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

Jane P Noyes,[1]* Lesley Lowes,[2] Rhiannon Whitaker,[3]
Davina Allen,[2] Cynthia Carter,[4] Rhiannon T Edwards,[5]
Joanne Rycroft-Malone,[1] Janice Sharp,[6]
Deborah Edwards,[2] Llinos Haf Spencer,[1]
Yvonne Sylvestre,[3] Seow Tien Yeo[5]
and John W Gregory[7]

[1]Centre for Health-Related Research, Bangor University, Bangor, UK
[2]School of Healthcare Sciences, Cardiff University, Cardiff, UK
[3]North Wales Organisation for Randomised Trials in Health (NWORTH), Bangor University, Bangor, UK
[4]Cardiff School of Journalism, Media and Cultural Studies, Cardiff University, Cardiff, UK
[5]Centre for Health Economics and Medicines Evaluation, Bangor University, Bangor, UK
[6]Media Resources Centre, University Hospital of Wales, Cardiff, UK
[7]Department of Child Health, Wales School of Medicine, Cardiff University, Cardiff, UK

*Corresponding author

Declared competing interests of authors: Professor John Gregory has received payments from Pfizer, Bayer and Ipsen for lectures, development of educational presentations and travel/accommodation to attend scientific meetings and advisory board meetings. His employer (Cardiff University) has also received funding from Novo Nordisk to support the development of patient-support materials used in the Development and Evaluation of a Psychosocial Intervention for Children and Teenagers Experiencing Diabetes (DEPICTED) research study. Novo Nordisk provided financial support for Dr Lesley Lowes to attend the 38th meeting of the International Society for Paediatric and Adolescent Diabetes (ISPAD) but she has no other financial relationships with commercial entities that might have an interest in the submitted work, or any non-financial interests that may be relevant to the submitted work.

Published March 2014
DOI: 10.3310/hsdr02080

Scientific summary

Child-centred intervention for diabetes medicine management

Health Services and Delivery Research 2014; Vol. 2: No. 8
DOI: 10.3310/hsdr02080

NIHR Journals Library www.journalslibrary.nihr.ac.uk

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 (HbA_{1c}) levels, which showed that as a group their diabetes self-management would generally need to improve to achieve the HbA_{1c} 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 HbA_{1c} 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.

Funding

The National Institute for Health Research Health Services and Delivery Research programme.

Health Services and Delivery Research

ISSN 2050-4349 (Print)

ISSN 2050-4357 (Online)

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

The full HS&DR archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hsdr. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Services and Delivery Research* journal

Reports are published in *Health Services and Delivery Research* (HS&DR) if (1) they have resulted from work for the HS&DR programme or programmes which preceded the HS&DR programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

HS&DR programme

The Health Services and Delivery Research (HS&DR) programme, part of the National Institute for Health Research (NIHR), was established to fund a broad range of research. It combines the strengths and contributions of two previous NIHR research programmes: the Health Services Research (HSR) programme and the Service Delivery and Organisation (SDO) programme, which were merged in January 2012.

The HS&DR programme aims to produce rigorous and relevant evidence on the quality, access and organisation of health services including costs and outcomes, as well as research on implementation. The programme will enhance the strategic focus on research that matters to the NHS and is keen to support ambitious evaluative research to improve health services.

For more information about the HS&DR programme please visit the website: www.netscc.ac.uk/hsdr/

This report

The research reported in this issue of the journal was funded by the HS&DR programme or one of its proceeding programmes as project number 08/1704/211. The contractual start date was in April 2008. The final report began editorial review in October 2012 and was accepted for publication in March 2013. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HS&DR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).

Health Services and Delivery Research Editor-in-Chief

Professor Ray Fitzpatrick Professor of Public Health and Primary Care, University of Oxford, UK

NIHR Journals Library Editor-in-Chief

Professor Tom Walley Director, NIHR Evaluation, Trials and Studies and Director of the HTA Programme, UK

NIHR Journals Library Editors

Professor Ken Stein Chair of HTA Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

Professor Andree Le May Chair of NIHR Journals Library Editorial Group (EME, HS&DR, PGfAR, PHR journals)

Dr Martin Ashton-Key Consultant in Public Health Medicine/Consultant Advisor, NETSCC, UK

Professor Matthias Beck Chair in Public Sector Management and Subject Leader (Management Group), Queen's University Management School, Queen's University Belfast, UK

Professor Aileen Clarke Professor of Health Sciences, Warwick Medical School, University of Warwick, UK

Dr Tessa Crilly Director, Crystal Blue Consulting Ltd, UK

Dr Peter Davidson Director of NETSCC, HTA, UK

Ms Tara Lamont Scientific Advisor, NETSCC, UK

Professor Elaine McColl Director, Newcastle Clinical Trials Unit, Institute of Health and Society, Newcastle University, UK

Professor William McGuire Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads Honorary Professor, Business School, Winchester University and Medical School, University of Warwick, UK

Professor Jane Norman Professor of Maternal and Fetal Health, University of Edinburgh, UK

Professor John Powell Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK

Professor James Raftery Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts Professorial Research Associate, University College London, UK

Professor Helen Snooks Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Please visit the website for a list of members of the NIHR Journals Library Board:
www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: nihredit@southampton.ac.uk