ISRCTN77710993 https://doi.org/10.1186/ISRCTN77710993

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	Recruitment status	[_] Prospectively registered
09/05/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/09/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/10/2013	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Not Specified

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 years

Upper age limit
9 years

Sex
All

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
United Kingdom

England

Study participating centre
Nutritional Epidemiology Group
Leeds
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Sponsor information

Organisation
Food Standards Agency (UK)

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

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