More good than harm: a randomised controlled trial of the effect of education about familial risk of diabetes on psychological outcomes

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SUMMARY

Background. *Offspring of people with type 2 diabetes underestimate their risk of developing the disease and know little about primary prevention. However, education about risk might cause psychological harm.*

Aim. *To examine cognitive and psychological effects of education about personal risk.*

Method. *Patients with type 2 diabetes were recruited from randomly selected general practices. One of their adult offspring was randomly selected and randomly allocated into one of three groups:*

1. *Group 1: given an initial interview, education, and a final interview;*
2. *Group 2: given an initial and final interview; and*
3. *Group 3: given one interview only.*

Psychological outcomes were assessed using Hospital Anxiety and Depression Scale (HAD) and Positive Well-Being Scale (PWB) scores.

Results. *Sixty-nine per cent (105/152) of eligible offspring participated. Ninety-one per cent (96/152) completed the study. Comparing first and final interviews, in Group 1, significantly fewer responders at final interview (after education) thought that their risk of developing diabetes was 'low' (65% versus 41%, P = 0.027), while in Group 2, there was no significant change in risk perception (P = 0.13). Significantly fewer people in the educated group (Group 1, final interview) than in the control group (Group 3) thought their risk of developing diabetes was 'low' (41% versus 77%, P = 0.002). Risk education did not affect total HAD scores or PWB scores significantly.*

Conclusion. *Educating offspring of people with type 2 diabetes in this way about their risk of diabetes and possible preventive strategies increases their perception of personal risk but does not cause psychological harm.*

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Submitted: 9 September 1999; Editor's response: 24 January 2000; final acceptance: 24 May 2000.

Keywords: diabetes; randomised controlled trials; patient education.

Introduction

CHILDREN with one parent with type 2 diabetes mellitus have two to four times the population risk of developing the disease,[1] equivalent to a lifetime risk of 20% to 40%.[2] Lifestyle modification (achieving adequate levels of physical exercise and avoiding obesity) can be an effective means of primary prevention.[3-7] People with diabetes[2] and their offspring[8] underestimate the offspring's risk of diabetes and know little about preventive strategies. If the offspring are to be encouraged to modify their lifestyles it is necessary to increase their awareness of risk and prevention.

Such education could have desirable and undesirable effects, so evaluation is essential. It must be shown to be effective in producing cognitive change, and the benefits of raising risk awareness must not be outweighed by the psychological costs. Informing people that they are at risk of a potentially serious disease might increase their levels of anxiety.[9] Offspring[8] and siblings[10] of people with type 2 diabetes who estimate their own risk as being high worry more frequently about developing diabetes. Concern raised to a certain point can motivate people to change their behaviour. However, further increases can become counterproductive.

The aim of this study was to examine the cognitive and psychological effects of an educational intervention to increase awareness of personal risk of type 2 diabetes among the offspring of people with the disease.

Method

Patients with type 2 diabetes, recruited from five randomly selected general practices in south London, were asked for permission to contact their children. The offspring's eligibility criteria were:

- over 18 years of age;
- no diagnosed diabetes;
- living within the south-east quadrant of the M25 motorway; and
- only one parent with diabetes.

One eligible son or daughter randomly selected from each family was approached.

Pilot studies

Questionnaires designed for the parent group[2] were modified for offspring use after qualitative interviews held with seven people with one diabetic parent each. The educational intervention and the evaluation were piloted with six other offspring.

Study design

Eligible offspring were randomly allocated into one of three groups:

1. Group 1: given an initial interview, two educational sessions, and a final interview;
2. Group 2: given an initial and final interview; and
3. Group 3: given one interview only (contemporaneous with the other final interviews).

Group 2 controlled for the effect of the interview on knowledge. Its purpose was to check for a potential effect of arousing participants' interest after the first interview leading them to seek information independently. This group was kept small because of concerns about asking participants potentially worrying questions and leaving them unanswered for six months.

The median time between the initial and final interviews was 24 weeks.

Interviews

A research nurse (DH) conducted the interviews in the participant's home. She was not informed of the participant's allocated groups. Interviews included:

- A questionnaire about diabetes risk asking: 'How likely do you think it is that you will develop diabetes?' We dichotomised responses into 'high' ('very likely' or 'quite likely') and 'low' ('not very likely' or 'not at all likely'). And: 'Do you worry that you might get diabetes?' We dichotomised responses into 'not worried' ('no' or 'rarely') and 'worried' ('sometimes' or 'often').
- The Hospital Anxiety and Depression Scale (HAD),[11] designed to detect relatively mild mood disorder in adults and monitor progress over time,[12,13] consists of two subscales: seven items related to anxiety and seven to depression. Each scored zero, one or two.
- The Positive Well-Being Scale (PWB) is a six-item subscale of the Well-Being questionnaire developed for use in tablet-treated diabetes[14] and has been shown to be sensitive to change in clinical trials.[15] Items are scored on a Likert scale, where zero indicates the item applied 'not at all' in the past few weeks and three indicates 'all the time'. The PWB was included because education may reduce psychological well-being without necessarily producing measurable anxiety or depression.

Statistical methods

Differences of four in the HAD scores and of three in the PWB scores are clinically meaningful. Sample sizes were calculated to provide sufficient power to detect meaningful differences in the HAD and the PWB in the between-groups comparisons; i.e. Group 1 final interview versus Group 3. With 95% power at the 0.05 significance level this required 35 in each group for the PWB and 26 in each group for the HAD.

Analysis of the trial results was by intention to treat. Mann–Whitney tests were used to compare HAD and PWB scores between groups and Wilcoxon matched pairs tests were used to compare the change in these scores between interviews within groups. For categorical data chi-squared tests were used to make comparisons between groups and McNemar's tests were used to compare changes between interviews within groups (both with continuity corrections).

Group 2 comparisons before and after education were done only to examine the effect on cognitions. Confidence intervals were determined using rank-based methods.[16]

Educational intervention

Educational sessions were all done by one general practitioner (GP) (MP). In one-to-one discussions, lasting about one hour, she established the offspring's beliefs about diabetes risk and prevention and, in a Socratic dialogue, modified those beliefs in accord with a pre-established list of educational objectives developed from topics in Box 1. Later, MP went through a diabetes fact sheet covering the same topics plus a simple explanation of the physiology of diabetes and its symptoms. This was left with the interviewee, as was a personalised list of recommendations for the avoidance of diabetes and heart disease and relevant Health Education Authority leaflets on healthy eating, exercise, smoking, and alcohol. MP discussed how the offspring might adopt relevant recommendations. A 45-minute 'revision' session was held six weeks later. After the study, participants in Groups 2 and 3 received the same education as those in Group 1.

The Guy's Hospital and the Camberwell Ethics Committees approved the study.

Results

Response rates

Sixty per cent (152/254) of the diabetic adults had eligible offspring. Sixty-nine per cent of the offspring (105/152) agreed to participate and 91% (96) completed the trial. Table 2 shows reasons for dropping out.

Participants' characteristics (Table 1)

The study population was middle-aged (reflecting the typical age of onset of type 2 diabetes in the parents), largely of Northern European White ethnic origin, and from social classes I, II, and III non-manual. More women than men participated. Participants' ethnicity was similar to that of inner London.

Effect of education on risk perception (Table 2)

Comparing first and final interviews:

- In Group 1, significantly fewer responders at final interview (after education) thought that their risk of developing diabetes was 'low'.
- In Group 2, more responders regarded their risk as 'low' at final interview. However, the group was small, the confidence interval large, and this finding was not statistically significant.
- Comparing the educated group (Group 1, final interview) with the control group (Group 3), significantly fewer people in the educated group thought that their risk of developing diabetes was 'low'.

Effect of education on worrying about developing diabetes (Table 3)

There was no evidence of any significant effect of education on the proportion of subjects worried about developing diabetes.

Risk factors for diabetes: family history, obesity, physical inactivity, age.
Importance of early diagnosis: possibility of having diabetes for many years before diagnosis, avoiding complications.
Age of onset and early symptoms.
Diagnostic tests (urine, blood, glucose tolerance tests) and where to get them.
Relationship between cardiovascular disease and diabetes.
Risk factors for cardiovascular disease and how to reduce your risk.
Reducing your risk of diabetes by avoiding obesity and increasing exercise.
Consulting your GP if you think you might have diabetes.
Further information is available from the British Diabetic Association.

Box 1. Topics covered in the educational intervention.

Table 1. Characteristics of the participants in the trial.

	Group 1 (n = 43)	Group 2 (n = 18)	Group 3 (n = 44)	Total (n = 105)
Median age (interquartile range)	35 (29–47)	44 (39–49)	38 (33–46)	38 (32–47)
Number male (%)	15 (35)	9 (50)	21 (48)	45 (43)
Number (%) White Northern European[a]	31 (72)	16 (89)	36 (82)	83 (79)
Social class (%)[b]				
I and II	11 (26)	4 (22)	16 (36)	31 (30)
III non-manual	16 (27)	6 (33)	11 (25)	33 (31)
III manual	4 (9)	4 (22)	11 (25)	19 (18)
IV and V	6 (14)	4 (22)	3 (7)	13 (12)
Other	6 (14)	0	3 (7)	9 (9)

[a]Comparative data for inner London: 80% White (1991 Census, Office of National Statistics); [b]comparative data for England and Wales: 5% SCI, 27% SCII, 22% SCIIIn, 20% SCIIIm, 21% SCIV and V, 4% 'other' (1991 Census, Office of National Statistics).

Table 2. The effect of education on beliefs about risk.

		Group 1 (n = 37)[a,c,e]			Group 2 (n = 15)[a,d]			Group 3 (n = 43)[b,e]	
		Final interview			Final interview			Final interview	
		Low risk	High risk	Total	Low risk	High risk	Total	Low risk	High risk
Initial interview	Low risk	13	11	24	9	0	9	-	-
	High risk	2	11	13	4	2	6	-	-
	Total	15	22	37	13	2	15	33	10

[a]Only includes responders to both first and final interviews. Reasons for dropping out: developed diabetes: one person in Group 1; unable to contact for second interview: one person in each of Groups 1 and 2; moved to an unknown address: two in Group 1 and one in Group 2; refused a second visit: one person in each of Groups 1 and 2. [b]One person in Group 3 did not answer the risk question at final interview. Group 3 had only one interview (contemporaneous with final interviews for Groups 1 and 2). [c]Comparing Group 1 before and after education: change (reduction) in the percentage of the group estimating their risk as 'low' = 24% (65%-41%, 95% CI = 7% to 42%, McNemar's test P = 0.027). [d]Comparing Group 2 before and after education: change (increase) in the percentage estimating their risk as 'low' = 27% (87%-60%, 95% CI = 2% to 56%, McNemar's test P = 0.13). [e]Comparing educated group (Group 1, final interview) with the control group (Group 3): difference in percentage estimating their risk as 'low' = 36% (77%-41%, 95% CI = 16% to 56%, chi-squared test P = 0.002). Group 3 had only one interview (contemporaneous with final interviews for Groups 1 and 2).

Table 3. Effect of education on median HAD and PWB scores and number of people 'worried' about developing diabetes.

	Group 1 (n = 37)[a]		Group 3 (n = 44)[a]
	Initial interview	Final interview	Only interview
HAD median total scores (95% CI)	10.5[b,c] (6.5–15)	9.5[b] (6.5–14)	10.5[c] (6.5–18)
PWB median scores (95% CI)	11[b,c](8–16)	11[b](10–14)	10[c](7–15)
Number (%) 'worried' about developing diabetes	10[b,c] (27)	12[b] (32)	12[c] (27)

[a]Only includes responders to both initial and final interviews. [b]In Group 1 before and after education: comparing the HAD scores, Wilcoxon matched pairs test P = 0.06, median difference = -1.25 (95% CI = -3 to 0); comparing the PWB scores, Wilcoxon matched pairs test P = 0.82, median difference = 0 (95% CI = -1 to 1); comparing proportion 'worried' about developing diabetes, McNemar's test P = 0.69, difference in proportions = 5% (95% CI = -7% to 18%). [c]Comparing the educated group (Group 1, final interview) with Group 3: HAD scores Mann–Whitney test P = 0.30, difference in medians = -2 (95% CI = -5 to 1); PWB scores Mann–Whitney test P = 0.18, difference in medians = 2 (95% CI = -1 to 4); proportion of responders 'worried': difference in proportions = 5% (95% CI = -7% to 18%).

Effect of education on HAD and PWB scores

Table 3 shows the median total HAD and PWB scores for Groups 1 and 3 at the various interviews. Education had no statistically significant effect on total HAD scores nor on the anxiety and the depression subscales. In Group 1 there was a trend towards a decrease in the HAD scores but that was not statistically significant ($P = 0.06$). There was no evidence of any effect of the education on PWB.

Discussion

Effect on risk perception and psychological state

The results suggest the educational intervention was effective, producing desired cognitive changes without any demonstrably harmful effect on psychological state. However, there are some issues related to the study design. The lack of baseline data on perception of risk and psychological measures for Group 3 leaves no way of testing the possibility that the groups were not

balanced, although this should have been minimised by the randomisation.

Group 3 responders may have been made aware of the study by their parents at the same time as the other groups. This reflects real life where the issue of telling people about increased risk of diabetes is balanced against the possibility that they are aware of their risk through their family. Cross-sectional data suggest that an offspring's risk perception is higher in families where a parent has discussed risk.[8]

The pilot study showed that it was impossible to develop any meaningful placebo education based on another topic that would be sufficiently pertinent to attract and hold a participant's attention, yet not impinge upon the issues in the trial.

Only medium- rather than long-term recall was tested. The average interval between the second education session and the final interview was 10 weeks. The effect on people offered education who did not accept it, or those who were educated but lost to follow-up, is not known.

Generalisability of the study

Social classes IV and V were under-represented in the study group compared with national data.[17,18] Despite including a substantial proportion of participants from minority ethnic populations, the study was too small to examine differences between ethnic groups. Care must be taken if extrapolating these findings to groups with different demographic characteristics, particularly ethnicity and social class.

The study's response rate was high, considering the demands of the intervention, and the retention rate was even greater. Evidently the intervention was acceptable to the majority of those approached. We cannot know the extent to which acceptability was specific to this educator.

Comparison with other findings

The study demonstrated that people can be made more aware of their risk of type 2 diabetes without having an adverse effect on their psychological well-being. This contrasts with studies in other conditions, such as cervical cancer,[19] cystic fibrosis,[20] and hypertension[21] where increasing perceptions of own personal risk through screening has been shown to be associated with a sometimes marked increase in anxiety levels. However, the literature on the psychological effects of increasing risk perception does not present a simple coherent model. In both Huntingdon's disease[22] and hereditary breast-ovarian cancer (HBOC)[23] psychological benefits have been demonstrated related to screening, with both those who screened positive and those who screeed negative having reduced levels of anxiety after screening. This has been attributed to reduction of uncertainty but may also be related to selection bias, as less than one-third of families offered testing accepted.

It would appear that healthy people who believe that they are at risk carry a substantial stress burden because of the threat of the disease and the uncertainty of the risk. Baum suggests that this stress is increased if risk is very high, uncertainty is not reduced, no preventive course of action is offered, people do not feel able to take up the advice on prevention, or people lack psychosocial resources such as social support or coping skills.[9] This explanatory model fits well with the findings of the current study.

The educational intervention used was based on a counselling model and delivered by a practising GP offering opportunities to air uncertainties and concerns. Moreover, the information about risk was part of a package that also discussed possible preventive activities and how they might be put into practice in the context of the individual's daily life. The beneficial impact of coupling counselling with delivery of potentially threatening information has been shown in hypertension,[24] Huntingdon's disease,[22] and HBOC.[23]

Implications

Clinicians can feel reassured that those people responding positively to an invitation to receive such education are unlikely to suffer psychological damage. Those responsible for the care of families affected by type 2 diabetes are encouraged to offer education about these issues to the adult offspring. Given current understanding of the growing prospects for prevention, it is no longer enough to ask about family history of diabetes, document it, and wait for the offspring to present with the symptoms or even the complications of frank diabetes.

Although effective, the educational method used here was relatively costly. Could the same result be obtained by using a specially trained nurse or non-medical educator in the practice rather than in the patient's home? Could some of the information be delivered in a group setting? These modifications would reduce the cost of the intervention but perhaps also alter its effectiveness.

Currently, those who have regular contact with offspring of people with type 2 diabetes are the primary care team. It is likely that, in the absence of any new major initiatives, this education would have to be delivered through primary care. In this context, and given the frequency with which people attend their GP, it would appear to be feasible to deliver these educational messages incrementally over time. This will require raising the awareness of primary care about the inherited risk and possibilities for the prevention of type 2 diabetes and training and support for those offering lifestyle advice.[25]

This project was not designed to examine effects on behaviour. Interventions designed to document and support behaviour change in offspring of people with type 2 diabetes are currently being developed.

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Acknowledgements

Funding was received from the British Diabetic Association. We would like to thank the practices and the patients and their children who took time to participate in the study.

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