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The role of behaviours, values and institutions in the comparative exploration of patient behaviour following structured education programmes for people with Type 1 diabetes: Ireland, UK and Germany

Submission date
03/06/2011

Recruitment status
No longer recruiting

Registration date
28/07/2011

Overall study status
Stopped

Last Edited
22/01/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Type 1 diabetes is a lifelong condition that causes a person's blood sugar level to become too high. The skills necessary to manage type 1 diabetes are delivered through structured education programmes such as the Insulin Training and Teaching Programme (ITTP) in Germany and the Dose Adjustment For Normal Eating (DAFNE) programme in the UK and Ireland. These programmes are virtually identical as DAFNE was closely modelled on ITTP. With the disease, treatment and education similar across Germany, the UK and Ireland, why do diabetes outcomes differ so much across European countries? To date there have been few comparisons of outcomes following structured education programmes across countries. This study will try to identify the key ingredients of successful self-management of type 1 diabetes through a cross country comparison. Currently the data suggests that German people do better than people in the UK following structured education programmes in diabetes. This study will help identify why that is. Is it to do with the cultural or healthcare context that these structured education programmes are delivered in, or is to do with how individual people value their own health? This study aims to explore how values, institutions, health care organisation and health care structure impact on the behaviour of patients and on their ability to self manage their type 1 diabetes following structured education in Germany, the UK and Ireland.

Who can participate?
Patients aged 18 or over with type 1 diabetes who are currently enrolled for a DAFNE programme in one of the participating centres (Sheffield Teaching Hospitals and University Hospitals of Leicester).

What does the study involve?
Two DAFNE centres in the UK are involved in this study. All aspects of one course in each of these centres are observed by the researchers, including how the course is delivered, where the

course is delivered, and formal and informal interactions between course participants and educators. Sixteen patients are approached to participate in an interview lasting about 60 minutes before completing DAFNE and about 6 months after DAFNE to explore their attitudes, experiences and behaviours. Four educators at these hospitals are also approached to participate in one in-depth interview each.

What are the possible benefits and risks of participating?
This study involves no intervention. It is a low to non-risk study. Participants (both educators and patients) and centres involved in the study will be anonymised to ensure participant data remains confidential. Participation should cause no adverse effects, pain, discomfort, distress or changes to lifestyle. To minimise any intrusion or inconvenience participants will be invited to suggest a time and venue for the interviews. Light refreshments will also be provided. Transcripts will be made available to each participant for their approval and comments. Any topics that are particularly sensitive, embarrassing or upsetting will be brought up at the discretion of the participant only, not by the researcher. The participant does have to discuss anything they do not wish to. Medical records will not be required.

Where is the study run from?
The study will take place in the outpatient diabetes centres of participating hospitals (Sheffield Teaching Hospitals and University Hospitals of Leicester) (UK).

When is the study starting and how long is it expected to run for?
May 2011 to June 2012

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

Who is the main contact?
Mary Clare O'Hara
MaryClare.OHara@hse.ie

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
10365

Study information

Scientific Title
The role of behaviours, values and institutions in the comparative exploration of patient behaviour following structured education programmes for people with type 1 diabetes: a non-randomised qualitative observational study

Acronym
DRN 595 (Qualitative exploration of diabetes outcomes poststructured)

Study objectives
Type 1 diabetes is a disease causing autoimmune beta cell destruction, this disease is the same no matter where you are in the world and is managed by insulin replacement, mainly by subcutaneous multiple daily injections. The skills necessary to effective manage type 1 diabetes are delivered through structured education programmes (SEPs), such as the Insulin Training and Teaching Programme (ITTP) in Germany and the Dose Adjustment For Normal Eating (DAFNE) programme in the UK & Ireland. These programmes are virtually identical as DAFNE was closely modelled on ITTP. With the disease condition, treatment and education similar across Germany, the UK and Ireland, why then should diabetes outcomes differ so much? To date the evidence base for the effectiveness of these programmes have been published but there remains little comparison of outcomes following SEPs across countries. This study aims to use a qualitative approach to explore how values, institutions, health care organisation and health care structure impacts on the behaviour of patients and on their ability to self-manage their type 1 diabetes following structured education in Germany, the UK and Ireland.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber Sheffield, Yorkshire and the Humber REC Office, 21 /04/2011, ref: m11/YH/0075

Primary study design
Observational

Study design
Non-randomised qualitative observational study

Study type(s)
Treatment

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

Interventions
Two DAFNE centres in UK will be involved in this study. Professor Simon Heller is lead consultant involved in this study based in the University of Sheffield and Dr Ian Lawrence is lead Consultant

Diabetologist in University Hospitals, Leicester. All aspects of one course in each of these centres will be observed by the PhD researcher (Mary Clare O' Hara), including how the course is delivered, where the course is delivered, and formal and informal interactions between course participants and educators. These data will be in the form of detailed descriptive fieldnotes, accompanied by any additional comments made by the researcher. This observational material will be used to inform the issues and areas explored with participants and educators in their interviews, and to contextualise and enhance interpretation of their interview responses. A DAFNE course runs Monday to Friday from approximately 9am to 5pm. Educators and patients will be contacted approximately 12 weeks prior to their commencement on the DAFNE programme and asked to provide written consent for their course to be observed. Centre, educator and patient will be anonymised.

Qualitative Interviews:
At the commencement of the study open sampling will be used, whereby participants are identified who will furnish information of relevance to the aims of the study. In addition purposive sampling will be used to insure diversity with respect to age, gender, education, socioeconomic status, and years since diagnosis. Sixteen patients enrolled into the DAFNE programme in Sheffield Teaching Hospitals and University Hospitals, Leicester will be approach to participate to an interview prior to completing DAFNE and approximately 6 month after DAFNE. Four educators at these hospitals will also be approached to participate in one in-depth interview each. Patients and educators will be provided a Participant Information Sheet that fully explains the study. They will be assigned a study number and their anonymity will be protected at all times. Educators and DAFNE graduates from University Hospital Galway (UHG), Ireland took part in focus groups in October 2010 to guide the development of the interview schedule. The interview schedule for both educators and patients were piloted in November 2010 with four patients and 2 educators in UHG. Adjustments were made following these focus groups and pilot interviews a draft schedule was circulated to the study team (Consultants, Psychologists, Nurses, patients and dietitians) for final comments. Observations and interviews will be staggered to allow for concurrent data collection and analysis. Any further adjustments to the interview schedule following observations and/ or commencement of interviews will be documented as explore any emerging themes. Data analysis will commence after the first observation and will continue until the final interview. The researcher and 2 other member of the study team (Professor Eamon O' Shea and Dr Sean Dinneen) will repeatedly read through and cross-compare transcripts and field-notes, each undertaking their own independent, iterative thematic analysis. Interpretations will be compared and discussed in regular data analysis meetings both during and after the data collection period to reach agreement on recurrent themes. Data will then be organised into initial and higher codes. NVivo, a qualitative data indexing package, was used to facilitate data coding and retrieval. All participants will be sent copies of their interview transcript to confirm that it is a accurate reflection of the interview and they will be invited to make additional comments. Consenting participants will be conducted by the researcher to schedule an appropriate time and venue for the interview that will last approximately an hour. The time and venue will be at the discretion of the participant.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

As the study is entirely qualitative and explorative the main outcomes will emerge through analysing the interview data.

Baseline qualitative data will be analysed in November 2011 and 6-month data will be analysed in May 2012

Key secondary outcome(s)
No secondary outcome measures

Completion date
18/06/2012

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
1. Patients diagnosed with type 1 diabetes and a duration of 12 months
2. Both males and females patients who were 18 years old or greater at recruitment
3. Patients attending the adult diabetes clinic in one of the participating DAFNE centres
4. Patients who could speak and read English
5. Patients who are currently enrolled for a DAFNE programme in one of the participating DAFNE centres

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients with type 2 diabetes
2. Patients attending a paediatric clinic
3. Patients who are pregnant or planning a pregnancy in the next 2 years
4. Patients who have advanced diabetic complications (e.g. kidney failure with serum creatinine >250 µmol/L)
5. Patients with serious comorbidity likely to interfere with study participation
6. Patients who have had previous DAFNE training or current use of a continuous subcutaneous insulin infusion pump

Date of first enrolment
31/05/2011

Date of final enrolment
18/06/2012

Locations

Countries of recruitment
United Kingdom

Germany

Ireland

Study participating centre
Endocrinology and Diabetes Centre
Galway
Ireland
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Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Trust (UK)

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Research organisation

Funder Name
Health Research Board (Ireland)

Alternative Name(s)
HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

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?
Abstract results	protocol presented at Diabetes UK Professional Conference (see abstract P355)	13/03/2013	22/01/2019	No	No
Abstract results	qualitative results of patients' experiences of diagnosis were presented at the European Association for the Study of Diabetes (EASD) (see abstract 1125)	01/09/2013	22/01/2019	No	No