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

Submission date	Recruitment status
16/11/2010	No longer recruiting
Registration date	**Overall study status**
03/03/2011	Completed
Last Edited	**Condition category**
04/02/2019	Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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

UNOLE 0106

Study information

Scientific Title
To test an integrated approach for promoting effective self management in people with established Type 2 Diabetes Mellitus (T2DM): a cluster randomised controlled trial of the DESMOND Ongoing education programme

Study objectives
An approach integrating ongoing self-management education with clinical management in those with established Type 2 Diabetes Mellitus (T2DM) within a primary care setting will improve glycaemic control, other biomedical parameters and patient level outcomes

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leicestershire Northampton and Rutland Committee 1, 07/09/2010, ref:10/H0406/54

Study design
Multicentre cluster randomised controlled trial with randomisation at the level of the GP Practice

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format. Please use contact details below to request a patient information leaflet

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus (T2DM)

Interventions
Patients in the intervention group will receive the following:
1. DESMOND Foundation. An existing DESMOND 6-hour group education course which provides introductory information for managing type-2 diabetes
2. Six group sessions of DESMOND-Ongoing (4 in the 1st year and 2 in the 2nd year) delivered by specially trained DESMOND Educators which concentrate on developing self-management skills in people with established type-2 diabetes and covers specific topics related to type-2 diabetes including diet, exercise, managing hypo- and hyper-glycaemia

3. Two Care Planning sessions (delivered at yearly intervals) delivered at the level of the GP Practice by trained GPs and/or Practice Nurses. Care Planning focuses on 'looking with rather than at' someone with diabetes to plan their care and areas for improvement over the forthcoming year. Patients are helped to identify goals and make action plans to acheive these. The healthcare professionals delivering the Care Planning sessions will first be given in-depth training in Care Planning by DESMOND Eductors within the study group.

The intervention is a rolling intervention. In the real world it will comprise a six hour introductory session (DESMOND Foundation), a Care Planning session, and then four rolling sessions of DESMOND ongoing delivered at 6 monthly intervals (meaning that the complete material is delivered in 2 years. However, for the trial we are condensing the intervention during the first years as a proof of concept and then will change to the frequency that it would be delivered in the real world during the 2nd year. Therefore intervention patients will receive the six sessions mentioned above during the first year and then a further Care Planning session and 2 sessions of Going Forward with Diabetes during the 2nd year.

Intervention Type
Behavioural

Primary outcome measure
Reduction in HbA1c at 24 months

Secondary outcome measures
1. Reduction in the following biomedical measures measured at 12 and 24 months
1.1. HbA1c (at 12 months)
1.2. Cholesterol (total, HDL and LDL)
1.3. Triglyceride
1.4. Blood pressure (BP) Systolic
1.5. BP Diastolic
1.6. Weight
1.7. Waist circumference
1.8. Hip circumference

2. Improvement in the following scores at 12 and 24 months
2.1. EQ5D
2.2. Illness Perceptions Questionnaire revised
2.3. Diabetes Illness Representations Questionnaire
2.4. Summary of Diabetes Self Care Activities questionnaire
2.5. Hospital Anxiety and Depression Score
2.6. Problem Areas in Diabetes Score
2.7. International Physical Activity Questionnaire

Overall study start date
01/01/2011

Completion date
30/09/2013

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 04/02/2019:
1. Individuals with established Type 2 Diabetes Mellitus
2. Diabetes duration of 12 months or more
3. HbA1c between 7.8 and 11%

Previous participant inclusion criteria:
1. Individuals with established Type 2 Diabetes Mellitus
2. Diabetes duration of 12 months or more
3. HbA1c between 7.0 and 11%

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
532

Key exclusion criteria
1. Receiving insulin therapy
2. Have existing comorbidities that could interfere with participation in the study over the 24 months
3. Unable to give informed consent
4. Severe and enduring mental health problems
5. Patients who are not primarily responsible for their own care
6. Unable to participate in a group programme (e.g. housebound)
7. Insufficient understanding of English to participate in the group education
8. Visually impaired or hard of hearing to the level that they can not participate in the group education
9. Aged under 18 years

Date of first enrolment
01/01/2011

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Leicester Diabetes Centre (Broadleaf)
Leicester
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Sponsor information

Organisation
University of Leicester (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www2.le.ac.uk/offices/researchsupport/researchsupportoffice

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

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

Funder Name
Leicestershire, Northamptonshire and Rutland CLARHC and CLAHRC for South Yorkshire (UK)

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?
Basic results		04/02/2019	04/02/2019	No	No