

# A pilot study to investigate the effects of increasing meal frequency and snacking on blood glucose measurements in patients with type 2 diabetes on insulin treatment

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|----------------------------------------|----------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>30/09/2004   | <b>Recruitment status</b><br>No longer recruiting              | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>30/09/2004 | <b>Overall study status</b><br>Completed                       | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>25/05/2018       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                                | <input type="checkbox"/> Results                     |
|                                        |                                                                | <input type="checkbox"/> Individual participant data |
|                                        |                                                                | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Gary Frost

### Contact details

Nutrition & Dietetics Department  
2nd Floor, C Block  
Hammersmith Hospital  
Du Cane Road  
London  
United Kingdom  
W12 0HS  
+44 (0)208 383 3048 (bleep 9027)  
g.frost@imperial.ac.uk

## Additional identifiers

### Protocol serial number

N0016132016

# Study information

## Scientific Title

A pilot study to investigate the effects of increasing meal frequency and snacking on blood glucose measurements in patients with type 2 diabetes on insulin treatment

## Study objectives

What this study hopes to answer is whether giving appropriate advice on snacking and spreading out the Kcal intake throughout the day reduces the incidence of hypoglycaemia and improves control in patients with type II diabetes on insulin without increasing Kcal intake

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Primary study design

Interventional

## Study design

Randomised controlled trial

## Study type(s)

Not Specified

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

Diabetes

## Interventions

Inclusion of snacks and reduction of main meal portions will reduce overall measurements of blood glucose and reduce incidence of hypoglycaemic episodes whilst maintaining similar energy intake per day.

The study design is a randomized controlled trial. Subjects will be randomly assigned to intervention or control groups.

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome(s)

The results will be incorporated into the departments dietetic protocol and may be used alter the focus of dietary advice for this patient group to help in the prevention of hypoglycaemia and weight gain. It will also highlight areas for further research.

## Key secondary outcome(s)

Not provided at time of registration

**Completion date**

01/05/2004

## Eligibility

**Key inclusion criteria**

Patients with type II diabetes who attend the diabetes clinic chx

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

All

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/11/2003

**Date of final enrolment**

01/05/2004

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

Nutrition & Dietetics Department

London

United Kingdom

W12 0HS

## Sponsor information

**Organisation**

Department of Health

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Hammersmith Hospital NHS Trust (UK)

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration