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)

Submission date	Recruitment status	Prospectively registered
30/09/2004	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2004	Completed	Results
Last Edited	Condition category	Individual participant data
02/11/2016	Nutritional, Metabolic, Endocrine	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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

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.

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

13 years

Upper age limit

15 years

Sex

All

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

United Kingdom

Study participating centre University of Sussex Brighton United Kingdom BN1 9QH

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Sussex NHS Research Consortium (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?

Participant information sheet
Participant information sheet
11/11/2025 No Yes