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The Efficacy of Self-MONitoring of blood glucose in patients with type two diabetes mellitus

Submission date	Recruitment status	[ ] Prospectively registered
08/01/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/04/2008	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
RRG5.7

Study information

Scientific Title

Acronym
ESMON

Study objectives
Self blood glucose monitoring is not associated with benefit in terms of improved glycaemic control or psychological indices.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. University of Ulster Ethics Committee on the 17th August 2001 (ref: 01/29)
2. Altnagelvin Hospitals Health and Social Services Trust on the 14th June 2000

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

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

Interventions
Self monitoring of blood glucose versus non-monitoring.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Between-group differences in glycaemic control (HbA1c)
2. Between-group differences in psychological indices
3. Between-group differences in reported hypoglycaemia

Secondary outcome measures
1. Between-group differences in body mass index (BMI)
2. Between-group differences in oral hypoglycaemic drug usage
3. Longitudinal within-group changes in HbA1c, BMI and psychological indices

Overall study start date
01/12/2000

Completion date
01/01/2006

Eligibility

Key inclusion criteria
1. Patients with newly diagnosed type two diabetes
2. Aged less than 70 years old

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Secondary diabetes
2. Insulin use
3. Previous monitoring
4. Pregnancy
5. Previous malignancy
6. Major illness within 6 months (including major surgery, myocardial infarction (MI), acute coronary syndrome, stroke, acute limb ischaemia)
7. Liver disease
8. Creatinine > 150 µmol/L
9. Proteinuria > 0.5 g/ 24 h
10. Chronic use of oral steroids
11. Alcohol abuse

Date of first enrolment
01/12/2000

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
School of Nursing
Coleraine
United Kingdom
BT52 1SA

Sponsor information

Organisation
University of Ulster (UK)

Sponsor details
c/o Prof Vivien Coates
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Sponsor type
University/education

Website
http://www.ulster.ac.uk

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type

Government

Funder Name
Northern Ireland Department of Health, Research and Development Office (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?
Results article	Results	24/05/2008		Yes	No