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Dietary intake and changes in relation to BMI SDS and metabolic measures in a childhood obesity intervention – Finnmark Activity School

Master's thesis

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Abstract

Background: Overweight and obesity in childhood doubles the risk of becoming overweight as an adult, as well as it increases the risk of related comorbidities. Cardiovascular diseases are a consequence of obesity and the most common cause of death worldwide. Diet and physical activity are modifiable causes of overweight. Overweight and obesity should be prevented, but treatment must be optimized as well.

Aim/objective: Describe dietary characteristics at baseline and 24-month for children participating in an overweight and obesity intervention. Further, evaluate which dietary changes that are effective for Body Mass Index Standard Deviation Score (BMI SDS) decrease and improvement in metabolic measures.

Methods: We used data from Finnmark Activity School (RCT) conducted from 2009-2013. 83 children were eligible for this thesis and included in our analysis. Data were collected through a food frequency questionnaire (FFQ). Anthropometrical and metabolic were measured by standardized methods. Change variables were made for BMI SDS, total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides, blood pressure and dietary variables. Baseline characteristics were included to describe participant's diet at baseline. We analyzed our data as a prospective cohort.

Results: Participants diet was round about similar to data from nationwide studies. Mean decrease in BMI SDS were -0.13 units (p=0.006) and total cholesterol decreased by -0.39 mmol/L (p=0.001). Intake of snacks and fast-foods decreased by 0.75 (p=0.010) and 0.26 times/week (0.036). Linear regression analysis showed no association between dietary change-variables and change in BMI SDS. In addition, no association were found between dietary change-variables and changes in total cholesterol. Logistic regression showed no increased or decreased OR for change in blood-pressure from changes in diet.

Conclusion: The decrease in BMI SDS and total cholesterol shows that the intervention was successful. However, due to limitations in our methods we cannot conclude that this effect was caused by changes in dietary intake. Future research should focus on accurate collection of dietary data, which is appropriate for the current age-groups involved

Sammendrag

Bakgrunn: Barn med overvekt eller fedme har økt risiko for å få overvekt i voksen alder, i tillegg øker risikoen for relaterte konsekvenser som blant annet kardiovaskulære sykdommer. Årsakene til overvekt og fedme er multifaktorielle og komplekse, men kosthold, fysisk aktivitet og stillesittende adferd er blant årsakene som kan endres. Overvekt og fedme blant barn og unge bør forebygges, men optimalisering av behandling er like viktig.

Hensikt: Beskrive kostholdet til deltakerne ved baseline og 24 måneder. Undersøke om utvalgte kostholdsendringer er assosiert med endring i grad av overvekt og metabolsk profil (målt ved lipider og blodtrykk) hos barn som er under behandling for overvekt og fedme.

Metode: Vi benyttet data fra Aktivitetsskolen i Finnmark (RCT) som ble gjennomført for barn med overvekt og fedme fra Troms og Finnmark 2009-2013. Data om grad av overvekt, blodlipider, blodtrykk og kosthold fra baseline og 24 måneder ble benyttet i denne studiens analyser. Endringsvariabler ble laget for både kosthold, grad av overvekt (KMI SDS) og metabolske målinger. Baseline karakteristikk, lineær regresjon og logistisk regresjons – analyser ble gjennomført og data ble analysert som en kohort.

Resultat: Deltakerne hadde en gjennomsnittlig nedgang i grad av overvekt på -0.13 enheter ($p=0.006$). Total kolesterol hadde en nedgang på -0.39 mmol/L ($p=0.001$). Inntak av fast-food og snacks gikk ned med tilsvarende -0.26 ($p=0.036$) og 0.75 ($p=0.010$) ganger/uke. Lineær regresjon viste ingen sammenheng mellom endring i grad av overvekt og endring i inntak av kostholdsvariablene. Tilsvarende var det ingen sammenheng mellom endring i total kolesterol og kostholdsvariabler. Logistisk regresjon viste ingen økt eller redusert OR for blodtrykksendring ved endring i kostholdsvariabler.

Konklusjon: Nedgangen i grad av overvekt og total kolesterol viser at intervensjonen hadde en effekt. Vi kan ikke med sikkerhet si at denne effekten kom av kostholdsendringer, på grunn av svakheter i metodene for å samle inn kostholdsdata. For videre forskning bør fokuset ligge i nøyaktig innsamling av kostholdsdata, med metoder som passer for den yngre populasjon. Fysisk aktivitetsnivå og endring må også tas i betraktning i intervensjonsstudier for overvekt og fedme.

Abbreviations

BMI = Body mass index

BMI SDS = BMI standard deviation score

BP = Blood-pressure

CVD = Cardiovascular diseases

DXA = Dual-energy X-ray absorptiometry

E% = Percent of energy intake

HBSC = Health Behaviour in School Children

Iso-BMI = age and gender adjusted BMI values

IOTF = International Obesity Task Force

NIPH = National Institute of Public Health

WHO = World Health Organization

24-HDR = 24-hour dietary recall

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1 Background

Childhood overweight and obesity doubles the risk of becoming overweight or obese as adult (1-3). Additionally, childhood obesity is associated with increased mortality from cardiovascular disease later in life - explained by an accumulation of cardiovascular risk factors such as hypertension and dyslipidemia (4-7). Most of the worlds' population live in countries were overweight takes more lives than underweight (8). Prevalence is increasing in in low - and middle-income countries but seems to be stable at high levels in the United States and Europe (8). Additionally, those who have overweight or obesity seems to stay overweight or obese (1-3).

There are various underlying explanations for why a person develops overweight or obesity (9). Multidisciplinary interventions are considered the most appropriate treatment method for the younger population (10, 11). Treatment often aims to stabilize rapid weight gain by increasing physical activity, promoting healthy eating and decreasing sedentary behaviour and unfavorable food-choices (12).

Researchers and health workers strive to find the best fitted treatment for overweight and obese children, but due to the various causes and individual differences there may not be a one-fits-all model (10). Main aim should be prevention however we also need to improve treatment for those already affected by childhood obesity. In order to maximize the effect of treatment we need to explore and evaluate all aspects of management including dietary changes for children undergoing treatment.

1.1 Childhood overweight and obesity

1.1.1 Definition

According to the World Health Organization (WHO) overweight and obesity is defined as "abnormal or excessive fat accumulation that may impair health" (8). For the adult population overweight is referred to as a body mass index (BMI) over 25 kg/m^2 while obesity and severe obesity is defined as BMI over 30 kg/m^2 and 35 kg/m^2 respectively (13).

We cannot interpret a child's BMI the same way as for adults, this because children are growing and have a reduced muscle – and skeletal mass (12). Overweight in terms of BMI for the younger population varies with age and differ between genders. Age - and gender adjusted BMI values, referred to as iso-BMI, are developed for children and adolescents. Iso-BMI values for children in between 2 to 18 years are presented in appendix 1 (14). In addition, several countries, the international obesity task force and WHO have developed weight standards that are used in clinics and research (15-17). Moreover, in childhood overweight and obesity research, overweight is often referred to in terms of BMI SDS. Which describes a persons' weight according to how many standard deviations one is above or below the average person within same age and gender in a given reference population (18). BMI SDS is a common method of defining overweight and obesity among children in epidemiological settings, because it is standardized and comparable across age and gender (18, 19).

1.1.2 Prevalence

According to the World Health Organization worldwide obesity has tripled since 1975 (8). Over 340 million children and adolescents globally in ages 5-19 years, were considered overweight or obese in 2016. In between 15 and 20% of Norwegian children are considered to have overweight or obesity, while approximately 25% of young adults are overweight or obese (11, 20).

According to the National Institute of Public Health (NIPH) the prevalence of childhood obesity and adolescent obesity seem to be higher in the northern most region of Norway (20). NIPH also states that prevalence of Norwegian children having overweight or obesity seems to be 50% higher in rural areas, compared to urban areas (20). This demographic difference in distribution of overweight and obese citizens is also seen in other countries, e.g. research form the United States shows a greater number of citizens having overweight or obesity in rural areas compared to the cities (21).

As for the global overweight – and obesity trends, the proportion of overweight and obesity seems to have stabilized at high levels in Norway and other North-Western countries (22). The Child Growth Study from NIPH reports that the percentage of schoolchildren having overweight or obesity has been stable over the last decade. Among 3rd grade school children, prevalence of overweight is 14% among girls and 11% among boys, while prevalence of obesity is 3% among girls and 2% among boys (20).

There are no nationwide prevalence-studies of the Norwegian populations weight-development over time but the studies we do have (Tromsø-study og HUNT) indicates that a majority of the adult population has overweight or obesity today (20). Additionally, the same studies indicate an alarming high prevalence of overweight and obesity among the young adults.

1.1.3 Measuring overweight and obesity

Methods to measure body-composition varies in terms of precision, expenses and availability (23). In this thesis body-composition refers to the various compartments our body consist of: atoms, cells and tissue that makes up water, organs, bones and muscles (24). We can measure these compartments separately or as one whole (e.g. weight). Weight and height are both inexpensive and less time-consuming compared to other existing methods and are most frequently used in both clinical and epidemiological settings. Height and weight are usually calculated into BMI and BMI SDS (25). BMI is an accepted measure of overweight and obesity, although it does not provide information about the distribution of fat (26). Waist-circumference is the recommended method for assessing central obesity (24). But as for BMI, waist circumference and the risk of disease is highly dependent on age and gender. Waist-circumference is an objective method, but the approach can easily bias the result - even if measurements are done by the same personnel there are always a risk of incorrect measurement which can lead to wrongful results. To this day, waist-circumference is often used as a measure to follow-up effect of treatment, but not as diagnostic criterium in children (12).

Other methods to measure overweight and obesity includes densitometry, dual-energy X-ray absorptiometry (DXA), skinfold measurements, bioelectrical resistance (BIA), computed tomography (CT) and magnetic resonance imaging (MRI) (23, 25). There are advantages and limitations to each method and what method is chosen varies from clinical settings to epidemiological research settings. In clinical routine practice anthropometrical measuring-methods, such as weight and height, are often used instead of the gold standards; MRI and CT (27).

1.2 Causes of childhood obesity

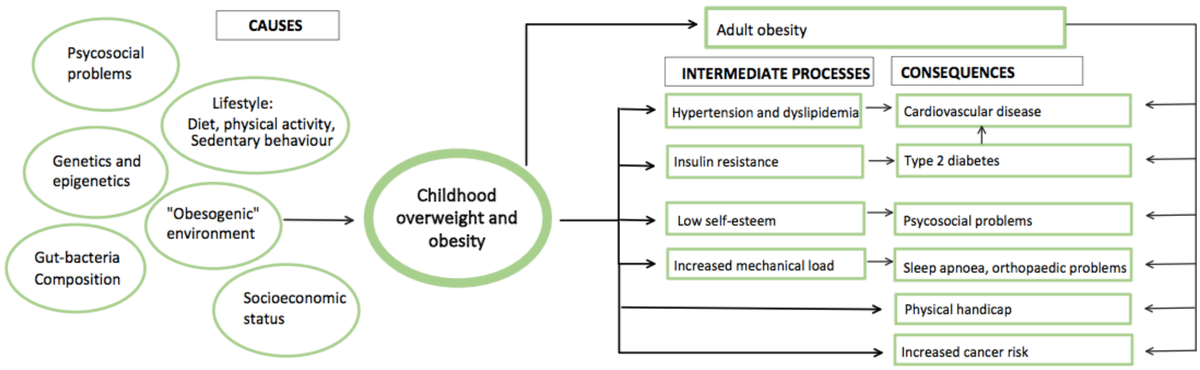

Figure 1: Causes and consequences of childhood overweight and obesity
Figure 1 Illustrates causes of childhood overweight and obesity (explained further in sections below) and intermediate processes and consequences. Childhood obesity doubles the risk of adult obesity which also is established risk-factor for the mentioned consequences of overweight and obesity. The figure is modified from the following review article by Weihrauch-Blüher et al. (28).

The practical explanation for overweight and obesity is a positive energy-balance over time (12). If energy-intake is high while energy-consumption is low, remaining energy will be stored within the body as fat tissue. The underlying causes for this energy-imbalance is multifactorial and complex (29-32) The relationship between genetics, environment and behavior seems to be essential (33). Psychological disorders are also proven to be associated with the development of obesity. According to a meta-analysis by Mannan et al. the association between depression and obesity seems to be bi-directional – meaning depression may lead to obesity and obesity may lead to depression (34). Socioeconomical status is also found to be associated with overweight and obesity, where children from families with lower socioeconomic state have a higher prevalence of overweight and obesity compared to children from families with higher socioeconomical state (31).

Gut-bacteria composition has received attention over the last years as a potential cause of overweight and obesity (35, p.72). Studies have showed that lean people have a better suited bacterial-composition in their gut than people with an overweight. Scientists believe that an imbalanced gut-bacteria composition may be a cause of overweight – and obesity development explained by disturbances in processes in the gut which is related to weight-gain (36).

1.2.1 Genetics and epigenetics

There is evidence to support genetic background to be central in the development of overweight and obesity (33). The molecular pathways underlying genetic causes of obesity are still not fully understood, but association-studies have found polymorphisms associated with obesity (37). Single nucleotide polymorphisms (SNPs) are DNA sequence variations that occur when a single nucleotide in the genome sequence is altered. It is believed that some SNPs may affect biological functions such as regulation of energy-balance. Genetic disturbance resulting in SNPs may affect intake of foods through increased appetite and increased feeling of hunger (38).

Another type of genetic disturbance referred to as "monogenetic disorders" are rare in obese children (presence in 3-5% of obese children) (33). The most common monogenetic disorder is called MC4R-mutation. MC4R-mutation influences the long-term maintenance of weight-loss which may explain why some people have troubles maintaining weight-loss over a longer period of time.

To summarize, genetic background has an important role in developing and maintenance of overweight and obesity. It is important to be aware of potential genetic causes in cases where lifestyle interventions are not successful, this might be because of an unfavorable genetic background (33). Genes alone cannot explain the rapid development of overweight over the last decades – since overweight and obesity have rapidly increased in a genetically stable population other causal aspects must be evaluated (39). Environmental causes of overweight and obesity include both current environment and former fetal and postnatal environment. Both may be causal in the development of overweight and obesity (40).

Epigenetics refers to processes that induce heritable changes in gene expression without altering DNA sequence (33). According to Lillycrop et al. epigenetic processes are integral in determining when specific genes are expressed and alterations in epigenetic regulation of genes may lead to changes in phenotype (40). The most important epigenetic processes include DNA methylation, modifications of the histones on which DNA winds and micro RNA (40). Existing evidence strongly support fetal and early postnatal environment to partly influence these epigenetic processes and by that increasing the risk of developing obesity later in life. Environmental factors proven to have an effect on epigenetic processes are: Over – and undernutrition during pregnancy, gestational diabetes, maternal smoking during pregnancy, elevated birth weight, rapid weight-gain in early life and feeding practices (40, 41).

1.2.2 Obesogenic environment

In addition to fetal and postnatal environment the current environment children are growing up in may have causal impacts on the development of overweight and obesity (42). The term ''Obesogenic environment'' is often used to describe an environment identified with chronic positive energy balance. Environmental changes and a transition to a more modern environment has led to a lifestyle characterized by sedentary behavior, easy access to high energy-dense foods and low levels of physical activity (43). In other words, an environment that promotes the development of overweight and obesity. "*The national guidelines for prevention, identification and treatment of children with overweight and obesity"* reports an increase in sedentary behavior, and a decrease in levels of physical activity among Norwegian school children (12). Norwegian school-children are often being transported by car to school and after-school activities, even if the distance from home to school is under one kilometer (12). The guidelines also describe that Norwegian children are at top of the statistics when it comes to sedentary behavior: 11-16-year-old boys are sitting still up to 40 hours per week (44). A meta-analysis by Marshall et al. found an association between time spent in front of a screen and overweight and obesity (45). Additionally, a recent study from 2020 demonstrated that risk of obesity among children who were genetically vulnerable to overweight and obesity development, increased by some particular environmental and sociodemographic factors (31). For example, increased screen-time seemed to increase the risk for overweight and obesity among genetically vulnerable children (31).

1.2.3 Dietary risk-factors

According to WHO the fundamental reason for overweight and obesity is “a shift in diet towards an increased intake of energy-dense foods that are high in fats and sugars” …. “And a trend towards decreased levels of physical activity” (8). Diet is defined as consumption of foods over a period of time and varies among individuals and within individuals (46, p.20). Depending on the components of our diet it may contribute to an increased or decreased risk of non-communicable diseases such as cardiovascular diseases and type 2 diabetes (46, p.334). Total energy-intake is associated with the development of overweight and obesity (20).

High energy-dense foods are typically foods that are high in sugars and/or saturated fats, and often low in fiber, e.g. fast-foods, candy and chips (47). A shift in diet toward an increased intake of such foods combined with low levels of physical activity may easily lead to an energy intake higher than requirements (i.e. development of overweight). On the contrary, low energy-dense foods have low levels of calories per gram and are typically foods like fruit, vegetables and legumes. These types of foods are associated with better health outcome (48).

Over the last 100 years dietary trends have changed substantially among the Norwegian population (49). Several dietary items are associated with increased energy-intake in people, but very few specific food items are found directly associated with the development of overweight and obesity (50). Sugar-sweetened beverages and typical high energy-dense foods such as fast-foods and snacks, are found to be associated with weight-gain. (39, 50-52)

Intake of sugar-sweetened beverages have increased in line with the obesity pandemic and is associated with the development of overweight and obesity in children (53, 54). According to a nationwide report, Ungkost-3, Norwegian children (4^{th} and 8^{th} graders) consume 1,5-2 dl/day of sugar-sweetened beverages (55). However, the recent publication “Development in Norwegian diet” reported a decrease in wholesale consumption of sugar-sweetened sodas by 19% from 2015 to 2018 (56). According to the Norwegian HBSC-study the percentage of boys consuming sugar-sweetened beverages >5 times/week is increasing by age (57). The suggested mechanism for weight-gain in relation to high intakes of sugar-sweetened beverages include: a lack of stimulation of satiety when consuming caloric drinks instead of solid foods, which may lead to an excessive energy-intake (51). A direct impact of lipogenesis, insulin secretion and leptin production – which independently can increase weight-gain (58).

In addition to sugar-sweetened beverages, fast-foods have become more accessible in line with prevalence of obesity worldwide and high consumption of fast-foods have been linked to weight-gain (39). There are several mechanisms that may contribute to fast-food being a dietary risk factor for overweight and obesity: Fast foods are high energy-dense foods containing elevated levels of saturated fat, sugars and salt (39). The portion sizes are often large which easily can contribute to excessive energy-intake (59). Fast-foods have high palatability and its primordial taste easily makes it a more preferable food (39). In addition, fast-foods are associated with emotional eating (EE) - a term used to describe eating caused by emotional distress instead of actual hunger (60). Emotional eating may come as a result of phycological disorders, such as depression (60)

Main sources for saturated fat in Norwegian diet are whole fat dairy, meat and processed meats and butter/margarine (55). Fast-foods usually contains several of the components mentioned above. The dietary surveys of the Norwegian population show that some aspects of diet have improved over the last decades but overall, we still eat too much of foods that are not recommended to consume at a high level. This represents a concern for public health and particularly for the younger population who are in a period of life where lifelong dietary habits are shaped (61).

A diet corresponding to the Norwegian dietary guidelines is associated with a healthy lifestyle and decreased risk of non-communicable diseases and the development of overweight and obesity (61). The report "Ungkost-3" from 2015/16 – a report of Norwegian 4th and 8th grade children's diet shows that the young population follow the national dietary recommendations, although their intake of saturated fat, added sugar are a high while intake of fruit, vegetables and fish is low (55). The Norwegian HBSC-study states that children from families with higher socioeconomical status tend to eat more fruit and vegetables, and they tend to have a lower consumption of soda and candy (i.e. a healthier diet compared to families with lower socioeconomical status) (57). This corresponds to findings from Hüls et al. where low intake of fiber were associated with the development of overweight and obesity in children who were genetically vulnerable for overweight development (31). Sources to dietary fiber are among other foods, fruit and vegetables (62). According to the report "development in Norwegian diet" the proportion of 15-year old who eat at least 1 fruit a day has declined from 2009-2018 (56). Among 11-year old in Norway about 40% of girls eat fruit on a daily basis, and about 42% eat vegetables daily. For boys the same age 36% eat fruit and 37% eat vegetables daily. These numbers correspond to findings by Kolle et al. which showed percentage of Norwegian 6-, 9- and 15-year old's having a daily intake of fruit and vegetables to be approximately 30-35% (63).

To sum up dietary causes of overweight and obesity; there are numerous potentials causes to overweight and obesity, they are also complex and not fully understood to this point. An unhealthy diet is associated with both development of overweight and obesity, as well as increased risk of adverse consequences (61).

1.3 Consequences of childhood overweight and obesity

Childhood overweight and obesity is related to several negative health effects, including both physical and psychological consequences (11). Hypertension, dyslipidaemia, musculoskeletal conditions due to an increased mechanical load, respiratory conditions (sleep-apnoea and asthma), insulin resistance and psychological problems are common consequences of childhood overweight and obesity (4). Common psychological disorders in children with overweight or obesity are anxiety, depression, behavioural problems as low self-esteem. Depression is found to be bidirectional in terms of occurrence – meaning it is an increased risk of developing overweight if one has depression and an increased risk of depression if one has obesity (34). Overweight – and obesity related consequences such as hypertension, dyslipidaemia and insulin resistance have earlier been referred to as typical adult consequences (5, 6, 64). These consequences are now becoming more prevalent in the younger population – establishing themselves as childhood consequences of overweight and obesity (64). Hypertension and dyslipidaemia are risk factors for developing cardiovascular diseases, which usually occurs in adult age (5, 65).

Cardiovascular diseases are the most common cause of death nationally and globally and takes an estimation of 17,9 million lives each year (66). According to WHO, four out of five deaths are caused by heart-attack or stroke, and about 33% of deaths affecting people < 70 year (66). Cardiovascular diseases are the most common cause of death in Norway, although mortality-rates have decreased by 80% for people <65 years over the last 40 years (35, p.125). Most common cardiovascular diseases are atherosclerosis which commonly leads to stroke and heart attack (67). Atherosclerosis is a result of having dyslipidemia (explained in chapter 1.3.1). Being overweight in childhood and bringing the excess weight into adult life may increases the risk of having medical conditions such as dyslipidemia over time, which increases the risk of CVD further (68).

1.3.1 Dyslipidemia

Dyslipidemia is characterized by an abnormal lipid profile that increases the risk of atherosclerotic cardiovascular diseases (69, p.648). This is characterized by either high levels of total cholesterol and/or LDL-cholesterol and/or low levels of HDL-cholesterol. One can measure the concentration of Total-c, LDL-c and HDL-c by blood samples. Dyslipidemia is seen more and more rapidly in the younger population and in relation to those having overweight or obesity (70). The condition is also seen in relation to high intakes of saturated - and trans fats (70). The normal range of blood lipids change as we grow and mature; acceptable, borderline and high levels of lipids in plasma will therefore vary from childhood to adulthood. Table 1 presents acceptable, borderline and high levels of lipids in children.

Table 1: Acceptable, borderline and high levels for Total cholesterol, LDL-c, HDL-c and Triglycerides.

	Acceptable mmol/L	Borderline mmol/L	High mmol/L
Total Cholesterol	4.4	4.4-5.2	5.2
LDL-C	2.8	2.8-3.3	3.4
TG			
▪ 0-9 years	0.8	0.8-1.1	1.1
▪ 10-19 years	1.0	1-1.5	1.5
HDL-C	1.2	1-1.2	1.0

Values given are in mmol/L and mg/dl. The figure is modified from a report by Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents (71). First found at Uptodate (70). Note that these values are consisted with guidelines of the National heart, lung and blood Institute, The American Academy of pediatrics, and the American Heart Association / American College of Cardiology. These values are not validated as accurate predictors for accelerated atherosclerosis or CVD.

Lipids are insoluble in water and cannot transport themselves in plasma without functional transporters, known as lipoproteins (72, p.275). The most common lipoprotein is the LDL-particle (35). Lipids (e.g. cholesterol) binds to lipoproteins, which then transports the cholesterol molecule through the blood-flow. All lipoproteins < 70 nm in diameter containing Apo-B can pass the endothelial barrier and arterial walls (67). Lipoproteins trapped in arterial walls will result in lipid deposition and initiation of arterial plaque. People who have a higher level of lipoprotein LDL will have a faster lipid deposition and possibly more rapid development of atherosclerotic plaque (67).

HDL-cholesterol forms in peripheral tissue where free cholesterol and phospholipids binds to Apolipoprotein A1 (67). Apo-A1 moves from peripheral tissue to the liver where cholesterol is excreted as bile. HDL-c is often referred to as the good cholesterol and while LDL-c are causally and cumulative associated with increased risk of cardiovascular disease, HDL-c has to recent time been inversely associated with cardiovascular risk. Recent reports are not completely sure about the inverse association between HDL-c and cardiovascular risk, because increased levels of HDL-c are often seen in parallel with decreased levels of LDL-c (67). A great amount of resources has been used to develop medications meant to increase levels of HDL-C, but these have not proven to be effective in decreasing risk of cardiovascular diseases which contradict the inverse association (35). To summarize, a correction of abnormal lipid profile in childhood reduces the risk of CVD in adulthood (70).

1.3.2 Hypertension

Hypertension is a condition were the pressure from blood flow to the arterial wall is elevated (73). Hypertension in adults is an established risk factor for cardiovascular diseases while hypertension in children increases the risk for hypertension in adult life, which includes an increased risk of atherosclerosis and cardiovascular death (74, 75).

Initially hypertension was known as an adult consequence of overweight and obesity but over time it has become more prevalent in the younger population (76). We distinguish between primary and secondary hypertension (75). Primary hypertension is defined as elevated blood pressure that cannot be explained by a secondary cause, while secondary hypertension is caused by another medical condition. Primary hypertension comes as a result of increased thickness in the arterial walls and arterial stiffness, which leads to an increased pressure against the arterial wall. Table 2 presents borderline values (measured in mmHg) for both systolic and diastolic blood pressure corresponding to the 90th and 95th percentiles for ages 6-16 years. Blood pressure in between the 90th-95th percentile for age and gender corresponds to elevated blood pressure, while blood pressure over 95th percentile for age and gender is classified as hypertension (77, 78).

Table 2: 90th and 95th percentiles for systolic and diastolic blood-pressure for ages 6-16 years

Age		6	7	8	9	10	11	12	13	14	15	16
						Girls						
	Percentiles											
SBP	90	107	108	111	113	115	117	119	121	122	124	125
	95	111	113	115	117	119	121	123	125	126	128	128
DBP	90	69	70	71	73	74	75	76	78	79	79	80
	95	73	74	75	77	78	79	80	82	83	83	84
						Boys						
SBP	90	110	111	112	113	115	117	119	122	125	127	130
	95	114	115	116	117	119	121	123	126	128	131	134
DBP	90	70	72	73	74	75	76	77	77	78	79	81
	95	74	76	77	79	80	80	81	82	82	83	85

The table shows 90th and 95th percentiles for systolic blood pressure and diastolic blood pressure for boys and girls in ages 6-16. 50th percentiles for height is used to calculate the values for each percentile. The table is modified from "The national guidelines for prevention, assessment and treatment of children with overweight and obesity" from the Directorate of Health (12). Abbreviations: SBP = systolic blood-pressure, DBP = diastolic blood-pressure. BP = Blood pressure.

1.4 Treatment

Interventions to treat obesity can occur at many levels; surgical, pharmacological and behavioural (10, 79). Given the complex causes of obesity there may not be a one-fits-all treatment-method and optimal treatment method may vary among individuals (10).

1.4.1 Surgical and pharmacological treatment

Surgical treatment (e.g. bariatric surgery) is not common treatment of obese children but seen in some studies of morbid obesity in adolescents (80). The most common bariatric procedures are gastric sleeve, gastric banding and gastric bypass (10). An RCT conducted with Australian adolescents investigated the effectiveness of bariatric surgery (gastric banding) compared to lifestyle interventions and proved a greater body weight loss as a result of surgery (80). Despite these findings there is need for more research within this field. Pharmacological drugs that have proven to be effective, Sibutramin and Orlistat, are not currently on the marked (10). Sibutramin is not approved by the European Medicine Agency and was withdrawn from market due to its adverse cardiovascular effects. Orlistat is approved, but not for children under the age of 12. New potential drugs that are targeting appetite regulation are currently being developed or assessed (10).

1.4.2 Lifestyle interventions

Lifestyle interventions are defined as "diet and exercise interventions that involve the use of behavioural techniques'' (81). Lifestyle interventions are the least invasive form of treatment and recommended as primary treatment for overweight and obese children in Norway (12). Lifestyle interventions has its benefits of tackling all aspects of manageable causes of overweight: diet, physical activity and behavior. Lifestyle interventions regarding diet is a subject for discussion. Children cannot be put on hypocaloric diets like adults, because they are in growth and need adequate energy, vitamins and minerals to continue growing and evolving muscle - and skeletal mass (81). Restricting calories over time may affect growth in a negative way.

"*The national guidelines for prevention, identification and treatment of children with overweight and obesity"* focuses on dietary habits, such as eating slower, healthier food-choices and establishing regular meals in treatment of overweight and obesity among children (12). Dietary treatment often aims to follow the Norwegian dietary guidelines which are presented in Appendix 3. The guidelines are based on systematic research over decades and are developed to promote a healthier lifestyle among the Norwegian population (35, p.17. 82). The guidelines are used by clinical dietitians in dietary treatment and eating according to the guidelines is associated with healthier lifestyle, increased life expectancy and reduced risk of non-communicable diseases.

There are several reviews and meta-analysis about treatment of childhood overweight and obesity; A Cochrane review from 2017 proved multi-component lifestyle interventions including diet, physical activity and behaviour changes to be beneficial for short-term effects in BMI SDS, BMI and weight in children aged 6-12 years (83). One study found that children aged 5-12 years, having overweight instead of obesity, may profit from lifestyle interventions (81). The mentioned studies show that degree of weight-loss from lifestyle interventions is only moderate and success rate is low after 2 years of intervention. Participants in Finnmark Activity School reduced their BMI SDS throughout the active intervention, as well as 1-year after ended intervention (84, 85). The various results from lifestyle interventional studies proves that treating children is difficult and it may be explained by several reasons: Lack of motivation, unfavourable genetics and/or adaptive basal metabolic rate, hunger and satiety hormones that occur with weight loss (81). In conclusion, multicomponent lifestyle interventions are proven to be the most appropriate tool for weight-management in children although effects are varying (11). Positive effects from interventions seem to remain up to 24-months after start-up. According to Elvsaas et al. further research should aim to optimize lifestyle interventions in the future (11).

In order to evaluate dietary interventions for overweight and obesity dietary intake and habits must be measured in relation to weigh-development. Dietary intake and habits can be measured through food frequency questionnaires, 24-hour dietary recall, double portion method, biomarkers and dietary records (86, p. 403-408). Measuring dietary intake in general is challenging and all methods have their limitations (86, p.403). The most common method for measuring dietary intake in nutritional epidemiology is use of food frequency questionnaires (87). FFQ's are usually self-administrated (i.e. participants fill out the questionnaire by themselves) but can also be assessed as a structured interview.

2 Aim

Our aim was to explore dietary characteristics and changes among children in a lifestyle intervention for childhood overweight and obesity. From previously published results we knew that participants had moderate effects (BMI SDS and metabolic measures) from the intervention, both 2 - and 3-years from baseline (85, 88). We therefore aimed to explore what dietary changes that are effective in relation to changes in BMI SDS (e.g. weight stabilization/loss) and changes in metabolic outcomes (e.g. improved lipid profile and blood pressure).

The superior aim of Finnmark Activity School was to increase knowledge about factors that can promote lifestyle changes (88). To this point dietary data from Finnmark activity school have not been analyzed, and through this thesis we aim to explore the dietary aspect of the intervention. Our aim was to:

1. Explore characteristics of participants diet at baseline and 24-months
2. Explore changes in intake of sugar-sweetened beverages, fruit and vegetables, fast-foods and snacks change from baseline to 24-months
3. Evaluate if there were any association between change in BMI-SDS (from baseline to 24-months) and change in intake of the following dietary variables:
   I. Fruit and vegetables
   II. Sugar-sweetened beverages
   III. Fast foods (Pizza, hamburgers, hot dogs, kebabs)
   IV. Snacks (sweets/chocolate/chips)
4. Evaluate if there were any association between change in metabolic outcomes (from baseline to 24-months) and change in intake of the following dietary variables:
   I. Fruit and vegetables
   II. Sugar-sweetened beverages
   III. Fast foods (Pizza, hamburgers, hot dogs, kebabs)
   IV. Snacks (sweets/chocolate/chips)

3 Material and methods

This master thesis used data from "Finnmark Activity School" (RCT) conducted from 2009-2013 in Finnmark county in northern Norway. Our data is analyzed as a prospective cohort. We chose this method because all participants received one out of two treatments and both groups had the same overall goal (explained in chapter 3.1). Previously published results from Finnmark Activity School showed minimal differences between the two groups in BMI SDS decrease at 24-months and no between-group difference in BMI SDS was detected 1-year after ended active intervention (85, 89). The two groups combined decreased their BMI SDS by -0.14 units at 24-months (88). At 36 months, a significant decrease in BMI SDS were detected in both groups (-0.13 BMI in individual family and -0.24 BMI SDS in group intervention, respectively). Our aim was to explore dietary changes in relation to BMI SDS and metabolic outcomes– what kind of treatment participant received is therefore considered less relevant in terms of the research question.

3.1 Finnmark Activity School

Finnmark Activity School was a single-blinded clinical trial that started at Hammerfest hospital in Finnmark county in 2009. The project was collaboration with the University Hospital of North Norway (UNN) and the Arctic University of Norway (UiT). The purpose of the clinical trial was "to evaluate the effectiveness of a new comprehensive family orientated treatment for children having overweight or obesity. The superior aim was to increase knowledge about factors that can promote lifestyle changes in the current families" (84). Staff at Hammerfest Hospital conducted the study, collected data and organized courses for other health-care providers involved in the project.

Participants in Finnmark Activity School were children and their families from six municipalities in Finnmark county and the municipality of Tromsø. 109 participants were interested in joining Finnmark Activity School, but 97 were included at last. Detailed inclusion and exclusion of participants in Finnmark Activity School is described elsewhere (84). Briefly explained, all children were in between ages 6-12 years at baseline and were included if they had a BMI corresponding to BMI $\geq$ 27.5 kg/m^2 for adults. The clinical trial compared two treatment methods for childhood overweight and obesity; Group intervention and individual family intervention. The overall focus of treatment was equal in both groups, although treatment was carried out a bit different between the two groups. In both groups dietary counselling and guidance focused on each family's resources and aimed to reduce sedentary behavior, increase physical activity and promote healthy eating according to National Guidelines (88). The individual group received a 30-minute individual dietary counselling with clinical dietitian at baseline, 3-, 12 and 24-month. The group intervention had group-based classes at the same times, which focused on cooking, reading nutrition information on food items, how to make healthier food choices while grocery shopping etc.

The main outcome in Finnmark Activity School was defined as BMI and BMI SDS, and secondary outcome included physical activity, anthropometrical, metabolic and psychological measures (90). Finnmark Activity Schools active intervention lasted for 24-months and the 36-months measurements were used as a 1-year follow-up. In this thesis we look at baseline and 24-months measurement which is recognized as start and end of the active intervention period. Data in Finnmark Activity School was collected at baseline, 6-, 12-, 24- and 36 months. Figure 2 represents an overview of when the different data was collected in Finnmark Activity School and the data which is included in this thesis.

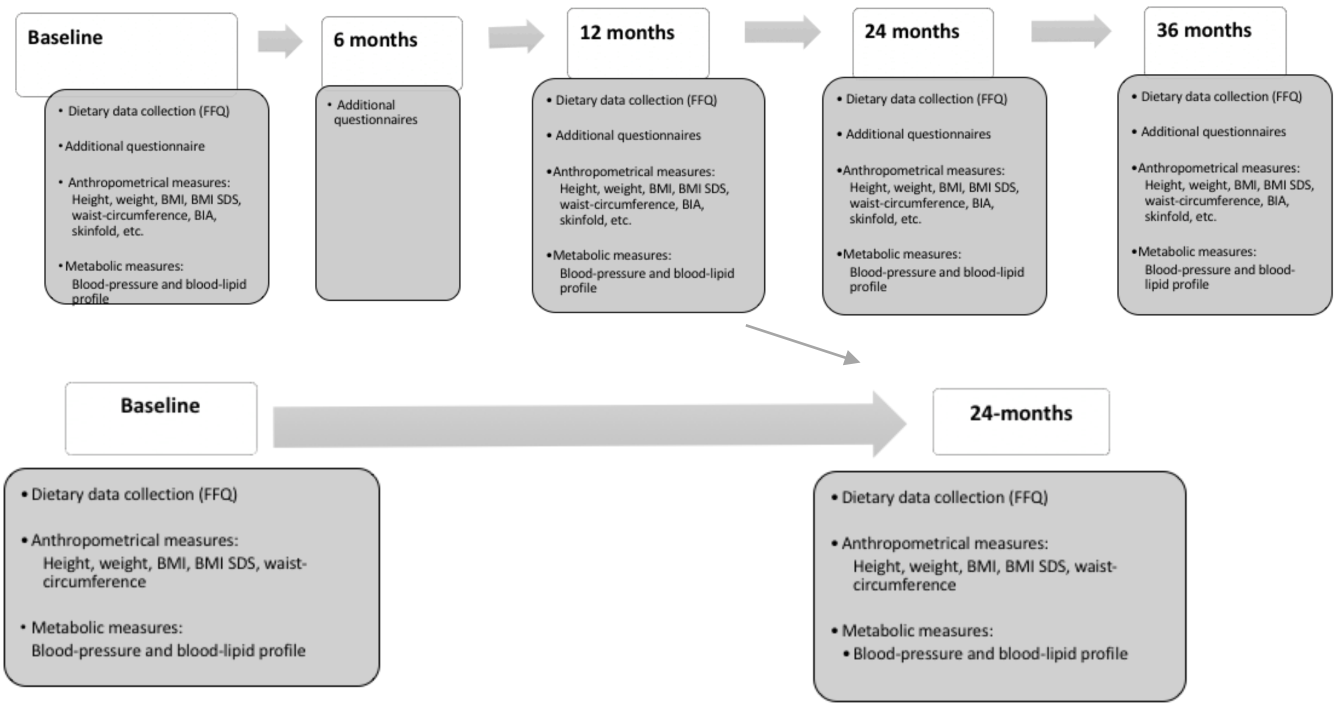

Figure 2: Timeline for data-collection a/upper panel Finnmark Activity School and b/lower panel the current thesis.
The arrow in between the panels indicates that 12-months measurement were imputed due to high amount missing at 24-months (described in chapter 3.3). In addition to anthropometrical measures used in this thesis, Finnmark Activity School also measured skinfolds, BIA impedance (84). Abbreviations: FFQ (Food Frequency Questionnaire). Additional questionnaire (sleep, family-relation, socioeconomics questionnaire). Anthropometrical and metabolic measures conducted at Hammerfest Hospital. Additional questionnaires collecting psychological aspects of the interventions were also handed out.

3.2 Study population

Of the 97 participants who were randomized in Finnmark Activity School, 91 attended the baseline appointment. These 91 represents the available study sample for this particular study. However, the available baseline sample differ from this number because of the inclusion criteria: participants needed to have available dietary data. Numbers of participants included and excluded in the current thesis is represented in Figure 3.

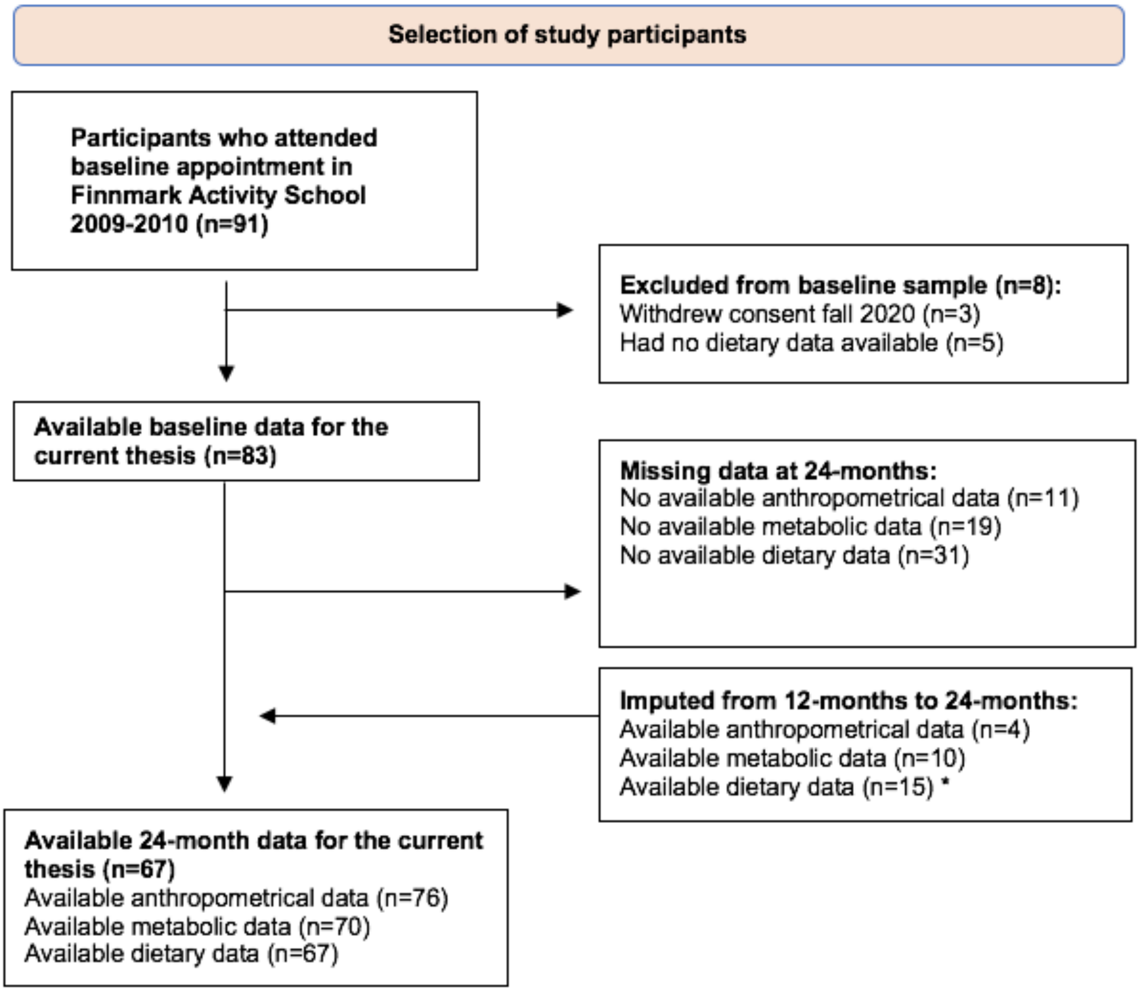

Figure 3: Flow-chart

* Included at 24-months (n=67) is number of participants who had anthropometrical measures and dietary data accessible. Data from FFQ imputed from 12-months measures to 24-months varied among different dietary variables.

3.3 Measures

Measures include intake of selected foods and beverages collected through a food frequency questionnaire. All anthropometrical and metabolic measurements were done by trained personnel.

3.3.1 Anthropometric measures

Anthropometric measures in this study includes height and weight converted to BMI SD score (BMI SDS). Height and weight were measured by trained personnel at Hammerfest hospital following Hospital Trust Guidelines. Height was measured to the nearest 0.1 cm by a portable Harpenden stadiometer and weight was measured to the nearest 0.1 kg by a digital Seca Portable Scale. Participants were measured lightly clothed and between 08:00-11:00 A.M. Height and weight were converted to BMI SDS using an online calculator based on a British reference population (91).

BMI SDS is defined as: $\frac{(Observed\ value - median\ value\ for\ reference\ population)}{Standard\ deviation\ value\ for\ reference\ population}$ $(84, 91)$.

Researchers in Finnmark Activity School had already applied the British 1990 reference for calculating BMI SDS (91). Since this reference is frequently used internationally and makes comparison across studies easier, we chose to continue with this reference in this current thesis. Maternal and paternal height and weight data at baseline and 24-months were collected from self-reported questionnaires.

3.3.1.1 Missing

No missing values for baseline measurements was observed. The number of missing at 24-months for BMI SDS were n=13. Due to a low number of participants in total and BMI SDS being the outcome variable we chose to impute BMI values from 12-months measurements for those who had missing BMI SDS values at 24-months. 6 participants had available BMI SDS values at 12-months and missed BMI SDS at 24-months. 7 participants did not have any data for BMI at either 12-months or 24-months. The number of participants with BMI SDS data after imputation was 81.

3.3.1.2 Creating change variables (BMI SDS)

BMI SDS at baseline and 24-months were recoded into a change variable called by subtracting BMI SDS 0 – BMI SDS 24. The change variable indicates increase or decrease in BMI SDS throughout the study. A positive change variable for BMI SDS value indicates a decrease in BMI SDS. Correspondingly a negative change-variable for BMI SDS value indicates increase in BMI SDS from baseline to 24-months.

3.3.2 Metabolic measurements

Fasting blood samples were collected by biomedical laboratory scientists at Finnmark Hospital in Hammerfest, following hospital Trust guidelines. Samples were collected fasting at both baseline and 24-months. Total cholesterol, triglycerides, LDL-cholesterol and HDL-cholesterol were analyzed by Siemens Advia Chemistry enzymatic methods (Siemens Healthineers).

Prior to blood-pressure measurement the children were asked to rest for 5 minutes. Blood pressure were then measured using Dinamap ProCare100 calibrated sphygmomanometer (Med-electronics) while the participant was sitting in a supine position. Three measurements of blood pressure were completed, and the average score was then classified according to percentile for height and gender (77). Participants were placed into one of three categories depending on their blood pressure results; 1 = Blood pressure ≤ 90^{th} percentile, 2 = Blood pressure 90^{th} – 94t^{h} percentile and 3 = Blood pressure ≥ 95^{th} percentile.

3.3.2.1 Missing metabolic measurements

Four participants had missing values for total cholesterol, LDL cholesterol, HDL-cholesterol and Triglycerides at baseline. Data from 24-month measurement had an increased number of missing (n=26). As for BMI SDS, 12-month metabolic measurements were imputed where 24-month metabolic measurements were missing. This was done due the amount of missing at 24-months, a low number of participants in total and metabolic outcome being a secondary outcome. There were 13 missing values after imputation. Missing values for blood-pressure were n=2 at baseline but n=0 at 24-months, and no imputation was required.

3.3.2.2 Creating change variables (metabolic measurements)

Change variables for total cholesterol, LDL-cholesterol, HDL-cholesterol and Triglycerides was made using baseline variables and subtracting 24-month variables. As for BMI SDS a positive change-value indicated decrease in each of them from baseline to 24-months, while a negative change-value indicated an increase in metabolic measurements.

Change in blood-pressure was defined as moving from a percentile to a lower percentile, e.g. from ≥ 95th percentile to either 90th-94th percentile or ≤ 90th percentile or moving from 90th-94th percentile to ≤ 90th percentile. Staying within the same percentile was classified as no change in blood-pressure. 2 participants had an upwards change in blood pressure class, but these was classified as no change.

3.3.3 Dietary intake

Dietary intake throughout the study were collected through an FFQ filled out by parent and child at baseline and at 24-months. The questionnaire consisted of 17 questions in total, regarding dietary preferences, restrictions in diet and frequency of intake of beverages, selected foods and beverages. Questions in the FFQ were closed and did not cover each child's diet in its entirety meaning complete energy-intake is not measured.

Three questions in the questionnaire is used to collect dietary data for this study. The questionnaires layout can be seen in appendix 5. The dietary variables fruit, vegetables, junk-food, pizza, sugar-sweetened soda and cordial and candy, chocolate and chips were chosen prior to other available data because they are considered to be important dietary components in either development or treatment of overweight and obesity (explained theory section). Both parents were invited to answer questionnaire, but majority of questionnaires were filled out by mother and child, only three questionnaires were filled in by father. At baseline and 24-months there were no cases (n=0) were both mother and father had answered separate questionnaires. Questionnaires filled in by mother and father could therefore be used interchangeably.

Dietary intake was measured at baseline and 24-months using an FFQ and data was transformed into change-variables by using measurement at baseline and subtracting measurement from 24-months. Hence a positive value on a change variable denotes a decrease in intake from baseline to follow-up. Detailed information about dietary measurements is presented below and in chapter 3.5.

3.3.3.1 Transforming dietary data

Participants were asked how often they drink each type of beverage and answers were originally categorical:

1 = Never/rarely, 2 = 1-3 glasses/month, 3 = 1-3 glasses/week, 4 = 4-6 glasses/week, 5 = 1-3 glasses/day, 6 = 4-6 glasses/day and 7 = 7 glasses/day or more.

Three glasses were specified as 5 decilitres in the FFQ. All answers were recoded into glasses per week. For variables that were listed as a range (e.g. 1-3 times/month) we used the category midpoint to convert intake into glasses per week. For example; 1-3 times/month → median value = 2 times/month = 0.5 times/week. The following recoding was performed:

Never/rarely = 0 glasses/week, 1-3 glasses/month = 0.5 glasses/week, 1-3 glasses/week = 2 glasses/week, 4-6 glasses/week = 5 glasses/week, 1-3 glasses/day = 14 glasses/week, 4-6 glasses/day = 35 glasses/week and 7 glasses/day or more = 49 glasses/week.

Questions about frequency of intake of foods were answered on a categorical scale:

1 = never/rare, 2 = 1-3 times/month, 3 = 1-3 times/week, 4 = 4-6 times/week, 5 = 1 time/day, 6 = 2 times/day, 7 = 3 times/day and 8 = 4 times/day or more.

As for beverages, these variables were recoded into frequency of intake per week. The same method as for beverages was used were variables were labeled as a range. The following recoding was performed:

Never/rarely = 0 times/week, 1-3 times/month = 0.5 times /week, 1-3 times/week = 2 times /week, 4-6 times/week = 5 times /week, 1 time/day = 7 times/week, 2 times/day = 14 times /week, 3 times/day = 21 times /week, 4 times/day = 28 times /week.

The dietary variables were added together to form new grouped variables. This was carried out for variables within the same category; fruit and vegetables, sugar-sweetened soda and cordial, pizza and junk-food, and chocolate, chips and candy. The following was carried out:

Table 3: Overview of original variables and new grouped variables

Original variables		New grouped variable
Fruit and berries and vegetables (2 variables)	⟶	Fruit and vegetables
Sugar-sweetened soda and cordial (2 variables)	⟶	Sugar-sweetened beverages
Chocolate, chips and candy (3 variables)	⟶	Snacks
Pizza and Junkfood (2 variables)	⟶	Fast-foods

The table represents an overview of what variables that were merged together to form the new grouped variables.

3.3.3.2 Missing

Missing values were set to the value 1 (1 = 0 times or glasses/week) if the participant had answered a minimum of one question within the same group of questions. For example, if a question about intake of sugar-sweetened soda was given the answer "5 glasses/week", but all other questions about beverages were left blank - I assumed that this participant only drinks sugar-sweetened soda. All missing values within the same grouping of questions were therefore set to 1 (1=0 glasses/week). Frequency of intake of selected food items were listed within one question in the FFQ. Although the question contained several different types of food items, from fruit to pizza to chocolate, we decided to impel the same method for missing values as for beverages.

For 24-month dietary data there were a great number of missing (numbers varying up to n=31). Missing data were imputed from 12-month measurement if 12-month data were available. This decision was made due to a low number at participants in total and the overall high number of missing. Number of missing after imputation varied for each variable.

3.3.3.3 Creating change variables (diet)

Dietary change variables were computed using baseline measurements for each grouped dietary variable and subtracting the 24-months measurements for the same variable. A positive change-variable indicated a decrease in intake from baseline to 24-months, correspondingly a negative change-variable indicated an increase in intake. If change-variable were equal to 0 no changes in intake of the dietary variable were carried out throughout the study-period.

3.3.4 Fitness level

Fitness level was measured using Andersens test, which is an indirect method to measure VO_{2max} in children specifically (92). Participants were asked to run/walk for 15 seconds followed by a 15 seconds break. Participants were running within a field of 20 meter and total distance is measured at the end of the test. During break participants could not move forward within the field. Total time of the test was 10 minutes. After running for 10 minutes, the distance for each participant was calculated and put into the following equation to calculate VO_{2max} (endurance score):

VO_{2max}=18.38 + (0.033 x distance in m) – (5.92 x gender) $^{(\text{Boys} = 0 \text{ and girls} = 1)}$

The method is described by Aadland et al. (93).

3.4 Ethical considerations and approvals

We applied to both Regional ethical committee of Northern Norway (REK) and Norwegian data inspectorate (NSD). Because of the amount of time since Finnmark Activity School started, NSD required that all participants were informed about this project and given an opportunity to withdraw their participation. All participants of Finnmark Activity School were reached out to by letter informing them about this particular thesis. Participants were informed about the start of this particular study and were asked to give a written confirmation if they did not want a further participation in Finnmark Activity School. 3 participants were removed from the study and were not included in the data set. Regional ethical committee of Northern Norway (REK) and Norwegian data inspectorate (NSD) approved the project through year 2021 (Appendix 7).

3.5 Statistics

This project is analyzed as a prospective cohort. Statistical analyzes were performed with IBM SPSS version 27 and all p-values under 0.05 were considered to be statistically significant. Descriptive statistics, paired samples t-test, simple linear regression and logistic regression was used to answer research questions. Some independent variables were transformed prior to analysis (explained in paragraph 3.5.1).

Main outcome is defined as change in BMI SDS and secondary outcome is defined as changes in total cholesterol, LDL cholesterol, HDL-cholesterol, triglycerides, systolic and diastolic blood-pressure. Exposure in terms of this study is defined as changes in intake of fruit and vegetables, sugar-sweetened beverages, snacks and fast-foods.

3.5.1 Descriptive statistics

To describe the participants and their dietary intake at baseline different types of descriptive statistics were used, including frequencies, mean, median and percentage of participants. Baseline intake of intake of the four grouped dietary variables were combined into three categorical answers: regularly, occasionally and rarely/never. This was done in order present variations in consumption in a simple way. Recoding was carried out the following way:

- Fruit and vegetables were recoded the following way:
  Regularly: ≥ 21 portions/week which responds to ≥ 3 portions/day
  Occasionally: 7-21 portions/week which responds to 1-3 portions/day
  Rarely/never: ≤ 7 portions/week which responds to ≤ 1 portion/day

- Fast-food, snacks and sugar-sweetened beverages were recoded the following way:
  Regularly: ≥ 2 portions/week
  Occasionally: 0.5-2 portions/week
  Rarely/never: 0 portions/week

Dietary variables were recoded differently into categorial variables because they belong to separate food-groups which are recommended to eat in different amounts. National recommendations suggest an intake of fruit and vegetables equal 5 portions/day (82). On the contrary national recommendations suggest a limited intake of added sugar, saturated fat and salt. Sugar-sweetened beverages, snacks and fast-foods all consists of these components we should limit in our diet.

Dietary variables were not normally distributed. Median is normally used as a measure of central tendency when data is not normally distributed. Although median is the preferred method, mean was chosen due minor differences between median and mean. This is considered an appropriate method if difference between the two is minimal (94).

Mean change in intake of fruit and vegetables, fast-foods, snacks and sugar-sweetened beverages was estimated using a paired samples t-test. The test aimed to determine whether there was statistically significant difference in mean intake of the selected foods and beverages from baseline to 24-months. The paired sample t-test was also used to determine change in BMI SDS and metabolic outcomes from baseline to 24-months.

3.5.2 Linear regression and scatter-plot

Simple linear regression with the change-variable for BMI SDS as dependent variable was carried out with the dietary change-variables as independent variables. We also did a simple regression analysis with change-variables for Total Cholesterol as dependent variable and dietary change-variables as independent variables.

Scatterplots were made to visualize the association from the simple regression analysis. 67 participants had both anthropometrical and dietary data on both baseline and 24-months and were included in linear regression analysis. Because of small study sample the regression analysis was carried out without any adjustments.

The following equation represents the simple linear regression analysis:

Let $Y = \Delta$-BMI SDS

$X_1 = \Delta$-Fruit and vegetables, Δ-Sugar-sweetened beverages Δ-Snack and Δ-Fast-foods

B_0= intercept

B_1= Population slope coefficient

$$Y = B_0 + B_1 * X_1$$

3.5.3 Logistic regression

Logistic regression analysis was carried out with binominal variable "Blood pressure change" as dependent variable. As explained in chapter 3.3.2.2; change in blood-pressure was defined as moving from one percentile to a lower percentile (e.g. $\geq 95^{th}$ percentile to 90^{th}-94^{th} percentile or $\leq 90^{th}$ percentile, or from 90^{th}-94^{th} percentile to $\leq 90^{th}$ percentile).

Independent variables were the same dietary change variables as the linear regression analysis: Fruit and vegetables, Sugar-sweetened beverages Snack and Fast-foods.

4 Results

4.1.1 Participants characteristics and dietary intake at baseline

Table 4: Baseline characteristics

	n	mean	SD	n (%)
Age in years	83	10.4	1.70	
Gender girls (%)	83	-	-	45 (46)
BMI (kg/m^2)	83	27.3	4.35	-
BMI Standard Deviation Score	83	2.77	0.58	-
Waist-Circumference (cm)	83	88.67	12.08	-
Maternal BMI (kg/m^2)	79	29.87	7.30	-
Paternal BMI (kg/m^2)	36	30.30	5.10	-
Total-cholesterol (mmol/l)	79	4.76	0.80	-
LDL- cholesterol (mmol/l)	79	3.10	0.80	-
HDL- cholesterol (mmol/l)	79	1.35	0.36	-
Triglycerides (mmol/l)	79	1.10	0.70	-
Elevated blood pressure (%)	81	-	-	18 (22)
Distance (in meters) Andersens test	82	637	124	-
Endurance Score (According to Andersens Test)	82	36	4.7	-

Baseline characteristics represented as mean +/- standard deviation for continuous variables. Categorical variables are presented by the distribution of categories and percentage (%).

Mean age at baseline was 10.4 years, 52% girls and 48% boys. Mean BMI was 27.3 kg/m^2 (SD 4.35) and mean BMI SDS 2.77 (SD 0.58). Mean maternal BMI was 29.87 kg/m^2 (SD 7.30) and mean paternal BMI was 30.30 kg/m^2 (SD 5.10). At baseline mean total cholesterol, LDL-cholesterol, Triglycerides and HDL-cholesterol were all considered borderline values according to the American Academy of pediatrics and the American Heart Association (Table 2). At baseline 22.2% of participants had elevated blood pressure according to their age and gender. Mean endurance score was 36.

Table 5: Mean weekly intake of selected dietary variables

	mean	SD	median
Sugar-sweetened cordial	1.2	(3.2)	0
Sugar-sweetened soda	1.3	(1.4)	0.5
Sugar-sweetened beverages (grouped)	2.5	(3.7)	2
Fruit	6.6	(5.9)	5
Vegetables	4.1	(4.2)	2
Fruit and vegetables (grouped)	10.7	(9.0)	9
Pizza	1.0	(0.5)	0.5
Junkfood	0.7	(0.5)	0.5
Fast-foods (grouped)	1.7	(1.2)	1
Chocolate	1.9	(0.9)	2
Candy	1.6	(1.0)	2
Chips	1.2	(0.9)	0.5
Snacks (grouped)	4.7	(2.0)	4.5

Mean refers to mean frequency of intake per week. The variables sugar-sweetened beverages (grouped), fruit and vegetables (grouped), fast-food (grouped) and snacks (grouped) refers to the total intake of the dietary variables listed above each of these grouped-variables. Number of participants included in the table were n=83.

In table 5 both mean and median weekly intake of the selected dietary variables is included. Although there are some differences between the two measures of central tendency, they seem to be approximately the same for the grouped variables.

Table 5 shows that participants consumed sugar-sweetened beverages 2.5 times/per week at baseline. The two sugar-sweetened components, soda and cordial were consumed 1.2 and 1.3 times per week respectively. Fruit were consumed more frequently than vegetables (6.6 times/week vs 4.1 times/week). The total intake of fruit and vegetables were 10.7 times/week which is equal to 1.5 times/day. Participants ate pizza and junk-food 1 and 0.7 times/week. Chocolate, candy and chips were consumed 1.9, 1.6 and 1.2 times/week respectively. Total snack intake at baseline were 4.7 times/week.

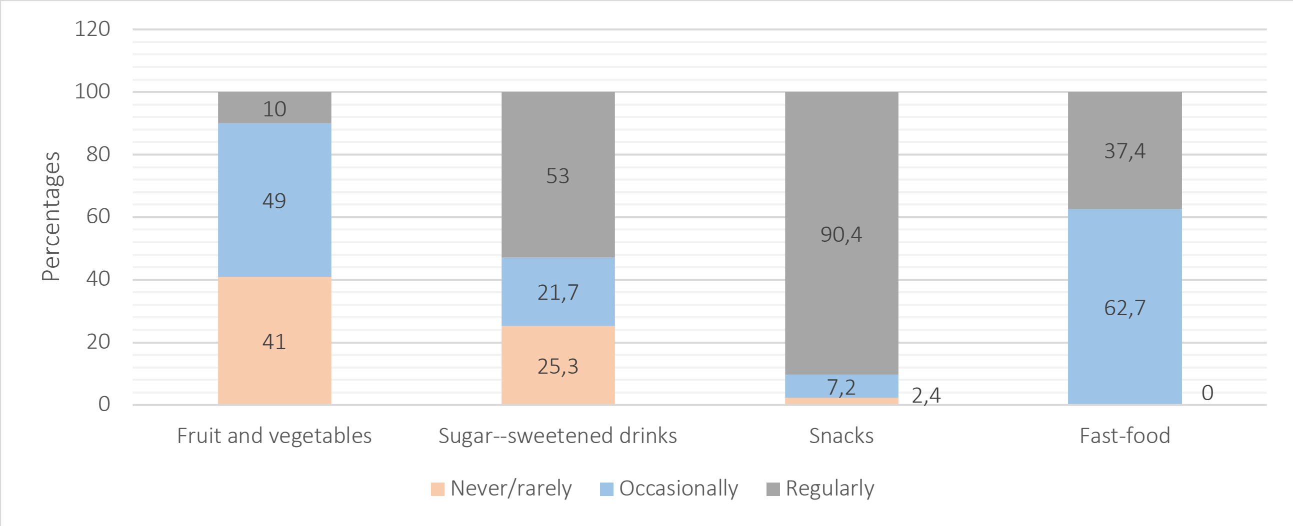

Figure 4: Baseline-intake of fruit and vegetables, sugar-sweetened beverages, snacks and fast-foods (represented in percentage)
Baseline intake of fruit and vegetables, sugar-sweetened beverages snacks and fast-foods presented in the categories regularly, occasionally and rarely/never. Fruit and vegetables were recoded the following way: Regularly: ≥ 21 times/week, Occasionally: 7-21 times/week, Rarely/never: ≤7 times/week. Fast-food, snacks and sugar-sweetened beverages were recoded the following way: Regularly: ≥ 2 times/week, Occasionally: ≥0.5-2 times/week, Rarely/never: 0 times/week. Further information in chapter 3.7.1. Number of participants included in the graph above were n=83.

10% participants ate fruit and vegetables at a regular basis (≥3 times/day), while 49% ate fruit or vegetables occasionally (1-3 times/day) and 41% consumed fruit and vegetables rarely (<1 time/day) (Figure 4). 59% of participants ate fruit and/or vegetables daily.

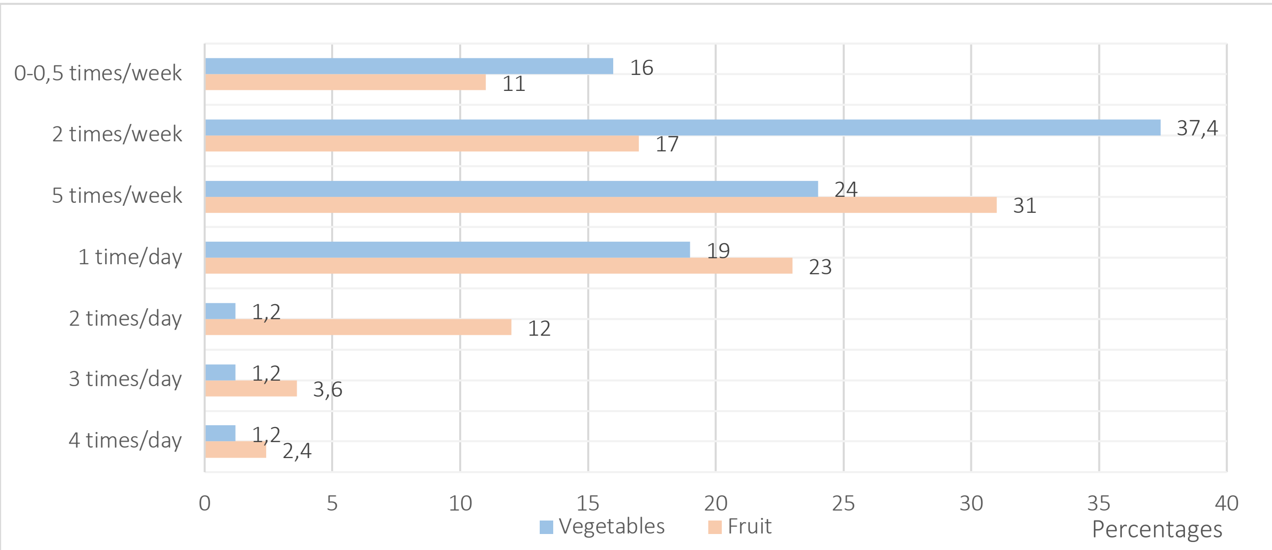

Figure 5: Baseline intake of fruit and vegetables represented as percentages of each separate variable
Number of participants included in the graph above were n=83.

Figure 5 shows a more detailed presentation of baseline consumption of fruit and vegetables separately. Overall intake of fruit and vegetables were low – the majority of participants ate fruit or vegetables 1 time/day or less. Vegetables were most commonly eaten 2 times/week (by 37.4% of the participants) and fruits were most commonly consumed (by 31%) 5 times/week. 16% of participants ate vegetables 0.5 times/week or less and 11% ate fruit 0.5 times/week or less.

53% of the participants consumed ≥2 glasses/week or more of sugar-sweetened beverages, while the remaining participants had a less frequent consumption (Figure 4). 90.4% of participants ate snacks regularly, which corresponds to ≥2 times/week. A more detailed graph of frequency of intake of snacks is presented in Figure 6.

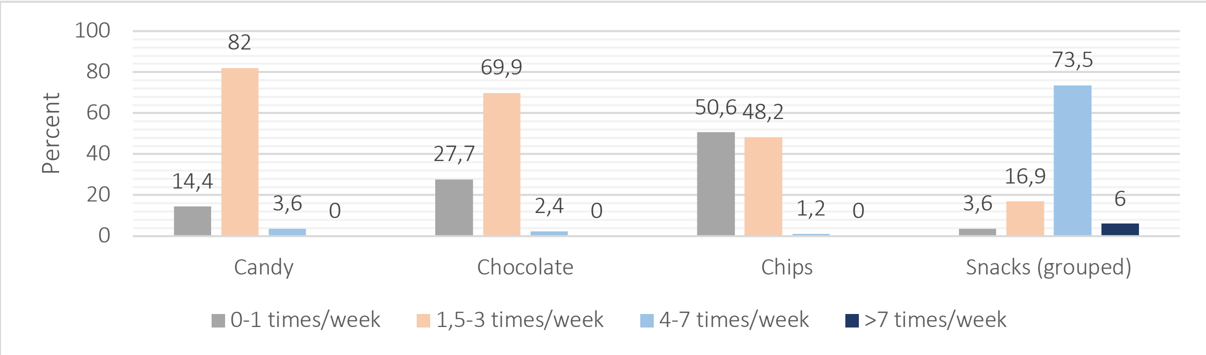

Figure 6: Baseline intake of candy, chocolate, chips and snacks (grouped) presented in percent (%)
Number of participants included in the above graph were n=83.

The majority of the participants had an intake of candy and chocolate of 1.5-3 times/week. Chips were consumed less frequently compared to candy and chocolate. When combining candy, chocolate and chips into one variable "Snacks (grouped)" the majority of the participants (73.5%) had an intake of 4-7 times/week. 6% of the participants consumed snacks (grouped) >7 times/week and 3.6% ate snacks 0-1 time/week.

4.1.2 24-months characteristics and mean changes in dietary changes (baseline to 24-months)

Table 6: 24-month study-sample characteristics

	n	mean	SD	n (%)
BMI (kg/m^2)	76	28.72	4.81	
BMI standard deviation score	76	2.63	0.67	
Waist-circumference (cm)	73	89.2	11.8	
Maternal BMI (kg/m^2)	67	29.4	7.08	
Paternal BMI (kg/m^2)	40	29.4	4.04	
Total-cholesterol (mmol/l)	70	4.34	0.77	
LDL-cholesterol (mmol/l)	70	2.88	0.74	
HDL-cholesterol (mmol/l)	70	1.34	0.35	
Triglycerides (mmol/l)	70	1.05	0.59	
Elevated blood pressure (%)	81	-	-	7 (8.6)
Distance (in meters) Andersens test	60	753	115	
Endurance score (Andersens test)	60	40	4.52	

24-months characteristics: Continuous variables is represented as mean +/- standard deviation. Blood pressure is presented as n and percentage (%) of participants having elevated blood pressure.

Mean BMI and BMI SDS were 28.72 kg/m^2 and 2.63 respectively (Table 6). Mean maternal and paternal BMI were lower compared to baseline for those included at 24-months, however the number of mothers reporting their weight and height have decreased and number of fathers have increased. Mean levels of total cholesterol and HDL-cholesterol are considered acceptable values at 24-months according to levels presented in table 2 (70, 71). Mean LDL-cholesterol and triglycerides were still considered borderline levels at 24-months (Table 2). The percentage of participants having elevated blood-pressure were 8.6% at 24 months. Endurance score were equal to 40 at 24-months, which indicates an overall increased mean activity level.

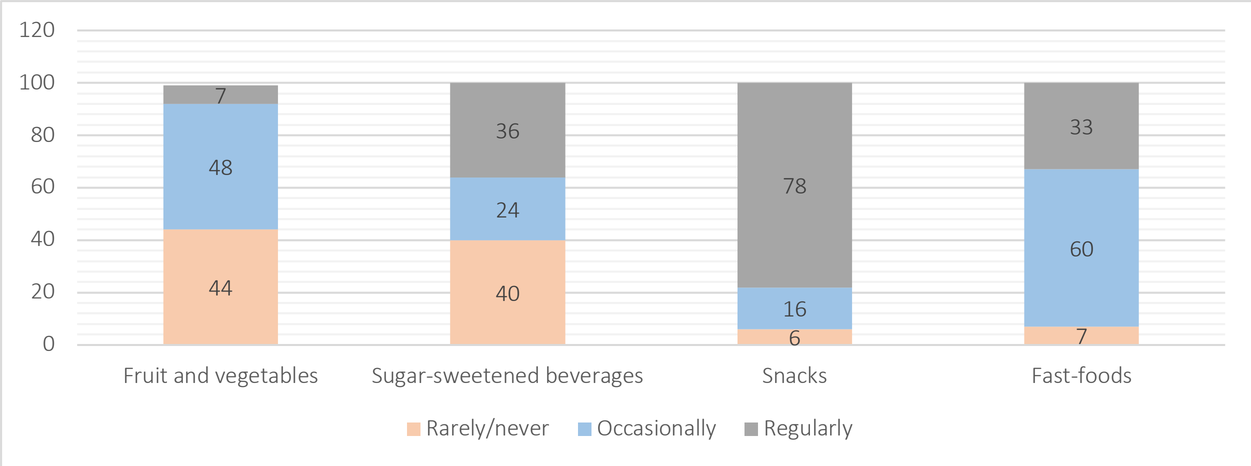

Figure 7: 24-month intake of fruit and vegetables, sugar-sweetened beverages, snacks and fast-foods (represented in percentage)

The graph shows 24-month intake of fruit and vegetables, sugar-sweetened beverages, snacks and fast-food represented in three categories regularly, occasionally and rarely/never. Fruit and vegetables were recoded the following way: Regularly: $\geq$ 21 times/week, Occasionally: 7-21 times/week, Rarely/never: $\leq$7 times/week. Fast-food, snacks and sugar-sweetened beverages were recoded the following way: Regularly: $\geq$ 2 times/week, Occasionally: $\geq$0.5-2 times/week, Rarely/never: 0 times/week. Further information in chapter 3.7.1. Number of participants who had available data at 24-months were n=67.

Figure 7 shows the distribution of participants who consumed and did not consume the selected foods and beverages at 24-months. 7% of the participants ate fruit or vegetables regularly ($\geq$3 times/day) while 48% ate fruit or vegetables 1-3 times/day. Percentage of participants having a regular intake sugar-sweetened beverages, snacks and fast-foods have decreased.

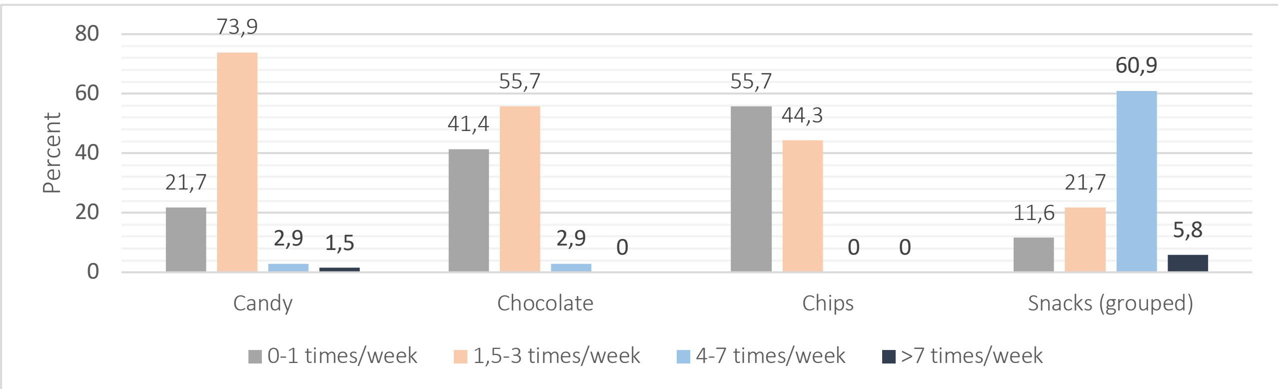

Figure 8: 24-months intake of chocolate, chips, candy and snacks (grouped)

Number of participants in total were n=67 in the graph above.

Figure 8 shows candy and chocolate to be the most frequently eaten snacks at 24-months. The highest percentage of participants consume candy and chocolate 1.5-3 times/week. Chips was less frequently consumed compared to candy and chocolate. For snacks (grouped) 60.9% of participants have an intake equal to 4-7 times/week and 5.8% eat snacks (grouped) >7 times/week. 11.6% of participants eat snacks 0-1 times/week.

Table 7: Mean changes in BMI SDS, metabolic measures and selected dietary variables

Variables	Mean (0)	Mean (24)	Mean (Δ)	95% confidence interval of the difference	Sig. (2-tailed)
BMI SDS	2.75	2.63	0.13	0.04 – 0.21	0.006
Total-cholesterol (mmol/l)	4.69	4.31	0.39	0.17 – 0.60	0.001
HDL-cholesterol (mmol/l)	1.36	1.34	0.02	-0.08 – 0.12	0.697
LDL-cholesterol (mmol/l)	3.03	2.86	0.17	-0.05 – 0.39	0.126
Triglycerides (mmol/l)	1.09	1.05	0.04	-0.16 – 0.24	0.702
Fast-foods	1.6	1.4	0.26	0.02 – 0.51	0.036
Snacks	5.0	4.3	0.75	0.18 – 1.31	0.010
Fruit and vegetables	10.4	9.6	0.88	-0.73 – 2.49	0.279
Sugar-sweetened beverages	2.7	2.0	0.74	-0.54 – 1.31	0.251

BMI SDS change is defined as units. Change in metabolic measures is defined as mmol/l. Change in dietary variables is defined as frequency of intake per week

Mean values may vary from baseline characteristics because of the paired samples t-test model used to determine mean intake at baseline and at 24-months and mean change from between these two times. Number of participants included in the analysis varied between the variables; BMI SDS n=76, metabolic measures n=70 and dietary variables n=67.

Table 7 presents mean changes in BMI SDS, metabolic measures and intake of selected dietary variables. Mean change in BMI SDS from baseline to 24-months were 0.13 units decrease (p=0.002). Change in total cholesterol was statistically significant from baseline to 24-months (p<0.005) with a mean decrease of 0.39 units. LDL-c and triglycerides did decrease but changes were not considered significant at a mean level (p=0.126 and p=0.702 respectively). HDL-c decreased by 0.02 units and change was not considered statistically significant (p=0.740).

Intake of snacks and fast-foods were statistically significant changed from baseline to 24-months with a decrease of 0.75 (p=0.010) and 0.26 portions per week (p=0.036) respectively.

Table 8: Crosstab of percentage of participants within the different percentiles for blood-pressure levels at baseline and 24-months

		Baseline			
		≤ 90th percentile	90–94th percentiles	≥ 95th percentile	Total
24-months	≤ 90th percentile	75 (61)	7 (5)	10 (8)	92 (74)
	90–94th percentiles	1 (1)	1 (1)	1 (1)	3 (3)
	≥ 95th percentile	1 (1)	0 (0)	4 (3)	5 (4)
	Total	77 (63)	8 (6)	15 (12)	100 (81)

Numbers is presented as percentage (n) of participants within each blood-pressure percentile for age - and gender at baseline and 24-months. Total number of participants were n=81 (in which had data on blood pressure at both baseline and 24-months)

Percentage of participants with blood pressure ≥ 95th percentile decreased from 15% to 5% from baseline to 24-months. 8% were within the 90th-94th percentiles at baseline, and this percentage decreased to 3% at 24-months. Percentage within the <90th percentile increased from 78% to 92%.

2 participants moved from <90th percentile (baseline) to either 90th-94th percentile or >95th percentile at 24-months. In logistic regression analysis these were considered as “no change”.

4.1.3 Association between changes in BMI SDS and changes in dietary intake of snacks and fast-foods throughout the active intervention

Linear regression analysis showed no linear association between change variables BMI SDS and Fast-foods and Snacks throughout the study-period. In the scatter-plot below, each participant is represented by a dot, and the color indicates the intervention group (Figure 9).

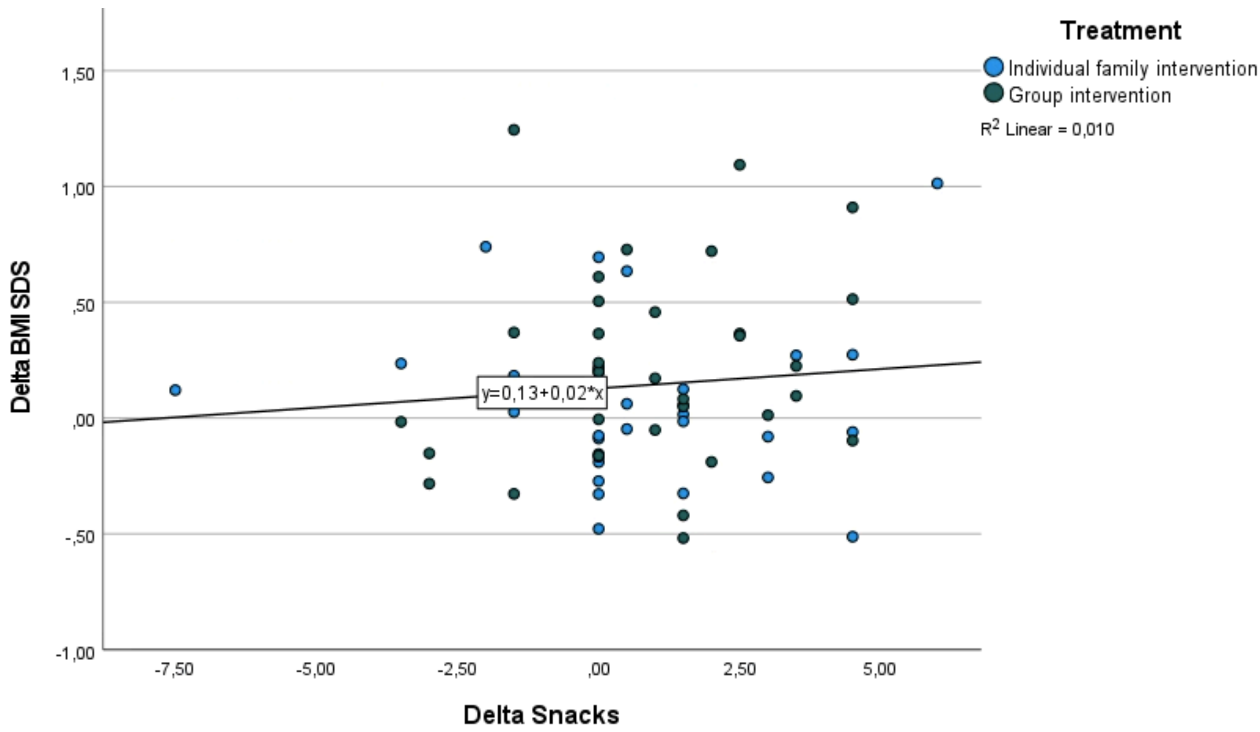

Figure 9: The association between changed intake of snacks and changes in BMI SDS after 24-month participation in Finnmark Activity School

No linear relationship between changes in BMI SDS and changes in intake of snacks were found ($p=0.418$). From looking at the distribution of the scatter-plot most of the participants is positioned around 0 or above 0 on the X-axis. This indicates that majority of participants either kept eating the same amounts of snacks or decreased their intake of snacks throughout the study. However, this finding is too small to conclude on a trend and is not associated with BMI SDS.

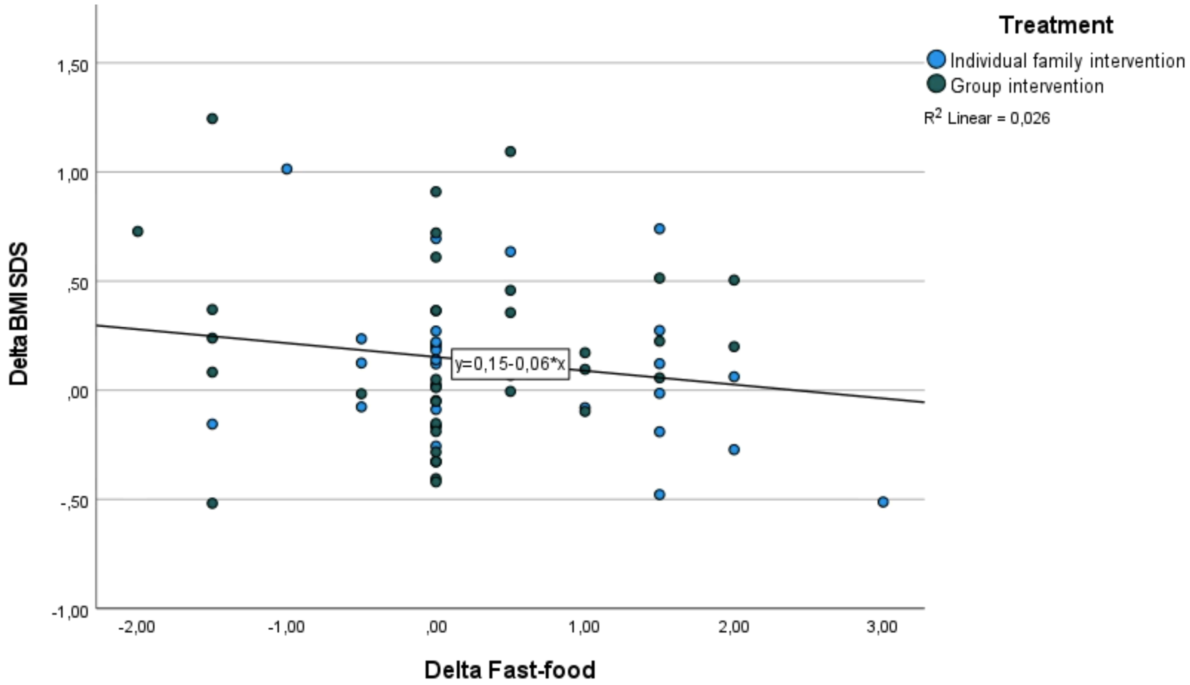

Figure 10: The association between changes in intake of fast-foods and changes in BMI SDS after 24-month participation in Finnmark Activity School

No linear relationship between changes in BMI SDS and changes in intake of fast-foods were found (p=0.189) (Figure 10). From looking at the distribution of the scatter-plot most of the participants were positioned around 0 on the X-axis which indicates small or no changes in intake of fast-foods throughout the study. A negative slope coefficient indicates a decrease in change-variable for BMI SDS, when change-variable for snacks increases. However, this association is not significant. No adjustments for covariates were done in neither of these analyses.

4.1.4 The association between changes in total cholesterol and changes in intake of snacks and fast-foods throughout the active intervention

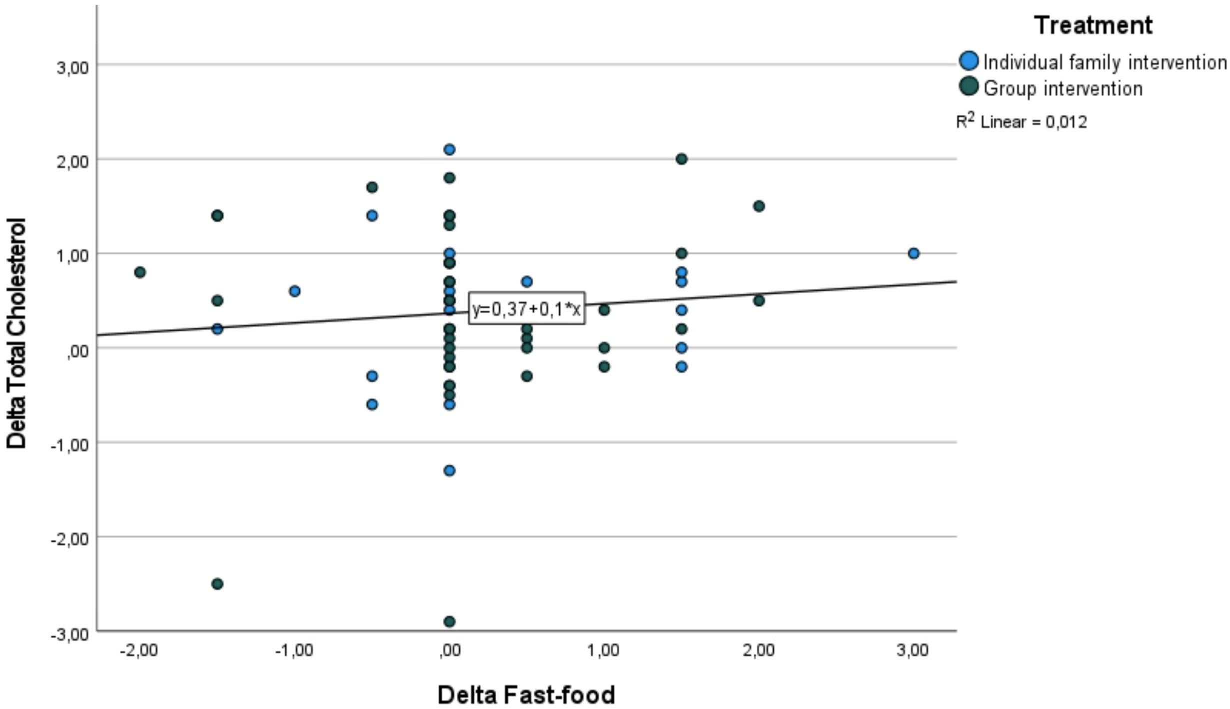

Figure 11: The association between changes in intake of fast-foods and changes in total cholesterol after 24-month participation in Finnmark Activity School

No linear relationship between changes in total cholesterol and change in intake of fast-food were observed (p=0.411) (Figure 11). As seen in the scatter-plot above majority of participants is positioned around 0 on the X-axis, which indicates small or no changes in intake for fast-foods from baseline to 24-months.

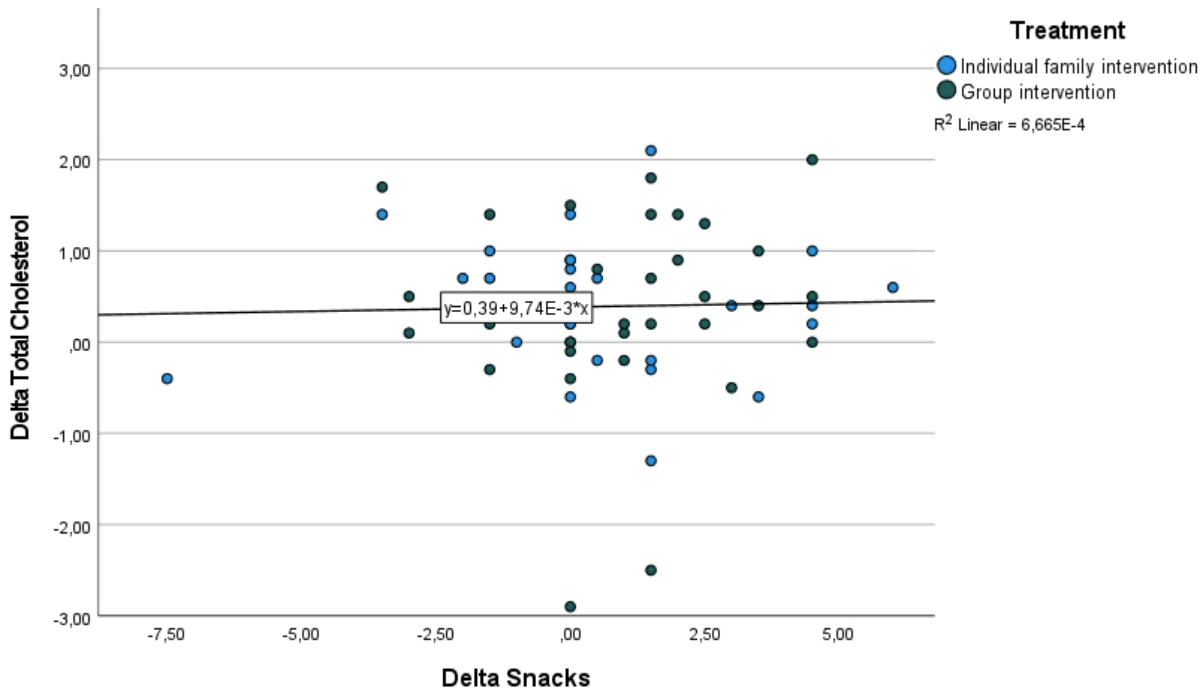

Figure 12: The association between changes in intake of snacks and changes in total cholesterol after 24-month participation in Finnmark Activity School

No linear relationship between changes in total cholesterol and changes in intake of snacks was found (p=0.843) (Figure 12). As for the other scatter-plots a majority of participants are positioned around 0 on the x-axis, indicating small to no changes in intake of snacks throughout the study. One outlier was observed in the scatter-plot. However, the linear regression analysis showed no difference in association when the outlier was removed.

4.1.5 Blood-pressure changes in relation to dietary changes

Logistic regression analysis did not show any association between the dependent variable blood pressure change (yes/no) and the independent dietary change variables (Fruit and vegetables, sugar-sweetened beverages, snacks and fast-foods). OR for all dietary change variables were approximately equal to 1, which indicates a minimal effect on OR for changed blood-pressure when dietary change-variables increase by one unit. For example, if fast-food intake per week decreases from baseline to 24-months by one unit (change-variable increases by one unit) the OR for changing blood-pressure percentile is not changed. Dietary variables do not increase or decrease the OR for decreasing blood-pressure percentile.

Table 9: Logistic regression analysis results

			95% Confidence interval	
	OR	Sig (p-values)	Lower	Upper
Δ Fast food	1.138	0.744	0.524	2.472
Δ Sugar-sweetened beverages	1.040	0.640	0.881	1.228
Δ Snacks	0.981	0.905	0.714	1.347
Δ Fruit and vegetables	0.945	0.355	0.837	1.066

The table shows OR for dietary variables in relation to change in blood pressure percentile. Number of participants included were n=67.

5 Discussion

This chapter is built up by two parts: 5.1 discussing the results and findings, while 5.2 discuss the material and methods. Additionally, a separate part, 5.4 discusses implications for further research within this topic.

5.1 Results

This thesis aimed to describe changes in the selected dietary variables and their relation to changes in BMI SDS and metabolic outcomes independent of treatment method. Mean intake of snacks and fast-food were statistically significant decreased from baseline to 24-months. Albeit, no relationship between dietary change-variables and change in BMI SDS or metabolic outcomes were found. Our study found mean BMI SDS to decrease by -0.13 units from baseline to 24-months, while previous results with pooled data from the two treatment groups showed a significant decrease (-0.14 units) in BMI SDS from baseline to 24-months (88). In this current thesis, total cholesterol decreased by -0.39 mmol/ from baseline to 24-months, which resulted in change from borderline levels to acceptable levels for total cholesterol (Table 1). Previous results also showed decrease in total cholesterol at 36-months for both groups combined (85). Finnmark Activity School's results and our findings regarding BMI SDS and total cholesterol, shows that both interventions had an effect. However, it is unclear what this effect is caused by. The following section will focus on results concerning dietary characteristics at baseline and 24-months, as well as dietary changes throughout the study and potential explanations for the findings.

5.1.1 Baseline characteristics and dietary intake

In this overweight – and obesity intervention study, BMI SDS at baseline was equal to 2.77 SDS above mean for children within the same age and gender. Mean levels of metabolic measures were all according to Table 2 considered borderline levels. Additionally, 22% of participants had elevated blood-pressure levels at baseline. Dietary baseline characteristics included intake of fruit and vegetables, sugar-sweetened beverages, snacks and fast-foods.

2.4 % of participants ate vegetables and 18% ate fruit according to national recommendations at baseline (82). Mean intake of fruit and vegetables combined were 10.4 times/week which is equal to 1.5 times/day. In our study we assumed that in each reported eating (drinking) occasion, one portion/serving was consumed. One serving fruit or vegetables is equal to one handful and the size of one handful for children varies with age and gender. Mean intake in grams from 1.5 handfuls fruit or vegetables for children may be around 75-100 grams in total (95). The amount is low compared to nationwide numbers from Ungkost-3 where mean intake of fruit and vegetables for 4th and 8th graders was approximately 230 grams for both ages (55). However, the method to collect dietary data in Ungkost-3 differs from our method which makes it difficult to compare results.

A physical activity survey from the Norwegian School of Sports science (which included dietary data) by Kolle et al. found that approximately between 30-35% of 6-, 9- and 15-year-old ate fruit and vegetables daily (63). The study by Kolle et al. used the same structured FFQ as our study which makes comparison easier. Our study found 10% of the participants consumed fruit and vegetables ≥ 3 times/day (regularly) and 49% of the participants consumed fruit and vegetables 1-3 times/day (occasionally). Albeit, one specific difference between data in our study compared to Kolle et al., is how the two variables "fruit" and "vegetables" were calculated into one grouped variable. Kolle et al. added intake of fruit and vegetables together at baseline, but participants needed to eat both fruit and vegetables each day to be categorized as daily eaters. In our study, intake of fruit and vegetables were also added together to form one grouped variable, but participants were not required to eat both items to be categorized as "regular" or "occasional" eaters. This may explain why the percentage of participants having a daily intake of fruit and vegetables is lower in the study by Kolle et al. Despite this finding intake for most participants seem to be lower than national recommendations. Perhaps not so surprising considering reported numbers from the HBSC-study which found intake of fruit and vegetables to be low for the majority of children in Norway (57, 61).

A study by Øverby et al. reported a negative association between intake of added sugar and intake of fruit and vegetables (96). This means that when high levels of sugars were observed in children's diet, low intakes of fruit and vegetables were observed as well. High amounts added sugar in diet may replace sufficient intake of fruit and vegetables and lead to a lower intake (96). Total intake of added sugar was not measured in our study, but frequency of intake of sugar-sweetened beverages and snacks were measured. According to Ungkost-3 sugar-sweetened beverages, candy and other sweets are the most common sources of added sugar in Norwegian diet (55). 26-31% of added sugar comes from sugar-sweetened beverages and 31-35% come from sweets and candy (55). Sugar-sweetened beverages were consumed ≥2 times/week by approximately 53% of the participants in this current study. Kolle et al. measured intake of sugar-sweetened soda in 6-, 9- and 15-year old children and found that an intake ≥ 2 times per week varied from about 40-56.7% among participants (intake being highest in 9-year-old boys) (63). Intake of sugar-sweetened beverages were a bit higher in our study compared to Kolle et al. However, our data included both sugar-sweetened soda and cordial, in which Kolle et al. where limited to only sugar-sweetened soda (63).

When comparing our results to the national dietary surveys on children in 4th grade, intake of sugar-sweetened beverages among participants seems to be under the mean nationwide intake (55). Ungkost-2000 found mean intake of sugar-sweetened beverages among 4th grade children to be up to 3 deciliters per day (97). More recent numbers from Ungkost-3 found mean intake among 4th graders to be 1.5 deciliters per day in 2015 (55). Our findings are remarkably lower than nationwide mean intake and only 8.4% of participants consumed sugar-sweetened beverages 1 time/day or more. This may partly be explained by limited types of beverages being included in the FFQ. It is also a possibility that participants were aware of the benefits of limiting sugar-sweetened beverages and had therefore reduced their intake in advance of the baseline survey. Noteworthy, some participants had decreased their BMI SDS in the period from they were accepted to the study to the intervention started (approximately 3 months). This may support our theory that perhaps some dietary changes were carried through before start of the study-period. In addition, there are risk of bias as in all epidemiological studies and these are explained in paragraphs further down.

High intake of energy-dense foods may promote weight-gain explained by the high level of calories per gram in these foods (98). Snacks and fast-foods are considered high energy-dense foods and mean baseline intake were 4.7 times/week (snacks) and 1.7 times/week (fast-foods). Approximately in between 4-5% of Norwegian 6th graders consume candy >5 times/week is according to HBSC-study (99). Data from the HBSC-study only included candy while our data included candy, chocolate and chips. In our study 3.6% of participants had an intake of only candy equal to 4-7 times/week, which shows intake to be lower than results from HBSC-study. There is no direct national recommendation to reduce intake of snacks, but intake of added sugar, saturated fats and salt is recommended to be limited (61, 82). As for snacks, there are no direct dietary recommendation regarding intake of fast-foods, although intake of processed meat, salt and saturated fats is recommended to be limited to a minimum in regular diet (82).

To summarize participants' baseline dietary characteristics: fruit and vegetable intake seems to be below national recommendations. However, compared to the study by Kolle et al. intake of fruit and vegetables seems to be above intake in their study (63). Intake of sugar-sweetened beverages seems to be low compared to nationwide intake. However, our findings may be influenced by limitations in the FFQ. Due to no direct recommendations regarding intake of snacks or fast-foods, we cannot conclude on intake being high or low according to national recommendations. Additionally, comparing results to other studies is challenging due to different methods to collect dietary data and how data is processed.

5.1.2 Dietary changes

Dietary changes were measured by mean change in frequency of intake from baseline to 24-months, using a paired sample t-test. Median change was also measured, although mean change was used due to small differences between the two methods. Mean frequency of intake of snacks decreased by -0.75 times/week and mean frequency of intake of fast-foods decreased by -0.26 times/week.

The significant decrease in snacks and fast-foods and the decrease in fruit and vegetable intake by 0.88 times/week may come as a result of how dietary treatment and counselling were carried through. A randomized controlled trial by Epstein et al. showed a greater decrease in BMI SDS for children who were encouraged to eat healthy and increase low energy-dense foods (such as fruit, vegetables, and low-fat dairy), compared to children who were encouraged to reduce high-energy dense, low-nutrient dense foods (100). It might in dietary treatment of overweight and obese children to limit focus-points during treatment. Changing dietary habits may feel more achievable if focus is either on increasing the healthy or decreasing the unhealthy foods, at least to begin with. In this current study dietary counselling were a combination of reducing the unhealthy and increasing the healthy. A combination of the two is not considered unappropriated, but perhaps limited focus points would be beneficial for children and their families to begin with. These theories may also partly explain why participants decreased their intake of fruit and vegetables, which is considered low energy dense foods, while also decreasing their intake of high energy dense foods such as snacks and fast-foods. Perhaps too much dietary information leads to not all dietary advice being followed.

On the contrary from Epstein et al., a critical review by Griffith et al. discusses more comprehensive dietary treatment to be more successful for weight-management in children (101). Griffith argues that the different structural approaches to dietary therapy in the pediatric population has different effects on children weight (101). Structure in dietary therapy were defined as: low structure focusing on simple tasks as increasing or decreasing intake of dietary items, while high and very high structure targeted larger parts of the diet and had an increased focus on energy-restriction, lower energy dense foods, healthier food-choices. I.e. the more detailed dietary counselling, the better BMI SDS outcome (101). The review by Griffith et al. shows us that greater focus and perhaps resources used on dietary treatment in overweight and obesity interventions may be beneficial for weight loss even in the childhood population.

Although not statistically significant changed, mean frequency of intake of fruit and vegetables decreased from baseline to 24-months. This finding was surprising because dietary counselling throughout the study focused on the promotion of healthy food choices in relation to national dietary guidelines and guidelines for treatment of overweight and obesity in children (12, 82). Fruit and vegetables are often encouraged in dietary treatment of overweight and obesity because these foods can fill up the stomach and increase satiety without adding too many calories to total energy intake (48). On the other hand, this study is conducted on children in ages were interest and preference for fruit and vegetables might be low or non-existing. Additionally, foods presented to children after ages 2-3, are more likely to be disliked because children’s taste preferences are already formed (68). However, in a systematic review by Bourke et al. where interventions to increase fruit and vegetables among children were evaluated, the largest effect size were reported from an intervention carried out in older children. This may indicate that older children may have a better understanding of why they should eat fruit and vegetables, even though it is not their preferable food (68).

The study by Kolle et al. presented frequency of intake of fruit and vegetables for 6-, 9- and 15-year-olds (63). Although Kolle et al. did not measure change in intake, intake in three age-groups was presented. This may tell us something about change in dietary trends and intake of fruit and vegetables as children grow older. Their results show a higher percentage of 6-year-old boys eating fruit and vegetables daily (34.7%) compared to intake among 15-year-olds boys (27%) (63). The same trend was also found in Ungkost-3 (55). This may indicate a decreased interest for fruit and vegetables as children grow older, especially among boys. Ungkost-3 also illustrates that children tend to decrease intake of fruit and vegetable as they start 8th grade (55). This may be seen in relation to children this age receiving more freedom to do their own food-choices, often in parallel with starting a new school and access to cafeterias at school (which is not so common in elementary school 1st-7th grade). Some of the participants in our study were around 8th grade age by the time 24-month measurements were carried out. This information may indicate that the Activity School intervention was not enough to prohibit age-related decrease in intake of fruit and vegetables, which are seen in nationwide studies of children's dietary intake (55).

5.1.3 Dietary changes in relation to BMI SDS change and change metabolic outcomes

No statistically significant association were found between changes in BMI SDS and dietary change-variables, nor any association between dietary changes and changes in metabolic measures (total cholesterol). However, we were able to find a significant decrease in intake of snacks and fast-foods independent of changes in BMI SDS and total cholesterol. As well as both BMI SDS and total cholesterol decreased from baseline to 24-months.

As seen in the scatter-plots presented in chapter 4.1.3 and 4.1.4 there is a high number of participants positioned around 0 on the x-axis, which indicates many of the participants did not change their intake of snacks and fast-foods. The significant decrease in intake of snacks and fast-food may be an important exposure for change in BMI SDS and total cholesterol for some participants (e.g. those having a strong positive change variable). However, our study was not able to prove an association between decrease in snacks or fast-foods with a decrease in BMI SDS or total cholesterol.

In addition, there may be other potential factors associated with change in BMI SDS and total cholesterol, e.g. physical activity. Because of our low number of participants, we did not adjust for physical activity in this current thesis. In conclusion, participants did decrease their BMI SDS and total cholesterol, but we were not able to prove an association with the selected dietary change variables.

5.2 Material and methods

Material and measurements were collected during the active intervention of Finnmark Activity School, in 2009-2013. This chapter includes a discussion about methods to collect anthropometrical, metabolic and dietary data. Further discussion will include how data was processed including how we transformed the dietary variables in order to measure change and how we dealt with missing data.

5.2.1 Study design, representativeness and recruitment

Finnmark Activity School was originally a randomized single-blinded controlled trial, but our data was analyzed as a prospective cohort. Because of the aims of our study, a prospective cohort was considered a better method. Our research question did not aim to evaluate the differences between the two interventions, but rather if there were any association between dietary changes and changes in BMI SDS and metabolic outcomes. Power calculations were carried out for the primary outcome in Finnmark Activity School (RCT) and the study sample were considered large enough to detect differences in primary outcomes (BMI and BMI SDS) (88). However, the study sample size required in an RCT is lower compared to a prospective cohort (102). In addition, our high number of missing at 24-months resulted in a smaller study sample then first predicted.

88 participants were available for our analysis with data from Finnmark Activity School and 83 of these had available dietary data at baseline and were therefore included in this current thesis. From these 83 precisely 67 had dietary data at 24-months measurements (after imputation), which resulted in an attrition equal to 19% from first measurement to second measurement. This attrition was a result of participants not filling out the FFQ and were not necessarily a result of drop-out from the entire study. However, the effects of missing values may be compared to the effects of drop-out. However, we cannot for sure say that there was no difference in dietary characteristics between those who filled out FFQ and those who did not. Non-responder might have certain characteristics that separate them from the remaining participants, which may lead to selection bias (86, p.201). Finnmark Activity School main project did not show any significant difference between participants who dropped out and participants who continued the study (85). We cannot conclude that an intervention is effective, when a high number of participants diet were not measured.

All municipalities in Finnmark were invited to join the study and seven municipalities agreed to participate in the Finnmark Activity School intervention (six in Finnmark and one in Troms county). The Finnmark Activity School trial was a collaborative initiative across primary and specialist care setting, and municipalities included had to agree to contribute to the intervention program. The intervention was mainly carried out in the municipalities, an agreement between hospital and participating municipalities was therefore mandatory. Although the study is limited to seven municipalities these municipalities represent a variation in terms of geographic and demographics: They were both located inland and by the coast as well as in urban and rural areas of the county of Finnmark. The one municipality from Troms county was Tromsø, which is a city of 77 000 habitants (103). Despite the variation in terms of geographic and demographics in Finnmark Activity School the high amount of missing dietary data (19%) presents a challenge in whether we can conclude our subjects being 100% representative for the general population of children having overweight and obesity.

Recruitment of participants were done within a time-period of two years and methods to recruit were through advertisements and media coverage. All eligible participants living within the included municipalities were invited to join the study. A larger study-sample may have strengthened our study. However, the study sample was considered large enough for the original study design (RCT). A larger study sample may not have been realistic to achieve, within the frames of the project Finnmark Activity School. Participants needed to have a BMI equal to BMI $\geq$ 27.5 kg/m^2 for adults. Finnmark county has a high prevalence of childhood overweight and obesity (89). However, when the Activity School intervention were conducted, Finnmark was one of the counties with least inhabitants in total (104). It may not have been a remarkable higher number of children in the specific ages, living in the included municipalities, with a BMI corresponding to adult BMI $\geq$27.5 kg/m^2. As mentioned all municipalities in Finnmark were invited to join to study but not all accepted the invitation. There may have been eligible children living outside the seven included municipalities, but recruitment of children living in other municipalities was not possible. Finnmark Activity School could have invited further municipalities in Troms and/or Nordland county, however the original study had achieved enough statistical strength for their analysis. In addition, several international interventional studies have lower study samples than Finnmark Activity School (105). However, it is not necessarily so that a larger sample size would result in different results. Perhaps the largest limitations in our study is our methods, and particularly the methods to collect dietary data.

5.2.2 Methods

5.2.2.1 Data Collection and transforming dietary data

All anthropometrical and metabolic measures were done by trained personnel and within well-established hospital routines, which increases chances for accurate measures. BMI SDS and metabolic measurements were main and secondary outcomes, and it is considered a strength that they were measured properly. Using BMI SDS as main outcome and the primary measurement for overweight and obesity – has both advantages and limitations (106). BMI SDS is age – and gender adjusted, which makes it a suitable tool for assessing overweight and obesity among children (14, 16). Limitations related to BMI SDS will vary in parallel with the reference population used to calculate the BMI SD score. Moreover, one cannot compare BMI SDS across studies if different reference population is used in the equation. All anthropometrical and metabolic measures were done by trained personnel according to hospital Trust Guidelines, and reliability is considered to be high. However, we could have implemented data from either BIA impedance or DXA scans to validate our anthropometrical measures.

FFQ

Dietary data was collected through an FFQ at baseline and 24-months. The FFQ used in this current thesis was not developed specifically for Finnmark Activity School. The same FFQ was used by Kolle et al. in their study, but it has not been validated to our knowledge (63). Use of FFQ to measure diet is a frequently used in epidemiological settings due to its modest burden on study participants and aims to measure long-term diet (107). Dietary data collection was not a main aim of the Activity School intervention, which is reflected by the simple and limited FFQ used to collect data (Appendix 5). Considering our small study-sample size, it might have been both possible and beneficial to use a different method to collect dietary data.

Other methods to collect dietary data would have been more accurate in order to measure changes in diet in this particular study. For example, 24-hour dietary recall (24-HDR) and dietary records (86, p.403-408). Neither dietary records and 24-HDR aims to measure long-term diet, which in contrary is a strength of using FFQ. However, in order to measure change in diet a long-term method is not necessary (especially not for the second measurement). If these methods were performed frequently throughout the study, they might have been useful in terms of measuring changes in diet.

24-HDR with an interviewer asking the questions would perhaps reduce the amount of missing. However, this method would have to be done multiple times in order to be representative for the participants regular diet at the time, i.e. one day intake is not enough to conclude on a change. Limitations related to 24-HDR may include an increased burden upon the participants. Implementing this method may propose a challenge in resources if the method should be carried through frequently. In addition, this method would be prone to observer bias.

A dietary record method with instructing questions would invite the participant to share their actual dietary intake and we could direct the questions according to what we aimed to measure. In this way we could achieve more information compared to when using an FFQ with closed questions. Dietary records were used in both Ungkost-3 and in the study by Steinsbekk et al. (55, 108). To assure the accuracy of these methods we could combine technology with the main core of dietary records, which have been suggested to reduce participants burden and risk of recall bias, as well as improve the accuracy of dietary measurement (109). A review by Boushey et al. found accuracy of dietary records to improve when using pictures to capture every meal (110). An instant thought is that these methods would imply perfectly to our study. However, these methods are fully dependent on children and families having the technological devices needed to report their diet in pictures – which may present a challenge regarding social differences in society. In addition, this method would present a challenge in recording school-meals or other meals when parents are not with the child.

It is a possibility that dietary recall or 24-HDR method may have improved accuracy in this study. However, we must also consider the overall burden upon participants by changing the method. Given the fact that Finnmark Activity School was a complex intervention with several measurements and questionnaires filled in at different times (Figure 2), it is important to evaluate if changing the method would do more "harm" than good. In conclusion, a more precisely structured FFQ could result in more accurate measures of dietary changes. The amount of missing could have been reduced by researcher going through the questionnaires after they were filled in and quality-checked the respondent's answers. For future dietary research in children, a supplementary method (like records including pictures) to assure accuracy of dietary measure might be beneficial. Moreover, the supplementary methods should be carefully considered to not overgo the overall burden of participants. To optimize use of FFQ's the questionnaire should be developed for the particular study it is used in. In this way it could be used to evaluate effects of the dietary treatment. However, developing new questionnaires is time-consuming and not always prioritized for clinical studies (86, p.403).

Transforming dietary data

Dietary data in our study were originally categorical data and were first recoded into a common scale, i.e. intake per week. Dietary data were then combined (e.g. fruit and vegetables were added together) and at last transformed into change-variables. As seen by the spread of data in the presented scatter-plots (4.1.3 and 4.1.4) the data did not turn completely continuous. However, given the small study-sample and the limited questions in the FFQ, this is not surprising. Perhaps more detailed question, including several types of food items (e.g. different types of fruit and vegetables), would result in wider spread in answers and easier to detect dietary changes. However, we cannot conclude that it would have helped to find changes in intake.

5.2.2.2 Missing data and imputation methods

The dietary data material suffered from a great amount of missing at second measurement. In our study we handled missing values in two steps:

Our FFQ consisted of 3 question that were used to collect dietary intake at baseline and 24-months. One question included a list of beverages, one included water and the last one listed several food items. Missing values for each dietary variable were set to 1 (1=0 times/week or 0 glasses/week) if respondents had answered any value ≥ 1 for any of the food - or beverages within the same question (explained previously in chapter 3.3). This was done because the questionnaire consisted of only 3 dietary questions in total and it seemed reasonable that participants would chose not to answer a question if their intake were equal to zero. We assumed this would be accurate if participants had given an answer to another food – or beverage item within the same question. It may be argued that this method is unprecise, but due to the structure of the FFQ it seemed reasonable to carry through this method. Additionally, we wanted to include as many participants as possible because of a low total number of participants in total and this method is not uncommon (111). However, there is a risk of underestimating intake of foods and beverages by implementing this null-method.

Further, in order to reduce the amount of missing data from 24-month data, we chose to impute values from 12-months measurements where 24-month data were missing. This imputation method is referred to as "Last observation carried forward method" (LOCF) and indicates that the last observed value will be implemented (86, p.292). This method may be considered a conservative imputation-method, but after advice from a statistician we chose this method over other imputation methods such as multiple imputation. Considering the low number of participants in total, we assumed other methods would increase the risk of more inaccurate values. The LOCF-method implies an assumption about no change from last observation. This method risk underestimating values for both BMI SDS, metabolic outcomes and dietary variables. As the results from Finnmark Activity School main project showed a continued decrease in both BMI SDS and total cholesterol from 24-months to 36-months, LOCF will likely lead to an underestimation (85). There is a risk of underestimating dietary intake by implementing the LOCF-method, because participants were part of an intervention and received treatment which aimed to change intake of the measured dietary variables. However, we considered it an advantage in the LOCF-method that we used values from each participant themselves, and not values estimated based on other participants values, as you would do in a multiple imputation. With the lower number of participants and the high number of missing values, finding a suitable set of similar peers to impute from was considered difficult, and it was feared that the imputed values would be inaccurate.

5.2.2.3 Statistical methods

Our statistical methods aimed to detect changes in intake of selected dietary variables. A paired sample t-test was chosen to explore changes in intake of the four selected dietary variables. Mean and median values for dietary variables were compared in advance, and due to small differences between the two a paired sample t-test was chosen. Pearson's - and Spearman's correlation both detected strong correlation between baseline and 24-month dietary variables. Wilcoxon sign rank test could potentially be used and might have been a better fitted test considering our data were not 100% normally distributed. However, after advice from a statistician we analyzed data as if they were normally-distributed.

Linear regression and logistic regression analysis were chosen to explore associations between changes in BMI SDS and dietary change-variables. As well as the association between changes in blood pressure percentile and dietary change variables. Limitations regarding these tests were the decrease in study sample size as a result of a high number of participants missing dietary data at second measurement. A different statistical method may have solved this problem, e.g. Linear Mixed Models. However, this was considered out of scope for this master project.

5.2.3 Confounding

In this current thesis we did not adjust for confounding factors due to the small sample size. Additionally, we used BMI SDS as a measure for outcome, which is age and gender adjusted. Hence, there was no need for adjusting for age and gender in the analysis with BMI SDS as outcome. We considered to adjust for intervention group (treatment), but after advice from a statistician we decided to not adjust due to the small sample-size. However, we included the spread of the two interventions in our scatter-plots in 4.1.3 and 4.1.4. In this way, if there were to be visual differences between the distribution of the two intervention groups, we would be able to see them there.

Physical activity may be a confounding factor for dietary changes and BMI SDS decrease. Baseline and 24-month characteristics included physical activity level which was measured by a fitness test (Andersens test). Although not further analyzed, we could see that mean level of fitness level increased throughout the study (Table 4 and 6). However, further physical activity analysis is required to conclude on an association between decrease in BMI SDS and increase in physical activity level. Participants in Finnmark Activity School measured physical activity level by using an ActiGraph over a couple of days, but these data have not analyzed to this point (41). It is a possibility that participants start to eat healthier when increasing the level of physical activity, this explained by a better regulated appetite (112).

5.3 Limitations and strengths

5.3.1 Strengths

Strengths in Finnmark Activity School included standardized methods for measuring outcome variables: BMI SDS and metabolic measures (Total-cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides and blood pressure). Using standardized hospital methods assures measures of outcome variables to be both accurate and precise. The amount of time the children are followed is considered a strength considering it being an overweight and obesity interventional study. Several interventional studies for overweight and obese children last for about 12 weeks to under a year (105).

In most cases children and parents filled in the questionnaire together. Child and parent filling in information together may be seen as a strength because parents alone may not be able to accurately report the child's dietary intake (87). Additionally, children may not be able to accurately report their normal diet by themselves. Given the method of reporting dietary intake in our study, which aimed to report average intake over time, this method might not be the best suitable method for children alone. However, parents may be prone to for example social desirability bias, which may lead to inaccurate reported intake (113).

5.3.2 Limitations and bias

5.3.2.1 Limitations

Limitations regarding our study includes our methods to collect dietary data. Using an FFQ to collect dietary data is common in epidemiological settings and weaknesses varies with different types of FFQ. FFQ's can be either non-quantitative, semi-quantitative or quantitative (86, p.403-408). Non-quantitative FFQ's does not include amount or portion size, while semi-quantitative FFQ often includes amount within the question, e.g. "how often do you drink 1 glass of soda". The FFQ used in our study was a combination of non-quantitative and semi-quantitative. Additionally, this thesis did not include adjustments for cofounding factors, such as physical activity level.

Portion size

The non – and semi quantitative FFQ is considered a limitation to our study because the FFQ did not collect information about amount or portion size for any of the included food items. No information about amount of food eaten makes it hard to measure changes in dietary intake accurately. According to Willett et al., it is not always necessary to include further information about portion-size or amount if the dietary question is about foods that come in natural units, such as fruit and vegetables (107). Although this may be true for foods such as fruit, vegetables and perhaps hamburgers and hot-dogs, this theory does not withhold strength for all food items included in this current thesis.

In our study we assumed that each reported eating (drinking) occasion, one portion/serving was consumed. However, one portion/serving may vary among individuals and perhaps especially between children in different ages. There is a possibility that participants and parent have quantified each serving differently, which is considered a weakness since we aimed to measure change in intake.

Pizza, chips, candy and sweets are typical energy-dense foods were a “normal portion” may vary between individuals. For example, one portion of chips may be perceived as a small serving bowl (3 deciliters) for one person but as the whole chips-bag for another. Additionally, the serving that is stated on the product is not always realistic for a persons’ actual intake. This particular limitation may lead to some dietary changes not being recognized by our FFQ. If a participant has gone from eating 7 slices of pizza to 3 slices of pizza each time she eats pizza, the FFQ will not be able to detect this dietary change. Similarly, if a person has consumed 1 vegetable for dinner and for lunch each day, and then starts to consume 2 vegetable for both lunch and dinner the FFQ will not notice this change. Although fruit and vegetables are considered low energy-dense foods and intake of two or three carrots may not affect total energy-intake the same way as typical high energy-dense foods, it is important to precisely measure these food items as they were focused on during dietary treatment and counselling. This specific weakness in the structure of our FFQ may have contributed to an underestimation of dietary changes.

FFQ's content

The limited content in the FFQ is a weakness in our study. Although intake of fruit and vegetable, sugar-sweetened beverages, snacks and fast-foods were collected, it may not have been collected with the accuracy required to measure changes over time. Additionally, there are several foods that are not included in the FFQ that may have been focused on in treatment and are important dietary items in overweight – and obesity intervention. This includes cakes, cookies, ice-cream and milk-shakes. Sugar-sweetened soda and cordial makes up the variable sugar-sweetened beverages in terms of this study, and other potential sources are not included. Preferably the FFQ should have covered intake of beverages such as ice tea, chocolate drinks, energy-drinks and soft drinks (Gatorade, powerade etc.). On the other side, a FFQ should not be too long, as it can increase the burden and risk overreporting answers as the participant may get tired (109).

In addition to the limited content, the FFQ should include all dietary aspects that treatment focused on. Treatment focused on national guidelines for prevention and treatment overweight and obesity among children as well as the national dietary guidelines (12, 82) (Appendix 2 and 3). *"The national guidelines for prevention, identification and treatment of overweight and obesity"* aim to promote the following points in treatment: portion sizes and quantify, making healthier food choices, amount snacks, evaluation of types of drinks consumed and meal habits – and patterns. In order to evaluate if participants had an effect of the dietary intervention, the FFQ should cover intake of foods and beverages as well as meal patterns and habits that were focused on in treatment and counselling.

Parents filling in the FFQ

As mentioned previously, the FFQ were filled in by parent and child together, which is both considered a weakness and a strength. Majority of the participants were under 12 years old at baseline and questionnaires were filled in by mother of the child, while only a few participants had their dad fill out the questionnaire (n=3 at baseline). Some participants did turn 12 years within the study-period and were supposed to fill in the FFQ by themselves. However, in our received data material there were no dietary data specified as being filled out by children alone. Perhaps all children filled in the FFQ with their parent(s). Despite this confusion, it is considered a strength that child and parent filled in the questionnaire together. According to Livingstone et al. parent's ability to correctly report child's diet is adequate in home settings, but the method rises concerns because parents are not in the child's presence every hour of every day (87). Parents cannot know by 100% accuracy what their child eat when they are not around and perhaps this is extra challenging when the child gets older and receives more freedom to do their own food choices. We cannot exclude the possibility that our dietary data were influenced by several types of bias.

5.3.2.2 Bias

Use of FFQ to gather dietary information retrospectively were practical for baseline measures because of its approach to collect long-term dietary intake. Despite this advantage there is, as for the other methods to collect dietary information, always a risk of bias. Bias are errors that may influence the validity of the study (86, p.40). Information bias include all type of bias related methods of measuring data, participants reporting and how data is transformed (114). This includes a wide range of different types of bias, in which some of are discussed below:

All anthropometrical metabolic measures were done by trained personnel within Hospital Trust Guidelines. However, one can never exclude the possibility that errors regarding measurement have occurred. For example, plotting wrong data for height and weight may result in wrongful values for BMI SDS. However, no extreme values in terms of BMI SDS were detected in this current thesis.

FFQ is a retrospective method and especially prone to recall bias. Participants were asked to report their average intake, which may result in wrongful reporting simply because it is challenging to remember what you normally consume within your diet (109). Since the FFQ were filled in by child and parent, answers in the FFQ are influenced by parent's ability to recall their child's accurate dietary intake. As mentioned above there is a variation in mothers' ability to report accurate amounts the child eats, and reporting seems to be accurate only for those hours of the day the family spends together (87). In addition, it is not uncommon that study participants achieve a learning-effect by being part of a study and as the study continues more accurate information may be collected. Studies show that when repeated measures are done, for example by participants filling out multiple 24-HDR's correlations between reported intake and "true" intake increases with time (109). The first measures often tend to be more incorrect than the second, third etc. In our study this may lead to wrong results because baseline measurements are especially prone to being biased, i.e. not representing the participants true intake.

Response bias may occur when participants intentionally or unintentionally report answers that does not reflect their true state (115, p.411). For example, participants may unintentionally under-report their dietary intake. Level of under-reporting seem to vary with individual characteristics and is perhaps reinforced by the non-quantitative FFQ structure (116). One type of bias, referred to as social desirability bias often occur when “respondents answer is based on what is perceived as socially acceptable and not the respondents true state” (115, p.411). Hebert et al. explain that social desirability may occur because study-participants want to avoid criticism of their true state and often in situations when they withhold a feeling of being tested (113). It is a possibility that participants reported dietary intake in the FFQ are biased by social desirability. A typical structure of food frequency questionnaires is similar to a test-format and may increase this type of bias according to Hebert et al. (113).

Selection bias refers to how subjects are selected or excluded in the study (114). Considering our high number of missing for dietary data, specially at 24-months it may be a possibility that a high number of participants excluded differ from the subjects included. There is a possibility that participants who were excluded due to missing dietary data differed from the remaining participants in terms of dietary characteristics. It is not uncommon that participants who do not answer to the dietary measurements, are those who do not “succeed” or feel like they do not succeed in terms of the dietary treatment. If participants excluded did not succeed to change their dietary intake, this may have resulted in dietary changes found in our study being “larger” than one in reality could expect.

5.4 Implications for future research and treatment

Finnmark Activity School was conducted a decade ago and several things might have been carried out differently if the study were to be done today. For example, it may have been beneficial to improve the method of collecting dietary data. This may have resulted in more accurate information about participants diet and dietary changes throughout the study. Although we did find some dietary changes to be statistically significant changed, there is a chance that participants did other changes in their diet that methods were not able to measure. In addition, our conservative imputation methods may have resulted in wrongful estimations for dietary intake and changes.

Perhaps a more detailed FFQ, including portion size and several food/drink items as well as improved methods to quality check the given response, could lead to more accurate results. Additionally, dietary measures in an overweight and obesity intervention should include the foods and beverages, as well as dietary behaviour, that were focused on during treatment. This is important in order to evaluate the effect of the dietary intervention. Although this was not our aim, we cannot ignore the topic because majority of overweight – and obesity interventions for children have proven to have moderate to low effects in terms of reducing BMI SDS (11). In order to optimize lifestyle interventions for overweight and obesity, the dietary aspect of the intervention must be carefully evaluated. And to evaluate if dietary changes in relation to treatment focus is carried out by the participant, the method to collect dietary information must aim to measure what treatment focused on.

In order to achieve maximum effect of dietary interventions in the future, it might be beneficial to use technological devices in both treatment and follow-up throughout the active intervention. This could result in closer follow-up and a larger effect from the intervention, specially from the dietary aspect of the intervention. With today's technology and available devices follow-up throughout the study could easily been done by for an example video conference. However, this requires participants to have device required for electronic follow-up. A key advantage of a technological approach is increased accessibility for participants living far away from health centers and hospitals (117). Considering a higher prevalence of overweight and obesity in rural areas, this approach might be beneficial (20). It is not uncommon that questions or issues regarding diet may occur frequently during a year and even more frequently for people in a transition-period of their life. In my opinion, a persistent follow-up by a registered dietitian through video-conferences, for example, once every second month, would be helpful for participants and to achieve better effects of the intervention. This would also assure quality information about diet and dietary struggles, as well as perhaps increased motivation throughout the study-period by achieving encouragement and guidance.

The review by Griffith et al. reported a greater increase in BMI SDS when dietary therapy aimed to target several aspects of diet (101). For future implications, it might be beneficial to focus more on dietary treatment and quality information from dietician. Activity School intervention did perhaps focus on physical level at a higher level compared to dietary therapy. Considering the moderate effects from lifestyle interventions in general, it is important to pay dietary treatment the same amount of focus (11). In addition, implementing dietary treatment at different levels (home, school, community) have proven to be effective in some studies (68). Perhaps future interventions should target dietary therapy more aggressively and individualize the treatment. Group based treatment may not be favorable considering there were no differences in BMI SDS decrease after 3 years in Finnmark Activity School (85). Individual dietary treatment may be the best method considering how different dietary habits across families, cultures, preferences etc. If a more aggressive dietary therapy were to be suggested, it will be even more important with closer follow-up and more frequent counselling sessions with clinical dietitian to optimize quality dietary treatment.

Moreover, to understand what participants and their families were missing from the intervention, a qualitative analysis targeting the children could have been added at the end of the study. In this way, we could achieve knowledge about factors participants were missing during the active intervention, what they experienced as challenging etc. This could show us what we in the future could do differently to maximize the effect of overweight – and obesity interventions for children. A qualitative study by Havdal et al. found dietary behaviors to vary in between children and families with low and high socioeconomic positions (118). Their study found different environmental factors to influence dietary behaviour in the younger population, and these varied with the socioeconomic status. Perhaps interventions need to tackle overweight and obesity at several levels, for example by implementing more community-based approaches.

6 Conclusion

The overweight and obesity intervention Finnmark Activity School had a decreasing effect on BMI SDS and total cholesterol, but we were not able to show a significant explanation for this decrease related to dietary changes. This may be due to the limitations in our methods to collect dietary data. However, we were able to find a decrease in participants intake of snacks and fast-foods from baseline to 24-months. In addition, participants in this overweight and obesity intervention did not seem to differ from the average childhood population in Norway. However, this current study is limited by several weaknesses.

This thesis demonstrates a common challenge in complex intervention studies; it is difficult to obtain good, quality data on several exposure variables without surpassing the overall burden of participants. Albeit, this study suggests the importance of appropriate dietary collection methods which are suited for the study sample and aims of the study. To optimize lifestyle interventions in the future, we must obtain information about what dietary changes are effective. In order to do this, dietary measurements must be focused on.

Further, physical activity level among participants in Finnmark Activity School should be further analyzed in order to evaluate the association between physical activity level and BMI SDS decrease.

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Appendix 1: Iso-BMI 25, 30 and 35 for ages 2-18

Table 10: Iso-BMI 25, 30 and 35 for ages 2-18 (Appendix 1)

Age (year)	Iso-BMI 25 Overweight		Iso-BMI 30 Obesity		Iso-BMI 35 Severe obesity	
	Boys	Girls	Boys	Girls	Boys	Girls
2	18	18	20	20	25	25
2,5	18	18	20	20	25	25
3	18	18	20	19	25	24
3,5	18	17	19	19	24	24
4	18	17	19	19	24	24
4,5	17	17	19	19	24	24
5	17	17	19	19	24	24
5,5	17	17	19	19	24	24
6	18	17	20	20	25	25
6,5	18	18	20	20	25	25
7	18	18	21	21	26	26
7,5	18	18	21	21	26	26
8	18	18	22	22	27	27
8,5	19	19	22	22	27	27
9	19	19	23	23	28	28
9,5	19	19	23	24	28	29
10	20	20	24	24	29	29
10,5	20	20	25	25	30	30
11	21	21	25	25	30	30
11,5	21	21	26	26	31	31
12	21	22	26	27	31	32
12,5	22	22	26	27	31	32
13	22	23	27	28	32	33
13,5	22	23	27	28	32	33
14	23	23	28	29	33	34
14,5	23	24	28	29	33	34
15	23	24	28	29	33	34
15,5	24	24	29	29	34	34
16	24	24	29	29	34	34
16,5	24	25	29	30	34	35
17	24	25	29	30	34	35
17,5	25	25	30	30	35	35
18	25	25	30	30	35	35

The table is modified from “Guidelines for prevention, detection and treatment of overweight and obesity in children» from the Norwegian Directorate of Health (12).

Appendix 2: Dietary circle

Figure 13: Dietary circle (Appendix 2)
The dietary circle is from the Norwegian directorate of Health first found at (82).

Appendix 3: The Norwegian dietary Guidelines

Table 11: The Norwegian Dietary Guidelines from the Norwegian Directorate of Health (Appendix 3)

1	Enjoy a varied diet with lots of vegetables, fruit and berries, whole grain foods and fish, and limited amounts of processed meat, red meat, salt and sugar.
2	Maintain a good balance between the amount of energy you obtain through food and drink and the amount of energy you expend through physical activity.
3	Eat at least five portions of vegetables, fruit and berries every day (1 portion = 100 gram for adults).
4	Eat whole grain foods every day (70-90 g/day whole grain).
5	Eat fish two to three times a week, equivalent to 300-450g unprocessed fish (200g should come from fat fish)
6	Choose lean meat and lean meat products. Limit the amount of processed meat and red meat (max. 500 g/week).
7	Include low-fat dairy foods in daily diet.
8	Choose edible oils, liquid margarine and soft margarine spreads instead of hard margarines and butter.
9	Choose foods that are low in salt and limit the use of salt when preparing food and at the table.
10	Avoid foods and drinks that are high in sugar.
11	Choose water as a thirst-quencher.
12	Be physically active for at least 30 minutes each day.

The Norwegian Dietary Guidelines found at Norwegian Directorate of Health (82)

Appendix 4: Timeline for data collection in Finnmark Activity School

12.1 Tidsplan

Antall måneder i studien

Aktivitet	**0**	**1**	**2**	**3**	**5**	**7**	**10**	**12**	**15**	**18**	**21**	**24**	**30**	**36**
Gruppe 1[1]														
Barneavdeling	3 dager			X				X				X		X
Spørreskjema[2]	X							X				X		X
Klinisk og suppl us.[3]	X							X				X		X
Kroppsfett[4]	X	BMI	BMI	X	BMI	BMI	BMI	X	BMI	BMI	BMI	X	BMI	X
Aktivitet og kondisjon[5]	X							X				X		X
Kosthold[6]	X							X				X		X
Livskvalitet og psyk. Helse[7]	X				X			X				X		X
Bioimpedans-måling	X			X				X				X		X
Helsestasjon		X	X		X	X	X		X	X	X		X	
Friluftsskole					X									
Treningstilbud x 2/uke[8]	→	→	→	→	→	→	→	→	→	→	→	→	→	→
Gruppe 2[10]														
Barneavdeling	X			X				X				X		X
Helsestasjon		X	X		X	X	X		X	X	X		X	

[1] Familiene innkalles gruppevis (7-8 familier pr gruppe) og følges opp gruppevis både på helsestasjon og i barneavdeling.
[2] Sosiodemografiske forhold, søvn
[3] Inkl. Tanners modenhetsvurdering, blodtrykk, RTG ve. hånd. Fastende total, HDL og LDL kolesterol, triglyserider, fastende insulin og glukose, HbA1c, lipoprotein a, c-peptid, leptin, TNFα, FT4, TSH, Vit D,Folinsyre.CRP.
[4] BMI hos barn (inkl BMI SDS) og foreldre, hudfoldmål (subscapular, biceps, triceps, iliac), midjemål
[5] Selvrapportering vha. skjema, skritteller, accellerometri (7 dagers registrering), Andersens test.
[6] Kostdagbok som i Ungkoststudien
[7] Strength and Difficulty Questionnaire, Kindl, Følelse av mening, Foreldreerfaringer (IPE), Selvfølelse (SPPC).
[8] Organisert av aktivitetsteam kommune
[10] Familiene innkalles enkeltvis og følges opp enkeltvis på helsestasjon og i barneavdeling. Følges opp med samme undersøkelser og kontakt frekvens som gruppe1.

Appendix 5: Food Frequency Questionnaire

Kort spørreskjema

1. Alder: ☐☐ år **2.** Kjønn: Jente ☐ Gutt ☐

3. Høyde: ☐☐☐ cm Vekt: ☐☐☐ kg

4. Passer noe av dette for deg? (Sett ett kryss for hver linje)

	Ja	Nei
Spiser vanlig "norsk" kost	☐	☐
Er vegetarianer/veganer	☐	☐
Har diabetes (sukkersyke)	☐	☐
Har matvareallergi	☐	☐
Forsøker å gå ned i vekt	☐	☐
Har spesiell diett av andre grunner	☐	☐
Annet ______	☐	☐

5. Hva syns du om vekta di? (Sett ett kryss)

- Den er passe ☐
- Jeg veier for mye ☐
- Jeg veier for lite ☐

6. Røyker du? (Sett ett kryss)

- Nei ☐
- Ja, av og til ☐
- Ja, daglig ☐

7. Tror du kostholdet spiller noen rolle for helsa di? (Sett ett kryss)

- Nei ☐
- Ja, men ikke nå, bare når jeg blir eldre ☐
- Ja, både nå og seinere i livet ☐
- Vet ikke ☐

8. Hvordan vurderer du ditt eget kosthold? (Sett ett kryss)

- Det er veldig sunt ☐
- Det er ganske sunt ☐
- Det er usunt ☐
- Vet ikke ☐

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9. Utenom skoletid: **Hvor ofte** driver du idrett, eller mosjonerer du så mye at du blir andpusten og/eller svett (Sett ett kryss)?

- ☐ Aldri
- ☐ Mindre enn en gang i mnd.
- ☐ 1-3 ganger i mnd.
- ☐ En gang i uka
- ☐ 2-3 ganger i uka
- ☐ 4-6 ganger i uka
- ☐ Hver dag

10. Utenom skoletid: **Hvor mange timer i uka** driver du idrett, eller mosjonerer så mye at du blir andpusten og/eller svett (Sett ett kryss)?

- ☐ Ingen
- ☐ omtrent 1/2 time
- ☐ omtrent 1 time
- ☐ omtrent 2-3 timer
- ☐ omtrent 4-6 timer
- ☐ 7 timer eller mer

11. Utenom skoletid: **Hvor mange timer per dag** pleier du å se på TV og/eller sitte foran PC'en (Sett ett kryss)?

- ☐ Ikke i det hele tatt
- ☐ mindre enn en 1/2 time om dagen
- ☐ 1/2-1 time
- ☐ 2-3 timer
- ☐ 4 timer
- ☐ mer enn 4 timer

12. Hvilken utdanning har din mor og far? (Sett ett kryss for høyest fullførte utdannelse hos mor og ett kryss for høyest fullførte utdannelse hos far)

	Mor	Far
9-årig skole eller kortere	☐	☐
Grunnkurs/ett-årig utdannelse utover 9-årig skole	☐	☐
Videregående skole/gymnas/yrkesskole (3 årig)	☐	☐
Høyskole- eller universitetsutdanning på 4 år eller mindre	☐	☐
Høyskole- eller universitetsutdanning på mer enn 4 år	☐	☐
Annet ______	☐	☐

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I det følgende spør vi om dine spisevaner slik de vanligvis er. Vi er klar over at kostholdet varierer fra dag til dag. Prøv derfor så godt du kan å gi et "gjennomsnitt" av dine spisevaner. Ha det siste året i tankene når du svarer. Der du er usikker, anslå svaret.

13. Hvor ofte pleier du å spise følgende måltider i løpet av en uke ? (Sett ett kryss for hvert måltid)

	Aldri/ Sjelden	1 gang i uken	2 ganger i uken	3 ganger i uken	4 ganger i uken	5 ganger i uken	6 ganger i uken	Hver dag
Frokost	☐	☐	☐	☐	☐	☐	☐	☐
Formiddagsmat/lunsj	☐	☐	☐	☐	☐	☐	☐	☐
Middag	☐	☐	☐	☐	☐	☐	☐	☐
Kveldsmat	☐	☐	☐	☐	☐	☐	☐	☐

14. Hvis du spiser formiddagsmat/lunsj på hverdagene, hvor ofte spiser du følgende i løpet av en uke? (Sett ett kryss for hver linje)

	Aldri/ Sjelden	1 gang i uken	2 ganger i uken	3 ganger i uken	4 ganger i uken	5 ganger i uken
Matpakke hjemmefra	☐	☐	☐	☐	☐	☐
Kjøper mat i kantine/matbod på skolen	☐	☐	☐	☐	☐	☐
Kjøper mat fra butikk/kiosk i nærheten	☐	☐	☐	☐	☐	☐

15. Hvor mye drikker du vanligvis av følgende drikker? (Sett ett kryss for hver drikke) (3 glass=1/2 liter)

	Drikker aldri/sjelden	1-3 glass per md	1-3 glass per uke	4-6 glass per uke	1-3 glass per dag	4-6 glass per dag	7 glass el. mer per dag
Helmelk (søt/sur)	☐	☐	☐	☐	☐	☐	☐
Lettmelk (søt/sur)	☐	☐	☐	☐	☐	☐	☐
Ekstra lett lettmelk	☐	☐	☐	☐	☐	☐	☐
Skummet melk (søt/sur)	☐	☐	☐	☐	☐	☐	☐
Appelsinjuice	☐	☐	☐	☐	☐	☐	☐
Saft med sukker	☐	☐	☐	☐	☐	☐	☐
Saft kunstig søtet	☐	☐	☐	☐	☐	☐	☐
Brus med sukker	☐	☐	☐	☐	☐	☐	☐
Lett brus, kunstig søtet	☐	☐	☐	☐	☐	☐	☐

16. Bruker du vanligvis margarin/smør på brødskiven? ☐ Ja ☐ Nei

45203

17. Hvor mange ganger spiser du følgende matvarer? (Sett ett kryss for hver matvare)

	Aldri/ Sjelden	1-3 ganger per mnd	1-3 ganger per uke	4-6 ganger per uke	1 gang per dag	2 ganger per dag	3 ganger per dag	4 ganger eller flere per dag
Kokte poteter	☐	☐	☐	☐	☐	☐	☐	☐
Pommes frites	☐	☐	☐	☐	☐	☐	☐	☐
Grønnsaker	☐	☐	☐	☐	☐	☐	☐	☐
Frukt, bær	☐	☐	☐	☐	☐	☐	☐	☐
Grovbrød	☐	☐	☐	☐	☐	☐	☐	☐
Fisk til middag	☐	☐	☐	☐	☐	☐	☐	☐
Pizza	☐	☐	☐	☐	☐	☐	☐	☐
Hamburger/pølse med brød/kebab	☐	☐	☐	☐	☐	☐	☐	☐
Godterier	☐	☐	☐	☐	☐	☐	☐	☐
Sjokolade	☐	☐	☐	☐	☐	☐	☐	☐
Potetgull o.l.	☐	☐	☐	☐	☐	☐	☐	☐
Peanøtter	☐	☐	☐	☐	☐	☐	☐	☐
Tran, trankapsler	☐	☐	☐	☐	☐	☐	☐	☐
Vitamintilskudd	☐	☐	☐	☐	☐	☐	☐	☐

ID nummer, internt bruk

45203

Appendix 6: Letter to participants

FINNMARKSSYKEHUSET
FINNMÁRKKU BUOHCCIVIESSU

Hammerfest 27.10.2020

Kjære deltaker i Aktivitetsskolen i Finnmark
I perioden 2009-2013 ble det samlet inn om opplysninger om deg i forbindelse med Aktivitetsskolen. Det var dine foresatte som samtykket til det siden du da var under 16 år. Siden du nå er over 16 år kan du selv bestemme om vi fortsatt skal kunne bruke disse opplysningene. Vi sender deg dette brevet for å informere om at vi fremdeles ønsker å bruke data fra Aktivitetsskolen til forsking dersom du selv ikke ønsker å reservere deg mot dette.

Ved å delta i Aktivitetsskolen har du bidratt til viktig helseforskning. For at vi skal kunne gjøre ytterligere studier så er det nødvendig å gi deg denne informasjon og samtidig gi anledning til å reservere deg mot videre forskning på opplysninger og blodprøver du har bidratt med i prosjektet.

Nytt masterprosjekt i Aktivitetsskolen

Tittelen på det tiltenkte prosjektet er ''Effekten av kostholdsendringer på overvekt hos barn som deltok i et 24 måneders langt behandlingsløp''. Hensikten med prosjektet er å undersøke hvilken betydning kostholdsendringer spilte hos deltakerne i Aktivitetsskolen som ved slutten av prosjektet oppnådde en vektstabilisering. Det er av interesse å undersøke hvilke kostholdsendringer som er effektive og gjennomførbare hos barn som har overvekt. Behandling av overvekt hos barn består som regel av en kombinasjon av hjelp til endringer i hverdagen i form av mer fysisk aktivitet og sunnere kost i de aktuelle familier. Dette prosjektet med utgangspunkt i Aktivitetsskolens datamateriale kan være et viktig steg på veien for å optimalisere behandlingen av overvekt hos barn. **Vi planlegger prosjektstart tre uker fra når dette brevet er datert.**

Reservasjonsrett og rett til innsyn
Det er frivillig å delta i Aktivitetsskolen. Du har rett til innsyn i hvilke opplysninger som er registrert om deg og kan til **ethvert tidspunkt** be om å få rettet opplysninger, reservere deg, og be om at vi fjerner innsamlede prøver og opplysninger om deg. Vi kan ikke fjerne vitenskapelige artikler der dine data allerede er brukt i anonymisert form og uansett ikke kan knyttes til deg som enkeltperson.

Du kan klage på behandlingen av dine opplysninger til Personvernombudet (se over) eller til Datatilsynet. Datatilsynet kan nås på e-post: postkasse@datatilsynet.no eller telefon: (+47) 22 39 69 00.
Dersom du aksepterer at dine helseopplysninger brukes som beskrevet over, trenger du ikke foreta deg noe.

Postadresse
Finnmarkssykehuset
Sykehusveien 35
9601 Hammerfest

Besøksadresse
Hammerfest sykehus
Sykehusveien 35
9601 Hammerfest

Tlf, sentralbord: 78 42 10 00
postmottak@finnmarkssykehuset.no
www.finnmarkssykehuset.no

Organisasjonsnummer
983 974 880

Appendix 7: Approvals

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK nord	Maren Melsbø	77620748	07.09.2020	151865
			Deres referanse:	

Guri Skeie

151865 Hvilken effekt har kostholdsendringer på vektnedgang og blodlipidnivå; En studie av barn med overvekt og fedme som fulgte 2-års behandlingsprogram

Forskningsansvarlig: UiT Norges arktiske universitet

Søker: Guri Skeie

Søkers beskrivelse av formål:

Masterprosjektet har som formål å undersøke hvilke kostholdsendringer som er effektive i behandlingen av barn med overvekt og fedme. Det er en høy forekomst av barn og unge med overvekt eller fedme i dagens samfunn, og behandlingen er ikke alltid vellykket.

Studien er en del av tidligere prosjekt ''Aktivitetsskolen i Finnmark'' og bruker samme datamateriale for å besvare problemstillingen. Studiedeltakerne i studien er barn i alderen 6-12 år, som i studieperioden var bosatt i daværende Troms eller Finnmark fylke. Inklusjonskriterier var BMI over eller lik 27,5 og tilstedeværelse av 1-2 foreldre. Eksklusjonskriterier var basert på om barnet ikke var i stand til å delta på aktiviteter og gruppebehandling.

Studien inkluderer data om høyde og vekt, som brukes i form av BMI standard deviation score (SDS) og alders – og kjønnsjustert BMI. I tillegg inkluderer studien blodprøver med alle aktuelle blodlipidnivåer (Total kolesterol, LDL kolesterol, HDL kolesterol, Triglyserider). Alle målinger er målt på tidspunktene 0, 12 og 24 måneder etter oppstart av Aktivitetsskolen, og blodprøvene er ferdig analyserte.

Informasjon om kosthold er samlet inn ved hjelp av et matvarefrekvensskjema, som er fylt ut av barn og foreldre ved tilsvarende tidspunkt, 0, 12 og 24 måneder. Kostholdsskjemaene som er brukt til innsamling av data er enkelt strukturert og inneholder blant annet spørsmål om frukt og grønnsaker, ulike drikkevarer, inntak av prosesserte kjøttprodukter, fisk og bruk av smør/margarin, i tillegg til søtsaker og snacks.

Studien er en prospektiv kohort, som skal ta for seg de studiedeltakerne som hadde en vellykket behandling. BMI SDS (muligens supplementert av BMI) vil brukes som mål på om deltakeren i studien har oppnådd en vellykket behandling i løpet av en 2 års periode (Baseline til 24 mnd). Det er definert grenseverdier for hva som regnes som vellykket behandling for BMI SDS. I denne studien skal man gå tilbake å se på hva slags type kostholdsendringer som kjennetegner gruppen med vellykket behandling, og om det er noen kostholdsendringer som denne gruppen kan tillegges, i motsetning til gruppen som ikke oppfyller kriteriene for vellykket behandling.

Informasjon om kostholdsendringer hos deltakerne med god effekt av behandlingen vil

REK nord **Telefon**:77 64 61 40 | **E-post**:rek-nord@asp.uit.no
Besøksadresse: MH-2, 12. etasje, UiT Norges arktiske universitet, Tromsø **Web**:https://rekportalen.no

være med og bidra med nytte og råd for helsepersonell i denne kliniske utfordringen. Det kan være med å gi informasjon om hva slags type endringer som er relevante og gjennomførbare for barn med alvorlig overvekt og fedme.

REKs vurdering

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk REK Nord i møtet 20.08.2020.

Formål
Av prosjektbeskrivelsen følger at formålet med studien er: *«å undersøke hvilke kostholdsendringer som er effektive i behandlingen av barn med overvekt og fedme.»*

Av protokollen følger: «*The aim of the study is to investigate the importance and relevance of diet in an obesity treatment program for children, in order to maximize effect of treatment in the future. Research question: Are there any changes in diet that are recognized from baseline to 12 and 24 months, that are associated with weight decrease (BMI SDS > 0,20) after 1- or 2-year treatment?»*

Om prosjektet
Prosjektet er del av en master i klinisk ernæring.

Prosjektstart er i søknaden satt til 17.08.2020. REK forutsetter at prosjektet ikke igangsettes før nødvendige godkjenninger foreligger.

Studien ønsker å belyse «hvilke type kostholdsendringer som kjennetegner gruppen med vellykket behandling, og om det er noen kostholdsendringer som denne gruppen kan tillegges, i motsetning til gruppen som ikke oppfyller kriteriene for vellykket behandling.» Studien skal benytte et datasett som allerede er samlet inn i prosjektet 21089 «Gir Aktivitetsskolen i Finnmark organisert for barn med fedme og deres familier bedre behandlingsresultater enn dagens behandlingstilbud i barnepoliklinikken?», en RCT som sammenlikner to ulike intervensjoner. Dette prosjektet ble godkjent av REK nord i 2007 og har godkjenning frem til 30.12.2021.

REK presiserer at prosjektet 21089 ikke har hjemmel til å dele data med nå omsøkte prosjekt etter at godkjenning for dette løper ut 30.12.2021. Dette innebærer at koblingsnøkkel skal behandles iht. godkjenningen i prosjekt 21089 og slettes innen 30.12.2021.

Data/materiale
Studien skal benytte allerede innsamlede data om kosthold, høyde og vekt, bakgrunnsvariabler som alder, kjønn og fysisk aktivitet, samt lipidverdier fra tidligere analyserte blodprøver.

Deltakere
Alle tidligere deltakere i prosjektet «Aktivitetsskolen i Finnmark» inkluderes. I studien deltok 91 barn i alderen 6 til 12 år.

Forespørsel/informasjon/samtykkeerklæring
Alle deltakerne i prosjekt 21089 samtykket til deltakelse. I samtykket ble det opplyst at deltakerne skulle besvare spørreskjema om spisevaner, kost, aktivitet og trivsel.

Under formålet med studien 21089 i protokollen står det at *«Det overordnede målet er å øke kompetansen om hvilke metoder som er effektive og hensiktsmessige med hensyn til å behandle barn med fedme og å øke kunnskapen om faktorer som fremmer livsstilsendring i de aktuelle familier.»*

I det omsøkte prosjektet skal analysene utføres på det allerede innsamlede datasettet, på variabler som tidligere er blitt analysert. Formålet med nå omsøkte prosjekt er å undersøke hvilke kostholdsendringer som er effektive i behandlingen av barn med overvekt og fedme.

Med bakgrunn i ovennevnte vurderer REK at nå omsøkte prosjekt ligger innenfor deltakernes opprinnelige samtykke.

Data utleveres fra prosjektet 21089 uten direkte eller indirekte personopplysninger i henhold til avgitt samtykke.

Vedtak

Godkjent

REK har gjort en helhetlig forskningsetisk vurdering av alle prosjektets sider og godkjenner det med hjemmel i helseforskningsloven § 10.

Prosjektet er godkjent frem til omsøkt sluttdato 01.06.2022. Data skal oppbevares for kontrollhensyn i 5 år etter prosjektslutt. Etter dette skal data anonymiseres eller slettes.

Vi gjør samtidig oppmerksom på at etter personopplysningsloven må det også foreligge et behandlingsgrunnlag etter personvernforordningen. Dette må forankres i egen institusjon.

MVH
May Britt Rossvoll
Sekretariatsleder

Sluttmelding
Søker skal sende sluttmelding til REK nord på eget skjema senest seks måneder etter godkjenningsperioden er utløpt, jf. hfl. § 12.

Søknad om å foreta vesentlige endringer
Dersom man ønsker å foreta vesentlige endringer i forhold til formål, metode, tidsløp eller organisering, skal søknad sendes til den regionale komiteen for medisinsk og helsefaglig forskningsetikk som har gitt forhåndsgodkjenning. Søknaden skal beskrive hvilke endringer som ønskes foretatt og begrunnelsen for disse, jf. hfl. § 11.

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK nord	Maren Melsbø	77620748	21.10.2020	21089
			Deres referanse:	

Ane Sofie Kokkvoll

21089 Gir Aktivitetsskolen i Finnmark organisert for barn med fedme og deres familier bedre behandlingsresultater enn dagens behandlingstilbud i barnepoliklinikken?

Forskningsansvarlig: Finnmarkssykehuset

Søker: Ane Sofie Kokkvoll

REKs vurdering

Vi viser til søknad om prosjektendring for ovennevnte forskningsprosjekt mottatt 16.10.2020. Søknaden er behandlet av sekretariatet i REK nord på delegert fullmakt fra komiteen, med hjemmel i forskningsetikkforskriften § 7, første ledd, tredje punktum. Søknaden er vurdert med hjemmel i helseforskningsloven § 11.

Av endringssøknaden fremgår følgende: *"I forbindelse med det nye masterprosjektet «Hvilken effekt har kostholdsendringer på vektnedgang og blodlipidnivå; En studie av barn med overvekt og fedme som fulgte et 2-års behandlingsprogram» REK151865, ble det i dialog med Finnmarkssykehusets personvernombud og NDS anbefalt at det sendes ut et nytt informasjonsskriv til deltakere i Aktivitetsskolen. De er nå alle fylt 16 år og trenger nå å få oppdatert informasjon om forskningen i Aktivitetsskolen og at de kan reservere seg mot videre bruk av deres personopplysninger, dersom de ønsker det."*

I informasjonsskrivet opplyses det at mastergradsprosjektets varighet er til 01.01.2022. Informasjonsskrivet gjelder for hele prosjektet (Aktivitetsskolen) ikke bare for masterprosjektet, det er derfor godkjent dato for hele prosjektet, 30.12.2021, som skal oppgis i informasjonsskrivet.

Videre mangler informasjonsskrivet følgende setning: «Opplysningene om deg vil bli oppbevart i fem år etter prosjektslutt av kontrollhensyn». Eventuelle avvik fra dette må redegjøres for i teksten. Redegjør også dersom opplysningene skal oppbevares et annet sted enn egen institusjon.

Under forutsetning av at informasjonsskrivet rettes i tråd med ovennevnte har REK ingen innvendinger til nytt informasjonsskriv til deltakere i Aktivitetsskolen.

Revidert informasjonsskriv imøteses og kan sendes inn som vedlegg til henvendelse i portalen.

REK nord **Telefon**:77 64 61 40 | **E-post**:rek-nord@asp.uit.no
Besøksadresse: MH-2, 12. etasje, UiT Norges arktiske universitet, Tromsø **Web**:https://rekportalen.no

Etter fullmakt er det fattet slikt

Vedtak

Godkjent

Med hjemmel i helseforskningsloven § 11 godkjennes prosjektendringen.

Med vennlig hilsen

May Britt Rossvoll
sekretariatsleder

Monika Rydland
rådgiver

Søknad om å foreta vesentlige endringer
Dersom man ønsker å foreta vesentlige endringer i forhold til formål, metode, tidsløp eller organisering, skal søknad sendes til den regionale komiteen for medisinsk og helsefaglig forskningsetikk som har gitt forhåndsgodkjenning. Søknaden skal beskrive hvilke endringer som ønskes foretatt og begrunnelsen for disse, jf. hfl. § 11.

Sluttmelding
Søker skal sende sluttmelding til REK nord på eget skjema senest seks måneder etter godkjenningsperioden er utløpt, jf. hfl. § 12.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK nord. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK nord, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag (NEM) for endelig vurdering.

NORSK SENTER FOR FORSKNINGSDATA

NSD sin vurdering

Prosjekttittel

The effect of changes in diet to improve BMI SDS and blood lipid levels: a study of children with overweight or obesity who followed a 24-month treatment program

Referansenummer

633686

Registrert

03.07.2020 av Thea Berglund - tbe107@post.uit.no

Behandlingsansvarlig institusjon

UIT – Norges Arktiske Universitet / Det helsevitenskapelige fakultet / Institutt for helse- og omsorgsfag

Prosjektansvarlig (vitenskapelig ansatt/veileder eller stipendiat)

Guri Skeie, Guri.skeie@uit.no, tlf: 41042690

Type prosjekt

Studentprosjekt, masterstudium

Kontaktinformasjon, student

Thea Berglund, tbe107@uit.no, tlf: 91156683

Prosjektperiode

01.08.2020 - 31.12.2021

Status

09.11.2020 - Vurdert

Vurdering (1)

09.11.2020 - Vurdert

BAKGRUNN
Prosjektet er vurdert og godkjent av Regionale komiteer for medisinsk og helsefaglig forskningsetikk (REK) etter helseforskningsloven (hfl.) § 10, med påfølgende endringsmelding etter helseforskningsloven (hfl.) § 11

(REK sin ref: 151865).

Det er vår vurdering at behandlingen av personopplysninger i prosjektet vil være i samsvar med personvernlovgivningen så fremt den gjennomføres i tråd med det som er dokumentert i meldeskjemaet den 09.11.2020 med vedlegg, samt i meldingsdialogen mellom innmelder og NSD. Behandlingen kan starte.

MELD VESENTLIGE ENDRINGER
Dersom det skjer vesentlige endringer i behandlingen av personopplysninger, kan det være nødvendig å melde dette til NSD ved å oppdatere meldeskjemaet. Før du melder inn en endring, oppfordrer vi deg til å lese om hvilke type endringer det er nødvendig å melde: https://nsd.no/personvernombud/meld_prosjekt /meld_endringer.html
Du må vente på svar fra NSD før endringen gjennomføres.

TYPE OPPLYSNINGER OG VARIGHET
Prosjektet vil behandle særlige kategorier av personopplysninger om helseforhold og alminnelige kategorier av personopplysninger frem til 31.12.2021.

LOVLIG GRUNNLAG
De registrerte har samtykket til behandlingen av personopplysninger. Vår vurdering er at prosjektet legger opp til et samtykke i samsvar med kravene i art. 4 nr. 11 og art. 7, ved at det er en frivillig, spesifikk, informert og utvetydig bekreftelse, som kan dokumenteres, og som den registrerte kan trekke tilbake.

Lovlig grunnlag for behandlingen vil dermed være den registrertes uttrykkelige samtykke, jf. personvernforordningen art. 6 nr. 1 bokstav a, jf. art. 9 nr. 2 bokstav a, jf. personopplysningsloven § 10, jf. § 9 (2).

PERSONVERNPRINSIPPER
NSD vurderer at den planlagte behandlingen av personopplysninger vil følge prinsippene i personvernforordningen om:

- lovlighet, rettferdighet og åpenhet (art. 5.1 a), ved at de registrerte får tilfredsstillende informasjon om og samtykker til behandlingen
- formålsbegrensning (art. 5.1 b), ved at personopplysninger samles inn for spesifikke, uttrykkelig angitte og berettigede formål, og ikke viderebehandles til nye uforenlige formål
- dataminimering (art. 5.1 c), ved at det kun behandles opplysninger som er adekvate, relevante og nødvendige for formålet med prosjektet
- lagringsbegrensning (art. 5.1 e), ved at personopplysningene ikke lagres lengre enn nødvendig for å oppfylle formålet

DE REGISTRERTES RETTIGHETER
Så lenge de registrerte kan identifiseres i datamaterialet vil de ha følgende rettigheter: åpenhet (art. 12), informasjon (art. 13), innsyn (art. 15), retting (art. 16), sletting (art. 17), begrensning (art. 18), underretning (art. 19), dataportabilitet (art. 20).

I utgangspunktet har alle som registreres i forskningsprosjektet rett til å få slettet opplysninger som er registrert om dem. Etter helseforskningsloven § 16 tredje ledd vil imidlertid adgangen til å kreve sletting av sine helseopplysninger ikke gjelde dersom materialet eller opplysningene er anonymisert, dersom materialet etter bearbeidelse inngår i et annet biologisk produkt, eller dersom opplysningene allerede er inngått i utførte analyser. Regelen henviser til at sletting i slike situasjoner vil være svært vanskelig og/eller ødeleggende for forskningen, og dermed forhindre at formålet med forskningen oppnås.

Etter personvernforordningen art 17 nr. 3 d kan man unnta fra retten til sletting dersom behandlingen er nødvendig for formål knyttet til vitenskapelig eller historisk forskning eller for statistiske formål i samsvar med artikkel 89 nr. 1 i den grad sletting sannsynligvis vil gjøre det umulig eller i alvorlig grad vil hindre at målene med nevnte behandling nås.

NSD vurderer dermed at det kan gjøres unntak fra retten til sletting av helseopplysninger etter helseforskningslovens § 16 tredje ledd og personvernforordningen art 17 nr. 3 d, når materialet er bearbeidet slik at det inngår i et annet biologisk produkt, eller dersom opplysningene allerede er inngått i utførte analyser.
Vi presiserer at helseopplysninger inngår i utførte analyser dersom de er sammenstilt eller koblet med andre opplysninger eller prøvesvar. Vi gjør oppmerksom på at øvrige opplysninger må slettes og det kan ikke innhentes ytterligere opplysninger fra deltakeren.

Det skal sendes ut ny informasjon til utvalget om den videre behandlingen av personopplysninger og dette prosjektet. NSD vurderer at informasjonen som de registrerte vil motta oppfyller lovens krav til form og innhold, jf. art. 12.1 og art. 13.

Vi minner om at hvis en registrert tar kontakt om sine rettigheter, har behandlingsansvarlig institusjon plikt til å svare innen en måned.

FØLG DIN INSTITUSJONS RETNINGSLINJER
NSD legger til grunn at behandlingen oppfyller kravene i personvernforordningen om riktighet (art. 5.1 d), integritet og konfidensialitet (art. 5.1. f) og sikkerhet (art. 32).

UiO gjennom lagring på TSD er databehandler i prosjektet. NSD legger til grunn at behandlingen oppfyller kravene til bruk av databehandler, jf. art 28 og 29.

For å forsikre dere om at kravene oppfylles, må dere følge interne retningslinjer og eventuelt rådføre dere med behandlingsansvarlig institusjon.

OPPFØLGING AV PROSJEKTET
NSD vil følge opp ved planlagt avslutning for å avklare om behandlingen av personopplysningene er avsluttet.

Lykke til med prosjektet!

Kontaktperson hos NSD: Jørgen Wincentsen
Tlf. Personverntjenester: 55 58 21 17 (tast 1)