

Development and evaluation by a cluster randomised trial of a psychosocial intervention in children and teenagers experiencing diabetes: the DEPICTED study

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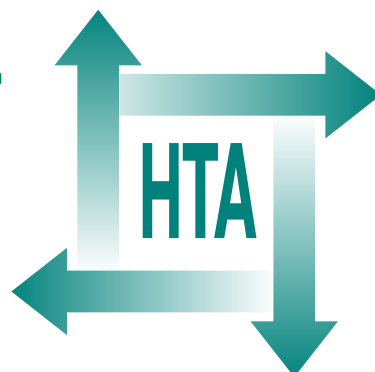
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Executive summary

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Executive summary

Background

Children and teenagers with type 1 diabetes frequently experience suboptimal glycaemic control, which may be improved by changes in their self-management. Previous systematic reviews of psychoeducational interventions have shown modest improvements in glycosylated haemoglobin (HbA_{1c}) levels and psychosocial outcomes, although there is little evidence of their clinical effectiveness and cost-effectiveness in a UK setting. We have previously demonstrated in both a pilot and a randomised controlled trial (RCT) that motivational interviewing is effective in facilitating behaviour change in teenagers with diabetes, leading to falls in their HbA_{1c} levels. However, techniques such as these require trained therapists. Owing to the shortage of trained psychologists, there is a need to improve the skills of paediatric diabetes health-care professionals (HCPs) in counselling their patients and carers during routine clinical encounters, particularly in relation to issues requiring behaviour change.

Objectives

1. To survey existing evidence regarding the effectiveness of psychoeducational interventions applied in paediatric diabetes services.
2. To assess children's and their families' expectations from consultations with HCPs working in children's diabetes services.
3. To develop a training package for paediatric diabetes HCPs to help them counsel their patients and families more skilfully during routine health-care encounters, particularly in relation to issues requiring behaviour change.
4. To evaluate the effect of communication skills training for HCPs on HbA_{1c} levels and psychosocial outcomes on patients and on the latter in their carers.
5. To evaluate the costs associated with this intervention.

Methods

This project consisted of a developmental phase during which the communication skills training programme was developed, followed by a trial phase in which the effectiveness of the training was evaluated.

Developmental phase

1. Telephone survey of 112 UK hospital trusts providing paediatric diabetes services to establish past and current practice in relation to psychoeducational interventions.
2. Postal survey of 385 HCPs working in 67 UK paediatric diabetes services to evaluate the feasibility and acceptability of training options.
3. Six focus groups involving children and teenagers with diabetes and their carers to establish their perceptions of living with diabetes and expectations from health-care encounters with their paediatric diabetes services.
4. Identification of recent publications of psychoeducational interventions in childhood diabetes.
5. Observational study of clinic consultations in three paediatric diabetes services. Presentation of findings and the evolving intervention and training programme for critical review and

modification on three occasions to a specially constituted lay and professional Stakeholder Action Group (SAG).

6. Role play and experimental consultations to test the feasibility, acceptability and face validity of the developing intervention.
7. Design, developing and piloting the training programme.

Trial phase

Setting

A cluster RCT in 26 paediatric diabetes services in England and Wales.

Study population, case definition and study criteria

Six hundred and ninety-three children, aged 4–15 years, with type 1 diabetes of at least 1 year's duration and one of their carers were recruited. Children were excluded if they were in the care of social services, experiencing a comorbid chronic illness that is likely to impact on HbA_{1c} levels independent of the patient's ability to manage diabetes, in receipt of ongoing psychiatric/psychological therapy at the start of the study or were judged by their clinical carer to be vulnerable because of an existing medical or social condition.

Baseline measures

For patients, baseline measures included sociodemographic factors (age, gender, ethnicity), measures of physical health [HbA_{1c} levels, hypoglycaemic episodes, body mass index (BMI), insulin regimen, duration of diabetes]. For patients and carers the baseline measures included a set of quality-of-life (QoL) and psychosocial measures, comprising diabetes-specific QoL, self-care (mismanagement questions relating to diet, number of injections and monitoring), patient enablement and patient perceptions of the diabetes team – importance of, and confidence in, their ability to undertake diabetes care and monitoring activities (patients aged > 11 years only).

Randomisation

Allocation was based on clusters (i.e. paediatric diabetes services), with half randomised to the intervention and half to the control arm, in three phases, balanced for patient list size. It was planned that patients would be approached and recruited before services knew which arm of the study they had been allocated to, but in practice this was not always possible.

Outcome measures

The primary trial outcome was change in HbA_{1c} levels between the start and finish of a 12-month study period. Secondary trial outcomes included change in QoL, other clinical (including BMI) and psychosocial measures (assessed at participant level as listed above) and cost (assessed at service level).

In addition, patient details (HbA_{1c} levels, height, weight, BMI, insulin regimen), health service contacts and patient-borne costs were recorded at each clinic visit, along with details of who patients consulted with, for how long, and whether or not patients consulted on their own at each visit. Patients and carers were also asked to complete an interim questionnaire assessing patient enablement (or feelings towards clinic visit for younger patients aged 7–10 years) at their first clinic visit following the start of the trial. The cost of the intervention included the cost of training intervention teams.

Statistical analyses

The primary and secondary analyses were intention-to-treat comparisons of outcomes using multilevel modelling to allow for cluster (service) and individual effects and involved two-level linear models. No interim analyses were undertaken.

The economic element of the study also involved the assessment of preferences for delivery of care, using a discrete choice experiment (DCE) administered as a separate questionnaire at 1 year only.

Intervention and training

The intervention involved training teams using a blended learning programme, including web-based training and interactive workshops. It was anticipated that this would produce changes in the style of communication in health-care encounter with patients (including the use of an agenda-setting tool).

Results

Developmental phase results

Health-care professionals described using a combination of advice, education, listening and shared goal-setting to help encourage their patients to change behaviour. However, they also reported limited previous experience of communication training and less confidence ($p < 0.001$) in discussing psychosocial than medical issues despite the perception of their greater importance than medical issues ($p < 0.001$). One-day workshops and computer-based learning were deemed feasible options for training. Focus group work confirmed that patients and their carers felt that HCP communication skills were poor, with patients undertaking passive roles and a need for joint agenda-setting identified. The SAG contributed to the design of the evolving intervention and training programme (particularly the design of the agenda-setting tool and DCE questionnaire) and the planned trial to assess its effectiveness.

The training intervention for HCPs was a blended learning programme involving web-based interactive modules and two 1-day workshops. Participants were then asked to reflect on three consultations in which the skills had been applied.

Trial-phase results

There was no effect of the training of HCPs on the primary trial outcome of HbA_{1c} level in patients attending their services ($p = 0.5$), even although throughout the follow-up period trained staff showed better skills than controls in agenda-setting and consultation strategies (including greater use of the guiding style), albeit waning from 4 to 12 months. Although gender was significantly associated with follow-up HbA_{1c} levels, adjusting for age and gender did not alter the results.

With respect to secondary outcomes, patients in intervention services experienced a loss of confidence in their ability to manage diabetes, whereas controls showed, surprisingly, reduced barriers ($p = 0.03$) and improved adherence ($p = 0.05$). Patients in intervention services reported short-term increased ability ($p = 0.04$) to cope with diabetes. Carers in the intervention arm experienced greater excitement ($p = 0.03$) about clinic visits and improved continuity of care ($p = 0.01$) without the adverse effects seen in their children.

Despite perceptions of longer subsequent consultations, a follow-up process evaluation showed that none of the intervention sites had increased allocated clinic time, and practitioners in control groups also reported that consultations were regularly over-running the allocated times.

The mean cost of training was £13,145 per site or £2163 per trainee. There was no significant difference in total NHS costs (including training) between groups ($p = 0.1$).

Conclusions

Implications for health care

1. The training of HCPs as developed in the Development and Evaluation of a Psychosocial Intervention for Children and Teenagers Experiencing Diabetes (DEPICTED) trial cannot be recommended to achieve short-term (1-year) impacts on HbA_{1c} levels and QoL.
2. Practitioners nevertheless remain keen to improve their consulting skills and the lack of impact of the HCPs' improved communication skills implies that either more training to increase and reinforce skill levels or more contact with patients is required to produce a benefit on outcomes.
3. Given the limited effectiveness of the diabetes clinic staff in optimising their patients' glycaemic control and addressing psychosocial issues, continued involvement of clinical psychologists in paediatric services remains important.

Recommendations for research (in priority order)

1. To examine how communication skills can be practised, maintained and further improved in a cost-effective manner during routine clinical practice.
2. To evaluate the effect on glycaemic control and psychosocial outcomes of contact time during consultations between HCPs and their patients.
3. To explore the effectiveness and added value of incorporating reflective listening into the existing training package.
4. To follow up the effect on HbA_{1c} levels of an intervention based on the principles of the DEPICTED study over a longer time period, such as 2 years.

Trial registration

This trial is registered as ISRCTN61568050.

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Publication

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