

Kids In Control OF Food (KICK-OFF)

Submission date 07/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 07/07/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/11/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.kick-off.org.uk>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

5015

Study information

Scientific Title

A multicentre, randomised controlled trial comparing intensive structured education with standard education in 11 - 16 year olds on intensive insulin therapy

Acronym

DRN191 KICK-OFF

Study objectives

Kids In Control OF Food: a multi-centre, cluster randomised controlled trial comparing structured education (the KICK-OFF course) with standard care in 11 - 16 year olds with type 1 Diabetes (T1DM) on intensive insulin therapy.

More details can be found here: <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=5015>

Ethics approval required

Old ethics approval format

Ethics approval(s)

North Sheffield Local Research Ethics Committee, 18/09/2008, ref: 08/H1308/201

Study design

Multicentre randomised interventional treatment 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Diabetes Research Network, Medicines for Children Research Network; Subtopic: Type 1 , All Diagnoses; Disease: Diabetic Control, Education, Insulin Initiation, Nutrition, Paediatric, Service delivery

Interventions

Intervention: 5 day, outpatient, skills training course, designed and piloted specifically for this age group

Control: Standard care

Treatment and follow-up duration: 24 months in both arms

Intervention Type

Other

Phase

Phase III

Primary outcome measure

Change in HbA1c %, measured at baseline, 6 months, 12 months and 24 months

Secondary outcome measures

Measured at baseline, 6 months, 12 months and 24 months:

1. Change in psychological outcome in parents and children
2. Changes in weight, height and body mass index (BMI)
3. Diet related behaviours
4. Health economic analysis
5. Health economic modelling of long term cost/benefits
6. Change in the number and severity of hypoglycaemic episodes

Overall study start date

01/09/2008

Completion date

31/08/2012

Eligibility

Key inclusion criteria

1. T1DM of at least 1 year's duration
2. Already on or willing to use multiple dose insulin (MDI)
3. Aged 11 - 16 years (in Secondary School years 7 - 12), either sex

Participant type(s)

Patient

Age group

Child

Lower age limit

11 Years

Upper age limit

16 Years

Sex

Both

Target number of participants

Planned sample size: 576; UK sample size: 576

Key exclusion criteria

1. Factors which will impair group participation
2. Non-English speaking
3. Learning disability - additional help in school
4. Major behavioural problems
5. Evidence of an eating disorder
6. Associated illness that may influence control

Date of first enrolment

01/09/2008

Date of final enrolment

31/08/2012

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Sheffield Children's Hospital

Sheffield

United Kingdom

S10 2TH

Sponsor information**Organisation**

Sheffield Children's NHS Foundation Trust (UK)

Sponsor details

Western Bank

Sheffield

England

United Kingdom

S10 2TH

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crf@sch.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.sheffieldchildrenscrf.nhs.uk>

ROR

<https://ror.org/02md8hv62>

Funder(s)

Funder type

Charity

Funder Name

Diabetes UK (UK)

Alternative Name(s)

DIABETES UK LIMITED, British Diabetic Association

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/01/2013		Yes	No

Results article	cost-effectiveness results	01/01/2016	Yes	No
Results article	results	01/02/2016	Yes	No