Health checks and coronary risk: further evidence from a randomised controlled trial

P Hanlon, J McEwen, L Carey, H Gilmour, C Tannahill, A Tannahill, M Kelly

Abstract

***Objectives*—To determine the effectiveness of a health check and assess any particular benefits resulting from feedback of plasma cholesterol concentration or coronary risk score, or both.**

***Design*—Randomised controlled trial in two Glasgow work sites.**

***Subjects*—1632 employees (89% male) aged 20 to 65 years.**

***Interventions*—At the larger work site, (*a*) health education; (*b*) health education and feedback on cholesterol concentration; (*c*) health education and feedback on risk score; (*d*) health education with feedback on cholesterol concentration and risk score (full health check); (*e*) no health intervention (internal control). At the other work site there was no health intervention (external control).**

***Main outcome measures*—Changes in Dundee risk score, plasma cholesterol concentration, diastolic blood pressure, body mass index, and self reported behaviours (smoking, exercise, alcohol intake, and diet) in comparison with internal and external control groups.**

***Results*—Comparisons between the full health check and the internal control groups showed a small difference (0·13 mmol/l) in the change in mean cholesterol concentration (95% confidence interval 0·02 to 0·22, P=0·02) but no significant differences for changes in Dundee risk score (P=0·21), diastolic blood pressure (P=0·71), body mass index (P=0·16), smoking (P=1·00), or exercise (P=0·41). Significant differences between the two groups were detected for changes in self reported consumption of alcohol (41% in group with full health check *v* 17% in internal control group, P=0·001), fruit and vegetables (24% *v* 12%, P<0·001), and fat (30% *v* 9%, P<0·001). Comparison of all groups showed no advantage from feedback of cholesterol concentration or risk score, or both.**

***Conclusions*—The health check only had a small effect on reversible coronary risk. It was effective in influencing self reported alcohol consumption and diet. Feedback on cholesterol concentration and on risk score did not provide additional motivation for a change in behaviour.**

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Introduction

We report the findings from a study that was designed to assess the impact of a health check on health related behaviours and risk of coronary heart disease. We also examined the effects of personalised feedback of plasma cholesterol concentration or coronary risk score, or both.

The study was carried out in Glasgow, where mortality from coronary heart disease is 10% above the Scottish average. Scotland has death rates from coronary heart disease that are among the highest in western Europe.[1,2] Consequently, within Scotland, the prevention of heart disease is a priority for health[3] and research.[4] It is also an issue of particular concern for the people of Glasgow.[5]

Few large scale studies have been carried out to establish the impact of health checks on lifestyle or clinical measures.[6-8] One early influential study showed that multiphasic screening was not beneficial,[9] but the relevance of that study to the current debate is reduced because its emphasis was on screening for early evidence of disease, rather than on health education and the feedback of information to modify behaviour —the thrust of most current health check programmes. The fact that health checks have increasingly been used in a variety of settings without persuasive evidence to support their use has generated considerable debate. A prominent feature of this often heated debate has been controversy about the value of measuring cholesterol concentration. In response to this, in 1989, the King's Fund organised a consensus conference on blood cholesterol measurement and the prevention of coronary heart disease.[10] The conference report called for further research into the effectiveness of health checks and for assessment of the motivational impact on subjects of knowing their cholesterol concentration.

The issues addressed by the King's Fund conference had already been the subject of considerable discussion within Glasgow,[5] and in 1990 Glasgow's "Good Hearted Glasgow" heart disease prevention programme was identified as a test bed for these issues. We used the health check of the "Good Hearted Glasgow" programme in this study.

Subjects and methods

AIMS

This study was established as a randomised controlled trial to answer two questions. Firstly, do health checks modify risk factors for coronary heart disease or other health related behaviours, or both? Secondly, are any particular benefits conferred by personalised feedback of plasma cholesterol concentration or coronary risk score, or both?

STUDY POPULATION

The study took place in two work sites in Glasgow. The main intervention site was a large engineering factory that employed just over 2600 people in 1991, when the study started. The other site, which provided the external control group, was an engineering and repair facility with a workforce of 290. Both workforces were predominantly middle aged male blue collar workers (skilled manual workers). Table 1 gives a breakdown of the age and sex distribution of the study samples. Although the proportion of women in the workforce was small, both sexes were included so that the study would reflect the operational realities faced by workplace health check programmes.

RECRUITMENT, INITIAL ASSESSMENT, AND RANDOMISATION

In the main intervention site 1600 subjects were randomly selected. Those working permanent night shifts were excluded because of practical difficulties. A total of 1381 subjects accepted the invitation, 10 of whom were excluded because they were participants in another coronary intervention study or were taking lipid lowering agents. Subjects with high plasma cholesterol concentrations (>7·8 mmol/l) or high blood pressure (>160 mm Hg systolic pressure or >100 mm Hg diastolic pressure) were referred to their general practitioner but remained as participants in the study.

We calculated that 200 subjects in each of the study groups would allow a difference in the mean change between any two groups of 0·3 of a standard deviation to be detected with 80% power at the 5% significance level. We selected a slightly larger sample size to allow for non-responders.

At the main intervention site 1371 subjects were allocated, by means of computer generated randomisation, to one of five groups. Each received different information and feedback.

Group 1 received health education without feedback on cholesterol concentration or risk score.

Group 2 received health education with feedback on cholesterol concentration but without feedback on risk score.

Group 3 received health education with feedback on risk score but not on cholesterol concentration.

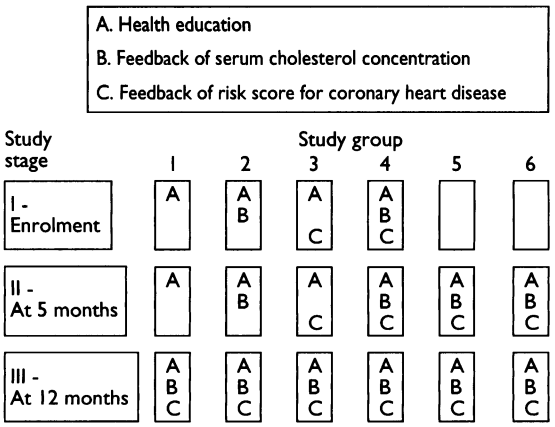
Group 4 received a full health check: health education with feedback on cholesterol concentration and on risk score.

Group 5 acted as an internal control group, their intervention being delayed.

Two hundred and sixty one subjects from the other workforce acted as the external control group (group 6). Their intervention was also delayed.

All six groups were seen at enrolment (stage I), after five months (stage II), and after 12 months at the completion of the study (stage III). This timetable is illustrated in the figure. A common dataset was collected from participants at each visit. The data comprised sociodemographic data including age, sex, address, general practitioner, education, and occupation or employment; relevant details of family and personal medical history including height, weight, blood pressure (using a random zero sphygmomanometer, measured twice after resting for five minutes), and non-fasting plasma cholesterol concentration for both desk top and laboratory measurement; and health related behaviour including diet, alcohol intake, smoking, and exercise.

To minimise bias in self reported behaviour that might arise from a subject's desire to please an interviewer, data on smoking, drinking, and exercise were collected separately at each stage and replies analysed later for change (rather than asking the subjects for self reported changes).



Design of study

The health education package was an interview backed up by written information. Each component of the health message and the feedback on risk score and cholesterol concentration was written and rehearsed by the counsellors to ensure consistency of advice. However, issues of most relevance to each subject were emphasised by the counsellors. When group allocation determined that feedback was not to be given on risk score or cholesterol concentration, or both, the counsellor and the subject remained blind to the relevant measurements.

The internal and external control groups were both assessed at stage I but received no health education, feedback, or written information. In this way groups 5 and 6 acted as control groups between stages I and II. We recognised that subjects in group 5 (internal control) were open to influences from colleagues because the messages given to other participants were being freely discussed in the workplace. The external control group did not have these influences. After five months (stage II) groups 5 and 6 were reassessed and provided with a full health check. Although delaying any intervention in these groups until the end of the study would have been advantageous from a scientific perspective, we judged this approach to be impractical as it might have led to poor participation at follow up.

ANALYSIS

The key baseline characteristics of the study groups were compared using one way analysis of variance or Kruskal-Wallis tests for continuous variables and χ^2 tests for categorical variables. The effect of the full health check was assessed by comparing changes over the five months between stages I and II in group 4 (full health check) and group 5 (internal control) and in group 4 and group 6 (external control). Comparisons were made separately with each control group because they came from different locations and a comparison of changes between the two control groups provides an indication of the degree to which the internal control group had taken up the health education messages that were being discussed in the workplace. Results were analysed on the basis of intention to treat, with non-attenders at stage II being deemed to have made no change (table 2). Two sample *t* tests or Mann-Whitney U tests were used for continuous variables, while χ^2 tests were used to compare the number who had made a positive change, no change, or a negative change for categorical variables.

In assessing the interventions and, therefore, the effect of feedback, analysis was carried out on the basis of intention to treat and then, separately, on subjects who had attended all stages (full attenders) (table 2). Changes over time from stages I to II were compared by one way analysis of variance or Kruskal-Wallis tests for continuous variables and χ^2 tests, as described

Table 1—*Age and sex distribution of study sample*

	Main intervention site			External control site		
	Men	Women	Total	Men	Women	Total
Age (years):						
20-29	185	29	214	51	5	56
30-39	227	20	247	69	2	71
40-49	312	60	372	66	3	69
50-59	370	56	426	58	4	62
60-65	110	2	112	3	0	3
Total	1204	167	1371	247	14	261

Table 2—*Numbers of participants by study group and stage*

	Main intervention site						
	Study group						External control site (group 6)
	1	2	3	4	5	Total	
Study stage:							
I (Enrolment)	293	297	285	263	233	1371	261
II (At 5 months)	247	250	241	219	200	1157	246
III (At 12 months)	240	237	226	211	193	1107	234
I-III (Full attendance)	229	226	214	199	185	1053	230

above, for categorical variables. Follow up multiple comparisons were used with the Bonferroni correction to determine which groups differed significantly from which others.

The health check computer programme generated a risk score for immediate feedback based on a risk factor algorithm. However, for analytical purposes, and to facilitate comparison with other published studies, we considered it useful to use the more recently developed Dundee risk score as an outcome measure. The Dundee risk score is a well validated method of estimating reversible cardiac risk based on a score that runs from 1.5 to 50 derived from the subject's smoking habit, blood pressure, and blood cholesterol concentration.[11]

SUMMARY OF STUDY DESIGN

The study design achieved two objectives. Firstly, it created a narrow randomised controlled trial on the basis of intention to treat between group 4 (full health check) and group 5 (internal control) and separately between groups 4 and 6 (external control) over five months (stages I to II). Secondly, it allowed multiple comparisons between all the study groups to assess the impact of components of the health check including feedback of cholesterol concentration. This paper concentrates on these two issues between stages I and II. Changes in the workforce as a whole over a longer follow up period (until stage III) will be reported elsewhere.

Results

There were no significant differences between study groups in key baseline measurements at stage I.

EFFECTIVENESS OF THE HEALTH CHECK

Tables 3 and 4 summarise the comparison of 263 subjects in group 4 (full health check) and 233 subjects in group 5 (internal control) between stages I and II. The analysis was conducted on the basis of intention to treat. Changes in clinical measurements (plasma cholesterol concentration, diastolic blood pressure, and body mass index) were small. Although small, the change in mean cholesterol concentration was significantly higher in group 4 (0·16 mmol/l) than in group 5 (0·03 mmol/l) (difference in change 0·13 mmol/l (95% confidence interval for difference in change 0·02 to 0·22), P=0·02). There were no significant differences between the two groups for changes in Dundee risk score (P=0·21), diastolic blood pressure (P=0·71), or body mass index (P=0·16).

Changes in the prevalence of smoking were small and showed no significant difference between the groups (P=1·00) (table 4). Changes in reported exercise were large, but the proportion of participants who reported exercising less than 20 minutes aerobically three times a week at stage I who had increased above this level by stage II were similar in both groups (42% in group 4 and 37% in group 5, P=0·41). Changes in self reported alcohol consumption were large and

Table 3—*Comparison of changes in risk factors for coronary heart disease at five months in groups 4 and 5.* Values are means (SD)*

	Full health check (group 4)		Internal control (group 5)		Difference in change between groups (95% confidence interval)	P value†
	Stage I	Change between stages I and II	Stage I	Change between stages I and II		
Dundee risk score	5·47 (3·99)	0·53 (1·59)	5·61 (4·17)	0·34 (1·81)	0·19 (−0·11 to 0·50)	0·21
Cholesterol (mmol/l)	5·88 (1·14)	0·16 (0·57)	5·81 (1·05)	0·03 (0·55)	0·13 (0·02 to 0·22)	0·02
Diastolic blood pressure (mm Hg)	82·41 (10·94)	1·16 (7·56)	82·66 (10·34)	0·91 (7·29)	0·25 (−1·07 to 1·56)	0·71
Body mass index	25·90 (3·76)	0·11 (0·92)	25·54 (3·13)	0·02 (0·62)	0·09 (−0·04 to 0·24)	0·16

*Intention to treat analysis.
†*t* Test.

Table 4—*Comparison of positive changes in health related behaviours at five months in groups 4 and 5.* Values are percentages (proportional)*

	Full health check (group 4; n=263)		Internal control (group 5; n=233)			
	At risk	Percentage of those at risk making positive change at stage II	At risk	Percentage of those at risk making positive change at stage II	Difference between groups (95% confidence interval)	P value†
Smoking	35·4	3·2	36·9	3·5	−0·3 (−5·56 to 4·98)	1·00‡
Drinking	35·0	41·3	35·2	17·1	24·2 (11·3 to 37·1)	0·001
Exercise	49·4	42·3	48·5	37·2	5·1 (−7·2 to 17·4)	0·41
Diet (self reported):						
Increase in fruit and vegetables	100	24·3	100	11·6	12·7 (6·2 to 19·2)	<0·001
Increase in fibre	100	14·5	100	9·0	5·5 (−0·2 to 11·1)	0·06
Reduction in fat	100	30·0	100	9·4	20·6 (13·9 to 27·3)	<0·001

*Intention to treat analysis.
†χ^2 Test.
‡Fisher's exact (two tailed) test.

Table 5—*Comparison of changes in risk factors for coronary heart disease at five months in groups 4 and 6.* Values are means (SD)*

	Full health check (group 4; n=263)		Internal control (group 6; n=261)		Difference in change between groups (95% confidence interval)	P value†
	Stage I	Change between stages I and II	Stage I	Change between stages I and II		
Dundee risk score	5·47 (3·99)	0·53 (1·59)	4·93 (4·29)	0·25 (1·77)	0·28 (−0·01 to 0·58)	0·05
Cholesterol (mmol/l)	5·88 (1·14)	0·16 (0·57)	5·66 (1·03)	−0·01 (0·59)	0·17 (0·07 to 0·27)	0·001
Diastolic blood pressure (mm Hg)	82·41 (10·94)	1·16 (7·56)	79·31 (10·07)	0·60 (8·04)	0·56 (−0·78 to 1·90)	0·41
Body mass index	25·90 (3·76)	0·11 (0·92)	25·65 (3·68)	0·11 (0·71)	0·00 (−0·14 to 0·14)	0·98

*Intention to treat analysis.
†*t* Test.

Table 6—*Comparison of positive changes in health related behaviours at five months in groups 4 and 6.* Values are percentages (proportional)*

	Full health check (group 4; n=263)		Internal control (group 6; n=261)			
	At risk	Percentage of those at risk making positive change at stage II	At risk	Percentage of those at risk making positive change at stage II	Difference between groups (95% confidence interval)	P value†
Smoking	35·4	3·2	32·6	4·7	−1·5 (−7·26 to 4·30)	0·61
Drinking	35·0	41·3	45·2	21·2	20·1 (7·68 to 32·54)	0·002
Exercise	49·4	42·3	53·3	38·8	3·5 (−8·30 to 15·22)	0·56
Diet (self reported):						
Increase in fruit and vegetables	100	24·3	100	18·8	5·5 (−1·5 to 12·6)	0·12
Increase in fibre	100	14·5	100	8·1	6·4 (1·0 to 11·8)	0·02
Reduction in fat	100	30·0	100	13·8	16·2 (9·3 to 23·2)	<0·001

*Intention to treat analysis.
†χ^2 Test.

Table 7—*Percentages (numbers) of subjects in each study group reporting specific dietary changes at five months†*

	Increase in fruit and vegetables	Increase in fibre	Reduction in fat
Study group:			
1 (Health education; n=228)	17·9	11·4	21·0*
2 (Health education and feedback on cholesterol; n=226)	23·9*	20·8*	30·5*
3 (Health education and feedback on risk factors; n=214)	22·9	16·8	23·8*
4 (Health education and feedback on cholesterol and risk factors; n=199)	30·2*	18·6	36·7*
5 (Internal control; n=185)	12·4	10·3	10·3
1-5 (n=1053)	21·6	15·7	24·7
6 (External control; n=230)	20·1	8·2	14·6

*P<0·005 compared with group 5.
†Analysis based on full attenders.

showed significant differences between groups. Of those at stage I who were drinking above recommended limits (21 units weekly for men and 14 units weekly for women), 41% in group 4 and 17% in group 5 reduced alcohol consumption (P=0·001). All participants made some improvement in their diet. Significant differences were found for self reported increases in the consumption of fruit and vegetables (24% *v* 12%, difference 13% (6·2% to 19·2%), P<0·001) and self reported reductions in consumption of fat (30% *v* 9%, difference 21% (13·9% to 27·3%), P<0·001).

Tables 5 and 6 show the comparable set of results for group 4 (full health check) and 261 subjects in group 6 (external control). The pattern of results in tables 5 and 6 is similar to that in tables 3 and 4. In tables 5 and 6, however, the difference in mean change in Dundee risk score is significant (0·28 (−0·01 to 0·58), P=0·05), the difference in proportion increasing fruit and vegetable consumption is not significant (5·5%; P=0·12), and the difference in proportions increasing fibre consumption is significant (6·4% (1·0 to 11·8), P=0·02).

BENEFITS OF FEEDBACK OF CHOLESTEROL CONCENTRATION AND RISK SCORE

There were no differences between groups to suggest that feedback of cholesterol concentration or risk score had additional impact on any of the outcomes. All six groups were compared with each other to assess their impact on each outcome measure. To isolate the effect of feedback of cholesterol concentration we paid particular attention to detecting differences between group 1 (health education only) and group 2 (health education and cholesterol feedback) and between group 3 (health education and feedback on risk score but not cholesterol concentration) and group 4 (full health check). In the same way, we compared groups 1 and 3 and groups 2 and 4 to identify any additional benefits from feedback of risk score. Analysis was carried out on the basis of intention to treat, to determine the impact of feedback, and on full attenders, to maximise sensitivity to any effect of feedback.

Some differences were detected between the intervention groups and the control groups. For several categories of self reported dietary behaviour (table 7) each of the four intervention groups (groups 1-4) showed greater improvements than the internal control group (group 5). All four intervention groups reduced fat consumption significantly better than the internal control group. The differences between groups 5 and 2 were also significant for increases in fibre consumption and between group 5 and groups 2 and 4 for increase in fruit and vegetable consumption (P<0·005 in each case).

Group 4 showed an improvement in self reported alcohol consumption that was significantly larger than that in group 5 (P=0·001). None of these differences in

outcomes, however, showed an enhanced effect from feedback of cholesterol concentration or risk score.

Discussion

This study showed no convincing additional benefit from feedback of cholesterol concentration or risk score. The King's Fund consensus conference on blood cholesterol measurement had called for research into this issue because knowledge of cholesterol concentration might help in motivating subjects to change their health related behaviour.[10] Whatever the intuitive appeal of this argument, our results do not support it. We analysed data on the basis of intention to treat and on full attenders separately. This ensured that we could estimate the potential operational effectiveness of feedback and measure any benefit as sensitively as possible. Despite this, there was no significant enhancement of any outcome measure in groups that received feedback of cholesterol concentration.

The full health check seems to have been effective in motivating health related behaviour change—for example, in self reported alcohol consumption and diet. However, we found no effect on Dundee risk score, diastolic blood pressure, body mass index, or smoking. The fall in mean plasma cholesterol concentration was significant but small in absolute terms. It is difficult to judge the validity of this fairly large change in some self reported behaviours. The fall in cigarette smoking was small, but over 40% of those drinking above recommended levels at the beginning of the study reported reductions in their intake. Responses to questions about food consumption indicated considerable increases in consumption of fresh fruit, vegetables, and fibre. Also, changes in self reported exercise activity were high in intervention and control groups (about 40% overall).

These changes in self reported behaviour must be interpreted with caution, not least because they were not confirmed by external measurements. For example, although self reported changes in diet were large, reductions in mean cholesterol concentration were small and the mean body mass index showed a slight increase. Changes in all forms of self reported behaviour are open to bias, particularly by the subject's desire to please the interviewer. None the less, some aspects of the study design strengthen the reliability of the findings on behaviour change. Data on smoking, drinking, and exercise (but not diet) were collected separately at each stage and replies analysed later for change (rather than asking the subjects for self reported changes). Another strength was the inclusion of two control groups, the second from a different location. The similarity in results between the internal and external control groups strengthens confidence in changes in the intervention group and also suggests that members of the internal control group were not excessively influenced by colleagues who had been given health education.

The findings of this workplace based study are in line with recent primary care based studies. The family heart health study[12] and the OXCHECK study[13] both showed that nurse led programmes to prevent coronary heart disease in primary care produce some modification in behaviour and coronary risk factors. A longer term follow up of the population in the OXCHECK study showed that these benefits were sustained over three years.[14] Both sets of authors and others[15] have, however, questioned whether these effects are sufficiently large to justify the effort and cost required.

Our results suggest that health checks in workplaces may influence a variety of health related behaviours without affecting more objective measures of the risk of coronary heart disease. They also add weight to the argument against cholesterol measurement as a factor in motivating behaviour change. Health checks may have a role in individualised health education to encourage healthy lifestyles as part of a broader health promotion strategy. None the less, these potential benefits must be weighed against their cost in relation to other priorities.

Key messages

- The health check used in this workplace study had no effect on reversible coronary risk
- Feedback on cholesterol concentration or coronary risk had no additional motivating effect on health related behaviour
- Self reported changes in behaviour for some things such as alcohol consumption and diet were large
- Cholesterol measurement should not be used as a health promotion tool to motivate change in behaviour
- From this evidence, health checks have little role in preventing coronary heart disease, but they may help to promote healthy lifestyles

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