

# Pilot trial to assess the effect of non-medical diabetic kitbag on medication and monitoring adherence amongst adolescent diabetics (15/12/04: STUDY REMOVED FROM NRR AND NHSTCT REGISTER)

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 02/11/2016	<b>Condition category</b> 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**  
Ms Jenny Statham

**Contact details**  
Graduate School of Social Sciences  
University of Sussex  
Brighton  
United Kingdom  
BN1 9QH  
+44 (0)1273 723447  
jennyfisha1@hotmail.com

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0283124722

## **Study information**

### **Scientific Title**

Pilot trial to assess the effect of non-medical diabetic kitbag on medication and monitoring adherence amongst adolescent diabetics (15/12/04: STUDY REMOVED FROM NRR AND NHSTCT REGISTER)

### **Study objectives**

It is predicted that patients in the kitbag condition will show fewer fluctuations in their daily reporting.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Local medical ethics committee, ref: 15/03

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

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

Diabetes

### **Interventions**

This feasibility study aims to determine whether adherence for both these health behaviours improves between Time 1 and Time 2 in patients issued with a kitbag, compared to patients who are provided with routine medical care.

Two questionnaires will be completed by experimental and control subjects at Time 1 and Time 2, which will measure self-reported adherence for both blood glucose monitoring and insulin injection.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Differences in blood glucose levels from the norm between the experimental and control conditions, obtained from their diabetic clinic at Time 1 and Time 2.

**Secondary outcome measures**

Self-reported changes in:

1. Self-efficacy
2. Attitudes towards diabetes
3. Attitudes towards adherence
4. Self-esteem
5. Social norms

Between Time 1 and Time 2.

**Overall study start date**

09/04/2003

**Completion date**

01/05/2003

**Eligibility****Key inclusion criteria**

1. 40 patients from the Worthing Hospital Paediatric Diabetic Clinic
2. Between 13 and 15 years of age

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

13 Years

**Upper age limit**

15 Years

**Sex**

Both

**Target number of participants**

40

**Key exclusion criteria**

Adolescent diabetics who have been diagnosed for less than 3 years

**Date of first enrolment**

09/04/2003

**Date of final enrolment**

01/05/2003

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

University of Sussex

Brighton

United Kingdom

BN1 9QH

**Sponsor information****Organisation**

Department of Health

**Sponsor details**

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

# **Funder(s)**

## **Funder type**

Government

## **Funder Name**

Sussex NHS Research Consortium (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