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Implementing and evaluating a structured education programme and a new model of ongoing care for type 1 diabetes: the Irish Dose Adjustment For Normal Eating (DAFNE) study

Submission date
08/01/2007

Recruitment status
No longer recruiting

Registration date
09/02/2007

Overall study status
Completed

Last Edited
16/06/2014

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Studies of diabetes care in Ireland suggest that good blood sugar control is being achieved only by a minority of patients. Medical care for a person with type 1 diabetes is usually delivered in hospital outpatient clinics and frequently involves healthcare professionals telling patients how much to adjust their insulin doses. Patients frequently lack good self-management skills. The Dose Adjustment for Normal Eating (DAFNE) programme was developed in the UK and is delivered to groups of patients with type 1 diabetes. In an evaluation in the UK the programme led to a marked improvement in blood sugar control at 6 months but this improvement diminished considerably by 12 months, probably because patients were unable to maintain the skills that they acquired. This study aims to introduce a new model of group education after patients have completed the DAFNE programme, emphasising self-management. The study will compare this new model of group education support with traditional one-to-one clinic visits. The group support model will be based on peer support and expert patient input. This study has the potential to change the way that diabetes care is delivered and to introduce a new model of chronic disease management in Ireland.

Who can participate?
Patients who are already on waiting lists to complete a DAFNE course in Diabetes Centres in Ireland and Northern Ireland are able to take part. Patients must be over 18 years old, with type 1 diabetes and with a HbA1c of less than 13%.

What does the study involve?
Patients will be randomly allocated to receive either DAFNE and group support follow-up or DAFNE and one-to-one clinic visits. We will measure blood sugar control, frequency of hypoglycaemia (low blood sugar reactions), patient well-being and satisfaction with care (assessed using questionnaires). We will undertake in-depth interviews with some of the

patients to explore how the programme influences a persons life with diabetes. We will do a health economic analysis to ensure that the extra cost of delivering DAFNE pays for itself in terms of improvement in health outcomes.

What are the possible benefits and risks of participating?
Studies have reported that patients usually enjoy being involved in research. People who take part will help to answer the important question of how best to support patients after they complete a structured education programme like DAFNE.

Where is the study run from?
The study will be run from the Diabetes Centre in University Hospital Galway (Ireland).

When is the study starting and how long is it expected to run for?
The study started in January 2007 and finished in September 2011.

Who is funding the study?
The Health Research Board (Ireland).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HS-05-25

Study information

Scientific Title
Implementing and evaluating a structured education programme and a new model of ongoing care for type 1 diabetes: the Irish Dose Adjustment For Normal Eating (DAFNE) study - a randomised controlled trial

Acronym
DAFNE Ireland

Study objectives
The long-term objectives of this work are to embed structured education for patients with type 1 diabetes in the Irish Health Service and to develop a more patient-centred approach to ongoing diabetes care. This will be accomplished through collaborative work within Ireland (North and South) and with centres in the UK experienced in delivering the DAFNE self-management education programme. These objectives will be accomplished through the following specific aims:
1. To develop a new model of ongoing care for DAFNE graduates based on group follow-up and peer support
2. To undertake an exploratory trial comparing this new model of care (group follow-up of DAFNE graduates) with usual care, i.e. a return to one-to-one clinic visits following DAFNE training
3. To incorporate a health economic analysis to inform future policy making
4. To undertake in-depth interviews on a subset of DAFNE graduates to explore their understanding and experiences of participating in DAFNE and to explore the factors that facilitate or hinder self-management following DAFNE training and how these might change over time and in light of receiving 'usual' versus group follow-up

On 13/02/2009 the scientific title was added. Recruitment finished in December 2008. 450 participants have been enrolled to date and are through baseline.

On 20/07/2010 the end date of this trial was extended from 31/12/2009 to 30/09/2011.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Galway Regional Hospital Research Ethics Committee, approved in January 2006
2. National University of Ireland, Galway (NUIG) Research Ethics Committee, approved in July 2006
3. Royal NHS R&D, approved on 20/09/2006
4. Central Office for Research Ethics Committees, approved on 07/11/2006
5. Beaumont Ethics Committee, approved in January 2007

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
After obtaining informed consent participants will be assigned to the next available DAFNE course in their participating centre. Prior to commencement of the course, baseline data will be collected. If a change to a basal/bolus insulin regimen is required this will be undertaken over the weekend prior to DAFNE training. Participants assigned to usual care will be offered appointments at a diabetes clinic at 6 and 12 months after DAFNE training. These visits will not be structured but efforts will be made to have patients seen by the educator(s) and doctor who participated in their DAFNE training.

Those individuals assigned to the group follow-up arm of the study will receive their follow-up in the original group in which they underwent DAFNE training. Visits will be arranged as close as possible to 6 and 12 months after the course and will be facilitated by one of the group's original 2 DAFNE educators. The curriculum developed in the first phase of the project will be used during these sessions.

An experienced DAFNE educator will combine delivery of a curriculum with a patient-centred approach to priority setting and problem solving. Each group follow-up session will last approximately 2 hours.

Three self-administered questionnaires will be used to measure wellbeing and quality of life. These will be administered at baseline and again at 6, 12 and 18 months after recruitment. Forms will be completed in the diabetes centre as part of a visit to measure study outcomes.

In a subset of participants an in-depth interview will be undertaken to explore the impact that DAFNE training has on the participants' ability to live with and self-manage their diabetes.

In a subset of participants follow-up telephone interviews will be used to establish how the different models of follow-up care being delivered in the study impact on participants' ability to self-manage their diabetes.

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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Longitudinal change in mean HbA1c level between baseline and follow-up.

Added as of 17/02/2009: All primary and secondary outcomes will be assessed at 6, 12 and 18 months.

Secondary outcome measures
1. Rates of severe hypoglycaemia
2. Change in weight and psychological measures of wellbeing and quality of life

Added as of 17/02/2009:
The following scales are used to assess psychological measures of wellbeing and quality of life:
1. Hospital Anxiety and Depression Scale (HADS)
2. Problem Areas in Diabetes (PAID) Questionnaire
3. Disease Specific Quality of Life questionnaire (DSQOL)
4. Euroqol EQ-5D
5. Sub-study: comparison of Audit of Diabetes-Dependent Quality of Life (ADDQOL) vs Diabetes Treatment Satisifaction Questionnaire (DTSQ)
6. Health Economics Questionnaire (developed for the study)

All primary and secondary outcomes will be assessed at 6, 12 and 18 months.

Overall study start date
01/01/2007

Completion date
30/09/2011

Eligibility

Key inclusion criteria
1. Patients diagnosed with type 1 diabetes for over one year
2. Attending the adult diabetes clinic in one of the participating centres
3. Ability to speak and read English
4. Willingness to monitor blood sugar levels at regular intervals
5. Willingness to transition to a basal/bolus insulin regimen prior to DAFNE training (if not already on such a regimen)
6. Glycosylated haemoglobin (HbA1c) level below 13 percent at recruitment

Added as of 13/02/2009:
7. Both males and females, 18 years old or greater

Please note that as of 30/07/07, the previous inclusion criteria point six read as:
6. Glycosylated haemoglobin (HbA1c) level between 7.5 and 13 percent at recruitment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
As of 20/07/2010: 438 (previously 360). Added 20/10/2011: Please note that the trial recruited to target (n= 437)

Key exclusion criteria
1. Patients with type 2 diabetes
2. Attending a paediatric clinic
3. Pregnant or planning a pregnancy in the next 2 years
4. Presence of advanced diabetic complications (e.g. kidney failure with serum creatinine >250 µmol/L)
5. Serious co-morbidity likely to interfere with study participation
6. Previous DAFNE training or current use of a continuous subcutaneous insulin infusion pump

Date of first enrolment
01/01/2007

Date of final enrolment
30/09/2011

Locations

Countries of recruitment
Ireland

Study participating centre
Irish DAFNE Study Project Manager
Galway
Ireland
-

Sponsor information

Organisation

Health Research Board (Ireland)

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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
Health Research Board (Ireland) (ref: HS-05-25)

Alternative Name(s)
HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

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	23/09/2009		Yes	No
Results article	results	30/08/2011		Yes	No
Results article	follow-up results	01/04/2013		Yes	No
Results article	follow-up results	14/06/2014		Yes	No