

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

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
26/11/2007	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
10/03/2008	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
19/10/2012	Nutritional, Metabolic, Endocrine	

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

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

Study type(s)

Quality of life

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(s)

Glycaemic control (HbA1c) at 12 months follow-up

Key secondary outcome(s)

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

Completion date

01/09/2010

Eligibility

Key inclusion criteria

Adolescents with type 1 diabetes aged 11-16 years old

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

11 years

Upper age limit

16 years

Sex

All

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

United Kingdom

England

Study participating centre

Diabetes Centre

Ipswich

United Kingdom

IP4 5PD

Sponsor information

Organisation

The Ipswich Hospital NHS Trust (UK)

Funder(s)

Funder type

Charity

Funder Name

Diabetes UK

Alternative Name(s)

The British Diabetic Association, 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

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?
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[Results article](#)

results

01/08/2012

Yes

No