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

Submission date	Recruitment status	[_] Prospectively registered
22/12/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/02/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/06/2015	Nutritional, Metabolic, Endocrine	

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
1

Study information

Scientific Title
Testing a newly-developed training programme for lay educators delivering the Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) programme

Study objectives
The main aim of the study is to test the hypothesis that joint teams of lay educators and health care professionals can deliver structured education in diabetes with the same degree of interaction fidelity, quality and efficacy as health care professional teams. Equivalence of outcomes for patients who have attended sessions delivered by the two categories of team will be used as a proxy for equivalence in terms of delivery of effective education.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leicestershire, Northamptonshire and Rutland Research Ethics Committee 1, 19/08/2009, ref: 09/H0406/87

Study design
Open label parallel trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Diabetes

Interventions
GP/practice nurse will inform patients about the study and if interested hands them a study recruitment pack, which contains the Patient Information leaflet. The referral form is completed and sent to the local coordinator informing them patients interested. The co-ordinator contacts the patient by phone within a week, but not less than 24 hours after referral.

Patients who indicate their wish to join the study will be offered the first available study course. If the first course is judged unsuitable, they will be offered the next available study course. Once patients have been booked onto a study course they will be sent an appointment letter with a questionnaire booklet. When patients attend the course their consent will be taken by the health care professional educators before the start of the study course. The study courses will be delivered either as one full day or two half days.

This will be a one-off course that they will attend as part of the study and 4 months after attending the course patients will be sent a reminder letter, along with a questionnaire booklet, to have their data collected at their practice. GPs will be informed via a letter if their patients are taking part or not.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in coherence score. This is an illness belief score which provides a measure of an individuals understanding of their diabetes and is determined using a validated tool, the Diabetes Illness Perceptions Questionnaire (IPQ-R).

Secondary outcome measures
Based on changes between baseline and four months:
1. Change in personal responsibility score (obtained using the IPQ-R self-report questionnaire)
2. Change in depression score (obtained using the Hospital Anxiety and Depression Scale [HADS-D] self-report questionnaire)
3. Changes in biomedical and anthropometric measures

Overall study start date
08/01/2010

Completion date
01/09/2010

Eligibility

Key inclusion criteria
1. Over the age of 18 years, either sex
2. Newly diagnosed with type 2 diabetes
3. Can participate in the education programme preferably within 6 months of diagnosis

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
256

Key exclusion criteria
1. Type 1 diabetes
2. Taking insulin
3. Unable to give informed consent
4. Severe and enduring mental health problems (i.e. under the care of the specialist mental health team)
5. Unable to take part in a group programme
6. Not primarily responsible for their own care
7. Unable to participate in groups conducted in English (only for the non-BME sites)

Date of first enrolment
08/01/2010

Date of final enrolment
01/09/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leicester Royal Infirmary
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

Sponsor details
Gwendolen Road
Leicester

England
United Kingdom
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Sponsor type
Hospital/treatment centre

Website
http://www.uhl-tr.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK (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?
Results article	results	01/11/2014		Yes	No
Results article	results	01/11/2014		Yes	No