ISRCTN04179596 https://doi.org/10.1186/ISRCTN04179596

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 [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/05/2010	**Overall study status** Completed	
Last Edited 12/09/2016	**Condition category** 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Secondary outcome measures
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

Overall study start date
16/09/2009

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

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 64; UK sample size: 64

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
England

United Kingdom

Study participating centre
Royal Hallamshire Hospital
Sheffield
United Kingdom
S10 2JF

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

Sponsor details
Research Department
1st Floor
11 Broomfield Road
Sheffield

England
United Kingdom
S10 2SE

Sponsor type
University/education

Website
http://www.sth.nhs.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

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	01/12/2014		Yes	No