Article:
Deakin, TA, Cade, JE, Williams, DRR et al. (1 more author) (2006) Structured patient education: the Diabetes X-PERT Programme makes a difference. Diabetic Medicine, 23 (9). 944 - 954. ISSN 0742-3071

https://doi.org/10.1111/j.1464-5491.2006.01906.x

Structured Patient Education: The Diabetes X-PERT Programme makes a Difference

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Word count (paper excluding references): 3142
Abstract: words 249
Number of tables/figures: 6

Abstract

Aims To develop a patient-centred, group based self-management programme (X-PERT), based on theories of empowerment and discovery learning, and evaluate 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 randomised to either individual appointments (controls) (n=157) or the X-PERT Programme (n=157). X-PERT patients were invited to attend six, two hour group sessions of self-management education. Outcomes were assessed at baseline, four and 14 months.

Results 149 participants (95%) attended the X-PERT Programme with 128 (82%) attending ≥4 sessions. By 14 months the X-PERT group compared with controls showed significant improvements in the mean HbA_{1c} (-0.6% versus +0.1%, repeated measures ANOVA, $P<0.001$). The number needed to treat (NNT) for preventing diabetes medication increase was 4 (95% CI: 3 to 7) and NNT for reducing diabetes medication was 7 (95% CI: 5 to 11). Statistically significant improvements were also shown in the X-PERT patients compared to the control patients for body weight, BMI, waist circumference, total cholesterol, self-empowerment; diabetes knowledge; physical activity levels; foot care; fruit and vegetable intake; enjoyment of food; 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.

WORDS 249

Keywords Randomised controlled trial, structured group education, type 2 diabetes, glycated haemoglobin, patient-centred care

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

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 (NSF) [1,2] and the NICE technology appraisal of patient-education models [3] make it clear that all Primary Care Trusts (PCTs) will need to commit to offering structured education programmes to people with type 2 diabetes. Primary care services will need to provide high quality structured education programmes to people 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 found short-term (less than six months) positive effects on knowledge, dietary habits and glycaemic control [6]. A meta-analysis showed a decrease in glycated haemoglobin by 0.8% at immediate follow-up and 0.3% at four months or longer follow-up. Hence the benefit of self-management education on glycated haemoglobin has been shown to decline between one and three months [7]. However, these reviews synthesised 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 evaluated.

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 volunteer.

Randomisation

Participants were randomised 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 versus 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 health care 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, were 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 pre-arranged individual appointments with a dietician (30 minutes), practice nurse (15 minutes) and GP (10minutes).

Members of the intervention group were invited to attend the X-PERT Programme. This involved six, weekly sessions, each lasting two hours (figure 1). Sessions were held in community venues with an average of 16 participants plus four to eight carers in each programme. It 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 (TAD) 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 unpinning 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 the 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. BMI (kg/m^2) was calculated from height and weight measurements. The Tanita Body Fat Monitor analyzed 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 to that prescribed at baseline. A medication increase was defined as commencing on, or an increase, in oral hypoglycemic agents (OHAs) or insulin. A medication decrease was defined as a reduction in the type or quantity of OHAs or the number of units of insulin injected.

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 hypoglycemia and hyperglycemia (scored 0-6) [18]; quality of life (ADDQoL) with three independently validated sub-scales 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 HbA1c levels of one percentage point between groups at the 5% significance level, assuming a standard deviation of 2%. We recruited 314 participants (157 in each group) to allow for attrition.

X-PERT and 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 HbA1c as the primary outcome and interpreting others as hypothesis generating. Stata version 9 and SPSS for Windows version 11.0 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 group and control group for either demographic or outcome variables indicating that randomisation 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 figure 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 (Inter-quartile range 2 to 10). Eighty-three (26%) participants were being 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 or younger.

Biomedical Outcomes (Table 2)
By 14 months, the X-PERT patients group compared to the control group had: greater reduction in HbA_{1c} (-0.6% versus +0.1%, repeated measures ANOVA, P<0.001); greater reduction in total cholesterol (-0.3 mmol/l versus -0.2 mmol/l, P=0.01); greater reduction in body weight (-0.5 Kg versus +1.1 Kg, P<0.001); reduced BMI (-0.2 Kg/m^2 versus +0.4 $Kg.m^2$, P<0.001); greater reduction in waist circumference (women: -4 cm versus -1 cm; men -2 cm versus 0 cm; P<0.001). There was no statistically significant difference between the groups in respect of systolic blood pressure, diastolic blood pressure, HDL and 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%) XPERT 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 14 months, number needed to treat (NNT) = seven patients [95% confidence interval (CI) 5, 11]. The $\chi 2$ 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, four 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 versus +0.8, P<0.001).

At four 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 to 1.6), performing foot care self-management (difference 0.7 day; 95% CI: 0.4 to 1.1) and self-monitoring blood glucose levels (difference 0.9 day; 95% CI: 0.2 to 1.6) compared to those participants receiving individual appointments. That increase remained significant in respect of exercise and foot care at 14 months (difference 0.9 day; 95% CI: 0.1 to 1.6; difference 0.6 day; 95% CI: 0.2 to 1.0, respectively) but not in respect of self-monitoring of blood glucose levels (difference 0.5 day; 95% CI: -0.3 to 1.3).

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

Psychosocial Outcomes (Table 4)
X-PERT patients were "much more satisfied" with their diabetes treatment compared to patients receiving individual appointments (P=0.04) but also reported an increased frequency of hyperglycemia (P=0.02).

The X-PERT patients showed significant improvements, compared with controls, 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 patients and controls for total empowerment score (P=0.04) and for subscales: psychosocial adjustment (P=0.03), readiness to change (P=0.01); 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 the hypothesis. Participation in the X-PERT Programme showed at 14 months to have led to improved glycaemic control; reduced requirement for diabetes medication; reduced body weight, BMI and waist circumference; lowering of total cholesterol levels; increased fruit & 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.

Although X-PERT patients had increased self-monitoring of blood glucose levels at four 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 (four 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 four months as it has previously been shown that benefits from self-management strategies can be lost between one and three 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 in 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 only lost 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 hours 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 to delivering 12 hours 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 his or her 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 take active participation in the learning process and to discuss their feelings towards living with their condition and the affect 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 people with diabetes [29] and several participants were in receipt of prescribed anti-depressants, 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 only recruit participants with poor diabetes control and are therefore more likely to experience a positive outcome [31]. The study was also better powered in comparision to other education studies [32]. The response rate of questionnaires was excellent at baseline and although the response rate declined overtime, it was still considered good for a clinical trial [33].

The X-PERT Programme is likely to be generalisable 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 both white 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.

Acknowledgements – This study was supported with research monies from the former NHS Executive North West; the former Burnley Healthcare NHS Trust; the former Pendle Primary Care Group; the British Dietetic Association; all based in the United Kingdom.

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Table 1 Comparison between the intervention and control group for demographic variables

Variable (mean)	Intervention group (SD)	Control group (SD)	Difference (95% CI)	P-value
Age (yrs)	61.3 (9.7) n=157	61.8 (11.0) n=157	0.5 (-1.8 to 2.8)	P=0.64
Time with diabetes (yrs)	6.7 (6.4) n=157	6.7 (6.7) n=157	0.0 (-1.4 to 1.5)	P=0.96
Age left full time education	15.3 (2.0) n=122	16.2 (5.4) n=112	0.9 (-0.5 to 1.9)	P=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%)		P=0.13*
Employment				
- ever had a job (%)	121 (91%)	114 (95%)	4% (-3 to 11%)	P=0.23†
- job at present (%)	19 (16%)	25 (24%)	8% (-3 to 18%)	P=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%)		P=0.46*

* Chi-squared test for trend
† Fisher's exact test

Table 2 Clinical outcomes: differences between the intervention (X-PERT program) group and the control (routine treatment) group. Values are means (standard deviations) unless stated otherwise.

	BASELINE DATA (n=157)			FOUR MONTH DATA			14 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 to 0.4)	7.4 (1.3)	7.8 (1.6)	0.4 (0.1 to 0.7)	7.1 (1.1)	7.8 (1.6)	0.7 (0.3 to 1.0)	P<0.001
Systolic blood pressure (mmHg)	147.5 (19.8)	147.8 (23.7)	0.3 (-4.6 to 5.1)	142.6 (18.8)	147.8 (22.7)	4.6 (-0.2 to 9.3)	141.3 (16.8)	144.4 (23.5)	3.1 (-1.6 to 7.9)	P=0.1
Diastolic blood pressure (mmHg)	82.6 (11.0)	82.2 (12.2)	-0.4 (-3.0 to 2.2)	79.4 (9.5)	81.1 (12.3)	1.7 (-0.8 to 4.2)	78.4 (9.6)	80.2 (10.9)	1.7 (-0.6 to 4.1)	P=0.1
Total Cholesterol (mmol/l)	5.1 (1.1)	4.9 (1.0)	-0.2 (-0.4 to 0.1)	4.9 (1.0)	5.0 (1.0)	0.1 (-0.1 to 0.4)	4.8 (1.1)	4.7 (1.0)	-0.1 (-0.3 to 0.1)	P=0.01
HDL Cholesterol (mmol/l)	1.3 (0.3)	1.3 (0.4)	0.0 (-0.1 to 0.1)	1.2 (0.3)	1.2 (0.4)	0.0 (0.0 to 0.1)	1.1 (0.4)	1.1 (0.4)	0.0 (-0.1 to 0.1)	P=0.3
LDL Cholesterol (mmol/l)	2.7 (0.9)	2.7 (0.8)	0.0 (-0.2 to 0.2)	2.7 (0.9)	2.8 (0.8)	0.1 (-0.1 to 0.3)	2.7 (0.9)	2.7 (0.8)	0.0 (-0.3 to 0.1)	P=0.1
T.Chol:HDL Ratio	4.3 (1.3)	4.2 (1.1)	-0.1 (-0.4 to 0.2)	4.4 (1.3)	4.4 (1.3)	0.0 (-0.3 to 0.3)	4.7 (1.3)	4.7 (1.4)	0.0 (-0.3 to 0.3)	P=0.1
Triglycerides (mmol/l)* (95% CI)	2.2† (2.0 to 2.4)	2.0 (1.9 to 2.2)	0.9‡ (0.8 to 1.0)	2.0 (1.8 to 2.2)	2.1 (1.9 to 2.3)	1.0 (0.9 – 1.2)	1.8 (1.6 to 2.0)	1.8 (1.6 to 1.9)	1.0 (0.9 to 1.1)	P=0.3
Body Weight (Kg)	83.2 (14.5)	82.8 (17.6)	-0.4 (-4.0 to 3.2)	82.9 (14.9)	82.6 (17.9)	-0.3 (-4.1 to 3.5)	82.7 (14.8)	83.9 (18.8)	1.2 (-2.7 to 5.2)	P<0.001
BMI (Kg/m^2)	30.8 (5.3)	30.6 (5.7)	-0.3 (-1.5 to 1.0)	30.7 (5.4)	30.4 (5.8)	-0.4 (-1.7 to 0.9)	30.6 (5.5)	31.0 (6.4)	0.4 (-1.0 to 1.7)	P<0.001
Body Fat (%)	35.2 (9.6)	34.1 (9.2)	-1.1 (-3.2 to 1.1)	34.2 (9.4)	33.4 (9.0)	-0.8 (-2.9 to 1.4)	33.6 (9.3)	33.4 (9.2)	-0.2 (-2.4 to 1.9)	P=0.08
Waist Size (cm)										P<0.001
Female	103 (12)	101 (18)	-3 (-8 to 2)	101 (12)	99 (16)	-1 (-6 to 3)	99 (12)	100 (16)	1 (-4 to 6)	
Male	103 (11)	105 (11)	1 (-2 to 5)	102 (11)	105 (11)	3 (0 to 7)	101 (10)	105 (12)	4 (0 to 7)	

* based on log-transformed outcome
† geometric means
‡ ratio of means

Table 3 Lifestyle outcomes: differences between the intervention (X-PERT programme) group and the control (routine treatment) group. Values are means (standard deviations) unless stated otherwise.

OUTCOMES	BASELINE DATA			FOUR MONTH DATA			14 MONTH DATA			Overall change
	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[1]	7.5 (3.5)	7.0 (3.1)	-0.5 (-1.3 to 0.3)	10.4 (2.8)	7.8 (2.9)	-2.7 (-3.5 to -1.9)	9.3 (3.1)	7.8 (2.7)	-1.5 (-2.3 to -0.7)	P<0.001
Self-care activity[2]:										
Exercise	1.8 (2.3)	1.4 (2.5)	-0.4 (-1.0 to 0.2)	2.8 (2.2)	1.9 (2.6)	-0.9 (-1.6 to -0.3)	2.6 (2.4)	1.7 (2.7)	-0.9 (-1.6 to -0.1)	n/a[3]
Foot care	2.4 (1.4)	2.3 (1.5)	-0.1 (-0.5 to 0.3)	3.3 (1.2)	2.6 (1.5)	-0.7 (-1.1 to -0.4)	2.8 (1.3)	2.2 (1.4)	-0.6 (-1.0 to -0.2)	n/a[3]
Blood testing	1.7 (2.8)	1.5 (2.7)	-0.2 (-1.0 to 0.5)	2.9 (2.4)	2.0 (2.7)	-0.9 (-1.6 to -0.2)	2.6 (2.7)	2.0 (2.6)	-0.5 (-1.3 to 0.3)	n/a[3]
Nutrient intake[4]:										
Energy (Kcal/day)	1473 (933)	1550(1094)	76 (-185 to 338)	1452 (824)	1565 (1028)	113 (-145 to 371)	1724 (1811)	1687(1589)	-37 (-525 to 451)	P=0.5
Fruit & Veg (portions/day)	2.8 (1.8)	2.9 (2.2)	0.1 (-0.4 to 0.7)	4.4 (2.6)	3.4 (2.8)	-1.0 (-1.8 to -0.2)	5.2 (3.8)	3.1 (3.5)	-2.2 (-3.2 to -1.1)	P=0.008
% Energy from carbohydrate	50.6 (11.7)	49.0 (11.9)	-1.6 (-4.7 to 1.4)	54 .0 (12.6)	49.9 (14.3)	-4.1 (-7 9 to –0.4)	53.5 (13.2)	50.2 (11.2)	-3.3 (-6.9 to 0.3)	P=0.8
% Energy from total sugars	17.4 (7.0)	17.4 (6.7)	0.1 (-1.7 to 1.8)	23.1 (10.1)	18.0 (9.4)	-5.1 (-7.9 to –2.4)	25.8 (13.4)	19.2 (8.0)	-6.6 (-9.9 to -3.4)	P=0.02
% Energy from starch	33.5 (11.6)	31.8 (11.7)	-1.7 (-4.7 to 1.3)	30.8 (12.2)	31.9 (16.0)	1.0 (-2.9 to 5.0)	27.6 (10.5)	30.9 (11.6)	3.4 (0.15 to 6.6)	P=0.3
% Energy from sucrose	6.5 (3.4)	6.5 (3.6)	0.0 (-0.9 to 0.9)	9.2 (4.8)	7.0 (4.1)	-2.2 (-3.5 to -0.9)	9.9 (6.1)	7.2 (3.7)	-2.7 (-4.2 to -1.3)	P=0.01
% Energy from fat	28.7 (9.6)	29.5 (9.5)	0.8 (-1.7 to 3.2)	26.4 (10.2)	28.8 (10.5)	2.4 (-0.5 to 5.2)	26.6 (11.3)	29.3 (8.9)	2.7 (-0.3 to 5.6)	P=0.5
% Energy from saturated fat	9.9 (3.9)	10.6 (4.5)	0.8 (-0.3 to 1.8)	9.2 (4.1)	10.0 (4.3)	0.8 (-0.4 to 2.0)	9.2 (4.3)	10.3 (3.6)	1.1 (0.0 to 2.3)	P=0.4
Non-starch Poly-saccharides (g/day)	14.2 (9.8)	14.2 (10.1)	0 (-1.7 to 3.22)	16.7 (7.5)	15.3 (11.9)	1.3 (-1.3 to 4.1)	19.6 (13.2)	15.8 (13.2)	3.8 (0.03 to 7.6)	P=0.9

[1] Multiple choice questions: scored from 0 – 14
[2]Self-care activities: scored by a self-report measure of the frequency of completing different regimens activities over the preceding seven days
[3] Repeated measures ANOVA not appropriate for ordered categorical outcomes
[4] Nutritional intake calculated from food frequency questionnaire

Table 4 Psychosocial outcomes: differences between the intervention (X-PERT programme) group and the control (routine treatment) group. Values are means (standard deviations) unless stated otherwise.

OUTCOMES	BASELINE DATA			FOUR MONTH DATA			14 MONTH DATA			Overall change
	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[5] Satisfaction	24.5 (9.4)	23.3 (12.1)	-1.2 (-3.8 to 1.5)	11.2 (5.8)	6.8 (6.9)	-4.4 (-6.1 to -2.6)	9.5 (7.3)	5.8 (8.2)	-3.7 (-6.0 to-1.5)	P=0.04
Frequency of Hyperglycaemia	2.8 (1.9)	2.1 (1.8)	-0.7 (-1.2 to -0.3)	0.4 (1.8)	0.3 (1.5)	-0.1 (-0.6 to 0.3)	0.4 (1.9)	0.1 (1.3)	-0.3 (-0.7 to 0.2)	P=0.02
Frequency of Hypoglycaemia[6]	1.2 (1.7)	0.9 (1.5)	-0.3 (-0.7 to 0.1)	-0.1 (1.6)	0.0 (1.3)	0.1 (-0.3 to 0.5)	-0.2 (1.6)	0.0 (1.3)	0.2 (-0.3 to 0.6)	P=0.6
ADDQoL[7]										
'Freedom to eat as I choose'	-3.8 (3.0)	-3.6 (3.4)	0.2 (-0.7 to 1.0)	-2.2 (2.5)	-3.9 (3.0)	-1.7 (-2.5 to -0.8)	-2.5 (2.9)	-3.6 (2.9)	-1.1 (-2.1 to -0.2)	P=0.1
'Enjoyment of food'	-3.3 (2.8)	-3.0 (3.3)	0.3 (-0.6 to 1.1)	-1.9 (2.6)	-3.1 (3.5)	-1.2 (-2.1 to -0.2)	-1.8 (2.9)	-2.8 (3.1)	-1.1 (-2.0 to -0.1)	P=0.004
'Freedom to drink as I choose'	-2.9 (2.7)	-2.5 (2.7)	0.4 (-0.4 to 1.2)	-1.5 (3.0)	-2.9 (3.3)	-1.5 (-2.5 to -0.4)	-1.7 (2.8)	-3.2 (3.2)	-1.5 (-2.6 to -0.5)	P=0.03
Average Quality of life score (18 questions)	-2.2 (2.2)	-1.9 (2.2)	0.3 (-0.3 to 0.8)	-1.5 (1.7)	-1.5 (1.7)	0.0 (-0.5 to 0.5)	-1.4 (1.7)	-1.7 (2.1)	-0.3 (-0.8 to 0.3)	P=0.2
Total Diabetes Empowerment Score[8]	2.9 (1.3)	2.8 (1.4)	-0.1 (-0.4 to 0.2)	3.6 (1.1)	3.3 (1.1)	-0.3 (-0.6 to 0)	3.5 (1.2)	3.2 (1.1)	-0.3 (-0.6 to-0.04)	P=0.04
3 subscales: 1) Psychosocial adjustment to diabetes	3.0 (1.3)	2.9 (1.4)	-0.1 (-0.4 to 0.3)	3.7 (1.2)	3.4 (1.2)	-0.3 (-0.6 to -0.1)	3.7 (1.3)	3.4 (1.2)	-0.3 (-0.7 to -0.02)	P=0.03
2) Readiness to change	3.6 (0.6)	3.6 (0.5)	0.0 (-0.1 to 0.2)	4.0 (0.5)	3.6 (0.5)	-0.4 (-0.5 to -0.2)	3.9 (0.6)	3.6 (0.6)	-0.3 (-0.5 to -0.1)	P=0.01
3) Setting and achieving goals	3.6 (0.6)	3.7 (0.7)	0.1 (-0.1 to 0.2)	4.0 (0.5)	3.7 (0.6)	-0.3 (-0.5 to -0.2	4.0 (0.6)	3.8 (0.7)	-0.2 (-0.4 to -0.05)	P=0.003

[5] Scored 0-36 (baseline), -18 to +18 (2 months post-intervention); higher scores indicate greater diabetes treatment satisfaction.
[6] Scored 0-6 (baseline), -3 to +3 (2 months post-intervention); higher scores indicate greater perceived frequency of hyperglycaemia / hypoglycaemia.
[7] 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 (+) scores, that diabetes has a positive effect on quality of life.
[8] Scored 0-5: higher scores indicate either greater self-empowerment for either total score and / or subscales.