

## Randomised controlled trial of health promotion in general practice for patients at high cardiovascular risk

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### Abstract

**Objective**—To assess the value of health education for patients with angina in reducing risk factors for cardiovascular disease and lessening the effect of angina on everyday activities.

**Design**—Randomised controlled trial of personal health education given every four months.

**Setting**—18 general practices in the greater Belfast area.

**Subjects**—688 patients aged less than 75 years and known to have had angina for at least six months; 342 randomised to receive education and 346 to no education.

**Main outcome measures**—Restriction of everyday activities, dietary habit, smoking habit, frequency of physical exercise; blood pressure, body mass index, and serum total cholesterol concentration at entry to trial and after two years.

**Results**—317 in the intervention group and 300 in the control group completed the trial. At the two year review more of the intervention group (140, 44%) reported taking daily physical exercise than the control group (70, 24%). The intervention group also reported eating a healthier diet than the control group and less restriction by angina in any everyday activity. No significant differences were found between the groups in smoking habit, systolic or diastolic blood pressure, cholesterol concentration, or body mass index.

**Conclusion**—Despite having no significant effect on objective cardiovascular risk factors, personal health education of patients with angina seems to increase exercise and improve dietary habits and is effective in lessening the restriction of everyday activities.

### Introduction

Cardiovascular disease is the main cause of premature death in Northern Ireland.<sup>1</sup>

Although the risk of cardiovascular disease can be reduced by primary prevention,<sup>2,3</sup> trials of interventions in general practice have reported poor success.<sup>4-7</sup> Secondary prevention can also be effective.<sup>8-10</sup> Changes in exercise, diet, and smoking have been shown to produce regression of stenotic lesions on coronary arteriography.<sup>11</sup>

A mass public health education programme is aiming to increase awareness of healthy lifestyles in Northern Ireland.<sup>12</sup> We studied the value of secondary prevention for high risk patients in general practice by giving personal health education to patients with angina. Angina is associated with increased cardiovascular mortality and restriction of everyday activities.<sup>13-18</sup>

### Patients and methods

Patients were identified from 18 group general practices in the greater Belfast area. General prac-

tioners were asked to identify patients aged under 75 years who had had angina for at least six months and did not have any other severe illness. Angina was defined as recurrent, transient, and reproducible discomfort in the chest, arms, jaw, or shoulders, the discomfort being reproduced by physical exertion or emotional excitement and relieved by rest or drugs.

We sent letters to 1431 patients, asking for their consent to be interviewed by a research worker interested in angina. The initial appointment took place in the patient's local health centre or surgery or in their own home. Trained health visitors asked questions about the effect of angina on everyday activities, the frequency of attacks of angina, drugs taken, smoking, exercise, and diet. They also administered a questionnaire to determine intake of various foods based on that used in a Department of Health and Social Services survey in Northern Ireland.<sup>19</sup>

Exercise levels were rated as the number of episodes each week of physical activity sustained for at least 20 minutes. Patients' height (Microtois tape, Raven Equipment, Dunnow), weight (Seca scales, Seca, Birmingham), blood pressure (random zero sphygmomanometer, Hawksley and Son, Lancing), and breath carbon monoxide concentration (Smokerlyzer, Bedfont Technical Instruments, Sittingbourne) were measured. An electrocardiogram was recorded and a sample of blood taken for measurement of serum cholesterol and thiocyanate concentration and a urine sample for cotinine assay.

Each subject was then randomly allocated to one of two groups. The health visitor opened an opaque, sealed, and numbered envelope containing the allocation, which had been generated by a computer program using random permuted blocks.

For the control group the interview ended at this point. Patients in the intervention group were given practical relevant advice regarding cardiovascular risk factors. They were reviewed at four monthly intervals and given appropriate health education. After two years both groups were reviewed by a research worker who had not previously been involved with the subjects.

### STATISTICAL METHODS

Comparisons between the control and intervention groups were done by  $\chi^2$  analysis. Analysis of variance was used to compare measurements of blood pressure, cholesterol, and body mass index between the two groups. Paired *t* tests were used to compare the differences within the control and intervention groups. Logistic regression was used to compare the mortality in the two groups.

A previous study of patients with angina in general practice identified 22% with "severe" angina—that is, they had attacks once or more a day when walking on the level and during sexual activity, sport, housework, or shopping.<sup>18</sup> We estimated that effective intervention should reduce this to about 10%. We calculated that we

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would require 325 patients in each group to show a significant difference at the 5% level of probability. To allow for numbers diminishing through default or death we tried to recruit 350 to each group.

## Results

A total of 688 patients entered the study. Of the 342 in the intervention group, 317 completed the study, 13 died, and 12 defaulted from review. Of the 346 in

TABLE I—Characteristics of intervention and control groups at entry to trial

	Intervention group (n=342)	Control group (n=346)	Significance
Age (years):			
Mean (SD)	62.7 (7.1)	63.6 (6-8)	P=0.097
Range	38-74	39-74	
Sex:			
Male	203	205	$\chi^2=0.000$ , P=1.0
Female	139	141	
Social class:			
I and II	37	35	$\chi^2=0.49$ , P=0.78
III non-manual and manual	157	168	
IV and V	148	143	
Family history of heart disease:			
Yes	223	231	$\chi^2=0.18$ , P=0.66
No	119	115	
Previous myocardial infarction:			
Yes	150	159	$\chi^2=0.22$ , P=0.63
No	192	187	
Electrocardiographic evidence of ischaemia:			
Yes	212	216	$\chi^2=0.0016$ , P=0.96
No	130	130	
No of cigarettes smoked/day:			
None	272	268	$\chi^2=0.84$ , df=2, P=0.84
1-10	43	44	
11-20	21	26	
>20	6	8	
Severity of angina:			
Severe*	21	18	$\chi^2=0.13$ , P=0.71
Not severe	321	328	

\*Severe angina defined as attacks occurring once or more per day when walking on the level and in sex, sport, housework, or shopping.

TABLE II—Frequency of physical exercise in patients with angina at baseline and review after two years. Values are numbers (percentages)

No of episodes/week	At baseline		At review	
	Intervention group (n=317)	Control group (n=300)	Intervention group (n=317)	Control group (n=300)
0	47 (15)	33 (11)	46 (15)	71 (24)
1-2	57 (18)	50 (17)	31 (10)	58 (19)
3-4	49 (15)	42 (14)	46 (15)	33 (11)
5-6	42 (13)	49 (16)	54 (17)	68 (23)
7-10	59 (19)	64 (21)	93 (29)	53 (18)
≥11	63 (20)	62 (21)	47 (15)	17 (6)

$\chi^2$  for trend=29.69, df=1; P<0.0001.

TABLE III—Changes in frequency of physical exercise in patients with angina between baseline and review at two years

	No (%) of patients	
	Intervention group	Control group
Increased	108 (34)	63 (21)
No change	120 (38)	74 (25)
Decreased	89 (28)	163 (54)

$\chi^2$  for trend=35.66, df=1; P<0.0001.

TABLE IV—Changes in eating habits among patients with angina between baseline and review at two years. Values are numbers of patients

Food	Improved*		No change		Deteriorated		$\chi^2$ for trend	P Value
	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group		
Poultry	100	78	175	173	42	59	5.39	0.02
Green vegetables	139	113	146	122	32	65	9.66	0.002
High fibre food	115	88	175	170	27	42	6.04	0.01
Red meat	178	142	95	115	43	59	7.79	0.005
Fried food	85	79	168	127	64	94	3.99	0.045
Biscuits and sweets	116	79	134	128	67	103	14.53	0.0001
Saturated fat	33	25	250	220	34	55	6.13	0.013

\*Improved=increased frequency of eating poultry, green vegetables, and high fibre food and decreased frequency of eating red meat, fried foods, biscuits, sweets, and saturated fat.

the control group, 300 completed, 29 died, and 17 defaulted. No significant differences were found between the two groups at baseline (table I).

Table II shows that the reported frequency of physical exercise was similar in the two groups initially. At review, more of the intervention group (140, 44%) than the control group (70, 24%) took daily physical exercise (seven or more times per week). More of the intervention group reported increased activity and fewer reported decreased activity compared with the control group (table III).

Initially the eating patterns of the two groups did not differ, but at review more of the intervention group reported improved dietary habits (table IV). More people in the control group reported an increase than a decrease in the frequency of eating poultry, green vegetables, and high fibre foods—that is, an improved dietary habit—but more people also reported eating increased amounts of fried food, biscuits, sweets, and saturated fat.

Of the 688 patients who entered the study, 187 stated that they had never smoked and 501 said that they had ever smoked. Of these 501, 148 said that they still smoked cigarettes and 31 that they smoked cigars or a pipe. Measurements of breath carbon monoxide, serum thiocyanate, and urinary cotinine concentrations were fully completed for 460 of the reported non-smokers and showed that 28 (6%) of the reported non-smokers had values that were more than two standard deviations above the mean for non-smokers and similar to values for those who reported smoking cigarettes.

The reported rate of stopping smoking at review was 21.5% (14/65) in the intervention group and 17.7% (11/62) in the control group. This difference was not statistically significant (P=0.82). There was also no difference in the number of patients who had increased or decreased their smoking between the groups.

At baseline there was no significant difference between the two groups in reported restriction of activities (table V). At review 27 (8.5%) of the intervention group claimed no restriction compared with eight (2.7%) of the control group (P=0.003). The numbers with severe angina fell from 39 (5.7%) initially to 22 (3.6%) at review, but there was no significant difference between the groups. The mean number of episodes of angina per week in the intervention group decreased from 3.2 (95% confidence interval 2.7 to 3.7) at baseline to 2.6 (1.7 to 3.5) at review (P=0.04), but no significant change was seen in the control group (2.5 (2.1 to 2.9) at baseline and 2.14 (1.7 to 2.5) at review (P=0.13)).

At baseline 252 (36.6%) patients reported taking prophylactic drugs for angina with no significant difference between the groups. At review significantly more of the intervention group (166 (53%)) than the control group (120 (40%)) did so (P=0.004).

The groups did not differ significantly either initially or at review with regard to systolic or diastolic blood pressure, serum cholesterol concentration, or body mass index (table VI). Diastolic blood pressure and body mass index fell in both groups over the study period (P<0.0001). The intervention group showed a significant reduction in serum cholesterol concentration (P=0.003) of 2.4% but the fall was not significantly different from that in the control group (P=0.06).

There were 29 deaths in the control group and 13 in the intervention group. The relative odds of death in the control group was 2.32 (95% confidence interval 1.18 to 4.53). Ten of the deaths in the intervention group and 28 in the control group were attributed to cardiovascular causes. The relative odds of death was 2.20 (1.06 to 4.57) after age, sex, history of myocardial infarction, blood pressure, cholesterol, body mass

TABLE V—Effect of angina on everyday activities. Values are numbers (percentages) of patients

Activity	Restricted				Not restricted				Not applicable			
	At baseline		At review		At baseline		At review		At baseline		At review	
	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group
Distance of walking	201 (64)	181 (60)	177 (56)	173 (58)	114 (36)	118 (39)	139 (44)	122 (41)	1 (0.3)	1 (0.3)	2 (0.6)	5 (2)
Speed of walking	279 (72)	229 (76)	210 (66)	198 (66)	87 (27)	70 (23)	106 (33)	97 (32)	1 (0.3)	1 (0.3)	2 (0.6)	5 (2)
Sports	60 (19)	63 (21)	57 (18)	64 (21)	49 (15)	53 (17)	34 (11)	41 (14)	215 (68)	184 (61)	226 (71)	195 (65)
Sex	68 (21)	65 (22)	64 (20)	74 (25)	121 (38)	118 (39)	118 (37)	104 (35)	128 (40)	117 (39)	135 (43)	122 (41)
Housework	182 (57)	118 (59)	161 (51)	166 (55)	117 (37)	94 (31)	141 (45)	112 (37)	18 (6)	28 (9)	15 (5)	22 (7)
Shopping	125 (40)	105 (35)	147 (46)	151 (50)	166 (52)	172 (57)	151 (48)	135 (45)	26 (8)	24 (8)	19 (6)	14 (5)
Climbing stairs	254 (80)	245 (82)	238 (75)	227 (76)	60 (19)	52 (17)	73 (23)	65 (22)	2 (0.6)	3 (1)	6 (2)	8 (3)
Carrying objects	241 (76)	234 (78)	258 (81)	255 (85)	47 (15)	35 (12)	48 (15)	31 (10)	29 (9)	31 (10)	12 (4)	14 (5)
Social visiting	72 (23)	58 (19)	78 (25)	72 (24)	239 (75)	235 (78)	228 (72)	212 (71)	6 (2)	7 (2)	12 (4)	16 (5)
Driving a car	23 (7)	27 (9)	38 (12)	28 (9)	127 (40)	102 (34)	112 (35)	105 (35)	166 (52)	172 (57)	167 (53)	167 (56)

TABLE VI—Mean values of cardiovascular risk factors in patients with angina at baseline and review

	Baseline	Review	Mean difference		P Value
			(95% confidence interval)	% Reduction	
Systolic blood pressure (mm Hg):					
Intervention group (n=317)	137.2	136.5	0.59 (-1.75 to 2.93)	0.4	0.616
Control group (n=300)	137.0	136.0	0.98 (-1.64 to 3.60)	0.7	0.459
Diastolic blood pressure (mm Hg):					
Intervention group (n=317)	83.1	76.9	6.1 (4.8 to 7.5)	7.4	<0.0001
Control group (n=300)	82.0	77.0	5.0 (3.4 to 6.5)	6.1	<0.0001
Serum cholesterol (mmol/l):					
Intervention group (n=313)	6.2	6.05	0.15 (0.05 to 0.25)	2.4	0.003
Control group (n=285)	6.12	6.08	0.03 (-0.91 to 0.97)	0.5	0.439
Body mass index:					
Intervention group (n=317)	27.3	26.8	0.5 (0.28 to 0.72)	1.8	<0.0001
Control group (n=300)	27.4	26.8	0.5 (0.29 to 0.71)	1.9	<0.0001

index, smoking status, family history, social class, diabetes, and recent worsening of angina were adjusted for.

### Discussion

We have shown benefits from secondary prevention of cardiovascular disease for a group of high risk patients. Although there was no difference in values of risk factors between the intervention and control groups at review, patients in the intervention group were significantly less restricted by their angina than the control group.

The slight reductions in systolic blood pressure and significant reductions in diastolic blood pressure seen in both groups may have been partly due to an accommodation effect from repeated measurements<sup>20,21</sup> but also to the reduction in body mass index.<sup>22</sup> The reductions in diastolic blood pressure and body mass index in both groups suggest that the present medical care of patients with angina in combination with a background public health education campaign is effective. Additional personal health education could not be justified on the basis of these observations.

### Practical implications

- Health education for patients with angina
- In this study personal health education improved patients' dietary habits, increased their frequency of taking physical exercise, and decreased their restriction of activity by angina
- Patients receiving personal health education reported increased use of prophylactic drugs
- No improvements were seen in blood pressure, cholesterol concentration, or rate of stopping smoking
- Health education can improve the quality of life of patients with angina and should be incorporated into routine care in general practice

### LIFESTYLE HABITS

Though elderly patients with angina might be expected to become less active over two years, only 28% of the intervention group compared with 54% of the control groups did so, and significantly more of the intervention group increased their frequency of physical exercise. We did not validate patients' reporting of their activities and some reporting bias may have occurred. However, the difference between the groups is in keeping with the intervention group's reporting of less restriction of activity.

The patterns of restriction of activities differed and were not directly related to physical effort or exercise tolerance. Psychological factors are obviously also important.<sup>17</sup> The percentage of patients in the intervention group who took drugs prophylactically increased significantly. This behaviour could have caused a reduction in symptoms.

There was no significant difference in reported rates of giving up smoking cigarettes between the two groups. Education aimed at smoking may be more effective in specific programmes than as part of a multifactorial programme.<sup>6</sup>

The intervention group reported eating a healthier diet than the control group at review. The education may have encouraged the intervention group to report a more healthy diet than they were actually eating. We tried to minimise such bias by using someone unknown to the patient to make the review observations. Corroboration of dietary habit was not feasible in this study, but questionnaires are often used to assess diet.<sup>23</sup>

Changing diet has been shown to reduce serum cholesterol concentration,<sup>24,25</sup> but we found no such correlation. This may be because food frequency questionnaires reflect trends in dietary habits but cannot accurately quantify intake.

### MORTALITY

Logistic regression analysis did not explain the mortality difference between the two groups. Although there were no significant differences in objective risk factors, the improved wellbeing resulting from increased physical exercise and a healthy diet may have had an effect on coronary mortality. The observation could be a chance occurrence, but we should remember that psychological factors affect patients with angina.

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## Statistics Notes

### Quartiles, quintiles, centiles, and other quantiles

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This is the eighth in a series of occasional notes on statistics

When presenting or analysing measurements of a continuous variable it is sometimes helpful to group subjects into several equal groups. For example, to create four equal groups we need the values that split the data such that 25% of the observations are in each group. The cut off points are called quartiles, and there are three of them (the middle one also being called the median). Likewise, we use two tertiles to split data into three groups, four quintiles to split them into five groups, and so on. The general term for such cut off points is quantiles; other values likely to be encountered are deciles, which split data into 10 parts, and centiles, which split the data into 100 parts (also called percentiles). Values such as quartiles can also be expressed as centiles; for example, the lowest quartile is also the 25th centile and the median is the 50th centile. We consider below some common applications of quantiles.

A common confusion is to use the terms tertiles, quartiles, quintiles, etc, not for the cut off points but for the groups so obtained, but these are properly called thirds, quarters, fifths, and so on.

**Data description**—The mean and standard deviation are useful to summarise a set of observations. When the data have a skewed distribution it is often preferable to quote instead the median and two outer centiles, such as the 10th and 90th. The first and third quartiles (25th and 75th centiles) are sometimes used; these define the interquartile range. The median is a useful summary statistic when some of the values are not actually measured—for example, because some values are outside the range of the measuring equipment. Similarly, the median is frequently used when summarising survival data, when it is usual for some of the survival times to be unknown.

**Reference intervals and centiles**—A special type of data description arises in the construction of a reference interval (normal range). A 95% reference interval is defined by the values that cut off 2½% at each end of the distribution. (These values are often quite reasonably called the 2½ and 97½th centiles, although

it is not strictly correct to have half centiles.) Reference intervals are widely used in clinical chemistry. By contrast, charts for the assessment of human size or growth usually show several centiles.<sup>1</sup> Reference centiles are sometimes derived using the normal distribution,<sup>2</sup> in which case any new observation can be placed at a specific centile.

**Analysis of continuous variables**—Continuous variables, such as serum cholesterol concentration and lung function, are often categorised in statistical analyses. It is usual to use quantiles, so that there are the same number of individuals in each group. Such grouping discards information but may allow for simpler presentation, such as in tables. The fewer groups created the greater is the loss of information. In regression analyses continuous explanatory variables are often categorised into two or more groups. Although this slightly complicates the analysis, it avoids a direct assumption that there is a linear relation between the variable and the outcome of interest. However, it leads to a model in which risk apparently jumps at certain values of the predictor variable rather than increasing smoothly.

**Calculation of quantiles**—The calculation of centiles and other quantiles is not as simple as it might seem. The data should be ranked from 1 to  $n$  in order of increasing size. The  $k$ th centile is obtained by calculating  $q=k(n+1)/100$  and then interpolating between the two values with ranks either side of the  $q$ th. For example, for the 5th centile of a sample of 145 observations we have  $q=5 \times 146/100=7.3$ . We estimate the 5th centile as the value 0.3 of the way between the 7th and 8th ranked observations. If these data values are 11.4 and 14.9 the estimated centile is 12.45. Confidence intervals can be constructed for any quantile.<sup>3</sup>

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