ISRCTN25675619 https://doi.org/10.1186/ISRCTN25675619

DESMOND (Diabetes Education and Self Management for Ongoing and Newly Diagnosed) Foundation Study

Submission date
03/06/2010

Recruitment status
No longer recruiting

Registration date
29/07/2010

Overall study status
Completed

Last Edited
08/07/2021

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Type 2 diabetes is a long-lasting and debilitating disease. It is linked with reduced quality of life and serious complications. The life expectancy of people with type 2 diabetes can be shortened by as much as 10 years. The number of people with type 2 diabetes is growing and it estimated that almost 3.7 million people in the UK have type 2 diabetes. It appears likely that the how much care people take of their health is linked to their long-term wellness. This goes beyond just taking medication or attending their annual review with a doctor (although both are important). Decisions around eating, weight loss strategies, undertaking exercise and stopping smoking all influence how well treatment works. The National Institute for Health and Care Excellence (NICE) advises that structured education should be available to all patients with type 2 diabetes at the time of diagnosis, with annual reinforcement and review also provided. The aims of this study are to assess the effectiveness of a 6-hour group education programme. The study is being run in Leicester and Birmingham to enable a multi-ethnic population to be recruited.

Who can participate?
People who have been diagnosed with type 2 diabetes for 1-9 years who are not taking insulin, but are taking medication for diabetes orally (by mouth).

What does the study involve?
Eligible patients are identified by searches of their GP practice's database and then are sent an invitation letter and information leaflet. Patients who express an interest are contacted and if they are eligible and interested in taking part they are booked to attend a recruitment clinic. These are staffed by trained research nurses and held in local community venues. Written informed consent is requested and the study measurements are made – blood tests, body weight, blood pressure and waist measurement. The participant is asked to complete a questionnaire which includes questions about their wellbeing, physical activity levels, illness beliefs and quality of life. Participants from practices which have been randomised to the intervention arm are invited to attend the DESMOND Education Programme while participants

from practices randomised to the control arm continue with their usual care. 12 months after the study started all participants are invited to a follow-up clinic when the measures made at recruitment are repeated.

What are the possible benefits and risks of participating?
As the study intervention is a group education programme there are unlikely to be any risks to taking part. Patients who attend the programme should benefit by increasing their knowledge about type 2 diabetes. On a larger scale the findings of the research should help in improving the care that is provided to the growing number of people with type 2 diabetes.

Where is the study run from?
Leicester Diabetes Centre

When is the study starting and how long is it expected to run for?
August 2010 to September 2013

Who is funding the study?
National Institute for Health Research (NIHR)

Who is the main contact?
Professor Melanie Davies, melanie.davies@uhl-tr.nhs.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
1

Study information

Scientific Title
A randomised controlled trial of the DESMOND Foundation Programme for people with established Type 2 diabetes in a multi-ethnic population in Leicester and South Birmingham

Study objectives
The main aim of the study is to test the hypothesis that a structured education module in diabetes with proven effectiveness in a white, newly diagnosed population can be modified for use in a multi-ethnic population with established diabetes (>=12 months < 10 years duration), to improve biomedical, lifestyle and psychological patient outcomes 6 and 12 months post intervention.

As of 27/06/2012, the anticipated end date of trial was amended from 01/12/22012 to 30/09/2013.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leicestershire, Northamptonshire & Rutland Research Ethics Committee 1 approved on the 25th February 2010 (ref: 09/H0406/116)

Study design
Multi centre cluster randomised controlled trial with randomisation at practice level.

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Established Type 2 diabetes mellitus (≥ 12 months < 10 years duration)

Interventions
The DESMOND structured group education programme for patients with established Type 2 diabetes. When delivered in English this a 6 hour programme (two sessions of 3 hours each) or when delivered in Gujarati, Urdu or Punjabi a 12 hour programme (4 sessions of 3 hours each) with an interpreter present.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
HbA1c measured at 6 and 12 month follow up

Key secondary outcome(s))
Measures at 6 and 12 month follow up:
1. Blood cholesterol
2. Body weight
3. Blood pressure
4. Waist and hip circumference

5. Lifestyle (smoking and physical activity)
6. Questionnaire tools listed below:
6.1 Illness Perception Questionnaire Revised (IPQ-R)
6.2 Diabetes Illness Representations Questionnaire (DIRQ)
6.3 The Hospital Anxiety & Depression Scale (HADS)
6.4 International Physical Activity Questionnaire (IPAQ)
6.5 Problem Areas in Diabetes Scales (PAIDS)
6.3 International Physical Activity Questionnaire (IPAQ)

Completion date
30/09/2013

Eligibility

Key inclusion criteria
1. Patients have established Type 2 diabetes of a duration ≥ 12 months < 10 years duration
2. Not receiving insulin therapy
3. Controlling their diabetes by diet or any combination of OHAs (oral hypoglycaemic agents)
4. HbA1c ≥ 7.0% and ≤ 10.0%
5. Able to participate in a group programme
6. Age ≥ 18 and < 75 years of age
7. South Asian patients whose first language is not English, will need to be Gujarati speaking (Leicester) or Urdu or Punjabi speaking (South Birmingham)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients who have already attended a DESMOND programme
2. Unable to give informed consent
3. Severe and enduring mental health problems e.g. diagnosed with psychotic illness
4. Patient not primarily responsible for their own care
5. Unable to participate in a group programme (e.g. housebound)
6. Do not have Type 2 diabetes
7. Newly diagnosed with Type 2 diabetes (< 12 months)
8. Currently taking part in a research study
9. Receiving insulin therapy

Date of first enrolment
26/08/2010

Date of final enrolment
07/09/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leicester Diabetes Centre
Leicester General Hospital
Leicester
United Kingdom
LE5 4PR

Study participating centre
Centre for Endocrinology Diabetes and Medicine
University of Birmingham Medical School
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Collaboration for Leadership in Applied Health Research and Care (CLAHRC)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the study are not expected to be made publically available due to ethical restrictions. An anonymized minimal dataset will be made available to bonafide researchers interested in collaborative research through requests sent to the lead author.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes