Managing childhood obesity
The Finnmark Activity School

Ane Sofie Kokkvoll

A dissertation for the degree of Philosophiae Doctor – December 2014
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Dedicated my parents and caregivers
Randi, Arne, Titti and Gunleif
who had faith in me from the beginning

Makjella, Sørøya Finnmark

Photo: Tor Harry Bjørn
1 Preface

1.1 Perspective

As a paediatrician working in a small paediatric department in the northernmost county of Norway, I met parents and their children struggling with obesity several times a week. The impaired general health and well-being presented by many of these children made a strong impact on me. The absence of evidence based tools and guidelines in order to alleviate the condition left me with the feeling of insufficiency and an urge to find better ways to help these families. This thesis is written from a medical doctor’s perspective, being aware that the global obesity epidemic is a complex challenge that needs comprehensive approaches in order to be understood and managed on the individual as well as on the public level.

1.2 Acknowledgement

Many people have contributed in this project and it is with deep and humble gratitude I write these words.

Firstly, I would like to thank the children and parents participating in both the pilot and the main project, who shared their experiences with me in their process towards even more healthy food and increased physical activity. The barriers they met within their own families and with friends, as well as the challenges they faced in our society in general, are considerable. By these stories, I have also learned how to overcome these barriers and that sustainable change is possible. I am really impressed by participating families and all the efforts they put in to this project 24/7.

I will address my special thanks to project and psychiatric nurse Lin Hagen Sjøgren who has been my closest co-worker since 2008. Without her positive suggestions and skilful contributions towards participants, colleagues and in the leadership, this project would never have been as successfully carried out.

The contribution from my supervisors Inger Njølstad, Sameline Grimsgaard and Trond Flægstad has been vital in carrying out this long lasting project. You have contributed with invaluable scientific and practical advices, patience, discussions and inspiration through all these years, many thanks!
Public health nurses deserve appreciation for being aware early on the obesity challenge in our region and their positive involvement in this project. They contributed with data in the prevalence study as well as with preparation for an intervention study. I also want to thank intensive nurse and researcher Elisabeth Jeppesen who collected data from the child health care centres in accordance with this project and analysed them for her Master of Public Health 2009. Further analysis on this data formed the basis for Paper I. A special thanks go to public health nurse leader Gro Hågensen and her co-workers in Hammerfest municipality with the early idea of a shared care approach.

I am also grateful for the advices from Clinical Research Department, University Hospital of North Norway and a special thanks go to Inger Sperstad for her invaluable help on the database.

I want to thank former and present members of the multidisciplinary team at Finnmark Hospital for doing a fabulous job together! We developed the multiple family intervention (MUFI) through preparations and meetings, carried out the intervention professionally, with mutual respect and also with a lot of fun. You have inspired me in so many ways that I will never again choose to work alone with comprehensive tasks. A warm thanks goes to paediatric nurse Lena Jensen and public health nurse Torild Ebeltoft for their outreached guidance towards providers in the municipalities.

Further, the providers and their leaders participating in the trial from primary care deserve particular attention. They have been engaged in this issue from the beginning, speaking up for health care service for obese children, participating in network meetings, courses, and keeping the families motivated throughout the project. A sincere thanks goes to the staff who organised the physical activity in the MUFI approach which was characterised as fun and caring for the children.

I am grateful for the support from managers and colleagues at Finnmark Hospital Trust and the Paediatric Ward who have been enthusiastic about my work, and facilitated leave of absence when necessary for the members of the multidisciplinary team. They also provided me with a silent room in an encouraging environment at the Research Department. I want to thank personnel at the Medical outpatient clinic who have performed all height and weight measurements in this clinical trial; your contribution has been indispensable! The personnel at the Laboratory have had additional work in terms of analyses and storage of blood tests in this study, which also has been an invaluable contribution. Staff from finance, human resources and administration units has given me
support, highly necessary for the management of this study. I want to express my
gratitude to Pal Ivan, the manager of the Paediatric Ward for his genuine interest and
personal support throughout this project.

I also want to thank Lars Bo Andersen, John A Rønning, participants in the early Activity
School Reference Group, representatives from Finnmark County Authority, County
Governor of Finnmark and Finnmark Sport Council who all contributed with valuable
support in the development of this project. Special thanks go to Tom Wilsgaard for advice
and quality assurance of the statistical analysis in paper II and III.

I am grateful for the financial support provided by Finnmark Hospital Trust, Northern
Norway Regional Health Authority, the Norwegian Foundation for Health and
Rehabilitation and the Norwegian Directorate of Health, the University of Tromsø, the
Ministry of Health and Care Services, SpareBank 1 Nord-Norge and Odd Berg Fund.

Warm regards goes to fellow-researchers in Hammerfest, Tromsø, Trondheim, Bergen and
Kristiansand who have all contributed with supportive advice. I also want to thank our
collaborators from other disciplines who have looked at our project from other
perspectives and contributed with new knowledge. I have had many talks about childhood
obesity in various formal and informal settings through this project period. I want to thank
friends, relatives, course leaders, collaborators, all persons with critical or supportive
comments on this project; you have all inspired me.

I want to express gratitude towards my mother Randi who has always been a full-time
working woman and has a genuine positive attitude towards life; that everything is
possible! My appreciation and love goes to my husband Tor Harry for continuous support
and belief in me and this project. He has contributed with his knowledge, passion for
outdoor life and early ideas of family camp as well as wonderful photos of Finnmark. A
warm thanks goes to our children Arja, Gaute, Vida, Simen and Miriam; who have all
contributed in their own valuable way to this project.

Hammerfest August 19th 2014, Ane Kokkvoll
1.3 Summary of thesis

1.3.1 Summary in English
Childhood obesity has reached epidemic proportions globally and represents a major threat to children's physical and mental health. The causes of childhood obesity and the epidemic are complex and not fully understood. The impact of childhood obesity on health throughout the life-span has led to urgent calls for action. Preventive efforts are essential, but effective management for obese and overweight children at high-risk are also highly required. Standard hospital treatment of obese children is reported as ineffective, whereas family based life style programmes focusing on nutrition, physical activity and behaviour change can reduce the level of overweight after 6-12 months of intervention. Data on effectiveness of treatment programmes beyond one year is however limited. There is a need for evidence of long-term effects of childhood obesity interventions and to recommend cost-effective treatment strategies applicable for primary care. At the Paediatric Department at Finnmark Hospital Trust we experienced increasing numbers of referrals concerning obese children and adolescents. Long travelling distances and limited hospital resources stimulated new treatment strategies based on collaboration between specialised and primary health care.

This thesis comprises two studies; a cross sectional study of overweight and obesity prevalence and a clinical trial. The main objective of this project was to evaluate the effectiveness of a new comprehensive family based treatment for overweight children and their parents. A superior aim was to increase knowledge about factors that can promote life style change in the current families.

In order to enhance planning and recruitment process for an intervention study, we aimed at documenting the prevalence of childhood overweight and obesity, including obesity variations within Finnmark county (Paper I). The objective of the clinical trial was to compare a multidisciplinary approach comprising meeting with other families in groups (multiple family intervention, MUFI) with a more conventional single-family intervention (SIFI) with respect to primary outcome parameters (BMI kg/m\(^2\) and BMI SD score) and secondary outcome parameters (physical activity, anthropometrical, metabolic and psychological measures) up till two years of intervention. Solution focused approach was applied in both groups in a collaborative model between primary and specialised care, a shared care approach (Paper II and III).
Results

A survey of 1774 children born during 1999 and 2000 collected from 18 child health care centres in Finnmark 2007, showed a prevalence of overweight (included obesity) of 16 % and 22 % among 6 – year old boys and girls, respectively. The prevalence of overweight and obesity among preschool children in Finnmark was higher than reported from other regions in Norway in the same period. The results justify both preventive and treatment initiatives (Paper I).

Altogether 97 families were randomised and 91 children provided baseline data in Finnmark Activity School. Anthropometrical data after 24 months was collected from 69 children. Additionally height/weight data from 10 children was reported from local child healthcare centres, adding up to 81% retention for primary end points. No between-group differences in baseline variables were detected. No between-group differences were observed for BMI kg/m\(^2\) (raw), BMI SD score adjusted for baseline values or psychological outcome measures after 24 months. Both 12 months interim results and 24 months follow-up data from the current trial showed a significant between-group difference in waist circumference in favour of the MUFI intervention. Pooled data from both intervention groups showed a significant improvement in parent and self-reported measures of mental health, a significant improvement in self- reported athletic competence combined with a significant decrease in BMI SD score of 0.14. The modest between-group effect in waist circumference in favour of the MUFI will probably not justify this high-intensive approach in a conventional clinical setting, however further research should investigate subgroup effects and cardiometabolic risk factors. The pooled favourable effect on measures of mental health and degree of overweight may indicate that a family based solution focused treatment model performed in a shared care approach has been helpful to obese children and adolescents (Paper II and III).
1.3.2 Short summary in Norwegian


Sandfjellet, Sørøya 2011

Photo: Finnmark Activity School
### 1.4 Definitions and abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>BMI</td>
<td>Body mass index, a person’s weight in kilograms divided by the square of his height in meters (kg/m²).</td>
</tr>
<tr>
<td>BMI SDS</td>
<td>Body mass index standard deviation score. Defines how many standard deviations from median the value is placed, adjusted for age and sex.</td>
</tr>
<tr>
<td>IOTF</td>
<td>International Obesity Task Force</td>
</tr>
<tr>
<td>OW</td>
<td>Overweight corresponds to adult BMI ≥ 25 kg/m²</td>
</tr>
<tr>
<td>OB</td>
<td>Obese corresponds to adult BMI ≥ 30 kg/m²</td>
</tr>
<tr>
<td>OWOB</td>
<td>Overweight including obesity</td>
</tr>
<tr>
<td>SIFI</td>
<td>Single-family intervention</td>
</tr>
<tr>
<td>MUFI</td>
<td>Multiple-family intervention</td>
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<tr>
<td>PA</td>
<td>Physical activity</td>
</tr>
<tr>
<td>WC</td>
<td>Waist circumference</td>
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<td>WHtR</td>
<td>Waist to height ratio</td>
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<td>SDQ</td>
<td>The Strengths and Difficulties Questionnaire</td>
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<tr>
<td>SPPC</td>
<td>The Self Perception Profile for Children</td>
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<tr>
<td>KINDL</td>
<td>The “Kinder Lebensqualität Fragebogen” German health related quality of life questionnaire</td>
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<tr>
<td>SOP</td>
<td>Standard operational procedures</td>
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<tr>
<td>BIA</td>
<td>Bioelectrical Impedance Analysis</td>
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<td>SFBT</td>
<td>Solution Focused Brief Therapy</td>
</tr>
<tr>
<td>SOFT</td>
<td>Standardized Obesity Family Therapy</td>
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</table>
1.5 List of papers


2. Introduction

2.1 Childhood obesity definition

According to World Health Organisation (WHO) overweight including obesity (OWOB) is defined as "abnormal or excessive fat accumulation that may impair health" (1). Body mass index (BMI kg/m$^2$) has emerged as the most practical anthropometric indicator for classifying overweight and obesity in children although it is an indirect measure of adiposity (2). Magnetic resonance imaging (MRI), dual-energy X-ray absorptiometry (DEXA), total body water, bioelectrical impedance analysis (BIA), either measure fat tissue directly or give information about proportion fat tissue. These methods are not generally available, they are more costly and reference data are limited. The direct measures skinfold and waist circumference are generally available, but is dependent on observer skills and training in order to avoid measurement errors. In spite of the fact that weight-for-height does not differentiate between bone, muscle and fat tissue and the distribution of fat tissue (central vs peripheral); a high BMI-for-age is a good indicator of excess fat mass in children (3). In order to be able to compare prevalence data between countries; international cut-off values of BMI for overweight and obesity in childhood has been provided (4, 5). The international cut off points from 2000 (4) establishes age and gender specific values defining overweight and obesity between 2 and 18 years, defined to pass through body mass index of 25 and 30 kg/m$^2$ at age 18 and is reproduced in table 1.
Table 1 (Cole TJ et al 2000)

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Body mass index 25 kg/m²</th>
<th>Body mass index 30 kg/m²</th>
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<tr>
<td></td>
<td>Males</td>
<td>Females</td>
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<td>18.02</td>
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<td>2.5</td>
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2.1.2 Prevalence of childhood obesity

Childhood overweight and obesity (OWOB) have reached epidemic proportions worldwide, and the obesity problem is on the rise in low and middle-income countries, particularly in urban settings (6).

Data from the USA 2009-2010 showed a OWOB prevalence of 31.8 % and obesity (OB) prevalence of 16.9 % among youngsters aged 2-19 years (7). International surveillance data suggest a similar worldwide epidemic following US trends (8, 9). Overall, about 30% of American adolescents and 22-25% of European adolescents aged 10 to 19 years were OWOB according to a worldwide review (10). Although recent studies indicate that the prevalence rates stabilise in some countries, the prevalence is still high (11). In Norway, prevalence studies concerning overweight among children in the urban areas of Oslo and Bergen reports an OWOB prevalence rate of 17-21 % among children aged 6-9 years (11, 12). According to a national sample study, the prevalence of OWOB in Norwegian 8-year-old children was 16 % in 2012 and indicated a stabilising of figures from previous studies in 2008 and 2010 (13). Studies have indicated higher prevalence of OWOB among children and adolescents in North Norway than in southern parts of Norway (14-16). In Norway as in other countries, an association has been observed between OWOB in children and socio-economic factors (12, 15, 17, 18).

2.3 Complex causes

2.3.1 Introduction

The causes of obesity and the obesity epidemic are not yet fully understood. In the following I will list some of the most applied theories in order to demonstrate the complexity of this phenomenon. Treatment approaches in Norway is reported to be influenced by different theories about causes of obesity (19). In my personal view; the importance of predisposing intrinsic human factors (e.g. genetics, endocrinology, immunology) is given limited attention in the public debate. I experience that obesity prevalence is presented, usually followed by a discussion of how to stop the epidemic and the responsibility of society and individuals. Individual biological factors contributing to vulnerability or protection in a human; why obesity strikes differently, have usually limited attention. Initiatives to stop the epidemic (eat less and move more) might also be perceived as the only causal factors on the individual level, which in turn may lead to stigma towards obese individuals. In the following I have therefore dealt with causes of obesity in an individual and the causes of the obesity epidemic separately. New insight and
ongoing research will contribute to the knowledge base and presumably give us more effective tools in order to counteract the obesity epidemic in the future.

2.3.2 Factors contributing to obesity in a child

Genetics and epigenetics

Twin research concludes that genetic factors contribute 50-90% of the individual variance in BMI (20). Studies performed in children concludes with a genetic effect size of 60-78% (21, 22). Polygenic obesity (common obesity) results from the effects of several altered genes. Association studies have found representative polymorphisms associated with common human obesity (23). The understanding of the molecular pathways underlying common obesity is limited but identification of monogenic forms of obesity has contributed to valuable insight (20). Monogenic obesity results from an alteration of a single gene. Inactivating mutations affecting these genes may account for 3-4% of severe, early-onset obesity and they all affect the central regulation of appetite (23, 24). Syndromic obesity is caused by discrete genetic defects or chromosomal abnormalities. Multiple genetic syndromes involve obesity as part of their clinical presentation such as mental retardation, dysmorphic features and organ-specific developmental abnormalities. The cause of obesity in these disorders is often poorly understood.

Epigenetics refers to processes inducing heritable changes in gene expression without altering the gene sequence. They are essential in determining when and where specific genes are expressed (25). These changes include DNA methylation, modifications of the histones around which DNA winds and micro RNAs. Some pre- and perinatal factors seem to be involved in programming towards obesity; under and over nutrition during pregnancy, maternal smoking during pregnancy, gestational diabetes, elevated birth weight, rapid weight gain early in life and feeding practices (26). Several human genes have been described as regulated by epigenetic mechanisms involved in obesity (27).

Endocrine factors

Only a small minority (<3%) of children referred for evaluation of their overweight has identifiable endocrinopathy (24). Endocrinopathies as hypothyreodism and Cushing syndrome are however frequently considered in clinical practise because treatment will resolve the condition.
Energy balance, nutrition and physical activity:

The energy balance theory explains obesity as a condition where total energy intake exceeds total energy needs. This relationship is described by the energy balance equation:

\[ ES = EI - EE \]

\( ES \) = rate of energy storage \( EI \) = rate of energy intake \( EE \) = rate of energy expended (28). \( EI \) represents the metabolisable energy content of food, usually expressed as kilocalories or kcal provided by the four macronutrient categories (carbohydrates, protein, fat and alcohol) (29). \( EE \) occurs through three sources: RMR (resting metabolic rate), thermic effect of food (TEF) and physical activity.

A variety of known and unknown systems influence the components of energy balance (29). Some authors claim that public health interventions designed to reduce obesity is based on a simplistic model of energy balance (i.e. eat less, move more) and this may explain the disappointing results of these interventions (30). The more complex homeostatic feedback model developed from human biochemistry and physiology indicates that energy input and expenditure are interdependent and regulated at several levels. This theory details a more complex model of how multiple feedback mechanism operate to regulate energy balance and maintain body weight within a narrow range (31). The set-point theory suggested that body weight is regulated at a predetermined or preferred level by feedback control mechanism (32). These compensatory changes may account for the poor long-term efficacy of obesity interventions (33).

The energy balance theory is challenged by authors who argue that the findings in free-living conditions are inconsistent with this theory (34). They claim that there is no evidence that children who become fatter than their peers tend to ingest more energy or expend less energy than their leaner friends, in fact, some studies have shown inverse relationship between body fatness and energy intake (35, 36). However, underreporting of unhealthy food might represent a bias (37). An alternate developmental theory proposes that the mechanical stimulation provided by vigorous PA stimulates immature stem cells to differentiate into lean tissue rather than into fat cells and that this development of new tissue is most evident in growth and thus most operative in youngsters (34, 38). According to a recent essay; there have been two main competing hypotheses in history explaining what makes us fat, the energy balance and the alternate endocrinological theory (39). The author claims that after Second World War; the alternate insulin and fat accumulation theory lost and the energy balance theory won out.
Psychological factors

Obesity and impaired psychological well-being in children are correlated; however the direction of the relationship remains unclear. Impaired mental health and wellness among obese children is documented (40) while emotional problems and low self-esteem predicted weight gain into adulthood in a prospective study (41). Adverse childhood events is associated with obesity in adults, presumably through epigenetic mechanisms, but also increased inflammatory markers and chronically elevated cortisol levels are suggested as biological mechanisms underlying these findings (42). Chronic stress contributes to obesity and metabolic diseases, probably through dysregulation of the hypothalamic-pituitary-adrenal axis (43). Both psychological and biological processes interact and once fully developed, the process seems hard to stop.

Levajok, Finnmark 200

Photo: Finnmark Activity School
2.3.3 Factors contributing to the paediatric overweight epidemic

*Positive energy balance*

According to WHO, increased intake of energy-dense food that are high in fat and an increase in physical inactivity globally can explain the overweight epidemic (1). The technology of today has reduced the need for physical activity (PA) in daily life. The low-level demands of exercise have occurred gradually as also the prevalence of obesity has increased worldwide. The average decline in daily energy expenditure in the United Kingdom from the end of the Second World War to 1995 has been estimated as 800 kilocalories, the equivalent of walking 16 km less (44). Modernisation has caused development of food supplies, storage, availability and price which all influence the eating pattern of populations. Social trends towards families where parents are in the workplace rather than in the home have resulted in decreased time available for meal preparation with corresponding increase in high fat fast-food consumption (45, 46). Historical data concerning energy intake concludes that the total energy intake has had a modest increase, 28 kcal /d/y 1977- 2003-06 (47). There is however evidence of a substantial change towards energy-dense food (high in fat and/or sugar) and low fibre diets, increased numbers of eating occasions and portion sizes (47, 48). A modest increase in energy intake combined with less energy expenditure will lead to an excess rate of energy storage and cause obesity in the long term.

*Early life events / programming*

As described earlier, epigenetic deals with the study of how existing genes can be activated or de-activated by environmental factors and inherited through generations. Especially prenatal factors have been of interest and studies have pointed out an association between over- and under –nutrition in pregnancy, adverse effects in the off-springs and later obesity development. A study from the county of Finnmark showed a significant positive correlation between serum cholesterol values among men and women aged 35-49 years and the infant mortality rate previously present in the home municipalities for the study population. Poor living conditions in early childhood were suggested as an important risk factor for arteriosclerotic heart disease (49). A study from Britain pointed out an inverse association between birth weight and cardiovascular disease as adults, and the hypothesis was developed that an unfavourable in utero environment could predispose for adverse health effects later in life, known as the Barker hypothesis (50).
The “thrifty gene” theory was originally proposed for explanation of the rise in diabetes prevalence, but the theory has also been suggested as an explanation for the increased prevalence in obesity (51). Genes who enable individuals to collect and deposit fat stores during periods of food abundance were in ancient times advantageous, in order to survive in periods with shortage of food. In modern societies with no famine, these genes are not longer useful and may lead to obesity and adverse metabolic health effects.

**Other factors contributing to the epidemic, ongoing research**

Fatty acids and saturated fat, sugar and fructose contented beverages are postulated involved in obesity development among other nutritional factors (52, 53). Breastfeeding seems to protect obesity development as opposed to formula feeding (54). Infant formula containing less protein, reduced obesity risk at school age in a randomised trial (55). Increased intake of cold water demonstrated increased resting expenditure in overweight children (56). Association between short sleep duration and increased risk for weight gain and obesity has been reported in population studies (57, 58) Assortative mating, e.g. the fact that obese tend to marry obese might increase the offspring's predisposition to obesity (59). Factors suggested as contributing factors to the obesity epidemic are also human adenovirus-36, gut micro biota, thermo genesis and different pollutants.
2.4 Consequences of childhood obesity

Considerable evidence links childhood obesity with multiple cardiovascular risk factors including high blood pressure, dyslipidemia, inflammatory markers and insulin resistance (60-62). There is an increased risk of overweight and obese children becoming overweight adults and the risk increases with age and parental obesity (63-65). The incidence of obesity between the ages of 5 and 14 years was four times as high among children who had been overweight at the age of 5 as among children who had a normal weight, according to a recent study (66). In the longitudinal Bogalusa Heart study 77% of obese children became obese adults (67).

According to a study from Norway, very high adolescent BMI was associated with 30-40% higher mortality compared to medium BMI, adjusting for adult BMI explained most of the association (68). Analysis of data from four longitudinal cohort studies showed that a decrease in adiposity between childhood and adulthood was associated with marked reduction in the risks of type 1 diabetes, hypertension and dyslipidemia. The cardiovascular risk factors among overweight and obese children who became non-obese by adulthood were similar to those among persons who were never obese (62).

In addition to future risks, obese children and adolescents already have an increased risk of hypertension and early markers of cardiovascular disease (ECG changes and atherosclerosis) orthopaedic problems, non-alcoholic fatty liver disease (NAFDL), idiopathic intracranial hypertension, polycystic ovary syndrome, sleep apnea and breathing difficulties (60, 69, 70) (71).

Adverse psychological consequences might be even more evident than physical consequences at young age. The most frequent psychological symptoms documented among obese children and adolescents are anxiety, depression and behaviour problems (40, 72, 73). Childhood obesity is also associated with reduced self-esteem (74) and impaired quality of life (74-76).

Authors claim that weight stigmatization and teasing contributes to higher level of body dissatisfaction, disturbed body image, reduced self-esteem and rates of depression among overweight and obese youths (77).

The negative effects of the increasing BMI in US population overwhelmed the positive effects of declines in smoking in a paper forecasting US life expectancy (78).
2.5 Treatment of obesity in childhood and adolescence

Treatment of childhood and adolescent obesity covers various lifestyle interventions. Among adolescents, also pharmacological and surgical treatments have been investigated in randomised trials. The treatment with gastric bypass for morbid obese adolescents seems an effective alternative (79) whereas lifestyle interventions for this particular group show less encouraging results (80, 81).

Since medical treatment and surgical treatment are not generally available for adolescents or children in Norway, the following presentation is restricted to psychological approaches applied in lifestyle interventions for obese children and adolescents. Recent studies have also indicated favourable effect of active video games incorporated in evidence based weight management programmes (82). Future innovation and research may presumably give us new tools in lifestyle interventions for treating childhood obesity.
2.5.1 Behavioral change and psychological methods applied in child obesity interventions

The social learning theory by Bandura maintains the importance of observing and modelling the behaviours, attitudes and emotional reactions of others (83). Social learning theory explains human behaviour as a result of interactions between cognitive, behavioural and environmental influences. Several models have been developed in order to explain why individuals do or do not engage in particular health behaviours (84).

The transtheoretical model of behaviour change (TMM) or stages of change is a frequently applied approach in order to assess readiness for change and is also used in stage matched behaviour interventions (85).

**Figure 1 Stages of change (86)**


**Behavioural therapy**

Behaviour therapy teaches children and their parents some principles and techniques in order to eat healthy and increase physical activity. The most frequently applied techniques in behaviour therapy include stimulus-control, goal setting and self-monitoring (87).
Cognitive behaviour therapy

Cognitive elements are often incorporated in behaviour therapy and include identifying and modifying aversive thinking patterns and mood states in order to facilitate weight loss. It builds on the assumption that thoughts influence behaviour and implies recognition of negative automatic thoughts, which are often linked to devaluation of one’s own abilities (45).

Solution focused brief therapy (SFBT)

The Solution-focused brief therapy approach grew from the work of Steve de Shazer, Insoo Kim Berg, and their team. Quotations about this therapy written by their establishers are informative: “as the name suggests, it is about being brief and focusing on solutions rather than on problems” “We discovered that people do many positive things they are not fully aware of. By bringing these small successes into their awareness and repeating the successful things they do when the problem is less severe, people improve their lives and become more confident about themselves.” “The client creates his own solution, based on his or hers own resources and successes” “If it works, do more of it. If it does not work, don’t do it again, do something else” (88, 89)

Family therapy

The early family based approach was developed after recognizing the positive effect of educating parents and primary caretakers about developing and using behavioural approaches to reduce weight in obese children as opposed to life style modification targeting the child only(90, 91). The traditional family based behavioural interventions focuses primarily on working with parent-child subsystem with an emphasis on strengthening the parent’s role, while the family system theory considers a broader role of the family. The family system theory maintains that family dynamics are essential to understand how the family as a social system influence children's behaviour through patterns of familial interaction. An alternative family-based approach based on family systems theory was developed and applied as a model of treatment for overweight children by involving entire families (92, 93). The model integrated Minuchin structural model and solution-focused theory (94, 95). The standardised obesity family therapy (SOFT) consists of three key elements approach, language and process (96, 97)
Motivational interview (MI)

MI is a collaborative and person-centred form of guiding developed in order to elicit and strengthen motivation for change. The concept of motivational interviewing are evolved from experience in the treatment of problem drinkers, and are developed by William R Miller and Stephen Rollnick. The approach appreciates personal autonomy and encourages clients to explore and resolve their ambivalence. MI is an example of how clinicians could help people to move from precontemplation and contemplation to preparation and action in the stages of change model (98).

Group therapy

Research in the treatment of obesity suggests that group interventions may be at least as effective as individual interventions among adults, presumably due to the social support created among individuals in the group and it might be more cost-effective (99). There has however been limited research whether group interventions are more or less effective than individual treatment. Group based approach among youngsters is of interest because of the possible mutual effect of the group facilitator and group members towards behaviour change combined with cost-effectiveness (100). Group based weight management targeting children and youths performed in intensive programs have shown significant between-group effects on BMI compared to traditional weight management in some programs (81, 101-103).

2.5.2 Reviews of interventions for the treatment of childhood obesity

Authors reviewing interventions for treating obesity in children have not been able to range one intervention over another (104). A review of family based models for childhood obesity interventions, maintained that family based interventions rooted in behaviour theory achieved better results that those theoretically connected to family systems theory (105). Another author have suggested that the best way to develop treatment programmes for children is to take the “best parts” of the different therapies and combine them into a general programme for obesity treatment and at the same time use scientific tools to be able to identify the most efficient techniques and aspects of each major treatment programme (93). However beyond the various psychological theories, authors also maintain the importance of relations between provider and client in the outcome of various therapies (106). Exploration of strategies to enhance clinician-family interaction in obesity treatments has been addressed (104).
Reviews published after 2005 report that comprehensive family based life style programmes focusing on nutrition, physical activity and behaviour change can reduce the level of overweight one year from baseline, without any evidence of adverse effects. Data on long-term effectiveness of treatment programmes (beyond 1 year) is however limited, there is little high-quality evidence to recommend one treatment over another and authors comment the need for developing cost effective programmes applicable to primary care (104, 107, 108). Further there is a lack of reporting psychological outcomes in intervention studies (104, 108-110).

2.6 Hammerfest Activity School pilot project.

The 10-month pilot project started as a joint initiative from the primary health care and specialised care represented by leading public health nurse Gro Hågensen and paediatrician Ane Kokkvoll respectively, in order to improve health care services for obese children and their parents. The project was initiated in April 2005 and was summed up in a project report sent to the Norwegian Directorate of Health in May 2006 (111). The program was worked out by a multidisciplinary team with personnel from both Hammerfest hospital and the municipality of Hammerfest. The content of the intervention was practical and theoretical counselling in family-groups with focus on increasing
physical activity levels, reducing sedentary behaviour and promote healthy eating. The members of the multidisciplinary team contributed with their own knowledge and experience. Public health nurse, physiotherapist, paediatric nurse, paediatric consultant, coach and sports consultant constituted the “Physical activity team”. Public health nurse, nutritionist, teacher and paediatric nurse constituted the “Nutritional team”. Twelve families recruited from the child health care centre in Hammerfest and neighbouring municipality participated with their children categorised as obese according to IOTF cut-offs (4). Ten out of twelve families met for the last follow-up in March 2006, retention from start to 10 months was 83%. The children’s mean BMI increased by 0.4 kg /m² and a mean decrease in BMI SDS of 0.10 units was detected. The parents reported increased total physical activity and decreased sedentary activity. Parents reported of their child being more social and that well-being seemed to have improved. Small sample size, lack of control group, limited objective measures and standardised outcome parameters made further conclusion about this new intervention difficult, in spite of positive experiences reported from participating families and providers. Based on the limited, yet positive experiences from the pilot project we decided to carry out a full-scale randomised intervention project.

*Activity School Pilot project autumn 2005*

*Photo: Tor Harry Bjørn*
3. Objective and aim

Aim and research question

The main objective of this current study was to evaluate the effectiveness of a new comprehensive family based treatment for overweight children and their parents, a treatment model further developed from the pilot study formerly described (111). A superior aim of the current study was to increase knowledge about factors that could promote lifestyle change (112). In our preparation for an intervention study we realised that we needed to learn more about the extent of childhood overweight and obesity in the region of Finnmark. We aimed at documenting the prevalence of childhood overweight and obesity, including obesity variations within the county in order to enhance planning and recruitment processes for an intervention study. This thesis therefore comprises two studies; a cross sectional study of overweight and obesity prevalence and a clinical trial addressing following research questions:
1) What is the prevalence of childhood overweight and obesity among pre-school children in Finnmark?

2) Are differences between municipalities in ethnicity, rural/urban patterns and socioeconomic factors associated with the prevalence of childhood overweight and obesity?

3) Is a comprehensive lifestyle programme performed in groups of overweight children and their parents more effective than conventional individual follow-up in order to bring about behaviour change as measured by:

   a) Between-group differences in the primary outcome body mass index (BMI) kg/m² up till 2 years of intervention.

   b) Between-group differences in the secondary outcomes physical activity, nutrition and anthropometrical, metabolic and psychological measures up till 2 years of intervention.
4. **Subjects and methods**

4.1 **Paper I: The cross sectional study of overweight and obesity prevalence.**

4.1.1 **Study population**

Finnmark is the northernmost, largest (46,000 km²) and most rural county of Norway, with a total population of 73,000 inhabitants. The largest municipality has a population of 19,000, while 13 out of the 19 municipalities have less than 3,000 inhabitants. Three main ethnic groups live in this region; the indigenous Sami, the ethno cultural Kvens of Finnish origin, and the majority population of Norwegians.

We sent a request to all child health care centres in Finnmark during spring 2007 (Appendix 3) asking for data on height and weight measurements among 1st grade school children born during 1999 and 2000. Overall, 18 municipalities provided data; one municipality did not participate because of vacancies at the centre at the time the study was performed. This municipality had a total population of 972 and only 16 children born during 1999 and 2000.

4.1.2 **Methods: Measurements, data extraction and analysis**

Local public health nurses performed the measurements as a part of routine examinations. Height and weight were measured to the nearest 0.1 cm and 0.1 kg, respectively, with the child wearing light clothing, according to general principles in the routine preventive health program. Anonymised data on age, sex, height, weight and municipality of residence was extracted retrospectively in 2007 from local health records by the staff at the municipality child health care centre. BMI was calculated as kg/m² and the children were categorized as normal weight, overweight or obese according to IOTF reference values (4). Age at latest birthday and reference values at midyear were used to classify children as overweight or obese. Underweight was calculated and estimated as defined in a large international survey (113). For the purpose of this survey, the underweight group was combined with the normal weight group for further analysis.

We characterized the municipality as Sami according to the administrative area of the Sami language, as urban if the municipality had an official status as a town and numbers of inhabitants according to Statistics Norway 2011(114).
Data on education and income level was made available by Statistics Norway; Facts on municipalities (114). These variables were used by Statistics Norway as key socio-demographic indicators on the municipality level. The percentage of adult population with a high (tertiary) educational level was given for each municipality, defined as more than 13 years of education. This corresponds to education at academy, college or university level. The proportion of inhabitants above the age of 18 who were fully employed and information on mean annual income was also collected for each municipality, and figures from 2008 and 2009 were utilised. For each of the three indicators, we allocated the municipalities into two groups, either above or below the mean value for Finnmark. The mean proportion of inhabitants with a high academic educational level in Finnmark (Norway) was 21 % (26 %), mean level of full employment was 69 % (70 %) and mean annual total income was 306 000 NOK (345 000 NOK).

Statistics: All statistical analyses were performed with SPSS, version 15 (SPSS Inc. Chicago, IL, USA) or Stata version 11.0 (StataCorp 4905 Lakeway Drive, College Station, Texas 77845 USA). Pearson Chi² tests were used to analyse differences in proportions. Significance level was set at p = 0.05.

4.2 Paper II and paper III: Finnmark Activity School – a clinical trial

4.2.1. Study sample

The clinical trial started in 2009 at the Paediatric Department at Hammerfest Hospital in collaboration with the University Hospital of North Norway (UNN) and the University of Tromsø. Municipalities of Finnmark were invited to participate through an initiative of public health carried out by Finnmark County Authority and County Governor of Finnmark. Prior to enrolment, formal representatives of the hospital and each participating municipality signed a mutually binding agreement (appendix 3). Families from six municipalities in Finnmark County and one municipality in neighbouring Troms County (Tromsø city, 70.000 inhabitants) were recruited through advertising and media coverage. Inclusion criteria were age 6-12 years and BMI corresponding to adult BMI ≥ 27.5 kg /m². The latter was calculated as the mean between the two international cut-off points defining overweight and obesity in children (4) by age and gender. Exclusion criteria were diseases incompatible with ordinary physical activity and psychosocial disorders incompatible with group interaction. Staff at Hammerfest Hospital conducted the study, collected data and organised courses for all health care providers involved. The intervention period was completed by November 2013.
4.2.2 Study design

The “Finnmark Activity School” was a randomised single-blind (primary outcome assessors) trial with two parallel arms. The family was the interventional unit and included the child, parents and in some cases (n=8), a sibling. Children were randomised to either single-family intervention (SIFI) or multiple-family intervention (MUFI). The trial was designed, conducted and reported in accordance with Consolidated Standards of Reporting Trials (CONSORT) guidelines (115). There has been no deviation from the study protocol other than recruiting in two cycles to obtain sufficient number of participants.

Randomisation and concealment

Following eligibility assessment and written informed consent, the study nurse phoned the central randomisation unit at UNN for group allocation. Randomisation lists were computer generated (block randomisation, random block size) and stratified by age, (6-9 and 10-12 years). Personnel involved in the randomisation did not take any further part in the study.

Single-family intervention (SIFI)

Families allocated to (SIFI) met at the hospital outpatient clinic. The children underwent baseline anthropometric measurements, followed by 30 min counselling by a paediatric study nurse. Subsequently, a paediatric consultant performed a clinical interview and examination (30 min), and outlined definite aims towards the next consultation. All families met with a nutritionist after 1-2 months. They were followed up by a public health nurse in their own municipality at 1, 2, 5, 8, 10, 15 and 18 months from baseline; and at the hospital by a paediatric nurse and a paediatric consultant at 3, 12, 24 and 36 months.

Multiple-family intervention (MUFI)

Families allocated to MUFI underwent anthropometric measurements and individual counselling identical to those of the SIFI programme. Additional elements were: 1) A 3-days inpatient programme at the Paediatric Department focusing on physical activity and healthy food, 2) Group sessions with other families and a multidisciplinary hospital team (paediatric and psychiatric nurse, paediatric consultant, nutritionist, physiotherapist, coach and clinical educationalist), 3) Municipality follow-up including individual (30 min) and groupwise counselling (1 h) with a public health nurse, 4) Group based physical activities twice weekly (each session lasting one hour, organised by coach and by parents respectively), 5) Family participation in a 4-day camp after 4–6 months.
Throughout the second year both intervention groups were followed up every three month by public health nurse (included 1 hour group-session for MUFI) and weekly physical activity sessions was continued for the MUFI group.
Figure 2 First 12 months Finnmark Activity School H=Hospital C=Community

Months of treatment

100 children Randomized

100 children Randomized

Individ 49 children “controll”

Group 48 children “Interv.”

Organized Physical Activity x 2/week. (With PA leader x1 / parent leader x1)

Camp x 1
4 days

Figure 3 12-36 months Finnmark Activity School  H= Hospital  C= Community

100 children Randomized

Individ 49 children “controll”

Group 48 children “Interv.”

Organized Physical Activity x 2/week. (With PA leader x1 / parent leader x1)

Camp x 1
4 days
4.2.3 Data collection and methods

Both interventions were performed in a shared model across primary and specialised health care. Principles from Solution- Focused Brief Therapy and Standardized Obesity Family Therapy were applied in addition to elements from motivational interviewing (95, 96, 98) in addition to providers own knowledge and experience. Counselling based on the families 'own resources aiming at increasing physical activity, reducing sedentary activity and healthy food according to national guidelines were the main approach in both intervention arms. Public health nurses, nutritionists, paediatric nurses and paediatric consultants were involved in both interventions where as clinical educationalist, physiotherapist and coach were only involved in the MUFI approach. Study personnel participated in four courses (1.5 days each) covering causes and consequences of childhood obesity, as well as nutrition, physical activity, introduction to family therapy and brief solution focused method.

Outcomes

Data were collected during prescheduled hospital visits at baseline and at 3, 12, 24 and 36 months of follow-up and included anthropometric measurements, blood samples, bioelectrical impedance analysis, clinical examinations and questionnaires. Additionally, psychological health and well-being was assessed by questionnaires completed at home after 6 months of intervention.
**Height** was measured to the nearest 0.1 centimeter with a portable Harpenden Stadiometer® and **weight** to the nearest 0.1 kilogram with a digital Seca® portable scale. All children were measured between 08:00 and 11:00 am wearing underwear and a shirt. **BMI** kg/m² were calculated and BMI standard deviation score (BMI SDS) extracted from an obesity calculator based on British reference data (116, 117). **Waist circumference (WC)** was measured at the mid-point between the lowest rib and the top of the iliac crest with a measuring tape at the end of normal expiration. **Waist to height ratio (WHtR)** was calculated as WC in cm divided by height in cm. **Skin fold** was picked up on the posterior part of m.triceps by the thumb and forefinger and measured with a Holtain Tanner /Whitehouse Skinfold Caliper® (118). If inter-assessor measurements deviated > 1.0 cm in waist circumference and > 1.0 mm in skin fold, the two measurements were repeated once, if the child admitted to it. Mean value of the two observations was used in all analyses. **Fat- and lean body mass** were obtained by bioelectrical impedance analysis (Tanita Bodycompositon analyzer BC-418® ) with the child in standing position. **Clinical examination** included scaling pubes stages by pubic hair growth (119).

**Mental health** was measured with the validated Norwegian version of Strengths and Difficulties Questionnaire (SDQ)(120, 121). The SDQ is a widely used child psychological health questionnaire consisting of 25 items divided into five scales: The hyperactivity scale, conduct problem scale, emotional symptoms scale, peer problem scale and pro-social scale. Each item is scored 0 not true, 1 somewhat true 2 certainly true, generating a total difficulty score ranging from 0 to 40. The pro-social score is not included in the total difficulty score. Teacher, parents and children ≥11 years of age completed the questionnaire.

**Self-esteem** was measured using the Norwegian version of Self–Perception Profile for Children, SPPC (122, 123). The SPPC comprises five domain specific subscales and one global self-worth subscale. These subscales are scholastic competence, social acceptance, athletic competence, physical appearance and behavioural conduct. 36 items with six items pr domain, scale 1-4 from negative to positive. The questionnaire was completed by all children, parents interviewed their smaller children.

A Norwegian version of the parent- and self-reported “Kinder Lebensqualitet Fragebogen” (KINDL) was used to measure **quality of life** (124). The separate forms of the 8-12 and 13-16 years age groups were applied, both consisting of 24 items distributed into six subscales; physical well-being, emotional well-being, self-esteem, family, friends and
school. Each item addresses experiences over the past week and is rated on a five-point scale. Mean scores are calculated for each of the six subscales and for the total scale and linearly transformed to a 0-100 scale. The self-reported subscales were omitted from the analysis after a survey pointed out a decreased reliability for these items in the current age-group (125).

4.2.4 Methodological issues and statistics

Quality assurance

In order to attend to quality assurance in the current study, SOP (Standard operation procedures) were worked out for all practical procedures, e.g. measurements of height, weight; waist circumference, skinfold, bioimpedance, fitness test, measurements of motivation. We also made SOPs for different tasks in the treatment program. The SOPs were used in practical training of the staff involved in data collection before study start.

Blinding

Nurses employed at the medical outpatient clinic performed the primary outcome measures height and weight and were blinded to group allocation where as two study nurses not blinded to group allocation measured waist circumference, triceps skin fold thickness and body composition. Precautions were taken to keep primary outcome assessors blinded to group allocation. Nurses who measured height and weight were neither employed at the Paediatric Department nor involved in the intervention in other respects. Families were instructed not to talk about the intervention with the primary outcome assessors and these nurses were instructed to report if blinding was no longer present.

Sample size, power and statistics

Sample size calculations resulted in the need of 40 families in each group in order to detect a difference between intervention and control group of at least 0.5 (kg/ m²) in mean BMI change with 5 % risk of type 1 error and 20 % risk of type 2 error and a standard deviation of 0.8. With an expected withdrawal of 20 %, a total of 100 families were needed. Difference between two means, \( \mu_1 - \mu_2 \) Standard deviation in each group, \( \sigma_1 \) and \( \sigma_2 \); \( u= 0.84 \) and \( v=1.96 \)
\[
\frac{(u + v)^2 \left( \sigma_1^2 + \sigma_2^2 \right)}{(\mu_1 - \mu_2)^2}
\]

\[
n = \frac{(0.84 + 1.96)^2 \left( 0.8^2 + 0.8^2 \right)}{0.5^2}
\]

\[n = 40\]

Differences between intervention groups at baseline were assessed by two sample t-test and Pearson chi square tests. All data were analysed by the intention-to-treat principle. Linear mixed models (126) were used to compare time trends in BMI (and secondary anthropometrical outcomes) between the two groups over three (paper II) and four (paper III) time points. The independent variables were: Group, time (as two indicator variables) and cross product terms between each indicator variable of time with group. A significant group-by-time interaction indicated different time trends between the intervention groups.

In secondary analyses we adjusted for random differences at baseline. All analyses were performed using Stata version 12.1 (StataCorp 4905 Lakeway Drive College Station, TX, USA). Two-sided p < 0.05 was considered statistically significant.

**Qualitative studies invited**

The project group invited other professions in to the trial in order to explore processes going on within the trial period and get a more comprehensive perspective on the issue of childhood obesity and treatment. The invitation resulted in interviews of mothers participating in the MUFI programme (127), parents’ experience through a successful lifestyle change (128), parents explaining their child’s overweight (129) and interview of public health nurses participating in the Finnmark Activity School (130).

**4.3 Approvals**

The Regional Committee for Medical and Health Research Ethics approved the study. REK nord 2011/ 1498. The Norwegian Social Science Data Services consented to the privacy protection in the study.
<table>
<thead>
<tr>
<th><strong>Content of the intervention</strong></th>
<th><strong>Single-family intervention</strong></th>
<th><strong>Multiple-family intervention</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Who is the target</td>
<td>Parents and child</td>
<td>Parents and child</td>
</tr>
<tr>
<td>Responsible for the intervention</td>
<td>Community and hospital</td>
<td>Community and hospital</td>
</tr>
<tr>
<td>Start</td>
<td>Outpatient clinic 1 day</td>
<td>Inpatient clinic stay for 3 days</td>
</tr>
<tr>
<td>Who delivers the intervention</td>
<td>Project nurse, paediatrician and nutritionist at the hospital. Public health nurse in the municipality.</td>
<td>Multidisciplinary team at the hospital. Public health nurse, physiotherapist and coach in the municipality.</td>
</tr>
<tr>
<td>How</td>
<td>Every family individually</td>
<td>Families both individually and in groups</td>
</tr>
<tr>
<td>Physical activity for children</td>
<td>Not arranged</td>
<td>2 hours a week in groups</td>
</tr>
<tr>
<td>Camp for families</td>
<td>No camp</td>
<td>4 days 6-8 months from baseline</td>
</tr>
<tr>
<td>Solution focused counselling</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Follow up intervals</td>
<td>1,2,3,5,7,10,12,18,24,36 months</td>
<td>Equal intervals as the single-family group</td>
</tr>
<tr>
<td>Hours of contact first 12 months</td>
<td>8</td>
<td>36</td>
</tr>
<tr>
<td>Organised physical activity first 12 months</td>
<td>0</td>
<td>38</td>
</tr>
<tr>
<td>Hours of contact 12-24 months</td>
<td>2.5</td>
<td>6.5</td>
</tr>
<tr>
<td>Organised physical activity 12-24 months</td>
<td>0</td>
<td>38</td>
</tr>
</tbody>
</table>
5. Results

5.1 Paper I: Prevalence of overweight and obesity among 6–year-old children in Finnmark County

We received data on 1779 children born in 1999 and 2000 who had been examined at the local children’s health care centre. This number comprises 85 and 87 per cent respectively, of 1st grade children in these municipalities during 2005 and 2006. Weight data were missing for five children. Overall, 19 % (n=331) had a BMI above the IOTF cut-off values for overweight including obesity (OWOB) and 5 % (n=91) of the children had a BMI above the cut-off value for obesity (OB). The prevalence of OWOB was 22 % among girls and 16 % among boys (p<0.01). The prevalence of obesity did not differ significantly between girls and boys (5.8 % versus 4.4 %, p= 0.12) A total of 7.8 % (n=138) children were categorised as underweight; no sex differences were found.

Table 3 The prevalence of underweight, overweight (OWOB) and obesity (OB) among 6-year-old children, born during 1999 and 2000. Finnmark County, Norway.

<table>
<thead>
<tr>
<th>Gender</th>
<th>Normal</th>
<th>Underweight*</th>
<th>Overweight (OWOB)*</th>
<th>Obese (OB)*</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Girls</td>
<td>629</td>
<td>70.2</td>
<td>70</td>
<td>7.8</td>
<td>197</td>
</tr>
<tr>
<td>Boys</td>
<td>668</td>
<td>76.1</td>
<td>68</td>
<td>7.7</td>
<td>142</td>
</tr>
<tr>
<td>Total</td>
<td>1297</td>
<td>73.1</td>
<td>138</td>
<td>7.8</td>
<td>339</td>
</tr>
</tbody>
</table>

* Underweight, overweight including obesity and obesity according to IOTF cut-off criteria and Cole et al (Cole 2000)(Cole 07).

† p< 0.01 Chi-square for gender difference

The prevalence of OWOB ranged from 9 % to 35 % in the municipalities and three municipalities had figures above 30 %. No difference in the prevalence of OWOB was seen between Sami and other municipalities, between municipalities defined as urban or rural, or between municipalities with numbers of inhabitants more than 9000 compared with the others. Furthermore we did not observe any variation in the prevalence of obesity
associated with the proportion of inhabitants with higher academic educational level, level of employment or mean annual income at the municipality level.

5.2 Paper II: Method and 12-months interim results from the Finnmark Activity School

A total of 127 enquiries by phone resulted in 109 meetings for eligibility assessment. Following assessment, 97 (89%) families consented and were randomised, 11 declined to participate and one did not meet the inclusion criteria. Median interval between randomisation and baseline measurements was 50 days. Six participants (three in each group) withdrew from the study before start (baseline). Subject retention from inclusion to 12 months was 80%. There was no difference in attendance between the two intervention groups and no adverse effects were reported. Baseline data showed that 77% of the children were obese and everyone had a waist circumference above the 95 percentile according to British reference values (131), table 4.

Mean BMI increased in both intervention groups during the first 12 months of study but less so in the MUFI (0.37mg/m²) than in the SIFI group (0.77kg/m²). This between-group difference of 0.40 kg/m² was not significant (95% CI -0.99 to 0.18). Adjustment for baseline values did not change this result. Mean decrease in BMI SDS was 0.16 units in the MUFI group and 0.07 units in the SIFI group, p=0.07. Waist circumference decreased in the MUFI group (-0.94cm) and increased in the SIFI group (+0.95), p=0.036. No between-group difference was observed for skinfold thickness or body fat at 12 months. In pooled data from both intervention groups BMI SDS decreased significantly (-0.12 BMI SDS units (95% CI -0.17 to -0.07))
### Table 4 Baseline variables

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Single-family intervention n=46</th>
<th>Multiple-family Intervention n=45</th>
<th>Between group P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years</td>
<td>10.5 ± 1.7</td>
<td>10.1 ± 1.7</td>
<td>0.24</td>
</tr>
<tr>
<td>Female/male</td>
<td>22/24</td>
<td>27/18</td>
<td>0.24</td>
</tr>
<tr>
<td>Tanner puberty ≥ 2 at baseline</td>
<td>14 (31)</td>
<td>14 (31)</td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>27.6 ± 4.3</td>
<td>26.9 ± 4.2</td>
<td>0.42</td>
</tr>
<tr>
<td>BMI SDS †</td>
<td>2.81 ± 0.60</td>
<td>2.76 ± 0.58</td>
<td>0.70</td>
</tr>
<tr>
<td>Obesity at baseline ‡</td>
<td>36 (78)</td>
<td>34 (76)</td>
<td>0.76</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>89.2 ±11.9</td>
<td>87.9± 12.0</td>
<td>0.62</td>
</tr>
<tr>
<td>Body fat (%) §</td>
<td>35.8 ± 5.2</td>
<td>35.3 ± 5.0</td>
<td>0.66</td>
</tr>
<tr>
<td>Triceps skin fold (mm)</td>
<td>26.1 ± 4.3</td>
<td>25.4 ± 4.5</td>
<td>0.47</td>
</tr>
<tr>
<td>Mother BMI (kg/m²) (n)</td>
<td>29.8 ± 6.8 (43)</td>
<td>29.9 ± 8.1 (41)</td>
<td>0.95</td>
</tr>
<tr>
<td>Father BMI (kg/m²) (n)</td>
<td>29.5 ± 4.3 (20)</td>
<td>30.3 ± 5.5 (21)</td>
<td>0.63</td>
</tr>
</tbody>
</table>

Baseline characteristics are presented as mean ± standard deviation for continuous variables and number (percent) for binary variables.

*Pubes development according to Tanner (Marshall WA 1969, Marshall WA 1970)

†BMI SDS according to British reference (Cole 1990)

‡Obesity according to Cole 2000 (Cole 2000)

§Body composition measured by bioelectrical impedance analysis (BIA)
5.3 Paper III: Two-year anthropometrical and psychological outcome in Finnmark Activity School

Anthropometrical data after 24 months of follow-up was collected from 69 children (retention 71%), additionally height/weight data from 10 children was reported from their local child healthcare centre, adding up retention to 81% for primary end points. No between-group differences in baseline variables were observed.

*Figure 4 Flow of participants through 24 months of treatment in Finnmark Activity School*

*Siblings are not included in the analysis.

†Longitudinal analyses include all available data from every subject through withdrawal or study completion.
**BMI and BMI SDS**

After 24 months BMI increased 2.02 kg/m² in the SIFI group and 1.29 kg/m² in the MUFI group, p = 0.075. Mean decrease in BMI SD score was 0.08 units in the SIFI group and 0.20 units in the MUFI group, which scarcely reached the level of significance, p = 0.046, and when adjusted for baseline this finding was no longer significant, p = 0.058.

**Figure 5 BMI kg/m² and BMI SD score through 24 months of treatment by intervention group. Finnmark Activity School**

Mean (95% CI) changes in body mass index and BMI SD score from baseline to 24-months’ follow-up by intervention group.

**Waist circumference**

Waist circumference increased by 2.60 cm in the SIFI group and 0.21 cm in the MUFI group, (p = 0.038) Adjustment for baseline values did not change these results and waist to height
ratio showed corresponding between-group difference after 24 months, (p =0.029). No between-group difference was observed for skin fold or body fat. Pooled data from both treatment groups showed a significant decrease in BMI SD score of 0.14 units.

*Figure 6 Waist circumferences through 24 months of treatment by intervention group. Finnmark Activity School*

Mean (95% CI) changes in waist circumference from baseline to 24-months follow up by intervention group.
Table 5 Changes in BMI, BMI SDS and secondary anthropometrical outcomes through 24 months in Finnmark Activity School; by treatment group.

<table>
<thead>
<tr>
<th></th>
<th>Difference (95% confidence intervals) at follow up</th>
<th>Between group difference</th>
<th>P value‡ group by time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Single-family intervention</td>
<td>Multiple-family intervention</td>
<td>Koef (95% confidence interval)</td>
</tr>
<tr>
<td><strong>BMI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>-0.09 (-0.47 to 0.65)</td>
<td>-0.28 (-0.83 to 0.32)</td>
<td>-0.37 (-1.15 to 0.42)</td>
</tr>
<tr>
<td>12 months</td>
<td>0.78 (0.21 to 1.35)</td>
<td>0.37 (-0.18 to 0.91)</td>
<td>-0.41 (-1.20 to 0.38)</td>
</tr>
<tr>
<td>24 months</td>
<td>2.02 (1.44 to 2.60)</td>
<td>1.29 (0.74 to 1.84)</td>
<td>-0.73 (-1.53 to 0.07)</td>
</tr>
<tr>
<td><strong>BMI SDS‡</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>-0.05 (-0.14 to 0.03)</td>
<td>-0.13 (-0.21 to -0.05)</td>
<td>-0.08 (-0.20 to 0.04)</td>
</tr>
<tr>
<td>12 months</td>
<td>-0.07 (-0.16 to 0.01)</td>
<td>-0.15 (-0.23 to -0.07)</td>
<td>-0.08 (-0.17 to 0.01)</td>
</tr>
<tr>
<td>24 months</td>
<td>-0.08 (-0.17 to 0.01)</td>
<td>-0.20 (-0.29 to -0.12)</td>
<td>-0.12 (-0.24 to 0.00)</td>
</tr>
<tr>
<td><strong>BMI SDS adjusted</strong>*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>-0.05 (-0.14 to 0.03)</td>
<td>-0.13 (-0.21 to -0.05)</td>
<td>0.08 (-0.19 to 0.04)</td>
</tr>
<tr>
<td>12 months</td>
<td>-0.08 (-0.16 to 0.01)</td>
<td>-0.15 (-0.23 to -0.07)</td>
<td>0.07 (-0.19 to 0.04)</td>
</tr>
<tr>
<td>24 months</td>
<td>-0.09 (-0.17 to 0.02)</td>
<td>-0.20 (-0.29 to -0.12)</td>
<td>0.11 (-0.23 to 0.00)</td>
</tr>
<tr>
<td><strong>Waist circumference</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>-0.03 (-1.51 to 1.45)</td>
<td>-1.44 (-2.90 to 0.53)</td>
<td>-1.41 (-3.49 to 0.67)</td>
</tr>
<tr>
<td>12 months</td>
<td>0.96 (-0.56 to 2.48)</td>
<td>-0.96 (-2.45 to 0.52)</td>
<td>-1.92 (-4.05 to 0.20)</td>
</tr>
<tr>
<td>24 months</td>
<td>2.50 (0.95 to 4.26)</td>
<td>0.21 (-1.32 to 1.74)</td>
<td>-2.39 (-4.64 to -0.14)</td>
</tr>
<tr>
<td><strong>Waist to height ratio</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>-0.01 (-0.02 to 0.00)</td>
<td>-0.02 (-0.03 to -0.01)</td>
<td>-0.01 (-0.02 to 0.00)</td>
</tr>
<tr>
<td>12 months</td>
<td>-0.02 (-0.03 to -0.01)</td>
<td>-0.03 (-0.04 to -0.02)</td>
<td>-0.01 (-0.03 to 0.00)</td>
</tr>
<tr>
<td>24 months</td>
<td>-0.03 (-0.04 to -0.02)</td>
<td>-0.04 (-0.05 to -0.03)</td>
<td>-0.02 (-0.03 to 0.00)</td>
</tr>
<tr>
<td><strong>Skinfold</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>-1.5 (-2.4 to -0.6)</td>
<td>-3.00 (-3.91 to -2.20)</td>
<td>-1.5 (-2.8 to -0.3)</td>
</tr>
<tr>
<td>12 months</td>
<td>-4.0 (-4.9 to -3.1)</td>
<td>-4.5 (-5.38 to -3.36)</td>
<td>-0.5 (-1.8 to 0.7)</td>
</tr>
<tr>
<td>24 months</td>
<td>-6.2 (-7.1 to -5.2)</td>
<td>-6.5 (-7.43 to -5.64)</td>
<td>-0.4 (-1.7 to 0.9)</td>
</tr>
<tr>
<td><strong>Body fat</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>0.51 (-0.89 to 1.90)</td>
<td>-0.35 (-1.73 to 1.03)</td>
<td>-0.85 (-2.82 to 1.11)</td>
</tr>
<tr>
<td>12 months</td>
<td>0.39 (-1.04 to 1.83)</td>
<td>-0.05 (-1.45 to 1.36)</td>
<td>-0.44 (-2.45 to 1.56)</td>
</tr>
<tr>
<td>24 months</td>
<td>1.87 (0.31 to 3.42)</td>
<td>0.76 (-0.67 to 2.19)</td>
<td>-1.11 (-2.22 to 1.01)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pooled effects BMI SDS</th>
<th>Both treatment groups pooled (95%KI)</th>
<th>P value - change from baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 months</td>
<td>-0.09 (-0.15 to 0.03)</td>
<td>0.002</td>
</tr>
<tr>
<td>12 months</td>
<td>-0.11 (-0.17 to 0.05)</td>
<td>0.000</td>
</tr>
<tr>
<td>24 months</td>
<td>-0.14 (-0.21 to 0.08)</td>
<td>0.000</td>
</tr>
</tbody>
</table>

Data based on mixed models analysis with single-family intervention as reference group

*Analysis adjusted for values at baseline
†BMI SD score according to British reference (23)
‡P value for equality between groups, group-by-time effect

There was no between-group difference in the course of mental health (SDQ) from baseline to 24 months. However, pooled data from both interventions pointed out a significant decrease in parent and self-reported total difficulty score of 1.9 units with a significant change in the emotional symptoms and peer problem sub score.
Mean (95% CI) changes in Strength and Difficulty Questionnaire Total score from baseline to 24-month follow-up by intervention group.

There was no difference in the course of domain specific and global self-worth subscales of self-perception between the two intervention groups. In pooled data from both interventions there was a significant increase in athletic competence, social acceptance and behavioral conduct after 12 months but only a significant increase in athletic competence sustained after 24 months. The self- and parent reported quality of life data showed no difference in change between the intervention groups at any time points. Pooled data pointed out a significant increase in self-reported total score after 12 months but this improvement waned after 24 months. No overall change in self-reported or parent reported total score of quality of life from baseline to 24 months was detected.

5.4. BMI changes from eligibility, a curiosity

When analysing the mean change in BMI from eligibility assessment to 12 months’ follow up from baseline, a significant between-group effect appeared; the difference between individual intervention and group intervention was -0.62 kg/ m² (95% CI -1.18 to -0.05)
as shown in figure 8. No other anthropometrical measures were obtained at eligibility. Because the study was not formally started at this point and height and weight measurements were not standardised, these results are not earlier published.

**Figure 8** BMI kg/m² from eligibility assessment to 12 months by intervention group. Finnmark Activity School
6. Discussion

6.1 Results paper I

This survey showed a prevalence of overweight among 6-year-old children in Finnmark of 19% and that OWOB was more frequent among girls (22%) versus 16% in boys (p< 0.01). The prevalence of overweight ranged from 9% to 35% in the municipalities and we were not able to identify factors associated with this variation on the population/municipality level.

These figures were somewhat higher compared with other surveys in Norway carried out in the same period (12, 14, 132) with the exception of a study among 8 and 12 year-old children from Oslo (17) where the prevalence of OWOB was slightly higher.

We know from earlier surveys that adult inhabitants of Finnmark have a lower mean educational level, are to larger extent daily smokers, have higher mortality from coronary heart disease and have a shorter life time expectancy compared with national average for Norway (114, 133). A high prevalence of overweight and obesity among adults and adolescents in the three northernmost counties of Norway has been shown in earlier studies (15) and a national representative study among 8-year-old-children has suggested a higher prevalence of overweight and obesity in the northern and central part of Norway compared with other regions(14).

A higher prevalence of overweight was observed in girls in the current study in accordance with several other studies of children at preschool age and in contrast to studies among older children(17, 132) The sensitivity of the IOTF- criteria has been estimated significantly lower among 7-year-old boys as compared to girls (134), and the findings in this study might be due to classification criteria and not due to gender differences as such.

We did not find associations between the prevalence of childhood overweight and obesity and socio-demographic factors on the municipality level. This is in contrast with studies who have demonstrated higher prevalence of childhood obesity in rural areas (135), and studies pointing out inverse relationship between obesity and parental education level/socio economic measures (12, 136-138) This discrepancies in findings might be due to methodological issues discussed in the next section. There might be only small variations within Finnmark County related to these possible associated factors and the samples are
small. In an overriding perspective this entire county would be regarded as rural and has a lower income and education level compared with nationwide figures which in turn can be associated with the overall high prevalence rate.

### 6.2 Strength and weaknesses of the prevalence study

The data was collected in connection with routine child health services and no standardised or quality control procedures were performed. Although we cannot exclude the possibility of systematic measurement errors because of unequal routines in the different municipalities, we anticipate such errors to be non-differential, affecting categorisation of weight groups equally (139).

The major weakness of this study was the lack of individual information on ethnicity, parent’s education, work position and income. Individual information on socio-demographic factors are also lacking, analysing these factors on a municipality level was a crude approach.

The strength of this study was the use of data from the municipality public health centres which in general report high attendance rates, 89 % and 92 % for the years 2005 and 2006 respectively. In this survey 86 % of the children attending 1st grade at primary school met at the child health care centre. Public health nurses involved in this study reported that reasons for non-attendance were non-differential conditions such as illness, family temporarily absent from home, emigration/immigration etc, and there were no indications of an attendance bias based on socio-economic status or ethnicity.

Another study collecting data from school health services also pointed out high prevalence figures of childhood overweight and obesity (17). Recruitment is a difficult aspect of health research, particularly in studies on childhood overweight and obesity (140). One might speculate if low attendance in health surveys may affect categorisation of weight groups differently, e.g. fewer children categorized as obese do participate and as a result this may affect prevalence estimates.
6.3 Results paper II and III

6.3.1 Anthropometrical outcome, between-group effects

The between-group effect in BMI increased from 0.41 kg/m² at 12 months to 0.73 kg/m² after 24 months (p=0.075). The BMI SD score bordered on significance in favour of multiple-family intervention with a between-group difference of 0.11 units adjusted (p=0.058) for baseline values at 24 months. A BMI SD score reduction of 0.20 units in the MUFI approach is comparable to results from the latest Cochrane review evaluating interventions for treating obesity in children pointing out a reduction in BMI SD score ranging from 0.17 to 0.24 in behaviour interventions for children < 12 years after 12 months. The borderline significant between-group effect in BMI SD score in the current study is corresponding to the effect size reported when evaluating life style interventions versus standard care, self help or waiting list control (104, 107, 141). An increased effect size is reported when life style interventions is compared with no treatment or waiting list control as opposed to comparison with usual care or minimal intervention (108).

The significant between-group effect in waist circumference and waist to height ratio in favour of MUFI approach of 2.39 cm at 24 months (p= 0.038), is promising; taken to
account the strong association between excess abdominal fat and cardiovascular risk factors (142). An authors claimed that this measure predicts adiposity better than BMI in children and adolescents (143). Waist circumference is associated with visceral fat and was considered the best predictor of children with metabolic syndrome in a paediatric clinical setting (144). One intervention focusing on both diet and physical activity reported significant between-group effect in waist-circumference after 6 months, the author argued that waist circumference may be a more appropriate outcome when studying effects of physical activity (101). We may speculate that the physical activity sessions organised for MUFI could have contributed to the favourable change in waist circumference. However, the complex MUFI programme consisted of several elements in addition to SIFI which all may have contributed to a favourable life style change and the current design does not allow us to conclude further.

The mean effect size in the current intervention did not reach the level of 0.25 units BMI SD score reduction, an effect size necessary to induce significant cardiovascular risk reduction according to a British study (145). However, the favourable development in waist circumference may imply a metabolic risk reduction in spite of a modest BMI change.

### 6.3.2 Group treatment

Results from this trial did not demonstrate obvious beneficial effects of group based treatment. A positive relationship between hours of contact and treatment effect is observed when evaluating weight management programmes applicable for primary care (107). The current MUFI approach can be considered as moderate intensive according to Whitlock scale with 38 hours of direct contact and totally 74 hours included PA sessions first 12 months (107). Diverging results of group based treatment is published and one might speculate if variation can be explained by treatment intensity in the different trials (73, 81, 101-103, 146, 147). Increasing the hours of contact in the current study could possibly have contributed to an increased treatment effect, but would also imply increased use of resources, and thus make the programme less feasible for primary health care. Group based multidisciplinary approach for treating childhood obesity might be cost-effective but also time consuming in terms of scheduling appointments and coordination of group sessions with other participating group members and providers.

**Psychological outcome in group approach**

The group approach did not prove any particular advantage or disadvantage in terms of measures of mental health and well-being. Two obesity trials involving group interventions
Involving children and adolescents reported on improvement in self-esteem and quality of life in the intervention groups compared to control (101, 148). To the best of my knowledge psychological outcomes in group based trials addressing childhood obesity is lacking.

6.3.3 Long term effects

The treatment effect in terms of BMI SDS after 24 months in this study is considerably smaller than the effect size reported in Epstein's review of family-based obesity treatments over the last 25 years (149). However few recent randomised trials life style interventions reported between-group difference in BMI and BMI SD score between new comprehensive approaches and control group (conventional, self help or no treatment) (102, 150) whereas two trials showed no between-group difference after 24 months (146, 151). These results underline the challenge of long-term sustainability in life style change. The modest long term effect in the current trial might be explained by considerate reduction in adiposity during first months of intervention, social facilitation, increased contact and longer duration of treatment; strategies put forward by authors evaluating obesity interventions (141, 146). The shared care approach with providers available in the participant's home town might also make scheduling more flexible for both children and parents which may represent an important issue in childhood obesity management (152).
6.3.4 Pooled effects, mental health and well-being

Pooled results from both treatment groups showed a significant decrease in BMI SD score from baseline of 0.11 units at 12 months and 0.14 units at 24 months, respectively. Significant improvements in psychological outcome measures were detected in both treatment groups.

Authors have raised the concern that too much focus on weight is not only ineffective but could also be damaging (153). In this study we have not detected any adverse effects in terms of psychological outcomes after two years, on the contrary we found an overall improvement in mental health rated by both child and parents and a significant improvement in self reported athletic competence. This finding is in the line with former reviewers’ evaluation of weight management programmes, concluding with no psychological harm in children (104, 154). The general lack of reporting psychological outcomes in intervention studies is surprising, taking into account the well known association between childhood obesity and impairment of mental health and well-being. Only a few childhood obesity trials reported on mental health outcome parameters and some more reported on self-esteem and quality of life (101, 148, 155, 156). In general authors report of an overall improvement in these parameters post-treatment, but long-term effects (beyond 1 year) are waning or often not reported (80).

A beneficial psychosocial effect of physical activity is thoroughly documented (44, 157). This intervention had a strong emphasis on physical activity in both intervention groups but only the MUFI had organised PA sessions. Provided that participating children managed to increase their intensity and/or quantity of PA, this favourable change may have affected mental health and well-being. The overall self reported improvement in athletic competence might possibly imply such mechanism.

The solution focused approach with emphasise on what families already are doing well for themselves and their child, may make the children and their parents more confident about themselves and further achievements which again may affect psychological outcomes. In a qualitative interview parents reported that their confidence in achievements were vital for managing life style change (128).
Primary care represented by general practitioners and public health nurses should be central in treating childhood obesity because of their accessibility to all children throughout childhood. However, general practitioner led behavioural treatment of individual families did not show any significant reduction in measures of degree of obesity (158), another cluster randomised controlled trial performed in primary care for children aged 2-6 years did not significantly reduce BMI (159) and a shared care approach showed disappointing results (160). The pooled results on reduction of degree of overweight (-0.14 BMI SD score) in this study corresponds to results from a recent trial showing a favourable effect of a six months programme (161) and another trial detecting that a shared care approach was just as effective as a hospital approach (162). These recent findings implies that treatment approaches for childhood obesity in primary care can be effective. As mentioned earlier treatment intensity might have contributed to the favourable effect in this current study but also the real shared care approach based on team-work between providers from primary and specialised care might have facilitated this outcome. Primary care providers have reported lack of knowledge and skills in the treatment of childhood obesity (163). This current intervention has worked specifically with perceived knowledge gaps among providers in the municipalities through organised courses, meetings and outreaching guidance in order to improve their confidence and ability to treat childhood obesity and reduce the feeling of professional loneliness. This may have resulted in improved results with a somewhat higher intensity in the MUFI group. Parents needed to
be reassured that providers would address their child’s weight in a non-judgemental sensitive matter and were able to treat childhood obesity effectively, reported in a qualitative study of childhood obesity management in primary care (164).

A shared care approach might be a better solution for the time being than primary care solely. In Finnmark we have a shortage of health professionals in the municipalities and challenges in terms of high personnel turnover. Project nurses in offered new employees in the participating municipalities outreached guidance by phone and meetings in addition to the organised courses. A solely primary care approach would have faced considerable challenges linked to work force instability and would probably have made both treatment arms less successful.

6.4 Strength and weaknesses of the clinical trial Finnmark Activity School.

The strengths of this study include the choice of a randomised design in order to answer the research question, the pre-specified primary and secondary outcome measures, the allocation concealment, the blinding of primary outcome assessors, sample size determined from power calculation achieved, appropriate statistical methods including intention to treat analysis and linear mixed models applied, moderate withdrawal,
reporting according to CONSORT guidelines and appropriate piloting performed before start.

Limitations include a lower study power than anticipated because of a larger variability in BMI kg/m² than expected. We used a standard deviation of 0.8 in both groups when calculating power, but the standard deviation turned out to be considerately higher. Ideally we should have recruited more participants but the recruitment period in this trial was already quite long (February 2009 to November 2010) and considerable efforts were made in order to recruit municipalities and families through advertising and media coverage. An even longer period would have caused extraordinary expenses in terms of time and resources. A pragmatic approach was chosen; recruit as many participants as possible within the time frame available, have continuous preparedness on retention and then calculate the difference we will be able to detect. With the standard deviation observed in the current study of 2.45 in MUFI and 2.73 in SIFI after 24 months, we were able to detect a between group difference in BMI of 1.16 kg/m² with 79 observations using two sample t-test

\[ n = \frac{(u + v)^2(\sigma_1^2 + \sigma_2^2)}{(\mu_1 - \mu_2)^2} \]

\[ 79 = \frac{(0.84 + 1.96)^2(2.45^2 + 2.73^2)}{(x)^2} \]

\[ x = 1.16 \]

The eligibility criteria of BMI corresponding to ≥ 27.5 kg/m² in adults was calculated as the mean between the two international cut-off points defining overweight and obesity in children, by age and gender. This was a pragmatic choice in order to recruit sufficient participants from each municipality and at the same time exclude children only slightly overweight. This is however not a generally applied criterion.

We observed that the measures of waist circumference and skinfold had a high within-observer and between observer variability and tried to minimise this problem by reducing the number of nurses involved in these procedures. Giving priority to quality control and continuity, we chose two experienced paediatric nurses to obtain the above mentioned measurements. These nurses were however also involved in the study conduct and
therefore not blinded to group allocation. Waist circumference is considered an objective measure, but it may be argued that this approach could bias study results.

The primary outcome parameter BMI SD score has certain limitations related to evaluation of treatment trials. Different reference populations for the calculation of BMI SD score makes comparison between studies challenging and one should also be aware of the documented reduced variability of BMI SD score in very overweight children. BMI kg/m$^2$ and BMI % was therefore considered favourable to BMI SD score in treatment studies (165).

Performing a clinical trial in small municipalities is challenging because of high contamination risk between treatment groups. Initiatives were taken in order to minimise these effects by scheduling SIFI and MUFI appointments at different days, but casual contact between families was inevitable. Due to the small municipalities and shortage of personnel, same providers were employed in both treatment arms. As a consequence the outreached guidance and courses for providers, reached the SIFI as well as the MUFI approach. This strategy might have attenuated group differences. It is possible that both treatments would be successful relative to no treatment or even standard care. Retrospectively one might speculate if the choice of active control receiving more than standard treatment impaired the scientific value of this trial. Our main objective was to find a better treatment than conventional treatment and a third treatment arm receiving only standard care had been beneficial. However, the sample size had to be increased considerably and the feasibility of such a study in our region is questionable.

In order to assess the natural course of adiposity and psychological well-being in obese children, a true control group would be optimal. However, a control group receiving no intervention or waiting list would be regarded as impossible in long-term studies for ethical reasons.

**Limitations**

In absence of a control group receiving conventional or no treatment we cannot rule out if the pooled favourable effects in this study in terms of overall decrease in degree of overweight and measures of mental health are due to the two interventions as such. The favourable change in BMI from eligibility to start (page 48) might be explained by the Hawthorne effect; human subject of an experiment change their behaviour, simply because they are being studied (166). Alternate hypothesis for the pooled favourable effect may be
that most families were highly motivated. This current design contributes to a less degree
to explanation theories and overriding perspectives on these issues.

6.5 Ethical considerations

Due to research on children considered a vulnerable group with impaired autonomy the
clinical trial Finnmark Activity School has been the subject of various ethical
considerations. We wanted to protect the autonomy and the individual informed consent.
Families interested in participating contacted study nurse after advertising and media
coverage. They received oral information by phone and written information by post. An
appointment for eligibility assessment and conversation with study nurse and
paediatrician were offered 1-2 weeks later. If they had made a decision to participate;
families gave their written informed consent, signed by parents and all children ≥12 years.
Research in children requires significant attention because they are considered a
vulnerable group with impaired autonomy. In this current project all children were asked
about their view of participating. In general families were encouraged to spend the time
needed for considering the issues related to this project. Children who clearly expressed
reluctance to participate should not be recruited. None of the families had a therapeutic
relationship with the paediatrician and no undue influence should be performed.

There was no evidence of harm in interventions for treatment of obesity in children by the
time this current trial was carried out, however the psychological outcome results were
limited and potential side effect of group treatment was not formerly tested. Measures of
psychological outcome were therefore recorded at baseline and already after 6 mon,
in order to monitor and discover potential adverse effects as early as possible.

“As a general rule, research subjects in the control group of a trial of a diagnostic,
therapeutic, or preventive intervention should receive an established effective
intervention”, according to Council for International Organizations of Medical Sciences
2002(167). The international ethical guidelines also state: “A clinical trial cannot be
justified ethically unless it is capable of producing scientifically reliable results”. In this
current trial we chose an active control who received more than conventional treatment in
terms of structured follow-up by public health nurse in the municipality with knowledge in
childhood obesity and solution focused counselling. These solution focused approach were
already proven effective in child obesity treatment (96). The multidisciplinary team
experienced standard care as unsatisfactory and authors reported standard hospital
treatment of obese children as ineffective (168). The control group in this clinical trial
therefore received more than standard care. The possible decreased scientific reliability as a result of this choice is formerly described.

**Conflict of interest**

Some reviewers of obesity treatments discuss the challenge when operators of a specialist clinic also carry out research. I am not in charge in our clinic but I could still have interests in the intervention to work. My interest above all was to offer evidence-based, cost-efficient treatment programmes to families seeking help for their child’s obesity in the future. I hoped that this study could contribute to this evidence base. The methods have to be good and transparent to meet this query. I have not taken part in the data collection, punching or “cleaning” of the raw data in the data base. Staff at Clinical Research Centre University Hospital of North Norway has received a copy of the original dataset before I started to analyse. We have had a continuous preparedness on this issue in the project group. No conflicts of interests are disclosed.
7. Conclusion

- In Finnmark County 2007 the prevalence of overweight (included obesity) was 16 % and 22 % among 6–year old boys and girls, respectively. These figures were somewhat higher compared with other surveys in Norway performed in the same period.
- The Finnmark Activity School randomised trial did not show any between-group differences in BMI and BMI SDS adjusted after 24 months.
- A significant between-group effect in waist circumference was detected in favour of the multiple family intervention.
- Overall there was a favourable effect in both interventions pooled, in terms of degree of obesity (BMI SD score) and psychological outcome measures.
8. Implications, unanswered questions and future aspects

Findings from paper I confirmed that the prevalence of childhood overweight and obesity is high in the county of Finnmark, and that preventive initiatives in order to counter act the obesity epidemic and evidence based management for obese children is highly warranted. Child healthcare centres collect valuable information on child health and this information should be made more readily available in order to monitor the epidemic, evaluate the effects of former initiatives and address new initiatives.

Results from paper II and III do not provide sufficient evidence for implementation of the multiple family intervention (MUFI) in a conventional clinical setting. In spite of borderline between-group effects in terms of BMI SD score and significant between group effects in waist circumference, the increased expenditure in MUFI can probably not be justified by these modest finding. Concerning the between-group effect in waist circumference, further research is needed in order to explore possible between-group effects in cardio metabolic risk factors and physical activity. The overall decrease in degree of overweight and favourable improvement in measures of mental health is promising, but as we do not have a true control group we cannot conclude that these findings are caused by the two interventions as such. We might however suggest that the shared care approach, the provider network, guidance and the solution focused approach may have contributed to the favourable outcomes. In order to explore elements effective in life style change, qualitative interviews of participating parents and children themselves are strongly recommended. Research in health care service for obese children and interviews of providers involved in both preventive and treatment initiatives are also needed. Family characteristics as predictor for favourable outcome needs to be explored, in order to better canalise recourses and tailor treatment to each individual child.
Sandfjellet; Sørøya 2011

Photo: Finnmark Activity School
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10. Papers I–III
11. Appendices

1. Approvals
2. Questionnaire
3. Letter to the municipalities, agreement
4. Content of the interventions, programme
Appendix 1 – Approvals
Appendix 2 – Questionnaire
Appendix 3 – Letter to the municipalities, agreement
Appendix 4 – Content of the interventions, programme