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The effect of breakfast consumption on physical activity in girls

Submission date	Recruitment status
17/05/2017	No longer recruiting
Registration date	**Overall study status**
23/05/2017	Completed
Last Edited	**Condition category**
07/03/2018	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Many children and adolescents often skip breakfast and do not engage in the recommended amounts of physical activity. Research has shown that breakfast consumption frequency (i.e., days per week that breakfast is consumed) is linked with increased physical activity in young people. However, these results have not been consistent when using an accelerometer (activity monitor) to measure physical activity. It is also not known whether increased breakfast consumption frequency causes an increase in physical activity, or whether the link is simply because those who eat breakfast generally engage in a range of healthy lifestyle habits. Although some studies in adults have indicated that breakfast consumption can increase physical activity, others have reported no effect, and no study has examined the effects of breakfast consumption frequency on physical activity in children or adolescents. This is particularly important for adolescent girls, who frequently skip breakfast and have low physical activity levels. Therefore, the aim of this study is to examine the effect of daily compared with intermittent breakfast consumption on physical activity in adolescent girls.

Who can participate?
Healthy girls aged 11 to 13

What does the study involve?
The study consists of two periods that last 7 days each: daily breakfast consumption and intermittent breakfast consumption. Daily breakfast consumption involves eating a standard breakfast every day for 7 days. Intermittent breakfast consumption involves eating breakfast on three intermittent days (i.e., days 2, 4 and 6) with four days without breakfast (i.e., days 1, 3, 5 and 7). There is a 7-10 day break in between the two periods. The girls are fitted with a chest-worn combined heart-rate accelerometer device to measure their physical activity throughout each 7-day period.

What are the possible benefits and risks of participating?
The benefits of participating include education on health-related scientific research and use of research equipment. In addition, the participants receive a certificate stating that they have completed the study and receive their individual results in an anonymous format. The research also has indirect benefits for the participants, as the findings will help to inform interventions to

increase physical activity in adolescent girls. In the long term, this could help with the prevention of obesity and diseases such as type 2 diabetes and heart disease. Possible risks included feeling light-headed during the exercise tests, but the cool down helps to reduce this and it rarely lasts more than a few minutes. There is also a risk of skin irritation caused by wearing the activity monitor. Therefore, all participants are shown how to remove and fit the monitor and wash the skin appropriately. Those who are allergic to any of the ingredients in the breakfast meals or had certain health conditions (e.g. diabetes, epilepsy) are not able to participate for their own safety.

Where is the study run from?
1. University of Bedfordshire (UK)
2. Loughborough University (UK)

When is study starting and how long is it expected to run for?
July 2014 to December 2016

Who is funding the study?
1. British Academy (UK)
2. Leverhulme Trust (UK)
2. University of Bedfordshire (UK)
3. Loughborough University (UK)

Who is the main contact?
Dr Julia Zakrzewski-Fruer
Julia.Fruer@beds.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Julia Zakrzewski-Fruer

ORCID ID
https://orcid.org/0000-0003-4167-4100

Contact details
University of Bedfordshire
Bedford
United Kingdom
MK41 9EA
+44 (0)123 479 3410
Julia.Fruer@beds.ac.uk

Additional identifiers

Protocol serial number
SG142106

Study information

Scientific Title
Comparison of daily and intermittent breakfast consumption on physical activity energy expenditure in girls

Study objectives
Seven days of daily breakfast consumption will result in higher physical activity energy expenditure when compared with intermittent breakfast consumption.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Bedfordshire Institute for Sport and Physical Activity Research Ethics Panel, 22/09/2015, ref: 2015ISPAR013
2. Loughborough University Ethics Approvals (Human Participants) Sub-Committee, 30/03/2016, ref: R16-PO39

Study design
Interventional within-participants cross-over study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Physical inactivity

Interventions
The participants completed two, 7-day conditions. The order of the conditions for each participant was produced using a computer-based random number generator by the principal investigator ensuring that the order across the total sample was counterbalanced. The conditions were not masked to the participant.

1. Daily breakfast consumption (DBC): the consumption of a standardized 400 kcal breakfast before 0900 h for 7 consecutive days
2. Intermittent breakfast consumption (IBC): the abstinence from all energy-providing nutrients until at least 1030 h on days 1, 3, 5 and 7 and the consumption of the 400 kcal standardized breakfast on days 2, 4 and 6

All breakfasts were weighed, pre-packaged and provided to the participants prior to each condition. The participants were instructed to consume the breakfasts provided at home. Participants completed both of the conditions and there was a 7-10 day washout between the conditions.

Intervention Type
Other

Primary outcome(s)

1. Physical activity energy expenditure from sedentary activities (<1.5 metabolic equivalent (METs)) during wake time to <1030 h (kJ/day)
2. Physical activity energy expenditure from sedentary activities (<1.5 METs) during 1030 h to <1530 h (kJ/day)
3. Physical activity energy expenditure from sedentary activities (<1.5 METs) during 1530 to bed time (kJ/day)
4. Physical activity energy expenditure from light activities (1.5-2.9 METs) during wake time to <1030 h (kJ/day)
5. Physical activity energy expenditure from light activities (1.5-2.9 METs) during 1030 h to <1530 h (kJ/day)
6. Physical activity energy expenditure from light activities (1.5-2.9 METs) during 1530 to bed time (kJ/day)
7. Physical activity energy expenditure from moderate activities (3.0-5.9 METs) during wake time to <1030 h (kJ/day)
8. Physical activity energy expenditure from moderate activities (3.0-5.9 METs) during 1030 h to <1530 h (kJ/day)
9. Physical activity energy expenditure from moderate activities (3.0-5.9 METs) during 1530 to bed time (kJ/day)
10. Physical activity energy expenditure from vigorous activities (>5.9 METs) during wake time to <1030 h (kJ/day)
11. Physical activity energy expenditure from vigorous activities (>5.9 METs) during 1030 h to <1530 h (kJ/day)
12. Physical activity energy expenditure from vigorous activities (>5.9 METs) during 1530 to bed time (kJ/day)
All primary outcomes are measured using combined heart rate/accelerometry continuously throughout each 7-day condition.

Key secondary outcome(s))
1. Time spent in sedentary activities (<1.5 metabolic equivalent (METs)) during wake time to <1030 h (min/day)
2. Time spent in sedentary activities (<1.5 METs) during 1030 h to <1530 h (min/day)
3. Time spent in sedentary activities (<1.5 METs) during 1530 to bed time (min/day)
4. Time spent in light activities (1.5-2.9 METs) during wake time to <1030 h (min/day)
5. Time spent in light activities (1.5-2.9 METs) during 1030 h to <1530 h (min/day)
6. Time spent in light activities (1.5-2.9 METs) during 1530 to bed time (min/day)
7. Time spent in moderate activities (3.0-5.9 METs) during wake time to <1030 h (min/day)
8. Time spent in moderate activities (3.0-5.9 METs) during 1030 h to <1530 h (min/day)
9. Time spent in moderate activities (3.0-5.9 METs) during 1530 to bed time (min/day)
10. Time spent in vigorous activities (>5.9 METs) during wake time to <1030 h (min/day)
11. Time spent in vigorous activities (>5.9 METs) during 1030 h to <1530 h (min/day)
12. Time spent in vigorous activities (>5.9 METs) during 1530 to bed time (min/day)
All secondary outcomes are measured using combined heart rate/accelerometry continuously throughout each 7-day condition.

Completion date
16/12/2016

Eligibility

Key inclusion criteria

1. Aged 11 to 13 years old
2. Female

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
11 years

Upper age limit
13 years

Sex
Female

Key exclusion criteria
1. Allergies to the breakfast meals
2. Fitted with a pacemaker
3. Unable to walk
4. Unable to wear a chest-worn combined heart rate/accelerometer
5. Health related issues that could be affected by participation in the study (e.g., uncontrolled exercise-induced asthma, diabetes, epilepsy)

Date of first enrolment
01/10/2015

Date of final enrolment
12/09/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Bedfordshire
Polhill Avenue
Bedford
United Kingdom
MK41 9EA

Study participating centre
Loughborough University
Epinal Way
Loughborough
United Kingdom
LE11 3TU

Sponsor information

Organisation
University of Bedfordshire

Organisation
Loughborough University

Organisation
University of Bedfordshire

ROR
https://ror.org/0400avk24

Funder(s)

Funder type
University/education

Funder Name
British Academy

Alternative Name(s)
BA British Academy, The British Academy, BA

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
University of Bedfordshire

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Loughborough University

Alternative Name(s)
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Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Leverhulme Trust

Alternative Name(s)
The Leverhulme Trust

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Julia Zakrzewski-Fruer (Julia.Fruer@beds.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2018		Yes	No