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A randomised controlled trial to investigate the effect of a high fibre diet on blood pressure and plasma fibrinogen

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SUMMARY Two hundred and one subjects (147 men and 54 women) were randomly allocated to either a high cereal fibre diet or a low cereal fibre diet for four weeks. Each group then followed the alternative diet for a further four weeks. Cereal fibre intakes were 19g/d (31g/d total fibre) and 6g/d (19g/d total fibre) on the high and low fibre diets respectively ($p<0{\cdot}001$). Energy, protein, fat, carbohydrate, and alcohol intakes calculated from weighed intake records did not differ between the two diets, although there was a slight difference in body weight, the mean being 0·3 kg heavier at the end of the high fibre period. The high cereal fibre diet had no detectable effect on blood pressure or plasma fibrinogen.

An increase in cereal fibre intake is often recommended on health grounds. Among the many postulated benefits of cereal fibre is a protective effect against heart disease. One of the major risk factors for heart disease is blood pressure, which has shown an inverse relationship with cereal fibre intake in some studies[1–3] but not in others.[4 5] Plasma fibrinogen is another factor that is associated with both ischaemic heart disease[6] and (negatively) with cereal fibre intake.[2 7] The available evidence does not, however, indicate whether these associations are causal.

A randomised controlled trial was therefore set up to test the hypothesis that an increase in cereal fibre intake reduces blood pressure and plasma fibrinogen. The opportunity was taken to see what other changes occur in the diets of people who are advised to increase their cereal fibre intake, since a change in one ingredient of the diet may have indirect effects on the intake of a wide range of nutrients.

Subjects and methods

The study was conducted among office workers in two local government offices. A letter was circulated among the staff giving a brief account of the study and asking for subjects in good health to participate. Those who responded were randomly allocated to either a high cereal fibre diet or a low cereal fibre diet for four weeks. The high cereal fibre diet group were asked to eat *at least* six large slices of wholemeal bread per day or to consume an equivalent amount of cereal fibre from a combination of wholemeal bread, wholegrain breakfast cereals, and bran. The low cereal fibre diet group were asked to avoid wholemeal bread, medium and high fibre breakfast cereals, and wheat bran. Each group then followed the alternative diet for a further four weeks.

Compliance was assessed by means of diaries of the amount of wholemeal bread, amount and type of breakfast cereal, and amount of wheat bran eaten for each day throughout the high cereal fibre period, and weighed inventories of all food and drink consumed for three days (Sunday, Monday, Tuesday)[8] during both the high and low cereal fibre diet periods.

At the beginning of the study, and at the end of each period, blood pressure was measured and a blood sample was taken for determination of plasma fibrinogen and viscosity. The subjects were seen during the morning and were not asked to fast. On each occasion a single blood pressure measurement was taken with the subject seated, using a Hawksley random-zero sphygmomanometer. All the measurements were made by the same observer who did not know which diet the subjects had been taking. Diastolic pressures were recorded as the point of disappearance of the sounds. The blood samples were taken with a short application of a venous tourniquet. Body weight was also measured on each occasion.

Plasma fibrinogen was measured by the chemical method of Thorp *et al*[9] using EDTA plasma. Plasma viscosity was determined using a Coulter viscometer as described by Harkness.[10]

The statistical methods were those described by Hills and Armitage.[11] The first stage was to test whether there was an interaction between diet and period, that is, if the effect of the high fibre diet was different in the two periods. In this situation only the data from the first period could be used to estimate the effect of the high fibre diet. The effect of the high fibre diet was estimated after allowing for the order of administration of the diets.

Results

Two hundred and eleven office workers volunteered to take part, of whom 201 (147 men and 54 women) completed the study. Their ages ranged from 18 to 65 years, the mean being 36 years for the men and 41 years for the women. Only three subjects (2 men and 1 woman) took medication acting on the cardiovascular system, and in each case the same medication was taken throughout the whole course of the subject's time in the trial. Sixteen other subjects (10 men and 6 women) were receiving regular medication unrelated to the cardiovascular systems.

Ninety seven subjects (66 men and 31 women) took the high cereal fibre diet first and 104 (81 men and 23 women) took the high cereal fibre diet second. The mean age of both groups was 37 years.

The diaries of bread and cereal consumption recorded throughout the high fibre diet period confirmed that, with only a few exceptions, subjects did manage to consume the amount of cereal fibre advised. In addition, 193 subjects completed the three day weighed inventories for both periods (96% of the sample). There was no interaction between diet and period for any nutrient. An effect of order of administration was found for energy, fat, and carbohydrate, intakes being lower during the second period than during the first period. There was no effect of order of administration for cereal fibre, total fibre, protein or alcohol intake. Mean nutrient intakes on the high and low cereal fibre diets are shown in table 1. The mean differences given in the table have been adjusted to take order of administration into account. On the high cereal fibre diet, cereal fibre intake trebled, whereas fruit and vegetable fibre intake was unchanged. Mean cereal fibre intake was 19g/d during the high fibre period, compared with 6g/d during the low fibre period. Total fibre intakes were 31g/d and 19g/d respectively. Differences in intakes of energy, protein, fat, carbohydrate, and alcohol were small and not statistically significant.

Initial systolic blood pressures ranged from 97 to 185 mmHg, being 160 mmHg or more in three men and two women. Initial diastolic pressures ranged from 58 to 109 mmHg, being 100 mmHg or more in five men and one woman. Blood pressure increased with age, as expected, in both men and women. Blood pressure, plasma fibrinogen, viscosity, and body weight measurements are shown by time period in table 2. Initial concentrations of fibrinogen and viscosity were similar in the two groups, although both body weight and blood pressure tended to be lower in the group who took the high fibre diet first. This suggests that the randomisation may not have been entirely successful in producing two similar groups. There was a greater proportion of women in the group taking the high fibre diet first (32%, compared with 22% in the group taking the high fibre diet second), and this may explain the lower mean blood pressure and body weight of this group. There was a fall in blood pressure between the initial measurement and that at the end of the first diet period in both groups (table 2). This may have been due to anxiety caused by unfamiliarity with the procedure when the initial

Table 1 *Mean daily nutrient intakes on the high and low cereal fibre diets*

Nutrient	*High fibre diet*	*Low fibre diet*	*Difference (high-low fibre)†* Mean	(SE)	*Mean difference* (%)
Energy (kcal)	2245	2279	−32	(49)	−1
Protein (g)	84·1	80·9	3·3	(2·4)	+4
Fat (g)	92·1	97·4	−5·2	(2·8)	−5
Carbohydrate (g)	265·5	261·3	4·4	(6·2)	+2
Cereal fibre (g)	19·1	6·5	12·6	(0·5)***	+196
Total fibre (g)	30·6	18·5	12·0	(0·6)***	+65
Alcohol (g)	11·5	13·6	−2·0	(1·2)	−15

† Mean differences adjusted to take order of administration into account
*** p<0·001

Table 2 *Mean (SD) blood pressure, plasma fibrinogen, viscosity, and body weight by time period*

Variable/group	*Before trial*	*End of first period*	*End of second period*
Systolic BP (mmHg)			
High fibre first	130·4 (14·0)	125·1 (13·3)	125·7 (13·8)
Low fibre first	133·7 (15·7)	130·3 (14·6)	130·0 (15·6)
Diastolic BP (mmHg)			
High fibre first	79·2 (9·9)	75·4 (10·9)	74·9 (10·8)
Low fibre first	80·3 (10·3)	78·4 (11·4)	78·2 (10·7)
Fibrinogen (g/l)			
High fibre first	3·34 (0·66)	3·30 (0·66)	3·27 (0·70)
Low fibre first	3·30 (0·83)	3·37 (0·85)	3·33 (0·83)
Viscosity (cp)			
High fibre first	1·66 (0·09)	1·64 (0·08)	1·63 (0·08)
Low fibre first	1·67 (0·07)	1·65 (0·08)	1·65 (0·08)
Body weight (kg)			
High fibre first	71·8 (12·3)	71·9 (12·5)	71·5 (12·0)
Low fibre first	73·2 (11·6)	72·9 (11·6)	73·1 (11·7)

measurement was made. There was no further change between the first and second diet periods.

There was no diet period interaction for plasma fibrinogen, viscosity or body weight. For both systolic and diastolic blood pressure the formal test for an interaction was statistically significant at the 5% level. However, if the randomisation was not entirely successful in producing two similar groups, this would have been transmitted to the interaction effect. Inspection of the pre-trial baseline values suggested that this was the case and therefore further analyses assumed that there were no genuine diet period interactions.

There was no effect of order of administration for plasma fibrinogen, viscosity, blood pressure or body weight. Mean values on both the high and low cereal fibre diets are shown in table 3. Differences were very small. Mean body weight was 0·3 kg heavier on the high cereal fibre diet than on the low cereal fibre diet ($p<0·05$). There was no difference in blood pressure, plasma fibrinogen or viscosity.

Discussion

The current epidemic of ischaemic heart disease has been attributed to many different factors. One hypothesis which has gained wide acceptance is that it is due in part to a decline in cereal fibre intake. This belief was based on geographical and historical evidence[12] and obtained some support from a prospective study of London busmen and bank clerks.[4] If this hypothesis was correct, cereal fibre may influence one or more of the physiological variates known to be associated (positively or negatively) with ischaemic heart disease.

There have been some reports of an inverse relationship between cereal fibre intake and blood pressure. Wright *et al*[1] found that changes in cereal fibre intake were accompanied by changes (in the opposite direction) in blood pressure. A fall in diastolic pressure occurred when 32 hypertensives took a diet low in sodium and high in fibre.[13] A nutritional survey by Fehily *et al*[2] found some evidence for an inverse relationship between cereal fibre and blood pressure; this did not, however, quite achieve statistical significance. An inverse relationship was also found by Burr *et al.*[3]

None of these studies was a randomised controlled trial, and it is possible that the relationships reported were non-causal. Some studies[4 5] have failed to confirm this association. In a controlled trial of various dietary modifications, Brussard *et al*[14] found no effect on blood pressure consequent upon a rise in cereal fibre intake. But the numbers were small—only 16 subjects received the bran supplements—so that only a very large effect could have been discovered.

In the present study a high intake of cereal fibre had no detectable effect on blood pressure. Various alternative explanations must of course be considered. Firstly, it may be suggested that blood pressure fluctuates to such an extent that a single reading on each of two occasions provides insufficient evidence for a change to be detected. On the other hand the associations that formed the basis of this trial were detected in studies[2 3] in which single readings of blood pressure had been taken. Furthermore, the size of this trial would have detected a difference of 1·9 mmHg with a power of 80%; a greater number of measurements per subject would have increased the sensitivity of the trial, but differences of less than 1·9 mmHg are unlikely to be clinically important. Secondly, perhaps a period of four weeks was too short a time for an effect to emerge, although in the study by Wright *et al*[1] this was apparently long enough. Thirdly, a larger intake of fibre may produce an effect, although the amounts tested in this trial are comparable to those that were reported in the studies which suggested that an association existed. Fourthly, an effect may occur only in hypertensive patients or other special groups under-represented in our rather selected group of subjects; but again negative associations between cereal fibre and blood pressure have been reported in non-hypertensive subjects.[1 3] Fifthly, the subjects may not have eaten as much fibre as they claimed, or they may have failed to abstain from it during the "low fibre" period. We have no objective means of ascertaining their truthfulness in completing the fibre diaries and weighed inventories, but they were all conscientious volunteers and ten who were unable to comply reported their difficulties and left the trial.

A number of studies have reported a positive association between blood pressure and body mass index.[2 15 16] In the present study, mean body weight was slightly heavier at the end of the high fibre period than at the end of the low fibre period. However, the difference between the two periods was very small (0·3

Table 3 *Mean blood pressure, plasma fibrinogen, viscosity, and body weight on the high and low cereal fibre diets*

Variable	*High cereal fibre diet*	*Low cereal fibre diet*	*Mean difference (high-low fibre)*†	*(SE)*
Systolic blood pressure (mmHg)	127·7	128·1	−0·4	(0·67)
Diastolic blood pressure (mmHg)	76·9	76·8	+0·2	(0·61)
Fibrinogen (g/l)	3·32	3·33	0·00	(0·06)
Viscosity (cp)	1·64	1·64	0·00	(0·01)
Body weight (kg)	72·5	72·2	+0·29	(0·11)*

†Mean differences adjusted to take order of administration into account
*$p<0·05$

kg) and was therefore unlikely to have masked an effect of cereal fibre. Dietary components other than cereal fibre which have been suggested to affect blood pressure, such as fat[17] and alcohol,[15 16 18 19] did not differ significantly between the high and low fibre diets.

The effect of dietary fibre on plasma fibrinogen has been little studied. Simpson *et al*[20] reported no effect of a high fibre diet on plasma fibrinogen. However, fibre was obtained mainly from legumes, whereas cross-sectional data[2 7] indicated that plasma fibrinogen is associated with cereal fibre not vegetable fibre. Miller *et al*[21] studied the effect of a low fat diet high in fibre on haemostatic factors and also found no change in plasma fibrinogen. The source of the fibre consumed was not stated. It is not likely that the four week diet period was insufficient to produce a change since Pickard[22] reported that plasma fibrinogen can be altered within one day by a variety of stimuli. Nevertheless it is possible that a change in diet may take longer than other stimuli to produce an effect. The inter-individual variation in plasma fibrinogen concentrations is quite large. However, the sample size of 201 would have detected a difference in mean fibrinogen concentrations of 0·21g/l with a power of 90%. This difference is smaller than that found in the Caerphilly data[2] between men having a high cereal fibre intake and those having a low cereal fibre intake (0·65g/l). Thus it is likely that the association between cereal fibre intake and plasma fibrinogen is not directly causal.

The most likely explanation for the negative findings of this trial is that cereal fibre does not affect blood pressure or plasma fibrinogen to any important extent. People who choose to eat a high fibre diet probably differ from other people in various ways, and the reported negative associations were probably due to associated factors rather than to the cereal fibre itself.

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