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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

Registration date
30/09/2004

Overall study status
Completed

Last Edited
02/11/2016

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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