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Education programme (DESMOND-ID) for the self-management of type 2 diabetes for adults with intellectual disabilities (ID)

Submission date
18/08/2014

Recruitment status
No longer recruiting

Registration date
11/09/2014

Overall study status
Completed

Last Edited
08/11/2018

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
The need for structured education programmes for type 2 diabetes is considered to be very important for many governments around the world. One such national education programme in the UK is DESMOND. DESMOND has been shown to be successful for patients in general, but these programmes have not offered to people with intellectual disabilities (learning difficulties). We have adapted DESMOND for people with intellectual disabilities and type 2 diabetes to produce an amended programme known as DESMOND-ID. Here, we are doing a small scale, initial study (called a pilot trial) to see whether it is possible to test if DESMOND-ID is better at helping adults with intellectual disabilities to self-manage their diabetes than the original programme. In particular, we will see if using the programme leads to a fall in Hb1Ac (haemoglobin that has bound to glucose in the blood) levels, improve psychological well-being and quality of life, and promote a healthier lifestyle. This is important as the lack of appropriate structured education programmes and educational materials for people with intellectual disabilities can result in a number of other health problems and premature death.

Who can participate?
Adults with intellectual disabilities and type 2 diabetes, and their family/paid carers.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 attend the DESMOND-ID programme. Those in group 2 receive their usual routine care.

What are the possible benefits and risks of participating?
To our knowledge, this is the first study looking at a structured diabetes education for adults with intellectual disabilities which also involves their family/paid carers. NICE Diabetes Guidelines state that it is very important that people who have been diagnosed with type 2 diabetes should be offered a place on a structured education programme within 6 months to help them manage their condition and avoid complications. There are, therefore, significant benefits to be gained if adapting structured education programmes shown to work for the general population are beneficial for people with intellectual disabilities and other cognitive

impairments. The trial will have both national and international relevance, helping to influence how governments and service providers support adults with intellectual disabilities and their family/paid carers to manage the persons type 2 diabetes.There are no potential risks involved in participating in this study.

Where is the study run from?
This is currently being decided upon: N Ireland (probably Antrim area), Scotland: Edinburgh, and Wales; Cardiff.

When is the study starting and how long is it expected to run for?
January 2015 to June 2015

Who is funding the study?
Diabetes UK

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
NA

Study information

Scientific Title
A study protocol for a pilot randomised trial of a structured education programme (DESMOND-ID) for the self-management of type 2 diabetes for adults with intellectual disabilities (ID)

Acronym
DESMOND-ID

Study objectives
This protocol is for a pilot trial to determine whether a large-scale, randomised trial is feasible to test if DESMOND-ID is more effective than usual care in adults with intellectual disabilities for self-management of their type 2 diabetes (T2D), in particular as a means to reduce Hb1Ac, improve psychological well-being and quality of life, and promote a healthier lifestyle.

Ethics approval required
Old ethics approval format

Ethics approval(s)
HSC REC B, 29/10/2014, REC ref: 14/NI/1104

Study design
The study is a two arm, individually randomised, pilot trial in adults with ID and T2D, and their family/paid carers. It compares the DESMOND-ID programme with usual routine care.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Participants with ID will be screened for eligibility by the primary healthcare team or community ID nurse, who will provide the potential participants with a user friendly information sheet and consent form. Participants with a paid/family carer will be provided with an information sheet and consent form. It is only after consent has been obtained that the research team will contact the participant and family/paid carer to arrange baseline data collection.

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
The DESMOND-ID programme is an amended version of the original DESMOND structured education programme that supports adults with T2D to self-manage their condition. The original

DESMOND programme is based upon non-ID participants with T2D attending a six-hour education programme in a locality near them (i.e. hospitals, community centres, health centres, etc.), over one day or two-half days. A detailed description of how the DESMOND-ID intervention was developed and piloted is being currently written for publication which used the Template for Intervention Description and Replication (TIDieR) checklist and guide. The DESMOND-ID programme has an additional introductory education session that is held separately for the family/paid carers in order to support their understanding about T2D and how it is managed. Carers gain an understanding of how the DESMOND-ID programme works and their specific role in supporting the person with ID throughout the programme. The DESMOND-ID programme will be delivered in a day-centre or health centre, over six weeks with one session per week, lasting approximately two and a half hours. The participant with ID and their family/paid carer will be encouraged to attend the sessions together. The education sessions will be delivered by two trained educators who have been given two days training encompassing the DESMOND core newly diagnosed and DESMOND-ID programme training. These educators are likely to be health facilitators, community ID nurses, DSN or dieticians. Two educators will be trained in each of the three countries.

The educational intervention focuses on the concepts of self-management. The DESMOND programme is based upon the following theories:
1. Self-Regulation Theory (Leventhal) that focuses on individuals illness representations as a key determinant of their behavioural and emotional responses to illness
2. Social Learning Theory that focuses on individuals perceptions of their ability to carry out behaviours and support behaviour change through developing a personal action plan
3. Dual Process Theory that is used to guide the educational process of addressing individuals current understanding of diabetes. This process is used to actively engage participants in the learning process.

The educational content of the DESMOND-ID programme mirrors that of DESMOND. The way in which educators deliver this content is adapted to make it accessible for people with ID, and it covers:
1. What is diabetes
2. Food choices
3. Monitoring
4. Physical activity
5. Risks and complications and
6. Self-management plan

Each of the education sessions is composed of two 30-45 minute education sections with a break in the middle for refreshments. Previous work has shown that flexibility is required in delivery and timing of the education sessions in order to meet individuals concentration and learning needs.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
This pilot randomised trial will enable us to:
1. Examine the feasibility of delivering the DESMOND-ID programme

2. Assess eligibility, attendance levels, recruitment process, loss to follow-up, compliance and Hb1Ac of adults with ID and T2D
3. Determine the acceptability of randomisation to the adults with ID and their family/paid carers, using retention rates as a surrogate for acceptability
4. Determine the appropriateness and the acceptability of the outcome measures to the adults with ID through completion rates, in order to see whether the primary outcome measure (HbA1c) and secondary outcome measures (BMI, waist circumference, blood pressure, lipid profiles, CVD risk score, smoking, alcohol use, exercise, perceptions and severity of beliefs and quality of life) can be collected
5. Determine the appropriateness and the acceptability of the outcome measures for the family /paid carers through completion rates
6. Measure compliance of the trainers in delivering the DESMOND-ID programme
7. Estimate the treatment effect to determine whether this suggests a clinically important effect which will support the conduct of the full trial

Timepoints for all outcomes:
Baseline (Time 1): Jan/Feb 2015
Intervention: Feb 2015
Focus Groups: April/May 2015
Follow-up (Time 2): May/June 2015

Secondary outcome measures
N/A

Overall study start date
26/01/2015

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. 18 years of age or older
2. Living in the community
3. Has mild/moderate ID and T2D identified in their clinical notes and by the ID team, GP, practice nurse and Diabetes Nurse Specialist (DSN)
The definition of a family/paid carer is someone who is either a family relative or residentialmember of staff who engages in the support of the person with ID. Verbal and/or written consent will be required from people with ID and from carers before they enter the study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
72 adults with ID and their family/paid carers

Key exclusion criteria
1. Patients with type 1 diabetes
2. Patients with a severe/profound ID as assessed by the community ID team
3. Inability to communicate
4. Inability to give their verbal and/or written consent

Date of first enrolment
26/01/2015

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Room 12J19
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Sponsor information

Organisation
University of Ulster (UK)

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Sponsor type
University/education

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK

Alternative Name(s)
DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

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?

Protocol article	protocol	10/04/2015		Yes	No
Results article	results	01/01/2018		Yes	No
HRA research summary			28/06/2023	No	No