

A cluster randomised controlled trial of a lunchbox template, designed to improve the content of lunchboxes in primary school children in the UK

Submission date
09/05/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
27/09/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
30/10/2013

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

FSA N14R0004

Study information

Scientific Title

Study objectives

The use of a smart lunchbox approach is more effective in improving healthy food consumption in primary school children at lunchtime, than providing a healthy eating leaflet alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Leeds. Date of approval:26/10/06 (ref: 1706)

Study design

Cluster randomised controlled trial (randomised by schools)

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Nutrition

Interventions

Randomisation: The schools in England were stratified to tertiles according to the percentage of pupils in the school eligible for free school meals, and quintiles according to the key stage 2 Standard Assessment Tests (SATs) exam results (percentage of pupils reaching level 4 in mathematics, English and science). These are approximate measures of deprivation of the catchments area of the school. Stratification ensured that the intervention and control groups contained equal numbers of schools at different levels of both factors.

Intervention materials were devised according to best practice and the results of an earlier video ethnography study. In that preliminary study, parents were videoed about their choices of food

for their childrens lunchboxes. The intervention group in this study received a smart lunchbox template and associated materials and activities (the smart lunchbox approach) to provide an aid to parents for shopping for lunchbox food and preparation, and encouragement to children to adopt healthier eating patterns. The template itself is a physical resource (a lunchbox), with different compartments containing information and pictures about the choices open to parents. This template has been developed in collaboration with organisations involved in designing, developing and producing new food packaging materials (e.g. Faraday Packaging Partnership and Design Futures). The collaborative approach has ensured that the expertise of relevant parties from academia and industry can be capitalised on throughout the development phase.

The template aimed to support healthier lunchbox preparation in three ways:

1. Support at the point of food shopping
2. Support during lunchbox preparation at home
3. Support for the child at school lunch to encourage eating the healthier lunch

The template was based on the Balance of Good Health to guide parents regarding the balance to be aimed at in preparation of a lunchbox. Parents and children also received supporting materials such as magnets, shopping bags, drink bottles, stickers, games, healthy eating information, the School Foods Trust leaflet on packed lunches and ideas for three weeks of packed lunchboxes. In combination this is known as the smart lunchbox approach.

The control group received the School Foods Trust leaflet.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Nutritional and food based measurements indicating improvements in the contents of lunch boxes
2. Levels of macronutrients:
 - 2.1. Fat
 - 2.2. Sugar
 - 2.3. Energy
 - 2.4. Protein
 - 2.5. Sodium
3. Food types (e.g. sandwiches, savoury snacks, confectionery, dairy)

The outcomes above will be assessed by the following:

1. A questionnaire in June 2006 (baseline) and an identical follow up questionnaire repeated in June 2007
2. All food in the lunch box was weighed before and after lunch to measure the amount of food consumed and left over

Secondary outcome measures

Micronutrients (e.g. iron, zinc, vitamin A) assessed by:

1. Weighing each food item in the lunch box before and after lunch to measure the amount of

food consumed and left over, as for primary outcome measures

2. Questionnaire in June 2006 (baseline) and an identical follow up questionnaire repeated in June 2007, as for primary outcome measures

Overall study start date

01/06/2006

Completion date

30/06/2007

Eligibility

Key inclusion criteria

All primary schools in England, Wales, Scotland and Northern Ireland were eligible for inclusion in the study, All children in Year 4 (8 to 9 years old) of participating schools who bring in a packed lunch were eligible for inclusion in the study.

Participant type(s)

Patient

Age group

Child

Lower age limit

8 Years

Upper age limit

9 Years

Sex

Both

Target number of participants

600

Key exclusion criteria

Primary schools involved in another healthy eating study (the evaluation of the National School Fruit Scheme).

Date of first enrolment

01/06/2006

Date of final enrolment

30/06/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Nutritional Epidemiology Group
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Sponsor information

Organisation
Food Standards Agency (UK)

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Sponsor type
Government

Website
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ROR
<https://ror.org/05p20a626>

Funder(s)

Funder type
Government

Funder Name
Food Standards Agency (UK)

Alternative Name(s)
The Food Standards Agency, FSA

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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	01/11/2010		Yes	No