International Journal of Obesity (2004) 0, 000–000
 0307-0565/04 $30.00
www.nature.com/ijo

PAPER

Freiburg Intervention Trial for Obese Children (FITOC): results of a clinical observation study

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BACKGROUND: The Freiburg Intervention Trial for Obese Children (FITOC) is an interdisciplinary, outpatient program for obese children consisting of regular physical exercise and comprehensive dietary and behavioral education. Parental involvement is required. The study is designed as a longitudinal, nonrandomized clinical observation study. An 8-month intensive phase preceded a follow-up phase of 1 y or longer.
METHODS: Data were collected from 31 groups comprising 496 children (267 girls, 229 boys), with an average age of 10.5 y. Body height and weight, fasting total-cholesterol (CH), low-density lipoprotein-cholesterol (LDL-C), high-density lipoprotein-cholesterol (HDL-C) and physical performance were measured initially and after 8.5 months. A group of $n=35$ obese children (16 girls, 19 boys) who did not take part in this intervention program served as controls.
RESULTS: After the intensive intervention phase, body mass index (BMI, kg/m^2) as well as BMI deviation scores (BMI-SDS) decreased in both sexes ($P<0.001$). In the controls, BMI increased ($P<0.001$) and BMI-SDS remained constant. Whereas CH was only significantly lower ($P<0.01$) in boys after 8.5 months, LDL-C decreased significantly in both sexes. HDL-C tended to increase in both sexes (not significant). The controls showed no significant changes in CH, LDL-C and HDL-C. The fitness levels (W/kg body weight) improved in the intervention group ($P<0.001$), but not in the control group.
CONCLUSIONS: The results indicate that obese children can be successfully treated in such an intervention program. BMI-SDS and risk factors decreased and physical performance improved. To maintain therapeutical success, we highly recommended that these children enroll in community-based exercise programs in order to help them maintain a more active lifestyle after the follow-up phase.
International Journal of Obesity (2004) **0,** 000–000. doi:10.1038/sj.ijo.0802875

Keywords: obesity treatment; parental involvement; outpatient; physical activity; lifestyle; children

Introduction

Over the last 20 y, human lifestyle has changed dramatically. Sedentariness, excessive availability of food, as well as socioeconomic changes have led to an increase in both adult and childhood obesity. In addition, physical activity has dramatically decreased with a potential impact on weight gain in all age groups.[1,2] It is evident that there is a significant correlation between the degree of obesity and the number of hours spent watching television or using other media.[3,4] Therefore, lifestyle education is a key element in obesity therapy.

Childhood obesity is an important predictor of adult obesity with potential cardiovascular risk factors.[5–9] The socioeconomic cost factor is enormous.[10] Thus, it is essential to develop strategies for the prevention of childhood obesity and effective treatments for overweight children. Despite growing scientific knowledge about obesity treatments, long-term intervention programs are rare.

Established at the Freiburg University Hospital in 1987,[11] the Freiburg Intervention Trial for Obese Children (FITOC) is an interdisciplinary outpatient treatment program for obese children. In contrast to other approaches, parental involvement plays a major role in the FITOC program. Besides supporting their own children, the parents themselves are given theoretical and practical information about nutrition, as well as background information about the psychological and physiological problems of obese children. We are in the process of testing the effectiveness of the Freiburg FITOC obesity intervention program on atherogenic risk factors and physical fitness. This paper summarizes changes in weight, physical performance and cholesterol values over a period of

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Received 4 April 2004; revised 4 August 2004; accepted 6 October 2004

Journal: IJO ☐ Disk used: com Despatch Date: 18/11/2004
Article: NPG_IJO_0802875 Pages: 1–6 Op: VVC Ed: Suja

8 months. Data on skinfolds, questionnaires and psychosocial evaluations will be the subject of future publications.

Methods and subjects

In the period between 1990 and 2003, 31 groups underwent an 8-month intervention program. Children participating in the program were referred by either family doctors, pediatricians or school doctors. Some were outpatients at two university clinics (Universitäts-Kinderklinik, Kinder- und Jugendpsychiatrie der Universitätsklinik). We began requiring that parents sign a contract, which informs them about the program and mutual responsibilities over a specified period, 2 y ago. Except for a nominal sum, costs of the intervention program were completely paid by medical insurance.

The program consisted of regular physical exercise (three times a week) plus comprehensive dietary and behavioral education. A manual and audiovisual materials were used. During the program, there were no changes in the team personnel, which consisted of a physician, a nutritionist, a sports teacher and a psychologist.

At 4- to 6-week intervals during the 8-month program, seven information sessions with parents and seven with their children were held. At these meetings, staff members gave parents theoretical and practical information on obesity and nutrition and answered individual questions. Children were separately given the same basic information. Questionnaires concerning nutrition (food frequencies) and behaviour were regularly completed.

Medical check-ups and all activities except sports took place in our outpatient clinic. The sports program was carried out in a Freiburg sports center and consisted of three sessions per week. Sessions (1 h) began with 10 min of endurance training followed by psychomotoric activities and exercises to improve coordination, flexibility, strength and speed performance capacity. The exercise program was designed to enhance the joy of movement, body awareness and team spirit in order to bring about long-term changes in behavioral patterns. The primary goal was to increase self-esteem and daily energy expenditure through pleasurable activities.

We established long-term goals for the individual child as recommended in the guidelines of the 'Arbeitsgemeinschaft Adipositas im Kindes- und Jugendalter'. Depending on individual progress, appropriate goals for changes in lifestyle were periodically discussed and individually set by the child and parent. These goals conformed to those established by the guidelines of the German 'Arbeitsgemeinschaft Adipositas im Kindes- und Jugendalter' (AGA—www.a-g-a.de).

The inclusion criteria was a body mass index (BMI, kg/m^2) above the 97th percentile based on up-to-date BMI curves for German children.[12]

Children with a BMI between the 90th and 97th percentile were included in the program if they had somatic comorbidities or one overweight parent.

Initial examinations of all 496 children (boys $n=229$; girls $n=267$) were conducted. At the beginning of the program, boys were 10.6 ± 1.5 and girls 10.5 ± 1.6 y of age. Follow-up examinations after the intensive program were carried out 8.5 ± 1.2 months later. The structure of the 31 groups was almost identical with regard to the number of participants, the ages of the children and their sex distribution. Thus, there were no significant differences with regard to the average number of participants ($n=16\pm2.5$) and the age of the children (10.5 ± 1.5). There were slightly fewer boys (46.3 ± 15.0%) than girls (53.6 ± 15.0%) in the groups, but this was not significant ($\chi^2=0.06$).

A group of 35 obese children aged 9.9 ± 2.2 y, who could not take part in our intervention program due to a lack of therapy places or time, school or transportation difficulties, served as controls. They underwent only the initial and follow-up examinations after 9.2 ± 5.9 months.

Anthropometrical, biochemical and fitness data were collected. Measurements of body height and weight, fasting total-cholesterol (CH), low-density lipoprotein-cholesterol (LDL-C), high-density lipoprotein-cholesterol (HDL-C) and physical performance followed identical, standardized guidelines.[11] Total cholesterol was assayed using enzymatic colorimetric tests (cholesterol CHOD-PAP-method); LDL-C and HDL-C with electrophoretic qualification (Helena REP Diagnostic, Greiner Bio Chemica). Physical performance was gauged with a standard bicycle ergometer (Lode, Groningen, The Netherlands) using a typical test protocol starting at 50 W and increasing the work load by 25 W every 3 min until exhaustion.[13] Heart rate and lactate concentration were also recorded every 3 min.

The study was approved by the University of Freiburg Ethics Committee.

Depending on individual progress, appropriate goals for changes in lifestyle were periodically discussed and individually set by the child and parent. These goals conformed to those established by the guidelines of the German 'Arbeitsgemeinschaft Adipositas im Kindes- und Jugendalter'.

Statistical analysis

To analyze the weight status, BMI was calculated as body weight in kilograms divided by the square of height in meters. To correct for age and sex, individual BMI-values were converted to *Z*-scores (SDS values = standard deviation−score values). Calculation of SDS values was based on the national reference data for German children.[12] These references were derived using the LMS method from Cole,[14] which allows BMI in individual subjects to convert into SD scores as follows:

$$\mathrm{SDS} = [(X/M(t))^{L(t)} - 1]/L(t)S(t)$$

where X is the individual BMI value, L is the Box–Cox

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power, M the median and S the coefficient of variation for individual age (t) and sex from the reference group. Results are indicated as BMI-SDS values.

The Kolmogorov–Smirnov test was used to verify the assumption of normality. T-test for dependent samples was used to evaluate differences between the initial examination and the examination after the intensive phase of the program.

Trends in BMI-SDS changes between the examinations (increase or decrease) of sexes were tested by using a χ^2 test for categorical variables.

Statistical inferences were drawn at a significance level of 5%. All analyses were performed using the SPSS 10.0 software package (SPSS Inc., Chicago, IL, USA).

Results

The 8-month intensive phase with 31 groups was completed by 461 children (92.9%) (Table 1). The drop-out rate showed no gender-specific differences ($P = 0.35$). All main study variables were normally distributed. The variation in the number of subjects between the subsequent time points are explained by missing values in different measurements. After the intensive phase, 72.8% of the children had lower BMI-SDS values (responders) compared to those at the beginning of the program. There was no significant difference in BMI-SDS response between boys and girls (Table 1).

During the intensive phase of the program, the average BMI and BMI-SDS of all subjects decreased significantly in the intervention group. Whereas plasma cholesterol and LDL-C decreased, HDL-C tended to increase (NS). Physical performance (W/kg body weight) had improved in the intervention group when postprogram values were compared with initial measurements (Table 2).

Table 1 Characteristics of the intervention group

	Total	*Boys*	*Girls*
Drop-out			
n	35	13	22
%	7.1	5.7	8.2
Missing data			
n	15	7	8
%	3.0	3.1	3.0
BMI-SDS[a] $\geq$ *BMI-SDS EU*[b] *(nonresponders)*			
n	85	34	51
%	17.1	14.8	19.1
BMISDS[a] $<$ *BMI-SDS EU*[b] *(responders)*			
n	361	175	186
%	72.8	76.4	69.7
Total			
n	496	229	267
%	100	100	100

Gender differences not significant (χ^2 test; $P = 0.35$). [a]Initial BMI-SDS. [b]BMI-SDS after 8.5 ± 1.6 months.

In the controls, BMI increased and BMI-SDS remained constant. Plasma cholesterol, LDL-C and HDL-C showed no significant changes. The fitness levels (W/kg body weight) remained unchanged in the controls (Table 2).

BMI and BMI-SDS decreased significantly in boys and girls with no gender differences (Table 3). In boys, total plasma cholesterol and LDL-C decreased. In girls, only LDL-C decreased significantly. HDL-C showed no significant change in either sex. Physical performance (W/kg body weight) improved in girls as well as in boys. Generally, smaller changes occurred in girls than in boys.

Discussion

After 8 months of intensive treatment, we found a small but significant decrease in BMI and BMI-SDS for both boys and girls. In contrast, in the controls, BMI increased and BMI-SDS remained unchanged. Pediatric weight management programs should emphasize realistic goals. During periods of rapid growth, a relatively moderate weight loss can be considered a success. Depending on therapeutical progress, new goals were set to meet the individual needs of each child and parent. During the intensive period, children learn to control themselves so that they can achieve their goals.[15] The drop-out rate showed no gender-specific differences and was very low. This indicates that this program suited the needs of the children and their families. Development around the age of 10 y is important.[16]

Several studies reported a gender-related development of relative body weight and fat distribution in children of this age. Wilmore and Costill[17] found an impressive increase in subcutaneous fat tissues in nonobese girls at the onset of their sexual maturation, whereas boys showed no changes in the percentage of their body fat over time. However, van Lenthe *et al*[18] found no differences in fat distribution between nonobese males and females between the ages 13 and 27 y. However, they did find higher mean trunk-oriented skinfold ratios in girls with early menarche. Therefore, in girls, advanced sexual maturation during adolescence seems to be a determinant of the development of a trunk-oriented fat distribution pattern from adolescence through adulthood. Since most of the obese girls are included in the 'early sexual maturity group', our results might in parts be influenced by the role of hormones in the development of fat patterns and weight gain.

The lipoprotein measurements in our study showed some inconsistent values. The boys showed a significant decrease in total cholesterol levels, yet no significant decrease in girls was found. Whereas the LDL-C values decreased significantly in boys as well as in girls, the HDL-C levels tended to increase in both sexes. We little knowledge about the influence of weight reduction programs on lipoproteins in obese children. In general, HDL-C levels are negatively associated with

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Table 2 Results of the intervention group and the control group

	Intervention group						Control group					
	Initial examination			Follow-up examination[a]			Initial examination			Follow-up examination[b]		
	N	Mean	s.d.	Mean	s.d.	P-value*	N	Mean	s.d.	Mean	s.d.	P-value*
BMI (kg/m^2)	446	25.5	3.3	25.0	3.5	<0.001	35	26.5	5.4	27.6	6.0	<0.001
BMI-SDS	446	2.08	0.51	1.86	0.59	<0.001	35	2.30	0.71	2.30	0.74	0.861
CH (mg/dl)	405	179.9	33.7	176.1	30.7	<0.001	11	167.6	26.5	178.8	19.4	0.108
LDL-C (mg/dl)	422	106.0	28.9	100.2	25.8	<0.001	15	90.2	20.6	92.7	20.6	0.581
HDL-C (mg/dl)	419	47.8	11.3	48.5	12.0	0.183	16	58.4	19.7	54.5	12.5	0.553
Watt/kg	411	1.9	0.4	2.2	0.5	<0.001	16	2.2	0.5	2.4	0.6	0.284

BMI-SDS = BMI deviation scores; CH = total cholesterol; LDL-C = low-density lipoprotein-cholesterol; HDL-C, high-density lipoprotein-cholesterol; Watt/kg, W/kg body weight. *Differences between examinations; *t*-test for dependent samples. [a]Examination after intensive phase (8.5 ± 1.2 months). [b]Examination after 9.2 ± 5.9 months.

Table 3 Results in boys and girls after intensive phase

	Boys						Girls					
	Initial examination			Follow-up examination[a]			Initial examination			Follow-up examination[a]		
	N	Mean	s.d.	Mean	s.d.	P-value[b]	N	Mean	s.d.	Mean	s.d.	P-value[b]
BMI (kg/m^2)	209	25.8	3.5	25.2	3.7	<0.001	237	25.2	3.1	24.9	3.3	<0.001
BMI-SDS	209	2.10	0.51	1.87	0.61	<0.001	237	2.07	0.51	1.87	0.58	<0.001
CH (mg/dl)	190	183.7	33.9	177.8	30.9	<0.001	215	176.5	33.4	174.7	30.6	0.208
LDL-C (mg/dl)	195	109.3	29.4	101.4	25.4	<0.001	227	103.2	28.3	99.3	26.2	0.001
HDL-C (mg/dl)	194	49.3	22.4	49.8	13.1	0.553	225	46.6	11.1	47.4	10.8	0.170
Watt/kg	190	2.0	0.4	2.3	0.5	<0.001	221	1.9	0.4	2.1	0.5	<0.001

BMI-SDS = BMI deviation scores; CH = total cholesterol; LDL-C = low-density lipoprotein-cholesterol; HDL-C, high-density lipoprotein-cholesterol; Watt/kg, W/kg body weight. [a]Examination after intensive phase (8.5 ± 1.2 months). [b]Differences between examinations; *t*-test for dependent samples.

testosterone and positively associated with estrogen.[19,20] These findings are well known in adults and indicate generally higher HDL-C levels in postmenarchal females.[21]

Suter *et al*[22] examined a cohort of 10- to 15-y-old boys and girls. In concordance with our results, they described higher HDL-C levels in younger boys than in older boys. In addition, independent of age, they found higher HDL-C values in girls than in boys. The same trend was seen in Northern Ireland by Boreham *et al*,[23] who described a cohort of subjects between the ages 12 and 15 y. All these results are primarily explained by the influence of sex hormones in that age group. In light of these findings, our own results show a positive effect even in boys.[24] It is well known that an unfavorable lipoprotein profile during childhood results in an unfavorable risk profile in adult life.[25] We conclude that the changes in cholesterol and cholesterol subfractions in our study were due to our therapeutical approach and predict a more favorable profile for these children in adulthood.[26]

Besides dietary and behavioral education, physical activity patterns and levels seem to play a major role in modulating relative weight and body composition, especially in young children and adolescents. In our study, physical performance of both sexes increased significantly after the 8-month intensive intervention period. In a recent review about the relation between physical activity and obesity in children and adolescents, it was concluded that boys are more active than girls, and that physical activity decreases with age, especially in girls.[27] In accordance with these findings, Goran *et al*[28] showed a significant decline in physical activity in girls before puberty. They found a 50% reduction in the physical activity of girls between 7 and 10 y of age. In contrast, boys increased their physical activity over the same period by 20%. Berkey *et al*[29] studied the association between changes in BMI over a period of 1 y and changes in recreational physical activity *vs* recreational inactivity (TV/videos/video games) during this same period. Increased physical activity led to a lower BMI in both boys and girls. Many children can benefit from an increase in physical activity and a decrease in the time spent watching TV or videos and playing video games.

Physical activity seems to be one of the key elements in the treatment of childhood obesity. Trost *et al*[30] compared physical activity patterns in obese and nonobese middle school children. From this, they concluded that physical inactivity is an important contributing factor in the maintenance of childhood obesity. As a consequence, they suggest that physical activity must be included as a major

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component in therapy programs. We seemed to be able to increase the awareness of and the access to physical activity in boys and girls. Above all, the major problem with most exercise training programs is that they do not take into account the natural activity patterns of children and the different interests of boys and girls.[16] Based on these, we plan to modify our future approaches and offer more gender-specific physical activities. In addition, we will explore strategies to involve obese children in community-based physical activity programs.

Pediatric overweight is known to be a major predictor of adulthood obesity, a factor in higher morbidity and mortality.[31,32] Future efforts to treat obesity should focus on early initiation of treatment and long-term follow-up regimens to prevent weight cycling and therapy failure. We intend to include more children as controls and to document long-term results after about 3 y. This will be content of further publications. To achieve the goals of our treatment, therapists, as well as health administrators, must develop new ideas to motivate obese children and their families to join and stay in obesity treatment programs. Furthermore, FITOC is more economical than inpatient treatment. Efforts may include financial incentives, such as lower personal health insurance costs as well as improved status.

In conclusion, childhood obesity, a chronic disease, needs time and observation for appropriate treatment to be effective. In the present study, we were able to show that successful outpatient treatment for obese children is possible. It was obvious that to maintain the success achieved in therapy, it is essential to get the children involved in community-based exercise programs.

Primary prevention programs are important to decrease the incidence of obesity. This can be achieved by prevention programs[3,33–36] on school base with a modification of eating, behavioral and activity patterns.

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