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A randomised controlled trial of an interactive family-based lifestyle programme

Submission date	Recruitment status	[ ] Prospectively registered
12/05/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
31/05/2016	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
31/05/2016	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This is an international study taking place in the UK, Spain, Germany, Portugal and Greece. The study aims to look at novel prevention strategies for young people at increased risk of developing Type 2 Diabetes. We know that certain characteristics and lifestyle behaviours that can made people more likely to develop diabetes (such as having a family member who has diabetes, eating the wrong types of foods and not getting enough physical activity). We want to know whether an 8-week, family-based interactive workshop series that focuses on improving these lifestyle behaviours can increase healthy behaviours and improve the health of young people and their families.

Who can participate?
Any young person aged 12, 13 or 14 at increased risk of developing Type 2 Diabetes

What does the study involve?
Height, weight, waist size and blood pressure are measured and a small blood sample is taken from a prick to the finger. Both the parent/guardian and the child are asked to complete some questions about their lifestyle habits and family health history. After the first visit each family is randomly allocated into one of two groups. Families in one group are given a healthy lifestyle leaflet and told to continue with life as normal. Families in the other group are invited to attend the lifestyle programme, which involves fun, family based group workshops once a week or fortnight that will last for about an hour and a half. There are eight of these workshops and each one is different. The overall aim is to help young people and their families to lead a healthier lifestyle. There are two follow-up visits which everyone attends at 3 months and 6 months after the first sessions. We take all the same measurements that we did at the first visit at these follow up visits. Each visit takes about 90 minutes.

What are the possible benefits and risks of participating?
Those participants who go on to receive the intervention will benefit from the education in relation to increasing physical activity and better nutrition, which will ultimately have a positive effect on their overall health and reduce their risk of developing Type 2 Diabetes in the future. Participants will also receive a Health M.O.T and a £5 shopping voucher. Participants may feel some very mild discomfort when their blood pressure is taken and the cuff tightens around their

arm. To minimise this, we will ensure that the procedure is performed by a member of the research team who is fully qualified and experienced in taking blood pressure and that the appropriate age and cuff size is used. Participants may also experience mild discomfort when the finger prick blood sample is taken. We have chosen to use capillary blood sampling over venous blood sampling to minimise any discomfort with obtaining these samples for the study. This test has been performed as part of the measurements in a previous study with participants of the same age, and this has been well accepted and tolerated.

Where is the study run from?
University Hospitals of Leicester (UK)

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

Who is funding the study?
European Commission

Who is the main contact?
1. Georgie Surridge
2. Dr Emer Brady

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

Protocol serial number
65436

Study information

Scientific Title
PRE-STARt (Phase 2): a randomised controlled trial of an interactive family-based lifestyle programme

Study objectives
To investigate whether the lifestyle programme leads to increased levels of objectively measured, moderate-to-vigorous physical activity (MVPA) at 6 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Leicester South Research Ethics Committee – approval pending

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
Randomised controlled trial across 5 European sites (locally approved and co-ordinated) to test the effectiveness of a series of 8 lifestyle workshop sessions to see whether this will lead to increased levels of objectively measured, moderate-to-vigorous physical activity at 6 months compared to the control group.

Control Group
Children randomised to this group will be sent a leaflet with general information about increasing physical activity, reducing sedentary behaviour and improving nutrition. Their parents will also receive a general advice leaflet on improving lifestyle.

Intervention Group
Once the children have been randomised to the intervention group they will be invited to attend the PRE-STARt interactive workshop series. The workshops will be delivered in interactive group-based workshops for the children and their parent/guardian(s), and will be delivered by facilitators trained in the theory and philosophies underpinning the programme and in delivery of the curriculum and supporting resources. These sessions can be delivered between 10-12

families at a time (family is defined as one young person and their adult carer). These eight sessions last 90 minutes each and we envisage these sessions taking place in a local school, community setting or at The Leicester Diabetes Centre.

Intervention Type
Behavioural

Primary outcome(s)
Objectively measured physical activity and sedentary behaviour levels at 6 months (parent(s) /guardian(s) and child): Participating children and adults will be asked to wear the wrist worn GENEActiv accelerometer (ActivInsights, Kimbolton, Cambridgeshire, UK) continuously for up to 8 days.

Key secondary outcome(s)
Measured at 3 and 6 months after baseline assessment:
1. Objectively measured total volume of physical activity: Participating children and adults will be asked to wear the wrist worn GENEActiv accelerometer (ActivInsights, Kimbolton, Cambridgeshire, UK) continuously for up to 8 days.
2. Proportion meeting MVPA guidelines (measured objectively)
3. Time spent sedentary (measured objectively and self-reported)
4. Self-reported physical activity: The physical activity questionnaire for adolescents (PAQ-A) will be used to assess the Types and context of physical activity in order to investigate changes in the Types of sports/exercise/activities the participating child may participate in (information which is not available from the accelerometer or the majority of other validated self-report questionnaires).
5. Measures of adiposity (body mass index percentile, percent body fat): Body mass will be measured to the nearest 0.1kg and height will be measured to the nearest 0.1 cm using a clinically approved bioelectrical impedance scale and a portable stadiometer, respectively. BMI will be calculated as weight/height2 and will be converted to a BMI percentile based on WHO growth charts. Body fat percentage will be measured to the nearest 1% also using the bioelectrical impedance scale. All circumferences will be measured with an inelastic anthropometry tape. Waist circumference will be measured to the nearest 0.1 cm as the midpoint between the lower costal margin and iliac crest.
6. Psychological factors that may mediate physical activity participation: Participating children will also complete a questions assessing self-efficacy for increasing physical activity, decreasing sedentary behaviour and making positive dietary changes that have been used previously. The Investigators will also collect data on motivation for physical activity change, attitudes towards physical activity and nutrition, barriers to nutritional change and perceived social support for physical activity that the child receives from the general family and specifically from the child's mother and father.
7. Healthy food provision and parenting practices for healthy food
8. Diet composition: The Investigators will query the nutrition habits of participants to investigate any changes in the behaviours targeted in the workshops. A food frequency questionnaire (FFQ) taken from the ISCOLE study that was adapted from the HBSC Study will be used to query the consumption of 23 food categories in a "usual" week. The Investigators will also collect data on breakfast consumption for weekdays and weekend. The Investigators also created ad hoc questions on other intervention targets of snacking behaviours, fruit and vegetable intake and fizzy drink consumption. This ad hoc method has been used in other international multi-site studies.
9. Knowledge of physical activity and nutrition (parent(s)/guardian(s) and child): Questions on attitudes towards physical activity and nutrition will be completed by participating children.

Questionnaires have been chosen that have demonstrated factorial validity and have been used in young people previously. Questions on knowledge of physical activity and nutrition practices will be ascertained by developing ad hoc questions based on the content of the workshops adapted from questions from the ENERGY project.
10. Cardio-metabolic variables (blood pressure, glucose, HbA1c, cholesterol) (child measure): Arterial blood pressure will be measured using an automated sphygmomanometer with an appropriate sized cuff while the patient is seated, and having rested quietly for 5 minutes. Three measurements will be obtained for blood pressure and an average of the last two will be used in any analysis. HbA1c, triglycerides, glucose, HDL-C and total cholesterol will be measured using a point-of-care testing (POCT) and LDL-C will be calculated. Capillary blood samples will be taken from each child using the finger prick method. The CardioChek® system will be used as the POCT method. The CardioChek® system is a portable hand held device that requires between 15 to 40 µL capillary sample from a finger-stick for each test. The CardioChek® system is certified by the Cholesterol Reference Method Laboratory Network (CRMLN) and National Cholesterol Education Program (NCEP), is FDA-cleared, CE-marked, internationally registered, and is CLIA-waived by the Centers for Medicare & Medicaid Services, USA.

We will also include qualitative data collected from:
1. Evaluation forms following each intervention workshop session which will be completed by the parent/guardian, child and facilitator
2. Feedback from focus groups to be held following completion of the total intervention i.e. 8 sessions

Completion date
31/12/2016

Eligibility

Key inclusion criteria
Participants will be invited to participate if they are 12-14 years old inclusive (12 years 0 days to 14 years 354 days old) and are identified as having the following risk factors for development of Type 2 Diabetes (which will be identified from the eligibility questionnaire):
BMI > 95th percentile for age and gender
OR
BMI > 85th percentile PLUS one other from the following list:
1. Family history of Diabetes (first degree relative)
2. Non-white ethnicity
3. Watching TV/play computer games for more than 2 hours a day (self-report)
4. Sugar intake more than 1.5 cans (or 532 ml) of fizzy pop/fruit juice per day (self-report)

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 Years

Upper age limit
14 Years

Sex
All

Key exclusion criteria
1. Outside the age range of interest (<11 years and 364 days or >14 years and 1 day)
2. Have an existing diagnosis of Type 1 or Type 2 Diabetes
3. BMI < 85th percentile
4. Young people will also be excluded if they themselves do not provide written assent or their parent/guardian does not provide written consent

Date of first enrolment
02/05/2016

Date of final enrolment
01/08/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Leicester
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Sponsor information

Organisation
University Hospitals of Leicester (UK)

ROR
https://ror.org/02fha3693

Funder(s)

Funder type

Other

Funder Name
European Commission

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes