Improved Blood Glucose Control, Cardiovascular Health and Empowerment in people attending X-PERT Structured Diabetes Education

Abbreviated title: Improved markers of health in participants attending X-PERT Structured Diabetes Education

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Key Points

- The efficacy of structured diabetes education is well established, but ongoing audit of programmes is important to demonstrate continued effectiveness
- The current analysis demonstrates that there were significant improvements in blood glucose control, cardiovascular health and empowerment, as well as a reduction in medication requirements, in people who attended X-PERT programmes

- Current outcomes are superior to those of the original X-PERT clinical trial, suggesting the effectiveness of the programme may have improved
- The role of structured diabetes education should not be underestimated, and healthcare professionals should promote its benefits to people with diabetes to encourage attendance

Abstract

Aims: The aim of the audit was to assess the change in key health markers in people with, or at risk of, diabetes who attended X-PERT structured diabetes education.

Methods: Data from X-PERT programmes are entered into a central database. Twelve month changes in anthropometric and clinical variables – and diabetes medication usage - are reported for programmes run between 1st January 2017 and 31st December 2018. Where appropriate, paired t-tests were performed.

Results: 29,703 participants were registered to attend a programme during this period, of which 23,118 (78%) attended at least one session. Of those who attended at least one session 18,039 (78%) completed a programme. 99% (3,342) of participants with clinical data available had Type 2 diabetes. Meaningful reductions in HbA1c were seen (-8.6 mmol/mol, 95%CI -9.2 to -8.0 mmol/mol (-0.8%, 95%CI -0.8 to -0.7%); n = 2,957; p<0.001); and there were statistically significant reductions in body weight, BMI, waist circumference, fasting blood glucose, total cholesterol, LDL-c, triglycerides, total cholesterol to HDL-c ratio, and triglycerides to HDL-c ratio (all P<0.001). No change in HDL-c was observed. Of the 1,180 participants who were recorded as taking diabetes medication at baseline, 632 (54%) were able to reduce the number of medications they were taking and 278 (24%) were able to omit them entirely. Participant empowerment score increased by 20%.

Conclusions: Improvements in glycaemic control, weight management and cardiovascular disease risk, as well as reduced medication requirements and an increased feeling of empowerment, were observed in people who attended X-PERT structured diabetes education programmes.

Key words: education, health care delivery, lifestyle, nutrition and diet, self-management

Introduction

In the UK, 4.7 million people have been diagnosed with diabetes[1]. As well as the potentially serious health consequences[2], this places a huge financial burden on health services[3]. Structured diabetes education (SDE), which has been shown to be a cost-effective[4, 5] means of improving diabetes related health and wellbeing[6-10], can help to address this growing issue. SDE facilitates improved self-management, which is essential as, on average, people with diabetes spend only three hours per year with their care team[1].

SDE is included as a key priority for implementation in the National Institute of Health and Care Excellence (NICE) guidelines for the management of Type 2 diabetes in adults[11]. NICE state that such programmes should be evidence based, have a written curriculum, meet individual needs, support self-management, be delivered by trained educators, and be quality assured by an independent assessor. They also state that outcomes should be audited.

X-PERT Health is a registered charity which has provided NICE compliant SDE to more than 300,000 people. The X-PERT Diabetes and X-PERT Insulin Programmes are both delivered over six weeks; with one 2.5 hour session delivered each week by a trained educator, most commonly a NHS dietitian or nurse. The programmes are based on the principles of patient empowerment and discovery learning, with an overriding ethos of "one size doesn't fit all" - helping participants to understand their options so they can make informed choices. The X-PERT Diabetes Programme has been shown to be effective in a clinical trial[12] and in routine national implementation[13]; and was the most cost-effective in an independent review of lifestyle interventions[4]. It has previously been estimated that national implementation of the programme could result in annual savings to the NHS of £367 million[13].

In order to continue meeting NICE guidelines, and to ensure X-PERT programmes continue to be effective, outcomes are regularly audited. Outcomes for programmes delivered between 1st January 2017 and 31st December 2018 are presented here.

Participants and Methods

The current paper is a clinical audit of outcomes in adults with, or at an increased risk of, diabetes who attended X-PERT SDE between 1st January 2017 and 31st December 2018. Baseline and post-

programme data are entered into the X-PERT Audit Database by authorised users at organisations, mostly NHS trusts, licenced to deliver X-PERT programmes. Data are collected as part of routine care, thus additional ethical approval is not required. Participants are informed that their data are recorded for the purpose of audit, and are able to opt out at any stage.

Programme attendance was recorded, and participant satisfaction scores were calculated using an eight point questionnaire specifically developed for X-PERT Programmes. This questionnaire provides a satisfaction score as a percentage, where 100% is the maximum (demonstrating total satisfaction with the programme). Patient empowerment was recorded using the Diabetes Empowerment Scale-Short Form (DES-SF); a validated questionnaire[14]. Participant level data was recorded for demographic factors and, where available, for height, weight, waist circumference, systolic and diastolic blood pressure, fasting blood glucose, glycated haemoglobin (HbA1c), total cholesterol (TC), low-density lipoprotein cholesterol (LDL-c), high-density lipoprotein cholesterol (HDL-c) and triglycerides (TG). Where relevant data had been entered body mass index (BMI), waist to height ratio (WHtR), non-HDL-c, TC to HDL-c ratio, and TG to HDL-c ratio were calculated. Data on medication usage were also recorded; though data for participants with Type 1 diabetes were not included in analyses related to medication use.

The results presented here are based on changes at 12 months, unless stated otherwise. Statistical analyses were performed using IBM SPSS Statistics 25 (IBM, Armonk, NY, USA). Paired t-tests were used to assess changes, with an alpha level of $p < 0.05$ used to define statistical significance.

Results

2,304 programmes were run between 1st January 2017 and 31st December 2018. 29,703 participants were registered to attend, of which 23,118 (78%) attended at least one session. Of those attending at least one session, 18,039 (78%) completed the programme. The mean participant satisfaction score was 96%. Participant empowerment score increased by 20%, from 3.76 (out of 5) at baseline to 4.52 after Session 6.

Characteristics for participants who had data recorded at baseline and 12 months for at least one of the included health markers (n = 3,376) are presented in Table 1. There were a similar number of male and female participants (52.5% male), over half were between 55 and 74 years of age (58.1%), and

69.5% were white. The majority of participants had Type 2 diabetes (99.0%). Dividing participants based on diabetes type or the type of programme they attended did not influence the outcomes (results not included), so results from all participants were pooled.

Baseline and 12 month values for anthropometric and clinical measures are reported in Table 2. Clinically meaningful improvements in HbA1c were observed (-8.6 mmol/mol, 95%CI -9.2 to -8.0 mmol/mol (-0.8%, 95%CI -0.8 to -0.7%); n = 2,957; $p < 0.001$). Small but statistically significant changes in fasting blood glucose, body weight, BMI, WC, blood pressure (both systolic and diastolic), TC, LDL-c, Non-HDL-c, TG, TC to HDL-c ratio, and TG to HDL-c ratio were also seen ($P < 0.001$ for all). There was no change in HDL-c ($p = 0.591$).

Of the 1,607 participants whose medication use was recorded at baseline 1,180 (73%) were taking at least one medication for their diabetes. Of those taking diabetes medication at baseline, 632 (54%) were able to reduce the number of medications they were taking by 12 months (but were still taking at least one diabetes medication) and 278 (24%) were able to omit diabetes medications altogether. Medication usage was increased in 110 (9%) and remained the same in 160 (14%) of these participants. An additional 211 (13% of the 1,607 participants for whom medication usage was known) participants were recorded as having commenced medication after the onset of the programme. The percentage of participants who reported that they "always" take their medication as prescribed increased by 10.4%, from 83.8% at baseline to 94.2% by Session 6.

Discussion

HbA1c was the primary outcome in the X-PERT clinical trial[12], against which the outcomes of ongoing implementation are benchmarked. In the current analysis, the improvement in HbA1c at 12 months (-8.6 mmol/mol (0.8%)) was greater than that seen in the clinical trial at 14 months (-6.0 mmol/mol (0.5%)). Comparison with the clinical trial is essential to ensure programme standards continue to be met, so it is encouraging that routine implementation exceeds the performance of the clinical trial for this key metric. An 11 mmol/mol (1.0%) reduction in HbA1c has been associated with a 21% decrease in both the risk of diabetes related complications and in the risk of deaths related to diabetes[15]. The mean improvements in the current audit are approaching this threshold, and 932 participants (32% of those with relevant data) achieved a reduction of greater than this. This suggests that the risk of complications is significantly reduced after attendance of X-PERT SDE.

Patient empowerment is a key factor in the management of all long-term conditions, due to the high proportion of time spent self-managing one's health. In the current analysis empowerment score increased by 20%, indicating a greater degree of confidence in the participants' perceived ability to manage their own health. Other analyses of SDE have also seen improvements in empowerment related outcomes[9, 16], supporting this finding. It is likely that increased feelings of empowerment are at least partly responsible for the observed improvements in a range of health markers, but, as noted in the limitations below, it is not possible to assess this directly within the current audit.

A reduced requirement for medication provides a strong motivation for many individuals, and results in a reduction of the costs associated with the management of diabetes. In the current audit, considering only those with data available at baseline and 12 months, 910 (78%) of the 1,180 participants who were recorded as using diabetes medication at baseline were able to reduce the amount they were taking by 12 months. 278 of these (24%) were able to omit medication entirely. Diabetes medications account for approximately 12.5% of all prescription costs in England, with an average cost of diabetes medications per patient of £327.78 per year[3]. Based on this, an annual reduction of £91,122.84 in NHS expenditure would be expected for the 278 participants recorded as omitting medication in the current audit; a saving that would be increased to approximately £258 million on prescriptions alone if extrapolated to the entire population of diabetes medication users in England. Further, these estimates only include those who were able to omit diabetes medication altogether, thus further savings would be expected for those who were able to reduce their requirements but without fully omitting diabetes medications. It should however also be noted that medication was increased in 110 (9%) of participants who were taking medication at baseline, and an additional 211 were recording as having commenced medication after the onset of the programme.

Adherence to the usage of medication as prescribed was also increased in people who attended X-PERT programmes. General adherence to medications is often poor[17], so methods of improving this are important. This can also have meaningful effects, not least because improper use of some-hyperglycaemic medications can increase the risk of hypoglycaemia. Hospital admission rates for hypoglycaemia increased by 173% in England and Wales between 1999 and 2016[18], and so interventions that can help people with diabetes to take their medication in the intended manner (i.e. as prescribed) are important. Further, as severe hypos are predominantly due to the overuse of medication (particularly insulin and/or sulphonylureas), the reduction in medication requirements seen following attendance at X-PERT SDE should further alleviate the problem.

Improvements in cardiovascular disease risk factors were relatively small in the current audit, though this was likely influenced by the fact mean baseline levels were not indicative of significantly elevated risk. This in itself is noteworthy, as Type 2 diabetes is associated with an increased risk of cardiovascular disease. However, data were not available to explore the possible reasons for why this did not appear to be the case in the current audit; such as whether there may be some kind of selection bias in relation to who takes up SDE. Despite this, all health markers showed a positive change; with the exception of HDL-c, which did not change but was already within a healthy range at baseline.

Audits of this nature have a number of strengths, including the ability to assess effectiveness in a large number of people, and that they better reflect real-world effectiveness than more controlled trials do. The current analysis was also strengthened by the inclusion of a range of different outcomes. Other audits often focus on just one or two markers, omitting important relevant information such as changes in medication usage. Without this information the context of any change in blood glucose control, for example, cannot be fully considered.

There are however a number of limitations with assessments of this nature, particularly in relation to the availability of data. In order for data to be available for the current audit it must have been manually entered into the X-PERT Audit Database, even where data exists elsewhere (for example on a GP system). This data entry is not always completed however, at least in part due to the demands on the time of persons working within healthcare. Having data unavailable for a high proportion of participants presents challenges in interpreting the data. For example, at baseline, 73% of participants were recorded as taking medication for their diabetes, but medication status was only recorded for 1,607 (38.1%) of the 4,215 participants for which some individual level data was available. It is therefore difficult to assess whether the apparent finding that a high proportion of attendees of X-PERT programmes are prescribed diabetes medication at baseline is true, or whether alternative factors, such as the possibility that users of the X-PERT Audit Database may be more likely to enter medication data when the user is taking medication than when they aren't, are a better explanation for the observed data. Issues of this nature could be reduced with improvements in data sharing between healthcare providers, particularly in relation to automatic data sharing between computer systems.

An additional limitation with the current audit is in relation to how certain elements of the data are collected. For example, participant attendance and empowerment are recorded at the programme

level (i.e. an average for each programme is entered into the audit database) rather than at the individual level. This precludes in depth analysis of how these factors might influence outcomes, such as whether there is a relationship between the change in empowerment and the change in relevant health markers, or whether the specific sessions that are attended have an impact on participant results. However, as the results presented here are based on an ongoing audit rather than constituting a piece of primary research it is inevitable, for pragmatic reasons, that there will be limits to the nature and depth of the available data.

Although evidence supports the efficacy of SDE, the results of the National Diabetes Audit in the UK suggest that attendance of programmes is poor[19]. It is essential that the reasons for this are addressed. Reasons for non-attendance are diverse and complex[20], but that is not to say improvements are unobtainable. One method that can be effective is ensuring that healthcare professionals who refer patients to SDE fully understand the benefits of programmes, and that this is clearly communicated to people with diabetes[20]. Alternative modes of delivering education should also be developed in order to engage individuals who cannot, or will not, attend group sessions. Digital programmes provide an obvious platform for this, with an increasing number of options, including the X-PERT Diabetes Digital Programme, becoming available. Although there is currently less research supporting the use of digital education, early evidence provides some support for its effectiveness[21]. It is essential however that programmes, irrelevant of the mode of delivery, are evidence based and quality assured. Education, in any format with demonstrated efficacy, should be at the heart of care efforts. Only by increasing participant knowledge and empowerment do we help them to manage their health in a sustainable manner.

In conclusion, clinically meaningful improvements in blood glucose control, increased feelings of empowerment, and statistically significant improvements in markers of body weight and cardiovascular disease risk were recorded in people who attended X-PERT structured diabetes education programmes. A high proportion of the participants who were taking diabetes medication at baseline had reduced their requirements, or were able to omit it altogether, at 12 months too.

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Table 1. Participant characteristics at baseline

		Number (percentage)
Age (n = 3,237)	< 25 years	3 (0.9%)
	26-34 years	61 (1.9%)
Mean: 61.2 years (SD = 21.4)	34-44 years	280 (8.6%)
	45-54 years	577 (17.8%)
	55-64 years	895 (27.6%)
	65-74 years	988 (30.5%)
	75-84 years	394 (12.2%)
	≥ 85 years	39 (1.2%)
Sex (n = 2,790)	Male	1,465 (52.5%)
	Female	1,325 (47.5%)
Ethnicity (n = 2,712)	White	1,885 (69.5%)
	Black	91 (3.4%)
	Asian	596 (22.0%)
	Chinese	14 (0.5%)
	Mixed	44 (1.6%)
	Other	82 (3.0%)
Diabetes Type (n = 3,374)	Type 1	28 (0.8%)
	Type 2	3,342 (99.1%)
	Prediabetes	3 (0.1%)
	Other	1 (< 0.1%)
Diabetes Duration (n = 2,099)	< 1 years	231 (11.0%)
	1-5 years	1,351 (64.4%)
	6-9 years	195 (9.3%)
	≥ 10 years	322 (15.3%)
Programme Attended (n = 3,376)	X-PERT Diabetes	3,155 (93.5%)
	X-PERT Insulin	188 (5.6%)
	Other*	33 (1.0%)

* programmes specific to Type 2 diabetes prevention or low carbohydrate dietary approaches

Table 2. Anthropometric and clinical characteristics at baseline and 12 months

	Baseline (mean ± SD)	12 months (mean ± SD)	Difference (mean ± 95%CI)
HbA1c (mmol/mol) [n = 2,957]	63.1 ± 19.5	54.5 ± 14.8	-8.6* (-9.2 to -8.0)
HbA1c (%) [n = 2,957]	7.9 ± 1.8	7.1 ± 1.4	-0.8* (-0.8 to -0.7)
Fasting Blood Glucose (mmol/L) [n = 212]	7.9 ± 3.6	6.9 ± 2.7	-1.0* (-1.4 to -0.5)
Body Weight (Kg) [n = 1,987]	87.6 ± 20.6	84.9 ± 20.2	-2.7* (-3.0 to -2.4)
Body Mass Index (Kg/m^2) [n = 1,848]	31.2 ± 6.2	30.3 ± 6.2	-1.0* (-1.1 to -0.9)
Waist Circumference (cm) [n = 320]	105.6 ± 16.2	103.2 ± 16.3	-2.4* (-3.4 to -1.3)
Systolic Blood Pressure (mmHg) [n = 1,866]	130.7 ± 14.3	128.7 ± 13.5	-2.0* (-2.7 to -1.3)
Diastolic Blood Pressure (mmHg) [n = 1,862]	77.6 ± 9.5	75.9 ± 8.9	-1.6* (-2.1 to -1.2)
Total Cholesterol (mmol/L) [n = 2,407]	4.6 ± 1.2	4.2 ± 1.1	-0.4* (-0.4 to -0.3)
LDL Cholesterol (mmol/L) [n = 1,145]	2.6 ± 1.0	2.3 ± 0.9	-0.3* (-0.3 to -0.2)
HDL Cholesterol (mmol/L) [n = 1,981]	1.3 ± 0.5	1.3 ± 0.5	0.0 (0.0 to 0.0)
Non-HDL Cholesterol (mmol/L) [n = 1,898]	3.3 ± 1.2	2.9 ± 1.0	-0.4* (-0.4 to -0.3)
Triglycerides (mmol/L) [n = 1,343]	2.0 ± 1.2	1.8 ± 1.0	-0.3* (-0.3 to -0.2)

Total Cholesterol to HDL Ratio [n = 1,902]	3.9 ± 1.3	3.5 ± 1.1	-0.4* (-0.4 to -0.3)
Triglycerides to HDL Ratio [n = 1,137]	2.0 ± 1.5	1.7 ± 1.1	-0.3* (-0.4 to -0.2)

LDL = Low density lipoprotein, HDL = High density lipoprotein

* $p < 0.001$