ISRCTN17457198 https://doi.org/10.1186/ISRCTN17457198

Effects of breakfast and supper on energy expenditure

Submission date	Recruitment status	[ ] Prospectively registered
10/08/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/08/2016	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/11/2019	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
It is often said that breakfast is the most important meal of the day. However, the benefits of breakfast consumption have not been thoroughly investigated in well-designed studies. A recent study carried out in The University of Sheffield clearly showed that consuming a fortified cereal (cereal enriched with vitamins and minerals) with milk every day for 12 weeks led to an increase in the intake of vitamins and minerals and improved measures of nutritional status. The study was carried out in adolescent girls who rarely ate breakfast. Interestingly, if the cereal and milk was consumed for supper there was a small weight gain. This could not be explained by an increase in the amount of energy consumed. It is thought possible that taking cereal and milk as a breakfast might lead to an increase in the amount of energy used in physical activity (physical activity energy expenditure) later in the day, and that this is not seen when cereal with milk is taken as a supper. The aim of this study is to find out whether eating cereal with milk as breakfast will lead to an increase in physical activity energy expenditure compared with eating cereal with milk for supper.

Who can participate?
Healthy women aged 18-24 of normal weight who regularly skip breakfast

What does the study involve?
Participants are randomly allocated into two groups, who either eat cereal with milk for four days for breakfast or for supper. After a one week break, the two groups swap so that those who were eating the cereal for breakfast now eat it for dinner and vice versa. Participants are asked to wear an accelerometer (device to measure physical activity) on their wrist for all of their waking hours during the two four day study periods. Participants also complete a food diary for four days before and during the four day study periods. At the end of the study, energy expenditure is calculated from the accelerometer readings and dietary intakes are compared.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
The University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
April 2007 to December 2015

Who is funding the study?
Kelloggs Company of Great Britain (UK)

Who is the main contact?
Professor Hilary Powers

Contact information

Type(s)
Scientific

Contact name
Prof Hilary Powers

ORCID ID
http://orcid.org/0000-0002-0496-5446

Contact details
Department of Oncology and Metabolism
The Medical School
The University of Sheffield
Sheffield
United Kingdom
S102RX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
007629

Study information

Scientific Title
A comparison of the effect of consuming cereal with milk as a breakfast or as a supper, on physical activity energy expenditure

Acronym
BEES

Study objectives

The consumption of cereal with milk as breakfast will elicit an increase in physical activity energy expenditure compared with consumption of cereal with milk as supper.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Sheffield Research Ethics Committee, 12/02/2016, ref: 007629

Study design
Single-centre randomised crossover trial

Primary study design
Interventional

Secondary study design

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Energy expenditure

Interventions
Participants are randomly allocated to eat 50g fortified breakfast cereal with 150ml semi-skimmed milk for breakfast or dinner for four days in a random order. There is a wash out period of one week between the two interventions.

Participants are asked to wear the Actigraph monitor for all their waking hours for each of the 4 day intervention periods. They are asked to take the monitor off when bathing or showering or swimming. They are asked not to wear the monitor when they go to bed.

Participants complete a food and beverage diary on three occasions - for 4 days prior to intervention and for 4 days for each of the interventions (i.e. cereal and milk at supper and at breakfast time). Participants are shown how much detail to put in the diaries and at the end of each 4-day period they meet with the researcher to discuss the details of their diary entries. They are asked to eat and drink what they liked, as long as they took their intervention cereal and milk. There is no follow-up. Data collection finishes when the last food diary has been completed and discussed.

Intervention Type
Other

Primary outcome measure

Physical activity energy expenditure is measured using an accelerometer (Actigraph), worn on the wrist during waking hours of each 4 day intervention period.

Secondary outcome measures
Dietary intake is assessed using 4-day food and beverage diaries, facilitated by using food portion booklets.

Overall study start date
09/05/2016

Completion date
31/08/2016

Eligibility

Key inclusion criteria
1. Female
2. Age 18-24 years
3. BMI between 18.5 and 25kg/m2
4. Report regularly skipping breakfast

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
24 Years

Sex
Female

Target number of participants
20

Key exclusion criteria
1. BMI outside 18.5-25 kg/m2 range
2. Report in training for sporting event
3. Known allergy to wheat, barley or milk

Date of first enrolment
09/05/2016

Date of final enrolment
31/08/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The University of Sheffield
Sheffield Medical School
Beech Hill Road
Sheffield
United Kingdom
S10 2RX

Sponsor information

Organisation
The University of Sheffield

Sponsor details
The medical School
Beech Hill Road
Sheffield
England
United Kingdom
S102RX

Sponsor type
University/education

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Industry

Funder Name
Kelloggs Company of Great Britain

Results and Publications

Publication and dissemination plan
Anticipated publishing a peer reviewed paper within 6 months of completion of the study. Potential target journals are: European Journal of Nutrition, British Journal of Nutrition, Public Health Nutrition.

Intention to publish date
31/12/2016

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?
Participant information sheet		10/08/2016	11/08/2016	No	Yes