The HEalth In Adolescence (HEIA) study

Submission date 10/06/2013	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 11/07/2013	Overall study status Completed	[_] Statistical analysis plan[X] Results
Last Edited 19/03/2014	Condition category Nutritional, Metabolic, Endocrine	Individual participant data

Plain English summary of protocol

Background and study aims

There has been an increase in prevalence of overweight and obesity (fatness) among adolescents. The overall goal of this study was to design, conduct and assess a comprehensive school-based programme to promote healthy weight development among young adolescents (11-13 year olds). The programme aimed to increase total physical activity and intake of fruit and vegetables and to decrease the time spent in front of television or computer (screen time) and consumption of sugar-sweetened drinks.

Who can participate?

All 6th grade students in the participating schools and their parents/legal guardians were invited to participate.

What does the study involve?

Schools were randomly assigned to one of two groups: 12 to the intervention group and 25 to the control group. The programme was systematically developed and consisted of a classroom component, including dietary behaviour lessons, computer-tailored personal advices, fruit /vegetable and physical activity breaks and posters and an environmental component including active transport campaigns, sports equipment for recess (break), suggestions for easy improvements of schoolyards, inspirational physical activity courses for teachers, and fact sheets to parents.

What are the possible benefits and risks of participating?

The schools got access to expertise in nutrition and physical activity, as well as some material resources to stimulate active play and fruitbreaks. The pupils were made aware of their nutritional and physical activity behaviours and given various support to improve them over a long period (20 months). The main risks of the study were that it might contribute to increased rates of unnecessary dieting among children, eating disorders or weight-related bullying. The focus was thus kept on the behaviours and teachers and school nurses were informed to report if any of these risks were observed.

Where is the study run from?

The study was conducted in seven counties in the eastern part of Norway.

When is the study starting and how long is it expected to run for? The study started with a pre-test in September 2007 and ended with a post-test in May 2009.

Who is funding the study?

This study was funded by the Norwegian Research Council (Norway) with additional funds from Throne Holst Nutrition Research Foundation (Norway), University of Oslo (Norway), and the Norwegian School of Sport Sciences (Norway).

Who is the main contact? Professor Nanna Lien nanna.lien@medisin.uio.no

Study website https://www.med.uio.no/imb/english/research/projects/heia/index.html

Contact information

Type(s) Scientific

Contact name Prof Knut-Inge Klepp

Contact details Department of Nutrition PO Box 1046, Blindern Oslo Norway 0316 k.i.klepp@medisin.uio.no

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 175323/V50 Norwegian Research Council

Study information

Scientific Title Promoting healthy weight among school children

Acronym The HEIA study

Study objectives

The research hypotheses to be tested in the main study are:

1. A healthy weight promotion program can be designed and successfully implemented in collaboration with schools, local health care services, community youth organizations and parents.

2. A successfully implemented healthy weight promotion program will lead to a more healthy diet and increase physical activity patterns among the children.

3. A healthy diet and increased physical activity levels will lead to reduced rates of overweight and obesity among the children.

4.The healthy weight promotion program will not contribute to increased rates of unwarranted dieting behavior among the children, or to increased rates of eating disorders.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was approved by the Regional Committees for Medical Research Ethics (Date: 22.03.07 / Ref.number: 2.2007.743) and the Norwegian Social Science Data Service (Date: 19.06.2007/ Ref. number: 16434).

Study design Group-based randomized controlled intervention trial

Primary study design Interventional

Secondary study design

Randomised controlled trial

Study setting(s) Other

Study type(s)

Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Primary prevention of overweight/obesity among school-aged children.

Interventions

The study has benefited from applying the intervention mapping methodology, by including the following phases: (1) needs assessment comprising a situational analysis of weight, diet, and activity patterns and environmental and personal determinants; (2) development of specific intervention components aimed to influence determinants; (3) implementation of the intervention following intervention mapping guidelines; and (4) a thorough process and outcome evaluation of the intervention.

Twelve out of 37 schools were randomly assigned to the intervention group. The control group received no intervention, but was offered the revised material after the study was finished. The intervention program lasted for two school years (20 months, 6th and 7th grade) and was delivered by the teachers.

The intervention programme consisted of a classroom component, including dietary behavior lessons (5 lessons, 6th grade), computer tailored personal advise (5 modules 7th grade), fruit /vegetable and physical activity breaks (once weekly), and posters (one per month), and an environmental component including active transport campaigns (thrice a week), sports equipment for active recess, suggestions for easy improvement of schoolyards, inspirational courses on physical activity for teachers (1 day per year), and fact sheets to parents (one per month).

There were measurement conducted at pre-test (September 2007), midway (May 2008) and posttest (May 2009). The midway and post-test evaluation of the intervention arm included process evaluation data from teachers, pupils and parents.

The power calculations were done on 10 + 30, but we only managed to recruit 37 and we were afraid of drops outs so we increased the intervention schools to 12

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Anthropometric measures were taken by same-sex project staff in a suitable room in the schools. The height was measured to the nearest 0.1 cm, using a wall-mounted tape with the child standing upright against the wall and without shoes. The weight was measured with the child in light clothing, to the nearest 0.1 kg using Tanita scales (TBF-300; Tanita Corporation of America, Illinois, USA). The scales were new at the start of the study and were not recalibrated during the project. Waist circumference was measured to the nearest 0.1 cm with a flexible measuring tape between the lower rib and the iliac crest at the end of a normal expiration. Hip circumference was measured at the widest circumference of the hip. The pubertal scale utilised is based on the Pubertal Category Scores and included body hair growth (both genders), voice and facial hair (boys), and breast development and menarche (girls).

Potential negative consequences of the intervention were assessed in the questionnaire by two questions on weight-related cognitions (perception of own weight, its importance to self-esteem), two on receiving weight-related comments (frequency and by whom), and two on slimming behavior (frequency question and a open-ended question inquiring what they had done to slim) for those who had tried to lose or maintain weight in the last year.

Self-reported height and weight, waist, and hip circumferences were obtained from the parents /guardians through the questionnaires. Parents were provided with a measurement tape and written instructions on how to measure waist and hip circumference. The same behaviors as for the children were assessed for each of the parents. In additon, they were asked about whether encouragement of weight loss was practised among the family members. Perceived barriers and

facilitators influencing their childs level of physical activity and consumption of unhealthy foods /drinks were assessed. Finally, a food shelf inventory in the mothers questionnaire assessed the availability of 71 items/categories of food, drinks, and dietary supplements.

Secondary outcome measures

Intake of beverages was assessed by frequency and amount (in glasses) for weekdays and by amount for weekends. Soft drinks and squash with sugar were the main behaviors, but other beverages (such as light soft drinks, light squash, ice tea, water, juice, nectar) were monitored to see whether decreases of the former were accompanied by increases in the latter. Frequency of consumption of fruit and raw and cooked vegetables was assessed by one question for each. In addition, frequency of consumption of sweets/chocolate, salty snacks, sweet cookies, buns /muffins, and five meals/snacks was assessed by nine questions.

Physical activity on weekdays was measured with regards to frequency and length of time spent on active transport to/from school, during recess, in PE class, and after school to assess context specific physical activity. For weekends, there was one question on frequency and one on length of time. Four questions assessed the number of hours spent on watching TV/DVDs and on surfing the internet or playing electronic games separately for weekdays and weekends.

Physical activity was also measured objectively by accelerometers to assess intensity and total physical activity. The children wore accelerometers (GT1 M/CSA model 7164; ActiGraph, Fort Walton Beach, FL, USA) for 5 consecutive days and were instructed to wear the monitor continuously all awake hours except when doing water activities. The output was sampled every 10 seconds for 2 weekdays and 2 weekends. The criteria defined for acceptable use of the monitor were that activity should be registered during a minimum of 3 days and at least for 8 hours each day.

Overall study start date

01/06/2006

Completion date

31/08/2012

Eligibility

Key inclusion criteria

Schools from the 3-4 large towns/municipalities in seven counties surrounding the county of Oslo (south-eastern region of Norway) and with a minimum of 40 enrolled pupils in 6th grade in fall 2007 were to be invited. All 6th grade pupils and their parents in the participating schools were eligible for participation.

Participant type(s) Patient

Age group Child

Sex Both

Target number of participants

37 schools (12 intervention and 25 control) with an average of 45 pupils participating from each school.

Key exclusion criteria Schools from the area of interest with less than 40 enrolled pupils in 6th grade in the fall of 2007.

Date of first enrolment 01/06/2006

Date of final enrolment 31/08/2012

Locations

Countries of recruitment Norway

Study participating centre Department of Nutrition Oslo Norway 0316

Sponsor information

Organisation The Research Council (Norges forskningsråd) (Norway)

Sponsor details Postboks 2700 St. Hanshaugen Stensberggata 26 Oslo Norway 0131 post@forskningsradet.no

Sponsor type Research council

ROR https://ror.org/00epmv149

Funder(s)

Funder type Research council

Funder Name Norwegian Research Council (Norway) (grant no. 175323/V50)

Funder Name Supplementary funds from:

Funder Name Throne Holst Nutrition Research Foundation, University of Oslo (Norway)

Funder Name Norwegian School of Sport Sciences (Norway)

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 output	S
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Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	baseline survey	01/11/2010		Yes	No
Other publications	design	01/11/2010		Yes	No
<u>Results article</u>	mid-way assessment results	17/06/2011		Yes	No
Other publications	baseline data	01/12/2011		Yes	No
<u>Results article</u>	results	01/12/2011		Yes	No
Results article	results	29/05/2012		Yes	No

<u>Results article</u>	results	21/09/2012	Yes	No
<u>Results article</u>	results	06/12/2012	Yes	No
<u>Results article</u>	results	05/02/2013	Yes	No
Results article	results	25/02/2014	Yes	No
<u>Results article</u>	results	01/05/2014	Yes	No