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A randomised controlled trial to determine the effect of blood glucose self-monitoring in people with type two diabetes

Submission date 13/01/2004	**Recruitment status** No longer recruiting
Registration date 13/01/2004	**Overall study status** Completed
Last Edited 07/05/2009	**Condition category** Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.herc.ox.ac.uk/research/trials/digem.shtml

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 01/38/05

Study information

Scientific Title

Acronym
DiGEM

Study objectives
Tight blood glucose control is recommended for many people with type two diabetes to delay and prevent the occurrence of complications. Glycaemic monitoring is required to attain this objective and current guidelines suggest that HbA1c levels below 7% should be achieved where possible. Although many people find that checking-blood glucose levels at home is a helpful way to undertake glycaemic monitoring, there is a need for more evidence to support its systematic use among people with type two diabetes. Previous trials have been small and have not incorporated a consistent approach to applying the results of tests to lifestyle. The aim of this open randomised controlled trial is to compare the use of blood glucose self monitoring to the standard practice of intermittent HbA1c checks in people managing their type two diabetes with diet or oral hypoglycaemic tablets. All patients will receive additional information about managing their diabetes. Patients randomised to blood glucose testing will be trained in the use of the blood glucose meters and given additional support to help them interpret the results in relation to the measures they are undertaking to improve HbA1c.

The main outcome is HbA1c levels in the different groups, with additional measurement of other risk factors for cardiovascular disease, satisfaction with care, quality of life and costs of care. In addition to a direct comparison of the different groups, the study will inform routine clinical practice by an exploratory study of those people who might gain particular benefit from using different techniques to check glycaemic control and a series of in-depth interviews with study participants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study protocol was approved by the Oxfordshire B Research Ethics Committee.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Type two diabetes

Interventions
Please note that, as of 15 January 2008, the end date of this trial has been updated from 30 June 2005 to 31 March 2007.

Interventions:
1. Control arm: three-monthly HbA1c measurement
2. Monitoring arm: use of blood glucose monitor and clinician interpretation of results
3. Intensive arm: use of blood glucose monitor, patient interpretation of results and application to lifestyle

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome measure is HbA1c, while additional outcome measures include blood pressure, cholesterol, self-reported smoking status, frequency of hypoglycaemia, symptom severity, changes in oral hypoglycaemic medication, addition of insulin to medication regimens and changes in Diabetes Treatment Satisfaction, Diabetes Self Care Activities and Well-being Questionnaire scales at one year.

Secondary outcome measures
1. Change in systolic and diastolic blood pressure
2. Weight
3. Serum cholesterol and High Density Lipoprotein (HDL)
4. Self-reported smoking status
5. Dietary intake and physical activity (the Diabetes Self Care Activities Questionnaire)
6. Medication adherence (the Medication Adherence Rating Scale)
7. Scores in the Diabetes Treatment Satisfaction Questionnaire and the Well-being Questionnaire (12 item)

Overall study start date
01/10/2002

Completion date
31/03/2007

Eligibility

Key inclusion criteria
1. Aged 25 or above
2. With type two diabetes

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
48 general practices in Oxfordshire and South Yorkshire; 453 patients

Key exclusion criteria
1. Use of blood glucose monitor twice a week or more often over the previous three months
2. Current use of insulin
3. Co-morbidity or limited life expectancy that would make intensive glycaemic control inappropriate
4. Last clinic HbA1c or HbA1c at the assessment visit less than 6.2%
5. Unable to follow trial procedures
6. Not independent for activities of daily living

Date of first enrolment
01/10/2002

Date of final enrolment
31/03/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Health Sciences
Oxford
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Sponsor information

Organisation
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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?
Protocol article	protocol	16/06/2005		Yes	No
Results article	results	21/07/2007		Yes	No
Other publications	economic evaluation	24/05/2008		Yes	No
Other publications	HTA monograph:	01/02/2009		Yes	No