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Marja Kalavainen

# *Treatment of Obesity in Children*

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Author´s address: Department of Pediatrics
Kuopio University Hospital
KUOPIO
FINLAND

Supervisors: Outi Nuutinen, PhD
Department of Clinical Nutrition
Institute of Public Health and Clinical Nutrition, School of Medicine
Faculty of Health Sciences
University of Eastern Finland
KUOPIO
FINLAND

Professor Matti Korppi, MD, PhD
Pediatric Research Center
Tampere University and University Hospital
TAMPERE
FINLAND

Reviewers: Adjunct Professor Hanna Lagström, PhD
Turku Institute for Child and Youth Research
University of Turku
TURKU
FINLAND

Adjunct Professor Matti Salo, MD, PhD
Division of Children's and Women's Health
Tampere University Hospital and University of Tampere
TAMPERE
FINLAND

Opponent: Professor Pertti Mustajoki, MD, PhD
University of Helsinki
HELSINKI
FINLAND

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## ABSTRACT

Obesity has a severe impact on children's psychosocial and physical health. The aim of this randomised controlled study was to compare the efficacy of a behavioural family-based group program consisting of 15 sessions for parents and children with routine counselling ("current care") consisting of two appointments for children in the treatment of childhood obesity.

Seventy 7-9-year old obese children (weight for height 115% to 182%) were randomised to routine (n=35) or group (n=35) program. Children's weights and heights were measured at baseline, after the 6-month intervention, and at 2- and 3-year follow-ups. In addition, children's body composition and metabolic indicators were assessed pre- and post-intervention, and the mean costs of the programs were calculated from the perspective of the service provider. The changes of weight for height and BMI standard deviation scores (BMI-SDS) were used as main outcome measures.

After the intervention, there were significant differences between the treatment programs in favour of the group program in the changes of children's weight for height (on average, a 6.8% reduction vs. a 1.8% reduction, p=0.001) and BMI-SDS (0.3 vs. 0.2, p=0.022). In addition, the decrease in waist/height was greater in the group program (mean 0.02, 95% CI 0.03 to 0.01) than in the routine program (0.01, 95% CI 0.02 to 0.00), respectively, but there were no significant differences between the treatment arms in the changes of other metabolic indicators. The costs per treated child were 392€ and 74€ in the group treatment and in routine counselling, respectively. Both group and routine programs were feasible with very low, 3% or less, attrition rate from the programs. In the long term, from baseline to 2 years or to 3 years, there were no significant differences in the changes of the adiposity indicators between the children in the two treatment arms. In both programs, children's BMI-SDS decreased moderately from baseline to three years (in group program on average a 0.3 reduction, 95% Cl from -0.5 to -0.2 and in routine counselling on average a 0.3 reduction, 95% Cl from -0.5 to -0.1). However, weight for height was rather similar to baseline at those points in time (in group program on average a 1.4% reduction, from -5.0 to 2.2 and in routine counselling on average a 0.8% increase, from -4.6 to 6.1).

In conclusion, the more intensive group program is more effective than routine program in reducing children's adiposity and abdominal adiposity, when assessed shortly after intervention. However, in the long term, there is no difference in efficacy between the programs and the routine counselling is cheaper. New approaches are needed to improve long-term efficacy of childhood obesity treatment.

National Library of Medicine (NLM) Classification: WD 210, WS 130
Medical Subject Headings (Mesh): Child; Obesity, therapy; Counselling; Group Processes; Treatment Outcome; Costs and Cost Analysis; Randomized Controlled Trial

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## TIIVISTELMÄ

Lihavuus heikentää lapsen somaattista ja psykososiaalista terveyttä. Tämän satunnaistetun, kontrolloidun tutkimuksen tarkoituksena oli verrata kahden lasten lihavuuden hoito-ohjelman, ryhmähoidon ja tavanomaisen hoidon, vaikuttavuutta. Käyttäytymisterapiaa soveltava ryhmähoito koostui 15 lapsille ja vanhemmille tarkoitetusta tapaamiskerrasta ja tavanomainen hoito (yksilöhoito) kahdesta lapsille suunnatusta tapaamiskerrasta.

70 iältään 7-9 –vuotiasta lihavaa (pituuspaino 115 – 182 %) lasta satunnaistettiin ryhmähoitoon tai tavanomaiseen hoitoon. Lasten painot ja pituudet mitattiin lähtötilanteessa, kuuden kuukauden intervention jälkeen sekä 2- ja 3-vuotisseurannassa. Lisäksi lasten kehon koostumus ja metaboliset mittarit mitattiin ennen interventiota ja sen jälkeen. Hoitomuotojen kustannukset laskettiin palveluntuottajan näkökulmasta. Pituuspaino ja BMI-SDS (painoindeksi ilmoitettuna keskihajontayksikköinä) olivat keskeisiä vastemuuttujia.

Ryhmähoito oli tavanomaista hoitoa vaikuttavampaa hoitoa lasten pituuspainomuutosten (keskimäärin 6,8 % lasku vs. 1,8 % lasku, p=0.001) ja BMI-SDS-muutosten (0,3 vs. 0,2, p=0.016) pohjalta intervention jälkeen arvioituna. Lisäksi lasten vyötärö/pituussuhde laski enemmän ryhmähoidossa (keskimäärin 0,02, 95 % luottamusväli 0,03-0,01) verrattuna tavanomaiseen hoitoon (0,01, 95 % luottamusväli 0,02-0,00), mutta toisaalta hoitomuotojen välillä ei ollut eroa muiden metabolisten mittareiden muutoksissa. Kustannukset hoidettua lasta kohden olivat 392 € ryhmähoidossa ja 74 € tavanomaisessa hoidossa. Molemmat ohjelmat olivat toteuttamiskelpoisia, ja keskeyttämisprosentti oli enintään 3 %. Pitkäaikaisseurannassa, kaksi tai kolme vuotta tutkimuksen alkamisesta, hoitomuotojen välillä ei ollut enää merkitseviä eroja pituuspainon tai BMI-SDS:n muutoksissa. Molemmissa ohjelmissa lasten BMI-SDS laski kohtuullisesti lähtötilanteen ja 3-vuotisseurannan välillä (ryhmähoidossa keskimäärin 0,3 yksikön lasku, 95 % luottamusväli välillä -0,5 ja -0,2, tavanomaisessa hoidossa keskimäärin 0,3 yksikön lasku, 95 % luottamusväli välillä -0,5 ja -0,1). Kuitenkaan pituuspainossa ei ollut juuri muutosta näiden ajankohtien välillä (ryhmähoidossa keskimäärin 1,4 % lasku, luottamusväli välillä -5,0 ja + 2,2, tavanomaisessa hoidossa keski-määrin 0,8 % lisäys, luottamusväli välillä -4,6 ja +6,1).

Johtopäätöksenä voidaan todeta, että intensiivinen ryhmäohjelma vähentää tavanomaista hoitoa enemmän lasten rasvakudoksen määrää ja vatsakkuutta intervention jälkeen mitattuna. Sen sijaan ohjelmien pitkäaikaisessa vaikuttavuudessa ei ole eroa ja tavanomainen hoito on edullisempaa. Tarvitaan uusia lähestymistapoja parantamaan lasten lihavuuden hoidon pitkäaikaista vaikuttavuutta.

Luokitus: WD 210, WS 130
Yleinen suomalainen asiasanasto (YSA): lapset, lihavuus, hoitomenetelmät, neuvonta, ryhmäterapia, kustannukset, vaikuttavuus

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# List of the original publications

This dissertation is based on the following original publications:

I Kalavainen MP, Korppi MO, Nuutinen OM. Clinical efficacy of group-based treatment for childhood obesity compared with routinely given individual counseling. *Int J Obes (Lond) 31: 1500-1508, 2007.*

II Kalavainen M, Karjalainen S, Martikainen J, Korppi M, Linnosmaa I, Nuutinen O. Cost-effectiveness of routine and group programs for treatment of obese children. *Pediatr Int 51: 606-611, 2009.*

III Kalavainen M, Utriainen P, Vanninen E, Korppi M, Nuutinen O. Impact of childhood obesity treatment on body composition and metabolic profile. World J Pediatr (in press) DOI: 10.1007/s12519-011-0324-2.

IV Kalavainen MP, Korppi MO, Nuutinen OM. Long-term efficacy of group-based treatment for childhood obesity compared with routinely given individual counselling. *Int J Obes (Lond) 35: 530-533, 2011.*

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# Contents

# Abbreviations

| | |
|---|---|
| BIA | bioelectrical impedance analysis |
| BMI | body mass index |
| BMI-SDS | body mass index standard deviation score |
| QALY | quality adjusted life years |
| CI | confidence interval |
| CT | computed tomography |
| DALY | disability adjusted life years |
| DBP | diastolic blood pressure |
| G1-5 | stages of the development of genitals (G) in boys (Tanner and Whitehouse 1976) |
| HDL-C | high-density lipoprotein cholesterol |
| HOMA-IR | homeostasis model assessment for insulin resistance (Matthews el al. 1985) |
| ICER | incremental cost-effectiveness ratio |
| IOTF | International Obesity Task Force |
| LEAP | Live, eat and play (obesity treatment study) (McCallum et al. 2005) |
| LDL-C | low-density lipoprotein cholesterol |
| M1-5 | stages of the development of breast tissue (M) (Tanner and Whitehouse 1976) |
| MRI | magnetic resonance imaging |
| RCT | randomised controlled trial |
| SDS | standard deviation score |
| SIGN | Scottish Intercollegiate Guidelines Network |
| SBP | systolic blood pressure |
| SD | standard deviation |
| TG | triglycerides |
| TC | total cholesterol |
| UK | United Kingdom |
| US | United States |

# 1 Introduction

Obesity in children and adolescents (Hakanen et al. 2006, Kautiainen et al. 2009, Vuorela et al. 2009, Saari et al. 2010) shows alarmingly high rates in Finland as well as worldwide (Wang and Lobstein 2006). In Espoo in Southern Finland, the prevalence of overweight and obesity in 2-18 years old boys was 21.8% and 4.4%, respectively, using the International Obesity Task Force (IOTF) definitions (Saari et al. 2010). Respective figures for girls were 12.2% and 1.8% (Saari et al. 2010).

Although obesity is due to excess energy intake (diet) in relation to energy expenditure (metabolism, physical activity), the aetiology of obesity is very complex (Aronne et al. 2009). However, environmental factors, termed collectively as the "toxic environment", are the main reason for the current epidemic of childhood obesity (Friedman and Schwartz 2008). Paradoxically, current western societies support unhealthy lifestyle habits but stigmatise obesity and promote unrealistic thinness (Fitzgibbon and Stolley 2006).

Childhood obesity has severe impacts on children's psychosocial and physical health (Canning and Mayer 1967, Riley et al. 1976, Freedman et al. 1987, Gortmaker et al. 1993, Hill and Silver 2005). For example, prepubertal obese children have increased levels of cardiovascular risk factors compared with normal-weight children (Morrison et al. 1999a, Morrison et al. 1999b, Garces et al. 2005). As a result, since 1950's there has been growing interest in the treatment of childhood obesity (Lloyd and Wolff 1961, Brook et al. 1974, Brownell et al. 1983, Ylitalo 1981, Nuutinen 1991). However, until the early 2000's most of the randomised controlled trials assessing the efficacy of childhood obesity treatment were performed by one study group (Epstein et al. 2007). Their pioneering work has included studies focusing on family-based obesity treatment (Epstein et al. 1985c), physical activity (Epstein et al.1985a, Epstein et al. 1995, Epstein et al. 2000a), diet (Epstein et al. 1985b) and applications of behavioural therapy (Epstein et al. 1994). Nowadays, the importance of a family-based multi-component approach in childhood obesity treatment is widely recognised (Oude Luttikhuis et al. 2009, Whitlock et al. 2010).

As late as 2003, a Cochrane review (Summerbell et al. 2003) noted the uncertainty of the efficacy of childhood obesity treatment because of the poor validity and generalisability of many of the 18 randomised controlled trials included in the review. It also emphasised that there remained un urgent need for the assessment of the cost-effectiveness of the treatment programs (Summerbell et al. 2003). However, during the last few years, there has been a remarkable rise in the quantity and quality of published papers in the field of childhood obesity (Atkinson and Macdonald 2009). The treatment of childhood obesity has a modest, but clinically significant impact on children's adiposity, at least in the short term (Oude Luttikhuis et al. 2009), and it may reduce the level of cardiovascular risk factors (Reinehr and Andler 2004, Reinehr et al. 2004, Ford et al. 2010). Still, few conclusions of the cost-effectiveness of the treatment can be made (Cawley 2007, John et al. 2010).

The purpose of this study is to compare a new group-based treatment of childhood obesity with current routine treatment in school health-care in 7-9 year-old children. In line, the review of literature focuses on studies in young school-aged children.

# 2 *Review of the Literature*

## 2.1 DEFINITION OF CHILHOOD OVERWEIGHT AND OBESITY

Overweight and obesity are an excess of adiposity (=amount of adipose tissue) in body. However, the definition of overweight or obesity in children is arbitrary and difficult due to several factors. Firstly, the assessment of body composition is challenging, and there is no method which is accurate, cheap and easily accessible, and thus suitable to clinical work and field studies (Mattson and Thomas 2006, Reilly 2010). Secondly, the use of reference values of overweight and obesity in children is complicated, because values must be adjusted by gender and age due to changes in body composition during growth (Ellis 2000). Thirdly, as many adverse health effects associated with childhood obesity are not seen before adulthood (Reilly et al. 2003), defining "excess" fat mass in children is difficult.

Most accurate measures of body composition, e.g. underwater weighing (hydrodensitometry), computed tomography (CT), magnetic resonance imaging (MRI) and dual-energy x-ray absorptiometry (DXA), are used mainly as validation methods for less reliable measures of body fatness due to their high costs and limited access (Ellis 2000). Indirect methods of body composition assessment, bioelectrical impedance analysis (BIA) and skinfold measurement, are inexpensive and thus suitable for field studies (Ellis 2001). The advantages of BIA include that it is easy to perform and, and its precision is not operator-dependent (Ellis 2001). However, there are no national of international BIA reference values for children.

The definitions of overweight and obesity in children are most commonly based on body mass index (BMI). BMI is useful as a proxy measure of adiposity in children, because it is associated with body adiposity (Pietrobelli et al. 1998) and concurrent health risk (Freedman et al. 2009b), and furthermore, with adult adiposity (Freedman et al. 2005, Thompson et al. 2007) and mortality (Baker et al. 2007). In the assessment of paediatric adiposity, BMI values are usually compared with age- and gender-specific national data using percentiles (Reilly 2010). However, there are no internationally accepted cut-off values for childhood overweight or obesity. In the United States (US), cut-off percentiles 85th-94th and ≥95th are recommended for the definitions of overweight and obesity, respectively (Barlow and the Expert Committee 2007, August et al. 2008, Daniels et al. 2009, US Preventive Services Task Force 2010), whereas respective cut-offs for clinical practice in United Kingdom (UK) are the 91st and 98th percentiles (Reilly 2010, SIGN, Scottish Intercollegiate Guidelines Network 2010). Alternative approach for the definitions of paediatric overweight and obesity is such called IOTF (The International Obesity Task Force) method, which sets children's age- and gender-specific cut-offs for overweight and obesity corresponding with adult BMI cut-off points of 25 and 30 $kg/m^2$, respectively (Cole et al. 2000). IOTF cut-offs are based on international data and were originally set for international epidemiological comparisons (Cole et al. 2000). BMI values can also be adjusted with gender and age by calculating a standard deviation score (SDS, z score) (Kipping et al. 2008).

Weight for height monitoring in children is in routine use in the health care system in Finland. Since 2005, overweight and obesity in children over seven years has been defined as weight for height 120-140% and >140%, respectively (Childhood obesity: Current Care Guideline 2005). A criterion for childhood obesity was not established earlier, and for example weight for height ≥120% has been used previously as a cut-off for obesity (Lautala 1990, Klish 1998).

Abdominal (visceral) obesity is associated with metabolic abnormalities in children (Zimmet et al. 2007). Direct methods for the assessment of abdominal obesity include CT and MRI (Ellis 2000, Mattson and Thomas 2006), but it can be assessed in clinical work and field studies by measuring waist circumference. Waist circumference values can be adjusted to child's gender and age using z scores or waist-to-height ratios (McCarthy and Ashwell 2006). There are population-based values of waist circumference in children available in some countries (Schwandt et al. 2008). However, there are no internationally accepted children's age- and gender-specific cut-off points. Although the usage of waist circumference has been suggested for the diagnosis of obesity, a recent systematic review does not support the use of it as a proxy method for defining childhood obesity (Reilly et al. 2010).

## 2.2 CONSEQUENCES OF CHILDHOOD OBESITY

### 2.2.1 Health consequences in childhood

Childhood obesity has many adverse psychological and somatic consequences. The most common health impacts of obesity on children are likely psychosocial problems. Obese females and adolescents are particularly vulnerable to negative psychological consequences (Wardle and Cooke 2005). Obese children are bullied (Lumeng et al. 2010), stigmatised (Latner and Stunkard 2003), and seen as fat, friendless and unhealthy because of negative stereotypes (Hill and Silver 1995). They also have lower quality of life than their normal-weight peers (Friendlander et al. 2003). However, in community-based samples few obese children have been significantly depressed or had low self-esteem (Wardle and Cooke 2005). Moreover, obesity in children may affect specific domains of self-esteem (Lowry et al. 2007); pre-adolescent overweight and obese girls had significantly lower self-esteem regarding physical appearance and athletic competence than normal-weight girls, with no difference in global self-worth (Phillips and Hill 1998). It is unclear whether there are differences in psychological consequences of childhood obesity between nations, e.g. between Finland and the US or the UK.

Childhood obesity is associated with increased risk factors for cardiovascular disease (Freedman et al. 1999, Morrison et al. 1999a, Morrison et al. 1999b, Garces et al. 2005, Freedman et al. 2009b) and type 2 diabetes (Garces et al. 2005). As plasma lipid levels (Niinikoski et al. 2007, Pinhas-Hamiel et al. 2007), insulin sensitivity (Pinhas-Hamiel et al. 2007) and blood pressure (Falkner et al. 2006, Jackson et al. 2007) levels change during growth, the age and pubertal status of the child need to be taken into consideration when the of impact of obesity on metabolic markers is assessed. In prepubertal obese children, the main metabolic abnormalities are increased serum triglyceride (TG) levels (Morrison et al. 1999a, Morrison et al. 1999b, Garces et al. 2005), decreased high density lipoprotein cholesterol (HDL-C) levels (Morrison et al. 1999a, Morrison et al. 1999b, Garces et al. 2005) and impaired insulin sensitivity (Garces et al. 2005) compared with normal-weight children. In addition, increased low density lipoprotein cholesterol (LDL-C) levels and increased blood pressure levels (Morrison et al. 1999a, Morrison et al. 1999b, Falkner et al. 2006) have been detected. Differences between populations may be explained by differences in lifestyle and genetics (Merino et al. 2010). Of importance, metabolic abnormalities in obese children are associated with increased carotid intima-media thickness (Iannuzzi et al. 2004, Wunsch et al. 2006, Schiel et al. 2007), which is a marker of early subclinical atherosclerosis.

Cardiovascular risk factors cluster, and they are associated with abdominal obesity in children (Morrison et al. 1999a, Morrison et al. 1999b, Freedman et al. 2009a), like in adults (Alberti et al. 2005). In adults, the clustering of cardiometabolic risk factors has led to the concept and definition of the metabolic syndrome (Alberti et al. 2005). However, in children there is no consensus of the use or the definition of metabolic syndrome (Ford and Li 2008). The International Diabetes Federation suggests that the metabolic syndrome should not be diagnosed in children under the age of 10 years (Zimmet et al. 2007). In children aged 10 to 16 years, metabolic syndrome is defined by abdominal obesity and the presence of two or more other clinical features (elevated triglycerides, low HDL-cholesterol, high blood pressure or increased plasma glucose) (Zimmet et al. 2007).

Other weigh-related physical conditions in children include pulmonary, orthopaedic, neurological and gastrointestinal problems (Lobstein et al. 2004). Of special concern is the prevalence of non-alcoholic fatty liver disease ranging from steatosis to even cirrhosis in obese children (Lobstein et al. 2004).

### 2.2.2 Health consequences in adulthood

Childhood obesity commonly tracks to adulthood. The persistence of weight status increases with age and with increasing level of overweight (Singh et al. 2008). This was also seen in a population-based Finnish longitudinal cohort study consisting of 6280 participants born 1966 (Laitinen et al. 2001). Of males who were overweight at 14 years, 25% were obese in early adulthood, but as many as 47% of males who were obese at 14 years were still obese in early adulthood (Laitinen et al. 2001). The respective figures for females were 22% and 55% (Laitinen et al. 2001). However, the tracking of childhood obesity into adulthood may be even stronger in the current "obesogenic" environment than in the past.

Childhood and adolescent obesity is associated with increased morbidity and mortality in adulthood (Must et al. 1992, Reilly et al. 2003). In accordance, in a Danish population study, childhood obesity was associated with coronary heart disease in adulthood (Baker et al. 2007). However, the link between childhood obesity and later mortality or morbidity is unclear. A recent systematic review suggests that the relationship between childhood obesity and adulthood cardiovascular disease is dependent on the tracking of BMI from childhood to adulthood. Thus, childhood obesity may not be an independent risk factor for adulthood cardiovascular disease (Lloyd et al. 2010).

### 2.2.3 Economic consequences

The economic burden of a disease can be categorised into direct, indirect (John et al. 2010) and intangible costs (Meltzer 2001). Economic analysis can be performed from the perspective of the patient, the physician, the hospital, the payer and the society (Meltzer 2008).

The direct costs of obesity comprise the costs of obesity treatment and the costs of conditions associated with or caused by it (Lobstein et al. 2004). Adulthood obesity is associated with high costs (Pekurinen 2006, Muller-Riemenschneider et al. 2008), but the direct economic consequences of childhood obesity are ambiguous. Obese children have had higher health care expenditures than normal-weight children (Estabrooks and Shetterly 2007, Hampl et al. 2007), and obesity-related annual hospital costs in children have increased absolutely and proportionally (compared with all costs) in the US (Wang and Dietz 2002) and in Ireland (Vellinga et al. 2008). However, in some studies increased costs associated with childhood obesity were found only in females (Monheit et al. 2009) or in adolescents (Finkelstein and Trogdon 2008), or there was no association at all (Skinner et al. 2008). A recent systematic review emphasises poor comparability of the studies on the economic consequences of childhood obesity (John et al. 2010). Besides, the costs may vary in different populations and subgroups (Finkelstein and Trogdon 2008, Monheit et al. 2009). Like in adults (Andreyeva et al. 2004), the severity of obesity may be an important determinant of the costs in children. Furthermore, overweight children may not have appropriate access to health care services (Skinner et al. 2008). The cost-effectiveness of the treatment of obesity is dealt with in 2.5.2.

The indirect costs of obesity refer to the losses of income due to the excess morbidity or mortality of obese people (Lobstein et al. 2004). In childhood obesity, another definition of indirect costs could be applied: they comprise e.g. time off school for obese children and time off work for parents for caring for sick obese children (Lobstein et al. 2004). Indeed, a US study suggested that obese children have more school absenteeism than their normal-weight peers (Geier et al. 2007).

The intangible costs of a disease comprise pain, suffering and fear (Meltzer 2001). Though intangible costs may have a major impact on the individual, economic valuing is challenging (Meltzer 2001).

The persistence of childhood obesity to adulthood may cause substantial costs in the future. A US study estimated that current adolescent overweight will produce costs of $254 billion, of which 82% are indirect costs, in 2020 to 2050 due to excess obesity and associated diabetes and cardiovascular disease (Lightwood et al. 2009).

Of importance, most studies assessing the economic consequences of childhood obesity have been performed in the US. Thus, the results cannot be generalised to Finland or any other country with a lower prevalence of childhood obesity and furthermore, with a different health care system.

## 2.3 COMPONENTS IN THE TREATMENT PROGRAMS OF CHILHOOD OBESITY

### 2.3.1 Common components in treatment programs

Although aetiology of obesity comprises many interacting genetic, physiologic, environmental, psychological, social, economic and political factors (Aronne et al. 2009), a few of these are modifiable, at least at the family level. Thus, treatment of obesity is based on lifestyle changes, decreasing energy intake (diet) and increasing energy consumption (physical activity) with the help of behavioural therapy (Childhood obesity: Current Care Guideline 2005, Oude Luttikhuis et al. 2009, Whitlock et al. 2010). Furthermore, a prudent diet and active lifestyle are recommended to all children in order to promote health and to prevent diseases (Nicklas et al. 2008). In addition, childhood dietary patterns (Mikkila et al. 2005) and physical activity (Yang et al. 2007) seem to track to adulthood. Thus, the basis for health-promoting lifestyle of adulthood is created already in childhood. In line, an Expert Committee (Barlow and the Expert Committee 2007) emphasises as the primary goal of obesity management a permanent healthy lifestyle. In addition, an individualised weight goal ranging from weight velocity maintenance to weight loss is recommended for overweight and obese 6-11-year old children (Barlow and the Expert Committee 2007). The role of diet and physical activity in childhood obesity treatment is discussed in more detail in chapters 2.3.2 and 2.3.3, respectively.

Research evidence highlights the importance of family-based treatment programs (McLean et al. 2003, Kitzmann and Beech 2006, Epstein et al. 2007, Young et al. 2007, Nowicka and Flodmark 2008, Kitzmann et al. 2010), that is a program in which parents are included as an integral part of the treatment (Kitzmann and Beech 2006). In line, recommendations emphasise the inclusion of parents in the treatment (Barlow and the Expert Committee 2007, Spear et al. 2007, SIGN 2010), as parents act as role models to their children and create environment for healthy habits (Golan and Weizman 2001, Golan and Crow 2004a).

Obviously, changing lifestyle requires motivation. Therefor it is recommended that motivating techniques should be used in the treatment of obesity (Childhood obesity: Current Care Guideline 2005, Barlow and the Expert Committee 2007, Spear et al. 2007, SIGN 2010). Although the importance of motivation in lifestyle changes has been noted, the studies evaluating the efficacy of childhood obesity treatment rarely describe the used motivating techniques or the assessment of the motivation of participants. Research-based motivation techniques include motivational interviewing (Rollnick et al. 2010, Spahn et al. 2010) and the transtheoretical model of behaviour change (DiClemente et al. 1991, Andres et al. 2009). Motivational interviewing is based on the use of guiding, not on directing, and it aims to elicit the motivation from the ambiguous participant by skilfully asking, listening and informing (Rollnick et al. 2010). The transtheoretical model suggests that an individual adopting a new behaviour moves through a series of stages of change (Andres et al. 2009). It was originally applied in the cessation of smoking (DiClemente et al. 1991) and later e.g. in obesity treatment (Andres et al. 2009). The concepts of transtheoretical model may help to tailor obesity treatment according to individual needs and motivation (Andres et al. 2009).

### 2.3.2 Diet

All children are recommended to follow a diet, which is nutritionally balanced, appropriate for growth and development, acceptable and feasible (Hasunen et al. 2004, Gidding et al. 2005, Nicklas et al. 2007). Moreover, a diet suitable for obesity treatment needs to lead to decreased energy intake (Childhood obesity: Current Care Guideline 2005).

In the studies of the treatment of paediatric obesity, wide varieties of diets have been applied (American Dietetic Association 2006, Collins et al. 2007). American Dietetic Association (2006) has defined the dietetic components of childhood obesity treatment programs as dietary counselling (the prescription of a specified caloric and/ or nutrient content per day) and as nutrition education (more general information to promote healthful eating). Altered macronutrient diets have included modified carbohydrate diets (low-carbohydrate, reduced-glycaemic-load diet), high-protein diets (McGovern et al. 2008) and low-fat diets (Collins et al. 2007), and they have been mainly used in studies on the treatment of obesity in adolescents.

Most commonly used dietary approach in randomised controlled trials is "Traffic light diet" (Collins et al. 2007), which was originally developed by Epstein and his group and later modified by Epstein and co-workers (Epstein et al. 2007, Epstein et al. 2008) and also by other research groups (Stewart et al. 2005). Shortly, it is based on categorizing foods to three groups: "red" (high energy density foods), "yellow" (the bulk of the food intake) and "green" (very low energy density). Children are allowed to eat restricted amount of red and yellow foods, but freely green foods, usually leading to energy intake of 1200 – 1500 kcal (Collins et al. 2007). The Traffic Light diet approach also usually includes daily self-monitoring of diet and body weight in a habit diary (Collins et al. 2007).

Systematic reviews have assessed diet as a component of childhood obesity treatment, but the lack of good-quality trials limits the possibilities to conclusions (Gibson et al. 2006, Collins et al. 2007). A review assessing 88 studies, which included dietary components as isolated or combined with other components, concluded that diet therapy generally resulted in weight loss at least in the short term (Collins et al. 2007). However, it was not possible to separate the effects of diet from the other components of treatment or to give detailed recommendations of dietary approach (Collins et al. 2007). Another review assessing nine studies, which included only dietary components, suggested that reduced carbohydrate and low-glycaemic-index diets are at least as effective as low-fat energy-restricted diets for short-term weight loss (Gibson et al. 2006). However, there are no trials, which show long-term feasibility, efficacy and safety of the modified carbohydrate diets in the treatment of paediatric obesity.

In line with many earlier recommendations of childhood obesity treatment (Uli et al. 2008), SIGN (2010) recommends to obese children a balanced healthy diet, portion control and regular meals (Table 1). In addition, parents are encouraged to eat with their children and to separate eating from other activities, like watching television (SIGN 2010).

*Table 1. Recommendations for the treatment of obese children. Based on the Scottish Intercollegiate Guidelines Network (SIGN) (2010).*

| **Component** | **Recommendation** |
|---|---|
| **Diet** [1] | |
| *Regular meals* | Eat regularly, including breakfast |
| *Quality of diet* | |
| Bread, pasta, potatoes, rice | Eat plenty, choose wholegrain varieties when possible |
| Fruit and vegetables | Eat plenty |
| Milk and dairy foods | Eat some, choose lower fat alternatives |
| Meat, fish, eggs, beans | Eat some, choose lower fat alternatives |
| Food and drinks high in fat/sugar | Consume just a small amount |
| *Portions* | Choose according to energy need<br>Listen to internal hunger cues |
| **Physical activity and sedentary behaviour** | All children: ≥1 hour moderate to vigorous activity/day, overweight children may need more<br>Less than 2 hours sedentary behaviour |
| **Behavioural techniques** | Stimulus control, self-monitoring, goal setting rewards, problem solving |

[1] for children over the age of five years

### 2.3.3 Physical activity and sedentary behaviour

Physical activity is a prerequisite for normal development of cardiorespiratory endurance, and muscle and bone development. Furthermore, physical activity reduces risk factors for chronic diseases and increases self-esteem (Nowicka and Flodmark 2007). Physical activity can be classified by intensity into light (e.g. walking slowly), moderate (e.g. climbing stairs) and vigorous activity (e.g. jogging) (Nowicka and Flodmark 2007). Exercise is a subcategory of physical activity and it refers to voluntary, planned, structured and repetitive physical activity (Nowicka and Flodmark 2007).

All children should have regular physical activity (American Academy of Pediatrics 2006, Lasten ja nuorten liikunnan asiantuntijaryhmä 2008). However, obese children may find physical activity less inviting than their normal-weight peers, as they are particularly vulnerable to self-perceived body-related barriers (e.g. not willing for people to see their body while doing physical activity) (Zabinski et al. 2003) and physical barriers (e.g. musculoskeletal pain) (Shultz 2009).

Physical activity is an efficacious component of childhood obesity treatment (Epstein et al. 1996, Maziekas et al. 2003, Atlantis et al. 2006, McGovern et al. 2008). Most studies have evaluated the efficacy of aerobic exercise. In addition, some studies have evaluated the efficacy of combined aerobic and weight-training exercise (Atlantis et al. 2006). The small number of short-term trials supports the efficacy of aerobic exercise of 155-180 minutes/week at moderate-to-high intensity in the treatment of paediatric obesity (Atlantis et al. 2006), but more research is needed to clarify optimal intensity, duration, frequency and mode of physical activity in the treatment of childhood obesity.

Another approach to increasing physical activity is to decrease sedentary behaviour (physical inactivity), which refers to recreational screen time, but not educational activities like doing homework or reading (Epstein et al. 2000a). Interventions aiming at reducing sedentary behaviour have resulted in improvements of health behaviour and weight measures (DeMattia et al. 2007).

SIGN (2010) recommends that obese children should increase their physical activity and decrease sedentary behaviour (Table 1). Children should be supported to be active in their daily lives, also with their parents, as well as to do structured physical activity (SIGN 2010). It is essential that children choose physical activity that is enjoyable to them, e.g. organised sports should focus more on enjoyment than on competition (Childhood obesity: Current Care Guideline 2005, American Academy of Pediatrics 2006).

**2.3.4 Behavioural therapy**

The importance of behavioural therapy in childhood obesity treatment has been recognised for a long time (Varni and Banis 1985, Epstein and Wing 1987, Robinson 1999, Epstein et al. 2001b, Childhood obesity: Current Care Guideline 2005), because education alone does not induce changes in lifestyle effectively (Jelalian and Saelens 1999). However, terminology in the field of behavioural therapy is still not established. For example, behavioural therapy and behavioural modification are common terms that are sometimes used interchangeably, and sometimes considered to have different meanings. For the treatment of childhood obesity, the behavioural approach has varied from traditional behavioural therapy (including techniques like goal setting and self-monitoring) (Dietz and Robinson 2005) to the use of family therapy (Nowicka and Flodmark 2010).

Traditional behavioural therapy is based primarily on the principles of classic conditioning, e.g. on the concept that behaviour (e.g. eating) is often the result of antecedent events (cues), and that in order to change behaviour, a person should pay attention to cues that trigger inappropriate behaviour (Foster et al. 2005). In addition, positive behaviours should be reinforced or rewarded (Foster et al. 2005). Traditional behavioural therapy techniques include goal setting, self-monitoring of habits and weight, stimulus control, problem solving and praising (Dietz and Robinson 2005). In some studies, specific behavioural modification techniques have been stressed, e.g. problem solving (Graves et al. 1988, Epstein et al. 2000b), the training of parents (Israel et al. 1985) or enhanced self-regulation training (Israel et al. 1994). In addition, behavioural therapy has been combined with cognitive therapy, which stresses the importance of cognitive processing in behavioural changes (Duffy and Spence 1993, Braet and Van Winckel 2000, Munsch et al. 2008).

Flodmark (1997, 2005) has emphasised the role of psychological aspects instead of precise techniques in the process of lifestyle changes, and he and his group have used family therapy applying systemic and solution-focused theory in the treatment of childhood obesity (Flodmark et al. 1993, Nowicka et al. 2007). The principles of a solution-focused approach include paying attention on the strengths, abilities and resources of families (Greenberg et al. 2001). A solution-focused treatment approach has later been applied also in the Australian LEAP (Live, eat and play) study (McCallum et al. 2005, McCallum et al. 2007). In addition, the competence of health professionals in creating a positive non-judgmental atmosphere and giving support to clients has been stressed (Lask 2003, Stewart et al. 2009).

A recent Cochrane review concludes that behavioural therapy is an essential part of childhood obesity treatment, but it is not possible to give evidence-based recommendations of the use of any specific type of behavioural therapy (Oude Luttikhuis et al. 2009). In line, SIGN (2010) recommends the use of behavioural components in the childhood obesity treatment (Table 1).

## 2.4 EFFICACY OF THE CHILDHOOD OBESITY TREATMENT

### 2.4.1 Impact on adiposity indicators in the short term

Early systematic reviews have assessed the efficacy of randomised controlled trials in the treatment of childhood obesity covering the studies published in 1960's – 1990's (Jelalian and Saelens 1999) and in 1980's -1990's (Glenny et al. 1997). The reviews suggested that the management of childhood obesity is effective at least in the short term (Glenny et al. 1997, Jelalian and Saelens 1999). Still, as late as 2003 a Cochrane review stated that 'there is a limited amount of quality data on the effects of programs to treat childhood obesity, and as such no conclusions can be drawn with confidence' (Summerbell et al. 2003).

During the last years, there has been an increase in the quality and quantity of the studies evaluating the efficacy of childhood obesity treatment (Oude Luttikhuis et al. 2009, Whitlock et al. 2010), and in addition, many systematic reviews have been published (Wolfenden et al. 2010). Randomised controlled trials have been performed mainly in specialised obesity treatment units (Epstein et al. 2007, Weigel et al. 2008, Ford et al. 2010a), but also in primary health care (McCallum et al. 2007), in a children's health and sports training centre (Nemet et al 2005), community settings (Okely et al. 2010, Sacher et al. 2010) or based on doctor's home visits (Jiang et al. 2005). Interventions have been traditionally group-based (e.g. Epstein et al. 2007), but there has been growing interest in individual-based programs (McCallum et al. 2005, McCallum et al. 2007, Hughes et al. 2008). The intensity of treatment programs has varied from very low intensity (McCallum et al. 2007, Hughes et al. 2008) to moderate and high intensity (Nemet et al. 2005, Savoye et al. 2007) when the categorisation of intensity is based on the hours of contact (very low intensity = <10 hours, low intensity = 10-25 hours, moderate intensity = 26-75 hours, high intensity = >75 hours) (Whitlock et al. 2010). The intensity of an intervention consists of the length of treatment and the frequency of meetings (Whitlock et al. 2010). In addition, primary outcome indicator has been BMI-SDS, percentage overweight, absolute BMI, fat mass and BMI percentile.

Based on the research evidence, the treatment of childhood obesity clearly is effective (Wilfley et al. 2007b, Young et al. 2007, McGovern et al. 2008, Oude Luttikhuis et al. 2009, Kitzmann et al. 2010, Whitlock et al. 2010). However, as the study designs of obesity interventions have been very varied, few evidence-based recommendations on childhood obesity treatment can be made (Oude Luttikhuis et al. 2009, Whitlock et al. 2010). As discussed earlier in chapter 2.3., most authors have recommended using a multi-component family-based program. In addition, the intervention should be of moderate to high intensity (US Preventive Services Task Force 2010), since the intensity of interventions seems to be associated with efficacy (Whitlock et al. 2010).

Several RCTs with varied study designs have evaluated the efficacy of obesity treatment in young obese (Hughes et al. 2008) and overweight and obese (Golan et al. 2006, Golley et al. 2007a, McCallum et al. 2007) schoolchildren (Tables 2, 3). A family-based multi-component trial of low intensity was effective in reducing children's adiposity, and suggested that targeting parents may be more effective than targeting both parents and children (Golan et al. 2006). In contrast, in several interventions of very low intensity and low intensity, there were no significant differences in changes in children's adiposity between treatment and control groups (Golley et al. 2007a, McCallum et al. 2007, Hughes et al. 2008). However, an Australian study suggested that parenting skills training combined with the promotion of healthy lifestyle might be effective in the treatment childhood obesity (Golley et al. 2007a).

Childhood obesity treatment seems to improve children's self-esteem (Lowry et al. 2007) and health-related quality of life (Tsiros et al. 2009). Behavioural childhood obesity treatment is evidently safe (Whitlock et al. 2008, Whitlock et al. 2010). For example, behavioural family-based childhood obesity treatment was not associated with disordered eating (Epstein et al. 2001a).

*Table 2. Study designs of randomised controlled trials of obesity treatment in health care in young schoolchildren lasting at least six months and published 2005 or later*

| **Study reference** | **Participants** | **Intervention** | **Intervention** |
|---|---|---|---|
| | **Age, intervention, control Drop-outs/at baseline** | **Description of treatment arms** | **Length of intervention; contact time in intervention vs. in control** |
| *Group + individual counselling* | | | |
| Golan et al. 2006 | 8.8[1], 8.7[2] years 5/32 | Targets at parents (multi-component) vs. targets at parents and children (multi-component) | 6 months; 21 h vs. 21 h |
| Golley et al. 2007a,b | 8.2 years (combined) 18/111 | Parenting skills training vs. parenting skills training + multi-component lifestyle support vs. waiting list control | 6 months; parenting skills training 10 h vs. parenting skills training + multi-component lifestyle support 21 h vs. waiting list control 20 minutes |
| *Individual counselling for family* | | | |
| Hughes et al. 2008 | 9.1[1], 8.5[2] years 37/134 | Individualised behavioural care (multi-component) vs. standard care (mainly diet) | 6 months (standard care up to 10 months); 5 h vs. 1.5 h |
| McCallum et al. 2005, 2007, Wake et al. 2008 | 7.5[1], 7.4[2] years 3/163 | Solution-focused multi-component individual counselling vs. no treatment[3] | 3 months; ~4 h vs. no treatment |

Definitions: multi-component treatment includes healthy diet, physical activity and behavioural component
Abbreviations: h = hour
[1] intervention group, [2] control group, [3] called standard treatment

*Table 3. Results of randomised controlled trials of obesity treatment in health care in young schoolchildren lasting at least six months and published 2005 or later.*

| Study reference | Baseline BMI-SDS<br><br>intervention, control | Change in BMI-SDS after intervention, significance of difference<br>Change in BMI-SDS at follow-up (from the beginning), significance of difference<br>Conclusions |
|---|---|---|
| Golan 2006 | 2.0, 2.1 | Target at parents -0.4, target at parents and at child -0.1; p=0.024<br>At 18 months: target at parents -0.5, target at parents and at child +0.1; p NR<br>Targeting only at parents more effective than targeting at parents and at child |
| Golley 2007a | P 2.76, P + DA 2.74, WLC 2.75 | P[3] -0.13, P + DA[3] -0.22, WLC NR<br>At 12 months P -0.15, P + DA -0.24, WLC -0.13; p=NS<br>Parenting skills training combined with the promotion of healthy lifestyle may be effective |
| Hughes 2008 [1] | 3.2, 3.3 | Individualised behavioural care -0.10, std. dietetic care -0.06; p=0.4<br>At 12 months: individualised care -0.07, std. dietetic care -0.19; p=0.5<br>Treatment may need to be longer and more intensive |
| McCallum 2007[2] | 2.0, 1.9 | At 9 months[4] difference[5] in BMI-SDS between treatment arms -0.09; p=0.12<br>At 15 months difference[5] in BMI-SDS between treatment arms -0.03; p=0.62<br>Brief solution-focused intervention not effective or intervention not intensive enough |

Abbreviations: BMI-SDS=body mass index standard deviation score, NR=not reported, P=parenting-skills training, P + DA=parenting skills training + lifestyle support, WLC=waiting list control, std.=standard, NS=not significant
[1]median BMI-SDS reported, [2]changes in treatment arms not reported, [3]calculated of published means [4]not after intervention, [5]intervention-control, adjusted for socioeconomic status and the baseline measures

### 2.4.2 Impact on adiposity indicators in the long term

The evidence of the long-term efficacy of the treatment of childhood obesity is limited (McGovern et al. 2008, Oude Luttikhuis et al. 2009, Whitlock et al. 2010), although some randomised (Epstein et al. 1990, Golan and Crow 2004b) and non-randomised studies (Reinehr et al. 2007) have suggested long-lasting beneficial impacts. However, the gradual waning of the original positive results seems to be common in children (Wilfley et al. 2007b), like in adults (Franz et al. 2007). In adults, the probability of long-term successful results greatly increases, if the reduced weight has been maintained two or more years (Wing and Phelan 2005).

The factors associated with the long-term success of childhood obesity interventions are poorly known. However, the German ”Opeldicks” study, assessing the long-term efficacy of childhood obesity treatment, suggests that a major reduction in adiposity (BMI-SDS decrease 0.33) during the first months of treatment is highly predictive for beneficial long-term results (Reinehr et al. 2007). In addition, the age of participating children may predict long-term success (Reinehr et al. 2010). For example, 8-10-year old children had less decrease in BMI-SDS (0.30) than 4-7-year old children (0.50 decrease) or 11-12-year old children (0.38 decrease) at 5-year follow-up (Reinehr et al. 2010). In contrast, there was no association between the gender of participating children and the long-term outcome (Reinehr et al. 2010).

A prerequisite for successful weight maintenance is a permanent healthy lifestyle, for example regular physical activity and a low-calorie and low-fat diet (Wing and Phelan 2005), which obviously requires persistent self-regulation (Wilfley et al. 2010). It has been suggested that these specific self-regulation skills are different from weight loss skills and include for example the ability to adjust the lifestyle to the results of regular self-weighing (Wilfley et al. 2010). In line, the effects of two specific 4-month weight maintenance programs, behavioural skills maintenance program and social facilitation maintenance program, have been compared with controls receiving no maintenance treatment (Wilfley et al. 2007a). The maintenance programs, starting after the 5-month obesity treatment program, resulted in significantly improved child weight management during the maintenance period compared with controls (Wilfley et al. 2007a). However, the beneficial effects partially declined during follow-up, and the differences in changes between maintenance programs and controls were no longer significant two years after the beginning of the maintenance programs (Wilfley et al. 2007a).

Evidently, the prevention of obesity is of utmost importance. Furthermore, the prevention of childhood obesity should be started very early, as children who are overweight at adolescence often have gained excessive weight already from the first years of life (Lagstrom et al. 2008). However, even though many prevention programs have yielded small positive changes in targeted behaviours, like reducing unhealthy dietary habits and increasing physical activity, they have had no significant effect on adiposity measured objectively by BMI (Kamath et al. 2008).

## 2.5 ECONOMIC ANALYSIS OF CHILDHOOD OBESITY TREATMENT

### 2.5.1 Economic evaluation in health care

Cost-effectiveness analyses evaluate the health outcomes in relation to resource costs in health interventions to facilitate the allocation of health care resources efficiently (Russell et al. 1996). The need of economic evaluations in health care is emphasised because of increasing healthcare costs and limited resources of society (American College of Physicians 2008).

Cost-effectiveness analysis, cost-utility analysis and cost-benefit analysis are the three main methods in the assessment of economic costs and advantages (Meltzer 2008). These analyses value costs similarly, in monetary units, but they measure benefits in different ways: cost-effectiveness analysis in natural units of health outcome (e.g. the change in BMI), cost-utility analysis in terms of utility or quality (e.g. quality-adjusted life years, QALY, or disability-adjusted years, DALY) and cost-benefit analysis in monetary terms only (Meltzer 2008). The use of cost-utility analysis is widely recommended because it allows the comparison of different types of interventions (e.g. the treatment of obesity or idiopathic short stature) and it takes the quality of life into consideration. However, its use in paediatric research is complicated especially due to the complexity and variability of estimating QALYs in children (Griebsch et al. 2005).

The results of economic analysis can be summarised as an incremental cost-effectiveness ratio (ICER), which can be interpreted as an additional investment of resources needed for each additional unit of health effects gained (Drummond and Jefferson 1996). A decision maker can use an ICER as a tool when choosing between treatment options, if an intervention is both more costly and more effective than an alternative (Siegel et al. 1996).

Health economic evaluations can be performed from the perspective of e.g. society, the service producer, or the patient. The use of societal perspective is recommended, because it takes into consideration the health effects and the costs of everyone affected by the intervention (Russell et al. 1996). Economic analyses require a relevant time horizon over which costs and benefits are assessed (Drummond and Jefferson 1996). If the time horizon exceeds one year, costs and benefits must be discounted, and the rate of 3-6% is usually recommended (Drummond and Jefferson 1996).

Uncertainty in economic analyses can be handled by using several types of sensitivity analyses (Drummond and Jefferson 1996). One-way sensitivity analysis is commonly used and it evaluates the impact of one variable by varying it across of a plausible range of values (Briggs et al. 1994). Another type of analysis, extreme scenario analysis, uses the most optimistic and pessimistic values of an intervention in order to generate the best- and worst-case scenarios (Briggs et al. 1994).

### 2.5.2 Cost-effectiveness of childhood obesity treatment

Although the need for studies assessing the cost-effectiveness of childhood obesity treatment has been emphasised (Summerbell et al. 2003, Carter et al. 2009), only few studies have evaluated it. The study designs have differed: two US studies had two active treatment arms (Goldfield et. al 2001, Janicke et al. 2009), while the Australian LEAP (Wake et al. 2008) and LEAP 2 (Wake et al. 2009) studies compared active treatment with no treatment (Table 4). Furthermore, the intensity of the studies has varied in terms of the length of intervention and the number of appointments or sessions in active treatment arms. In these studies (Goldfield et al. 2001, Wake et al. 2008, Wake et al. 2009, Janicke et al. 2009), there was no difference in the efficacy between two treatment options. In the US studies (Goldfield et al. 2001, Janicke et al. 2009) the less costly and more cost-effective programs were group program solely (vs. group treatment incorporating individualised treatment) (Goldfield et al. 2001) and the parent-only treatment (vs. family-based treatment) (Janicke et al. 2009). In the Australian trials (Wake et al. 2008, Wake et al. 2009), active interventions were ineffective but more costly, and thus not worth implementing, although the researchers suggested in their preliminary analyses that the intervention was cost-effective (Moodie et al. 2008).

The two effective US interventions had highly different costs per 0.1 decrease of BMI-SDS (Table 4): US$ 100 (Goldfield et al. 2001) and US$ 579 (Janicke et al. 2009). However, the comparison between the studies assessing cost-effectiveness of childhood obesity treatment must be done very cautiously because of different study designs, settings, time points and purchasing power. Furthermore, none of the studies had follow-ups exceeding 15 months.

In conclusion, the available research data allow few conclusions to be made regarding the cost-effectiveness of childhood obesity treatment (Cawley 2007, John et al. 2010). It is impossible to justify what is the most cost-effective way of preventing or treating childhood obesity. Furthermore, policy makers must take into consideration not only cost-effectiveness, but also the feasibility of interventions, equity and potential positive and negative side effects while deciding between prevention and treatment options (Haby et al. 2006).

## 2.6 IMPACT OF CHILDHOOD OBESITY TREATMENT ON METABOLIC INDICATORS

Studies on childhood obesity treatment have demonstrated conflicting impacts on children's metabolic indicators (Whitlock et al. 2010). The impact of obesity treatment on metabolic variables in prepubertal children has been evaluated in an Australian 6-month randomised controlled obesity treatment trial in 111 on average 8.2-year-old children (Golley et al. 2007a). The study assessed the efficacy of two active treatment arms, parenting-skills training + intensive lifestyle education and parenting-skills training alone versus waiting list controls (Golley et al. 2007a). At 12 months, the children had a reduction in BMI-SDS in all treatment arms (by about 10% with parenting-skills training + intensive lifestyle education, and by about 5% with parenting-skills training alone and with waiting list controls), although there were no significant differences between the treatment arms (Golley et al. 2007a). However, there were no differences in the changes of metabolic indices between the treatment arms or between baseline and 12 months (Golley et al. 2007a).

In contrast to the Australian study (Golley et al. 2007a), some obesity treatment trials have shown beneficial changes in children's TC (Jiang et al. 2005, Nemet et al. 2005, Savoye et al. 2007), LDL-C (Nemet et al. 2005) and TG (Jiang et al. 2005) concentrations, blood pressure (Jiang et al. 2005), fasting insulin (Savoye et al. 2007) and insulin resistance (Savoye et al. 2007). Because of the different age groups, designs and outcome measures of the studies, the comparison of the results must be done cautiously. For example, compared with the Australian study (Golley et al. 2007a), children in other studies have been older (on average 11 – 13 years) and differences in changes of BMI between the intervention and control groups have been substantial (Jiang et al. 2005, Nemet et al. 2005, Savoye et al. 2007).

*Table 4. Economic evaluation of the randomised controlled studies assessing childhood overweight and obesity treatment*

| **Reference** | **Number, age of children** | **Treatment arms<br>Length and intensity of intervention** | **Main results, costs per 0.1 BMI-SDS decrease (dominating arm)[3)]** |
|---|---|---|---|
| Goldfield et al. 2001 | 31, 8-12 yr | Group vs. mixed treatment[2)]<br>5 months, 13 sessions | No difference in efficacy (0.64[4)]); group less expensive, US$ 100 (€79)[5)] at 12 months |
| Janicke et al. 2009 | 93, 8-14 yr[1)] | Parent-only vs. family treatment<br>4 months, 12 sessions | No difference in efficacy (~0.1[4)]); parent-only less expensive, US$ 579 (€458)[5)] at 10 months |
| Wake et al. 2008 | 163, 5-9 yr[1)] | 4 appointments vs. control<br>3 months, 4 vs. 0 sessions | Both arms ineffective, appointments more costly at 15 months |
| Wake et al. 2009 | 258, 5-9 yr[1)] | 4 appointments vs. control<br>3 months, 4 vs. 0 sessions | Both arms ineffective, appointments more costly at 12 months |

Abbreviations: yr=years; BMI-SDS = body mass index deviation score
[1)]children overweight or obese; [2)]mixed treatment combined group treatment with individual counselling; [3)]perspective of health care; [4)]decrease in BMI-SDS; [5)]currency conversions 5th May, 2010

There is no agreement of the degree of the decline in BMI-SDS needed to produce beneficial changes in metabolic indices. In a German non-randomised 1-year obesity treatment trial in 130 on average 11-year-old children with a mean BMI-SDS of 2.5, beneficial changes, that is an increase in HDL-C and decreases in TG, LDL-cholesterol, HOMA-IR and blood pressure were seen, when the BMI-SDS decrease was 0.5 or more (Reinehr and Andler 2004). In addition, there was a decrease in LDL-cholesterol when the BMI-SDS decrease was ≥0.25 but <0.5 (Reinehr and Andler 2004). On the other hand, a recent 1-year prospective cohort study of a hospital outpatient weight management clinic with 88 adolescents (median age 12.4 years, mean BMI-SDS 3.23) suggested that improvements in metabolic health are seen already with a BMI-SDS decrease ≥0.25 (Ford et al. 2010b). In the study, a BMI-SDS decrease of ≥0.25 but <0.5 improved TG, TC/HDL-ratio, HOMA-IR and blood pressure, while a BMI-SDS decrease ≥0.50 accrued greater metabolic benefits (Ford et al. 2010b).

# 3 *Aims of the Study*

The purpose of this prospective randomised controlled intervention study was to compare the efficacy of a group-based program consisting of 15 sessions for parents and children with routine counselling ("current care") consisting of two appointments for children in the treatment of obesity in young schoolchildren.

The specific goals were to assess

1. the feasibility of group treatment and routine counselling
2. the efficacy of the programs in the short term (≤ 1 year) and in the long term (2-3 years)
3. the cost-effectiveness of the programs
4. the impact of the programs on children's body composition and metabolic indicators.

# 4 Subjects and Methods

## 4.1 DEFINITIONS

Following definitions have been used in the field study:

*Adiposity* referred to the amount of fat tissue.

*Behavioural modification* referred to methods, which were applied to help to make permanent changes in lifestyle, for example goal-setting, self-monitoring, stimulus control, cue elimination, preplanning, problem solving and relapse preventing (Robinson 1999).

*BMI* (body mass index) was calculated by using the formula {weight (kg) / [height (m)] $^2$}.

*BMI-SDS* implied to the distance from the mean expressed as standard deviations (Kipping et al. 2008).

*HOMA-IR*, insulin resistance, was calculated by using formula [insulin (mU/L) x glucose (mmol/L)]/22.5 (Matthews et al. 1985).

*ICER*, the incremental cost-effectiveness ratio, was calculated using the following formula:

$$\mathrm{ICER} = \frac{\overline{C}_G - \overline{C}_R}{\overline{E}_G - \overline{E}_R} = \frac{\Delta\overline{C}}{\Delta\overline{E}}$$

, where $\overline{C}_i$ and $\overline{E}_i$ represented sample means for the costs and effects of the group (G) and the routine (R) programs (Drummond et al. 2005). In the present study, the ICER described additional costs per 1% weight for height decrease or per 0.1 BMI-SDS decrease, respectively.

*IOTF (the International Obesity Task Force) criteria for overweight and obesity* estimated childhood BMI values which correspond with adult BMI cut off points of 25 and 30 kg/m$^2$, respectively (Cole et al. 2000).

*Perspective of the service provider* implied that all the direct costs of treatment programs were included in the economic analysis, but the time and travelling costs of patients were excluded (Russell et al. 1996). In addition, resources were valued by using prices net of value-added taxes (Russell et al. 1996).

*Social class* was defined by the highest school education achieved by either mother or father: "low" to those who attended school for ≤ 9 years, "middle" to those who attended school for 10-12 years and "high" to those who achieved an advanced level of education (≥ 13 years).

*Solution-focused therapy* referred to counselling that concentrated on solutions instead of problems and furthermore, on participants strengths, abilities and resources (Greenberg et al. 2001).

*Waist/height ratio* was calculated by dividing waist circumference (cm) by height (cm) (McCarthy and Ashwell 2006).

*Weight for height* was defined as the percentage deviation of weight from the median height-related gender-specific weight. This deviation means the deviation in % units. For simplicity, the unit of deviation is called % in this thesis. The criterion for *obesity* in the present study was weight for height ≥ 120% (Lautala 1990, Klish 1998).

## 4.2 STUDY DESIGN

Families were informed about the study by school nurses and newspaper articles (Figure 1). Obese children (weight for height from 120% to 200%) attending the grades 1-3 (7-9 years) in primary school were eligible for the study. The exclusion criteria were a disease or a medication causing obesity, obvious movement disturbance, major mental problems in either children or parents, or a family member participating in an alternative weight management program. The interested families contacted by phone the researcher (MK), and after receiving preliminary information, 83 families were invited to a structured interview. The purpose of the interview was to give the families a thorough chance to reflect their willingness to participate in the study, and in addition, fulfilment of the entrance criteria was checked and background data were gathered. In total, the parents of 70 children decided to participate, and the children were invited to a health examination for baseline measurements. Thereafter, children were randomly allocated to 6-month treatment, either routine or group program. Identical health examination was performed before and after the end of the intervention.

Follow-up measurements (children's heights and weights) were performed by the school nurses one, two and three years after the beginning of the intervention, and the number of children participating was 69, 69 and 68, respectively (Figure 1).

The intervention was performed in two phases, in 2002-2003 (all 25 participants from Kuopio) and in 2004-2005 (29 participants from Kuopio and 16 from four neighbouring rural municipalities). As there were no significant differences in the demographic and anthropometric characteristics of the study participants or treatment efficacy between the children enrolled at the two phases of the study, all analyses have been performed as combined.

Power analysis was performed based on the assumptions that the mean baseline weight of the children was 50 kg and that there would be 10% difference in beneficial outcomes with 7.5 kg standard deviation. At a level of statistical significance of 0.05 and level of power of 0.80, the estimated sample size was 37 children in both treatment groups. Our goal was to enrol 40 children in both arms. Despite of major efforts, no more than 70 study subjects were recruited.

## 4.3 STUDY CHILDREN

The baseline demographic and anthropometric characteristics of the study children and their parents are presented in Table 5. At baseline, the mean age of the children was 8.1 years (range 6.6-9.7), the mean weight for height 142% (115-182) and the mean BMI-SDS 2.6 (1.3-3.8). According to the IOTF criteria (Cole et al. 2000), 23 (33%) of the children were overweight and 47 (67%) obese. There were no significant differences in the background data of the children or the parents between the two treatment arms (Table 5).

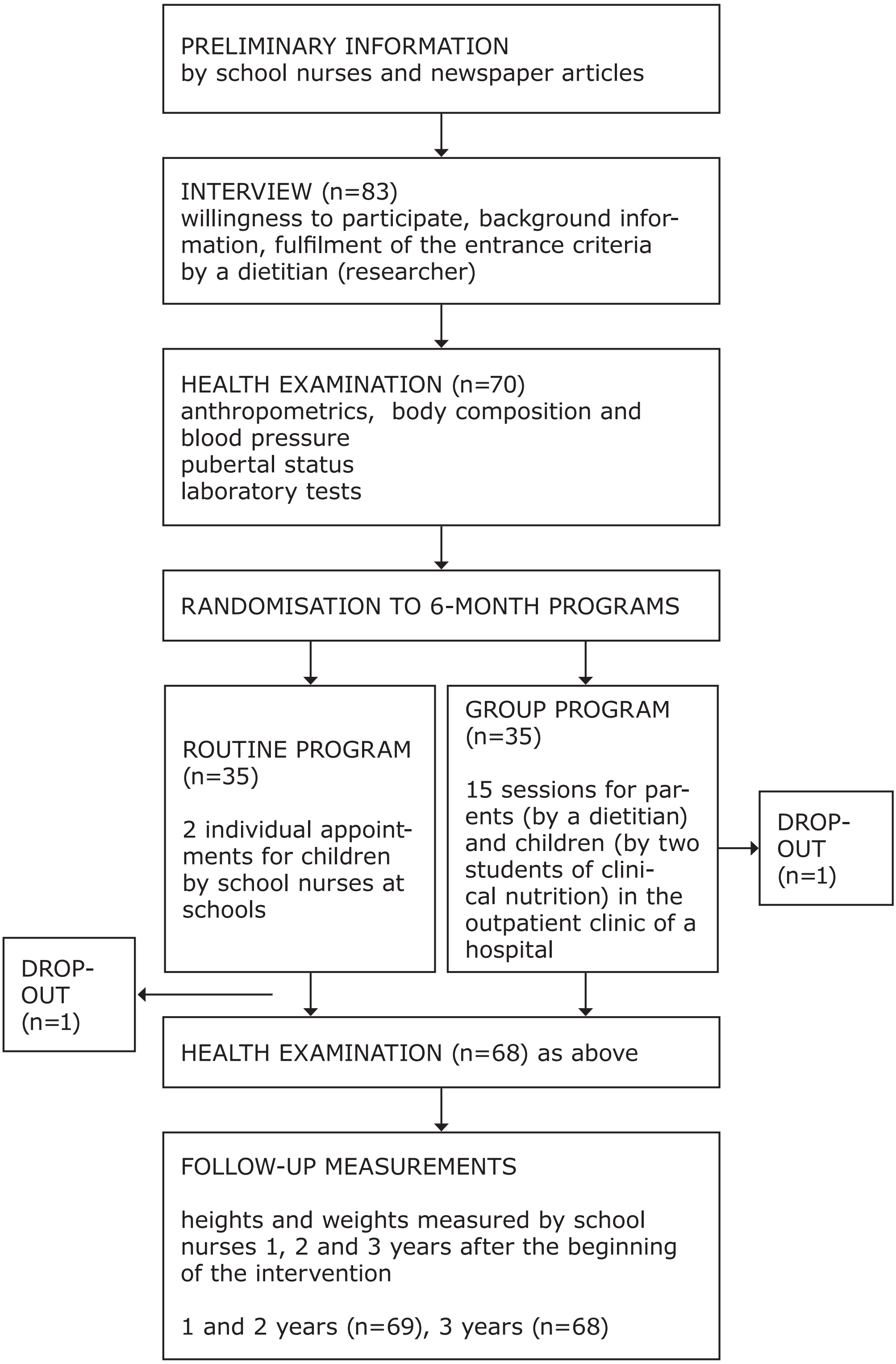



*Figure 1. Study design*

*Table 5. Baseline characteristics of children and parents in treatment programs and control children*

| **Characteristics** | **Treatment programs** | | **Controls (n=62)** |
|---|---|---|---|
| | **Routine program (n=35)** | **Group program (n=35)** | |
| Age (years) | 8.0[1)] (0.8)[2)] | 8.1[1)] (0.9)[2)] | 7.8[1)] (0.7)[2)] |
| *Gender* | | | |
| Boys | 12 (34%) | 16 (46%) | 13 (21%) |
| Girls | 23 (66%) | 19 (54%) | 49 (79%) |
| *Anthopometrics* | | | |
| Weight for height (%) | 141[1)] (15)[2)] | 143[1)] (14)[2)] | 100[1)] (1)[2)] |
| BMI (kg/m2) | 22.9 (2.5) | 23.4 (2.6) | 15.8 (1.3) |
| BMI-SDS | 2.5 (0.6) | 2.6 (0.6) | -0.1 (0.8) |
| *Adiposity status*[3)] | | | |
| Overweight | 13 (37%) | 10 (29%) | 0 |
| Obese | 22 (63%) | 25 (71%) | 0 |
| *Health status* | | | |
| Healthy | 18 (51%) | 23 (66%) | 62 (100%) |
| Asthma or any other disease | 17 (49%) | 12 (34%) | 0 |
| *Family structure* | | | |
| Family with both parents | 31 (88%) | 25 (71%) | |
| Parent and step-parent | 2 (6%) | 2 (6%) | |
| Family with single parent | 2 (6%) | 8 (23%) | |
| *Social class* | | | |
| Low | 0 | 3 (8%) | |
| Middle | 13 (37%) | 16 (46%) | |
| High | 22 (63%) | 16 (46%) | |
| *Parents*[4)] | | | |
| Mothers' BMI | 27.0[1),5)] (6.3)[2)] | 26.1[1)] (5.4)[2)] | |
| Fathers' BMI | 27.7[5)] (3.9) | 26.9[6)] (3.8) | |

Abbreviations: BMI = body mass index; BMI-SDS = BMI standard deviation score (calculated based on the British reference (see methods)
[1)] mean; [2)] standard deviation; [3)] based on the International Obesity Task Force criteria (Cole et al. 2000); [4)] calculated from self-reported heights and weights; [5)] n=34; 6) n=27

There were no statistically significant differences in any baseline characteristics between the treatment programs, analysed by independent samples t-test for continuous and by chi square test for discrete variables.

## 4.4 CONTROL CHILDREN (ARTICLE III)

For the comparison of the metabolic profile of the obese study children with normal weight children, control group was created (Table 5). It comprised healthy prepubertal children with normal weight (mean weight for height 100%, range -119 to 118), matched for age (mean 7.8 years, 5.5 to 8.9) and gender (49 girls, 13 boys) with the study children. It was collected for a study on premature adrenarche (control group) from the same area (Utriainen et al. 2009). Their bioimpedance, laboratory and blood pressure measurements were used as reference values. As the data on control children's waist and waist/height were lacking, those of 87 German 8-year-old girls were used as reference values (Schwandt et al. 2008).

## 4.5 STUDY ETHICS

The study was performed according to the principles of the Declaration of Helsinki, and informed consent was obtained from the parents. The study was approved by the Ethics Committee of Kuopio University and University Hospital (62/2002).

## 4.6 INTERVENTIONS

### 4.6.1 Routine program

Routine program was modified from the counselling practice for obese children in school health care in Kuopio region, and it consisted of two standardised individual appointments for the children by their school nurses. The themes of the appointments were self-knowledge and physical activity. The children were given workbooks, which they fulfilled partly with school nurses and partly at home with parents. In addition, booklets were sent to families at the beginning of the intervention, and they contained information about weight management, healthy diet and physical activities.

### 4.6.2. Group program

The main components of group treatment included health-promoting diet, increasing physical activity and decreasing sedentary behaviour, which were realised with the help of behavioural modification (Robinson 1999) and solution-focused therapy (Sharry 2001) (Table 6). The program focused on a healthy lifestyle and well-being of obese children and their families instead of weight management. The parents were targeted as the main agents of change, and they were responsible for inducing changes at home.

The group program consisted of 15 sessions held separately for parents and children, except one joint session of making healthy snacks. The parent's groups were led by an experienced dietitian, and the children's groups were led by two advanced students of clinical nutrition. Parents were provided with treatment manuals and children with workbooks. Material was modified from national (Korhonen et al. 1999, Nykänen et al. 2000) materials and from a cognitive behaviour therapy workbook (Stallard 2002), and was supplemented with additional self-developed material. Homework was provided to both parents and children to give a chance to practice between sessions. The children's program was adjusted to their cognitive developmental level and thus consisted mainly of functional activities. In addition, most sessions included non-competitive physical activities.

*Table 6. Components and main themes of the group program with examples*

| Component | Main themes | Examples of applications during sessions | |
|---|---|---|---|
| | | Parents | Children |
| Diet | Regular meals (Hasunen et al. 2004) | Regular meal pattern as part of good daily rhythm | The healthy lifestyle of a rabbit |
| | Quality of diet (in line with Finnish nutrition recom-mendations) (Hasunen et al. 2004) | Decreasing intake of high-fat and high-sugar foods, increasing the consumption of fruits and vegetables, label reading | Children as product demonstrators in a heart friendly shop<br><br>Tasting vegetables and fruits |
| | | Healthy snacks (cooking class with children) | Healthy snacks (cook-ing class with parents) |
| | Portions (Hasunen et al. 2004) | According to energy need | Illustrating plate model with plastic food models |
| Physical activity/ inactivity | Increasing physical activity (Washington et al. 2001) | Planning of physical activities for every day (family, child) | Physical activities in most sessions |
| | Decreasing physical inactivity (Epstein et al. 1995) | Time limits (< 2 hours/ day) for television, video and computer games | Activities of a lively rabbit |
| Behavioural component | Principles of behavioural modification (Robinson 1999) | Goal-setting, self-moni-toring, stimulus con-trol, problem-solving, relapse prevention, parents as models | Small realistic chang-es in every day habits emphasised |
| | Principles of solution-focused therapy (Sharry 2001) | Attention on the strengths, abilities and resources of families | Attention on what is already functioning |

## 4.7 MEASUREMENTS

### 4.7.1 Before and after intervention

Children's health examinations were carried out using a standard protocol in the morning after fast at baseline and after the intervention.

Height and waist circumference were measured three times and weight twice, and the average was used for analysis. Height was measured to the nearest 0.1 cm using a Harpenden Stadiometer (Practical Metrology, UK) and weight (light underwear included) to the nearest 0.1 kg using an electronic scale (Seca Vogel & Halke, Germany). Waist circumference was measured at the midpoint between the lateral iliac crest and the lowest rib to the nearest 0.5 cm using a flexible tape.

Tanner pubertal status was assessed (Tanner and Whitehouse 1976). The diameters of areola and palpable breast tissue in girls and testicular length in boys were measured with a ruler. Children with Tanner stage G1/M1 were recorded as prepubertal, and those with G2-5/M2-5 as pubertal (Tanner and Whitehouse 1976).

Fat mass and lean body mass were assessed by bioelectrical impedance analysis (BIA) with Inbody 3.0® (Biospace, Seoul, Korea (20) for subjects in upright position after voiding.

Blood pressure was measured automatically on the right arm of a seated child by a Dinamap™ XL monitor with appropriate-sized cuffs. Three measurements were performed after rest for five minutes, and second and third were averaged for analysis.

Plasma total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C) and triglyseride (TG) concentrations were determined by enzymatic methods (Thermo Electron Co., Vantaa, Finland) and plasma glucose concentrations by a hexokinase method (Thermo Electron Co., Vantaa, Finland). Serum insulin was analysed with a time-resolved immunofluorometric method by AutoDelfia (PerkinElmer Life and Analytical Sciences Wallac Oy, Turku, Finland).

### 4.7.2 At follow-ups

Follow-up measures consisted of the children's heights and weights obtained by their school nurses at varied times of the school days. The school nurses were carefully instructed and the measurements were performed using the same standardised protocol as described earlier. In addition, all stadiometers and scales were calibrated annually before measurements.

### 4.7.3 Adiposity indicators

The primary outcome measure of the study was the change of the weight for height. Weight for height is in routine use through the whole health care system in Finland, and population-based gender-specific growth charts from birth to the age of 18 years are available (Sorva et al. 1990, Pere 2000). Weight for height was assessed by using the Pediator program (Tilator 2004).

Since national, population-based BMI references were not available, BMI and BMI-SDS were used as secondary outcome measures. BMI was classified according to the International Obesity Task Force (IOTF) criteria (Cole et al. 2000). BMI-SDS was computed by an automatic calculator (Northwest Institute for Bio-Health Informatics 2009), which uses the British gender-specific growth reference from 1990, produced by the LMS method (Cole et al. 1995, Freeman et al. 1995), and revised in 1996 (Cole et al. 1998). The LMS method summarises the distribution of BMI at each age by its median (M), coefficient of variation (S), and a measure of skewness expressed as a Box-Cox power (L) required to transform the data to normality (Cole 1990). BMI-SDS changes were categorised into four groups: any BMI-SDS increase, BMI-SDS decrease <0.25, BMI-decrease ≥ 0.25 but < 0.5 and BMI-SDS decrease ≥0.5 (Reinehr and Andler 2004).

## 4.8 COST-EFFECTIVENESS ANALYSIS

The cost-effectiveness analysis was performed from the perspective of the service provider. The total costs of the treatment arms consisted of the recruitment and treatment costs. The recruitment costs were obtained by summing the material costs (information leaflets, interview sheets) and salaries of the researcher and school nurses. The costs were allocated to the treatment arms in equal proportions.

The treatment costs consisted of the material costs and salaries of school nurses (routine program) and group leaders (group program). In the routine program, the material costs consisted of the booklets for the families and the workbooks for the children. In the group program, the material costs consisted of the treatment manuals for the parents and of the workbooks for the children, and of the prices of food and hobby items. The material costs were based on the micro costing approach by the researcher. The 2004 price level was estimated from the 2002 price level by taking into account the average percent increase in the consumer price index

(Statistics Finland 2005), and further the 2009 price level was estimated from the 2004 price level (Statistics Finland 2010a).

Data on working hours were based on micro costing by the employees. The labour costs were valued using the hourly salary of school nurses (recruitment, the routine program), and the hourly salary of dietitians (recruitment, the parent's groups), calculated from the monthly salaries in 2008 (Tilastokeskus 2008). The hourly salaries of school nurses were also applied to calculate the salary costs of the students working as the children's group leaders. Even though there were two leaders, working hours of one leader only were valued. The 2009 monthly and hourly salaries were estimated by taking into account the average percentage increase in the income level, as indicated by the wage and salary index (Statistics Finland 2010b). The estimated salaries were multiplied by 1.31 in order to take into account the employer's social security payments.

The incremental cost-effectiveness ratio (ICER) was calculated (Drummond et al. 2005).

## 4.9 STATISTICAL ANALYSES

Data were analysed using SPSS-PC for windows, and SPSS 16.0 and 17.0 softwares (SPSS Inc., Chicago, IL). All continuous variables were tested for normality with the Kolmogorov-Smirnov or the Saphiro-Wilk test. Logarithmic (log) transformation was performed if necessary. Baseline differences of continuous variables between the treatment arms were analysed by the independent samples t-test or Mann-Whitney U test. Differences in changes in adiposity indicators between the two treatment arms were analysed using independent samples t-test (after intervention, 1-year follow-up), and repeated measures analysis of variance (2- and 3-year follow-up). Analyses were performed also adjusted for gender, mother's BMI, social class of the family and for either baseline weight for height, baseline BMI or baseline BMI-SDS using analysis of covariance (after the intervention, 1-year follow-up) and repeated measures analysis of variance with adjustments (2- and 3-year follow-up). Differences in changes of metabolic markers between the treatment arms were analysed by the independent samples t-test or Mann-Whitney U test. Differences within BMI-SDS change categories were analysed by the paired-samples t-test or Wilcoxon signed-ranks test. Differences in discrete variables between the treatment arms were analysed using chi square test or Fisher's exact test. Correlations between continuous variables were evaluated by calculating Pearson's linear correlation coefficients (r); $r = 0.3$-$0.5$ means low, $r = 0.5$-$0.7$ moderate and $r > 0.7$ high correlation.

# 5 Results

## 5.1 FEASIBILITY OF THE PROGRAMS (ARTICLE I)

Children and parents participated actively in appointments and sessions in both programs. The participation rate was 99% (children) in the routine treatment and 87% (parents and children) in the group treatment. There was one drop-out from the group treatment, and none from the routine counselling.

## 5.2 EFFICACY OF THE PROGRAMS (ARTICLES I, IV)

After intervention, there were significant differences between the treatment programs in favour of the group program in the changes of children's weight for height (on average, a 6.8% vs. a 1.8% reduction, p=0.001), BMI (on average, 0.8 vs. 0.0, p=0.003) and BMI-SDS (on average, 0.3 vs. 0.2, p=0.022) (Table 7). The differences remained significant when the analyses were performed also with adjustments for gender, baseline weight for height (or BMI or BMI-SDS), mother's BMI and social class of the family. Among the adiposity indicators and the selected confounders, only gender had a significant association with the change of weight for height (on average, a 4.8% decrease in girls vs. 0.9% in boys, p=0.016), with BMI (on average, a 0.5 decrease in girls vs. a 0.1 increase in boys) and with BMI-SDS (on average, a 0.3 decrease in girls vs. a 0.1 decrease in boys).

At the 1-year follow-up, there were significant differences between the treatment arms in favour of the group program in the changes of children's weight for height (on average, a 3.4% reduction vs. a 1.8% increase, p=0.008) and BMI (on average, a 0.1 increase vs. a 0.8 increase, p=0.016) (Table 7). The BMI-SDS values decreased (on average, 0.2 in the group treatment and 0.1 in the routine treatment, p=0.081), thus showing only a trend between the treatment groups. The differences remained significant for weight for height and BMI when the analyses were performed also with adjustments for gender, baseline weight for height (or BMI), mother's BMI and social class of the family. Among the selected potential confounders, only children's weight for height at baseline had a statistically significant association with the change of weight for height (p=0.049), but there were no significant associations with BMI change. For BMI-SDS changes, there still was a trend between the treatment groups. After adjustment for selected confounders, there was a significant association (p=0.050) between gender and BMI-SDS change (on average, a 0.2 decrease in girls and no change in boys).

From baseline to 2 years or to 3 years, there were no significant differences in the changes of the adiposity indicators between the children in the two treatment arms (Table 7). The differences remained non-significant in adjusted analyses. There were no significant differences between the outcome measures and any of the single covariates, nor were there significant interactions between the covariates.

The changes in weights for height had a high correlation with changes in BMI between baseline and the end of intervention (r=0.98), one year (r=0.97), two years (r=0.94) and three years (r=0.94). In line, the changes in weights for height had a high correlation with changes in BMI-SDS, and the respective figures were r=0.94, r=0.92, r=0.91 and r=0.89.

Changes in adiposity indicators were also analysed after categorisation. When changes in BMI-SDS were analysed using cut-offs of 0, -0.25 and -0.5, the difference between the treatment arms was not significant after intervention nor at follow-ups (Figure 2).

There were no significant changes in the children's weight for height between baseline and the 2- or 3-year measurements in either treatment arm (Table 7). In contrast, BMI increased, whereas BMI-SDS decreased from baseline to two years and three years in both treatment arms.

There were high correlations between weight for height at baseline and at one year (r=0.84) and at baseline and at two and three years (r=0.80 and r=0.70 respectively). For BMI and BMI-SDS, the respective figures were even higher: for BMI r=0.88 at one year, r=0.85 at two years and r=0.76 at three years, and for BMI-SDS r=0.87, r=0.83 and r=0.73 at the respective time points.

*Table 7. Changes in outcome measures after the intervention and at the 1-, 2- and 3-year follow-ups compared with baseline in treatment arms*

| | **Change in treatment programs** | | **Between programs** |
|---|---|---|---|
| | **Routine program** | **Group program** | **p** |
| *Weight for height,%* | | | |
| Post-intervention | - 1.8[1)] [-3.9 to 0.4] [2),3)] | -6.8 [-8.9 to -4.7] [3)] | 0.001 [5)] |
| 1-year follow-up | +1.8 [-0.9 to 4.5] [3)] | +3.4 [-6.0 to -0.7] [4)] | 0.008 [5)] |
| 2-year follow-up | +1.8 [-1.8 to 5.3] [3)] | -0.2 [-3.2 to 2.9] [4)] | 0.426 [6)] |
| 3-year follow-up | +0.8 [-4.6 to 6.1] [4)] | -1.4 [-5.0 to 2.2] [4)] | 0.493 [6)] |
| *BMI, $kg/m^2$* | | | |
| Post-intervention | 0.0 [-0.4 to 0.3] [3)] | - 0.8 [-1.1 to -0.5] [3)] | 0.003 [5)] |
| 1-year follow-up | +0.8 [0.4 to 1.3] [3)] | +0.1 [-0.3 to 0.5] [4)] | 0.016 [5)] |
| 2-year follow-up | +1.5 [1.0 to 2.1] [3)] | +1.3 [0.8 to 1.9] [4)] | 0.624 [6)] |
| 3-year follow-up | +2.3 [1.4 to 3.2] [4)] | +2.1 [1.4 to 2.7] [4)] | 0.700 [6)] |
| *BMI-SDS* | | | |
| Post-intervention | -0.2 [-0.3 to -0.1] [3)] | -0.3 [-0.4 to -0.3] [3)] | 0.022 [5)] |
| 1-year follow-up | -0.1 [-0.2 to 0.0] [3)] | -0.2 [-0.3 to -0.1] [4)] | 0.081 [5)] |
| 2-year follow-up | -0.2 [-0.3 to -0.1] [3)] | -0.2 [-0.4 to -0.1] [4)] | 0.840 [6)] |
| 3-year follow-up | -0.3 [-0.5 to -0.1] [4)] | -0.3 [-0.5 to -0.2] [4)] | 0.916 [6)] |

Abbreviations: BMI = body mass index; BMI-SDS = BMI standard deviation score (see methods)
[1)] mean; [2)] 95% confidence interval; [3)] n=35; [4)] n=34; [5)] statistical significance for the difference between treatment arms, independent samples t-test [6)] statistical significance for the difference between treatment arms, repeated measures analysis of variance (n=68)

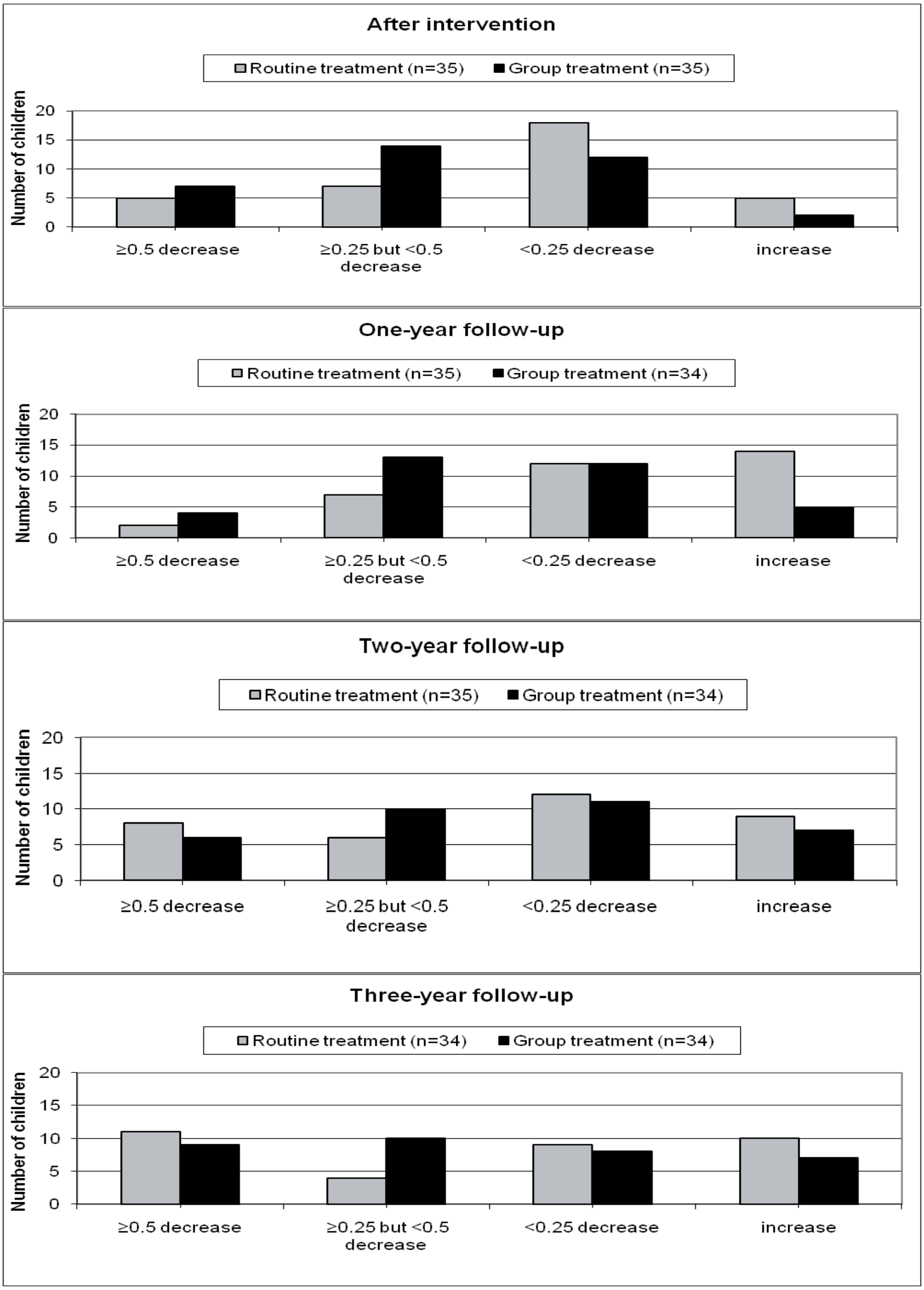



*Figure 2. The change of BMI-SDS (body mass index standard deviation score) (see methods) after intervention and at follow-ups by treatment mode. Statistical significance was analysed with Fisher's exact test (p>0.05 in all phases).*

## 5.3 COST-EFFECTIVENSS OF THE PROGRAMS (ARTICLE II)

In routine treatment, the costs per treated child were 74€ after intervention and at one year follow-up. In group treatment, the respective figures were 392€ and 403€ (Table 8). Post-intervention ICER estimates, presenting additional costs per 1% weight for height decrease and per 0.1 BMI-SDS decrease, were €64 and €318, respectively. At one year follow-up, the respective ICER estimates were €63 and €329. Because there were no differences in treatment efficacy by weight for height or BMI-SDS between the two treatment arms at two or three years, no indicators of cost-effectiveness were calculated at these dates.

The cost structures of the programs were very different (Table 8). In the routine treatment, the recruitment costs formed about two-thirds and the appointments one-third of the total costs, whereas in the group program, the session costs formed about 90% of the total costs. Labour costs formed most of the costs in both routine (88%) and group (86%) programs. In all, school nurses spent 58 hours 41 minutes and the dietitian 83 hours 35 minutes on recruitment. In routine treatment, school nurses spent on average 29 minutes per appointment with the child, and an additional seven minutes for the preparation of the appointment. In group treatment, the leaders of the parents' groups and the leaders of the children's groups spent on average 89 and 102 minutes per session, respectively. The respective number for the attendant tasks were 108 and 102 minutes per session.

*Table 8. The cost structure and the costs of the routine and group programs in the 2009 price level (€)*

| | | **Routine program (n=35)** | **Group program (n=35)[1)]** |
|---|---|---|---|
| **Total costs** | | 2576 (100%) | 13705 (100%) |
| Cost items (%) | | | |
| Recruitment costs [2)] | | 1678 (65%) | 1678 (12%) |
| | Material | 183 | 183 |
| | Labour | 1495 | 1495 |
| Treatment costs | | 898 (35%) | 12027 (88%) |
| | Material | 136 | 1669 |
| | Labour | 762 | 10358 |
| **Costs** | | | |
| Per treated child | | | |
| | After intervention | 74 | 392 |
| | At 1-year follow-up | 74 | 403 |
| Per 1% weight for height reduction | | | |
| | After intervention | 41 | 58 |
| | At 1-year follow-up [3)] | - | 119 |
| Per 0.1 BMI-SDS [4)] reduction | | | |
| | After intervention | 37 | 131 |
| | At 1-year follow-up | 74 | 202 |

Abbreviations: BMI-SDS=body mass index standard deviation score (see methods)
[1)] n = 34 at 1-year follow-up
[2)] recruitment costs were common to both programs, and they were split evenly for the routine and group programs
[3)] not calculable for routine treatment at the 1 year follow-up since the children's weight for height increased

## 5.4 IMPACT OF THE PROGRAMS ON BODY COMPOSITION AND METABOLIC MARKERS (ARTICLE III)

Sixty-three children were pre-pubertal at baseline, and seven were in early puberty. Nine children entered puberty during the intervention, and data on post-intervention pubertal status was lacking in two children. There were no significant differences between the subgroups in pre- or post-intervention pubertal status (data not shown).

At baseline, the study children had in on average a higher fat mass (13.7 vs. 4.1 kg) and lean body mass (28.1 vs. 22.0 kg) than the normal-weight control children (Table 9). The study children had on average lower HDL-C (1.15 vs. 1.50 mmol/L), and higher LDL-C (2.73 vs. 2.47 mmol/L), TG (0.88 vs. 0.58 mmol/L), glucose (5.2 vs. 4.8 mmol/L), fasting insulin (9.4 vs. 4.1 mU/L) and HOMA-IR (2.17 vs. 1.07) than the control children (Table 9).

At baseline, there were no significant differences in the body composition or in the metabolic profile between the children in the routine and group programs. During the intervention, the decrease in waist/height was greater in the group program (mean 0.02, 95% CI 0.03 to 0.01) than in the routine program (0.01, 95% CI 0.02 to 0.00), respectively (Table 10). However, there were no significant differences in the changes of other metabolic indices between the programs (Table 11).

The changes in body composition and metabolic profile were analysed jointly for all children in the four BMI-SDS change categories (BMI-SDS increase, a BMI-SDS decrease $<0.25$, a BMI-decrease $\geq 0.25$ but $<0.5$ and a BMI-SDS decrease $\geq 0.5$). The corresponding changes in body composition and metabolic indices with major deviation from the control children are presented in Figures 3 and 4. Declines in fat mass, waist/height and fasting insulin were seen in the two categories of children with a BMI-SDS decrease of 0.25 or more. A decline in TG was seen only in the children with a BMI-SDS decrease $\geq 0.5$. The associations between HDL-cholesterol and BMI-SDS changes were small and inconsistent (data not shown).

*Table 9. Comparison of body composition and metabolic markers between control and study children*

| **Outcome measures** | **Baseline mean (standard deviation)** | | **Difference between groups p** |
|---|---|---|---|
| | **Control children (n=62) [1)]** | **Study children (n=70)** | |
| Fat mass (kg) | 4.1 (1.5) | 13.7 (4.1) | <0.000 |
| Lean body mass (kg) | 22.0 (2.6) | 28.1 (4.5) | <0.000 |
| Waist (cm) | 58.7 (6.5) | 76.3 (6.8) | |
| Waist/height | 0.44 (0.04) | 0.57 (0.04) | |
| SBP (mm Hg) [2)] | 98.8 (7.5) | 109.4 (7.7) [4)] | <0.000 |
| DBP (mm Hg) [2)] | 59.3 (7.2) | 55.2 (6.5) [4)] | 0.001 |
| TC (mmo/L) | 4.2 (0.6) | 4.2 (0.7) [4)] | 0.854 |
| LDL-C (mmol/L) | 2.47 (0.52) | 2.73 (0.62) [4)] | 0.012 |
| HDL-C (mmol/L) | 1.50 (0.31) | 1.22 (0.27) [4)] | <0.000 |
| TG (mmol/L) | 0.58 (0.20) | 0.88 (0.48) [5)] | <0.000 |
| F-glucose (mmol/L) [3)] | 4.8 (0.3) | 5.2 (0.3) [5)] | <0.000 |
| F-insulin (mU/L) | 4.1 (1.9) | 9.4 (5.2) [5)] | <0.000 |
| HOMA-IR | 1.07 (0.38) | 2.17 (1.25) [5)] | <0.000 |

Abbreviations: SBP= systolic blood pressure; DBP= diastolic blood pressure; TC = total cholesterol; LDL-C = low-density lipoprotein cholesterol; HDL-C = high-density lipoprotein cholesterol; TG = triglycerides; F = fasting; HOMA-IR = homeostasis model assessment for insulin resistance (Matthews et al. 1985)

[1)] Finnish normal-weight children, matched for age and gender, n=62 (see control children in methods); for waist and waist/height German 8-year-old girls (n=87) (Schwandt et al. 2008)
[2)] For control children, a standard manual sphygmomanometer; in the study children, an automated device
[3)] For control children, by glucose oxidase method (Clarke Electrode, Rapidlab 865/1265; Bayer,Tarrytown, NY); in the study children, by a hexokinase method (Thermo Electron Co., Vantaa, Finland). The methods were calibrated in the same laboratory to match each other.
[4)] n=69, [5)] n=68

*Table 10. Efficacy of the 6-month routine and group programs, expressed as changes in body composition and blood pressure (III)*

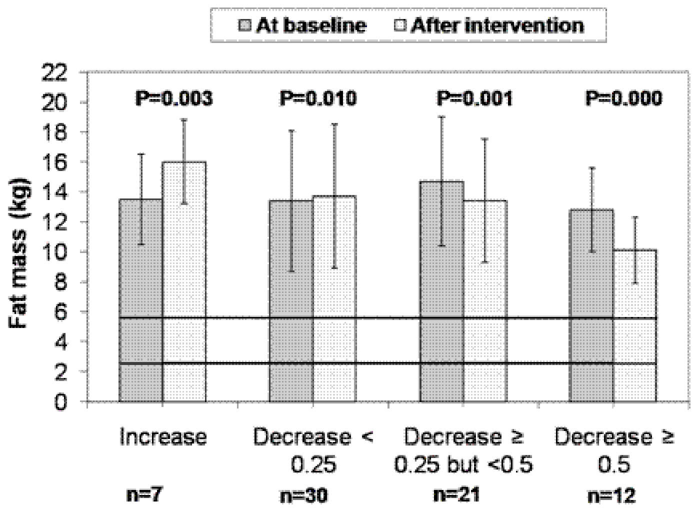
| **Outcome measures** | **Routine program (n=35)** | | **Group program (n=35)** | |
|---|---|---|---|---|
| | **Baseline M** | **Change M [95% CI]** | **Baseline M** | **Change M [95% CI]** |
| Fat mass (kg) | 13.1 (3.9) | -0.2 [-0.8 to 0.5] | 14.4 (4.3) | -0.9 [-1.5 to -0.2] |
| Lean body mass (kg) | 27.4 (3.7) | +1.9 [+1.4 to 2.4] | 28.8 (5.2) | +1.4 [+1.0 to 1.8] |
| Waist ( cm) | 75.3 (6.1) | +0.8 [-0.4 to 2.0] | 77.3 (7.4) | -0.7 [-1.7 to 0.4] |
| Waist/height | 0.57 (0.04) | -0.01 [-0.02 to 0.00] | 0.57 (0.04) | -0.02 [-0.03 to -0.01] |
| SBP (mm Hg) | 108.1 (6.8) | 0.0 [-1.7 to 1.6] | 110.8 (8.3) [1)] | -0.9 [1)] [-3.2 to 1.3] |
| DBP (mm Hg) | 55.2 (6.5) | -0.7 [-2.9 to 1.4] | 55.2 (6.5) [1)] | +0.2 [1)] [-1.3 to 1.6] |

Abbreviations: M=mean; CI=confidence interval; SBP=Systolic blood pressure; DBP=Diastolic blood pressure
[1)] n=34

*Table 11. Efficacy of the 6-month routine and group programs, expressed as changes in laboratory values*

| **Outcome measures** | **Routine program (n=35)** | | **Group program (n=35)** | |
|---|---|---|---|---|
| | **Baseline M** | **Change M [95%CI]** | **Baseline M** | **Change M [95%CI]** |
| TC (mmo/L) | 4.2 (0.7) | +0.1 [-0.1 to 0.3] | 4.3 (0.6) [1)] | +0.2 [1)] [0.0 to 0.4] |
| LDL-C (mmol/L) | 2.77 (0.69) | +0.01 (0.51) [-0.17 to 0.18] | 2.69 (0.55) [1)] | +0.03 [1)] [-0.09 to 0.14] |
| HDL-C (mmol/L) | 1.12 (0.27) | +0.07 [0.00 to 0.15] | 1.18 (0.27) [1)] | +0.12 [1)] [+0.07 to 0.18] |
| TG (mmol/L) | 0.85 (0.40) | -0.02 [-0.15 to 0.10] | 0.91 (0.56) [2)] | -0.23 [2)] [-0.39 to -0.07] |
| F-glucose (mmol/L) | 5.2 (0.3) [1)] | +0.1 [1)] [0.0 to 0.2] | 5.2 (0.3) [1)] | 0.0 [1)] [-0.1 to 0.1] |
| F-insulin (mU/L) | 8.5 (4.4) [1)] | 0.0 [1)] [-1.5 to 1.6] | 10.2 (5.8) [1)] | -1.6 [1)] [-3.1 to -0.1] |
| HOMA-IR | 1.96 (1.03) [1)] | +0.07 [1)] [-0.32 to 0.47] | 2.39 (1.43) [1)] | -0.37 [1)] [-0.74 to -0.01] |

Abbreviations: M=mean; CI=confidence interval; TC = total cholesterol; LDL-C = low-density lipoprotein cholesterol; HDL-C = high-density lipoprotein cholesterol; TG = triglycerides; F = fasting; HOMA-IR = homeostasis model assessment for insulin resistance (Matthews et al.1985)
[1)] n=34; [2)] n=33



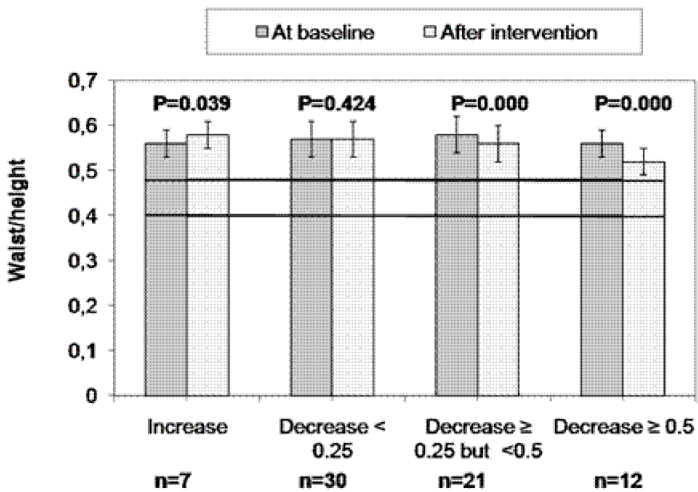




*Figure 3. Alterations in fat mass and waist/height (means +/- 1 SD) in BMI-SDS (body mass index standard deviation score) change categories during the 6-month treatment. The normal values (means +/- 1 SD) based on normal-weight controls are marked with horizontal lines. (III)*

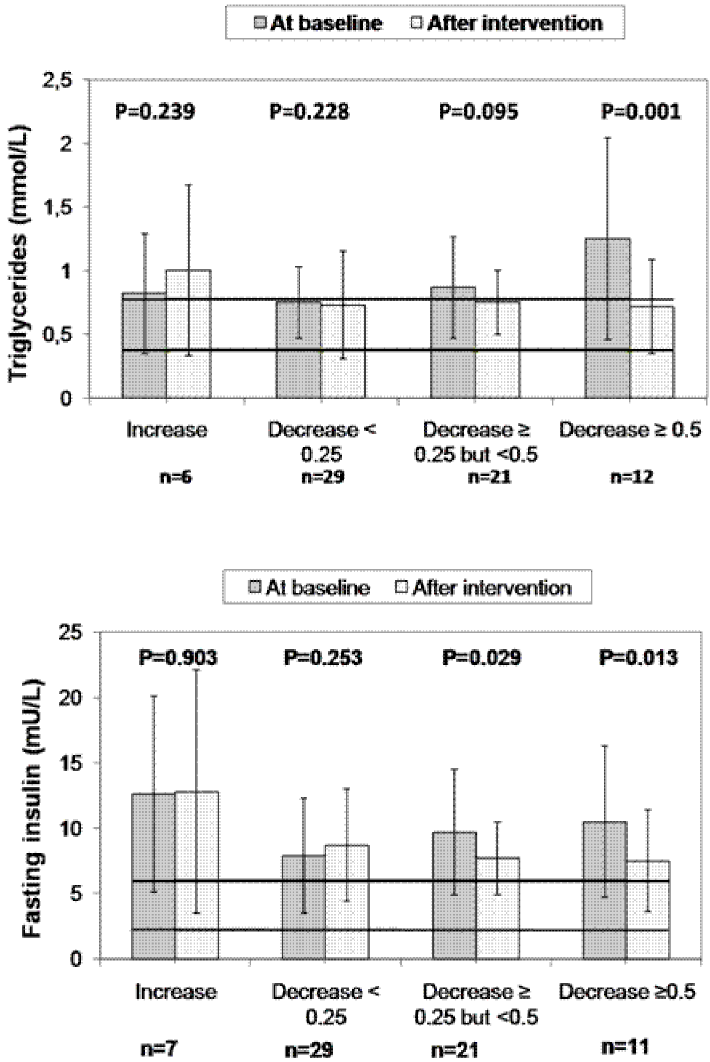



*Figure 4. Alterations in triglycerides and fasting insulin (means +/- 1 SD) in BMI-SDS (body mass index standard deviation score) change categories during the 6-month treatment. The normal values (means +/- 1 SD) based on normal-weight controls are marked with horizontal lines. (III)*

# 6 Discussion

## 6.1 FEASIBILITY OF THE PROGRAMS

Group and routine programs were feasible, as seen in high participation rates in sessions and appointments (87-99%) and much lower attrition rates (0-3%) than in most other studies (0-42%) (Oude Luttikhuis 2009). A recent qualitative study (Stewart et al. 2008) suggested that parents' adherence to treatment is motivated by their perceived benefits of treatment to the child's wellbeing and quality of life.

The recruitment of families into the treatment of childhood obesity is a challenge (McCallum et al. 2007, Munsch et al. 2008), as was also seen in the present study. In spite of major efforts, we were able to recruit only 70 children, even though our target was 80 children. Our recruitment was mainly active, by school nurses, and supplemented with passive recruitment (e.g. newspapers), as recommended by Robinson et al. (2007) and Raynor et al. (2009). The difficulties in recruitment may be due to several factors. Many parents were obviously unaware of their child's overweight (Jain et al. 2001, Jeffery et al. 2005, Eckstein et al. 2006, Taulu 2010, Vuorela et al. 2010). In addition, our study design, a randomised controlled trial, was an obstacle to some families, because it did not allow a client-centred choice of the treatment. For example, some families who would have preferred individual counselling, mainly due to time constraints, could not participate.

## 6.2 EFFICACY OF THE PROGRAMS

### 6.2.1 Changes of adiposity indicators in the short term

After the 6-month intervention, the group program was more effective than individually given routine counselling in the treatment of childhood obesity. Group treatment included dietary, physical activity and behavioural components, and the parents were targeted as the main agents of the lifestyle changes at home in line with evidence-based recommendations (Barlow and the Expert Committee 2007, SIGN 2010). Groups can have many advantageous therapeutic factors like group support, group learning and group optimism (Sharry 2001, Whitaker 2001), but it is still unclear whether group-based treatment is more effective than individual treatment (SIGN 2010). In accordance with the results of the present study, children have benefited from obesity treatment in the short term also in many other studies (Epstein et al. 1995, Golan et al. 2006, Munsch et al. 2008, Weigel et al. 2008, Okely et al. 2010, Sacher et al. 2010).

The comparison of the efficacy of childhood obesity treatment is difficult because of different study designs, settings, characteristics of participants and outcome indicators. In addition, many studies have not provided analyses based on the intention-to-treat principle (Oude Luttikhuis et al. 2009). In the present study, the decreases in BMI-SDS after the 6-month intervention in group program and routine counselling were 0.3 and 0.2, respectively. A recent meta-analysis of the efficacy of the treatment of obesity in children under the age of 12 years (Oude Luttikhuis et al. 2009), included the present study and three other lifestyle interventions (Golan et al. 2006, Golley et al. 2007a, Hughes et al. 2008). On average a 0.06 decrease (95% CI from -0.12 to -0.01) in BMI-SDS favouring behavioural treatment over standard care was detected at six months (Oude Luttikhuis et al. 2009).

In the present study, the decreases in BMI-SDS at 1-year follow-up in group program and routine counselling were 0.2 and 0.1, respectively, but the difference was not statistically significant. In line, when the above mentioned meta-analysis (Oude Luttikhuis et al. 2009) including the present study and two other studies (Golley et al. 2007a, Hughes et al. 2008) was performed at 12 months, the difference in BMI-SDS decrease (0.04, 95% CI from -0.12 to 0.04) between behavioural treatment and standard care was no longer significant. However, in the study by Golan et al. (2006) at the 18-month follow-up, the differences between treatment groups were a 0.5 decrease in children's BMI-SDS versus a 0.1 increase in favour of targeting only parents (instead of parents and children).

An important question is whether routine counselling in the present study was advantageous to participating children. Although the efficacy of very low intensity studies has been disappointing (McCallum et al. 2007, Hughes et al. 2008), paradoxically in some studies children may have benefited from standard care (Hughes et al. 2008) or being as waiting list controls (Golley et al. 2007a), possibly by the increased awareness and motivation of families (Hughes et al. 2008).

### 6.2.2 Changes of adiposity indicators in the long term

In the present study, two and three years after the beginning of the intervention, there were no longer any significant differences between the programs in changes in children's adiposity indicators. On the other hand, an encouraging observation was that in both groups children's adiposity moderately decreased (on average a 0.3 reduction in BMI-SDS) between baseline and the 3-year follow-up, although weight for height was rather similar at those points in time.

In the present study, maintaining weight loss after the intervention was a major challenge, as seen also in other studies (Kalarchian et al. 2009). In contrast, some studies have suggested long-lasting beneficial impacts of childhood obesity treatment (Epstein et al. 1990, Golan and Crow 2004b, Reinehr et al. 2007). The factors associated with favourable long-term results are poorly known, though a German study suggested that the age of participating children might predict long-term success (Reinehr et al. 2010). The age group of the present study may be demanding, since in the German study 8-10-year-old children had less decrease in BMI-SDS (on average 0.30) at a 5-year follow-up compared with younger or older children (Reinehr et al. 2010).

Several approaches have been suggested for improving the long-term results of obesity management. Firstly, treatments may need to continue through puberty if started in prepubertal children (Reinehr et al. 2010). Secondly, a major reduction in adiposity (0.33 in BMI-SDS) during the first months of intervention is highly predictive for beneficial long-term results (Reinehr et al. 2007). Finally, special maintenance programs after active interventions may be beneficial (Wilfley et al. 2007a).

The evaluation of the clinical significance of the decreases of BMI-SDS in the present study in the long term is difficult, since there are no universally accepted goals for weight change in childhood obesity interventions. However, the use of the cut-offs of BMI-SDS decrease of 0.25 (Ford et al. 2010b) and 0.50 (Reinehr and Andler 2004, Wunsch et al. 2006) have been suggested as indicators of successful weight management. Using these cut-offs, in all in the programs, 34 and 20 children were successful, respectively, at the 3-year follow-up.

Our results, high correlations (at least 0.70) in weight for height, BMI and BMI-SDS between baseline and the 3-year follow-up, suggested strong tracking of adiposity, in line with population-based studies in childhood (Fuentes et al. 2003) and adolescence (Wardle et al. 2006). Furthermore, children's BMI at 14 years was predictive of BMI in early adulthood in a Finnish population-based study (Laitinen et al. 2001).

## 6.3 COST-EFFECTIVENESS OF THE PROGRAMS

The costs of group treatment per treated child were about 5.3-fold compared with those of routine counselling. However, the group program was more effective than routine counselling in reducing children's adiposity only in the short term. Thus, from the perspective of decision-making, in the present study design routine counselling was the dominating option in the long term.

There were two fundamental decisions in the present analyses. Firstly, the recruitment costs, which in the routine program were the major costs, were included in total cost. These costs are lower if routine counselling is offered as part of school health care. Secondly, even though there were two group leaders (students) in children's sessions, the salary costs were calculated for one group leader only. In clinical practice, one experienced leader evidently is sufficient for the group meetings.

The comparison of cost-effectiveness between treatment studies must be done cautiously because of different study designs, settings, time points and purchasing power. In the present study, the group treatment costs per child after intervention (€327 in the 2004 price level, US$435, 20 March 2007) were surprisingly similar to the corresponding costs in a US study (US$491) (Goldfield et al. 2001), even though there was one minor difference in the calculations. We calculated the costs per child, instead of per family, as there were three families with two attending children. However, the US program was more effective (0.64 decrease in BMI-SDS at one year vs. 0.2 in the present study). Unfortunately, the US study (Goldfield et al. 2001) did not have follow-up exceeding one year.

The proper length and intensity of obesity treatment is of major concern from the perspective of efficacy and costs. Unfortunately, low-intensity low-cost approaches in childhood obesity treatment have been unfruitful (Wake et al. 2008, Wake et al. 2009), and thus extending treatment length improves weight management results (Snethen et al. 2006, Oude Luttikhuis et al. 2009, Whitlock et al. 2010) and costs. In the present study, the waning of the effects of group treatment call for some continued counselling or low frequency group activities after the intervention period, which evidently would increase the costs.

As labour costs formed 86% from total costs in the group program, our decision to include also children in the treatment and to have separate sessions for parents and children had a fundamental effect on costs. Though some studies (Golan et al. 1998, Golan et al. 2006, Munsch et al. 2008, Janicke et al. 2009, Okely et al. 2010) have suggested that parents only can be targeted in childhood obesity treatment, the feasibility of parent-only approach is unclear in a country like Finland, where both fathers and mothers often work outside home and single-parent families are common. In addition, in the present study, based on clinical experience, it was not reasonable to treat parents and on average 8-year-old children in the same sessions. On the other hand, if the efficacy of routine counselling would be improved by including the parents in the treatment, as suggested by Kitzmann et al. (2010), the costs would increase only marginally from the perspective of the service provider.

The present study or previous studies (Cawley 2007, John et al. 2010) do not allow any conclusions on the most cost-effective modalities of childhood obesity treatment. Furthermore, besides of the costs of obesity treatment, the decision maker has to take into consideration the monetary and intangible costs of childhood obesity, and furthermore, ethical issues (Haby et al. 2006).

## 6.4 IMPACT OF THE PROGRAMS ON CHILDREN`S BODY COMPOSITION AND METABOLIC INDICATORS

At baseline, blood pressure and laboratory measures of the obese study children were, on average, within normal limits. However, the metabolic profile of the obese children was unfavourable when compared with the normal-weight control children, as the study children had on average substantially lower HDL-C, higher TG and impaired insulin sensitivity than the control children. Thus, our findings are in line with many other studies, which have shown obesity-related metabolic abnormalities in children (Morrison et al. 1999a, Morrison et al. 1999b, Garces et al. 2005). In the present study, the blood pressure values of study children differed marginally from those of the control children, but were in line with the values in the children of same age from Great Britain (Jackson et al. 2007).

There were no differences in the changes of fat mass between the group and routine programs in spite of differences in the changes of adiposity indicators. A decrease of 0.5-0.6 in BMI-SDS may be required in order to produce an actual body fat percentage loss, as was seen in on average 12.8- year-old children with BMI-SDS 3.38 (Hunt et al. 2007).

In our study, the children in the group program lost more abdominal adiposity, as estimated by the waist/height, than those in the routine program, but there were no differences in the changes of other metabolic indicators between the programs. These findings are in accordance with an Australian 6-month randomised controlled obesity treatment study with on average 8.2-year-old children (Golley et al. 2007a). At 12 months, the children had a moderate weight loss, with a BMI-SDS decrease of approximately by 5-10% in study groups, but the intervention had no impact on the children's lipids, insulin or blood pressure. Both in the present study and the Australian study (Golley et al. 2007a), the lack of changes might be because the metabolic indicators were within normal limits before intervention and weight loss was only moderate.

In contrast to the present and the Australian study (Golley et al. 2007a), some obesity treatment trials have shown beneficial changes in children's lipids (Jiang et al. 2005, Nemet et al. 2005, Savoye et al. 2007), blood pressure (Jiang et al. 2005) and insulin resistance (Savoye et al. 2007). Compared with the present and the Australian study (Golley et al. 2007a), children in other studies (Jiang et al. 2005, Nemet et al. 2005, Savoye et al. 2007) have been older (on average 11 – 13 years) and differences in changes of BMI between the intervention and control groups have been substantial (at least 1.5 units).

In the combined groups, BMI-SDS decreases were associated with beneficial changes in TGs, when BMI-SDS decreased 0.5 or more, and in fasting insulin, when BMI-SDS decreased 0.25 or more. There is no agreement of the degree of the decline in BMI-SDS needed for the positive changes of metabolic indices. A German non-randomised 1-year obesity treatment trial suggested that multiple beneficial changes in metabolic indicators require a BMI-SDS decrease 0.5 or more (Reinehr and Andler 2004, Reinehr et al. 2004). On the other hand, a recent 1-year cohort study of a hospital outpatient weight management clinic offered that some favourable changes in metabolic indicators were associated already with a BMI-SDS decrease of ≥0.25 but <0.5, whereas some only with a BMI-SDS decrease ≥0.50 (Ford et al. 2010b).

## 6.5 METHODOLOGICAL DISCUSSION

The results of the study cannot be generalised, even in Finland, to all obese children. Firstly, participating families may have had more motivation and resources to solve children's weight problems than non-participating families. To decrease selection bias, we included also single-parent families (23% in group treatment) and children with common chronic diseases, such as asthma and allergic diseases (34% in group treatment). Secondly, our study group consisted only of young school-age children, and the long-term efficacy of treatment may be less promising at that age than in younger or older children (Reinehr et al. 2010).

The number of study children (70 children) in the present study was reasonable when compared with many childhood obesity interventions (38/54) having less than 30 children at least in one study arm (Oude Luttikhuis et al. 2009). In addition, low attrition rate during follow-ups (1-3%) increased the reliability of the results of long-term efficacy. However, the number of study participants restricted the use of stratified analyses. Furthermore, the study was evidently underpowered to detect small differences between the subgroups. Moreover, we did not have a control group of obese children with no intervention, which would have helped to assess whether the encouraging long-term reductions of BMI-SDS in both programs were due to the normal growth of obese children or whether the participation in the study had any beneficial impact on the adiposity of participating children. Some studies have suggested continuous increase in the degree of adiposity of untreated obese children (Quattrin et al. 2005, Rudolf et al. 2006). However, long-term controlled trials with waiting list groups may be impossible for ethical reasons.

The study design was prospective, randomised and controlled, which is the "gold standard" for intervention trials. The main analyses of treatment efficacy were performed with adjustment for the potential confounders, and thus, these results of the study can be considered trustworthy. Furthermore, we were able to assess the long-term efficacy of childhood obesity treatment, which is a relatively neglected aspect in childhood obesity research (Oude Luttikhuis et al. 2009). However, in growing children, longer follow-ups are clearly needed to assess the efficacy and safety of obesity treatment programs from childhood possibly even to adulthood, even though the lengthening of follow-ups means more confounding variables and drop-outs.

Before and after intervention, all measurements were performed in a fasting state using standard protocols. However, for practical reasons, the children were measured by school nurses at various times of the school day at the follow-ups. Thus, weights and heights measured at baseline and immediately after intervention are not fully comparable with those measured at follow-ups. To increase the reliability of follow-up measurements, all measurements were performed using standardised protocol, participating school nurses were trained, and stadiometers and scales were annually calibrated.

The outcome was assessed by three different adiposity indicators, weight for height, BMI and BMI-SDS. Because there were no Finnish BMI-SDS reference values, we calculated those applying British population-based references. The high correlations (0.89 or more) between changes in weights for height and BMI-SDSs after intervention and at follow-ups implied that the use of the British BMI-SDS references was justified. However, the use of three different adiposity indicators was not unequivocal, but at present, there is no universal agreement of the best proxy indicator of children's adiposity in weight management studies. The use of BMI-SDS is recommended e.g. by the British standard evaluation framework for weight management interventions (National Obesity Observatory 2009).

The efficacy of the intervention was evaluated from the economic perspective as recommended (American College of Physicians 2008). The costs were registered reliably, by an online micro costing program. However, we had two drawbacks in the economic analyses. In the present study, a cost-effectiveness analysis was performed, even though the use of cost-utility analysis is widely recommended (Russell et al. 1996). However, the use of cost-utility analysis in paediatric research is complicated (Griebsch et al. 2005). In addition, the cost-effectiveness was analysed from the perspective of the service provider only, instead of the recommended societal perspective (Russell et al. 1996).

The evaluation of clinical efficacy was supplemented with the assessments of the impacts of the programs on body composition and metabolic markers. We assessed children`s adiposity with bioelectrical impedance, which is a non-invasive and well-established method for body composition assessment (Kyle et al. 2004). In addition, we had a population-based control group from the same area consisting of normal-weight children matched for age and gender (Utriainen et al. 2009) for the comparisons of metabolic indicators at baseline. Unfortunately, we could not assess study children's pubertal status, body composition or metabolic indicators at long-term, because resources were limited, and the follow-up measures were performed in school health care.

Because of limited resources, we had to exclude from the study design such outcomes as the impact of the programs on children's lifestyle, quality of life and self-esteem. In addition, we were not able to assess factors related to child, family, or environment that may have been associated with the long-term outcome.

## 6.6 IMPLICATIONS FROM THE PERSPECTIVE OF SERVICE PROVIDER

Judging by international audits (Kolagotla and Adams 2004, O'Brien et al. 2004, Dorsey et al. 2005), there is a need for the improvement of obesity treatment in children, evidently also in Finland.

When considering the implementation of the group program and routine counselling in the health care system, several standpoints must be taken into consideration. Firstly, parents should be involved in routine treatment, which may improve the efficacy of the program. Secondly, many children in any treatment program will need continued contact with health care personnel after initial treatment, especially to learn skills for maintenance of weight loss. Thirdly, there may be need for both very low intensity and more intensive programs, and the choice of the program should be individualised. In fact, an Expert Committee (Barlow and the Expert committee 2007) has suggested that the system of obesity treatment should consist of four stages of increasing intensity ("prevention plus", "structured weight management", "comprehensive multidisciplinary intervention", ”tertiary care intervention"), and that the choice of the program should be based on the child's age, BMI, health risks, motivation and response to treatment.

In the battle against obesity and obesity-related diseases, a broad approach encompassing multiple sectors, including educational system, food industry and media, is evidently needed (Sarlio-Lahteenkorva 2007, Lindstrom et al. 2010). More health-promoting childhood environments may translate to outcomes that are more favourable in childhood obesity prevention and treatment. In Finland we have had positive experiences of population-based dietary changes, induced by co-operation of various stakeholders, in the prevention of cardiovascular disease (Puska 2009).

# 7 Summary and Conclusions

The purpose of this prospective randomised controlled intervention was to compare the efficacy of a group-based program consisting of 15 sessions for parents and children with routine counselling ("current care") consisting of two appointments for children in the treatment of obesity in young school-aged children.

Both programs were feasible, with high participation rates and low attrition rates. Problems with recruitment suggested that parents' awareness of childhood overweight and obesity should be increased.

The group program was more effective than routine counselling after intervention, but the efficacy of the programs was rather similar in the long term. On the other hand, an encouraging observation was that in both programs children's BMI-SDS moderately decreased between baseline and 3-year follow-up, although weight for height was rather similar at those points in time. A further study should evaluate the efficacy of the programs of the present study after children have passed puberty. In addition, future studies of childhood obesity management should assess the impact of the interventions on the children's lifestyle, self-esteem and quality of life in addition to factors associated with short-term and long-term success.

Salary costs formed most of the treatment costs in both programs. The more intensive group program was both more effective and costly when assessed shortly after intervention, but in the long term, there was no difference in efficacy between the programs and the routine treatment was cheaper. The future studies should assess the cost-efficacy of routine counselling with parents participating in the program. Secondly, the feasibility, costs and efficacy of special maintenance programs should be evaluated. Finally, if the programs are modified and implemented in the health care system, the feasibility and effectiveness of the modified programs should be evaluated. In any case, the decision maker has to take into consideration not only cost-effectiveness, but also the monetary and intangible costs of obesity, the need for individualised treatment and ethical issues.

Obese children had an unfavourable metabolic profile compared with the normal-weight children, even though metabolic indicators were on average within normal limits. After intervention, the children in the group program lost more abdominal adiposity than those in the routine program, but there were no differences in the changes of other metabolic indicators or fat mass between the treatments. The associations between changes in BMI-SDS and metabolic indicators in the combined treatment groups suggested that there is no clear threshold for favourable BMI-SDS decrease. Preliminary evidence was found for a cut-off of 0.5 or greater decrease in BMI-SDS.

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**Marja Kalavainen**

# *Treatment of Obesity in Children*

*A Study on the Efficacy of a Family-based Group Program Compared with Routine Counselling*

This randomised controlled study compared the efficacy of a behavioural family-based group program with routine counselling ("current care") in the treatment of childhood obesity. The more intensive group program (15 sessions for parents and children) was more effective than routine program (two appointments for children) in reducing children's adiposity, when assessed shortly after intervention. However, in the long term, there was no difference in efficacy between the programs. New approaches are needed to improve long-term efficacy of childhood obesity treatment.

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