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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>		
24/12/2009	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
18/05/2010	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
27/10/2022	Nutritional, Metabolic, Endocrine			

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Prof Simon Heller

#### Contact details

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### Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

 ${\bf Clinical Trials. gov\ number}$ 

## Study information

#### Scientific Title

Does self-monitoring of blood glucose as opposed to urinalysis provide additional benefit to newly diagnosed individuals with Type 2 diabetes receiving structured education?

#### Study objectives

To compare the effectiveness of urine and blood glucose monitoring strategies, when taught as part of a structured education programme, on glycaemic control in patients newly diagnosed with Type 2 diabetes. The measure of glycaemic control will be level of HbA1c in the blood 18 months after attending the programme.

Please note, as of 03/11/2011 the anticipated start and end dates have been updated. The previous dates were as follows:

Original start date: 01/12/2009 Original end date: 01/03/2010

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Cambridgeshire 1 Research Ethics Committee approved on the 6th February 2008 (ref: 07/H0304/129)

#### Study design

Multicentre cluster randomised controlled trial with randomisation at practice level

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

GP practice

#### Study type(s)

Other

#### Participant information sheet

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

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

Type 2 diabetes (newly diagnosed)

#### Interventions

DESMOND structured group education programme. This is a 7 hour programme (two sessions of 3.5 hours each) which includes a session on self monitoring (blood or urine depending on randomisation of people attending)

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome measure

HbA1c measured at 18 month follow-up

#### Secondary outcome measures

- 1. Blood cholesterol
- 2. Body weight
- 3. Blood pressure
- 4. Waist circumference
- 5. Lifestyle (smoking and physical activity)
- 6. Questionnaire tools listed below
- 6.1. Diabetes Treatment Satisfaction Questionnaire
- 6.2. Well Being Questionnaire 28
- 6.3. EQ-5D
- 6.4. Confidence in Self Care (CIDS)
- 6.5. Brief Diabetes Perceptions Questionnaire
- 6.6. Short Form 36 questionnaire
- 6.7. Summary of Diabetes Self Care Activities

#### Overall study start date

28/09/2008

#### Completion date

21/12/2011

## **Eligibility**

#### Key inclusion criteria

- 1. Age over 18 years
- 2. Newly diagnosed and able to attend a DESMOND course within 12 weeks of diagnosis
- 3. Capable of giving informed consent
- 4. Primarily responsible for their own care
- 5. Able to participate in a group programme
- 6. Can understand both written and spoken English

#### Participant type(s)

Patient

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

400

#### Total final enrolment

292

#### Key exclusion criteria

- 1. Severe medical problems (eg severe heart failure, advanced cancer) that would result in the patient gaining no benefit from attending an education programme. This will be at the discretion of the general practitioner.
- 2. Taking part in another research study

#### Date of first enrolment

28/09/2008

#### Date of final enrolment

21/12/2011

#### Locations

#### Countries of recruitment

England

**United Kingdom** 

## Study participating centre Professor of Clinical Diabetes Sheffield United Kingdom S10 2RX

## Sponsor information

#### Organisation

University Hospitals of Leicester (UK)

#### Sponsor details

Gwendolen Road Leicester England United Kingdom LE5 4PW

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carolyn.maloney@uhl-tr.nhs.uk

#### Sponsor type

University/education

#### 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

Not provided at time of registration

**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	14/03/2012		Yes	No
Other publications	educators' views	09/01/2014		Yes	No
Results article		01/03/2015	27/10/2022	Yes	No