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Brief Intervention for Type 1 diabetes: Education for Self efficacy

Submission date	Recruitment status	[_] Prospectively registered
04/06/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/06/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/10/2009	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jonathan Thow

Contact details
York Hospital
Wigginton Road
York
United Kingdom
YO318HE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BITES1

Study information

Scientific Title

Acronym
BITES

Study objectives
Our hypothesis was that the effectiveness of a brief (2.5-day) psycho-educational intervention for self-management in people with type 1 diabetes in a realistic clinical out-patient setting would be comparable to that of established longer interventions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by York Research Ethics Commitee. Ref: 01/08/016

Study design
Pragmatic, randomised controlled trial. Secondary care setting.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Type 1 diabetes

Interventions
Brief Intervention in Type 1 Diabetes:
Education for Self-Efficacy Course (BITES), developed by a multi-disciplinary team including Consultant Diabetologist, Diabetes Specialist Nurse, Specialist Diabetes Dietician and Clinical Health Psychologist, and delivered as a 2.5-day course over a 6-week period to allow participants time to practice and reflect between sessions. The sessions were facilitated by a Diabetes Specialist Nurse and Specialist Diabetes Dietician.

The goal of BITES is to motivate and enable the patients to strive for blood glucose values as normal as possible. All those agreeing to participate will be asked to convert to a basal bolus insulin regime based on two injections of isophane insulin (morning and evening) and meal-related rapid acting insulin. Insulin dose adjustment skills will be based on the Dusseldorf and DAFNE (Dose Adjustment For Normal Eating) principles of treatment to target glucose and insulin matching to carbohydrate portions. The nutritional emphasis will be on normal eating and unrestricted patient choice.

The control group recieved standard care.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The following were meausred at 3, 6 and 12 months:
1. HbA1c
2. Severe Hypoglycaemia

Secondary outcome measures
The following were meausred at 3, 6 and 12 months:
1. Blood pressure
2. Weight
3. Height
4. Total cholesterol
5. Triglycerides
6. Psychological questionnaire with the following scales:
6.1. Short Form 36
6.2. Illness Perception Questionnaire (IPQ)
6.3. Diabetes Knowledge Test (DKT)
6.4. Diabetes Empowerment Scale (DES)
6.5. Diabetes Treatment Satisfaction Questionnaire (DTS-Q)
6.6. Hypoglycaemia Fear Scale (HFS)
6.7. Diabetes Health Profile (DHP)
6.8. Diabetes Self-Managing Adherence questionnaire (DSMA-Q)

Overall study start date
01/06/2003

Completion date
01/07/2007

Eligibility

Key inclusion criteria
Participants were recruited from the Diabetes Centre of York Health Services NHS Trust.
Eligibility criteria were:
1. Type 1 diabetes for longer than 12 months
2. Multiple injection therapy for at least two months
3. Minimum age 18
4. Able and willing to participate in the intervention

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Children under age 18
2. Type 1 for less than 12 months
3. Incapacity to participate fully in the programme

Date of first enrolment
01/06/2003

Date of final enrolment
01/07/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
York Hospital
York
United Kingdom
YO318HE

Sponsor information

Organisation
York Hospitals NHS Foundation Trust (UK)

Sponsor details
York Hospital
Wigginton Road
York
England

United Kingdom
YO318HE

Sponsor type
Hospital/treatment centre

Website
http://www.yorkhealthservices.org/

ROR
https://ror.org/027e4g787

Funder(s)

Funder type
Government

Funder Name
York NHS Trust Research and Development Innovation Fund. (UK) (Ref 01/08/016)

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	14/09/2007		Yes	No
Results article	Results	01/12/2008		Yes	No