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Evidence into Practice: evaluating a Child-centred intervention for diabetes medicine management

Submission date	Recruitment status	[X] Prospectively registered
12/06/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/06/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/02/2015	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0001653

Study information

Scientific Title
Evidence into Practice: evaluating a Child-centred intervention for diabetes medicine management

Acronym
EPIC

Study objectives
Little evidence exists concerning the effectiveness of the types and formats of information that could empower children to make decisions regarding medicines and self-care. For children with type one diabetes, intensive structured education programmes exist, however there is insufficient evidence about the effectiveness of information underpinning these programmes or routine clinical management.

Aim:
To develop and evaluate an individually-tailored, age-appropriate information resource to support decision-making and self-care relating to insulin management and electronic blood glucose monitoring for children aged 6 - 18 years with type one diabetes, compared with available resources (if any) in routine clinical practice.

Objectives:
1. Review gold-standard clinical guidelines, currently available information including findings from completed Phase 1 of current SDO/145/2007 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. Develop an age-appropriate child-centred information resource for children/young people, to support appropriate use of blood glucose meters to optimise management of and concordance with their insulin regime
3. Explore the utility of the resource within different contexts in which children manage their routine diabetes care (home, school, community) with and without support from parents or healthcare professionals, and in alternative settings
4. Explore how children with and without their parents, teachers, nurses, doctors use (or not) the information resource to support decision-making; in particular how children/parents 'self-prescribe' the correct (or incorrect) dose of insulin
5. Identify similarities and differences between the resource developed for adolescents and those available within adult diabetes services
6. Evaluate the resource within the context of routine diabetes care in relation to patient outcomes (diabetes-specific, health-related quality-of-life concordance, acceptability, ease of use, and glycaemic control)
7. Identify gaps in knowledge

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval pending as of 12/06/2008.

Study design
Pragmatic randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Type one diabetes

Interventions
The investigation is a mixed-method study informed by the 'Promoting Action on Research Implementation in Health Services' (PARIHS) framework which has been widely used to inform design and evaluation of evidence-into-practice initiatives.

To meet our objectives which are aligned with the phases of the Medical Research Council (MRC) framework for randomised controlled trials (RCTs) of complex interventions we have designed a four-stage study:
Stage 1: Review and, where appropriate, undertake further work to identify types/formats of information most likely to assist age-appropriate decision-making/choices related to children /young people with type one diabetes. Duration: April 2008 to October 2008.
Stage 2: Construct an exemplar information resource, piloting for variations as necessary. Duration: November 2008 to October 2009.
Stage 3: Conduct a pragamatic evaluation to assess utility, acceptability effectiveness and cost effectiveness of the information resource. Duration: November 2009 to June 2010.
Stage 4: Undertake data synthesis and comparative analysis. Duration: July 2009 to March 2011.

The intervention lasts for 8 months with a follow-up at 3 months from baseline and 3 months from first follow-up.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Choice of outcomes is guided by Health Technology Assessment (HTA) commissioned systematic reviews recommending that HbA1c (glycaemic control measure) is not the appropriate primary outcome on which to assess benefits of an intervention designed to more directly effect behaviour/self-management. Therefore, the primary outcome measure is diabetes self-efficacy and quality-of-life using the Diabetes Pediatric Quality of Life Inventory (PedsQol).

Outcomes will be measured at baseline, 3 months (follow-up 1) and 6 months (follow-up 2).

Secondary outcome measures
1. HbA1c
2. Generic quality of life
3. Routinely collected NHS/child-held data costs
4. Service use
5. Acceptability/utility

Outcomes will be measured at baseline, 3 months (follow-up 1) and 6 months (follow-up 2).

Overall study start date
01/02/2009

Completion date
01/09/2010

Eligibility

Key inclusion criteria
1. Children aged 6 - 18 years, either sex
2. Type one diabetes

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria

1. Severe learning difficulties
2. Significant social problems
3. Needle phobias

Date of first enrolment
01/02/2009

Date of final enrolment
01/09/2010

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Nursing, Health and Social Care Research Centre
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University/education

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ROR
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Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Service Delivery and Organisation (SDO) Programme (ref: 0001653)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	27/09/2010		Yes	No
Results article	results	01/03/2014		Yes	No