

Developing a Dose Adjustment For Normal Eating (DAFNE) structured education course for adults with Type 1 diabetes incorporating insulin infusion pump start

Submission date
21/05/2010

Recruitment status
No longer recruiting

Prospectively registered

Registration date
21/05/2010

Overall study status
Completed

Protocol

Statistical analysis plan

Results

Last Edited
12/09/2016

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

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Additional identifiers

Protocol serial number

7480

Study information

Scientific Title

Developing a Dose Adjustment For Normal Eating (DAFNE) structured education course for adults with Type 1 diabetes delivering the skills to undertake both DAFNE insulin adjustment and continuous subcutaneous insulin infusion: pilot study

Acronym

DRN 385 (DAFNE Pump Pilot study)

Study objectives

1. To establish that both the skills of DAFNE insulin dose adjustment, and use of an insulin infusion pump can be taught during a 5-day outpatient course
2. To ensure that the proposed outcome measures (biomedical, psychosocial, additional measures for a health economic analysis) can be collected during the 5 day course
3. To establish the proportion of patients on established DAFNE waiting lists who would be prepared to be randomised to either a standard course or one in which pump training is given
4. To obtain data on change in the primary outcome measure (HbA1c) to confirm power calculations for the main randomised controlled trial (RCT)
5. To validate the algorithms in the DAFNE programme which have been modified to exploit the facilities of continuous subcutaneous insulin infusion

Ethics approval required

Old ethics approval format

Ethics approval(s)

Sheffield REC, 24/04/2009, ref: 09/H1398/39

Study design

Multicentre randomised interventional process of care and treatment trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Diabetes Research Network; Subtopic: Type 1; Disease: Diabetic Control, Education

Interventions

Intervention: a DAFNE educational course, 5 day, outpatient, skills training course, incorporating the additional training necessary to teach participants to use an insulin infusion pump (CSII) as therapy for diabetes.

Comparator: standard DAFNE education course (DAFNE course plus multiple injections of insulin as therapy for diabetes).

The standard DAFNE educational course is held over 5 consecutive days (full day) with a 2 hour visit at 6 weeks for a recap of course core details.

Both arms:
Follow-up length: 6 months post-course
Study entry: single randomisation only

Intervention Type

Mixed

Primary outcome(s)

Change in HbA1c %, measured at baseline and 6 months post-course

Key secondary outcome(s)

1. Change in psychological outcome, specifically reduction in anxiety and depression scores on Hospital Anxiety and Depression Scale (HADS), measured at baseline and 6 months
2. Changes in weight, measured at baseline and 6 months
3. Diet related behaviours, measured at baseline and 6 months
4. Number and severity of hypoglycaemic episodes, measured at baseline, 6 weeks post-course and 6 months post-course

Completion date

15/03/2010

Eligibility

Key inclusion criteria

1. T1DM of at least 1 year's duration
2. Waiting to attend a standard DAFNE skills 5 day course
3. Aged 18 - 80 years, either sex
4. Not been treated by continuous subcutaneous insulin infusion pump for the last four years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Factors which will impair participation in group education, i.e., non-English speaking
2. Evidence of an eating disorder
3. Previous significant experience of pump therapy (greater than 6 months in the last 4 years)

Date of first enrolment

16/09/2009

Date of final enrolment

15/03/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Royal Hallamshire Hospital

Sheffield

United Kingdom

S10 2JF

Sponsor information

Organisation

Sheffield Teaching Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/018hjpz25>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

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?
Results article	results	01/12/2014		Yes	No