

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

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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

England

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