ISRCTN61568050 https://doi.org/10.1186/ISRCTN61568050

Development and Evaluation of a Psychosocial Intervention for Children and Teenagers Experiencing Diabetes

Submission date
15/02/2007

Recruitment status
No longer recruiting

Registration date
16/02/2007

Overall study status
Completed

Last Edited
16/01/2018

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof John Gregory

Contact details
Department of Child Health
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XN
+44 (0)29 20 747747
gregoryjw@cardiff.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 03/46/09

Study information

Scientific Title
Development and Evaluation of a Psychosocial Intervention for Children and Teenagers Experiencing Diabetes

Acronym
DEPICTED

Study objectives
The primary objective of the study is to determine whether a psychosocial intervention can improve clinical and psychological outcomes for children and teenagers experiencing diabetes. The intervention comprises a training programme for non-psychologist members of a paediatric diabetes team, incorporating the use of a patient agenda setting tool. The secondary objectives of the study are: 1) to evaluate the cost effectiveness of a psychosocial intervention for children and teenagers with diabetes; 2) to assess skill retention, competency and confidence of non-psychologist members of the paediatric diabetes team, in delivering the intervention.

More details can be found at http://www.hta.ac.uk/1450

Ethics approval required
Old ethics approval format

Ethics approval(s)
An application for ethical approval for the study (cluster-randomised multi-centre trial) has been submitted to the Thames Valley MREC. Decision pending (ref: 07/MRE12/9).

Study design
Cluster randomised trial of a psychosocial intervention for young people with diabetes involving 24 UK paediatric diabetes clinics.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Paediatric diabetes (type 1)

Interventions
Please note that, as of 16 January 2008, the start and anticipated end date of this trial have been updated from 1 April 2007 and 31 December 2008 to 1 June 2005 and 31 March 2009, respectively.

Interventions:
The intervention under study comprises two components: an agenda-setting tool for patients and parents (consisting of a rigid folder and a pad of tear-off sheets) and training paediatric diabetes care clinicians to incorporate the tool into routine care, and to conduct conversations about behaviour change in relation to diabetes management. The agenda-setting tool will enable patients and parents to set the agenda for consultations and identify the topics they feel are most important in terms of disease management. Clinician training will enable the diabetes care team to talk about behaviour change and psychosocial issues related to management, and to guide patients and parents in using the tool.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome measure for patients is glycaemic control assessed using HbA1c at 1 year.

Secondary outcome measures
For diabetes care teams:
1. Competency in delivery of the psychosocial intervention immediately, 3 months and 1 year post training
2. Importance and confidence in conducting behaviour change discussions during consultations (before and after training and at 1 year)
3. Systemic service changes (including consultation times, and telephone/home contacts)

Clinical outcomes for patients at each clinic visit:
1. Height, weight, Body Mass Index (BMI)
2. Insulin type, dose and number of injections
3. Hypoglycaemic episodes

Psychosocial outcomes for patients at study entry and 1 year:
1. Diabetes-specific quality of life (Pediatric Quality of Life Inventory [PEDSQoL diabetes module]; Problem Areas in Diabetes [PAID: emotional impact]; global quality of life measure)
2. Diabetes self-care (items relating to mis-management)
3. Self-efficacy (perceived competency scale)
4. Patient enablement (coping)
5. Perceptions of diabetes care team (Health Care Climate Questionnaire [HCCQ]; items relating to communication between clinicians, feelings towards next visit, continuity of care)
6. Preferences for care (as measured by a Discrete Choice Experiment)

Psychosocial outcomes for parents/guardians at study entry and 1 year:
1. Parent quality of life/anxiety (Problem Areas in diabetes; global quality of life item)

2. Perceptions of diabetes team (HCCQ: items relating to communication between clinicians, feelings towards next visit, continuity of care)
3. Preferences for care (Discrete Choice Experiment)

Parent-completed proxy measures (for children aged 5-11):
1. Diabetes specific quality of life (PEDSQoL diabetes module; Problem Areas in Diabetes; global quality of life item)
2. Diabetes self care (mis-management)

Service use and cost outcomes:
1. Cost of intervention (including training)
2. Travel to clinic
3. School absences
4. Time off work (parent)
5. In-patient admissions (including Intensive Therapy Unit [ITU] and High Dependency Unit [HDU], particularly with ketoacidosis)
6. Accident and Emergency (A&E) attendances
7. Clinic attendances
8. Contacts with the diabetes team (home, telephone, electronic)
9. Other health service contacts (GP attendances, any other)
10. Medication/equipment use (insulin type & dose; testing strips; lancets; analysis strips; hypostop/glucogel/glucagon)

Overall study start date
01/06/2005

Completion date
31/03/2009

Eligibility

Key inclusion criteria
For teams/clinics:
Teams include a paediatrician with an interest in diabetes and a diabetes specialist nurse

For patients:
1. Type 1 diabetes
2. Aged 4-15
3. Under care of diabetes team for duration of trial
4. Diagnosed more than 1 year ago
5. Parental/guardian and child consent (or assent where appropriate) given
6. ability of patient and at least one parent/guardian to complete study materials (questionnaires)

Children aged 4-15 will be included to reflect as broad a range of patients as possible. Young people aged 16+ may be in transition between paediatric and adult services at some point during the trial and are therefore excluded. Data collected from questionnaires is crucial to determining the effectiveness of the intervention. However, questionnaires are only available in English, as measures included have not been validated in other languages: this would be beyond the scope of the current study.

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
15 Years

Sex
Not Specified

Target number of participants
700 patients across 24 centres

Key exclusion criteria
For teams/clinics:
<40 potentially eligible children/adolescents (diagnosed more than 1 year ago) attending the clinic

For patients:
1. Not under care of parent or guardian (i.e. a looked after child)
2. Co-morbid chronic illness likely to impact on HbA1c independent of patient's ability to manage their diabetes (e.g. condition requiring steroid treatment, cystic fibrosis, renal failure)
3. In receipt of ongoing psychiatric/psychological therapy at the start of the study
4. Other patients judged by their clinical carer to be vulnerable due to existing medical or social condition

Criteria have been designed in order to be as inclusive as possible. Clinics with less than 40 patients will be excluded due to practicalities of recruiting sufficient patient numbers (30 per clinic) and fewer than 40 patients is not felt to constitute an adequate size for a specialist children's service. It is unfortunately not feasible to recruit children under a care order, due to the practical difficulties of obtaining appropriate consent: this is felt to be outside the scope of the current study. However, patients attending clinics where health professionals have undergone training are likely to benefit from increased awareness of psychosocial issues.

Date of first enrolment
01/06/2005

Date of final enrolment
31/03/2009

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Department of Child Health
Cardiff
United Kingdom
CF14 4XN

Sponsor information

Organisation
Cardiff University (UK)

Sponsor details
-
Cardiff
Wales
United Kingdom
CF10 3XQ

Sponsor type
University/education

Website
http://www.cf.ac.uk/index.html

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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	09/02/2010		Yes	No
Results article	results	01/08/2011		Yes	No