Multi-disciplinary group intervention versus standard treatment for obese children involving parents (GRIB2004). A Randomized Clinical Pilot Trial. Original Article

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Appendix:1

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Abstract

Objective: To compare the effect of a multi-disciplinary group intervention versus standard treatment for obese children involving parents.

Setting: Recruitment via local health nurses and general practitioners. Centralized randomization; treatment and follow-up at a department of paediatrics.

Participants: 45 overweight children (10-15 years) were randomized into two groups, stratified by sex and degree of obesity.

Interventions: The experimental intervention was a multi-disciplinary group intervention. The control group received standard treatment: one hour of nutritional advice plus a 20-minute follow-up after one month.

Main outcome measures: The primary outcome measure was change in BMI measured monthly during 12 months. Secondary outcome measures were percentage of body fat measured by dexascan, hip/waist ratio, and skin fold.

Results: Using a mixed-model analysis, the follow-up data for all time-points showed no significant difference between the intervention group and the control group for any of the outcome measures. A subgroup analysis of moderately overweight children (BMI: 135% - 145%) revealed a significant ($p = 0.005$) beneficial main effect of the experimental

intervention (mean BMI 24.5 (95% confidence interval 23.8 to 25.2) in the experimental group versus 26.1 (95% confidence interval 25.5 to 26.7) in the control group) as well as significant effect for time regarding the BMI measurements. In both groups, the dexascan fat percentage dropped significantly from entry to 6 months.

Conclusion: Multi-disciplinary group intervention may have beneficial effect on BMI in moderately overweight children. Further randomized trials are needed.

Keywords: Children, Clinical trial, Group intervention, Obesity, Overweight, Parents, Psychological intervention.

Trial Registration: NCT00554645

The Danish Regional Committee on Biomedical Research Ethics: Journal no 2003-1-40

The Danish Data Protection Agency: Journal no 2033-41-3214 approved the trial.

INTRODUCTION

The number of obese children is increasing **1.** Obese children have negative self-perception, experience bullying, other psychological and psychiatric difficulties, and have psycho-social problems **1, 2, 3**. Schwimmer et al showed that severely overweight children have health-related quality of life similar to those with cancer **4.** Obese children have a significantly higher risk of serious, chronic physical diseases **5, 6**.

Treatment of obese children has traditionally been based on nutritional advice alone or in combination with psychotherapeutic counselling. The counselling offered to supplement nutritional advice varies in intensity, duration, theoretical approach, and psychological aim **7, 8.** There is increasing consensus, that parent participation increases the effectiveness of anti- obesity interventions **9, 14, 15** .There seems to be some evidence, that long-term treatment (6-12 months) has a greater effect than short-term treatment **5**. The need for further randomized trials in this area has been stressed **7.**

The research question we attempted to answer was, “Is initial family-oriented advice on nutrition and exercise combined with psychotherapeutic counselling and motivational exercise with monthly control of body weight for one year more effective in the reduction of BMI than the family-oriented initial advice with monthly control of body weight?”

PARTICIPANTS AND METHODS

Local health nurses and general practitioners in the county of Frederiksborg recruited participants. Criteria for participation included a BMI larger than 135% of the Danish norms **16**, age between 10 and 15 years, command of the Danish language, and at least one parent willing to participate in the parent group. If the weight problem was caused by a somatic disease (e.g., hypothyroidism, polycystic ovary syndrome, etc.), if one or both parents suffered from a psychiatric disorder, if the child was maltreated, or if a sibling participated in the trial, then the child was excluded from participation prior to randomization. The blood pressure, 24-hour urine cortisol, plasma TSH, plasma free T_3, plasma free T_4, fasting serum triglycerides, HDL, LDL, and cholesterol, and haemoglobin A1c were measured. Girls suffering from hirsutism had polycystic ovary syndrome tests and girls with height less than 50% of that corresponding to their age were examined for Turner's syndrome. The Danish Regional Committee on Biomedical Research Ethics (Journal no 2003-1-40) and the Danish Data Protection Agency (Journal no 2033-41-3214) approved the trial. Written informed consent was obtained from both children and parents before inclusion in the study.

Interventions

The experimental intervention was multidisciplinary. It included 27 sessions of counselling, 21 sessions of physical exercise, 18 sessions of parent counselling, an initial lecture on the general principles of nutrition, and exercise by an authorized clinical nutritionist. In the first 6 months, the children, distributed in four groups, attended one-hour long

psychotherapeutic group sessions once a week followed by one hour of exercise. In the following 6 months, the children in the four groups attended the psychological group session once a month without exercise. The parents attended a psychotherapeutic group session every second week in the first 6 months and then once a month in the following 6 months. Once a month, the children were weighed and their height was measured. A child psychologist, who is a certified psychoanalytic child psychotherapist, led the parent group. The child psychologist alone or the child psychologist and a student of psychology led the children's psychotherapeutic group sessions. The exercise sessions were led by either a certified social education worker or a student of psychology. All sessions were supervised by the child psychologist in order to secure coherence in the attitude and communication towards each child in the psychotherapeutic sessions, the exercise sessions, and the parents group. There were six children at most in each of the four groups. The mean attendance was 16 sessions and the median attendance was 19 sessions out of 27 possible sessions. Details of the psychodynamics of the intervention program are given in appendix 1.

In the control group, individual advice based on the general principles of encouraging physical exercise and a high protein diet was given to each family by a registered clinical nutritionist for 60 minutes. Furthermore, there was a follow-up session of 20 minutes with each family after one month. The child was weighed and the height was measured once a month.

Objectives

In the current trial we aimed to test the benefits and harms of a multi-disciplinary group intervention based on psychotherapeutic counselling plus exercise versus standard nutritional advice in reducing BMI in obese children.

Outcome measures and measuring equipment

The primary outcome measure was BMI measured every month for 12 months, using Stadiometer TYPE 3, FORCE INSTITUTTET and SECA DELTA, MODEL 707 (with no shoes, wearing light garment). Secondary outcome measures were percentage of fat determined by a dual-energy x-ray absorptiometry (dexascan), skin fold thickness measured with a Harpenden's skin fold calliper, and hip/waist ratio. The secondary outcome measures were obtained at baseline, at 6 and 12 months.

Sample size

The resources available determined the sample size of this pilot trial. We aimed at forming four teams, each comprising of six children in the experimental group and 24 children in the control group, in order to obtain a total of 48 children.

Randomization and blinding

Randomization was conducted centrally at the Copenhagen Trial Unit (CTU). The randomization was stratified by sex and degree of obesity (between 135%-145% and over 145%, according to the Danish norms for weight and height)[16] as we expected, that the severely obese children would be more difficult to treat. At randomization the child's sex, and degree of obesity was recorded by the CTU and the allocation (experimental or control) was then given to the principle investigator, who informed the families by letter. The intervention was not masked or blinded to the therapists who administered the interventions (i.e. clinical nutritionist, child psychologist, social education worker) or outcome assessors. However, data-analyses and drawing of conclusion were conducted blindly.

Statistical methods

A repeated-measures analysis of each outcome measure with, and without the protocol specified stratification factors (sex and degree of obesity) included was conducted to test for significance ($p < 0.05$) of the main effect of the intervention (different mean BMI levels in the two intervention groups) and interaction between intervention and time (different time course of the outcome quantity in the two groups) using a mixed-effects model (proc mixed SAS 9.1). The entry value was included as a co-variate.

The assumption that the measurements follow Gaussian distributions was tested (Kolmogorow Smirnov test and the Wilk Shapiro test) using a significance level of $p = 0.005$ and supplemented by a graphical analysis of the cumulative distributions.

The Akaike's information criterion and the Schwartz' Bayesian criterion were used to find the covariance structure that best fitted the data. An unstructured, a compound symmetric, and an autoregressive order 1 covariances (ar(1)) were examined.

A non-parametric test (Mann Whitney) was used to examine if the fraction of missing data (number of missing values over the number of measurements planned for a participant) differed significantly ($p < 0.05$) between the two intervention groups and between the two overweight groups.

RESULTS

Ninety-eight children were referred for assessment of eligibility. Of these, only 67 families (68.4%) came to the department of paediatrics to be evaluated. Of these, 45 children met the inclusion criteria and were randomized; 21 to the multi-disciplinary intervention group and 24 to the control group.

Table 1 shows the mean value of each of the demographic quantities (sex, age, degree of obesity group, systolic blood pressure, diastolic blood pressure) and the entry values of each outcome quantity in each intervention group and in the total cohort. For continuous quantities the standard deviation is also shown.

Table 2 shows the mean fraction of missing values of the children in each of the intervention groups for each of the outcome quantities and the p-values of the comparisons between groups. The mean fraction of missing dexascan values of the experimental group is significantly lower than in the control group. The same trend, but of borderline significance, is noted in case of the other three outcomes. We found no significant differences between the two overweight groups.

Table 3 shows the mean value and standard deviation of each outcome quantity in each intervention group at the determined time points. None of the outcome value distributions differed significantly from the Gaussian distribution.

Neither the mean level nor the time course of the outcome measures differed significantly between the intervention groups for any of the four outcome measures. When the intervention groups were combined and the entry values were included, we found a significant effect of time on the dexascan fat percentage, which decreased over the first 6 months as compared to the entry value and then remained constant.

The analysis of the subgroup comprising children with 135% to 145% obesity revealed a significant ($p = 0.005$) beneficial main effect of the experimental intervention as well as a significant ($p = 0.01$) interaction between time and intervention in case of the BMI (table 4). The mean BMI was 24.5 (95% confidence interval (C.I.) 23.8 – 25.2) in the experimental group and 26.1 (95% C.I. 25.5 – 26.7) in the control group.

When the analysis was confined to the initial visit and the bi-annual visits, where relatively few values are missing, similar results were obtained. The same was true when the protocol-specified stratification factor sex was included.

Table 5 shows the number of BMI observations and their mean value in each intervention group prior to randomization (time 0) and at each of the 12 control visits. In addition, the results obtained when pooling the values of the first 6 visits, the last 6 visits, and all visits are shown.

DISCUSSION

The multi-disciplinary group intervention seems to have a beneficial effect on the BMI of moderately obese children, but we found no significant effect on the group of severely overweight children. It is unclear, whether they were more resistant to treatment or whether this was due to a type II error (false negative). The absence of evidence of effect may not be the same as evidence of absence of effect **17.** On the other hand, the observed effect on the BMI of moderately overweight children could also represent an enhanced type I error (false positive)**18**, although following pre-defined stopping rules we did not require that the trial was stopped early for benefit.

One asset of this trial is that it was randomized centrally, to avoid selection bias **17, 18, 19.** The randomization was stratified in order not to get confounded by sex and the degree of obesity. To avoid a biased statistical analysis and conclusions, the statistical analysis was blinded **17, 19, 20.** We designed an experimental intervention, which takes into account a

number of psychological considerations, which are thought to be of importance for overweight children **2**. The group treatment design draws therapeutic benefits from group dynamics, whereby the substantial expense in such programs can be limited **21.**

Our trial also has limitations. Even though the randomization has been successful in that the two groups became quite similar (table 1), the sample size was very small, as it was determined by availability of resources, and not on a sample size calculation based on an estimated intervention effect. Thus, this trial should be considered a pilot trial. Furthermore, we only observed an effect of the experimental intervention in a subgroup. Such findings may be misleading **18** A very conservative approach to a subgroup analysis is to require that the subgroup class interacts with the intervention **22**. This interaction was, however, only significant at the 10% level. Therefore, even though our results may seem quite positive, we recommend the conservative approach, i.e., our results should be confirmed or refuted in an independent trial. We did not manage to blind the BMI measurements, although this would have been an advantage **17,19, 20.** Accordingly, we are not able to exclude observer bias when reading the BMI **17, 19, 20.** However, dexascans were conducted and assessed without the assessor's knowledge of the interventions provided. Our trial was not blinded to the participants, as this form of intervention cannot be masked **23.** A non-intervention control group was not included in the design, due to ethical and methodological problems **23**. Instead we used the standard treatment as control intervention. It is difficult to establish whether the effect was due to the length of the treatment, to the approach of the treatment or both. To address this problem, a controlled trial comparing different approaches should be conducted.

The statistical methods used allow all observations to be utilized. By contrast, a traditional complete-case analysis does not utilize the observations made in the incomplete cases (participants with one or more values missing). The analysis of the missing value fractions revealed that they tended to be related to the type of intervention. This is not surprising. The aim of the trial was to compare two interventions that differed in terms of the intensity of the psychological support given to the participants. One may expect that with less psychological support the participant may be more frequently absent from control visits. Our results indicate, but do not prove, that the values may not be missing completely at random (MCAR). The missing at random (MAR) condition implies that data are only missing as a function of those values that have actually been observed, e.g. intervention group membership. As long as the values are MAR, the results of the mixed-model analysis will not be biased because all observations are used to estimate the likelihood function **24.**

Problems may arise if the fraction of missing values depends on the values that are actually missing. However, in the present case it is difficult to imagine that a high fraction of missing values is related to a decreasing value of the BMI and thereby to a successful effect of the intervention. A much more plausible hypothesis would be that those participants with unchanged or increasing BMI, i.e., with lack of beneficial response to the intervention, are more likely to drop out than those in whom this is not the case. This hypothesis is supported in previous studies **25, 26.**

Few values were missing from the measurements obtained at entry and at the bi-annual visits. In the experimental group only one participant had missing values (table 5). When

these missing values were replaced by the baseline value assuming no effect of intervention, the effect of the experimental group on the main outcome as well as the interaction between group and time were still significant ($p < 0.0207$ and $p < 0.0359$, respectively). Furthermore, according to the above reasoning, one would expect the BMI in the control group to be higher and not lower had there been no missing values and, therefore, the difference between the two intervention groups to be even more pronounced. Thus, it is not likely that the positive results of the subgroup analysis may be explained by the fact that values were missing. But conclusions based on the results of the subgroup analysis should still be tempered.

It could be argued, that the dexascan and the hip/waist-ratio would be more appropriate primary outcomes than change in the BMI. Our present results do not suggest an intervention effect on the secondary outcome measures. However, the frequency of the height and weight measurements is higher than that of the other measurements, thus providing greater precision.

As noted earlier, the amount of randomized trials in this area is still small and comparison between the trials is difficult. However, recent randomized trials of intensive, multidisciplinary programs point towards beneficial effects on obesity for up to 12 months**15, 21**. Our present trial highlights the possibility of focused psychological counselling plus exercise as the main element in weight reduction programs. In order to verify or refute the result of the current trial, we propose a large randomized trial examining multidisciplinary group intervention versus standard treatment.

Conclusion

Based on the results of this pilot trial we hypothesize that there is a potentially beneficial effect of multidisciplinary intervention based on psychotherapeutic interventions in combination with exercise compared with brief nutritional advice alone for moderately obese children. This hypothesis needs to be tested in further randomized trials in order to confirm or refute the effect of the suggested intervention.

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Figure 1. Flow chart for enrolment, randomization, and follow-up of trial participation

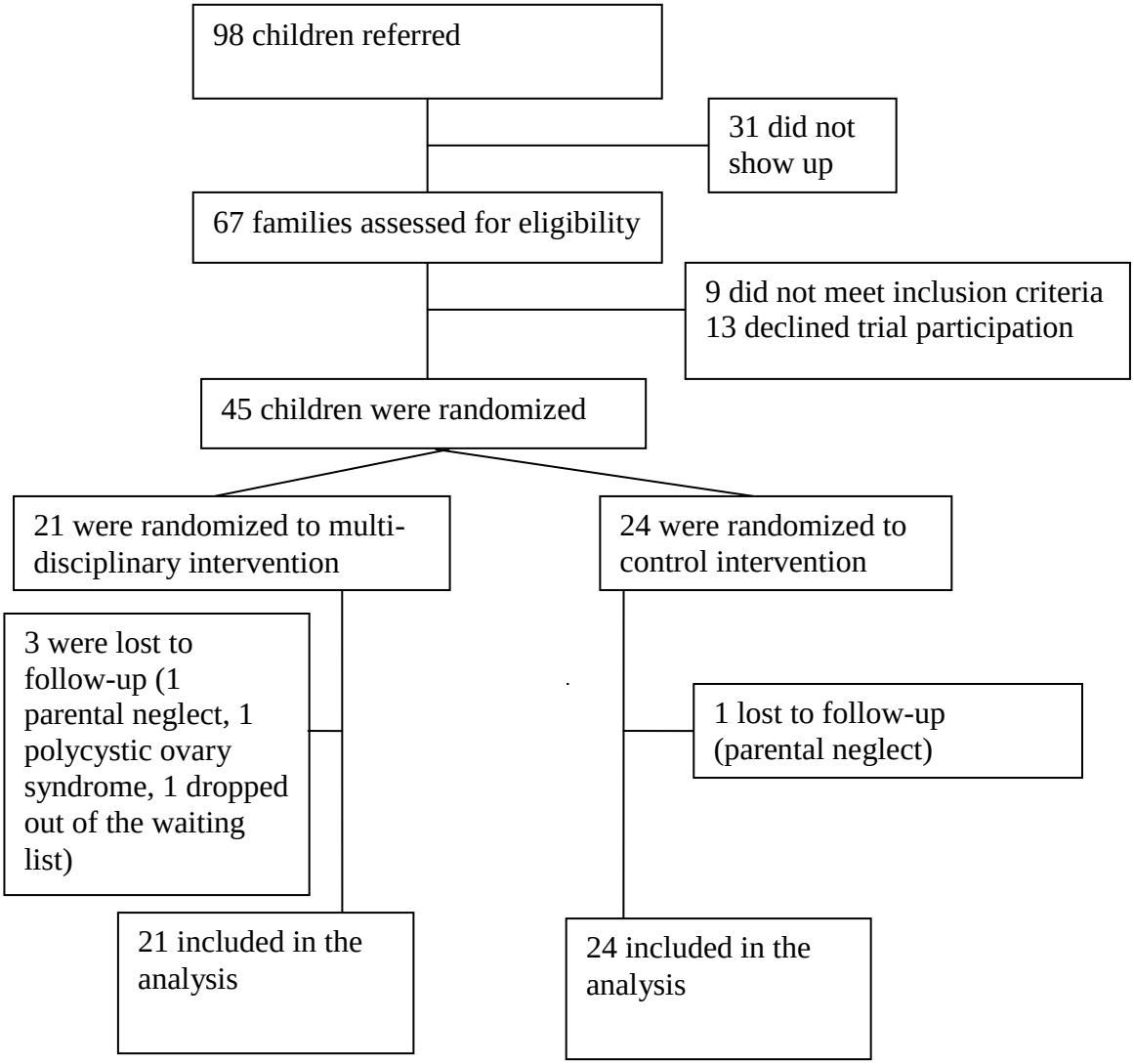

Table 1. Demographic quantities and entry values of outcome variables as measured in each intervention group and the total cohort.

Quantity	Experimental group (n=21)	Control group (n = 24)	All patients (n = 45)
Females no (%)	6 (29)	11 (46)	17 (38)
More than 145% overweight no (%)	15 (71)	15 (63)	30 (67)
Age (year) (mean (SD))	12.2 (1.4)	12.0 (1.6)	12.1 (1.5)
Systolic blood pressure (mm Hg) (mean (SD))	126 (11)	123 (13)	125 (12)
Diastolic blood pressure (mmHg) (mean (SD))	69 (10)	71 (13)	70 (12)
BMI* (kg/m^2) (mean (SD))	29.4 (4.4)	29.2 (4.1)	29.3 (4.2)
Skin fold (cm) (mean (SD))	3.86 (0.86)	3.95 (0.63)	3.91 (0.74)
HWR** (mean (SD))	1.08 (0.08)	1.09 (0.10)	1.09 (0.09)
Dexascan*** (fat %) (mean (SD))	39.5 (7.7)	37.9 (5.7)	38.7 (6.7)

* BMI is body mass index, which is weight/$height^2$ (kg/m^2).
** HWR is hip circumference (cm)/waist circumference (cm).
*** Dexascan is assessed by dual-energy x-ray absorptiometry scanning.

Table 2. The mean of the fraction of missing values relative to the number planned to be measured in a patient of each of the outcome measures in each intervention group and in the total cohort.

Outcome quantity	Experimental group	Control group	All patients	P-value
BMI*	0.45	0.63	0.54	0.09
HWR**	0.24	0.40	0.32	0.07
Skinfold (cm)	0.22	0.39	0.31	0.06
Dexascan*** (fat %)	0.21	0.43	0.37	0.03

* BMI is body mass index, which is weight/height^2 (kg/m^2).
** HWR is hip circumference (cm)/waist circumference (cm).
*** Dexascan is assessed by dual-energy x-ray absorptiometry scanning.

Table 3. Number of observations, mean and standard deviations (SD) of the outcome measures in each intervention group at each time of measurement during the trial.

Quantity (t)*	Experimental group			Control group		
	n	mean	SD	n	mean	SD
BMI** (0)	21	29.2	4.06	24	29.4	4.40
BMI (1)	14	28.0	3.88	15	28.1	3.87
BMI (2)	13	28.5	5.15	10	28.9	4.25
BMI (3)	15	29.0	4.57	13	28.5	4.14
BMI (4)	11	29.4	5.70	9	28.6	4.46
BMI (5)	13	25.4	1.32	6	28.9	4.32
BMI (6)	14	28.7	5.25	12	28.7	4.60
BMI (7)	7	26.6	4.52	6	30.4	4.29
BMI (8)	9	26.4	4.28	6	27.7	4.31
BMI (9)	5	28.6	5.34	3	29.4	4.55
BMI (10)	8	28.2	5.60	5	29.1	3.73
BMI (11)	5	23.2	1.92	2	30.5	3.99
BMI (12)	14	28.2	4.79	9	28.9	5.20
HWR*** (0)	19	1.09	0.10	23	1.08	0.08
HWR (6)	16	1.09	0.11	12	1.10	0.06
HWR (12)	13	1.08	0.06	8	1.12	0.05
Skinfold (cm) (0)	20	3.95	0.63	24	3.86	0.86
Skinfold (cm) (6)	16	4.06	1.24	12	3.89	1.14
Skin fold (cm) (12)	13	3.73	0.83	6	4.06	1.31
Dexascan (fat %) **** (0)	20	37.91	5.69	20	39.51	7.66
Dexascan (fat%) (6)	16	36.18	6.42	12	37.14	8.20
Dexascan (fat %) (12)	14	34.3	4.42	9	36.29	9.49

* Quantity stands for the quantity name and t for the time of measurement in months from time of randomization.

** BMI is body mass index, which is weight/height^2 (kg/m^2).

*** HWR is hip circumference (cm)/waist circumference (cm).

**** Dexascan is assessed by dual-energy x-ray absorptiometry scanning.

Table 4. Results of mixed-model analyses of the BMI values measured in the subgroup of 15 children with overweight between 135% and 145%.

Number of follow-up visits included in analysis	P of main effect of intervention in subgroup	P of interaction between intervention and time in subgroup	Mean proportion of missing values per patient in experimental group	Mean proportion of missing values per patient in control group
All	0.005	0.010	0.37	0.54
1, 6, and 12 months[a]	0.008	0.026	0.13	0.28

a: Analysis confined to the measurements made at visits at 1, 6, and 12 months was also included to confirm the analysis of all visits due to the fact that the proportion of missing values was very high in the latter analysis.

Table 5. Mean and number of measurements made of BMI* in each intervention group prior to randomization (Month = 0) and monthly during the following 12 months in patients whose overweight was between 135% and 145%. The grand mean value of the first 6 months, the last 6 months, and all 12 months following randomization are also shown.

Month	Experimental group		Control group	
	n	mean	n	mean
0	6	25.0	9	26.6
1	5	24.5	8	26.2
2	4	24.2	6	26.3
3	5	23.9	6	26.8
4	4	24.0	3	26.0
5	4	23.6	4	26.1
6	5	23.6	6	26.4
Month 1 - 6	33	24.0	42	26.0
7	2	24.9	3	26.1
8	4	23.6	3	26.2
9	2	24.5	1	27.1
10	2	24.0	1	25.6
11	1	24.8	1	24.5
12	5	22.9	3	26.2
Month 7 -12	16	23.8	12	26.3
Month 1 - 12	49	24.5	54	26.1

*BMI is body mass index, which is defined as weight/height^2 (kg/m^2).

Appendix 1.

The psychodynamics of Multi-disciplinary group intervention

In the psychotherapeutic group sessions the general psychodynamic psychotherapeutic technique used on a variety of psychological problems was modified to focus on the children's thoughts and feelings about being overweight and how they see themselves and others. The psychotherapeutic group sessions were conducted in a non-moralizing and understanding atmosphere. The children were encouraged to share with the group their emotional distress and lack of self-confidence in order to receive understanding and emotional support from each other and the therapist. The groups worked with a variety of psychological group tasks including: cognitive techniques, communication exercises, exercises to promote self-consciousness, behaviour modification techniques, exercises to facilitate creative thinking, mentalization, imagination, externalizing, and reflection upon oneself and others. The problems connected to obesity were thus addressed from multiple angles and psychological levels encouraging the child to develop his or her own strategy to cope with the problem. Furthermore, care was taken to underscore the emotional support from the group to the individual member and to focus on the group processes.

The exercise sessions consisted of exercises on apparatus, a physically active game, and a closing round. The exercises aimed to stimulate the child to increase physical activity, to introduce new games, encourage team spirit through games, strengthen motivation, and increase bodily awareness. The child's behaviour, emotional state and social conduct were observed. These observations were thought about and discussed in the following psychotherapeutic group session and in order to address the psychological hindrances to exercise.

In the parent group, the parents were encouraged to discuss their distress and frustration as well as sharing successes and advice with each other. General parental skills counselling was offered focusing on supporting the child's own effort with positive expectations while maintaining a strict nutritional policy.