ISRCTN48994721 https://doi.org/10.1186/ISRCTN48994721

Supporting kids with diabetes in physical activity

Submission date
19/09/2016

Recruitment status
No longer recruiting

Registration date
28/09/2016

Overall study status
Completed

Last Edited
05/04/2019

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and Study Aims
Diabetes mellitus is a life-long condition where a person is unable to control their blood sugar levels. There are two main types of diabetes, type 1 (around 10% of cases) and type 2. In type 1 diabetes (T1DM) the immune system attacks specialised cells in the pancreas called β-cells (which are responsible for producing the hormone insulin). This means that people suffering from T1DM have to regularly inject insulin in order to keep their blood sugar levels in a healthy range. T1DM is a life-long condition, which is usually detected in childhood. Management of the condition can therefore be difficult for both sufferers and their parents. Exercising regularly has huge benefits for people with T1DM, although many children with T1DM do not follow exercise recommendations. This may be because some children lack confidence in their ability to be active and they (and their parents) may worry about drops in blood sugar during exercise. Face-to-face programmes can be effective but are costly to deliver, may be less convenient for families and may potentially have long waiting lists. Parents and clinic staff suggested developing an online package, as research shows that children with T1DM are comfortable with and prefer electronic media, and their parents are receptive to the use of technology as part of diabetes management. However, appropriate online resources are not currently available within routine care. The research team has developed an online programme called STAK-D (Steps to Active Kids with Diabetes). This interactive programme promotes safe physical activity through building children's confidence, reducing barriers to exercise and encouraging children (and their parents) to set achievable goals, whilst recording and monitoring their own physical activity. The aim of this study is to find out more about the acceptability of the STAK-D programme to children with T1DM and their parents, to help decide whether a large-scale study is needed to assess the effectiveness of the STAK-D.

Who can participate?
Children aged 9-12 years who were diagnosed with T1DM at least 3 months ago, and their parents/carers.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive access to an online web-based program to promote physical activity in children with T1DM. Children are encouraged to visit the website as often as possible (preferably daily) for a minimum of six weeks. Parents/carers are asked to monitor, prompt and reinforce this (using praise) and to access the parent features of STAK-D to learn more about lifestyle and physical activity

alongside T1DM. Children are encouraged to practice strategies from the website at home (e.g. selecting goals, setting physical activity targets). The child is also encouraged to monitor their performance with daily physical activity goals, and is provided with a wrist-worn activity monitor to support this process. Those in the second group continue with their usual treatment for the duration of the study. If the STAK-D program is shown to be beneficial at the end of the study, these participants are given access to the online resources after the study has ended. Participants in both groups complete a range of questionnaires at the start of the study and then again after eight weeks and six months to assess the programme effectiveness. The number of participants who take part and remain in the study until the end are recorded to find out whether a larger study would be possible.

What are the possible benefits and risks of participating?
No benefits can be guaranteed, but participants may benefit by becoming more confident to engage in physical activity with type 1 diabetes, and by finding ways to keep physically active. There are no notable risks involved with participating other than the possible risk of hypoglycaemia (low blood sugar) or hyperglycaemia (high blood sugar), which are normal responses to insulin therapy.

Where is the study run from?
1. Nottingham Children's Hospital (UK)
2. Leicester Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?
January 2016 to February 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Holly Blake
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
31881

Study information

Scientific Title
SKIP (Supporting Kids with diabetes In Physical activity): Feasibility of an online multimedia intervention to promote physical activity in children with type 1 diabetes (T1DM)

Acronym
SKIP

Study objectives
The aim of this study is to investigate the feasibility of an interactive online programme called STAK-D (Steps to Active Kids with Diabetes) in children aged 9-12 years (and parents) with Type 1 Diabetes Mellitus (T1DM).

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Nottingham 2 Research Ethics Committee, 07/06/2016, ref: 16/EM/0223

Study design
Randomised; Interventional; Design type: Prevention, Process of Care, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Physical, Management of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Children, Primary sub-specialty: Diabetes and endocrinology; UKCRC code/ Disease: Metabolic and Endocrine/ Diabetes mellitus

Interventions
Eligible and consenting children with Type 1 diabetes will be randomly assigned to either the STAK-D intervention or the 'treatment as usual' control condition (children will be asked to continue with normal daily activity). No participant will receive less than standard care.

Simple randomisation with a 1:1 allocation ratio will be used. Randomisation will be managed through the Sealed Envelope company (www.sealedenvelope.com) which can be accessed from any location via website, SMS text messaging or telephone call (thus the allocation procedure will be concealed from the research team).

The researcher obtaining consent will send an SMS text message to the sealed envelope company, which will automatically randomise the participant to the intervention or control group. Participants will be asked to complete baseline measure before being randomised to their treatment group.

Intervention group: Participants will receive access to an online web-based intervention to promote physical activity in children with Type 1 diabetes. Children will be encouraged to visit the website as often as possible, daily if possible, for a minimum of 6 weeks. Parent/carers will be asked to monitor, prompt and reinforce this (using praise); parents/carers will also be encouraged to access the same website to learn more about lifestyle and physical activity in Type 1 diabetes. Children will be encouraged to practice strategies from the website at home (e. g., selecting goals, setting step targets). The child will be encouraged to monitor their performance with daily physical activity goals, and will be provided with a wrist-worn activity monitor to support this process. The intervention combines educational (activity diary, diabetes-specific advice, physical activity guidance, safety information), behavioural (daily physical activities) and cognitive-behavioural (daily physical activity monitoring and goal-setting) strategies.

Control group: Participants will continue with treatment as usual; no participant will receive less than standard care. If the outcome of the STAK-D evaluation is desirable, the control group will be offered access to the web-based resources at the end of the study (after follow-up).

All participants in both groups will complete outcome assessments at baseline (T0), 8 weeks (T1) and 6 months (T2).

Intervention Type
Other

Primary outcome measure
Feasibility outcomes:
1. Recruitment rate is recorded as the number of eligible participants that consented to participate during the recruitment period. Records will also be kept regarding the number of children screened for entry to the trial. If not admitted to the trial, the reason why the person

was ineligible for inclusion will be recorded. Similarly, if eligible, the reason for a person declining to participate will be recorded, if available
2. Pattern of intervention use will be monitored through assessing website traffic data at regular intervals between baseline and eight weeks and between eight weeks and six months
3. User satisfaction with STAK-D (e.g. navigation, ease of use, technical issues) will be assessed by interview at six months
4. Retention rate, defined as the number of participants completing the STAK-D programme including all scheduled follow-up data collection (baseline, eight weeks and six months) compared to the number started
5. Data completion rate is determined by recording the proportion of participants who complete the outcome measures at baseline, eight weeks and six months
6. Feasibility of gathering routinely collected clinic data from patients' electronic diabetes record (height, weight, glycosylated haemoglobin (HbA1c) level, and insulin dosage) is determined at baseline, eight weeks and six months
7. Occurrence of adverse events related to the intervention (e.g., incidence of hypoglycaemia or hyperglycaemia as a result of the intervention) will be assessed by reviewing patient notes and reviewing patient reports via the website throughout the study period

Secondary outcome measures

Child measures:
1. Self-reported physical activity will be assessed with a 55-item physical activity questionnaire (PAQ) at baseline, eight weeks and six months
2. Self-efficacy for physical activity will be measured using the Children's Self-Perceptions of Adequacy in and Predilection for Physical Activity scale (CSAPPA) at baseline, eight weeks and six months
3. Fear of hypoglycaemia will be assessed using the Children's Hypoglycemia Fear Survey (CHFS) at baseline, eight weeks and six months
4. Health-related quality of life will be measured using the Child Health Utility 9D (CHU9D) at baseline, eight weeks and six months
5. Clinician-patient communication (frequency and difficulty of physical activity discussions with their diabetes healthcare team) will be measured using a short questionnaire developed specifically for this study at baseline, eight weeks and six months
6. Physical activity will be measured objectively using a Polar Active wrist-worn activity watch (Polar Electro Inc, Lake Success, New York) at baseline, eight weeks and six months
7. Clinical outcome measures will be collected by the diabetes healthcare team and, with consent, will be taken from the child's clinic notes at baseline, eight weeks and six months, specifically:
7.1. Glycosylated haemoglobin (HbA1c)
7.2. Insulin dosage
7.3. Body composition - Height (cm) and weight (kg)

Parent measures:
1. Participant Characteristics will be assessed using a demographic questionnaire to assess ethnic background, family composition, parent(s) education, and parent(s) occupation at baseline
2. Parental fear of hypoglycaemia will be assessed using the parents' Hypoglycemia Fear Survey (PHFS) at baseline, eight weeks and six months
3. Physical and psychosocial wellbeing of the child, from parent perspective, will be measured using the child health questionnaire for parents (CHQ-PF28) at baseline, eight weeks and six months
4. Number of additional contacts with the diabetes team other than routine clinic visits in the last six months is measured using questionnaire developed for this study at baseline, eight

weeks and six months
5. Number of hospital admissions other than routine clinic visits in the last six months is measured using questionnaire developed for this study at baseline, eight weeks and six months
6. Days off school in the last six months is measured using questionnaire developed for this study at baseline, eight weeks and six months
7. Additional medications in the last six months is measured using questionnaire developed for this study at baseline, eight weeks and six months
8. Perceived frequency of communication about physical activity in consultations with the diabetes healthcare team is measured using questionnaire at baseline, eight weeks and six months

Health Care Professional measures:
Clinician-patient communication (how often clinicians have discussed physical activity with their patients and how clinicians feel about talking about physical activity based on how much they agree with six statements) is assessed using a clinician-patient communication questionnaire has been developed for this study at baseline, eight weeks and six months.

Overall study start date
01/01/2016

Completion date
28/02/2018

Eligibility

Key inclusion criteria
1. Children aged 9-12 years
2. Diagnosis of Type 1 Diabetes for at least 3 months
3. Willingness of child and parent for the child to wear a wrist-worn device

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 50 parent and child dyads

Key exclusion criteria
1. Recurrent hypoglycaemia or consultant concern
2. Inability to communicate in the English language (due to limited resources we are unable to have materials translated into other languages in this feasibility study)

Date of first enrolment
30/09/2016

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen’s Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

Sponsor details
Trust Headquarters
Queens Medical Centre
Derby Road
Nottingham
England
United Kingdom
NG7 2UH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Study information will be made available to NHS Evidence and on the project website, and websites of associated partners (e.g. NIHR MindTech). A lay summary of findings will be provided to study participants, and service users through the Families with Diabetes Network, Type 1 Kids support group, Diabetes UK Parents Support Groups, and via our PPI Advisory Panel networks; we will disseminate findings through society newsletters, events and meetings.
2. Study findings will be disseminated in open-access peer-reviewed journals and professional newsletters with wide coverage
3. Findings will be presented at national and international conferences
4. Findings will be disseminated to the clinical and research active community in both primary and secondary care through local, regional and national networks (e.g. UK Paediatric Diabetes Network, NHS East Midlands Paediatric Medicine Clinical Reference Group, Institute of Mental Health Collaboration and Leadership in Applied Health Research and Care (CLAHRC) Children and Young Person's Theme, and University of Nottingham research groups and networks)

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository at the University of Nottingham.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Protocol published at:	01/12/2016		Yes	No
Basic results		12/02/2019		No	No
Results article	results	03/04/2019		Yes	No
HRA research summary			28/06/2023	No	No