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Assessment of a Family-based Behavioural Intervention Program for obese children

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Keywords: child obesity, family therapy, long-term intervention, single-group study design, intention-to-treat analysis.

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ABSTRACT

Objective: To assess a 2-year Family-based Behavioural Intervention Program against child obesity implemented in Swedish paediatric outpatient care.

Design and setting: Single-group pre- and post-test design and an intention-to-treat analysis in Swedish paediatric outpatient care.

Patients: Twenty-six obese children aged 8–11.9 years and their parents.

Interventions: Twenty-five paediatric outpatient group sessions over a 2-year period with parallel groups for children and parents. The basis for the program was a manual developed by a psychologist and a dietician.

Main outcome measures: The primary outcome was change in standardized body mass index (z-BMI) between baseline and 36 months. The secondary outcomes were change in the waist-to-height ratio, metabolic parameters and program adherence. The participants were examined at baseline and after 3, 12 and 24 months of therapy and at follow-up 12 months after the end of the program.

Results: z-BMI declined significantly from the mean of 3.3 (0.7 SD) to 2.9 (SD 0.7) at follow-up 12 months after the end of the program. However, there was no change in the waist-to-height ratio. Biomedical markers of blood glucose metabolism and lipid status remained in the normal range. Ninety-six percent of the families completed the program.

Conclusions: This 2-year Family-based Behavioural Intervention Program in paediatric outpatient care seems to be an effective and useful new model for obese children with high participant adherence.

ARTICLE SUMMARY

Article focus

• Family-based behavioural interventions have exposed promising results in controlled studies, while their effectiveness in community settings remains to be shown.

Key messages

• High family adherence is an important success factor for childhood obesity therapy.

• A 2-year family-based intervention for management of childhood obesity in paediatric outpatient care showed a high participation rate and promising effects on weight gain.

Strengths and limitations of this study

The main methodological strengths of the study are that the primary end point measurement was performed 12 months after the end of the long-term intervention program and that an intention-to-treat analysis was used. The major weakness of the study is the the single-group design. The design implies that the observed decline in z-BMI cannot be firmly interpreted as an effect of the intervention program. The results would also have been even more convincing if all the secondary outcome measures had displayed similar trends.

INTRODUCTION

Child and adolescent obesity has increased globally.[1-3] The United Kingdom is no exception.[4] In Sweden, obesity in 10-year-old children increased fourfold in less than two decades,[5] but recent results from Stockholm have shown that the prevalence of overweight and obesity in childhood is levelling off.[6] In the United States, childhood obesity has more than tripled for children aged 6–11 years in the past three decades, with around 9 million obese children aged over 6 years.[7]. Childhood obesity is resulting in significant short-term consequences,[2, 8] long-term consequences on health and wellbeing,[2, 8-10] and increased mortality.[10] This situation calls for evidence-based child obesity management programs, which in turn requires research, re-formulation of health policies, and re-organization in the health care system.[11] A natural target for these efforts is the family. Almost 50 years ago, the idea of a family as a system was presented, an emotional completeness where the individuals are strongly tied to each other.[12] The family system perspective visualizes how the relationship with family diet, caregiver resources, and child character can be mediated or moderated by a variety of influences ranging from cultural characteristics and motherly input into family economic decisions and social support.[13] A child's success with behaviour changes in association with obesity treatment has been found to be strongly contingent on the participation of the entire family in the process.[14, 15] A current Cochrane review concluded that family-based behavioural lifestyle interventions intended to change diet and exercise patterns together with self-help can reduce weight in children in the short- as well as in the long-term.[2] Two approaches that have shown promising results in European contexts are behavioural cognitive therapy and family treatment.[11] However, implementation of behavioural cognitive therapy and treatments involving families require financial and personal resources that seldom are at hand for service supply to all families with obese children.

Obese children have an increased risk of becoming overweight and obese adults.[16, 17] Therefore, it is necessary to offer early intervention against childhood obesity.[18] Present evidence suggests that it is difficult to maintain changes in children's diet- and physical habits over time without professional support.[19, 20] This study therefore assesses a 2-year Family-based Behavioural Intervention Program (FBIP) against child obesity implemented in Swedish paediatric outpatient care, where the intervention was provided by school nurses, paediatric nurses and dieticians. The specific aims of the study were to investigate clinical outcomes and program adherence.

METHODS

A single-group pre- and post-test design and an intention-to-treat (ITT) analysis were used for the study.

Inclusion criteria

The inclusion criteria for the study were age 8–11.9 years, obesity defined according to the International Obesity Taskforce (IOTF) criteria (above age- and sex-specific cutoffs corresponding to adult body mass index (BMI, calculated as weight in kilograms divided by the square of height in meters) ≥30 kg/m^2)[21] and absence of other diseases. Both children and parents had to give consent that they were motivated and willing to participate in regular group sessions for the 2-year intervention period, to change eating and physical exercise habits, and to note changes in a diary during the period.

Participant recruitment

Figure 1 presents the flow of subjects referred to the program and eventually included in the study. School nurses in two municipalities in southeast Sweden with 63 elementary schools were asked to refer obese children and their parents for suitability evaluation, resulting in referral of 61 children. When invited, 10 families declined to participate in the

selection interview. The remaining 51 children and their parents were given a structured interview regarding their motivation to change habits and participate in group sessions. Fourteen boys and 12 girls fulfilled all inclusion criteria. The parent group included biological parents, foster parents and step-parents.

The Family-based Behavioural Intervention Program

The FBIP for management of childhood obesity was delivered using the regular community-level health service resources. A manual for group-based family interventions developed by a psychologist and a dietician[22] was used as the basis for the program. The manual contained instructions for tutor-supervised group sessions with obese children and their parents.

During the first 3 months, the groups met once weekly (intensive phase 1). Throughout the second phase (months 4–12), group sessions were held once monthly (phase 2) and during the third phase (months 13–24) once every 3 months. The practical goals of the activities in the FBIP included how to promote sustainable and healthy eating habits among the children, stimulate regular physical activities, discuss influences from commercials on eating and exercise, teach them how to handle stress and disappointments, solve problems and find alternative ways to contentment. The tutors write down the children's suggested and completed changes in a notebook. After the first phase, the tutors offered individual talks with the parents. The purpose is to discuss what results the children have achieved and how to maintain these.

Program implementation

Group sessions were conducted in three child groups and three parental groups. Four tutors in the FBIP were registered nurses specializing in paediatrics. Two tutors were dieticians. The tutors were instructed before and during the intervention by one of the authors of the manual

and then continuously supervised during the intervention period by another clinical psychologist.

Group session children

The 2-hour sessions with the children were held after school. At the first meeting, the children received a diary. The diary was used to write down the child's eating and physical activity habits and to write down their steps of change. The changes were later presented and discussed in the children's group. The tutors and the other children gave feedback on the notes and it was important to increase the children's awareness of their own behaviour. During each group session in phase 1, the children were encouraged to work with two small and realistic steps of changes concerning diet and physical activity until the next session. The tutors presented information handouts regarding diet and physical activities and from those the children were given homework tasks. If the children had not implemented the agreed-upon changes, these were postponed to the next session. Some weeks the children also had to list the rewards they wanted if they had done well with their changes. However, food, drinks or sweets could not be chosen. Physical exercise was not scheduled in the sessions but sometimes the tutors and the children went for a walk. Each session included a light meal.

The children were reassured that everything that was said was confident within the group and for the parents. Therefore, the diaries were not accessible to the researchers.

Group session parents

The 1.5-hour sessions with the parents were held in the evening. Documented changes in the child's eating and physical activity habits were communicated to the parents. The parents were given the same information about diet and physical activities and they were also given homework tasks from the session content. Moreover, the parents were given various food recipes and information about the risk factors and diseases associated with obesity. Parents

presented to the group how the changes had turned out during the week. They gave examples of difficulties that had arisen from a parent perspective.

Data collection

The participating children were clinically examined at baseline, after 3, 12 and 24 months of group therapy, and 12 months after the end of the program. At each examination, waist circumference measurements were collected by one of the authors (P.B.). Weight, height, fasting glucose, fasting insulin, cholesterol, triglycerides, low-density lipoprotein cholesterol (LDL-cholesterol) and high-density lipoprotein cholesterol (HDL-cholesterol) were also collected according to standard procedures at each examination by two registered paediatric nurses. The blood samples were analysed at an accredited medical laboratory (Vrinnevi Hospital, Norrköping, Sweden). An oral glucose tolerance test performed at the baseline examination was calculated according to the World Health Organization.[23] The LDL-cholesterol was calculated according to the Friedewald formula.[24] Data on family participation in the intervention was collected from the tutors.

Statistical analysis

To compensate for BMI varying with age and gender the standardized BMI (z-BMI) was calculated.[25] The waist-to-height ratio (WHtR)[26,27] was calculated by dividing waist circumference (cm) by height (cm). Standard descriptive statistics (mean and standard deviation) were computed. The *t*-test was used for to test for significance. The significance level was set at $p<0.05$. Statistical Package for the Social Sciences (SPSS) version 17 was used for the analyses.

Ethics approval

The study was approved by the Research Ethics Committee at Faculty of Health Sciences, Linköping University, Sweden (dnr. 03-600).

RESULTS

Clinical outcomes

The primary outcome measure, z-BMI, was significantly reduced from 3.3 at baseline to 2.9 ($p<0.001$) at the end point measurement (12 months after completion of the program) ($p<0.001$). A decrease in z-BMI was noted after 3 months (table 1). The boys had higher z-BMI at baseline (mean 3.5 (SD 0.6)) compared with the girls (mean 3.0 (SD 0.6)) ($p=0.028$). At the 36 months follow-up there were no gender differences in the decrease in z-BMI ($p=0.141$). Regarding the secondary outcome measures, there was no significant reduction of WHtR (table 1). There was a decrease in the LDL-cholesterol ($p<0.001$) and cholesterol ($p<0.01$) values in the study group at the end point measurement (12 months after completion of the program), but no significant differences in HDL-cholesterol or triglyceride values (table 1). The oral glucose tolerance test at baseline was in the normal range for all children (data not shown). Fasting glucose was higher at the end point measurement (table 1). All biomedical markers were within the normal range at all measurements.

Table 1 Anthropometric and body composition and metabolic variables at baseline and at different follow-up times (intention-to-treat analysis).

Variables (references value)	0 months		3 months		12 months		24 months		36 months		0–36 month change		
	n	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (95% CI)	*p*-value
z-BMI	26	3.3 (0.7)	25	3.1 (0.8)	26	3.0 (0.8)	24	2.9 (0.8)	23	2.9 (0.7)	23	–0.4 (–0.6 to –0.2)	<0.001
WHtR	26	0.67 (0.06)	25	0.66 (0.07)	26	0.66 (0.07)	23	0.66 (0.07)	22	0.67 (0.08)	22	–0.01 (–0.03 to 0.01)	0.332
P-fasting-glucose (mmol/L) (4.2–6.0)	26	4.6 (0.4)	25	4.7 (0.4)	26	5.1 (0.3)	23	4.9 (0.3)	23	5.0 (0.3)	23	0.4 (0.2 to 0.6)	<0.001
S-fasting-insulin (pmol/L) (18–	26	78.5 (45.1)	24	76.0 (37.6)	25	77.6 (41.8)	23	80.0 (37.8)	23	76.7 (35.9)	23	–5.5 (–27.5 to 16.5)	0.608

175)												
P-LDL-cholesterol (mmol/L) (1.2–4.3)	26	2.7 (0.5)	25	2.3 (0.4)	23	2.3 (0.5)	23	2.2 (0.5)	23	2.3 (0.5)	23	–0.3 (–0.5 to –0,2)	<0.001
P-HDL-cholesterol (mmol/L) (1.0–2.7 girls, 0.8–2.1 boys)	26	1.3 (0.2)	25	1.3 (0.2)	25	1.3 (0.2)	23	1.5 (0.3)	23	1.2 (0.2)	23	0.0 (–0.1 to 0.1)	0.433
P-Cholesterol (mmol/L) (3.1–5.2 at 2–12 years)	26	4.4 (0.6)	25	4.1 (0.5)	25	4.1 (0.6)	22	4.3 (0.6)	23	4.1 (0.5)	23	–0.3 (–0.5 to –0.1)	0.004
P-fasting-triglycerides (mmol/L) (0.30–1.40 at <10 years, 0.30–1.60 at 10–14 years)	26	1.06 (0.39)	25	1.11 (0.53)	25	1.17 (0.74)	22	1.3 (0.46)	23	1.18 (0.48)	23	0.09 (–0.13 to 0.31)	0.384

Abbreviations: BMI, body mass index; CI, confidence interval; HDL, high-density lipoprotein; LDL, low-density lipoprotein; WHtR, waist-to-height ratio.

Program adherence

Ninety-six percent (*n*=25) of the families completed the program. Only one family withdrew from the programme after the first 3-month phase of intervention. The child did not feel comfortable in the group and did not see obesity as a problem.

DISCUSSION

Using a single-group pre- and post-test design and ITT analysis, we found that a 2-year FBIP delivered in an outpatient care setting was effective for reducing the z-BMI of obese children 12 months after program completion. Among secondary end point measures, the WHtR showed no change, but the measurements for lipid status showed favourable trends.

The main strength of our study is that the primary end point measurement was performed 12 months after the end of the long-term intervention program. We also used ITT analysis. Both these factors are important to evaluate the effectiveness of the intervention program because high drop-out rates and short follow-up tend to overestimate the results of the program.[18]

The mean decline in z-BMI was 12.1%. Our findings are better than other studies, which show a lower level of weight reduction.[18, 28] Even if the weight reduction was limited, it could be of importance for development of long-term complications. Children with only moderately increased BMI display higher levels of metabolic variables and increased risk for cardiovascular factors.[29] We found a trend towards more favourable lipid profiles, even if the values were always within the normal range.

A further strength of this FBIP was the high completion rate. One previous study has shown that high family adherence is an important success factor for long-term weight reductions in childhood obesity.[30] In comparison, results from the similar Families for Health program provided in a community setting in England reported that only 18 of 27

(67%) children completed a 3-month program.[28] A reason for the more favourable adherence to our program could be that the families were interviewed before starting the group sessions and estimated by the tutors to be highly motivated to act on the obesity and also motivated to participate in the whole group program. This also means that our program cannot be provided to all obese children and must be complemented with other interventions. Another factor contributing to the high adherence in our study could be the weight reduction at the beginning of the program. The assessment from an outpatient treatment program with an 8-year follow-up of 90 obese children with a mean age of 10.1 years at baseline indicated that the mean reduction of 8% in adjusted BMI was a result of the children's success at the beginning of their treatment.[31] Initial weight decrease is the most important factor for success and for reducing the risk of drop-out from the treatment program.[32]

A major weakness of the single-group design is that the observed decline in z-BMI cannot be firmly interpreted as an effect of the intervention program. The results would have been even more convincing if all the secondary outcome measures had displayed similar trends. The WHtR did not change, but perhaps the decline in z-BMI was too low to affect this measurement. The fasting glucose values increased at 12 months follow-up after the end of the program. The most plausible explanation is that the children reached pubertal age, i.e. this was not a primary deterioration in their metabolic status. A Swedish study points out that BMI, level of physical activity, seasonal variations in physical activity and biological age (pubertal development) rather than chronological age must be taken into consideration when interpreting clinical laboratory data.[33]

Our intervention selected only highly motivated families who had more resources to manage their children's weight than an average family. However, it is plausible to assume that the main part of the decrease in z-BMI in our study was an effect of the intervention program.

CONCLUSION

Our FBIP for management of childhood obesity in paediatric outpatient care in a single-group pre- and post-intervention study showed promising outcomes with high participation rates and an effect on further weight gain. The detailed manual and the structured program make it possible for available primary care or paediatric outpatient staff to lead groups. However, this FBIP assessment must be confirmed in a randomized study before it can be implemented on a larger scale. Another interesting topic for further research is a comparison of the cost-effectiveness between FBIP and other family-based behavioural interventions in treating obese children.

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Competing interests: None.

Contributorship statement

MT was involved in the conception and design of the project, as well as the analysis and interpretation of the data. She drafted and revised the manuscript, and provided intellectual content. EM was involved in the conception and design of the project and in the interpretation of the data. She drafted and revised the manuscript, providing intellectual content. PB conceived and designed the project He drafted and revised the manuscript, providing intellectual content. MN was involved in the conception and design of the project and in the interpretation of the data. She revised the manuscript, providing intellectual content. JE helped with data interpretation, revised the manuscript, and provided intellectual content. TT accepts direct responsibility for the manuscript. He was involved in the design of the project and the interpretation of the data. He drafted and revised the manuscript.

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relation to biological, social and lifestyle factors. Scand J Clin Lab Invest 2005;**65**:65-76.

Figure 1 Flowchart for the study of families referred to the FBIP.

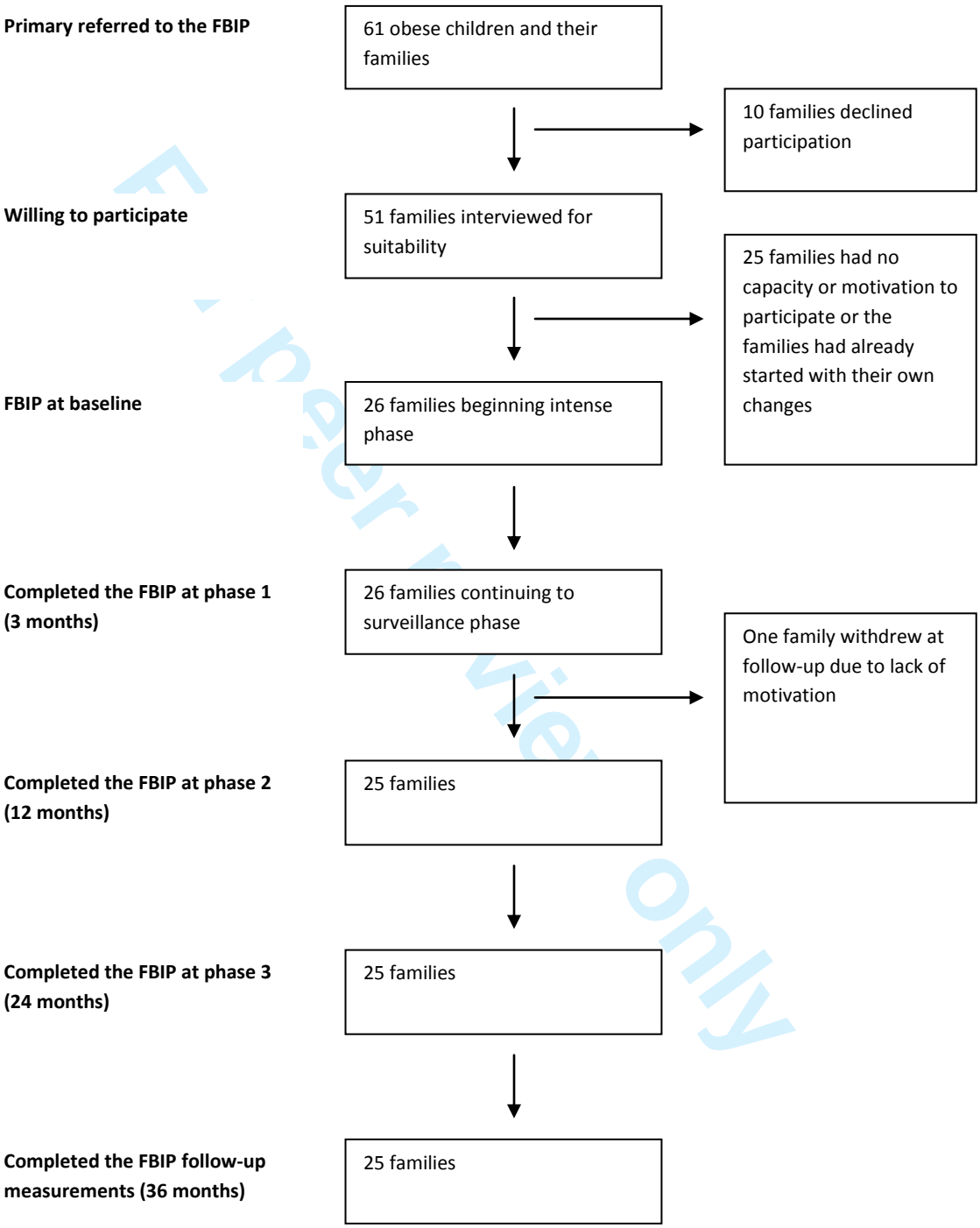

Figure 1

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5-6
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	5-6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*8*
Bias	9	Describe any efforts to address potential sources of bias	10-12
Study size	10	Explain how the study size was arrived at	5-6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	8
		(*c*) Explain how missing data were addressed	8
		(*d*) If applicable, explain how loss to follow-up was addressed	N/A
		(*e*) Describe any sensitivity analyses	N/A
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	5-6
		(b) Give reasons for non-participation at each stage	5-6
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	9
		(c) Summarise follow-up time (eg, average and total amount)	5,9
Outcome data	15*	Report numbers of outcome events or summary measures over time	9
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9-10
		(*b*) Report category boundaries when continuous variables were categorized	9-10
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	11
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	12-13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Family-based behavioural intervention program for obese children: a feasibility study

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Family-based behavioural intervention program for obese children: a feasibility study

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ABSTRACT

Objectives: To assess a 2-year family-based behavioural intervention program against child obesity.

Design: Single-group pre- and post-intervention feasibility study.

Setting: Swedish paediatric outpatient care.

Participants: Twenty-six obese children aged 8.3–12.0 years and their parents who had consented to actively participate in a 2-year intervention.

Interventions: Twenty-five paediatric outpatient group sessions over a 2-year period with parallel groups for children and parents. The basis for the program was a manual containing instructions for tutor-supervised group sessions with obese children and their parents.

Primary and secondary outcome measures: The primary outcome measure was change in z-BMI between baseline and after 36 months. The secondary outcome measures were change in the waist-to-height ratio (WHtR), metabolic parameters and program adherence. The participants were examined at baseline and after 3, 12 and 24 months of therapy and at follow-up 12 months after completion of the program.

Results: The primary outcome measure, z-BMI, declined from a mean of 3.3 (0.7 SD) at baseline to 2.9 (0.7 SD) (p<0.001) at follow-up 12 months after completion of the program. There was no change in the WHtR. Biomedical markers of blood glucose metabolism and lipid status remained in the normal range. Ninety-six percent of the families completed the program.

Conclusions: This feasibility study of a 2-year family-based behavioural intervention program in paediatric outpatient care showed promising results with regard to further weight gain and program adherence. These findings must be confirmed in a randomized

controlled trial with longer follow-up before the intervention program can be implemented on a larger scale.

ARTICLE SUMMARY

Article focus

- Family-based behavioural interventions have produced promising results in controlled studies, but their effectiveness in paediatric outpatient settings remains to be shown.

Key messages

- A 2-year family-based behavioural intervention program for the management of childhood obesity in paediatric outpatient care showed promising results with regard to weight gain 1 year after the program.
- The completion rate of the program was high, which is important as high family adherence is a success factor for childhood obesity therapy.

Strengths and limitations of this study

- The main methodological strengths of this study are that the primary end point measurement was performed 12 months after the end of the long-term intervention program and that all participants were included in the data analysis at the study end point whether or not they had completed the intervention.
- The major weaknesses of the study are the small study sample and single-group design. The design implies that the observed decline in z-BMI cannot be firmly interpreted as an effect of the intervention program. The results would have been even more convincing if all the secondary outcome measures had displayed similar trends. Longer follow-up than 12 months is necessary to examine sustainable effects of the intervention.

INTRODUCTION

Child and adolescent obesity has increased globally.[1-3] In the United States, childhood obesity has more than tripled for children aged 6–11 years in the past three decades with around 9 million obese children aged over 6 years.[4] In Sweden, obesity in 10-year-old children increased fourfold in less than two decades,[5] although recent results have shown that the prevalence of overweight and obesity in childhood is levelling off.[6] Childhood obesity is resulting in significant short-term[2,7] and long-term[2,7-9] consequences on health and wellbeing, and increased mortality.[9] This situation calls for evidence-based child obesity management programs, which in turn requires research, re-formulation of health policies, and re-organization in the health care system.[10]

A natural target for these efforts is the family. Almost 50 years ago, the idea of a family as a system was presented, an emotional completeness where the individuals are strongly tied to each other.[11] The family system perspective visualizes how the relationship with family diet, caregiver resources, and child character can be mediated or moderated by a variety of influences ranging from cultural characteristics and motherly input into family economic decisions and social support.[12] A child's success with behaviour changes in association with obesity treatment has been found to be strongly contingent on the participation of the entire family in the process,[13,14] and on the treatment being initiated at an early age.[15] A recent Cochrane review concluded that family-based behavioural lifestyle interventions intended to change diet and exercise patterns together with self-help can reduce weight in children in the short-term as well as in the long-term.[2] Two approaches that have shown promising results for childhood obesity in specialist settings are cognitive behavioural therapy[16] and family-based lifestyle intervention.[17] However, implementation of cognitive behavioural therapy and treatments involving families require financial and personal resources that seldom are at hand for service supply to all families with obese children; however, present evidence suggests that

it is difficult to maintain changes in children's diet- and physical habits over time without professional support.[18,19] Therefore there is an urgent need to develop treatment programs that can be used in paediatric outpatient care. This feasibility study assesses a 2-year family-based behavioural intervention program (FBIP) against child obesity implemented in Swedish paediatric outpatient care, where the intervention was provided by the regular nurses and dieticians guided by a manual and supervised by a clinical psychologist. The specific aims of the study were to investigate clinical outcomes and program adherence.

METHODS

A single-group pre- and post-intervention design was used for the study. The primary outcome measure was change in standardized body mass index (z-BMI) between baseline and after 36 months, 12 months after the end of the program. The secondary outcome measures were change in the waist-to-height ratio (WHtR), metabolic parameters and program adherence. The participants were examined at baseline and after 3, 12 and 24 months of therapy and at follow-up 12 months after the end of the program.

Inclusion criteria

The inclusion criteria for the study were age 8– <12 years, obesity defined according to the International Obesity Taskforce (IOTF) criteria (above age- and gender-specific cut offs corresponding to adult body mass index (BMI), calculated as weight in kilograms divided by the square of height in meters, ≥ 30 kg⁄m^2)[20] and absence of other diseases. Both children and parents had to give consent that they were motivated and willing to participate in regular group sessions for the 2-year intervention period, to change eating and physical exercise habits, and to note food and beverage intake and physical activities in a diary during the period.

Participant recruitment

Figure 1 presents the flow of subjects referred to the program and eventually included in the study. School nurses in two municipalities in southeast Sweden with 63 elementary schools were asked to refer obese children and their parents for suitability evaluation, resulting in referral of 61 children. When invited, 10 families declined to participate in the selection interview. The remaining 51 children and their parents were given a structured interview regarding their motivation to change habits and participate in group sessions. Twenty-six children fulfilled all inclusion criteria (Table 1). The parent group included biological parents, foster parents and step-parents.

Table 1 Display of mean age (SD) and z-BMI (SD) for the study population at baseline

	Total (*n*=26)		Boys (*n*=14)		Girls (*n*=12)	
	Mean	(SD)	Mean	(SD)	Mean	(SD)
Age	10.9	(0.9)	10.9	(1.1)	10.8	(0.7)
z-BMI	3.3	(0.7)	3.5	(0.6)	3.0	(0.6)

The family-based behavioural intervention program

The FBIP for management of childhood obesity was delivered using the regular community-level health service resources. A manual for group-based family interventions developed by a psychologist and a dietician[21] was used as the basis for the program. The manual contained instructions for family selection (equivalent to the inclusion criteria used in this study) and for tutor-supervised group sessions with obese children and their parents.

The program started in 2004 and ended in 2006. During the first 3 months, the groups met once weekly (intensive phase 1). Throughout the second phase (months 4–12), group sessions were held once monthly (phase 2) and during the third phase (months 13–24) once every 3 months. The practical goals of the activities in the FBIP included how to promote sustainable and healthy eating habits among the children and stimulate regular physical activities, discussion on influences from commercials on eating and exercise, teaching them how to handle stress and disappointments, solving problems and finding alternative ways to contentment. The tutors wrote down the children's suggestions and changes accomplished in a notebook. After the first phase, the tutors offered individual talks with the parents. The purpose was to discuss the results the children achieved and how to maintain these.

Program implementation

Group sessions were conducted in three child groups and three parental groups. Four tutors in the FBIP were paediatric registered nurses. Two tutors were dieticians. The tutors were instructed before and during the intervention by one of the authors of the manual and then continuously supervised during the intervention period by a clinical psychologist.

Group session for children

The 2-hour sessions with the children were held after school. At the first meeting, the children received a diary. The diary was used to record the child's eating and physical activity habits and their steps of change. During the first 3 months they were encouraged to write in the diary every day, then 1 week before each session. The parents helped the youngest children. The changes were later presented and discussed in the children's group. The tutors and the other children gave feedback on the notes; it was important to increase the children's awareness of their own behaviour. During each group session in phase 1, the children were encouraged to work with two small and realistic steps of changes concerning diet and physical activity until the next session. The tutors presented information handouts regarding diet and physical activities and from those the children were given homework tasks. If the children had not implemented the agreed changes, these were postponed to the next session. Some weeks the children also had to list the rewards they wanted if they had done well with their changes. However, food, drinks or sweets could not be chosen. Physical exercise was not scheduled in the sessions but sometimes the tutors and the children went for a walk. Each session included a light meal.

The children were reassured that everything that was said was in confidence within the child and parental groups. Therefore, the diaries were not accessible to the researchers.

Group session for parents

The 1.5-hour sessions with the parents were held in the evening. Documented changes in the child's eating and physical activity habits were communicated to the parents. The parents were given the same information about diet and physical activities and they were also given homework tasks from the session content. Moreover, the parents were given various food recipes and information about the risk factors and diseases associated with obesity. Parents presented to the group how the changes had turned out during the week. They gave examples of difficulties that had arisen from a parent's perspective.

Data collection

The participating children were clinically examined at baseline, after 3, 12 and 24 months of group therapy, and 12 months after the end of the program.

Weight wearing trousers and a T-shirt was measured to an accuracy of 0.1 kg. Height was measured using a stadiometer attached to a wall according to standard procedures by two paediatric registered nurses, to an accuracy of 0.5 cm. To compensate for BMI varying with age and gender, the z-BMI was calculated using Swedish national reference values for children from 2001 and the Box transformation formula.[22] At each examination, waist circumference measurements were always done by one of the authors (PB) at the navel plane to an accuracy of 0.5 cm. The waist-to-height ratio (WHtR) was calculated by dividing the waist circumference (cm) by the height (cm).[23,24] Fasting blood samples for analysis of glucose, insulin, triglycerides, total cholesterol and high-density lipoprotein cholesterol (HDL-cholesterol) were taken. The low-density lipoprotein cholesterol (LDL-cholesterol) was calculated according to the Friedewald formula.[25] An oral glucose tolerance test was performed only at baseline. After overnight fasting, the child was given a glucose dose of 1.75 g/kg (max 75 g) and plasma glucose was then analysed after 120 minutes.[3] Insulin was analysed using AutoDELFIA™ from Wallac® (fluoroimmunoassay method), Turku Finland.

Total plasma cholesterol, HDL-cholesterol, and triglycerides were analysed using Siemens® Advia-1650, Siemens Healthcare Diagnostics, Deerfield, Illinois. Plasma glucose was measured using Hemocue® from HemoCue AB, Ängelholm, Sweden. All blood samples were analysed at an accredited medical laboratory (Vrinnevi Hospital, Norrköping, Sweden). Data on family participation in the intervention was collected from the tutors.

Statistical analysis

Standard descriptive statistics (mean and standard deviation) were computed. Based on that the variables were normally distributed, paired 2-tailed T-tests were used for significance testing. The significance level was set at $p<0.05$. The Statistical Package for the Social Sciences (SPSS) version 17 was used for the analyses.

Ethics approval

The study was approved by the Research Ethics Committee at Faculty of Health Sciences, Linköping University, Sweden (dnr. 03-600).

RESULTS

Ninety-six percent (n=25) of the families completed the group sessions. Only one family withdrew from the group sessions after the first 3-month phase of intervention. The child did not feel comfortable in the group and did not see obesity as a problem. Not all children agreed to participate in all examinations, even if they participated in the entire intervention program. One to three children dropped out at each examination, but it was not the same children every time and some children agreed to the weight and height measurements but not the blood sampling or vice versa (Table 2).

Table 2 Values of anthropometric, body composition, and metabolic variables at baseline and at 3-, 12-, 24, and 36-month follow-ups

Variables (reference value)	Baseline		3 months		12 months		24 months		36 months		0–36 month change		
	n	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (95% CI)	*p*-value
z-BMI	26	3.3 (0.7)	25	3.1 (0.7)	26	3.0 (0.8)	24	2.9 (0.7)	23	2.9 (0.7)	23	–0.4 (–0.6 to – 0.2)	<0.001
WHtR	26	0.67 (0.06)	25	0.66 (0.07)	26	0.66 (0.07)	23	0.66 (0.07)	22	0.67 (0.08)	22	0 (–0.03 to 0.01)	0.332
P-fasting-glucose (mmol/L) (4.2–6.0)	26	4.6 (0.4)	25	4.7 (0.4)	26	5.1 (0.3)	23	4.9 (0.3)	23	5.0 (0.3)	23	+0.4 (0.2 to 0.6)	<0.001
S-fasting-insulin (pmol/L) (18–175)	26	78.5 (45.1)	24	76.0 (37.6)	25	77.6 (41.8)	23	80.0 (37.8)	23	76.7 (35.9)	23	-1.8 (–27.5 to 16.5)	0.608
P-LDL-cholesterol (mmol/L) (1.2–4.3)	26	2.7 (0.4)	25	2.3 (0.4)	23	2.3 (0.5)	23	2.2 (0.5)	23	2.3 (0.5)	23	–0.4 (–0.5 to – 0,2)	<0.001
P-HDL-cholesterol (mmol/L) (1.0–2.7 girls, 0.8–2.1 boys)	26	1.3 (0.2)	25	1.3 (0.2)	25	1.3 (0.2)	23	1.5 (0.3)	23	1.2 (0.2)	23	-0.1 (–0.1 to 0.1)	0.433
Total P-cholesterol (mmol/L) (3.1–5.2 at 2–12 years)	26	4.4 (0.5)	25	4.0 (0.5)	25	4.1 (0.6)	22	4.3 (0.6)	23	4.1 (0.5)	23	–0.3 (–0.5 to – 0.1)	0.004
P-fasting-triglycerides (mmol/L) (0.30–1.40 at <10 years, 0.30–1.60 at 10–14 years)	26	1.06 (0.39)	25	1.11 (0.53)	25	1.17 (0.74)	22	1.3 (0.46)	23	1.18 (0.48)	23	+0.12 (–0.13 to 0.31)	0.384

Abbreviations: BMI, body mass index; CI, confidence interval; HDL, high-density lipoprotein; LDL, low-density lipoprotein; P, plasma; S, serum; WHtR, waist-to-height ratio.

Clinical outcomes

The primary outcome measure, the mean z-BMI, was reduced from 3.3 (SD 0.7) at baseline to 2.9 (SD 0.7) (p<0.001) at the end point (12 months after completion of the program). A

decrease in z-BMI was noted already after 3 months (Table 2). The boys had higher z-BMI at baseline (mean 3.5 (SD 0.6)) compared with the girls (mean 3.0 (SD 0.6)) (p=0.028). At the 36-month follow-up there were no gender differences in the decrease in z-BMI (p=0.141) (data not shown). Regarding the secondary outcome measures, there was no significant reduction of WHtR (Table 2). There was a decrease in the LDL-cholesterol (p<0.001) and total cholesterol (p<0.01) in the study group at the end point (12 months after completion of the program), but no significant differences in HDL-cholesterol or triglyceride values (Table 2). All children displayed normal values for the oral glucose tolerance test at baseline (data not shown). Fasting glucose was higher at the end point measurement (Table 2). However, all biomedical markers were within the normal range throughout the study.

DISCUSSION

In this feasibility study, we found that obese children who agreed to a 2-year FBIP delivered in a paediatric outpatient care setting had reduced their z-BMI 12 months after program completion. The mean decline in z-BMI was 12.1%. Even though the weight reduction was limited, it could be of importance in the prevention of long-term complications. Also moderate changes in BMI among children are known to influence metabolic risk indicators for cardiovascular disease.[26]

The small study sample and the single-group design imply that the observed decline in z-BMI cannot be firmly interpreted as an effect of the intervention program. Without a randomized control group it is impossible to know if the decrease in z-BMI was an effect of the intervention program per se. One bias in this study could be that the intervention procedure selected only highly motivated families, who may have managed their children's weight without FBIP support.

Among secondary end point measures, the WHtR showed no change; the measurements for lipid status showed favourable trends. The results would have been even more convincing if all the secondary outcome measures had displayed similar trends. WHtR did not change, but perhaps the decline in z-BMI was too low to affect this measurement. The fasting glucose values increased at the follow-up 12 months after the end of the program. A Swedish study points out that BMI, level of physical activity, seasonal variations in physical activity and biological age (pubertal development) must be taken into consideration when interpreting clinical laboratory data.[27] Puberty signs were not consistently investigated in this study, which made it more difficult to interpret the biochemical data. Initial pubertal development in girls starts at approximately 10.9 years of age (range of 8.5–13.3 years) and in boys at 11.9 years of age on average (range 10.1–13.7 years).[28] Some children in this study may thus have reached the age for initiation of pubertal development when they started the FBIP (Table 1). It can be inferred that at least the interpretation of the metabolic parameters is complicated by the fact that the children entered puberty during the study period. It is thus possible that the higher blood glucose at follow-up could be explained by older age and more mature pubertal stage and not deterioration of metabolic status.

A methodological strength of this study is that the primary end point measurement was performed 12 months after the end of the intervention program. Although this follow-up period is longer than in many other studies, an even longer follow-up is necessary to evaluate the persistence of intervention effects. For instance, a randomized study of a 6-month obesity program in children aged 7–9 years in which a family-based group treatment was compared with routine counselling showed positive short-term effects,[29] but no difference in z-BMI at 2 and 3 years after the start of the intervention.[30] Another strength is that all participants were included in the data analysis at the study end point whether or not they completed the intervention. To improve the reliability of follow-up measurements, the height was measured

by the same two paediatric registered nurses and waist circumference was always measured by the same person.

An interesting observation is the high rate of families (96%) completing the 2-year intervention program. A previous study has shown that high family adherence is an important success factor for long-term weight reductions in childhood obesity.[31] In comparison, results from the similar Families for Health program provided in a community setting in England reported that only 18 of 27 (67%) children completed a 3-month program.[32] One reason for the more favourable adherence to the present FBIP could be that the families were interviewed before starting the group sessions and estimated to be highly motivated to act on the obesity and to participate in the whole group program. Another factor contributing to the high adherence in this study could be the weight reduction during the intensive phase at the beginning of the program. Initial weight decrease has been suggested to be an important factor for success and for reducing the risk of drop-out from the treatment program.[33] A recent assessment of an outpatient treatment program with an 8-year follow-up of 90 obese children with a mean age of 10.1 years at baseline indicated that the mean reduction of 8% in adjusted BMI was a result of the children's success at the beginning of their treatment.[34] Another 1-year outpatient obesity intervention program of 170 children with a mean age 10.5 years showed promising results regarding weight outcomes 3 years after the end of the program. Also here, the weight reduction was interpreted to be connected to the initial weight reduction in the first 3 months of the program intervention.[35]

The recent Cochrane review of randomized controlled trials of interventions on childhood obesity reported that family-based behavioural lifestyle intervention programs are superior to regular care and self-help in the short and the long term.[2] Our feasibility study suggests that a long-term obesity management FBIP supported by a detailed manual can be implemented in

routine paediatric outpatient care. We agree with the recommendations from the Cochrane review that more research is needed on obesity treatment in children and adolescents, especially large randomized effectiveness studies of different intervention programs with evaluations of the long-term outcome. In addition, we agree with the conclusion from the review that more research is needed to evaluate psychosocial, ethnic and cost-effectiveness aspects.

CONCLUSION

This feasibility study of an FBIP for management of childhood obesity in a paediatric outpatient care setting using a single-group pre- and post-intervention design showed promising outcomes and high adherence with 96% of families completing the 2-year intervention. The detailed manual and the structured program make it possible for available primary care or paediatric outpatient staff to lead groups. However, this FBIP assessment must be confirmed in a larger randomized controlled trial with a longer follow-up period before it can be implemented on a larger scale. Another interesting topic for further research is a comparison of the cost-effectiveness between FBIP and other family-based behavioural interventions in treating obese children.

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Competing interests

None.

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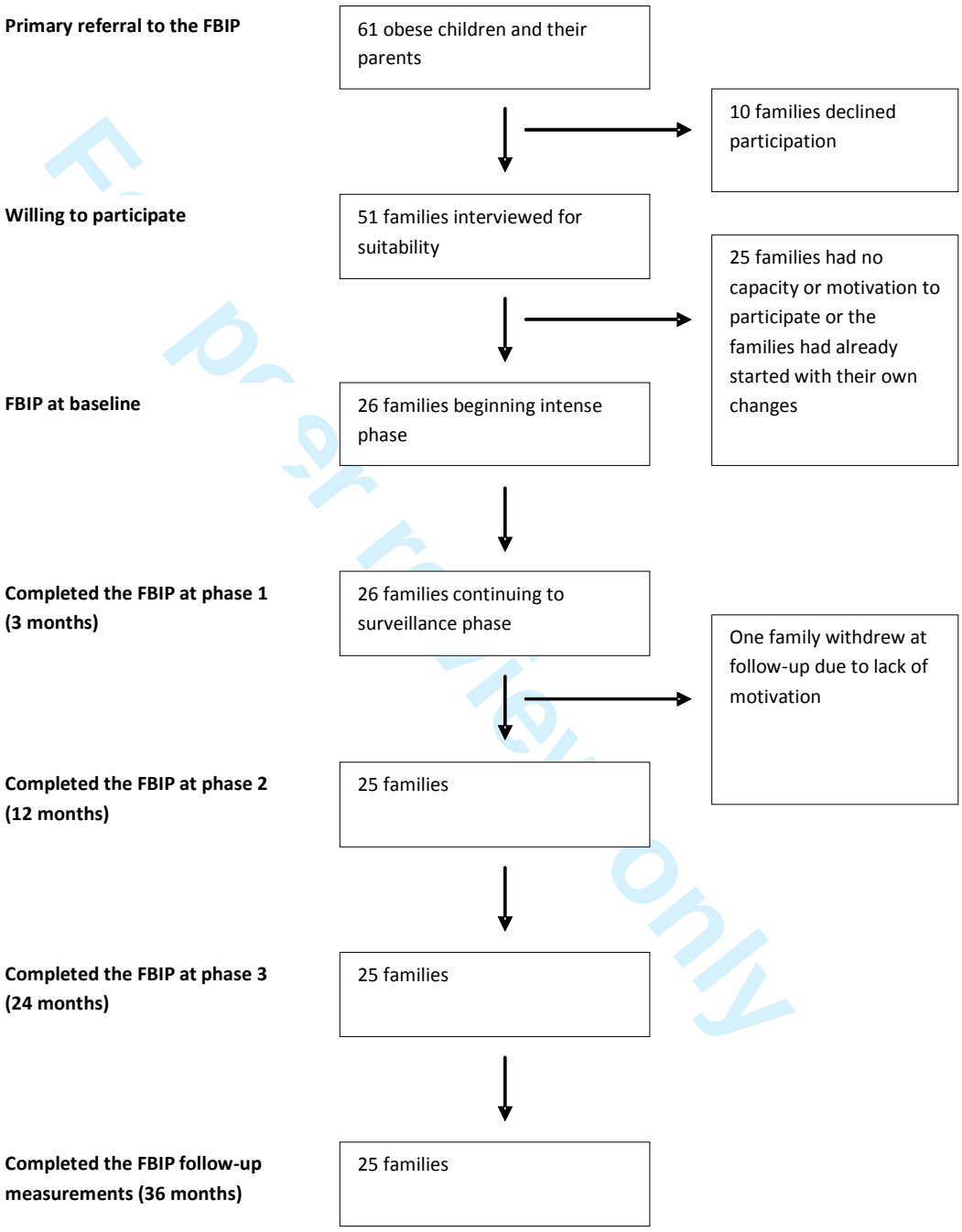
Contributorship statement

MT was involved in the conception and design of the project, as well as the analysis and interpretation of the data. She drafted and revised the manuscript, and provided intellectual content. EM was involved in the conception and design of the project and in the interpretation of the data. She drafted and revised the manuscript, providing intellectual content. PB conceived and designed the project. He drafted and revised the manuscript, providing intellectual content. MN was involved in the conception and design of the project and in the interpretation of the data. She revised the manuscript, providing intellectual content. JE helped with data interpretation, revised the manuscript, and provided intellectual content. TT accepts direct responsibility for the manuscript. He was involved in the design of the project and the interpretation of the data. He drafted and revised the manuscript.

Data sharing statement

No additional data available.



433

434 **Figure 1** Flowchart for the study of families referral to the FBIP

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations and relevant dates, including periods of recruitment, exposure?, follow-up, and data collection	7- 8, 1 0-11
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	6-7
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	10-11
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	10-11
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10-11
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10- 11
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	11
		(*d*) If applicable, explain how loss to follow-up was addressed	
		(*e*) Describe any sensitivity analyses	
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Figure 1 page 24
		(b) Give reasons for non-participation at each stage	Figure 1 page 24
		(c) Consider use of a flow diagram	Figure 1 page 24
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Table 1 page 8
		(b) Indicate number of participants with missing data for each variable of interest	Table 1 page 8 and Table 2 page 12
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	Table 2 page 12
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	15
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	11-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	16-17

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Family-based behavioural intervention program for obese children: a feasibility study

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Family-based behavioural intervention program for obese children: a feasibility study

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Keywords: child obesity, family therapy, long-term intervention, single-group study design

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ABSTRACT

Objectives: To assess a 2-year family-based behavioural intervention program against child obesity.

Design: Single-group pre- and post-intervention feasibility study.

Setting: Swedish paediatric outpatient care.

Participants: Twenty-six obese children aged 8.3–12.0 years and their parents who had consented to actively participate in a 2-year intervention.

Interventions: Twenty-five paediatric outpatient group sessions over a 2-year period with parallel groups for children and parents. The basis for the program was a manual containing instructions for tutor-supervised group sessions with obese children and their parents.

Primary and secondary outcome measures: The primary outcome measure was change in z-BMI between baseline and after 36 months. The secondary outcome measures were change in the waist-to-height ratio (WHtR), metabolic parameters and program adherence. The participants were examined at baseline and after 3, 12 and 24 months of therapy and at follow-up 12 months after completion of the program.

Results: The primary outcome measure, z-BMI, declined from a mean of 3.3 (0.7 SD) at baseline to 2.9 (0.7 SD) (p<0.001) at follow-up 12 months after completion of the program. There was no change in the WHtR. Biomedical markers of blood glucose metabolism and lipid status remained in the normal range. Ninety-six percent of the families completed the program.

Conclusions: This feasibility study of a 2-year family-based behavioural intervention program in paediatric outpatient care showed promising results with regard to further weight gain and program adherence. These findings must be confirmed in a randomized

controlled trial with longer follow-up before the intervention program can be implemented on a larger scale.

ARTICLE SUMMARY

Article focus

- Family-based behavioural interventions have produced promising results in controlled studies, but their effectiveness in paediatric outpatient settings remains to be shown.

Key messages

- A 2-year family-based behavioural intervention program for the management of childhood obesity in paediatric outpatient care showed promising results with regard to weight gain 1 year after the program.
- The completion rate of the program was high, which is important as high family adherence is a success factor for childhood obesity therapy.

Strengths and limitations of this study

- The main methodological strengths of this study are that the primary end point measurement was performed 12 months after the end of the long-term intervention program and that all participants were included in the data analysis at the study end point whether or not they had completed the intervention.
- The major weaknesses of the study are the small study sample and single-group design. The design implies that the observed decline in z-BMI cannot be firmly interpreted as an effect of the intervention program. The results would have been even more convincing if all the secondary outcome measures had displayed similar trends. Longer follow-up than 12 months is necessary to examine sustainable effects of the intervention.

INTRODUCTION

Child and adolescent obesity has increased globally.[1-3] In the United States, childhood obesity has more than tripled for children aged 6–11 years in the past three decades with around 9 million obese children aged over 6 years.[4] In Sweden, obesity in 10-year-old children increased fourfold in less than two decades,[5] although recent results have shown that the prevalence of overweight and obesity in childhood is levelling off.[6] Childhood obesity is resulting in significant short-term[2,7] and long-term[2,7-9] consequences on health and wellbeing, and increased mortality.[9] This situation calls for evidence-based child obesity management programs, which in turn requires research, re-formulation of health policies, and re-organization in the health care system.[10]

A natural target for these efforts is the family. Almost 50 years ago, the idea of a family as a system was presented, an emotional completeness where the individuals are strongly tied to each other.[11] The family system perspective visualizes how the relationship with family diet, caregiver resources, and child character can be mediated or moderated by a variety of influences ranging from cultural characteristics and motherly input into family economic decisions and social support.[12] A child's success with behaviour changes in association with obesity treatment has been found to be strongly contingent on the participation of the entire family in the process,[13,14] and on the treatment being initiated at an early age.[15] A recent Cochrane review concluded that family-based behavioural lifestyle interventions intended to change diet and exercise patterns together with self-help can reduce weight in children in the short-term as well as in the long-term.[2] Two approaches that have shown promising results for childhood obesity in specialist settings are cognitive behavioural therapy[16] and family-based lifestyle intervention.[17] However, implementation of cognitive behavioural therapy and treatments involving families require financial and personal resources that seldom are at hand for service supply to all families with obese children; however, present evidence suggests that

it is difficult to maintain changes in children's diet- and physical habits over time without professional support.[18,19] Therefore there is an urgent need to develop treatment programs that can be used in paediatric outpatient care. This feasibility study assesses a 2-year family-based behavioural intervention program (FBIP) against child obesity implemented in Swedish paediatric outpatient care, where the intervention was provided by the regular nurses and dieticians guided by a manual and supervised by a clinical psychologist. The specific aims of the study were to investigate clinical outcomes and program adherence.

METHODS

A single-group pre- and post-intervention design was used for the study. The primary outcome measure was change in standardized body mass index (z-BMI) between baseline and after 36 months, 12 months after the end of the program. The secondary outcome measures were change in the waist-to-height ratio (WHtR), metabolic parameters and program adherence. The participants were examined at baseline and after 3, 12 and 24 months of therapy and at follow-up 12 months after the end of the program.

Inclusion criteria

The inclusion criteria for the study were age 8– <12 years, obesity defined according to the International Obesity Taskforce (IOTF) criteria (above age- and gender-specific cut offs corresponding to adult body mass index (BMI), calculated as weight in kilograms divided by the square of height in meters, ≥ 30 kg⁄m^2)[20] and absence of other diseases. Both children and parents had to give consent that they were motivated and willing to participate in regular group sessions for the 2-year intervention period, to change eating and physical exercise habits, and to note food and beverage intake and physical activity in a diary during the period.

Participant recruitment

Figure 1 presents the flow of subjects referred to the program and eventually included in the study. School nurses in two municipalities in southeast Sweden with 63 elementary schools were asked to refer obese children and their parents for suitability evaluation, resulting in referral of 61 children. When invited, 10 families declined to participate in the selection interview. The remaining 51 children and their parents were given a structured interview regarding their motivation to change habits and participate in group sessions. Twenty-six children fulfilled all inclusion criteria (Table 1). The parent group included biological parents, foster parents and step-parents.

Table 1 Display of mean age (SD) and z-BMI (SD) for the study population at baseline

	Total (*n*=26)		Boys (*n*=14)		Girls (*n*=12)	
	Mean	(SD)	Mean	(SD)	Mean	(SD)
Age	10.9	(0.9)	10.9	(1.1)	10.8	(0.7)
z-BMI	3.3	(0.7)	3.5	(0.6)	3.0	(0.6)

The family-based behavioural intervention program

The FBIP for management of childhood obesity was delivered using the regular community-level health service resources. A manual for group-based family interventions developed by a psychologist and a dietician[21] was used as the basis for the program. The manual contained instructions for family selection (equivalent to the inclusion criteria used in this study) and for tutor-supervised group sessions with obese children and their parents.

The program started in 2004 and ended in 2006. During the first 3 months, the groups met once weekly (intensive phase 1). Throughout the second phase (months 4–12), group sessions were held once monthly (phase 2) and during the third phase (months 13–24) once every 3 months. The practical goals of the activities in the FBIP included how to promote sustainable and healthy eating habits among the children and stimulate regular physical activity, discussion on influences from commercials on eating and exercise, teaching them how to handle stress and disappointments, solving problems and finding alternative ways to contentment. The tutors wrote down the children's suggestions and changes accomplished in a notebook. After the first phase, the tutors offered individual discussion sessions with the parents. The purpose was to discuss the results the children achieved and how to maintain them.

Program implementation

Group sessions were conducted in three child groups and three parental groups. Four tutors in the FBIP were paediatric registered nurses. Two tutors were dieticians. The tutors were instructed before and during the intervention by one of the authors of the manual and then continuously supervised during the intervention period by a clinical psychologist.

Group session for children

The 2-hour sessions with the children were held after school. At the first meeting, the children received a diary. The diary was used to record the child's eating and physical activity habits and their steps of change. During the first 3 months they were encouraged to write in the diary every day, and thereafter once 1 week before each session. The parents helped the youngest children. The changes were later presented and discussed in the children's group. The tutors and the other children gave feedback on the notes; it was important to increase the children's awareness of their own behaviour. During each group session in phase 1, the children were encouraged to work with two small and realistic steps of changes concerning diet and physical activity until the next session. The tutors presented information handouts regarding diet and physical activity and from those the children were given homework tasks. If the children had not implemented the agreed changes, these were postponed to the next session. Some weeks the children also had to list the rewards they wanted if they had done well with their changes. However, food, drinks or sweets could not be chosen. Physical exercise was not scheduled in the sessions but sometimes the tutors and the children went for a walk. Each session included a light meal.

The children were reassured that everything that was said was in confidence within the child and parental groups. Therefore, the diaries were not accessible to the researchers.

Group session for parents

The 1.5-hour sessions with the parents were held in the evening. Documented changes in the child's eating and physical activity habits were communicated to the parents. The parents were given the same information about diet and physical activity and they were also given homework tasks from the session content. Moreover, the parents were given various food recipes and information about the risk factors and diseases associated with obesity. Parents presented to the group how the changes had turned out during the week. They gave examples of difficulties that had arisen from a parent's perspective.

Data collection

The participating children were clinically examined at baseline, after 3, 12 and 24 months of group therapy, and 12 months after the end of the program.

Weight wearing trousers and a T-shirt was measured to an accuracy of 0.1 kg. Height was measured using a stadiometer attached to a wall according to standard procedures by two paediatric registered nurses, to an accuracy of 0.5 cm. To compensate for BMI varying with age and gender, the z-BMI was calculated using Swedish national reference values for children from 2001 and the Box transformation formula.[22] At each examination, waist circumference measurements were always done by one of the authors (PB) at the navel plane to an accuracy of 0.5 cm. The waist-to-height ratio (WHtR) was calculated by dividing the waist circumference (cm) by the height (cm).[23,24] Fasting blood samples for analysis of glucose, insulin, triglycerides, total cholesterol and high-density lipoprotein cholesterol (HDL-cholesterol) were taken. The low-density lipoprotein cholesterol (LDL-cholesterol) was calculated according to the Friedewald formula.[25] An oral glucose tolerance test was performed only at baseline. After overnight fasting, the child was given a glucose dose of 1.75 g/kg (max 75 g) and plasma glucose was then analysed after 120 minutes.[3] Insulin was analysed using AutoDELFIA™ from Wallac® (fluoroimmunoassay method), Turku Finland.

Total plasma cholesterol, HDL-cholesterol, and triglycerides were analysed using Siemens® Advia-1650, Siemens Healthcare Diagnostics, Deerfield, Illinois. Plasma glucose was measured using Hemocue® from HemoCue AB, Ängelholm, Sweden. All blood samples were analysed at an accredited medical laboratory (Vrinnevi Hospital, Norrköping, Sweden). Data on family participation in the intervention was collected from the tutors.

Statistical analysis

Standard descriptive statistics (mean and standard deviation) were computed. Given that variables were normally distributed, paired 2-tailed T-tests were used for significance testing. The significance level was set at $p<0.05$. The Statistical Package for the Social Sciences (SPSS) version 17 was used for the analyses.

Ethics approval

The study was approved by the Research Ethics Committee at Faculty of Health Sciences, Linköping University, Sweden (dnr. 03-600).

RESULTS

Ninety-six percent (n=25) of the families completed the group sessions. Only one family withdrew from the group sessions after the first 3-month phase of intervention. The child did not feel comfortable in the group and did not see obesity as a problem. Not all children agreed to participate in all examinations, even if they participated in the entire intervention program (Table 2).

Table 2 Values of anthropometric, body composition, and metabolic variables at baseline and at 3-, 12-, 24, and 36-month follow-ups.*

Variables [reference value]	Baseline		3 months		12 months		24 months		36 months		0–36 month change		
	n	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (95% CI)	*p*-value
z-BMI	26	3.3 (0.7)	25	3.1 (0.7)	26	3.0 (0.8)	24	2.9 (0.7)	23	2.9 (0.7)	23	–0.4 (–0.6 to – 0.2)	<0.001
WHtR	26	0.67 (0.06)	25	0.66 (0.07)	26	0.66 (0.07)	23	0.66 (0.07)	22	0.67 (0.08)	22	0 (–0.03 to 0.01)	0.332
P-fasting-glucose (mmol/L) [4.2–6.0]	26	4.6 (0.4)	25	4.7 (0.4)	26	5.1 (0.3)	23	4.9 (0.3)	23	5.0 (0.3)	23	+0.4 (0.2 to 0.6)	<0.001
S-fasting-insulin (pmol/L) [18–175]	26	78.5 (45.1)	24	76.0 (37.6)	25	77.6 (41.8)	23	80.0 (37.8)	23	76.7 (35.9)	23	-1.8 (–27.5 to 16.5)	0.608
P-LDL-cholesterol (mmol/L) [1.2–4.3]	26	2.7 (0.4)	25	2.3 (0.4)	23	2.3 (0.5)	23	2.2 (0.5)	23	2.3 (0.5)	23	–0.4 (–0.5 to – 0,2)	<0.001
P-HDL-cholesterol (mmol/L) [1.0–2.7 girls, 0.8–2.1 boys]	26	1.3 (0.2)	25	1.3 (0.2)	25	1.3 (0.2)	23	1.5 (0.3)	23	1.2 (0.2)	23	-0.1 (–0.1 to 0.1)	0.433
Total P-cholesterol (mmol/L) [3.1–5.2 at 2–12 years]	26	4.4 (0.5)	25	4.0 (0.5)	25	4.1 (0.6)	22	4.3 (0.6)	23	4.1 (0.5)	23	–0.3 (–0.5 to – 0.1)	0.004
P-fasting-triglycerides (mmol/L) [0.30–1.40 at <10 years, 0.30–1.60 at 10–14 years]	26	1.06 (0.39)	25	1.11 (0.53)	25	1.17 (0.74)	22	1.3 (0.46)	23	1.18 (0.48)	23	+0.12 (–0.13 to 0.31)	0.384

Abbreviations: BMI, body mass index; CI, confidence interval; HDL, high-density lipoprotein; LDL, low-density lipoprotein; P, plasma; S, serum; WHtR, waist-to-height ratio.

* One to three children dropped out at each examination, but it was not the same children every time and some children agreed to the weight and height measurements but not the blood sampling or vice versa

Clinical outcomes

The primary outcome measure, the mean z-BMI, was reduced from 3.3 (SD 0.7) at baseline to 2.9 (SD 0.7) ($p<0.001$) at the end point (12 months after completion of the program). A decrease in z-BMI was noted already after 3 months (Table 2). The boys had higher z-BMI at baseline (mean 3.5 (SD 0.6)) compared with the girls (mean 3.0 (SD 0.6)) ($p=0.028$). At the 36-month follow-up there were no gender differences in the decrease in z-BMI ($p=0.141$) (data not shown). Regarding the secondary outcome measures, there was no significant reduction of WHtR (Table 2). There was a decrease in the LDL-cholesterol ($p<0.001$) and total cholesterol ($p<0.01$) in the study group at the end point (12 months after completion of the program), but no significant differences in HDL-cholesterol or triglyceride values (Table 2). All children displayed normal values for the oral glucose tolerance test at baseline (data not shown). Fasting glucose was higher at the end point measurement (Table 2). However, all biomedical markers were within the normal range throughout the study.

DISCUSSION

In this feasibility study, we found that obese children who agreed to a 2-year FBIP delivered in a paediatric outpatient care setting had reduced their z-BMI 12 months after program completion. The mean decline in z-BMI was 12.1%. Even though the weight reduction was limited, it could be of importance in the prevention of long-term complications. Also moderate changes in BMI among children are known to influence metabolic risk indicators for cardiovascular disease.[26]

The small study sample and the single-group design imply that the observed decline in z-BMI cannot be firmly interpreted as an effect of the intervention program. Without a randomized control group it is impossible to know if the decrease in z-BMI was an effect of the intervention program per se. One bias in this study could be that the intervention

procedure selected only highly motivated families, who might have managed their children's weight without FBIP support.

Among secondary end point measures, the WHtR showed no change; the measurements for lipid status showed favourable trends. The results would have been even more convincing if all the secondary outcome measures had displayed similar trends. WHtR did not change, but perhaps the decline in z-BMI was too low to affect this measurement. The fasting glucose values increased at the follow-up 12 months after the end of the program. A Swedish study points out that BMI, level of physical activity, seasonal variations in physical activity and biological age (pubertal development) must be taken into consideration when interpreting clinical laboratory data.[27] Puberty signs were not consistently investigated in this study, which made it more difficult to interpret the biochemical data. Initial pubertal development in girls starts at approximately 10.9 years of age (range of 8.5–13.3 years) and in boys at 11.9 years of age on average (range 10.1–13.7 years).[28] Some children in this study may thus have reached the age for initiation of pubertal development when they started the FBIP (Table 1). It can be inferred that at least the interpretation of the metabolic parameters is complicated by the fact that the children entered puberty during the study period. It is thus possible that the higher blood glucose at follow-up could be explained by older age and more mature pubertal stage and not deterioration of metabolic status.

A methodological strength of this study is that the primary end point measurement was performed 12 months after the end of the intervention program. Although this follow-up period is longer than in many other studies, an even longer follow-up is necessary to evaluate the persistence of intervention effects. For instance, a randomized study of a 6-month obesity program in children aged 7–9 years in which a family-based group treatment was compared with routine counselling showed positive short-term effects,[29] but no difference in z-BMI at 2

and 3 years after the start of the intervention.[30] Another strength is that all participants were included in the data analysis at the study end point whether or not they completed the intervention. To improve the reliability of follow-up measurements, the height was measured by the same two paediatric registered nurses and waist circumference was always measured by the same person.

An interesting observation is the high rate of families (96%) completing the 2-year intervention program. A previous study has shown that high family adherence is an important success factor for long-term weight reduction in childhood obesity.[31] In comparison, results from the similar Families for Health program provided in a community setting in England reported that only 18 of 27 (67%) children completed a 3-month program.[32] One reason for the more favourable adherence to the present FBIP could be that the families were interviewed before starting the group sessions and estimated to be highly motivated to act on the obesity and to participate in the whole group program. Another factor contributing to the high adherence in this study could be the weight reduction during the intensive phase at the beginning of the program. Initial weight decrease has been suggested to be an important factor for success and for reducing the risk of drop-out from the treatment program.[33] A recent assessment of an outpatient treatment program with an 8-year follow-up of 90 obese children with a mean age of 10.1 years at baseline indicated that the mean reduction of 8% in adjusted BMI was a result of the children's success at the beginning of their treatment.[34] Another 1-year outpatient obesity intervention program of 170 children with a mean age 10.5 years showed promising results regarding weight outcomes 3 years after the end of the program. Also here, the weight reduction was interpreted to be connected to the initial weight reduction in the first 3 months of the program intervention.[35]

The recent Cochrane review of randomized controlled trials of interventions on childhood obesity reported that family-based behavioural lifestyle intervention programs are superior to regular care and self-help in the short and the long term.[2] Our feasibility study suggests that a long-term obesity management FBIP supported by a detailed manual can be implemented in routine paediatric outpatient care. We agree with the recommendations from the Cochrane review that more research is needed on obesity treatment in children and adolescents, especially large randomized effectiveness studies of different intervention programs with evaluations of long-term outcomes using changes in z-BMI and metabolic parameters as measures. In addition, we agree with the conclusion from the review that more research is needed to evaluate psychosocial, ethnic and cost-effectiveness aspects.

CONCLUSION

This feasibility study of an FBIP for management of childhood obesity in a paediatric outpatient care setting using a single-group pre- and post-intervention design showed promising outcomes and high adherence with 96% of families completing the 2-year intervention. The detailed manual and the structured program make it possible for available primary care or paediatric outpatient staff to lead groups. However, this FBIP assessment must be confirmed in a larger randomized controlled trial with a longer follow-up period before it can be implemented on a larger scale. Another interesting topic for further research is a comparison of the cost-effectiveness between FBIP and other family-based behavioural interventions in treating obese children.

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Competing interests

None.

Data Sharing

The authors are willing to share data from the study with researchers having an interest in comparative studies on family intervention effects.

Contributorship

MT was involved in the conception and design of the project, as well as the analysis and interpretation of the data. She drafted and revised the manuscript, and provided intellectual content. EM was involved in the conception and design of the project and in the interpretation of the data. She drafted and revised the manuscript, providing intellectual content. PB conceived and designed the project. He drafted and revised the manuscript, providing intellectual content. MN was involved in the conception and design of the project and in the interpretation of the data. She revised the manuscript, providing intellectual content. JE helped with data interpretation, revised the manuscript, and provided intellectual content. TT accepts direct responsibility for the manuscript. He was involved in the design of the project and the interpretation of the data. He drafted and revised the manuscript.

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Contributorship statement

MT was involved in the conception and design of the project, as well as the analysis and interpretation of the data. She drafted and revised the manuscript, and provided intellectual content. EM was involved in the conception and design of the project and in the interpretation of the data. She drafted and revised the manuscript, providing intellectual content. PB conceived and designed the project. He drafted and revised the manuscript, providing intellectual content. MN was involved in the conception and design of the project and in the interpretation of the data. She revised the manuscript, providing intellectual content. JE helped with data interpretation, revised the manuscript, and provided intellectual content. TT accepts direct responsibility for the manuscript. He was involved in the design of the project and the interpretation of the data. He drafted and revised the manuscript.

Data sharing statement

No additional data available.

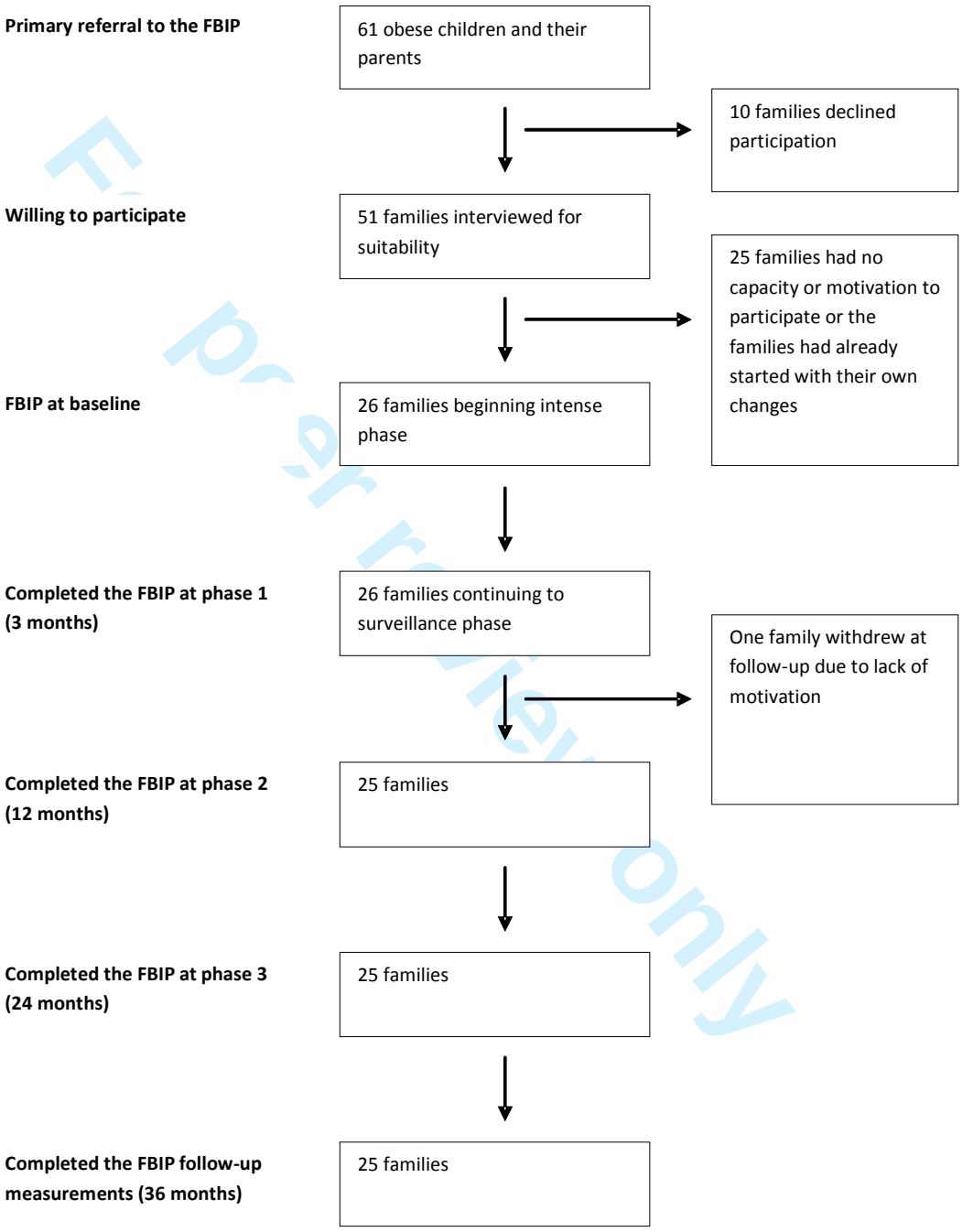

Figure 1 Flowchart for the study of families referral to the FBIP

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations and relevant dates, including periods of recruitment, exposure?, follow-up, and data collection	7- 8, 1 0-11
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	6-7
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	10-11
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	10-11
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10-11
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10- 11
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	11
		(*d*) If applicable, explain how loss to follow-up was addressed	
		(*e*) Describe any sensitivity analyses	
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Figure 1 page 24
		(b) Give reasons for non-participation at each stage	Figure 1 page 24
		(c) Consider use of a flow diagram	Figure 1 page 24
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Table 1 page 8
		(b) Indicate number of participants with missing data for each variable of interest	Table 1 page 8 and Table 2 page 12
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	Table 2 page 12
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	15
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	11-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	16-17

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Family-based behavioural intervention program for obese children: a feasibility study

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Keywords: child obesity, family therapy, long-term intervention, single-group study design

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ABSTRACT

Objectives: To assess a 2-year family-based behavioural intervention program against child obesity.

Design: Single-group pre- and post-intervention feasibility study.

Setting: Swedish paediatric outpatient care.

Participants: Twenty-six obese children aged 8.3–12.0 years and their parents who had consented to actively participate in a 2-year intervention.

Interventions: Twenty-five paediatric outpatient group sessions over a 2-year period with parallel groups for children and parents. The basis for the program was a manual containing instructions for tutor-supervised group sessions with obese children and their parents.

Primary and secondary outcome measures: The primary outcome measure was change in z-BMI between baseline and after 36 months. The secondary outcome measures were change in the waist-to-height ratio (WHtR), metabolic parameters and program adherence. The participants were examined at baseline and after 3, 12 and 24 months of therapy and at follow-up 12 months after completion of the program.

Results: The primary outcome measure, z-BMI, declined from a mean of 3.3 (0.7 SD) at baseline to 2.9 (0.7 SD) (p<0.001) at follow-up 12 months after completion of the program. There was no change in the WHtR. Biomedical markers of blood glucose metabolism and lipid status remained in the normal range. Ninety-six percent of the families completed the program.

Conclusions: This feasibility study of a 2-year family-based behavioural intervention program in paediatric outpatient care showed promising results with regard to further weight gain and program adherence. These findings must be confirmed in a randomized

controlled trial with longer follow-up before the intervention program can be implemented on a larger scale.

ARTICLE SUMMARY

Article focus

- Family-based behavioural interventions have produced promising results in controlled studies, but their effectiveness in paediatric outpatient settings remains to be shown.

Key messages

- A 2-year family-based behavioural intervention program for the management of childhood obesity in paediatric outpatient care showed promising results with regard to weight gain 1 year after the program.
- The completion rate of the program was high, which is important as high family adherence is a success factor for childhood obesity therapy.

Strengths and limitations of this study

- The main methodological strengths of this study are that the primary end point measurement was performed 12 months after the end of the long-term intervention program and that all participants were included in the data analysis at the study end point whether or not they had completed the intervention.
- The major weaknesses of the study are the small study sample and single-group design. The design implies that the observed decline in z-BMI cannot be firmly interpreted as an effect of the intervention program. The results would have been even more convincing if all the secondary outcome measures had displayed similar trends. Longer follow-up than 12 months is necessary to examine sustainable effects of the intervention.

INTRODUCTION

Child and adolescent obesity has increased globally.[1-3] In the United States, childhood obesity has more than tripled for children aged 6–11 years in the past three decades with around 9 million obese children aged over 6 years.[4] In Sweden, obesity in 10-year-old children increased fourfold in less than two decades,[5] although recent results have shown that the prevalence of overweight and obesity in childhood is levelling off.[6] Childhood obesity is resulting in significant short-term[2,7] and long-term[2,7-9] consequences on health and wellbeing, and increased mortality.[9] This situation calls for evidence-based child obesity management programs, which in turn requires research, re-formulation of health policies, and re-organization in the health care system.[10]

A natural target for these efforts is the family. Almost 50 years ago, the idea of a family as a system was presented, an emotional completeness where the individuals are strongly tied to each other.[11] The family system perspective visualizes how the relationship with family diet, caregiver resources, and child character can be mediated or moderated by a variety of influences ranging from cultural characteristics and motherly input into family economic decisions and social support.[12] A child's success with behaviour changes in association with obesity treatment has been found to be strongly contingent on the participation of the entire family in the process,[13,14] and on the treatment being initiated at an early age.[15] A recent Cochrane review concluded that family-based behavioural lifestyle interventions intended to change diet and exercise patterns together with self-help can reduce weight in children in the short-term as well as in the long-term.[2] Two approaches that have shown promising results for childhood obesity in specialist settings are cognitive behavioural therapy[16] and family-based lifestyle intervention.[17] However, implementation of cognitive behavioural therapy and treatments involving families require financial and personal resources that seldom are at hand for service supply to all families with obese children; however, present evidence suggests that

it is difficult to maintain changes in children's diet- and physical habits over time without professional support.[18,19] Therefore there is an urgent need to develop treatment programs that can be used in paediatric outpatient care. This feasibility study assesses a 2-year family-based behavioural intervention program (FBIP) against child obesity implemented in Swedish paediatric outpatient care, where the intervention was provided by the regular nurses and dieticians guided by a manual and supervised by a clinical psychologist. The specific aims of the study were to investigate clinical outcomes and program adherence.

METHODS

A single-group pre- and post-intervention design was used for the study. The primary outcome measure was change in standardized body mass index (z-BMI) between baseline and after 36 months, 12 months after the end of the program. The secondary outcome measures were change in the waist-to-height ratio (WHtR), metabolic parameters and program adherence. The participants were examined at baseline and after 3, 12 and 24 months of therapy and at follow-up 12 months after the end of the program.

Inclusion criteria

The inclusion criteria for the study were age 8– <12 years, obesity defined according to the International Obesity Taskforce (IOTF) criteria (above age- and gender-specific cut offs corresponding to adult body mass index (BMI), calculated as weight in kilograms divided by the square of height in meters, ≥ 30 kg⁄m^2)[20] and absence of other diseases. Both children and parents had to give consent that they were motivated and willing to participate in regular group sessions for the 2-year intervention period, to change eating and physical exercise habits, and to note food and beverage intake and physical activity in a diary during the period.

Participant recruitment

Figure 1 presents the flow of subjects referred to the program and eventually included in the study. School nurses in two municipalities in southeast Sweden with 63 elementary schools were asked to refer obese children and their parents for suitability evaluation, resulting in referral of 61 children. When invited, 10 families declined to participate in the selection interview. The remaining 51 children and their parents were given a structured interview regarding their motivation to change habits and participate in group sessions. Twenty-six children fulfilled all inclusion criteria (Table 1). The parent group included biological parents, foster parents and step-parents.

Table 1 Display of mean age (SD) and z-BMI (SD) for the study population at baseline

	Total (*n*=26)		Boys (*n*=14)		Girls (*n*=12)	
	Mean	(SD)	Mean	(SD)	Mean	(SD)
Age	10.9	(0.9)	10.9	(1.1)	10.8	(0.7)
z-BMI	3.3	(0.7)	3.5	(0.6)	3.0	(0.6)

The family-based behavioural intervention program

The FBIP for management of childhood obesity was delivered using the regular community-level health service resources. A manual for group-based family interventions developed by a psychologist and a dietician[21] was used as the basis for the program. The manual contained instructions for family selection (equivalent to the inclusion criteria used in this study) and for tutor-supervised group sessions with obese children and their parents.

The program started in 2004 and ended in 2006. During the first 3 months, the groups met once weekly (intensive phase 1). Throughout the second phase (months 4–12), group sessions were held once monthly (phase 2) and during the third phase (months 13–24) once every 3 months. The practical goals of the activities in the FBIP included how to promote sustainable and healthy eating habits among the children and stimulate regular physical activity, discussion on influences from commercials on eating and exercise, teaching them how to handle stress and disappointments, solving problems and finding alternative ways to contentment. The tutors wrote down the children's suggestions and changes accomplished in a notebook. After the first phase, the tutors offered individual discussion sessions with the parents. The purpose was to discuss the results the children achieved and how to maintain them.

Program implementation

Group sessions were conducted in three child groups and three parental groups. Four tutors in the FBIP were paediatric registered nurses. Two tutors were dieticians. The tutors were instructed before and during the intervention by one of the authors of the manual and then continuously supervised during the intervention period by a clinical psychologist.

Group session for children

The 2-hour sessions with the children were held after school. At the first meeting, the children received a diary. The diary was used to record the child's eating and physical activity habits and their steps of change. During the first 3 months they were encouraged to write in the diary every day, and thereafter once 1 week before each session. The parents helped the youngest children. The changes were later presented and discussed in the children's group. The tutors and the other children gave feedback on the notes; it was important to increase the children's awareness of their own behaviour. During each group session in phase 1, the children were encouraged to work with two small and realistic steps of changes concerning diet and physical activity until the next session. The tutors presented information handouts regarding diet and physical activity and from those the children were given homework tasks. If the children had not implemented the agreed changes, these were postponed to the next session. Some weeks the children also had to list the rewards they wanted if they had done well with their changes. However, food, drinks or sweets could not be chosen. Physical exercise was not scheduled in the sessions but sometimes the tutors and the children went for a walk. Each session included a light meal.

The children were reassured that everything that was said was in confidence within the child and parental groups. Therefore, the diaries were not accessible to the researchers.

Group session for parents

The 1.5-hour sessions with the parents were held in the evening. Documented changes in the child's eating and physical activity habits were communicated to the parents. The parents were given the same information about diet and physical activity and they were also given homework tasks from the session content. Moreover, the parents were given various food recipes and information about the risk factors and diseases associated with obesity. Parents presented to the group how the changes had turned out during the week. They gave examples of difficulties that had arisen from a parent's perspective.

Data collection

The participating children were clinically examined at baseline, after 3, 12 and 24 months of group therapy, and 12 months after the end of the program.

Weight wearing trousers and a T-shirt was measured to an accuracy of 0.1 kg. Height was measured using a stadiometer attached to a wall according to standard procedures by two paediatric registered nurses, to an accuracy of 0.5 cm. To compensate for BMI varying with age and gender, the z-BMI was calculated using Swedish national reference values for children from 2001 and the Box transformation formula.[22] At each examination, waist circumference measurements were always done by one of the authors (PB) at the navel plane to an accuracy of 0.5 cm. The waist-to-height ratio (WHtR) was calculated by dividing the waist circumference (cm) by the height (cm).[23,24] Fasting blood samples for analysis of glucose, insulin, triglycerides, total cholesterol and high-density lipoprotein cholesterol (HDL-cholesterol) were taken. The low-density lipoprotein cholesterol (LDL-cholesterol) was calculated according to the Friedewald formula.[25] An oral glucose tolerance test was performed only at baseline. After overnight fasting, the child was given a glucose dose of 1.75 g/kg (max 75 g) and plasma glucose was then analysed after 120 minutes.[3] Insulin was analysed using AutoDELFIA™ from Wallac® (fluoroimmunoassay method), Turku Finland.

Total plasma cholesterol, HDL-cholesterol, and triglycerides were analysed using Siemens® Advia-1650, Siemens Healthcare Diagnostics, Deerfield, Illinois. Plasma glucose was measured using Hemocue® from HemoCue AB, Ängelholm, Sweden. All blood samples were analysed at an accredited medical laboratory (Vrinnevi Hospital, Norrköping, Sweden). Data on family participation in the intervention was collected from the tutors.

Statistical analysis

Standard descriptive statistics (mean and standard deviation) were computed. Given that variables were normally distributed, paired 2-tailed T-tests were used for significance testing. The significance level was set at $p<0.05$. The Statistical Package for the Social Sciences (SPSS) version 17 was used for the analyses.

Ethics approval

The study was approved by the Research Ethics Committee at Faculty of Health Sciences, Linköping University, Sweden (dnr. 03-600).

RESULTS

Ninety-six percent (n=25) of the families completed the group sessions. Only one family withdrew from the group sessions after the first 3-month phase of intervention. The child did not feel comfortable in the group and did not see obesity as a problem. Not all children agreed to participate in all examinations, even if they participated in the entire intervention program (Table 2).

Table 2 Values of anthropometric, body composition, and metabolic variables at baseline and at 3-, 12-, 24, and 36-month follow-ups.*

Variables [reference value]	Baseline		3 months		12 months		24 months		36 months		0–36 month change		
	n	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (95% CI)	*p*-value
z-BMI	26	3.3 (0.7)	25	3.1 (0.7)	26	3.0 (0.8)	24	2.9 (0.7)	23	2.9 (0.7)	23	–0.4 (–0.6 to – 0.2)	<0.001
WHtR	26	0.67 (0.06)	25	0.66 (0.07)	26	0.66 (0.07)	23	0.66 (0.07)	22	0.67 (0.08)	22	0 (–0.03 to 0.01)	0.332
P-fasting-glucose (mmol/L) [4.2–6.0]	26	4.6 (0.4)	25	4.7 (0.4)	26	5.1 (0.3)	23	4.9 (0.3)	23	5.0 (0.3)	23	+0.4 (0.2 to 0.6)	<0.001
S-fasting-insulin (pmol/L) [18–175]	26	78.5 (45.1)	24	76.0 (37.6)	25	77.6 (41.8)	23	80.0 (37.8)	23	76.7 (35.9)	23	-1.8 (–27.5 to 16.5)	0.608
P-LDL-cholesterol (mmol/L) [1.2–4.3]	26	2.7 (0.4)	25	2.3 (0.4)	23	2.3 (0.5)	23	2.2 (0.5)	23	2.3 (0.5)	23	–0.4 (–0.5 to – 0,2)	<0.001
P-HDL-cholesterol (mmol/L) [1.0–2.7 girls, 0.8–2.1 boys]	26	1.3 (0.2)	25	1.3 (0.2)	25	1.3 (0.2)	23	1.5 (0.3)	23	1.2 (0.2)	23	-0.1 (–0.1 to 0.1)	0.433
Total P-cholesterol (mmol/L) [3.1–5.2 at 2–12 years]	26	4.4 (0.5)	25	4.0 (0.5)	25	4.1 (0.6)	22	4.3 (0.6)	23	4.1 (0.5)	23	–0.3 (–0.5 to – 0.1)	0.004
P-fasting-triglycerides (mmol/L) [0.30–1.40 at <10 years, 0.30–1.60 at 10–14 years]	26	1.06 (0.39)	25	1.11 (0.53)	25	1.17 (0.74)	22	1.3 (0.46)	23	1.18 (0.48)	23	+0.12 (–0.13 to 0.31)	0.384

Abbreviations: BMI, body mass index; CI, confidence interval; HDL, high-density lipoprotein; LDL, low-density lipoprotein; P, plasma; S, serum; WHtR, waist-to-height ratio.

* One to three children dropped out at each examination, but it was not the same children every time and some children agreed to the weight and height measurements but not the blood sampling or vice versa

Clinical outcomes

The primary outcome measure, the mean z-BMI, was reduced from 3.3 (SD 0.7) at baseline to 2.9 (SD 0.7) ($p<0.001$) at the end point (12 months after completion of the program). A decrease in z-BMI was noted already after 3 months (Table 2). The boys had higher z-BMI at baseline (mean 3.5 (SD 0.6)) compared with the girls (mean 3.0 (SD 0.6)) ($p=0.028$). At the 36-month follow-up there were no gender differences in the decrease in z-BMI ($p=0.141$) (data not shown). Regarding the secondary outcome measures, there was no significant reduction of WHtR (Table 2). There was a decrease in the LDL-cholesterol ($p<0.001$) and total cholesterol ($p<0.01$) in the study group at the end point (12 months after completion of the program), but no significant differences in HDL-cholesterol or triglyceride values (Table 2). All children displayed normal values for the oral glucose tolerance test at baseline (data not shown). Fasting glucose was higher at the end point measurement (Table 2). However, all biomedical markers were within the normal range throughout the study.

DISCUSSION

In this feasibility study, we found that obese children who agreed to a 2-year FBIP delivered in a paediatric outpatient care setting had reduced their z-BMI 12 months after program completion. The mean decline in z-BMI was 12.1%. Even though the weight reduction was limited, it could be of importance in the prevention of long-term complications. Also moderate changes in BMI among children are known to influence metabolic risk indicators for cardiovascular disease.[26]

The small study sample and the single-group design imply that the observed decline in z-BMI cannot be firmly interpreted as an effect of the intervention program. Without a randomized control group it is impossible to know if the decrease in z-BMI was an effect of the intervention program per se. One bias in this study could be that the intervention

procedure selected only highly motivated families, who might have managed their children's weight without FBIP support.

Among secondary end point measures, the WHtR showed no change; the measurements for lipid status showed favourable trends. The results would have been even more convincing if all the secondary outcome measures had displayed similar trends. WHtR did not change, but perhaps the decline in z-BMI was too low to affect this measurement. The fasting glucose values increased at the follow-up 12 months after the end of the program. A Swedish study points out that BMI, level of physical activity, seasonal variations in physical activity and biological age (pubertal development) must be taken into consideration when interpreting clinical laboratory data.[27] Puberty signs were not consistently investigated in this study, which made it more difficult to interpret the biochemical data. Initial pubertal development in girls starts at approximately 10.9 years of age (range of 8.5–13.3 years) and in boys at 11.9 years of age on average (range 10.1–13.7 years).[28] Some children in this study may thus have reached the age for initiation of pubertal development when they started the FBIP (Table 1). It can be inferred that at least the interpretation of the metabolic parameters is complicated by the fact that the children entered puberty during the study period. It is thus possible that the higher blood glucose at follow-up could be explained by older age and more mature pubertal stage and not deterioration of metabolic status.

A methodological strength of this study is that the primary end point measurement was performed 12 months after the end of the intervention program. Although this follow-up period is longer than in many other studies, an even longer follow-up is necessary to evaluate the persistence of intervention effects. For instance, a randomized study of a 6-month obesity program in children aged 7–9 years in which a family-based group treatment was compared with routine counselling showed positive short-term effects,[29] but no difference in z-BMI at 2

and 3 years after the start of the intervention.[30] Another strength is that all participants were included in the data analysis at the study end point whether or not they completed the intervention. To improve the reliability of follow-up measurements, the height was measured by the same two paediatric registered nurses and waist circumference was always measured by the same person.

An interesting observation is the high rate of families (96%) completing the 2-year intervention program. A previous study has shown that high family adherence is an important success factor for long-term weight reduction in childhood obesity.[31] In comparison, results from the similar Families for Health program provided in a community setting in England reported that only 18 of 27 (67%) children completed a 3-month program.[32] One reason for the more favourable adherence to the present FBIP could be that the families were interviewed before starting the group sessions and estimated to be highly motivated to act on the obesity and to participate in the whole group program. Another factor contributing to the high adherence in this study could be the weight reduction during the intensive phase at the beginning of the program. Initial weight decrease has been suggested to be an important factor for success and for reducing the risk of drop-out from the treatment program.[33] A recent assessment of an outpatient treatment program with an 8-year follow-up of 90 obese children with a mean age of 10.1 years at baseline indicated that the mean reduction of 8% in adjusted BMI was a result of the children's success at the beginning of their treatment.[34] Another 1-year outpatient obesity intervention program of 170 children with a mean age 10.5 years showed promising results regarding weight outcomes 3 years after the end of the program. Also here, the weight reduction was interpreted to be connected to the initial weight reduction in the first 3 months of the program intervention.[35]

The recent Cochrane review of randomized controlled trials of interventions on childhood obesity reported that family-based behavioural lifestyle intervention programs are superior to regular care and self-help in the short and the long term.[2] Our feasibility study suggests that a long-term obesity management FBIP supported by a detailed manual can be implemented in routine paediatric outpatient care. We agree with the recommendations from the Cochrane review that more research is needed on obesity treatment in children and adolescents, especially large randomized effectiveness studies of different intervention programs with evaluations of long-term outcomes using changes in z-BMI and metabolic parameters as measures. In addition, we agree with the conclusion from the review that more research is needed to evaluate psychosocial, ethnic and cost-effectiveness aspects.

CONCLUSION

This feasibility study of an FBIP for management of childhood obesity in a paediatric outpatient care setting using a single-group pre- and post-intervention design showed promising outcomes and high adherence with 96% of families completing the 2-year intervention. The detailed manual and the structured program make it possible for available primary care or paediatric outpatient staff to lead groups. However, this FBIP assessment must be confirmed in a larger randomized controlled trial with a longer follow-up period before it can be implemented on a larger scale. Another interesting topic for further research is a comparison of the cost-effectiveness between FBIP and other family-based behavioural interventions in treating obese children.

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Competing interests

None.

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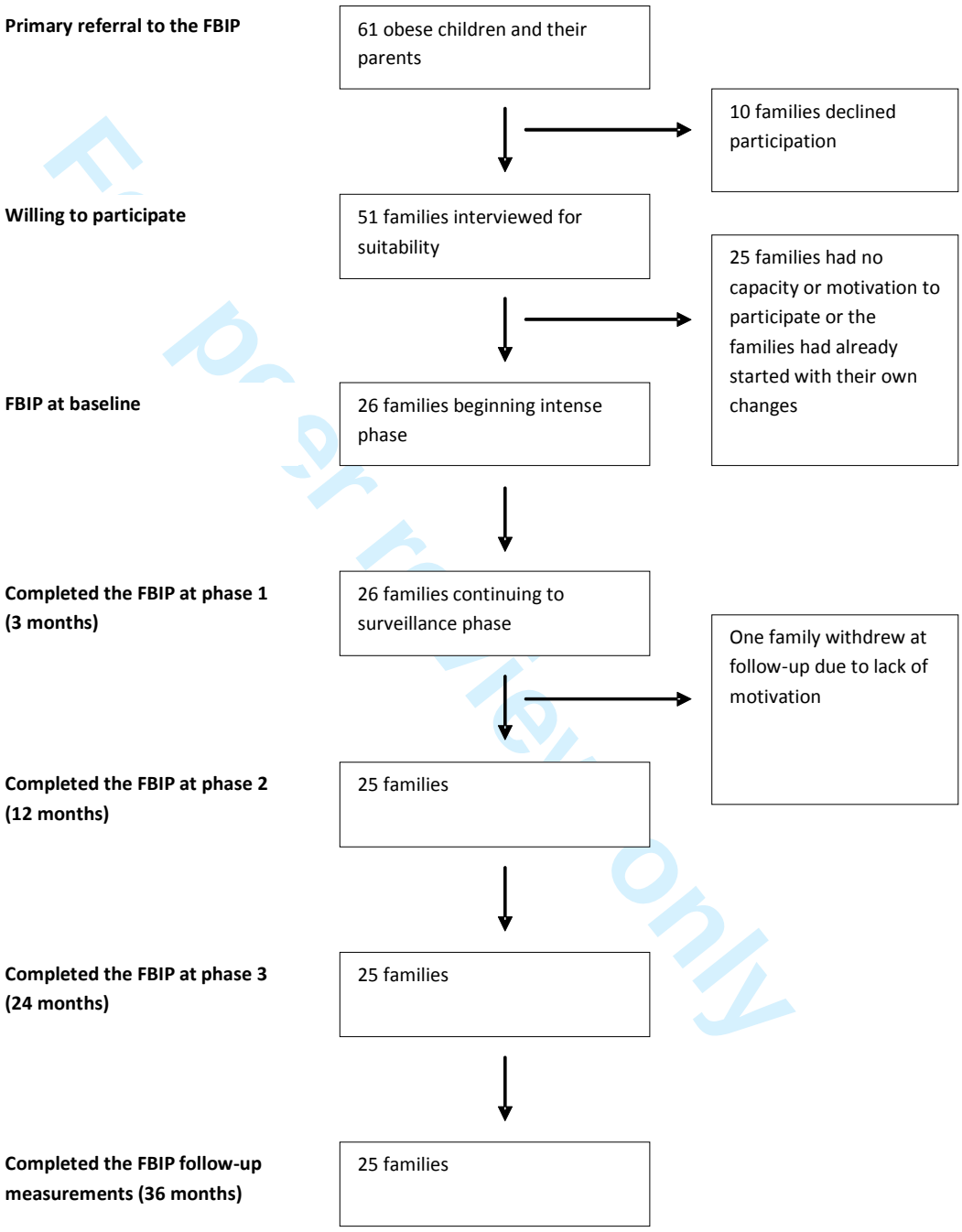
Contributorship statement

MT was involved in the conception and design of the project, as well as the analysis and interpretation of the data. She drafted and revised the manuscript, and provided intellectual content. EM was involved in the conception and design of the project and in the interpretation of the data. She drafted and revised the manuscript, providing intellectual content. PB conceived and designed the project. He drafted and revised the manuscript, providing intellectual content. MN was involved in the conception and design of the project and in the interpretation of the data. She revised the manuscript, providing intellectual content. JE helped with data interpretation, revised the manuscript, and provided intellectual content. TT accepts direct responsibility for the manuscript. He was involved in the design of the project and the interpretation of the data. He drafted and revised the manuscript.

Data sharing statement

No additional data available.



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437 **Figure 1** Flowchart for the study of families referral to the FBIP