Preliminary trial of the effect of general practice based nutritional advice

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SUMMARY. Despite formal recommendations for dietary change to reduce the incidence of ischaemic heart disease, the acceptability and effectiveness of the proposed diets have not been well investigated in population based studies. In this preliminary investigation of nutritional advice in a well population, subjects in one group practice were randomized to receive either dietary instruction or simple follow up without instruction. The dietary recommendations were well received, and a substantial proportion of subjects reported altering their diets in accordance with them. There were modest beneficial changes in plasma lipid levels among men. Thus, using general practice as an avenue for promoting dietary change is feasible, and may be effective among men.

Introduction

OFFICIAL organizations in the United Kingdom have recommended that the British public modify its present diet in order to reduce the incidence of ischaemic heart disease.[1,2] Common to many of these recommendations is advice concerning maintenance of optimal body weight, increased dietary fibre, reduced total fat intake, and an increased ratio of polyunsaturated to saturated fat intake. Although there have been several clinical trials that have studied dietary intervention for ischaemic heart disease, these have stressed multifactorial intervention (with a variable dietary focus), have featured diets high in total fat, or have used a very high ratio of polyunsaturated to saturated fats.[3] Only a few of the studies have been population based.[3] The acceptability of the currently recommended dietary advice to the healthy UK population (as distinct from patients or high risk subgroups) has not, therefore, been well studied. Also, for the general population, there is little information concerning the effect of such dietary change on the metabolic parameters that are associated with ischaemic heart disease, such as serum lipoproteins.

This report describes the results of a preliminary, general practice based randomized controlled trial of the current dietary recommendations. Its aim was to assess the acceptance of the diet to a healthy UK population, to ascertain whether a general practice based approach would promote its use, and to provide preliminary information on its effectiveness in lowering lipid levels in this population.

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Method

Subjects

Five hundred and seven potential subjects, between 25 and 60 years of age, were randomly chosen from over 20 000 patients on the lists of a group general practice in Abingdon (Oxfordshire). From this sample, 70 subjects were excluded who had moved or died; had severe psychosis, debilitating chronic illness, or chronic gastrointestinal disease; or were being treated for hyperlipidaemia or symptomatic coronary artery disease. The remaining 437 subjects were randomly assigned to either a control or a dietary intervention group and invited by telephone to participate in the study. Of these, 368 (84%) accepted the invitation and were enrolled.

Study

All subjects completed a self-administered questionnaire concerning general health, smoking habits, and present diet. Those in the dietary intervention group were also given instruction regarding optimal body weight and diet by a nurse associated with the practice. This was done individually or in small groups, and took about 30 minutes per session. The dietary advice was directed towards a modest decrease in total fat intake from an expected level greater than 40% of calories to 30–35% of calories, with an increase in the ratio of polyunsaturated to saturated fats to approximately 0.4 from an expected level of less than 0.3. In addition, the value of increased dietary fibre, including soluble fibre,[4] was stressed. The potential benefits of physical exercise, and moderation of salt, alcohol, and tobacco intake were also mentioned, but not particularly emphasized. A booklet was given to intervention subjects which summarized the basic ideas of the diet, provided recipes, and offered advice concerning local restaurants. During a three month intervention period, the study nurse offered these subjects encouragement and advice regarding dietary modification. Promotional material was on display at the practice and brief follow-up/counselling sessions were scheduled for one and three months after entry to the study. The control group, on the other hand, were told that they were part of a nutrition survey, and were followed up on the same schedule by the same nurse, but without the dietary advice.

A fasting blood sample was obtained from each subject at entry, with repeated samples taken at one, three and 12 months after initial interview. Serum and plasma samples were processed promptly and frozen at −20°C until analysis. Cholesterol concentrations were determined by an automated Liebermann–Burchardt reaction,[5] and lipoproteins were assayed by precipitation techniques.[6,7] Triglycerides were measured using a glycerokinase method,[8] and plasma glucose was determined by a glucose oxidase method (Boehringer). Triglycerides were not measured at one year. Triglyceride and cholesterol ester linoleic acid levels reflect dietary intake and thus were used to assess compliance with the diet. These were measured by methods as previously described[9] and expressed as the percentage of the total. Weight was measured by the study nurse.

A self-administered questionnaire developed by Gear and colleagues[10] was given at each encounter. This instrument used a simple food frequency format, and provided an accurate assessment of daily fibre intake. Although all aspects of diet (including alcohol) were reflected in the questionnaire, it was not designed

to measure total calorie intake or to estimate precisely the intake of nutrients other than fibre. A separate brief questionnaire addressing attempts at dietary change was given to both groups at three months and one year, and one year. Intervention subjects were queried at one month, three months and one year about difficulties encountered with the recommendations.

Analysis

Because of the known sex differences in lipid levels, all statistical analyses were done separately for men and women. Differences between means were evaluated for statistical significance by standard t-tests.[11] For baseline frequency data, statistical significance was determined by contingency table chi-square tests.[11]

Results

Baseline characteristics

A total of 368 subjects randomized into control (92 men, 89 women) or dietary intervention (97 men, 90 women) groups. In general, baseline characteristics were similar in the two groups (Table 1). However, control men had a higher percentage of current smokers than intervention men ($P<0.05$), and a higher proportion of intervention women were in social class 1 or 2 compared with controls ($P<0.01$). Intervention subjects tended to be heavier, though the differences were not statistically significant. Women in the two study groups did not differ substantially with regard to history of gestational hypertension, hormone problems, hormone replacement therapy, use of oral contraceptives or parity.

In general subjects cooperated well with the study. Losses to follow up were modest, especially during the three month intervention period. Five subjects were unavailable at one month, 10 at three months (three control and seven intervention subjects) and 33 subjects (9.0%) were lost to follow up at 12 months (13 controls and 20 intervention subjects).

Acceptance of diet

The dietary intervention appeared to be well accepted by the intervention group (Table 2). No one complained that the dietary advice was difficult to understand, and very few (at most 8%) thought the recommended regimen was hard to prepare or difficult to find in restaurants. However, approximately 10% of the intervention group noted that they or their families disliked the recommendations, and subjects with this complaint were more likely to drop out of the study.

Reported changes in diet

At three months, more than two thirds of the diet group subjects reported consciously attempting to eat more fibre, compared with less than 2% of the controls (Table 3). There were similar large differences in the proportions attempting to reduce dietary fat, though reported efforts to increase intake of polyunsaturated fats were less marked. At one year, these trends continued, although there were some decreases in the proportion reporting continued efforts.

Reported dietary intake confirmed these patterns (Table 4). In contrast with controls, the intervention subjects reported dramatically increased intake of fibre and use of polyunsaturated fats, and decreased use of saturated fats. These patterns persisted at one year, though with some regression toward baseline values. There were no consistent differences between men and women with regard to uptake of the dietary recommendations.

The weights of the participants remained fairly stable at least during the first three months of participation, and at no time was there a significant difference between the two groups. There was a slight drop in the mean weight of the control group men after one year by 1.1 kg.

Plasma lipid estimations

Changes in linoleic acid content of the circulating triglycerides and cholesterol esters were modest but consistent with the participants' reported increase in the dietary polyunsaturated: saturated fat ratio (Table 5).

Among the men, there were modest differences between diet groups in the changes in lipoproteins which generally paralleled

Table 2. Difficulties encountered with the dietary advice among subjects randomized to the intervention group.

	Men		Women	
	(No. of subjects[a])	%	(No. of subjects[a])	%
Family or subject disliked diet				
1 month	(95)	11	(87)	9
3 months	(93)	8	(87)	6
Diet hard to prepare				
1 month	(95)	2	(87)	1
3 months	(93)	1	(87)	0
1 year	(83)	0	(83)	4
Hard to eat out on diet				
1 month	(95)	4	(87)	2
3 months	(93)	8	(87)	1
1 year	(83)	5	(83)	5
Hard to understand diet				
1 month	(95)	0	(87)	0
3 months	(93)	0	(87)	0
1 year	(83)	0	(83)	0
Diet too expensive				
1 month	(95)	1	(87)	1
3 months	(93)	0	(87)	1
1 year	(83)	3	(83)	6

[a]Number of subjects evaluated vary because of losses to follow up and missing data.

Table 1. Baseline characteristics of subjects by sex and group assignment.

	Men		Women	
	Control group	Intervention group	Control group	Intervention group
No. of subjects	92	97	89	90
Mean age ± standard error (years)	41.6 ± 1.0	42.1 ± 1.0	41.9 ± 1.1	41.1 ± 1.0
Mean weight ± standard error (kg)	76.3 ± 1.1	78.7 ± 1.2	62.6 ± 1.2	65.3 ± 1.4
Mean height ± standard error (m)	1.77 ± 0.01	1.77 ± 0.01	1.62 ± 0.01	1.63 ± 0.01
% in social class 1 or 2	*30.0*	*39.0*	*24.0*	*43.0***
% with diagnosis of hypertension	*14.0*	*12.0*	*15.0*	*8.0*
% who currently smoked	*48.0*	*32.0**	*30.0*	*28.0*
% who ever smoked	*74.0*	*67.0*	*57.0*	*49.0*

* $P<0.05$, ** $P<0.01$ versus control group.

Table 3. Reported efforts at dietary change by sex and group assignment.

	Men				Women			
	Control		Intervention		Control		Intervention	
	(No. of subjects)	%	(No. of subjects)	%	(No. of subjects)	%	(No. of subjects)	%
3 months								
Increased intake of fibre	(91)	*1*	(93)	*67*	(87)	*2*	(86)	*70*
Decreased intake of fat	(91)	*1*	(93)	*76*	(87)	*1*	(86)	*80*
Increased polyunsaturated fat	(91)	*0*	(93)	*29*	(87)	*0*	(86)	*53*
1 year								
Increased intake of fibre	(86)	*3*	(83)	*52*	(79)	*3*	(81)	*42*
Decreased intake of fat	(86)	*5*	(83)	*55*	(79)	*0*	(81)	*38*
Increased polyunsaturated fat	(86)	*1*	(83)	*22*	(79)	*1*	(81)	*30*

Differences between treatment groups were all statistically significant, $P<0.001$.

the reported dietary changes (Table 5). By three months, total cholesterol declined slightly in men in the intervention group compared with a small increase in controls. Much of the reduction in the intervention group was due to a particularly large decrease in low density lipoprotein (LDL) cholesterol. In both groups, high density lipoprotein (HDL) cholesterol declined slightly during the three month diet period. By one year, the differences between the two groups of men had disappeared, with both showing reductions in total cholesterol and LDL cholesterol, and rises in HDL cholesterol. Among women there were no important differences between the diet groups at any time. HDL cholesterol tended to decrease in both groups. Analysis restricted to those in the highest quartile of total cholesterol (within sex group) was hampered by small numbers, but there were no statistically significant differences between treatment groups (data not shown).

Discussion

In this randomized controlled trial of dietary advice in a well British population, we found the dietary recommendations to be well accepted by a sample of adults registered in one group practice. Those randomized to receive the intervention found it understandable and affordable, and these subjects made few negative comments about the recommendations. High percentages of the intervention subjects reported increasing their intake of fibre and polyunsaturated fat and decreasing their intake of saturated fat. The long-term nature of the dietary change was particularly encouraging: despite the relatively brief intervention, there was substantial reported compliance with the recommendations at one year.

Triglyceride and cholesterol ester linoleic acid levels reflect dietary intake and thus were used to assess compliance with the diet. By these measures there was objective confirmation of the

Table 4. Reported dietary consumption of fibre and fat by sex and group assignment.

	Men				Women			
	Control		Intervention		Control		Intervention	
(No. of subjects) mean total dietary fibre ± standard error (g per day)								
Baseline	(92)	19.3 ± 0.7	(97)	20.4 ± 0.8	(89)	16.4 ± 0.7	(89)	18.9 ± 0.7
1 month	(92)	19.8 ± 0.8	(95)	27.0 ± 1.0	(88)	15.8 ± 0.6	(88)	24.2 ± 1.0
3 months	(91)	21.1 ± 0.9	(93)	27.8 ± 1.1	(85)	15.7 ± 0.7	(87)	24.8 ± 1.2
1 year	(69)	20.1 ± 1.0	(56)	22.8 ± 1.0	(68)	15.4 ± 0.8	(65)	21.4 ± 1.0
(No. of subjects) % using polyunsaturated fat for spreading								
Baseline	(92)	*12*	(97)	*6*	(89)	*11*	(90)	*9*
1 month	(92)	*8**	(95)	*67*	(88)	*14**	(88)	*74*
3 months	(91)	*8**	(93)	*70*	(87)	*12**	(87)	*77*
1 year	(87)	*15**	(83)	*58*	(81)	*15**	(83)	*54*
(No. of subjects) % using polyunsaturated fat for frying								
Baseline	(92)	*14*	(97)	*14*	(89)	*11*	(90)	*10*
1 month	(92)	*13**	(95)	*75*	(88)	*14**	(88)	*67*
3 months	(91)	*8**	(93)	*78*	(87)	*8**	(87)	*72*
1 year	(85)	*14**	(77)	*66*	(79)	*16**	(83)	*65*
(No. of subjects) % using saturated fat for frying								
Baseline	(92)	*23*	(97)	*26*	(89)	*19*	(90)	*20*
1 month	(92)	*17**	(95)	*4*	(88)	*26**	(88)	*7*
3 months	(91)	*19**	(93)	*3*	(87)	*25**	(87)	*5*
1 year	(85)	*26**	(77)	*9*	(79)	*14**	(83)	*7*
(No. of subjects) % using saturated fat for spreading								
Baseline	(92)	*24**	(97)	*41*	(89)	*36*	(90)	*31*
1 month	(92)	*28**	(95)	*5*	(88)	*34**	(88)	*5*
3 months	(91)	*24**	(93)	*3*	(87)	*43**	(87)	*0*
1 year	(87)	*23**	(83)	*6*	(81)	*37**	(83)	*2*

* $P<0.05$ versus intervention group.

Table 5. Fasting plasma lipids by sex and group assignment.

	Men				Women			
	Control		Intervention		Control		Intervention	
(No. of subjects) mean triglyceride linoleic acid ± SE (% of total)								
Baseline	(91)	*12.99±0.43*	(92)	*13.13±0.50*	(85)	*13.77±0.66*	(86)	*15.08±0.63*
1 month	(88)	*12.29±0.48**	(91)	*15.39±0.57*	(85)	*12.98±0.40**	(87)	*15.13±0.54*
3 months	(89)	*12.62±0.51**	(90)	*15.17±0.61*	(85)	*13.24±0.43**	(85)	*15.49±0.55*
1 year	(87)	*12.65±0.60**	(84)	*14.52±0.63*	(78)	*13.94±0.60**	(79)	*15.98±0.62*
(No. of subjects) mean cholesterol ester linoleic acid ± SE (% of total)								
Baseline	(90)	*42.59±0.86*	(92)	*40.80±0.76*	(86)	*44.70±0.73*	(86)	*43.56±0.87*
1 month	(88)	*42.30±0.90*	(91)	*42.36±0.90*	(86)	*40.95±0.70*	(87)	*42.82±0.79*
3 months	(88)	*38.58±0.89*	(89)	*40.51±0.83*	(85)	*41.87±0.77*	(82)	*43.22±0.99*
1 year	(84)	*44.30±0.82**	(81)	*46.70±0.79*	(78)	*46.63±0.95**	(77)	*49.84±0.83*
(No. of subjects) mean total cholesterol ± SE (mM)								
Baseline	(92)	4.81±0.08	(97)	4.92±0.08	(89)	4.88±0.10	(89)	4.79±0.09
1 month	(92)	4.72±0.08	(95)	4.70±0.08	(87)	4.87±0.10	(88)	4.65±0.09
3 months	(91)	4.92±0.09	(93)	4.73±0.08	(87)	4.75±0.11	(87)	4.73±0.10
1 year	(86)	4.50±0.08	(85)	4.52±0.08	(80)	4.84±0.11	(82)	4.80±0.11
(No. of subjects) mean LDL cholesterol ± SE (mM)								
Baseline	(80)	2.87±0.09	(85)	2.96±0.08	(87)	2.76±0.10	(84)	2.70±0.09
1 month	(82)	2.77±0.09	(81)	2.73±0.07	(84)	2.81±0.09	(85)	2.77±0.09
3 months	(81)	2.83±0.08*	(89)	2.57±0.08	(81)	2.79±0.11	(77)	2.70±0.09
1 year	(85)	2.31±0.08	(83)	2.36±0.07	(79)	2.73±0.10	(81)	2.71±0.09
(No. of subjects) mean HDL cholesterol ± SE (mM)								
Baseline	(85)	1.36±0.03	(88)	1.33±0.03	(87)	1.67±0.04	(87)	1.64±0.04
1 month	(86)	1.36±0.03	(84)	1.29±0.03	(86)	1.58±0.04	(86)	1.49±0.03
3 months	(86)	1.32±0.02	(92)	1.29±0.03	(84)	1.51±0.04	(81)	1.44±0.05
1 year	(86)	1.48±0.03	(84)	1.41±0.03	(79)	1.53±0.03	(81)	1.49±0.03

* $P<0.05$ versus intervention group. SE = standard error. LDL = low density lipoprotein. HDL = high density lipoprotein.

reported dietary patterns, although the changes in linoleic acid were small compared with those reported in another dietary intervention study (among subjects with hyperlipidaemia).[9] This smaller effect may be due to several factors, including our focus on a normal population, and the more moderate nature of our intervention.

Among men there were modest differences between the diet groups with regard to changes in lipoproteins. At the end of the three month diet period, the intervention group had experienced a significantly greater reduction in LDL cholesterol than the control group, though by one year the differences had narrowed. This suggests that the effects on lipoproteins may be strongest during the period of active encouragement of dietary change. Among women, there was little apparent impact of the diet programme, despite apparently similar levels of compliance among intervention subjects. Both intervention and control women experienced only minor changes in total and LDL cholesterol, with a slight fall in HDL cholesterol in both.

It is not clear why there was no apparent effect of the intervention among men at one year, or among women at any time, despite differences in reported diet similar to those among men in the first three months. The differences in linoleic acid content of cholesterol esters and circulating triglycerides suggest that this was not due simply to biased dietary reporting. One possible explanation for the results in men is the weight loss in the control subjects, which might have resulted in a lowering of LDL cholesterol in this group.[12] Also, it should be noted that other risk factor intervention studies have reported differences in the responses of men and women.[13-16] It is not clear what may underlie these differences, though hormonal factors are a possibility.

Several aspects of our study deserve comment. First, though the study population permits quite wide generalization, the results apply only to the particular intervention we employed. It is likely that different dietary advice or a different manner of motivating change might lead to different results. Secondly, the fact that the two groups were drawn from one geographical area and one practice may have permitted some of the control subjects to become aware of the intervention advice. This would lead to a conservative bias in our estimates of intervention effectiveness. Thirdly, our relatively small sample size provides only modest power for the detection of effects on lipids.

Finally, there were several differences in baseline characteristics between the two study groups, including lower baseline use of saturated fat for spreading among control men, higher social class among intervention women, and lower percentage of smokers among intervention men. Some of these differences may have been due to our relatively small sample size and the results of multiple comparisons. However, the differences could also have been due to selective recruitment. As noted above, subjects in the two treatment groups were given different explanations of the study at the first visit, and it is conceivable that the proportion cooperating thereafter varied differently in the two groups according to personal characteristics. For example, men who were smokers might have been willing to cooperate with the dietary survey presented to the control subjects, but not with the dietary change presented to the intervention group. This does not seem plausible,

however, in light of the high (84%) acceptance rate among those invited to take part.

Previous investigations of dietary change in the primary prevention of coronary artery disease have employed various interventions. The earlier trials[3] used diets relatively high in fat (approximately 40% of calories) with polyunsaturated to saturated fat ratios greater than 1. More recently, interventions have been tested that employ diets somewhat lower in fat and with ratios of 0.4 to 0.8. (These have typically been in the setting of multifactorial trials.) In aggregate these have found that dietary change can be effective in lowering lipid levels, at least in high risk men. Our data show that current dietary recommendations made through general practice are acceptable to both sexes, but may have only limited efficacy, particularly among women. A larger, more detailed study will be required to document details of the effect.

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