

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

**Submission date**  
08/01/2007

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
26/02/2007

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
21/04/2008

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Vivien Coates

### Contact details

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## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Screening

**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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

Northern Ireland

**Study participating centre****School of Nursing**

Coleraine

United Kingdom

BT52 1SA

# Sponsor information

## Organisation

University of Ulster (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

## 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?
<a href="#">Results article</a>	Results	24/05/2008		Yes	No