Structured, intensive education maximising engagement, motivation and long-term change for children and young people with diabetes: a cluster randomised controlled trial with integral process and economic evaluation – the CASCADE study

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Scientific summary

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Background

Type 1 diabetes (T1D) in children and young people is increasing worldwide, with a particular increase in children aged < 5 years. Effective glycaemic control requires a careful balancing act between insulin, food and physical activity. Intensive regimens offer the best possible control; however, they are oppressive for children, young people and families. Fewer than one in six children and young people achieve glycosylated fraction of haemoglobin (HbA_{1c}) values in the range identified as providing best future outcomes. One-third have a HbA_{1c} value that puts them at significant risk for development of long-term complications. Moderate evidence supports the effectiveness of psychological interventions; however, only 20% of UK paediatric diabetes services have adequate access to psychological services.

There is an urgent need for clinic-based pragmatic, feasible and effective interventions that improve both glycaemic control and quality of life (QoL). The intervention was designed to respond to policy goals and addresses strengths and weaknesses of other approaches. The intervention offers both structured education, to ensure young people know what they need to know, and a delivery model designed to motivate self-management.

Objectives

To assess the:

1. feasibility of providing a structured psychoeducational programme in a standard clinic setting for a diverse range of young people
2. effects on long-term glycaemic control
3. impact on diabetes-specific QoL using self-report and parental measures of QoL
4. impact on psychosocial functioning including (1) emotional and behavioural adjustment of children and young people; (2) family functioning; and (3) self-management, decision-making and self-efficacy
5. cost-effectiveness.

Methods

The study was a pragmatic, cluster randomised controlled trial (RCT) with integral process and economic evaluation in 28 sites with paediatric/adolescent diabetes clinics across London, south-east (SE) England and the Midlands.

Clinics that were eligible to participate were staffed by at least one paediatrician and paediatric nurse with an interest in diabetes not running a group education programme at time of recruitment and had not taken part in a similar paediatric diabetes trial within the last 12 months. The study recruited 362 children aged 8–16 years, diagnosed with T1D for > 12 months, with a mean 12-month HbA_{1c} value of ≥ 8.5 mmol/l who had not taken part in a similar paediatric diabetes trial within the last 12 months. Children were excluded if they had a comorbid chronic illness that was likely to impact on HbA_{1c} level, were in receipt of ongoing psychiatric/psychological therapy, or had a significant learning disability or insufficient command of English to enable participation.

The intervention is a structured education programme using psychological approaches to increase engagement and enhance behaviour change in children, young people and families. It was designed to be delivered by diabetes multidisciplinary teams as part of routine care.

Randomisation

Allocation was based on clusters (paediatric diabetes services), with half randomised to the intervention and half to the control arm. Randomisation was minimised by factors that were likely to influence clinic mean HbA_{1c} value, such as age of clinic population (paediatric or adolescent) and clinic specialisation (district general hospital clinic or teaching hospital/tertiary clinic). Clinic size was added as a minimisation factor to balance numbers between arms. Allocation was concealed until after clinics had consented and a first participant was recruited to minimise selection biases at entry of clusters to the trial. Where possible, young people and families were blind to allocation until recruitment finished.

Outcomes

Primary outcome

The primary trial outcome was glycaemic control, assessed at the individual level using venous HbA_{1c} level, measured at baseline, 12 and 24 months. All samples were sent to a single UK laboratory for measurement of HbA_{1c} level, which was blind to participant allocation.

Secondary outcomes

Secondary outcomes were directly and indirectly related to diabetes management, including hypoglycaemic episodes and hospital admissions, diabetes regimen, knowledge and skills associated with diabetes management, responsibility for diabetes management, compliance with intervention and clinic utilisation, emotional and behavioural adjustment, and general and diabetes-specific QoL. Service users commented on the structure and content of questionnaires created for 8- to 12-year-olds, 13- to 16-year-olds, patients using injections, patients on pumps and carers.

Follow-up data were collected 12 and 24 months after the baseline blood sample.

Process evaluation

A mixed-methods approach was used in the integral process evaluation (PE). Specific aims of the PE were to (1) report on the feasibility and acceptability of organising and delivering groups for both staff and families; (2) assess quality and fidelity of training workshops and satisfaction for trained staff; (3) describe parent/carer and young people's perceptions of impact of participation in the intervention on themselves and their families, and views of staff regarding the impact on young people and their own practice; and (4) describe NHS paediatric/adolescent diabetes service standard care delivered across control and intervention sites. Questionnaires, semistructured interviews, informal discussion following observation sessions, fieldwork notes and case note review were used to collect qualitative and quantitative data from key stakeholder groups (University College London Hospitals trainers, site staff, young people and parents) at specific time points in the trial.

Statistical analyses

Primary and secondary analyses were intention-to-treat comparisons of outcomes at 12 and 24 months, using analysis of covariance with a random effect for clinic to allow for clustering at that level. For skewed data 95% confidence intervals (CIs) were estimated using 2000 bootstrap samples. For binary outcomes,

logistic regression was used to estimate the effect of the intervention. Prespecified subgroup analyses based on age, gender, initial HbA_{1c} value and socioeconomic status were estimated from models that included an interaction term. A per-protocol analysis of all primary and secondary outcomes was carried out with the same statistical analysis techniques used as for the intent-to-treat analysis.

Economic analysis

The economic analysis estimated the cost of the intervention, and compared long-term costs and quality-adjusted life-years (QALYs) predicted for patients receiving routine NHS care with those for patients receiving the educational intervention.

Intervention and training

The intervention consists of four modules led by a Paediatric Diabetes Specialist Nurse with an additional member of the diabetes team. The intervention uses a group education approach, with three to four families per group.

Two 1-day workshops taught delivery of the structured education programme. A detailed intervention manual and resources were provided. It was anticipated that training would increase daily use of behaviour change techniques and improve communication in health-care encounters with patients, as well as greater consideration of emotional and physical needs of young people and the social constraints of family life. The cost of the intervention included the cost of training the intervention teams.

Results

The intervention did not improve HbA_{1c} at 12 months (intervention effect 0.11; 95% CI −0.28 to 0.50; $p = 0.584$) or 24 months (intervention effect 0.03; 95% CI −0.36 to 0.41; $p = 0.891$). In total, 298 out of 362 patients (82.3%) provided blood samples at 12-month follow-up, and 284 out of 362 (78.5%) at 24-month follow-up. A total of 307 patients (85.3%) completed follow-up questionnaires at 12 months and 295 (81.5%) at 24 months. Intervention group parents at 12 months (0.74; 95% CI 0.03 to 1.52) and young people at 24 months (0.85; 95% CI 0.03 to 1.61) have higher scores on the diabetes family responsibility questionnaire. Young people in the intervention group report reduced happiness in body weight at 12 months (−0.56; 95% CI −1.03 to −0.06).

Only 68% of possible groups were run. Of the 180 families recruited, 96 (53%) attended at least one module. Reasons for low uptake included difficulties organising groups and work and school commitments. Young people with the highest HbA_{1c} levels were less likely to attend. Parents and young people who attended groups described improved family relationships, improved knowledge and understanding, greater confidence and increased motivation to manage diabetes. Twenty-four months after the intervention nearly half of the young people reported that the groups had made them want to try harder and that they had carried on trying.

A high-quality, complex, pragmatic trial of structured education can be delivered alongside standard care in NHS diabetes clinics. Health-care providers benefited from behaviour change skill training and can deliver pragmatic aspects of a National Institute for Health and Care Excellence (NICE)-compliant structured education programme after relatively brief training. The PE provides insight into aspects of the model and highlights strengths and aspects that may have contributed to the failure to influence primary and secondary outcomes. Current NHS practice dominates CASCADE (Child and Adolescent Structured Competencies Approach to Diabetes Education), in that it achieves the same number of QALYs at a lower cost. The mean cost of providing the intervention was £5098 per site or £683 per child.

The CASCADE study shows that a high-quality, complex, pragmatic trial of structured education can be successfully conducted alongside standard care in NHS diabetes clinics. We were able to recruit teams and patients from clinical services reflecting a wide range of philosophies and research experience throughout London, SE England and the Midlands. The pragmatic components of a NICE-compliant structured education programme can be successfully delivered following a relatively brief two-day training workshop whilst paediatric health-care professionals benefit from training in behaviour change skills. The intervention has been evaluated in 'real-life' and representative settings, and provides invaluable information on barriers and opportunities regarding future, similar interventions. A low dropout rate and good attendance for the subgroup that attended the intervention, as well as reported impact by this group, strengthens the findings of the study, but, however, suggests there might be improved uptake if offered to young people with lower HbA1c. Understanding why 37% chose not to attend is another important area. Testing whether or not this approach can be more successful with a robust ongoing supervisory element should be a target of further research.

Trial registration

This trial is registered as ISRCTN52537669.

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