ISRCTN13331558 https://doi.org/10.1186/ISRCTN13331558

Diabetes education for adolescents

Submission date	Recruitment status	[ ] Prospectively registered
14/02/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/04/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/04/2017	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

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
N/A

Study information

Scientific Title

Evaluation of a structured education programme for adolescents with type 1 diabetes

Acronym
Choice (CHO Insulin Collaborative Education)

Study objectives
1. Does a structured education programme for adolescents improve glycaemic control, perceived quality of life, perceived empowerment and management strategies at 1, 3, 5, 12 and 24 months post-intervention?
2. Does improved ability to manage diabetes in adolescence lead to weight gain?
3. Can the educational intervention be sustained in routine clinical practice?
4. What is the estimated cost of running the structured educational programme compared with the cost of routine care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Committee in Northern Ireland (ORECNI), 01/12/2006, ref: 06/NIR01 /114. A major amendment was approved in November 2007.

Study design
Multi-centre 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 1 diabetes

Interventions
A multi-centre randomised controlled trial (RCT) to evaluate the efficacy of a structured education programme for adolescents with type 1 diabetes involving four sites over 18 months. Individuals will be followed up for 24 months.

Control group:
The protocols for usual care across the four sites have been collated and are consistent in their delivery. Usual care includes three monthly clinic visits in which adolescents will see a physician

and a specialist nurse; if required they will also visit the dietitian. Diabetes control is reviewed, education is focused on problem solving and safety issues. All those randomised to the control group will continue to receive usual care and will also be asked to complete the data gathering instruments and allow access to clinical results. If found to be effective the educational programme will be offered to all those in the control group.

Intervention group:
The structured programme developed in Germany (Muhlhauser et al, 1987; Jörgens et al, 1993) is the basis for the educational intervention. It has been translated into English and modified for UK use by the pharmaceutical company Roche. The content of the package is being specifically tailored for adolescents allowing for their lifestyle and need to respond to peer pressure and to be socially accepted. It focuses on the carbohydrate content of food and drinks, the interaction of carbohydrates and insulin requirements, timing of food and the effects of exercise on blood glucose levels and insulin. Ways in which insulin adjustment can be achieved with both twice daily and multiple bolus injections are being developed. Other topics include the effects of alcohol and so-called recreational drugs on metabolic control and finally, management during ill health.

Analyses:
Demographic data:
A profile of participants in terms of age, gender, duration of diabetes and current school status will be recorded. This will be gathered at baseline only.

Clinical data:
Clinical data to include treatment regimen, self-monitoring practices, HbA1c results, documented hypogylycaemia, body mass index (BMI), weight and height for use with growth charts, frequency of clinic attendance and missed appointments will be collected from study participants pre- and post-intervention. A proforma will be developed to facilitate rapid documentation of the required data. No extra blood tests will be asked of the participants.
Clinical data will be gathered prior to the intervention at two points in time pre-intervention:
Time 1: most recent set of recorded results
Time 2: from 3 - 6 months earlier
Post-intervention data will be collected at months 1, 3, 5, 12 and 24.

Psychosocial outcomes:
Three instruments have been combined into a single booklet that the participants complete for themselves; it is brief and easy to complete:
1. Quality of life: this instrument comprises three scales:
1.1. Diabetes life satisfaction
1.2. Disease impact
1.3. Disease-related worries
This instrument is short, uses closed questions and can be rapidly completed.
2. The profile of self-management: it is adapted from the work of Anderson and colleagues at the Michigan Diabetes Research and Training Center. From the complete profile the following are included:
2.1. Section IV: Understanding (1 question)
2.2. Section VI: Control problems scale (6 questions)
2.3. Section VII: Social and personal factors scale (4 questions)
2.4. Section VIII: Attitudes towards diabetes scale (questions 11, 12 and 13 - 17)
2.5. Section IX: Diet adherence scale (8 questions)
2.6. Section XII: Monitoring barriers and understanding management practice scales (4 questions)
3. The Diabetes Empowerment Scale - short form (DES-SF): this instrument comprises eight items

Psychosocial data will gathered at baseline and post-intervention data will be collected at months 1, 3, 5, 12 and 24.

Sustainability in routine practice:
This will be estimated using qualitative methodology. A SWOT Analysis (Strengths, Weaknesses, Opportunities and Threats) will be performed by the research team and will include key stakeholders at the end of the post-intervention follow-up stage (around month 30 of the project timetable).

Joint sponsors:
1. Western Health and Social Care Trust (UK)
2. South East Health and Social Care Trust (UK)
3. Belfast Health and Social Care Trust (UK)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
HbA1c

See interventions section above for details of timepoints.

Secondary outcome measures
1. Weight gain
2. Self-management strategies
3. Quality of life
4. Empowerment
5. Hypoglycaemic episodes
6. Completion rate

See interventions section above for details of timepoints.

Overall study start date
01/03/2008

Completion date
01/09/2011

Eligibility

Key inclusion criteria
1. Adolescents of either sex between the ages of 13-19 years
2. Have been diagnosed with diabetes for no less than 12 months

Every effort will be made to include all adolescents who wish to form part of the study population.

Participant type(s)

Patient

Age group
Child

Lower age limit
13 Years

Upper age limit
19 Years

Sex
Both

Target number of participants
180

Key exclusion criteria
1. Adolescents who have been diagnosed for less than 12 months
2. Other medical conditions affecting diabetes management
3. Adolescents with a registered learning disability
4. Intensive involvement of social services with the family (verified in medical notes)
5. Psychiatric admission in past 6 months
6. Diagnosis of psychosis
7. Documented behavioural difficulties/disorder in the adolescents medical notes where a referral has been made for further specialist help
8. Major depression managed by anyone other than the adolescents general practitioner (GP), e. g. psychiatry
9. Documented substance abuse disorder
10. Documented eating disorder or suspected eating disorder in adolescents medical notes
11. History of self-harm documented in the adolescents medical notes

Date of first enrolment
01/03/2008

Date of final enrolment
01/09/2011

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre

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ROR
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Funder(s)

Funder type
Charity

Funder Name
Diabetes UK (UK) - phase 1 patient education learning materials funded by Roche (ref: BDA: RD06 /0003340)

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