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Maximising engagement, motivation and long-term change in a structured intensive education programme in diabetes for children, young people and their families: Child and Adolescent Structured Competencies Approach to Diabetes Education

Submission date
08/10/2007

Recruitment status
No longer recruiting

Registration date
08/10/2007

Overall study status
Completed

Last Edited
13/06/2016

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol
Background and study aims
Managing diabetes within a full and active life is challenging for both children and young people. Despite parental support and 'expert' education many children and young people struggle to control their diabetes. Combining educational and psychological approaches can achieve long term-change, particularly in young people with poorly controlled diabetes who have not responded to other approaches. Children, young people and families have been involved in developing a structured psycho-educational programme with the UCLH diabetes teams. Four monthly group sessions will be offered to 3-4 similarly aged young people (and parents). The aim is to develop confidence in the use of flexible self-management approaches, including how to adapt the amount of insulin given, eat normally and manage daily challenges (e.g. exercise, illness, and holidays). The programme is acceptable to a broad range of families and can be delivered within a busy clinical service. For 170 families attending our clinics there has been a steady and consistent improvement in diabetes control that is maintained over time.

Who can participate?
Children and young people (aged 8-16) and their families from 26 participating clinics

What does the study involve?
Clinical Nurse Specialists at 13 randomly chosen clinics attend training workshops. Children and young people and their families from the participating clinics are invited to participate in the programme and a two-year follow-up. We assess how acceptable the programme is, ease of delivery, participation and impact on health-related quality of life, self-management behaviour,

emotional, behavioural and family functioning, and service use. The costs of the programme are compared to the economic impact of improvements in diabetes control and reduced risk of long-term complications.

What are the possible benefits and risks of participating?
In the short term, improving participants' control of their diabetes may also improve general well-being. In the longer term improvement in diabetes control may reduce their later risk of complications of diabetes. There are no risks involved in the study.

Where is the study run from?
University College London Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2008 to December 2012

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
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Study website
http://www.cascadestudy.com/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 06/44/05

Study information

Scientific Title
Maximising engagement, motivation and long-term change in a structured intensive education programme in diabetes for children, young people and their families: Child and Adolescent Structured Competencies Approach to Diabetes Education

Acronym
CASCADE

Study objectives
There is a significant increase in the number of children and young people diagnosed with diabetes. The current estimate of prevalence in the UK is 1 per 700 - 1000 children yielding a total population aged under 25 of approximately 15,000 - 25,000. The peak age for diagnosis is between 10 and 14 years of age.

The long-term complications of diabetes include microvascular and macrovascular disease, reduced life and higher cardiovascular and all-cause mortality. Complications are often first detected in adolescence. Improved diabetes control from diagnosis in childhood can reduce the incidence and progression of microvascular complications including retinopathy, nephropathy and neuropathy. Overall metabolic control in children and adolescents has improved little in the UK in the past decade. Only 14 - 20% of children and young people with type 1 diabetes meet the recommended HbA1c of less than 7.5%.

CASCADE, is a competency-driven, motivational and patient-centred structured intensive psycho-educational programme specifically designed by our team to improve diabetic control, self-management and quality of life in children and adolescents. CASCADE is a complex intervention and our proposed investigation is based on the Medical Research Council (MRC) complex intervention evaluation framework. We have already conducted the Phase I study (Modelling - defining components of the intervention) and Phase II study (Exploratory Trial Phase). We now propose a Phase III large multi-centre cluster randomised controlled trial with integral process and economic evaluation to investigate the effectiveness of CASCADE.

Our extensive experience in teaching and training will be used to identify the time and resources required to train members of the study centres which will be incorporated into the economic modelling process.

Research objectives:
1. To assess the feasibility of the proposed structured intensive educational programme provided within a standard clinic setting for a diverse range of young people
2. To investigate the effects of the above intervention on long term metabolic control of diabetes
3. To evaluate the impact of the intervention on diabetes-specific quality of life using:
3.1. Well validated and reliable self report and parental measures of quality of life in children and young people
3.2. Specific measures of parental quality of life
4. To investigate the impact of the intervention on psychosocial functioning including:
4.1. Emotional and behavioural adjustment of children and young people

4.2. Family functioning
4.3. Self-management, decision making and self-efficacy
5. To investigate the cost effectiveness of the intervention

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/064405
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0017/51443/PRO-06-44-05.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Joint UCL/UCLH Committees on the Ethics of Human Research (Committee A), 11/07/2007, ref: 07/H0714/112

Study design
Multi-centre cluster randomised control trial with integral process and economic evaluation

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
http://cascade.lshtm.ac.uk/information.html

Health condition(s) or problem(s) studied
Diabetes

Interventions
Structure of CASCADE intervention: The intervention is delivered in 4 group sessions, delivered monthly over a 4 month period. Children will be grouped by age (either 8 -11 or 12 -16 years) and participate in groups with 3 - 4 families per group. A developmentally appropriate curriculum supports flexible self-management in partnership with the young person, their diabetes regimen and their family. The programme focuses on achievement of increasing competency in self-management of diabetes using eight competency levels. The Kaufman competencies were developed at the Childrens Hospital, Los Angeles as an 8-stage competency system surrounding diabetes knowledge and skills (including adaptation of insulin dosage, carbohydrate counting and management of daily challenges (e.g., exercise, illness and/or holidays). This system was developed to assess suitability for intensive therapy using Continuous Subcutaneous Insulin Infusion (CSII), but is applicable to all current insulin regimens. The competency level of each child can be used to ensure that the psycho-educational programme is delivered in a flexible and developmentally appropriate manner.

Components of CASCADE:
CASCADE is consistent with the five key criteria necessary to fulfill the National Institute for Clinical Excellence (NICE) requirements for a structured diabetes education programme. These are patient centred philosophy, structured curriculum, trained educators, quality assured and audited.

CASCADE module content:
Module 1: Living with diabetes - challenges and choices
Module 2: Blood sugar testing - the pros and cons
Module 3: Adjusting insulin doses - the pros and cons
Module 4: HELP with food, activity and exercise - a Healthy Eating Lifestyle Plan

Each module will include the following educational and motivational structure:
1. Identify learning objectives: Trainers invite families to identify recent aspects of diabetic management that have gone well to encourage them to see themselves as experts in their diabetes and to help them identify strengths, resources and abilities. Participants are encouraged to identify what they would find useful or helpful to discuss and think about during the session. This ensures that participants collaborate in the identification of learning objectives
2. Addressing ambivalence: Desired behaviour change choices are discussed using motivational enhancement techniques that address ambivalence. Participants identify the pros and cons of behaviour change acknowledging that any change in behaviour will have both costs and benefits. Motivational interviewing focuses on encouraging the individual to identify the personal and systemic benefits of the desired behaviour to them and their family
3. Externalising: Externalising language encourages participants to characterise the diabetes as something that is external to the individual and therefore controllable. This creates opportunities for young people and families to work with the health care professionals by identifying ways to take control of diabetes rather than it being something that controls them

Pre and post session knowledge will be evaluated as well as inviting feedback on how useful and helpful the session has been and what actions the young person plans to initiate in between sessions.

Control arm:
Control families will continue to receive standard care from their clinical team, being regular 3-monthly clinic visits and telephone contact as required with the clinical nurse specialist and consultant. The process evaluation will monitor and describe standard care as well as the new intervention being tested.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in HbA1c between baseline and 12 months after intervention.

NB. It is not possible to directly evaluate the effects of the intervention on diabetes complications because of low incidence during adolescence.

Secondary outcome measures

1. HbA1c at 24 months: the HbA1c measurement at 24 months post intervention will be examined as a secondary outcome assessing maintenance of effect
2. Economic evaluation: this will include within-trial cost-effectiveness analysis and a cost-utility analysis based on a model combining data from the trial with data from the literature. The perspective adopted will be that of the NHS, that is, the economic evaluation will only consider costs to the NHS and health benefits to patients
3. Psychosocial outcomes (using validated instruments appropriate for age):
3.1. Health related Quality Of Life (QOL): PedsQL with Diabetes module
3.2. Self-Efficacy in Diabetes scale
3.3. Diabetes Family Responsibility Questionnaire
3.4. Strengths and Difficulties Questionnaire (parent and child report versions)
4. Diabetes outcomes directly related to patient management:
4.1. Kaufman Competency level
4.2. Diabetes regimen (insulin delivery/number of injections/insulin types)
4.3. Hypoglycaemic episodes (frequency, severity)
4.4. Admissions to Hospital and reason (e.g. episodes of ketoacidosis, hypoglycaemia)
5. Diabetes outcomes indirectly related to patient management: knowledge and skills associated with diabetes
6. Compliance with intervention/control:
6.1. Attendance at intervention sessions
6.2. Service utilisation rate
6.3. Clinic attendance
6.4. Number of contacts with diabetes nurse specialists and diabetes teams

Process evaluation:
The study will incorporate an integral process evaluation, similar to other trials conducted by Social Service Research Unit (SSRU). The overall aims of this will be to:
1. Monitor the implementation (including extent of uptake) of the intervention in experimental clinics and any alternative intervention received by young people and families attending control clinics
2. Document factors influencing the implementation of the intervention
3. Identify components of the intervention which contribute to its effectiveness
4. Assess the acceptability of the interventions to young people, parents and clinic staff
5. Examine perceived impact of the intervention on outcomes

Specific issues that will be addressed include:
1. The quality of training for clinic staff and satisfaction with this
2. The extent to which the sessions with young people and families are delivered as intended and according to underlying principles and theories (e.g. patient centred and non didactic, motivational and solution focused), barriers and facilitating factors to the uptake and engagement with the different components of the sessions by young people and families (e.g. structural such as timing of sessions, accessibility of clinics, and interpersonal such as views about relevance of content, qualities of educators)
3. Perceived impact of the sessions on management of the condition by young people and their parents. This might include examining how decisions are made and responsibilities for different aspects of the condition-management are shared, including transfer of responsibilities and changing patterns of self-care by the young person in different contexts (e.g. during school time, at home)
4. Issues such as whether interventions should be targeted for different age groups, for the different disease stages, or for young people with different types of diabetes management problems will also be explored

Overall study start date
01/05/2008

Completion date
31/12/2012

Eligibility

Key inclusion criteria
Current inclusion criteria as of 16/10/2012:
1. Subjects 8 - 16 years with type 1 diabetes
2. HbA1c greater than or equal to 8.5 (defined as mean 12 month HbA1c greater than or equal to 8.5%)
3. Cared for in participating paediatric and adolescent diabetes clinics (defined as clinic specific for paediatric and/or adolescent diabetes conducted by a specialist or general paediatrician with an interest in diabetes)

An average of 40 - 50 young people per clinic will be eligible to take part in the study with an expected recruitment rate of 25% based on our pilot study.

Previous inclusion criteria until 16/10/2012:
An average of 80 - 100 young people per clinic will be eligible to take part in the study with an expected recruitment rate of 25% based on our pilot study.

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
28 clinics, 308 children and young people

Key exclusion criteria
1. Subjects with significant mental health problems unrelated to diabetes that require specific mental health treatment
2. Subjects with significant other chronic illness in addition to diabetes that may confound the results of the intervention
3. Subjects with significant learning disability or lack of command of English sufficient to render them unable to participate effectively in the planned intervention. Note that there is research evidence from this population that the great majority of eligible young people from black or

minority ethnic groups in this population have good command of English, although their parents may not. Given the wide range of ethnicities in the sample population, and given the importance of group dynamics to the intervention, it will not be possible to use interpreters to enable parents with poor English to participate. We will ensure that the validity of the study is maintained by the following:
3.1. Young people with good command of English but whose parents have poor command of English will be eligible to attend by themselves if they wish
3.2. Another relative who is one of the primary diabetes carers (e.g. sibling, aunt or uncle) who has good command of English may participate instead of the parents

While inclusive elsewhere, we will not recruit clinics that are unlikely to be able to recruit sufficient participants with a good command of English. We anticipate that this pertains to only one clinic within our sample area.

Date of first enrolment
01/05/2008

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London Hospital
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
http://www.uclh.nhs.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	15/09/2009		Yes	No
Results article	results	01/03/2014		Yes	No
Results article	results	01/06/2016		Yes	No