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Title:

Does an intensive self-management structured education course improve outcomes for children and young people with type 1 diabetes? The Kids In Control OF Food (KICk-OFF) cluster randomised controlled trial protocol.

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Abstract

Introduction: KICk-OFF is a cluster-randomised controlled trial, which aims to determine the efficacy of a 5 day structured education course for 11-16 year olds with type 1 diabetes when compared with standard care, and its cost effectiveness.

Less than 15% of children and young people with type 1 diabetes in the UK meet the recommended glycaemic target. Self-management education programmes for adults with type 1 diabetes improve clinical and psychological outcomes but none have been evaluated in the paediatric population. KICk-OFF is a 5 day structured education course for 11-16 year olds with type 1 diabetes. It was developed with input from young people, parents, teachers and educationalists.

Methods and analysis: 36 paediatric diabetes centres across the UK, randomised into intervention and control arms. Up to 560 participants recruited prior to centre randomisation. KICk-OFF courses are delivered in the intervention centres, with standard care continued in the control arm. Primary outcomes are change in glycaemic control (HbA1c) and quality of life between baseline and 6 months post intervention, and the incidence of severe hypoglycaemia. Sustained change in self-management behaviour is assessed by follow-up at 12 and 24 months. Health economic analysis will be undertaken. Data will be reported according to the CONSORT statement for cluster randomised clinical trials. All analyses will be by intention-to treat with a two-sided P-value of < 0.05 being regarded as statistically significant. The study commenced in 2008. Data collection from participants is ongoing and the study will be completed in 2013.

Ethics: The study has been approved by the Sheffield Research Ethics Committee.
Dissemination: Results will be reported in peer reviewed journals and conferences.

Trial registration: Current Controlled Trials ISRCTN37042683

Background

Structured education for paediatric diabetes management in the UK:

The glycaemic control of children with type 1 diabetes (TIDM), the key determinant of long term complications and mortality, is less good in the UK than in many other European countries (1). Successive audits in Scotland, England and Wales have shown no improvement in recent years (2,3) and less than 15% achieve the recommended target of an HbA1c of less than 7.5%. Support, education and self-management skills are thought to be key influences on control. Of the educational and psychological interventions that have been reported in children and adolescents, there is considerable diversity both in the methods used and their theoretical underpinnings. These range from simple skills and knowledge acquisition to more complex interventions involving family and friends. In a systematic review commissioned by the National Institute for Health Research (NIHR) Health Technology Assessment programme, Hampson and colleagues highlight a lack of well-designed clinical trials of educational interventions in the UK. They emphasise the need for programme development in the UK to be guided by theory and involve consultation with the various groups of people involved, including patients and their families (4) . A more recent update on this systematic review shows some progress in quality and quantity of research but no improved outcomes (5). The systematic review underpinning the National Institute for Health and Clinical Excellence (NICE) appraisal of diabetes education notes a shortage of high quality information regarding the efficacy of education and that most studies exclude children and adolescents. The Department of Health (DH) and Diabetes UK confirm this finding (6) and highlight key criteria for structured education: a structured, written curriculum meeting the learning needs of participants, delivered by trained educators; with quality assurance; and audit.

The DAFNE (**D**ose **A**djustment **F**or **N**ormal **E**ating) course is one current option for adult education. This 5-day outpatient course is adapted from a German adult education model (7). Patients are taught carbohydrate counting and insulin dose algorithms, enabling them to eat freely and administer a dose of insulin that matches the intended meal. Six months after completing the course there was a 0.9% improvement in glycated haemoglobin (HbA1c) levels in the DAFNE group compared with controls, sustained at 0.5% overall improvement by 1 year (8). Furthermore, a quarter of participants improved their HbA1c by more than 1.5% over 12 months without an increase in severe hypoglycaemia. Many described a greatly improved quality of life (QOL) and economic analysis suggests that such a course could pay for itself within 4 years as a result of reduced diabetes related complications (9). The DAFNE course has been identified as the only intervention meeting DH requirements for a structured educational programme in T1DM and has now been rolled out to over 60 centres in UK and Ireland.

Whilst structured education courses have been delivered to children in Germany for many years, there have been no randomised controlled trials (RCT) of a DAFNE-type intervention in children (10). Adolescence is often associated with relatively poor glycaemic control, but is potentially an ideal time to intervene as patients assume responsibility for their own control and disease management (11). The adolescents who participated in the Diabetes Control and Complications Trial (DCCT) intensive management group demonstrated significantly improved control during the 7.4 years of the trial compared with those in the control group (12). During the subsequent four years those in the intensive group have shown progression of retinopathy reduced by

74% compared with controls, despite the fact that the HbA1c levels of both groups converged (13). The benefits of improved glycaemic control clearly continued beyond the duration of the trial, supporting the argument that educational interventions should be offered soon after diagnosis of T1DM. However, we must acknowledge there are potential challenges for young people in undertaking such a regimen. The need for repeated blood tests, carbohydrate portion estimation and multiple insulin injections may compromise quality of life and challenge the cognitive abilities of some young people.

The KICk-OFF course is based on DAFNE principles and aims to provide young people with self-management skills and strategies to help overcome some of the barriers to effective self-management associated with intensive insulin regimen. It was developed and piloted using the five phase approach recommended by the Medical Research Council (MRC) framework for the development of complex interventions (14), to culminate in this randomised controlled trial. The theoretical phase explored educational and motivational theory, the KICk-OFF package being based on the information-motivation-behavioural model (15). During the development phase of the project we worked with young people, parents, educationalists and school teachers, using the constructivist educational theory, to develop a package which would meet the very varied learning needs of adolescents (16).

The pilot phase involved 11-16 year olds (n=48) from three centres and demonstrated significant improvements in QOL and self-efficacy at 3 and 6 months post intervention. Glycaemic control showed no significant change overall, though there was a trend to improvement in those with the poorest control at baseline and also in the younger age group (11-13 years) (17). Our pilot work indicated that key ingredients in the KICk-OFF package include involvement of parents and parent-child communication, support of friends without diabetes, creating a feeling of being like everyone else and social support from other young people with diabetes.

The KICk-OFF intervention:

Each course takes place over five consecutive days and is delivered to groups of eight young people in two age bands, 11-13 years or 14-16 years. The curriculum uses a progressive modular structure to improve self-management in a variety of medical and social situations. Knowledge and skills are built up throughout the week with active participant involvement and problem solving as key methods of learning. The key modules include: what is diabetes; food and diabetes; insulin management; management of hypoglycaemia; sick day rules; diabetes in school and social situations. Learning objectives for each day and each session are clearly identified and educators have instructions on session preparation and teaching materials. Lesson plans give guidance on timing and a student activity section serves to give an idea of expected responses. Each meal and snack is used as an opportunity to practise carbohydrate estimation and insulin dose adjustment. Additional support is provided through dedicated parent sessions, involvement of friends and the provision of a school resource pack. Following process evaluation during the pilot phase, the model of parental education has been altered and parents are now invited to a specific parent education session prior to their children attending the 5-day course. This will provide them with a brief guide to the KICk-OFF principles and allow them to better support their child during the early days of the course.

A website developed to support the learning process allows those in the intervention arm interactive practise at carbohydrate counting and access to educational material and a message forum.

Study objective:

The aim of the study is to assess whether provision of the KICk-OFF structured education course improves clinical and psychological outcomes in adolescents with T1DM, when compared with usual care and education. It also aims to assess cost effectiveness.

Methods/Design

Design:

The KICk-OFF study is a cluster randomised controlled trial. Blinding is not possible as the intervention is evident both to those providing care and those receiving it. In addition, as educational expertise increases within teams, the likelihood of contamination of control groups is high and therefore a cluster randomised design is indicated (18). Centres are therefore randomised to control or intervention arms.

To minimise differences in delivery of the course between centres, three teams of educators travel to centres to teach the course alongside members of the local diabetes team,

Study duration:

The total study duration is 60 months, with the intervention (KICk-OFF courses) being delivered over a 15-month period. Follow-up is for 2 years post intervention.

Setting:

We aimed to recruit patients from up to 36 NHS paediatric diabetes centres in England, Scotland and Wales, with each intervention centre running two age-banded courses. There are eight children in each age-band (11-13 and 14-16 years).

Sample size calculations:

Sample size is based upon the primary outcome measure - HbA1c - and is calculated using data on average HbA1C values from the centres that have expressed an interest in participating (by email communication) and the pilot study. Kinmonth et al, examining patient-centred care of diabetes in general practice, estimated the intraclass correlation coefficient as 0.047 for HbA1c (19). Assuming that each centre will run two courses, each including 8 participants, the average cluster size will be 16. Data from the pilot study indicated that the standard deviation of the minimal clinically meaningful difference of 0.5% is between 1.3% and 1.4%. Taking the upper limit of this standard deviation range as a conservative estimate for the standard deviation, the study needs 448 patients in total (224 per group: 14 clusters per group with an average cluster size of 16) in order to have 80% power to detect a difference of 0.5% in HbA1c with a two-sided significance level of 5%. Assuming a 20% loss to follow-up at 12 months, the study requires 560 patients to be recruited from 18 centres per treatment group. The pilot study demonstrated an improvement in both the generic and diabetes related QOL scores of at least 7 points (SD: 12). Assuming that there will be no improvement in either score for the control participants, the sample size outlined above will have at least 80% power at the two-sided 5% level to detect a minimum difference of 4.5 points. In addition, this sample size will also have over

80% power at the two-sided 5% level to detect a difference in HUI2 score of 0.03 (SD: 0.08).

Centre randomisation:
Centres are randomised to one of two groups: (1) usual care (control), (2) KICk-OFF course (intervention), in a 1:1 ratio, using a computer generated allocation schedule prepared in advance of the trial to conceal centre allocation. Randomisation takes account of centre stratification according to current educational provision. Three key educational factors have been identified and centres asked to self assess against these, with independent review by the paediatric clinicians.

Inclusion and exclusion criteria:
These are shown in table 1. Participants are not selected on the basis of their existing HbA1c level as it was felt that all children have potential to benefit from the KICk-Off intervention, including those with existing good control.

Table 1: Inclusion/exclusion criteria

Inclusion criteria
T1DM of at least 1 year's duration
Already on or willing to use an intensive insulin regimen (basal – bolus regimen)
Age 11-16 years (in Secondary School years 7-12)
Exclusion criteria
Factors which will impair participation in group education:
Non - English speaking child
Learning disability requiring additional help in school
Major behaviour problems
Evidence of an eating disorder
Associated illness that may influence control (treated coeliac disease with at least 6 months on a gluten free diet is not an exclusion)

Patient recruitment:
All eligible families receive written and verbal information regarding the KICk-OFF course from their local diabetes team. Centres are not, at this stage, aware of whether they are control or intervention centres. Recruitment ceases in the centre when a maximum of 16 participants have been recruited and centres is then notified if they are in the control or intervention arm of the study.

Involvement of friends: Each KICk-OFF participant is asked to invite a friend to a half-day session.

Subject withdrawal: Subjects are withdrawn from the study if their behaviour during the KICk-OFF course proves, in the view of the educators, to be detrimental to the continued learning of other participants. This is an unlikely occurrence and will only occur after discussion with the child and their parents. Analysis will be by intention to treat and subjects who are withdrawn will be included in final analysis.

Educator recruitment and training:
Each course is taught by two research educators (a paediatric diabetes specialist nurse and a paediatric diabetes dietitian) and one member of the local team. Research and

local team educators attend a 5-day teaching skills course developed during the pilot phase with the Department of Education, Sheffield Hallam University. A core training team has been established, comprising the KICk-OFF lead educator, professional educationalist and teachers. It includes a structured school placement, the purpose of which is to familiarise the educators with aspects of the school curriculum, observe experienced teachers in classroom settings and practice selected activities with pupil groups under the guidance of a qualified teacher. The course includes instruction in:

- role of teachers – in comparison with health professionals
- training in the KICk-OFF curriculum and teaching materials
- use of IT, lap top computers, interactive boards etc in the classroom setting
- the pace/timing of sessions
- ability to be flexible within the curriculum
- behaviour management
- motivating, involving all group members
- the role of questioning

Ethical consideration, possible risks and benefits:
The North Sheffield Local Research Ethics Committee approved the study (ref. 08/H1308/201).
During the course, participants are encouraged to discuss diabetes management and how it affects their social, school and family life; future health with diabetes, and other relevant topics such as alcohol, smoking, driving and contraception. All these topics are routinely discussed with this age group in diabetes clinics, as well as in school. Staff are alert to any concerns, and where appropriate may discuss with parents or the child's paediatrician. Child protection or other disclosures would be dealt with according to local Safeguarding Children Policies. The website forum is mediated by a member of the research team.
Given that intensive insulin regimens are commonly used in this age group it is difficult to envisage significant risks from participation in this study. Given "permission" to eat a less restricted diet there is the possibility that participants may make unhealthier food choices, with potential for weight gain. With improving glycaemic control there is a potential risk of increasing severe hypoglycaemia. Educated in avoidance, recognition and management of hypoglycaemia is an essential part of the course. The course aims to provide children with the skills to match their insulin dose to their food choice and regularly correct their blood sugar. The anticipated benefits are therefore improved blood sugar control, quality of life and self-efficacy. This in turn may lead to less family conflict and better social integration. Study results will be disseminated via peer review journals and oral presentation.

The control arm:
Children in the control group are already established on, or changed to, a basal-bolus regimen at the start of the study. They will receive the normal educational input provided to children on basal bolus regimens in their clinic. The control centres will be offered the teaching skills course for their team at the end of the 2 year follow-up period.

Assessment:

Assessments are undertaken by the research team and local diabetes team, at baseline, 6 months, 12 months and 24 months.

Outcome measures:
Primary outcomes are the change in biomedical and psychosocial measures at the end of 6 months, adjusted for baseline. Change between 6 months and 2 years will allow an assessment of sustainability of learning. The research team believe that improving quality of life is a very positive outcome in young people who carry a heavy psychological burden and therefore wish to ensure that this outcome carries equal weight to glycaemic outcomes.

Table 2: Primary/secondary outcomes

Primary outcomes	***Secondary outcomes***
HbA1c (mmol/mol)	Health economic analysis and modelling of long term cost/benefits
Psychological outcome in parents and children	Evaluation of the KICk-OFF course by educationalists
Number and severity of hypoglycaemic episodes.	Diabetic ketoacidosis
	Time off school
	Change in diet
	Changes in BMI
	Evaluation of website use

Biomedical outcomes:
HbA1c is measured by a central laboratory. Body mass index will be calculated from weight and height measurements and pubertal status (which has a potential influence on glycaemic control) will be assessed, using height velocity as a surrogate marker. It was felt that direct assessment of pubertal status through clinical examination would deter recruitment. Episodes of diabetic ketoacidosis and severe hypoglycaemia are assessed by patient recall and from medical records.

Psychological outcomes:
Psychosocial measures have been chosen to reflect the key components of the psychological model (adherence information, motivation, behavioural skills). All measures are completed by children and by one parent: Fear of hypoglycaemia (20); Expectations - a specially developed measure based on the results of our pilot study to determine the child and parents' commitment, enthusiasm and expectations about the course outcomes; Self efficacy for diabetes (21); Quality of life – generic (22) and diabetes specific (23);.

Health economic analysis:
The economic component of this study will be undertaken from the perspective of the UK NHS. The primary measure of outcome for the economic analysis will be the cost per quality adjusted life year (QALY) gained as measured by the HUI2 instrument. The items of resource use relating to educator time and educational and teaching materials will be measured within the trial by means of a semi-structured telephone

interview with key educators. The items of resource use relating to primary and secondary care utilisation will be measured by means of the patient report completed throughout the course of the trial cross referenced with resource use information obtained from patient records at participating centres. All resources will be costed using national average unit costs where possible. In the absence of national average unit costs local unit costs will be obtained from individual hospital finance departments

From an economic perspective, the main measure of effectiveness is the number of QALYs gained. For the estimation of QALYs, a generic health related quality of life instrument is required which allows the estimation of health state utilities. The HUI2 is a well validated instrument which has been used successfully in previous studies relating to diabetes and in adolescent children (24, 25, 26, 27). The HUI2 has been designed for self-completion and will be administered to all trial participants and their parents as proxies at the defined time intervals. Parental assessment will facilitate an empirical investigation of the degree of convergence or otherwise between adolescents' assessment of their own health related quality of life and parental assessment of adolescent health related quality of life. The UK general population tariff of utility values for HUI2 defined health states (28) will be used to calculate a QALY gain for each patient using area under the curve methods. These data will then be aggregated to estimate the total QALY gain for intervention and control groups respectively.

The CHU 9D, a new preference based measure of health related quality of life, has been developed in Sheffield, exclusively for and tested with children (29). It consists of 9 questions, each with 5 response options. This will be used as a secondary measure of calculating QALYs.

Mean costs and effectiveness between the intervention and control groups will be compared and incremental cost effectiveness ratios presented (ICERs) in terms of the cost per unit reduction in HbA1c% and the cost per QALY gained. Confidence intervals will be presented around the ICERs. Cost effectiveness acceptability curves for varying threshold values of cost effectiveness will also be presented. Any costs incurred beyond the base year of the evaluation will be discounted at the recommended treasury rate for public sector projects. An assessment of the sensitivity of the results obtained to variation in measured resource use, effectiveness and/or unit costs will be undertaken using appropriate one-way and multi-way sensitivity analysis.

Long-term cost effectiveness modelling:

Given that we anticipate a difference in risk factors, particularly HbA1c, between the intervention and control arm, and that these risk factor differences can potentially be maintained over the longer-term, there is a strong economic hypothesis that the upfront investment in the education programme will pay off in terms of avoided clinical events over the longer-term. Reductions in HbA1c will be used to predict reduced long-term complications and improved mortality and QALYs. We will extend this with an updated search. Cost effectiveness models will also account for uncertainty in line with good practice guidance.

Change in diet:

The KICk-OFF course potentially provides participants with the freedom to widen their dietary choices, although healthy eating is encouraged. The Food Intake

Questionnaire is a validated recall questionnaire that has been used to assess dietary intake in children (30).

Website evaluation:
During development:
1. Views of young people sought on materials and graphics, to determine the style of the website
2. Potential barriers to using the website explored with young people
3. All web pages will be assessed with a tool called DISCERN, a brief questionnaire which provides users with a valid and reliable way of assessing the quality of written information on treatment choices for a health problem (31)
At each follow-up time point (6, 12, 24 months):
4. From login information, we will identify a) place of use (i.e. during taught session or through own choice at home); b) total number of logins and average duration of use per individual.
5. All users are encouraged to complete an online user satisfaction scale to assess acceptability and identify areas for improvement. Phone interviews with a random selection of participants will also be used e.g. to identify barriers to using the website.

Educational evaluation:
Developing and evaluating complex educational interventions, such as KICk-OFF, is challenging. Many factors will influence outcomes and process evaluation i.e. trying to identify the key active ingredients of such a package is important. Therefore in addition to measuring effect in terms of participant outcomes, we are undertaking independent educational evaluation of the package. Two academic educationalists observe courses, hold focus groups with educators and have informal discussions with participants. They will produce an independent report of the educational content of the KICk-OFF package, identifying areas of effective education and also provide suggestions for change to the curriculum and teaching material. They will also work with the lead research educator to develop quality assurance checklists that can be used to assess consistency of teaching between educator groups and adherence to the learning aims and objectives of the curriculum.

Statistical analysis:
Data will be reported according to the CONSORT statement for cluster randomised clinical trials (32). All analyses will be by intention-to treat with a two-sided P-value of < 0.05 being regarded as statistically significant. Baseline characteristics will be compared across intervention groups to ensure the groups are balanced. Where differences are found they will be adjusted for in the analysis. The paediatric diabetes centre will be the unit of randomisation, cluster, intervention and analysis, because that is where the intervention is aimed, though the effect will be evaluated at the patient level.
The primary outcome variable is HbA1c and differences in this between the two study groups at 6 months will be compared using a marginal model, with coefficients and their associated 95% confidence intervals estimated using generalised estimating equations. This type of modelling allows for the clustered nature of the data, in which the observations within clusters are not assumed to be independent. In addition the model will include terms for the stratification factor and any potential confounders in the baseline characteristics. For the other outcomes, including QOL and the

anthropometrical measures, differences in the mean values at 6 months will be analysed using a similar model, whilst differences in hypoglycaemia event rates and school attendance will be analysed using a Poisson random effects model. The data will be analysed using STATA v10® software and SAS v9.1 software.

Trial monitoring and management:
The project manager and chief investigator meet weekly and the project management group 3 monthly, with additional meetings as necessary. An independent steering group includes a statistician and young person representative. Centres and participants are communicated with by email and 6 monthly newsletters.

Discussion

KICk-OFF is a highly complex educational intervention that has potential to improve glycaemic control and/or psychological outcomes. Our hypothesis is that behaviour change as a result of attending a KICk-OFF course is likely to take place within 6-12 months of the intervention. We felt that 2 year follow-up was necessary to assess sustainability of learning but also accept that the adolescent years are a time of great change and many other confounding factors such as puberty, school and peer pressure will influence adherence to a diabetes regimen and long-term outcomes.
Sustainability of learning will also be influenced by ongoing support from local diabetes team. They are asked to run follow-up sessions within 6 months of the intervention and to encourage participants to continue to use their KICk-OFF self-management skills in everyday life. Paediatric diabetes care across the UK is changing rapidly, with many more children using an intensive insulin regimen from diagnosis and also moving onto insulin infusion pumps. Many centres routinely teach carbohydrate counting, though none with an intensive course such as KICk-OFF. Whilst the KICk-OFF course is not specifically designed for those on pumps, many of the skills required to successfully manage a pump are taught on the course. We anticipate that a number of our original cohort will move onto pumps during the study and will examine this group as a subgroup analysis. Change in educational practise by local centres across the study period will also be examined by repeating the stratification process at the end of the study.
We aim to reduce inter-educator variability by having just three teams of educators who will all receive specialist teacher training prior to teaching KICk-OFF courses. Practical factors such as weather and illness may impact on attendance at a KICk-OFF course. We shall attempt to provide catch-up education for those who miss days but any participant who is present for < 3 days will be deemed to be non compliant with the intervention.
Unlike other interventions we decided not to use the existing HbA1c level as an inclusion or exclusion criteria. We are therefore recruiting participants with a wide range of glycaemic control. Some will have an HbA1c within the recommended target of less than 58 mmol/mol (7.5%) at baseline and therefore may not change. Those with very tight control at baseline may be suffering from frequent hypoglycaemia or hypoglycaemia unawareness. Their glycaemic control could deteriorate somewhat but we hypothesise that concurrent reduction in hypoglycaemia could result in improved quality of life.
Structured education, providing knowledge and skills training to young people with diabetes, is an essential component of self-management. We hope that the KICk-OFF study will add important information to the literature by assessing the impact of

intensive group education. We acknowledge however that the acquisition of effective self-management skills is highly complex and many other factors such as family support and functioning, diabetes team interaction with families and other pressures within the lives of young people also influence their development.

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract - *Does an intensive self-management structured education course improve outcomes for children and young people with type 1 diabetes? The Kids In Control OF Food (KICk-OFF) cluster randomised controlled trial protocol*			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	5
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	4
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	6
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results - *this submission is a protocol paper for work in progress, data not yet available*			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	n/a
	13b	For each group, losses and exclusions after randomisation, together with reasons	n/a
Recruitment	14a	Dates defining the periods of recruitment and follow-up	n/a
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	n/a
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	n/a
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	n/a
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	n/a
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	n/a
Other information			
Registration	23	Registration number and name of trial registry	Current Controlled Trials ISRCTN37042683
Protocol	24	Where the full trial protocol can be accessed, if available	n/a
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Diabetes UK,

	ref. 07/0003555. Provision of funding only

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Does an intensive self-management structured education course improve outcomes for children and young people with type 1 diabetes? The Kids In Control OF Food (KICk-OFF) cluster randomised controlled trial protocol.

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Title:

Does an intensive self-management structured education course improve outcomes for children and young people with type 1 diabetes? The Kids In Control OF Food (KICk-OFF) cluster randomised controlled trial protocol.

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Key words: type 1 diabetes mellitus; adolescent; child; education, patient:

Word count: 4932

Abstract

Introduction: KICk-OFF is a cluster-randomised controlled trial, which aims to determine the efficacy of a 5 day structured education course for 11-16 year olds with type 1 diabetes when compared with standard care, and its cost effectiveness.

Less than 15% of children and young people with type 1 diabetes in the UK meet the recommended glycaemic target. Self-management education programmes for adults with type 1 diabetes improve clinical and psychological outcomes but none have been evaluated in the paediatric population. KICk-OFF is a 5 day structured education course for 11-16 year olds with type 1 diabetes. It was developed with input from young people, parents, teachers and educationalists.

Methods and analysis: 36 paediatric diabetes centres across the UK, randomised into intervention and control arms. Up to 560 participants recruited prior to centre randomisation. KICk-OFF courses are delivered in the intervention centres, with standard care continued in the control arm. Primary outcomes are change in glycaemic control (HbA1c) and quality of life between baseline and 6 months post intervention, and the incidence of severe hypoglycaemia. Sustained change in self-management behaviour is assessed by follow-up at 12 and 24 months. Health economic analysis will be undertaken. Data will be reported according to the CONSORT statement for cluster randomised clinical trials. All analyses will be by intention-to treat with a two-sided P-value of < 0.05 being regarded as statistically significant. The study commenced in 2008. Data collection from participants is ongoing and the study will be completed in 2013.

Ethics: The study has been approved by the Sheffield Research Ethics Committee.
Dissemination: Results will be reported in peer reviewed journals and conferences.

Trial registration: Current Controlled Trials ISRCTN37042683

Background

Structured education for paediatric diabetes management in the UK:

The glycaemic control of children with type 1 diabetes (TIDM), the key determinant of long term complications and mortality, is less good in the UK than in many other European countries (1). Successive audits in Scotland, England and Wales have shown no improvement in recent years (2,3) and less than 15% achieve the recommended target of an HbA1c of less than 7.5%. Support, education and self-management skills are thought to be key influences on control. Of the educational and psychological interventions that have been reported in children and adolescents, there is considerable diversity both in the methods used and their theoretical underpinnings. These range from simple skills and knowledge acquisition to more complex interventions involving family and friends. In a systematic review commissioned by the National Institute for Health Research (NIHR) Health Technology Assessment programme, Hampson and colleagues highlight a lack of well-designed clinical trials of educational interventions in the UK. They emphasise the need for programme development in the UK to be guided by theory and involve consultation with the various groups of people involved, including patients and their families (4) . A more recent update on this systematic review shows some progress in quality and quantity of research but no improved outcomes (5). The systematic review underpinning the National Institute for Health and Clinical Excellence (NICE) appraisal of diabetes education notes a shortage of high quality information regarding the efficacy of education and that most studies exclude children and adolescents. The Department of Health (DH) and Diabetes UK confirm this finding (6) and highlight key criteria for structured education: a structured, written curriculum meeting the learning needs of participants, delivered by trained educators; with quality assurance; and audit.

The DAFNE (**D**ose **A**djustment **F**or **N**ormal **E**ating) course is one current option for adult education. This 5-day outpatient course is adapted from a German adult education model (7). Patients are taught carbohydrate counting and insulin dose algorithms, enabling them to eat freely and administer a dose of insulin that matches the intended meal. Six months after completing the course there was a 0.9% improvement in glycated haemoglobin (HbA1c) levels in the DAFNE group compared with controls, sustained at 0.5% overall improvement by 1 year (8). Furthermore, a quarter of participants improved their HbA1c by more than 1.5% over 12 months without an increase in severe hypoglycaemia. Many described a greatly improved quality of life (QOL) and economic analysis suggests that such a course could pay for itself within 4 years as a result of reduced diabetes related complications (9). The DAFNE course has been identified as the only intervention meeting DH requirements for a structured educational programme in T1DM and has now been rolled out to over 60 centres in UK and Ireland.

Whilst structured education courses have been delivered to children in Germany for many years, there have been no randomised controlled trials (RCT) of a DAFNE-type intervention in children (10). Adolescence is often associated with relatively poor glycaemic control, but is potentially an ideal time to intervene as patients assume responsibility for their own control and disease management (11). The adolescents who participated in the Diabetes Control and Complications Trial (DCCT) intensive management group demonstrated significantly improved control during the 7.4 years of the trial compared with those in the control group (12). During the subsequent four years those in the intensive group have shown progression of retinopathy reduced by

74% compared with controls, despite the fact that the HbA1c levels of both groups converged (13). The benefits of improved glycaemic control clearly continued beyond the duration of the trial, supporting the argument that educational interventions should be offered soon after diagnosis of T1DM. However, we must acknowledge there are potential challenges for young people in undertaking such a regimen. The need for repeated blood tests, carbohydrate portion estimation and multiple insulin injections may compromise quality of life and challenge the cognitive abilities of some young people.

The KICk-OFF course is based on DAFNE principles and aims to provide young people with self-management skills and strategies to help overcome some of the barriers to effective self-management associated with intensive insulin regimen. It was developed and piloted using the five phase approach recommended by the Medical Research Council (MRC) framework for the development of complex interventions (14), to culminate in this randomised controlled trial. The theoretical phase explored educational and motivational theory, the KICk-OFF package being based on the information-motivation-behavioural model (15). During the development phase of the project we worked with young people, parents, educationalists and school teachers, using the constructivist educational theory, to develop a package which would meet the very varied learning needs of adolescents (16).

The pilot phase involved 11-16 year olds (n=48) from three centres and demonstrated significant improvements in QOL and self-efficacy at 3 and 6 months post intervention. Glycaemic control showed no significant change overall, though there was a trend to improvement in those with the poorest control at baseline and also in the younger age group (11-13 years) (17). Our pilot work indicated that key ingredients in the KICk-OFF package include involvement of parents and parent-child communication, support of friends without diabetes, creating a feeling of being like everyone else and social support from other young people with diabetes.

The KICk-OFF intervention:

Each course takes place over five consecutive days and is delivered to groups of eight young people in two age bands, 11-13 years or 14-16 years. The curriculum uses a progressive modular structure to improve self-management in a variety of medical and social situations. Knowledge and skills are built up throughout the week with active participant involvement and problem solving as key methods of learning. The key modules include: what is diabetes; food and diabetes; insulin management; management of hypoglycaemia; sick day rules; diabetes in school and social situations. Learning objectives for each day and each session are clearly identified and educators have instructions on session preparation and teaching materials. Lesson plans give guidance on timing and a student activity section serves to give an idea of expected responses. Each meal and snack is used as an opportunity to practise carbohydrate estimation and insulin dose adjustment. Additional support is provided through dedicated parent sessions, involvement of friends and the provision of a school resource pack. Following process evaluation during the pilot phase, the model of parental education has been altered and parents are now invited to a specific parent education session prior to their children attending the 5-day course. This will provide them with a brief guide to the KICk-OFF principles and allow them to better support their child during the early days of the course.

A website developed to support the learning process allows those in the intervention arm interactive practise at carbohydrate counting and access to educational material and a message forum.

Study objective:

The aim of the study is to assess whether provision of the KICk-OFF structured education course improves clinical and psychological outcomes in adolescents with T1DM, when compared with usual care and education. It also aims to assess cost effectiveness.

Methods/Design

Design:

The KICk-OFF study is a cluster randomised controlled trial. Blinding is not possible as the intervention is evident both to those providing care and those receiving it. In addition, as educational expertise increases within teams, the likelihood of contamination of control groups is high and therefore a cluster randomised design is indicated (18). Centres are therefore randomised to control or intervention arms.

To minimise differences in delivery of the course between centres, three teams of educators travel to centres to teach the course alongside members of the local diabetes team,

Study duration:

The total study duration is 60 months, with the intervention (KICk-OFF courses) being delivered over a 15-month period. Follow-up is for 2 years post intervention.

Setting:

We aimed to recruit patients from up to 36 NHS paediatric diabetes centres in England, Scotland and Wales, with each intervention centre running two age-banded courses. There are eight children in each age-band (11-13 and 14-16 years). 36 centres initially expressed interest in the study, 27 of which acquired research approval and recruited patients. An additional 5 centres were therefore sought when recruitment targets appeared to be compromised by centre withdrawal and lower than anticipated recruitment rates in some centres. 31 centres are therefore participating in the study.

Sample size calculations:

Sample size is based upon the primary outcome measure - HbA1c - and is calculated using data on average HbA1C values from the centres that have expressed an interest in participating (by email communication) and the pilot study. Kinmonth et al, examining patient-centred care of diabetes in general practice, estimated the intraclass correlation coefficient as 0.047 for HbA1c (19). Assuming that each centre will run two courses, each including 8 participants, the average cluster size will be 16. Data from the pilot study indicated that the standard deviation of the minimal clinically meaningful difference of 0.5% is between 1.3% and 1.4%. Taking the upper limit of this standard deviation range as a conservative estimate for the standard deviation, the study needs 448 patients in total (224 per group: 14 clusters per group with an average cluster size of 16) in order to have 80% power to detect a difference of 0.5% in HbA1c with a two-sided significance level of 5%. Assuming a 20% loss to follow-up at 12 months, the study requires 560 patients to be recruited from 18 centres per treatment group. The pilot study demonstrated an improvement in both the generic

and diabetes related QOL scores of at least 7 points (SD: 12). Assuming that there will be no improvement in either score for the control participants, the sample size outlined above will have at least 80% power at the two-sided 5% level to detect a minimum difference of 4.5 points. In addition, this sample size will also have over 80% power at the two-sided 5% level to detect a difference in HUI2 score of 0.03 (SD: 0.08).

Centre randomisation:
Centres are randomised to one of two groups: (1) usual care (control), (2) KICk-OFF course (intervention), in a 1:1 ratio, using a computer generated allocation schedule prepared in advance of the trial to conceal centre allocation. Randomisation takes account of centre stratification according to current educational provision. Three key educational factors have been identified and centres asked to self assess against these, with independent review by the paediatric clinicians.

Inclusion and exclusion criteria:
These are shown in table 1. Participants are not selected on the basis of their existing HbA1c level as it was felt that all children have potential to benefit from the KICk-Off intervention, including those with existing good control.

Table 1: Inclusion/exclusion criteria

Inclusion criteria
T1DM of at least 1 year's duration
Already on or willing to use an intensive insulin regimen (basal – bolus regimen)
Age 11-16 years (in Secondary School years 7-12)
Exclusion criteria
Factors which will impair participation in group education:
Non - English speaking child
Learning disability requiring additional help in school
Major behaviour problems ,identified by the clinical team, and requiring mental health team involvement
Evidence of an eating disorder
Associated illness that may influence control (treated coeliac disease with at least 6 months on a gluten free diet is not an exclusion)

Patient recruitment:
All eligible families receive written and verbal information regarding the KICk-OFF course from their local diabetes team, who also take assent/consent from both the child and a parent/ legal guardian. Centres are not, at this stage, aware of whether they are control or intervention centres. Recruitment ceases in the centre when a maximum of 16 participants have been recruited and centres is then notified if they are in the control or intervention arm of the study.

Involvement of friends: Each KICk-OFF participant is asked to invite a friend to a half-day session.

Subject withdrawal: Whilst clinical teams are aware of diagnosed behavioural problems and those children are excluded from recruitment, it is possible that challenging behaviour will emerge in some children during the week of the KICk-

OFF course which has not been anticipated. Every effort is made to support them to remain involved but subjects are withdrawn if their behaviour during the KICk-OFF course proves, in the view of the educators, to be detrimental to the continued learning of other participants. This is an unlikely occurrence and will only occur after discussion with the child and their parents. Analysis will be by intention to treat and subjects who are withdrawn will be included in final analysis.

Educator recruitment and training:
Each course is taught by two research educators (a paediatric diabetes specialist nurse and a paediatric diabetes dietitian) and one member of the local team. Research and local team educators attend a 5-day teaching skills course developed during the pilot phase with the Department of Education, Sheffield Hallam University. A core training team has been established, comprising the KICk-OFF lead educator, professional educationalist and teachers. It includes a structured school placement, the purpose of which is to familiarise the educators with aspects of the school curriculum, observe experienced teachers in classroom settings and practice selected activities with pupil groups under the guidance of a qualified teacher. The course includes instruction in:

- role of teachers – in comparison with health professionals
- training in the KICk-OFF curriculum and teaching materials
- use of IT, lap top computers, interactive boards etc in the classroom setting
- the pace/timing of sessions
- ability to be flexible within the curriculum
- behaviour management
- motivating, involving all group members
- the role of questioning

Ethical consideration, possible risks and benefits:
The North Sheffield Local Research Ethics Committee approved the study (ref. 08/H1308/201).
During the course, participants are encouraged to discuss diabetes management and how it affects their social, school and family life; future health with diabetes, and other relevant topics such as alcohol, smoking, driving and contraception. All these topics are routinely discussed with this age group in diabetes clinics, as well as in school. Staff are alert to any concerns, and where appropriate may discuss with parents or the child's paediatrician. Child protection or other disclosures would be dealt with according to local Safeguarding Children Policies. The website forum is mediated by a member of the research team.
Given that intensive insulin regimens are commonly used in this age group it is difficult to envisage significant risks from participation in this study. Given "permission" to eat a less restricted diet there is the possibility that participants may make unhealthier food choices, with potential for weight gain. With improving glycaemic control there is a potential risk of increasing severe hypoglycaemia. Educated in avoidance, recognition and management of hypoglycaemia is an essential part of the course. The course aims to provide children with the skills to match their insulin dose to their food choice and regularly correct their blood sugar. The anticipated benefits are therefore improved blood sugar control, quality of life and self-efficacy. This in turn may lead to less family conflict and better social integration. Study results will be disseminated via peer review journals and oral presentation.

The control arm:
Children in the control group are already established on, or changed to, a basal-bolus regimen at the start of the study. They will receive the normal educational input provided to children on basal bolus regimens in their clinic. The control centres will be offered the teaching skills course for their team at the end of the 2 year follow-up period.

Assessment:
Assessments are undertaken by the research team and local diabetes team, at baseline, 6 months, 12 months and 24 months. All participants will be allocated a unique identifying number which is used on all data reporting forms and samples. Access to personal information is restricted to the project manager and chief investigator. All data returns are kept in locked files. No personal information will be shared during publication.

Outcome measures:
Primary outcomes are the change in biomedical and psychosocial measures at the end of 6 months, adjusted for baseline. Change between 6 months and 2 years will allow an assessment of sustainability of learning. The research team believe that improving quality of life is a very positive outcome in young people who carry a heavy psychological burden and therefore wish to ensure that this outcome carries equal weight to glycaemic outcomes.

Table 2: Primary/secondary outcomes

Primary outcomes	***Secondary outcomes***
HbA1c (mmol/mol)	Health economic analysis and modelling of long term cost/benefits
Psychological outcome in parents and children	Evaluation of the KICk-OFF course by educationalists
Number and severity of severe hypoglycaemic episodes. (Categorised as those requiring third party help and seizures).	Diabetic ketoacidosis
	Time off school
	Change in diet
	Changes in BMI
	Evaluation of website use

Biomedical outcomes:
HbA1c is measured by a central laboratory. Body mass index will be calculated from weight and height measurements and pubertal status (which has a potential influence on glycaemic control) will be assessed, using height velocity as a surrogate marker. It was felt that direct assessment of pubertal status through clinical examination would deter recruitment. Episodes of diabetic ketoacidosis and severe hypoglycaemia are assessed by patient recall and from medical records.

Psychological outcomes:
Psychosocial measures have been chosen to reflect the key components of the psychological model (adherence information, motivation, behavioural skills). All measures are completed by children and by one parent: Fear of hypoglycaemia (20); Expectations - a specially developed measure based on the results of our pilot study to determine the child and parents' commitment, enthusiasm and expectations about the course outcomes; Self efficacy for diabetes (21); Quality of life – generic (22) and diabetes specific (23);.

Health economic analysis:
The economic component of this study will be undertaken from the perspective of the UK NHS. The primary measure of outcome for the economic analysis will be the cost per quality adjusted life year (QALY) gained as measured by the HUI2 instrument. The items of resource use relating to educator time and educational and teaching materials will be measured within the trial by means of a semi-structured telephone interview with key educators. The items of resource use relating to primary and secondary care utilisation will be measured by means of the patient report completed throughout the course of the trial cross referenced with resource use information obtained from patient records at participating centres. All resources will be costed using national average unit costs where possible. In the absence of national average unit costs local unit costs will be obtained from individual hospital finance departments
From an economic perspective, the main measure of effectiveness is the number of QALYs gained. For the estimation of QALYs, a generic health related quality of life instrument is required which allows the estimation of health state utilities. The HUI2 is a well validated instrument which has been used successfully in previous studies relating to diabetes and in adolescent children (24, 25, 26, 27). The HUI2 has been designed for self-completion and will be administered to all trial participants and their parents as proxies at the defined time intervals. Parental assessment will facilitate an empirical investigation of the degree of convergence or otherwise between adolescents' assessment of their own health related quality of life and parental assessment of adolescent health related quality of life. The UK general population tariff of utility values for HUI2 defined health states (28) will be used to calculate a QALY gain for each patient using area under the curve methods. These data will then be aggregated to estimate the total QALY gain for intervention and control groups respectively.
The CHU 9D, a new preference based measure of health related quality of life, has been developed in Sheffield, exclusively for and tested with children (29). It consists of 9 questions, each with 5 response options. This will be used as a secondary measure of calculating QALYs.

Mean costs and effectiveness between the intervention and control groups will be compared and incremental cost effectiveness ratios presented (ICERs) in terms of the cost per unit reduction in HbA1c% and the cost per QALY gained. Confidence intervals will be presented around the ICERs. Cost effectiveness acceptability curves for varying threshold values of cost effectiveness will also be presented. Any costs incurred beyond the base year of the evaluation will be discounted at the recommended treasury rate for public sector projects. An assessment of the sensitivity of the results obtained to variation in measured resource use, effectiveness and/or unit

costs will be undertaken using appropriate one-way and multi-way sensitivity analysis.

Long-term cost effectiveness modelling:
Given that we anticipate a difference in risk factors, particularly HbA1c, between the intervention and control arm, and that these risk factor differences can potentially be maintained over the longer-term, there is a strong economic hypothesis that the upfront investment in the education programme will pay off in terms of avoided clinical events over the longer-term. Reductions in HbA1c will be used to predict reduced long-term complications and improved mortality and QALYs. We will extend this with an updated search. Cost effectiveness models will also account for uncertainty in line with good practice guidance.

Change in diet:
The KICk-OFF course potentially provides participants with the freedom to widen their dietary choices, although healthy eating is encouraged. The Food Intake Questionnaire is a validated recall questionnaire that has been used to assess dietary intake in children (30).

Website evaluation:
During development:
1. Views of young people sought on materials and graphics, to determine the style of the website
2. Potential barriers to using the website explored with young people
3. All web pages will be assessed with a tool called DISCERN, a brief questionnaire which provides users with a valid and reliable way of assessing the quality of written information on treatment choices for a health problem (31)
At each follow-up time point (6, 12, 24 months):
4. From login information, we will identify a) place of use (i.e. during taught session or through own choice at home); b) total number of logins and average duration of use per individual.
5. All users are encouraged to complete an online user satisfaction scale to assess acceptability and identify areas for improvement. Phone interviews with a random selection of participants will also be used e.g. to identify barriers to using the website.

Educational evaluation:
Developing and evaluating complex educational interventions, such as KICk-OFF, is challenging. Many factors will influence outcomes and process evaluation i.e. trying to identify the key active ingredients of such a package is important. Therefore in addition to measuring effect in terms of participant outcomes, we are undertaking independent educational evaluation of the package. Two academic educationalists observe courses, hold focus groups with educators and have informal discussions with participants. They will produce an independent report of the educational content of the KICk-OFF package, identifying areas of effective education and also provide suggestions for change to the curriculum and teaching material. They will also work with the lead research educator to develop quality assurance checklists that can be used to assess consistency of teaching between educator groups and adherence to the learning aims and objectives of the curriculum.

Participant retention/ missing data
Principal investigators in each centre are sent regular updates regarding completeness of data returns from their participants and encouraged to ensure as complete a data set as possible. Participants are sent a 6 monthly newsletter and all returned questionnaires are entered into a prize draw (a total of 8 throughout the study).
In the case of missing data: information about growth, DKA admissions and severe hypoglycaemia is sought from clinical records. Locally measured HbA1c results are also obtained. At each time point information is collected to identify those who have deviated from protocol by no longer using a basal-bolus insulin regimen or who have moved onto continuous subcutaneous insulin infusion.

Statistical analysis:
Data will be reported according to the CONSORT statement for cluster randomised clinical trials (32). All analyses will be by intention-to treat with a two-sided P-value of < 0.05 being regarded as statistically significant. Baseline characteristics will be compared across intervention groups to ensure the groups are balanced. Where differences are found they will be adjusted for in the analysis. The paediatric diabetes centre will be the unit of randomisation, cluster, intervention and analysis, because that is where the intervention is aimed, though the effect will be evaluated at the patient level.
The primary outcome variable is HbA1c and differences in this between the two study groups at 6 months will be compared using a marginal model, with coefficients and their associated 95% confidence intervals estimated using generalised estimating equations. This type of modelling allows for the clustered nature of the data, in which the observations within clusters are not assumed to be independent. In addition the model will include terms for the stratification factor and any potential confounders in the baseline characteristics. For the other outcomes, including QOL and the anthropometrical measures, differences in the mean values at 6 months will be analysed using a similar model, whilst differences in hypoglycaemia event rates and school attendance will be analysed using a Poisson random effects model. The data will be analysed using STATA v10® software and SAS v9.1 software.

Trial monitoring and management:
The project manager and chief investigator meet weekly and the project management group 3 monthly, with additional meetings as necessary. The project management group comprises the project manager, chief investigator, all co-applicants, study sponsor, and representatives of the Health Economic evaluation team who have been directly involved in study design, data collection and who will be undertaking the health economic analysis. The project management group are involved in all aspects of the study design and progress. Publications will be co-authored by this group.
Database management is undertaken by the Clinical Trials Unit, School of Health and Related Research, University of Sheffield
An independent steering group includes an independent chair (Prof. N Waugh), an independent statistician and paediatric diabetologist and a young person representative.

Centres and participants are communicated with by email and 6 monthly newsletters.

Discussion

KICk-OFF is a highly complex educational intervention that has potential to improve glycaemic control and/or psychological outcomes. Our hypothesis is that behaviour change as a result of attending a KICk-OFF course is likely to take place within 6-12 months of the intervention. We felt that 2 year follow-up was necessary to assess sustainability of learning but also accept that the adolescent years are a time of great change and many other confounding factors such as puberty, school and peer pressure will influence adherence to a diabetes regimen and long-term outcomes.

Sustainability of learning will also be influenced by ongoing support from local diabetes team. They are asked to run follow-up sessions within 6 months of the intervention and to encourage participants to continue to use their KICk-OFF self-management skills in everyday life. Paediatric diabetes care across the UK is changing rapidly, with many more children using an intensive insulin regimen from diagnosis and also moving onto insulin infusion pumps. Many centres routinely teach carbohydrate counting, though none with an intensive course such as KICk-OFF. Whilst the KICk-OFF course is not specifically designed for those on pumps, many of the skills required to successfully manage a pump are taught on the course. We anticipate that a number of our original cohort will move onto pumps during the study and will examine this group as a subgroup analysis. Change in educational practise by local centres across the study period will also be examined by repeating the stratification process at the end of the study.

We aim to reduce inter-educator variability by having just three teams of educators who will all receive specialist teacher training prior to teaching KICk-OFF courses. Practical factors such as weather and illness may impact on attendance at a KICk-OFF course. We shall attempt to provide catch-up education for those who miss days but any participant who is present for < 3 days will be deemed to be non compliant with the intervention.

Unlike other interventions we decided not to use the existing HbA1c level as an inclusion or exclusion criteria. We are therefore recruiting participants with a wide range of glycaemic control. Some will have an HbA1c within the recommended target of less than 58 mmol/mol (7.5%) at baseline and therefore may not change. Those with very tight control at baseline may be suffering from frequent hypoglycaemia or hypoglycaemia unawareness. Their glycaemic control could deteriorate somewhat but we hypothesise that concurrent reduction in hypoglycaemia could result in improved quality of life.

Structured education, providing knowledge and skills training to young people with diabetes, is an essential component of self-management. We hope that the KICk-OFF study will add important information to the literature by assessing the impact of intensive group education. We acknowledge however that the acquisition of effective self-management skills is highly complex and many other factors such as family support and functioning, diabetes team interaction with families and other pressures within the lives of young people also influence their development.

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application and are represented on the project management group. They have no direct involvement in data collection or interpretation. Overall responsibility for project management and publications rests with the chief investigator and co-applicants.

Competing interests: None of the authors has competing interests in this study.

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Title:

Does an intensive self-management structured education course improve outcomes for children and young people with type 1 diabetes? The Kids In Control OF Food (KICk-OFF) cluster randomised controlled trial protocol.

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Abstract

Introduction: KICk-OFF is a cluster-randomised controlled trial, which aims to determine the efficacy of a 5 day structured education course for 11-16 year olds with type 1 diabetes when compared with standard care, and its cost effectiveness.

Less than 15% of children and young people with type 1 diabetes in the UK meet the recommended glycaemic target. Self-management education programmes for adults with type 1 diabetes improve clinical and psychological outcomes but none have been evaluated in the paediatric population. KICk-OFF is a 5 day structured education course for 11-16 year olds with type 1 diabetes. It was developed with input from young people, parents, teachers and educationalists.

Methods and analysis: 36 paediatric diabetes centres across the UK, randomised into intervention and control arms. Up to 560 participants recruited prior to centre randomisation. KICk-OFF courses are delivered in the intervention centres, with standard care continued in the control arm. Primary outcomes are change in glycaemic control (HbA1c) and quality of life between baseline and 6 months post intervention, and the incidence of severe hypoglycaemia. Sustained change in self-management behaviour is assessed by follow-up at 12 and 24 months. Health economic analysis will be undertaken. Data will be reported according to the CONSORT statement for cluster randomised clinical trials. All analyses will be by intention-to treat with a two-sided P-value of < 0.05 being regarded as statistically significant. The study commenced in 2008. Data collection from participants is ongoing and the study will be completed in 2013.

Ethics: The study has been approved by the Sheffield Research Ethics Committee.
Dissemination: Results will be reported in peer reviewed journals and conferences.

Trial registration: Current Controlled Trials ISRCTN37042683

Background

Structured education for paediatric diabetes management in the UK:

The glycaemic control of children with type 1 diabetes (TIDM), the key determinant of long term complications and mortality, is less good in the UK than in many other European countries (1). Successive audits in Scotland, England and Wales have shown no improvement in recent years (2,3) and less than 15% achieve the recommended target of an HbA1c of less than 7.5%. Support, education and self-management skills are thought to be key influences on control. Of the educational and psychological interventions that have been reported in children and adolescents, there is considerable diversity both in the methods used and their theoretical underpinnings. These range from simple skills and knowledge acquisition to more complex interventions involving family and friends. In a systematic review commissioned by the National Institute for Health Research (NIHR) Health Technology Assessment programme, Hampson and colleagues highlight a lack of well-designed clinical trials of educational interventions in the UK. They emphasise the need for programme development in the UK to be guided by theory and involve consultation with the various groups of people involved, including patients and their families (4) . A more recent update on this systematic review shows some progress in quality and quantity of research but no improved outcomes (5). The systematic review underpinning the National Institute for Health and Clinical Excellence (NICE) appraisal of diabetes education notes a shortage of high quality information regarding the efficacy of education and that most studies exclude children and adolescents. The Department of Health (DH) and Diabetes UK confirm this finding (6) and highlight key criteria for structured education: a structured, written curriculum meeting the learning needs of participants, delivered by trained educators; with quality assurance; and audit.

The DAFNE (**D**ose **A**djustment **F**or **N**ormal **E**ating) course is one current option for adult education. This 5-day outpatient course is adapted from a German adult education model (7). Patients are taught carbohydrate counting and insulin dose algorithms, enabling them to eat freely and administer a dose of insulin that matches the intended meal. Six months after completing the course there was a 0.9% improvement in glycated haemoglobin (HbA1c) levels in the DAFNE group compared with controls, sustained at 0.5% overall improvement by 1 year (8). Furthermore, a quarter of participants improved their HbA1c by more than 1.5% over 12 months without an increase in severe hypoglycaemia. Many described a greatly improved quality of life (QOL) and economic analysis suggests that such a course could pay for itself within 4 years as a result of reduced diabetes related complications (9). The DAFNE course has been identified as the only intervention meeting DH requirements for a structured educational programme in T1DM and has now been rolled out to over 60 centres in UK and Ireland.

Whilst structured education courses have been delivered to children in Germany for many years, there have been no randomised controlled trials (RCT) of a DAFNE-type intervention in children (10). Adolescence is often associated with relatively poor glycaemic control, but is potentially an ideal time to intervene as patients assume responsibility for their own control and disease management (11). The adolescents who participated in the Diabetes Control and Complications Trial (DCCT) intensive management group demonstrated significantly improved control during the 7.4 years of the trial compared with those in the control group (12). During the subsequent four years those in the intensive group have shown progression of retinopathy reduced by

74% compared with controls, despite the fact that the HbA1c levels of both groups converged (13). The benefits of improved glycaemic control clearly continued beyond the duration of the trial, supporting the argument that educational interventions should be offered soon after diagnosis of T1DM. However, we must acknowledge there are potential challenges for young people in undertaking such a regimen. The need for repeated blood tests, carbohydrate portion estimation and multiple insulin injections may compromise quality of life and challenge the cognitive abilities of some young people.

The KICk-OFF course is based on DAFNE principles and aims to provide young people with self-management skills and strategies to help overcome some of the barriers to effective self-management associated with intensive insulin regimen. It was developed and piloted using the five phase approach recommended by the Medical Research Council (MRC) framework for the development of complex interventions (14), to culminate in this randomised controlled trial. The theoretical phase explored educational and motivational theory, the KICk-OFF package being based on the information-motivation-behavioural model (15). During the development phase of the project we worked with young people, parents, educationalists and school teachers, using the constructivist educational theory, to develop a package which would meet the very varied learning needs of adolescents (16).

The pilot phase involved 11-16 year olds (n=48) from three centres and demonstrated significant improvements in QOL and self-efficacy at 3 and 6 months post intervention. Glycaemic control showed no significant change overall, though there was a trend to improvement in those with the poorest control at baseline and also in the younger age group (11-13 years) (17). Our pilot work indicated that key ingredients in the KICk-OFF package include involvement of parents and parent-child communication, support of friends without diabetes, creating a feeling of being like everyone else and social support from other young people with diabetes.

The KICk-OFF intervention:

Each course takes place over five consecutive days and is delivered to groups of eight young people in two age bands, 11-13 years or 14-16 years. The curriculum uses a progressive modular structure to improve self-management in a variety of medical and social situations. Knowledge and skills are built up throughout the week with active participant involvement and problem solving as key methods of learning. The key modules include: what is diabetes; food and diabetes; insulin management; management of hypoglycaemia; sick day rules; diabetes in school and social situations. Learning objectives for each day and each session are clearly identified and educators have instructions on session preparation and teaching materials. Lesson plans give guidance on timing and a student activity section serves to give an idea of expected responses. Each meal and snack is used as an opportunity to practise carbohydrate estimation and insulin dose adjustment. Additional support is provided through dedicated parent sessions, involvement of friends and the provision of a school resource pack. Following process evaluation during the pilot phase, the model of parental education has been altered and parents are now invited to a specific parent education session prior to their children attending the 5-day course. This will provide them with a brief guide to the KICk-OFF principles and allow them to better support their child during the early days of the course.

A website developed to support the learning process allows those in the intervention arm interactive practise at carbohydrate counting and access to educational material and a message forum.

Study objective:

The aim of the study is to assess whether provision of the KICk-OFF structured education course improves clinical and psychological outcomes in adolescents with T1DM, when compared with usual care and education. It also aims to assess cost effectiveness.

Methods/Design

Design:

The KICk-OFF study is a cluster randomised controlled trial. Blinding is not possible as the intervention is evident both to those providing care and those receiving it. In addition, as educational expertise increases within teams, the likelihood of contamination of control groups is high and therefore a cluster randomised design is indicated (18). Centres are therefore randomised to control or intervention arms.

To minimise differences in delivery of the course between centres, three teams of educators travel to centres to teach the course alongside members of the local diabetes team,

Study duration:

The total study duration is 60 months, with the intervention (KICk-OFF courses) being delivered over a 15-month period. Follow-up is for 2 years post intervention.

Setting:

We aimed to recruit patients from up to 36 NHS paediatric diabetes centres in England, Scotland and Wales, with each intervention centre running two age-banded courses. There are eight children in each age-band (11-13 and 14-16 years). 36 centres initially expressed interest in the study, 27 of which acquired research approval and recruited patients. An additional 5 centres were therefore sought when recruitment targets appeared to be compromised by centre withdrawal and lower than anticipated recruitment rates in some centres. 31 centres are therefore participating in the study.

Sample size calculations:

Sample size is based upon the primary outcome measure - HbA1c - and is calculated using data on average HbA1C values from the centres that have expressed an interest in participating (by email communication) and the pilot study. Kinmonth et al, examining patient-centred care of diabetes in general practice, estimated the intraclass correlation coefficient as 0.047 for HbA1c (19). Assuming that each centre will run two courses, each including 8 participants, the average cluster size will be 16. Data from the pilot study indicated that the standard deviation of the minimal clinically meaningful difference of 0.5% is between 1.3% and 1.4%. Taking the upper limit of this standard deviation range as a conservative estimate for the standard deviation, the study needs 448 patients in total (224 per group: 14 clusters per group with an average cluster size of 16) in order to have 80% power to detect a difference of 0.5% in HbA1c with a two-sided significance level of 5%. Assuming a 20% loss to follow-up at 12 months, the study requires 560 patients to be recruited from 18 centres per treatment group. The pilot study demonstrated an improvement in both the generic

and diabetes related QOL scores of at least 7 points (SD: 12). Assuming that there will be no improvement in either score for the control participants, the sample size outlined above will have at least 80% power at the two-sided 5% level to detect a minimum difference of 4.5 points. In addition, this sample size will also have over 80% power at the two-sided 5% level to detect a difference in HUI2 score of 0.03 (SD: 0.08).

Centre randomisation:
Centres are randomised to one of two groups: (1) usual care (control), (2) KICk-OFF course (intervention), in a 1:1 ratio, using a computer generated allocation schedule prepared in advance of the trial to conceal centre allocation. Randomisation takes account of centre stratification according to current educational provision. Three key educational factors have been identified and centres asked to self assess against these, with independent review by the paediatric clinicians.

Inclusion and exclusion criteria:
These are shown in table 1. Participants are not selected on the basis of their existing HbA1c level as it was felt that all children have potential to benefit from the KICk-Off intervention, including those with existing good control.

Table 1: Inclusion/exclusion criteria

Inclusion criteria
T1DM of at least 1 year's duration
Already on or willing to use an intensive insulin regimen (basal – bolus regimen)
Age 11-16 years (in Secondary School years 7-12)
Exclusion criteria
Factors which will impair participation in group education:
Non - English speaking child
Learning disability requiring additional help in school
Major behaviour problems ,identified by the clinical team, and requiring mental health team involvement
Evidence of an eating disorder
Associated illness that may influence control (treated coeliac disease with at least 6 months on a gluten free diet is not an exclusion)

Patient recruitment:
All eligible families receive written and verbal information regarding the KICk-OFF course from their local diabetes team, who also take assent/consent from both the child and a parent/ legal guardian. Centres are not, at this stage, aware of whether they are control or intervention centres. Recruitment ceases in the centre when a maximum of 16 participants have been recruited and centres is then notified if they are in the control or intervention arm of the study.

Involvement of friends: Each KICk-OFF participant is asked to invite a friend to a half-day session.

Subject withdrawal: Whilst clinical teams are aware of diagnosed behavioural problems and those children are excluded from recruitment, it is possible that challenging behaviour will emerge in some children during the week of the KICk-

OFF course which has not been anticipated. Every effort is made to support them to remain involved but~~S~~ subjects ~~are~~ are withdrawn ~~from the study~~ if their behaviour during the KICk-OFF course proves, in the view of the educators, to be detrimental to the continued learning of other participants. This is an unlikely occurrence and will only occur after discussion with the child and their parents. Analysis will be by intention to treat and subjects who are withdrawn will be included in final analysis.

Educator recruitment and training:
Each course is taught by two research educators (a paediatric diabetes specialist nurse and a paediatric diabetes dietitian) and one member of the local team. Research and local team educators attend a 5-day teaching skills course developed during the pilot phase with the Department of Education, Sheffield Hallam University. A core training team has been established, comprising the KICk-OFF lead educator, professional educationalist and teachers. It includes a structured school placement, the purpose of which is to familiarise the educators with aspects of the school curriculum, observe experienced teachers in classroom settings and practice selected activities with pupil groups under the guidance of a qualified teacher. The course includes instruction in:

- role of teachers – in comparison with health professionals
- training in the KICk-OFF curriculum and teaching materials
- use of IT, lap top computers, interactive boards etc in the classroom setting
- the pace/timing of sessions
- ability to be flexible within the curriculum
- behaviour management
- motivating, involving all group members
- the role of questioning

Ethical consideration, possible risks and benefits:
The North Sheffield Local Research Ethics Committee approved the study (ref. 08/H1308/201).
During the course, participants are encouraged to discuss diabetes management and how it affects their social, school and family life; future health with diabetes, and other relevant topics such as alcohol, smoking, driving and contraception. All these topics are routinely discussed with this age group in diabetes clinics, as well as in school. Staff are alert to any concerns, and where appropriate may discuss with parents or the child's paediatrician. Child protection or other disclosures would be dealt with according to local Safeguarding Children Policies. The website forum is mediated by a member of the research team.
Given that intensive insulin regimens are commonly used in this age group it is difficult to envisage significant risks from participation in this study. Given "permission" to eat a less restricted diet there is the possibility that participants may make unhealthier food choices, with potential for weight gain. With improving glycaemic control there is a potential risk of increasing severe hypoglycaemia. Educated in avoidance, recognition and management of hypoglycaemia is an essential part of the course. The course aims to provide children with the skills to match their insulin dose to their food choice and regularly correct their blood sugar. The anticipated benefits are therefore improved blood sugar control, quality of life and self-efficacy. This in turn may lead to less family conflict and better social integration. Study results will be disseminated via peer review journals and oral presentation.

The control arm:
Children in the control group are already established on, or changed to, a basal-bolus regimen at the start of the study. They will receive the normal educational input provided to children on basal bolus regimens in their clinic. The control centres will be offered the teaching skills course for their team at the end of the 2 year follow-up period.

Assessment:
Assessments are undertaken by the research team and local diabetes team, at baseline, 6 months, 12 months and 24 months. All participants will be allocated a unique identifying number which is used on all data reporting forms and samples. Access to personal information is restricted to the project manager and chief investigator. All data returns are kept in locked files. No personal information will be shared during publication.

Outcome measures:
Primary outcomes are the change in biomedical and psychosocial measures at the end of 6 months, adjusted for baseline. Change between 6 months and 2 years will allow an assessment of sustainability of learning. The research team believe that improving quality of life is a very positive outcome in young people who carry a heavy psychological burden and therefore wish to ensure that this outcome carries equal weight to glycaemic outcomes.

Table 2: Primary/secondary outcomes

Primary outcomes	***Secondary outcomes***
HbA1c (mmol/mol)	Health economic analysis and modelling of long term cost/benefits
Psychological outcome in parents and children	Evaluation of the KICk-OFF course by educationalists
Number and severity of severe hypoglycaemic episodes. (Categorised as those requiring third party help and seizures).	Diabetic ketoacidosis
	Time off school
	Change in diet
	Changes in BMI
	Evaluation of website use

Biomedical outcomes:
HbA1c is measured by a central laboratory. Body mass index will be calculated from weight and height measurements and pubertal status (which has a potential influence on glycaemic control) will be assessed, using height velocity as a surrogate marker. It was felt that direct assessment of pubertal status through clinical examination would deter recruitment. Episodes of diabetic ketoacidosis and severe hypoglycaemia are assessed by patient recall and from medical records.

Psychological outcomes:
Psychosocial measures have been chosen to reflect the key components of the psychological model (adherence information, motivation, behavioural skills). All measures are completed by children and by one parent: Fear of hypoglycaemia (20); Expectations - a specially developed measure based on the results of our pilot study to determine the child and parents' commitment, enthusiasm and expectations about the course outcomes; Self efficacy for diabetes (21); Quality of life – generic (22) and diabetes specific (23);.

Health economic analysis:
The economic component of this study will be undertaken from the perspective of the UK NHS. The primary measure of outcome for the economic analysis will be the cost per quality adjusted life year (QALY) gained as measured by the HUI2 instrument. The items of resource use relating to educator time and educational and teaching materials will be measured within the trial by means of a semi-structured telephone interview with key educators. The items of resource use relating to primary and secondary care utilisation will be measured by means of the patient report completed throughout the course of the trial cross referenced with resource use information obtained from patient records at participating centres. All resources will be costed using national average unit costs where possible. In the absence of national average unit costs local unit costs will be obtained from individual hospital finance departments
From an economic perspective, the main measure of effectiveness is the number of QALYs gained. For the estimation of QALYs, a generic health related quality of life instrument is required which allows the estimation of health state utilities. The HUI2 is a well validated instrument which has been used successfully in previous studies relating to diabetes and in adolescent children (24, 25, 26, 27). The HUI2 has been designed for self-completion and will be administered to all trial participants and their parents as proxies at the defined time intervals. Parental assessment will facilitate an empirical investigation of the degree of convergence or otherwise between adolescents' assessment of their own health related quality of life and parental assessment of adolescent health related quality of life. The UK general population tariff of utility values for HUI2 defined health states (28) will be used to calculate a QALY gain for each patient using area under the curve methods. These data will then be aggregated to estimate the total QALY gain for intervention and control groups respectively.
The CHU 9D, a new preference based measure of health related quality of life, has been developed in Sheffield, exclusively for and tested with children (29). It consists of 9 questions, each with 5 response options. This will be used as a secondary measure of calculating QALYs.

Mean costs and effectiveness between the intervention and control groups will be compared and incremental cost effectiveness ratios presented (ICERs) in terms of the cost per unit reduction in HbA1c% and the cost per QALY gained. Confidence intervals will be presented around the ICERs. Cost effectiveness acceptability curves for varying threshold values of cost effectiveness will also be presented. Any costs incurred beyond the base year of the evaluation will be discounted at the recommended treasury rate for public sector projects. An assessment of the sensitivity of the results obtained to variation in measured resource use, effectiveness and/or unit

costs will be undertaken using appropriate one-way and multi-way sensitivity analysis.

Long-term cost effectiveness modelling:
Given that we anticipate a difference in risk factors, particularly HbA1c, between the intervention and control arm, and that these risk factor differences can potentially be maintained over the longer-term, there is a strong economic hypothesis that the upfront investment in the education programme will pay off in terms of avoided clinical events over the longer-term. Reductions in HbA1c will be used to predict reduced long-term complications and improved mortality and QALYs. We will extend this with an updated search. Cost effectiveness models will also account for uncertainty in line with good practice guidance.

Change in diet:
The KICk-OFF course potentially provides participants with the freedom to widen their dietary choices, although healthy eating is encouraged. The Food Intake Questionnaire is a validated recall questionnaire that has been used to assess dietary intake in children (30).

Website evaluation:
During development:
1. Views of young people sought on materials and graphics, to determine the style of the website
2. Potential barriers to using the website explored with young people
3. All web pages will be assessed with a tool called DISCERN, a brief questionnaire which provides users with a valid and reliable way of assessing the quality of written information on treatment choices for a health problem (31)
At each follow-up time point (6, 12, 24 months):
4. From login information, we will identify a) place of use (i.e. during taught session or through own choice at home); b) total number of logins and average duration of use per individual.
5. All users are encouraged to complete an online user satisfaction scale to assess acceptability and identify areas for improvement. Phone interviews with a random selection of participants will also be used e.g. to identify barriers to using the website.

Educational evaluation:
Developing and evaluating complex educational interventions, such as KICk-OFF, is challenging. Many factors will influence outcomes and process evaluation i.e. trying to identify the key active ingredients of such a package is important. Therefore in addition to measuring effect in terms of participant outcomes, we are undertaking independent educational evaluation of the package. Two academic educationalists observe courses, hold focus groups with educators and have informal discussions with participants. They will produce an independent report of the educational content of the KICk-OFF package, identifying areas of effective education and also provide suggestions for change to the curriculum and teaching material. They will also work with the lead research educator to develop quality assurance checklists that can be used to assess consistency of teaching between educator groups and adherence to the learning aims and objectives of the curriculum.

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Participant retention/ missing data

Principal investigators in each centre are sent regular updates regarding completeness of data returns from their participants and encouraged to ensure as complete a data set as possible. Participants are sent a 6 monthly newsletter and all returned questionnaires are entered into a prize draw (a total of 8 throughout the study).

In the case of missing data: information about growth, DKA admissions and severe hypoglycaemia is sought from clinical records. Locally measured HbA1c results are also obtained. At each time point information is collected to identify those who have deviated from protocol by no longer using a basal-bolus insulin regimen or who have moved onto continuous subcutaneous insulin infusion.

Statistical analysis:

Data will be reported according to the CONSORT statement for cluster randomised clinical trials (32). All analyses will be by intention-to treat with a two-sided P-value of < 0.05 being regarded as statistically significant. Baseline characteristics will be compared across intervention groups to ensure the groups are balanced. Where differences are found they will be adjusted for in the analysis. The paediatric diabetes centre will be the unit of randomisation, cluster, intervention and analysis, because that is where the intervention is aimed, though the effect will be evaluated at the patient level.

The primary outcome variable is HbA1c and differences in this between the two study groups at 6 months will be compared using a marginal model, with coefficients and their associated 95% confidence intervals estimated using generalised estimating equations. This type of modelling allows for the clustered nature of the data, in which the observations within clusters are not assumed to be independent. In addition the model will include terms for the stratification factor and any potential confounders in the baseline characteristics. For the other outcomes, including QOL and the anthropometrical measures, differences in the mean values at 6 months will be analysed using a similar model, whilst differences in hypoglycaemia event rates and school attendance will be analysed using a Poisson random effects model. The data will be analysed using STATA v10® software and SAS v9.1 software.

Trial monitoring and management:

The project manager and chief investigator meet weekly and the project management group 3 monthly, with additional meetings as necessary. The project management group comprises the project manager, chief investigator, all co-applicants, study sponsor, and representatives of the Health Economic evaluation team who have been directly involved in study design, data collection and who will be undertaking the health economic analysis. The project management group are involved in all aspects of the study design and progress. Publications will be co-authored by this group.

Database management is undertaken by the Clinical Trials Unit, School of Health and Related Research, University of Sheffield

An independent steering group includes an independent chair (Prof. N Waugh), an independent statistician and paediatric diabetologist and a young person representative.

Centres and participants are communicated with by email and 6 monthly newsletters.

Discussion

KICk-OFF is a highly complex educational intervention that has potential to improve glycaemic control and/or psychological outcomes. Our hypothesis is that behaviour change as a result of attending a KICk-OFF course is likely to take place within 6-12 months of the intervention. We felt that 2 year follow-up was necessary to assess sustainability of learning but also accept that the adolescent years are a time of great change and many other confounding factors such as puberty, school and peer pressure will influence adherence to a diabetes regimen and long-term outcomes.

Sustainability of learning will also be influenced by ongoing support from local diabetes team. They are asked to run follow-up sessions within 6 months of the intervention and to encourage participants to continue to use their KICk-OFF self-management skills in everyday life. Paediatric diabetes care across the UK is changing rapidly, with many more children using an intensive insulin regimen from diagnosis and also moving onto insulin infusion pumps. Many centres routinely teach carbohydrate counting, though none with an intensive course such as KICk-OFF. Whilst the KICk-OFF course is not specifically designed for those on pumps, many of the skills required to successfully manage a pump are taught on the course. We anticipate that a number of our original cohort will move onto pumps during the study and will examine this group as a subgroup analysis. Change in educational practise by local centres across the study period will also be examined by repeating the stratification process at the end of the study.

We aim to reduce inter-educator variability by having just three teams of educators who will all receive specialist teacher training prior to teaching KICk-OFF courses. Practical factors such as weather and illness may impact on attendance at a KICk-OFF course. We shall attempt to provide catch-up education for those who miss days but any participant who is present for < 3 days will be deemed to be non compliant with the intervention.

Unlike other interventions we decided not to use the existing HbA1c level as an inclusion or exclusion criteria. We are therefore recruiting participants with a wide range of glycaemic control. Some will have an HbA1c within the recommended target of less than 58 mmol/mol (7.5%) at baseline and therefore may not change. Those with very tight control at baseline may be suffering from frequent hypoglycaemia or hypoglycaemia unawareness. Their glycaemic control could deteriorate somewhat but we hypothesise that concurrent reduction in hypoglycaemia could result in improved quality of life.

Structured education, providing knowledge and skills training to young people with diabetes, is an essential component of self-management. We hope that the KICk-OFF study will add important information to the literature by assessing the impact of intensive group education. We acknowledge however that the acquisition of effective self-management skills is highly complex and many other factors such as family support and functioning, diabetes team interaction with families and other pressures within the lives of young people also influence their development.

Acknowledgements:

This work is funded by Diabetes UK, grant number 07/0003555. The grant application was subject to peer review and minor revisions were made to the protocol as a result of this process. Funders receive annual reports but have no direct influence over study management, data collection or interpretation or publication.

The study is sponsored by Sheffield Children's NHS Foundation Trust. Sponsors oversee research governance. They were involved in development of the grant application and are represented on the project management group. They have no direct involvement in data collection or interpretation. Overall responsibility for project management and publications rests with the chief investigator and co-applicants.

Competing interests: None of the authors has competing interests in this study.

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract - *Does an intensive self-management structured education course improve outcomes for children and young people with type 1 diabetes? The Kids In Control OF Food (KICk-OFF) cluster randomised controlled trial protocol*			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	5
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	4
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	6
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results - *this submission is a protocol paper for work in progress, data not yet available*			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	n/a
	13b	For each group, losses and exclusions after randomisation, together with reasons	n/a
Recruitment	14a	Dates defining the periods of recruitment and follow-up	n/a
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	n/a
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	n/a
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	n/a
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	n/a
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	n/a
Other information			
Registration	23	Registration number and name of trial registry	Current Controlled Trials ISRCTN37042683
Protocol	24	Where the full trial protocol can be accessed, if available	n/a
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Diabetes UK,

	ref. 07/0003555. Provision of funding only

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.