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# New Approaches in Obesity Treatment

Judith Evelyn de Niet

# **New Approaches in Obesity Treatment**

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The work presented in this dissertation was performed at the Department of Medical Psychology and Psychotherapy, Erasmus MC, Rotterdam and the Division of Reproductive Medicine, Erasmus MC, Rotterdam.

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# **New Approaches in Obesity Treatment**

Nieuwe benaderingen voor het behandelen van obesitas

Proefschrift

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## **PROMOTIECOMMISSIE**

### **Promotoren:**

Prof.dr. J. Passchier

Prof.dr. J.S.E. Laven

### **Overige leden:**

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Prof.dr. S.L.S. Drop

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Jan de Niet

Vincent de Niet

Aan Jan, Vincent en Willeke





Somewhere there's a river looking for a stream  
Somewhere there's a dreamer looking for a dream  
Somewhere there's a drifter trying to find its way  
Somewhere someone's waiting to hear somebody say

I believe in you and I can't even count the ways that  
I believe in you and all I want to do is help you to believe in you

Somewhere someone's reaching trying to grab that ring  
Somewhere there's a silent voice learning how to sing  
Some of us can't move ahead we're paralyzed with fear  
And everybody's waiting to hear somebody say

I believe in you and I can't even count the ways that  
I believe in you and there are just so many ways that  
I believe in you and all I want to do is help you to believe in you

*Amanda Marshall*



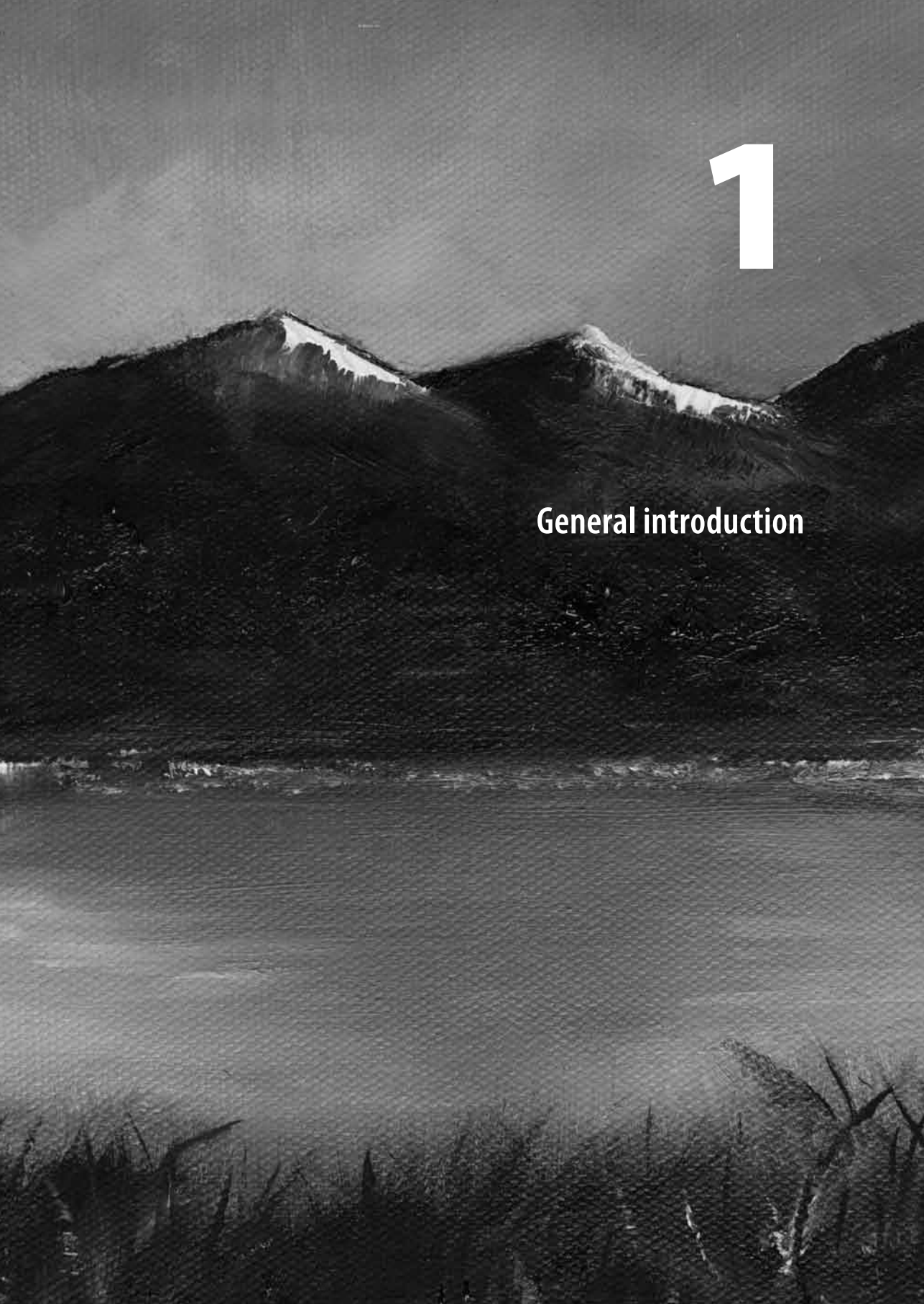
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# 1

## General introduction





## 1.1 GENERAL INTRODUCTION

Obesity has become a global epidemic among all age groups [1, 2]. A number of countries have even experienced a notable shift from under- to over nutrition in youngsters or a double burden of both malnutrition and obesity [3]. The World Health Organization (WHO) defines overweight and obesity as “abnormal or excessive fat accumulation that may impair health”. Worldwide, the impairment of health includes a number of diseases related to obesity causing death in at least 2.6 million people each year [2]. The prevalence of childhood overweight and obesity is alarming and increasing at a faster rate than before. Globally, in 2005 approximately 1.6 billion individuals of the world population aged 15 years and older were overweight and at least 400 million adults were obese. By 2015, the WHO expects approximately 2.3 billion adults to be overweight and more than 700 million to be obese. By 2030, the global burden of obesity is projected to be a total of 3.3 billion obese adults [4].

In the Netherlands, the rate of increase in the prevalence of overweight and obesity in children almost tripled between 1997 and 2003 with reference to the years between 1980 and 1997 [5]. In 2009, the prevalence of overweight and obesity in children and adolescents aged 2-20 years in the Netherlands was 15.1% and for adults the prevalence of overweight and obesity was 47.2% [6]. The alarming prevalence of overweight and obesity in the Netherlands resulted in important initiatives such as the Covenant overweight by the Ministry of Health and partners to reduce the prevalence of overweight, obesity, and related chronic diseases.

More efficient storage of body fat did have evolutionary advantages; however, overweight and obesity are no longer advantageous in a more developed country in which food is generally available *ad libitum*. The magnitude of the epidemic has increased even more due to the fact that in overweight or obese people, energy expenditure is generally decreased which, in turn, further aggravates the balance between intake and expenditure. Unfortunately, being obese is associated with a great amount of negative health consequences, which often become life-threatening. Given the expectation that the prevalence of obesity continues to increase, these negative consequences will also increase.

### 1.1.1 Classification of overweight and obesity

In this dissertation, the operational definitions of overweight and obesity are based on the Body Mass Index (BMI) of an individual. BMI is a simple index of weight adjusted for height to classify weight in adults. BMI is defined as the weight in kilograms divided by the square of the height in meters ( $\text{kg}/\text{m}^2$ ) [7]. According to the cut-off points of the World Health Organization (WHO) overweight is classified as a  $\text{BMI} \geq 25.00 \text{ kg}/\text{m}^2$  and obesity is classified as a  $\text{BMI} \geq 30.00 \text{ kg}/\text{m}^2$ . Obesity is divided into three classes: obese

class I is defined as a BMI from 30.00 kg/m<sup>2</sup> to 34.99 kg/m<sup>2</sup>; obese class II from 35.00 kg/m<sup>2</sup> to 39.99 kg/m<sup>2</sup>; and obese class III  $\geq$  40.00 kg/m<sup>2</sup>. A WHO expert consultation found that the health risks associated with obesity might occur at a different BMI level in ethnic populations due to differences in the distribution of body fat [8]. In Asians for example, the proportion of people with a high risk of type 2 diabetes and cardiovascular disease is substantial at BMI's lower than the existing WHO cut-off point for overweight.

Different from the adult BMI, BMI in children is also dependent on age as well as gender because children are still growing. Furthermore, cut-off points are more difficult to determine because children have fewer health risks associated with BMI than obese adults [9]. The international BMI cut-off points defined for childhood overweight and obesity are based on the percentile values of adult BMI scores and are adjusted for age and gender. Body Mass Index-Standard Deviation Scores (BMI-SDS), BMI scores corrected for age and gender, greater than 1.1 indicates overweight, and BMI-SDS greater than 2.3 indicates obesity [10].

## **1.2 DETERMINANTS OF OVERWEIGHT AND OBESITY**

In sections 1.2 and 1.3, determinants and consequences of overweight and obesity are selectively summarized, as the number of studies conducted in the field of obesity is enormous. I made a selection of determinants and consequences that are primarily related and associated with the Chapters in this dissertation. Because the articles presented in this dissertation are mainly focused on children and adolescents, most of the research described in the following sections is conducted in childhood populations.

### **1.2.1 Genetic influences**

A large number of studies in humans and in a diversity of species indicate a genetic component for obesity or, more generally, adiposity [11]. Besides adoption and family studies, twin studies have been an integral part of the research on the genetic influence of obesity. Monozygotic twins (identical twins) share identical genes, and the assumption is that behavioral and physical differences are explained by environmental factors. Shared as well as non-shared environmental influences contribute to inter-individual differences in body fat. Dizygotic twins share on average half of their genes. Twin studies indicate that BMI is strongly influenced by genetic factors, with greater heritability of body fat in monozygotic twins than in dizygotic twins [12, 13]. Wardle et al. found that genetic factors accounted for 60% of the variance in abdominal adiposity (waist circumference) [13]. This percentage of heritability is similar to the percentage that has been found for Body Mass Index [14]. However, twins, adoption, and family studies generally



show a divergence of heritability estimates, ranging from 20% to 90% [11]. Nevertheless, these studies provide unequivocal support for genetic influences on adiposity.

Besides revealing the genetic influences on adiposity, studies suggest that genetic influences also operate on behavioral aspects, such as eating behavior and physical activity. With respect to eating behavior, it has been found that genes account for food intake [15], meal pattern (e.g. frequency and size) [16], the speed of eating [17], impulsive eating behavior [18], and food preferences [19, 20]. Studies investigating the genetics of physical activity are scarce. However, the existing studies indicate that there is a heritable component to resting energy expenditure [21]. In addition, other studies showed that genetic predisposition to adiposity does not seem to reduce the effect of physical activity on body fat mass in females [22], and that heritability also seems to account for reported physical activity in twins [23]. In one twin study, Stubbe et al. [24], found that environmental factors determine sports participation in young adolescence (accounts 78-84% for individual differences), whereas genes are of no importance. After the age of 18 years, individual differences in sports participation are largely due to genetic variation (85%), and common environmental factors no longer contribute.

Obesity seems to have a genetic susceptibility based on different genetic polymorphic variants (single nucleotide polymorphisms (SNP's)) that may reveal additional rare variants [25]. They compose the final phenotype of overweight or obesity, which is therefore a complex genetic trait. The heritability percentages of adiposity in recent studies are fairly similar to the percentages in older studies which were conducted in a less obesogenic environment ('obesogenic': an environment that facilitates eating more and exercising less). In summary, it is possible that the gene pool changed somewhat, but not enough to explain the obesity epidemic. Therefore, the increased prevalence of overweight and obesity seems to be attributable to environmental components. Hence, obesity should be regarded as a complex genetic trait in which genetics extensively interact with numerous different environmental factors.

### **1.2.2. Environmental and psychological influences on eating behavior and physical activity**

Changes in lifestyle have contributed to the emerging problem of obesity through an imbalance between food intake and energy expenditure. In youth, as in adults, poor dietary habits and low levels of physical activity are significant factors in the onset of overweight and obesity. In general, temptations in our obesogenic environment are increased by a larger and easier availability of high-calorie density foods and triggers as well as by an increase in the marketing and media attention to foods.

With respect to physical activity, the norm for children for a healthy physical activity level in the Netherlands is physical activity at a moderate intensity level for 60 minutes daily. It is recommended that adults engage in modest physical activity for 30 minutes

about 5 times a week [26]. Less than 30% of the children and about half of the adults met this recommendation in 2008 [27]. Sedentary behaviors play an important role in the development of obesity. For example, an increase in television viewing might be one of the mechanisms behind the obesity epidemic [28, 29], although it should not be considered as the key contributor towards inactivity [30]. Larger meals consumed while watching TV were found to be associated with increases in children's television viewing. Moreover, higher levels of television viewing were related to higher BMI [31].

Several studies indicated that the household environment also influences youth health behaviors. Parents are primarily the main caregivers who provide the environmental context for eating and exercising behavior and might therefore influence children's food intake and energy expenditure. Parental practices, styles, and modeling seem to influence eating behavior and physical activity in children. For example, the influence of parental restriction on the access of palatable foods and foods high in fat and sugar, has been studied [32]. Fisher et al. [33] found that the restriction of palatable foods is not an effective means of promoting moderate intake of those foods. Moreover, restriction increased subsequent selection and intake of those foods. Additionally, Fisher and colleagues [33] found a positive influence for parental modeling on young girls' fruit and vegetable intake, though pressure to eat fruits and vegetables seemed to discourage the intake. It was also found that parental encouragement to eat fruit and vegetables was associated with daily servings of these products and that the availability of healthy snacks and foods around the house was related to lower fat intake in children [34]. Furthermore, Franko and colleagues [35] found that greater family cohesion, or a more positive family climate, was associated with less soda intake and higher rates of breakfast consumption. This finding supports the results of other studies reporting that family cohesion positively influences healthy eating behavior [36, 37]. Additionally, it has been found that children in two-parent families ate breakfast on more days than children from single families. Similarly, children describing their parents as authoritative ate breakfast on more days [38, 39]. Parental role modeling of physical activity seems to be one of the factors that influences physical activity in children [40]. Parents' physical activity patterns and overall support seem to predict physical activity in adolescent girls [41, 42].

Children's and adolescents' health behaviors are not only influenced by their parents, but also by their peers. For example, Lieberman et al. [43] reported that peer modeling was a strong predictor of dieting behavior in adolescents girls. Another study found that peer influence was associated with the intake of foods high in saturated fats [44]. Several studies have related the availability of snacks and drinks sold in schools to higher intakes of calories, soft drinks consumption, and lower intakes of fruits and vegetables [45, 46].

Eating styles have also been found to be related to overweight. Van Strien et al. [47] described three eating styles: two overeating styles, namely emotional eating (eating

in response to negative emotions) and external eating (eating in response to the sight or smell of food), and dietary restraint (eating less than desired to lose or maintain weight). Eating styles seem to be related to BMI in women [48] and overconsumption in the general population [49]. Furthermore, eating styles are also related to energy intake in young women [50], loss of control over eating in obese youngsters [51], and binge eating in children and adolescents [52]. Additionally, Van Strien et al. [53] indicated that parental restriction of their children's food intake was negatively related to emotional and external eating in children. Parents might influence their children's eating styles through their own eating behavior. For example, the results of Snoek and colleagues [54] suggested a modeling effect of parents' emotional eating on their children's emotional eating. In addition, higher maternal weight concern as perceived by the child was found to be related to higher restrained eating of the child [50].

In conclusion, factors influencing overweight are best understood at various levels considering genetic, behavioral and psychological determinants. The relation between various mechanisms and the onset of obesity is complicated due to multiple causes and maintenance factors.

## **1.3 CONSEQUENCES OF OBESITY**

### **1.3.1 Physical health consequences**

Childhood obesity is related to multiple physical consequences. The prevalence of metabolic syndrome is about 50% in obese youngsters and increases with more severe obesity [55]: soft biomarkers of adverse cardiovascular outcomes are already present in these adolescents. Levels of waist/height ratio (WHtR) rather than levels of BMI for age or skinfold thickness are related to cardiovascular risk factors [9] such as triglycerides, concentrations of low-density lipoprotein (LDL) cholesterol, fasting insulin, and levels of systolic blood pressure. BMI appears to be associated with fasting insulin, and hyperinsulinism or insulin resistance only in overweight children. Moreover, an increase over time in WHtR and abdominal obesity has been observed in children and adolescents [56]. This increase is associated with negative consequences, especially because it has been shown that visceral fat primarily explains the obesity-related health risks [57]. Due to insulin resistance, the obesity epidemic is accompanied by an increase in the number of children suffering from type 2 diabetes mellitus [58, 59], a disease with a considerable health impact that was traditionally considered a disease of middle age. Furthermore, a higher BMI is associated with nonalcoholic fatty liver disease [60], gallstones [61], obstructive sleep apnea [62], and headache frequency [63]. One study even found that a BMI > 25 at age 18 was associated with increased mortality rates in men within 20 years [64].

One study in this dissertation focuses on women with polycystic ovary syndrome (PCOS). As in female adults, obesity in pre- and mid pubertal girls is associated with hyperandrogenaemia and hyperinsulinaemia across puberty [65]. Hyperinsulinaemia plays an important role in the pathogenesis of adult PCOS and places adolescent girls at risk for PCOS. It is estimated that 5-10% of reproductive-aged women suffer from PCOS [66, 67] which makes PCOS the most common endocrine disorder in women. The major characteristics of PCOS are enlarged ovaries with a polycystic morphology along with menstrual irregularities such as amenorrhoea or oligomenorrhoea, excessive growth of body hair (hirsutism) or biochemical hyperandrogenism, and to a lesser extent, acne [68]. Subsequently, a greater incidence of obesity, about 50% compared to 30% in the general American as well as in the European population, is found in women with PCOS [69]. As can be expected, a higher BMI in PCOS women is accompanied by several negative physical and psychological consequences too. A more atherogenic lipid profile [70] and metabolic syndrome is more common in women with PCOS compared to controls with a regular menstrual cycle, particularly in women with higher BMI levels [71]. Moreover, maternal obesity doubles the risk for stillbirth and neonatal death [72], and obese women with PCOS are even more at risk for developing pre-eclampsia [73]. Overweight and obese women with PCOS being treated with fertility problems require larger doses of gonadotrophins [74]. In addition, they have a less favorable, cost ineffective outcome of ovulation induction [75] and increased miscarriage rates and complications during pregnancy [76-78].

Finally, several studies pointed out that children with high BMI scores are likely to become obese adults [79, 80], particularly older children [81]. These associations are the strongest with adult BMI  $\geq 35$ . Furthermore, one study found that among both obese and non-obese children under the age of ten, parental obesity more than doubles the risk of obesity in adulthood [81].

### 1.3.2 Psychosocial consequences

Obesity is not only associated with physical consequences, but it also affects psychological well-being. Obese children are more likely to experience psychological problems than non-obese children [82]. There is some evidence that depression is the most prevalent psychological problem in overweight and obese children [83, 84], though contradictory results have been found in relation to depression [85-88]. Girls seem to be more at risk than boys to have depressive symptoms [85]. Depression seems to be explained by factors such as overweight concerns and shame [85] and parental separation [86] rather than by BMI directly.

Furthermore, obese boys and girls are more likely to be victims of bullying than average weight peers [89, 90]; lower self-esteem and body satisfaction seem to influence this relationship [90]. Obese youth also seem to have lower global self-esteem and quality

of life (QoL) than healthy weight children and adolescents [91]. There is some evidence that physical competence, physical appearance, and social functioning [91] are affected in obese youngsters. For example, Braet et al. [92] found that obese children reported more negative physical self-perceptions and lower general self-worth than non-obese peers. Greater impaired general and physical health has been found in obese children [93-95] and there is also some evidence that their psychosocial functioning is impaired [93, 94]. Caregiver-reported physical and social QoL is lower for obese children than for children with other chronic illnesses, such as Cystic Fibrosis, epilepsy, type 1 diabetes and inflammatory bowel disease [96]. Furthermore, adolescent girls with PCOS experience lower QoL than healthy adolescents [97] with BMI as a primary mediator of health related QoL [98].

### 1.3.3. Economic consequences

Worldwide, the direct costs of obesity are estimated to account for 0.7% to 2.8% of a country's total healthcare expenditures, with obese individuals having medical costs that are about 30% higher than normal weight individuals. In these estimates, psychological and social costs have not been taken into account [99]. However, it is still unclear which specific determinants of obesity account for the direct costs.

Obesity seems to have direct economic consequences for the obese individual as well: female adolescents who were obese at age 16 were found to have earned less than their non-obese peers [100]. Gortmaker et al. [101] found in a follow-up study that women who were overweight seven years earlier had lower household incomes as well as higher rates of household poverty seven years later.

In conclusion, all the above mentioned physical, psychosocial, and economic consequences indicate enough reason to start the battle against obesity at young age.

## 1.4 TREATMENT OF CHILDHOOD OVERWEIGHT AND OBESITY

The increased prevalence of obesity in children and adolescents as well as in adults highlights the need for evidence based interventions, particularly given the increased risks of physical and psychosocial health consequences associated with obesity. The Expert Committee on the treatment of overweight and obesity in children and adolescents recommends that the treatment of obesity has to start early [68]. Age is an important predictor of weight reduction in children and adolescents: younger children seem to achieve more weight loss [102-105]. The best chance to reduce overweight was found in children younger than twelve years of age [105]. This finding emphasizes the need for effective weight reducing interventions which have to be initiated at a young age.

Weight reduction seems to be an effective preventive measure for most of the negative health consequences of obesity. Decreasing one's weight by 6.5% leads to a decrease in health risks in adolescents as well as in adults [106]. Furthermore, the arteriogenic profile and insulin sensitivity in obese children improves when BMI-SDS decreases by at least 0.5 over a one year period [107, 108]. Weight reduction is therefore associated with a reduction in adverse cardiovascular risk factors and an improvement in insulin sensitivity. Finally, decreases in overweight lead to an improvement in psychological functioning [109].

Medium- to high-intensity behavioral programs have shown the best weight loss results [110, 111]. However, in the past years various studies have also evaluated medical treatments such as the use of pharmacotherapy, either alone or combined with behavioral interventions. For example, Orlistat® and Sibutramine® are two medications that are FDA approved for attaining sustainable weight loss. Drug treatment with either Orlistat®, or Sibutramine® combined with a behavioral treatment leads to an effective sustainable weight reduction in moderate to severely obese adolescents. However, various adverse effects in adolescents receiving Sibutramine® such as mild hypertension and tachycardia (rapid heartbeat) [112] and flatulence and diarrhea in youngsters treated with Orlistat® [113] have been observed indicating that drug treatment should be used with caution [114].

#### **1.4.1 Lifestyle interventions and treatment success**

Poor dietary habits, lack of physical activity, and sedentary lifestyles play an important role in the onset of overweight and obesity. Therefore, most behavioral interventions for overweight and obese individuals are aimed at modifying lifestyle behaviors. Behavioral programs aimed at improving lifestyle factors are also referred to as lifestyle interventions. Accordingly, lifestyle modification interventions include the following three components: dietary intake, physical activity, and behavioral therapy. The 2009 Cochrane review of interventions for treating obesity in children and adolescents showed that family-based lifestyle programs achieve the best results in relation to weight reduction [110]. Behavioral programs have also been shown to be effective in the treatment of adult obesity [115, 116]. The behavioral component includes changing thinking patterns and actions, especially in relation to eating and exercising behaviors. Various behavioral skills are needed to achieve and maintain weight reduction goals. The principles and techniques of behavioral therapy help individuals to adopt new diet and exercise habits. The child's household food and physical environment also need to be targeted as a part of the intervention. Parental involvement has been found to be an important component in the treatment of childhood obesity [83, 117, 118].

Lifestyle interventions with an emphasis on improving healthy eating behavior as well as on improving physical activity levels accomplish greater weight loss results than

interventions with an emphasis on diet or physical activity alone [110, 116]. With respect to weight loss results, Reinehr et al. [105] found mean BMI-SDS changes that ranged from  $-0.20 \pm 0.32$  after 6 months of lifestyle intervention,  $-0.19 \pm 0.40$  at 12 months, and  $-0.20 \pm 0.54$  at 24 months when studying only children with complete follow-up data. These BMI-SDS changes are in line with other studies [110]. Several factors have been found to influence treatment success. Family characteristics may negatively predict treatment success: maternal depression, maternal avoidant attachment attitude, obese siblings [102], and parental obesity [103, 119] appear to be negatively associated with weight reduction. Weight loss in parents seems to be related to weight reduction in their children [120, 121]. Both parental and child psychological problems might negatively influence treatment success [120]. For example, maternal psychopathology has been found to be a negative determinant of treatment outcome [122], whereas the child's global self-worth at baseline positively predicted long-term weight loss [122, 123]. Furthermore, there is some evidence that the most impulsive children lose less weight [124]. Contradicting results have been found for gender [102, 103, 105] and weight at baseline [121, 125] as predictors of treatment success.

A major challenge for overweight and obese individuals is not only to lose weight, but also to maintain their weight loss. Unfortunately, those who initially lost weight often regain weight very quickly [126]. Reinehr et al. [105] conducted a two-year follow-up study in overweight children. These authors found, when utilizing only children with complete follow-up data in their analysis, that 82% of the overweight children and adolescents ranging from 2 to 20 years of age attained a reduction of overweight after 12 months and 76% after 24 months [105]. Intention to treat analysis with variables set back to baseline in lost to follow-up revealed that 22% of the children reduced their BMI-SDS at 6 months, 15% after 12 months, and 7% after 24 months. However, the problem was that complete follow-up data were only available for 17% of the children after 12 months and for 8% of the children at two-year follow-up. Another study found that after 5 years, 49% of the children had achieved a decrease of at least 10% in relative weight after treatment [121]. Epstein et al. [83] investigated weight reduction in children over a 10 year period and found that after 10 years, 30% of the study population achieved a non-obese status and about one third had a decrease of at least 20% overweight [83, 122]. A more recent study of Moens et al. [122] indicated an average decrease of 8% in BMI after childhood obesity treatment at their 8-year follow-up. At the start of the treatment, the percentages of overweight and obese children were 28% and 72% respectively. At 8-year follow-up, 19% of the treated children were no longer overweight, 34% were overweight, and 47% obese.

However, if individuals successfully maintain weight loss for 2-5 years, maintaining weight loss over the long-term seems to get easier. It has been found that the best predictor of change over 10 years was weight reduction during the first 5 years [83].

Furthermore, Reinehr et al. [127] found that BMI reduction during the intervention predicted long-term outcome after 5 years. Identifying those who benefit the most and least in terms of weight reduction can contribute to a better understanding behind the mechanisms of weight management and can improve obesity treatment.

#### **1.4.2 Dropout in the treatment of childhood overweight and obesity**

Dropout refers to premature ending of the treatment that is offered to the patient. Some studies addressed the understanding of parent-reported reasons for dropout from pediatric obesity programs. One study indicated that lower perceived overall quality of care was associated with premature discontinuation between start and 3 months [128]. Other reasons for dropout included difficulties with insurance coverage, child's desire to leave the program, inconvenience of appointment times [128], treatment focus, and distance to the location of the program [129]. Another study reported physical barriers, organizational barriers, and program educational content as reasons for non return in a nutrition focused weight management program [130]. Furthermore, Braet et al. [131] showed that dropouts more often reported problems in perceived relevance of the treatment and appointment problems. There is some evidence that non-completers in weight management programs are likely to be older [131, 132], have an ethnic minority status, and are likely to self-report depressive symptoms and a more negative self-concept [132]. However, contrary results have been found regarding the association between age and dropout [104, 129] and between gender and dropout [129, 133]. There is some evidence that psychosocial variables, such as self-perception and social support related to exercise habits are unrelated to dropout [134]. Parent rated psychological problems in the child were found to be non-significant but there was still a trend that psychological problems in the child were related to higher dropout rates [131]. Contradictory findings have been found in relation to the child's BMI [104, 129, 131]. Van den Akker et al. [135] found that, compared with the treatment completers, dropouts were older, had a higher BMI-SDS before the start of treatment, and were less successful in BMI-SDS reduction during treatment. With respect to family characteristics, Braet et al. [131] found that parents of completers have greater motivation for treatment at intake. Some studies showed that higher parent BMI at baseline was associated with dropout [134, 136], whereas others did not find this relation [131]. Gronbaek et al. [136] found that more families with unemployed mothers dropped out. Finally, a group intervention targeted on parents of obese children resulted in fewer dropouts than a similar intervention targeted at obese children only [118].

Dropout rates exceeding 90% have been found in childhood obesity treatment [137]. One study reported incompleteness of follow-up data in even 92% of the study population at the two year follow-up [105]. The high dropout rates in the treatment of obesity highlight the need to detect those children who are dropping out of treatment and to



develop interventions reducing dropout rates. The field is challenged to develop techniques aimed at reducing dropout rates and improve compliance to obesity treatment.

## **1.5 THE USE OF E-HEALTH APPLICATIONS IN HEALTH CARE AND SPECIFICALLY IN THE TREATMENT OF OVERWEIGHT AND OBESITY**

The integration of E-health applications, the delivery of health information and services via the internet and related technologies into health care, has increased in the past years. Various internet weight loss programs for children as well as for adults have been studied. For example, Tate et al. [138] showed adults receiving an internet behavioral intervention combined with individualized feedback achieved greater weight reductions than those given links to educational Web sites. Hand held computers may be effective tools for increasing physical activity levels among underactive adults [139].

Results also suggest the potential for internet-based behavioral change programs for weight management in overweight children and adolescents [140]. For example, Sloomaker et al. [141] found that adolescent girls who were provided with an accelerometer in addition to receiving web-based individualized physical activity advice, increased their moderate intensity physical activity after 3 months, whereas boys decreased their sedentary time after 8 months. However, a comparable intervention did not show improvements in adult office workers [142].

Almost every Dutch household owns a mobile phone and mobile phones as well as text messaging are even more popular amongst youngsters than in adults [143, 144]. Given that text messaging has become a very common way of communication, this technology seems appropriate for delivering additional treatment. Especially in the treatment of chronic diseases and diseases requiring long term behavior changes, new technologies in healthcare such as Short Message Service (SMS) as an additional treatment seem to have several advantages. Besides the amount of time and manpower that long term vis-à-vis support demands, long term support also has a great appeal on health care costs. SMS might be an effective method with limited time and cost investment for providing long-term support.

Text messaging has been used in various patient groups. With respect to mobile phones, studies in children and adults showed that sending reminders, disease monitoring and management, and education through mobile voice and text messaging might improve compliance with medicine taking, asthma symptoms, HbA1C in diabetes patients, stress levels, smoking quit rates, and self-efficacy [145]. Fjeldsoe et al. [146] reviewed the use of text messaging specifically in healthcare and found that SMS seems to have positive short-term behavioral outcomes. Furthermore, children with type 1 diabetes (age 8-18) who received intensive insulin therapy improved self-efficacy and adherence via text

messaging [147, 148]. SMS has also been used in youngsters to reduce alcohol-related consequences and to improve alcohol related attitudes and behaviors [149], to manage asthma [150] and to improve attendance in an orthodontic clinic [151]. In addition, the acceptability and preliminary effectiveness of text messaging on days of purging in bulimia nervosa patients has been shown [152]. Furthermore, in adult bulimia nervosa patients the acceptability and preliminary effectiveness of a text messaging intervention on days of purging has been demonstrated [152]. Still, the use of SMS in health care is in its early stages and more research in this field is required [146].

In the specific case of overweight and obesity, decreasing overweight requires substantial behavioral change and long term support from health professionals. Maintenance interventions in the treatment of overweight and obesity were recommended by various researchers [153, 154]. The use of SMS in the treatment of overweight and obesity has been studied by few researchers. Patrick et al. [155] for example, demonstrated that adults who received daily personalized messages via SMS and small pictures via multi-media message service, as well as printed materials and brief monthly phone calls from a health counselor, lost more weight than participants receiving monthly printed materials about weight control. In overweight and obese children and adolescents, self-monitoring via SMS has been reported to be a feasible addition to the treatment of overweight and obesity [156]. Moreover, SMS seems to be a more successful self-monitoring tool for decreasing television viewing than paper & pencil diaries [157].

### **1.5.1 Psychological models and behavior change methods used in SMS interventions**

In the current dissertation, a Short Message Service Maintenance Treatment (SMSMT) in addition to a lifestyle program in a population of overweight and obese children is introduced. Children in the SMSMT intervention (SMS+) were supposed to send self-monitoring data on weekly hours of physical activity, days of adherence to a healthy eating pattern, and on days of feeling happy. The SMSMT intervention is based on various behavior change methods from the social learning and cognitive theories [158, 159], self-regulation theories, and behavioral models [160]. The theories of Bandura propose that self-efficacy needs to be enhanced for behavioral change. Self-efficacy refers to the belief that one is capable of performing a certain behavior and the belief that one can attain certain goals. A previous study showed that text messaging might improve self-efficacy [146]. Behavioral models use various methods which are directed at changing behavior directly. Self-regulation refers to a series of self-care behaviors including behavioral methods such as self-monitoring (self-observation), goal setting (self-evaluation), and reinforcement [161]. Self-monitoring and personalized feedback on behavior change are the methods primarily used in the SMSMT.

### ***Self-monitoring***

Self-monitoring refers to the self-recording of behavior by an individual. Wilde et al. clarified the concept of self-monitoring and distinguished this concept from similar concepts such as symptom management [162]. The results of their concept analysis showed that self-monitoring consists of two complementary components: (1) awareness of bodily symptoms, sensations, daily activities, and cognitive processes; and (2) measurements, recordings and observations that provide information for independent action or consultation of health care providers [162]. Self-monitoring may make patients more aware of their actual health behavior (such as physical and eating behavior), of the symptoms of their health condition, and of the refining of their goals. The treatment of overweight and obesity is usually limited to a short period of time because of high cost health care resources and the limited availability of health care providers. Self-monitoring aimed at improving self-management skills can be an effective strategy to enhance or sustain weight loss in patients by giving them more control over their weight.

Various studies reported positive associations between self-monitoring and weight loss. Self-monitoring seems to be an effective strategy to improve adherence to treatment and it has been used in the treatment of overweight and obesity to achieve behavior modification and greater successful treatment outcome [163, 164]. Self-monitoring in weight management programs mostly consists of monitoring the amount of foods eaten, the level of exercise [165, 166], self-weighing [167, 168], and counting calories [169]. It has been found that higher frequency of self-monitoring in a program for low-income minority children with morbid obesity was positively associated with weight loss. In addition, frequent self-monitoring of the child as well as parental monitoring was associated with more weight loss compared to less frequent self-monitoring [165, 166]. These results are consistent with studies in middle-class populations, although low educational level as well as higher levels of psychological stress might decrease the frequency of self-monitoring [165]. Furthermore, holidays might be a challenging period for children and their families to maintain healthy eating behavior and to meet the required levels of physical activity. Indeed, weight gain has been shown to occur during holiday weeks [169]. It has been found that self-monitoring during holidays has a positive impact on weight maintenance. Additional phone calls and mailings focused on self-monitoring during two weeks of holidays were associated with greater weight loss [163, 169, 170].

In adults it has also been found that frequent recording of food intake [171, 172] and exercise [173] leads to greater weight loss. Furthermore, one study found that greater adherence to pre-treatment monitoring of food intake and physical activity for two weeks was associated with completion of treatment [174].

Although self-monitoring is associated with greater weight loss, studies also pointed out that adherence to self-monitoring deteriorates over time [163, 169, 170]. Some stud-

ies have investigated the use of popular self-monitoring tools such as mobile phones. Self-monitoring by the use of mobile phones has many advantages. These advantages include instantaneous entry of data into a central database, date and time stamping of data, and easy integration into daily life [175]. Pen & paper diaries are often used in health care for assessing the patient's behavior and experiences. Recent studies investigated the acceptability of paper diaries versus mobile phones as tools for self-monitoring. Mobile phones as a device for monitoring eating and exercise behavior were more acceptable than pen & paper diaries by children aged 7-13 years. Furthermore, greater adherence to self-monitoring was found with mobile phones [157]. Stone et al. [176] reported that adults with chronic pain also showed greater adherence to electronic self-monitoring than to pen & paper self-monitoring.

### ***Personalized feedback***

There is evidence indicating that feedback providing personally relevant information (i.e. personalized feedback) is more effective in behavior change than other types of feedback such as generic or targeted feedback [177]. Personal feedback has a greater probability of addressing the person's unique need than general feedback. For example, Tate et al. [138] showed that overweight adults who received an internet behavioral intervention combined with individualized feedback lost more weight than those given links to educational Web sites. Furthermore, it has been shown that personalized feedback reduces the weekly consumption of alcohol drinking in college students [178, 179]. Woolford and colleagues [156] studied the feasibility of an SMS intervention in addition to a weight management program in twenty adolescents. Participants were automatically sent tailored SMSs based on adolescents' characteristics obtained from an initial questionnaire by a computer application on their mobile phone daily. In addition, tailored educational messages on dietary intake and screen time were sent. The adolescents perceived the intervention as enjoyable. Few studies evaluated an SMS intervention in adolescents aimed at increasing physical activity. For example, Sirriyeh et al. [180] found that healthy adolescents who received daily SMSs based on affective (emphasis on enjoyable, pleasant, optimistic) associations for two weeks increased physical activity in inactive adolescents more than instrumental SMSs or neutral weekly SMSs.

In the SMSMT intervention in the current dissertation, tailoring aspects included taking into account previous SMS responses, participant's name, personal behavioral goals, and difficulties or problems. The feedback messages were formulated according to four principles: 1) promoting social support; 2) encouraging and motivating participants; 3) reinforcing positive changes and existing behavioral self-management strategies; and 4) suggesting and encouraging behavior modification and self-management.

## 1.6 DISSERTATION OUTLINE

### 1.6.1 The current dissertation

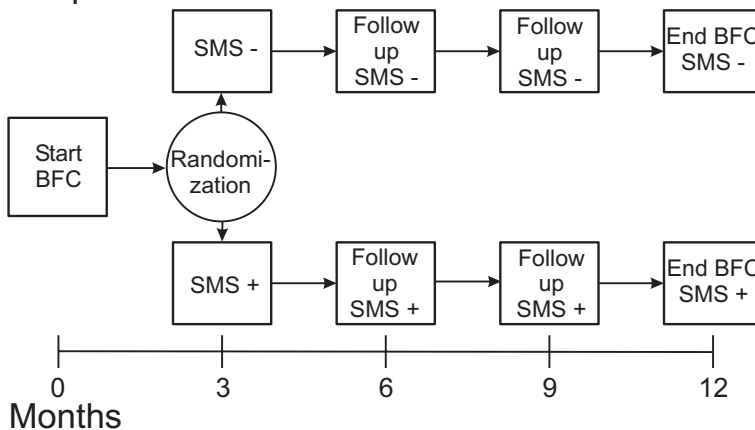
This dissertation is mainly focused on the treatment of childhood overweight and obesity. The Big Friends Club (BFC), a family-based multidisciplinary cognitive behavioral group treatment, was studied with respect to several research questions related to treatment success and dropout (Figure 1.1). Maintenance treatment methods such as the SMSMT might improve adherence to follow-up visits by increasing the awareness of the treatment progress and existing lifestyle behaviors. Moreover, given the extensive health care costs related either directly or indirectly, interventions that provide additional long-term support in a cost-effective way should be evaluated in the light of dropout and their treatment effects.

The final study of this dissertation focuses on women with polycystic ovary syndrome (PCOS). As described in paragraph 1.3.1, an increased incidence of obesity is found in women with PCOS compared to those without PCOS [69]. Obesity and to a lesser extent overweight in PCOS women is associated with negative physical and psycho-social parameters. We studied self-esteem, body satisfaction, fear of negative appearance, and sexarche in women with PCOS as the first step for a developed lifestyle program combined with SMSMT for PCOS women.

### Chapter 2 - inclusion 1996-2006



### Chapter 3 - inclusion 2006-2009



**Figure 1.1** Flowchart of the BFC treatment of the studies presented in Chapter 2 and 3

### 1.6.2 Research questions

The following research questions were addressed in the current dissertation:

1. Do child and familial baseline characteristics of overweight and obese children and their families predict treatment success during the Big Friends Club program? (*Chapter 2.1*)
2. Do different child and familial baseline characteristics of overweight and obese children and their families predict dropout at various stages in the Big Friends Club program? (*Chapter 2.2*)
3. Is self-monitoring and tailored feedback via Short Message Service (SMS) a feasible tool in health care? (*Chapter 3.1*)
4. Does a tailored Short Message Service Maintenance Treatment (SMSMT) reduce dropout during the Big Friends Club program? (*Chapter 3.2*)
5. Does a tailored Short Message Service Maintenance Treatment (SMSMT) during the Big Friends Club program influence Body Mass Index and psychological well-being? (*Chapter 3.3*)
6. Which characteristics of the polycystic ovary syndrome (PCOS) are associated with psychological well-being and sexarche? (*Chapter 4.1*)

# 2

**The Big Friends Club: a multidisciplinary  
lifestyle group treatment for  
overweight and obese children**





# 2.1

## **Somatic complaints and social competence predict treatment success in childhood overweight and obesity treatment**

JE de Niet, R Timman, C Rokx, M Jongejan, J Passchier & ELT van den Akker

*This chapter is under revision in the International Journal of Pediatric Obesity*

**ABSTRACT**

**BACKGROUND:** To determine baseline predictors of treatment success in terms of Body Mass Index-Standard Deviation Scores (BMI-SDS) in a multidisciplinary family-based behavioral lifestyle intervention program for overweight and obese children.

**PATIENTS AND METHODS:** Overweight and obese children (N=248; age 8-14 years) and their caregivers participated in a prospective study and attended a lifestyle intervention program. Baseline data assessment included anthropometrics, demographics, breakfast behavior, competence and behavioral problems (Child Behavior Checklist (CBCL)), family functioning (Family Adaptability and Cohesion Evaluation Scales (FACES) III), and personality (Dutch Personality Questionnaire-Youth (NPV-J)). BMI-SDS was measured at start and after 3, 9, and 12 months of treatment. Mixed modeling was used for analysis.

**RESULTS:** Greater BMI-SDS reductions over the course of one year were found in children with lower baseline BMI-SDS, younger children and in children with Caucasian or non-overweight and obese parents. Moreover, children with lower CBCL-somatic scores and higher CBCL-social competence scores were more successful in BMI-SDS reduction. No effects on treatment success were found for the number or position of siblings, having divorced parents or a working mother, educational level of the parents, breakfast behavior, family functioning, and personality.

**CONCLUSION:** These results suggest that screening for baseline characteristics in overweight and obese children could identify who will benefit most from a pediatric lifestyle intervention. Tailored programs should be developed and the treatment team should focus on children who are less successful in achieving weight reductions. Future research should study the mechanisms by which somatic complaints and social competence influence treatment success.

## INTRODUCTION

Worldwide, overweight and obesity in children and adolescents continues to be a growing health problem. In addition to a higher risk for negative psychological [181], social [89], and economic consequences [101], obesity is associated with numerous health problems. Childhood obesity increases the risk for adult obesity [9, 82, 182] and increases the risk for diabetes [183] and cardiovascular risk factors [184]. Epstein et al. [185] showed that children are more likely to achieve weight reduction than adults. The serious health consequences are reason enough to initiate weight reduction interventions at a young age. Many interventions have been studied in recent years and have demonstrated that family-based cognitive behavioral interventions combined with diet and exercise show the best weight loss results in children [110, 117, 186-189]. However, the variability of treatment success remains large [190].

The Big Friends Club (BFC) program, a family-based behavioral lifestyle intervention for children with overweight and obesity described in the current study, is aimed at stabilizing weight as children still grow. Changing lifestyle behaviors play an important role in achieving treatment success. Various researchers have studied the association between health behavior and its determinants. Several studies focused on environmental influences such as food restriction and its consequences on food intake [32] and also on associations with health behavior such as personality in relation to fruit and vegetable intake and physical activity [191]. Furthermore, it has been shown that family cohesion is associated with less soda intake and higher rates of breakfast consumption in adolescent girls [35]. This evidence suggests that personality and family functioning are associated with health behavior in youngsters and raised the question whether these child and family factors also predict treatment success in terms of Body Mass Index-Standard Deviation Scores (BMI-SDS). The ultimate goal is to use the outcomes of this study for future adjustments to the BFC program to improve treatment success.

Studies addressing predictive factors of treatment success in weight reduction programs are scarce. Clearly, not all children benefit from weight reduction programs. An interesting question remains therefore mainly unanswered: which factors contribute to successfully reducing weight in the treatment of childhood overweight and obesity? Three groups of predictors seem to contribute to treatment success: (1) characteristics of the child; (2) characteristics of the family; and (3) process variables. With respect to child factors, some studies showed that a younger age [103], being male, and being non-Hispanic White [134] were associated with greater weight loss after a weight reduction program, while others showed that age and sex had no influence on treatment success [121, 192]. Furthermore, impulsivity [124] and social problems [84] seem to negatively predict weight loss. Concerning family factors, it has been shown that parental obesity [102, 103, 193, 194], family adaptability [193], maternal depression and maternal avoidant

attachment attitude [102] and psychiatric symptoms in the mother and father [120] were negatively related to the child's success in weight management programs. Finally, it has been indicated that weight reduction is greater in a weight loss intervention with only parents participating rather than interventions where only children participated [117, 118]. To our knowledge, only few studies evaluated the child factors competence and behavioral problems [120], personality and family functioning [193] as predictors of success in childhood overweight and obesity treatment. Hence, the aim of the current study is to identify if these baseline characteristics predict treatment success in terms of BMI-SDS during the BFC program. In addition, we analyzed the influence of anthropometrics, demographics, and breakfast behavior on BMI-SDS reduction. The results of this study might contribute to the improvement of childhood overweight and obesity treatment.

## **METHODS**

### **Study population and study design**

Children aged 8-14 years who were overweight or obese and participating in the Big Friends Club (BFC) program during the period 1996-2007 were included in this study. The children were examined for at least 3 months while on the waiting list, before starting the program at the pediatric department of the Sint Franciscus Hospital in Rotterdam, the Netherlands. Exclusion criteria included behavioral problems defined as a score exceeding 70 on the Child Behavior Checklist (CBCL) [195], a disease causing overweight that could be treated with drugs, mental retardation, those insufficiently fluent in the Dutch language, and parents or a child with insufficient motivation to actively participate in the program. The study protocol was approved by the Ethics Committee.

### **The Big Friends Club intervention**

The BFC is a family-based multidisciplinary cognitive behavioral group therapy for children aged 8 to 14 years that is limited to groups of 10 children [135]. The treatment team includes a psychologist, dietician, pediatrician, and physiotherapist. The BFC focuses on 4 elements: (1) teaching children about a healthy diet and physical activity; (2) coping with psychosocial consequences of overweight and obesity; (3) creating a positive self-image and higher self esteem; and (4) reducing BMI-SDS, preferably by maintenance of weight during growth. The program provides for an intake session, 8 children's sessions, and a minimum of 3 parent's sessions during the first 3 months. Both at the start and the end of this intensive 12-week period, the children are seen by the BFC team and a pediatrician. The program uses different behavioral modification techniques such as goal setting, problem-solving, and self-regulation skills. The first 90 minutes of the children's sessions addresses healthy eating and exercise behavior and strategies to deal

with difficulties concerning eating or physical activity. By providing group therapy, the children can recognize and share their concerns and learn from each other. Furthermore, attention is paid to the psychosocial aspects of obesity like being picked on by peers. The last hour of each session is led by the physiotherapist. By creating positive exercise experiences through games and sports, the children improve their physical condition and exercise behavior. Implementing more exercise in daily life and therefore decreasing sedentary behavior is another goal of this part of the session. Parents participate in two parents' sessions. The first takes place before the children's first session. In this session the BFC team explains the key elements and the content of the program. During this session the parents learn about a healthy diet, exercise behavior, psychosocial aspects of obesity, and the fact that obesity increases the risk of physical and psychological morbidity. Part of the session is devoted to changing interaction patterns between the parents and their children by teaching them how to support their child instead of controlling them, how to give positive feedback, and how to apply positive reinforcement. The second parent-session takes place 4 weeks later. During this session the parents are invited to ask questions and to share their problems. The BFC team stimulates the parents to search for answers within the group to increase the parent's problem-solving capacity. After the intensive 12-week period, the children are awarded an A-diploma if they managed to decrease or maintain their BMI-SDS. At 6, 9 and 12 months after start of the program, children's and parent's sessions aimed at prevention of relapse are organized. The goals are evaluated and the children receive feedback on their diet and exercise pattern. Psychosocial problems such as being picked on by peers are also addressed. Additionally, B- and C-diplomas are awarded during these sessions for children who retained or further reduced BMI-SDS.

## Measures

### *Anthropometric variables*

Overweight and obesity were measured in terms of Body Mass Index ( $\text{kg}/\text{m}^2$ ) - Standard Deviation Scores (BMI-SDS), which are BMI-scores corrected for age and gender. BMI-SDS greater than 1.1 indicates overweight and BMI-SDS greater than 2.3 indicate obesity [10]. The children's weight and height was measured in the hospital by a physician. The BMI-SDS was calculated using the Growth Analyzer Version 3.5 (Dutch Growth Foundation, Rotterdam, The Netherlands; [www.growthanalyser.org](http://www.growthanalyser.org)) [196]. Data on BMI-SDS were collected at 4 time points: start of treatment ( $t = 1$ ), end of the 3 month intensive program ( $t = 2$ ), follow-up after 9 months ( $t = 3$ ), and follow-up after 12 months ( $t = 4$ ). No data could be collected after the child had dropped out of the program and hence stayed out of sight. The parent's BMI was self-reported and categorized as 'none', 'one', or 'both parents are overweight or obese'.

### ***Demographic variables***

Information on demographics including age, gender, marital status of the parents, the number of siblings and the position of the child within the siblings, whether the mother was working, educational level of the parents, and ethnicity were collected. Ethnicity was divided into two categories: Caucasian (both parents Dutch) and non-Caucasian (at least one parent).

### ***Breakfast behavior***

At the start of the treatment the dietician established whether having breakfast was a standard ritual of the day.

## **Questionnaires**

### ***Adaptability and Cohesion Evaluation Scales***

For evaluating the effect of family functioning, the revised Dutch version of the Family Adaptability and Cohesion Evaluation Scales (FACES) III [197-200] was completed by the parents. The Dutch version of the FACES III comprises 44 items in 3 subscales: Family Cohesion, Adaptability, and Social Desirability. The subscales consist of two extremes (low versus high) and two middle levels. The families with scores in the middle level are designated as most functional. Only the extremes of these dimensions were entered as dummy covariates with the values 0 and 1, respectively. The questionnaire has been validated and has reasonably good internal consistency (Chronbach's  $\alpha=0.87, 0.81, \text{ and } 0.78$ , respectively) [197, 198].

### ***Child Behavior Check List***

Competences, emotional, and behavioral problems of the participants were assessed by the Child Behavior Check List (CBCL), a parent rating scale for problems in children and adolescents aged 4-18 years [195]. The CBCL consists of a competence part (activity, social, and school) and a problems part. The problems part includes an internalizing (anxiety, mood, and somatic complaints) and externalizing (aggressive and antisocial/delinquent behavior) score. The norms for the total score are: normal behavior  $<60$ , sub-clinical behavior 60-63, and clinical problematic behavior  $>63$ .

### ***The Dutch Personality Questionnaire – Youth***

To study the effects of personality on treatment effect, the Dutch Personality Questionnaire – Youth (NPV-J) was administered. This is a validated, 105-item self-reported personality measurement for children 9-16 years that provides information on five subscales; Inadequacy, Persistence, Social inadequacy, Recalcitrance, and Dominance.

The internal consistency of the subscales are reasonable to good (Chronbach's  $\alpha=0.71$  to  $0.89$ ) [201].

### **Statistical evaluation**

The course of BMI-SDS in time was analyzed with mixed modeling [202]. This technique allows the use of incomplete cases if missing is at random [203, 204]. Mixed modeling is a multilevel regression technique that facilitates within subject analyses. Restricted maximum likelihood was applied to determine the random part of the model. Then, a saturated model was postulated with BMI-SDS as dependent variable. Reductions of BMI-SDS over time were defined as treatment success. Linear, quadratic, and cubic time, anthropometric and demographic variables, breakfast behavior, FACES III facets, and CBCL and NPV-J subscales were entered as main effects. Interaction effects with linear and quadratic time were included. The model was simplified in a backward procedure, all (interaction) effects with a  $p\text{-value}>0.05$  were removed from the model until a parsimonious model remained, respecting that interaction effects must be nested under their respective main effects. A number of measures had missing values and these were imputed using the Expectation Maximization method [205, 206] in the Missing Value Analysis module in SPSS (version 17.0). Missing values included: education father (21 missing values), education mother (4), mother working (1), overweight and obese father and mother (46), FACES III cohesion (3), FACES III adaptation (4), FACES III social desirability (3), CBCL (1) and NPV-J (68). These values were imputed before mixed model analyses.

## **RESULTS**

### **Baseline characteristics**

In the period between 1996 and 2007, data were obtained from a total of 248 children (Table 2.1.1). Boys had significant higher BMI-SDS at start and were also younger than their siblings compared to girls. Completers had a mean reduction of 0.42 BMI-SDS after one year ( $P < 0.001$ ). At the start of treatment, 82% ( $n=202 / N=248$ ) of the children were obese, while 40% ( $n=61 / N=151$ ) of the children were obese after one year of treatment. After 3 months, the dropout rate was 4% and this percentage increased at 9 and 12 months follow-up (28% and 39%, respectively). At one year follow-up, 97 children dropped out of the treatment. At baseline, boys scored significantly higher on the CBCL total score compared to girls, however they scored still within the norm of normal behavior. Boys as well as girls had an average score on all NPV-J subscales comparable to the Dutch norm population [201]. In line with the Dutch norm population, boys also scored higher on the NPV-J subscales recalcitrance and dominance than girls. Further-

more, families scored in the middle level for family cohesion, adaptability, and social desirability on the FACES III, which is designated as functional.

### **Predictors of BMI-SDS reduction**

Restricted maximum likelihood pointed out that intercept as well as time should be included as random effects in the model. In the analysis of changes in BMI-SDS, the parsimonious model (-2 log likelihood=-999.6, df=19) did not significantly differ from the saturated model (-2 log likelihood=-1062.0, df=108;  $\chi^2(89)=62.64$ ,  $P = 0.99$ ). Table 2.1.2 shows the weights and significances of the final model. To facilitate the interpretation of this model, the significant effects are depicted in Figure 2.1.1. The main linear time effect indicates that generally BMI-SDS decreases and the quadratic time effect indicates that this reduction in BMI-SDS tends to become less over time. Greater BMI-SDS reductions over the course of one year were established in children with lower BMI-SDS scores at start as well as in younger children. Children with Caucasian (Dutch) or with non-overweight and obese parents had greater BMI-SDS reductions after one year. Furthermore, children with less somatic complaints and higher social competence scores at start of the treatment had greater BMI-SDS reductions. Seventy-two children (29%) had social competence scores in the clinical range and 27 (11%) had somatic complaints in the clinical range. Although the social competence and somatic complaint scores were entered as continuous variables in the model, the children in the clinical range are depicted separately in Figure 2.1.1. No significant differences over the course of time were found for other demographic variables, having breakfast, family characteristics, other CBCL subscales, and personality.

## **DISCUSSION**

In the current study we identified baseline characteristics as predictors of treatment success in a pediatric lifestyle intervention. The intervention was more effective in terms of BMI-SDS reduction for children with lower BMI-SDS at start of the intervention. Furthermore, we found that younger children and children with Caucasian or non-overweight or obese parents achieve greater BMI-SDS reductions over the course of one year. Moreover, children with higher social competence scores had greater BMI-SDS reductions, while children with more somatic complaints had less BMI-SDS reduction over time.

First of all, we observed that lower BMI-SDS at start of the intervention was the most important predictor of treatment success. Epstein et al. [125] found that children with higher BMI-SDS scores were most successful in losing weight during the initial phase of treatment. However, this finding was not significant after 8 and 12 months. Pott et al. [102] did not report initial BMI-SDS to be related to treatment outcome after 12 months.

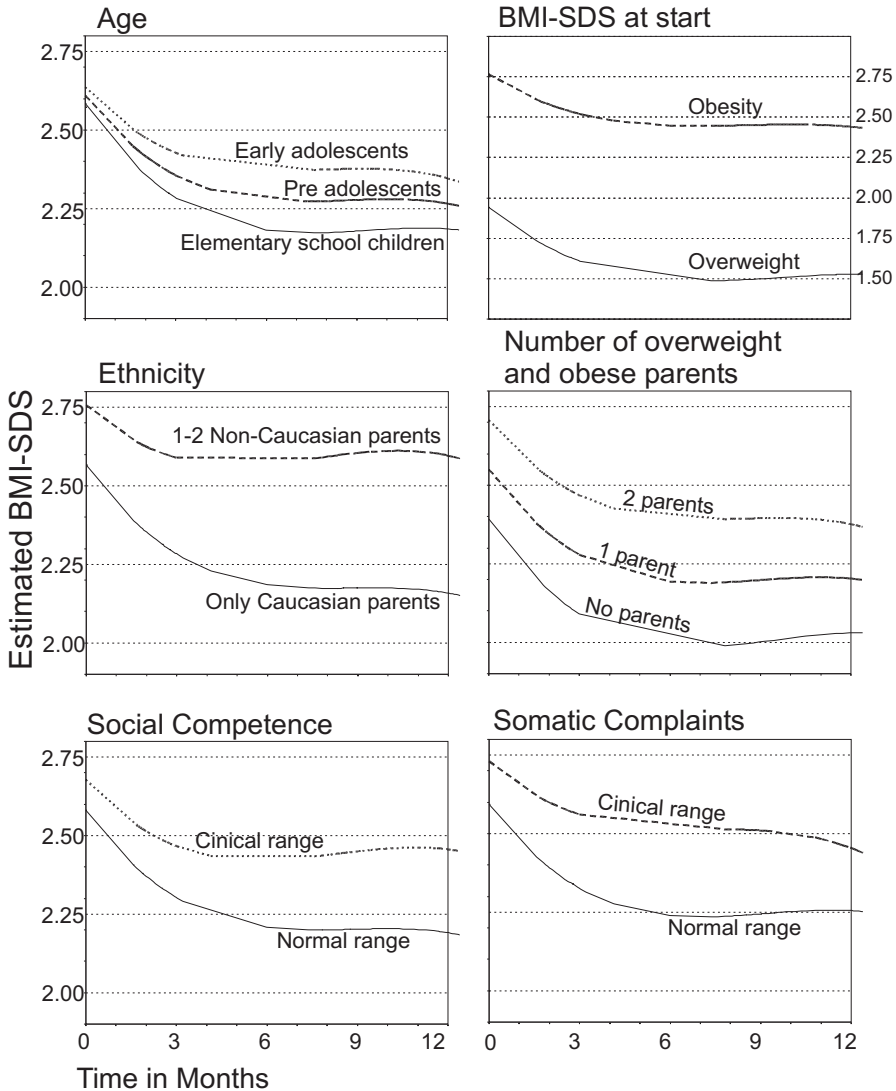


**Table 2.1.1** Characteristics of the study population<sup>1</sup>

|  | Boys         | Girls        | P-value* | Total                     |
|--|--------------|--------------|----------|---------------------------|
| Age                                    | 11.1 (1.6)   | 10.9 (1.6)   | 0.6      | 11.0 (1.6) [8.0-14.9]     |
| BMI kg/m <sup>2</sup>                  | 27.7 (3.9)   | 27.9 (3.7)   | 0.7      | 27.8 (3.8) [19.7-41.6]    |
| BMI-SDS                                | 2.7 (0.4)    | 2.5 (0.5)    | 0.003*   | 2.6 (0.44) [1.3-3.7]      |
| <i>Reduction at 3 months</i>           | -0.24 (0.18) | -0.24 (0.19) | 0.78     | -0.24 (0.19) [-1.01-0.12] |
| <i>Reduction at 9 months follow-up</i> | -0.39 (0.35) | -0.39 (0.35) | 1.00     | -0.39 (0.35) [-1.92-0.33] |
| <i>Reduction at 9 months follow-up</i> | -0.39 (0.40) | -0.44 (0.41) | 0.49     | -0.42 (0.41) [-1.87-0.30] |
| Number of children                     | 86           | 162          |          | 248                       |
| Dropout (n/%dropout)                   |              |              |          |                           |
| <i>After 3 months of start</i>         | 82 / 4%      | 156 / 5%     | 0.74     | 238 / 4%                  |
| <i>9 months follow-up</i>              | 65 / 30%     | 113 / 24%    | 0.38     | 178 / 25%                 |
| <i>12 months follow-up</i>             | 54 / 40%     | 97 / 37%     | 0.68     | 151 / 37%                 |
| Divorced parents                       | 21 (24%)     | 36 (22%)     | 0.75     | 57 (23%)                  |
| Number of siblings                     | 1.2 (0.9)    | 1.3 (1.0)    | 0.3      | 1.3 (1.0) [0-5]           |
| Rank in siblings                       | 1.6 (0.8)    | 1.8 (0.9)    | 0.03*    | 1.7 (0.9) [1-4]           |
| Mother working                         | 57 (66%)     | 112 (69%)    | 0.67     | 169 (68%)                 |
| Education parents                      |              |              |          |                           |
| <i>Father&gt;high school</i>           | 33 (38%)     | 52 (32%)     | 0.33     | 85 (34%)                  |
| <i>Mother&gt;high school</i>           | 53 (33%)     | 26 (30%)     | 0.76     | 79 (32%)                  |
| Non-Caucasian ethnicity                | 15 (17%)     | 40 (25%)     | 0.20     | 55 (22%)                  |
| Overweight parents                     |              |              |          |                           |
| <i>0 parents overweight</i>            | 12 (14%)     | 14 (9%)      | 0.20     | 26 (11%)                  |
| <i>1 parent overweight</i>             | 40 (47%)     | 63 (39%)     | 0.12     | 103 (42%)                 |
| <i>Both parents overweight</i>         | 34 (40%)     | 85 (53%)     | 0.04*    | 119 (48%)                 |
| Having breakfast on regular basis      | 63 (73%)     | 121 (75%)    | 0.88     | 184 (74%)                 |
| FACES III                              |              |              |          |                           |
| <i>Cohesion</i>                        | 73.4 (6.4)   | 72.8 (6.3)   | 0.50     | 73.0 (6.3)                |
| <i>Adaptation</i>                      | 20.6 (4.6)   | 21.1 (5.0)   | 0.50     | 21.0 (4.8)                |
| <i>Social desirability</i>             | 21.4 (3.9)   | 21.5 (4.2)   | 1.00     | 21.5 (4.0)                |
| CBCL-Total                             | 58.1 (10.3)  | 54.6 (11.0)  | 0.01*    | 55.8 (10.9)               |
| NPV-J                                  |              |              |          |                           |
| <i>Inadequacy</i>                      | 15.0 (9.4)   | 15.8 (11.2)  | 0.60     | 15.5 (10.6)               |
| <i>Perseverance</i>                    | 38.0 (6.9)   | 37.7 (6.2)   | 0.80     | 37.8 (6.4)                |
| <i>Social inadequacy</i>               | 12.0 (5.7)   | 12.2 (5.2)   | 0.80     | 12.1 (5.3)                |
| <i>Recalcitrance</i>                   | 20.0 (6.7)   | 18.0 (6.4)   | 0.04*    | 18.7 (6.6)                |
| <i>Dominancy</i>                       | 11.0 (4.1)   | 9.6 (3.7)    | 0.01*    | 10.6 (3.8)                |

BMI, Body Mass Index; SDS, Standard Deviation Scores; FACES III, Family Adaptability and Cohesion Evaluation Scales; CBCL, Child Behaviour Checklist; NPV-J, Dutch Personality Questionnaire-Youth.

<sup>1</sup>Values are mean (SD), range, or number (%) of patients; Continuous data were tested by T-test and categorical data by Fisher's Exact test or Chi-Square Test at a 0.05 level of significance.



**Figure 2.1.1** Baseline predictors of treatment success

Altogether, these findings suggest different mechanisms at various time points in relation to BMI-SDS at initiation. This might reflect the fact that higher BMI-SDS at initiation provides more motivation to lose weight, but this motivation disappears and changes in the long term. Our finding suggests that a lifestyle intervention only is not sufficient to treat severely obese children. It has been recommended that medication and surgery should be considered as an additional treatment [207]. We also found that younger children did have greater weight loss in the long term. This may be due to greater flex-

ibility of younger children and to the content of our program being focused on interplay between the children in the group sessions, while older children may require more autonomy. However, contrary results have been found with respect to the association between age and treatment success in weight loss programs [83, 103, 104, 121]. Moreover, we observed that children with Dutch parents had greater BMI-SDS reductions over the course of one year. Likewise, Jelalian et al. [134] indicated that not being from an ethnic minority group was associated with more weight loss in adolescents. Our finding might be due to cultural differences, such as advice given in our program may not correspond to values about food and physical activity in different cultures.

Not surprisingly, we revealed that parental overweight and obesity is a negative predictor of weight reduction. Likewise, other studies revealed that parental overweight and obesity was associated with less favorable weight reductions in weight reduction programs for overweight and obese children and adolescents [103, 194], while contrary results were also found [112, 134]. Changing eating and exercise behavior could be seen in the light of the social learning theory, in which children might learn health behavior by modeling parental behavior. In the current study, education of the parents, having a working mother, gender, marital status, the number of siblings, and the position within the siblings were not predictors of treatment outcome. Previous research established contradictory results concerning socio-economic status (SES) [103, 134, 192] gender [134] and number of obese siblings [192].

We did not find family cohesion and adaptability to have a predictive value in relation to BMI-SDS reduction. Although it has been found that family cohesion is associated with lower soda intake and more days of breakfast consumption [35], it might be that other family mechanisms are even more directly associated with BMI-SDS. Previous research indicates that social support from friends and family concerning eating and exercise behavior is a predictor of long term weight loss after 10 years [83] and highlights the importance of parental motivation in predicting premature termination [131].

We also questioned whether competences, emotional, and behavioral problems measured with the CBCL might hinder children in achieving weight reductions. We observed that children in our study population with more somatic complaints such as fatigue, pains, headache, and stomach-ache had less BMI-SDS reduction over time. Given that some physical complaints, such as asthma and orthopedic issues might hinder children from following the program, children with these somatic complaints were currently excluded at intake by the pediatrician. Previous research revealed that psychopathology [208] and chronic daily headache (CDH) [209] are more common among obese children compared to normal weight individuals. It has been found that children with higher BMI scores were more disabled in home, school, and social functioning due to headaches [63]. The somatic complaints might have hindered the children from following the program or to adhere to physical activities, although it might also be that the

**Table 2.1.2** Final mixed model parameters of BMI-SDS decrease

| Effect   | Estimate  | P-value  |
|--|-----------|----------|
| Intercept  | - 0.08    | 0.12     |
| Time linear  | - 0.27    | < 0.0001 |
| <i>Time quadratic</i>                              | 0.024     | < 0.0001 |
| <i>Time cubic</i>                                  | - 0.00059 | < 0.0001 |
| BMI-SDS baseline                                   | 1.02      | < 0.0001 |
| <i>BMI-SDS baseline*time linear</i>                | 0.014     | 0.01     |
| Age  | 0.0022    | 0.52     |
| <i>Age*time linear</i>                             | 0.008     | 0.0006   |
| <i>Age*time quadratic</i>                          | - 0.0005  | 0.002    |
| Ethnicity (Dutch=0, other=1)                       | - 0.00073 | 0.96     |
| <i>Ethnicity*time linear</i>                       | 0.041     | < 0.0001 |
| <i>Ethnicity*time quadratic</i>                    | - 0.0018  | 0.007    |
| CBCL Social competence                             | 0.0004    | 0.86     |
| <i>CBCL Social*time linear</i>                     | - 0.003   | 0.01     |
| Overweight and obese parents (0,1,2)               | 0.00029   | 0.97     |
| <i>Overweight and obese parents*time linear</i>    | 0.009     | 0.0985   |
| <i>Overweight and obese parents*time quadratic</i> | - 0.001   | 0.02     |
| CBCL Somatic complaints                            | - 0.00007 | 0.97     |
| <i>CBCL Somatic*time linear</i>                    | 0.0056    | < 0.0001 |
| <i>CBCL Somatic*time quadratic</i>                 | - 0.00042 | < 0.0001 |

BMI, Body Mass Index; SDS, Standard Deviation Scores; CBCL, Child Behavior Checklist.

children had difficulties coping with specific somatic complaints. Future research should evaluate the causes of somatic complaints in overweight and obese children and which coping strategies they use focus as well as whether this finding reflects a somatising family culture. Specific questionnaires measuring the type of somatic symptoms, pain and coping strategies should be addressed in relation to treatment success.

Finally, we found that children with higher social competence scores had greater BMI-SDS reduction. It might be imaginable that a consequence of having less friends or activities is that children spend more time at home in an inactive way which makes it more difficult to achieve a substantial amount of weight loss. Various studies have suggested a relation between obesity and being bullied and between obesity and adjustment problems such as self-esteem and loneliness [90, 210, 211], which might be the mechanism behind our finding. Being bullied in turn might cause emotional eating that may result in less BMI-SDS reduction. Furthermore, the character of the therapy might

also explain this result: the BFC is a group therapy in which social competence might enhance therapy success.

We did not find personality to be a predictive factor of therapy success. A possible reason for failing to find a significant personality effect might be a lack of power. As the NPV-J was not assessed after 2003, one of the limitations of this study is that the scores for 68 (27%) participants had to be imputed. It must be noted that the missing of these data can be regarded as completely at random. However, personality traits might indirectly influence attempts to achieve weight reduction through their association with other psychological or social-environmental factors. For instance, it has been reported that emotional eating was associated with lower scores on conscientiousness and extraversion in an obese adult population [212]. With respect to the imputation of having an overweight or obese father or mother, we run the mixed model again without imputed data which resulted in a solution that did not differ much from the solution with imputed data. This supports the stability of the model. Another limitation is that our results might be influenced by the exclusion of children with insufficient motivation and scores in the clinical range of the CBCL. Excluding less motivated families and children with greater competence and behavioral problems may have resulted in greater treatment success in this sample. Therefore, the rate of success in the BFC treatment is more difficult to compare to treatment success in other weight management programs that did not use these exclusion criteria.

One of the strengths of this research is that we used the method of mixed modeling which allows the use of incomplete cases. Incomplete cases due to dropout are common in obesity treatment [110]. Besides, we had a relatively large sample size, we analyzed treatment success over the long term, and we used various child and familial measurements which gave new insights in predicting treatment success in childhood obesity treatment. We analyzed only baseline predictors of treatment success, but we are aware that treatment success does not entirely depend on baseline characteristics but also for example on attendance rate and other mechanisms underlying health behavior. Our results might also be affected by a lack of a reference group measuring spontaneous weight loss in the absence of therapy, although the literature shows that medium-to high intensive treatment is needed to achieve weight loss [111].

Research on the improvement of obesity treatment is challenged, partly because of the various genetic, environmental and behavioral influences and maintenance factors. Understanding predictors of treatment success and failure could be helpful in the development of patient-tailored obesity treatment. The knowledge, for example, that the program is less effective for ethnic minorities highlights the need for adjustments to the program for these groups or the formation of minorities-only groups. Also, adapting weight reduction programs for different age groups might enhance weight reduction. Moreover, a protocol is needed for the treatment of severely obese children.

The knowledge that a lower social competence score is a predictor of reduced therapy success highlights the focus on social skills training. It seems that parental modeling plays an important role in eating and exercising behavior, given the evidence that parental overweight and obesity is related to childhood obesity and treatment success and that parental obesity doubles the risk of adult obesity among both obese and non-obese children [81]. For example, modeling both by parents and peers is reported to be a strong determinant of soda consumption in adolescents [213], which is in line with Social Learning Theory. Parental involvement in the treatment of obesity is proven to be important [117]. We suggest that educating parents on healthy parental modeling skills should also be a substantial part of the parent training in weight reduction programs. In addition, positive relations are observed between the parents and the child's weight losses [125]. Management of the parents' weight seems also to be important in achieving weight losses in children. Future research should study the effect of tailored obesity treatments taking into account various important predictors of treatment success.

# 2.2

## **Predictors of participant dropout at various stages of a pediatric lifestyle program**

JE de Niet, R Timman, M Jongejan, J Passchier & ELT van den Akker

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**ABSTRACT**

**OBJECTIVE:** To evaluate baseline predictors of dropout at various stages in a multidisciplinary family-based lifestyle intervention for overweight and obese children.

**PATIENTS AND METHODS:** Children (n=248; age 8–14 years) and their caregivers participated in a prospective study and attended a lifestyle intervention. At baseline, anthropometric and demographic data were assessed. Competence and behavioral problems were measured with the Child Behavior Checklist (CBCL) and family functioning with the Family Adaptability and Cohesion Evaluation Scales (FACES) III. Dropout was analyzed at various stages in treatment with logistic regression analyses.

**RESULTS:** Non-Caucasian maternal ethnicity, children with higher BMI-SDS, having fewer activities, not having breakfast regularly, and those not living in families with a 'static' adaptability structure were more likely to dropout between 0-12 months of treatment. Different baseline characteristics predicted dropout at different stages of treatment: (1) having an ethnic minority status and being older predicted dropout from the intensive 3-month program; (2) having a non-Caucasian mother, fewer activities, higher delinquency scores, and not presenting the family as extremely positive predicted dropout between 3-9 months; and (3) having higher BMI-SDS, having fewer social problems, and not living in families with a 'static' adaptability structure predicted dropout between 9-12 months of treatment.

**CONCLUSIONS:** The results indicate that dropout from a pediatric lifestyle program at various stages in treatment might be predicted by different baseline characteristics. These findings highlight the need for tailored interventions targeting different characteristics at various stages of treatment to reduce treatment dropouts.



## INTRODUCTION

Dropout from mental health interventions and loss to follow-up is a recurring problem. Dropout results in incomplete health care for the patient and insufficient treatment results, and might contribute to a failure experience, frustration for health care providers, missing data, and incremental costs. Garfield [214] stresses that with regard to the term dropout, “the use of varying definitions and criteria of dropouts or premature terminators makes it difficult to compare studies and to secure meaningful generalizations (...), the extreme variability among these operational definitions leads to chaos”. Few studies focused on predictors of dropout from child therapy, although we know from the literature that dropout rates among different patient groups are high. Research distinguishing early and late dropouts in child psychotherapy found that different factors predicted dropout for both groups [215]. For example, in a sample of children with anxiety disorders, completers experienced more enduring anxious symptomatology than dropouts [216]. In addition, dropouts were more likely to have an ethnic minority status and to come from a single-parent household. Likewise, one study found the same characteristics for dropouts in children with conduct disorders such as aggressive and antisocial behavior, but dropouts experienced more conduct disorder symptoms than completers [215].

Differences in dropout characteristics may vary among different patient groups. We wanted to address dropouts in a specific child population: namely, overweight and obese children, given the increasing worldwide prevalence [2]. Childhood obesity increases the risk for adult obesity [82, 182, 217], diabetes [183], and the risk of mortality from cardiovascular disease [183, 218]. Whitlock and colleagues found that behavioral lifestyle programs can reduce the level of overweight [111]. A major concern in the treatment of pediatric obesity is dropout [110]: dropout rates exceeding the 90% have been found [137]. Zeller et al. found that dropouts in a weight management program were more likely to be older, to have an ethnic minority status, and were more likely to self-report depressive symptoms [132]. Israel et al. identified an association between baseline adherence to dietary intake and activity monitoring and dropout [174].

The current study evaluated the influence of anthropometric and demographic variables, familial characteristics, the child’s competence and behavioral problems as baseline predictors of dropout during a one year family-based lifestyle intervention, the ‘Big Friends Club’ (BFC). Children who dropped out over the period of one year were defined as ‘dropouts’. Furthermore, we wanted to study whether different baseline characteristics predict dropout at various stages of treatment.

## **PATIENTS AND METHODS**

### **Patients and study design**

Children aged 8-14 years who were overweight or obese and participating in the Big Friends Club (BFC) program during the period 1996-2007 were included in this study. The children were examined for at least 3 months while on the waiting list, before starting the program at the pediatric department of the Sint Franciscus Hospital in Rotterdam, the Netherlands. Families were primarily Dutch (n=78%). Exclusion criteria included: 1) behavioral problems defined as a total problem T-score exceeding 70 (meaning two standard deviations above the mean of the normal population) on the Child Behavior Checklist (CBCL) [195], indicating that these children were expected to have too much behavioral problems to function properly in the group sessions; 2) a disease causing overweight that could be treated with drugs; 3) mental retardation; 4) insufficient fluently in the Dutch language; and 5) parents or a child with insufficient motivation to actively participate in the program. All parents gave written informed consent before entering the study.

### **The Big Friends Club intervention**

The BFC is a family-based multidisciplinary cognitive behavioral group intervention for children aged 8-14 years that is limited to groups of 10 children [135]. The therapy is aimed at reducing BMI-SDS, preferably by maintaining weight during growth, adopting a healthy lifestyle, and creating a positive self-image. The program consists of an intake session, 8 children's sessions, and a minimum of 3 parent's sessions during the first 3 months. At 6, 9, and 12 months after start of the program, children's and parent's sessions are organized. A more elaborate description of the treatment is given by Van den Akker et al. [135].

### **Dropout periods**

We distinguished 4 groups of dropouts: (1) dropouts during the total treatment period (0-12 months), defined simply as 'dropouts'; (2) 'premature terminators' were defined as those who dropped out during the first 3 months; (3) 'non remainers' were defined as those who dropped out between 3-9 months; and (4) 'non completers' were defined as those who dropped out between 9-12 months. Children who remained in the program during the one year period are defined as 'completers'.

## Measures

### *Anthropometric variables*

Childhood overweight and obesity were measured in terms of Body Mass Index ( $\text{kg}/\text{m}^2$ ) - Standard Deviation Scores (BMI-SDS), which are scores corrected for age and gender. BMI-SDS greater than 1.1 represents the threshold for overweight, and BMI-SDS greater than 2.3 indicates obesity [10]. BMI-SDS was calculated using the Growth Analyzer Version 3.5 (Dutch Growth Foundation, Rotterdam, The Netherlands; [www.growthanalyser.org](http://www.growthanalyser.org)). The parent's BMI was categorized as 'none', 'one', or 'both parents are overweight'.

### *Demographic variables*

Information on demographic characteristics including age, gender, marital status of the parents, the number of siblings and the position of the child within the siblings, whether the mother was working, educational level of the parents, ethnicity mother, ethnicity father, and ethnicity dichotomous were collected. Ethnicity dichotomous had two categories: Caucasian (both parents) and non-Caucasian (foreign ethnicity of at least one parent).

### *Breakfast behavior*

At the start of the treatment the dietician established whether having breakfast was a standard ritual of the day.

## Questionnaires

### *Family Adaptability and Cohesion Evaluation Scales*

The revised Dutch version of the Family Adaptability and Cohesion Evaluation Scales (FACES) III [197-200, 219] was completed by the parents. The Faces III comprises 44 items in 3 subscales: Family Cohesion, Adaptability, and Social Desirability. The subscales consist of two extremes (low versus high) and two middle levels designated as most functional. Only the extremes of these dimensions were entered as dummy covariates. The questionnaire has been validated and has reasonably good internal consistency (Chronbach's  $\alpha=0.87, 0.81$  and  $0.78$ , respectively) [197, 198].

### *Child Behavior Check List*

Competences, emotional and behavioral problems of the participants were assessed with the Child Behavior Check List (CBCL), a parent-administered rating scale for problems in children aged 4-18 years [195]. The CBCL consists of a competence part (activity, social and school) and a problems part. The problems part includes an internalizing (anxiety, mood, and somatic complaints) and externalizing (aggressive and antisocial/

delinquent behavior) score. The scores of the (sub)scales are adjusted for age (6-11 and 12-18 years) and gender. The norms for the total score are normal behavior <60; sub-clinical behavior 60-63; and clinical problematic behavior >63.

### **Statistical analyses**

All analyses were performed using the Statistical Package for the Social Sciences (SPSS version 15.0). Logistic regression analyses with dropout as a dependent variable were performed using backward elimination with a removal significance level of  $P = 0.05$ . Anthropometric and demographic variables, Faces III facets, and the CBCL subscales were entered as effects. CBCL scores were transformed into z-scores in order to facilitate the meaning of the outcome odds ratios.

Missing values were imputed using the Expectation Maximization method [205, 206] in the Missing Value Analysis module in SPSS. Missing values included: education father (21 missing values), education mother (4), mother working (1), weight status parents (46), FACES III cohesion (3), FACES III adaptation (4), FACES III social desirability (3), and CBCL (1).

## **RESULTS**

### **Baseline characteristics**

Data were obtained from a total of 248 children (Table 2.2.1). Families were primarily Caucasian ( $n=193$ , 78%), with other ethnicities including blacks (Surinam, Antillean, Cape Verdean,  $n=16$ , 6%), Turkish ( $n=19$ , 8%), Moroccan ( $n=6$ , 2%), other European ( $n=8$ , 3%), and other ( $n=6$ , 2%). We found 10 (4%) children to be premature terminators, 60 (24%) non-remainers, and 40 (16%) non-completers. Completers had a mean reduction of 0.42 BMI-SDS after one year ( $P < 0.001$ ). Furthermore, families scored on average compared with the Dutch norm population on the FACES III [201]. The mean score for the total CBCL score was within the range of normal behavior [195].

### **Dropouts versus completers (0-12 months)**

The results showed that children having a non-Caucasian mother were 2.66 times more likely to dropout between 0-12 months ( $P = 0.007$ ) (Table 2.2.2). In addition, children with a standard deviation (0.44) higher BMI-SDS at the start were 1.38 times more likely to dropout ( $P = 0.025$ ). Children with fewer activities were 0.69 times less likely to dropout ( $P = 0.010$ ). Furthermore, children who did not have breakfast on a regularly basis were 0.52 times more likely to dropout ( $P = 0.040$ ). Finally, children who came from families with a 'static' adaptability structure were 0.44 times less likely to dropout ( $P = 0.004$ ).

**Table 2.2.1** Characteristics of the study population

|   | Total (N=248)<br>Mean (SD) [Range] | Dropouts<br>(n=110)<br>Mean (SD) | Completers<br>(n=138)<br>Mean (SD) |
|---|------------------------------------|----------------------------------|------------------------------------|
| Age   | 11.0 (1.6) [8-14]                  | 11.2 (1.7)                       | 10.8 (1.5)                         |
| BMI kg/m <sup>2</sup>   | 27.8 (3.8) [19.7-41.6]             | 28.8 (3.9)                       | 27.0 (3.5)                         |
| BMI-SDS   | 2.6 (0.44) [1.3-3.7]               | 2.7 (0.4)                        | 2.5 (0.4)                          |
| <i>Success rate at 3 months<br/>(Decrease in BMI-<br/>SDS&gt;=0.15) (%)</i> | 149/238 63%                        | 48/100 48%                       | 101/138 73%                        |
| <i>Success rate at 9 months<br/>follow-up</i>                               | 131/178 74%                        | 25/40 63%                        | 106/138 77%                        |
| <i>Success rate at 12 months<br/>follow-up</i>                              | 104/138 75%                        | -                                | 104/138 75%                        |
| Number of siblings  | 1.3 (1.0) [0-5]                    | 1.3 (1.1)                        | 1.2 (0.9)                          |
| Rank in siblings  | 1.7 (0.9) [1-4]                    | 1.8 (0.9)                        | 1.7 (0.8)                          |
|   | Total<br>n (%)                     | Dropouts<br>n (%)                | Completers<br>n (%)                |
| Divorced parents  | 57 (23%)                           | 30 (27%)                         | 27 (20%)                           |
| Mother working  | 169 (68%)                          | 71 (65%)                         | 98 (71%)                           |
| Education parents   |                                    |                                  |                                    |
| <i>Father&gt;high school</i>  | 85 (34%)                           | 30 (27%)                         | 55 (40%)                           |
| <i>Mother&gt;high school</i>  | 79 (32%)                           | 28 (26%)                         | 51 (37%)                           |
| Ethnicity   |                                    |                                  |                                    |
| <i>Ethnicity child, non-<br/>Caucasian</i>                                  | 55 (22%)                           | 33 (30%)                         | 22 (16%)                           |
| <i>Ethnicity mother, non-<br/>Caucasian</i>                                 | 47 (19%)                           | 31 (28%)                         | 16 (12%)                           |
| <i>Ethnicity father, non-<br/>Caucasian</i>                                 | 53 (21%)                           | 33 (30%)                         | 20 (14%)                           |
| Overweight parents  |                                    |                                  |                                    |
| <i>0 parents overweight or<br/>obese</i>                                    | 26 (11%)                           | 14 (13%)                         | 12 (9%)                            |
| <i>1 parent overweight or<br/>obese</i>                                     | 103 (42%)                          | 39 (36%)                         | 64 (47%)                           |
| <i>Both parents overweight<br/>or obese</i>                                 | 119 (48%)                          | 57 (52%)                         | 62 (45%)                           |

table continued on next page

|                               | Total<br>Mean (SD) | Dropouts<br>Mean (SD) | Completers<br>Mean (SD) | Chronbach's $\alpha$<br>Study sample |
|-------------------------------|--------------------|-----------------------|-------------------------|--------------------------------------|
| <b>FACES III</b>              |                    |                       |                         |                                      |
| <i>Cohesion</i>               | 73.0 (6.3)         | 72.4 (6.3)            | 73.4 (6.4)              | 0.77                                 |
| <i>Adaptation</i>             | 21.0 (4.8)         | 21.7 (4.5)            | 20.3 (5.0)              | 0.83                                 |
| <i>Social desirability</i>    | 21.5 (4.0)         | 21.1 (4.4)            | 21.7 (3.7)              | 0.81                                 |
| <b>CBCL competence scales</b> |                    |                       |                         |                                      |
| <i>Activities</i>             | 4.7 (1.8)          | 4.3 (1.6)             | 5.1 (2.0)               | 0.87                                 |
| <i>Social</i>                 | 5.5 (2.0)          | 5.3 (2.0)             | 5.6 (1.9)               | 0.68                                 |
| <i>School</i>                 | 4.6 (1.1)          | 4.6 (1.2)             | 4.7 (1.1)               | 0.73                                 |
| <b>CBCL problem scales</b>    |                    |                       |                         |                                      |
| <i>Withdrawn</i>              | 3.5 (3.1)          | 3.9 (3.1)             | 3.3 (3.0)               | 0.73                                 |
| <i>Somatic complaints</i>     | 2.9 (2.8)          | 3.0 (2.8)             | 2.8 (2.8)               | 0.67                                 |
| <i>Anxious/Depressive</i>     | 5.5 (5.0)          | 5.7 (4.6)             | 5.4 (5.2)               | 0.78                                 |
| <i>Thought problems</i>       | 0.8 (1.2)          | 0.9 (1.1)             | 0.8 (1.2)               | 0.58                                 |
| <i>Attention problems</i>     | 4.0 (3.1)          | 4.2 (3.1)             | 3.8 (3.1)               | 0.76                                 |
| <i>Social problems</i>        | 4.8 (2.6)          | 4.9 (2.6)             | 4.8 (2.7)               | 0.72                                 |
| <i>Delinquent behavior</i>    | 1.4 (1.6)          | 1.5 (1.7)             | 1.3 (1.5)               | 0.48                                 |
| <i>Aggressive behavior</i>    | 6.5 (5.1)          | 7.1 (4.8)             | 6.1 (5.3)               | 0.88                                 |

BMI, Body Mass Index; SDS, Standard Deviation Scores; Faces III, Family Adaptability and Cohesion Evaluation Scales; CBCL, Child Behavior Checklist.

### Premature terminators versus non-premature terminators (0-3 months)

Non-Caucasian children were 4.71 times more likely to dropout during the intensive treatment period ( $P = 0.027$ ) and children had a 2.26 increased chance of dropping out for each year of age older they were ( $P = 0.002$ ).

### Non-remainers versus remainers (3-9 months)

In this analysis, 60 non-remainers were compared with the 178 children who did not dropout before 9 months. The results show that children having a non-Caucasian mother had a 2.66 increased chance of dropping out ( $P = 0.015$ ). Having fewer activities resulted in a 1.40 higher chance of dropout ( $P = 0.026$ ) and a higher CBCL-Delinquency score resulted in a 0.65 times higher chance of dropout ( $P = 0.007$ ). Furthermore, not having high social desirability FACES III scores resulted in a 0.35 higher chance of dropout ( $P = 0.021$ ).

### Non completers versus completers (9-12 months)

Children with higher BMI-SDS at start had a 1.89 times higher chance of dropout during this period ( $P = 0.002$ ). Furthermore, a higher CBCL-Social Problems score is associated with a 0.58 times lower chance of dropout ( $P = 0.017$ ). Children living in families with a

**Table 2.2.2** Logistic model of independent variables predicting dropout at various time points in a one-year long, family-based behavioral obesity program

| Dropout group                              | Regression weight | P-value | Odds ratio<br>[95% CI] | n / N (%)       |
|--|-------------------|---------|------------------------|-----------------|
| <u>Dropouts</u>                            |                   |         |                        | 110 / 248 (44%) |
| Dropout between 0-12 months                |                   |         |                        |                 |
| <i>Ethnicity mother</i>                    | 0.98              | 0.007   | 2.66 [1.31 – 5.42]     |                 |
| <i>BMI-SDS</i>                             | 0.32              | 0.025   | 1.38 [1.04 – 1.84]     |                 |
| <i>CBCL-Activities</i>                     | -0.36             | 0.010   | 0.69 [0.53 – 0.92]     |                 |
| <i>Breakfast consumption</i>               | -0.66             | 0.040   | 0.52 [0.28 – 0.97]     |                 |
| <i>FACES III-Adaptability facet Static</i> | -0.82             | 0.004   | 0.44 [0.25 – 0.77]     |                 |
| Nagelkerke R <sup>2</sup> = 0.19           |                   |         |                        |                 |
| <u>Premature terminators</u>               |                   |         |                        | 10 / 248 (4%)   |
| Dropout between 0-3 months                 |                   |         |                        |                 |
| <i>Ethnicity child</i>                     | 1.55              | 0.027   | 4.71 [1.23 – 18.37]    |                 |
| <i>Age</i>                                 | 0.82              | 0.002   | 2.26 [1.35 – 3.78]     |                 |
| Nagelkerke R <sup>2</sup> = 0.22           |                   |         |                        |                 |
| <u>Non remainers</u>                       |                   |         |                        | 60 / 238 (25%)  |
| Dropout between 3-9 months                 |                   |         |                        |                 |
| <i>Ethnicity mother</i>                    | 0.98              | 0.015   | 2.66 [1.21 – 5.83]     |                 |
| <i>CBCL-Activities</i>                     | -0.43             | 0.026   | 1.40 [1.04 – 1.89]     |                 |
| <i>CBCL-Delinquency</i>                    | 0.34              | 0.007   | 0.65 [0.47 – 0.89]     |                 |
| <i>FACES III- Social desirability</i>      | -1.05             | 0.021   | 0.35 [0.14 – 0.85]     |                 |
| Nagelkerke R <sup>2</sup> = 0.14           |                   |         |                        |                 |
| <u>Non completers</u>                      |                   |         |                        | 40 / 178 (23%)  |
| Dropout between 9-12 months                |                   |         |                        |                 |
| <i>BMI-SDS</i>                             | 0.64              | 0.002   | 1.89 [1.25 – 2.86]     |                 |
| <i>CBCL-Social problems</i>                | -0.55             | 0.017   | 0.58 [0.37 – 0.97]     |                 |
| <i>FACES III-Adaptability facet Static</i> | -0.77             | 0.049   | 0.46 [0.21 – 1.00]     |                 |
| Nagelkerke R <sup>2</sup> = 0.14           |                   |         |                        |                 |

BMI, Body Mass Index; SDS, Standard Deviation Scores; FACES III, Family Adaptability and Cohesion Evaluation Scales; CBCL, Child Behavior Checklist.

'static' family structure had a 0.46 times lower chance of not completing the treatment (P = 0.049).

## DISCUSSION

We evaluated baseline characteristics that predicted dropout from a pediatric lifestyle intervention. Initially, we studied which baseline characteristics of children with overweight and obesity and their families are associated with dropout after one year. We

found that children having a non-Caucasian mother, children with higher BMI-SDS, having fewer activities, not having breakfast on a regular basis, and those not living in families with a 'static' adaptability structure were more likely to dropout between 0-12 months of treatment. Additionally, we analyzed whether different baseline characteristics could predict dropout at various stages of treatment. Indeed, we found that different characteristics are associated with dropout at different times: (1) having an ethnic minority status and being older predicted dropout from the intensive 3-month program; (2) having a mother with a non-Caucasian ethnicity, fewer activities, higher delinquency scores, and not presenting high social desirability predicted dropout between 3-9 months; and (3) having higher BMI-SDS, having fewer social problems, and not living in families with a 'static' adaptability structure predicted dropout between 9-12 months.

Firstly, children having a non-Caucasian mother were more likely to dropout between 0-12 months. Mothers were usually the caregivers that came to the group sessions and filled in the questionnaires. The non-Caucasian mothers might have had more troubles coming along in the group sessions due to for example cultural differences. This might have led to less understanding of the focus of the BFC treatment and motivation to complete the program. Secondly, we found that higher baseline BMI-SDS predicted dropout. Contradictory results have been found with respect to the association between dropout and BMI-SDS [104, 220, 221]. One explanation for our result might be that heavier children had experienced more failing attempts to lose weight in the past which might have reduced motivation. Remarkably, we found that not having breakfast on a regularly basis is a predictor of dropout. Children not having breakfast on a regular basis might live in less organized families. Children need structure and practical support from the parents, which may be more difficult to organize in less structured families. In addition, it has been found that children in two-parent families ate breakfast on more days compared to children from single families as well as children describing their parents as authoritative [38, 39]. We also found that not living in families with a 'static' adaptability structure predicted dropout. 'Static' or rigid and authoritative families with fixed rules and solutions might have stricter and sharper rules that force the child to go to all sessions. Finally, we found that fewer activities including the time spent on sports, hobbies, and house keeping is predictive of dropout. Children and parents with more activities outside the house might be more used to organizing and going to appointments, which predisposes them to be more organized and more likely to adhere to the treatment.

Being older and from an ethnicity minority group predicted for premature termination. During this period, children as well as parents are intensively attended by a multidisciplinary team and participate in group sessions. Other studies also indicated that ethnicity and older age were predictors of dropout from various treatment programs [132, 215, 216]. Our finding in respect to age might be due to the flexibility of younger children. Moreover, age may be especially important during the group sessions because



older children coming into puberty may have a specific need for autonomy in a group and might get frustrated dealing with the comparative immaturity of the younger children. Our finding that age predicted dropout is compatible with the results of other studies [102, 132]. Additionally, younger children seem to achieve larger reductions in BMI-SDS [102, 103], which might motivate them to complete the treatment. Moreover, non-Caucasian children as well as parents might not find a connection with other members in the group session because of cultural differences, and the advice given may not correspond with different cultural values about food and physical activity.

In the period between 3-9 months, children and their parents experience a transition from regular contact with the multidisciplinary team to a period without intensive attendance. During this period, having a non-Caucasian mother and children living in families who did not present their family as extreme positive were more likely to dropout. It might be that families that did not present high social desirability were less motivated to actually complete the treatment as they were not idealizing regarding to family functioning and might had less difficulties not attending the follow-up sessions. Furthermore, parent-rated delinquency problems such as not feeling guilty, getting along with troubled peers, lying, and stealing predicted dropout between 3-9 months. It is plausible that children with more delinquency problems had more difficulty feeling responsible and focusing on the program without regular guidance. Likewise, other studies with children [222] and adolescents [223] found that dropouts from mental health care treatments had greater externalizing problems than continuers. Finally, lower activity scores predicted dropout between 3-9 months. It seems that staying involved in this less intensive part of the treatment is dependent on the practice children have in attending various activities, including coming back for meetings.

Different baseline characteristics predicted dropout between 9-12 months, the period in which learned information should be sustained. Higher BMI-SDS scores and not having rigid and authoritative families became independent predictors of dropout. At the end of the treatment program, higher BMI-SDS at start might diminish the child's motivation to finish treatment. Moreover, during this period where perseverance is needed, more authoritarian families might be better able to induce their children to adhere to the program. Furthermore, having fewer social problems like behaving immaturely, being dependent, and being bullied, also predicted dropout. One of the key elements of the follow-up sessions are sharing concerns and the psychosocial aspects of obesity, such as being picked on by peers: children with fewer social problems might feel less need to attend these follow-up sessions.

The current study showed that several characteristics of the child and family predict dropout at different stages of a pediatric lifestyle program. At present, 8 health care centers in the Netherlands comply with the BFC protocol, and a national committee has been founded in which all centers participate. The goals of this group are to improve

treatment outcomes and conducting research. From the current study we learned that adjustments in the BFC program might improve adherence to treatment. The following adjustments can be taken into consideration: The treatment team addresses previous weight loss attempts, discuss these attempts, and addresses frustrations, expectations and pitfalls. Children with high BMI-SDS at baseline might have experienced more failing attempts to lose weight in the past which could reduce motivation. Furthermore, we found that older children are more likely to dropout. As a result of the current study, the BFC national committee decided to only include children within the age range of 7 to 12 years old. For older children adjustments should be developed, for example a program with a greater focus on addressing the autonomy of the child. We also found that having a non-Caucasian mother predicted dropout. The treatment team might pay more attention to cultural differences in dietary habits and physical activity. Maybe even cultural-specific programs should be developed, for which input from persons of that culture is needed. We also found that children not living in 'static' or rigid and authoritative families with fixed rules and solutions dropped out more often. The BFC team can pay even more attention in the parent sessions to rule setting, assertiveness, planning and organizing, and stimulating the awareness of their role in treatment. Lastly, the results indicated that less activities and less social problems predict dropout. The BFC program focuses on improving physical activities on social problems such as bullying in group discussions. Future research might analyze this predictor as well as other predictors more in detail and discuss how these predictors can be addressed in pediatric obesity treatment.

### **Limitations**

In this study, we did only measure baseline characteristics of dropout. However, we are aware that dropout does not entirely depend on baseline characteristics. Furthermore, we did not assess self-reported reasons of parents and their children for dropping out. This information would have been helpful to understand which factors contributed to dropout and to improve the treatment. Various other studies have evaluated parent reasons for non-return in the treatment of childhood obesity. The most reported reasons for dropout included difficulties with insurance coverage, child's desire to leave the program, inconvenience of appointment times, identified dissatisfaction with the staff or treatment focus, and distance to the program [128, 129]. In the present study, dropout due to lack of insurance did not occur because the costs of the BFC program were covered by the insurance company or by the hospital. However, the advantage of having knowledge about baseline characteristics is that (1) tailored programs can be developed to target different characteristics, and (2) clinicians may know which characteristics need to be kept in mind or require attention at an earlier stage in treatment. For instance, the results of the current study indicated that structure and fixed rules in

a family may be important information to share with parents in the group sessions and at follow-up.

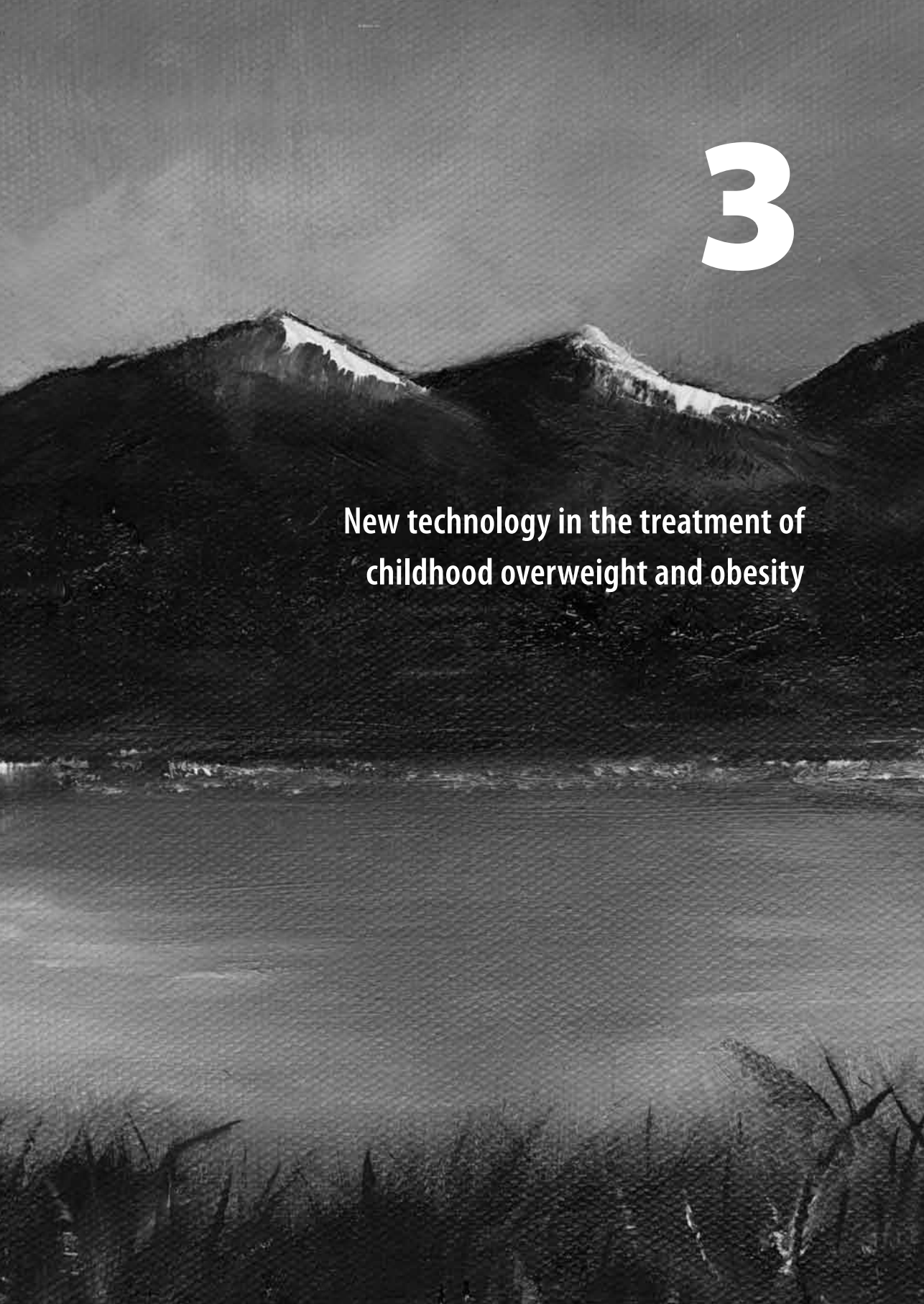
### **Conclusions**

From the literature, we know that dropout rates are high in the treatment of pediatric obesity. Furthermore, not all children benefit from lifestyle treatment. We showed that different characteristics predicted dropout at different stages in treatment. It seems to be important to pay attention at an earlier stage to the characteristics that predict dropout at various stages in therapy. Future research is needed to evaluate the predictors of dropout and the mechanisms behind this process, as well as to study tailored weight-management programs and methods to enhance the attendance in the treatment of overweight. To evaluate the influence of an attractive tool for children to lower dropout rates, our future study will evaluate a Short Message Service (SMS) maintenance treatment using mobile phones.



# 3

**New technology in the treatment of  
childhood overweight and obesity**





# 3.1

**Enhancement of care through self-monitoring and tailored feedback via text messaging and their use in the treatment of childhood overweight**

S Bauer, JE de Niet, R Timman & H Kordy

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**ABSTRACT**

**OBJECTIVE:** Firstly, this paper illustrates the general potential of Short Message Service (SMS) for symptom and behavior monitoring and the provision of tailored feedback. Secondly, an SMS-based maintenance treatment (SMSMT) in addition to a lifestyle treatment was introduced aimed at enhancing the treatment of childhood overweight.

**PATIENTS AND METHODS:** After a 12-week cognitive behavioral group treatment (CBGT), 40 children were assigned to the SMSMT for a period of 36 weeks. Children were asked to send weekly self-monitoring data on dietary intake, exercise behavior, and emotions and received tailored feedback. The adherence to SMSMT and changes in Body Mass Index Standard Deviation Scores (BMI-SDS) during the first and second treatment phase were analyzed.

**RESULTS:** Children (mean age = 10.05, SD=1.28) submitted 67% of the weekly SMSs that they were expected to send in. During CBGT, a significant reduction by 0.20 BMI-SDS was observed. The reduction of 0.07 BMI-SDS during the SMSMT did not reach statistical significance.

**CONCLUSION:** The results support the feasibility of SMSMT in the treatment of childhood overweight. The efficacy of the intervention needs to be demonstrated in an RCT.

**PRACTICAL IMPLICATIONS:** SMSMT is a promising intervention that may extend the reach of treatment centers for childhood overweight at reasonable cost and effort.



## INTRODUCTION

Over the past decades, psychotherapy research has established the overall positive effects of psychotherapeutic interventions on mental health and behavior change and well-being. However, research has also proven the shortcomings of existing treatments. A substantial proportion of individuals either do not respond to treatment, fail to fully recover or relapse after successful completion of a treatment program. Other limitations concern failure to take up treatment and high attrition and drop out rates [224].

In response to these findings, researchers and clinicians have mostly focused on developing and evaluating new programs rather than tackling these challenges in existing approaches. For example, very little is known about how to reduce barriers in the uptake of interventions, or ways to improve compliance, increase treatment adherence and retention or to reduce dropout rates. Similarly, it is unclear for many psychosocial interventions how positive effects can be maintained after treatment termination. Acknowledging that in many conditions sufferers have a considerable risk for relapse and many clients follow a chronic course of illness, the field is challenged to extend the reach of treatment providers thus allowing long-term support of their clients. Following the idea of stepped care [225], such extensions may precede regular treatment (“step-up” interventions such as prevention or early intervention programs) or follow thereafter (“step-down” interventions, e.g. relapse prevention or maintenance programs). In the light of limited health care resources, their implementation has to be realized with reasonable costs and efforts for the provider as well as for the client.

Approaches based on information and communication technologies (ICT) offer innovative possibilities to deal with some of the abovementioned limitations [226]. Over the past years, a number of ICT-enhanced interventions aimed at an optimization of mental health care have been introduced. Systematic research is still in the beginning. However, evidence for the feasibility and efficacy of various ICT-based interventions is rapidly increasing [226-228]. While the majority of approaches are based on internet technology, mobile phones and the Short Message Service (SMS) are also increasingly used [146, 229, 230]. Several specific advantages are inherent to their use: (1) SMS is accessible at almost any time and everywhere; (2) SMS is a fast and interactive medium; (3) SMS can be used with little effort; and (4) communication via SMS is inexpensive. Overall, mobile phones are becoming increasingly integrated into all areas of everyday life and thus may be an ideal device for delivering e-mental health interventions to clients.

To date, only a few studies evaluated SMS-based interventions. Promising findings have been reported for example for smoking cessation [231], diabetes [148] and adult weight loss programs [232]. A recent systematic review observed positive behavior change in 13 out of 14 studies and suggests that SMS-delivered interventions have posi-

tive short-term behavioral outcomes. However, methodological concerns were raised and more research in this field is required [146].

The main aim of the present paper is to illustrate the potential of SMS-based approaches for mental health promotion and enhancement of healthy behavior using the example of a recently developed intervention for the maintenance treatment of childhood overweight. Two specific aspects inherent to ICT-based interventions are of specific relevance in the context of this approach and should therefore be introduced at this point: firstly, the possibility to continuously monitor symptoms and health behaviors and secondly, the possibility to provide tailored feedback to support clients.

### ***Symptom and behavior monitoring***

Approaches to continuously track clients' impairment and symptoms during treatment ("outcome monitoring") have gained a lot of attention in psychotherapy research over the last decade. ICT-based systems such as the monitoring software Web-Akquasi [233] allowing for repeated assessments of psychometric information at short time intervals (e.g. session by session) contributed substantially to the feasibility of monitoring approaches. They allow the provision of immediate feedback on the clients' course of improvement to all involved parties who may use this information for further treatment optimization. Various outcome monitoring strategies have been introduced and evaluated with promising results [234, 235].

In the past years, mobile devices (e.g. mobile phones) further increased the flexibility of monitoring systems allowing for real-time data assessments practically at any time (i.e., independent of the availability of a computer). An increasing number of studies used such methods, referred to as e.g. ecological momentary assessment [236] or ambulatory assessment [237] which promises to substantially improve our knowledge on the longitudinal courses of symptoms and health behaviors and may ultimately lead to an improvement of care provision.

The use of mobile devices also appears to facilitate self-monitoring procedures which are an integral component of many therapeutic interventions, especially but not exclusively of those based on cognitive behavioral approaches. Some studies postulate that self-monitoring is a cornerstone for successful behavior change [165, 166]. However, adherence to self-monitoring has been found to be problematic [238]. Furthermore, the accuracy of paper-pencil self-monitoring data is questionable due to recall bias, delayed data entries, and missing information [175]. Using mobile phones as a device for the entry of monitoring data may be better accepted and may improve participants' compliance with self-monitoring [157, 176]. Additionally, they allow sending automated reminders in case a client does not enter his data at a scheduled time-point. Another advantage is that time-stamps document the exact time of data entry impeding back entries and faked dates.

### ***Tailored feedback***

A number of studies indicate that personally tailored messages have greater impact on health behavior change than untailored or bulk messages [146, 239, 240]. ICT-based programs allow to flexibly adapting feedback in relation to specific client characteristics or health information a client provides.

Feedback messages may also take into account the specific treatment situation of the client. For example, it is known that many clients experience difficulties to transfer skills they learnt in the protected therapeutic environment to their everyday life. ICT-based step-down approaches may enhance this translation by reminding clients at regular intervals of strategies and skills acquired in treatment. For instance, Bauer et al. [229] introduced a SMS-delivered program for the maintenance treatment of patients with bulimia nervosa who underwent inpatient treatment. Following their discharge from treatment, patients submitted weekly text messages on key bulimic symptoms via SMS. A software program automatically analyses each incoming message according to a pre-defined algorithm (i.e. it compares the current symptoms to those of the previous week) and suggests a feedback message out of a large pool of pre-formulated statements which is tailored to the person's individual pattern of change. The feedback messages were formulated in an encouraging tone, provided social support, reminded patients of skills they learnt in the hospital, reinforced positive changes, and suggested alternative behaviors in case of deteriorations. The program has proven technically feasible and well-accepted by patients [241] and is currently studied in terms of its efficacy and cost-effectiveness. Recently, an adaptation of this program for the maintenance treatment of childhood overweight and obesity was developed for the purpose of the present study.

### ***The present study***

Worldwide, the incidence of overweight increased in all age groups in the last two decades. It is estimated that four out of five overweight adolescents become obese in adulthood [242]. This is an alarming number, especially when taking into account the increased health risks associated with overweight. It has been shown that treatment programs aimed at reducing overweight are more successful for children than for adults [185]. Eating habits and exercise patterns are not yet fully developed at a young age, which underlines the need for interventions addressing young age groups. A variety of interventions aimed at an improvement of nutrition, an increase of physical activity and a reduction of time spent with watching TV or playing computer games were studied [243-245]. An essential component of successful programs seems to be the self-monitoring of relevant parameters, such as intake, expenditure, and weight [126]. Considering obesity as a chronic disease, maintenance treatments supporting patients on the long-term seem to be of special importance. However, the adherence to self-

monitoring as well as the consequent implementation of modified lifestyle behaviors is known to be problematic. Moreover, dropout rates are a substantial concern [110].

This can be illustrated using the example of a short-term multidisciplinary cognitive behavioral group therapy (CBGT) entitled "The Big Friends Club (BFC)". The BFC addresses overweight children aged 7-12 years and is conducted in groups of 8-10 children. The therapy is aimed at reducing Body Mass Index ( $\text{kg}/\text{m}^2$ )-Standard Deviation Scores (BMI-SDS), preferably by maintaining weight during growth, adaptation of a healthy lifestyle and a positive self-image and improved self-esteem. The program comprises an intake session, 8 sessions for children, and a minimum of 3 sessions for parents during the first 3 months. At 6, 9, and 12 months after start of the program, follow-up visits are organized. The BFC has proven feasible and effective; however, the sustainability of these effects on the longer term was limited due to a high dropout rate of 33% at follow-up [135] which is comparable to drop out rates in other research [110]. To improve children's adherence to the program and to enhance the sustainability of the treatment effects, an SMS-based maintenance treatment (SMSMT) was performed by the Erasmus MC University Medical Centre to support children for 36 weeks after 3 months of the BFC.

We explored two research questions: First, we analyzed the adherence of children to the SMSMT. Secondly, the maintenance effects of the intervention were explored by analyzing changes in children's BMI-SDS during the first phase (CBGT) and the second phase (SMSMT) of treatment.

## METHODS

### The SMS-based maintenance treatment (SMSMT)

Following the completion of the 3-month intensive phase of the BFC, children were instructed to send in weekly self-monitoring data on relevant parameters (eating, exercise behavior, and emotions) in a standardized format via SMS for a period of 36 weeks. The SMS included the answers to the following monitoring questions: (1) For how many hours did you engage in physical activity during last week? i.e. sporting, cycling, walking or playing outside; (2) how many days did you adhere to a healthy eating pattern last week?; and (3) how often have you felt sad or unhappy last week? Children answered the questions on a 5-point Likert scale, with higher scores reflecting more positive answers. In response, children received one tailored feedback message per week that commented on the development of the above-mentioned parameters. Besides the weekly monitoring text message, children were allowed to send additional text messages at any time.

A software program automatically analyzed each incoming message according to the algorithm described by Bauer et al. [229] for the aftercare of bulimia nervosa (i.e. it compared the current self-monitoring report to that of the previous week). The feed-

back messages were formulated in a supportive tone and aimed at: (1) promoting social support; (2) reinforcing positive behavior changes; (3) reminding participants of skills learned in the CBGT; and (4) encouraging and motivating participants. The program contains hundreds of pre-formulated feedback messages to minimize repetitions.

### **Technical aspects**

While children used the mobile phones that were provided for the duration of the study, the provider handled the SMS communication with a software program. Incoming messages arrived at a modem that is connected to a secure web server. A project assistant assessed the software via the Internet. The program automatically evaluated an incoming message with respect to previous assessments and suggested a feedback message that is tailored to the participant's pattern of change. A psychologist checked the feedback suggested by the program for plausibility, tailored the feedback message when necessary and sent the feedback message in return to the patients' mobile phone via the software.

### **Data set**

The sample is part of an ongoing RCT on the efficacy of the SMS-based maintenance program. In the present analyses, 40 children (17 boys and 23 girls) were included who were assigned to the SMSMT after 3 months of CBGT. Participants were recruited from 8 hospitals across the Netherlands that are certificated to conduct the BFC program. Data from overweight and obese children aged 7-12 years who participated in the BFC program in these hospitals between 2006 and 2008 were included in the present analyses.

The mean age of the sample was 10.05 years ( $SD=1.28$ ;  $Min=7$ ;  $Max=12$ ). Overweight and obesity were measured in terms of BMI-Standard Deviation Scores (BMI-SDS), which are BMI scores corrected for age and gender. A BMI-SDS of 1.1 represents the threshold for overweight, and a BMI-SDS of 2.3 indicates obesity [10]. At the beginning of the BFC the mean BMI-SDS in the present sample amounted to 2.62 ( $SD=.47$ ; range: 1.85 – 3.60).

To explore the maintenance effects of the SMS-based intervention, the difference in children's BMI-SDS at the end of the 3-month CBGT and at the 12-months follow-up visit was analyzed.

The study protocol was approved by the Ethics Committee of the Erasmus University Medical Centre of Rotterdam. All parents gave written informed consent prior to the inclusion of their child in the study.

### **Statistical analyses**

Paired t-tests were used to analyze the change in BMI-SDS during the CBGT (i.e. at baseline and 3 months thereafter) and during SMSMT (i.e. at three months and after one year). Pearson correlations were calculated to analyze the relationship between changes

in BMI-SDS and number of submitted SMS. All tests used a 0.05 level of significance. Analyses were performed using the Statistical Package for the Social Sciences (SPSS version 15.0).

## RESULTS

### Adherence

On average, children adhered to the program for a duration of 32.60 weeks ( $SD=9.69$ ). During their participation, they submitted on average 67% of the expected weekly SMSs (boys: 68%, girls: 66%). Ten children (25%) sent in more than 75% of the requested 36 weekly SMSs. Five children (12.5%) submitted less than 25% of the requested SMSs. The lowest number of submitted SMSs was 4.

### Maintenance effects

During their participation in the CBGT, children's BMI-SDS decreased on average by 0.20 ( $SD=0.23$ ;  $t(36) = 5.20$ ,  $p < 0.001$ ). A slightly further decrease by 0.07 BMI-SDS ( $SD=0.26$ ) was observed between children's BMI-SDS at the end of the CBGT (i.e. after 12 weeks;  $M = 2.42$ ;  $SD=0.58$ ) and the end of the SMS program (i.e. 12 months after the start of the CBGT;  $M = 2.35$ ;  $SD=0.64$ ). This difference was not significant on the group level ( $t(36) = 1.70$ , n.s.). Half of the children (51.4%) maintained or reduced their BMI-SDS during their participation in the SMS program. 27% showed a slight increase of 0.10 BMI-SDS and 21.6% of the sample gained more than 0.10 BMI-SDS during their participation in SMSMT.

To explore the relationship between change in BMI-SDS and adherence to the SMS intervention, correlations between BMI-SDS change during the CBGT and during the SMSMT phase on the one side and number of submitted SMSs on the other side were calculated. The results revealed that a greater BMI-SDS reduction during the CBGT was related to the submission of more SMSs during the maintenance phase ( $r = 0.45$ ,  $p < 0.01$ ). There was no relationship between BMI-SDS changes during follow-up and number of submitted SMSs ( $r = 0.07$ , n.s.).

## DISCUSSION AND CONCLUSION

### Discussion

The field of e-mental health is growing and the consensus on its general potential to optimize health care is increasing among researchers and treatment providers. However, research in this area is still in an early phase and evidence is lacking for many promises.

Potential benefits of technology-enhanced interventions include that they can extend the reach of treatment centers beyond the termination of traditional interventions. This paper introduced an SMS-based maintenance intervention for childhood overweight supporting children for 36 weeks following completion of a 12 weeks CBT group treatment. The main research aspect addressed here referred to the question to which extent children adhere to the SMS-based intervention. We decided to base the program on text messaging because mobile phones are commonplace, and text messaging has become a widely used and inexpensive means of communication. The software allows for an easy management of the communication between participants and provider and ensures an efficient exchange of information. Especially the use of pre-formulated feedback messages tailored to the client's individual pattern of change may improve time management during maintenance interventions. The program proved feasible and children reported no major problems related to the participation.

The results indicate a very good adherence of children to the SMS intervention. Overall, participants sent in 67% of the weekly messages. This is especially promising given that self-monitoring is known to be both essential as well as problematic in the target group of overweight children and adolescents. The finding is in line with the results of Shapiro et al. [157] who found substantially better adherence to SMS-based monitoring (43% of requested self-monitoring completed) of children and their parents as compared to paper-pencil monitoring (19% completed). Our results also confirm the findings of Bartlett et al. [246] and Stone et al. [176] that technology-enhanced systems may have positive effects on participants' adherence rates.

The exploration of the maintenance effects of the SMS intervention revealed that on the group level, children's BMI-SDS stayed stable over their 36 weeks of participation in the SMS program. The majority of participants (about 80%) showed no more than a slight increase in their BMI-SDS during this period. This finding can be considered as a first indicator that the program introduced here can contribute to the maintenance of treatment gains in overweight children.

The positive relationship between BMI-SDS change during the initial treatment phase and number of SMSs submitted during the maintenance phase indicates that children who are more successful in reducing their BMI during the first 12 weeks had greater adherence to the maintenance treatment. This may be due to the fact that these children may be more motivated to engage in the maintenance treatment due to the previous positive experience and of feelings of success. It is also plausible to assume that these children show higher initial motivation for treatment which caused both, their relatively greater success in reducing their BMI during the first 12 weeks as well as their better adherence to the SMS program.

The limitations of this study include the small sample size and the lack of control group data. At this point we cannot finally answer the question whether the mainte-

nance effect is due to the effect of the CBGT or the SMSMT. However, these pilot findings support the assumption that SMS-based interventions may be well-accepted and useful in the maintenance treatment of childhood overweight. Results of the ongoing RCT will inform us about the efficacy of the SMS-based aftercare intervention and its effects on the dropout rate which was found problematic in earlier research on the BFC [135].

## Conclusions

Poor diet and inactivity are known to be the primary reasons for increasing proportions of overweight children and adolescents. The program introduced here, promises to overcome a major limitation of weight management interventions that often fail to involve participants in self-monitoring of relevant behaviors such as nutrition and exercise patterns on the longer term.

Given the high penetration of mobile phones and SMS in the general population and their increasing availability to younger age groups, the SMSMT could be implemented at larger scale in populations of children and adolescents undergoing treatment for overweight. Although mobile phones were provided to the participants for the duration of the present study, the program is in principle accessible via participants' personal phones, i.e. no extra technical device is needed to participate in the program. Communication via SMS is inexpensive which may also enhance the translation of the intervention to routine care beyond the study setting. Overall, the intervention is characterized by its easy access and low thresholds for participation which may contribute to its potential public health impact.

## Practice implications

The use of technology-enhanced interventions in health care is increasing. Positive short-term behavior changes have been reported for various patient groups. More research on the potential of such interventions for maintenance treatment and long-term outcomes is needed. The present study showed that SMS is a feasible tool to deliver maintenance care in children with overweight and obesity with limited time and cost. Future research will study the efficacy of the intervention and address the question whether SMSMT itself can improve long-term treatment outcome or whether it may be rather used as a tool to enhance the adherence to follow-up visits which in turn may improve outcome.

For treatment providers who are challenged to find a balance between providing optimal care and holding cost of care down, the semi-automated character of the SMS program may be of special relevance. It allows providing tailored feedback based on the information that the participants send in. At the same time, the use of flexible automated components in combination with professional input limits the required resources. Therefore, the program introduced here promises to be a cost-effective way of maintaining treatment gains in overweight children. However, its connection to a



treatment institution providing the first level program (in this case the BFC) is probably essential to a successful implementation of such a minimum intervention.

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# 3.2

## Short Message Service reduces dropout in childhood obesity treatment: a randomized controlled trial

JE de Niet, R Timman, S Bauer, ELT van den Akker, C de Klerk, H Kordy & J Passchier

*This chapter is under revision in Health Psychology*

**ABSTRACT**

**OBJECTIVE:** The prevalence of overweight and obesity in children is alarming. Although lifestyle programs can reduce the level of overweight, dropout rates are substantial. New technologies, such as the Short Message Service (SMS), are a common and popular way of communication among youngsters and might be a promising tool to enhance existing interventions. The effect of the current SMS approach in addition to a lifestyle intervention, aimed at reducing dropout rates in overweight and obese children, is explored.

**PATIENTS AND METHODS:** Overweight and obese children (N=141; age 7–12 years) who were participating in a lifestyle program the 'Big Friends Club' were randomly assigned to an intervention group receiving an SMS Maintenance Treatment (SMSMT) after 3 months of participating in the BFC for 38 weeks (n=73) or to a control group receiving no SMSMT (n=68). Children were asked to send weekly self-monitoring data on physical activity, dietary intake, and emotions. In return, they received personally-tailored feedback messages. Dropout was analyzed with logistic regression analysis.

**RESULTS:** Children in the SMSMT intervention group had 3.25 times less probability of dropping out after one year ( $P = 0.01$ ) compared to controls. We found no significant correlation between the number of sent SMSs and BMI-SDS changes. In the first 3 months of SMSMT, the SMSMT completers sent 0.80 SMSs per week, and approximately 0.50 SMSs in the final 3 months. Younger children sent more SMSs ( $P = 0.03$ ).

**CONCLUSIONS:** These results indicate that SMSMT is effective and feasible in reducing dropout rates from a pediatric lifestyle intervention. Future research should examine the effectiveness of SMSMT on weight management and related psychosocial variables.

## INTRODUCTION

Obesity is a worldwide problem and, as a new chronic disease, surpasses all other childhood chronic diseases in frequency [247]. In 2009 more than 13% of girls in the Netherlands aged 2-20 years were overweight, as were almost 13% of boys [248]. The increasing prevalence of childhood obesity is accompanied by several physical and psychosocial health-related consequences [82]. These include an increased risk for diabetes mellitus [218], cardiovascular risk factors [9], asthma [249], stigmatization and discrimination [181], lower income at later age [100], and lower self-esteem in the future [250]. Two recent reviews of interventions for treating obesity in children and adolescents found that moderate to high intensity behavioral lifestyle programs can reduce the level of overweight [110, 111]. However, a substantial concern in the treatment of pediatric obesity is treatment dropout: dropout rates exceeding the 90% have been found in the treatment of pediatric obesity [137]. Premature termination results in incomplete health care for the patient and insufficient treatment results. It might also contribute to a failure experience for the child, frustration for healthcare providers, and incremental costs.

Various definitions of dropout are used. Dropout from intervention programs is sometimes defined as not appearing for any session after intake [251, 252]. However, Garfield comments that these patients never began formal treatment and therefore should not be considered as dropouts; he suggests use of the term 'refusers' instead [214]. The 2009 Cochrane review showed that many studies reported high dropout rates; only about 50% of the studies reported follow-up of more than 80% of the baseline participants [110]. Another study found incompleteness of follow-up data in 92% of the study population after two years [105].

Self-monitoring and providing feedback by professionals might enhance adherence to lifestyle programs and follow-up appointments. Self-monitoring can be defined as the enhancement of the awareness of symptoms through measurements, recordings, and observations which provide information to improve self-management [162]. One study showed that families monitoring food intake and activity level at baseline had lower dropout rates than families who showed less monitoring adherence [174]. Short Message Service (SMS) systems through mobile phones might be an effective self-monitoring tool and a means to provide an additional intervention to improve health behavior [146], and might be especially more attractive for children. New technologies, such as SMS, are an interesting medium for self-monitoring and delivering feedback and support. Improving lifestyle requires substantial health behavioral change and long-term support from health professionals. Self-monitoring seems to be an important behavioral strategy in weight-loss programs [170, 253]. Furthermore, SMS has become a common way of communication and is especially popular among youngsters. In the Netherlands, 81% of all children aged 8–18 years have a mobile phone and the posses-

sion of a mobile phone increases with age among this age group [144]. In addition, 93% of the adolescents aged 15–24 years prefer SMS to other mobile phone services [143]. Moreover, SMS as a medium of communication has several advantages: 1) SMS through mobile phones is accessible almost anytime and everywhere; 2) it can be used with little effort; 3) it is limited in costs; 4) it is a fast and interactive medium; 5) SMS messages can be stored in the phone; and 6) technically, SMS can be pre-programmed and tailored to the needs of the individual.

SMS systems have been studied in pediatric health care to support youngsters with diabetes [148], as a medium of maintenance care for bulimia nervosa patients [152], to reduce alcohol-related consequences [149], to manage asthma [150], and to improve attendance in an orthodontic clinic [151]. Although various internet weight-loss programs for overweight and obese children and adolescents as well as for adults have been studied [138, 140, 254, 255], we found only one study that evaluated the feasibility of an SMS intervention in obese adolescents. The authors reported SMS to be a feasible adjunct to the treatment [156], however, they did not study the effect of SMS on dropout or treatment outcomes. Another study in healthy children (aged 5–13 years) showed that adherence to text messaging for increasing healthy eating and physical activity, and decreasing screen time, was more successful in decreasing screen time than self-monitoring via traditional pen & paper diaries [157].

We earlier reported preliminary results of a Short Message Service Maintenance Treatment (SMSMT) in addition to a pediatric lifestyle program showing the SMSMT to be a feasible way of communication [256]. Given the high dropout rates and the earlier possible mentioned consequences of dropout, it is important to study methods that may reduce dropout rates. The present study evaluates whether an SMSMT during a pediatric lifestyle intervention 'The Big Friends Club' (BFC) reduces treatment dropout after one year compared to a control group receiving no SMSMT. After 3 months of the intensive part of the BFC program, children in the SMSMT condition sent weekly information about the number of hours that they were physically active, how many days they adhered to a healthy eating pattern, and how many days they felt happy that week. We hypothesized that children in the SMSMT intervention group would be less likely to dropout within one year of BFC than children in the control group. An additional aim was to evaluate compliance with the SMSMT in terms of number of SMSs per week over time among the youngsters.

## SUBJECTS AND METHODS

### Study population

Eight hospitals across the Netherlands, complying with the Big Friends Club (BFC) protocol, participated in this multicenter study. Children aged 7–12 years who were overweight or obese and who were participating in the BFC program during the period 2007–2009 were included in this study. The BFC program is a family-based multidisciplinary cognitive behavioral group therapy intervention for children between the ages of 7 and 12 years that is limited to groups of 10 children [135]. The treatment team includes a psychologist, dietician, pediatrician, and physiotherapist who were all certificated and allowed to provide the BFC program in their institution after completing the BFC intervention training, which is led by experienced treatment team members. The therapy is aimed at reducing the Body Mass Index ( $\text{kg}/\text{m}^2$ )–Standard Deviation Scores (BMI-SDS), preferably by maintaining weight during growth, adopting a healthy lifestyle, and creating a positive self-image. The program provides for an intake session, 8 children's sessions, and a minimum of 2 parent's sessions during the first 3 months. The program uses different behavioral modification techniques such as goal setting, problem-solving, and self-regulation skills. Children's sessions are organized once every two weeks. The first 90 minutes of the children's sessions addresses healthy eating and exercise behavior and strategies to deal with difficulties concerning eating or physical inactivity. Furthermore, attention is paid to the psychosocial aspects of obesity like being picked on by peers. The last hour of each session is led by the physiotherapist. By creating positive exercise experiences through games and sports, the children improve their physical condition and exercise behavior. Parents participate in two parents' sessions. The first takes place before the children's first session and the second takes place 4 weeks later. During the session the parents learn about a healthy diet, exercise behavior, psychosocial aspects of obesity, and the fact that obesity increases the risk of physical and psychological morbidity. Part of the session is devoted to changing interaction patterns between the parents and their children by teaching them how to support their child instead of controlling them, how to give positive feedback, and how to apply positive reinforcement. At 6, 9 and 12 months after start of the program, follow-up sessions for the children and parents as well as individual appointments, are organized. In between these sessions children did not have contact with the treatment team.

The children were examined at least 3 months before starting the program at the pediatric department of the hospitals. Exclusion criteria included: 1) behavioral problems defined as a score exceeding a total problem T-score of 70 (meaning two standard deviations above the mean in the normal population) on the Child Behavior Checklist (CBCL) [195], indicating that the behavioral problems could interfere with properly functioning in the group sessions; 2) a disease causing overweight that could be treated with drugs;

3) mental retardation; 4) those insufficiently fluent in the Dutch language; and 5) parents or a child with insufficient motivation to actively participate in the program. All parents gave written informed consent before entering the study and therefore were eligible for randomization after completing 3 months of BFC intervention. The study protocol was approved by the Ethics Committee of the Erasmus Medical Center Rotterdam, as well as by the medical Ethics Committees of the participating institutions. In reporting our trial findings, we followed the recommendations of CONSORT [257].

## Procedure and design

### *Short Message Service Maintenance Treatment (SMSMT)*

After the first 3 intensive months of the BFC program, children and their parents experience a transition from regular contact with the interdisciplinary team to a period without intensive contact. Therefore, the SMSMT was introduced after 3 months of treatment. In this parallel trial design with balanced groups, participants were randomly assigned to the intervention group receiving SMSMT or to the control condition receiving no SMSMT. In the study of Van den Akker et al. a dropout rate of 33% was found [135]. To show statistical significance of a reduction in the dropout rate with a power of 80% and respecting an alpha level of 0.05, 69 participants should be randomized to each of the two arms [202]. All parents and children allocated to the SMSMT intervention agreed to participate. Randomization allocation in a 1:1 ratio was applied in a randomized block design to achieve balance between the two groups within each centre. The blocks were formed by the therapy groups (5 to 10 children). At the end of the intensive part of the treatment, the randomization allocation was printed on paper and placed in a sealed envelope. An equal number of SMSMT and control notes were present in the envelopes. It could not be inferred from the outside to which condition the notes referred to. The researcher randomized the children into the SMSMT or control condition by picking an envelope from a basket.

After the 3 months of intensive BFC treatment, participants in the intervention group received a mobile phone for the period of the SMSMT and were instructed face-to-face by a psychologist researcher on how to use the mobile phone and to use it only for the purpose of this study. The researcher that provided the SMSMT intervention to the children was not involved in the BFC treatment sessions. The children in the SMSMT group were asked to send weekly self-monitoring data on relevant parameters via SMS in a standardized format for a period of 9 months. Besides the contacts at the hospital with the treatment team at 6, 9, and 12 months follow-up, children in the SMSMT intervention condition had additional contact with the study team between 3 and 12 months in the form of text messaging. The children in the no SMSMT condition had contact with the treatment team at 6, 9, and 12 months follow-up only. Children in the SMSMT condi-

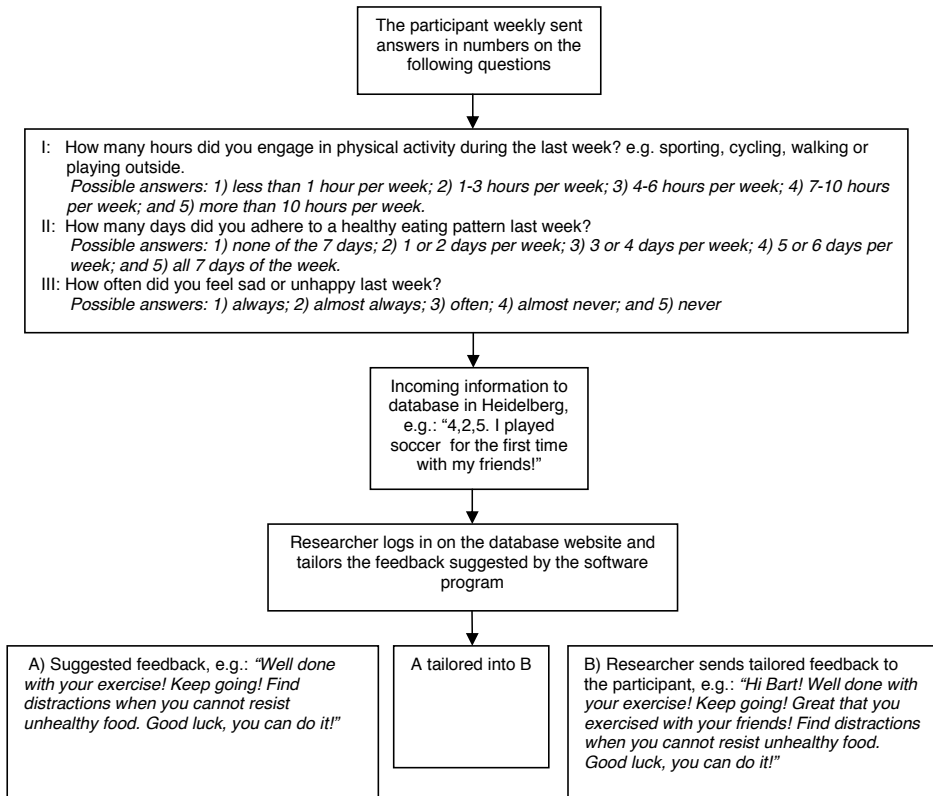


tion sent weekly information on the number of hours that they were physically active, how many days they adhered to a healthy eating pattern, and how many days they felt happy that week. This information was entered on a 5-point Likert scale. Besides the self-monitoring data on the relevant parameters, the children were allowed to send an SMS at any time during their participation about any positive or negative life events, thoughts or feelings, when they felt in need of communication. Every message had a 160-character limitation. Informational communication was stored on a secured web server at the Center for Psychotherapy Research at the University Hospital Heidelberg, Germany. A software program automatically analyzed each incoming message according to a predefined algorithm (i.e. it compared the current state to that of the previous week) and suggested a feedback message from a large pool of pre-formulated statements which was tailored to the child's individual pattern of change in lifestyle behavior. The algorithm followed the one described by Bauer et al. [229]. The researcher logged in to the program via internet, checked the feedback suggested by the program for plausibility, tailored the feedback message and sent the feedback message to the participant. Tailoring aspects included taking into account the previous SMS responses, participant's name, personal behavioral goals, and difficulties or problems. We provided every child who sent an SMS to report an additional problem such as feeling sad or feeling like snacking with extra tailored feedback. The extra tailoring aspect required a minimal time investment. We did not have a control process for the tailoring aspect. The feedback messages were formulated according to four principles: 1) promoting social support; 2) encouraging and motivating participants; 3) reinforcing positive changes and existing behavioral self-management strategies; and 4) suggesting and encouraging behavior modification and self-management skills that were learned during the BFC program in case of negative developments (Figure 3.2.1). The researcher enhanced compliance by sending an SMS reminder after 1 week of non-responding. The researcher uploaded calling credits of the participants through the internet.

## **Outcome measures**

### ***Dropout***

Treatment dropout was defined as dropout from the BFC treatment between 3–12 months after starting the program. In the intervention group (SMSMT+), treatment dropouts were those children who dropped out the BFC treatment as well as who dropped out the SMSMT treatment and SMSMT dropouts were those who only dropped out the SMSMT. In the control group (SMSMT-), dropouts were defined as those children who dropped out the treatment between 3 and 12 after starting the program.



**Figure 3.2.1** Flow chart of the Short Message Service Maintenance Treatment procedure

### ***Demographic and anthropometric measures***

Information on demographic characteristics including age, gender and ethnicity were collected. Ethnicity was divided into two categories: Caucasian (both parents) and non-Caucasian (at least one parent). Overweight and obesity were measured in terms of BMI-SDS, which are BMI scores corrected for age and gender. BMI-SDS of 1.1 represents the threshold for overweight, and BMI-SDS of 2.3 indicates obesity [10]. The children's weight and height was measured in the hospital by a physician. The BMI-SDS was calculated using the Growth Analyzer Version 3.5 [258].

### **Data analysis**

To test the demographic and anthropometric differences between the intervention group and the control group Student's t-tests were used in case of continuous variables and Fisher-exact tests were used in case of categorical variables. The difference between the intervention group and the control group in dropout rates was analyzed with lo-

gistic regression analysis with dropout as the dependent variable. SMSMT, age, gender, ethnicity and BMI-SDS at baseline were entered as covariates.

For calculation of the average number of SMSs per week, the SMSMT period for dropouts was limited by the date of their last SMS. One-way ANOVAs with LSD post-hoc tests were used to test the difference in the average number of SMSs per week between the treatment dropouts and completers (SMSMT completers and SMSMT dropouts) and to test the difference on BMI-SDS and dropout between the participating hospitals.

Pearson correlations were calculated to analyze the relation between changes in BMI-SDS and number of submitted SMS.

Repeated measures ANOVA was applied to evaluate whether the SMSMT completers differed in the average number of SMSs per week over the three periods 0–3 months of SMSMT, 3–6 months SMSMT, and 6–9 months of SMSMT. We chose these time points as cut-off points in our analyses, since the children and parents were expected to return for follow-up at these time points. Additionally, the influence of age, gender or ethnicity was evaluated in an analysis of covariance. All analyses were performed using the Statistical Package for the Social Sciences (SPSS version 17.02). Significant testing on all outcome measures was done at a 0.05 level of significance (two-tailed).

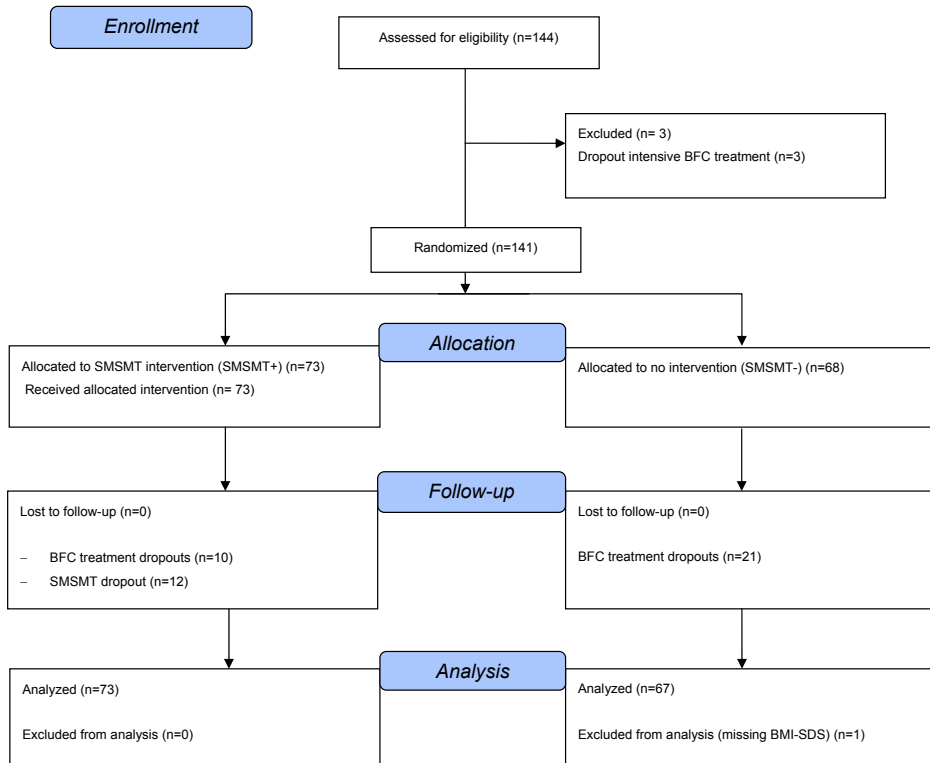
## RESULTS

### Study population

A total of 144 children were treated according to the BFC protocol in 18 different groups in the 8 participating hospitals. Three children dropped out in the first 3 months of treatment (Figure 3.2.2). Data with respect to the dropout analyses were obtained from 141 children with a mean age of 9.9 (SD=1.3) years and baseline BMI-SDS of 2.60 (Table 3.2.1). Overall, BMI-SDS after one year (mean=2.36; SD=0.58) decreased significantly ( $P = 0.001$ ) compared to baseline BMI-SDS (mean=2.59; SD=0.43). We found significant differences in changes in BMI-SDS after one year of BFC treatment for treatment completers between the 8 participating hospitals, with BMI-SDS changes ranging from -0.41 ( $n=21$ ) to 0.14 ( $n=3$ ). The results did not indicate a significantly different dropout rate between the hospitals ( $\chi^2 4.44$ ,  $df=7$ ,  $P = 0.73$ ), nor a significantly different percentage of SMSMT completers between the hospitals ( $\chi^2 16.7$ ,  $df=14$ ,  $P = 0.27$ ).

### Effect of the SMSMT on dropout

Our main objective was to evaluate the effect of SMSMT on dropout. In line with our hypothesis, logistic regression analysis indicated that children receiving SMSMT were 3.25 times less likely to dropout between 3 and 12 months of treatment ( $P = 0.01$ ) than children in the control group (Table 3.2.2). In the control group, 21 children



**Figure 3.2.2** CONSORT statement flow diagram

dropped out compared to 10 children in the intervention group. Baseline age, gender, ethnicity and baseline BMI-SDS were not significant in predicting dropout after one year.

### Compliance to the SMSMT

No relation was found between BMI-SDS decrease and the number of SMSs sent ( $r = 0.01$ ,  $p = 0.93$ ). A significant ( $P = 0.03$ ) difference in BMI-SDS at start of the SMSMT was found between completers (lower BMI-SDS) and SMSMT dropouts.

The SMSMT had a mean duration of 35.1 weeks for the SMSMT completers ( $n=51$ ), 14.6 weeks for the SMSMT dropouts ( $n=12$ ) and 11.4 weeks for the treatment dropouts ( $n=10$ ) (Table 3.2.3). The results showed a significant difference in the number of SMSs per week between the groups. In their short SMSMT period, the SMSMT dropouts sent significantly less SMSs in one week than treatment dropouts and SMSMT completers ( $P = 0.02$  and  $P < 0.001$ , respectively). SMSMT completers sent significantly more SMSs in one week in the first 3 months of SMSMT than between 3-6 months, and between 6 months to the end of the SMSMT ( $P < 0.001$ ). Gender and ethnicity had no influence on the number of SMSs sent in one week, albeit younger children sent more SMSs in one week (age  $P = 0.03$ ).

**Table 3.2.1** Characteristics of the study population

|  | Total (N=141)<br>Mean (SD) [Range] | No SMSMT<br>(n=68)<br>Mean (SD) | SMSMT<br>(n=73)<br>Mean (SD) | P-value |
|--|------------------------------------|---------------------------------|------------------------------|---------|
| Age                                      | 9.9 (1.3) [7 – 12]                 | 9.8 (1.3)                       | 10.1 (1.3)                   | 0.35    |
| Baseline BMI-SDS                         | 2.6 (0.4) [1.1 – 3.6]              | 2.5 (0.4)                       | 2.6 (0.5)                    | 0.21    |
|  | Total (N=141)<br>n (%)             | No SMSMT<br>(n=68)<br>n (%)     | SMSMT<br>(n=73)<br>n (%)     | P-value |
| Boys                                     | 51 (36%)                           | 23 (34%)                        | 28 (38%)                     | 0.60    |
| Ethnicity (Caucasian)                    | 105 (75%)                          | 48 (71%)                        | 57 (78%)                     | 0.34    |
| Obesity (BMI-SDS) at<br>baseline (n=137) | 104 (74%)                          | 53 (78%)                        | 51 (71%)                     | 0.44    |
| Dropout at 3-12 months<br>(n=137)        | 31 (22%)                           | 21 (31%)                        | 10 (14%)                     | 0.02    |

BMI, Body Mass Index; SDS, Standard Deviation Scores.

**Table 3.2.2** Logistic model\* of SMSMT on dropout between 3 and 12 months controlled for gender, age, ethnicity, and BMI-SDS (n=140)

| Effect           | Coefficient | Standard Error | P-value | Odds ratio<br>[95% CI] |
|------------------|-------------|----------------|---------|------------------------|
| Constant         | -6.11       | 2.56           | 0.02    |                        |
| No SMSMT         | 1.18        | 0.45           | 0.01    | 3.25 [1.35 – 7.86]     |
| Gender           | 0.66        | 0.50           | 0.18    | 1.93 [0.73 – 5.16]     |
| Age (baseline)   | 0.30        | 0.18           | 0.10    | 1.35 [0.95 – 1.92]     |
| Ethnicity        | 0.14        | 0.48           | 0.77    | 1.15 [0.45 – 2.95]     |
| Baseline BMI-SDS | 0.02        | 0.50           | 0.97    | 1.02 [0.38 – 2.72]     |

\*Nagelkerke  $R^2 = 0.12$ .

SMSMT, Short Message Service Maintenance Treatment; BMI, Body Mass Index; SDS, Standard Deviation Scores.

**Table 3.2.3** Feasibility of the SMSMT and number of SMSs per week

|   | SMSMT completers<br>(n=51)<br>Mean (SD)<br>[Range] | SMSMT dropouts<br>(n=12)<br>Mean (SD)<br>[Range] | SMSMT treatment<br>dropouts<br>(n=10)<br>Mean (SD)<br>[Range] |
|---|--|--|---|
| Duration of SMSMT in weeks                                      | 35.1 (4.1)<br>[26.2 – 25.4]                        | 14.6 (7.3)<br>[2.0 – 24.9]                       | 11.4 (10.3)<br>[5.0 – 34.0]                                   |
| Number of SMSs per week<br>Whole period (0 – 9 months of SMSMT) | 0.61 (0.20)<br>[0.2 – 1.0]                         | 0.55 (0.24)<br>[0.2 – 1.0]                       | 0.78 (0.28)<br>[0.4 – 1.2]                                    |
| Number of SMSs per week<br>Period 1 (0 – 3 months of SMSMT)     | 0.80 (0.19)<br>[0.4 – 1.1]                         | 0.55 (0.24)*<br>[0.2 – 1.0]                      | 0.78 (0.28)<br>[0.4 – 1.2]                                    |
| Number of SMSs per week<br>Period 2 (3 – 6 months of SMSMT)     | 0.55 (0.27)<br>[0.1 – 1.1]                         | -  | -   |
| Number of SMSs per week<br>Period 3 (6 – 9 months of SMSMT)     | 0.47 (0.25)<br>[0.1 – 1.1]                         | -  | -   |

\*Differed from SMSMT completers and SMSMT treatment dropouts at a 0.05 level of significance.  
SMSMT, Short Message Service Maintenance Treatment.

## DISCUSSION

This study investigated the use of a Short Message Service Maintenance Treatment (SMSMT) to decrease dropout from a pediatric lifestyle intervention. The results of this study were in line with our hypothesis, i.e. SMSMT significantly reduced dropout between 3-12 months of lifestyle treatment. Children who received an additional SMSMT after participating for 3 months in a family-based multidisciplinary cognitive behavioral group treatment were considerably less likely to dropout within one year of treatment than children who received no SMSMT. This is an important finding, since dropout rates in the treatment of childhood obesity are high [110]. Furthermore, the SMSMT seems to be a feasible way of providing maintenance care in the treatment of childhood overweight and obesity. The SMSMT completers sent on average 0.8 SMSs per week in the first three months of SMSMT, although adherence to the SMSMT declined after 3 months of maintenance care. However, in the last period of SMSMT, they still sent their self-monitoring data on average every 2 weeks. The treatment dropouts in the SMSMT group

sent significantly more SMSs per week than SMSMT dropouts. Furthermore, a younger age is associated with sending on average a higher number of SMSs per week.

The present study examined a modern tool to reduce the dropout rates in a pediatric lifestyle intervention. The main finding is that an additional SMSMT during a lifestyle intervention is an effective way of improving adherence to follow-up appointments in overweight and obese children with a limited time investment of the treatment providers. One of the main advantages of adherence to follow-up visits is that maintenance treatment might improve or sustain lifestyle changes and health behaviors. Families seem to have various reasons for dropping out of pediatric lifestyle programs, such as the travel distance to program, inconvenience of appointment times, lack of insurance [128, 129]. The SMSMT seems to transcend the arguments of dropping out. In the present study, dropout for lack of insurance did not occur because the costs of the BFC program were covered by the insurance company or by the hospital.

Several mechanisms might contribute to the finding that SMSMT reduces dropout rates. First, lower dropout rates in the intervention group might have been due to a positive effect of self-monitoring. Children were reminded weekly by SMSMT about the treatment progress, goals and strategies they learned in the BFC program, which might have enhanced their awareness to the program. Second, we used several evidence-based behavioral techniques in the feedback messages to optimize the effect of the SMSMT, such as providing coping skills, stimulus control, goal setting and positive reinforcement. Furthermore, personalized feedback seems to have the potential of increasing the effectiveness of health behavior interventions and increasing engagement and motivation [177]. We tailored the feedback messages with respect to personal aspects of the participants, such as their personal goals and difficulties, and the content of their previous messages. Furthermore, the participants' names were included in the messages. All feedback messages were formulated in a supportive and encouraging way. In the case of deteriorated health behavior, the feedback messages suggested self-management skills in an encouraging way or reinforced the behavior they were successful in. Finally, the popularity of mobile phones and SMS among youngsters might have made the treatment overall more attractive to the children and might have stimulated adherence to the follow-up visits. Although one study examined an SMS intervention that encourages increasing physical activity and decreasing screen time and intake of sugared-sweetened beverages in children [157], the number of dropouts was non-significantly lower in the SMS condition compared to the pen & paper diaries condition.

We found significant differences in BMI-SDS changes between the 8 participating hospitals. Although the participating hospitals followed the same protocol and used the same materials in the treatment sessions and follow-up, it might be that various therapeutic characteristics, characteristics of children and families, and region where the institutions were localized (e.g. urban vs. rural regions) contributed to the variation

in results. The national BFC committee has been founded in which all centers participate. The goals of this group are to improve the outcomes of the BFC and conducting research on the BFC treatment.

In their review, Fjeldsjoe et al. [146] suggested that future studies should report on process measures in interventions delivered by SMS. Overall, we found that SMSMT completers sent on average 0.60 SMSs per week over a 9-month period of SMSMT. Weekly, feedback messages were sent to the participants. This result indicates the acceptability and feasibility of the SMSMT, also taking into account the time span of on average 38 weeks of SMSMT. The simple way of monitoring by entering only four numbers might have contributed to the compliance, even for children only 7 years of age. In addition, younger SMSMT completers sent more SMSs per week. This is an important finding, suggesting that the SMSMT is more acceptable and feasible for them. Younger children are less likely to have their own phone [144] and the maintenance treatment might be more 'cool' for younger children. Future studies should further investigate this association and study the mechanisms involved, which might show that older children need a different approach than younger children. The treatment dropouts in the SMSMT group sent significantly more SMSs per week than SMSMT dropouts. First of all, the reasons for dropout from the treatment can be different among these groups. From the initial smaller rate of SMSs it can be inferred that the children dropping out the SMSMT intervention were already less enthusiastic from the start of the SMSMT. They might have dropped out of the SMSMT because the SMSMT intervention was not feasible for them. As they did continue with the BFC program, the SMSMT may not have seemed helpful to them. However, we did not ask for the reasons of dropping out. Second, it might be that child or family factors played a role in dropping out the SMSMT or the treatment.

The findings of the randomized controlled trial demonstrated the potential of SMSMT to reduce dropout rates. The SMSMT was a feasible and time-efficient tool to provide maintenance care in the treatment of pediatric overweight. This multicentre study includes participants and treatment providers from various locations and treatment centers in the Netherlands, which enlarges the generalizability of the study results. A limitation of the present study is that we did not assess self-reported reasons of parents and their children for dropping out. This information would have been helpful to understand which factors contributed to dropout. To our knowledge, we were the first who studied the effect of SMSMT on dropout during lifestyle treatment in a pediatric overweight population. Hence, variations of the content of SMSMT and intensity need to be further explored in the treatment of childhood overweight. In addition, the role of age in the SMSMT programs should be further investigated. Also, the duration of SMSMT and its effect on dropout rates should be evaluated, given our finding (and that of others) that adherence to self-monitoring deteriorates over time [253, 259]. In the near future we will analyze the effect of SMSMT on BMI-SDS and psychological well-being and



analyze whether SMSMT improves or maintains lifestyle changes. Future studies should also establish the cost-effectiveness of interventions based on new technology systems, the additional effect on weight loss, lifestyle behavior and psychological aspects, the effects of new communication technology interventions replacing parts of face-to-face therapy, and the long-term results of additional treatments.

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# 3.3

## **The effect of a Short Message Service Maintenance Treatment on Body Mass Index and psychological well-being in overweight and obese children: a randomized controlled trial**

JE de Niet, R Timman, S Bauer, ELT van den Akker, HIM Buijks, C de Klerk, H Kordy & J Passchier

*Submitted to Health Psychology*

**ABSTRACT**

**OBJECTIVE:** Although there is evidence that medium to high-intensity behavioral programs achieve the greatest weight loss results, long-term effects are difficult to monitor and achieve. Self-monitoring is associated with increased weight loss. Short Message Service (SMS) seems to improve adherence to self-monitoring of health behavior compared with paper & pencil diaries. This study analyzes whether self-monitoring through SMS with personalized feedback in addition to a lifestyle treatment maintains or improves further weight loss and psychological wellbeing in overweight and obese children.

**PATIENTS AND METHODS:** After 3 months of intensive lifestyle treatment, 141 overweight and obese children (7-12 years) were randomly assigned to an intervention group receiving Short Message Service Maintenance Treatment (SMSMT), or to the control group. The intervention group sent self-monitoring data on physical activity, healthy eating, and emotional well-being via mobile phones. Body Mass Index-Standard Deviation Scores (BMI-SDS) were collected at 4 time points. Additionally, children completed the Dutch Eating Behavior Questionnaire and the Self-Perception Profile for Children. Parents completed the Child Health Questionnaire-PF50. Data from this parallel randomized, multicenter clinical trial were analyzed using mixed modeling.

**RESULTS:** We did not find a significant effect of the SMSMT on BMI-SDS. Controls had a greater reduction in external eating and gained in physical health. More children dropped out from the control group ( $P = 0.02$ ). Children who had greater weight loss during the intensive lifestyle treatment and completed the SMSMT sent more SMSs ( $P = 0.04$ ).

**CONCLUSIONS:** SMSMT seems to reduce dropout rates. However, this study did not find an effect of SMSMT on weight or psychological well-being. Future research should study variations of this intervention to investigate how SMSMT can be more effective in improving treatment success.

## INTRODUCTION

Rates of pediatric overweight and obesity are rising worldwide [1, 2]. The obesity epidemic is accompanied by an increase in the number of children with type 2 diabetes mellitus [58], which was traditionally considered to be a disease of middle age. The increased prevalence and alarming consequences [82, 91] led to the development of many lifestyle interventions, which address physical activity and dietary intake and use behavioral strategies [110, 116]. Although medium to high intensity lifestyle programs have led to weight loss [110, 111] and psychological improvements [109, 260-263], not all children benefit from these interventions. Moreover, long-term follow-up is difficult to achieve and interpret, partially due to high dropout rates [83, 105].

A maintenance intervention (using mobile phones) is introduced for children with overweight and obesity, i.e. a Short Message Service Maintenance Treatment (SMSMT) to improve adherence to lifestyle treatment and its outcomes. We previously demonstrated that SMSMT is feasible and effective in reducing the dropout rate from a pediatric lifestyle intervention (unpublished data).

The present study examines the effect of SMSMT on Body Mass Index-Standard Deviation Scores (BMI-SDS), eating behavior, self-perceived competence, self-esteem, and quality of life (QoL). The variables under study are first briefly described in the context of overweight/obesity and lifestyle treatment.

### *Eating Behavior*

Eating behavior is classified by van Strien et al. [47] in two overeating styles including: emotional eating (e.g. eating in response to negative emotions such as irritability) and external eating (e.g. overeating in response to the sight or smell of food) [47]. The third eating style, restrained eating, is described as eating less than desired with the aim to lose or maintain weight. Contradictory results have been found for eating behavior in relation to weight gain [264-266]. Although restrained eating may not be associated with weight loss [266], there is evidence that restrained eaters restrict their energy intake [267]. High degrees of restrained eating [265, 266, 268, 269], emotional eating [49], and external eating [270, 271] seem to be related to higher BMI. Few studies have evaluated the effect of lifestyle interventions on eating behavior in children. Braet et al. [260, 261] showed that, after a behavioral inpatient treatment, obese children considered themselves more capable of coping with external eating stimuli. However, the degree of emotional and restrained eating did not decrease. Another study found significant improvements in all three eating behavior styles after behavioral treatment in the intervention group compared to the control group [272]. Moreover, Goossens et al. showed that a restrained eating style was a positive baseline predictor of weight loss at the end of treatment [104].

### ***Perceived competence and self-esteem***

Obesity is reported to have a considerable impact on several domains of self-perceived competences and self-esteem [273, 274], especially in girls [181, 273, 275, 276]. For example, Franklin et al. showed that obese children reported less athletic competence, physical competence, and global self-esteem than their normal-weight peers [276]. Lifestyle treatment significantly improves self-perceived athletic competence, physical competence, and global self-esteem in adolescents [260, 263, 277]. Wardle and Cooke [181] propose that attention and support provided by such treatment programs might result in improved psychological well-being, rather than weight loss. Moreover, self-esteem seems to be a predictor of positive health practices [278]. Therefore, overweight and obese children with a positive self-esteem might be more inclined to participate in healthy activities, such as exercise.

### ***Quality of Life***

Obese youth rate their general and physical health lower than their normal-weight peers [93-95, 279, 280], and also report impaired social functioning [93, 94]. Furthermore, overweight and obesity can lead to impaired psychosocial health in children [281]. Lifestyle treatment is reported to lead to improved subjective health scores in obese children [277, 282, 283]. Surprisingly, this improvement did not seem to be associated with improvements in BMI. Again, the attention and support received during the treatment program might have resulted in improved subjective health scores rather than weight loss.

### ***The present study***

The present study introduces an SMSMT in children who were participating in a one-year family-based multi-disciplinary cognitive behavioral group treatment, called the 'Big Friends Club' (BFC), which is aimed at reducing BMI, adopting a healthy lifestyle, and improving self-esteem. After three months of participation in the BFC the additional SMSMT was introduced. The two main components of the SMSMT are self-monitoring and personalized feedback. Self-monitoring is a behavioral strategy which refers to the awareness of bodily symptoms, daily activities and cognitive processes through the self-recording of behavior [162]. Self-monitoring in weight control programs is associated with weight loss [165, 166, 169] and mostly consists of self-monitoring the amounts of food taken, the level of exercise, and counting calories. Self-monitoring is an important element in the self-regulation theory and has been found an effective strategy in maintaining weight loss [168]. The intervention group in the current study sent self-monitoring data on physical activity, healthy eating, and emotional well-being and received tailored feedback. Personalized feedback is considered, personalized feedback is considered more effective than other types of feedback, such as generic or targeted feedback [177]. An increased awareness of lifestyle behavior combined with the positive

reinforcement through personalized feedback messages might result in sustained or improved outcomes of the BFC treatment.

SMS as a device of health care delivery has several advantages, such as accessibility any time and any place, interactivity and rapidity, limited costs, and technically SMS can be pre-programmed and tailored to the needs of an individual. Greater adherence to self-monitoring of health behavior has been found in healthy children and adolescents using SMS compared to paper & pencil diaries [157]. Despite some evidence that SMS has positive short-term behavioral outcomes [146], the use of SMS in health care is still in its early stages and needs to be further explored.

Our first aim of the present study is to analyze the effect of an additional SMS intervention with personalized feedback on BMI-SDS. The second objective of this study is to examine the effect of the SMS intervention on psychological well-being in overweight and obese children. We hypothesized that SMSMT with personalized feedback will reduce BMI and improves eating behavior, competence, global self-esteem, and QoL. Finally, we study whether children in the SMSMT intervention show an increased level of self-monitored health behaviors and emotional well-being.

## **METHODS**

### **Study design**

A multi-centre randomized controlled trial was conducted in several geographical areas in the Netherlands among overweight and obese children. All children participated in the Big Friends Club (BFC) program. After the first three intensive months of the BFC program, children and their parents experienced a transition from a period with regular contact with the interdisciplinary team to a period with less intensive contact. Therefore, the additional SMSMT was introduced after three months of BFC treatment. In this parallel trial design with balanced groups, participants were randomly assigned to the intervention group receiving SMSMT for nine months until the end of the BFC, or to the control condition receiving no SMSMT. In order to detect a medium-sized difference in BMI-SDS reduction between children in the SMSMT group and controls, respecting an alpha level of 0.05 and a power of 0.80, 64 cases were needed in each treatment group. Randomization allocation in a 1:1 ratio was applied in a randomized block design. The blocks were formed by the therapy groups (8 to 10 children). The randomization allocation was printed on paper in a sealed envelope. An equal number of SMSMT and control notes were put in the envelopes. The researcher randomized the children to the SMSMT or control condition by picking an envelope from a basket. Measures were assessed at the start of randomization after 3 months of BFC and at follow-up at 6, 9 and 12 months after the start of the BFC treatment.

## Participants

Eight hospitals complying with the BFC protocol participated. Children who were overweight or obese and who were participating in the BFC program during the period 2006–2009 were included in the present study. Exclusion criteria included behavioral problems defined as a score >70 on the Child Behavior Checklist (CBCL) [195], any disease causing overweight that could be treated with drugs, and mental retardation. Furthermore, both parents and the child had to be sufficiently fluent in the Dutch language, and show sufficient motivation to actively participate in the program. All parents gave written informed consent before entering the study. The study protocol was approved by the Medical Ethics Committee of the Erasmus MC University Medical Centre of Rotterdam and by the medical ethics committees of the participating institutions.

## Interventions

### *The Big Friends Club program*

The BFC program is a family-based multidisciplinary cognitive-behavioral group treatment for children aged 8 to 12 years that is limited to groups of 8-10 children. The program has been described in detail elsewhere [135]. The treatment team includes a psychologist, dietician, pediatrician, and physiotherapist. The therapy is aimed at reducing Body Mass Index-Standard Deviation Scores (BMI-SDS), preferably by maintaining weight during growth and adopting a healthy lifestyle. Other treatment goals include creating a positive self-image and improving skills to cope with the psychosocial consequences of obesity e.g. bullying. Behavioral techniques such as shaping, goal-setting, modeling, and positive reinforcement are used in the group sessions. The program consists of an intake session, 8 children's sessions, and a minimum of 2 parent's sessions during the first 3 months. Additionally, children's and parent's follow-up sessions and individual appointments are organized 6, 9, and 12 months after start of the program.

### *Short Message Service Maintenance Treatment (SMSMT)*

Participants in the SMSMT group received a mobile phone and were instructed face-to-face by a psychologist researcher on how to use the mobile phone and to use it only for the purpose of this study. No reward was given for participation in the study. The children were requested to send weekly self-monitoring data via SMS in a standardized format on the number of days per week of physical activity, adherence to the learned healthy eating pattern, and emotional well-being on a 5-point Likert scale. Additionally, the children could send an SMS at any time about any positive or negative life events, thoughts or feelings when they felt in need of communication. Every message had a 160-character limitation. Informational communication was stored on a secure web server at the Center for Psychotherapy Research at the University Hospital Heidelberg,



Germany. A software program automatically analyzed each incoming message according to a predefined algorithm, i.e. it compared the current state to that of the previous message. Next, the program suggested a feedback message out of a large pool of pre-formulated statements which was tailored to the child's individual pattern of change in lifestyle behavior. The program has been described in detail by Bauer et al. [229]. The researcher logged in to the program via a website, checked the feedback suggested by the program for plausibility, tailored the feedback message and sent the feedback message to the participant (e.g. Your exercise was well done! Keep going! Find distractions when you can't resist unhealthy food. Good luck, you can do it!). Tailoring aspects included taking into account previous SMS responses, the participant's name, personal behavioral goals, changes, and difficulties. The feedback messages were formulated according to four principles: 1) promoting social support; 2) encouraging and motivating participants; 3) reinforcing positive changes and existing behavioral self-management strategies; and 4) suggesting and encouraging behavior modification and self-management skills that were learnt during the BFC program in case of negative developments. The researcher enhanced compliance by sending an SMS reminder after one week of non-responding. The researcher could upload SMS credits of the participants through the internet.

## Measures

### *Demographic and anthropometric variables*

Information on demographic characteristics including age, gender and ethnicity were collected. Ethnicity was divided into two categories: Caucasian (both parents) and non-Caucasian (at least one parent). Overweight and obesity were measured in terms of BMI-SDS, BMI scores corrected for age and gender. A BMI-SDS of 1.1 represents the threshold for overweight, and a BMI-SDS of 2.3 indicates obesity [10]. The children's weight and height were measured in the hospital by a physician. The BMI-SDS was calculated using the Growth Analyzer Version 3.5 [258].

### *Eating behavior: Dutch Eating Behavior Questionnaire (DEBQ)*

The Dutch Eating Behavior Questionnaire (DEBQ) for 7-12 year-old-children [47] was administered to assess restrained, emotional, and external eating. The questionnaire consists of 20 items, including 7 items on restrained, 7 on emotional, and 6 on external eating. High scores reflect a high degree of the eating behavior in question. The subscales restrained, emotional, and external eating of the DEBQ have good internal reliability (Cronbach's  $\alpha = 0.81, 0.80, \text{ and } 0.74$ , respectively) [47]. We used norm scores of Dutch children from the general population with a mean age of 9.6 years and age range of 7-12 years [47].

***Self-perception: Self-Perception Profile for Children (SPPC)***

The Dutch version of the Self-Perception Profile for Children (SPPC) [284, 285] was used to measure self-perceived competence on 5 domains: Scholastic Competence, Social Acceptance, Athletic Competence, Physical Appearance, and Behavioral Conduct. In addition, the SPPC assesses Global Self-Worth. The self-report questionnaire consists of 36 items and was developed for children aged 8-12 years. The child has to choose between one of two alternative answers, and subsequently choose whether this item is 'somewhat true' or 'absolutely true'. High scores reflect greater perceived competence or global self-worth. In the analyses of this study we used the three subscales Athletic Competence, Physical Appearance, and Global Self-Worth. The Dutch version of the SPPC has moderate to good internal reliability with  $\alpha$  for boys and girls together ranging from 0.70 for the subscale Athletic Competence, 0.82 for Physical Appearance, and 0.74 for Global Self-Worth [285]. We used separate norm scores for boys and girls because of significant differences in scores between boys and girls. Norm scores were used of a population of Dutch schoolchildren with a mean age of 10 years and age range of 8-12 years [285]. The SPPC was measured at baseline and at 3, 6, and 12 months.

***Health-related Quality of Life (HRQoL): Child Health Questionnaire – PF50 (CHQ-PF50)***

The Dutch validated version [286] of the Child Health Questionnaire Parent-Form (CHQ-PF50) [287] was used to assess health-related QoL or health status. This generic health status questionnaire is a parent-rated 50-item version divided over 11 multi-item scales and 2 single item questions for children aged 4 years and older. We used the parent rated version since younger children are not yet considered able to rate their own health consistently [288, 289]. In the current study "Physical" and "Psychosocial" CHQ summary scores were used [287] which have good internal reliability ( $\alpha = 0.93$ , and  $0.87$ , respectively) [286]. The highest summary scores (100) reflect the best possible health states, and the lowest scores (0) the poorest health states. We used norm scores of a population of Dutch schoolchildren aged 5-13 years [286].

**Statistical analysis**

To test differences in the anthropometric and demographic variables between the intervention group (SMSMT) and the control group (no SMSMT) Student's t-tests were used for continuous variables and Fisher's exact tests were used for categorical variables. Student's t-tests for one sample were used to test differences between the study population and norm scores of the DEBQ, SPPC, and the CHQ-P50 and paired Student's t-tests were applied to test differences on BMI-SDS, DEBQ, SPPC, and the CHQ-50 between 0 and 3 months of BFC treatment. With respect to the SPPC, separate norm scores were used for boys and girls. In order to measure the magnitude of this difference, effect sizes (ES) as the standardized differences in means were calculated by dividing the difference

between the norm group and either the intervention or the control group by the pooled standard deviation. Effect sizes were categorized into small (0.2-0.5), moderate (0.5-0.8) or large ( $ES > 0.8$ ) [290].

Longitudinal analyses over the period 3 to 12 months were performed with mixed modeling using SAS 9.2 [291]. This technique allows the use of incomplete cases if the missing is at random [203, 204]. Mixed modeling is a multilevel regression technique that facilitates within subject analyses. Nine saturated models were postulated with the dependent variables BMI-SDS, emotional eating (DEBQ), external eating (DEBQ), restrained eating (DEBQ), athletic competence (SPPC), physical appearance (SPPC), global self-worth (SPPC), physical health (CHQ-P50), and psychosocial health (CHQ-P50). SMSMT, age, gender, linear time, and quadratic time and interactions were entered into the models as main effects. The covariance structure was determined using the Restricted Maximum Likelihood estimation method [292]. In a backward procedure (interaction) effects with a  $p$ -value  $> 0.05$  were removed, respecting that interaction effects must be nested under their respective main effects. In this way final parsimonious models were reached that did not differ significantly from the saturated models.

Pearson correlations were calculated to analyze the relation between changes in BMI-SDS and the number of submitted SMSs in the first 3 months of SMSMT.

The General Linear Model was applied to test the difference in mean self-reported scores on physical activity, healthy eating, and emotions over time for the total SMSMT group.

To test the differences in scores on self-monitored adherence of days per week to physical activity, a healthy eating pattern, and emotional well-being within the 3 SMSMT subgroups, namely completers (BFC program completers and SMSMT intervention completers), treatment dropouts, and SMSMT dropouts, ANOVA post-hoc analyses were applied.

## RESULTS

### Patient characteristics

A total of 144 children and their parents agreed to take part in this study (mean age 9.9, SD 1.3 yrs, range 7-12 years) (Table 3.3.1). Three children dropped out from the intensive part of the BFC treatment. Therefore, 141 children were randomly assigned to either the control group (no SMSMT) or the intervention group who received SMSMT (Chapter 3.2, Figure 3.2.2). The two groups did not differ from each other in terms of baseline clinical and demographic characteristics. The total group had a mean BMI-SDS of 2.6 (SD=0.4). At baseline, 74% of all children were obese compared to 56% after one year of BFC treatment. Between 3 and 12 months a larger proportion of children dropped out of the control group ( $n=21$ , 31%) than out of the SMSMT intervention ( $n=10$ , 14%) ( $P = 0.02$ ).

**Table 3.3.1** Characteristics of the study population

|                                   | Total (N=141)<br>Mean (SD) [Range] or<br>n (%) | No SMSMT (n=68)<br>Mean (SD) or<br>n (%) | SMSMT (n=73)<br>Mean (SD) or<br>n (%) | P-value |
|-----------------------------------|--|--|---------------------------------------|---------|
| Age (years)                       | 9.9 (1.3) [7 – 12]                             | 9.8 (1.3)                                | 10.0 (1.3)                            | 0.35    |
| Baseline BMI-SDS                  | 2.6 (0.4) [1.1 – 3.6]                          | 2.5 (0.4)                                | 2.6 (0.5)                             | 0.21    |
| Boys                              | 51 (36%)                                       | 23 (34%)                                 | 28 (38%)                              | 0.60    |
| Ethnicity (Dutch)                 | 105 (75%)                                      | 48 (71%)                                 | 57 (78%)                              | 0.34    |
| Obesity (BMI-SDS) at<br>baseline  | 102 (74%)                                      | 53 (78%)                                 | 49 (70%)                              | 0.34    |
| Obesity (BMI-SDS) at 3<br>months  | 74 (57%)                                       | 34 (54%)                                 | 40 (60%)                              | 0.60    |
| Obesity (BMI-SDS) at 6<br>months  | 60 (56%)                                       | 27 (51%)                                 | 33 (61%)                              | 0.33    |
| Obesity (BMI-SDS) at 9<br>months  | 49 (58%)                                       | 22 (59%)                                 | 27 (57%)                              | 1.00    |
| Obesity (BMI-SDS) at 12<br>months | 57 (56%)                                       | 26 (57%)                                 | 31 (55%)                              | 1.00    |

BMI, Body Mass Index; SDS, Standard Deviation Scores; SMSMT, Short Message Service Maintenance Treatment.

With respect to the effect of the 3 months intensive BFC intervention on psychological well-being, we found significant improvements for the total group on BMI-SDS ( $P = 0.000$ ), Athletic Competence ( $P = 0.012$ ), Physical Appearance ( $P = 0.004$ ), Global Self-Worth ( $P = 0.035$ ), Physical Health ( $P = 0.001$ ), Psychosocial Health ( $P = 0.017$ ), and a non-significant trend on Emotional eating ( $P = 0.067$ ).

### Comparisons with the general population

Comparisons with the general population were made at months 3, 6, 9, and 12. The children in the intervention group and control group had significantly higher scores on the Restraint eating scale of the DEBQ than the norm group at all time points (months 3, 6, 9, and 12) with moderate to large effect sizes (Cohen's  $d$  0.64 to 0.94). The children in the control group had lower scores on Emotional eating than the norm group at all time points (Cohen's  $d$  -0.25 to -0.47), whereas the intervention group showed lower scores than the norm group only at 6 and 12 months follow-up (Cohen's  $d$  -0.25 and -0.39,

respectively). Both the intervention and control group showed lower External eating scores than the norm group at 6, 9, and 12 months follow-up (Cohen's  $d$  -0.36 to -0.76). Figure 3.3.1 shows a separate line representing the normal population.

The girls in the SMSMT group showed lower scores on Athletic Competence than the norm group at all assessments (Cohen's  $d$  -0.55 to -0.78) whereas the boys in the intervention group showed lower scores at 3 and 12 months (Cohen's  $d$  -0.81 and -0.95, respectively). The boys in the control group had lower scores than the norm group only at 3 months (Cohen's  $d$  -0.84). Almost all groups showed lower scores on Physical Appearance than the norm group at all time points (Cohen's  $d$  -0.69 to -1.35), except for the girls in the control group at 6 months. The girls in the control group showed higher scores on Global Self-Worth at 6 months (Cohen's  $d$  0.61) and the boys in the intervention group at 3 and 12 months (Cohen's  $d$  -0.78 and -1.02, respectively).

The intervention and the control group had significantly lower Physical Health scores than the norm group at all time points (Cohen's  $d$  -0.41 to -0.96). Only the control group had significantly lower scores on Psychosocial Health than the norm group at start of randomization (Cohen's  $d$  -0.52).

### Longitudinal analyses of SMSMT

The intervention group receiving SMSMT and the control group did not change in different ways over time on BMI-SDS scores over time. Table 3.3.2 shows the estimated weights and significance levels of the longitudinal mixed models. The main linear time effects indicate that, in general, the scores of the dependent variables either decrease or increase. The quadratic time effects indicate that this reduction or increase tends to become less over time. The interaction of time and SMSMT is only significant with respect to External eating and Physical Health, which indicates that the two groups change in different ways over time on these variables. The significant interaction effect of time and SMSMT regarding External eating indicates that the SMSMT group had smaller reductions in External eating scores over time. However, the quadratic time SMSMT interaction effect indicates that this difference in reduction became less on the longer term. To facilitate the interpretation of this model, the effects are shown in Figure 3.3.1. Furthermore, the SMSMT group showed a decrease in Physical Health over time, while the control group reported an increase in Physical Health, although on the longer term this gain was somewhat moderated.

Besides these SMSMT interaction effects, the results showed older children had lower scores on the subscales Physical Appearance and Global Self-Worth, although in the long run this gain was somewhat moderated.

### SMSMT

We divided the SMSMT group into SMSMT completers (BFC program completers and SMSMT intervention completers), SMSMT dropouts, and SMSMT and BFC treatment

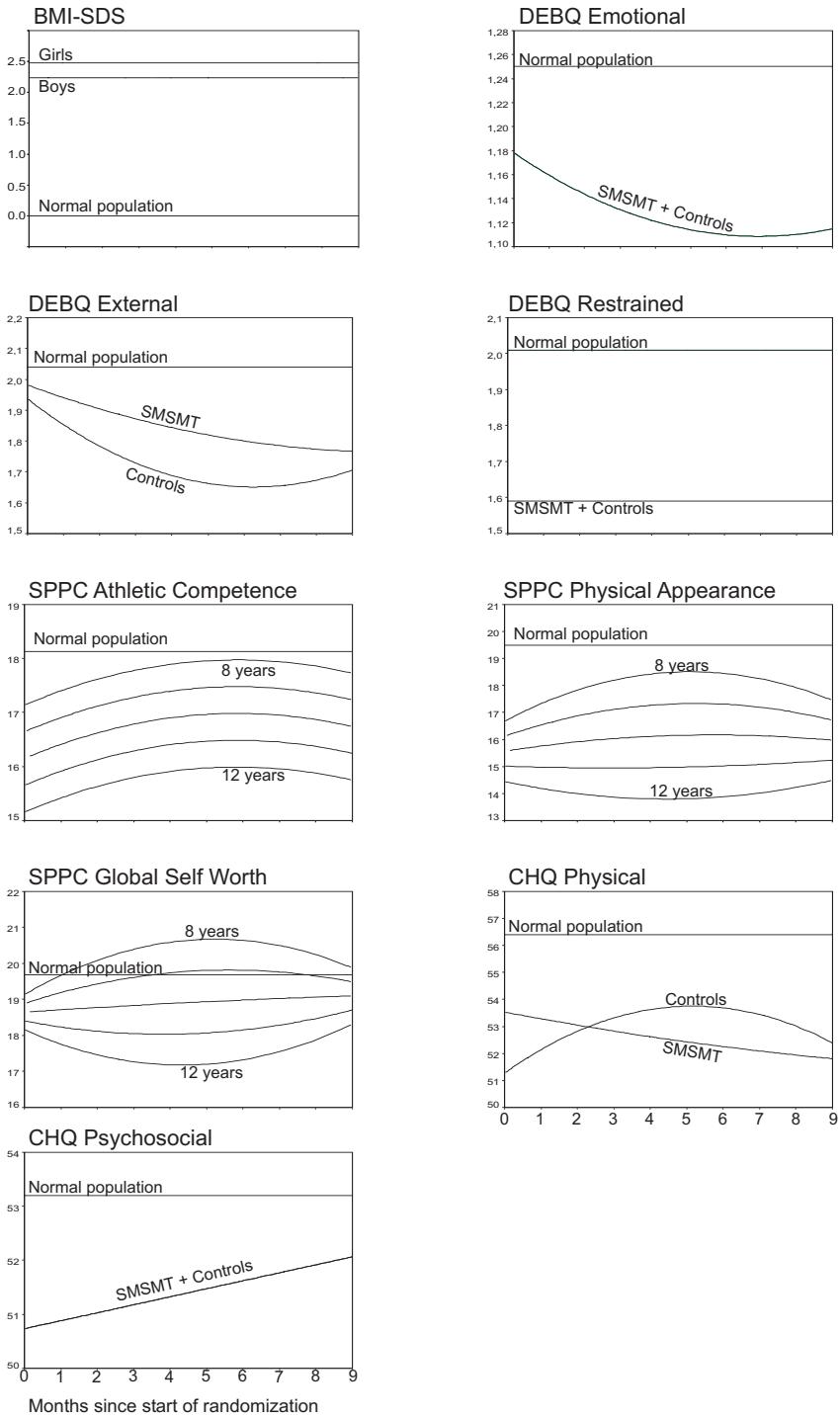


Figure 3.3.1 Differences between groups in the one-year course of BMI-SDS and psychological outcomes

**Table 3.3.2** Final mixed models

|                     | Intercept |        | SMSMT |      | Time linear |        | Time quadratic |        | Sex  |       | Age   |      | SMSMT * Time linear |      | SMSMT * Time quadratic |      | Age * Time linear |      | Age * Time quadratic |   |
|---------------------|-----------|--------|-------|------|-------------|--------|----------------|--------|------|-------|-------|------|---------------------|------|------------------------|------|-------------------|------|----------------------|---|
|                     | est.      | p      | est.  | p    | est.        | p      | est.           | p      | est. | p     | est.  | p    | est.                | p    | est.                   | p    | est.              | p    | est.                 | p |
| <b>BMI-SDS</b>      | 2.33      | <0.001 |       |      |             |        |                |        | 0.24 | 0.009 |       |      |                     |      |                        |      |                   |      |                      |   |
| <b>DEBQ</b>         |           |        |       |      |             |        |                |        |      |       |       |      |                     |      |                        |      |                   |      |                      |   |
| Emotional eating    | 1.18      | <0.001 |       |      | -0.02       | 0.007  | 0.001          | 0.05   |      |       |       |      |                     |      |                        |      |                   |      |                      |   |
| External eating     | 1.94      | <0.001 | 0.044 | 0.56 | -0.09       | <0.001 | 0.007          | <0.001 |      |       | 0.048 | 0.04 | -0.005              | 0.03 |                        |      |                   |      |                      |   |
| Restrained eating   | 2.01      | <0.001 |       |      |             |        |                |        |      |       |       |      |                     |      |                        |      |                   |      |                      |   |
| <b>SPPC</b>         |           |        |       |      |             |        |                |        |      |       |       |      |                     |      |                        |      |                   |      |                      |   |
| Athletic Competence | 21.91     | <0.001 |       |      |             |        |                |        |      |       | -0.55 | 0.04 |                     |      |                        |      |                   |      |                      |   |
| Physical Appearance | 21.45     | <0.001 |       |      | 2.96        | 0.01   | -0.29          | 0.01   |      |       | -0.56 | 0.07 |                     |      | -0.26                  | 0.02 | 0.03              | 0.02 |                      |   |
| Global Self-Worth   | 21.02     | <0.001 |       |      | 3.04        | 0.01   | -0.30          | 0.01   |      |       | -0.23 | 0.45 |                     |      | -0.28                  | 0.02 | 0.03              | 0.01 |                      |   |
| <b>CHQ</b>          |           |        |       |      |             |        |                |        |      |       |       |      |                     |      |                        |      |                   |      |                      |   |
| Physical Health     | 51.27     | <0.001 | 2.27  | 0.06 | 0.96        | 0.01   | -0.09          | 0.02   |      |       |       |      | -1.22               | 0.01 | 0.10                   | 0.04 |                   |      |                      |   |
| Psychosocial Health | 50.73     | <0.001 |       |      | 0.15        | 0.04   |                |        |      |       |       |      |                     |      |                        |      |                   |      |                      |   |

est. = estimated regression weight.  
 BMI, Body Mass Index; SDS, Standard Deviation Scores; DEBQ, Dutch Eating Behavior Questionnaire; SPPC, Self-perception Profile for Children; CHQ, Child Health Questionnaire.

dropouts, sending in the first 3 months on average 0.80 SMSs (SD=0.19, range=0.4-1.1), 0.55 (SD=0.24, range=0.2-1.0), and 0.78 (SD=0.28, range=0.4-1.2) per week, respectively. Pearson correlations showed that completers with the greatest BMI-SDS change during the first 3 intensive months of the BFC program sent the most text messages per week in the first 3 months of SMSMT ( $r=0.29$ ,  $P = 0.041$ ) as well as in the total SMSMT period ( $r=0.36$ ,  $P = 0.012$ ).

For self-reported days per week of adherence to a healthy eating pattern, children in the SMSMT group adhered less time per week to healthy eating over time (test within subjects contrast  $F=4.575$ ,  $df=1$ ,  $P = 0.037$ ). In the first 3 months of SMSMT they adhered 3.78 (SD=0.52) days to a healthy eating pattern, in months 3-6 of SMSMT 3.74 (SD= 0.55) days, and in the last 3 months 3.60 (SD=0.78) days. We found no significant effect with respect to physical activity or emotional well-being.

When separating the SMSMT group into the 3 abovementioned sub-groups, the results show that completers reported more physical activity per week over time ( $P = 0.030$ , 95% CI=0.04-0.81), and adhered more often to healthy eating ( $P = 0.015$ , 95% CI=0.09-0.78) compared to the SMSMT dropouts.

## DISCUSSION

In recent years, a variety of interventions for the treatment of pediatric overweight have been developed [110, 111]. To our knowledge, this is one of the first studies that examined the effect of a Short Message Service Maintenance Treatment on BMI, competence, self-esteem, and QoL in a sample of overweight and obese children participating in a lifestyle treatment. In a previous study, we found that children who received SMSMT were less likely to drop out from the lifestyle treatment than children who did not receive SMSMT (unpublished data). However, the hypotheses for the current study were not confirmed. The use of SMSMT does not seem to have a positive influence on BMI-SDS, eating behavior, competence, global self-esteem, and QoL. On the contrary, two significant differences in favor of the control group were found.

No significant reduction in BMI-SDS and no improvement in eating behavior, competence, global self-esteem, and QoL were found when comparing the SMSMT with the control group. In line with our findings, Newton et al., studying adolescents with type 1 diabetes who received motivational text messages for 3 months reminding them to wear a pedometer and be active, found no improvement in BMI and QoL [282]. Children in the present study might have greatly improved their BMI-SDS and psychological well-being during the intensive part of the BFC treatment in the first 3 months. Consequently, significant changes during the maintenance treatment might have been more difficult to achieve. Furthermore, it might be that the current self-monitoring procedure was too



low intensive to improve measures such as QoL and self-esteem. Future research on this method should examine more intensive self-monitoring, e.g. in this study children in the intervention group monitored their lifestyle behaviors only once a week. In addition, self-monitoring of various other behaviors should be included, e.g. sedentary behaviors, beverage intake, and weight monitoring. Sedentary behaviors (e.g. television watching) and the intake of sugar-sweetened beverages seem to be related to higher BMI [28, 293]. Epstein et al. showed that both stimulus control and reinforcing decreased sedentary behaviors in obese children [294]. Furthermore, self-monitoring of body weight is associated with greater weight loss and weight maintenance [168, 295, 296].

Children in the control group showed a larger improvement in external eating scores over time than the SMSMT group. However, neither of the two groups achieved scores comparable with the normative data. The difference between the control and the intervention group might be explained by selective dropout. As expected, the control group had a significantly higher dropout rate than the intervention group. An earlier study on the BFC treatment indicated that dropouts were less successful in BMI-SDS reduction during treatment [135]. We speculate that the children that would have dropped out without the SMSMT had poorer treatment outcomes. If so, retaining these children in the BFC program may have moderated the mean treatment effect of SMSMT. The children participating in our study reported higher levels of restrained eating than the general population, which is in line with the findings of Van Strien et al. [53]. Remarkably, all children reported lower levels of external eating at all follow-ups. There is some evidence that heavier children are subject to more parental control and food restriction [53]. Van Strien et al. suggested that parents of overweight children might be more likely to control external cues which therefore may result in lower levels of external eating.

Children in the two groups also changed in different ways over time with respect to physical health. The self-reported physical health of the children in the SMSMT group decreased, whereas the control group initially showed an improvement in physical health, although this increase was later somewhat moderated. Because the difference in scores existed at the start of randomization, the difference in main effects may probably be attributed to randomization bias and not to the effect of SMSMT. None of the children in the two groups achieved levels of physical health within the range of the norm group.

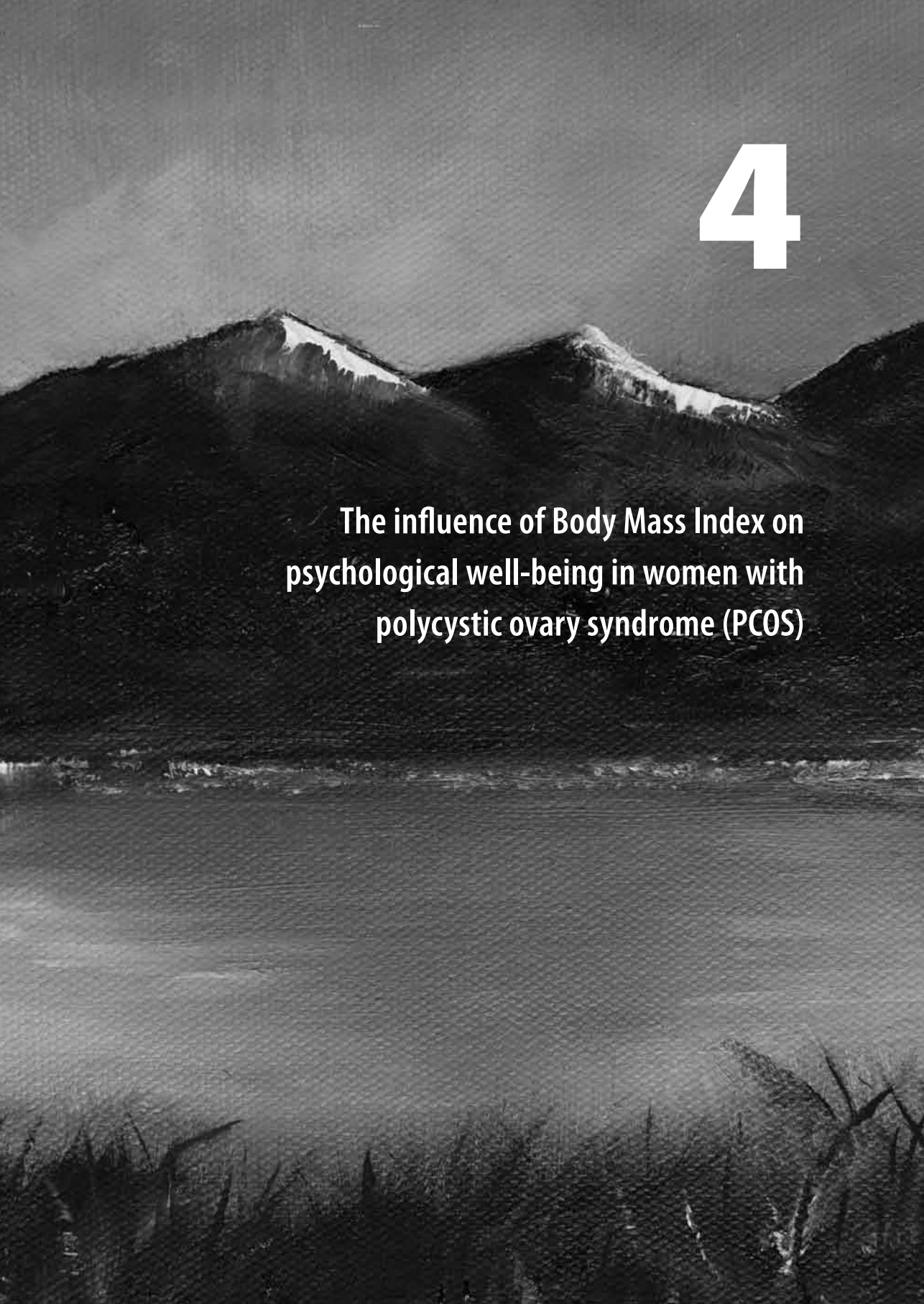
In line with our preliminary results [256], we found that completers with the greatest BMI-SDS change during the first 3 intensive months of the BFC program, sent the greatest amount of text messages per week during the SMSMT intervention. Whereas a successful experience might motivate children and improve their adherence to the SMSMT, a failure experience during the intensive treatment might be demoralizing and result in a higher chance of giving up. For example, it has been shown that BMI-SDS reduction during treatment predicts 5-year long-term outcome [127] and that those who are less successful in treatment are more likely to drop out [135].

In the SMSMT group, no improvement over time was found for self-reported emotions and adherence to physical activity, but a significant deterioration over time was found for self-reported adherence to a healthy eating pattern. It is difficult to interpret the size of this deterioration, because we had no reference group to test the difference in improvement/deterioration on self-reported adherence to health behaviors. However, no decrease in physical activity and no deterioration over time for negative emotions were found, implying that these patterns were stabilized over time. Furthermore, adherence to the specific health behaviors was measured with only one item using a 5-point Likert scale. Future studies should evaluate adapted/improved versions of the SMSMT and their effects by measuring physical activity by objective measures such as accelerometers and pedometers or by validated questionnaires, and by measuring dietary intake with validated questionnaires.

The use of SMS in the treatment of pediatric overweight has several advantages: the accessibility almost anytime at any place, the interactivity and rapidity, and limited time and costs. The method of text messaging seems to be particularly useful in maintenance treatment to reduce dropout rates. However, despite some evidence that SMS has positive short-term behavioral outcomes [146], we were unable to replicate these findings. The use of SMS in health care is still in its early stages and needs to be further explored. Adapted versions of the SMSMT should be developed and their effect on BMI-SDS and psychological well-being should be further studied, together with their cost-effectiveness.

# 4

**The influence of Body Mass Index on  
psychological well-being in women with  
polycystic ovary syndrome (PCOS)**





# 4.1

## Psychological well-being and sexarche in women with polycystic ovary syndrome (PCOS)

JE de Niet, CM de Koning, H Pastoor, HJ Duivenvoorden, O Valkenburg,  
MJ Ramakers, J Passchier, C de Klerk & JSE Laven  
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## ABSTRACT

**BACKGROUND:** The characteristics of polycystic ovary syndrome (PCOS) such as hyperandrogenism and anovulation can be highly stressful and might negatively affect psychological well-being and sexuality. The objective of this study was to evaluate the association between PCOS characteristics and psychological well-being as well as sexarche.

**PATIENTS AND METHODS:** Patients (n=1148) underwent standardized clinical evaluation. Psychological well-being was investigated in 480 patients with the Rosenberg Self-esteem Scale (RSES), the Body Cathexis Scale (BCS) and the Fear of Negative Appearance Evaluation Scale (FNAES). Sexarche was also assessed.

**RESULTS:** Amenorrhoea was associated with lower self esteem ( $P = 0.03$ ), greater fear of negative appearance evaluation ( $P = 0.01$ ), and earlier sexarche ( $P = 0.004$ ). Hyperandrogenism and acne were associated with poorer body satisfaction ( $P = 0.03$ ,  $P = 0.02$ , respectively). Hirsutism and Body Mass Index were negatively associated with all psychological variables (RSES,  $P = 0.01$ ; BCS,  $P = 0.05$ ; FNAES,  $P = 0.02$  and RSES,  $P = 0.03$ ; BCS,  $P = 0.001$ ; FNAES,  $P = 0.03$ , respectively).

**CONCLUSIONS:** Our results suggest that menstrual irregularities might be related to sexarche. Moreover, this study stresses that the treatment of women with PCOS should focus on not only physical, but also psychological and sexual characteristics.

## INTRODUCTION

Polycystic ovary syndrome (PCOS) is the most common endocrine disorder in women of reproductive age. It is estimated that 5-10% of the women have this disease [66]. The major characteristics of PCOS are enlarged ovaries with a polycystic appearance along with menstrual irregularities such as amenorrhoea or oligoamenorrhoea, excessive growth of body hair (hirsutism) or biochemical hyperandrogenism, and to a lesser extent acne. PCOS is associated with anovulatory infertility, obesity, insulin resistance, and lipid disorders [69, 70]. Moreover, women with PCOS are at increased risk of developing type 2 diabetes [297] and may have an increased risk for cardiovascular disease [298] and endometrial cancer [299].

In the clinic, the treatment of women with PCOS is mainly focused on the physical consequences. The negative associations that women with PCOS might experience in daily life besides the physical consequences, e.g. social contacts, sexual relationships, and self-esteem, are rarely discussed with PCOS patients during treatment. Studies addressing to what extent the abovementioned characteristics of PCOS do influence sexuality and psychosocial well-being are scarce. The existing studies indicate that women with PCOS may experience the characteristics of PCOS as stressful and are at increase risk for depression [300] and anxiety disorder [301]. In one study of Kitzinger & Willmot [302], interviews were conducted in women with PCOS to explore women's own experience of the syndrome. The women reported feeling less feminine. This feeling was associated with hirsutism, menstrual irregularities (amenorrhoea versus oligoamenorrhoea) and infertility. Menstrual irregularities [303] and concerns about infertility [303-305] have also been found to decrease quality of life (QOL). Overweight has been found to be one of the most important contributors reducing QOL in women with PCOS [306-308]. Furthermore, it has been shown that women with PCOS and clinical symptoms of hirsutism and acne have greater body dissatisfaction than healthy controls with regular cycles, even after adjustment for Body Mass Index (BMI) [309, 310]. Acne might also be a risk factor for clinically relevant anxiety in women with PCOS [301].

Sexuality in women with PCOS has been studied incidentally. The results of these studies showed that women with PCOS were less satisfied with their sex life than healthy control women and they also thought their partners were less satisfied with their sex life [308]. Furthermore, PCOS women did find themselves sexually less attractive and had the idea that their partners found them sexually less attractive. It has been found that women with PCOS believed that their body hair negatively influences their sexuality [308] and that their general appearance made it difficult to make social contacts [308, 311]. Hahn et al. found that higher BMI and hirsutism were negatively associated with physical aspects of QOL and sexual satisfaction [312]. Even though women with PCOS are less satisfied with their sex life, they do not seem to differ from controls in respect of

partner status and the frequency of sexual intercourse [308]. Still, another study showed that adolescent girls with PCOS were less likely to be sexually active than healthy adolescent controls [305], which might suggest that adolescents with PCOS have their sexarche later in life than the general population.

Most previous research focused on PCOS characteristics and their association with psychological disorders, such as anxiety and depression. In the present study, the principal focus was to study whether PCOS characteristics are associated with several aspects of psychological well-being namely self-esteem, body satisfaction and fear of negative appearance evaluation. We hypothesized that all clinical characteristics except polycystic ovaries are associated with psychological well-being. As far as we know, there is no literature available on the association between PCOS characteristics and sexarche. Therefore, our second objective was to explore whether PCOS characteristics are associated with sexarche.

## **MATERIAL AND METHODS**

### **Patients**

We included 1148 women with normogonadotropic anovulation (WHO II) and oligomenorrhoea or amenorrhoea who attended our fertility clinic between 1991 and 2006. The diagnosis of PCOS was established on the basis of the revised Rotterdam criteria [313]. Patients underwent a standardized evaluation that included cycle history, anthropomorphometric measurements (height and weight, Ferriman-Gallwey score), the presence or absence of acne and transvaginal ultrasonography to assess ovarian volume and follicle count for both ovaries. Exclusion criteria were the presence of related disorders with similar clinical presentation, such as congenital adrenal hyperplasia and Cushing's syndrome.

The study was approved by the local institutional medical ethics review board of the Erasmus University Medical Centre, Rotterdam. All patients gave informed consent prior to their inclusion in the study.

### **Procedure**

Patients who underwent clinical and endocrine evaluation in the period between 1991 and 2006 were approached in 2007 by posting a seventy-two item questionnaire with an accompanying letter. Two months after posting the questionnaire, non-respondents were sent a reminder together with the questionnaire.



## Clinical and laboratory measures

Oligoamenorrhoea was defined as an interval between menstrual periods  $\geq 35$  days and amenorrhoea as the absence of vaginal bleeding for at least 6 months i.e.  $> 199$  days. In accordance with the Rotterdam criteria, hyperandrogenism was defined as having either biochemical or clinical signs of androgen excess. Biochemical hyperandrogenism was defined by a free androgen index (FAI)  $> 4.5$ . Clinical hyperandrogenism (hirsutism) was assessed by the Ferriman–Gallwey score where patients estimated their hair growth on nine different body parts from 0 (no terminal hair) to 4 (maximal growth) with a maximum score of 36. A score of 8 or more indicates the presence of hirsutism [314]. The presence or absence of acne was evaluated by the physician. The presence of polycystic ovaries (PCO) was detected by vaginal ultrasound examination. Polycystic ovaries were defined as the presence of 12 follicles or more in one or both ovaries and/or increased ovarian volume ( $> 10$  ml).

Blood samples were obtained by venipuncture. Serum was isolated after centrifugation at 2163 g for 10 min at 20°C and subsequently stored at -20°C. Endocrine evaluation included serum levels of gonadotropic hormones (luteinizing hormone (LH), follicle-stimulating hormone (FSH)) and estradiol (E2), androgens (T, androstenedione (AD), dehydroepiandrosterone (DHEA), an dehydroepiandrosterone sulphate (DHEAS)), progesterone, sex hormone-binding globulin levels (SHBG), fasting glucose and insulin, thyroid-stimulating hormone (TSH) and prolactin. Immunofluorometric assays were used for the LH, FSH, TSH, prolactin and insulin, whereas serum E2, T, AD, and SHBG were measured by RIA provided by Diagnostic Products Corp. (Los Angeles, CA). Intraassay and interassay coefficients of variation were  $< 5\%$  and  $< 15\%$  for LH,  $< 3\%$  and  $< 5\%$  for T,  $< 8\%$  and  $< 11\%$  for AD,  $< 5\%$  and  $< 7\%$  for E2,  $< 4\%$  and  $< 5\%$  for SHBG, respectively [70].

## Demographical and psychological measures

### *Demographics*

Information on women's demographics such as age and ethnicity and the use of contraceptives was gathered from medical records and from the questionnaire.

### *Rosenberg Self-Esteem Scale (RSES)*

The RSES consists of 10 items that measure the level of self-esteem. Responses are recorded on a 4-point-Likert scale from 'strongly disagree' to 'strongly agree', with 5 positively worded items and 5 negatively worded items. Higher scores reflect a higher level of self-esteem. The Dutch version of the RSES was shown to have good validity and reliability with good internal consistency (Chronbach's  $\alpha = .87$ ). We used norm scores of a Dutch control population of college students and adults of the general population [315].

***Body Cathexis Scale (BCS)***

The BCS is a self-report questionnaire to measure body satisfaction [316]. The questionnaire consists of 52 items about a person's satisfaction with their body parts and body functions, such as hips and respiration. Body satisfaction is measured on a 5-point Likert scale from the most negative attitude towards a body part or function to the most positive attitude towards the body part or function. The Dutch version of the questionnaire has good test-retest reliability (Pearson product-moment correlation coefficient = .91). We used norm scores of a Dutch control student population [317].

***Fear of Negative Appearance Evaluation Scale (FNAES)***

The brief version of the FNAES was used to assess apprehension related to a negative appearance evaluative experience. The items are answered on 5-point Likert scales from 'not at all' to 'enormously'. The higher the score, the more they experienced fear of negative evaluation by others. This six-item questionnaire was shown to be valid and reliable with a high internal consistency (Chronbach's  $\alpha=0.87$ ) [318]. For this study, we have used a Dutch version that has not yet been validated. We used norm scores of a Dutch control population of women [319].

***Sexarche***

Subjects completed the two items 'Have you ever had intercourse?' and 'How old were you when you had your first intercourse?' of a Dutch questionnaire about sexual functioning [320]. A Dutch control population of girls aged 12-24 who had answered the same questionnaire was used in this study.

**Statistical analyses**

As measures for central tendency the means (for continuous data) and medians were estimated, while as measure for dispersion standard deviation was used. The observed score range was also presented. To test the demographical and clinical differences between PCOS responders and PCOS non-responders Student's t-test was used in case of continuous variables and Fisher-exact test was used in case of categorical variables. Student's t-test for one sample was used to test differences between the study population and norm scores.

To explore the association between the PCOS characteristics, sexarche and the psychological variables the method of multiple linear regression analysis was applied and the independent variables were entered into the regression analysis separately, albeit together with the confounding variables. Dependent variables included the variable sexarche and all psychological variables. Independent variables included the PCOS characteristics that were divided into the dichotomous variables: oligomenorrhoea (0) versus amenorrhoea (1); normandrogenism (0) versus hyperandrogenism ( $FAI>4.5$ ) (1);

no or doubtful hirsutism (0) versus hirsutism (1); few or no acne (0) versus acne (1); no PCO (0) versus PCO (1); and the continuous variable BMI which is associated with PCOS.

Because sexarche might have been prior to the clinical investigation, we entered years between sexarche and clinical investigation as a confounding variable in the regression analyses, besides ethnicity. For the time interval between the clinical investigation and the psychological measures in 2007, we entered the years between the clinical investigation and the psychological measures as a confounding variable in the regression analyses. Ethnicity was entered as a confounding variable because non-Caucasian women appeared to have sexarche later in life compared to Caucasian women and a higher percentage of non-Caucasian women had high clinical scores such as hirsutism. Finally, age was entered as a confounding variable. As a measure of performance of the relevant individual independent variables the standardized regression coefficient ( $\beta$ ) was estimated, including the corresponding p-values. As a measure of discrimination on the psychological measures Cohen's d was used. All analyses were performed using the Statistical Package for the Social Sciences (SPSS version 15.0). All statistical testing took place at 0.05 level of significance (two tailed).

## RESULTS

### Patients

Data were obtained from a total of 1148 WHO II patients, of whom 480 women with PCOS returned the questionnaire and were analyzed in this study. Participation was 51% of whom 42% had PCOS. Table 4.1 shows the demographical, clinical and endocrine characteristics of the responders and non-responders with PCOS in our study. Of the non-responders, 41% was Caucasian unlike 72% of the responders. Moreover, the non-responders with PCOS were slightly but significantly older than the responders. In the non-responding group, a higher percentage of the women with PCOS were overweight or obese and had hyperandrogenism compared to the responders (Table 4.1). Table 4.2 shows that PCOS women had lower self-esteem and poorer body satisfaction compared to norm scores, with Cohen's d scores of -0.12 and -0.17 respectively. We did not find a significant difference for fear of negative appearance between PCOS women and norm scores.

### Clinical characteristics and psychological well-being in women with PCOS

Table 4.3 shows the standardized regression coefficients ( $\beta$ ) and the corresponding p-values of PCOS characteristics and their association with psychological variables of self-esteem, body satisfaction, and fear of negative appearance. Besides ethnicity, we adjusted for age and the time interval in years between the endocrine evaluation and the psychological measures in the regression analyses.

**Table 4.1** Demographical and (bio)clinical characteristics of PCOS (non) responders<sup>1</sup>

|  | PCOS responders<br>(n=480)   | PCOS non responders<br>(n= 463) | P-value <sup>2</sup> |
|--|------------------------------|---------------------------------|----------------------|
| <u>Demographical characteristics</u>                   |                              |                                 |                      |
| <i>Age in years at date of endocrine investigation</i> | 28.8 (4.3) 14.2-40.0 (480)   | 28.0 (4.8) 18.3-43.3 (463)      | .01                  |
| <i>Caucasian</i>                                       | 72.1% (346/480)              | 41.6% (192/461)                 | .00                  |
| <u>Clinical</u>  |                              |                                 |                      |
| <i>Oligoamenorrhoea</i>                                | 71.7% (344/480)              | 75.2% (348/463)                 | .24                  |
| <i>Amenorrhoea</i>                                     | 28.3% (136/480)              | 24.8% (115/463)                 | .24                  |
| <i>Presence of hirsutism</i>                           | 31.9% (99/310)               | 39.9% (109/279)                 | .08                  |
| <i>Body Mass Index (BMI kg/m<sup>2</sup>)</i>          | 26.4 (6.0) [16.8-50.6] (479) | 28.2 (6.6) [15.8-59.8] (479)    | .45                  |
| <i>BMI ≥ 25 (kg/m<sup>2</sup>)</i>                     | 48.6% (233/479)              | 63.0% (290/460)                 | .00                  |
| <u>Endocrine</u>                                       |                              |                                 |                      |
| <i>Hyperandrogenism (FAI&gt;4.5)</i>                   | 53.1% (255/480)              | 67.4% (312/463)                 | .00                  |
| <i>LH</i>  | 7.2 (5.6) [1.0-37.9] (480)   | 8.0 (6.3) [0.5-76.4] (463)      | .11                  |
| <i>FSH</i>   | 4.9 (1.9) [1.1-10.5] (480)   | 4.7 (1.9) [1.0-9.8] (463)       | .13                  |

<sup>1</sup>Values are mean (SD), median (range), range, N, (N/total N), or number (%) of patients.

<sup>2</sup>Significant at a 0.05 level of significance (two-tailed).

**Table 4.2** Psychological measure scores distinguished by study population and norm group

|  | Study population<br>Mean (SD) | Normative data<br>Mean (SD) | P-value <sup>1</sup> |
|--|-------------------------------|-----------------------------|----------------------|
| Self-esteem (RSES)                             | 31.0 (5.4)                    | 31.6 (4.5)                  | .03                  |
| Body Satisfaction (BCS)                        | 3.6 (0.6)                     | 3.7 (0.6)                   | .03                  |
| Fear of negative appearance evaluation (FNAES) | 13.8 (5.9)                    | 14.1 (6.1)                  | .23                  |

<sup>1</sup>Significant at a 0.05 level of significance (two-tailed).

Women with amenorrhoea had lower self-esteem as well as greater fear of negative appearance evaluation than women with oligoamenorrhoea. Menstrual irregularities were not associated with body satisfaction.

Furthermore, women with biochemical hyperandrogenism experienced poorer body satisfaction than women with normandrogenism. Even after adjustment for years

**Table 4.3** The association between PCOS characteristics and psychological variables

|   | R <sup>1</sup> | β <sup>1</sup> | P-value <sup>3</sup> | R <sup>2</sup> | β <sup>2</sup> | P-value <sup>3</sup> |
|---|----------------|----------------|----------------------|----------------|----------------|----------------------|
| <u>Self-esteem (RSES)</u>                                   |                |                |                      |                |                |                      |
| <i>Cycle disturbances (amenorrhoea vs oligoamenorrhoea)</i> | .01            | -.10           | .04                  | .003           | -.10           | .04                  |
| <i>Hyperandrogenism</i>                                     |                | -.05           | .33                  |                | -.05           | .33                  |
| <i>Hirsutism</i>  | .03            | -.20           | .001                 | .03            | -.20           | .001                 |
| <i>Acne</i>   |                | -.03           | .70                  |                | -.04           | .62                  |
| <i>PCO</i>  |                | .02            | .70                  |                | .02            | .71                  |
| <i>BMI</i>  | .01            | -.12           | .01                  | .01            | -.12           | .01                  |
| <u>Body satisfaction (BCS)</u>                              |                |                |                      |                |                |                      |
| <i>Cycle disturbances (amenorrhoea vs oligoamenorrhoea)</i> |                | -.07           | .15                  |                | -.07           | .15                  |
| <i>Hyperandrogenism</i>                                     | .01            | -.10           | .03                  | .01            | -.11           | .02                  |
| <i>Hirsutism</i>  |                | -.11           | .06                  | .01            | -.12           | .05                  |
| <i>Acne</i>   | .02            | -.20           | .02                  | .02            | -.20           | .02                  |
| <i>PCO</i>  |                | .02            | .69                  |                | .02            | .66                  |
| <i>BMI</i>  | .06            | -.24           | .00                  | .06            | -.24           | .00                  |
| <u>Fear of negative appearance evaluation (FNAES)</u>       |                |                |                      |                |                |                      |
| <i>Cycle disturbances (amenorrhoea vs oligoamenorrhoea)</i> | .02            | .11            | .02                  | .03            | .10            | .03                  |
| <i>Hyperandrogenism</i>                                     |                | .04            | .38                  |                | .06            | .18                  |
| <i>Hirsutism</i>  | .02            | .12            | .04                  | .02            | .13            | .03                  |
| <i>Acne</i>   |                | .12            | .16                  |                | .11            | .19                  |
| <i>PCO</i>  |                | .05            | .30                  |                | .04            | .40                  |
| <i>BMI</i>  | .02            | .12            | .01                  | .03            | .13            | .01                  |

PCO, polycystic ovaries; BMI, Body Mass Index.

<sup>1</sup>Standardized regression coefficients adjusted for age and years between clinical investigation and psychological measures.

<sup>2</sup>Standardized regression coefficients adjusted for age, years between clinical investigation and psychological measures, and ethnicity.

<sup>3</sup>Significance level of the corresponding βs.

between endocrine evaluation and psychological measures, age, and ethnicity this association remained significant. No association was found with self-esteem or fear of negative appearance.

Multiple linear regression analysis indicated that hirsute women had lower levels of self esteem, poorer body satisfaction and greater fear of negative appearance evaluation compared to PCOS women without hirsutism.

Acne was associated with poorer body satisfaction but was not associated with self-esteem or fear of negative appearance.

The results in Table 4.3 indicate that no association between PCO and any of the psychological variables could be established. On the other hand, women with higher BMI scores had lower self-esteem, poorer body satisfaction and greater fear of negative appearance evaluation. Again after adjustment for years between clinical investigation and psychological measures as well as age and ethnicity this association remained significant.

### Clinical characteristics of PCOS and sexarche in women with PCOS

We did find a significant association between sexarche and menstrual irregularities (Table 4.4). Women with PCOS and amenorrhoea had their sexarche at younger age compared to women with PCOS and oligoamenorrhoea. This significant difference was also established after adjustment for the time interval between sexarche and the age at endocrine investigation as well as for ethnicity. Exploratory analyses within our study population showed that a higher percentage of non-Caucasian women with PCOS did have hirsutism (47.1%) compared to Caucasian women with PCOS (26.2%) ( $P = 0.01$ ).

**Table 4.4** The association between PCOS characteristics and sexarche

|   | R <sup>1</sup> | β <sup>1</sup> | P-value <sup>3</sup> | R <sup>2</sup> | β <sup>2</sup> | P-value <sup>3</sup> |
|---|----------------|----------------|----------------------|----------------|----------------|----------------------|
| Cycle disturbances<br>(amenorrhoea vs.<br>oligoamenorrhoea) | .29            | -.16           | .003                 | .30            | -.11           | .004                 |
| Hyperandrogenism<br>(FAI>4.5)                               |                | .05            | .21                  |                | -.07           | .08                  |
| Hirsutism   |                | .08            | .10                  |                | .06            | .21                  |
| Acne  |                | -.00           | .98                  |                | .01            | .91                  |
| PCO   |                | -.01           | .89                  |                | .01            | .96                  |
| BMI   |                | -.00           | .95                  |                | -.01           | .84                  |

FAI, free androgen index; PCO, polycystic ovaries; BMI, Body Mass Index.

<sup>1</sup>Standardized regression coefficients adjusted for years between sexarche and clinical investigation.

<sup>2</sup>Standardized regression coefficients adjusted for years between sexarche and clinical investigation and ethnicity.

<sup>3</sup>Significance level of the corresponding βs.

We did not establish any association between sexarche and biochemical hyperandrogenism, hirsutism, acne, PCO or BMI.

## DISCUSSION

The main objective of this study was to explore which PCOS characteristics were associated with self-esteem, body satisfaction, and fear of negative appearance evaluation. Women with PCOS and amenorrhoea had lower levels of self-esteem, greater fear of negative appearance evaluation, and had their sexarche at an earlier age. Furthermore, clinical characteristics such as hyperandrogenism and acne were associated with poorer body satisfaction and hirsutism and BMI unfavorably affects all measured psychological variables.

First of all, our results showed that women with PCOS and amenorrhoea have lower levels of self-esteem and greater fear of negative appearance evaluation compared to women with oligoamenorrhoea. It is imaginable that the absence of vaginal bleeding for a long period of time makes women feel insecure about their fertility as well as their femininity. Indeed, Keegan et al. showed that women with PCOS associated regular menstruation and the capacity to bear children with femininity [321]. Contrastingly, the results of Hahn et al. revealed no differences in QOL and psychological disturbances between patients with amenorrhoea compared to those with oligoamenorrhoea [312].

We also found that hyperandrogenism and acne were associated with poorer body satisfaction. Contrastingly, in the study of Hahn et al. the occurrence of acne versus the absence of it or hyperandrogenism versus normadrogenism were neither associated with QOL nor with psychological distress [312]. However, this study was examining different aspects of psychological distress than we measured.

Furthermore, the current study established that hirsutism was negatively associated with all psychological variables. Firstly, women with PCOS and hirsutism were found to have lower levels of self-esteem than PCOS women without hirsutism. Likewise, Hahn et al. found that hirsutism was negatively associated with sexual self-esteem [312] and Benson et al. indicated that the risk for clinically relevant depression was enhanced in patients who reported hirsutism [301]. In the same line with our results, half of the women with suspected PCOS in the study of Lipton et al. [322] felt that facial hair was greatly affecting their self-confidence and making them worry about their appearance. Contrastingly, Keegan et al. [321] did not report a difference in self-esteem between self-perceived hirsute and self-perceived non-hirsute women. These contradictory results might be explained by the fact that the RSES is a general self-esteem questionnaire which might not always be sensitive enough to measure fluctuations in self-esteem related to physical appearance. In the present study, we also found that women with hirsutism ex-

perienced poorer body satisfaction than women without hirsutism. Contrastingly, other reports did not find a relation between body satisfaction and self-perceived hirsutism in women with PCOS [321]. This difference in results might be explained by the fact that we used different criteria for hirsutism and different questionnaires to measure body satisfaction. Finally, we found that women with hirsutism had greater fear of negative appearance evaluation than women without hirsutism. Likewise, Barth et al. [323] found that two thirds of women with hirsutism avoided some social situations. Benson et al. [301] evaluated anxiety measured with the HADS in PCOS women and did not establish a relationship between hirsutism and anxiety. Women with excessive hair growth might experience feelings of discomfort in social contacts and fear for the evaluation of others concerning their appearance, rather than general anxiety.

Our results also indicate that BMI unfavorably affects all measured psychological variables self-esteem, body satisfaction, and fear of negative appearance. These findings support other studies in PCOS women that have shown that obesity decreases QOL [324] and may be a risk factor for psychological distress [303].

Comparisons between our study population and norm groups showed that PCOS women had lower self-esteem and poorer body satisfaction. However, the group differences were very small.

Furthermore, we explored whether in our study population sexarche was associated with the clinical PCOS characteristics. Surprisingly, we found that women with PCOS and amenorrhoea have sexarche earlier in life than women with oligoamenorrhoea. Women with PCOS and amenorrhoea might feel much safer during intercourse because they might believe that they are not fertile. Research is needed to further explore this relation. We found no association between bio- and clinical hyperandrogenism or BMI and sexarche. As expected, we revealed no association between PCO and sexarche. This finding might be explained by the fact that PCO is not a visible, readily detectable characteristic.

It is important to consider some drawbacks of our study. First of all, the PCOS patients in our study completed the questionnaires later in time than the laboratory and clinical tests were performed. Patients reasonably would have scored the psychological questionnaires different at the time when laboratory and clinical parameters were measured and reported to them. Therefore, we also adjusted for the time interval in years between the endocrine evaluation and the psychological measures. Secondly, we did not include a matched control group. The current results therefore particularly apply to differences within the PCOS population. Furthermore, we do not know whether the sexarche results of this Dutch study may be generalized to other countries, because of possible differences in sexual morality and cultural backgrounds in different countries. Finally, the non-responding rate in our study was high. This might be due to a high percentage of non-Caucasian patients in the non-responding group. A possible explanation is that the



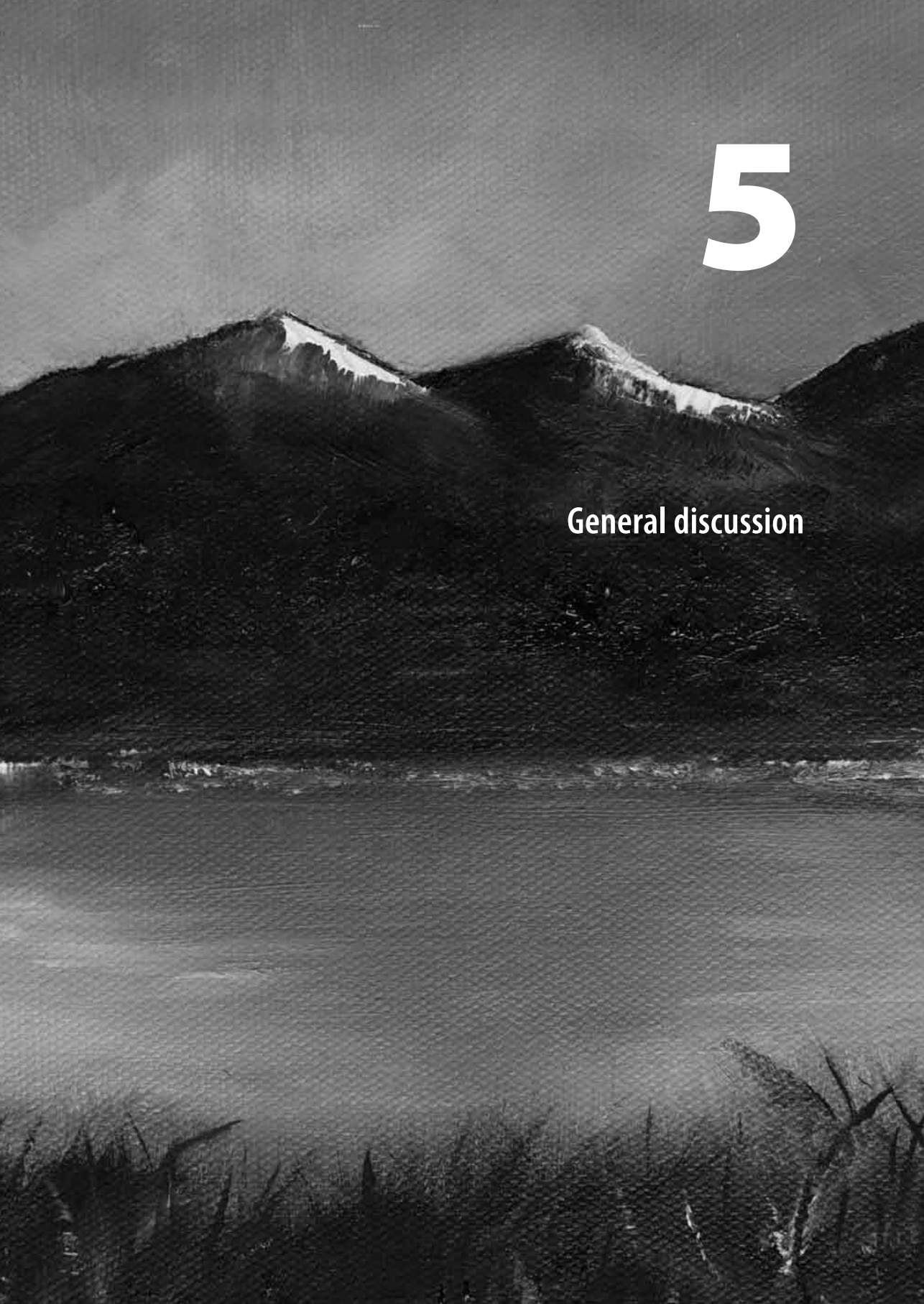
Caucasian non-responders had trouble completing the questionnaires due to insufficient command of the Dutch language. Therefore the results could not be generalized to all women with PCOS. Furthermore, it might be that those women returning the questionnaire were those PCOS women whose psychological well-being was the least affected by their disease. In the latter case the impact of PCOS on psychological well-being might even be underestimated. The impact of PCOS on self-esteem, body satisfaction and fear of negative appearance established in the current study might also be underestimated because the non-responders harbored the more pronounced phenotypes.

Our results suggest that amenorrhoea is associated with sexarche and that amenorrhoea, hyperandrogenism, hirsutism, acne, and BMI are negatively associated with self-esteem, body satisfaction, and fear of negative appearance evaluation. Future research should study these associations further against control populations and other aspects of sexuality, such as the number of sexual relations, the relation between endocrine variables and libido or the time span between different relations. It is important for physicians to pay attention to the physical aspects of PCOS as well as to the psychological aspects. Previous researchers suggested that clinicians should screen women with PCOS for psychological disorders (e.g. anxiety and depression). Our results suggested that clinicians should also be aware of other psychological distress that women with PCOS may face, such as low self-esteem and body dissatisfaction. In cases of impaired sexual and psychological health, patients can be referred to a psychologist or sexologist. BMI as well as hirsutism and amenorrhoea seem to be important factors that influence psychological domains in PCOS patients. About fifty percent of all women with PCOS are overweight, compared with thirty percent of women in the general European population [69]. We recommend physicians to encourage overweight women with PCOS to lose weight and to provide a proper advice concerning reproductive lifestyle.



# 5

General discussion





## 5.1 INTRODUCTION

*‘If we could give every individual the right amount of nourishment and exercise, not too little and not too much, we would have found the safest way to health’.*

The quote of Hippocrates shows that in 460 BC the belief in the relation between living habits and health already existed. Centuries later, scientists have gathered an extended amount of knowledge on the influence that diet and exercise can have on health. Unhealthy dietary habits [325-327], a lack of physical activity [327-331], and sedentary behaviors [30, 327, 329, 331, 332] are lifestyle patterns that were found to play an important role in the onset of overweight and obesity. Therefore, the treatment of overweight and obesity is aimed at changing these lifestyle behaviors [293, 326, 333-336].

Hippocrates description about the safest way to health seems a reasonable approach and easy to achieve. However, losing weight as well as maintaining weight loss is far from easy. Despite the difficulty of losing weight and maintaining weight loss, research supports that at least short-term weight loss can be achieved by medium to high-intensity behavioral treatments [110, 111, 116]. In addition, studies indicate that the greatest benefits can be achieved when the battle against obesity starts at young age [105].

The focus of this dissertation was mainly on overweight and obese children and adolescents. Not all children seem to benefit from obesity treatment. Health care professionals could improve their treatments by increasing their knowledge of predictors of treatment success. Hence, the first aim of this dissertation (Chapter 2.1) was to evaluate child and familial characteristics presented at the start of a family-based behavioral group treatment, the Big Friends Club (BFC) program, and the influence of these characteristics on treatment success.

Dropout in the treatment of childhood overweight and obesity has shown to be problematic: dropout rates as high as 90% were found [137]. Due to selective dropout, studies that did evaluate long-term weight loss are prone to be biased in the positive direction. Factors and characteristics associated with dropout have been studied by few researchers. The aim of the study presented in Chapter 2.2 was to evaluate baseline characteristics of the child and parents’ dropout in various stages of treatment. We hypothesized that dropout might depend on different characteristics at various stages in the treatment.

Innovative methods in the treatment of overweight and obesity include the use of time efficient techniques with minimal effort that might be especially attractive for children. It has been recommended that tailored interventions and less intense intervention strategies should be implemented to help children achieve healthy behaviors [207]. Behavioral methods, such as providing information, rehearsal of relevant skills, self-monitoring, social support and encouragement, and modeling in order to realize

behavior change, can be integrated into interventions to provide extra support. Various studies evaluated tailored interventions aimed at improving healthy behaviors with the use of innovative interventions through the web [138, 141, 337-340], phones [145], or personal digital assistants [341]. Considering obesity is a chronic condition, individuals will need follow-up care to support maintenance of healthy behaviors. Chapter 3 presents a randomized controlled study evaluating a Short Message Service Maintenance Treatment (SMSMT) through mobile phones aimed at reducing dropout from the BFC for overweight and obese children and adolescents.

We also explored the effect of the SMSMT on Body Mass Index (BMI), psychosocial well-being, and healthy behaviors in addition to the BFC (Chapter 3.3).

The incidence of obesity is greater in women with PCOS than in the general population [69, 70]. Women with PCOS who are obese are at increased risk for health problems and these risks appear to multiply in PCOS women who are being treated for fertility problems or who are pregnant [72, 73, 75, 77, 342]. Accordingly, lifestyle programs designed for this specific population are greatly needed. Several studies in PCOS women found that a higher BMI significantly contributed to impaired quality of life [306, 308, 312], decreased self-esteem [303], and sexual dissatisfaction [308]. However, the treatment of women with PCOS is mainly focused on the physical consequences of PCOS. A better understanding of the association between the characteristics of PCOS and a higher BMI and psychosocial well-being might further improve the treatment for women with PCOS. The last aim of this dissertation (Chapter 4.1) was to study which characteristics of PCOS are associated with psychosocial well-being and sexarche, as the first step for a developed lifestyle program combined with SMSMT for PCOS women.

## **5.2 MAIN FINDINGS**

### **5.2.1 What is the description of children and their family that benefit the least from the treatment?**

In our study described in Chapter 2.1, children that benefited the least from the treatment in terms of BMI-SDS were characterized by a higher BMI-SDS at the start of the BFC program, being older, having a non-Caucasian ethnicity, having fewer social activities and contacts, having obese parents, and having more somatic complaints. We found that baseline BMI-SDS at start was the most important predictor of treatment success over the period of one year. With respect to child characteristics as predictors of treatment success, contrasting results have been found with respect to BMI-SDS and treatment success [193, 194]. Epstein et al. [125] found that heavier children at baseline had more weight loss only during the first 2 months of treatment. It might be that heavier children

are more motivated to lose weight at the beginning of the treatment, but that this effect disappears or changes in the long term.

Other studies also found that older children benefit less from treatment [193, 194, 343]. It seems easier for younger children and their families to use behavioral modification skills and to improve health behaviors. Younger children might implement new health behaviors better because they are more flexible to make adjustments and depend more on their parents and the treatment team than older children.

The results showed that non-Caucasian children had less successful treatment outcomes. This finding is in line with the results of other studies [132, 134] and suggests that more culturally relevant treatment materials need to be developed for this group. Culturally different health attitudes and values might have played a role in the adherence to the treatment of non-Caucasian children. The cultural values and norms of these children and their families with respect to health behavior might have been different and may have influenced the implementation of this behavior. Brussaard et al. [344] studied nutrition and health among migrants in the Netherlands. They found that Turkish and Moroccan migrants showed both positive and negative differences in diet intake compared to the general Dutch diet, as well as that they skipped breakfast more often. The lower socio-economic status (SES) of migrant groups partly explained the differences in health status, such as overweight. Another study among children and adolescents in Germany indicated that Turkish and Russian migrants had a less favorable diet compared with non-migrants. These groups tended to consume higher amounts of soft drinks, potato chips, and snacks [345]. However, migrants also tended to consume more fruit. In their study, SES was also negatively associated with healthier food intake. Although we do not have compelling evidence yet, these results might reflect differences in the food culture of migrants and non-migrants which in turn may have accounted for less treatment success.

Children with more somatic complaints achieved less weight loss. Experiencing more aches, headaches, stomach pains and feeling dizzy and overtired more often might have prevented children from adhering to a healthy physical activity pattern and from doing activities outside the house. Previous studies found an association between somatic symptoms and coping [346]. More passive coping was related to a higher degree of somatic symptoms and pain. Passive coping generally involves orientation away from something stressful, in this case pain, and includes responses such as self-isolation, catastrophizing, and disengagement. In contrast, accommodative coping (acceptance, minimizing pain, self encouragement, and distraction) has been related to fewer somatic complaints [347]. In addition, another study showed that proactive coping, generally described as doing something in response to pain or symptoms was related to behavioral change and maintenance in diabetes patients [348]. In our study population, children with more somatic complaints may have used passive coping styles which may have negatively influenced treatment success by poorer adherence to a healthy eating

pattern and physical activity. They might have been more vulnerable to engage in self-isolation and 'doing nothing' than doing something in response to their complaints.

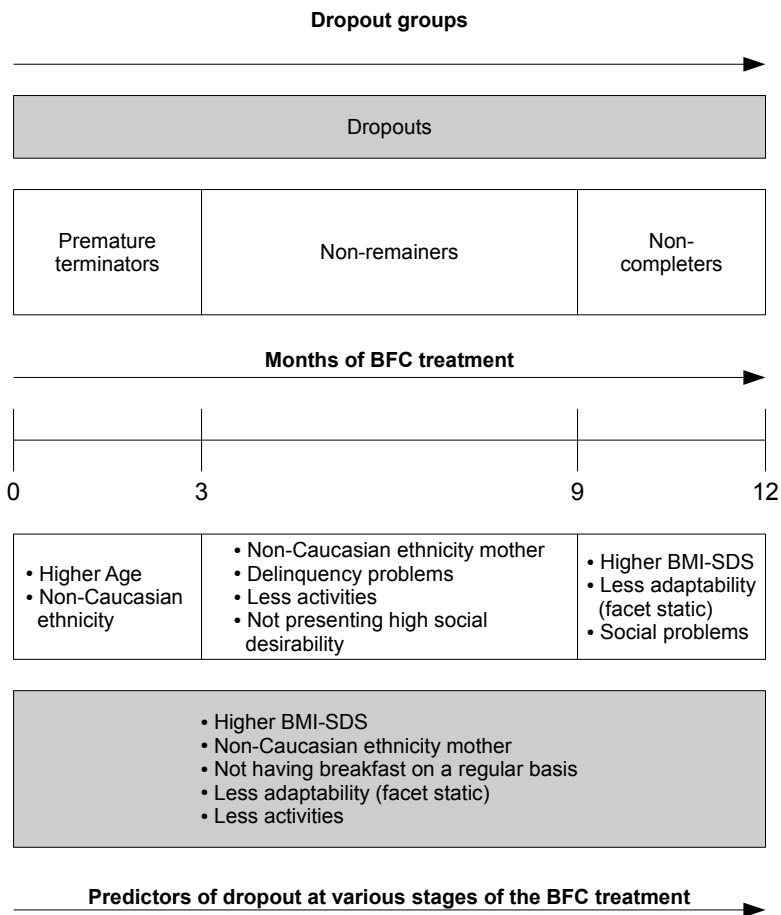
Furthermore, children having fewer friends, having less frequent contact with friends, and participating less in organizations achieved less treatment success. It is conceivable that children with fewer social activities and contacts are involved in more indoor (sedentary) activities and therefore are less physically active. Fewer social activities and friends might be caused by not being or feeling accepted by their peers. Being obese is related to being bullied in youngsters and might lead to decreased self-esteem and feelings of loneliness [90, 210, 211]. This in turn might lead children to engage less in social activities, physical activity and increased unhealthy eating. One study found that higher levels of reported peer support (e.g. complementing on eating behavior and greater encouragement of physical activity) and lower levels of peer sabotage (e.g. offering foods high in fat and suggesting doing physically inactive things) were associated with less 2-year weight gain in young healthy women [349]. Epstein et al. [84] found that greater social problems in children predicted a greater increase in weight during follow-up. Social problems such as feeling lonely, not getting along, getting teased, and feeling dependent might result in being less physically active.

We also found that the familial characteristic parental obesity predicted less weight loss. This finding is in line with previous studies [103, 125, 193, 194, 343]. Having a mother and/or a father who is obese might discourage children to change their health behavior and manage their own weight by the modeling of less healthy parental lifestyle behaviors. Parental participation in the treatment plays an important, positive role in the weight loss progress of their children [118]. Improving health behavior as a family seems to be important in improving healthy habits and achieving weight loss. Positive relations have been observed between the parent and the child's weight loss [125]. Parents' health behavior has been found to predict weight change in their children [350]. Furthermore, it was found that parental practices and styles influence children's health behaviors related to weight [32-34, 40-42] as well as that the parents' health behavior predicted weight change in their children [350]. Parents' health behavior may also have an impact on the child's understanding of the seriousness and the negative consequences of overweight and obesity. We did not find that family climate predicts treatment success. However, another study did find that family adaptability was associated with greater weight loss after three months of treatment [193], indicating that families who were more flexible had a greater ability to adopt changes. In relation to health behavior, family cohesion has been found to be associated with less soda intake and higher rates of breakfast consumption in adolescent girls [35]. These studies showed that family climate may be an important contributor to improving health behavior. The results of our study might indicate that family cohesion or adaptability might have been predictive in relation to health behaviors instead of weight loss.



### 5.2.2 Who is more vulnerable to dropout of the treatment?

The study presented in Chapter 2.2 revealed a picture of the children and families who dropped out at various stages of the BFC program. We distinguished dropout in several dropout groups, namely: (1) dropouts; (2) premature terminators; (3) non-remainers and (4) non-completers. Children who were more vulnerable to dropout were overall older, were non-Caucasian, and had a higher weight at the start of the treatment. Furthermore, they were more likely to ignore rules, had friends who got into trouble more often, did not have breakfast on a regular basis, had fewer activities, and had parents who rated them as more independent and mature. If we take a closer look at their family, having a mother with a non-Caucasian ethnicity, a lack of clearly stated rules, and providing a less idealized representation of their family were all independent predictors of dropout at various stages of the BFC program (Figure 5.1). What do these results mean?



**Figure 5.1** Predictors of dropout at various stages of the BFC treatment

Non-Caucasian ethnicity of the mother was found to predict dropout in the non-remainers group and in the dropouts group as well, whereas a non-Caucasian ethnicity of the child was a strong predictor for premature terminating during the intensive treatment. The finding that ethnicity is an important predictor of dropout in the treatment of childhood overweight and obesity corresponds with the results of other studies [132, 134]. This finding is especially important since a higher prevalence of overweight and obesity is observed in racial-ethnic minority populations, especially in black people, compared to in white people [351]. It is imaginable that cultural differences might have led to dropout. Non-Caucasian children might have had troubles connecting with other peers in the group sessions due to cultural differences. Furthermore, mothers with a non-Caucasian ethnicity might have had trouble finding activities and healthy eating habits that correspond with their cultural norms and values.

In line with previous research [102, 132], we found that older children were only more vulnerable to dropout during the more intensive group treatment. It might be that older children felt uncomfortable in groups with younger children, were more in need for autonomy, or preferred another form of treatment than group therapy. In addition, older children might have had other activities such as homework that interfered with attending the group sessions. Generally, in the literature the results are in favor of group-based interventions. Studies show that group therapy contributes to lower dropout rates [352] and greater maintenance of weight loss [353] when compared to individual treatment. Replacing group therapy with individual therapy might reduce treatment success. Therefore future research should focus on improving group treatments for older children rather than replacing group therapy with individual therapy.

Higher BMI-SDS at baseline predicted dropout in the non-completers as well as in the dropouts group. The failure to achieve weight loss during treatment might result in less self-efficacy and motivation, which subsequently could result in dropout. In addition, children with higher BMI-SDS at baseline might have engaged in previous unsuccessful weight loss attempts resulting in a decreased belief of being successful in this treatment. In adults it was found that dropouts were less likely to feel successful in weight control and behavior change, even though their weight loss results did not differ from completers [354] and that previous unsuccessful weight loss attempts resulted in dropout [355-358].

More delinquency related problems predicted dropout in the non-remainers group. During this period, there was a transition from regular contact with the health care providers to a period of less intensive contact. Less intensive guidance might have shifted their focus on the program to problems they experienced before the start of the treatment such as getting along with troubled peers, lying and stealing. An overall lack of discipline might have also contributed to this finding. Non-remainder status was also associated with parental reports that their child is involved in fewer activities such as

sport and hobbies. Previous research has indicated practical and organizational barriers as reasons for dropping out obesity treatment [130]. Participants in our study may have encountered such barriers.

The finding that less social problems predicted dropout in the last three months of the follow-up period might be explained by the feeling of being less in need for follow-up treatment. In addition, children with social problems are characterized by being dependent and behaving immature. It is imaginable that independent and mature children rely less on the treatment and support that is provided during the follow-up sessions which caused them to dropout.

We found that not having an authoritative family functioning is a predictor of being a dropout or a non-completer. Authoritative families are characterized by strict rule setting and solutions. Having clearly stated rules as a family seems to help families to attend treatment and follow-up appointments. Parents' clearly stated rules may provide a certain structure which seems to overrule reasons for not attending appointments. In line with our results, Kirschenbaum et al. reported that a chaotic family environment, in other words families that are less flexible, poorly organized, and had a lack of clearly stated rules, were more likely to dropout of treatment [359]. The finding that dropouts eat breakfast on a less regular basis might be linked to family functioning. It might be that children who consume breakfast less frequently tend to live in families characterized by less authoritative and more chaotic family functioning. There is some evidence that children who described their parents as authoritative eat breakfast on more days [38, 39].

Our results showed that parental report of less social desirability was related to non-remaining. Parents who are not trying to present their family in a socially desirable way might be less sensitive to what others think of their prematurely leaving the program. Being sensitive to what others think might motivate families to adhere to the treatment because they are sensitive to being criticized by their environment.

We used the same sample of overweight and obese children in the study on predictors of treatment success and the study on predictors of dropout. Corresponding results were found in both studies indicating that those children and families showing the least treatment success also seem to be the most vulnerable to drop out of the treatment. We showed that older, heavier, and Non-Caucasian children achieved less treatment success. Likewise, these characteristics also predict dropout at various stages of the treatment. Future research should study the mechanisms behind these characteristics and develop programs with the emphasis on improving treatment success and decreasing dropout rates in these specific groups.

### 5.2.3 Is SMSMT a helpful adjunct to childhood obesity treatment?

Little is known about interventions that might decrease dropout rates. SMS has several advantages, such as the accessibility almost anytime and everywhere and the low costs [256]. New technology programs might extend the reach of health care providers in the treatment of overweight and obesity. Research on SMS interventions and its effect on health behavior is increasing, but is still in its infancy [146] and has been studied scarcely in children. Maintaining weight loss after intensive treatment is a challenge for most individuals. Therefore, approaches with the emphasis on the maintenance of already achieved improvements are needed. Hence, we developed an SMS maintenance treatment for overweight and obese children introduced after the intensive first three months of the BFC program.

Chapter 3.1 discusses new technology approaches in health care and the preliminary results on the feasibility of our SMSMT in overweight and obese children. In our study, we used SMS as the method of a 'step down' or maintenance intervention. The results in Chapter 3.2 showed that adherence to self-monitoring in SMSMT completers in the first 3 months of SMSMT (80%) is comparable to 84% adherence to self-monitoring using an SMS program in bulimia nervosa patients [152]. Compared to other studies using SMS in health care [157, 360], our preliminary results revealed greater adherence to self-monitoring. In the same line with previous studies that compared adherence to paper & pencil diaries to electronic diaries [157, 176], we also found greater adherence percentages with our SMSMT compared to paper & pencil self-monitoring in other studies (adherence of 11-19%) [157, 361]. The use of information and communication technology (ICT)-based software programs in our SMSMT facilitates the process of tailoring feedback in relation to the child's outcome monitoring. The preliminary results showed that a greater BMI-SDS reduction in the intensive treatment period was related to more SMSs during the SMSMT. The number of text messages was not related to BMI-SDS change in the maintenance period. However, the majority of the participants stabilized their BMI-SDS during maintenance treatment. After this pilot study, a randomized controlled study was conducted to answer the question whether SMSMT is a helpful tool to childhood obesity treatment.

### 5.2.4 The effect of SMSMT on dropout rates

The aim of our multi-site randomized controlled trial in Chapter 3.2 was to reduce dropout rates by the use of SMSs, since dropout rates in the treatment of overweight and adolescents are high. The results presented showed that SMSMT is an effective additional intervention in reducing dropout from the BFC program.

Which mechanisms related to the SMSMT might have explained reduced dropout rates? The personalized feedback provided in our SMSMT intervention might have increased children's engagement and motivation [177]. Weight control skills such as self-

monitoring have been shown to be associated with better treatment outcomes [169, 362]. Self-monitoring might have enhanced the children's awareness of their health behavior and their recognition of their health status which in turn may have increased their willingness and motivation to attend the follow-up visits. The SMSMT intervention is focused on the child's self-monitoring only. Children were almost always accompanied by their parents at follow-up visits. One could hypothesize that parent's motivation to go to follow-up visits with their children is also indirectly increased, since parents are mostly the ones who take the responsibility to go with their children to the sessions. It has been reported that the child's desire not to return to the clinic is one of the parent reported reasons for dropout [128]. It might be that the child's desire to return to the clinic was increased by the SMSMT which in turn influenced the family's participation in the BFC program. The parents might also be more motivated to return to the clinic by the extra attention and support that is given to their children. In the conversations with the families and children that completed the SMSMT, many of the parents pointed out that they appreciated the additional care and considered the SMSMT as a helpful tool to stimulate and motivate their children.

The relatively high number of SMSs sent by children who dropped out of the SMSMT intervention as well as out of the BFC program, might imply that these children experienced the SMSMT as a feasible intervention. Other factors such as practical issues or environmental influences to go to follow-up visits might have outweighed participating in the SMSMT intervention and returning to follow-up. It would be interesting to study the reasons for dropout in this specific group. The results also showed that SMSMT seems to be more feasible for younger children. Younger children sent more SMSs, which might indicate that the SMSMT was more attractive to younger children. It might also indicate that younger children were more in need of additional support. Another possible explanation is that younger children were more driven by parent conscientiousness as parents might remind or stimulate them more to participate in the intervention than parents of older children.

### **5.2.5 The effect of SMSMT on BMI, psychosocial well-being, and healthy behaviors**

In Chapter 3.3 we explored the effect of the SMSMT on BMI-SDS, eating behavior, competences and self-esteem, and on physical and psychosocial quality of life. We compared the same two conditions as in Chapter 3.2: the SMSMT intervention group and the no SMSMT control group. Despite some evidence in other studies that the use of SMS has positive short-term behavioral outcomes [145], we were unable to replicate these outcomes. No significant differences between the two groups were found on BMI-SDS, emotional and restrained eating, athletic competence, physical appearance, global self-worth, and psychosocial health in favor of the intervention group. According to Social Cognitive Theory [158, 159], self-efficacy is needed for health behavior change and must be developed

specifically for health behaviors, such as being physically active and healthy eating. Self-efficacy might be improved by self-regulation skills such as self-monitoring and goal setting. Although the SMSMT included both self-monitoring of specific health behaviors and goal setting, the SMSMT program may have been too limited to establish differences in the study outcomes. The children were requested to send in answers on three standard questions weekly. Self-monitoring with respect to health behaviors consisted of sending in two numbers representing the number of days of exercising as well as of healthy eating in the previous week. The low frequency of self-monitoring as well as the fact that children only received one tailored feedback message in a week might not have had the effect we were aiming for. In addition, significant improvements might have been achieved during the first three intensive months of treatment. Consequently, significant effects may have been more difficult to find in the maintenance period. We did find that the control group had a greater reduction of external eating scores and an increase in physical health scores over a one year period compared to the intervention group, though this increase was somewhat moderated in the long run. The absence of a better result in the SMSMT group might also have been caused by another mechanism. Children who would have dropped out without the SMSMT may have had poorer treatment outcomes. Because these potential dropouts were retained in the SMSMT condition, they may have contributed to the poorer treatment outcome of the SMSMT condition. Thus, retaining these children in the BFC program may have moderated the mean treatment effect of SMSMT. Our results are in line with another study in adolescents with type I diabetes using pedometers and weekly text messaging as motivational tools. After three months no differences were found in physical activity, BMI-SDS or quality of life between adolescent in the intervention group and the control group receiving usual care [282]. This study did also find a trend toward lower quality of life in the intervention group.

We found that children in the SMSMT completers group sent on average two thirds of the requested SMSs over a 9 month period. In the first 3 months they sent about 80% of the weekly requested SMSs. Deterioration of adherence to self-monitoring is also reported in other studies [163, 169, 170]. Overall, this can be conceived of as an indication of the feasibility of SMSMT. Still, 12 children dropped out of the SMSMT but did return to the BFC follow-up. During the first 3 months of SMSMT these children sent significantly less SMSs (55%) than the SMSMT completers and treatment dropouts (78%). In another study, adolescents participating in an obesity management intervention were provided with semi-personalized e-mail contact and SMSs monthly for 10 months [363]. The reply rate of these adolescents was lower (22%) than the reply rate of the children participating in our study. In their study, no difference was found between adolescents who replied between 0 and 2 SMSs and those who replied more than three SMSs on BMI-SDS. We can conclude that research on the feasibility and the effect of SMSs on BMI-SDS and psychological well being is still in its infancy.

Our primary hypothesis that the SMSMT would reduce dropout rates was confirmed in the randomized controlled trial. However, the hypothesis that text messaging might set up a supportive context for youngsters in further improving their weight loss and psychological well-being after intensive treatment was not confirmed in our study. Failing to find significant effects does not mean that the program is not useful in other formats. Future research is needed to improve the SMSMT and to study its effectiveness to the maintenance treatment.

### **5.2.6 Do PCOS characteristics influence psychosocial well-being and sexarche?**

The study presented in Chapter 4.1 shifts from an overweight and obese childhood population to a population of women with PCOS. The prevalence of obesity is higher in women with PCOS than in the general population [69]. The presence of obesity in PCOS women is associated with various physical [69, 70, 297, 299, 364, 365] and psychological consequences [303, 308]. Further, the combination of obesity and PCOS in women being treated for fertility problems is associated with less favorable treatment and pregnancy outcomes [73, 75, 77, 78, 366-368]. In the study presented in Chapter 4.1 we evaluated which PCOS characteristics were associated with self-esteem, fear of negative appearance evaluation, body satisfaction, and sexarche. We found that amenorrhoea was associated with lower self-esteem, greater fear of negative appearance evaluation, and earlier sexarche than PCOS women with oligomenorrhoea. Both hyperandrogenism and acne were associated with poorer body satisfaction. Furthermore, hirsutism and BMI were negatively associated with all psychological variables. Although amenorrhoea is a non-visual characteristic of PCOS, women might feel insecure about their femininity and their fertility due to the absence of vaginal bleeding for a long period of time. One might speculate that women with amenorrhoea have their first intercourse at a younger age because they felt safer during intercourse caused by the belief that they are not fertile. Furthermore, the result hirsutism is related to impaired outcomes on all psychological measures is in line with the results of other studies that found that hirsutism is related to impaired psychosocial and sexual functioning [301, 312, 322, 323].

Our study showed that a higher BMI was related to impaired outcomes on all psychological measures. Various studies have investigated the effects of weight loss and weight loss interventions in women with PCOS, indicating the beneficial effects of weight loss on the clinical and biochemical manifestations of PCOS [369-372]. Specifically, weight loss has been shown to decrease abdominal fat [373, 374] and to improve insulin sensitivity [373-375], menstrual cyclicity and fertility [374, 376-379]. Likewise, self-esteem [376] and quality of life [380] have found to be improved by weight loss. These findings suggesting a negative association between higher BMI on the one hand and physical and psychological health and treatment outcomes on the other hand highlight the need for interventions targeting weight reduction in this specific population. The positive ef-

fect of weight loss on physical and psychosocial health related domains also support the need for weight loss interventions.

### 5.3 STUDY LIMITATIONS AND DIRECTIONS FOR FUTURE RESEARCH

The studies presented in this dissertation have several strengths (e.g. sample size, randomized controlled trial, validated questionnaires) and several drawbacks. As with most of the psychological studies evaluating long-term results of treatments for overweight and obese children and their families, our study presented in Chapter 2.1 showed a dropout rate of 39% after one year of treatment and follow up. This might have introduced a reporting bias. Hence, we analyzed the course of BMI-SDS in time with mixed modeling. This is a multilevel regression technique that allows the use of incomplete cases if missing at random. In the two studies evaluating predictors of treatment success (Chapter 2.1) and predictors of dropout at various stages of the BFC program (Chapter 2.2), we studied a selected number of variables. However, we know from the literature that additional child and parental characteristics and process variables seem to be important in the prediction of treatment success as well as dropout. Examples of these other variables include previous weight loss attempts [355-358], self-efficacy [355], and change in the child's [125] and parent's BMI [121] during the first months of treatment. Dropout has also been found to be related to the number of attended sessions in weight management interventions [192, 362, 381]. Another limitation is that we have not measured parents' and children's reasons for dropout. Although previous studies have evaluated reasons for dropout in childhood and adolescent weight management programs [128-130], it would have been interesting to have knowledge about the reasons for dropout in the BFC program specifically. We do know that financial resources were not a barrier to engage in the BFC program since the costs were covered by the insurance company or hospital. In addition, future research should specifically study perceived barriers in ethnic populations. A broader understanding of the personal, social-contextual, and interpersonal factors that predict dropout in ethnic minority groups might improve adherence to treatment in these specific populations. For example, it has been found that the relationship between the parent and the therapist influences the rate of the parent's participation in a conduct problem group-based prevention program [382]. In that study, it was found that family coordinator-parent racial and socioeconomic similarity and relevant life experiences were related to therapeutic engagement.

The SMSMT intervention in its current form reduced dropout rates significantly. Though a strength of the SMSMT intervention was the simplicity of the program with a minimal time investment for both the health care provider and for the participant as well, the SMS program might have been too limited to improve BMI-SDS and psycho-



logical well-being. However, failing to find significant effects with respect to weight and psychological well-being does not mean that the program is not useful in other formats. Future research is needed to confirm the current findings. Furthermore, we have several suggestions for how the SMSMT could be improved.

First of all, other self-efficacy enhancing strategies to improve engagement in healthy behaviors besides self-monitoring and goal setting could be implemented in the SMSMT. For example, problem solving to reduce barriers to healthy eating, a stronger emphasis on coping with difficult situations, and identifying peer support are skills that might be addressed in the SMSMT. Additionally, stimulating educational SMSs with the emphasis on the fun and pleasant part of exercising might be considered [180]. Although the children had the choice to send an SMS any time they felt the need to, future research should stimulate this by sending more frequent SMSs to the participants. Fry and colleagues [383] found some evidence for enhanced effectiveness of health behavior interventions when messages, reminders, or brief feedback received by mail, phone or SMS were sent more frequently. It is also interesting to study if health behavior improves when the children self-monitor daily instead of once every week. We measured physical activity and adherence to a healthy eating pattern only by asking the children how many of the week days they had adhered on a 5-point Likert scale. Validated measures of physical activity and dietary intake should be evaluated in order to draw significant conclusions with respect to the effect of SMSMT on health behaviors.

Although obesity is a chronic disease with multiple physical and psychological health consequences, about 52% of the moderate-severe obese and only about 35% of moderate obese adolescents express concerns about losing weight for medical reasons [384]. According to the Self-Regulatory Model of illness representations [385], individuals create mental representations of their illness. These representations include beliefs and expectations about their illness. These representations guide the development of illness coping behaviors and outcomes. Illness representations of both short-term treatment effectiveness and perceived consequences seem to be predictors of dietary self-care [386]. Children who believed that following their dietary recommendations was needed to control their diabetes were more likely to follow the recommended dietary activities. In addition, beliefs about the effectiveness of self-care and the perceived seriousness of their illness predicted physical activity in diabetes patients [387]. Future obesity interventions should implement SMSs that help youngsters to challenge misconceptions and erroneous beliefs regarding obesity and treatment and the relation to their health.

An additional possibility is to include parents in the SMSMT so that they also receive SMSs to assist them in improving their own health behavior. Behavioral internet based interventions in which the parents were also involved resulted in decreased body fat and lowered dietary fat intake in children and a decreased body weight and lowered dietary fat intake in parents [388].

More rigorous research is needed to understand the underlying mechanisms that promote behavior change in the treatment of overweight and obesity. With respect to the SMSMT, it might be that sub-populations of children and adolescents benefit more from SMSMT. We found that younger children sent more SMSs. It might be that children with specific family characteristics, such as low support, high conflict, or single parent caregivers, benefit more from the SMSMT presented in this study.

Finally, a limitation of the study evaluating the association between PCOS characteristics and psychological well-being and sexarche is that the clinical and laboratory measures were mostly taken a considerable time before the measurement of psychological well-being. In addition, as with many psychological studies, high non-response rates (49%) might have introduced a bias. It might be that women who did not respond were the most affected by their disease. We did find that more non-responders were non-Caucasian, overweight and that more non-responders had hyperandrogenism. Today, the treatment of PCOS is mainly focused on the physical consequences. Future studies should evaluate psychological treatment of PCOS women and the effect of different approaches in the treatment of PCOS on psychological well-being.

## 5.4 CLINICAL IMPLICATIONS

The studies presented in Chapter 2 showed various predictors of treatment success and dropout. Although there has been much progress in the field of childhood obesity treatment, not all children benefit from treatment. How can we use the knowledge of previous studies and our results to improve obesity treatment? First of all, the finding that younger children achieve greater treatment success highlights the importance of starting treatment at young age. Studies evaluating possible mechanisms underlying predictors are warranted to improve the treatment. Understanding why younger children benefit more from treatment could lead to effective ways to adapt the treatment which makes the treatment also more effective for older children. Treatment should also take into account differences in cognitive abilities between elementary school children, preadolescents, and early and late adolescents [389]. Depending on the developmental level, different age groups might need different materials and the use of different teaching techniques might be required.

Despite previous evidence that ethnicity is a predictor of treatment success and dropout in the treatment of overweight and obesity, little research has been conducted to investigate the reasons behind high dropout rates in specific ethnic populations. Previous research has indicated that ethnic minority children had higher levels of television viewing [390, 391] and lower levels of moderate to vigorous physical activity [390]. Non-Caucasian parents as well as their children should be interviewed and be

involved in the development of studies aimed at evaluating the underlying mechanisms of treatment success and dropout rates and improving treatment success. As Epstein and Wrotniak [389] argued, when two different treatments result in the same BMI-SDS change but differ in variability, the treatment of choice might be the one with smaller variability. However, when treatment success as well as variability differs, this choice would be much more challenging. One might say that different treatments should be developed for various groups with specific characteristics, but a more time and cost effective strategy might be to tailor the treatment so it best meets children's and families unique characteristics. Tailored treatment material might improve adherence to healthy behavior and treatment in non-Caucasian children and their families. It has been shown that targeted messages and materials for African Americans taking into account cultural, behavioral, and psychological characteristics have been more effective in improving fruit and vegetable intake and physical activity than general targeted messages [392, 393]. Similarly, taking into account the ethnic identity including elements such as religiosity, collectivism, and racial pride, has been shown to improve fruit and vegetable intake at 18-months follow-up in African American adults receiving content tailored health magazines [394], and non-significantly improved fruit and vegetable intake after 3 months follow-up in another study [395].

Our data showed that children with higher BMI-SDS have reduced treatment success and are also more vulnerable to dropout. In addition, severely obese children seem to have more health risks [9, 217]. Children in the 99th percentile of BMI for age may be candidates for weight management medications as adjunctive therapy [9, 217]. However, the effectiveness of medications need further research [207]. Bariatric surgery and gastric bypass procedures have generated growing interest in the treatment of severely obese adolescents [207]. However, more research is needed due to a lack of safety and efficacy data on bariatric surgery in adolescents.

During the BFC treatment the parents are taught about parent-child interaction patterns, about how to support their child instead of controlling them, how to give positive feedback, and how to apply positive reinforcement. The findings in this dissertation that parent reported somatic complaints and a less authoritative family predict treatment success, might suggest that health care providers should also pay attention to several additional parental practices. For example, it has been found that parental responses are related to child pain behavior [396] and are demonstrated as effective. Teaching parents how to use pain-reducing behavior such as verbal distraction and encouragement might be valuable. These skills might also be valuable in stimulating children to engage in healthy behaviors. The importance of rule setting and organizational skills in the family might be discussed by the health care providers at the start of the treatment, as a lack of these skills seem to make families more vulnerable to dropout.

Our results provide evidence that SMSMT reduces dropout rates from treatment. Do these findings imply that the SMSMT should be made a standard additional treatment for children attending a lifestyle program? The answer might be: not yet. At this point, we cannot say for certain, which mechanisms have led to lower dropout rates. Furthermore, the effectiveness of this intervention should be demonstrated in a broad sample of overweight and obese children and adolescents using multiple outcome measures. Self-efficacy for example has been found to improve adherence to health behaviors [146] and we have not measured this concept in our study. Institutions participating in the recently formed BFC National Committee, including eight health care centers in the Netherlands complying with the BFC protocol, might implement the current SMSMT program with the aim of replicating our current findings and studying the relation with several possible underlying mechanisms.

An important question is: how easy is the implementation of the SMSMT? Implementing the SMSMT requires a limited investment of time and money most of which are associated with pre-programming and training a psychologist. Both the participating children and their parents advised us to let the children use their own mobile phones, which would make implementation easier. Most children as young as seven years of age possess a mobile phone nowadays [143, 144]. One might argue that the sending of SMS reminders only just before the appointment might be sufficient to decrease dropout rates. However, we believe that weekly self-monitoring in combination with personalized feedback can lead to further improved return rates. By self-monitoring and personalized feedback the children were reminded weekly to the treatment progress, goals and strategies they learned in the BFC program, which might have enhanced their awareness to the program. Future research should be conducted to confirm this line of thinking.

Our results indicated that a higher BMI in PCOS women is associated with impaired psychological well-being. Given our findings and the results of other studies showing numeral negative consequences of a higher BMI in PCOS women [69, 70, 75, 366], we believe that all PCOS patients with overweight and obesity should receive an additional lifestyle treatment. Though several studies evaluating lifestyle programs have shown the positive effects of weight loss on several physical and psychological domains, more research is needed to study the effect of lifestyle programs in this specific population. Furthermore, methods to sustain lifestyle behavior changes over the long-term are also needed. The Erasmus University Medical Centre has recently developed a lifestyle program for PCOS women, which is combined with an SMSMT intervention based on the SMSMT that was developed for overweight and obese children participating in the BFC.

*'People's behavior makes sense if you think about it in terms of their goals, needs, and motives.'*

*Thomas Mann*

A black and white photograph of a mountain range. The mountains are dark, with snow or light-colored patches on their peaks and upper slopes. In the foreground, there is a calm body of water reflecting the sky. The overall scene is serene and somewhat somber due to the monochrome palette.

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A black and white photograph of a mountain range. The mountains are dark, with snow or light-colored patches on their peaks and ridges. In the foreground, there is a body of water, possibly a lake or a wide river, which reflects the sky. The sky is a uniform, light gray. The overall mood is serene and somewhat somber due to the monochromatic palette.

# S

Summary



## CHAPTER 1

Obesity has become a global epidemic among all age groups. In the Netherlands, the rate of increase in the prevalence of overweight and obesity in children almost tripled between 1997 and 2003 with reference to the years between 1980 and 1997. Being obese is associated with a great amount of negative health consequences, which might become life-threatening. Given the expectation that the prevalence of obesity continues to increase, the negative consequences will also increase. In the present chapter, the classification of overweight and obesity and several determinants and consequences of overweight and obesity are discussed. In addition, obesity treatments are described. Lifestyle modification interventions focusing on dietary intake, physical activity, and behavioral therapy have been shown to be effective in the treatment of overweight and obesity. Furthermore, several predictors of treatment success and dropout are described. Not all children seem to benefit from obesity treatment and dropout negatively influences treatment success. In the next section, the use of E-health applications in health care aimed at changing health behavior and specifically in the treatment of overweight and obesity is discussed. Several advantages of innovative technologies in healthcare are highlighted. In addition, several psychological models and behavior change methods used in Short Message Service (SMS) interventions are mentioned. Finally, the objectives of the present dissertation and research questions are described.

### CHAPTER 2.1

The objective of the study presented in this chapter was to determine baseline predictors of treatment success in terms of Body Mass Index-Standard Deviation Scores (BMI-SDS) in a multidisciplinary family-based behavioral lifestyle intervention program for overweight and obese children. Two hundred and forty-eight overweight and obese children and their caregivers agreed to participate in this study and attended a lifestyle intervention program. Baseline data assessment included anthropometrics, demographics, and breakfast behavior. In addition, competence and behavioral problems were measured by the Child Behavior Checklist, family functioning by the Family Adaptability and Cohesion Evaluation Scales, and personality by the Dutch Personality Questionnaire-Youth. BMI-SDS was also measured after 3, 9, and 12 months of treatment. Mixed modeling was used for analysis. Greater BMI-SDS reductions over the course of one year were found in children with lower baseline BMI-SDS, younger children and in children with Caucasian or non-overweight and obese parents. Furthermore, children with lower somatic problem scores and higher social competence scores on the Child Behavior Checklist were more successful in BMI-SDS reduction. The results of this study suggest that screening for

baseline characteristics in overweight and obese children could identify who will benefit most from a pediatric lifestyle intervention. Tailored programs should be developed and the treatment team should focus on children who are less successful in achieving weight reductions. Future research should study the mechanisms by which somatic complaints and social competence influence treatment success.

## **CHAPTER 2.2**

In this chapter, baseline predictors of dropout were evaluated at various stages in a multidisciplinary family-based lifestyle intervention for overweight and obese children. Two hundred and forty-eight children between the ages of eight and fourteen years and their caregivers participated in this prospective study and attended a lifestyle intervention program. At baseline, anthropometric and demographic data were assessed; competence and behavioral problems were measured by the Child Behavior Checklist, and family functioning by the Family Adaptability and Cohesion Evaluation Scales. Dropout was analyzed at various stages of the treatment with logistic regression analyses. The results of this study showed that non-Caucasian maternal ethnicity, children with higher Body Mass Index-Standard Deviation Scores (BMI-SDS), those who participate in fewer activities, those who not have breakfast regularly, and those not living in families with a 'static' adaptability structure were more likely to dropout between the start and the end of the one-year treatment. Furthermore, we found different baseline characteristics predicting dropout at different stages of treatment: (1) having an ethnic minority status and being older predicted dropout from the intensive three-month program; (2) having a non-Caucasian mother, fewer activities, higher delinquency scores, and not presenting the family as extremely positive predicted dropout between three and nine months; and (3) having higher BMI-SDS, having fewer social problems, and not living in families with a 'static' adaptability structure predicted dropout between nine and twelve months of treatment. In conclusion, dropout from a pediatric lifestyle program at various stages in treatment seems to be predicted by different baseline characteristics. These findings highlight the need for tailored interventions targeting different characteristics at various stages of treatment to reduce treatment dropouts.

## **CHAPTER 3.1**

The main objective of the paper presented in Chapter 3.1 was to illustrate the general potential of Short Message Service (SMS) for symptom and behavior monitoring and the provision of tailored feedback. Secondly, an SMS-based maintenance treatment



(SMSMT) was introduced aimed at enhancing the effect of the treatment of childhood overweight. After a twelve-week cognitive behavioral group treatment (CBGT), forty children were assigned to the SMSMT for a period of 36 weeks. Children were asked to send weekly self-monitoring data on physical activity, dietary intake, and emotions. The children then received tailored feedback on their monitoring data. Adherence to SMSMT and changes in Body Mass Index-Standard Deviation Scores (BMI-SDS) during the first and second treatment phase were analyzed. Children (mean age=10.05, SD=1.28) submitted 67% of the weekly SMSs that they were expected to send in. During CBGT a significant reduction of 0.20 BMI-SDS was observed. The reduction of 0.07 BMI-SDS during the SMSMT did not reach statistical significance. The results support the feasibility of SMSMT in the treatment of childhood overweight. The efficacy of the intervention needs to be demonstrated in a Randomized Controlled Trial. This feasibility study showed SMSMT to be a promising intervention that may extend the reach of treatment centers for childhood overweight at reasonable cost and effort.

## CHAPTER 3.2

In this chapter, we aimed to test the hypothesis that Short Message Service (SMS) reduces dropout rates in overweight and obese children during a lifestyle intervention. Although lifestyle programs can reduce the level of overweight, dropout rates are substantial. New technologies, such as the Short Message Service (SMS), are a common and popular way of communication among youngsters and might be a promising tool to enhance existing interventions. One hundred and forty-one children between the ages of seven and twelve years who were participating in a lifestyle program the 'Big Friends Club', were randomly assigned to an intervention group receiving an SMS maintenance treatment (SMSMT) for thirty-eight weeks (n=73) or to a control group receiving no SMSMT (n=68). Children were asked to send weekly self-monitoring data on physical activity, dietary intake, and emotions. In return, they received personally-tailored feedback messages. Dropout was analyzed with logistic regression analysis. The results of this randomized controlled study showed that children in the SMSMT intervention group had 3.25 ( $P = 0.01$ ) times less probability of dropping out after one year than controls. We found no significant correlation between the number of sent SMSs and BMI-SDS changes. In the first 3 months of SMSMT, the SMSMT completers sent 0.80 SMSs per week, and approximately 0.50 SMSs in the final 3 months. Younger children sent more SMSs ( $P = 0.03$ ). These results indicate that SMSMT is effective and feasible in reducing the dropout rate from a pediatric lifestyle intervention. Future research should examine the effectiveness of SMSMT on weight management and related psychosocial variables.

### CHAPTER 3.3

The objective of the current study was to analyze whether self-monitoring through the Short Message Service (SMS) with personalized feedback in addition to a lifestyle program maintains or improves further weight loss and psychological well-being in overweight and obese children. Although there is evidence that medium to high-intensity behavioral programs achieve the greatest weight loss results, long-term effects are difficult to monitor and achieve. Self-monitoring is associated with increased weight loss. Short Message Service (SMS) seems to improve adherence to self-monitoring of health behavior compared with paper & pencil diaries. After three months of intensive lifestyle treatment, one hundred and forty-one overweight and obese children between the ages of seven and twelve years were randomly assigned to an intervention group receiving Short Message Service Maintenance Treatment (SMSMT), or to the control group. The intervention group sent self-monitoring data on physical activity, healthy eating, and emotional well-being via mobile phones. Body Mass Index-Standard Deviation Scores (BMI-SDS) were collected at 4 time points. Additionally, children completed the Dutch Eating Behavior Questionnaire and the Self-Perception Profile for Children. Parents completed the Child Health Questionnaire-PF50. Data from this parallel randomized, multicenter clinical trial were analyzed using mixed modeling. We found that controls had a greater reduction in external eating and gained in physical health. More children dropped out from the control group ( $P = 0.02$ ). Children who had greater weight loss during the intensive lifestyle treatment and completed the SMSMT sent more SMSs ( $P = 0.04$ ). In conclusion, SMSMT seems to reduce dropout rates. However, this study did not find an effect of SMSMT on weight or psychological well-being. Future research should study variations of this intervention to investigate how SMSMT can be more effective.

### CHAPTER 4.1

The characteristics of polycystic ovary syndrome (PCOS) such as hyperandrogenism and anovulation can be highly stressful and might negatively affect psychological well-being and sexuality. The objective of the study in Chapter 4.1 was to evaluate the association between PCOS characteristics and psychological well-being as well as sexarche. Patients ( $n=1148$ ) underwent standardized clinical evaluation. Psychological well-being was investigated in 480 patients with the Rosenberg Self-esteem Scale (RSES), the Body Cathexis Scale (BCS) and the Fear of Negative Appearance Evaluation Scale (FNAES). Sexarche was also assessed. Amenorrhoea was associated with lower self esteem ( $P = 0.03$ ), greater fear of negative appearance evaluation ( $P = 0.01$ ) and earlier sexarche ( $P = 0.004$ ). Hyperandrogenism and acne were associated with poorer body satisfaction ( $P =$

0.03,  $P = 0.02$ , respectively). Hirsutism and Body Mass Index were negatively associated with all psychological variables (RSES,  $P = 0.01$ ; BCS,  $P = 0.05$ ; FNAES,  $P = 0.02$  and RSES,  $P = 0.03$ ; BCS,  $P = 0.001$ ; FNAES,  $P = 0.03$ , respectively). The results of the current study suggest that menstrual irregularities might be related to sexarche. Moreover, this study stresses that the treatment of women with PCOS should focus on not only physical, but also psychological and sexual characteristics.

## CHAPTER 5

In the final chapter, the main findings of the work presented in the current dissertation are discussed. In addition, study limitations and directions for future research are described. Depending on the developmental level, different age groups in obesity treatment might need different materials and different teaching techniques to enhance treatment success in older children. Furthermore, tailored treatment material for non-Caucasian families might improve adherence to healthy behavior and treatment in non-Caucasian children and their families. Before introducing the Short Message Service Maintenance Treatment (SMSMT) as a standard additional treatment for children attending a lifestyle program aimed at reducing dropout rates, the mechanisms behind the SMSMT and lower dropout should be studied. Furthermore, the effectiveness of the SMSMT on weight, health behavior, and psychological well-being should be studied with an adjusted version of the SMSMT in a broad sample of overweight and obese youngsters using multiple subjective and objective outcome measures. Finally, it was concluded that several characteristics and features of polycystic ovary syndrome (PCOS) are related to impaired psychological well-being. Specifically, a higher Body Mass Index in women with polycystic ovary syndrome (PCOS) is associated with impaired psychological well-being. All PCOS patients with overweight and obesity should receive additional lifestyle advice or lifestyle treatment.



A black and white photograph of a mountain range. The mountains are dark, with snow or light-colored patches on their peaks and ridges. In the foreground, there is a calm body of water reflecting the sky. The overall scene is serene and somewhat somber due to the monochrome palette.

# S

Samenvatting



## HOOFDSTUK 1

Obesitas is wereldwijd uitgegroeid tot een epidemie, zowel onder kinderen als onder volwassenen. Het voorkomen van overgewicht en obesitas onder Nederlandse kinderen is tussen 1997 en 2003 bijna verdrievoudigd in vergelijking tot de periode tussen 1980 en 1997. Obesitas gaat gepaard met veel negatieve gevolgen voor de gezondheid, die uiteindelijk zelfs levensbedreigend kunnen worden. Gezien de verwachting dat de prevalentie van obesitas blijft stijgen, zullen ook de negatieve gevolgen toenemen. In hoofdstuk 1 wordt onder andere de classificatie van overgewicht en obesitas besproken als ook mogelijke determinanten en gevolgen van overgewicht en obesitas. Daarnaast worden behandelingen voor obesitas beschreven. Gedragstherapeutische leefstijl interventies die zich richten op het veranderen van het voedingspatroon en lichamelijke beweging zijn succesvol gebleken in de behandeling van overgewicht en obesitas. In dit hoofdstuk worden vervolgens diverse voorspellers van behandelingssucces en uitval uit de behandeling beschreven. Niet alle kinderen lijken succes te boeken in de behandeling van hun overgewicht en daarnaast heeft uitval ook een negatieve invloed op het succes van de behandeling. Ook wordt in dit hoofdstuk het gebruik van E-health toepassingen in de gezondheidszorg besproken die gericht zijn op gedragsverandering en uiteindelijk de gezondheid. In het bijzonder worden E-health toepassingen beschreven die worden gebruikt bij de verandering van leefstijl en de behandeling van overgewicht en obesitas. Verschillende voordelen van het gebruik van innovatieve technologieën in de gezondheidszorg worden aangestipt. Hierbij wordt in het bijzonder aandacht besteed aan Short Message Service (SMS) interventies. Tot slot worden een aantal onderliggende psychologische modellen en methoden beschreven die worden gebruikt in SMS interventies die tot doel hebben het gezondheidsgedrag te beïnvloeden. Daarnaast worden de doelstellingen en onderzoeksvragen van dit proefschrift gepresenteerd.

### HOOFDSTUK 2.1

In het onderzoek in hoofdstuk 2.1 is onderzocht of bepaalde kind- en ouderkenmerken bij aanvang van de behandeling voorspellers zijn voor het slagen van een multidisciplinair gedragstherapeutische leefstijl interventie. Behandelingssucces werd gedefinieerd in termen van Body Mass Index-Standaard Deviatie Scores (BMI-SDS), BMI scores gecorrigeerd voor leeftijd en geslacht. Tweehonderdachtenveertig kinderen met overgewicht en obesitas en ook hun verzorgers die de leefstijl interventie gingen volgen hebben ingestemd om deel te nemen aan deze studie. Baseline gegevens werden verzameld van onder andere gewicht, leeftijd, ethniciteit, gezinssamenstelling en ontbijtgedrag. Competentie en gedragsproblemen werden gemeten door middel van de Child Behavior Checklist, de

persoonlijkheid van het kind door middel van de Dutch Personality Questionnaire-Youth en het functioneren van het gezin door middel van de Family Adaptability and Cohesion Evaluation Scales. Daarnaast werd BMI-SDS ook gemeten na 3, 9, en 12 maanden van de behandeling. Mixed modeling werd gebruikt voor de analyse. In de loop van het eerste jaar na de start van de interventie, werden sterkere BMI-SDS dalingen gevonden bij kinderen met een lagere baseline BMI-SDS, bij jongere kinderen, bij kinderen met ouders van Nederlandse afkomst en bij kinderen met ouders zonder overgewicht of obesitas. Bovendien hadden kinderen die minder somatische probleemscores rapporteerden en kinderen met een hogere sociale competentie meer succes in het verlagen van hun gewicht. De resultaten van deze studie suggereren dat screening op deze kenmerken bij kinderen met overgewicht en obesitas en hun ouders kan identificeren wie het meeste baat hebben bij een leefstijl interventie. Programma's die gericht zijn op moeilijker te behandelen groepen zouden moeten worden ontwikkeld. Toekomstig onderzoek zou inzicht moeten geven in de mechanismen achter de invloed van somatische klachten en sociale competentie op het succes van de behandeling.

## HOOFDSTUK 2.2

In hoofdstuk 2.2 worden voorspellers voor uitval in de verschillende stadia van een multidisciplinaire leefstijl interventie voor kinderen met overgewicht en obesitas geëvalueerd. Aan deze prospectieve studie namen tweehonderdachtenveertig kinderen in de leeftijd van acht tot veertien jaar met hun ouders deel en volgden gedurende twaalf maanden een leefstijl interventie. Voor aanvang van de interventie werden antropometrische en demografische gegevens gemeten. Competentie en gedragsproblemen werden gemeten door middel van de Child Behavior Checklist en het functioneren van het gezin door middel van de Family Adaptability and Cohesion Evaluation Scales. Uitval werd geanalyseerd in verschillende fasen van de behandeling met logistische regressie-analyses. De resultaten van deze studie toonden aan dat kinderen met een moeder van allochtone afkomst, kinderen met hogere Body Mass Index-Standaarddeviatie Scores (BMI-SDS), kinderen met minder activiteiten, kinderen die niet regelmatig ontbijten en kinderen die wonen in gezinnen met een niet 'statisch' aanpassingsvermogen, meer kans hadden om uit te vallen tijdens de behandeling. Daarnaast hebben we aangetoond dat uitval in de verschillende stadia van de behandeling door verschillende baseline kenmerken werd voorspeld: (1) een etnische minderheid status en een hogere leeftijd voorspelden uitval tijdens het intensieve deel van het programma in de eerste drie maanden; (2) een allochtone moeder, minder activiteiten, hogere delinquentie scores en het niet beschrijven van het gezin als uitermate positief, voorspelden uitval tussen de drie en negen maanden; en (3) een hogere BMI-SDS, minder sociale problemen, en het



herkomst uit een gezin met een niet 'statisch' aanpassingsvermogen voorspelden uitval in de laatste drie maanden van de behandeling. Samenvattend lijkt uitval tijdens de verschillende stadia van een leefstijl interventie te worden voorspeld door verschillende baseline kenmerken. Deze bevindingen onderstrepen de noodzaak van aangepaste interventies die mede gericht zijn op de voorspellers van uitval in verschillende behandelstadia met als doel uitval tijdens de behandeling te verminderen.

### **HOOFDSTUK 3.1**

De belangrijkste doelstelling van de studie die wordt gepresenteerd in hoofdstuk 3.1 was om de algemene bruikbaarheid van een Short Message Service (SMS) interventie te illustreren. De SMS interventies die worden beschreven bestaan uit het monitoren van symptomen en gedrag en het geven van op maat gesneden feedback. In de tweede plaats werd een op SMS-gebaseerde onderhoudsbehandeling (SMSMT) beschreven die werd aangeboden ter ondersteuning van een twaalf weken durende cognitief gedragstherapeutische groepsbehandeling (CBGT) voor kinderen met overgewicht en obesitas. Na afloop van het intensieve gedeelte van de behandeling werden veertig kinderen toegewezen aan de SMSMT voor een periode van 36 weken. Deze kinderen werden gevraagd om wekelijks hun lichaamsbeweging, eetgedrag, en emoties te registreren en deze naar de onderzoeker te SMSen. De kinderen kregen vervolgens op maat gesneden feedback terug. De mate van naleving van de SMSMT en de veranderingen in Body Mass Index- Standaarddeviatie Scores (BMI-SDS) tijdens de CBGT en de SMSMT werden onderzocht. De kinderen (gemiddelde leeftijd=10.05, SD=1.28) stuurden 67% van de wekelijkse SMSen die ze geacht werden te sturen. Tijdens de CBGT werd een aanzienlijke vermindering van 0.20 BMI-SDS waargenomen. De verlaging van 0.07 BMI-SDS tijdens de SMSMT bereikte geen statistische significantie. De resultaten ondersteunen de haalbaarheid van de SMSMT in de behandeling van kinderen met overgewicht. De werkzaamheid van de interventie moet worden aangetoond in een gerandomiseerd gecontroleerd onderzoek (zie hoofdstukken 3.2 en 3.3). Dit onderzoek toonde aan dat SMSMT een veelbelovende interventie is welke tegen redelijke kosten en inspanning zou kunnen worden gebruikt in behandelcentra voor kinderen met overgewicht.

### **HOOFDSTUK 3.2**

In dit hoofdstuk wordt gesteld dat Short Message Service (SMS) tijdens een leefstijl interventie het percentage uitvallers in een groep van kinderen met overgewicht en obesitas vermindert. Hoewel leefstijl interventies de mate van overgewicht kunnen ver-

minderen, blijft het aantal uitvallers aanzienlijk. Nieuwe technologieën, zoals SMS, zijn een populaire manier van communicatie tussen jongeren en lijken een veelbelovend instrument om bestaande interventies te verbeteren. Honderdeenveertig kinderen in de leeftijd van zeven en twaalf jaar die de leefstijl interventie de 'Dikke Vrienden Club' (DVC) volgden, werden willekeurig toegewezen aan een interventiegroep die de SMS onderhoudsbehandeling (SMSMT) ontving gedurende achtendertig weken (n=73) of aan een controlegroep die geen SMSMT (n=68) ontving. De kinderen werden gevraagd om wekelijks gegevens over hun lichamelijke beweging, eetgedrag en emoties te SMSen. In reactie op hun SMS kregen ze op maat gesneden feedback berichten. Uitval werd geanalyseerd met logistische regressie-analyse. De resultaten van deze gerandomiseerde studie toonden aan dat kinderen in de SMSMT interventie groep 3.25 (P = 0.01) keer minder kans op uitval hadden tijdens het eerste jaar na aanvang van de DVC dan de controlegroep. We vonden geen significante correlatie tussen het aantal verzonden SMSen en BMI-SDS veranderingen. De kinderen die de DVC behandeling en de SMSMT voltooiden, stuurden gemiddeld 0.80 SMSen per week gedurende de eerste 3 maanden van de SMSMT en ongeveer 0.50 SMSen in de laatste 3 maanden. Jongere kinderen verzonden meer SMSen (P = 0.03). Deze resultaten geven aan dat de SMSMT haalbaar is en effectief bij het terugdringen van uitval in een leefstijl interventie voor kinderen met overgewicht en obesitas. Toekomstig onderzoek zou de effectiviteit moeten onderzoeken van de SMSMT op het gewicht en ook het effect op psychosociale variabelen.

### HOOFDSTUK 3.3

Het doel van de studie in hoofdstuk 3.3 was om te onderzoeken of zelfregistratie met een Short Message Service (SMS) en op maat gesneden feedback naast een leefstijl interventie een effect heeft op het gewicht en op het psychisch welbevinden bij kinderen met overgewicht of obesitas. Hoewel er aanwijzingen zijn dat redelijk tot zeer intensieve leefstijl interventies succesvol zijn in het verlagen van het gewicht, zijn effecten op de lange termijn moeilijk te controleren en bereiken. Zelfregistratie is geassocieerd met gewichtsverlies. SMS lijkt het trouw blijven aan zelfregistratie van gezondheidsgedrag te verbeteren in vergelijking met paper & pencil dagboeken. Na drie maanden een intensieve leefstijl interventie gevolgd te hebben, werden honderdeenveertig kinderen met overgewicht en obesitas in de leeftijd van zeven en twaalf jaar willekeurig toegewezen aan een Short Message Service onderhoudsbehandeling (SMSMT) interventiegroep of aan een controlegroep. De interventie groep werd gevraagd zelfregistratie gegevens over de lichamelijke beweging, het voedingspatroon en emotioneel welzijn naar de onderzoeker te SMSen via mobiele telefoons. Body Mass Index-Standaard Deviatie Scores (BMI-SDS) werden verzameld op vier tijdstippen. Daarnaast vulden de kinderen

de Dutch Eating Behavior Questionnaire en de Self-Perception Profile for Children in. Ouders vulden de Child Health Questionnaire-PF50 in. Gegevens uit deze parallel gerandomiseerde, multicenter klinische studie werden geanalyseerd met behulp van mixed modeling. We vonden dat de controlegroep een wat sterkere vermindering had van extern eetgedrag en meer winst behaalden met betrekking tot fysieke gezondheid. Meer kinderen vielen uit in de controle groep ( $P = 0.02$ ). Kinderen met meer gewichtsverlies tijdens de intensieve leefstijl interventie en de kinderen die de SMSMT afmaakten, verzonden over het algemeen meer SMSen ( $P = 0.04$ ). SMSMT vermindert uitval uit de behandeling. Echter, deze studie vond geen effect van SMSMT op het gewicht of psychisch welbevinden. Toekomstig onderzoek zou variaties op deze interventie moeten onderzoeken om de effecten van de SMSMT te verbeteren.

## HOOFDSTUK 4.1

De kenmerken van het polycysteus ovarium syndroom (PCOS), zoals hyperandrogenisme en anovulatie, kunnen zeer stressvol zijn en kan een negatieve invloed hebben op het psychologisch welzijn en seksualiteit van vrouwen. Het doel van deze studie was om de associatie tussen PCOS kenmerken en psychologisch welzijn alsmede de leeftijd van de eerste geslachtsdaad (sexarche) te evalueren. Patiënten ( $n=1148$ ) ondergingen een gestandaardiseerde klinische evaluatie. Psychologisch welzijn werd onderzocht in 480 patiënten met de Rosenberg Self-esteem Scale (RSES), de Body Cathexis Scale (BCS) en de Fear of Negative Appearance Evaluation Scale (FNAES). Sexarche werd ook gemeten. Amenorroe was geassocieerd met een lager gevoel van eigenwaarde ( $P = 0.03$ ), een grotere angst voor een negatieve beoordeling van het uiterlijk ( $P = 0.01$ ) en een sexarche op jongere leeftijd ( $P = 0.004$ ). Hyperandrogenisme en acne werden geassocieerd met een negatievere lichaamsbeoordeling ( $P = 0.03$ ,  $P = 0.02$ , respectievelijk). Overbeharing en BMI waren beiden negatief geassocieerd met alle psychologische variabelen (RSES,  $P = 0.01$ ; BCS,  $P = 0.05$ ; FNAES,  $P = 0.02$  en RSES,  $P = 0.03$ ; BCS,  $P = 0.001$ ; FNAES,  $P = 0.03$ , respectievelijk). De resultaten van de huidige studie suggereren dat menstruele onregelmatigheden samengaan met een vroegere sexarche. Deze studie benadrukt dat de behandeling van vrouwen met PCOS zich niet alleen zou moeten richten op de fysieke aspecten van PCOS, maar ook op mogelijke psychologische en seksuele gevolgen.

## HOOFDSTUK 5

In het laatste hoofdstuk worden de belangrijkste bevindingen in dit proefschrift besproken. Bovendien worden studiebeperkingen en aanwijzingen voor toekomstig

onderzoek beschreven. Onder andere wordt besproken dat het ontwikkelingsniveau van het kind in acht zou moeten worden genomen bij het ontwikkelen van materialen voor de behandeling. Daarnaast zouden verschillende technieken nodig kunnen zijn in de behandeling van overgewicht en obesitas om het succes van de behandeling bij oudere kinderen te bevorderen. Bovendien kan toegesneden behandelingsmateriaal ook een positieve invloed hebben op de naleving van zowel een gezonde leefstijl als ook van het volgen van de behandeling in allochtone gezinnen. Voordat de Short Message Service onderhoud behandeling (SMSMT) als een standaard aanvullende behandeling kan worden gebruikt om uitval te verlagen, zouden eerst de mechanismen achter de SMSMT en uitval verlaging moeten worden onderzocht. Bovendien moet de effectiviteit van de SMSMT op gewicht, gezondheidsgedrag en psychologisch welzijn worden bestudeerd met een aangepaste versie van de SMSMT in een brede steekproef van kinderen met overgewicht en obesitas. Daarbij zouden ook meerdere subjectieve en objectieve uitkomstmaten moeten worden meegenomen. Ten slotte werd geconcludeerd dat een aantal karakteristieken en kenmerken van het polycysteus ovarium syndroom (PCOS) zijn gerelateerd aan een verminderd psychologisch welzijn. Een hogere Body Mass Index bij vrouwen met het polycysteus ovarium syndroom (PCOS) was geassocieerd met een verminderd psychologisch welbevinden. Alle PCOS patiënten met overgewicht en obesitas zouden extra leefstijladviezen moeten krijgen of zouden de mogelijkheid moeten hebben om een leefstijl interventie te volgen.

A black and white photograph of a mountain range. The mountains are dark, with snow or light-colored patches on their peaks and ridges. In the foreground, there is a body of water, possibly a lake or a wide river, which reflects the sky. The overall scene is serene and somewhat somber due to the monochromatic palette.

**D**

**Dankwoord**



Mijn eerste herinnering en dank gaat uit naar wijlen Prof. Wim Trijsburg. Tot onze grote schrik overleed Wim in 2007. In de paar maanden dat ik met Wim heb mogen samenwerken was hij voor mij een groot voorbeeld en heb ik met hem een veel te korte, maar een fantastische en leerzame samenwerking gehad. Zijn kundigheid en kennis, kritische reflectie, humor, persoonlijkheid, maar ook de kans die hij mij heeft geboden om onderzoek te doen naar de Dikke Vrienden Club, zijn onderdeel van mijn herinnering aan Wim.

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Co-promotor Dr. Reinier Timman, beste Reinier. Aan onze samenwerking denk ik terug met veel plezier. Naast alle uren die wij samen hebben doorgebracht met het uitvoeren van analyses, heb ik ook goede herinneringen aan onze leuke gesprekken. Ik kon altijd bij jou terecht met vragen of voor een praatje. Een leuk moment was altijd onze 'high five' wanneer we of een leuke bevinding hadden gedaan of we een ingewikkelde syntax hadden opgelost. Jouw kennis en alle tijd die wij samen hebben besteed aan de analyses in SAS en SPSS hebben mij enorm doen groeien in de methologie. Bedankt voor alles

Reinier, we houden Skype contact en als ik in Nederland ben kom ik weer een lekker visje bij jou eten ☺.

Co-promotor Dr. Cora de Klerk, beste Cora. Jouw kennis op het gebied van psychologie en infertiliteit en kritische reflectie op de artikelen voor dit proefschrift hebben mij enorm geholpen in mijn promotietraject. Ook jouw nauwe betrokkenheid bij het afronden van mijn proefschrift op afstand na mijn vertrek naar Vancouver waardeer ik enorm. Bedankt daarvoor!

Prof. Van Busschbach, beste Jan. Bedankt voor de samenwerking en ook voor je inzet en vertrouwen toen ik had besloten de Nederlandse bodem te verlaten.

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Dear Dr. Steffi Bauer and Dr. Hans Kordy from the Center for Psychotherapy Research, University of Heidelberg: dear Steffi, dear Hans: thank you and your research team for our great collaboration! Many thanks for the (technical) support of the Short Message Service and for sharing your expertise. Besides that, I have great memories of the time we spend together at conferences in Barcelona, Santiago de Chile, and Asilomar.

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mij bij. Mede door jouw vertrouwen in mijn wetenschappelijke kwaliteiten ('Tuurlijk gaan we dit artikel hoog inzetten!') hebben we het mooi voor elkaar gekregen om in Pediatrics te publiceren.

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Dr. Bonke, beste Benno. Jij hebt mij op de MPP aangenomen in verband met het geven van onderwijs aan de geneeskunde studenten. Onderwijs geven heb ik in de jaren dat ik werkzaam was op de MPP met heel veel plezier gedaan. Dank je voor de goede en leuke samenwerking op het onderwijsgebied. Ook onze muzikale samenwerking op promoties en andere feesten en partijen zal ik niet vergeten!

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Dear current colleagues: dear Louise, thank you for giving me the opportunity to do my postdoctoral fellowship at the University of British Columbia. Maria, it is so much fun to work with you! Thanks for editing my Introduction and General Discussion. And also to Daniel and Whitney: you are all great to work with!

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A black and white photograph of a mountain range with snow-capped peaks and a body of water in the foreground. The mountains are dark, and the snow is bright white. The water is calm and reflects the sky. The foreground shows some dark, silhouetted trees or bushes.

# CV

Curriculum vitae



Judith Evelyn de Niet was born on May 6th 1981 in 's-Gravenhage, the Netherlands. In 2000, after graduating from secondary school at the Christelijk Gymnasium Sorghvliet, she studied Clinical and Health Psychology at Utrecht University. She received her master's degree in Clinical and Health Psychology in 2004 after completing her traineeship at Heideheuveel, an obesity clinic in Hilversum. Her master's thesis focused on the relation between stress and eating behavior. After she graduated, Judith worked as a psychologist researcher at the National Ombudsman, where she conducted research on perceived difficult complaining behavior in individuals turning to the people's advocate. Furthermore, she advised employees of the National Ombudsman and provincial and national (government) institutions on this topic. In 2006, Judith joined the Department of Medical Psychology and Psychotherapy at the Erasmus Medical Centre to teach psychology and communication skills in the medical curriculum. In 2007, she started her PhD study under the supervision of Prof. Wim Trijsburg. The main focus of her research is on innovative technologies in the treatment of childhood obesity. Specifically, she studied a Short Message Service (SMS) intervention through mobile phones in addition to a multidisciplinary behavioral group treatment, named the Big Friends Club (BFC). In addition, she conducted research on predictors of treatment success and dropout in the BFC. Sadly, Wim Trijsburg passed away in 2007. Prof. Jan Passchier and Dr. Reinier Timman continued the supervision. In 2008, Judith also joined the Division of Reproductive Medicine at the Erasmus MC, where she developed a multidisciplinary lifestyle treatment and a supplemental Short Message Service intervention for women with polycystic ovary syndrome and overweight and obesity under the supervision of Prof. Joop Laven and Dr. Cora de Klerk. In 2009, Judith initiated the national BFC committee together with Dr. Erica van den Akker and Dr. Reinier Timman. In May 2010, Judith began her postdoctoral fellowship at the University of British Columbia, Vancouver, Canada. She is currently conducting research on an internet intervention targeted at overweight and obese youngsters and a study on the influence of school policies on eating behavior and physical activity.

## PHD PORTFOLIO

Name PhD student: Judith Evelyn de Niet  
 Erasmus MC departments: Medical Psychology and Psychotherapy  
 & Division of Reproductive Medicine  
 PhD period: 2007-2010  
 Promotoren: Prof. Jan Passchier & Prof. Joop Laven  
 Supervisors: Dr. Reinier Timman & Dr. Cora de Klerk

### 1. PHD TRAINING

#### Relevant courses

|      |   |
|------|---|
| 2010 | Repeated measurements (Mixed modeling) in clinical research, Netherlands Institute for Health Sciences, Erasmus MC, Rotterdam |
| 2009 | Research integrity, law and organization for clinical research, Erasmus MC, Rotterdam   |
| 2009 | Cognitive behavioral therapy, Rino Group  |
| 2008 | Biomedical English scientific writing and communication, Erasmus MC, Rotterdam  |
| 2008 | Health Status Measurement, Netherlands Institute for Health Sciences, Erasmus MC, Rotterdam                                   |
| 2007 | Big Friends Club training, Rino group   |

#### Publications presented in the present dissertation

Bauer S, de Niet JE, Timman R & Kordy H (2010). Enhancement of care through self-monitoring and tailored feedback via text messaging and their use in the treatment of childhood overweight. *Patient Education and Counseling*, 79(3), 315-319.

de Niet JE, Koning C, Pastoor H, Duivenvoorden H, Valkenburg O, Ramakers M, Passchier J, de Klerk C & Laven J (2009). Psychological well-being and sexarche in women with polycystic ovary syndrome. *Human Reproduction*, 25(6), 1497-1503.

de Niet JE, Timman R, Jongejan M, Passchier, J & van den Akker E (2010). Predictors of participant dropout at various stages of a pediatric lifestyle program. *Pediatrics* (accepted).

## 2. TEACHING

### 2.1 Presentations at national and international meetings related to the present dissertation

de Niet JE, de Koning C, Pastoor H, Duivenvoorden H, Valkenburg O, Ramakers M, Passchier J, de Klerk C & Laven J (2010). Psychological well-being and sexarche in women with polycystic ovary syndrome. Poster presentation at the Women's Health Congress: the 18th Annual Congress, Washington, DC, USA.

de Niet JE, Timman R, Bauer S, van den Akker ELT, de Klerk C, Kordy H & Passchier J (2010). The effects of a family based cognitive behavioral group treatment for overweight children combined with a Short Message Service Maintenance Treatment. Oral presentation at the 41st Society for Psychotherapy Research (SPR) International Meeting, Asilomar, California, USA.

de Niet JE, Timman R, Bauer S, van den Akker E, de Klerk C, Kordy H & Passchier J (2009). The effect of a Short Message Service Maintenance Treatment on drop out, lifestyle behavior, and competence in overweight children. Oral presentation at the 40th Society for Psychotherapy Research (SPR) International Meeting, Santiago, Chili.

de Niet JE, Buijks H, Bauer S, de Klerk C & Timman R (2008). The use of text messaging in the treatment of childhood overweight. Oral presentation at the 39th Society for Psychotherapy Research (SPR) International Meeting, Barcelona, Spain.

de Niet JE, van den Akker E, Jongejan M, Passchier J & Timman R (2008). Short Message Service and drop out in a lifestyle treatment for overweight and obese children: preliminary results. Oral presentation at the Big Friends Club symposium, Rotterdam, the Netherlands.

de Niet JE, van den Akker E, Passchier J & Timman R (2008). The Big Friends Club treatment for overweight and obese children combined with Short Message Service. Oral presentation at the symposium 'New technology in health care', Academic Medical Centre (AMC), Amsterdam, the Netherlands.

de Niet JE, de Koning C, Pastoor H, Duivenvoorden H, Valkenburg O, Ramakers M, Passchier J, de Klerk C & Laven J (2008). Psychological well-being and sexarche in women with polycystic ovary syndrome. Oral presentation at the Rotterdam Division of Obstetrics and Gynaecology (RCOG), Erasmus University Medical Centre, Rotterdam, the Netherlands.

## **2.2 Teaching**

2006 – 2010: Psychology and communication skills in the medical curriculum

## **3. POSTDOCTORAL TRAINING**

2010 – present: Postdoctoral fellowship at the University of British Columbia, Vancouver, Canada



