 at one year. People with individual high risk factors—current cigarette smokers and those with a body mass index ≥ 25, diastolic blood pressure ≥ 90 mm Hg, cholesterol concentration $\geq 6{\cdot}5$ mmol/l, or random glucose concentration ≥ 7 mmol/l—were also invited to reattend every month for up to three months. Patients with glucose concentration ≥ 10 mmol/l or diastolic pressure ≥ 115 mm Hg on any occasion were referred to their general practitioner, as were those with cholesterol concentration $\geq 6{\cdot}5$ mmol/l or diastolic pressure ≥ 100 mm Hg sustained for three months.

DATA MONITORING AND QUALITY ASSURANCE

Quality of data collection was assured by a series of routine checks of nurse records (JY), by a weekly review of computer disks (YK), by weekly quality assurance returns for cholesterol and glucose concentrations (CLG, RC) organised by the Wolfson Research Laboratories, and by routine data monitoring (SP). During the one year follow up these processes showed that one nurse in an intervention practice in one of the 14 towns originally included in the study had departed from a number of protocol requirements. A complete audit of the one year rescreening results in that practice showed inconsistencies between families attending and data recorded, which cast doubt on the reliability of this information. Before the main one year analyses were undertaken the executive committee decided, without sight of the data recorded, to discard all data from this intervention practice and therefore also to discard all data from the comparison practice in the same town. The statistical analyses in this report are thus based on 26 general practices from 13 towns (fig 2).

STATISTICAL METHODS

The protocol defined the main statistical comparison of risk factors to be between the intervention group rescreened at one year and the concurrently screened external comparison group. The intervention group was also compared, however, with the internal comparison group taken from the same practice. Because this latter comparison is not affected by variability between different practices it was expected to be more precise, although any effect might be diluted by some transfer of effect from the intervention to the comparison group within the same practice. The numbers of general practices and subjects recruited to the study

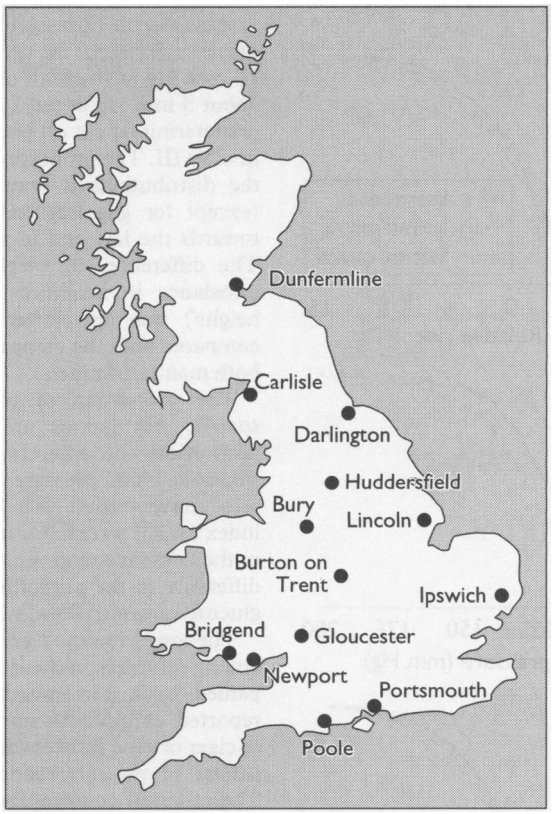

FIG 2—*Study towns*

were chosen on the basis of published information on variability of risk factors between and within different practices[18] so that the mean difference between the intervention group and external comparison group was anticipated to have a standard error of 0·05 mmol/l for blood cholesterol concentration and 2·0 mm Hg for systolic blood pressure. The principal outcome measured was defined as the Dundee risk score, an overall measure of modifiable coronary risk which depends on serum cholesterol concentration, systolic blood pressure, and previous and current smoking habit.[15] The distribution and means of individual risk factors were compared as well as the proportions of subjects with values greater than prespecified cut off points—namely, serum cholesterol concentration ⩾8·0 mmol/l, diastolic blood pressure ⩾100 mm Hg, body mass index ⩾30, and random blood glucose concentration ⩾10 mmol/l.

For each risk factor the differences in means or proportions between intervention and comparison groups were calculated separately in each town, together with standard errors. These differences were then pooled across the 13 towns using a random effects meta-analysis.[19] The estimated difference derived is an approximately unweighted average of the differences in each town, and the standard error or confidence interval presented takes into account sources of variation between and within towns.[20] Our results are based on the man (aged 40-59 at selection) from each family recruited and on his partner, regardless of her age. The Dundee risk score was designed only for subjects aged 35-64, however, and so a small proportion of women were excluded from this analysis. Few values for risk factors were missing (indicated in the footnotes to tables as appropriate). Because age was well balanced between the intervention and comparison groups (see table I) adjustments for age had only minimal effect and so unadjusted results are presented.

TABLE I—*Numbers of subjects, mean ages, and mean percentage reduction in risk of coronary heart disease in intervention group at one year compared with external and internal comparison groups*

Group	No of subjects*	Mean age (SD) (years)	Percentage reduction in risk† in intervention group (95% confidence interval)
		Men	
Intervention	1767	51·5 (5·7)	
Comparison:			
External	3519	51·5 (5·7)	16·1 (10·9 to 21·1)
Internal	2174	51·6 (5·8)	17·6 (14·0 to 21·1)
		Women	
Intervention	1217	49·1 (6·8)	
Comparison:			
External	2393	49·0 (7·1)	15·7 (7·4 to 23·3)
Internal	1402	49·0 (6·8)	13·2 (7·3 to 18·6)

*Excluding those randomised to no measurement of cholesterol concentration (202 men and 150 women) in the cholesterol/no cholesterol substudy.
†Odds of coronary heart disease calculated from the Dundee risk score (1), based on systolic blood pressure, cholesterol concentration, and smoking habit with adjustments for age and sex. Not calculated for 16 men and 12 women because of missing blood pressure or cholesterol measurements and for a further 143 women because they were not aged 35-64.

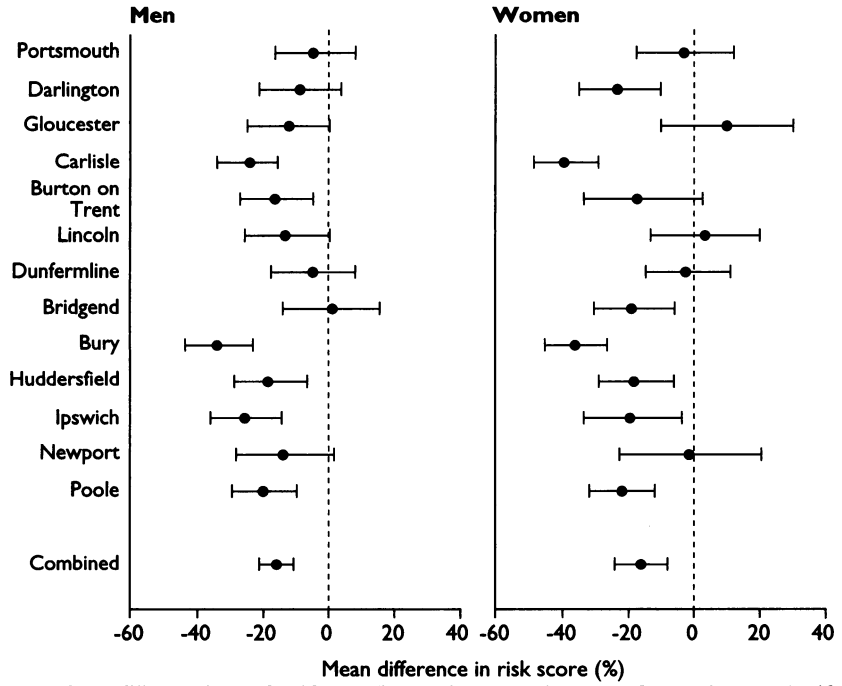

FIG 3—*Mean differences in Dundee risk score (intervention group minus external comparison group) with bars showing 95% confidence intervals for each of the 13 towns, and combined overall, for men and women separately*

Results

A total of 14 086 households were approached; 8605 households were represented by one or more adult members, giving a crude household response rate of 61%. After adjustment of the denominator for "ghosts" (patients on the practice lists who had died or left the practice; from a survey of non-responders we estimated the proportion of ghosts to be at least 16%), the true response rate was 73%. Crude (and adjusted) household response rates for the intervention and internal and external comparison groups were 57% (68%) (2373/4158); 62% (73%) (2342/3798); and 63% (76%) (3890/6130) respectively. Similar numbers of participants were recruited to the intervention and internal comparison groups (fig 1), but substantially more were recruited to the external comparison group because the time taken to see each family was shorter. At one year the reattendance rate of men and women in the intervention group was 88% (1969/2246) and 85% (1367/1604) respectively. At this point the age of the men in the intervention and internal and external comparison groups was between 40 and 61 (because of the selection criteria of the study), and 93% of the women were aged 35-59. The mean ages of the men and women were almost identical in all three groups. A total of 7460 men and 5012 women are included in this report.

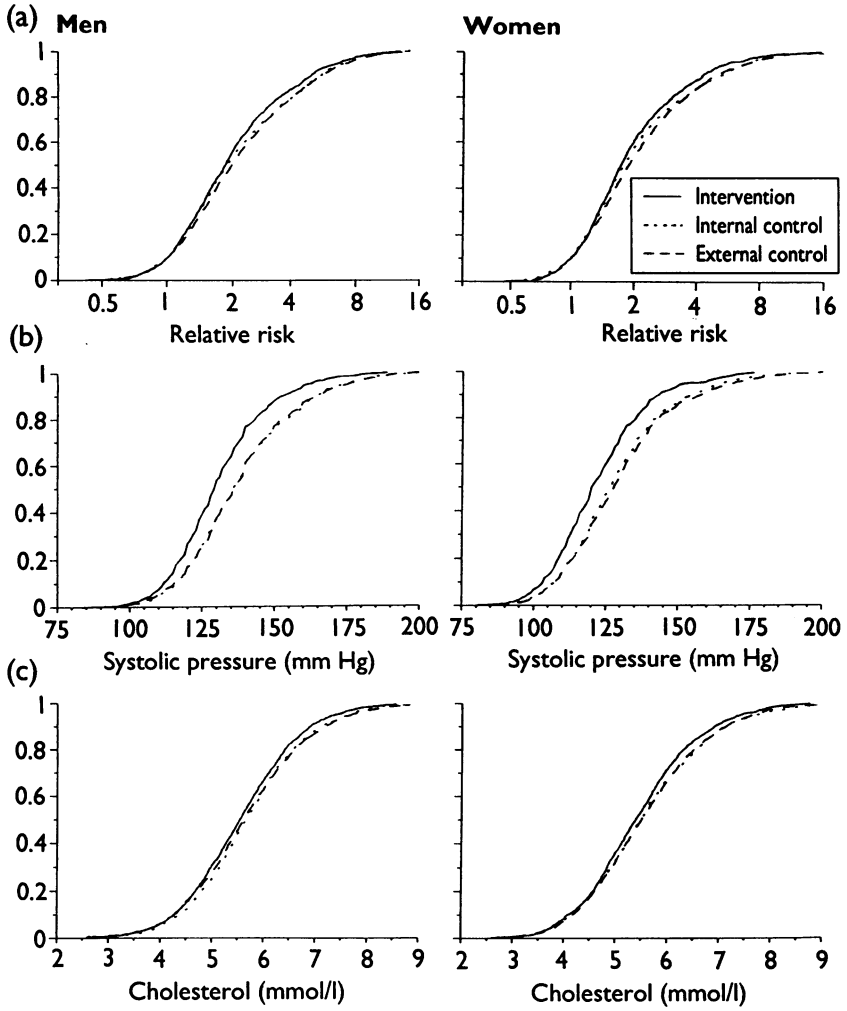

FIG 4—*Cumulative relative frequency distribution for relative risk (derived from the Dundee risk score), systolic blood pressure, and blood cholesterol concentration in intervention and comparison groups for men and women separately*

DUNDEE RISK SCORE

The Dundee risk score was approximately 16% lower at one year in the intervention group compared with either the external or internal comparison group (table I). The overall difference in mean risk score was similar in men and women but seemed to be rather more consistent across the 13 towns for men (fig 3). The distribution of risk scores shows that the difference was greatest at the top (high risk) end of the distribution (fig 4a), as the horizontal difference between the curves was greatest at high values. The risk factors did not contribute equally. For example, of the observed 16% lower risk score in men (as compared with the external comparison group), 7% was attributable to blood pressure, 5% to smoking, and 4% to cholesterol.

CARDIOVASCULAR RISK FACTORS

Individual differences in risk factors were similar in men and women, with both comparison groups giving consistent results (table II). In the intervention group at one year reported cigarette smoking among returners was lower by about 4%, systolic blood pressure by an average of 7 mm Hg and diastolic pressure by 3 mm Hg, weight by an average of about 1 kg, and cholesterol concentration by an average of about 0·1 mmol/l. For the latter, the standard errors were sufficiently large to include the possibility of no effect in women. There was no discernible shift in median random blood glucose concentrations.

The differences in the distributions of systolic blood pressure and serum cholesterol concentration are shown in figure 4 (b and c). There was a consistent tendency for greater changes at the top of the distribution than at the bottom. For example, for systolic blood pressure in men the average difference was about 10 mm Hg at the 80th centile of the distribution and about 5 mm Hg at the 20th centile. This is shown for predetermined cut off points for individual risk factors in table III. The proportion of subjects at the top end of the distributions is lower in the intervention group (except for glucose) and conversely the proportion towards the low end in the same group is increased. The differences in weight were not attributable to imbalance in height as body mass index (weight/height^2) was also lower in the intervention group compared with the comparison groups by about 0·4 in both men and women.

The proportion of patients with high levels of specific risk factors are shown in table IV. The proportions of subjects with high blood pressure (diastolic blood pressure $\geq$100 mm Hg), high cholesterol concentration ($\geq$8·0 mmol/l), or high body mass index ($\geq$30) were lower in the intervention group than in the comparison group, but there was no discernible difference in the proportions with high random blood glucose concentration ($\geq$10·0 mmol/l).

The lower reported prevalence of cigarette smoking among returners in the intervention group was accompanied by a correspondingly greater proportion of reported ex-cigarette smokers, while the proportions of cigar or pipe smokers and lifelong non-smokers were similar in the intervention and comparison groups. The reported consumption of cigarettes among cigarette smokers was slightly lower in the intervention group. For example, in men the reported average consumption was 16·8 cigarettes a day compared with 18·9 and 19·3 cigarettes a day in the external and internal comparison groups respectively. The corresponding proportions of male cigarette smokers reporting smoking 20 or more cigarettes a day were 46%, 59%, and 57% respectively. Self reported smoking habit may be biased, and breath carbon monoxide concentrations were measured in the inter-

TABLE II—*Differences in risk factors for coronary heart disease between intervention group at one year and external and internal comparison groups*

Group	Men		Women	
	Crude value*	Pooled difference (SE)†	Crude value*	Pooled difference (SE)†
	Smoking prevalence (% of subjects)			
Intervention	19·1		17·7	
Comparison:				
External	22·8	−4·1 (1·8)	21·2	−3·5 (2·1)
Internal	23·0	−4·1 (1·3)	21·5	−2·9 (1·5)
	Mean blood cholesterol (mmol/l)			
Intervention	5·58		5·48	
Comparison:				
External	5·69	−0·12 (0·06)	5·61	−0·12 (0·09)
Internal	5·72	−0·13 (0·03)	5·60	−0·09 (0·07)
	Mean systolic pressure (mm Hg)			
Intervention	131·6		123·2	
Comparison:				
External	138·8	−7·5 (1·2)	130·8	−7·7 (1·4)
Internal	139·0	−7·3 (0·8)	129·6	−6·2 (0·9)
	Mean diastolic pressure (mm Hg)			
Intervention	83·3		78·6	
Comparison:				
External	85·5	−2·5 (1·0)	80·7	−2·5 (0·9)
Internal	86·6	−3·5 (0·4)	81·3	−3·0 (0·4)
	Mean weight (kg)			
Intervention	79·55		66·06	
Comparison:				
External	80·70	−1·17 (0·36)	66·83	−1·09 (0·42)
Internal	80·76	−1·18 (0·43)	66·73	−0·74 (0·54)
	Median blood glucose (mmol/l)			
Intervention	5·54		5·50	
Comparison:				
External	5·56	−0·03 (0·08)	5·40	0·10 (0·09)
Internal	5·64	−0·11 (0·05)	5·49	0·01 (0·04)

*Calculated without regard to pairings within towns.
†Differences calculated for each town separately and then pooled over 13 towns. Pooled differences are therefore not exactly equal to differences in crude values.

vention and internal comparison groups. Among male reported ex-smokers of cigarettes who were not currently smoking pipe or cigars the proportion of men with carbon monoxide ≥10 ppm was 1·1% in the intervention group and 0·7% in the internal comparison group; the corresponding figures for women were 0·4% and 0·5%.

HIGH BLOOD PRESSURE, HIGH BLOOD CHOLESTEROL CONCENTRATION, DIABETES, AND CORONARY HEART DISEASE

The numbers of men and women referred to their general practitioners by the nurses with very high or sustained high individual risk factor values, expressed as a proportion of the total population screened, were respectively: blood pressure (diastolic ≥90 mm Hg) 2% (39/2246) and 1% (14/1604); cholesterol (≥6·5 mmol/l) 5% (102/2011) and 5% (68/1425); and glucose concentration (≥7 mmol/l) 3% (60/2246) and 1% (13/1604). At one year the proportions with reported high blood pressure and a high cholesterol concentration were substantially higher in the intervention group than in the comparison groups in both men and women, and the proportion with reported diabetes was slightly higher in the intervention group in men (table V). In the whole population there was no reported difference in the proportions of patients taking drugs to lower blood pressure or cholesterol concentrations or for diabetes between the intervention and comparison groups. The proportions of patients at one year with reported coronary heart disease (angina, heart attack, coronary artery surgery) were similar in intervention and comparison groups.

TABLE III—*Percentages of men and women at one year with coronary risk factors within the specified ranges in intervention and external and internal comparison groups*

	Men			Women		
	Intervention	External comparison	Internal comparison	Intervention	External comparison	Internal comparison
Blood cholesterol (mmol/l):						
<6·5	82	77	78	84	79	78
6·5-7·9	16	20	19	14	18	18
≥8·0	2	3	3	2	3	4
Diastolic pressure (mm Hg):						
<90	72	65	62	85	80	79
90-99	21	24	25	11	15	16
100-114	7	10	11	3	4	4
≥115	0	1	1	0	1	0
Body mass index (kg/m²):						
<20·0	2	2	1	5	4	5
20·0-24·9	38	34	33	54	48	49
25·0-29·9	48	50	52	29	34	33
30·0-34·9	11	11	12	9	10	10
≥35·0	1	3	2	3	4	4
Blood glucose (mmol/l):						
<7·0	87	85	85	90	93	90
7·0-9·9	11	13	13	9	7	9
≥10·0	2	2	2	1	1	1

TABLE IV—*Percentages (numbers) of men and women with high serum cholesterol concentration, diastolic pressure, body mass index, and blood glucose concentration at one year in intervention groups compared with external and internal comparison groups*

	Men		Women	
Group	Crude prevalence (%)*	Pooled difference (SE)†	Crude prevalence (%)*	Pooled difference (SE)†
	Blood cholesterol ≥8·0 mmol/l			
Intervention	2·0 (35)		2·1 (25)	
Comparison:				
External	3·4 (119)	−1·5 (0·8)	2·9 (69)	−1·1 (0·5)
Internal	2·7 (58)	−1·2 (0·4)	3·7 (52)	−1·7 (0·7)
	Diastolic pressure ≥100 mm Hg			
Intervention	7·0 (124)		3·5 (43)	
Comparison:				
External	11·2 (393)	−4·6 (1·4)	5·2 (125)	−2·2 (1·1)
Internal	12·5 (272)	−5·3 (1·1)	4·9 (68)	−1·4 (0·9)
	Body mass index ≥30 kg/m²			
Intervention	12·0 (212)		12·4 (151)	
Comparison:				
External	13·7 (481)	−1·8 (1·3)	14·1 (337)	−2·2 (1·5)
Internal	13·6 (296)	−1·7 (1·2)	13·8 (193)	−1·7 (1·3)
	Blood glucose ≥10·0 mmol/l			
Intervention	2·3 (40)		1·0 (12)	
Comparison:				
External	2·2 (76)	−0·1 (0·4)	0·5 (12)	0·3 (0·3)
Internal	2·3 (50)	0·1 (0·4)	0·8 (11)	0·2 (0·4)

*Calculated without regard to pairings within towns.
†Differences calculated for each town separately and then pooled over 13 towns. Pooled differences are therefore not exactly equal to differences in crude values.

TABLE V—*Percentages (numbers) of subjects at one year who reported having been diagnosed as having coronary heart disease (angina, coronary artery bypass graft, or heart attack), diabetes, high blood pressure, or high cholesterol concentration*

	Men		Women	
Group	Crude prevalence (%)*	Pooled difference (SE)†	Crude prevalence (%)*	Pooled difference (SE)†
	Coronary heart disease			
Intervention	5·9 (105)		1·9 (23)	
Comparison:				
External	6·5 (227)	−0·6 (0·9)	1·3 (31)	0·3 (0·4)
Internal	5·5 (119)	0·29 (0·9)	1·1 (16)	0·5 (0·5)
	Diabetes			
Intervention	3·3 (59)		1·2 (15)	
Comparison:				
External	2·4 (85)	0·6 (0·5	0·9 (22)	0·1 (0·3)
Internal	1·7 (38)	1·5 (0·5)	1·1 (16)	0·2 (0·4)
	High blood pressure			
Intervention	17·1 (302)		16·2 (197)	
Comparison:				
External	13·5 (474)	3·2 (1·6)	11·5 (275)	4·1 (2·3)
Internal	14·8 (322)	2·4 (1·2)	13·0 (182)	3·7 (1·4)
	High cholesterol			
Intervention	14·0 (247)		9·7 (118)	
Comparison:				
External	9·5 (336)	4·0 (1·7)	5·1 (123)	4·0 (1·2)
Internal	6·9 (150)	66 (1·5)	3·8 (53)	5·7 (1·3)

*Calculated without regard to pairings within towns.
†Differences calculated for each town separately and then pooled over 13 towns. Pooled differences are therefore not exactly equal to differences in crude values.

NON-RETURNERS

The intervention group necessarily comprised those who were recruited to the study one year before and who also returned at one year, while for the comparison groups the one year point represented their first screening visit. Table VI shows the effect of the potential bias introduced by non-returners by showing the mean risk factor values at initial recruitment in the intervention group among those who returned at one year (comprising 88% of men and 85% of women) compared with those who did not. There was a much greater prevalence of cigarette smoking among those who did not return compared with those who did. Weight was on aveage slightly higher among the non-returners, but no other measured risk factor showed clear differences. There was, however, generally a slightly higher prevalence of coronary heart disease and diagnosed diabetes, reported high blood pressure, and high blood cholesterol concentration among those who returned compared with those who did not.

Discussion

In this national trial of a nurse led cardiovascular screening and lifestyle intervention in general practice the overall Dundee risk score was 16% lower after intervention. This lower risk score was consistent when comparing the intervention group with either the external or internal comparison groups and was similar for both men and women. A lower blood pressure accounted for almost half of the observed lower risk, with smoking accounting for a third and cholesterol concentration for about a quarter. The true difference in coronary risk, however, is actually less because differences in smoking are considerably smaller when the smoking habits of those who did not return at one year are taken into account, and the lower blood pressure is likely to be due partly to acclimatisation to

TABLE VI—*Initial risk factor values among subjects on recruitment to intervention group according to whether they returned at one year*

	Men			Women		
	Returned at one year	Did not return at one year	Pooled difference (SE)*	Returned at one year	Did not return at one year	Pooled difference (%)*
No (%) of subjects	1767 (88)	244 (12)		1217 (85)	208 (15)	
Mean age (years)	50·5	49·9	0·7 (0·5)	48·2	47·7	0·4 (0·5)
% Of subjects with:						
Coronary heart disease	5·4	3·3	3·3 (1·3)	1·3	0·5	0·8 (1·2)
Diabetes	2·3	1·2	1·7 (1·1)	0·9	0·5	0·9 (1·2)
High blood pressure	14·5	16·4	0·8 (2·7)	14·5	9·6	6·6 (2·4)
High cholesterol	8·3	4·1	5·9 (1·4)	3·8	2·4	1·7 (1·3)
No (%) of subjects who smoked cigarettes	22·2	41·8	−19·0 (3·4)	19·4	38·9	−18·1 (4·5)
Mean blood cholesterol (mmol/l)	5·67	5·60	0·03 (0·08)	5·50	5·53	−0·01 (0·11)
Mean blood pressure (mm Hg):						
Systolic	138·9	140·7	−0·9 (1·5)	129·4	129·4	1·8 (1·5)
Diastolic	87·1	88·6	−1·2 (0·8)	81·6	82·1	0·1 (0·8)
Mean weight (kg)	79·9	81·7	−1·7 (0·8)	65·9	68·1	−1·9 (1·2)
Median blood glucose (mmol/l)	5·42	5·45	0·02 (0·08)	5·27	5·30	0·06 (0·07)

*Differences calculated for each town separately and then pooled over 13 towns. Pooled differences are therefore not exactly equal to difference in two values.

measurement in the intervention group. We now consider what reduction in the risk of coronary events could be anticipated from the results of this trial.

BIASES IN ASSESSING RISK FACTORS

The lower smoking prevalence observed in the intervention group is biased by two factors. Firstly, a proportion of those recruited at baseline in the intervention practices did not return at one year (12% of men and 15% of women) and the prevalence of smoking at baseline among these non-returners was more than twice as high in both men and women. Secondly, those returning in the intervention group at one year may also have underreported cigarette smoking, as found in other studies.[5-8] Measurement of breath carbon monoxide concentration in our study provided little direct evidence of differential misreporting of smoking habits between the intervention and internal comparison group but is not a very reliable validator of reported smoking habit because of short half life and non-specificity. If it is assumed that the intervention group participants seen at baseline who did not return at one year had not altered their smoking habit, and among the reported ex-cigarette smokers those with a breath carbon monoxide concentration of over 10 ppm were in fact still smoking cigarettes, the observed reduction in the crude proportion of cigarette smokers of 3·9% in men compared with the internal comparison group should be adjusted to 1·0%, and for women the 3·8% difference should be adjusted to 0·7%. The difference in prevalence of smoking between returners and non-returners clearly considerably weakens the evidence for a true reduction in cigarette smoking in the intervention group.

The observed lower blood pressure may also not be entirely true as it could be partly due to the acclimatisation or habituation effect with repeated measurements over time. This effect may be due to lower stress associated with knowing both the person taking the blood pressure and the procedures of screening. To what extent the reduction in blood pressure associated with intervention in this study could be due to such acclimatisation is difficult to assess. Directly comparable data in a population (as opposed to a group with high blood pressure, such as in a hypertension trial, which is also subject to regression to the mean) is needed for this evaluation. Repeated blood pressure measurements in population groups over a three week period in the Intersalt study showed on average a reduction of 3·5 mm Hg systolic and 1·5 mm Hg diastolic in men and almost identical results in women (P Elliot, personal communication). These data suggest, albeit indirectly, that acclimatisation may explain about half the reduction in blood pressure observed in this study.

The results for cholesterol are not open to these biases, but the average reductions were only about 0·1 mmol/l. Like the lower blood pressure this difference in cholesterol concentration will be partly due to the true difference in weight, about 1 kg lower in the intervention group.

If reductions of 0·1 mmol/l in blood cholesterol and 1·5 mm Hg in diastolic blood pressure (half that observed), but no reduction in cigarette smoking, were therefore attributed to the screening and intervention programme in this study, what effect would this have on the risk of coronary events? Using information from reviews of the effects of blood pressure[21] and cholesterol[22] on the risk of coronary heart disease (which allow for the effect of regression dilution bias) and making the crucial and untested assumption that the changes in risk factors would be maintained long term, we estimate the long term proportionate reduction in coronary heart disease risk to be 12%. This risk reduction was achieved by changes in lifestyle as there was no difference at one year in the use of drugs to lower blood pressure and cholesterol concentration between the intervention and comparison groups. If the screening and intervention programme used in this trial were implemented in the same way by every general practice in the country, and if such programmes achieved the same reductions in risk factors (which were then maintained long term), and if this was translated into prevention of myocardial infarction and saving of lives the overall impact on the population burden of coronary heart disease would be small. A risk reduction of 12% in men aged 40-59 participating in the programme would potentially prevent 788 myocardial infarctions and 853 deaths from coronary heart disease each year, which is about 8% of all such events in British men of this age.

APPLICABILITY OF INTERVENTION

The intervention evaluated in this study was designed to use the maximum resources currently available to general practice. The trial used an innovative approach to cardiovascular screening by offering screening to families rather than individual people because it seemed more likely that changes in lifestyle in relation to smoking habit, eating, and exercise would occur if the whole household participated.[23] This family approach, with its initial one and a half hour screening interview for each couple, is very different from the original government sponsored health promotion clincs based on payment for seeing 10 patients in one hour. It bears more similarities to the risk related team approach recommended in the new health promotion package for primary care,[2] but with a full time trained nurse dedicated to the screening and follow up programme and its focus on families rather than individual people our intervention is likely to exceed in its intensity all but that of the most dedicated practice teams elsewhere. The extent to which the nurses were incorporated into an effective primary care team in each practice was highly variable, and leading lifestyle groups was beyond the nurses' resources, although families were encouraged to seek help in other ways—for example, from Weight Watchers. The nurses were fully occupied with the demands of screening, counselling, and following up an average of 183 families (about 296 individuals) during the year. This represented about a sixth of the total practice population potentially eligible for this programme. So a practice with a list size of 1000 men (aged 40-59) that wanted to implement this family based screening and intervention programme would require at least four full time nurses to screen and interview men and their partners over a period of 18 months.

The nurses were trained to facilitate healthy behavioural changes in families using client centred counselling rather than simply giving advice, and they encouraged all families to make the same healthy lifestyle choices regardless of their level of risk. The intensity of nursing intervention, in relation to the family's smoking, dietary, and exercise habits and their subsequent follow up, was determined by the highest coronary risk score in that family, as well as by single risk factors alone. This reflected our belief that rational use of resources to encourage changes in lifestyle should be in proportion to the overall level of risk. Family members were told their risk relative to other men and women of their own age and this avoided classifying people's results as normal or abnormal according to the traditional model of medical screening. This approach was reflected in the change in risk that was achieved; it was greatest at the top (high risk) end of the distribution. Those with high values for one or more individual risk factors, such as blood pressure, were followed up in the traditional way with monthly review as well, and some were then referred to their general practitioner for consideration of drug treatment. However, there was in fact no difference at one year in the overall prevalence of drug treatment between the intervention and comparison groups.

The only randomised controlled trial of multiphasic screening previously reported from general practice was undertaken in two large group practices in south London and based on 3297 middle-aged men and women.[4] The response rate to the initial screening was 73% and to a second screening two years later was 65·5%. Multiphasic screenings included height, weight, blood pressure, smoking, and serum cholesterol concentration but no formal intervention was offered. Over the subsequent nine years there were no significant differences in morbidity or mortality between those screened and not screened. The power of this study to detect major differences in incidence of and mortality from cardiovascular disease was weak, and the trial result should be considered inconclusive for this end point.

Our systematic approach to cardiovascular screening and lifestyle intervention in general practice in this trial did not reach everybody in the population. Though most adults in the age range we studied are registered with a general practitioner, about 40% of those who were potentially eligible to attend did not do so. Some of these non-responders are ghosts on the practice lists. To estimate the impact of any intervention on the population as a whole the number and characteristics of non-responders need to be measured. Other surveys of non-responders in general practice have found a higher prevalence of smoking, obesity, and alcohol consumption compared with those who attend.[24,25] In our study the household response rate after allowing for ghosts was 73%, so about a quarter of the population did not participate. In addition, of those who came to the initial baseline screening, 12% of men and 15% of women did not return at one year despite every effort by the nurses to maximise response rates. These non-returners were twice as likely to be cigarette smokers and were more overweight than returners but interestingly showed a slightly lower prevalence of diagnosed disease. Thus it appears those who come for screening and then participate in an intervention programme over one year contain both a disproportionately larger number of people with lower risk factors and a slightly higher proportion of patients with diagnosed hypertension, hypercholesterolaemia, diabetes, or overt coronary heart disease.

SUMMARY

The results of this large national trial, which is one of two studies evaluating nurse led progrmmes of cardiovascular screening and lifestyle intervention in general practice,[26] found slightly lower weight, blood pressure, and blood cholesterol concentration at one year in the intervention group. Whether these small reductions could be sustained long term is not known, but even if they were they would correspond only to a 12% lower risk of coronary heart disease events. As this lower risk was achieved with a family based programme led by nurses trained in learner centred techniques, and with intensive follow up in relation to overall coronary heart disease risk, as well as individual risk factors, the government sponsored health promotion clinic sessions with no financial commitment to follow up, would probably have achieved considerably less and possibly no change at all. Whether the new health promotion package for general practice, which encourages a more opportunistic approach to screening the population reflecting the reiterative contact of patients with the primary care team, will achieve useful reductions in risk must remain in considerable doubt and cannot be justified in its present form from the results of this trial. Other options might include focusing limited primary care resources on high risk patients—for example, those with hypertension, hyperlipidaemia, diabetes, and established coronary heart disease. Whatever new approaches are advocated this trial emphasises the need for, and shows the feasibility of, rigorous scientific evaluation to measure the impact of such strategies in the future. Clearly, primary care alone cannot provide a population approach to reducing cardiovascular risk, and the government, in aiming to reduce the prevalence of risk factors, will also need to put in place more effective public health policies on tobacco control and healthy eating.

Clinical implications

- A national general practice nurse led cardiovascular screening and lifestyle intervention programme reached 73% of eligible families and maintained contact with 88% of men and 85% of women over one year
- After one year reported cigarette smoking was lower by about 4%, weight by 1 kg, systolic pressure by 7 mm Hg, diastolic pressure by 3 mm Hg, and cholesterol concentration by 0·1 mmol/l on average
- Smoking prevalence, however, was twice as high in those who did not return at one year compared with those who did
- This intensive family centred programme achieved at most an overall 12% reduction in coronary risk (Dundee risk score), similar in both men and women
- The voluntary health promotion package in primary care cannot be justified, in its present form, by these results, and alternative preventive strategies need to be developed and evaluated

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A PATIENT WHO CHANGED MY PRACTICE

Palliative care

David had already had his problem for many years when I joined the practice. He could stay dry for several weeks, but once he started drinking he could not stop. He was now in his early 30s, a builder who lived alone, and had been through the cycle of the local medical services for alcoholics a couple of times.

Slowly we got to know each other. There were lots of lies and deceits. Some small steps forwards and big steps back. There were frequent consultations as I dried him out and then nothing for months. Was he drinking again or was he in prison? Then he would reappear and I would start the cajoling again. I felt irritation, anger, and helplessness towards this man and his self inflicted problems, who would not do what he was told.

Gradually the physical effects came. First the numb feet, then the yellow in the eyes that came and went, and then the terrifying vomiting of blood. Then one day he let me see the light. The flash that made everything clearer.

"If you carry on drinking like this, you know, it's going to kill you," I said.

"I know, Doctor. You said that six months ago. What you didn't say was that it would take so long."

The patient knew that he had an incurable disease and that he was dying. And it was the patient who had to explain it to the doctor. Why had the doctor not seen what the patient could see?

Suddenly everything became easier. If the patient had an incurable disease and was dying the name of the game was palliative care. No more anger and frustration, no more fruitless discussions about stopping drinking. Suddenly I could give him sleeping tablets to help him sleep at night and long term sick notes without feeling guilty. Most of all, I could get to know him as a human being and help him prepare for his death.

After that day he came every few weeks and we would chat about his past and his future, his family and his friends. But then the vomiting of blood became more frequent and so did his hospital admissions. There was, however, a persisting difference in how his problems were perceived.

"Dear Doctor, Thank you for admitting this terminally ill alcoholic man for palliative care."

"Dear Doctor, This alcoholic discharged himself from hospital after 36 hours against medical advice. He refuses to stop drinking. I have told him that unless he does so. . . ."

One day it changed. The houseman telephoned me. David had a hepatoma—inoperable liver cancer. How did I think he would cope alone at home? He probably had not got long to live but it was important to make his life as comfortable as possible.

He never did come out of hospital. A couple of weeks later he died of liver failure. They did a necropsy and there was no sign of any liver cancer, just gross alcoholic cirrhosis. Never mind, one way or another he got his doctors to see things his way. I will always remember David as the man who taught me that cancer is not the only incurable disease that leads to untimely death. Alcoholism often is too, and if we wish to, we can see death coming and plan for it and palliate symptoms and distress along the way.—DAVID MEMEL *is a general practitioner in Bristol*

We are delighted to receive submissions of up to 600 words on *A paper (or patient or book) that changed my practice, A memorable patient, The one message I would like to leave behind,* or related topics.