# DESMOND (Diabetes Education and Self Management for Ongoing and Newly Diagnosed): a randomised controlled trial of a structured group education programme for people newly diagnosed with type two diabetes

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
19/04/2007		Protocol		
Registration date	Overall study status	Statistical analysis plan		
16/05/2007	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
30/07/2012	Nutritional, Metabolic, Endocrine			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

**Prof Melanie Davies** 

#### Contact details

Leicester Diabetes Centre (Broadleaf) Leicester General Hospital Gwendolen Road Leicester United Kingdom LE5 4PW

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

# Secondary identifying numbers

N/A

# Study information

#### Scientific Title

# Acronym

**DESMOND** 

# **Study objectives**

To evaluate the effectiveness and feasibility of delivering structured group self-management education to individuals newly diagnosed with type two diabetes.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Approval received from Multi-centre Research Ethics Committee (MREC) on the 16th June 2004.

# Study design

Cluster randomised controlled trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Not specified

# Study type(s)

Quality of life

#### Participant information sheet

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

Self management of type two diabetes

#### **Interventions**

A programme of six hours of structured group education consisting of two three-hour sessions offered as either one day or two half-days, facilitated by two health care professionals trained to deliver the intervention to groups of up to ten people newly diagnosed with type two diabetes, who may be accompanied by a partner, family member or friend.

This is compared to a control group receiving enhanced routine care.

# Intervention Type

#### Other

#### Phase

**Not Specified** 

# Primary outcome measure

Glycaemic control as measured by HbA1c at 12 months.

# Secondary outcome measures

- 1. Cardiovascular (CV) risk as measured by lipid profile and blood pressure
- 2. Quality of life indicators, diabetes control, self-care and illness belief perceptions of patients at 12 months

# Overall study start date

01/07/2004

# Completion date

31/01/2007

# **Eligibility**

#### Key inclusion criteria

- 1. Greater than 18 years of age
- 2. Referred to the study within four weeks of diagnosis of type two diabetes
- 3. In intervention group, able to attend the intervention within 12 weeks of diagnosis

# Participant type(s)

Patient

# Age group

Adult

# Lower age limit

18 Years

#### Sex

**Not Specified** 

# Target number of participants

1,000

#### Key exclusion criteria

- 1. Are unable to give informed consent
- 2. Have been recruited to take part, or are already taking part in other research
- 3. Have severe and enduring mental health problems
- 4. Are not primarily responsible for their own care
- 5. Are unable to participate in a group programme
- 6. Have insufficient understanding of English to participate in the group education

#### Date of first enrolment

# Date of final enrolment 31/01/2007

# Locations

#### Countries of recruitment

England

**United Kingdom** 

Study participating centre Leicester Diabetes Centre (Broadleaf)

Leicester United Kingdom LE5 4PW

# Sponsor information

# Organisation

University Hospitals of Leicester NHS Trust (UK)

# Sponsor details

Gwendolen House Gwendolen Road Leicester England United Kingdom LE5 4PW

#### Sponsor type

Hospital/treatment centre

#### Website

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

#### **ROR**

https://ror.org/02fha3693

# Funder(s)

# Funder type

#### **Funder Name**

Diabetes UK (UK) (ref: BDA:RD04/0002922)

# 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

#### **Funder Name**

Department of Health (UK)

#### **Funder Name**

NovoNordisk (UK) - unrestricted educational grant

# **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	01/03/2008		Yes	No
Results article	results	26/04/2012		Yes	No