

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

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<b>Registration date</b> 23/06/2008	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 03/02/2015	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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

### **Study type(s)**

Quality of life

### **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 pragmatic 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(s)**

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).

### **Key secondary outcome(s)**

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).

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 years

**Upper age limit**

18 years

**Sex**

All

**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  
Cardiff

United Kingdom  
CF24 0AB

## Sponsor information

### Organisation

Cardiff University (UK)

### ROR

<https://ror.org/03kk7td41>

## 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

### 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?
<a href="#">Results article</a>	results	01/03/2014		Yes	No
<a href="#">Protocol article</a>	protocol	27/09/2010		Yes	No