

# Childhood Obesity: Concept, Feasibility, and Interim Results of a Local Group-based, Long-term Treatment Program

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## ABSTRACT

**Objective:** The authors performed a group-based program for obese children and adolescents in Bavaria, Germany to enable them to establish a health-oriented lifestyle and to reduce overweight. The authors compared this program with a control approach based on the patients' own initiative.

**Design:** This is a controlled clinical trial.

**Setting:** A nutrition program for outpatients in a German university hospital.

**Participants:** Seventy-three obese patients aged 7 to 15 years (mean 11.2 years) were recruited by pediatricians and local newspaper reports and randomized into intervention and control groups. Children and adolescents in each group were divided into 3 groups according to age—7-8 years, 9-10 years, and 11-13 years. Children were classified overweight (defined as body mass index (BMI) > 90th percentile for age and gender), obese (BMI > 97th percentile), and extremely obese (BMI > 99.5th percentile), according to the European Childhood Obesity Group and the German Working Group on Pediatric Obesity, congruent with adult standards used to assess overweight and obesity.

**Intervention:** Thirty-seven patients (age 7-13 years, mean 10.9 years) for the 1-year intervention. This intervention consisted of modules for physical activity, nutritional education, and coping strategies. The program was performed twice each week and incorporated parental participation and medical supervision, including laboratory tests. The obese controls (n = 36, age 8-15 years, mean 11.6 years) received written therapeutic advice during a visit at 0 and 6 months in the outpatient clinic.

**Main Outcome Measure:** The primary outcome variable was the body mass index (BMI) z score.

**Analysis:** Analysis of variance and t test were used, and a P value < .05 was considered significant.

**Results:** There was a reduction of BMI z score in the active treatment group (P < .05), but not for controls. Moreover, the active group showed beneficial effects for body mass index (BMI), fat mass, and systolic blood pressure 12 months after beginning the intervention.

**Conclusions and Implications:** Group-based programs for young, obese patients can be effective tools for establishing a health-oriented lifestyle and reducing the burden of obesity.

**Key Words:** children, diet, obesity, program evaluation

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## INTRODUCTION

Pediatric obesity, a serious, global health issue, may cause metabolic abnormalities such as hyperlipidemia, hypertension, impaired glucose tolerance, or even type 2 diabetes early in childhood. Moreover, because obesity commonly persists into adulthood, affected children are at greater risk of developing a variety of metabolic and cardiovascular comorbidities along with increased mortality rates.<sup>1</sup>

The development of a successful therapeutic approach for obesity in children and adolescents remains a challenge. Basic treatment options include long-term changes in life-

style, especially eating habits and exercise behavior. The CATCH study (Child and Adolescent Trial for Cardiovascular Health) in the United States is a multiethnic school- and family-based intervention program promoting healthful meals and physical activity. However, in addition to an ethnicity effect, a significant increase in body mass index (BMI) and prevalence of obesity was found in both the intervention and control groups.<sup>2</sup> Therefore, more specific intervention programs for smaller, homogenous cohorts could be more successful in avoiding and treating risk factors for cardiovascular disease at younger ages.

Generally, long-term effects on body weight can be achieved only if the lifestyle is profoundly modified with respect to eating behavior and physical activity. In addition to treatment, prevention of obesity in childhood must be a key strategy. Family- and school-based primary prevention strategies, such as the Kiel Obesity Prevention Study (KOPS) in Germany, for example, have been shown to facilitate changes in lifestyle and body fat content.<sup>3</sup> It is of interest to note that obesity prevention programs are considered more effective than the treatment of adiposity.<sup>1,4</sup>

As has been described earlier for a large cohort of 4 610 young school children (age range 5.6-7.8 years, mean age 6.7 years) in the Erlangen district in Bavaria, Germany, the prevalence of overweight and obesity in children had increased within the 5-year interval from 1996 to 2001 from 6.3% to 9.5%.<sup>5</sup> This increase in prevalence of overweight and obesity was significant for both sexes.

The authors have, therefore, introduced a pilot concept for obese children and adolescents, of multidisciplinary design, aiming to promote an active, health-oriented lifestyle in children, adolescents, and their families. This group-based project for early obesity treatment was carried out for 1 year, followed by open lessons in a local sports club.

The objective of the present study was, firstly, to examine the feasibility and acceptability of the long-term outpatient program for obese children and adolescents. Secondly, standardized BMI values at 0, 6, and 12 months were compared, along with interim outcome data in the active intervention group, with controls who had received only written therapeutic advice at 2 outpatient visits.

## DESIGN

Seventy-three obese children aged 7 to 15 years (mean 11.2 years) were recruited by pediatricians and local newspaper reports and randomized into 2 groups (Table). The participants of the active intervention group joined a 1-year program, composed of modules for physical activity, nutritional education, and coping strategies, given in 2 sessions per week. There were also monthly parental meetings and medical supervision including laboratory tests at 0, 6, and 12 months. The controls received written therapeutic advice from a physician during an outpatient visit at 0 and 6 months in the outpatient clinic and were given medical supervision and laboratory tests at 0, 6, and 12 months.

The study was approved by the local ethics committee (Friedrich-Alexander-University of Erlangen-Nuremberg), and informed consent was obtained from the parents of each subject.

Body mass index was used to classify obesity according to recommendations of the World Health Organization.<sup>6</sup> Specifically, overweight was defined as BMI > 90<sup>th</sup> percentile for age and gender, obesity as BMI > 97<sup>th</sup> percentile, and extreme obesity as BMI > 99.5<sup>th</sup> percentile, according to the European Childhood Obesity Group and the German Working Group on Pediatric Obesity.<sup>7</sup> These levels

**Table.** Body Mass Index, Body Mass Index z Score, Fat Mass, Lean Mass, and Blood Pressure Values for German Children and Adolescents in Intervention and Control Groups at Baseline (0 months), During Intervention (6 months), and at End of Program (12 months) (Mean  $\pm$  SD)

	Intervention*			Controls†		
	0 mo	6 mo	12 mo	0 mo	6 mo	12 mo
Sex (n) female/male	22/15	21/15	21/15	18/18	18/16	14/16
BMI (kg/m <sup>2</sup> )	27.3 $\pm$ 3.3 <sup>¶</sup>	27.2 $\pm$ 4.1 <sup>#</sup>	25.8 $\pm$ 2.7 <sup>§**</sup>	30.0 $\pm$ 3.7 <sup>¶</sup>	31.7 $\pm$ 4.1 <sup>#</sup>	32.8 $\pm$ 4.0 <sup>  **</sup>
BMI z score	2.24 $\pm$ 0.42	2.10 $\pm$ 0.52 <sup>¶</sup>	1.90 $\pm$ 0.52 <sup>§#</sup>	2.48 $\pm$ 0.58	2.66 $\pm$ 0.56 <sup>¶</sup>	2.74 $\pm$ 0.55 <sup>§#</sup>
Fat mass <sup>‡</sup> (kg)	21.8 $\pm$ 6.4	20.9 $\pm$ 6.2 <sup>#</sup>	19.7 $\pm$ 5.5 <sup>**</sup>	26.0 $\pm$ 7.5	32.5 $\pm$ 8.3 <sup>§#</sup>	37.7 $\pm$ 9.1 <sup>  **</sup>
Lean mass <sup>‡</sup> (kg)	44.6 $\pm$ 8.4 <sup>¶</sup>	45.2 $\pm$ 6.8 <sup>¶</sup>	45.6 $\pm$ 8.2 <sup>**</sup>	49.9 $\pm$ 8.6 <sup>¶</sup>	52.9 $\pm$ 8.9 <sup>§¶</sup>	62.4 $\pm$ 9.0 <sup>  **</sup>
Systolic BP (mm Hg)	115 $\pm$ 11	115 $\pm$ 11	113 $\pm$ 10 <sup>#</sup>	118 $\pm$ 10	122 $\pm$ 12	123 $\pm$ 8 <sup>#</sup>
Diastolic BP (mm Hg)	65 $\pm$ 10	62 $\pm$ 8	61 $\pm$ 8	64 $\pm$ 7	63 $\pm$ 6	67 $\pm$ 11

BMI indicates body mass index; BP, blood pressure.

\*Intervention group participated in weekly exercise sessions plus weekly sessions focused on dietary education or coping strategies.

†Control group received written therapeutic advice at 0 and 6 months.

‡Fat and lean mass were measured by bioelectric impedance analysis.

§Significantly different from baseline values within the group ( $P < .05$ ).

||Significantly different from baseline values within the group ( $P < .01$ ).

¶Intervention group significantly different from control group ( $P < .05$ ).

#Intervention group significantly different from control group ( $P < .01$ ).

\*\*Intervention group significantly different from control group ( $P < .001$ ).

are congruent with adult standards used to assess overweight ( $25 \text{ kg/m}^2$ ) and obesity ( $30 \text{ kg/m}^2$ ). Pairs of weight and height measurements, obtained using calibrated equipment, were used to calculate BMI and were adjusted for age and gender to calculate BMI  $z$  score.<sup>8</sup> For control purposes, recent German reference data were used that had been obtained from 17 147 boys and 17 275 girls aged 0-18 years.<sup>9</sup>

In detail, 37 obese children, 22 girls and 15 boys, aged 7 to 13 years (mean  $10.9 \text{ years} \pm 1.4$ ), joined the active treatment program, which was called the "Sea Lion Club" (in German, the "Robbi-Club"). It was the authors' intention that the children empathize with the sea lion, awkward on land, but graceful in the water. Children and adolescents were divided into 3 groups according to age—7-8 years, 9-10 years, and 11-13 years—at the beginning of the program, to facilitate appropriate training according to age and level of education in small groups.

The intervention was based on exercise and the dietary approach laid down in the Consensus Statement of the Obesity Consensus Working Group.<sup>1</sup> The program was performed at a local sports center and health association for 12 months twice weekly, including during the summer vacation. It consisted of lessons on physical activity (alternating swimming and indoor sports), dietary education (adapted from the "Food Guide Pyramid" fruit and vegetable template),<sup>10-12</sup> and coping strategies (eg, awareness of eating behavior, habit books) suitable for each age. Each session lasted for 45 to 60 minutes and was performed in the late afternoon. Each participant was encouraged to compile a log, which included the names of all the fruits and vegetables consumed each day, daily physical activity, and a parent's signature, and to discuss the log weekly in the group. The first meeting in the week was reserved for sports, the second session for nutrition and coping strategies. Dietitians and psychologists took turns with a 4-week teaching block. Parental support was provided separately at monthly meetings and feedback discussions of up to 2 hours (including parent-child activities and social reinforcement). These meetings were offered as facultative sessions. In general, all sessions were performed by trained personnel (sports coaches, dietitians, and psychologists—the latter also attended the monthly meetings with the parents).

The "Sea Lion Club" was financed by health insurance companies and by membership fees from the parents. Medical supervision included case history, physical examination, arterial blood pressure (BP) at rest (by semi-automated Dinamap, Critikon, Tampa, FL), anthropometric measurements, and body composition with bioelectric impedance analysis (BIA, Nutriguard, Data Input, Frankfurt, Germany), and the measurements were performed prior to the program, at 6 months, and after completion. At each interval, fasting blood analyses were performed for the measurement of total cholesterol, high density lipoprotein (HDL) cholesterol, triglycerides, glucose, uric acid, thyroid stimulating hormone (TSH), cortisol, and transaminases (alanine aminotransferase [ALT] and aspartate aminotrans-

ferase [AST]). Laboratory tests were all carried out in the authors' laboratory using a clinical chemistry analyzer (Integra, Roche, Rottkreuz, Switzerland) or by electrochemoluminescence (Elexis, Roche).

The obese control group, consisting of 18 male and 18 female children and adolescents (age range 8-15 years, mean  $11.6 \text{ years} \pm 2.0$ ), received written therapeutic advice during an outpatient visit at 0 and 6 months at the outpatient clinic of the children's hospital in Erlangen/Germany, but the transfer to daily practice was left to their own initiative. The written instructions included recommendations concerning physical activity (such as cycling, walking, or swimming), dietary education (including the "Food Guide Pyramid" fruit and vegetable template, appropriate sizes per meal), and coping strategies (eg, awareness of eating behavior, recommendation of habit books). They were explained to the patient and his or her parents individually by a pediatrician (from a small group of 3 colleagues who were familiar with these topics). The instructions followed the guidelines of the German Working Group for Obesity in Childhood and Adolescence but also included adapted materials described elsewhere in more detail, such as "Got 5?" or the "Food Guide Pyramid."<sup>10-12</sup> There was a children's version, for participants under 12 years of age, and an adolescents' version of handouts containing the same sort of information. A physical checkup was carried out at 0 and 6 months. These sessions, which took place in the morning or in the afternoon, lasted for 30 to 45 minutes. Laboratory tests were provided, as in the former group, prior to the program, at 6 months, and at 12 months.

After 12 months, the participants of each group were offered open, fun-based lessons in the sports club where the active program had been performed.

At the commencement of the study, BMI of controls was higher than BMI of participants of the "Sea Lion Club" ( $P < .05$ ), as was mean age (nonsignificant). The primary outcome variable was, therefore, BMI  $z$  score (ie, standard deviation score, SDS). Recent cross-sectional data were used for reference.<sup>9</sup> The authors calculated BMI  $z$  score to assess obesity at the 3 stages 0, 6, 12 months after starting the scheme, because changes in BMI  $z$  score reflect percentage fat mass better than BMI in children.<sup>13</sup> This is especially important because some of the differences in BMI observed may be explained by the age range covered in the 2 cohorts.

Data were analyzed using GraphPad Prism software 4.0 (GraphPad Software, Inc, San Diego, Calif) and SPSS 14.0 (SPSS, Inc, Chicago, Ill), and values were calculated as mean  $\pm$  standard deviation (SD), if not otherwise stated. Comparisons were made between the active group and the control cohort and within each group. Statistical analysis was performed using parametric tests (2-tailed Student  $t$  test and analysis of variance [ANOVA]), if applicable. A  $P$  value  $< .05$  was considered significant.

## RESULTS

After 1 year, there was a significant reduction of BMI  $z$  score in the active group by  $-0.34$ , from  $+2.24$  to  $+1.90$  ( $P < .05$ ), and of mean BMI ( $-1.5 \text{ kg/m}^2$ ,  $P < .05$ ) (Table). Although BMI of participants of the active group was significantly lower than BMI of controls from the beginning ( $P < .05$ ), baseline values for BMI  $z$  score did not differ significantly ( $P = .07$ ). Assessment of body composition by bioelectric impedance analysis (BIA) showed that fat mass at baseline did not differ significantly between groups ( $P = .06$ ). Only for the active participants did the mean fat mass decrease slightly, but not significantly, by  $-2.1 \text{ kg}$ , whereas mean lean mass increased to the same extent. Moreover, systolic BP was significantly lower in the active group 12 months after the educational program began ( $P < .01$ ).

For the controls, both fat and lean mass increased significantly ( $P < .001$ ) over the study period. The control group, who had received therapeutic instructions on paper at the beginning of the study and 6 months later, did not show a statistically significant improvement for any of the parameters investigated 6 months after recruitment, or after 1 year. The participants in the control group exhibited an increase in BMI by  $+2.80 \text{ kg/m}^2$  ( $P < .01$ ) and BMI  $z$  score by  $+0.26$  ( $P < .05$ ) (Table).

All participants presented with normal growth and pubertal development (Tanner stages) at the time of medical examination. No statistically significant differences were found for the participants' triglycerides ( $-0.3 \text{ mmol/L}$ ), total cholesterol ( $-0.4 \text{ mmol/L}$ ), and diastolic blood pressure ( $-4 \text{ mm Hg}$ ). The authors did not find significant changes for uric acid, HDL cholesterol, serum ALT or AST, cortisol, TSH, or heart rate (data not shown).

Generally, 83% to 100% of participants attended each session, and there was only 1 dropout in the "Sea Lion Club." However, the financial support given by the health insurance companies did depend on regular attendance and completion of the program. The parental meetings and feedback discussions, offered monthly, were generally attended more often by mothers than by fathers.

Interestingly, one third of the participants of the "Sea Lion Club" joined the open sport activities once a week after completing the program. Conversely, in the control group, 6 children were lost to follow up despite telephone calls, and none joined the local sports club as offered 12 months after their first visit.

## LESSONS LEARNED

Local long-term therapeutic programs for young obese patients are an important tool in establishing a more active and health-oriented lifestyle, and to reduce the individual and public burden of obesity in childhood.<sup>14</sup> In growing children, stabilization of body weight slowly reduces BMI  $z$  score, and a value of less than 2.0, as in this project, is presumed to noticeably reduce comorbidity.<sup>1</sup> The authors focused primarily on BMI  $z$  score in this study because

BIA-derived measurements of body composition may be associated with inconsistencies, especially in children.<sup>15</sup> Compared with the controls, there were fewer dropouts in the "Sea Lion Club," and more participants joined the open sport activities thereafter, which is indicative of a more health-oriented lifestyle after completion of the program. However, the health insurance company would pay the total costs only if the children participated regularly, and this requirement certainly contributed to the high attendance rate. A financial incentive may be an additional stimulus for parents to support their children and to incorporate educational training into their daily lives.

The authors are aware that significant effects are difficult to achieve because of the limited number of participants. However, the more active lifestyle in these children and adolescents, and the trend toward a better metabolic profile, can be seen as changes in the right direction.

The authors have designated these data as interim results because they plan to extend the follow-up period of each group beyond 2 years, and they also intend to enroll more participants in the ongoing program, the "Sea Lion Club."

## DISCUSSION

Treatment for adiposity is usually intensive and requires multidisciplinary efforts. Local community-based projects, such as the one depicted here, promote good attendance with the lowest dropout rate. They should offer lessons in strengthening self-esteem, optimizing eating habits, and increasing physical activity as major lifestyle factors affecting body weight. It has been described by other groups, also, that community-based exercise programs may be a tool to establish an active lifestyle, and that parental involvement is required. The Freiburg Intervention Trial for Obese Children (FITOC) in Germany is such an interdisciplinary, outpatient program for obese children 8 to 11 years of age, consisting of regular physical exercise and comprehensive dietary and behavioral education.<sup>16</sup> Parents are also actively involved. In a cohort of 496 children (267 girls, 229 boys), BMI  $z$  score and LDL cholesterol decreased significantly in both sexes after 8.5 months, and physical fitness improved significantly in the intervention group compared with controls. However, fewer parameters were investigated compared with the present study. For example, the authors could demonstrate that the intervention group did not experience a significant gain of fat mass compared with the control group.

Based on the results of obesity treatment programs, the number of pediatric clinics in Germany that offer an interdisciplinary treatment program for obese children has now increased to over 175.<sup>7</sup> It has been found in other studies in Europe, such as the so-called OBELDICKS program, that in those obese children who gain weight despite an intervention program, insulin resistance increases significantly. Weight loss, on the other hand, is associated with an



improvement in the atherogenic profile (lipids, blood pressure) and in insulin resistance, but only if the BMI  $z$  score decreases by at least 0.5 over a 1-year period.<sup>17</sup>

Treatment studies based on the 3 components (eating habits/diet, sports/physical activity, and lifestyle/behavior change) represent most of the clinic-based studies for obesity therapy in children in the United States and in Europe. A concise overview summarizing behavioral-treatment approaches aimed at lifestyle change is given by Epstein and coworkers.<sup>18</sup> Briefly, a multidisciplinary approach integrating behavioral therapy in a comprehensive treatment program that includes diet and exercise is considered beneficial. However, translating the research setting into clinical practice and incorporating new scientific approaches remains a challenge. Furthermore, therapeutic success in subjects with extreme obesity and severe comorbidity has been, in general, disappointing. Along these lines, more aggressive approaches such as bariatric surgery may be indicated under certain circumstances.<sup>1,19</sup>

In summary, treatment strategies used to help pediatric obesity, such as the “Sea Lion Club” presented here, include group therapy along with individualized behavioral counseling, training, and family involvement. However, beneficial effects are difficult to achieve and may diminish over time. Furthermore, it is recommended that the social environment of the children and adolescents, for example the schools and the community, should support policies to help in the establishment of good nutrition and a healthful lifestyle.<sup>20</sup> In the face of the increasing obesity problem worldwide, future corrective actions should, therefore, focus primarily on preventive and potentially more effective approaches.

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