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Design of a 20 month comprehensive, multi-component school-based randomized trial to promote healthy weight development among 11-13 year olds: The HEIA-study

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Short title: Intervention and evaluation design of the HEIA-study

Keywords: adolescents, overweight, obesity, prevention, diet, physical activity, sedentariness, intervention, evaluation, socio-economic status

Abstract:

Background and purpose: The lack of effective school-based interventions for preventing obesity in children has caused a call for longer duration of interventions and better reporting on design and evaluation methodology. The purpose of this paper is to present the development of the intervention, the design of the effectiveness study and the test-retest reliability of the main outcome measures in the HEIA-study.

Methods/design: The HEIA-intervention program was developed based on literature reviews, a social ecological framework and focus groups. The intervention aimed to increase total physical activity (PA) and consumption of fruit and vegetables, and to decrease screen time and consumption of sugar-sweetened beverages. The intervention program consisted of a classroom component including; dietary behaviour lessons, computer tailoring, fruit/vegetable and PA breaks and posters, and an environmental component of; active transport campaigns, equipment, suggestions for easy improvements of schoolyards, inspirational courses for teachers (all with regards to PA), and facts sheets to parents. The effect of the intervention program is evaluated in a cluster randomized controlled trial design (intervention=12 schools, control=25 schools) including process evaluation. Main outcomes include anthropometry, PA, screen time and consumption of fruit, vegetables and sugar-sweetened beverages. A two week test-retest study was conducted among 114 pupils. Determinants of the behaviours were assessed. Similar data were collected from parents. Children's PA was measured objectively by accelerometers.

Conclusion: The HEIA-study represents a theoretically informed randomized trial comprising a comprehensive set of multilevel intervention components with a thorough evaluation using reliable outcome measures. The study will contribute to a better understanding of determinants of healthy weight development among young people and how such determinants can be modified.

Introduction

The prevalence of overweight and obesity among children in Europe has been shown to be increasing [1]. Treatment of obesity in childhood has proved difficult [2], and a recent systematic review showed moderate tracking of childhood overweight into adulthood [3]. This is a serious threat to public health as obesity is an important cause of non-communicable diseases such as cancer, coronary heart disease and type 2 diabetes [4].

During the past decade, environmental conditions as the driving force of the obesity epidemic have been fully recognized. Hence, social ecological frameworks to better understand or change the obesity epidemic have been forwarded [5,6]. Social-ecological frameworks aim to combine personal, social- and physical-environmental factors hypothesized to influence overweight and obesity in children mediated by dietary and PA behaviours. Moreover, the dual-process model [5] incorporates social cognitive theories of behaviour change with the ANGELO-matrix of environmental influences [6] and postulate that environmental factors may influence dietary behaviours and physical (in-) activity directly or through social-cognitive determinants, in turn affecting overweight and obesity. This has formed the basis for the conceptual model of the HEIA-study (Figure 1).

FIGURE 1 ABOUT HERE

Recent reviews of primarily school-based interventions for preventing obesity in children/adolescents conclude that studies have shown limited success in improving body mass index (BMI) and provide recommendations to improve intervention development and evaluation [7-9]. Interventions should aim at changing both dietary and PA behaviours and to this end changes in the physical and social environment would seem necessary [8]. Social differences in overweight/obesity should also be addressed [7,8]. Hence, using qualitative methods to inform the intervention and tailoring messages to different social target groups would also seem important. Moreover, interventions should be of greater length and intensity, but at the same time implementable, sustainable and cost-effective. Hence, there is also a need to identify stakeholders' view of the intervention approach through process evaluations [7,8]. In addition, monitoring potential adverse effects such as stigmatization of obese

children and increased prevalence of eating disorders [9] has been recommended. Finally, using the CONSORT-statement for reporting findings from intervention studies will make comparisons and quality assessments easier [10].

The purpose of this paper is to present the development of the intervention, the design of the effectiveness study and the test-retest reliability of the main outcome measures in the HEIA-study.

Design of the intervention and the effectiveness study

The overall goal of the HEIA-study was to design, implement and evaluate a comprehensive, intervention program to promote healthy weight development among young adolescent school-children (11-13 year olds). The research hypotheses to be tested in the study are that a healthy weight promotion program can be designed and successfully implemented in collaboration with schools and parents, and that this will lead to a more healthy diet and increased PA levels and consequently reduced rates of overweight/obesity among the children. The program will not contribute to increased rates of unwarranted dieting behaviour or eating disorders.

The study has benefited from applying the Intervention Mapping methodology [11], by including the following phases: 1) needs assessment comprising a situational analysis of weight, diet and activity patterns, 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.

Phase 1: Needs assessment

The needs assessment phase consisted of reviewing the published scientific literature to select the target behaviours and their determinants, to adjust these to local circumstances through focus groups and to obtain an overview of recent or ongoing interventions targeting these behaviours in Norway.

Target behaviours and determinants – a review of the literature.

For dietary intake a decrease in consumption of sugar-sweetened beverages was seen as the most promising target behaviour [12] together with increased consumption of fruit and vegetables which might displace more energy-dense snacks [13]. Determinants were mostly studied for fruit and vegetables [14,15] and the most important ones were: availability/accessibility, role models, preferences and awareness of recommendations and own behaviour. There was some support for the two environmental determinants also for soft drinks [14], whereas preferences and awareness were included on the theoretical assumption of similarity with fruit and vegetable determinants.

Increasing PA and decreasing sedentary behaviour have both been found to be important determinants of weight development in youth [16]. Specific target behaviours chosen to increase overall PA were: active transport, PA during recess, PA in physical education (PE) classes and PA during leisure time in general. Sedentary behaviours chosen to reduce were TV-watching and the use of computer/electronic games (screen time). Theoretically informed determinants of PA included enjoyment, self-efficacy, perceived social support from significant others and perceived opportunities at school and during leisure time, and for screen time the main determinant was perceived parental regulation [17-19]. In addition, awareness of recommendations and own PA level was included in accordance with the dietary behaviours.

Focus groups with children and parents

Focus groups interviews with 6th graders from 2 schools (10 groups, 5-9 participants in each) were conducted to elicit their views on PA, screen time, soft drinks, and how they spend the time right after school. Similarly, 4 focus group interviews (4-6 adults per group) with parents (mainly mothers) of 10-13 years olds were conducted to elicit their views on PA, screen time, vegetables for dinner and soft drinks as intervention target points, as well as their views on the relevance and efficiency of various intervention strategies and activities and modes of communication with children and parents.

Phase 2: Development of intervention components and the overall program

The logic model of the Intervention Mapping protocol is that the practical strategies in the intervention should be theory-based, but fitted to the target group and implementers, and be aimed at changing the determinants which will then cause a change in the behaviour and ultimately the health status. Due to the multiple behaviours in the HEIA-study we also adopted an overarching principle guiding the compilation of the intervention program which was that it should generate synergy effects on target behaviours and their determinants. Hence, the intervention program consisted of a mixture of individual-, group-, and environmental level strategies and activities previously proved efficient or promising by research [20-22, 28] or practice (Table I). These were provided several times and in different forms throughout the intervention so as to best orchestrate strategies and activities. Reference groups of parents, teachers and students were organized to provide feedback on the developed material.

TABLE I ABOUT HERE

Phase 3: Implementation of the intervention

Implementation was facilitated by a 3 hours kick-off meeting at each intervention school each year. The meetings were led by a team of two researchers (nutrition + PA). The pedagogic personnel at the grade level were invited together with the principal, the school nurse and a parent committee member. The first year included a 20 minutes project presentation for all the pedagogic personnel at the school, followed by a session based on the teacher's manual for the 6th-grade teachers. In the second year, feedback gained from the process evaluation set the stage for meetings with the 7th-grade teachers. Based on previous experiences and dialog with the teachers the following were conducted to facilitate smooth implementation. Teachers received monthly e-mails with brief reminders. All materials were ready to be handed out to students/parents. Equipment for the activities was provided, but fruit/vegetables for the breaks were brought from home. Students received binders for keeping the HEIA-study material.

Phase 4: A thorough evaluation of outcomes and processes of the intervention implementation

Study design and procedures

A cluster randomized controlled study design is used to evaluate the effectiveness of the intervention with baseline measurement at the beginning of 6th grade (2007) and follow-up (FU) measurements at the end of 6th (FU1) and 7th grade (FU2) (Table II).

TABLE II ABOUT HERE

At all time points, teams of trained project staff visited the schools and collected all data. Anthropometric measurements and PA measured by accelerometers were collected at baseline and FU2. The Internet based child questionnaire comprised mostly pre-coded answer categories and took about 45 minutes to complete. To ensure privacy, the children reported on puberty status on a separate paper form. Children who were absent were asked to fill in the Internet-questionnaire only, on a later day. Parental questionnaires (paper, one to each parent) were sent home with the child, returned to the teachers in a sealed envelope and collected from the schools by project staff. School management filled in a paper questionnaire and returned it in a pre-stamped envelope. The school nurses either filled in an Internet based questionnaire or a paper version of this. Observations of the PA quality of school grounds and the food outlets within 500 meters of the school were conducted. Process evaluation questions were added to the child questionnaires at FU1 and FU2, and as separate questionnaires filled in by one parent at each of these time points. Teachers at the intervention schools filled in process evaluation log books during the intervention years and surveys at the FUs.

Questions on behaviours and determinants were mostly modified from existing questionnaires; dietary behaviours [23-25]; PA [26,27] and screen time [19]. A test-retest study (two weeks) of the parent and child questionnaires (paper) and the measurement of the children's height, hip and waist was conducted among 114 6th graders in four schools in the same sampling area as the main study.

Recruitment and randomization

Eligible schools were those with more than 40 pupils in 6th grade and located in the 3-4 largest towns/municipalities in the 7 counties surrounding the county of Oslo. Thirty-seven of the 177 schools invited agreed to participate (Figure 2). Information letters to all pupils and parents were administrated through the teachers. The Norwegian Social Science Data Service granted permission for project staff to contact the parents who did not respond to the invitation. Consent was obtained for 1580 (73%) out of 2165 invited pupils. Twelve schools were randomly assigned by simple drawing to the intervention group and 25 to the control group. For ethical and practical reasons, no data can easily be obtained to assess bias due to schools or pupils declining participation. Baseline characteristics of the intervention and control groups are compared in Table III.

FIGURE 2 and TABLE III ABOUT HERE

Power calculations

Power calculations were made based on changes in BMI [12], intake of fruit, vegetables and soft drinks [28,29] and PA measured by accelerometers [30]. Taking the cluster effect of randomly assigning schools to intervention and control into account, assuming that 80% of the pupils would participate, that the attrition-rate would not exceed 15% per year, we aimed for 40 schools (10 intervention and 30 control) with an average of 45 pupils participating from each school. In the final study, we included 12 intervention schools and 25 control schools and had an initial participation rate of about 73% (n=1580). However, preliminary analyses indicate that the attrition-rate we experienced per year was only about 4% per year (data not shown), which is much better than the expected 15%. We thus conclude that the power we have in our final sample is sufficient according to the baseline assumptions and that the following differences between intervention and control schools would then be detectable after 2 years: BMI 0.72 kg/m², 0.60 times/week of soft drinks with sugar, 1.2 times/week of fruit, 1.0 times/week of vegetables and PA of 62 counts/minute.

Ethical issues

The study protocol was approved at the regional branch of The National Committee for Medical Research Ethics. Anthropometrics were not given to the children and they were advised to contact the school nurse or their family doctor for a more complete health examination if they expressed concerns about their weight. Care was taken throughout the intervention to focus on the behaviours rather than weight/obesity to avoid creating any pressure or discrimination related to weight and body image among the children. Teachers and school nurses were informed to notify the research team if they had reason to believe this was happening.

Measures

Primary outcomes: Anthropometric measurements (adjusted for pubertal status) and unintended negative effects

Anthropometric measures were taken by same sex project staff in a suitable room (lockable, windows blinded) 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, i.e. T-shirt and underwear, to the nearest 0.1 kg using new Tanita scales (Tanita TBF-300, Tanita Corporation of America, Illinois, USA). 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 utilized is based on the Pubertal Category Scores [31], 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 behaviour (frequency question and a open-ended question inquiring what they had done to slim) for those who had tried to loose or maintain weight in the last year.

Secondary outcomes: The behaviours

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 behaviours, 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 ones. Frequency of consumption of fruit, raw and cooked vegetables were assessed by one question for each. In addition, frequency of consumption of sweets/chocolate, salty snacks, sweet cookies, buns/muffins and 5 meals/snacks were assessed by nine questions.

PA 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 PA. For weekends there were 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 on the internet or playing electronic games separately for weekdays and weekend days.

Physical activity was also measured objectively by accelerometers to assess intensity and total PA. The children wore accelerometers (ActiGraph GT1M/CSA model 7164, 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 weekend days. 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.

Potential mediators and moderators of the intervention

Determinants of soft drinks/squash (12 questions) included availability/accessibility at home/school/leisure time activities, assessment of own consumption compared to others their age, situations for consumption and parental consumption. Similarly, for fruit and vegetables (12 questions) on availability/accessibility at home/school/leisure time activities, preferences for different types of fruit and vegetables, assessment of own consumption compared to others at their age (fruit), parental encouragement and parental consumption (vegetables) were included.

Determinants of PA included (# items): enjoyment (5), perceived social support from friends (3), from parents (5) and teachers (3), self-efficacy (5) and perceived opportunities for being physical active at school/during leisure time (4). Determinants of screen time: parental regulation (8 questions). Quality of relationship with peers and others at school (social capital) was assessed by six items.

Parents' length of education was collected on the consent forms. The children reported gender, and country of birth for themselves and each of the parents.

Parents' anthropometrics, behaviours and the home environment

Self-reported height, 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 behaviours as for the children were assessed for each of the parents. In addition they were asked about whether encouragement of weight loss was practiced among the family members. Perceived barriers and facilitators influencing their child's level of PA and consumption of unhealthy foods/drinks were assessed. Finally, a food shelf inventory in the mother's questionnaire assessed the availability of 71 items/categories of food, drinks and dietary supplements.

School and neighbourhood environment

Policies, practices and opportunities to practice healthy choices with regards to PA, food and drinks in school were assessed by an extensive questionnaire to the school management. The questionnaire was modified from a nation-wide school survey [32]. The school health services were given a less comprehensive questionnaire related to their weight-related services. Observations were conducted using observation forms including checklists to assess availability of opportunities for PA at and around the schools, and availability of foods/drinks that children are likely to buy themselves in food outlets (grocery/convenience stores, kiosks, bakeries, café's/restaurants) around the schools.

Process data

The log books and questionnaires to the teachers assessed fidelity (quality), dose delivered (completeness) and context, including teacher- and program-specific factors (such as acceptability, feasibility and adaptability), with regards to the implementation of the intervention [33]. Process evaluation of children and parents consisted of general questions on school practice and communication around PA and foods/drinks to all participants. Additional specific questions to participants at the intervention schools tapped into dose received (both exposure and satisfaction) and usefulness of each component. All expenses related to the development and implementation of the intervention has been recorded in order to conduct cost-effectiveness analyses.

Data analysis

Differences between intervention and control groups were assessed by ANOVA and Chi-square. The prevalence of overweight/obese was defined by international age and gender specific cut-offs [34]. The children's test-retest data on anthropometrics, puberty and the behaviours were analysed by paired t-test and correlation (Pearson's correlation coefficient and Kappa) using SPSS 16.0. To calculate average consumption of sugar-sweetened beverages on weekdays and weekend days a glass was set to be 167 ml, as the children were instructed to report ½ liter as three glasses.

Results

There were no significant differences in gender, parental education and BMI or prevalence of overweight/obese between the intervention and control group in the baseline survey (Table III).

The test-retest correlation coefficients for the outcome measures were moderate to high (mostly $r \geq 0.60$), except for voice change for the boys ($r=0.38$) and dieting frequency ($r=0.21$) (Table IV and V). This sample consisted of 46% boys and had a mean BMI of 17.3 (16.9-17.6) (data not shown).

TABLE IV AND V ABOUT HERE.

Discussion

Overweight and obesity is currently a major public health concern. Yet, there is no strong evidence-base for recommending appropriate intervention strategies in order to prevent childhood overweight and obesity and to secure a healthy weight development during adolescent years [8,35]. This lack of evidence has caused questioning about what are the best intervention strategies and evaluation designs of school-based obesity prevention interventions [35, 36]. The HEIA-study is designed to address some of these questions.

Issues discussed with regards to the design and development of the interventions are; the ideal number of behaviours targeted, use of theory, which components and aspects of the environment are more important, the training of the facilitators and the length of the intervention [8,35,37]. There is a general agreement that school-based interventions should target behaviour change and not just knowledge, but uncertainty exists as to whether it would be best to target multiple or single behaviours [8,37]. In line with other recent obesity prevention studies, we chose for multiple energy-balance related behaviours as it is not known which behaviours are the most influential on weight development and this may vary by sub-groups. In accordance with other studies [35], we made use of a social ecological framework incorporating elements from social cognitive theory as the starting point for our conceptual model. However, according to Brown and Summerbell [8], it is not clear whether long term obesity prevention interventions, underpinned by theory, involving existing school staff, the whole school community and environmental modification are more successful than other interventions. Peters et al [37] on the other hand did observe that use of theory, especially social cognitive theory, raised intervention effectiveness across all three behaviours reviewed. They also reported that addressing behavioural determinants of dietary

behaviours would seem a future research issue worthwhile to pursue [37]. Thus, there is support for use of theory and a systematic planning of interventions as applied in the HEIA-study. Other effective elements found by Peters et al [37] were: addressing social influence and cognitive-behavioural skills, training the facilitators and including multiple components, but they concluded that there was not enough evidence to single out specific components (i.e. family, teaching methods). When the obesogenic environment was first recognized focus was turned to the physical environment, but lately the need to address social norms both among peers and within the whole school community including the parents has been recognized [35]. In the HEIA-study, all school personnel are informed about the project and encouraged to use HEIA-activities in other classes if appropriate (i.e. the HEIA-breaks, the recess equipment and PE teaching methods). Social influence from peers is staged through the PA-activities and during consumption of fruit/vegetables, but the potential of peer educators as recognized by Lytle [35] is not used. The need for individually tailored advices, on the other hand, is facilitated by the computer tailoring component. The fact sheets to parents addresses barriers and facilitators of the targeted behaviours at home, including family rules regulating these behaviours, and encourage sharing of ideas among parents. In planning the intervention, we tried to include parents who struggled with these topics in the focus groups, but did not succeed. Finally, the teachers were trained several times, but were also repeatedly encouraged to adapt the intervention to their school to ensure ownership and sustainability. The optimal length of the interventions is an issue of debate and there is a concern that eventual effects of short interventions (< 6 months) are not sustainable [35], and that it takes time to obtain the recommended changes in the social and physical environment.

Issues discussed with regards to the evaluation of the intervention are; which anthropometric outcome is most appropriate, is the intervention equally effective across subgroups, are there effects in both mediating factors and outcomes as postulated in the logic model of the intervention, are the measures of environmental changes good enough, are the studies appropriately powered, how is the intervention implemented and received, what determines sustainability and is it cost-effective [7,8,35, 36]. The HEIA-study includes multiple anthropometric measures as previously recommended [7,9]. However, more recently the need to agree upon one relevant measure has been brought forward to facilitate comparison across studies and avoid just any significant effect being reported, but the difficulty of accomplishing this is acknowledged [35,36]. The effect of the interventions have rarely been reported by subgroups [8], despite the well-known fact that large social differences in

overweight/obesity exist [7] and that schools are seen as excellent arenas to reach everybody. In the HEIA-study, parental length of education was collected on the consent form ensuring completeness and good quality of this important indicator. Furthermore, the collection of extensive data on both potential mediators and process indicators from the children as well as the parents will allow us to examine implementation quality and whether intervention effects are mediated by changes in psychological and social-environmental factors. However, we recognize that due to the many potential determinants and behaviours addressed, the precision of the measures may have been lost by having to use single items to measure some of them. Furthermore, while we assessed the intervention and control school environments pre and post, the measurement tools used in this respect has not been previously validated. Despite the smaller number of schools and the slightly lower response rate obtained compared to those used in the power calculations, the final number at baseline was not much different as the schools were larger and the attrition rate seem much lower than expected. However, we have no data on the schools or the parent/children who declined the invitation to participate and can thus not assess response bias. The intervention schools were supported during the implementation of the intervention and the influence of this on intervention sustainability and possibilities for wider dissemination need to be studied together with the cost-effectiveness.

The results of the test-retest pilot study were used to modify questions about active transport to and from school and some of the questions on weight perception and slimming. The remaining coefficients were generally moderate to high, and especially high for the anthropometrics as has also recently been reported by others [38]. In accordance with other studies of the dietary behaviours [23,24,39], the correlations were moderate to high, except for soft drinks on week days which was probably due to the low consumption. The Pearson's correlation of the PA questions were also moderate to high, but somewhat lower Kappa which is more in line with the composite measures mostly reported by others [40,41]. Reliability of the type of screen time assessments used in HEIA has not been much reported, but our moderate results are higher than reported from the Youth Risk Behaviour study [42]. The reliability of the puberty and weight-related measures were also moderate to high, except for voice change for boys which may be the most difficult to define of the puberty measures, and slimming frequency. However, the latter question was only answered by 26 students due to the skip pattern in the questionnaire. The sample of the test-retest study consisted of slightly more girls

than the baseline sample and the mean BMI of this sample was also slightly lower, but the sample was recruited from the same area as the HEIA-sample and is thus considered reasonably similar.

In conclusion, the HEIA-study is designed to address critical questions raised concerning the development of intervention strategies and is believed to contribute with new insights regarding obesity prevention research for young people. In particular, strong focus on both diet and PA, strong methodological research design with reliable outcome measures, the use of multiple intervention components, the long duration and the thorough evaluation including primary and secondary outcomes and potential determinants, as well as process evaluation measures from teachers, children and parents are believed to be important to address the issues raised.

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Formatert: Skrift: Skriftfarge:
Automatisk, Engelsk
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CULTURAL ENVIRONMENT PHYSICAL ENVIRONMENT SOCIAL ENVIRONMENT PERSONAL FACTORS

Distal

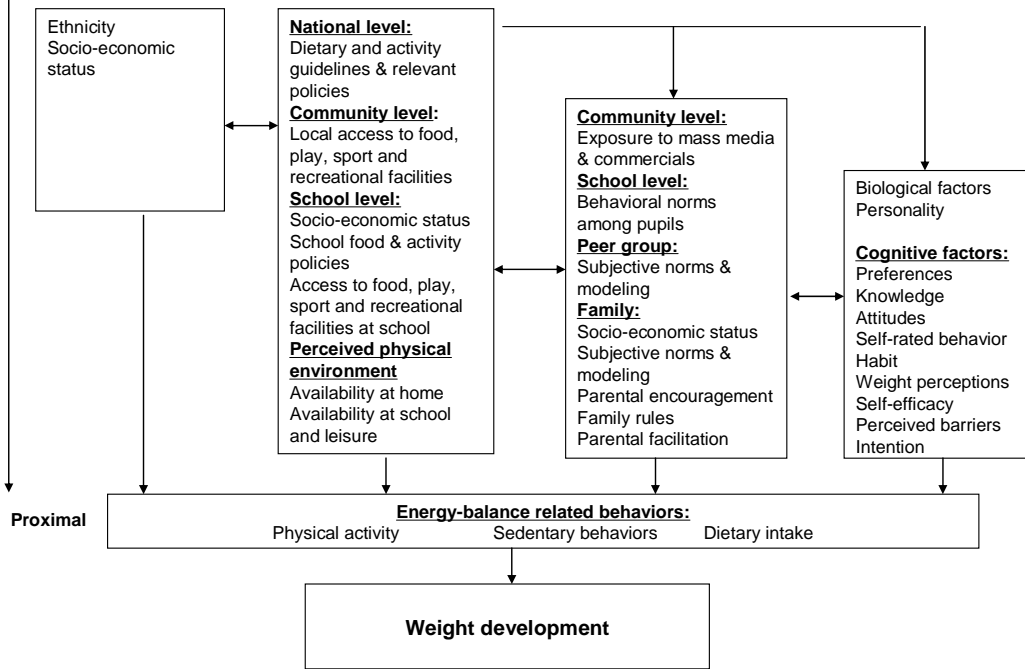


Figure 1: Proposed conceptual model for the “HEIA –HEalth In Adolescents” study.

Table I The intervention components of the HEIA-study implemented in 6th and 7th grade in 12 Norwegian schools in 2007/08 and 2008/09.

Setting/arena	What	Timing	Determinants (D)/purpose(P)^a	Source
Class	Lessons with student booklet: 1. Diet and physical activity 2. Meals 3. 5 a day 4. Sugar rich beverages 5. Your choice	Once per month - 6 th grade winter/spring	D: Awareness P: Increase awareness of recommended intake levels and own intake	- New - Pro Children (FV) (20) - Fruit and Vegetables Makes the Marks (28)
	Posters for classrooms - A4-size, placed on a larger “frame-poster” including the HEIA-logo	Monthly - through out project	D: Awareness P: Daily reminder of main messages, (topic matched fact sheets to parents)	New + from the Norwegian Cancer Society
	Fruit and vegetable break - cutting equipment per class provided, students brought FV	Once a week – through out project	D: Preference P: Cut, serve, taste and eat FV with class mates	Norwegian Cancer Society – “Spis mer”
	Activity break - 10 minutes activity breaks to be conducted in the regular classroom	Once a week – through out project	D: Enjoyment, self-efficacy, increase opportunities P: introduce activity also outside PE and by regular teachers	- Oslo Municipality idea booklet (6 th grade) - “Friskis & Sveltis”- sports club: The “Røris” program; poster, CD and training of teachers (7 th grade)
	Sports equipment for recess activities - 1-2 boxes per school, suggested system for maintaining the system. Examples of content: : Frisbee, jump-ropes, elastic bands, hockey-sticks, a variety of balls	Through out project – some refill at beginning of 7 th grade.	D: Enjoyment, Self-Efficacy, increase opportunities P: Stimulate activity during recess – especially among those who do not play ball.	“Aktiv ute”, a collaboration between Kristiansand Municipality and the University of Agder
	Active commuting - Register days with active transport to/from school for 3 weeks (campaigns)	6 th grade: fall, winter and spring 7 th grade: fall and winter	D: Enjoyment, Self-Efficacy, increase opportunities P: Stimulate activity	New + “Aktive skolebarn”, a collaboration between The Directorate of Health, The Norwegian

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				Public Roads Administration, The Norwegian Council for Road Safety and the police
	<u>Pedometer:</u> - one class set per school to be used in Spark/PE, as tasks at school, as home assignment and with active commuting	7th grade	D: Enjoyment, Self-Efficacy P: Stimulate activity	New + SPARK (22)
	<u>Computer tailoring</u> 1. Fruit 2. Vegetables 3. Physical activity 4. Screen time 5. Sugar sweetened beverages + one week action plans for each (what, where and when to try one of the advises for behaviour change)	7th grade Fall Fall Winter/spring Winter/spring Winter/spring	D: Awareness P: Increase awareness of - recommended intake and activity level - own intake, activity level and hours of screen time	Pro Children (20) “FataintPhat” (21)
<u>Home/parents</u>	<u>Fact sheets</u> Structure: Facts- challenge – ideas + tasks in 7 th grade <u>Brochures/information sheets</u> Teachers were provided info sheets about the FV break that they could use to inform parents about these. Brochures on - cutting fruit/ vegetables and - “Meals – a value worth fighting for” was handed out together with	Monthly - through out project	<u>Fact sheets</u> - focused on each behaviour and determinants multiple times through out the project. Stimulate parents to evaluate and change the home environment with regards to facilitate or regulate the behaviours targeted. <u>Tasks</u> to ensure that the fact sheets were read and discussed/applied to the home environment. <u>Brochures</u> to provide inspiration and knowledge.	- Fruit and Vegetables Makes the Marks (28) - Norwegian Cancer Society, “Spis mer” - Pro Children (20) - Norwegian fruit and vegetable information board - The information boards of all the major food groups: FV, grains, milk, read meat, white meat and

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	fact sheets on these topics.			egg
School wide	Kick-off meetings at each school Teacher manual Served FV Practical activities	6th and 7th grade (fall), 2-3 hours each time	Inform the school management, teachers, school nurse and parent committee about the project and establish the grade level teachers as the HEIA-team at school	- Fruit and Vegetables Makes the Marks (28) - Pro Children (20)
	Inspirational courses for PE-teachers	2 x 1 day courses at the Norwegian School of Sport Sciences	Provide PE teachers with methods/activities that could increase the time spent in activity for all students during PE-classes	SPARK (22)
	Resource box for school management Offer to order box with cutting and selling tools for FV Meeting with school environment group/parent committee		Focus on food/drinks offered in school or during school events, and on easy to do changes on the school grounds that could stimulate activity	- Norwegian fruit and vegetable information board – MER-campaign tool box - Guidelines for the school meal. - “Aktiv ute” - booklet
Leisure time activities (soccer, team handball and school band)	Information folder and offer to have a box with equipment for cutting and selling FV	7th grade (fall)	Create awareness about leisure time activity leaders as role models for dietary habits, to reflect upon availability of food/drinks during practices and special events (i.e. tournaments, weekend training sessions, flea markets for fund raising)	Norwegian fruit and vegetable information board – MER-campaign tool box

^a Purpose gives additional information on how the determinant should be influenced by the activity

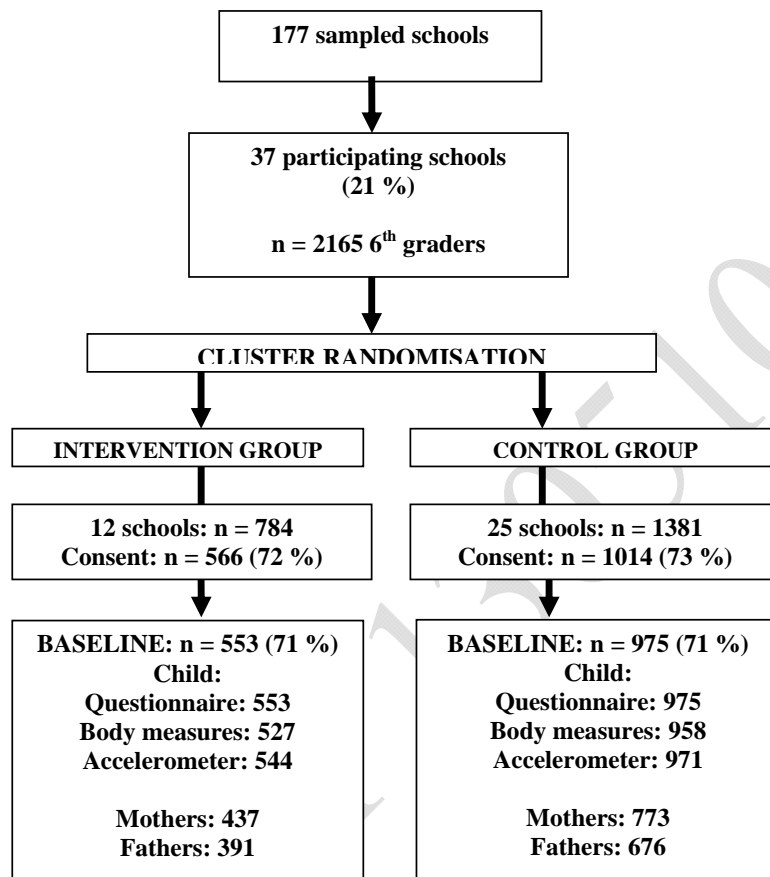


Figure 2 Flow diagram of recruitment, randomization and participation of children and parents at baseline in the Norwegian intervention study “HEIA – HEalth In Adolescents”.

Table II Design of the “HEIA-Health In Adolescents“-study and type of data collected at each time point.

	Baseline September 07	Intervention	Follow-up I May 08	Intervention	Follow-up II May 09
Intervention schools (n=12)	11-y olds & parents	X ^a	12 y-olds & parents	X ^a	13-y-olds & parents
Control schools (n=25)	11-y olds & parents		12 y-olds & parents		13-y-olds & parents
Data collected:	Anthropometrics ^b		Anthropometrics		Anthropometrics
	Puberty (children)		Puberty (children)		Puberty (children)
From child, mother & father ^c	Behaviors		Behaviors		Behaviors
	Determinants		Determinants		Determinants
	Dieting/weight perception		Dieting/weight perception		Dieting/weight perception
	Demographics ^d		Demographics		Demographics
			Process evaluation ^e		Process evaluation
At school level:	Objective PA (children)		Objective PA (children)		Objective PA (children)
	School headmaster questionnaire		School headmaster questionnaire		School headmaster questionnaire
	School nurse questionnaire				
	Observational data school yard & neighbourhood		Observational data school yard & neighbourhood		Observational data school yard & neighbourhood
Intervention schools:			Process evaluation teachers		Process evaluation teachers

^a X=Intervention program

^b Anthropometrics = weight, height, waist and hip circumference; measured by trained personnel for the children, self-reported by parents for themselves. For the children body composition was also measured.

^c The parents filled in separate questionnaires at baseline and follow-up II, but only one parent filled in the process evaluation at follow-up I and II

^d Demographics = gender, month and year of birth, (parents) country of birth. Parents' level of education was collected on the consent form

^e General process evaluation questions were asked to children and parents at both intervention and control schools

Table III Description of the intervention and control group of 6th graders at baseline in the HEIA-study.

	<u>Intervention</u> <u>N=523-553^a</u>	<u>Control</u> <u>N=958-984</u>	<u>p</u>
<u>Gender (% boys)</u>	<u>50</u>	<u>51</u>	<u>0.7</u>
<u>Parental education (%)</u>			<u>0.06</u>
<u>12 years or less</u>	<u>26.0</u>	<u>31.8</u>	
<u>Between 13 and 15 year</u>	<u>37.8</u>	<u>35.1</u>	
<u>16 years or more</u>	<u>36.3</u>	<u>33.1</u>	
<u>Mean BMI (95 CI)</u>	<u>17.9 (17.7-18.1)</u>	<u>18.0 (17.9-18.2)</u>	<u>0.3</u>
<u>Overweight/obese^b (%) (95 CI)</u>	<u>12 (9-15)</u>	<u>15 (13-17)</u>	<u>0.13</u>

^a N varies due to different sources of data: student questionnaire, consent form, anthropometric measurements

^b According to international age- and gender specific cut-offs (34)

Table IV: Test-retest reliability of anthropometric measures of 11-12 year olds for the HEIA-study.

	<u>n</u>	<u>Test</u> <u>(mean)</u>	<u>Retest</u> <u>(mean)</u>	<u>p^a</u>	<u>Pearson's</u> <u>correlation</u> <u>coefficient^b</u>
<u>Height (m)</u>	<u>89</u>	<u>151.1</u>	<u>151.2</u>	<u>0.34</u>	<u>0.99</u>
<u>Waist (cm)</u>	<u>89</u>	<u>59.9</u>	<u>59.8</u>	<u>0.58</u>	<u>0.94</u>
<u>Hip (cm)</u>	<u>89</u>	<u>75.8</u>	<u>75.7</u>	<u>0.77</u>	<u>0.97</u>

^a for paired t-test ^b all p-values were <.001

Table V: Test-retest reliability of self-reported behavioral outcomes and puberty measures of 11-12 year olds for the HEIA-study.

<u><i>Dietary behaviors</i></u>	<u>n</u>	<u>Pearson's r^a</u>	<u>Kappa^a</u>
<u>Fruit (frequency)</u>	<u>112</u>	<u>0.75</u>	
<u>Vegetables raw (frequency)</u>	<u>108</u>	<u>0.65</u>	
<u>Vegetables cooked (frequency)</u>	<u>109</u>	<u>0.60</u>	
<u>Soft drinks (w/sugar)</u>			
<u>total intake week days (frequency*amount)</u>	<u>96</u>	<u>0.46</u>	
<u>total intake weekend (frequency*amount)</u>	<u>109</u>	<u>0.67</u>	
<u>Squash (w/sugar)</u>			
<u>total intake week days (frequency*amount)</u>	<u>86</u>	<u>0.78</u>	
<u>total intake weekend (frequency*amount)</u>	<u>108</u>	<u>0.68</u>	
<u><i>Physical activity</i></u>			
<u><i>Recess</i></u>			
<u>What do you usually do in the short breaks?</u>	<u>107</u>	<u>0.77</u>	<u>0.77</u>
<u>What do you usually do in the long break?</u>	<u>108</u>	<u>0.86</u>	<u>0.83</u>
<u>How often do you move so much you get out of breath/sweaty?</u>	<u>111</u>	<u>0.58</u>	<u>0.50</u>
<u><i>PA at school after school</i></u>			
<u>How often do you stay after school for PA? (frequency)</u>	<u>107</u>	<u>0.84</u>	<u>0.56</u>
<u>For how long are you active each time? (minutes)</u>	<u>47</u>	<u>0.65</u>	
<u><i>PA during leisure time</i></u>			
<u>How often are you physically active outside school? (frequency)</u>	<u>109</u>	<u>0.50</u>	<u>0.38</u>
<u>For how long are you active each time? (minutes)</u>	<u>103</u>	<u>0.60</u>	<u>0.36</u>
<u><i>PA weekend</i></u>			
<u>How often are you physically active during weekends? (frequency)</u>	<u>77</u>	<u>0.62</u>	<u>0.27</u>
<u>For how long are you active each time? (minutes)</u>	<u>63</u>	<u>0.67</u>	<u>0.49</u>
<u><i>Screen-time</i></u>			
<u>TV/DVD week day (hours)</u>	<u>109</u>	<u>0.57</u>	
<u>TV/DVD weekend day (hours)</u>	<u>110</u>	<u>0.58</u>	
<u>Computer/games week day (hours)</u>	<u>106</u>	<u>0.50</u>	
<u>Computer/games week end day (hours)</u>	<u>109</u>	<u>0.65</u>	
<u><i>Weight perceptions and slimming behavior</i></u>			
<u>What do you think about your weight?</u>	<u>110</u>	<u>0.73</u>	<u>0.65</u>
<u>How often do you weight yourself?</u>	<u>109</u>	<u>0.79</u>	<u>0.52</u>
<u>Have you ever got negative weight related comments?</u>	<u>84</u>	<u>0.74</u>	<u>-^b</u>
<u>How often have you slimmed in the last year?</u>	<u>26^c</u>	<u>0.21</u>	<u>=</u>
<u><i>Puberty</i></u>			
<u>Body hair</u>	<u>101</u>	<u>0.77</u>	<u>0.67</u>
<u>Voice change (only boys)</u>	<u>52</u>	<u>0.38</u>	<u>0.43</u>
<u>Facial hair (only boys)</u>	<u>51</u>	<u>0.76</u>	<u>0.75</u>

<u>Breast growth (only girls)</u>	<u>56</u>	<u>0.80</u>	<u>0.74</u>
<u>Menarche (only girls)</u>	<u>57</u>	<u>0.90</u>	<u>0.90</u>

^a All p-values were <.001, except for Pearson's r for voice change for boys which was 0.006 and frequency of dieting which was 0.29

^b Unequal number of response categories used at test and retest, thus Kappa could not be calculated.

^c Only those who said yes to having tried to change their weight was routed to this question

Formatert: Engelsk (USA)

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