

A randomised controlled trial to determine whether family centred structured education improves blood glucose control in adolescents with type 1 diabetes

Submission date
26/11/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
10/03/2008

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
19/10/2012

Condition category
Nutritional, Metabolic, Endocrine

☐ 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Version 1.0 23 April 2007

Study information

Scientific Title

Acronym

FACTS 2 - Family's and Adolescent's Communication and Teamwork Study

Study objectives

Does structured education with family communication training help adolescents with type 1 diabetes to improve blood glucose control?

FACTS 1 study results in <http://www.ncbi.nlm.nih.gov/pubmed/17894831>

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Suffolk Research Ethics Committee (REC) on 15 August 2007 (ref: 07/H0307/67)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Type 1 diabetes

Interventions

Family centred structured education programme (intervention) vs standard outpatient care (control)

The key activities of the programme are:

6 x 90 min small group sessions at monthly intervals over 6 months with parents and adolescents seen together. It includes a combination of skills based and family-communication based

sessions addressing blood glucose monitoring, food flexibility, insulin dose adjustment, hypoglycaemia, sports, school issues, challenges during adolescence, family communication and conflict resolution. It has a written philosophy and curriculum with a programme for training and quality development of the educators.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Glycaemic control (HbA1c) at 12 months follow-up

Secondary outcome measures

1. Frequency of hypoglycaemia. Duration of follow-up: 12 months
2. Quality of Life and Family Responsibility questionnaire measures (Paediatric Quality of Life Inventory [PedsQL], Diabetes Family Responsibility [DFRQ], Problem Areas in Diabetes [PAID]) at 6 months

Overall study start date

24/10/2007

Completion date

01/09/2010

Eligibility

Key inclusion criteria

Adolescents with type 1 diabetes aged 11-16 years old

Participant type(s)

Patient

Age group

Child

Lower age limit

11 Years

Upper age limit

16 Years

Sex

Both

Target number of participants

300

Key exclusion criteria

Serious medical or psychological co-morbidity which would limit ability to participate in the group education sessions.

Date of first enrolment

24/10/2007

Date of final enrolment

01/09/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Diabetes Centre

Ipswich

United Kingdom

IP4 5PD

Sponsor information

Organisation

The Ipswich Hospital NHS Trust (UK)

Sponsor details

Heath Road

Ipswich

England

United Kingdom

IP4 5PD

+44 1473 704343

research.office@ipswichhospital.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.ipswichhospital.org.uk/>

Funder(s)

Funder type

Charity

Funder Name

Diabetes UK

Alternative Name(s)

DIABETES UK LIMITED, British Diabetic Association

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

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?
Results article	results	01/08/2012		Yes	No