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Structured patient education: the Diabetes X-PERT Programme makes a difference

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Abstract

Aims To develop a patient-centred, group-based self-management programme (X-PERT), based on theories of empowerment and discovery learning, and to assess the effectiveness of the programme on clinical, lifestyle and psychosocial outcomes.

Methods Adults with Type 2 diabetes (n = 314), living in Burnley, Pendle or Rossendale, Lancashire, UK were randomized to either individual appointments (control group) (n = 157) or the X-PERT Programme (n = 157). X-PERT patients were invited to attend six 2-h group sessions of self-management education. Outcomes were assessed at baseline, 4 and 14 months.

Results One hundred and forty-nine participants (95%) attended the X-PERT Programme, with 128 (82%) attending four or more sessions. By 14 months the X-PERT group compared with the control group showed significant improvements in the mean HbA_{1c} (– 0.6% vs. + 0.1%, repeated measures ANOVA, $P < 0.001$). The number needed to treat (NNT) for preventing diabetes medication increase was 4 [95% confidence interval (CI) 3, 7] and NNT for reducing diabetes medication was 7 (95% CI 5, 11). Statistically significant improvements were also shown in the X-PERT patients compared with the control patients for body weight, body mass index (BMI), waist circumference, total cholesterol, self-empowerment, diabetes knowledge, physical activity levels, foot care, fruit and vegetable intake, enjoyment of food and treatment satisfaction.

Conclusions Participation in the X-PERT Programme by adults with Type 2 diabetes was shown at 14 months to have led to improved glycaemic control, reduced total cholesterol level, body weight, BMI and waist circumference, reduced requirement for diabetes medication, increased consumption of fruit and vegetables, enjoyment of food, knowledge of diabetes, self-empowerment, self-management skills and treatment satisfaction.

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Keywords glycated haemoglobin, patient-centred care, randomized controlled trial, structured group education, Type 2 diabetes

Abbreviations BMI, body mass index; HDL, high-density lipoprotein; LDL, low-density lipoprotein; NNT, number needed to treat; OHA, oral hypoglycaemic agents; RD, individual appointments; SD, standard deviation

Introduction

Effective methods to deliver patient education and teach self-management skills that result in longer-term improvements to health are needed. The Diabetes National Service Framework

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(NSF) [1,2] and the National Instituite for Clinical Excellence (NICE) technology appraisal of patient-education models [3] make it clear that all Primary Care Organisations (PCOs) must offer structured education programmes to people with Type 2 diabetes. Primary care services will need to provide high-quality structured education programmes to those with diabetes in order to achieve the Performance and Planning Framework (PPF) target on practice-based registers [4,5].

A review of diabetes self-management education has found short-term (< 6 months) positive effects on knowledge, dietary habits and glycaemic control [6]. A meta-analysis has shown a decrease in glycated haemoglobin of 0.8% at immediate follow-up and 0.3% at 4 months or longer follow-up. Hence, the benefit of self-management education on glycated haemoglobin has been shown to wane between 1 and 3 months [7]. However, these reviews synthesized short-term studies that used different approaches and delivery methods.

The current study was undertaken to determine if any benefits from attending a patient-centred structured group diabetes education, based on the theories of empowerment and discovery learning, were sustained in the longer term. Consequently, a primary care structured group education initiative, The X-PERT Programme, for individuals with Type 2 diabetes was developed and assessed.

Patients and methods

Participants

Sixteen general medical practices, within Burnley, Pendle and Rossendale, Lancashire, UK were invited to take part in the study. Adults with Type 2 diabetes were identified from practice registers using the World Health Organization criteria [8]. Housebound patients and those with reduced cognitive ability were excluded. Included patients received a patient information leaflet.

Ethical approval was granted from the local ethics committee and written consent was obtained from each subject.

Randomization

Participants were randomized to intervention or control using random permuted blocks and sealed opaque envelopes.

Blinding

To maintain blind allocation, patient information leaflets stated that the study was to compare the effectiveness of an individual vs. group approach to diabetes education. Participants were therefore less likely to identify if they were in the intervention or control group. It was not possible to blind those delivering the interventions. Outcome assessments were carried out by a community nurse and a healthcare assistant blinded to treatment assignment.

Hypothesis

Primary care delivery of the patient-centred, structured diabetes education programme X-PERT for adults with Type 2 diabetes, based on theories of patient empowerment and discovery learning, develops skills and confidence leading to increased diabetes self-management and sustained improvements in clinical, lifestyle and psychosocial outcomes.

Interventions

In addition to routine care, the control group received diabetes education and review with prearranged individual appointments with a dietician (30 min), practice nurse (15 min) and general practitioner (10 min).

Members of the intervention group were invited to attend the X-PERT Programme. This involved six weekly sessions, each lasting 2 h (Fig. 1). Sessions were held in community venues with an average of 16 participants plus four to eight carers in each programme. The programme aimed to develop skills and build confidence, to enable patients to make informed decisions regarding their diabetes self-care. The X-PERT Programme was designed and delivered by a diabetes research dietitian (T.A.D.) who took on the role of a diabetes educator. The community venues were easily accessible. Separate sessions were held for Urdu-speaking South Asian participants, where a translator was present. If participants failed to attend one session, they received a telephone reminder. If they failed to attend two sessions, no further contact was made during the programme, but an 'intention to treat' analysis was carried out and outcome data collected where possible.

The theoretical models underpinning the X-PERT Programme are empowerment—'helping people discover and use their innate ability to gain mastery over their diabetes' [9]—and discovery learning—'the learner is a problem solver who uses tools and information to gain knowledge through discovery' [10].

Outcomes

Primary outcome

Glycated haemoglobin at 14 months.

Clinical outcomes

Venous blood samples were analysed at a central laboratory. Glycated haemoglobin (HbA_{1c}) was measured using a Diabetes Control and Complications Trial (DCCT) aligned method [11]. A full lipid profile was obtained. Blood pressure was measured, conforming to accepted methods [12] using a digital blood pressure monitor. Acceptable ranges for blood lipids and blood pressure were obtained from recent guidance reports [13].

Body weight was measured using calibrated electronic scales. A portable sonic machine was used to measure height. Body mass index (BMI) (kg/m^2) was calculated from height and weight measurements. The Tanita Body Fat Monitor analysed body fat to ± 0.5% precision. The recommended technique for measuring waist circumference was used [14].

Medication prescribed for the treatment of diabetes was reviewed at 14 months and compared with that prescribed at baseline. A medication increase was defined as commencing on, or an increase in the dose of, oral glucose-lowering agents or insulin. A medication decrease was defined as a reduction in the type or quantity of oral agents or the number of units of insulin injected.

	The X-PERT Program
Topic	Description
Week 1: What is Diabetes?	Explore what happens to food when we eat it; self-monitoring of diabetes; diabetes treatments; feelings about living with diabetes. Dispel myths by using visual educational materials.
Week 2: Weight Management	Examine the 'balance of good health' model and use food models to distinguish between food containing protein, fat and carbohydrate. Inform about sensible eating whilst exploring barriers in doing so. Advise about the benefits of exercise and give practical examples including information about local exercise-on-prescription schemes.
Week 3: Carbohydrate Awareness	Perform a group task, developed to show the effect of quantity and quality of carbohydrate food on blood glucose levels. Use ping-pong ball models and laminated food pictures to dispel the myths surrounding glucose, sucrose and starch.
Week 4: Supermarket Tour	Address some common confusion surrounding dietary fat, sugar and food labelling. Encourage a diet that is enjoyable, variable and balanced whilst dispelling the concept of 'good' and 'bad' foods.
Week 5: Complications & Prevention	Discuss how to reduce the risk of developing longer-term complications through lifestyle changes, treatment and regular monitoring. Use visual educational aids to explore medical conditions in layman terms such as nephropathy, retinopathy, arteriosclerosis, neuropathy and blood pressure.
Week 6: Evaluation & Question time	Play "Living with diabetes", a board game to bring the X-PERT program to a close in a relaxed manner, reinforcing the main messages whilst encouraging participants to reflect on how much they have learnt.
Goal Setting: Last 20 minutes each week	The final 20–30 minutes each week involves the goal setting component of the empowerment model. Participants obtain and examine their health results, the implications of them and acceptable ranges. If participants make an informed decision to work on improving any of their health results, they work through the five step empowerment model. Psychosocial aspects of diabetes i.e. fitting diabetes into life rather than fitting life into living with diabetes. An important aspect of the empowerment model is to respect the decisions made by some of the participants not to goal-set.
Patient Manual	Resource manual given to participants at the beginning of the course. Background reading, health results and goal setting material added each week as appropriate.

Figure 1 Content of the X-PERT Programme.

Lifestyle

Validated questionnaires assessed: diabetes knowledge with 14 multiple choice questions [15]; nutritional intake from food frequency questions [16]; diabetes self-care activities (SDSCA) measuring frequency of physical activity, blood glucose testing and foot care [17].

Psychosocial

Validated questionnaires assessed: diabetes treatment satisfaction at baseline (scored 0–36), 'change in treatment satisfaction' at follow-up (scored −18 to +18) and perceived frequency of hypoglycaemia and hyperglycaemia (scored 0–6) [18]; quality of life (ADDQoL) with three independently validated subscales relating to food and drink (range from −9 to +9) [19]; diabetes empowerment score (DES) with three validated subscales, managing the psychosocial aspects of diabetes, assessing dissatisfaction and readiness to change and setting and achieving diabetes goals [20].

Analysis

Sixty-four participants were required in each group to have 80% power to detect an absolute difference in HbA_{1c} levels of 1% between groups at the 5% significance level, assuming a SD of 2%. We recruited 314 participants (157 in each group) to allow for attrition.

Table 1 Demographic variables in the intervention and control group at baseline

Variable (mean)	Intervention group (SD)	Control group (SD)	Difference (95% CI)	*P*-value
Age (years)	61.3 (9.7) *n* = 157	61.8 (11.0) *n* = 157	0.5 (–1.8, 2.8)	0.64
Known duration of diabetes (years)	6.7 (6.4) *n* = 157	6.7 (6.7) *n* = 157	0.0 (–1.4, 1.5)	0.96
Age left full-time education (years)	15.3 (2.0) *n* = 122	16.2 (5.4) *n* = 112	0.9 (–0.5, 1.9)	0.10
Highest educational qualification (%)				
None	63 (34)	68 (37)		
'O'-level	12 (7)	15 (8)		
'A'-level	8 (4)	4 (2)		
Degree	6 (3)	7 (4)		0.13*
Employment				
Ever had a job (%)	121 (91)	114 (95)	4% (–3, 11)	0.23†
Job at present (%)	19 (16)	25 (24)	8% (–3, 18)	0.18†
Marital status				
Married (%)	92 (36)	75 (30)		
Divorced (%)	8 (3)	11 (4)		
Widowed (%)	24 (9)	26 (10)		
Single (%)	6 (2)	9 (4)		
Separated (%)	3 (1)	0 (0)		0.46*

*χ^2 test for trend.
†Fisher's exact test.

The X-PERT programme and the individual appointments groups were compared by testing the group by time interaction term from a repeated measures analysis of variance with Greenhouse–Geisser correction for sphericity, taking HbA_{1c} as the primary outcome and interpreting others as hypothesis generating. Stata version 9 (Stata Corp, College Station, TX, USA) and SPSS for Windows version 11.0 (SPSS Inc., Chicago, IL, USA) were used. The CONSORT statement was adhered to where possible [21] and an intention to treat analysis was carried out as far as possible.

Results

Recruitment

Sixteen general medical practices consented to take part in the study. Letters of invitation were sent to 1544 adults with Type 2 diabetes. Notification was received for 13 people who had either died or moved out of the area. Positive replies were received from 336 (21.8%) people, of whom 314 (93.5%) provided written consent. The age, sex and ethnicity of non-responders were similar to those in the study. The mean age of the participants at diagnosis of diabetes (54 years) was the same as the mean age of participants newly diagnosed with Type 2 diabetes in the United Kingdom Prospective Diabetes Study [22].

There were no statistically significant differences between the intervention and control groups for either demographic or outcome variables, indicating that randomization had been effective (Table 1). Baseline assessments were carried out for all 314 participants. Details regarding participant flow and follow-up can be seen in Fig. 2.

The mean age of the participants at recruitment was 61.5 years (SD 10, range 30–85) and there were similar numbers of men, 162 (52%), and women 152 (48%). The median duration of living with diabetes was 5 years (interquartile range 2–10). Eighty-three (26%) participants were treated with diet alone, 178 (57%) with tablets and 53 (17%) with insulin. Out of the 234 participants who responded to the question, 195 (83%) had left full-time education at the age of ≤ 16 years.

Biomedical outcomes (Table 2)

By 14 months, the X-PERT patients group compared with the control group had: greater reduction in HbA_{1c} (–0.6% vs. +0.1%, repeated measures ANOVA, $P < 0.001$); greater reduction in total cholesterol (–0.3 mmol/l vs. –0.2 mmol/l, $P = 0.01$); greater reduction in body weight (–0.5 kg vs. +1.1 kg, $P < 0.001$); reduced BMI (–0.2 kg/m^2 vs. +0.4 kg/m^2, $P < 0.001$); greater reduction in waist circumference (women –4 cm vs. –1 cm; men –2 cm vs. 0 cm; $P < 0.001$). There was no statistically significant difference between the groups with respect to systolic blood pressure, diastolic blood pressure, high-density lipoprotein (HDL)- and low-density lipoprotein (LDL)-cholesterol, total cholesterol to HDL ratio or triglycerides.

Diabetes medication

Twenty-four (16%) X-PERT patients reduced diabetes medication by 14 months compared with one (1%) control patient. Ninety-five (63%) X-PERT patients and 75 (53%) control patients remained on the same dose. Thirty-one (21%) X-PERT patients increased diabetes medication compared with 65 (46%) control patients. Therefore, for every seven patients who participated in the X-PERT Programme one patient could expect to have reduced their diabetes medication by

Table 2 Clinical outcomes: differences between the intervention (X-PERT Programme) group and the control (individual appointment) group

	Baseline data (n = 157)			Four-month data			Fourteen-month data			Overall change
Outcomes	Intervention group (SD) (n = 157)	Control group (SD) (n = 157)	Difference in means (95% CI)	Intervention group (SD) (n = 152)	Control group (SD) (n = 149)	Difference in means (95% CI)	Intervention group (SD) (n = 150)	Control group (SD) (n = 141)	Difference in means (95% CI)	Repeated measures ANOVA P-value
HbA_{1c} (%)	7.7 (1.6)	7.7 (1.6)	0.0 (−0.3, 0.4)	7.4 (1.3)	7.8 (1.6)	0.4 (0.1, 0.7)	7.1 (1.1)	7.8 (1.6)	0.7 (0.3, 1.0)	< 0.001
Systolic blood pressure (mmHg)	147.5 (19.8)	147.8 (23.7)	0.3 (−4.6, 5.1)	142.6 (18.8)	147.8 (22.7)	4.6 (−0.2, 9.3)	141.3 (16.8)	144.4 (23.5)	3.1 (−1.6, 7.9)	0.1
Diastolic blood pressure (mmHg)	82.6 (11.0)	82.2 (12.2)	−0.4 (−3.0, 2.2)	79.4 (9.5)	81.1 (12.3)	1.7 (−0.8, 4.2)	78.4 (9.6)	80.2 (10.9)	1.7 (−0.6, 4.1)	0.1
Total cholesterol (mmol/l)	5.1 (1.1)	4.9 (1.0)	−0.2 (−0.4, 0.1)	4.9 (1.0)	5.0 (1.0)	0.1 (−0.1, 0.4)	4.8 (1.1)	4.7 (1.0)	−0.1 (−0.3, 0.1)	0.01
HDL-cholesterol (mmol/l)	1.3 (0.3)	1.3 (0.4)	0.0 (−0.1, 0.1)	1.2 (0.3)	1.2 (0.4)	0.0 (0.0, 0.1)	1.1 (0.4)	1.1 (0.4)	0.0 (−0.1, 0.1)	0.3
LDL-cholesterol (mmol/l)	2.7 (0.9)	2.7 (0.8)	0.0 (−0.2, 0.2)	2.7 (0.9)	2.8 (0.8)	0.1 (−0.1, 0.3)	2.7 (0.9)	2.7 (0.8)	0.0 (−0.3, 0.1)	0.1
Total cholesterol:HDL ratio	4.3 (1.3)	4.2 (1.1)	−0.1 (−0.4, 0.2)	4.4 (1.3)	4.4 (1.3)	0.0 (−0.3, 0.3)	4.7 (1.3)	4.7 (1.4)	0.0 (−0.3, 0.3)	0.1
Triglycerides (mmol/l)* (95% CI)	2.2† (2.0–2.4)	2.0 (1.9–2.2)	0.9‡ (0.8, 1.0)	2.0 (1.8–2.2)	2.1 (1.9–2.3)	1.0 (0.9, 1.2)	1.8 (1.6–2.0)	1.8 (1.6–1.9)	1.0 (0.9, 1.1)	0.3
Body weight (kg)	83.2 (14.5)	82.8 (17.6)	−0.4 (−4.0, 3.2)	82.9 (14.9)	82.6 (17.9)	−0.3 (−4.1, 3.5)	82.7 (14.8)	83.9 (18.8)	1.2 (−2.7, 5.2)	< 0.001
Body mass index (kg/m2)	30.8 (5.3)	30.6 (5.7)	−0.3 (−1.5, 1.0)	30.7 (5.4)	30.4 (5.8)	−0.4 (−1.7, 0.9)	30.6 (5.5)	31.0 (6.4)	0.4 (−1.0, 1.7)	< 0.001
Body fat (%)	35.2 (9.6)	34.1 (9.2)	−1.1 (−3.2, 1.1)	34.2 (9.4)	33.4 (9.0)	−0.8 (−2.9, 1.4)	33.6 (9.3)	33.4 (9.2)	−0.2 (−2.4, 1.9)	0.08
Waist size (cm)										< 0.001
Female	103 (12)	101 (18)	−3 (−8, 2)	101 (12)	99 (16)	−1 (−6, 3)	99 (12)	100 (16)	1 (−4, 6)	
Male	103 (11)	105 (11)	1 (−2, 5)	102 (11)	105 (11)	3 (0, 7)	101 (10)	105 (12)	4 (0, 7)	

Values are means (standard deviations) unless stated otherwise.
*Based on log-transformed outcome.
†Geometric means.
‡Ratio of means.

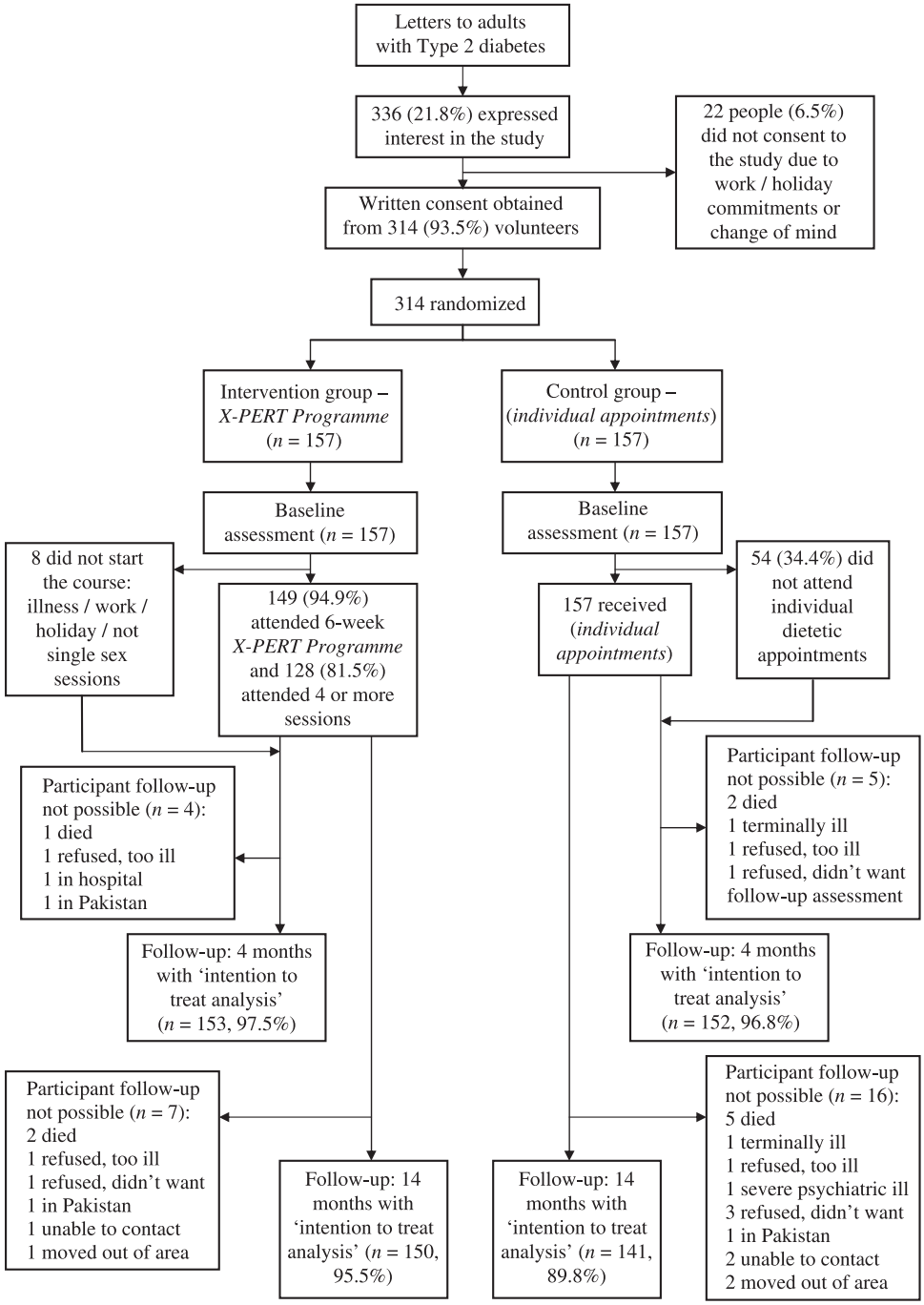

Figure 2 Flow of participants through the study.

14 months, number needed to treat (NNT) = seven patients [95% confidence interval (CI) 5, 11]. The χ^2 test for trend over the three ordered categories was statistically significant ($P < 0.0001$).

Validated questionnaires

Although the return rate of the full questionnaires at baseline, 4 months and 14 months was 83%, 67% and 61%, respectively, the number of responses to each question were progressively lower (see number of responses in Tables 2 and 3).

Lifestyle outcomes (Table 3)

Diabetes knowledge scores improved more in the X-PERT patients than in those receiving individual appointments (+1.8 vs. +0.8, $P < 0.001$).

Table 3 Lifestyle outcomes: differences between the intervention (X-PERT Programme) group and the control (individual appointment) group

	Baseline data			Four-month data			Fourteen-month data			Overall change
Outcomes	Intervention group (SD) (n = 135)	Control group (SD) (n = 125)	Difference in means (95% CI)	Intervention group (SD) (n = 112)	Control group (SD) (n = 95)	Difference in means (95% CI)	Intervention group (SD) (n = 100)	Control group (SD) (n = 91)	Difference in means (95% CI)	Repeated measures ANOVA P-value
Diabetes knowledge score*	7.5 (3.5)	7.0 (3.1)	−0.5 (−1.3, 0.3)	10.4 (2.8)	7.8 (2.9)	−2.7 (−3.5, −1.9)	9.3 (3.1)	7.8 (2.7)	−1.5 (−2.3, −0.7)	< 0.001
Self-care activity†										
Exercise	1.8 (2.3)	1.4 (2.5)	−0.4 (−1.0, 0.2)	2.8 (2.2)	1.9 (2.6)	−0.9 (−1.6, −0.3)	2.6 (2.4)	1.7 (2.7)	−0.9 (−1.6, −0.1)	NA‡
Foot care	2.4 (1.4)	2.3 (1.5)	−0.1 (−0.5, 0.3)	3.3 (1.2)	2.6 (1.5)	−0.7 (−1.1, −0.4)	2.8 (1.3)	2.2 (1.4)	−0.6 (−1.0, −0.2)	NA‡
Blood testing	1.7 (2.8)	1.5 (2.7)	−0.2 (−1.0, 0.5)	2.9 (2.4)	2.0 (2.7)	−0.9 (−1.6, −0.2)	2.6 (2.7)	2.0 (2.6)	−0.5 (−1.3, 0.3)	NA‡
Nutrient intake§										
Energy (kcal/day)	1473 (933)	1550 (1094)	76 (−185, 338)	1452 (824)	1565 (1028)	113 (−145, 371)	1724 (1811)	1687 (1589)	−37 (−525, 451)	0.5
Fruit and veg. (portions/day)	2.8 (1.8)	2.9 (2.2)	0.1 (−0.4, 0.7)	4.4 (2.6)	3.4 (2.8)	−1.0 (−1.8, −0.2)	5.2 (3.8)	3.1 (3.5)	−2.2 (−3.2, −1.1)	0.008
% Energy from carbohydrate	50.6 (11.7)	49.0 (11.9)	−1.6 (−4.7, 1.4)	54 .0 (12.6)	49.9 (14.3)	−4.1 (−7 9, −0.4)	53.5 (13.2)	50.2 (11.2)	−3.3 (− 6.9, 0.3)	0.8
% Energy from total sugars	17.4 (7.0)	17.4 (6.7)	0.1 (−1.7, 1.8)	23.1 (10.1)	18.0 (9.4)	−5.1 (−7.9, −2.4)	25.8 (13.4)	19.2 (8.0)	−6.6 (−9.9, −3.4)	0.02
% Energy from starch	33.5 (11.6)	31.8 (11.7)	−1.7 (−4.7, 1.3)	30.8 (12.2)	31.9 (16.0)	1.0 (−2.9, 5.0)	27.6 (10.5)	30.9 (11.6)	3.4 (0.15, 6.6)	0.3
% Energy from sucrose	6.5 (3.4)	6.5 (3.6)	0.0 (−0.9, 0.9)	9.2 (4.8)	7.0 (4.1)	−2.2 (−3.5, −0.9)	9.9 (6.1)	7.2 (3.7)	−2.7 (−4.2, −1.3)	0.01
% Energy from fat	28.7 (9.6)	29.5 (9.5)	0.8 (−1.7, 3.2)	26.4 (10.2)	28.8 (10.5)	2.4 (−0.5, 5.2)	26.6 (11.3)	29.3 (8.9)	2.7 (−0.3, 5.6)	0.5
% Energy from saturated fat	9.9 (3.9)	10.6 (4.5)	0.8 (−0.3, 1.8)	9.2 (4.1)	10.0 (4.3)	0.8 (−0.4, 2.0)	9.2 (4.3)	10.3 (3.6)	1.1 (0.0, 2.3)	0.4
Non-starch polysaccharides (g/day)	14.2 (9.8)	14.2 (10.1)	0 (−1.7, 3.22)	16.7 (7.5)	15.3 (11.9)	1.3 (−1.3, 4.1)	19.6 (13.2)	15.8 (13.2)	3.8 (0.03, 7.6)	0.9

Values are means (SD) unless stated otherwise.

*Multiple choice questions: scored from 0 to 14.

†Self-care activities: scored by a self-report measure of the frequency of completing different regimen activities over the preceding 7 days.

‡Repeated measures ANOVA not appropriate for ordered categorical outcomes.

§Nutritional intake calculated from food frequency questionnaire.

Table 4 Psychosocial outcomes: differences between the X-PERT Programme group and the control group

	Baseline data			Four-month data			Fourteen-month data			Overall change
Outcomes	Intervention group (SD) (n = 135)	Control group (SD) (n = 125)	Difference in means (95% CI)	Intervention group (SD) (n = 113)	Control group (SD) (n = 96)	Difference in means (95% CI)	Intervention group (SD) (n = 100)	Control group (SD) (n = 91)	Difference in means (95% CI)	Repeated measures ANOVA P-value
Diabetes treatment* satisfaction	24.5 (9.4)	23.3 (12.1)	−1.2 (−3.8, 1.5)	11.2 (5.8)	6.8 (6.9)	−4.4 (− 6.1, − 2.6)	9.5 (7.3)	5.8 (8.2)	−3.7 (−6.0, −1.5)	0.04
Frequency of hyperglycaemia	2.8 (1.9)	2.1 (1.8)	−0.7 (−1.2, − 0.3)	0.4 (1.8)	0.3 (1.5)	−0.1 (− 0.6, 0.3)	0.4 (1.9)	0.1 (1.3)	−0.3 (−0.7, 0.2)	0.02
Frequency of hypoglycaemia†	1.2 (1.7)	0.9 (1.5)	−0.3 (−0.7, 0.1)	−0.1 (1.6)	0.0 (1.3)	0.1 (− 0.3, 0.5)	−0.2 (1.6)	0.0 (1.3)	0.2 (−0.3, 0.6)	0.6
ADDQoL‡										
'Freedom to eat as I choose'	−3.8 (3.0)	−3.6 (3.4)	0.2 (−0.7, 1.0)	−2.2 (2.5)	−3.9 (3.0)	−1.7 (−2.5, −0.8)	−2.5 (2.9)	−3.6 (2.9)	−1.1 (−2.1, −0.2)	0.1
'Enjoyment of food'	−3.3 (2.8)	−3.0 (3.3)	0.3 (−0.6, 1.1)	−1.9 (2.6)	−3.1 (3.5)	−1.2 (−2.1, −0.2)	−1.8 (2.9)	−2.8 (3.1)	−1.1 (−2.0, −0.1)	0.004
'Freedom to drink as I choose'	−2.9 (2.7)	−2.5 (2.7)	0.4 (−0.4, 1.2)	−1.5 (3.0)	−2.9 (3.3)	−1.5 (−2.5, −0.4)	−1.7 (2.8)	−3.2 (3.2)	−1.5 (−2.6, −0.5)	0.03
Average quality of life score (18 questions)	−2.2 (2.2)	−1.9 (2.2)	0.3 (−0.3, 0.8)	−1.5 (1.7)	−1.5 (1.7)	0.0 (−0.5, 0.5)	−1.4 (1.7)	−1.7 (2.1)	−0.3 (−0.8, 0.3)	0.2
Total Diabetes Empowerment Score§	2.9 (1.3)	2.8 (1.4)	−0.1 (−0.4, 0.2)	3.6 (1.1)	3.3 (1.1)	−0.3 (−0.6, 0)	3.5 (1.2)	3.2 (1.1)	−0.3 (−0.6, −0.04)	0.04
Three subscales:										
1. Psychosocial adjustment to diabetes	3.0 (1.3)	2.9 (1.4)	−0.1 (−0.4, 0.3)	3.7 (1.2)	3.4 (1.2)	−0.3 (−0.6, −0.1)	3.7 (1.3)	3.4 (1.2)	−0.3 (−0.7, −0.02)	0.03
2. Readiness to change	3.6 (0.6)	3.6 (0.5)	0.0 (−0.1, 0.2)	4.0 (0.5)	3.6 (0.5)	−0.4 (−0.5, −0.2)	3.9 (0.6)	3.6 (0.6)	−0.3 (−0.5, −0.1)	0.01
3. Setting and achieving goals	3.6 (0.6)	3.7 (0.7)	0.1 (−0.1, 0.2)	4.0 (0.5)	3.7 (0.6)	−0.3 (−0.5, −0.2	4.0 (0.6)	3.8 (0.7)	−0.2 (−0.4, −0.05)	0.003

Values are means (SD) unless stated otherwise.
*Scored 0–36 (baseline), −18 to +18 (2 months postintervention); higher scores indicate greater diabetes treatment satisfaction.
†Scored 0–6 (baseline), −3 to +3 (2 months postintervention); higher scores indicate greater perceived frequency of hyperglycaemia/hypoglycaemia.
‡Scored from −9 (maximum negative impact on quality of life) to +9 (maximum positive impact on quality of life). Therefore a minus (−) score suggest that diabetes has a negative impact on quality of life and a plus (+) score, that diabetes has a positive effect on quality of life.
§Scored 0–5: higher scores indicate either greater self-empowerment for either total score and/or subscales.

At 4 months there was a significant difference in the number of days each week that the X-PERT patients were exercising (difference 0.9 day; 95% CI 0.3, 1.6), performing foot care self-management (difference 0.7 day; 95% CI 0.4, 1.1) and self-monitoring blood glucose levels (difference 0.9 day; 95% CI 0.2, 1.6) compared with those participants receiving individual appointments. The differences with respect to exercise and foot care remained significant at 14 months (difference 0.9 day, 95% CI 0.1, 1.6; difference 0.6 day, 95% CI 0.2, 1.0, respectively) but not with respect to self-monitoring of blood glucose levels (difference 0.5 day; 95% CI – 0.3, 1.3).

The food frequency questionnaire indicated that the X-PERT patients had increased their daily consumption of fruit and vegetables more than control subjects (+2.4 portions vs. +0.2 portions, $P = 0.008$).

Psychosocial outcomes (Table 4)

X-PERT patients were 'much more satisfied' with their diabetes treatment compared with patients receiving individual appointments ($P = 0.04$), but also reported an increased frequency of hyperglycaemia ($P = 0.02$).

The X-PERT patients showed significant improvements, compared with control patients, in the freedom to drink ($P = 0.004$) and enjoyment of food ($P = 0.03$), but not overall quality of life ($P = 0.2$).

There were significant statistical differences between the X-PERT and control patients in total empowerment score ($P = 0.04$) and in subscales: psychosocial adjustment ($P = 0.03$), readiness to change ($P = 0.01$) and goal setting ($P = 0.003$).

Discussion

We tested the hypothesis that the X-PERT Programme led to increased diabetes self-management and sustained improvements in clinical, lifestyle and psychosocial outcomes. The study has not refuted this hypothesis. Participation in the X-PERT Programme led to improved glycaemic control; reduced requirement for diabetes medication; reduced body weight, BMI and waist circumference; lowering of total cholesterol levels; increased intake of fruit and vegetables; increased knowledge of diabetes; enjoyment of food and freedom to drink; self-empowerment, psychosocial adjustment to diabetes, readiness to change and setting and achieving goals; self-management skill through increased physcial activity and foot care at 14 months.

Although X-PERT patients had increased self-monitoring of blood glucose levels at 4 months, frequency of self-monitoring blood glucose levels were not significantly different between groups at 14 months. This may suggest that, after initial experimentation, X-PERT patients became more confident with diabetes self-management, which resulted in reduced self-monitoring.

Glycated haemoglobin showed greater improvement at longer-term follow-up (primary outcome: 14 months) than the short-term (4 months). That finding differed from previous research [7] and may be due to the theoretical models, empowerment and discovery learning. Instructing patients what to do can often lead to patients making changes to please the health professional, but because those changes may not be intuitive for that patient, they may not be continued in the long term. The sustained improvements in this study may be due to patients developing the skills, knowledge and confidence to identify and address their own problems regarding diabetes self-management.

Even though glycated haemoglobin at 14 months was the primary outcome, outcomes were also collected at 4 months, as it has previously been shown that benefits from self-management strategies can be lost between 1 and 3 months [7]. The 14-month outcomes were collected to ascertain whether any benefits were sustained in the longer term. Although there were no statistically significant differences between the two groups with respect to blood pressure, there were potentially clinically important reductions in the X-PERT patients.

People with Type 2 diabetes find it difficult to lose weight [23]. Although the X-PERT patients lost only 0.5 kg in body weight, the trend towards weight gain seen in the control group had been reversed.

Educational programmes are frequently described as complex interventions where it is often difficult to define the 'active ingredient(s)' [24]. The effectiveness of the X-PERT Programme may be due to the theoretical models used; skills and motivation of the educator (therapist effect); peer support and group work; visual aids; shared health records; goal setting or other specific components of the education programme. The precise mechanism of action is likely to be a combination of all components. Therefore, an attempt has been made to develop the programme in a manner that enables it to be transported to, and put into operation in, other contexts. It is possible that the intervention was effective solely due to the 12 h of contact time. However, it has previously been shown that when patients receive the same structured diabetes education delivered over the same time period, on either a one-to-one or group basis, the group intervention is more effective [25]. Even if the success of the intervention was due, in part, to the length of contact time, it would be a cost-effective and realistic strategy compared with delivering 12 h of structured education to patients on an individual basis.

The X-PERT Programme was not delivered at each general practice but, instead, at local community venues, giving little opportunity for contamination between the intervention and control group. In addition, there was no evidence of any clustering within tutors (intraclass correlation = 0) for primary outcomes.

Empowerment cannot be given or taught, it is a process that people do for themselves [26]. The root of empowerment is to recognize that every person is an autonomous being. The influence of professionals is to enable the person to have knowledge and confidence to make informed choices about their actions

and activities [27]. It has been suggested that no published empirical study has tested the empowerment model in its entirety [28]. This study addressed the five components of empowerment. Participants with diabetes were valued and accepted as being experts at living with their condition. Participants were encouraged to participate actively in the learning process and to discuss their feelings towards living with their condition and the effect it has on their day-to-day lives. They were encouraged to have autonomy by working in alliance with professionals to identify successful strategies for diabetes self-management.

Although depression is common in those with diabetes [29] and several participants were prescribed antidepressants, depression scores were not measured in the trial. This could be seen as a possible limitation of the study, but many outcomes were necessary and, as the programme specifically aimed to increase self-empowerment, a decision was made to measure empowerment score in preference to depression score.

The X-PERT project was well received from the start with excellent attendance rates [30]. The mean glycated haemoglobin at baseline was 7.7%. This differs from many other diabetes education interventions that recruit only participants with poor diabetes control and are therefore more likely to experience a positive outcome [31]. The study was also better powered in comparision with other education studies [32]. The response rate of questionnaires was excellent at baseline and, although the response rate declined over time, it was still considered good for a clinical trial [33].

The X-PERT Programme is likely to be generalizable to the majority of people with Type 2 diabetes because: the X-PERT trial was a pragmatic trial with minimum exclusion criteria; it recruited people with Type 2 diabetes from both caucasian and South Asian backgrounds; it was delivered under normal conditions within primary care. A possible criticism may be that more motivated patients volunteered to participate. That could be said for all clinical trials but the control participants would also be motivated and therefore one would still be comparing similar groups.

Key criteria that a structured education programme should meet to fulfil the NICE requirements have been developed by a working party of users and providers sponsored jointly by Diabetes UK and the Department of Health [34]. An X-PERT pack has now been developed to meet those criteria and includes a written curriculum, visual aids, 'train the trainers' course, evaluation scheme and quality assurance programme. The X-PERT Programme is now being rolled out to benefit more people with Type 2 diabetes.

Competing interests

Following the RCT, Burnley, Pendle & Rossendale PCT now have a financial interest in delivery of the X-PERT train the trainers course and from the sale of the X-PERT educational resources. However, all monies received either employ X-PERT team staff or finance the production of the educational resources.

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References

1 DOH. *National Service Framework for Diabetes: Standards*. London: Department of Health 2001.
2 DOH. *National Service Framework for Diabetes: Delivery Strategy. 29895*. London: Department of Health 2003.
3 NICE. *Guidance on the Use of Patient-Education Models for Diabetes*. Technology Appraisal 60. London: National Institute for Clinical Excellence 2003.
4 DOH. *The Performance and Planning Framework for 2003–6—Improvement Expansion and Reform: the Next Three Years*. London: Department of Health 2003.
5 DOH. *National Standards, Local Action: Health and Social Care Standards and Planning Framework*. London: Department of Health 2004.
6 Norris SL, Engelgau MM, Venkat Narayan KM. Review: self-management training in type 2 diabetes mellitus is effective in the short term. *ACP J CLUB* Sept/Oct 2001; 45.
7 Norris SL, Lau J, Smith SJ, Schmid CH, Engelgau MM. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. *Diabetes Care* 2002; **25**: 1159–1171.
8 WHO Working Group. *Definition, Diagnosis and Classification of Diabetes Mellitus and its Complications*. Part 1: *Diagnosis and Classification of Diabetes Mellitus*. Geneva: World Health Organization, Department of Noncommunicable Disease Surveillance 1999: 1–59.
9 Anderson R, Funnell M. *The Art of Empowerment: Stories and Strategies for Diabetes Educators*. Alexandria, VA: American Diabetes Association 2000.
10 Brunner J. *Toward a Theory of Instruction*. Cambridge, MA: Harvard University Press 1966.
11 Rohlfing CL, Wiedmeyer HM, Little RR, England JD, Tennill A, Goldstein DE, *et al*. Defining the relationship between plasma glucose and HbA1c: analysis of glucose profiles and HbA1c in the Diabetes Control and Complications Trial. *Diabetes Care* 2002; **25**: 275–278.
12 Ramsay L, Williams B, Johnson G, MacGregor G, Potter J, Poulter N, *et al*. Guidelines for management of hypertension: report of the third Working Party of the British Hypertension Society. *J Hum Hypertens* 1999; **13**: 569–592.
13 NICE. *Management of Type 2 Diabetes: Management of Blood Pressure and Blood Lipids*. Ref. no. N0167. London: National Institute for Clinical Excellence 2002.
14 Després JP, Lemieux I, Prudhomme D. Treatment of obesity: need to focus on high risk abdominally obese patients. *BMJ* 2001; **322**: 716–720.
15 Fitzgerald JT, Funnell MM, Hess GE, Barr PA, Anderson RM, Hiss RG, *et al*. The reliability and validity of a brief diabetes knowledge test. *Diabetes Care* 1998; **21**: 706–710.
16 Little P, Barnett J, Margetts B, Kinmouth AL, Gabbay J, Thompson R, *et al*. The validity of dietary assessment in general practice. *J Epidemiol Commun Health* 1999; **53**: 165–172.
17 Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure. *Diabetes Care* 2000; **23**: 943–950.
18 Bradley C. The diabetes treatment satisfaction questionnaire: DTSQ. In Bradley C ed. *Handbook of Psychology and Diabetes*. Amsterdam: Harwood Academic Publishers GmbH 1994: 111–133.

19 Bradley C, Todd C, Gorton T, Symonds E, Martin A, Plowright R, *et al.* The development of an individualized questionnaire measure of perceived impact of diabetes on quality of life: the ADDQoL. *Qual Life Res* 1999; **8**: 79–91.
20 Anderson RM, Funnell MM, Fitzgerald JT, Marriott DJ. The Diabetes Empowerment Scale: a measure of psychosocial self-efficacy. *Diabetes Care* 2000; **23**: 739–743.
21 Altman D, Schulz K, Moher D, Egger M, Davidoff F, Elbourne D, *et al.* The Revised CONSORT statement for reporting randomised trials: explanation and elaboration. *Ann Intern Med* 2001; **134**: 663–695.
22 UKPDS Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 1998; **352**: 837–853.
23 Norris SL, Zhang X, Avenell A, Gregg E, Brown TJ, Schmid CH, *et al.* Longer-term non-pharmacologic weight loss interventions for adults with type 2 diabetes. *The Cochrane Database of Systematic Reviews*, Issue 2. 2005.
24 Medical Research Council. *A Framework for Development and Evaluation of RCTs for Complex Interventions to Improve Health*. London: Medical Research Council 2000.
25 Rickheim PL, Weaver TW, Flader JL, Kendall DM. Assessment of group versus individual diabetes education: a randomized study. *Diabetes Care* 2002; **25**: 269–274.
26 Rodgers J, Walker R. Empowerment—not for all? *J Diabetes Nursing* 2002; **6**: 38–39.
27 Walker R. Diabetes: reflecting on empowerment. *Nursing Standard* 1998; **12**: 49–56.
28 Skinner TC, Cradock S. Empowerment: what about the evidence? *Pract Diabetes Int* 2000; **17**: 91–95.
29 Garvard J, Lustman P, Clouse R. Prevalence of depression in adults with diabetes: an epidemiological evaluation. *Diabetes Care* 1993; **16**: 1167–1178.
30 Deakin TA, Cade JE, Williams DRR, Greenwood DC. EXpert Patient Education versus Routine Treatment (X-PERT): process evaluation. *Diabetologia* 2002; **45**: 317.
31 Norris SL, Engelgau MM, Venkat Narayan KM. Effectiveness of self-management training in Type 2 diabetes. *Diabetes Care* 2001; **24**: 561–587.
32 Griffin SJ, Kinmonth AL, Skinner C, Kelly J. *Educational and Psychosocial Interventions for Adults with Diabetes*. London: Diabetes UK (former British Diabetic Association) 1998.
33 Eaker S, Bergstrom R, Bergstrom A, Adami HO, Nyren O. Response rate to mailed epidemiologic questionnaires: a population-based randomised trial of variations in design and mailing routes. *Am J Epidemiol* 1998; **147**: 74–82.
34 DOH, Diabetes UK. *Key Criteria That a Structured Education Programme Should Meet to Fulfil the NICE Requirements*. London: National Diabetes Support Team 2004.

