

# Brief Intervention for Type 1 diabetes: Education for Self efficacy

**Submission date**  
04/06/2007

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☒ Protocol

**Registration date**  
07/06/2007

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
13/10/2009

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Jonathan Thow

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York  
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## 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 Committee. 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?
<a href="#">Protocol article</a>	Protocol	14/09/2007		Yes	No
<a href="#">Results article</a>	Results	01/12/2008		Yes	No