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Sheffield University Breakfast Study (SUBS): To determine the effectiveness of eating a fortified breakfast cereal in improving micronutrient status in adolescent girls

Submission date
20/11/2013

Recruitment status
No longer recruiting

Registration date
30/01/2014

Overall study status
Completed

Last Edited
18/07/2016

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Breakfast cereal consumption by adolescent girls has reduced over the last ten years with milk consumption also reducing over the same time period. Results from dietary surveys in the UK have also shown that the vitamin and mineral status of these adolescent girls is also poor with particular concern over vitamin B2 (riboflavin), calcium and iron. The consumption of breakfast cereals, which are often fortified with vitamins and minerals, together with milk, may be help in improving the nutritional status. Studies have shown a relationship between breakfast eating, a healthier lifestyle and improved nutritional well-being. However, such studies do not prove the health outcomes of breakfast cereal consumption. Rather, they demonstrate that those most likely to consume breakfast cereals on a regular basis do so as part of a generally healthy lifestyle. It is not fully understood if the relationship between breakfast consumption and nutritional health is because of eating breakfast as a meal or eating breakfast cereal products. This study aims to show specific improvements in nutritional status as a result of the regular consumption of a fortified breakfast cereal by adolescent girls. This study also aims to find out whether the consumption of breakfast cereal as a supper can lead to the same benefits as when consumed as a breakfast.

Who can participate?
The study aims to recruit girls aged between 16 and 19 years from schools, colleges and universities in Sheffield, UK. This particular age group was chosen as they have been shown to have inadequate intakes of micronutrients and poor nutritional status and this may well continue into young adulthood. Girls who regularly miss breakfast are selected for further study; riboflavin and iron status is measured using a small sample of blood from a finger. Girls with low riboflavin status and haemoglobin levels in the lower end of the normal range are invited to take part in the main study. Girls must be healthy, not taking any multivitamin supplements and not recent blood donors.

What does the study involve?
Girls taking part in the study are asked to eat either fortified or unfortified cereal with semi-skimmed milk daily for 12 weeks. Half of them are asked to eat their cereal at breakfast time and the other half at supper time. The type of cereal and time of day is selected at random by someone other than the researcher. Girls attend a central research facility to have a blood sample taken before starting the study and at the end. The blood is used to measure haemoglobin and other blood-related factors and nutritional status. In addition, girls are asked to fill in a 4-day food diary before the study and halfway through the study to measure their intake of a number of nutrients.

What are the possible benefits and risks of participating?
The girls have the opportunity to have their nutritional status evaluated and to be provided with a personalised assessment of the quality of their diets. They sometimes feel slight discomfort when taking finger prick sample or the blood sample taken from the arm.

Where is the study run from?
The study is run from the University of Sheffield with support from the Clinical Research Facility at the Royal Hallamshire Hospital, Sheffield, UK.

When is study starting and how long is it expected to run for?
July 2012 to December 2013

Who is funding the study?
Kellogg Group (UK)

Who is the main contact?
Prof. Hilary Powers
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Contact information

Type(s)
Scientific

Contact name
Prof Hilary Powers

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Additional identifiers

Protocol serial number

SMBRER223/ 14/8/12 version 2

Study information

Scientific Title
Randomised controlled trial of the effectiveness of a fortified breakfast cereal in improving micronutrient status in adolescent girls

Acronym
SUBS

Study objectives
It is hypothesised that the regular consumption of a fortified breakfast cereal by adolescent girls who often skip breakfast will lead to an improvement in biomarkers of micronutrient status compared with the consumption of an unfortified cereal. It is further hypothesised that the consumption of breakfast cereal at supper time elicits the same improvements in nutritional status as when consumed at breakfast time.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sheffield University Medical School Ethics Committee approved by the University Research Ethics Committee (UREC), Ref: SMBRER223, 9/5/12

Study design
Double-blind randomised placebo-controlled intervention trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Micronutrient status in adolescent girls, breakfast cereal consumption

Interventions
Girls are randomised to receive a daily intake of either fortified or unfortified cereal (50 g) with semi-skimmed milk (150 ml) for 12 weeks. Half of the girls are instructed to consume their cereal at breakfast time and the other half consume their cereal at supper time. All girls complete a 4-day food diary at the beginning and in the middle of the study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

Dietary intake: the 4-day diet diaries will be used to assess changes in micronutrient intakes and dietary patterns during the study.

Nutritional status: the following biomarkers of micronutrient status will be measured at baseline and midway at 6 weeks:
1. Riboflavin status, as the erythrocyte glutathione reductase activation coefficient
2. Folate status, as plasma 5-methyltetrahydrofolate (5-MeTHF)
3. Vitamin B-12 status as plasma holotranscobalamin
4. Vitamin D status as plasma 25-OH vitamin D
5. Full blood count, including haemoglobin (Hb), packed cell volume (PCV), mean cell volume (MCV), mean cell haemoglobin (MCH) and red blood cell numbers
6. Plasma ferritin

Key secondary outcome(s))
1. Height and weight are measured at the beginning and end of the study to calculate BMI measured at baseline and at the end (12 weeks)
2. Modulating effect of the time of consumption of cereal will also be examined by looking at the data from the point of view of timing of the cereal consumption

Completion date
30/12/2013

Eligibility

Key inclusion criteria
1. Female
2. Aged between 16 and 19 years
3. Skips breakfast on a regular basis
4. Healthy
5. Screening riboflavin status as measured by the erythrocyte glutathione reductase coefficient assay (EGRAC) of >1.4 and a haemoglobin level between 11.5 and 13.7g/L

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Blood donation within the last 3 months
2. Taking multivitamin or iron supplements
3. Pregnant or breastfeeding
4. Allergic to wheat, barley or milk

Date of first enrolment
01/07/2012

Date of final enrolment
30/12/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Sheffield
Sheffield
United Kingdom
S10 2RX

Sponsor information

Organisation
University of Sheffield (UK)

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Industry

Funder Name
Kellogg's (UK)

Alternative Name(s)
Kellogg Co., Kellogg Company, US. Kellogg's, WK KELLOGG CO

Funding Body Type
Government organisation

Funding Body Subtype

For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/07/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes