

Promoting physical activity among overweight and obese children

Effects of a family-based lifestyle intervention
on physical activity and metabolic markers

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Doris av Susanne Fredelius

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Abstract

Background Overweight and obesity in childhood is associated with physical, psychological and social consequences. Physical inactivity is regarded as one of the main factors that have contributed to the increase in childhood obesity through out the world. Overweight and obesity as well as physical activity level are shown to track from childhood to adolescence and adulthood, thereby influencing not only the current health status but also long-term health. The general purpose of this thesis was to evaluate the effect of a 2-year family-based lifestyle intervention on physical activity and metabolic health among children with overweight and obesity.

Methods Children with overweight or obesity living in northern Sweden were recruited to the study. In total 105 children, mean age 10.5 years (SD±1.09), were randomized into either an intervention or a control group. The intervention group was offered as a 2-year family-based lifestyle intervention; the 1st year consisted of 14 group sessions and during the 2nd year the intervention was web-based. The control group did not participate in any intervention sessions, but performed all measurements. Physical activity was measured in all children using SenseWear Pro₂ Armband (SWA) during 4 consecutive days before, in the middle and after the intervention, data regarding anthropometrics and blood values were collected in the same periods. Twenty-two of the children wore SWA during 14 days before the intervention in order to validate energy expenditure (EE) estimated by SWA against EE measured with double labelled water.

Results The SWA, together with software version 5.1, proved to be a valid device to accurately estimate EE at group level of overweight and obese children. There were no statistically significant differences between the groups neither before nor after the intervention regarding physical activity and screen-time. All children significantly decreased their time being active ≥3 METs during the study period. After the study period, significantly fewer in the control group achieved the national physical activity recommendation, and they had significantly increased their screen-time. However, these changes were not seen within the intervention group. The intervention group had a significantly lower apolipoprotein B/A1 compared to the control group at 1-year measurement; no other significant differences were found regarding metabolic markers. No statistical difference was found between the groups regarding body mass index after the 2-year study period.

Conclusion Even though a comprehensive program, the 2-year family-based lifestyle intervention had limited effects on physical activity and metabolic health in overweight and obese children. SWA is a device that can be used in future studies to measure energy expenditure among free-living overweight or obese children.

Abbreviations

BMI	Body mass index
BMI-sds	Body mass index standard deviation score
BMR	Basal metabolic rate
DEXA	Dual-energy x-ray absorptiometry
DLW	Double labelled water
EE	Energy expenditure
HDL	High-density-lipoprotein
HOMA	Homeostasis model assessment index
IOTF	International obesity task force
ITT	Intention-to-treat
LDL	Low-density-lipoprotein
MET	Metabolic equivalents
MetS	Metabolic syndrome
RCT	Randomized controlled trial
SWA	SenseWear Pro ₂ Armband
WHO	World Health Organization

Svensk sammanfattning

Bakgrund De senaste decennierna har förekomsten av övervikt och fetma bland barn och ungdomar markant ökat i Sverige och övriga världen. Under de senaste åren har den ökande förekomsten tenderat att avstanna något i vissa regioner och vissa åldersgrupper i Sverige och andra delar av världen. Trots det är förekomsten av övervikt och fetma bland barn betydligt högre idag jämfört med på 80-talet. Övervikt eller fetma under barnaåren påverkar såväl fysisk som psykosocial hälsa under uppväxtåren och leder till ökad risk för ohälsa och förtidig död i vuxen ålder. Orsakerna bakom den snabba utvecklingen av övervikt och fetma i befolkningen är bara till viss del kända. Många har en ärftlighet för övervikt och fetma men samhällsförändringar såsom förändrade levnadsvanor; fysisk inaktivitet och kostintag, i kombination med sociala och kulturella faktorer har också bidragit till utvecklingen. Det har även under de senaste decennierna rapporterats att barn minskat sin vardagsaktivitet liksom att barn med övervikt eller fetma är mer inaktiva jämfört med normalviktiga jämnåriga barn.

Syfte Det övergripande syftet med studien var att undersöka om en 2-årig livsstilsintervention, med fokus på mat- och aktivitets vanor som involverar familjen, kan hjälpa barn med övervikt eller fetma till en hälsosammare livsstil. Delsyftet var att utvärdera tillförlitligheten hos en aktivitets mätare, SenseWear Pro 2 Armband (SWA), när den används av barn med övervikt eller fetma samt att utvärdera interventionens effekt på fysisk aktivitet och metabola markörer.

Metod Till studien rekryterades 105 barn med övervikt eller fetma i åldern 9-12 år som bodde i Umeå eller någon av kranskommunerna. Barnen lottades till att delta i en interventionsgrupp eller en kontrollgrupp. Alla barn, oavsett grupptillhörighet, deltog i alla mätningar som avsåg energiomsättning, fysisk aktivitetsnivå, skärmtid, kroppssammansättning, blodtryck och blodprover innan studiestart, vid 1 år samt efter 2 års deltagande. Vid första mättillfället bar 22 av barnen SWA under 14 dagar för att dess förmåga att uppskatta energiomsättning skulle kunna jämföras med energiomsättning mätt med dubbelmärkt vatten. Interventionen bestod under första året av 14 gruppträffar med olika teman och hemuppgifter om motivation, beteendeförändring, fysisk aktivitet, kost och självkänsla. Både barn och föräldrar deltog i träffarna. Under andra året fortsatte interventionen med hjälp av en web-plattform genom vilken kontakt hölls

med familjerna samt att 12 hemuppgifter och information förmedlades som stöd för vidare arbete med livsstils förändringar.

Resultat Barnens energiomsättning mättes med SWA som, tillsammans med mjukvaruprogrammet Innerview software 5.1, visade sig ha god tillförlitlighet på gruppnivå. Ingen skillnad kunde påvisas mellan kontroll respektive interventionsgrupp beträffande vare sig tid i fysisk aktivitet eller skärmtid efter 2 års deltagande. I motsats till förväntat resultat så var barnen 40 min respektive 55 min mindre aktiva per dag i kontroll- och interventionsgrupp efter 2 år. Efter 2 år var det signifikant färre barn i kontroll gruppen som uppnådde rekommenderad aktivitetsnivå och de hade signifikant ökat sin skärmtid jämfört med vid studiestart. Dessa förändringar noterades inte bland barnen i interventionsgruppen. Ingen signifikant skillnad kunde påvisas mellan grupperna beträffande BMI efter vare sig 1 eller 2 års deltagande i studien. Deltagarnas BMI hade inte förändrats signifikant vare sig i interventions eller i kontrollgruppen under första året men i respektive grupp hade BMI ökat signifikant med 0.3 kg/m² och 0.6 kg/m² till 2 års mätning. Förekomsten av metabolt syndrom var låg bland barnen i studien, totalt 3 % vid studiens start och 5 % efter 1 år. Efter ett års deltagande i studien hade barnen i interventionsgruppen signifikant lägre apolipoprotein B/apolipoprotein A1 kvot jämfört med kontrollgruppen, det fanns inga andra signifikanta skillnader mellan grupperna beträffande blodprover.

Slutsats Den 2-åriga familjebaserade livsstilsintervention hade begränsad inverkan på fysisk aktivitetsnivå och metabola markörer hos barn med övervikt eller fetma. Barnen i studien hade vid studiestart en oväntat hög aktivitetsnivå och trots att de minskade sin aktivitetsnivå under studiens 2 år var aktivitetsnivån fortfarande högre jämfört med aktivitetsnivån hos barn i andra svenska studier. Framtida interventioner som har som mål att påverka fysisk aktivitet eller inaktivitet bör grundligt undersöka och beakta deltagarnas aktivitetsnivå innan barnen påbörjar interventionen. SWA är en tillförlitlig mätare för att undersöka energiomsättning hos barn med övervikt eller fetma på gruppnivå.

ORIGINAL PAPERS

This thesis is based on the following papers which will be referred to by their roman numerals.

- I Bäcklund C, Sundelin G and Larsson C. Validity of armband measuring energy expenditure in overweight and obese children. *Med Sci Sports Exerc.* 2010; 42(6):1154-1161.

- II Bäcklund C, Sundelin G and Larsson C. Effect of a 1-y lifestyle intervention on physical activity in overweight and obese children. Submitted 2010.

- III Bäcklund C, Sundelin G and Larsson C. Effects on physical activity of a 2-y lifestyle intervention in overweight children. Submitted 2010.

- IV Bäcklund C, Waling M, Lind T and Larsson C. Metabolic health in overweight and obese children – the effect of a family-based lifestyle intervention in a randomized controlled trial. Submitted 2010.

Paper I is reprinted with permission of the publisher: Lippincott Williams & Wilkins.

Introduction

Childhood overweight and obesity

Prevalence of overweight and obesity

Childhood obesity has increased throughout the world over the last decades (1, 2). In Sweden the prevalence of overweight and obesity was doubled among 10 year old children between 1987 and 2001 (3, 4). Recent studies from several countries around the world indicate that the obesity epidemic have reached a plateau in children and adolescents (5-7). Studies from Sweden also report that the increase of overweight and obesity may have begun to level off among both 4 and 10 year old children (8-11) and are possibly reversing among 10 year old girls (12).

In the Swedish city Umeå the prevalences of overweight and obesity among 10 year old children in 2006 were 18% and 2.7%, respectively (10), which were still higher compared to the prevalences before the rapid increase of overweight and obesity began (4).

Causes of overweight and obesity in children

Body weight is regulated by several physiological mechanisms that maintain balance between energy intake and energy expenditure. There are several factors (genetical, biological, behavioural, environmental and social) that may influence energy balance and therefore can be identified as contributors to childhood overweight and obesity (13-15). The genetic factors may have an important role for individual predisposition, but they interact with environmental factors in the development of childhood overweight and obesity (14, 15). Low levels of physical activity, sedentary behaviour, sleep, dietary intake and socioeconomic status are components that are reported to play an important role in the development of overweight and obesity in children (14).

Consequences of overweight and obesity in children

Overweight and obesity in childhood are associated with physical, psychological and social consequences (13, 14). Childhood obesity can affect almost every organ systems, e.g. pulmonary, endocrine, gastrointestinal, central nervous system, cardiovascular, musculoskeletal and renal system (14, 16). Further, childhood obesity predicts future mortality and disease such as, e.g. type 2 diabetes and cardiovascular diseases (17-20). Regarding psychological and psychosocial consequences, depression, poor quality of life and poor self-esteem have been reported to be associated with childhood overweight and obesity (21, 22). Moreover, children with overweight and

obesity are more often subjected to teasing and bullying than other children (23).

A recent review showed that the risk of overweight children to remain overweight in adulthood was reported to be at least twice that for normal weight children, and the risk was even greater among those who were obese during childhood (19). Thus, overweight and obesity are shown to track from childhood to adulthood, and thereby influencing not only the current health status but also long-term health (19, 24).

Definition of overweight and obesity in children

Overweight and obesity refer to conditions of excess body weight, relative to stature, and specifically excess adipose tissue (13). There is no universally adopted classification system for childhood overweight or obesity. The most implemented classification of childhood overweight and obesity, adopted by the International Obesity Task Force (IOTF) was developed by Cole et al. (25). That classification has gender and age-specific cut-off points for children and adolescents between the ages of 2 and 18 years, enabling Body Mass Index (BMI) in childhood to be related to BMI in adulthood. BMI is calculated as body weight in kilograms divided by height in meters squared.

BMI can also be expressed as a standardized age- and gender-dependent standard deviation score (BMI-sds), also called the z-score (14, 26). Other commonly used thresholds for being overweight or obese in childhood are 110% or 120% of ideal weight for height, and BMI at the 85th, 90th, 95th and 97th percentile (on the basis of international or country-specific reference populations) (14).

Physical activity

Definition of physical activity and sedentary behaviour

Physical activity is defined as “any bodily movement produced by skeletal muscles that result in energy expenditure” (27). Physical activity is not synonymous to physical exercise, which is defined as “physical activity that is planned, structured and repetitive bodily movements done to improve or maintain on one or more components of physical fitness” (27). Further, it is important to differentiate between the term physical activity and energy expenditure; physical activity refers to body movement while energy expenditure results from body movement (28). There are several domains in which physical activity can occur in childhood, including leisure-time, school, after-school activities, housework and active commuting.

Sedentary behaviour refers to a number of activities that have energy expenditure levels that do not increase energy expenditure substantially above resting level, i.e. 1.0-1.5 metabolic equivalents (METs) (29). Screen time (time with computer, TV, DVD, electronic games) is a commonly used indicator of sedentary behaviour.

Recommendations regarding physical activity in childhood

The most commonly used physical activity recommendation for children is: that “children should participate every day in 60 minutes or more of moderate to vigorous physical activity that is enjoyable and developmental appropriate” (30). This recommendation is however debated and a higher physical activity level, ≥ 90 min/d, is suggested in order to prevent clustering of cardiovascular disease risk factors (31). Tudor-Locke and colleagues have suggested cut-offs for recommended daily-steps; for girls the cut-off to prevent overweight is 12.000 steps/d and for boys the cut-off is 15.000 steps/d (32). The recommendation regarding screen-time is to limit the screen-time to a maximum of 2h/d (33, 34).

Current physical activity level among children

Studies from the US, Canada and several countries in Europe, using accelerometers to measure physical activity level, are all showing that a great majority (90-100%) of 9-11 years old children achieve the activity recommendation to be physically active ≥ 60 min/d in at least moderate intensity (35, 36). A similar physical activity level is reported from Sweden among 8-11-year-old children, where nearly all (99-100%) fulfilled the national recommendation for physical activity ≥ 60 min/d when measured with accelerometers (37, 38). Another study reported that only 33% of Swedish adolescents (10-16 years) reached the recommended activity level, but in that study the physical activity was self-reported (39).

When looking at the recommendation about daily steps, Wickel and colleagues report that only 16% of the boys and 18% of the girls in a sample of 6-12 year old children from the US, Sweden and Australia achieved the proposed recommendation on a daily basis (40). However, a study among 7-9 year old Swedish children showed that 67% of the boys and 75% of the girls achieved the recommended amount of daily steps (41).

Studies have shown that boys are more active than girls regardless of age, geographical location and ethnicity, and that the difference tends to be greater for physical activity at vigorous intensity (35, 36). Physical activity level is shown to decrease with increasing age; the decline may begin already

at the age of 6 years old (42, 43). Further, there are studies showing that children with overweight or obesity are less active compared to normal-weight children (36, 44).

Health effects of physical activity in childhood

Physical activity provides important health benefits for children and adolescents. The documented health effects include increased cardio-respiratory fitness and muscle strength, favourable cardiovascular and metabolic disease risk profiles, reduced adiposity and enhanced bone health (30, 45). Further, physical activity is associated with positive effect on several mental health outcomes such as self-concept, self-esteem, anxiety, depression and academic performance (30, 45). In addition low physical activity may be associated with overweight and obesity (34) and has also been shown to independently predict obesity in adulthood (46). Thus, similarly to overweight and obesity, physical activity tracks from childhood to adolescence (47) and from adolescence to adulthood (48), and influences not only the current health status but also long-term health.

Physical activity assessment in children

It is important to use accurate assessment of physical activity to enable further examination regarding the relationship with health. When assessing physical activity there are several dimensions that need to be regarded e.g. intensity, frequency and duration (28). Other dimensions that may be important are type of activity and setting in which the physical activity take place. Further, assessing physical activity in children and adolescents may be a challenge due to cognitive, physiological and biomechanical changes that occur during natural growth and development (49). Children also have a more intermittent physical activity pattern compared to adults (49). This has implications for all aspects of assessing physical activity in youth, for example frequency of data sampling, which epoch length to use and where to place the activity monitors (28, 49).

A wide range of methods for measuring physical activity of children are being used. These can be divided into subjective methods (questionnaires, activity logs, diaries and interviews) and objective methods (doubly labelled water, accelerometers, pedometers, heart rate monitors, combined sensors and direct observation) (28, 50) each with different strengths and limitations (28, 49, 50).

Self-reporting measures are seen as being easy to administer and low in cost. Further, they have the ability to capture both the type of physical activity and the context in which it is performed (28). However, self-reporting methods have limitations, especially among children under the age of 10 who have

difficulties recalling activities accurately, and also may have difficulties differentiating between sedentary behaviour and more intense activities (28).

The most valid method for measuring energy expenditure in free-living subjects is the doubly labelled water (DLW) method, which measures carbon dioxide production during a one to two-week period (51). This method is regarded as the gold standard and the most suitable criterion method. Validation studies have shown that the precision of the DLW method in measuring energy expenditure is 2-8%, depending on the isotope dose and the duration of the elimination period (51). However, because of its excessive cost, the DLW method is usually not possible to use within large populations (52). Consequently, less expensive objective methods like accelerometers, pedometers and heart rate monitors need to be used (28).

In addition to being cheaper, methods such as accelerometers, pedometers and heart rate monitors also give information about several of the dimensions of physical activity e.g. duration, frequency and intensity. However, accelerometers and pedometers have limited capability to accurately estimate activities in the horizontal plane (such as skating and cycling) which are common activities for many children, and they can not be worn in water (28, 49). Heart rate monitoring has been shown to be a valid and reliable method (49), but it also has limitations since heart rate monitors respond to a person's emotions (such as anxiety) and increased body temperature, which may lead to an overestimation of energy expenditure. Heart rate monitors also tend to lag momentarily behind changes in movement and remain elevated after the termination of the movement (28). This is a limitation that may be of significance in measuring children's activities, since an intermittent activity pattern is common among children.

During recent years, activity monitors that combine different variables such as accelerometry and physiological parameters have been developed to increase the accuracy in assessing physical activity (49, 53). One of these is the SenseWear Armband (SWA) (BodyMedia, Inc., Pittsburgh, PA, USA), which combines different sensors that detect movements and body heat production in one device that is attached around the upper arm. SWA provides estimates of energy expenditure, intensity (MET level), frequency, and duration of physical activity. Unfortunately, SWA can not be used in water.

Interventions for treating overweight and obesity in children

Overweight and obesity during childhood are major health problems that influence not only the current health status but also long-term health which emphasizes the importance of intervention in early childhood. Various strategies in different settings, e.g. community, health-care, school, and family, are suggested for prevention of childhood overweight (21, 54, 55). However, when interventions for treating childhood overweight and obesity are developed the primary setting seem to be the family with support from the health-care (21, 56, 57). Parental involvement is reported to be a key to the success of interventions aimed at children, as parents have primary control over their children's food and activity environments, but may also play an important role in interventions aimed at adolescents (58-60).

Structured lifestyle interventions addressing nutrition, physical activity and behavioural skills appear to be most efficacious in reducing weight and cardiovascular risk factors in children and adolescents (15, 34, 57, 59). Studies have reported a 0.8-2.3 BMI units difference between the treatment group and the control group after participation in family-based lifestyle intervention including obese children and adolescents (61, 62). Furthermore, a recent Cochrane review concluded that “family-based, lifestyle interventions with behavioural programs aiming at changing physical activity and dietary thinking patterns appear to provide a significant and clinically meaningful decrease in overweight among children” (56). There are studies that indicate that gender may affect the response to the intervention, reporting that boys both adhere better to treatment and have a greater treatment effect than girls (63, 64).

Rationale for this thesis

Overweight and obesity have rapidly increased in prevalence during the last decades (1), and even if there are reports of a stabilization of the increase (8, 10), the prevalence of childhood overweight is much higher than before the obesity epidemic begun (3). There are many factors that may influence energy balance and therefore can be identified as contributors to childhood overweight and obesity (14). Among these, behavioural factors such as physical activity and dietary intake are considered as significant contributors to the occurrence of childhood obesity (14). Even though physical activity is only one of the factors contributing to childhood obesity, it is one that may be modified through interventions.

Promoting physical activity in children is important because of the physiological consequences and psychosocial health benefits. Furthermore, promoting physical activity in overweight and obese children may be particularly important since these children are shown to be less physically active than normal weight children (36, 44). Physical activity level, as well as overweight, is shown to track from childhood to adulthood, thereby influencing not only the current health but also long-term health (46-48). Consequently, prevention and treatment of overweight and obesity ought to start early in life.

In order to further understand the relation between health and physical activity it is of great importance to have valid methods for measuring physical activity in children. Further, it is crucial to use measurement methods validated in children when evaluating the efficacy of physical activity interventions aimed for children. Today, there are relatively limited data evaluating which intervention is most effective in child obesity treatment. However, recent studies report that lifestyle interventions combining physical activity, dietary and other behavioural factors appear to be the most effective (56). There are also reports indicating that evidence-based multidisciplinary treatment can increase daily physical activity among overweight and obese children (65, 66). However, few studies have investigated the effect that child and adolescent overweight and obesity treatment have on physical activity.

AIMS

The general aim of the study was to evaluate if a 2-year family-based lifestyle intervention could decrease existing and/or prevent further development of overweight and obesity among 8-12 year old children with overweight or obesity.

The specific aims of this thesis were to evaluate:

- if SenseWear Pro2 Armband is a valid device for estimating energy expenditure among overweight and obese children (Paper I).
- the effect of a family-based lifestyle intervention after one year on physical activity level in overweight and obese children (Paper II).
- the effect of a family-based lifestyle intervention after two years on physical activity level in overweight and obese children (Paper III).
- the effect of a family-based lifestyle intervention after one year on metabolic markers in overweight and obese children (Paper IV).

Methods

This thesis consists of four pieces of work; I) Validation of a device for measuring physical activity, and II-IV) Evaluation of the effect of a family-based lifestyle intervention program for children with overweight or obesity. The intervention consisted of a 2-year program of lifestyle modification with focus on healthy physical activity and diet. The focus in this thesis is on physical activity; the dietary aspects of the intervention will be reported elsewhere.

Study design

The basis for this thesis are a validation of a device for measurement of physical activity and a randomized controlled trial with one intervention group and one control group (Figure 1). Participants assigned to the intervention group were offered a 2-year family-based program including regular group sessions and web-based support focusing on daily physical activity and healthy dietary habits. The control group participated in the same measurements as the intervention group but received no further intervention.

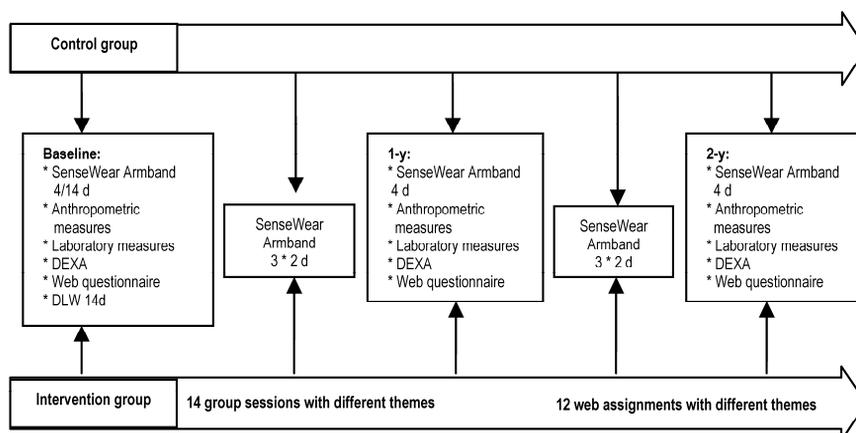


Figure 1. Study design of the physical activity related intervention during 2 year.

Participants

Children were recruited at four occasions during a 10 month period from August 2006 to May 2007 in and around Umeå municipality - a coastal

university town in northern Sweden with about 110.000 inhabitants. Several recruitment actions were performed; 1) school health nurses in the city of Umeå distributed information about the study to overweight children, 2) information about the study was given to families with children being overweight participating in an ongoing cohort study in Umeå, 3) all families with children born in the appropriate years were informed about the study through a postal letter, and 4) information about the study was published in two articles in the local daily papers.

To obtain a study power of 80% with $\alpha=0.05$ and to detect a 1.6 kg/m² difference between intervention and control children in primary outcome variable BMI, 42 subjects per group needed to be included. However, to allow for a drop-out rate we aimed to recruit 120 children with overweight or obesity (60 per group).

Criteria for participation included at first an age- and gender-adjusted BMI $\geq 25 < 30$ (25), being born 1995-1997, and living in or in the surroundings of Umeå. Since there were difficulties to recruit enough participants to the study; the inclusion criteria were enlarged to comprise BMI ≥ 25 and being born 1995-1998. Participants were excluded if they had any chronic disease that could influence the metabolic parameters, were diagnosed with an attention deficit disorder, or if they did not have access to the Internet.

In total, all 6.290 families in the study area received written information about the study and of those 112 families showed interest in participating. The families reported their interest to two investigators and were then contacted by phone to receive further information about the study and were interviewed to ascertain eligibility. Seven children did not meet the inclusion criteria or met the exclusion criteria and were therefore excluded. The children were consecutively randomised stratified by gender into either the intervention or the control group. The aim was to obtain groups of 10-15 children in four intervention and four control groups, starting at four different occasions. During the recruitment period but before the start of the study some drop-outs occurred especially from the intervention group. To compensate for this, 21 children were randomized to the intervention group and only five to the control group at the recruitment in May 2007. The randomization was made by three of the investigators and in the end 105 children were randomised to the intervention group (n=58, girls 47%) and the control group (n=47, girls 57%) (Figure 2).

Of the 105 participants, 22 children from both the intervention and control group (50% girls) were randomized to participate in a sub-study validating a device for measuring physical activity.

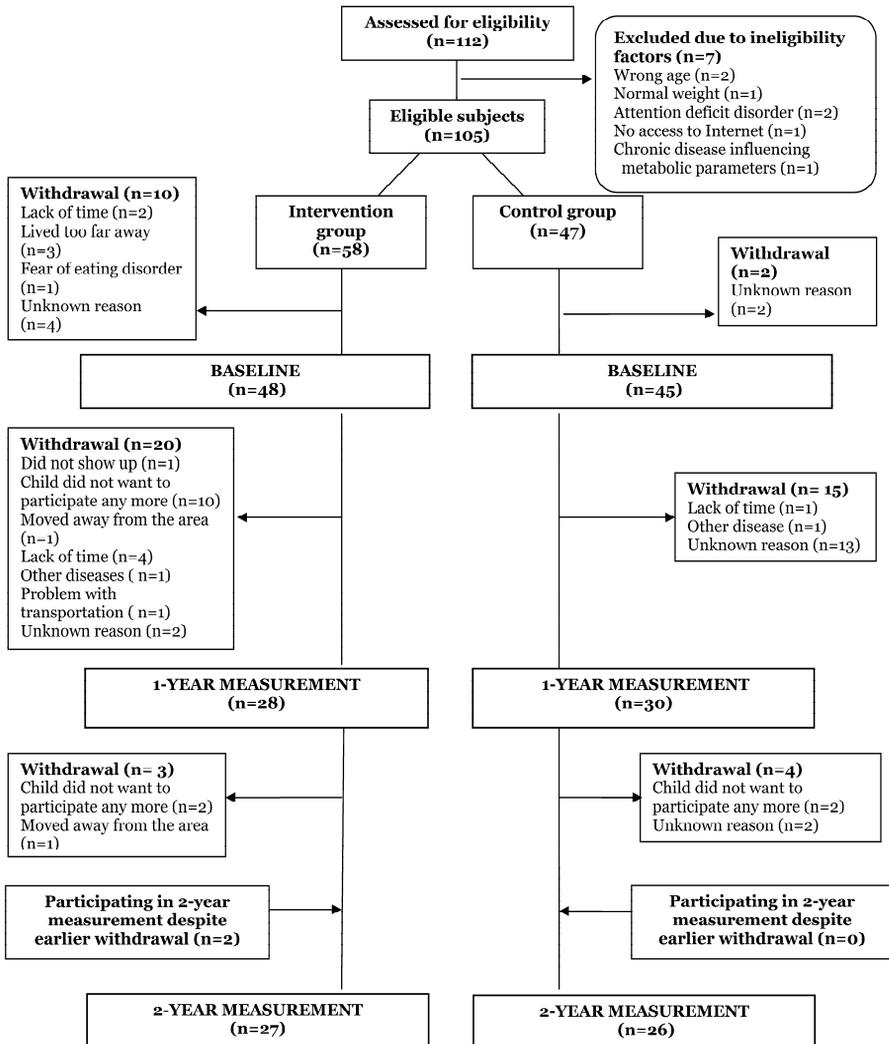


Figure 2. Flowchart of subject participating in an intervention study during 2 year.

Actions to maintain participants

In order to maintain the families and to motivate the children and their parents, and to continue participation throughout the whole study several actions were made. For example, a healthy breakfast was offered after each time fasting blood samples had been provided at baseline, at 1- and at 2-year. At the same visit the children received a small inexpensive gift, for example,

a complimentary ticket to a swim club, a book or a CD, and the parents received a complimentary ticket to a local fitness club.

Other actions made were raffles, during both intervention years connected to the 2-d measurements. Gift vouchers to the cinema were raffled twice each year among children with completed dietary measurements, and poles for Nordic walking were raffled among the parents after the children's 3rd physical activity measurement. Furthermore, among the children that had provided complete data on all 2-d dietary measurements, a digital camera was raffled at the end of the study.

Actions were also made in connection to the information meeting and group sessions. A healthy snack was served to participants in both groups attending the information meetings in the beginning of the study, and to the participants in the intervention group attending the last group session. Furthermore, at group session 8 juggle balls were raffled in the intervention group among the children that had done their home assignment. After the last group session before the intervention became solely web-based during the second year, the children in the intervention groups were invited to a family activity - a play at the laser hall aimed to support teambuilding.

Procedure

The participants were informed about the group they belonged to by a letter, and they were also invited to a meeting to receive further information about the procedure of the study, the different assessments (intervention groups and control groups separately), and the intervention program (intervention groups only). The information meeting occurred 2 weeks before the baseline assessments. The control group only received the single information meeting, while the intervention group was scheduled to participate in 14 group sessions during the first year and to receive home assignments and web-based support during the second year. All children, regardless of group belonging, provided data about anthropometrics, laboratory measures, dietary intake and physical activity. The parents of each participating child also provided anthropometric and laboratory measures.

The assessments comprising anthropometric measures and laboratory measurements were conducted at the Department of Paediatric Research, University Hospital of Umeå. The nurses performing the assessments were not informed about the group allocation of the child, however, it cannot be assured that they were blinded to the study

All participants leaving the study during the study period received a postal questionnaire including questions about their current weight, length, physical activity level, diet and the reason for them to leave the study. The aim with the questionnaire was to perform drop-out analyses. Participants that had dropt out during the two years of the study, were sent a letter at the time for the 2-year measurement asking them to participate in the last measurement at 2-year even though they had dropt-out earlier.

Data collection

Baseline data were collected for one intervention and one control group in October 2006 and in January, March and May 2007, respectively. For each child the 1- and 2-year data were collected during the same months as the baseline data but respectively 1 and 2 years later.

Physical activity

Physical activity was measured using SWA (BodyMedia, Inc., Pittsburgh, PA, USA) (Figure. 3). The SWA is a multiple-sensor device that is attached around the right upper arm and collects data from a skin temperature sensor, heat-flux sensor, near-body temperature sensor, galvanic skin response sensor and a biaxial accelerometer. Data registered by the SWA together with information about age, gender and handedness as well as measured weight and height are converted into energy expenditure using the computer software InnerView Professional (BodyMedia, Inc., Pittsburgh, PA, USA), which uses proprietary activity-specific algorithms. SWA also provides estimates of intensity (MET-level), frequency and duration of physical activity as well as step count. The children were instructed to wear the SWA during the whole measuring period and to remove the device only when showering/bathing or participating in other water activities. In this thesis, the physical activity data used from SWA are estimates of energy expenditure, steps count and time in physical activity at different intensities described as METs. The thresholds of 3.0, 6.0 and 9.0 METs were selected as they estimate a walking pace of 4 km/h, ans running paces of 7 and 10 km/h, respectively (67) and have been used by others when defining physical activity intensity in children (68, 69).

To enable validation of SWA regarding ability to measure energy expenditure, 22 children were instructed to wear the SWA during 14 consecutive days, the same period as covered by DLW (paper I). The epoch length was set to 1 minute to enable storage of several days of continuous data. The measuring period was 14 days, but since the memory capacity of the SWA was shorter, the children were instructed to change to a new SWA

on day seven. Due to practical reasons and the high demand of the other measurements and activities while participating in the study (Figure 1), it was unreasonable to ask the children to visit the university in order to download data from the first seven days and then use the same armband for the rest of the period. Therefore, a second SWA with empty memory was supplied to the child to be used during the last seven days of the measurement period. When validating SWA measurement, days with <19 h of measuring time were excluded before analyses of data. The motives for using the cut-off of ≥ 19 h of wearing time were to capture most of the energy expenditure during a day as well as to enable the inclusion of most of the 14 d of monitoring.



Figure 3. The device, SenseWear Pro₂ Armband, used to assess physical activity of overweight or obese children.

When the collection of data to be used to validate SWA started only InnerView Professional software version 5.1 was available. However, during the data collection period version 6.1 was released. All data used in paper I were therefore analyzed using both software versions. SWA together with software version 5.1 and 6.1 was validated against DLW method. The data regarding energy expenditure was shown to be more valid at group level of free-living overweight or obese children when using software 5.1. Therefore, all SWA data used in paper II and III were analysed using InnerView Professional software version 5.1 only.

In the intervention study the children from both the intervention and the control groups were instructed to wear SWA during 4 consecutive days, including 2 weekend days, each annual time point (Figure 1). In addition, six

shorter, 2-d, measurement periods were distributed throughout the 2-year intervention period covering all days of the week and all seasons of the year. The annual 4-d measurement was performed during the same days of the week and the same week (± 4 weeks) for each child. The epoch length was set to 1 minute to enable storage of several days of continuous data. In the intervention study a minimum SWA monitoring of ten hours per day, during the period 7:00 am to 9:00 pm for at least two days was required for inclusion in data analysis. The ten hours is based on the minimal daily wear time which is often used in youth participating in accelerometer studies (49). To provide information about the children's light activities, screen-time, leisure time activities and participation in organised leisure activities the children filled in a web questionnaire at baseline, and at 1- and 2-year measurement periods. The children, with help of their parents, reported how much time per day or week they had spent in each type of activity during the last four weeks. There were separate questions for week and weekend days. The web questionnaire has not been validated but has been used in a cohort study of 10-y olds from Umeå (70).

Total energy expenditure was measured during 14 consecutive days by the DLW method in order to provide reference data to validate SWA. The participant collected three baseline urine samples before ingesting an oral dose of $0.25 \text{ } ^{18}\text{O}$ and $0.12 \text{ } ^2\text{H}$ per kilogram of estimated body water (51, 71). The children ingested the DLW at the same visit as the baseline assessments were carried out (Figure. 1). Thereafter, single urine samples were collected at 12 and 24 h after dose administration and again on day 8, 13 and 14. Isotope concentrations in the urine were analyzed using isotope ratio mass spectrometry (Aqua Sira, VG, Middlewich, UK) (72). Energy expenditure was calculated using the Schoeller multipoint method (51) and the respiratory quotient was set at 0.85 (73).

Anthropometric and laboratory measurements

Height and weight were measured with the children wearing light clothing and without shoes. Height was measured using a wall stadiometer (Hyssna Measuring Equipment AB, Sweden) to the nearest 0.1 cm and weight was measured using an electronic scale (AJ Medical, Sweden) to the nearest 0.1 kg. BMI was calculated as weight (kg)/height (m) squared, and converted to BMI z-scores by using both US reference data (74) and a Swedish reference dataset (26). Children were classified as normal weight, overweight or obese using the International obesity task force (IOTF) standard definition (25). The parents' weight status was classified using the World Health Organization (WHO) definition (75). Waist circumference measurements were recorded to the nearest 0.1 cm midway between the tenth rib and the iliac crest with children in a standing position using a non-elastic flexible

tape. When defining the 90th percentile for waist circumference, age-specific reference data of 10-y old children collected in a cohort from Umeå was used (70). Hip circumference was measured at the widest point between hip and buttocks. Waist-to-hip ratio was calculated as waist circumference/hip circumference. Sagittal abdominal diameter was measured to the nearest 0.1 cm from bed to the top of the abdomen with the child in a supine position using a ruler. The same two nurses performed all anthropometric measurements.

Body composition was assessed by using dual-energy x-ray absorptiometry (DEXA) (Lunar prodigy whole-body scanner GE Medical Systems, Madison, WI, USA) with the child in a supine position (Figure 4). The same nurse performed all the scans using standard clinical procedures. Body-fat content was expressed in kilograms (fat mass kg) and as percent fat (fat mass %) in soft tissue. Fat content in soft tissue of the trunk was expressed as percent fat (truncal fat %).



Figure 4. Assessment of body composition of a child by dual-energy x-ray absorptiometry.

The systolic and diastolic blood pressure was measured on the right arm, after 5 min rest with the child in a supine position, using an electronic blood pressure device (Welch Allyn Spot Vital Signs, Welch Allyn AB, Sweden). A variety of cuff sizes were used to ensure appropriate fit according to the arm circumference.

Blood samples were drawn after overnight fasting, which was confirmed by the child before collecting the blood. All blood samples were analysed according to standard methods used at the Department of Clinical Chemistry, Umeå University Hospital, Umeå, Sweden. Homeostatic Model

Assessment (HOMA)-index was calculated according to the equation (S-insulin * P-glucose/22.5) (76).

Metabolic syndrome

The children were classified as having metabolic syndrome (MetS) according to the definition of the International diabetes federation (77); the presence of abdominal obesity (waist circumference \geq 90th percentile) in combination with at least two other clinical feature e.g. elevated triglycerides, low high-density-lipoprotein (HDL)-cholesterol, high blood pressure or increased plasma glucose.

Lifestyle intervention program

The family-based lifestyle intervention was based on principles of behavioural (78, 79) and solution-focused group work (80). The structure and the content of the family-based lifestyle intervention program was based on recommendations reported in a State-of art for behavioural treatment of childhood and adolescent obesity (79). These recommendations have been repeated in several later studies regarding treatment of childhood overweight and obesity (34, 56, 60). The intervention program developed for the present intervention was based on group treatment (79, 80) and parental participation (60, 79, 81). Diet, physical activity and behavioural was the main treatment components (34, 56, 79) in the intervention program, and the program focused on promoting a healthy lifestyle and well-being of overweight and obese children rather than on weight reduction. The main objective with the intervention was to prevent further development or decrease the prevalence of overweight and obesity among the children through adapting healthier habits regarding dietary intake and physical activity. Further, the intervention program was developed with the intention that it would be repeatable, e.g. in a clinical setting. Manuals and content developed for the sessions, as well as the sessions, were tested in groups of children 8-12 years old before being used in the study. The tests of the sessions were performed both in mixed groups of normal weight, overweight and obese children, and in clinical setting where groups of children received treatment for obesity.

Intervention year 1;

The first intervention year consisted of 14 group sessions with different themes (Table 1). Each session lasted 1.5 – 2 h and was held once or twice a month, with breaks during school holidays, at the Department of Food and Nutrition, Umeå University. Four of the sessions were related to physical activity, five to different aspects of healthy diet and the other sessions included themes such as motivation, goal-setting and self-esteem. The group

sessions regarding physical activity were planned and led by a physiotherapist (the thesis author). Other group sessions were led by dieticians or a child psychologist. A majority of the group sessions were led by two investigators to enable parallel group sessions with children and parents separated for some of the activities. Sessions were most often designed to suit both children and parents, but for some activities the children and parents were separated to enable discussions from a parental as well as a child perspective. A great deal of time of the sessions was devoted to practical tasks. At the end of each group session the participants were given a home assignment related to the theme at the next group session, some of which to be solved by the children and parents together and others to be solved separately (Figure. 5). The aim of the home assignments was to support the families in making behavioural changes arising from their individual goals and applicable in their home settings. In table 1 the goal of each session and a description of the content are found.



Figure 5. A child participating together with his parents in a group session of a family-based lifestyle intervention program for children with overweight or obesity.

The approach of the physical activity part of the interventions was, as well as the entire intervention, based on behavioural principles and family-based social support (82). The sessions were designed on the basis of the physical activity-key issues in treatment of childhood obesity listed by Nowicka and Flodmark (83). The overall goal with the four physical activity themes; “Why and how should I be physically active?”, “Every step counts”, “Physical activity together is more fun!” and “More physical activity – exercise”, was to increase the children’s physical activity level, and thereby increase their

energy expenditure. The emphasis in the message about physical activity was to set individual goals for the child with regard to their own activity level. However, to make the overall message communicable to the whole group of participants, four general goals were emphasized:

- To be physically active with at least moderate intensity ≥ 60 min per day (30).
- To take ≥ 12.000 (girls) or 15.000 (boys) steps a day (32).
- To limit the screen time to ≤ 2 h/d (34).
- To participate in vigorous activity at least 3 times/w (45)

Each of the group sessions had a theme related to at least one of those goals (Table 1).

Table 1. Goal and description of the group sessions in the family-based intervention program that overweight and obese children were invited to participate in during the first year of the study. Sessions regarding physical activity are marked with grey.

Session	Goal	Description	
1	Introduction	To make the children and parents aware of what it means to participate in the study as well as to inspire them in wanting to participate. Another goal was for them to get to know the supervisors and the other participants better.	General information about the intervention e.g. upcoming themes of sessions, home assignments and web-platform.
2	How to work with goals	To help the children and parents to reflect on what realistic and reachable goals are, and how they can be used when improving lifestyle. Another goal was to help the participants understand the advantages of physical activity and healthy food habits.	Children and parents practice to formulate goals that they perceive and reflect on what makes them realistic and reachable. They also discuss physical and psychological advantages on having a healthy lifestyle.
3	Tasting of healthy breakfast foods and snacks	To make the children eat a healthy breakfast and 1-3 in-between meals every day as well as to choose "key-hole" labelled foods.	Children and parents taste healthy alternatives of common eaten breakfast foods (e.g. bread, yoghurt, cold cuts) and use their senses to describe what they see, smell, feel, taste and hear.
4	Why and how should I be physically active?	To stimulate the children to achieve the physical activity goal, being active ≥ 60 min/d in at least moderate activity and in addition participate in vigorous activity at least 3 times/w.	Information was given and discussion was held about why physical activity is important and how it can be a part of a healthy lifestyle.
5	What are good food habits?	To make the children eat healthy breakfast, lunch, dinner and 1-3 in-between meals as well as to eat according to the "plate model". Another goal was to make the children and parents reflect on how much food is enough to eat during a meal.	Children and parents are introduced to what is meant by healthy food habits. The children are given practical tasks that are related to the theme of the session e.g. to set together what they think are healthy meals with help of food models.
6	Hunger & craving and responsibilities	To make the children aware of the difference in feeling hungry and craving. Another goal was to make children and parents aware of who is responsible in achieving good physical activity and food habits.	Children and parents reflect on hunger and craving based on a "hunger and crave registration" that the child had done before the session. The children and parents also discussed who is responsible for what, by reading questions on cards that they received e.g. "who is responsible for that the child doesn't spend too much time with sedentary activities?" or "who is responsible for planning meals?"
7	Every step counts	To stimulate the children to achieve the gender adjusted step recommendation $\geq 12,000$ steps/d for boys and $\geq 15,000$ steps/d for girls. And to minimize the screen time to ≤ 2 h/d.	Children and parents discuss in separate groups about how to integrate physical activity in the child's everyday life. The children also performed a practical task with pedometer.
8	Tasting of fruits and vegetables (children)	To encourage the children to eat more fruit and vegetables and to reach the daily recommendation of 500 g. To inspire the parents to cook meals that	Children taste different kind of fruits, vegetables and legumes and use their senses to describe what they see, smell, feel, taste and hear. Parents sent recipes on commonly cooked meals to the

Session	Goal	Description
Cooking (parents)	include "key hole" [™] labelled ingredients (where possible) and to serve a meal accordingly to the "plate model".	leaders before the session. The recipes were then slightly modified with the goal to make them healthier but still taste the same. At the session parents then practice cooking these modified healthy meals.
9 Handling stressful situations	To help the children and parents identify stressful and risky situations for living unhealthy and get them to reflect on what strategies they can use to handle these situations.	Children and parents discuss what situations can be identified as stressful and risky for living unhealthy and what can be done to prevent these situations to happen or how to deal with them.
10 Physical activity together is more fun	To encourage children to achieve the physical activity goal, being active ≥60 min/d in at least moderate activity.	Children and parents participate together in indoor- and outdoor games; activity games.
11 Exhibition of sugar rich foods	To make the children and parents aware of what commonly used foods are high in sugar but low in nutrients and what healthier alternatives there are to these foods. Another goal for the parents was to know how to interpret food labels.	An exhibition was presented to children and parents where foods rich in sugar but low in nutrients were presented along with healthier alternatives. A demonstration is made of the maximum amount of energy dense foods (according to the recommendations) that can be consumed by a 10 y old child a week was also done.
12 More physical activity - exercise	To encourage the children to participate in vigorous physical activity ≥ 3 times/w.	Children and parents try line dancing together and discussed what strenuous physical activities are.
13 Self image and self perception	To make the children and parents aware of how inner thoughts affect their wellbeing and to get the children to think positive thoughts about themselves.	Exercises concerning self images and self perception were performed followed by a concrete discussion. Discussion took place and concrete examples of the effect of commercials directed towards children were shown.
14 Ending session	To inspire the children and parents to continue improvement of food and physical activity habits during the second part of the program.	Discussion about how the participants could continue with lifestyle changes in the future and information about communication through a web-platform during the upcoming year.

[™]The "key hole" is a guide, created by the Swedish Food Administration, to help consumers to find food items that contain more dietary fibre or less salt, sugar and saturated fat compared to similar food items.

[™]The "plate model" is a pedagogic tool to show what proportion of different food groups that a healthy meal on a plate ought to consist of.

The session “Why and how should I be physically active” was designed to set the base for the physical activity themes of the intervention, and started with an overview and discussion about the physical and mental functions that are improved when being physical activity and a discussion about the national physical activity recommendation (84). This was followed by a “walking quiz” about healthy physical activity. In the home assignment given prior to the session the children had done a 3-d activity diary and during the session the children and their parents went through this diary to look at what physical activities were included and how much physical activity was accumulated each day. The participants then discussed in small groups, with guidance of the physical activity pyramid (Figure 6), how to include physical activity in everyday life to achieve the physical activity recommendation during both school- and weekend days, and shared good examples with each other.



Figure 6. The physical activity pyramid used at the sessions “ Why and how should I be physically active” and “More physical activity – exercise” to illustrate the importance of participation in everyday physical activity and more seldom sedentary behaviour. (Illustration from “Bra vikt - smarta val för ungdomar som vill få koll på vikten”, Svensk Köttinformation)

The session “*Every step counts*” focused on physical activity in everyday life and started with an overview of the step- and screen time recommendation and discussion of how physical activity can be implemented in the children’s every day life. The rest of the time children and parents participated in separate activities based on the home assignments. Prior to this group session the children had a home assignment to wear a pedometer and registered their daily steps during five days. During the session the children used this information to discuss how many steps they had taken, and how

and why it differed between the days and children. Further, we calculated the distance each child had walked during the measured days and pictured it on a local map (Figure. 7). In the end of the session the children were challenged to wear the pedometer, record and report their daily steps during the days to the next group session, and we marked a city on a map of Sweden that the group would reach if all children in the group achieved the step recommendation each day. At next session we followed-up the challenge and mapped out how far the group had reached. To motivate the children a small inexpensive prize was raffled among those who reported their daily step. The parent's home assignment prior to this session was to focus on their part as role models regarding including physical activity in every day life, and to write down three situations when they were good role models. During the session they discussed the home assignment and how they could support their child to have a more physically active life. Further possibilities and obstacles in relation to physical activity in every day life were discussed, and good examples regarding screen time were shared.



Figure 7. Children in a lifestyle intervention for overweight and obese children participating in the group session "Every step counts"

The session "*Physical activity together is more fun*" was mainly devoted to practical tasks with children and parents participating together in activity games. The activity games were chosen to represent games that could be performed both in- and outdoor with inexpensive equipment such as playing hopscotch, rope skipping and a diversity of ball games (Figure. 8). Prior to this group session the parents had as a home assignment that they together with their child should try out at least one new physical activity that could be performed in their neighbourhood. In the end of the session the families shared experiences from that assignment and discussed activities that involve physical activity (excluding participating in sport). The children's home assignment was to describe their favourite game and write down the

rules of that game. At the group session each child got a booklet where all the children's favourite games were summarized.



Figure 8. Children and parents participating in the group session “Physical activity together is more fun” included in a lifestyle intervention for overweight and obese children.

In the session “*More physical activity – exercise*”, the majority of the time was devoted to a practical task; children and parents tried out line dancing under the guidance of a professional line dance instructor (Figure. 9). The activity was chosen to represent an exercise that was not connected to sport activities and could also be performed by parents and children together. The home assignments of the children prior to this group session were to fill in a 3-d physical activity diary and the parent's assignment was to try out a new type of physical activity (this time choosing an activity with vigorous intensity) together with their children. The follow-up of the home assignments began with a discussion about physical activity at different intensities with help from the physical activity pyramid (Figure 6), followed by sharing experiences from the home assignment to try new physical activities. Further, the children and their parents went through the physical activity diaries to look at which and how much physical activities at vigorous intensity the child had conducted.



Figure 9. Families in a lifestyle intervention for overweight and obese children participating in the group session “More physical activity – exercise”

As a complement to the group sessions a website was designed, using the web-platform PingPong (PINGPONG AB, Sweden). Each of the four intervention groups had their own locked web site and the intervention site was only accessible to the participants and two of the investigators, one physical therapist and one dietician. The children and their parents had separate passwords to enable pages accessible for children respectively parents only. The web site consisted of an e-mail system for counselling and pages regarding topicalities from the study, supporting material, discussion forums for the children, discussion forums for the parents, and materials regarding home works from the first year.

Intervention year 2;

During the second year the intervention was internet based using the above mentioned web-platform, which was enlarged with a chat-room and a weekly letter with supporting material regarding both physical activity (e.g. concrete advice) and nutrition (e.g. recipes). The second intervention year comprised 12 home assignments with different themes given to parents and children, some to be solved together, others to be solved by parents and children separately (Table 2). Each home assignment was estimated to take about 2 h in total to solve, and they were posted on the web site once a month with breaks during the school holidays. The themes of the assignments were related to, and further developments of, the themes of the session during the first year. Four of the home assignments were related to physical activity;

- How do you do in order to be physically active?
- Every day physical activities.
- Physical activity together is more fun.

- My physical activities 2013 – a prophecy.

A typical assignment for the children could be to try a new activity during the school recess, write a short notice about the activity and post it on the web site, read your intervention friend's notices about the activities they had tried and also try at least one of those. Most of the assignments were accompanied with supporting material related to the theme such as a quiz or a crossword. The second year also contained a weekly scheduled opportunity to chat with the two investigators.

Table 2. Goal and description of home assignments given to overweight and obese children during the second year of the family-based lifestyle intervention. Four of the assignments were related to physical activity and are marked with grey.

Assignment	Goal	Description
1 Changes so far, changes to be	To make children and parents feel they are able to make lifestyle changes and to inspire them to continue making changes.	The children and parents discussed and reflected from 1 st year of the study; what had they learned, what changes had been made and what are the goals for the second year.
2 Healthy in-between meals	To make the children eat 1-3 in-between meals, choose "key hole" labelled foods and to reach the daily recommended 500g of fruits and vegetables.	The children tried out and commented on a new recipe of a healthy in-between meal. The parents made sure that ingredients to the new healthy in-between meal were available at home.
3 What are you doing to be physically active at playtime? (children) Physical activity during school time (parents)	To make the children achieve the physical activity goal, being active ≥ 60 min/d in at least moderate activity and in addition participate in vigorous activity at least 3 times/w.	The children shared and discussed their favourite activities and tried out activities recommended by other participants. The parents discussed how they could support their children to be physical active during school breaks, and shared good examples of playgrounds promoting physical activity.
4 Meal planning	To make the children and parents choose "key hole" labelled foods and eat according to the "plate model".	The children and parents planned a week ahead what they were going to eat and went shopping together. When they planned food for the week they were advised to use, "key hole" labelled foods and keep the "plate model" in mind.
5 Food advertisement	To make the children aware of how the food industry works to get people to buy and eat their products.	The children discussed how advertisement influences us. Children examined their favourite websites and magazines looking for advertisements regarding food and snacks.
6 Every day physical activities	To make the children achieve the gender adjusted step recommendation and to decrease the screen time to ≤ 2 h/d.	The children chose one of their everyday activities and tried to increase the weekly amount of that physical activity.
7 Five a day (children) Five a day (parents)	To achieve the recommended daily fruit and vegetable intake of 500g.	The children shared on the web-platform their best tip on how to fill the fruit and vegetable part of the "plate model". Parents made sure that fruit and vegetables were provided for the children at home as well as shared on the web-platform their best tip on how to get the children to eat more fruit and vegetables.
8 Physical activity together is more fun	To make the children achieve the physical activity goal, being active ≥ 60 min/d in at least moderate activity and to participate in vigorous physical activity ≥ 3 times/w.	The children shared examples of free physical activities that they do in their neighbourhood and tried out and commented on one of the others concrete suggestions.

Assignment	Goal	Description
9 Handling stressful situations	To make the children aware of stressful situations that could lead into eating unplanned unhealthy foods or skip planned physical activity.	Children and parents chose one stressful situation in their everyday life and used the tools from year 1 to improve the situation.
10 Unhealthy snacking	To make the children limit snack intake that is high in energy and low in nutrients to a maximum of 10 % of their total energy intake.	Children registered and reflected on when, why and with whom they eat food or snacks that are energy rich and low in nutrition. After that they reflected on if there is anything they could improve and if there is any advised they can use to make the change.
11 My physical activities 2013 – a prophecy (children)	To have a healthy physical activity level now and in the future.	Children discussed about physical activity level today and tomorrow, which strategies are useful to be able to achieve the physical activity level.
My physical activities 1975 (parents)		Parents discussed about physical activity level today and yesterday, how can and why does it change through life?
12 A healthy lifestyle	For the children to feel that it is possible to make lifestyle changes and give them self confidence in maintaining achieved changes and in making future lifestyle changes.	Children shared 3 of their healthy lifestyle habits changes and reported how they celebrated achieved goals.

*The "key hole" is a guide, created by the Swedish Food Administration, to help consumers to find food items that contain more dietary fibre or less salt, sugar and saturated fat compared to similar food items.

**The "plate model" is a pedagogic tool to show what proportion of different food groups that a healthy meal on a plate ought to consist of.

Statistics

All statistical analyses were performed using SPSS version 15.0 or 17.0 (SPSS INC, Chicago, IL, USA). All data were checked for normality before being statistically analysed. A p-value <0.05 was considered significant in all analyses. All analyses were done both per protocol and with an Intention-to-treat (ITT) approach; if data were missing last observation was carried forward. Since, there was no difference in results regardless of approach all data reported in this thesis are analyzed with the ITT approach. All analyses were done with both parametric and non-parametric test methods. Since, there was no difference in results regardless of method data reported in this thesis are from parametric test methods. The statistical methods that have been used in this thesis are presented in Table 3.

Table 3. Statistical methods used in paper I-IV.

	Paper I	Paper II	Paper III	Paper IV
Descriptive statistics	X	X	X	X
Independent t-test	X	X	X	X
Paired t-test	X	X	X	X
Bland Altman method	X			
Pearson's product moment correlation	X			
Wilcoxon signed rank test	X			
Chi Square test		X	X	X
One-way analysis of covariance		X	X	X

Ethical approval

A parent of each child signed an informed consent for study participation and verbal consent was ascertained from each child through their parents.

Some of the children also approved that photographs of them taken during the study could be used in future presentations. This was an optional approval that did not affect their participation in the study. Photographs in this thesis include only participants that have given written consent to the use of photographs.

The study was approved by the Regional Research Ethics Review Board at Umeå University (ref nr. 05-088M). The study is registered in Clinical Trials (reg. nr: NCT01012206).

Results

Validation of SWA

All recruited 22 children completed the data collection to enable validation of SWA. In total, information on physical activity at group level, estimated by SWA, was collected during 265 d (86%) of the planned 308 d. Forty-three days had to be excluded because of less than 19 h wearing time for SWA and children not wearing SWA during the planned measurement period of 14 days. The mean (standard deviation) of the number of days monitored was 12 (2.4) d per child and the mean wearing time of the SWA was 23.3 (0.98) h/d.

The mean difference between energy expenditure estimated by SWA 5.1 and 6.1, respectively, compared with the DLW method is illustrated in Bland Altman plots (Figure. 10). At group level, there was no statistically significant difference in energy expenditure estimated by SWA 5.1 compared with that measured with DLW method, 10 786 (166) kJ/d versus 10 803 (163) kJ/d, $p=0.946$. However, the energy expenditure estimated by SWA 6.1, 8 841 (169) kJ/d, was significantly lower compared with the one measured with DLW method ($p<0.001$).

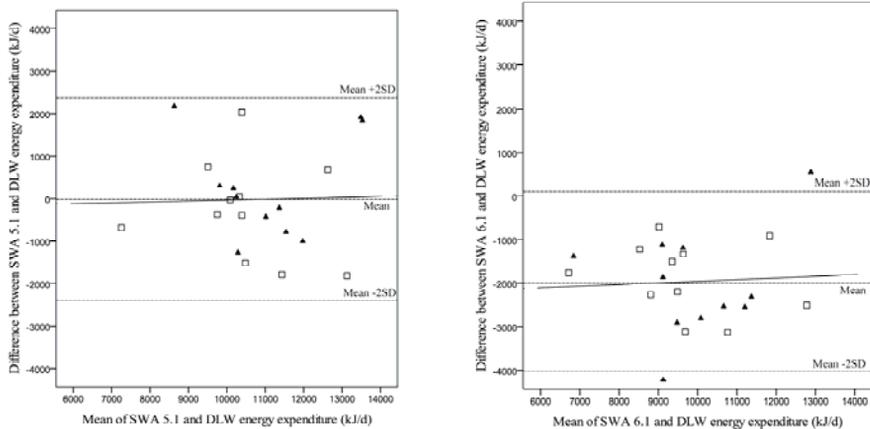


Figure 10. Difference between energy expenditure estimated by the SenseWear Pro2 Armband, software versions 5.1 (SWA 5.1) and 6.1 (SWA 6.1), respectively, and energy expenditure measured using the doubly labelled water (DLW) method plotted against the mean of the two variables, for 22 overweight and obese children, 11 boys (\blacktriangle) and 11 girls (\square). Correlation coefficient for SWA5.1 was 0.03 ($p=0.90$) and the linear regression equation $y = -268 + 0.23x$. Correlation coefficient for SWA 6.1 was 0.06 ($p=0.80$) and the linear regression equation $y = -2338 + 0.038x$. (paper I).

Intervention study

Participants flow and drop outs

A total of 93 subjects, 48 children (44% girls) in the intervention group and 45 children (58% girls) in the control group participated in the baseline measurements. Of those, 90 participants fulfilled the baseline measurement regarding physical activity consisting of 46 children (41% girls) in the intervention group and 44 children (57% girls) in the control group. There were nearly no differences in baseline characteristics between the intervention group and the control group regarding physical activity variables, anthropometric measures or metabolic markers (Tables 4 and 6). The only difference was found in fat mass, where the intervention group had a higher fat mass ($p=0.044$) than the control group, 39.2 (6.17) versus 37.0 (4.33) % (Table 4).

During the year between baseline and 1-year measurements, 42% of the children in the intervention group and 33% of the children in the control group dropt out. The number of children that dropt out during the 1st year did not significantly differ between the groups, $p=0.407$. Fifty five children participated in the 1-year physical activity measurement of which 46 had 1-year physical activity data fulfilling the inclusion criteria. In addition 24 participants had a 2-d measurement that could be used as a proxy for the 1-year measurement according to ITT principles. In total 70 children, 35 children in each group, were included in the 1-year analysis regarding physical activity variables (paper II). Further, 58 participants completed the 1-year measurements regarding metabolic markers and 35 participants were included in the analyses according to ITT-principles; in total 93 participants were included in the 1-year analyses regarding metabolic health (paper IV).

At the 2-year measurement, 21 participants in the intervention group and 19 participants in the control group had 2-year data regarding physical activity. Further 31 participants were included in the analyses of the 2-year data regarding physical activity according to ITT-principles; in total 71 children, 36 children (42% girls) in the intervention group and 35 children (54 % girls) in the control group were included in the analyses. There was no difference in gender distribution between the intervention group and the control group, $p=0.287$ of the children included in the analyses (paper III).

Table 4. Baseline characteristics; anthropometric measures and fasting blood values, of overweight or obese children. Presented as mean (standard deviation).

	Intervention group n=48	Control group n=45 or 44 ¹	p ²
Weight (kg)	52.1 (9.95)	50.4 (9.99)	0.402
Height (cm)	149 (7.86)	149 (8.64)	0.951
BMI (kg/m ²)	23.4 (2.79)	22.6 (2.39)	0.148
BMI z-score ³	2.03 (0.88)	1.77 (0.71)	0.130
BMI z-score ⁴	3.23 (1.34)	2.75 (1.04)	0.057
Waist circumference (cm)	78.0 (10.1)	74.7 (8.80)	0.094
Hip circumference (cm)	89.4 (7.53)	87.1 (7.57)	0.145
Waist/hip ratio	0.87 (0.07)	0.86 (0.07)	0.352
Sagittal abdominal diameter (cm)	17.6 (2.53)	17.0 (1.82)	0.153
Fat mass (kg)	19.8 (6.19)	17.9 (4.97)	0.121
Fat mass (%)	39.2 (6.17)	37.0 (4.33)	0.044
Trunkal fat mass (%)	38.4 (7.46)	36.2 (5.42)	0.115
Diastolic blood pressure (mm Hg)	66.6 (5.60)	66.7 (6.14)	0.959
Systolic blood pressure (mm Hg)	112 (8.92)	113 (8.80)	0.739
Total cholesterol (mmol/L)	4.44 (0.91)	4.51 (0.82)	0.711
LDL-cholesterol (mmol/L)	2.58 (0.78)	2.71 (0.74)	0.415
HDL-cholesterol (mmol/L)	1.46 (0.32)	1.35 (0.28)	0.104
S-triglycerides (mmol/L)	0.88 (0.53)	0.95 (0.39)	0.498
S-apolipoprotein B (g/L)	745 (173)	782 (174)	0.316
S-apolipoprotein A ₁ (g/L)	1350 (182)	1330 (169)	0.708
Apolipoprotein B/A ₁ ratio	0.56 (0.14)	0.59 (0.14)	0.280
P-glucose (mmol/L)	4.52 (0.43)	4.65 (0.42)	0.157
S-insulin (mU/L)	10.3 (6.77)	10.2 (6.82)	0.976
HOMA-index	2.06 (1.37)	2.18 (1.65)	0.722
Hb A _{1c} (%)	4.03 (0.24)	3.98 (0.27)	0.337

¹ One child refused to give a blood sample.

² P-value for difference between groups analysed by independent samples t-test

³ Reference population from the US.

⁴ Reference population from Sweden.

Attendance

The average intervention family participated in 7 (range: 1-14) sessions. Intervention families participating in the study during the whole first year (n=28) had an attendance rate of 10 (range: 4-14) sessions in average. Further, four intervention families attended all 14 sessions and seven participated in all 4 physical activity sessions. Of the intervention families that participated in the study during the whole first year the average family participated in 3 (range: 0-4) physical activity sessions. On the other hand 2 of the 28 intervention families did not participate in any physical activity session at all.

Of the intervention families that completed the whole study, all visited the website at least once and the average family visited the website 37 (range 3-109) times during the intervention period. During the second year, 20% of the children read all four physical activity assignments. The first physical activity assignment was read and accomplished by 26% of the children and the later physical activity assignments were read and accomplished by fewer

children for each assignment; the last physical activity assignment was read by 20% of the children.

SWA wearing time

The mean number of days monitored and mean duration of SWA monitoring at baseline, 1-year measurement and 2-year measurement are shown in table 5. The wearing-time was significantly higher in the control group at baseline 23.5 (0.69) versus 23.0 (1.08), $p=0.024$, but otherwise there were no significant differences in mean monitored days or mean duration of SWA.

Table 5. Average wearing time with SWA at the three 4 d measurement periods in the intervention study. Presented as mean (standard deviation).

	BASELINE			1 YEAR			2 YEAR		
	Intervention group n=46	Control group n=44	p-value	Intervention group n=35	Control Group n=35	p-value	Intervention group n=36	Control group n=35	p-value
Monitored days (d)	3.80 (0.47)	3.91 (0.28)	0.224	3.09 (0.98)	3.09 (0.92)	1.00	2.92 (0.91)	3.06 (0.94)	0.523
Wearing-time (h/d)	23.0 (1.08)	23.5 (0.69)	0.024	22.6 (2.17)	22.7 (2.22)	0.823	22.5 (2.14)	22.9 (1.45)	0.430

Effects on physical activity level

There were no statistically significant differences between the intervention and control groups regarding energy expenditure, steps/day, time spent in low activity (<3 MET), time spent being active at 3- <6 MET, 6 - >9 MET and ≥ 9 MET or screen time either at baseline, 1-year or 2-year measurement (Table 6).

Liggande Table 6.

There were no differences between the intervention and control group in the proportions of children achieving physical activity recommendations regarding duration of physical activity ≥ 60 min/d or screen time ≤ 2 h/d at baseline, 1-year or 2-year measurement (Figure. 11).

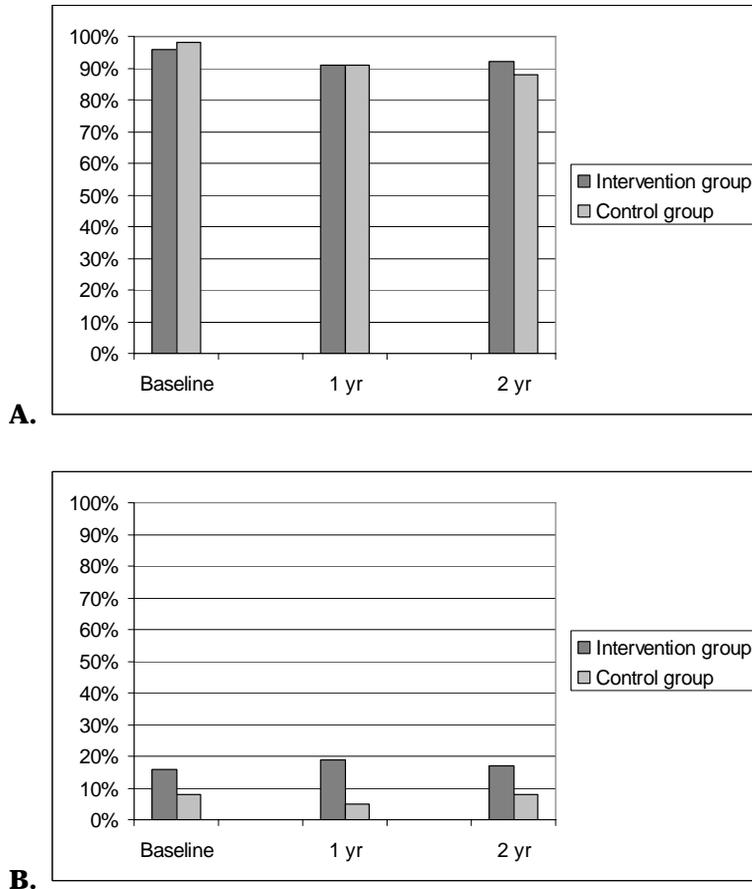


Figure 11. Proportion of overweight and obese children achieving the recommendation regarding physical activity and screen time; A) physical activity ≥ 60 min/d and B) screen time ≤ 2 h/d. No statistical differences were found between intervention and control group when using Chi Square-test.

There were no significant changes in the intervention group from baseline to 1-year and 2-year measurement regarding proportion of children achieving the recommendations to be physically active ≥ 60 min/d. However, there were significantly fewer children within the control group that reached the ≥ 60 min activity recommendation each measured day at both 1-year (91%)

and 2-year measurement (88%) compared to baseline (98%), $p= 0.046$ and 0.007 , respectively.

There were no significant changes within either the intervention group or the control group regarding the proportions of children achieving the recommendation regarding screen time.

The energy expenditure, expressed as MJ/kg·d, decreased within both the intervention group and the control group from baseline to 1-year and 2-year measurements, respectively (Table 7). The total decrease from baseline to 2-year measurement was 0.24 (2.12) MJ/d in the intervention group and 0.20 (1.81) MJ/d in the control group, which corresponds to a decrease of 12% and 14%, respectively. Further, the intervention group decreased their time spent on physical activity at ≥ 3 MET significantly with 16 % (48.7 min/d) from baseline to 1-year measurement. The decrease can mostly be explained by a statistically significant decrease in time spent at $3 < 6$ MET. During the second year the intervention group continued to decrease the time spent at $3 < 6$ MET, consequently giving a 19% decrease in total time spent at ≥ 3 MET (55.8 min/d) compared to baseline measurement (Table 7). The control group also decreased their time spent at ≥ 3 MET from baseline to both 1-year measurement and 2-year measurement with 14%, corresponding to 40 min/d. Between baseline and 2-year measurement the control group also had a statistically significant decrease in time spent at $3 < 6$ MET. The intervention group, but not the control group, decreased their number of daily steps significantly with 13% (1 230 (3210) steps/d) from baseline to 2-year measurement. In contrast to the intervention group, the control group increased their screen time from baseline to 2-year measurement significantly with 31.6 (84.3) min/d, corresponding to 14% (Table 7).

Liggande Table 7

Effects on metabolic markers

After 1-year the intervention had not affected the main outcome, BMI. There were no significant differences between the intervention and control group regarding BMI or BMI-sds, neither regarding the mean of the absolute value (Table 8) nor regarding the proportions of children being classified as being normal, overweight or obese (Table 9). However, at 1-year measurement there were statistical significant differences between intervention and control group regarding waist circumference, waist/hip ratio and apoB/A1 (Table 8). The change of proportions of normal weight, overweight and obese children in the control group was statistically significant ($p < 0.001$), with two fewer children being obese and six more being classified as normal weight (Table 9). While there were no significant change of proportion ($p = 0.182$) in the intervention group, where four fewer children were classified as being obese and two more as being normal weight.

At baseline, 3 children, one child in the intervention group and two children in the control group, were defined as having MetS (Table 9). From baseline to 1-year measurement it was a non significant increase of the occurrence of MetS in the intervention group, whereas the number of children defined as having MetS in the control group remained the same (Table 9). The increase in MetS prevalence in the intervention group is explained by increased levels of triglycerides in two children.

Liggande Table 8

Table 9. Proportion of normal weight, overweight or obesity and prevalence of metabolic syndrome among overweight and obese children. Presented as no. (%).

	Baseline			1-year		
	Intervention N=48	Control N=45	P ¹	Intervention N= 48	Control n =45	P ¹
BMI²						
Normalweight	2 (4)	1 (2)		4 (8)	7 (16)	
Overweight	28 (58)	33 (73)	0.311	30 (63)	29 (64)	0.431
Obese	18 (38)	11 (24)		14 (29)	9 (20)	
BMI sds³						
> 2 SD	22 (46)	13 (29)	0.092	17 (35)	13 (29)	0.501
BMI sds⁴						
> 2 SD	41 (85)	36 (80)	0.489	38 (79)	29 (64)	0.114
Metabolic syndrome⁵	1 (2)	2 (4)	0.520	3 (6)	2 (4)	0.700

¹ Difference in proportions between intervention group and control group analysed with Chi Square test

² Classification according to IOTF.

³ Reference population from the US.

⁴ Reference population from Sweden.

⁵ Defined according to the International Diabetes Federation.

Discussion

Main findings

One of the main results in this thesis was that SWA, together with software version 5.1, was shown to be a valid device to accurately estimate energy expenditure at group level of free-living overweight and obese children. SWA was therefore used to evaluate the effect on physical activity level of a family-based lifestyle intervention for overweight and obese children.

Another main result was that the 2-year family-based lifestyle intervention failed to show any significant difference between the intervention group and the control group regarding BMI and physical activity level, expressed as energy expenditure and time spent per day at different activity levels. Two interesting observations were, however, that in contrast to the intervention group, significantly fewer children in the control group achieved the physical activity recommendations at 2-year compared to baseline and the control group also increased their screen time during the study period.

Physical activity level of the participating children

The lifestyle intervention showed no significant increase in energy expenditure or time spent per day at different activity levels among overweight and obese children. In contrast to the hypothesis the results indicate that the physical activity level, expressed as time spent at ≥ 3 MET, decreased in both the intervention group (19%) and the control group (17%) during the study period. The difficulty to improve physical activity level when it is one among other target behaviours in multifactorial interventions is supported by the results from two recent studies (65, 66). The study by Hughes et al showed a modest increase, 0.2%, in time spent at moderate-to-vigorous physical activity after one-year (65). In the study by McCallum et al. there was a 3.2% increase in percentage of after-school time spent in moderate-to-vigorous physical activity at 9 months but this increase was not sustained 6 months later (66). However, these intervention studies were quite different regarding the study design compared to our study as both of the previous studies were delivered individually to the families and included younger children than in our study.

A possible explanation to why no significant effect on physical activity was seen in the present study is the amount of intervention regarding physical activity offered. Multifactorial interventions including both dietary habits and physical activity themes may lead to an inadequate amount of physical

activity as a theme. A total of 20 h, delivered as four group sessions and four web-based assignments over a 2-year intervention period may have been too little intervention to enable any impact on the physical activity level. Comparative data that identify optimal frequency of sessions or other contact with the participants in an intervention is hard to find. However, behavioural interventions with moderate (26-75 h/) or high (>75 h) intensity of contact with the participants tend to have a beneficial effect on BMI and percentage of overweight and obesity (85).

The lack of increase or maintained physical activity level in the intervention group may be explained by too-low activity goals in relation to the participant's physical activity level when entering the study. The participants' physical activity levels were measured at baseline, but was not analysed before the intervention was implemented, e.g. not until the 2-year study period was over. Therefore, the participant's original physical activity level was not taken in account when designing the sessions and formulating the intervention goals. In retrospective, the participant's activity level should have been considered when the intervention program was set up. The physical activity sessions of our intervention may therefore have focused too little on practical tasks, e.g. offered participation in physical activities at moderate-to-vigorous intensity. In this study we used the present national physical activity recommendation, i.e. to be physically active ≥ 60 min/d in at least moderate intensity every day (84), as one of the goals communicated with the children. This was in retrospective too-low of a goal since more than 96% of the children in the intervention group reached that goal already at the baseline measurement. On average the children in the intervention group were physically active during 293 min/d at baseline. The children in our study seem to be quite active when their time being physically active ≥ 3 MET is compared with the physical activity level of overweight and obese children in other studies (38, 44). In a study by Soric and Misigoj-Durakovic, also using SWA for activity measures, the children spent 136 and 179 min/d (girls and boys, respectively) being physically active (44). Further, a study among Swedish 9-year olds reports 182 and 220 min/d (girls and boys, respectively) of time being physically active ≥ 3 MET. Even though the children's activity decreased during the study period, they still substantially exceeded the level in physical activity recommendation, almost 4-fold among both intervention and controls (84).

Furthermore, physical activity may have been introduced too late in the intervention program; the first time physical activity was discussed was 2-4 months into the intervention. Out of four sessions during the 1st year of intervention, two sessions included participation in physical activity. A systematic review showed that the main factor that distinguish effective from

ineffective interventions to prevent childhood overweight and obesity was the provision of moderate to vigorous aerobic physical activity on relatively compulsory basis (55). The effect might have been different if we had included an activity, such as activity games, as a component in every intervention session irrespective of the main theme for the session. More regular, mandatory physical activities introduced early in the intervention may, according to the review by Connely et al, have had a more positive impact on the participant's physical activity level (55).

The children in our study may be regarded as quite active when physical activity is expressed as time being physically active and when compared with other study populations. On the other hand the children in our study seem to have a lower physical activity level when it is defined as steps/d and being measured by SWA. In another Swedish study a majority, 67 % of the boys and 90 % of the girls, 7-9 years old achieved the recommended amount of daily steps (41). In our study only 18 % of the children in the intervention group and 16 % of the children in the control group reached the step recommendation at baseline. The level of children achieving the step/d recommendation in our study is more comparable with the levels presented in a study of Australian, Swedish and US children where 16 % of the boys and 18 % of the girls in a sample of 6-12 year old children, achieved the proposed recommendation (40). With this in mind, we maybe should have focused more on the physical activity goal regarding steps/d when planning the sessions. It is also suggested that measuring and getting feed-back on one's own physical activity level is a good help to set and evaluate individual goals. At one session the home assignment was to use a pedometer to measure the daily step; the compliance was higher with this home assignment than the others. Since a pedometer is a device easy to handle, that can give instant feed-back, that we got positive feed-back from the participants who used it, it could advantageously be more used in future interventions aiming to stimulate physical activity among children.

When looking at time being sedentary the children in our study may also be regarded as being inactive. Data from NHANES in the US show that among overweight 2-15 year olds 49 % spent <2 h daily in screen-time (86). However, in our study only 16 % of the children in the intervention group stayed below the limited screen-time recommendation at baseline and the proportion of children achieving the recommendation was not changed at 2-year. Our intervention may have been more efficient if we had focused more on reducing sedentary time rather than trying to increase the children's already relatively large amount of time being physically active.

Metabolic markers of participating children

We found no difference in BMI between the groups either at baseline, 1-year or 2-year measurement. During the 2-year study period the children grew on average 6.5 cm and gained 7 kg in weight, causing a 2 % (0.52 kg/m²) increase in BMI. This is a small increase when compared to the reference growth of Swedish boys and girls (26), with BMI increasing 7 % (1.8 kg/ m²) and 8 % (1.2 kg/ m²), respectively, from 10 to 12 years, and might be a result of the study effect. The 2-year data regarding BMI has not yet been further analysed. The decrease in BMI z-score from baseline to 1-year measurement also supports the finding that the participants in both groups became leaner. The participation in a study addressed to overweight and obese children may have drawn the parents attention to the children's overweight and obesity, irrespective of group belonging. Merely the knowledge about the presence of overweight may have been an incitement to make lifestyle changes (87). Both the intervention group and the control group participated in the same dietary and physical activity measures and thereby they regularly became more or less aware of their dietary and physical activity habits. From a positive perspective, this may imply that health improving lifestyle may partly be maintained and or attained by regular help to become more aware of physical activity level and food intake in combination with a yearly health control.

The BMI z-score of the intervention group was reduced with 0.22 or 0.29 units from baseline to 1-year measurement depending on which reference population was used for comparison (26, 74). This change is close to those that are suggested to be of clinical relevance (reduction of 0.25-0.50 units) (88), whereas the reduction of BMI z-score in the control group was below that level irrespective of reference group used (i.e. 0.23 and 0.18 units, respectively). Ford et al. showed that a reduction of ≥ 0.25 in BMI z-score is needed for minor improvement in blood pressure, LDL-cholesterol, triglycerides and insulin sensitivity in adolescents (88). Further both the study by Ford et al and studies by Reinehr and colleagues (89, 90) showed that a BMI z-score decrease of at least 0.5 units was needed for a major improvement in metabolic health. With that in mind, it is not surprising that there are limited effects on metabolic markers in our study. Furthermore, the majority of the children in our study had blood pressures and biochemical measurements within the normal reference range for children already at baseline, thereby significant changes should not be expected.

The normal blood pressures and biochemical measurements contribute to the low occurrence of MetS in our study (3 % at baseline and 5 % at 1-year measurement). A recent review reported a prevalence of 11-32 % of MetS,

using various definitions of MetS, among overweight and obese children in Europe (16).

Methodological considerations

Study design

A major strength in the validation study (paper I) is the use of DLW to validate SWA, which is regarded as the most suitable method for measuring energy expenditure in free-living subjects (28). However, there are also limitations in the study design regarding the validation of SWA. One limitation is that by including days with ≥ 19 h of SWA measuring time in the analysis the average day length when measuring energy expenditure with SWA was 23.3 h instead as 24 h for measurement with DLW method. This may have biased the data from SWA toward underestimation. However, to reduce the possible underestimation, the off-body function in the SWA was used, which means that during the time off body the software program adds the children's estimated basal metabolic rate (BMR) to give a more accurate estimate of the total energy expenditure. However, the use of off-body function does not eliminate the possible underestimation completely especially not if SWA had been removed during daytime. Another limitation of the study design is that SWA was set to collect data at 1-min intervals which may have limited the ability to capture the sporadic and short burst of activities most often performed by children (49), which may have contributed to underestimation of the total energy expenditure.

In the intervention study (paper II-IV) we used a randomized study design which is appropriate for intervention studies (91). There were no differences in baseline characteristics, except for a small difference in fat mass, between the participants in the intervention and control groups, thus indicating a successful randomization. However, the randomization was done before the baseline measurements which resulted in three children becoming normal weight before the baseline measurements. Since they had been included in the study before being classified as normal weight they remained in the group they were allocated to and continued to participate in the study. However, the data have been analysed with and without these three participants, and no difference in results were seen.

There is a consensus that primary analysis of randomized controlled trials (RCT) should be based on the initial treatment assignment and include data for all participants that were initially enrolled and randomized (91, 92). However there are different methods to handle missing data which might bias the results (92). In this thesis all analyses in papers II-IV were performed according to the ITT-method. If a participant had missing data we

used the method last observation carried forward. The use of ITT may underestimate the magnitude of the treatment effect and thereby conceal a difference between the two groups (91).

The staff performing the anthropometric and laboratory measurements and DEXA was not informed of group allocation, but blindedness can not be assured. This probably did not have any substantial effect on the results, but this can not be known with certainty. Further, the author of this thesis was responsible for the interventions sessions regarding physical activity as well as for the distribution and administration of the device for measuring physical activity through all measurement periods. The likelihood that this has had any impact on the physical activity measures during the intervention period is limited since the analyses regarding physical activity level was performed after the 2-year measurement.

Participants

Due to difficulties to recruit families to the study the inclusion criteria were enlarged, to comprise both younger children and children with more overweight, after the recruitment period had begun. Despite the widened inclusion criteria and several different recruitment strategies (e.g. recruitment through the school-health system, letter to all families with children in the age of interest and newspaper articles) the recruited number of children was lower than aimed for. Instead of being able to recruit 120 children, 112 showed interest to participate but only 105 fulfilled the inclusion criteria. The recruitment period begun in 2006 and at this time the prevalence of overweight and obesity among 10-y old children in Umeå was 23 % (10), which means that only about 6.4% of the possible overweight and obese children were willing to participate in the study and fulfilled the inclusion criteria.

The participants were recruited from the northern Swedish town Umeå with surroundings, which is an area with a high proportion of higher educated habitants (compared with the Swedish general population), 34% versus 22%, and fewer habitants of foreign origin, 11% versus 18% (93). Even though we have not analyzed the data regarding the participating families' socioeconomic status, with the knowledge about the sociodemographics of the area the study population might not be representative for overweight and obese children with another background. Furthermore, when inviting participants to an out-clinic study there is a risk that the families who agreed to participate are those with greater interest in lifestyle changes. Thus, the setting of the study and the recruitment rate, in combination with the knowledge of the sociodemographics of the recruitment area weakens the generalisation of the results.

A limitation of the study is that 51 % of the children were lost to the 2-year measurement, which is higher than expected and also quite high when compared to the dropout rate in several other intervention studies involving children. A Cochrane review from 2009 reports a dropout rate range of 12-52 % in studies longer than 12 months (56). The high drop-out rate in the present study decreased the power of the study and thereby limited the ability to detect minor but existing differences between the groups. A possible explanation to the high drop-out rate may be the busy schedule of many families with children who are often participating in several after school activities with both parents commonly working full time outside the home, leaving limited time for recurrent group sessions. This is supported by a majority of the families leaving the study during the first, most intense intervention year, and seven families reporting “lack of time” as being the reason for leaving the study. However, the proportions of children lost to 1- and 2-year assessments, respectively, did not significantly differ between the intervention group and the control group, even though participating in the control group involved less burden on the families than participating in the intervention group. The most commonly reported reason (39 %) from families in the intervention group leaving the study was that “the children did not want to participate in the study any more”. This may indicate that we had failed in our aim to actively engage the children in the intervention program. Another possible cause to drop-outs in both groups could be the recurrent dietary and physical activity measures. Even though no family reported recurrent measurements as their main cause to leave the study, several families expressed that they had difficulties to engage and involve the children in these.

In previous studies, gender was shown to affect the results of overweight and obesity interventions for children and adolescents (63, 64) as well as physical activity level (35). A short coming in the study design of the intervention is that the power of the study did not allow sub-analysis e.g. according to gender or attendance at intervention sessions. Sub-group analyses may have given further information about the effect of the intervention program since there are studies reporting that session’s attendance as well as gender may affect the response to the intervention (63, 64, 94).

Lifestyle intervention program

In the present study the intervention program was developed for children with overweight, but since the inclusion criteria were enlarged, both children with overweight and obesity were included and participated together in the intervention program. However, recent recommendations regarding interventions for 6-11 y old children are mainly the same irrespective of

whether the children were overweight or obese (34). The main goal was to achieve weight maintenance with growth received by advices regarding choice of food, screen time and physical activity (34). If those advices do not have the desired effect after some month, children with obesity may be advanced to a more intensive level of treatment with more regular support and enhanced advice regarding diet, more limited screen-time and more and supervised time in physical activity (34). Two groups of children had begun participating in the intervention program before the inclusion criteria were changed, thereby limiting the possibilities to alter the content of the program in order to better suit children with obesity. Further, the focus of the intervention was to promote a healthy lifestyle rather than weight management. This may have caused a too inefficient or weak intervention program to enable any significant changes among the children with obesity.

A Swedish intervention for obese adolescents used a study design with few but lengthier meetings, the Family weight school treatment, and showed promising results in treating obesity (95). In the present study there were 14 groups sessions distributed throughout the year with breaks during the holidays, which gave 1-2 group sessions on a week evening for most of the months. This model was chosen to enable for most of the parents to participate after work hours and to give regular support throughout the year. However, the attendance rate at the intervention sessions during the first year indicates that this study design did not suite them. In retrospective, another study design with fewer but lengthier group sessions might have given the families better opportunities to participate in the sessions.

When designing the second intervention year we aimed for a continuation in support and sociability in various functions at the web-site, such as chat-room, discussion forums and special time to chat with the researcher each week. However, very few families were active on the web-site indicating that this may not be the kind of support they needed. Further, a majority of the families participating during the second year reported that they missed the group sessions, both the support from the research team and the sociability with the other families, when the intervention was web-based.

There are probably several reasons for the sparse use of the web-platform. Firstly, even though nearly all families in Sweden have a computer (90%) and access to internet (84%) at home (93), a common problem was that the parents had problems to use the web-platform (e.g. forgot how to find the web-platform, forgot user names and could not find out how to move around on the web-platform), thereby also limiting their support to the children's use of the web-platform. Secondly, a majority of children were not familiar with the use of internet and chat rooms. This was a bit surprising, since one-

fifth of the children aged 10-12 years reported using internet or chat-rooms at least an hour a day in a recent Swedish study (96). Further, 40-52% of the children in the same previous study reported that they had virtual contact with their friends at least once a week. Thirdly, the web-platform (Ping-Pong) was taken from the university setting and had not been developed especially for this intervention study. This gave limited possibilities to adapt the milieu of the web-platform to the children's levels and needs. In future web-based interventions a more practicable way would be to design the web-platform for the intervention and in collaboration with persons specialised in web-design. The web-platform should also be designed (for example in colours and shape) to attract the children and it should contain possibilities to incorporate games, movies, sound and more feasibilities to keep in contact with each other.

Measurements

In the present study physical activity was measured using SWA, which previously had been validated on healthy children in both laboratory settings and during free-living with various results (67, 97-99). However, validation studies using SWA among overweight or obese children are largely missing. In the present study we showed that there was no significant difference between energy expenditure by SWA 5.1 and DLW at group level. Further, we showed that SWA 6.1 underestimated energy expenditure among overweight or obese children with 18 %. These findings point in the same direction as the results from another study evaluating SWA together with software 6.1 showing a 6 % underestimation of energy expenditure (97). Based on the result of our validation of SWA 5.1 and 6.1 and DLW, we chose to continue using SWA 5.1 through out the study, despite not using the latest software version.

Physical activity among children is shown to vary day-to-day (49), between week days and weekend days (43) and with season (100). Therefore, when aiming to capture children's and adolescents' usual "activity", it is suggested that at least four days of monitoring including one weekend day are used (28, 49). With that in mind, participants in the present study were instructed to wear SWA four consecutive days including two weekend days at baseline, 1- and 2-year measurement. Our study also contained six measurement periods combining measuring of physical activity and dietary recording. These periods were shorter in order to limit the study load of the families, i.e. 2 d, and were spread throughout the 2 years in order to include all seasons, week days, weekend days, school days and days during school breaks. To have the possibility to use data from these measurements periods when a participant had no data from the 1- or 2- measurement, the criteria for inclusion in the analyses were therefore set to two days of SWA measuring.

This choice to use two days as a limit for inclusion may have confined the possibility to capture the children's normal activity level. On the other hand, a majority of the children participating in the 1- and 2- year measurement wore SWA for four days, and thus it is likely that the children's normal physical activity has been captured.

Another consideration when measuring physical activity among children is how much wearing time is needed to constitute a day of valid measurement. In accelerometer studies most often 10 h is the minimal daily wearing time used (49). The children in the present study were instructed to wear SWA 24 h a day but some participants removed the SWA due to inconvenience at night and some removed the SWA during shorter periods during day time (for example, when participating in water activities). Therefore, the 10 h minimum daily wearing time was applied when choosing the limits for inclusion of data (paper II and III). The 10 h of monitoring ought to have been completed during the period 7:00 am to 9:00 pm in order to capture a great part of the day, including transportation to and from school as well as after school activities.

Even though being aware of the problems that are associated with the use of self-reporting methods among children younger than 10 years of age (28, 49), the screen-time in the present study was estimated with a web-questionnaire. However, in order to minimize a possible recall bias the children were instructed to fill in the questionnaire together with their parents.

BMI is the most often recommended and used method for classifying children as overweight or obese. However, it has limitations when used at individual levels, e.g. it cannot discriminate between muscles and body fat as the cause to high weight. Therefore, in addition to BMI several methods for measuring visceral fat have been used in the present study, i.e. waist circumference and sagittal abdominal diameter, which have been reported to correlate with cardiovascular risk factors (101, 102), and DEXA which is commonly used in childhood obesity research and provides information about whole-body as well as regional measurements of fat mass.

Implications for further research

Due to the high prevalence of overweight and obesity among children (10) it is important to further investigate which intervention is most effective in child obesity treatment. Studies have reported that only half of the parents recognize when their children is overweight (103, 104) which ought to be considered when planning an intervention. If relying only on parent's referring their children to overweight or obesity interventions this may limit the recruitment of participants. The findings of high physical activity levels at baseline imply that the physical activity level of the participants should be measured and accounted for when setting up the intervention program. Further, the contradiction that some children may be regarded as being both highly physical active and sedentary on the same time (105) should be regarded when planning and designing further interventions aiming to affect physical activity level and/or time spent being sedentary. There is a need to further elucidate how physical activity level and sedentary behaviours are associated among children. Furthermore, it is important to elucidate which child could benefit by intervention aimed to increase or maintain physical activity level and which could benefit by an intervention aiming for less screen-time.

CONCLUSIONS

Studies in the thesis demonstrate the following:

- SenseWear Pro₂ Armband together with software version 5.1 is a valid device for accurately measuring energy expenditure at group level of free-living overweight and obese children (Paper I).
- The intervention showed no significant positive effect on overweight and obese children's physical activity level when expressed as energy expenditure and time spent per day at different activity levels (Paper II and III).
- Modest effects in sedentary time and achievement of physical activity recommendations among overweight and obese children were seen after the 2-year family-based lifestyle intervention (Paper III)
- The family-based lifestyle intervention had limited effect on anthropometric and metabolic outcomes of the overweight and obese children after 1 year (Paper IV).

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Table 6. Physical activity variables of overweight and obese children before and after a 2-year intervention presented as mean (SD).

Outcomes	BASELINE			1 YEAR			2 YEAR		
	Intervention n=46	Control n=44	p- value ¹	Intervention n=35	Control n=35	p- value ²	Intervention ¹ n=36	Control n=35	p- value ²
EE ³ (MJ/d)	11.0 (2.50)	10.8 (1.49)	0.759	10.5 (1.75)	10.5 (2.12)	0.879	10.9 (1.86)	10.9 (2.23)	0.893
EE ³ (MJ/kg·d)	0.21 (0.03)	0.22 (0.03)	0.574	0.20 (0.03)	0.19 (0.04)	0.715	0.19 (0.03)	0.19 (0.04)	0.586
Steps (steps/d)	12800 (4450)	12500 (2760)	0.723	11500 (3630)	11600 (4851)	0.966	11100 (3590)	12000 (5260)	0.428
< 3MET excluding sleep (min/d)	658 (105)	682 (86.1)	0.233	690 (110)	720 (116)	0.394	700 (100)	715 (117)	0.823
3-<6MET (min/d)	242 (85.1)	245(62.7)	0.840	211 (82.6)	215 (81.2)	0.793	204 (66.6)	200 (89.6)	0.905
6-<9 MET (min/d)	44.3 (41.1)	35.0 (32.3)	0.240	28.4 (24.5)	25.5 (31.9)	0.857	32.5 (31.8)	31.8 (36.7)	0.868
≥ 9 MET (min/d)	6.81 (8.76)	8.90 (15.1)	0.423	3.66 (4.63)	3.90 (6.29)	0.975	4.57 (4.92)	4.70 (7.38)	0.921
Screen time (min/d)	220 (110)	226 (104)	0.828	229 (107)	227 (90.5)	0.975	226 (92.7)	257 (116)	0.921

¹ Difference between groups at baseline tested with independent t-test.

² Difference between groups at 2-y measurement tested with one-way analysis of covariance.

³ Energy Expenditure

Table 7. Change from baseline to 1 year and 2 year within the intervention group and the control group.

	INTERVENTION GROUP				CONTROL GROUP			
	1 year n=35	p-value ¹	2 year n=36	p-value ¹	1 year n=35	p-value ¹	2 year n=35	p-value ¹
Energy expenditure (MJ/d)	-0.240 (2.12)	0.502	0.102 (0.035)	0.790	-0.200 (1.81)	0.517	0.135 (1.94)	0.682
Energy expenditure (MJ/kg-d)	-0.017 (0.035)	0.005	-0.025 (0.037)	<0.001	-0.021 (0.041)	0.002	-0.031 (0.043)	<0.001
Steps (steps/d)	-933 (3610)	0.136	-1230 (3210)	0.027	-914 (4440)	0.232	-523 (4920)	0.533
< 3 MET (min/d)	22.8 (117)	0.258	36.2 (117)	0.072	34.3 (117)	0.092	29.3 (107)	0.116
3-<6 MET (min/d)	-38.7 (106)	0.038	-46.2 (96.1)	0.007	-27.8 (92.2)	0.083	-42.7 (100)	0.017
6-<9 MET (min/d)	-10.6 (32.6)	0.063	-7.69 (34.6)	0.191	-8.16 (35.4)	0.181	-1.88 (45.2)	0.807
≥ 9 MET (min/d)	-2.86 (10.6)	0.120	-1.89 (9.45)	0.238	-4.30 (12.7)	0.053	-3.29 (15.9)	0.237
≥ 3 MET (min/d)	-48.7 (118)	0.020	-55.8 (110)	0.004	-40.3 (106)	0.031	-40.4 (97.1)	0.021
Screen time (min/d) ²	9.19 (53.5)	0.352	4.50 (98.3)	0.804	1.58 (63.4)	0.880	31.6 (84.3)	0.027

¹ Change within group tested with paired t-test. ² Data from web enquiry

Table 8. Anthropometric measures and fasting blood values after 1-year intervention of overweight and obese children, presented as mean (standard deviation).

	Intervention group n=48			Control group ¹ n=45 or 44			P ²
	1-year	Change from baseline	P ³	1-year	Change from baseline	P ³	
Weight (kg)	54.9 (10.4)	2.78 (0.50)	<0.001	54.0 (11.7)	3.65 (4.17)	<0.001	0.509
Height (cm)	152 (8.38)	3.67 (3.36)	<0.001	153 (9.33)	4.48 (3.53)	<0.001	0.324
BMI (kg/m ²)	23.5 (2.70)	0.08 (0.95)	0.572	22.8 (2.86)	0.20 (1.12)	0.240	0.747
BMI z-score ⁴	1.81 (0.82)	-0.22 (0.37)	<0.001	1.55 (0.82)	-0.23 (0.48)	0.003	0.844
BMI z-score ⁵	2.94 (1.22)	-0.29 (0.62)	0.002	2.57 (1.21)	-0.18 (0.59)	0.050	0.536
Waist circumference (cm)	79.3 (9.99)	1.29 (3.97)	0.029	78.1 (9.14)	3.49 (6.44)	0.001	0.043
Hip circumference (cm)	90.4 (7.65)	1.07 (2.82)	0.011	89.0 (8.29)	1.96 (3.98)	0.002	0.932
Waist/hip ratio	0.88 (0.07)	0.00 (0.03)	0.393	0.88 (0.06)	0.02 (0.06)	0.042	0.029
Sagittal abdominal diameter (cm)	17.9 (2.22)	0.28 (1.14)	0.097	17.5 (2.29)	0.54 (1.28)	0.007	0.590
Fat mass (kg)	20.6 (6.31)	0.88 (2.07)	0.005	19.3 (6.37)	1.43 (2.66)	0.001	0.483
Fat mass (%)	39.0 (6.11)	-0.21 (2.26)	0.514	36.9 (5.82)	-0.16 (3.34)	0.761	0.965
Trunkal fat mass (%)	38.0 (7.47)	-0.38 (2.63)	0.312	35.9 (7.46)	-0.29 (3.98)	0.640	0.830
Diastolic blood pressure (mm Hg)	66.7 (5.44)	0.10 (3.49)	0.837	66.6 (6.00)	-0.07 (5.07)	0.929	0.272
Systolic blood pressure (mm Hg)	111 (8.58)	-0.58 (5.81)	0.490	114 (9.28)	1.38 (6.99)	0.193	0.758
Total cholesterol (mmol/L)	4.32 (0.91)	-0.12 (0.49)	0.087	4.33 (0.82)	-0.18 (0.37)	0.002	0.520
LDL-cholesterol (mmol/L)	2.54 (0.78)	-0.05 (0.33)	0.342	2.64 (0.75)	-0.08 (0.35)	0.159	0.828
HDL-cholesterol (mmol/L)	1.39 (0.35)	-0.07 (0.18)	0.011	1.28 (0.29)	-0.07 (0.15)	0.005	0.983
LDL/HDL ratio	1.91 (0.60)	0.06 (0.27)	0.115	2.16 (0.74)	0.10 (0.42)	0.136	0.711
S-triglycerides (mmol/L)	0.87 (0.63)	-0.01 (0.43)	0.825	0.89 (0.40)	-0.06 (0.44)	0.338	0.286
S-apolipoprotein B (g/L)	733 (172)	-11.5 (67.5)	0.243	755 (162)	-26.7 (86.0)	0.048	0.860
S-apolipoprotein A ₁ (g/L)	1293 (195)	-51.5 (131)	0.009	1228 (149)	-104 (146)	<0.001	0.060
Apolipoprotein B/A ₁ ratio	0.57 (0.13)	0.01 (0.05)	0.134	0.62 (0.13)	0.03 (0.08)	0.032	0.041
P-glucose (mmol/L)	4.58 (0.42)	0.06 (0.25)	0.132	4.62 (0.41)	-0.02 (0.27)	0.623	0.565
S-insulin (mU/L)	11.2 (5.76)	0.90 (4.09)	0.136	10.4 (5.71)	0.21 (5.37)	0.797	0.699
HOMA-index	2.28 (1.19)	0.21 (0.93)	0.122	2.20 (1.34)	0.02 (1.26)	0.896	0.827
Hb A _{1c} (%)	4.11 (0.23)	0.07 (0.15)	0.002	4.03 (0.27)	0.04 (0.13)	0.037	0.612

¹ One child refused to give a blood sample. ² P-values for difference between groups at 1-year follow-up from one-way analysis of covariance.

³ P-values for difference between baseline and 1-year from paired samples t-test. ⁴ Reference population from the USA. ⁵ Reference population from Sweden.