Developing and evaluating a child-centred intervention for diabetes medicine management using mixed methods and a multicentre randomised controlled trial

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Scientific summary

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Scientific summary

Background

The Evidence into Practice Information Counts (EPIC) project was conducted alongside the parallel children’s Information Matters Project (IMP) (NIHR 08/1745/145), which researched the practice of and requirements for age-appropriate health information for children and young people. In type 1 diabetes (T1D), clinical guidelines indicate that high-quality, child-centred information underpins the achievement of optimal insulin management and glycaemic control with the aim of minimising acute readmissions and reducing the risk of complications in later life. Comprehensive, accessible and timely information about both risks and benefits and decision support are imperative if children and young people are to be active partners in decision-making about diabetes management and self-care choices.

The IMP was designed to explore these issues more broadly in common childhood long-term conditions, including diabetes. A lack of child-centred research has hampered the development of effective interventions to optimise long-term self-management and minimise the risk of complications.

The EPIC project was conceived to address the lack of appropriate children’s diabetes information and a diabetes diary in routine NHS care and to generate evidence of what works concerning delivery and use of diabetes information and diaries as a way of enabling children and young people to engage in optimal self-care with a focus on insulin management. The overarching aim of the multiple strands of work was to develop and evaluate an individually tailored, age-appropriate diabetes diary and information pack for children and young people aged 6–18 years with T1D to support decision-making and self-care with a specific focus on insulin management and electronic blood glucose monitoring, compared with available resources in routine clinical practice.

Type 1 diabetes is one of the most common chronic conditions in childhood, with a current estimated prevalence of one per 700–1000 children in the UK, giving a total population of 25,000 under-25s with T1D. The incidence in children under 5 years doubled between 1985 and 1995 and in children under 15 years there is an overall increase of around 4% each year. Children with T1D need individual insulin regimes, monitoring of their blood glucose levels four to six times a day and close attention to a healthy diet and exercise.

This report describes primary and secondary research undertaken to develop a range of child-centred diabetes information resources and describes the outcome of a pragmatic randomised controlled trial (RCT) to evaluate the effectiveness and cost-effectiveness of the EPIC diabetes information packs, including a diabetes diary, in routine practice.

Objectives

1. To review gold standard diabetes clinical guidelines, currently available diabetes information, including findings from the linked qualitative IMP project, to identify best practice, and types/formats of information most likely to assist age-appropriate decision-making and choices concerning blood glucose monitoring and insulin management.

2. To develop an age-appropriate diabetes information intervention (child-centred diabetes diary and information pack) for children and young people to support the appropriate use of blood glucose monitoring to optimise management of and concordance with their insulin regime.
3. To explore the utility of the child-centred diabetes diary and information pack (in this context utility refers to ease of use and fitness for purpose) within different contexts in which children and young people manage their routine diabetes care (home, school, community), with and without support from parents or health-care professionals (HCPs), and in alternative settings.

4. To explore how children and young people with and without their parents, teachers, nurses or doctors use (or not) the diabetes diary and information pack to support decision-making, in particular how children and parents ‘self-prescribe’ the correct (or incorrect) dose of insulin.

5. To identify similarities and differences between the diabetes diary and information pack developed for adolescents and those available within adult diabetes services.

6. To evaluate the diabetes diary and information pack within the context of routine diabetes care in relation to patient outcomes (diabetes-specific health-related quality of life, generic health-related quality of life, medicine and treatment concordance, acceptability, ease of use and glycaemic control).

7. To identify gaps in knowledge to inform a future research agenda.

**Theoretical frameworks**

In developing and evaluating a children’s diabetes information pack and diabetes diary we drew on the same three theoretical frameworks as in the IMP: a biopsychosocial and anthropological model of childhood and illness management; the Promoting Action on Research Implementation in Health Services framework; and the Medical Research Council (MRC) framework for developing and evaluating complex interventions.

At the conclusion of the IMP we developed two theoretical models and a proposition to describe the critical success factors for partnership and participation between children, parents and health professionals and services, and successful implementation of children’s health information in routine clinical practice. These two theoretical models and the proposition are used in the trial process evaluation to help interpret the findings and specifically to explain why the EPIC pack and diary did not have the desired effect on children’s diabetes outcomes.

**Methods**

To meet our objectives, which are aligned with the phases of the MRC framework for RCTs of complex interventions, a four-stage study was designed.

**Stage 1: context**

We conducted multiple strands of investigation to focus our understanding on the context of children’s diabetes care, including:

- a review of reviews and mixed-method systematic review of the barriers to and enablers of optimal diabetes self-care by children and young people in educational settings
- further searching for currently available children’s diabetes information to add to the database constructed for the IMP
- an extension and update of the IMP comparative analysis to establish whether key health messages in children’s diabetes information matched with diabetes clinical guidelines
- extension and refocusing the critical discourse analysis on diabetes to investigate content and meaning of selected currently available children’s diabetes resources.
Stage 2: intervention development – diabetes diaries and information packs

In addition to incorporating evidence from the IMP and conducting stage 1 of this study, we carried out further strands of investigation and consultation including:

- convening an expert clinical advisory group to advise on intervention development and clinical risk management
- undertaking qualitative interviews and focus groups with children and young people to ascertain their information preferences and self-care practices with an emphasis on children who had spent time away from their families
- obtaining children’s and young people’s perspectives on various iterations of the age-appropriate diabetes diary and information pack (web consultation and stall at diabetes charity family days).

Children’s diabetes information resources produced for the trial

In an iterative approach, integrating findings from the linked IMP and building throughout stages 1 and 2, we produced the following range of resources that can be individually tailored for pragmatic evaluation in routine clinical practice (stage 3):

- three diabetes diaries for children and young people using insulin injections (6–10 years, 11–15 years and 16–18 years)
- one diabetes diary (6–18 years) for children and young people using insulin pumps
- child-friendly sheets for recording carbohydrate intake
- three age-appropriate information packs containing published diabetes information bound in an age-appropriate folder (6–10 years, 11–15 years and 16–18 years)
- stickers (6–10 years) and stickers and marker pens (11–15 years) for children to personalise their folder.

We then applied to the National Institute for Health Research (NIHR) for permission to brand the diaries with the official NIHR logo, which was granted. Finally, selected clinical experts were asked to formally sign off the EPIC packs and diaries as being suitable for use in the NHS.

A detailed intervention programme theory was developed. Critical discourse analysis of current children’s diabetes information revealed a dominant discourse of ‘normalisation’ of medicine management and medicines as a social enabler, conveyed in a sometimes authoritarian way to children and young people through diabetes texts. A logic model was developed to show the implementation of the EPIC diabetes resources within routine diabetes care and existing diabetes clinical guidelines and care pathways.

Stage 3: randomised controlled trial to evaluate the diabetes diaries and information packs in routine practice

We designed and carried out a pragmatic RCT to assess the effectiveness and cost-effectiveness of the diabetes diaries and age-appropriate information packs in routine practice.

Stage 4: process evaluation

As the trial did not detect an intervention effect, we used the process evaluation to help explain the outcome. For the process evaluation we collected the following strands of evidence:

- interviews with HCPs in each site to document current routine practice and local clinical care pathways for children with T1D
- a baseline survey to determine the ethnic profile of trial participants
- baseline postcode analysis to determine the index of deprivation of trial participants
- qualitative interviews with children and parents to ascertain their experiences and perspectives
- a questionnaire completed by HCPs at the conclusion of the trial to ascertain their perspectives.
Findings

Randomised controlled trial and economic analysis
The RCT achieved 100% recruitment, was adequately powered and showed that the EPIC packs and diabetes diaries were no more effective than receiving diabetes information in an ad hoc way. The costs per unit of producing the child-centred and age-appropriate EPIC packs and diabetes diaries were low.

Compared with treatment as usual information, which may not, the EPIC packs fulfilled all NHS policy imperatives that children and young people should receive high-quality, accurate and age-appropriate information about their condition, self-management and wider lifestyle and well-being issues. As children’s diabetes practice recommends that children should use a diabetes diary as part of their diabetes care pathway and daily self-management, EPIC diaries fill a gap in current provision.

Process evaluation
Irrespective of allocation, children and young people in the EPIC RCT had a range of recorded glycated haemoglobin (HbA1c) levels, which showed that as a group their diabetes self-management would generally need to improve to achieve the HbA1c levels recommended in National Institute for Health and Care Excellence guidance. This concurs with the recent report on children’s outcomes that highlighted the need for children in England to have better control over their diabetes and lower HbA1c levels.

Inappropriate dominant theory underpinning children’s diabetes information
The discourse of ‘normalisation’ of medicine management and medicines as social enablers as key messages conveyed in a sometimes authoritarian way to children and young people through diabetes texts appears to be counterproductive with some children and young people. Findings point to an extra textual context of the relationship between children, parents and diabetes professionals as one possible reason why there seems to be a lack of ‘compliance’ to what children and young people, and sometimes parents, are being told and what diabetes professionals ‘expect’ of them. It is this tension in the relationship between these parties that may partly explain why some children, young people and parents become less interested in ‘optimal diabetes self-care and management’ as they grow older. It may be that children and young people just get fed up with the regimen and having life seemingly defined by diabetes and 3-monthly clinic visits, despite discourses which claim that life can be ‘normal’, but only if they do as they are told by adults.

Children’s ignorance of risky behaviour and long-term complications of diabetes
Very few children’s diabetes information resources that we located – especially for younger children – said anything about serious risks and long-term complications of poorly managed diabetes. In contrast, diabetes information produced for adults was explicit about the risks of long-term complications and the need to optimally self-manage to mitigate these risks.

Many children and young people interviewed were taking risks with their diabetes-related health but did not convey any significant degree of concern about the potential consequences; indeed, many teenagers appeared uninterested. Some parents wanted to protect their children from receiving information about risks and complications whereas others wanted to expose their children to the actual reality of serious life-threatening complications such as renal failure.

Non-use or inappropriate use of a diabetes diary
The diabetes diary is considered an essential tool for children and young people to record and observe trends and titrate their insulin dose. Irrespective of allocation, children – especially older children – mostly did not use a diabetes diary to record their blood glucose levels and insulin management. Many children and young people did not see the need to have this important information to titrate their insulin and appeared to think that they were recording this information for the benefit of diabetes professionals.
Promotion of the EPIC packs and diaries at randomisation not happening as intended

Although diabetes professionals were intended to actively promote and explain the pack and its optimal use by children at home, in reality the EPIC packs were mostly given to children by research nurses and not referred to in routine clinical encounters again. Minimal individualisation of packs occurred.

Service delivery and organisational issues

The current model of diabetes service delivery does not easily accommodate time for ongoing active facilitation or promoting children’s diabetes information as part of routine ongoing care.

Conclusions and recommendations

Other recently completed trials of interventions to promote children’s diabetes self-management conducted in the NHS have found no difference in outcomes. Optimising children’s diabetes care and self-management remains an unresolved challenge. The key unresolved question is what would work to improve children’s diabetes self-management.

Our findings clearly indicate a need to rethink context and the hierarchical relationships between children, young people, parents and diabetes professionals with regard to ‘partnership and participation’ in diabetes decision-making, self-care and self-management.

Additional research, implementation strategies and service redesign are needed to enable children, young people, parents and diabetes professionals to translate the available information into optimal self-management knowledge and subsequent optimal diabetes self-management action, including to:

- better understand the disconnection between children’s diabetes text and context
- develop age-appropriate Apps and e-records as an option for recording blood glucose measurements and insulin management
- develop interventions to reduce risk-taking behaviour by children and young people in relation to their diabetes management
- reconsider what could work to optimise children’s self-management of diabetes
- understand how best to reorganise currently available children’s diabetes services to optimise child-centred delivery of children’s diabetes information and services.

Study registration

This study is registered as Current Controlled Trials ISRCTN17551624.

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