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Cereal nutrition for child health trial

Submission date
21/08/2017

Recruitment status
No longer recruiting

Registration date
22/08/2017

Overall study status
Completed

Last Edited
03/10/2022

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
Type 2 diabetes is a major public health problem both worldwide and in the UK. There has been a rapid increase in the risk of type 2 diabetes in the UK over the last 30 years, suggesting that the condition is substantially preventable. An important feature of the recent type 2 diabetes epidemic has been the occurrence of type 2 diabetes in young people, which is preceded by the development of insulin resistance, when the body tissues respond poorly to circulating insulin. Dietary factors may well be important causes of type 2 diabetes, but this remains uncertain. There is evidence from a range of studies that a low intake of fibre from cereals may increase the risk of type 2 diabetes, although this remains unproven. There is a strong scientific case for establishing whether increasing cereal fibre intake can reduce insulin resistance in children. The aim of this study is to test whether providing children with high fibre cereal with support and encouragement can lead to an increase in cereal fibre intake.

Who can participate?
Pupils (boys and girls) attending London primary schools and aged 9-10, who currently eat a low fibre breakfast cereal but who find high fibre cereals palatable

What does the study involve?
Participating children are randomly allocate to receive a one-month supply of a breakfast cereal containing either high or low amounts of fibre. Encouragement and support are provided during the one-month period. They have a detailed assessment (weight and height measurements, dietary questionnaires, fasting blood sample) at the beginning and the end of the study.

What are the possible benefits and risks of participating?
There are no certain benefits or risks from participation. It is possible that children in the high fibre group will have slightly lower insulin resistance at the end of the study. No side effects are expected and all study procedures are classified as minimal risk.

Where is the study run from?
The study is based at St George's, University of London, which is the lead and only research centre in this investigation. The recruitment of participants takes place through London primary schools.

When is the study starting and how long is it expected to run for?
January 2017 to December 2018

Who is funding the study?
The Wellcome Trust (UK)

Who is the main contact?
Dr Angela Donin

Contact information

Type(s)
Scientific

Contact name
Dr Angela Donin

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.3

Study information

Scientific Title
Development of a randomised controlled trial to increase cereal fibre intake to reduce insulin resistance in children

Acronym
CRUNCH

Study objectives
This study will examine whether a school-based intervention aiming to increase average cereal fibre intake in 9-10 year-old children increases it by at least 2.5 grams per day at the end of a one month intervention period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
St. George's Research Ethics Committee, 21/03/2017, ref: SGREC17.0007

Study design
Single-centre parallel-group randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Prevention of type 2 diabetes, and particularly reduction of the degree of insulin resistance

Interventions
Participants will be recruited through London primary schools and randomised to the intervention group or the control group.

1. Participants in the intervention group will be provided with a free one-month supply of high fibre breakfast cereal in plain packaging (high fibre = at least 3.5 grams per portion) and encouraged to consume one portion daily at breakfast. Verbal and written instructions will be provided. Research team members will visit the school regularly to provide encouragement and support.
2. Participants in the control group will be provided with a free one-month supply of low fibre

breakfast cereal in plain packaging (low fibre = less than 1.0 grams per portion) and encouraged to consume one portion daily at breakfast. Verbal and written instructions will be provided. Research team members will visit the school regularly to provide encouragement and support.

Participants will have a detailed assessment (weight and height measurements, dietary questionnaires, fasting blood sample) at the beginning and the end of the one-month intervention period. All outcome measures will be assessed without knowledge of the participant's intervention status.

Intervention Type
Other

Primary outcome measure
Cereal fibre intake during the one-month intervention period, measured using a blood-based biomarker (plasma alkyl-resorcinol) and by dietary assessment (including a multiple pass 24 hour dietary recall and a food frequency questionnaire) at baseline and one month

Secondary outcome measures
1. Weight and fat mass index, assessed by bioelectrical impedance at baseline and one month
2. The acceptability of the intervention, assessed by questionnaire at one month

Overall study start date
01/01/2017

Completion date
30/12/2018

Eligibility

Key inclusion criteria
1. Children aged 9-10 years old attending London primary schools
2. No history of diabetes
3. Currently eating a breakfast cereal with low fibre content (≤1 gram of fibre per portion)
4. Able and willing to consume at least one of the high-fibre cereals being used in the trial
5. Able and willing to complete trial entry assessment (including providing a fasting blood sample)

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
9 Years

Upper age limit
10 Years

Sex

Both

Target number of participants
300

Total final enrolment
272

Key exclusion criteria
1. Outside the relevant age group
2. A history of diabetes
3. Not currently eating a breakfast cereal with low fibre content (≤1 gram of fibre per portion)
4. Not able and willing to consume at least one of the high-fibre cereals being used in the trial
5. Not able and willing to complete trial entry assessment (including providing a fasting blood sample)

Date of first enrolment
15/09/2017

Date of final enrolment
20/07/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Georges, University of London
Population Health Research Institute
Cranmer Terrace
London
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SW17 0RE

Sponsor information

Organisation
St George's, University of London

Sponsor details
Cranmer Terrace
London

England
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Sponsor type
University/education

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A website will be established for the study; the study protocol will be made available online on the study website in due course.

Key results from this preliminary fidelity trial will be submitted for publication in an appropriate peer-reviewed journal in the year following the trial end date.

Intention to publish date
30/12/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are still to be finalized and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2021	10/12/2020	Yes	No
Protocol file	version 1.2	28/02/2017	03/10/2022	No	No