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A school and community trial for improving 13-year-olds' fruit and vegetable consumption: the Boost study

Submission date
20/12/2011

Recruitment status
No longer recruiting

Registration date
06/01/2012

Overall study status
Completed

Last Edited
20/10/2017

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Scientific studies have shown the health-promoting effects of diets high in fruit and vegetables, but many children do not eat the recommended level of least 400 grams of fruit and vegetables per day. Eating habits in adolescence tend to continue into adulthood and it is therefore important to identify ways to enhance fruit and vegetable intake among young people. Research suggests that multi-component school-based interventions which combine increased access to fruit and vegetables with educational activities are most effective in increasing children's fruit and vegetable consumption. There is a lack of evidence on whether these interventions will work in Denmark, a country that does not have a tradition of providing school meals. The aim of this study is to test a multi-component school- and community-based intervention which aims to increase fruit and vegetable consumption among year 7 pupils.

Who can participate?
Boys and girls enrolled in school year 7 (12-14 years of age).

What does the study involve?
A random sample of 40 schools (selected from a random sample of 10 Danish municipalities) was invited to participate in the study in spring 2010. Schools were randomly allocated into the either the intervention group or the control group. At the 20 intervention schools pupils in school year 7 received the Boost intervention programme during the school year 2010/2011. The Boost program included daily provision of free fruit and vegetables to all year 7 pupils in schools for 9 months, pupil work books, teacher manuals, classroom activities, pupil-parent activities, newsletters, school events, information sheets and posters. The pupils at the control schools continued as usual without any intervention (some of the components of the intervention were offered to the control schools after the end of the study).

What are the possible benefits and risks of participating?
Pupils get a piece of fruit or vegetables for free daily. This has a potential to increase their fruit and vegetable intake, wellbeing and concentration. There are no known risks to participants.

Where is the study run from?
40 municipal schools will take part in the project. The study is run from the National Institute of Public Health, Denmark.

When is the study starting and how long is it expected to run for?
February 2010 to December 2012

Who is funding the study?
TrygFonden, the Danish Cancer Society, the Danish Consumers Co-operative Society, the EU School Fruit Scheme through the Danish Food Industry Agency at the Danish Ministry of Food, Agriculture and Fisheries, and Copenhagen Food House.

Who is the main contact?
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Study website
http://www.interventionsforskning.dk/side.asp?side=8&id=23&ver=uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A cluster-randomized controlled trial of a school and community based multi-component intervention for improving 13-year-olds' fruit and vegetable consumption: the Boost study

Study objectives
1. To examine whether a comprehensive intervention with a strong focus on increasing availability of fruit and vegetables in schools, homes and leisure time will increase fruit and vegetable consumption by 20% among children in intervention schools compared to control schools one year after the intervention start
2. To examine whether the intervention is able to produce a persistent increase in FV consumption among children in intervention schools compared to control schools at second year of follow-up

Ethics approval required
Old ethics approval format

Ethics approval(s)
Danish Committee System on Biomedical Research Ethics
Danish Data Protection Agency ref: J.nr. 2010-54-0974

Study design
Cluster-randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Lifestyle improvement, health promotion, fruit and vegetable consumption

Interventions
A random sample of 10 municipalities followed by a random sample of 4 schools within each municipality. Randomization into 20 intervention and 20 control schools.

Selection of target group, development of the Boost intervention programme and evaluation design were guided by the intervention mapping protocol, experiences from the Pro Children study (www.prochildren.org) and HEIA project (http://www.heia-prosjektet.org/), systematic reviews of determinants of FV consumption and systematic reviews of intervention studies.

Year 7 pupils at the 20 intervention schools received the Boost intervention programme (described below) during the school year 2010/2011 (9 months), whereas the pupils at the 20 control schools did not receive any intervention (no treatment). Part of the intervention components will be offered to the control schools after termination of the project.

Timeline: Baseline survey: August 2010, the intervention was delivered to intervention schools in September 2010-May 2011, 1st follow-up survey: May/June 2011 (one year after intervention start), 2nd follow-up: May/June 2012 (2 years after intervention start). The implementation of the intervention has been monitored by a thorough mixed methods process evaluation. The costs of the intervention will be collected to enable economic evaluation of the intervention.

Intervention:
Program activities were organized within three settings:

1. School:
1.1.Environmental component:
1.1.1 Daily provision of free FV to all year 7 pupils in schools for 9 months (delivery from local providers)
1.1.2 Pleasant and enjoyable eating atmosphere for eating FV:
1.1.2.1. Time allocated for eating FV together in class
1.1.2.2. free provision of class kit to all school classes (basket for FV, plate and bowl for FV snacks, apple slicer, candles, music, chopping board, cutlery, paring knife, lemon juice to prevent enzymatic browning of fruit snacks, dish washer, washing-up brush, dish towel, cloth)
1.1.2.3. Inspiration folder on how to conduct a successful, pleasant fruit break
1.1.2.4. Hygiene instructions and tips for cutting up different FV, 2.5 Pupils designated to be FV hosts responsible for bringing FV to class, cutting it up for appealing FV snacks, serving it to class mates and cleaning up afterwards
1.2.Educational component:
1.2.1. 1-day inspirational workshop for two teachers from each intervention school before intervention start. They were trained to cook FV dishes and implement FV school breaks and gave feedback on a preliminary draft of the Boost teaching material.
1.2.2. Boost pupil workbook/teacher manual to monthly guided classroom activities to be integrated in different school subjects
1.2.3. Boost computer tailored messages for 13-year-olds
1.2.4. Teacher script for an optional FV project week

2. Families:
2.1. Parent school meetings: In the beginning of the intervention period (August/September 2010) the Boost project group presented the Boost-project at parent meetings at all intervention schools accepting the invitation.
2.2. Guided child-parent activities (homework as part of pupil workbook)
2.3. Parental newsletters (n=6). The newsletters targeted home availability (variety, price), home accessibility (parental facilitation), nutritious needs of physically active children and parental barriers: Price, time costs, hungry teenagers, preparation, choosiness of children
2.4. An optional school event: As part of the FV project week we proposed that the pupils held an event at the school where parents were invited to taste some of the provided fruit and vegetable recipes and to have a look at the products (e.g. posters, maps) the children had created as part of the Boost curricular activities

3. Local community
3.1. Guided pupil visits to examine FV availability in grocery stores
3.2. Guided pupil visits to examine FV availability in local area

3.3. Information sheets to managers and coaches of sports clubs to increase teenagers access to FV in their leisure time
3.4. Information sheets to managers of youth clubs to increase teenagers access to FV in their leisure time
3.5. Boost-posters to participating local FV providers, youth clubs, sports clubs and intervention schools

Effect evaluation
The primary aim of the effect evaluation will be to assess whether our goal of a 20% increase in FV intake has been achieved. All further impacts of the intervention such as intended proximal effects (determinants) and unintended positive and negative side effects will also be subject to evaluation. Outcomes will be analysed after the principle of intention-to-treat. To account for the cluster-design and repeated measurements, changes in consumption from baseline to first- and second follow-up will be analyzed by multilevel multivariate regression analyses. All analyses will be stratified by gender and we will examine if the intervention have differential effects on FV intake among pupils from low and high social class.

In another analysis implementation degree (high/medium/low) will be included in analyses

In a third analysis we will try to examine if it possible to decompose the effects of the different intervention components through mediation analysis. We will analyse the effect of the different intervention components on the determinants (proximal outcomes) they have been tailored to. In a second analytical step we will examine if change in intake is preceded by changes in determinants.

Intervention Type
Behavioural

Primary outcome measure
1. Change in total fruit, vegetable and fruit & vegetable consumption in grams per day (in school + outside school) at 1st and 2nd follow-up versus baseline and between groups
1.1. The validated Pro Children 24-hour recall questionnaire (pupils' self-reported FV intake on the day prior to the data collection)
1.2. Pre-specified success indicator: We aimed at a 20% increase in FV intake at intervention schools compared to control schools at 1st follow-up based on the effect size obtained in the Pro Children study
2. Change in habitual intake of fruit, vegetables and fruit & vegetables
2.1 The validated Pro Children Food Frequency Questionnaire
2.2. Pre-specified success indicator: Significantly higher proportion of pupils eating fruit and vegetables daily at intervention schools at 1st and 2nd follow-up versus baseline and between groups

Secondary outcome measures
The Boost intervention is designed to create significant positive changes (at 1st versus baseline and between groups) in the following determinants of children's fruit and vegetable consumption identified from systematic literature reviews (Rasmussen 2006, Krølner 2011):
1. Environmental determinants:
1.1 Home availability/accessibility: quantity, variety, quality, convenience, visibility, appearance, parental facilitation (Pro Children and Boost items)
1.2 FV availability/accessibility in schools: quantity, variety, quality, convenience, visibility, appearance (Pro Children and Boost items)

1.3 FV availability in sport clubs and youth clubs: quantity, variety, quality, convenience, visibility, appearance (Pro Children and Boost items)

2. Social determinants:
2.1. Parental intake of FV (Pro Children item)
2.2. Parental knowledge of national fruit and vegetable recommendations (Pro Children item)
2.3. Parental attitude to the importance of children eating fruit and vegetables (Pro Children item)
2.4. Parental modelling (Pro Children item)
2.5. Parental barriers e.g. price, time issues (Adapted from CHAMP item)
2.6. Teachers' attitude to the importance of promoting children's FV intake in schools (Boost item)
Teacher modelling (Boost item)
2.7. Sports coaches' attitude to the importance of promoting children's FV intake in sports clubs (Boost item)
2.8. Sports coach modelling (Boost item)
2.9. Situational norms: number of meals, situations, occasions and settings perceived as appropriate for eating fruit and vegetables (Boost items)
2.10 Social peer norms for eating FV in school and leisure time activities (Boost items)

3. Personal determinants:
3.1. Children's knowledge of national fruit and vegetable recommendations (Pro Children item)
3.2. Children's awareness about whether they meet national fruit and vegetable recommendations (Pro Children item)
3.3. Children's taste preferences: number of fruit and vegetables liked (Pro Children item)
3.4. Short term outcome expectancies (Pro Children item)

4. Predefined explorative secondary outcomes:
4.1. Intended positive side-effects
4.2. A significant decrease in proportions of pupils at intervention schools who feel out of energy and have difficulties in concentrating during class in school at 1st follow-up versus baseline and between groups (measured by new Boost items)
4.3. A significant decrease in proportions of pupils at intervention schools
who eat unhealthy food almost daily at 1st follow-up versus baseline and between groups (measured by HBSC food frequency questionnaires)
4.4. Significant positive changes in pupil well-being at intervention schools at 1st follow-up versus baseline and between groups (measured by the HBSC questionnaire)
4.5. Second follow-up sustainability measure: At 2nd follow-up it will be measured whether participation in the Boost study has initiated some environmental changes and capacity building at the intervention schools (e.g. initiation of fruit and vegetable programmes, increased sale of FV in schools, increased focus on school food policies and limited access to unhealthy foods at school) by questionnaires to the school principals 2nd follow-up (based on Pro Children questionnaire and new Boost items).

5. Unintended adverse effects
We have aimed at designing an intervention which does not produce any adverse effects, but we will measure the following unintended adverse effects.
5.1. A significant increase in weight- and eating-related teasing and proportions of pupils being bullied at 1st follow-up versus baseline and between groups (measured by HBSC items and new Boost-items).
5.2 Assessment of whether the free fruit and vegetables in school replace fruit and vegetables eaten at other times of the day: A significant decrease in children eating FV at home (24 h recall

questionnaire) and in children bringing FV to school from home (Pro Children items) at 1st follow-up versus baseline and between groups.

As unintended adverse effects are difficult to predict they will also be illuminated through process evaluation.

Overall study start date
01/02/2010

Completion date
01/12/2012

Eligibility

Key inclusion criteria
1. Pupils attending school year 7 (aged 12 - 14 years)
2. Male and female participants
3. Eligible schools have minimum two school classes at school year level 7

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
12 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
2,289 Year 7 pupils (mean age: 13.2), their parents and school principals. Furthermore teachers, managers and coaches of sports - and youth clubs in the intervention group.

Key exclusion criteria
1. Pupils in school classes with special needs (e.g. dyslexia, psychological and cognitive disabilities)
2. Less than four municipal schools
3. Special needs schools and private schools

Date of first enrolment
01/02/2010

Date of final enrolment
01/03/2010

Locations

Countries of recruitment
Denmark

Study participating centre
National Institute of Public Health
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Sponsor information

Organisation
Tryg Foundation [TrygFonden] (Denmark)

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Sponsor type
Charity

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ROR
https://ror.org/02rcazp29

Funder(s)

Funder type
Government

Funder Name
TrygFonden (Denmark)

Funder Name
Centre for Intervention Research in Health Promotion and Disease Prevention (Denmark)

Funder Name
National Institute of Public Health, University of Southern Denmark (Denmark)

Funder Name
Kræftens Bekæmpelse

Alternative Name(s)
Danish Cancer Society, The Danish Cancer Society, DCS

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Denmark

Funder Name
The Danish Consumers Co-operative Society [Fællesforeningen for Danmarks Brugsforeninger (FDB)] (Denmark)

Funder Name
EU School Fruit Scheme, part of the Danish Food Industry Agency at the Danish Ministry of Food, Agriculture and Fisheries (Denmark)

Funder Name
Copenhagen Food House (Denmark)

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?
Protocol article	protocol	14/03/2012		Yes	No
Results article	results	11/02/2014		Yes	No
Results article	results	06/02/2015		Yes	No
Results article	results	05/06/2015		Yes	No
Results article	process evaluation results	26/10/2016		Yes	No
Results article	results	14/11/2016		Yes	No