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

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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.

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2
3 Obese children have an increased risk of becoming overweight and obese adults.[16, 17]
4
5 Therefore, it is necessary to offer early intervention against childhood obesity.[18] Present
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7 evidence suggests that it is difficult to maintain changes in children's diet- and physical habits
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9 over time without professional support.[19, 20] This study therefore assesses a 2-year Family-
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11 based Behavioural Intervention Program (FBIP) against child obesity implemented in
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13 Swedish paediatric outpatient care, where the intervention was provided by school nurses,
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15 paediatric nurses and dietitians. The specific aims of the study were to investigate clinical
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17 outcomes and program adherence.
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22 23 METHODS

24
25 A single-group pre- and post-test design and an intention-to-treat (ITT) analysis were used
26
27 for the study.
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29

30 31 **Inclusion criteria**

32
33 The inclusion criteria for the study were age 8–11.9 years, obesity defined according to the
34
35 International Obesity Taskforce (IOTF) criteria (above age- and sex-specific cutoffs
36
37 corresponding to adult body mass index (BMI, calculated as weight in kilograms divided by
38
39 the square of height in meters) $\geq 30 \text{ kg/m}^2$)[21] and absence of other diseases. Both children
40
41 and parents had to give consent that they were motivated and willing to participate in regular
42
43 group sessions for the 2-year intervention period, to change eating and physical exercise
44
45 habits, and to note changes in a diary during the period.
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50 51 **Participant recruitment**

52
53 Figure 1 presents the flow of subjects referred to the program and eventually included in
54
55 the study. School nurses in two municipalities in southeast Sweden with 63 elementary
56
57 schools were asked to refer obese children and their parents for suitability evaluation,
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59 resulting in referral of 61 children. When invited, 10 families declined to participate in the
60

1
2
3 selection interview. The remaining 51 children and their parents were given a structured
4
5 interview regarding their motivation to change habits and participate in group sessions.
6
7
8 Fourteen boys and 12 girls fulfilled all inclusion criteria. The parent group included biological
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10 parents, foster parents and step-parents.
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12 13 **The Family-based Behavioural Intervention Program**

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15
16 The FBIP for management of childhood obesity was delivered using the regular
17
18 community-level health service resources. A manual for group-based family interventions
19
20 developed by a psychologist and a dietician[22] was used as the basis for the program. The
21
22 manual contained instructions for tutor-supervised group sessions with obese children and
23
24 their parents.
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29 During the first 3 months, the groups met once weekly (intensive phase 1). Throughout the
30
31 second phase (months 4–12), group sessions were held once monthly (phase 2) and during the
32
33 third phase (months 13–24) once every 3 months. The practical goals of the activities in the
34
35 FBIP included how to promote sustainable and healthy eating habits among the children,
36
37 stimulate regular physical activities, discuss influences from commercials on eating and
38
39 exercise, teach them how to handle stress and disappointments, solve problems and find
40
41 alternative ways to contentment. The tutors write down the children's suggested and
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43 completed changes in a notebook. After the first phase, the tutors offered individual talks with
44
45 the parents. The purpose is to discuss what results the children have achieved and how to
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47 maintain these.
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53 **Program implementation**

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

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3 and then continuously supervised during the intervention period by another clinical
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5 psychologist.
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8 9 **Group session children**

10 The 2-hour sessions with the children were held after school. At the first meeting, the
11 children received a diary. The diary was used to write down the child's eating and physical
12 activity habits and to write down their steps of change. The changes were later presented and
13 discussed in the children's group. The tutors and the other children gave feedback on the
14 notes and it was important to increase the children's awareness of their own behaviour.
15
16 During each group session in phase 1, the children were encouraged to work with two small
17 and realistic steps of changes concerning diet and physical activity until the next session. The
18 tutors presented information handouts regarding diet and physical activities and from those
19 the children were given homework tasks. If the children had not implemented the agreed-upon
20 changes, these were postponed to the next session. Some weeks the children also had to list
21 the rewards they wanted if they had done well with their changes. However, food, drinks or
22 sweets could not be chosen. Physical exercise was not scheduled in the sessions but
23 sometimes the tutors and the children went for a walk. Each session included a light meal.
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42 The children were reassured that everything that was said was confident within the group
43 and for the parents. Therefore, the diaries were not accessible to the researchers.
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47 48 **Group session parents**

49 The 1.5-hour sessions with the parents were held in the evening. Documented changes in
50 the child's eating and physical activity habits were communicated to the parents. The parents
51 were given the same information about diet and physical activities and they were also given
52 homework tasks from the session content. Moreover, the parents were given various food
53 recipes and information about the risk factors and diseases associated with obesity. Parents
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3 presented to the group how the changes had turned out during the week. They gave examples
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5 of difficulties that had arisen from a parent perspective.
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8 9 **Data collection**

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11 The participating children were clinically examined at baseline, after 3, 12 and 24 months
12
13 of group therapy, and 12 months after the end of the program. At each examination, waist
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15 circumference measurements were collected by one of the authors (P.B.). Weight, height,
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17 fasting glucose, fasting insulin, cholesterol, triglycerides, low-density lipoprotein cholesterol
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19 (LDL-cholesterol) and high-density lipoprotein cholesterol (HDL-cholesterol) were also
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21 collected according to standard procedures at each examination by two registered paediatric
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23 nurses. The blood samples were analysed at an accredited medical laboratory (Vrinnevi
24
25 Hospital, Norrköping, Sweden). An oral glucose tolerance test performed at the baseline
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27 examination was calculated according to the World Health Organization.[23] The LDL-
28
29 cholesterol was calculated according to the Friedewald formula.[24] Data on family
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31 participation in the intervention was collected from the tutors.
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38 39 **Statistical analysis**

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41 To compensate for BMI varying with age and gender the standardized BMI (z-BMI) was
42
43 calculated.[25] The waist-to-height ratio (WHtR)[26,27] was calculated by dividing waist
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45 circumference (cm) by height (cm). Standard descriptive statistics (mean and standard
46
47 deviation) were computed. The *t*-test was used for to test for significance. The significance
48
49 level was set at $p < 0.05$. Statistical Package for the Social Sciences (SPSS) version 17 was
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51 used for the analyses.
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55 56 **Ethics approval**

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58 The study was approved by the Research Ethics Committee at Faculty of Health Sciences,
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60 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 (reference value) | 0 months | | 3 months | | 12 months | | 24 months | | 36 months | | 0–36 month change | | <i>p</i> - value |
|---|----------|----------------|----------|----------------|-----------|----------------|-----------|----------------|-----------|----------------|-------------------|--------------------------|---------------------|
| | <i>n</i> | Mean (SD) | <i>n</i> | Mean (SD) | <i>n</i> | Mean (SD) | <i>n</i> | Mean (SD) | <i>n</i> | Mean (SD) | <i>n</i> | Mean (95% CI) | |
| 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)

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|---|----|----------------|----|----------------|----|----------------|----|---------------|----|----------------|----|-------------------------|--------|
| 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

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3 (67%) children completed a 3-month program.[28] A reason for the more favourable
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5 adherence to our program could be that the families were interviewed before starting the
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7 group sessions and estimated by the tutors to be highly motivated to act on the obesity and
8
9 also motivated to participate in the whole group program. This also means that our program
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11 cannot be provided to all obese children and must be complemented with other interventions.
12
13 Another factor contributing to the high adherence in our study could be the weight reduction
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15 at the beginning of the program. The assessment from an outpatient treatment program with
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17 an 8-year follow-up of 90 obese children with a mean age of 10.1 years at baseline indicated
18
19 that the mean reduction of 8% in adjusted BMI was a result of the children's success at the
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21 beginning of their treatment.[31] Initial weight decrease is the most important factor for
22
23 success and for reducing the risk of drop-out from the treatment program.[32]
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30 A major weakness of the single-group design is that the observed decline in z-BMI cannot
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32 be firmly interpreted as an effect of the intervention program. The results would have been
33
34 even more convincing if all the secondary outcome measures had displayed similar trends.
35
36 The WHtR did not change, but perhaps the decline in z-BMI was too low to affect this
37
38 measurement. The fasting glucose values increased at 12 months follow-up after the end of
39
40 the program. The most plausible explanation is that the children reached pubertal age, i.e. this
41
42 was not a primary deterioration in their metabolic status. A Swedish study points out that
43
44 BMI, level of physical activity, seasonal variations in physical activity and biological age
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46 (pubertal development) rather than chronological age must be taken into consideration when
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48 interpreting clinical laboratory data.[33]
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54 Our intervention selected only highly motivated families who had more resources to
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56 manage their children's weight than an average family. However, it is plausible to assume that
57
58 the main part of the decrease in z-BMI in our study was an effect of the intervention program.
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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.

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12
13 Contributorship statement
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16
17 MT was involved in the conception and design of the project, as well as the
18
19 analysis and interpretation of the data. She drafted and revised the manuscript,
20
21 and provided intellectual content. EM was involved in the conception and design
22
23 of the project and in the interpretation of the data. She drafted and revised the
24
25 manuscript, providing intellectual content. PB conceived and designed the
26
27 project He drafted and revised the manuscript, providing intellectual content.
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33 MN was involved in the conception and design of the project and in the
34
35 interpretation of the data. She revised the manuscript, providing intellectual
36
37 content. JE helped with data interpretation, revised the manuscript, and provided
38
39 intellectual content. TT accepts direct responsibility for the manuscript. He was
40
41 involved in the design of the project and the interpretation of the data. He
42
43 drafted and revised the manuscript.
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REFERENCES

- [1] Lobstein T, Baur L, Uauy R; for the IASO International Obesity TaskForce. Obesity in children and young people: a crisis in public health. *Obes Rev* 2004;**5**:4-85.
- [2] Oude Luttikhuis H, Baur L, Jansen H, et al. Interventions for treating obesity in children. *Cochrane Database Syst Rev* 2009;**1**:1-175.
- [3] World Health Organization. Obesity: Preventing and Managing the Global Epidemic, Report of a WHO Consultation. WHO Technical Report Series. World Health Organization: Geneva 2000;894.
- [4] McCarthy HD, Ashwell M. A study of central fatness using waist-to-height ratios in UK children and adolescents over two decades supports the simple message--'keep your waist circumference to less than half your height'. *Int J Obes* 2006;**30**:988-92.
- [5] Marild S, Bondestam M, Bergstrom R, et al. Prevalence trends of obesity and overweight among 10-year-old children in western Sweden and relationship with parental body mass index. *Acta Paediatr* 2004;**93**:1588-95.
- [6] Sundblom E, Petzold M, Rasmussen F, et al. Childhood overweight and obesity prevalences levelling off in Stockholm but socioeconomic differences persist. *Int J Obes* 2008;**32**:1525-30.
- [7] Koplan JP, Liverman CT, Kraak VI, et al. Preventing childhood obesity: health in the balance: executive summary. *J Am Diet Assoc* 2005;**105**:131-38.
- [8] Reilly JJ, Methven E, McDowell ZC, et al. Health consequences of obesity. *Arch Dis Child* 2003;**88**:748-52.

- 1
2
3 [9] Reilly JJ, Kelly J. Long-term impact of overweight and obesity in childhood and
4
5 adolescence on morbidity and premature mortality in adulthood: systematic review.
6
7 Int J Obes 2010;1-8.
8
9
10
11 [10] Mossberg HO. 40-year follow-up of overweight children. Lancet 1989;2:491-93.
12
13
14
15 [11] Flodmark CE, Lissau I, Moreno LA, et al. New insights into the field of children and
16
17 adolescents' obesity: the European perspective. Int J Obes Relat Metab Disord
18
19 2004;28:1189-96.
20
21
22
23 [12] Bowen M. The use of family theory in clinical practice. Compr Psychiatry 1966;7:345-
24
25 74.
26
27
28
29 [13] Wachs TD. Multiple influences on children's nutritional deficiencies: a systems
30
31 perspective. Physiol Behav 2008;94:48-60.
32
33
34 [14] Pocock M, Trivedi D, Wills W, et al. Parental perceptions regarding healthy behaviours
35
36 for preventing overweight and obesity in young children: a systematic review of
37
38 qualitative studies. Obes Rev 2010;11:338-53.
39
40
41
42 [15] Yackobovitch-Gavan M, Nagelberg N, Phillip M, et al. The influence of diet and/or
43
44 exercise and parental compliance on health-related quality of life in obese children.
45
46 Nutr Res 2009;29:397-404.
47
48
49
50
51 [16] Singh AS, Mulder C, Twisk JW, et al. Tracking of childhood overweight into adulthood:
52
53 a systematic review of the literature. Obes Rev 2008;9:474-88.
54
55
56
57 [17] Whitaker RC, Wright JA, Pepe MS, et al. Predicting obesity in young adulthood from
58
59 childhood and parental obesity. N Engl J Med 1997;337:869-73.
60

- 1
2
3 [18] Reinehr T, Widhalm K, l'Allemand D, et al. Two-year follow-up in 21,784 overweight
4 children and adolescents with lifestyle intervention. *Obesity* 2009;**17**:1196-99.
5
6
7
8
9 [19] Whitlock EA, O'Connor EP, Williams SB, et al. Effectiveness of weight management
10 programs in children and adolescents. *Evid Rep Technol Assess* 2008;**170**:1-308.
11
12
13
14 [20] Whitlock EP, O'Connor EA, Williams SB, et al. Effectiveness of weight management
15 interventions in children: a targeted systematic review for the USPSTF. *Pediatrics*
16
17
18
19
20
21
22
23 [21] Cole TJ, Bellizzi MC, Flegal KM, et al. Establishing a standard definition for child
24 overweight and obesity worldwide: international survey. *BMJ* 2000;**320**:1240-43.
25
26
27
28
29 [22] Bonnedal U, Pettersson C. Gruppbehandling av barn med övervikt och fetma;
30
31
32
33
34
35 [23] World Health Organization. Definition, Diagnosis and Classification of Diabetes
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53 [25] Karlberg J, Kwan CW, Albertsson-Wikland K. Reference values for change in body
54
55
56
57
58
59
60

- 1
2
3 [26] Ashwell M, Hsieh SD. Six reasons why the waist-to-height ratio is a rapid and effective
4
5 global indicator for health risks of obesity and how its use could simplify the
6
7 international public health message on obesity. *Int J Food Sci Nutr* 2005;**56**:303-7.
8
9
- 10
11 [27] Nambiar S, Truby H, Abbott RA, Davies PS. Validating the waist-height ratio and
12
13 developing centiles for use amongst children and adolescents. *Acta Paediatr*
14
15 2009;**98**:148-52.
16
17
- 18
19 [28] Robertson W, Friede T, Blissett J, et al. Pilot of "Families for Health": community-based
20
21 family intervention for obesity. *Arch Dis Child* 2008;**93**:921-6.
22
23
- 24
25 [29] Larsson C, Hernell O, Lind T. Moderately elevated body mass index is associated with
26
27 metabolic variables and cardiovascular risk factors in Swedish children. *Acta Paediatr*
28
29 2011;**100**:102-8.
30
31
- 32
33 [30] Kalarchian MA, Levine MD, Arslanian SA, et al. Family-based treatment of severe
34
35 pediatric obesity: randomized, controlled trial. *Pediatrics* 2009;**124**:1060-8.
36
37
- 38
39 [31] Moens E, Braet C, Van Winckel. M.V. An 8-year follow-up of treated obese children:
40
41 children's, process and parental predictors of successful outcome. *Behav Res Ther*
42
43 2010;**48**:626-33.
44
45
- 46
47 [32] Elfhag K, Rossner S. Initial weight loss is the best predictor for success in obesity
48
49 treatment and sociodemographic liabilities increase risk for drop-out. *Patient Educ*
50
51 *Couns* 2010;**79**:361-6.
52
53
- 54
55 [33] Wennlof AH, Yngve A, Nilsson TK, et al. Serum lipids, glucose and insulin levels in
56
57 healthy schoolchildren aged 9 and 15 years from Central Sweden: reference values in
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relation to biological, social and lifestyle factors. Scand J Clin Lab Invest 2005;**65**:65-76.

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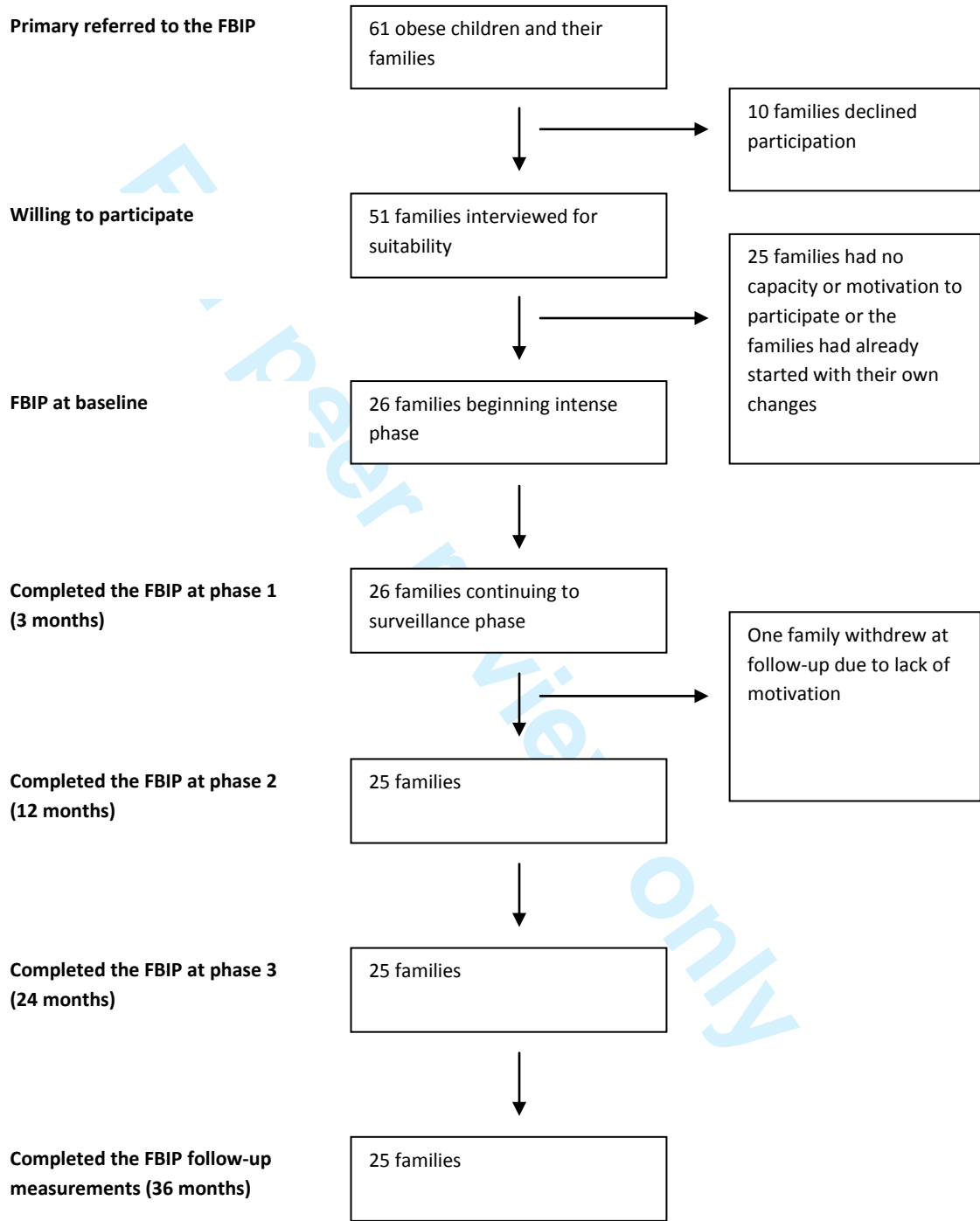


Figure 1

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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|---------------------------------|--|
| Journal: | <i>BMJ Open</i> |
| Manuscript ID: | bmjopen-2011-000268.R1 |
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| | |

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4 1 Family-based behavioural intervention program for obese
5 children: a feasibility study
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31 12 Keywords: child obesity, family therapy, long-term intervention, single-group study design
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18 ABSTRACT

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

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

22 **Setting:** Swedish paediatric outpatient care.

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

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

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

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

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

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42 controlled trial with longer follow-up before the intervention program can be
43 implemented on a larger scale.
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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 therapy¹⁶ 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

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2
3 91 it is difficult to maintain changes in children's diet- and physical habits over time without
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5 92 professional support.^{18,19} Therefore there is an urgent need to develop treatment programs that
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7 93 can be used in paediatric outpatient care. This feasibility study assesses a 2-year family-based
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9 94 behavioural intervention program (FBIP) against child obesity implemented in Swedish
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11 95 paediatric outpatient care, where the intervention was provided by the regular nurses and
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13 96 dieticians guided by a manual and supervised by a clinical psychologist. The specific aims of
14
15 97 the study were to investigate clinical outcomes and program adherence.
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20 98 **METHODS**

21
22 99 A single-group pre- and post-intervention design was used for the study. The primary
23
24 100 outcome measure was change in standardized body mass index (z-BMI) between baseline and
25
26 101 after 36 months, 12 months after the end of the program. The secondary outcome measures
27
28 102 were change in the waist-to-height ratio (WHtR), metabolic parameters and program
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30 103 adherence. The participants were examined at baseline and after 3, 12 and 24 months of
31
32 104 therapy and at follow-up 12 months after the end of the program.
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36 105 **Inclusion criteria**

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38 106 The inclusion criteria for the study were age 8– <12 years, obesity defined according to the
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40 107 International Obesity Taskforce (IOTF) criteria (above age- and gender-specific cut offs
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42 108 corresponding to adult body mass index (BMI), calculated as weight in kilograms divided by
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44 109 the square of height in meters, $\geq 30 \text{ kg/m}^2$)²⁰ and absence of other diseases. Both children and
45
46 110 parents had to give consent that they were motivated and willing to participate in regular
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48 111 group sessions for the 2-year intervention period, to change eating and physical exercise
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50 112 habits, and to note food and beverage intake and physical activities in a diary during the
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52 113 period.
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114 **Participant recruitment**

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

123

124 **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) |

125

126 **The family-based behavioural intervention program**

127 The FBIP for management of childhood obesity was delivered using the regular community-
 128 level health service resources. A manual for group-based family interventions developed by a
 129 psychologist and a dietician²¹ was used as the basis for the program. The manual contained
 130 instructions for family selection (equivalent to the inclusion criteria used in this study) and for
 131 tutor-supervised group sessions with obese children and their parents.

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

142 **Program implementation**

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

147 *Group session for children*

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

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

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3 165 *Group session for parents*

4 166 The 1.5-hour sessions with the parents were held in the evening. Documented changes in
5
6 167 the child's eating and physical activity habits were communicated to the parents. The parents
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8 168 were given the same information about diet and physical activities and they were also given
9
10 169 homework tasks from the session content. Moreover, the parents were given various food
11
12 170 recipes and information about the risk factors and diseases associated with obesity. Parents
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14 171 presented to the group how the changes had turned out during the week. They gave examples
15
16 172 of difficulties that had arisen from a parent's perspective.
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21 173 **Data collection**

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23 174 The participating children were clinically examined at baseline, after 3, 12 and 24 months
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25 175 of group therapy, and 12 months after the end of the program.
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28 176 Weight wearing trousers and a T-shirt was measured to an accuracy of 0.1 kg. Height was
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30 177 measured using a stadiometer attached to a wall according to standard procedures by two
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32 178 paediatric registered nurses, to an accuracy of 0.5 cm. To compensate for BMI varying with
33
34 179 age and gender, the z-BMI was calculated using Swedish national reference values for
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36 180 children from 2001 and the Box transformation formula.²² At each examination, waist
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38 181 circumference measurements were always done by one of the authors (PB) at the navel plane
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40 182 to an accuracy of 0.5 cm. The waist-to-height ratio (WHtR) was calculated by dividing the
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42 183 waist circumference (cm) by the height (cm).^{23,24} Fasting blood samples for analysis of
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44 184 glucose, insulin, triglycerides, total cholesterol and high-density lipoprotein cholesterol
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46 185 (HDL-cholesterol) were taken. The low-density lipoprotein cholesterol (LDL-cholesterol) was
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48 186 calculated according to the Friedewald formula.²⁵ An oral glucose tolerance test was
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50 187 performed only at baseline. After overnight fasting, the child was given a glucose dose of 1.75
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52 188 g/kg (max 75 g) and plasma glucose was then analysed after 120 minutes.³ Insulin was
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54 189 analysed using AutoDELFIA™ from Wallac® (fluoroimmunoassay method), Turku Finland.
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3 190 Total plasma cholesterol, HDL-cholesterol, and triglycerides were analysed using Siemens®
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5 191 Advia-1650, Siemens Healthcare Diagnostics, Deerfield, Illinois. Plasma glucose was
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7 192 measured using Hemocue® from HemoCue AB, Ängelholm, Sweden. All blood samples
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9 193 were analysed at an accredited medical laboratory (Vrinnevi Hospital, Norrköping, Sweden).
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11 194 Data on family participation in the intervention was collected from the tutors.

15 **Statistical analysis**

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17 196 Standard descriptive statistics (mean and standard deviation) were computed. Based on that
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19 197 the variables were normally distributed, paired 2-tailed T-tests were used for significance
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21 198 testing. The significance level was set at $p < 0.05$. The Statistical Package for the Social
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23 199 Sciences (SPSS) version 17 was used for the analyses.

27 **Ethics approval**

28
29 201 The study was approved by the Research Ethics Committee at Faculty of Health Sciences,
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31 202 Linköping University, Sweden (dnr. 03-600).

35 **RESULTS**

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37 204 Ninety-six percent ($n=25$) of the families completed the group sessions. Only one family
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39 205 withdrew from the group sessions after the first 3-month phase of intervention. The child did
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41 206 not feel comfortable in the group and did not see obesity as a problem. Not all children agreed
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43 207 to participate in all examinations, even if they participated in the entire intervention program.
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45 208 One to three children dropped out at each examination, but it was not the same children every
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47 209 time and some children agreed to the weight and height measurements but not the blood
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49 210 sampling or vice versa (Table 2).

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212 **Table 2** Values of anthropometric, body composition, and metabolic variables at baseline and
 213 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 | |
|---|----------|-------------|----------|-------------|-----------|-------------|-----------|-------------|-----------|-------------|-------------------|----------------------------------|
| | <i>n</i> | Mean (SD) | <i>n</i> | Mean (SD) | <i>n</i> | Mean (SD) | <i>n</i> | Mean (SD) | <i>n</i> | Mean (SD) | <i>n</i> | Mean (95% CI) <i>p</i> -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 |

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

216 Clinical outcomes

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

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3 219 decrease in z-BMI was noted already after 3 months (Table 2). The boys had higher z-BMI at
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5 220 baseline (mean 3.5 (SD 0.6)) compared with the girls (mean 3.0 (SD 0.6)) ($p=0.028$). At the
6
7 221 36-month follow-up there were no gender differences in the decrease in z-BMI ($p=0.141$)
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9 222 (data not shown). Regarding the secondary outcome measures, there was no significant
10
11 223 reduction of WHtR (Table 2). There was a decrease in the LDL-cholesterol ($p<0.001$) and
12
13 224 total cholesterol ($p<0.01$) in the study group at the end point (12 months after completion of
14
15 225 the program), but no significant differences in HDL-cholesterol or triglyceride values (Table
16
17 226 2). All children displayed normal values for the oral glucose tolerance test at baseline (data
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19 227 not shown). Fasting glucose was higher at the end point measurement (Table 2). However, all
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21 228 biomedical markers were within the normal range throughout the study.
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229 DISCUSSION

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

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

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3 242 Among secondary end point measures, the WHtR showed no change; the measurements for
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5 243 lipid status showed favourable trends. The results would have been even more convincing if
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7 244 all the secondary outcome measures had displayed similar trends. WHtR did not change, but
8
9 245 perhaps the decline in z-BMI was too low to affect this measurement. The fasting glucose
10
11 246 values increased at the follow-up 12 months after the end of the program. A Swedish study
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13 247 points out that BMI, level of physical activity, seasonal variations in physical activity and
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15 248 biological age (pubertal development) must be taken into consideration when interpreting
16
17 249 clinical laboratory data.²⁷ Puberty signs were not consistently investigated in this study, which
18
19 250 made it more difficult to interpret the biochemical data. Initial pubertal development in girls
20
21 251 starts at approximately 10.9 years of age (range of 8.5–13.3 years) and in boys at 11.9 years
22
23 252 of age on average (range 10.1–13.7 years).²⁸ Some children in this study may thus have
24
25 253 reached the age for initiation of pubertal development when they started the FBIP (Table 1). It
26
27 254 can be inferred that at least the interpretation of the metabolic parameters is complicated by
28
29 255 the fact that the children entered puberty during the study period. It is thus possible that the
30
31 256 higher blood glucose at follow-up could be explained by older age and more mature pubertal
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33 257 stage and not deterioration of metabolic status.
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39 258 A methodological strength of this study is that the primary end point measurement was
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41 259 performed 12 months after the end of the intervention program. Although this follow-up
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43 260 period is longer than in many other studies, an even longer follow-up is necessary to evaluate
44
45 261 the persistence of intervention effects. For instance, a randomized study of a 6-month obesity
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47 262 program in children aged 7–9 years in which a family-based group treatment was compared
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49 263 with routine counselling showed positive short-term effects,²⁹ but no difference in z-BMI at 2
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51 264 and 3 years after the start of the intervention.³⁰ Another strength is that all participants were
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53 265 included in the data analysis at the study end point whether or not they completed the
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55 266 intervention. To improve the reliability of follow-up measurements, the height was measured
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3 267 by the same two paediatric registered nurses and waist circumference was always measured
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5 268 by the same person.
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8 269 An interesting observation is the high rate of families (96%) completing the 2-year
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10 270 intervention program. A previous study has shown that high family adherence is an important
11
12 271 success factor for long-term weight reductions in childhood obesity.³¹ In comparison, results
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14 272 from the similar Families for Health program provided in a community setting in England
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16 273 reported that only 18 of 27 (67%) children completed a 3-month program.³² One reason for
17
18 274 the more favourable adherence to the present FBIP could be that the families were
19
20 275 interviewed before starting the group sessions and estimated to be highly motivated to act on
21
22 276 the obesity and to participate in the whole group program. Another factor contributing to the
23
24 277 high adherence in this study could be the weight reduction during the intensive phase at the
25
26 278 beginning of the program. Initial weight decrease has been suggested to be an important
27
28 279 factor for success and for reducing the risk of drop-out from the treatment program.³³ A recent
29
30 280 assessment of an outpatient treatment program with an 8-year follow-up of 90 obese children
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32 281 with a mean age of 10.1 years at baseline indicated that the mean reduction of 8% in adjusted
33
34 282 BMI was a result of the children's success at the beginning of their treatment.³⁴ Another 1-
35
36 283 year outpatient obesity intervention program of 170 children with a mean age 10.5 years
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38 284 showed promising results regarding weight outcomes 3 years after the end of the program.
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40 285 Also here, the weight reduction was interpreted to be connected to the initial weight reduction
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42 286 in the first 3 months of the program intervention.³⁵
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49 287 The recent Cochrane review of randomized controlled trials of interventions on childhood
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51 288 obesity reported that family-based behavioural lifestyle intervention programs are superior to
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53 289 regular care and self-help in the short and the long term.² Our feasibility study suggests that a
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55 290 long-term obesity management FBIP supported by a detailed manual can be implemented in
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3 291 routine paediatric outpatient care. We agree with the recommendations from the Cochrane
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5 292 review that more research is needed on obesity treatment in children and adolescents,
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7 293 especially large randomized effectiveness studies of different intervention programs with
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9 294 evaluations of the long-term outcome. In addition, we agree with the conclusion from the
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11 295 review that more research is needed to evaluate psychosocial, ethnic and cost-effectiveness
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13 296 aspects.

17 297 **CONCLUSION**

18
19 298 This feasibility study of an FBIP for management of childhood obesity in a paediatric
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21 299 outpatient care setting using a single-group pre- and post-intervention design showed
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23 300 promising outcomes and high adherence with 96% of families completing the 2-year
24
25 301 intervention. The detailed manual and the structured program make it possible for available
26
27 302 primary care or paediatric outpatient staff to lead groups. However, this FBIP assessment
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29 303 must be confirmed in a larger randomized controlled trial with a longer follow-up period
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31 304 before it can be implemented on a larger scale. Another interesting topic for further research
32
33 305 is a comparison of the cost-effectiveness between FBIP and other family-based behavioural
34
35 306 interventions in treating obese children.

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43
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316 **Competing interests**

317 None.

318

For peer review only

319 **REFERENCES**

- 320 1. Lobstein L, Baur R, Uauy for the IASO International Obesity TaskForce. Obesity in
321 children and young people: a crisis in public health. *Obes Rev* 2004;5:4-85.
- 322 2. Oude Luttikhuis H, Baur L, Jansen H, Shrewsbury VA, O'Malley C, Stolk RP, et al.
323 Interventions for treating obesity in children. *Cochrane Database Syst Rev* 2009; Jan
324 21;(1)(1):CD001872.
- 325 3. World Health Organization. Definition, Diagnosis and Classification of Diabetes Mellitus
326 and its Complications, Report of a WHO Consultation;Part 1:Diagnosis and Classification of
327 Diabetes Mellitus. *Department of Noncommunicable Disease Surveillance Geneva* 1999.
- 328 4. Koplan JP, Liverman CT, Kraak VI, Committee on Prevention of Obesity in Children and
329 Youth. Preventing childhood obesity: health in the balance: executive summary. *J Am Diet*
330 *Assoc* 2005; Jan;105(1):131-8.
- 331 5. Marild S, Bondestam M, Bergstrom R, Ehnberg S, Hollsing A, Albertsson-Wikland K.
332 Prevalence trends of obesity and overweight among 10-year-old children in western Sweden
333 and relationship with parental body mass index. *Acta Paediatr* 2004; Dec;93(12):1588-95.
- 334 6. Sundblom E, Petzold M, Rasmussen F, Callmer E, Lissner L. Childhood overweight and
335 obesity prevalences levelling off in Stockholm but socioeconomic differences persist. *Int J*
336 *Obes (Lond)* 2008; Oct;32(10):1525-30.
- 337 7. Reilly JJ, Methven E, McDowell ZC, Hacking B, Alexander D, Stewart L, et al. Health
338 consequences of obesity. *Arch Dis Child* 2003; Sep;88(9):748-52.

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56
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58
59
60

- 339 8. Reilly JJ, Kelly J. Long-term impact of overweight and obesity in childhood and
340 adolescence on morbidity and premature mortality in adulthood: systematic review. *Int J*
341 *Obes (Lond)* 2011 Jul;35(7):891-8.
- 342 9. Mossberg HO. 40-Year Follow-Up of Overweight Children. *Lancet* 1989; Aug
343 26;2(8661):491-3.
- 344 10. Flodmark CE, Lissau I, Moreno LA, Pietrobelli A, Widhalm K. New insights into the
345 field of children and adolescents' obesity: the European perspective. *Int J Obes Relat Metab*
346 *Disord* 2004; Oct;28(10):1189-96.
- 347 11. Bowen M. The use of family Theory in Clinical Practice. *Comprehensive Psychiatry*
348 1966;7:345-74.
- 349 12. Wachs TD. Multiple influences on children's nutritional deficiencies: a systems
350 perspective. *Physiol Behav* 2008; Apr 22;94(1):48-60.
- 351 13. Pocock M, Trivedi D, Wills W, Bunn F, Magnusson J. Parental perceptions regarding
352 healthy behaviours for preventing overweight and obesity in young children: a systematic
353 review of qualitative studies. *Obes Rev* 2010; May;11(5):338-53.
- 354 14. Yackobovitch-Gavan M, Nagelberg N, Phillip M, Ashkenazi-Hoffnung L, HersHKovitz E,
355 Shalitin S. The influence of diet and/or exercise and parental compliance on health-related
356 quality of life in obese children. *Nutrition Research* 2009;29:397-404.
- 357 15. Reinehr T, Kleber M, Lass N, Toschke AM. Body mass index patterns over 5 y in obese
358 children motivated to participate in a 1-y lifestyle intervention: age as a predictor of long-term
359 success. *Am J Clin Nutr* 2010; May;91(5):1165-71.

- 1
2
3 360 16. Braet C, Van Winckel M, Van Leeuwen K. Follow-up results of different treatment
4
5 361 programs for obese children. *Acta Paediatr* 1997; Apr;86(4):397-402.
6
7
8
9 362 17. West F, Sanders MR, Cleghorn GJ, Davies PS. Randomised clinical trial of a family-
10
11 363 based lifestyle intervention for childhood obesity involving parents as the exclusive agents of
12
13 364 change. *Behav Res Ther* 2010; Dec;48(12):1170-9.
14
15
16 365 18. Whitlock EA, O'Connor EP, Williams SB, Beil TL, Lutz KW. Effectiveness of weight
17
18 366 management programs in children and adolescents. *Evid Rep Technol Assess (Full Rep)* 2008;
19
20 367 Sep;(170)(170):1-308.
21
22
23
24 368 19. Whitlock EP, O'Connor EA, Williams SB, Beil TL, Lutz KW. Effectiveness of weight
25
26 369 management interventions in children: a targeted systematic review for the USPSTF.
27
28 370 *Pediatrics* 2010; Feb;125(2):e396-418.
29
30
31
32 371 20. Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition for child
33
34 372 overweight and obesity worldwide: international survey. *BMJ* 2000; May 6;320(7244):1240-
35
36 373 3.
37
38
39
40 374 21. Bonnedal U, Pettersson C. Gruppbehandling av barn med övervikt och fetma;
41
42 375 Utredningsintervju (MORSE) och Behandlingsmanual för barn och föräldrar. 2004; [Group
43
44 376 treatment of children with overweight and obesity; Investigation Interview (MORSE) and
45
46 377 Treatment Manual for Children and Parents]. 2004 (in Swedish).
47
48
49
50 378 22. Karlberg J, Luo ZC, Albertsson-Wikland K. Body mass index reference values (mean and
51
52 379 SD) for Swedish children. *Acta Paediatr* 2001; Dec;90(12):1427-34.
53
54
55
56 380 23. Ashwell M, Hsieh SD. Six reasons why the waist-to-height ratio is a rapid and effective
57
58 381 global indicator for health risks of obesity and how its use could simplify the international
59
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55
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- 382 public health message on obesity. *International Journal of Food Sciences and Nutrition*
- 383 2005; Aug;56(5):303-307.
- 384 24. Nambiar S, Truby H, Abbott RA, Davies PS. Validating the waist-height ratio and
- 385 developing centiles for use amongst children and adolescents. *Acta Paediatr* 2009;
- 386 Jan;98(1):148-52.
- 387 25. Friedewald WT, Levy RI, Fredrickson DS. Estimation of the Concentration of Low-
- 388 Density Lipoprotein Cholesterol in Plasma, Without Use of the Preparative Ultracentrifuge.
- 389 *Clinical Chemistry* 1972;18(6):499-502.
- 390 26. Larsson C, Hernell O, Lind T. Moderately elevated body mass index is associated with
- 391 metabolic variables and cardiovascular risk factors in Swedish children. *Acta Paediatr* 2011;
- 392 Jan;100(1):102-8.
- 393 27. Wennlof AH, Yngve A, Nilsson TK, Sjostrom M. Serum lipids, glucose and insulin levels
- 394 in healthy schoolchildren aged 9 and 15 years from Central Sweden: reference values in
- 395 relation to biological, social and lifestyle factors. *Scand J Clin Lab Invest* 2005;65(1):65-76.
- 396 28. Bramswig J, Dubbers A. Disorders of pubertal development. *Dtsch Arztebl Int* 2009;
- 397 Apr;106(17):295-304.
- 398 29. Kalavainen MP, Korppi MO, Nuutinen OM. Clinical efficacy of group-based treatment
- 399 for childhood obesity compared with routinely given individual counseling. *Int J Obes (Lond)*
- 400 2007; Oct;31(10):1500-8.
- 401 30. Kalavainen M, Korppi M, Nuutinen O. Long-term efficacy of group-based treatment for
- 402 childhood obesity compared with routinely given individual counselling. *Int J Obes (Lond)*
- 403 2011; Apr;35(4):530-3.

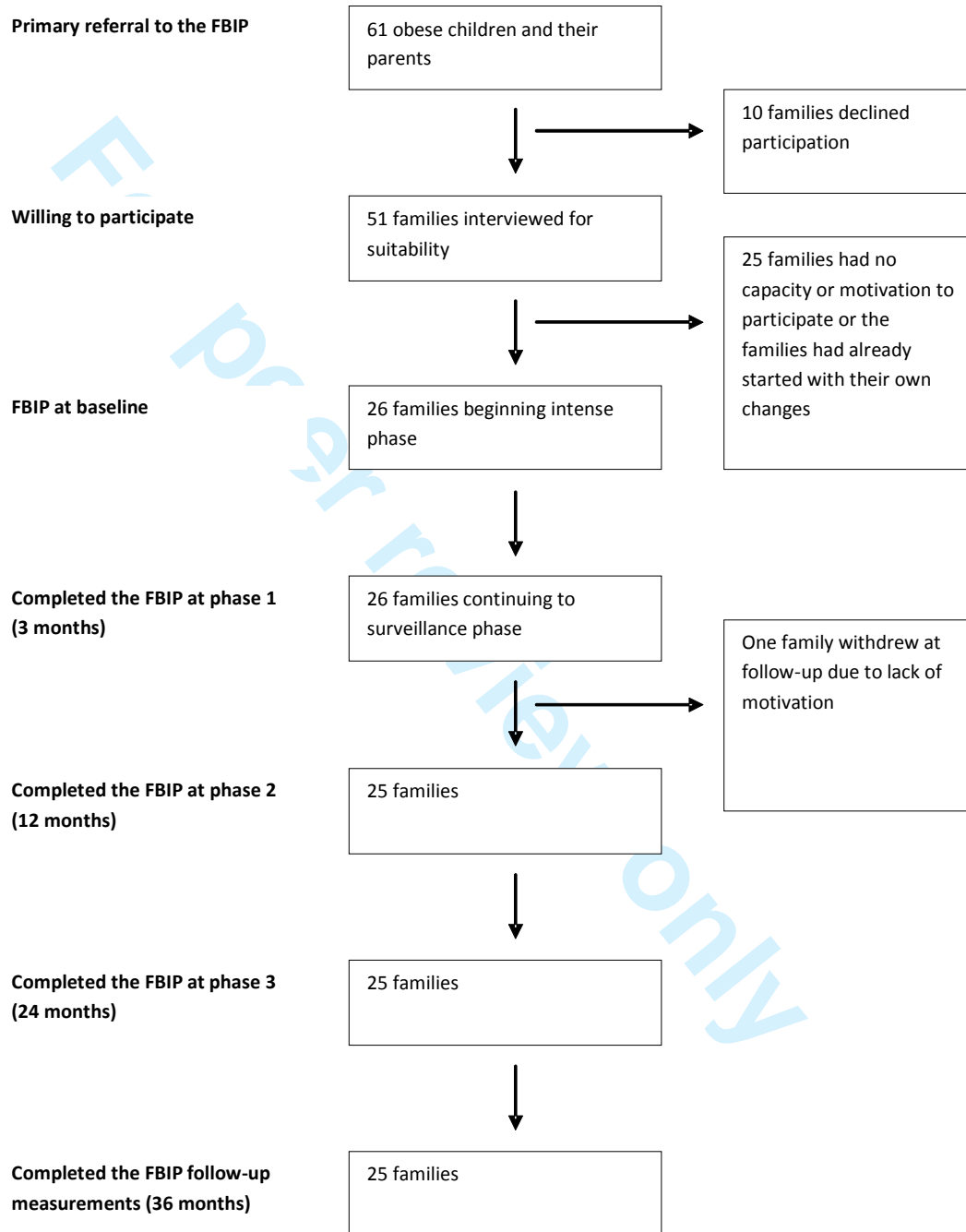
- 1
2
3 404 31. Kalarchian MA, Levine MD, Arslanian SA, Ewing LJ, Houck PR, Cheng Y, et al. Family-
4
5 405 based treatment of severe pediatric obesity: randomized, controlled trial. *Pediatrics* 2009;
6
7 406 Oct;124(4):1060-8.
8
9
10 407 32. Robertson W, Friede T, Blissett J, Rudolf.M.C.J., Wallis M, Stewart-Brown.S. Pilot of
11
12 408 "Families for Health": community-based family intervention for obesity. *Arch Dis Child*
13
14 409 2008;93:921-6.
15
16
17
18 410 33. Elfhag K, Rossner S. Initial weight loss is the best predictor for success in obesity
19
20 411 treatment and sociodemographic liabilities increase risk for drop-out. *Patient Educ Couns*
21
22 412 2010; Jun;79(3):361-6.
23
24
25
26 413 34. Moens E, Braet C, Van Winckel. M.V. An 8-year follow-up of treated obese children:
27
28 414 Children's, process and parental predictors of successful outcome. *Behaviour Research and*
29
30 415 *Therapy* 2010;48:626-33.
31
32
33
34 416 35. Reinehr T, Temmesfeld M, Kersting M, de Sousa G, Toschke AM. Four-year follow-up of
35
36 417 children and adolescents participating in an obesity intervention program. *Int J Obes (Lond)*
37
38 418 2007; Jul;31(7):1074-7.
39
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3 419 **Contributorship statement**
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7 420 MT was involved in the conception and design of the project, as well as the analysis and
8
9 421 interpretation of the data. She drafted and revised the manuscript, and provided intellectual
10
11 422 content. EM was involved in the conception and design of the project and in the interpretation
12
13 423 of the data. She drafted and revised the manuscript, providing intellectual content. PB
14
15 424 conceived and designed the project. He drafted and revised the manuscript, providing
16
17 425 intellectual content. MN was involved in the conception and design of the project and in the
18
19 426 interpretation of the data. She revised the manuscript, providing intellectual content. JE
20
21 427 helped with data interpretation, revised the manuscript, and provided intellectual content. TT
22
23 428 accepts direct responsibility for the manuscript. He was involved in the design of the project
24
25 429 and the interpretation of the data. He drafted and revised the manuscript.
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31 430 **Data sharing statement**
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33 431 No additional data available.
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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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|---------------------------------|--|
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| Keywords: | PAEDIATRICS, Childhood obesity, Family-based behavioural interventions, Health services research |
| | |

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4 1 Family-based behavioural intervention program for obese
5 children: a feasibility study
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29
30 12 Keywords: child obesity, family therapy, long-term intervention, single-group study design
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37 16 Word count: 2963
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18 ABSTRACT

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

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

22 **Setting:** Swedish paediatric outpatient care.

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

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

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

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

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

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42 controlled trial with longer follow-up before the intervention program can be
43 implemented on a larger scale.
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For peer review only

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 therapy¹⁶ 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

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2
3 91 it is difficult to maintain changes in children's diet- and physical habits over time without
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5 92 professional support.^{18,19} Therefore there is an urgent need to develop treatment programs that
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7 93 can be used in paediatric outpatient care. This feasibility study assesses a 2-year family-based
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9 94 behavioural intervention program (FBIP) against child obesity implemented in Swedish
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11 95 paediatric outpatient care, where the intervention was provided by the regular nurses and
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13 96 dieticians guided by a manual and supervised by a clinical psychologist. The specific aims of
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15 97 the study were to investigate clinical outcomes and program adherence.
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20 98 **METHODS**

21
22 99 A single-group pre- and post-intervention design was used for the study. The primary
23
24 100 outcome measure was change in standardized body mass index (z-BMI) between baseline and
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26 101 after 36 months, 12 months after the end of the program. The secondary outcome measures
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28 102 were change in the waist-to-height ratio (WHtR), metabolic parameters and program
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30 103 adherence. The participants were examined at baseline and after 3, 12 and 24 months of
31
32 104 therapy and at follow-up 12 months after the end of the program.
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36 105 **Inclusion criteria**

37
38 106 The inclusion criteria for the study were age 8– <12 years, obesity defined according to the
39
40 107 International Obesity Taskforce (IOTF) criteria (above age- and gender-specific cut offs
41
42 108 corresponding to adult body mass index (BMI), calculated as weight in kilograms divided by
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44 109 the square of height in meters, $\geq 30 \text{ kg/m}^2$)²⁰ and absence of other diseases. Both children and
45
46 110 parents had to give consent that they were motivated and willing to participate in regular
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48 111 group sessions for the 2-year intervention period, to change eating and physical exercise
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50 112 habits, and to note food and beverage intake and physical activity in a diary during the period.
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3 113 **Participant recruitment**
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5 114 Figure 1 presents the flow of subjects referred to the program and eventually included in
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7 115 the study. School nurses in two municipalities in southeast Sweden with 63 elementary
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9 116 schools were asked to refer obese children and their parents for suitability evaluation,
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11 117 resulting in referral of 61 children. When invited, 10 families declined to participate in the
12
13 118 selection interview. The remaining 51 children and their parents were given a structured
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15 119 interview regarding their motivation to change habits and participate in group sessions.
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17 120 Twenty-six children fulfilled all inclusion criteria (Table 1). The parent group included
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19 121 biological parents, foster parents and step-parents.
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123 **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) |

124

125 **The family-based behavioural intervention program**

126 The FBIP for management of childhood obesity was delivered using the regular community-
 127 level health service resources. A manual for group-based family interventions developed by a
 128 psychologist and a dietician²¹ was used as the basis for the program. The manual contained
 129 instructions for family selection (equivalent to the inclusion criteria used in this study) and for
 130 tutor-supervised group sessions with obese children and their parents.

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

142 **Program implementation**

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

147 *Group session for children*

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

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

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3 165 *Group session for parents*

4 166 The 1.5-hour sessions with the parents were held in the evening. Documented changes in
5
6 167 the child's eating and physical activity habits were communicated to the parents. The parents
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8 168 were given the same information about diet and physical activity and they were also given
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10 169 homework tasks from the session content. Moreover, the parents were given various food
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12 170 recipes and information about the risk factors and diseases associated with obesity. Parents
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14 171 presented to the group how the changes had turned out during the week. They gave examples
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16 172 of difficulties that had arisen from a parent's perspective.
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21 173 **Data collection**

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23 174 The participating children were clinically examined at baseline, after 3, 12 and 24 months
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25 175 of group therapy, and 12 months after the end of the program.
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28 176 Weight wearing trousers and a T-shirt was measured to an accuracy of 0.1 kg. Height was
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30 177 measured using a stadiometer attached to a wall according to standard procedures by two
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32 178 paediatric registered nurses, to an accuracy of 0.5 cm. To compensate for BMI varying with
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34 179 age and gender, the z-BMI was calculated using Swedish national reference values for
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36 180 children from 2001 and the Box transformation formula.²² At each examination, waist
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38 181 circumference measurements were always done by one of the authors (PB) at the navel plane
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40 182 to an accuracy of 0.5 cm. The waist-to-height ratio (WHtR) was calculated by dividing the
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42 183 waist circumference (cm) by the height (cm).^{23,24} Fasting blood samples for analysis of
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44 184 glucose, insulin, triglycerides, total cholesterol and high-density lipoprotein cholesterol
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46 185 (HDL-cholesterol) were taken. The low-density lipoprotein cholesterol (LDL-cholesterol) was
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48 186 calculated according to the Friedewald formula.²⁵ An oral glucose tolerance test was
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50 187 performed only at baseline. After overnight fasting, the child was given a glucose dose of 1.75
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52 188 g/kg (max 75 g) and plasma glucose was then analysed after 120 minutes.³ Insulin was
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54 189 analysed using AutoDELFIA™ from Wallac® (fluoroimmunoassay method), Turku Finland.
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3 190 Total plasma cholesterol, HDL-cholesterol, and triglycerides were analysed using Siemens®
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5 191 Advia-1650, Siemens Healthcare Diagnostics, Deerfield, Illinois. Plasma glucose was
6
7 192 measured using Hemocue® from HemoCue AB, Ängelholm, Sweden. All blood samples
8
9 193 were analysed at an accredited medical laboratory (Vrinnevi Hospital, Norrköping, Sweden).
10
11 194 Data on family participation in the intervention was collected from the tutors.

15 **Statistical analysis**

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17 196 Standard descriptive statistics (mean and standard deviation) were computed. Given that
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19 197 variables were normally distributed, paired 2-tailed T-tests were used for significance testing.
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21 198 The significance level was set at $p < 0.05$. The Statistical Package for the Social Sciences
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23 199 (SPSS) version 17 was used for the analyses.

27 **Ethics approval**

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29 201 The study was approved by the Research Ethics Committee at Faculty of Health Sciences,
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31 202 Linköping University, Sweden (dnr. 03-600).

35 **RESULTS**

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37 204 Ninety-six percent ($n=25$) of the families completed the group sessions. Only one family
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39 205 withdrew from the group sessions after the first 3-month phase of intervention. The child did
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41 206 not feel comfortable in the group and did not see obesity as a problem. Not all children agreed
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43 207 to participate in all examinations, even if they participated in the entire intervention program
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45 208 (Table 2).

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212 **Table 2** Values of anthropometric, body composition, and metabolic variables at baseline and
 213 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 | |
|---|----------|-------------|----------|-------------|-----------|-------------|-----------|-------------|-----------|-------------|-------------------|----------------------------------|
| | <i>n</i> | Mean (SD) | <i>n</i> | Mean (SD) | <i>n</i> | Mean (SD) | <i>n</i> | Mean (SD) | <i>n</i> | Mean (SD) | <i>n</i> | Mean (95% CI) <i>p</i> -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 |

214 Abbreviations: BMI, body mass index; CI, confidence interval; HDL, high-density
 215 lipoprotein; LDL, low-density lipoprotein; P, plasma; S, serum; WHtR, waist-to-height ratio.
 216 * One to three children dropped out at each examination, but it was not the same children
 217 every time and some children agreed to the weight and height measurements but not the blood
 218 sampling or vice versa

219 **Clinical outcomes**

220 The primary outcome measure, the mean z-BMI, was reduced from 3.3 (SD 0.7) at baseline
221 to 2.9 (SD 0.7) ($p<0.001$) at the end point (12 months after completion of the program). A
222 decrease in z-BMI was noted already after 3 months (Table 2). The boys had higher z-BMI at
223 baseline (mean 3.5 (SD 0.6)) compared with the girls (mean 3.0 (SD 0.6)) ($p=0.028$). At the
224 36-month follow-up there were no gender differences in the decrease in z-BMI ($p=0.141$)
225 (data not shown). Regarding the secondary outcome measures, there was no significant
226 reduction of WHtR (Table 2). There was a decrease in the LDL-cholesterol ($p<0.001$) and
227 total cholesterol ($p<0.01$) in the study group at the end point (12 months after completion of
228 the program), but no significant differences in HDL-cholesterol or triglyceride values (Table
229 2). All children displayed normal values for the oral glucose tolerance test at baseline (data
230 not shown). Fasting glucose was higher at the end point measurement (Table 2). However, all
231 biomedical markers were within the normal range throughout the study.

232 **DISCUSSION**

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

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

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3 243 procedure selected only highly motivated families, who might have managed their children's
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5 244 weight without FBIP support.
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8 245 Among secondary end point measures, the WHtR showed no change; the measurements for
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10 246 lipid status showed favourable trends. The results would have been even more convincing if
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12 247 all the secondary outcome measures had displayed similar trends. WHtR did not change, but
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14 248 perhaps the decline in z-BMI was too low to affect this measurement. The fasting glucose
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16 249 values increased at the follow-up 12 months after the end of the program. A Swedish study
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18 250 points out that BMI, level of physical activity, seasonal variations in physical activity and
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20 251 biological age (pubertal development) must be taken into consideration when interpreting
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22 252 clinical laboratory data.²⁷ Puberty signs were not consistently investigated in this study, which
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24 253 made it more difficult to interpret the biochemical data. Initial pubertal development in girls
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26 254 starts at approximately 10.9 years of age (range of 8.5–13.3 years) and in boys at 11.9 years
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28 255 of age on average (range 10.1–13.7 years).²⁸ Some children in this study may thus have
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30 256 reached the age for initiation of pubertal development when they started the FBIP (Table 1). It
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32 257 can be inferred that at least the interpretation of the metabolic parameters is complicated by
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34 258 the fact that the children entered puberty during the study period. It is thus possible that the
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36 259 higher blood glucose at follow-up could be explained by older age and more mature pubertal
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38 260 stage and not deterioration of metabolic status.
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45 261 A methodological strength of this study is that the primary end point measurement was
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47 262 performed 12 months after the end of the intervention program. Although this follow-up
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49 263 period is longer than in many other studies, an even longer follow-up is necessary to evaluate
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51 264 the persistence of intervention effects. For instance, a randomized study of a 6-month obesity
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53 265 program in children aged 7–9 years in which a family-based group treatment was compared
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55 266 with routine counselling showed positive short-term effects,²⁹ but no difference in z-BMI at 2
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3 267 and 3 years after the start of the intervention.³⁰ Another strength is that all participants were
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5 268 included in the data analysis at the study end point whether or not they completed the
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7 269 intervention. To improve the reliability of follow-up measurements, the height was measured
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10 270 by the same two paediatric registered nurses and waist circumference was always measured
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12 271 by the same person.

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14
15 272 An interesting observation is the high rate of families (96%) completing the 2-year
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17 273 intervention program. A previous study has shown that high family adherence is an important
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19 274 success factor for long-term weight reduction in childhood obesity.³¹ In comparison, results
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21 275 from the similar Families for Health program provided in a community setting in England
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23 276 reported that only 18 of 27 (67%) children completed a 3-month program.³² One reason for
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25 277 the more favourable adherence to the present FBIP could be that the families were
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28 278 interviewed before starting the group sessions and estimated to be highly motivated to act on
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30 279 the obesity and to participate in the whole group program. Another factor contributing to the
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32 280 high adherence in this study could be the weight reduction during the intensive phase at the
33
34 281 beginning of the program. Initial weight decrease has been suggested to be an important
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36 282 factor for success and for reducing the risk of drop-out from the treatment program.³³ A recent
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38 283 assessment of an outpatient treatment program with an 8-year follow-up of 90 obese children
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40 284 with a mean age of 10.1 years at baseline indicated that the mean reduction of 8% in adjusted
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42 285 BMI was a result of the children's success at the beginning of their treatment.³⁴ Another 1-
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44 286 year outpatient obesity intervention program of 170 children with a mean age 10.5 years
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46 287 showed promising results regarding weight outcomes 3 years after the end of the program.
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48 288 Also here, the weight reduction was interpreted to be connected to the initial weight reduction
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50 289 in the first 3 months of the program intervention.³⁵
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3 290 The recent Cochrane review of randomized controlled trials of interventions on childhood
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5 291 obesity reported that family-based behavioural lifestyle intervention programs are superior to
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7 292 regular care and self-help in the short and the long term.² Our feasibility study suggests that a
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9 293 long-term obesity management FBIP supported by a detailed manual can be implemented in
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11 294 routine paediatric outpatient care. We agree with the recommendations from the Cochrane
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13 295 review that more research is needed on obesity treatment in children and adolescents,
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15 296 especially large randomized effectiveness studies of different intervention programs with
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17 297 evaluations of long-term outcomes using changes in z-BMI and metabolic parameters as
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19 298 measures. In addition, we agree with the conclusion from the review that more research is
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21 299 needed to evaluate psychosocial, ethnic and cost-effectiveness aspects.
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26 300 **CONCLUSION**

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28 301 This feasibility study of an FBIP for management of childhood obesity in a paediatric
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30 302 outpatient care setting using a single-group pre- and post-intervention design showed
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32 303 promising outcomes and high adherence with 96% of families completing the 2-year
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34 304 intervention. The detailed manual and the structured program make it possible for available
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36 305 primary care or paediatric outpatient staff to lead groups. However, this FBIP assessment
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38 306 must be confirmed in a larger randomized controlled trial with a longer follow-up period
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40 307 before it can be implemented on a larger scale. Another interesting topic for further research
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42 308 is a comparison of the cost-effectiveness between FBIP and other family-based behavioural
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44 309 interventions in treating obese children.
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49 310 **Acknowledgements**

50
51 311 We are grateful to the school nurses for referring families and to all participating children
52
53 312 and their parents. We also thank statistician Olle Eriksson, PhD for assistance with the data
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55 313 analyses.
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10
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15 319 **Competing interests**
16

17 320 None.
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21 321 **Data Sharing**
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24 322 The authors are willing to share data from the study with researchers having an interest in comparative
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26 323 studies on family intervention effects.
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31 325 **Contributorship**
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33
34 326 MT was involved in the conception and design of the project, as well as the analysis and interpretation of
35
36 327 the data. She drafted and revised the manuscript, and provided intellectual content. EM was involved in
37
38 328 the conception and design of the project and in the interpretation of the data. She drafted and revised
39
40 329 the manuscript, providing intellectual content. PB conceived and designed the project. He drafted and
41
42 330 revised the manuscript, providing intellectual content. MN was involved in the conception and design of
43
44 331 the project and in the interpretation of the data. She revised the manuscript, providing intellectual
45
46 332 content. JE helped with data interpretation, revised the manuscript, and provided intellectual content. TT
47
48 333 accepts direct responsibility for the manuscript. He was involved in the design of the project and the
49
50 334 interpretation of the data. He drafted and revised the manuscript.
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3 335 **REFERENCES**
4
5
6

- 7 336 1. Lobstein L, Baur R, Uauy for the IASO International Obesity TaskForce. Obesity in
8 children and young people: a crisis in public health. *Obes Rev* 2004;5:4-85.
9
10 337
11
12 338 2. Oude Luttikhuis H, Baur L, Jansen H, et al. Interventions for treating obesity in children.
13
14 *Cochrane Database Syst Rev* 2009; Jan 21;(1)(1):CD001872.
15 339
16
17
18 340 3. World Health Organization. Definition, Diagnosis and Classification of Diabetes Mellitus
19 and its Complications, Report of a WHO Consultation;Part 1:Diagnosis and Classification of
20
21 341 Diabetes Mellitus. *Department of Noncommunicable Disease Surveillance Geneva* 1999.
22 342
23
24
25 343 4. Koplan JP, Liverman CT, Kraak VI, Committee on Prevention of Obesity in Children and
26 Youth. Preventing childhood obesity: health in the balance: executive summary. *J Am Diet*
27
28 344 *Assoc* 2005; Jan;105(1):131-8.
29 345
30
31
32
33 346 5. Marild S, Bondestam M, Bergstrom R, et al. Prevalence trends of obesity and overweight
34 among 10-year-old children in western Sweden and relationship with parental body mass
35 347 index. *Acta Paediatr* 2004; Dec;93(12):1588-95.
36 348
37
38
39 349 6. Sundblom E, Petzold M, Rasmussen F, et al. Childhood overweight and obesity
40 prevalences levelling off in Stockholm but socioeconomic differences persist. *Int J Obes*
41
42 350 *(Lond)* 2008; Oct;32(10):1525-30.
43 351
44
45
46 352 7. Reilly JJ, Methven E, McDowell ZC, et al. Health consequences of obesity. *Arch Dis Child*
47
48 353 2003; Sep;88(9):748-52.
49
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55
56
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58
59
60

- 354 8. Reilly JJ, Kelly J. Long-term impact of overweight and obesity in childhood and
355 adolescence on morbidity and premature mortality in adulthood: systematic review. *Int J*
356 *Obes (Lond)* 2011 Jul;35(7):891-8.
- 357 9. Mossberg HO. 40-Year Follow-Up of Overweight Children. *Lancet* 1989; Aug
358 26;2(8661):491-3.
- 359 10. Flodmark CE, Lissau I, Moreno LA, et al. New insights into the field of children and
360 adolescents' obesity: the European perspective. *Int J Obes Relat Metab Disord* 2004;
361 Oct;28(10):1189-96.
- 362 11. Bowen M. The use of family Theory in Clinical Practice. *Comprehensive Psychiatry*
363 1966;7:345-74.
- 364 12. Wachs TD. Multiple influences on children's nutritional deficiencies: a systems
365 perspective. *Physiol Behav* 2008; Apr 22;94(1):48-60.
- 366 13. Pocock M, Trivedi D, Wills W, et al. Parental perceptions regarding healthy behaviours
367 for preventing overweight and obesity in young children: a systematic review of qualitative
368 studies. *Obes Rev* 2010; May;11(5):338-53.
- 369 14. Yackobovitch-Gavan M, Nagelberg N, Phillip M, et al. The influence of diet and/or
370 exercise and parental compliance on health-related quality of life in obese children. *Nutrition*
371 *Research* 2009;29:397-404.
- 372 15. Reinehr T, Kleber M, Lass N, et al. Body mass index patterns over 5 y in obese children
373 motivated to participate in a 1-y lifestyle intervention: age as a predictor of long-term success.
374 *Am J Clin Nutr* 2010; May;91(5):1165-71.

- 1
2
3 375 16. Braet C, Van Winckel M, Van Leeuwen K. Follow-up results of different treatment
4
5 376 programs for obese children. *Acta Paediatr* 1997; Apr;86(4):397-402.
6
7
8
9 377 17. West F, Sanders MR, Cleghorn GJ, et al. Randomised clinical trial of a family-based
10
11 378 lifestyle intervention for childhood obesity involving parents as the exclusive agents of
12
13 379 change. *Behav Res Ther* 2010; Dec;48(12):1170-9.
14
15
16 380 18. Whitlock EA, O'Connor EP, Williams SB, et al. Effectiveness of weight management
17
18 381 programs in children and adolescents. *Evid Rep Technol Assess (Full Rep)* 2008;
19
20 382 Sep;(170)(170):1-308.
21
22
23
24 383 19. Whitlock EP, O'Connor EA, Williams SB, et al. Effectiveness of weight management
25
26 384 interventions in children: a targeted systematic review for the USPSTF. *Pediatrics* 2010;
27
28 385 Feb;125(2):e396-418.
29
30
31
32 386 20. Cole TJ, Bellizzi MC, Flegal KM, et al. Establishing a standard definition for child
33
34 387 overweight and obesity worldwide: international survey. *BMJ* 2000; May 6;320(7244):1240-
35
36 388 3.
37
38
39 389 21. Bonnedal U, Pettersson C. Gruppbehandling av barn med övervikt och fetma;
40
41 390 Utredningsintervju (MORSE) och Behandlingsmanual för barn och föräldrar. 2004; [Group
42
43 391 treatment of children with overweight and obesity; Investigation Interview (MORSE) and
44
45 392 Treatment Manual for Children and Parents]. 2004 (in Swedish).
46
47
48
49 393 22. Karlberg J, Luo ZC, Albertsson-Wikland K. Body mass index reference values (mean and
50
51 394 SD) for Swedish children. *Acta Paediatr* 2001; Dec;90(12):1427-34.
52
53
54
55 395 23. Ashwell M, Hsieh SD. Six reasons why the waist-to-height ratio is a rapid and effective
56
57 396 global indicator for health risks of obesity and how its use could simplify the international
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60

- 397 public health message on obesity. *International Journal of Food Sciences and Nutrition*
398 2005; Aug;56(5):303-307.
- 399 24. Nambiar S, Truby H, Abbott RA, et al. Validating the waist-height ratio and developing
400 centiles for use amongst children and adolescents. *Acta Paediatr* 2009; Jan;98(1):148-52.
- 401 25. Friedewald WT, Levy RI, Fredrickson DS. Estimation of the Concentration of Low-
402 Density Lipoprotein Cholesterol in Plasma, Without Use of the Preparative Ultracentrifuge.
403 *Clinical Chemistry* 1972;18(6):499-502.
- 404 26. Larsson C, Hernell O, Lind T. Moderately elevated body mass index is associated with
405 metabolic variables and cardiovascular risk factors in Swedish children. *Acta Paediatr* 2011;
406 Jan;100(1):102-8.
- 407 27. Wennlof AH, Yngve A, Nilsson TK, et al. Serum lipids, glucose and insulin levels in
408 healthy schoolchildren aged 9 and 15 years from Central Sweden: reference values in relation
409 to biological, social and lifestyle factors. *Scand J Clin Lab Invest* 2005;65(1):65-76.
- 410 28. Bramswig J, Dubbers A. Disorders of pubertal development. *Dtsch Arztebl Int* 2009;
411 Apr;106(17):295-304.
- 412 29. Kalavainen MP, Korppi MO, Nuutinen OM. Clinical efficacy of group-based treatment
413 for childhood obesity compared with routinely given individual counseling. *Int J Obes (Lond)*
414 2007; Oct;31(10):1500-8.
- 415 30. Kalavainen M, Korppi M, Nuutinen O. Long-term efficacy of group-based treatment for
416 childhood obesity compared with routinely given individual counselling. *Int J Obes (Lond)*
417 2011; Apr;35(4):530-3.

- 1
2
3 418 31. Kalarchian MA, Levine MD, Arslanian SA, et al. Family-based treatment of severe
4
5 419 pediatric obesity: randomized, controlled trial. *Pediatrics* 2009; Oct;124(4):1060-8.
6
7
8 420 32. Robertson W, Friede T, Blissett J, et al. Pilot of "Families for Health": community-based
9
10 421 family intervention for obesity. *Arch Dis Child* 2008;93:921-6.
11
12
13
14 422 33. Elfhag K, Rossner S. Initial weight loss is the best predictor for success in obesity
15
16 423 treatment and sociodemographic liabilities increase risk for drop-out. *Patient Educ Couns*
17
18 424 2010; Jun;79(3):361-6.
19
20
21 425 34. Moens E, Braet C, Van Winckel. M.V. An 8-year follow-up of treated obese children:
22
23 426 Children's, process and parental predictors of successful outcome. *Behaviour Research and*
24
25 427 *Therapy* 2010;48:626-33.
26
27
28
29 428 35. Reinehr T, Temmesfeld M, Kersting M, et al. Four-year follow-up of children and
30
31 429 adolescents participating in an obesity intervention program. *Int J Obes (Lond)* 2007;
32
33 430 Jul;31(7):1074-7.
34
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431 **Contributorship statement**

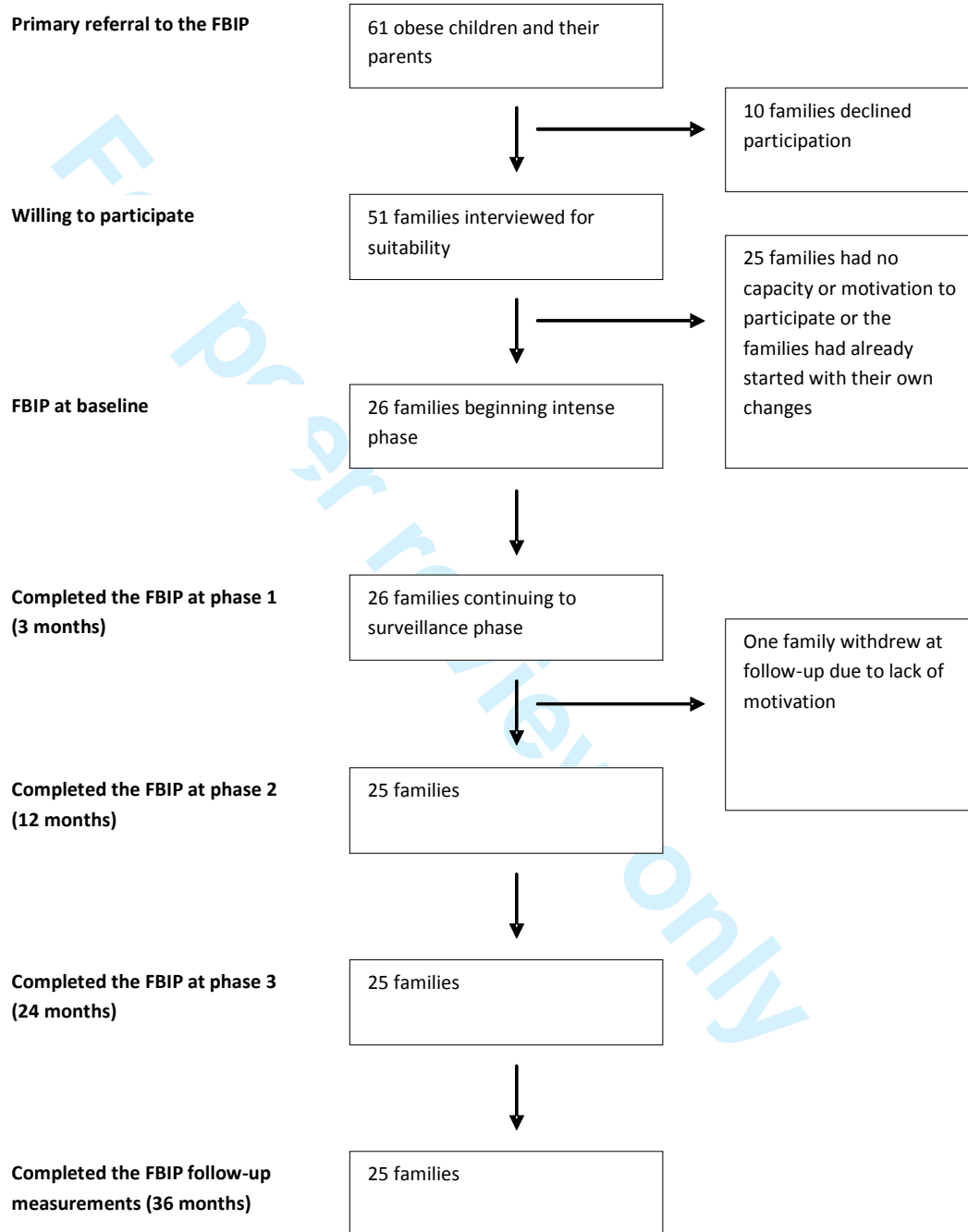
432 MT was involved in the conception and design of the project, as well as the analysis and
433 interpretation of the data. She drafted and revised the manuscript, and provided intellectual
434 content. EM was involved in the conception and design of the project and in the interpretation
435 of the data. She drafted and revised the manuscript, providing intellectual content. PB
436 conceived and designed the project. He drafted and revised the manuscript, providing
437 intellectual content. MN was involved in the conception and design of the project and in the
438 interpretation of the data. She revised the manuscript, providing intellectual content. JE
439 helped with data interpretation, revised the manuscript, and provided intellectual content. TT
440 accepts direct responsibility for the manuscript. He was involved in the design of the project
441 and the interpretation of the data. He drafted and revised the manuscript.

442 **Data sharing statement**

443 No additional data available.

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446 **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.

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4 1 Family-based behavioural intervention program for obese
5 children: a feasibility study
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8 3 Marie Teder¹, Evalotte Mörelius¹, Per Bolme^{2,3}, Maria Nordwall^{2,3}, Joakim
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31 12 Keywords: child obesity, family therapy, long-term intervention, single-group study design
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38 16 Word count: 2963
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18 ABSTRACT

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

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

22 **Setting:** Swedish paediatric outpatient care.

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

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

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

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

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

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42 controlled trial with longer follow-up before the intervention program can be
43 implemented on a larger scale.
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For peer review only

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 therapy¹⁶ 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

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2
3 91 it is difficult to maintain changes in children's diet- and physical habits over time without
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5 92 professional support.^{18,19} Therefore there is an urgent need to develop treatment programs that
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7 93 can be used in paediatric outpatient care. This feasibility study assesses a 2-year family-based
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9 94 behavioural intervention program (FBIP) against child obesity implemented in Swedish
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11 95 paediatric outpatient care, where the intervention was provided by the regular nurses and
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13 96 dieticians guided by a manual and supervised by a clinical psychologist. The specific aims of
14
15 97 the study were to investigate clinical outcomes and program adherence.
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20 98 **METHODS**

21
22 99 A single-group pre- and post-intervention design was used for the study. The primary
23
24 100 outcome measure was change in standardized body mass index (z-BMI) between baseline and
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26 101 after 36 months, 12 months after the end of the program. The secondary outcome measures
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28 102 were change in the waist-to-height ratio (WHtR), metabolic parameters and program
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30 103 adherence. The participants were examined at baseline and after 3, 12 and 24 months of
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32 104 therapy and at follow-up 12 months after the end of the program.
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36 105 **Inclusion criteria**

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38 106 The inclusion criteria for the study were age 8– <12 years, obesity defined according to the
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40 107 International Obesity Taskforce (IOTF) criteria (above age- and gender-specific cut offs
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42 108 corresponding to adult body mass index (BMI), calculated as weight in kilograms divided by
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44 109 the square of height in meters, $\geq 30 \text{ kg/m}^2$)²⁰ and absence of other diseases. Both children and
45
46 110 parents had to give consent that they were motivated and willing to participate in regular
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48 111 group sessions for the 2-year intervention period, to change eating and physical exercise
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50 112 habits, and to note food and beverage intake and **physical activity** in a diary during the period.
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113 **Participant recruitment**

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

122

123 **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) |

124

125 **The family-based behavioural intervention program**

126 The FBIP for management of childhood obesity was delivered using the regular community-
 127 level health service resources. A manual for group-based family interventions developed by a
 128 psychologist and a dietician²¹ was used as the basis for the program. The manual contained
 129 instructions for family selection (equivalent to the inclusion criteria used in this study) and for
 130 tutor-supervised group sessions with obese children and their parents.

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

142 **Program implementation**

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

147 *Group session for children*

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

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

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3 165 *Group session for parents*

4 166 The 1.5-hour sessions with the parents were held in the evening. Documented changes in
5
6 167 the child's eating and physical activity habits were communicated to the parents. The parents
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8 168 were given the same information about diet and **physical activity** and they were also given
9
10 169 homework tasks from the session content. Moreover, the parents were given various food
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12 170 recipes and information about the risk factors and diseases associated with obesity. Parents
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14 171 presented to the group how the changes had turned out during the week. They gave examples
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16 172 of difficulties that had arisen from a parent's perspective.
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20
21 173 **Data collection**

22
23 174 The participating children were clinically examined at baseline, after 3, 12 and 24 months
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25 175 of group therapy, and 12 months after the end of the program.
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28 176 Weight wearing trousers and a T-shirt was measured to an accuracy of 0.1 kg. Height was
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30 177 measured using a stadiometer attached to a wall according to standard procedures by two
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32 178 paediatric registered nurses, to an accuracy of 0.5 cm. To compensate for BMI varying with
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34 179 age and gender, the z-BMI was calculated using Swedish national reference values for
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36 180 children from 2001 and the Box transformation formula.²² At each examination, waist
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38 181 circumference measurements were always done by one of the authors (PB) at the navel plane
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40 182 to an accuracy of 0.5 cm. The waist-to-height ratio (WHtR) was calculated by dividing the
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42 183 waist circumference (cm) by the height (cm).^{23,24} Fasting blood samples for analysis of
43
44 184 glucose, insulin, triglycerides, total cholesterol and high-density lipoprotein cholesterol
45
46 185 (HDL-cholesterol) were taken. The low-density lipoprotein cholesterol (LDL-cholesterol) was
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48 186 calculated according to the Friedewald formula.²⁵ An oral glucose tolerance test was
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50 187 performed only at baseline. After overnight fasting, the child was given a glucose dose of 1.75
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52 188 g/kg (max 75 g) and plasma glucose was then analysed after 120 minutes.³ Insulin was
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54 189 analysed using AutoDELFIA™ from Wallac® (fluoroimmunoassay method), Turku Finland.
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3 190 Total plasma cholesterol, HDL-cholesterol, and triglycerides were analysed using Siemens®
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5 191 Advia-1650, Siemens Healthcare Diagnostics, Deerfield, Illinois. Plasma glucose was
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7 192 measured using Hemocue® from HemoCue AB, Ängelholm, Sweden. All blood samples
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9 193 were analysed at an accredited medical laboratory (Vrinnevi Hospital, Norrköping, Sweden).
10
11 194 Data on family participation in the intervention was collected from the tutors.

15 **Statistical analysis**

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17 196 Standard descriptive statistics (mean and standard deviation) were computed. **Given that**
18
19 197 **variables were normally distributed, paired 2-tailed T-tests were used for significance testing.**
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21 198 The significance level was set at $p < 0.05$. The Statistical Package for the Social Sciences
22
23 199 (SPSS) version 17 was used for the analyses.

27 **Ethics approval**

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29 201 The study was approved by the Research Ethics Committee at Faculty of Health Sciences,
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31 202 Linköping University, Sweden (dnr. 03-600).

35 **RESULTS**

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37 204 Ninety-six percent ($n=25$) of the families completed the group sessions. Only one family
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39 205 withdrew from the group sessions after the first 3-month phase of intervention. The child did
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41 206 not feel comfortable in the group and did not see obesity as a problem. Not all children agreed
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43 207 to participate in all examinations, even if they participated in the entire intervention program
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45 208 (Table 2).

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212 **Table 2** Values of anthropometric, body composition, and metabolic variables at baseline and
 213 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 | |
|---|----------|-------------|----------|-------------|-----------|-------------|-----------|-------------|-----------|-------------|-------------------|----------------------------------|
| | <i>n</i> | Mean (SD) | <i>n</i> | Mean (SD) | <i>n</i> | Mean (SD) | <i>n</i> | Mean (SD) | <i>n</i> | Mean (SD) | <i>n</i> | Mean (95% CI) <i>p</i> -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 |

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

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

219 **Clinical outcomes**

220 The primary outcome measure, the mean z-BMI, was reduced from 3.3 (SD 0.7) at baseline
221 to 2.9 (SD 0.7) ($p<0.001$) at the end point (12 months after completion of the program). A
222 decrease in z-BMI was noted already after 3 months (Table 2). The boys had higher z-BMI at
223 baseline (mean 3.5 (SD 0.6)) compared with the girls (mean 3.0 (SD 0.6)) ($p=0.028$). At the
224 36-month follow-up there were no gender differences in the decrease in z-BMI ($p=0.141$)
225 (data not shown). Regarding the secondary outcome measures, there was no significant
226 reduction of WHtR (Table 2). There was a decrease in the LDL-cholesterol ($p<0.001$) and
227 total cholesterol ($p<0.01$) in the study group at the end point (12 months after completion of
228 the program), but no significant differences in HDL-cholesterol or triglyceride values (Table
229 2). All children displayed normal values for the oral glucose tolerance test at baseline (data
230 not shown). Fasting glucose was higher at the end point measurement (Table 2). However, all
231 biomedical markers were within the normal range throughout the study.

232 **DISCUSSION**

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

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

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3 243 procedure selected only highly motivated families, who might have managed their children's
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5 244 weight without FBIP support.
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8 245 Among secondary end point measures, the WHtR showed no change; the measurements for
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10 246 lipid status showed favourable trends. The results would have been even more convincing if
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12 247 all the secondary outcome measures had displayed similar trends. WHtR did not change, but
13
14 248 perhaps the decline in z-BMI was too low to affect this measurement. The fasting glucose
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16 249 values increased at the follow-up 12 months after the end of the program. A Swedish study
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18 250 points out that BMI, level of physical activity, seasonal variations in physical activity and
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20 251 biological age (pubertal development) must be taken into consideration when interpreting
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22 252 clinical laboratory data.²⁷ Puberty signs were not consistently investigated in this study, which
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24 253 made it more difficult to interpret the biochemical data. Initial pubertal development in girls
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26 254 starts at approximately 10.9 years of age (range of 8.5–13.3 years) and in boys at 11.9 years
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28 255 of age on average (range 10.1–13.7 years).²⁸ Some children in this study may thus have
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30 256 reached the age for initiation of pubertal development when they started the FBIP (Table 1). It
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32 257 can be inferred that at least the interpretation of the metabolic parameters is complicated by
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34 258 the fact that the children entered puberty during the study period. It is thus possible that the
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36 259 higher blood glucose at follow-up could be explained by older age and more mature pubertal
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38 260 stage and not deterioration of metabolic status.
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45 261 A methodological strength of this study is that the primary end point measurement was
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47 262 performed 12 months after the end of the intervention program. Although this follow-up
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49 263 period is longer than in many other studies, an even longer follow-up is necessary to evaluate
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51 264 the persistence of intervention effects. For instance, a randomized study of a 6-month obesity
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53 265 program in children aged 7–9 years in which a family-based group treatment was compared
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55 266 with routine counselling showed positive short-term effects,²⁹ but no difference in z-BMI at 2
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3 267 and 3 years after the start of the intervention.³⁰ Another strength is that all participants were
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5 268 included in the data analysis at the study end point whether or not they completed the
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7 269 intervention. To improve the reliability of follow-up measurements, the height was measured
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10 270 by the same two paediatric registered nurses and waist circumference was always measured
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12 271 by the same person.

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15 272 An interesting observation is the high rate of families (96%) completing the 2-year
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17 273 intervention program. A previous study has shown that high family adherence is an important
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19 274 success factor for long-term **weight reduction** in childhood obesity.³¹ In comparison, results
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21 275 from the similar Families for Health program provided in a community setting in England
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23 276 reported that only 18 of 27 (67%) children completed a 3-month program.³² One reason for
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25 277 the more favourable adherence to the present FBIP could be that the families were
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28 278 interviewed before starting the group sessions and estimated to be highly motivated to act on
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30 279 the obesity and to participate in the whole group program. Another factor contributing to the
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32 280 high adherence in this study could be the weight reduction during the intensive phase at the
33
34 281 beginning of the program. Initial weight decrease has been suggested to be an important
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36 282 factor for success and for reducing the risk of drop-out from the treatment program.³³ A recent
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38 283 assessment of an outpatient treatment program with an 8-year follow-up of 90 obese children
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40 284 with a mean age of 10.1 years at baseline indicated that the mean reduction of 8% in adjusted
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42 285 BMI was a result of the children's success at the beginning of their treatment.³⁴ Another 1-
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44 286 year outpatient obesity intervention program of 170 children with a mean age 10.5 years
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46 287 showed promising results regarding weight outcomes 3 years after the end of the program.
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48 288 Also here, the weight reduction was interpreted to be connected to the initial weight reduction
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50 289 in the first 3 months of the program intervention.³⁵
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3 290 The recent Cochrane review of randomized controlled trials of interventions on childhood
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5 291 obesity reported that family-based behavioural lifestyle intervention programs are superior to
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7 292 regular care and self-help in the short and the long term.² Our feasibility study suggests that a
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9 293 long-term obesity management FBIP supported by a detailed manual can be implemented in
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11 294 routine paediatric outpatient care. We agree with the recommendations from the Cochrane
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13 295 review that more research is needed on obesity treatment in children and adolescents,
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15 296 especially large randomized effectiveness studies of different intervention programs with
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17 297 evaluations of long-term outcomes using changes in z-BMI and metabolic parameters as
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19 298 measures. In addition, we agree with the conclusion from the review that more research is
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21 299 needed to evaluate psychosocial, ethnic and cost-effectiveness aspects.
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26 300 **CONCLUSION**

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28 301 This feasibility study of an FBIP for management of childhood obesity in a paediatric
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30 302 outpatient care setting using a single-group pre- and post-intervention design showed
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32 303 promising outcomes and high adherence with 96% of families completing the 2-year
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34 304 intervention. The detailed manual and the structured program make it possible for available
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36 305 primary care or paediatric outpatient staff to lead groups. However, this FBIP assessment
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38 306 must be confirmed in a larger randomized controlled trial with a longer follow-up period
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40 307 before it can be implemented on a larger scale. Another interesting topic for further research
41
42 308 is a comparison of the cost-effectiveness between FBIP and other family-based behavioural
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44 309 interventions in treating obese children.
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52
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55 313 analyses.
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11 318 Studies Linköping University Sweden.
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15 319 **Competing interests**
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18 320 None.
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2
3 322 **REFERENCES**
4
5
6

- 7 323 1. Lobstein L, Baur R, Uauy for the IASO International Obesity TaskForce. Obesity in
8
9 324 children and young people: a crisis in public health. *Obes Rev* 2004;5:4-85.
10
11
12 325 2. Oude Luttikhuis H, Baur L, Jansen H, Shrewsbury VA, O'Malley C, Stolk RP, et al.
13
14 326 Interventions for treating obesity in children. *Cochrane Database Syst Rev* 2009; Jan
15
16 327 21;(1)(1):CD001872.
17
18
19 328 3. World Health Organization. Definition, Diagnosis and Classification of Diabetes Mellitus
20
21 329 and its Complications, Report of a WHO Consultation;Part 1:Diagnosis and Classification of
22
23 330 Diabetes Mellitus. *Department of Noncommunicable Disease Surveillance Geneva* 1999.
24
25
26
27
28 331 4. Koplan JP, Liverman CT, Kraak VI, Committee on Prevention of Obesity in Children and
29
30 332 Youth. Preventing childhood obesity: health in the balance: executive summary. *J Am Diet*
31
32 333 *Assoc* 2005; Jan;105(1):131-8.
33
34
35
36 334 5. Marild S, Bondestam M, Bergstrom R, Ehnberg S, Hollsing A, Albertsson-Wikland K.
37
38 335 Prevalence trends of obesity and overweight among 10-year-old children in western Sweden
39
40 336 and relationship with parental body mass index. *Acta Paediatr* 2004; Dec;93(12):1588-95.
41
42
43
44 337 6. Sundblom E, Petzold M, Rasmussen F, Callmer E, Lissner L. Childhood overweight and
45
46 338 obesity prevalences levelling off in Stockholm but socioeconomic differences persist. *Int J*
47
48 339 *Obes (Lond)* 2008; Oct;32(10):1525-30.
49
50
51
52 340 7. Reilly JJ, Methven E, McDowell ZC, Hacking B, Alexander D, Stewart L, et al. Health
53
54 341 consequences of obesity. *Arch Dis Child* 2003; Sep;88(9):748-52.
55
56
57
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43
44
45
46
47
48
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50
51
52
53
54
55
56
57
58
59
60

- 342 8. Reilly JJ, Kelly J. Long-term impact of overweight and obesity in childhood and
343 adolescence on morbidity and premature mortality in adulthood: systematic review. *Int J*
344 *Obes (Lond)* 2011 Jul;35(7):891-8.
- 345 9. Mossberg HO. 40-Year Follow-Up of Overweight Children. *Lancet* 1989; Aug
346 26;2(8661):491-3.
- 347 10. Flodmark CE, Lissau I, Moreno LA, Pietrobelli A, Widhalm K. New insights into the
348 field of children and adolescents' obesity: the European perspective. *Int J Obes Relat Metab*
349 *Disord* 2004; Oct;28(10):1189-96.
- 350 11. Bowen M. The use of family Theory in Clinical Practice. *Comprehensive Psychiatry*
351 1966;7:345-74.
- 352 12. Wachs TD. Multiple influences on children's nutritional deficiencies: a systems
353 perspective. *Physiol Behav* 2008; Apr 22;94(1):48-60.
- 354 13. Pocock M, Trivedi D, Wills W, Bunn F, Magnusson J. Parental perceptions regarding
355 healthy behaviours for preventing overweight and obesity in young children: a systematic
356 review of qualitative studies. *Obes Rev* 2010; May;11(5):338-53.
- 357 14. Yackobovitch-Gavan M, Nagelberg N, Phillip M, Ashkenazi-Hoffnung L, HersHKovitz E,
358 Shalitin S. The influence of diet and/or exercise and parental compliance on health-related
359 quality of life in obese children. *Nutrition Research* 2009;29:397-404.
- 360 15. Reinehr T, Kleber M, Lass N, Toschke AM. Body mass index patterns over 5 y in obese
361 children motivated to participate in a 1-y lifestyle intervention: age as a predictor of long-term
362 success. *Am J Clin Nutr* 2010; May;91(5):1165-71.

- 1
2
3 363 16. Braet C, Van Winckel M, Van Leeuwen K. Follow-up results of different treatment
4
5 364 programs for obese children. *Acta Paediatr* 1997; Apr;86(4):397-402.
6
7
8 365 17. West F, Sanders MR, Cleghorn GJ, Davies PS. Randomised clinical trial of a family-
9
10 366 based lifestyle intervention for childhood obesity involving parents as the exclusive agents of
11
12 367 change. *Behav Res Ther* 2010; Dec;48(12):1170-9.
13
14
15
16 368 18. Whitlock EA, O'Connor EP, Williams SB, Beil TL, Lutz KW. Effectiveness of weight
17
18 369 management programs in children and adolescents. *Evid Rep Technol Assess (Full Rep)* 2008;
19
20 370 Sep;(170)(170):1-308.
21
22
23
24 371 19. Whitlock EP, O'Connor EA, Williams SB, Beil TL, Lutz KW. Effectiveness of weight
25
26 372 management interventions in children: a targeted systematic review for the USPSTF.
27
28 373 *Pediatrics* 2010; Feb;125(2):e396-418.
29
30
31
32 374 20. Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition for child
33
34 375 overweight and obesity worldwide: international survey. *BMJ* 2000; May 6;320(7244):1240-
35
36 376 3.
37
38
39 377 21. Bonnedal U, Pettersson C. Gruppbehandling av barn med övervikt och fetma;
40
41 378 Utredningsintervju (MORSE) och Behandlingsmanual för barn och föräldrar. 2004; [Group
42
43 379 treatment of children with overweight and obesity; Investigation Interview (MORSE) and
44
45 380 Treatment Manual for Children and Parents]. 2004 (in Swedish).
46
47
48
49 381 22. Karlberg J, Luo ZC, Albertsson-Wikland K. Body mass index reference values (mean and
50
51 382 SD) for Swedish children. *Acta Paediatr* 2001; Dec;90(12):1427-34.
52
53
54
55 383 23. Ashwell M, Hsieh SD. Six reasons why the waist-to-height ratio is a rapid and effective
56
57 384 global indicator for health risks of obesity and how its use could simplify the international
58
59
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46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

- 385 public health message on obesity. *International Journal of Food Sciences and Nutrition*
386 2005; Aug;56(5):303-307.
- 387 24. Nambiar S, Truby H, Abbott RA, Davies PS. Validating the waist-height ratio and
388 developing centiles for use amongst children and adolescents. *Acta Paediatr* 2009;
389 Jan;98(1):148-52.
- 390 25. Friedewald WT, Levy RI, Fredrickson DS. Estimation of the Concentration of Low-
391 Density Lipoprotein Cholesterol in Plasma, Without Use of the Preparative Ultracentrifuge.
392 *Clinical Chemistry* 1972;18(6):499-502.
- 393 26. Larsson C, Hernell O, Lind T. Moderately elevated body mass index is associated with
394 metabolic variables and cardiovascular risk factors in Swedish children. *Acta Paediatr* 2011;
395 Jan;100(1):102-8.
- 396 27. Wennlof AH, Yngve A, Nilsson TK, Sjostrom M. Serum lipids, glucose and insulin levels
397 in healthy schoolchildren aged 9 and 15 years from Central Sweden: reference values in
398 relation to biological, social and lifestyle factors. *Scand J Clin Lab Invest* 2005;65(1):65-76.
- 399 28. Bramswig J, Dubbers A. Disorders of pubertal development. *Dtsch Arztebl Int* 2009;
400 Apr;106(17):295-304.
- 401 29. Kalavainen MP, Korppi MO, Nuutinen OM. Clinical efficacy of group-based treatment
402 for childhood obesity compared with routinely given individual counseling. *Int J Obes (Lond)*
403 2007; Oct;31(10):1500-8.
- 404 30. Kalavainen M, Korppi M, Nuutinen O. Long-term efficacy of group-based treatment for
405 childhood obesity compared with routinely given individual counselling. *Int J Obes (Lond)*
406 2011; Apr;35(4):530-3.

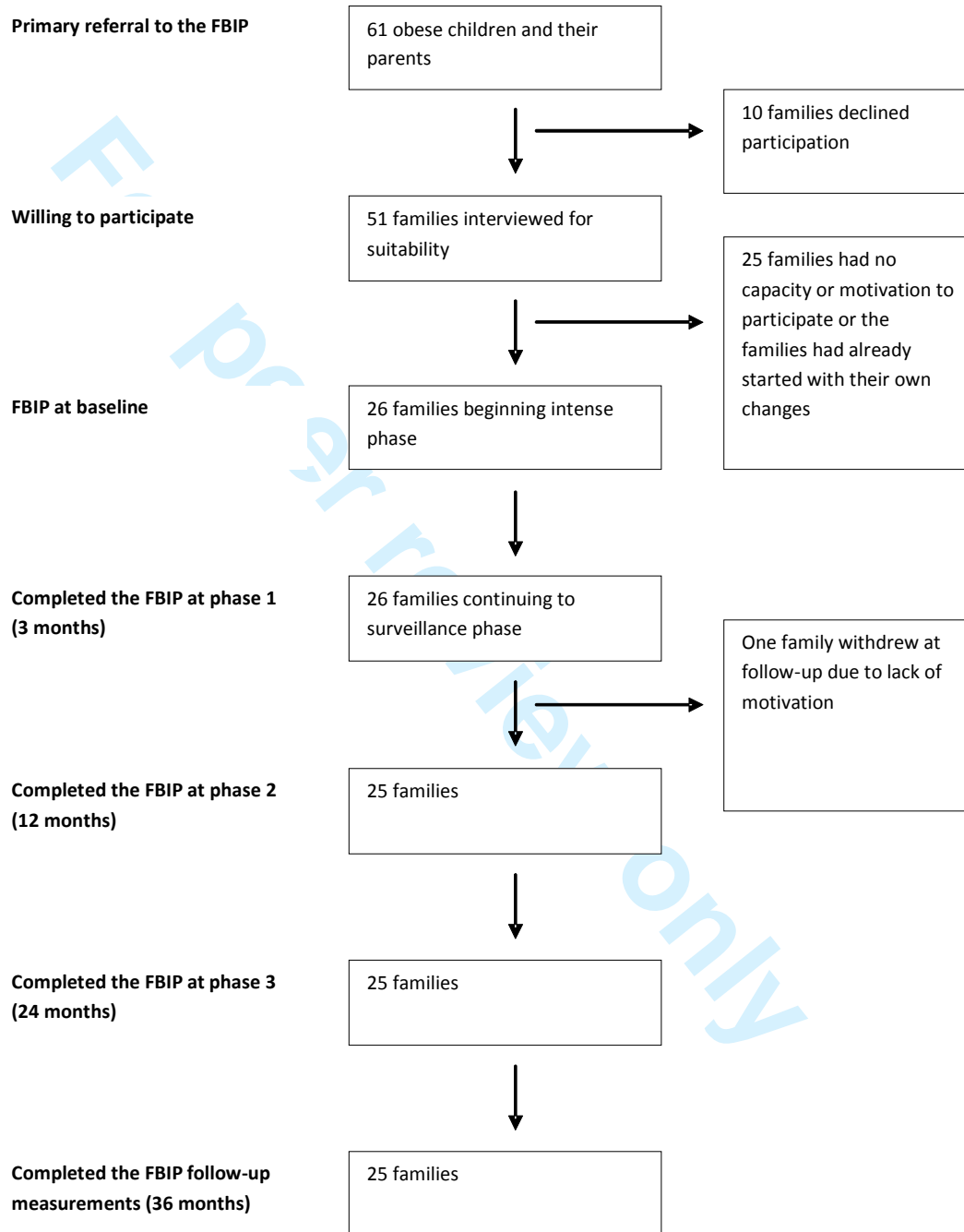
- 1
2
3 407 31. Kalarchian MA, Levine MD, Arslanian SA, Ewing LJ, Houck PR, Cheng Y, et al. Family-
4
5 408 based treatment of severe pediatric obesity: randomized, controlled trial. *Pediatrics* 2009;
6
7 409 Oct;124(4):1060-8.
8
9
10 410 32. Robertson W, Friede T, Blissett J, Rudolf.M.C.J., Wallis M, Stewart-Brown.S. Pilot of
11
12 411 "Families for Health": community-based family intervention for obesity. *Arch Dis Child*
13
14 412 2008;93:921-6.
15
16
17
18 413 33. Elfhag K, Rossner S. Initial weight loss is the best predictor for success in obesity
19
20 414 treatment and sociodemographic liabilities increase risk for drop-out. *Patient Educ Couns*
21
22 415 2010; Jun;79(3):361-6.
23
24
25
26 416 34. Moens E, Braet C, Van Winckel. M.V. An 8-year follow-up of treated obese children:
27
28 417 Children's, process and parental predictors of successful outcome. *Behaviour Research and*
29
30 418 *Therapy* 2010;48:626-33.
31
32
33
34 419 35. Reinehr T, Temmesfeld M, Kersting M, de Sousa G, Toschke AM. Four-year follow-up of
35
36 420 children and adolescents participating in an obesity intervention program. *Int J Obes (Lond)*
37
38 421 2007; Jul;31(7):1074-7.
39
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3 422 **Contributorship statement**
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7 423 MT was involved in the conception and design of the project, as well as the analysis and
8
9 424 interpretation of the data. She drafted and revised the manuscript, and provided intellectual
10
11 425 content. EM was involved in the conception and design of the project and in the interpretation
12
13 426 of the data. She drafted and revised the manuscript, providing intellectual content. PB
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15 427 conceived and designed the project. He drafted and revised the manuscript, providing
16
17 428 intellectual content. MN was involved in the conception and design of the project and in the
18
19 429 interpretation of the data. She revised the manuscript, providing intellectual content. JE
20
21 430 helped with data interpretation, revised the manuscript, and provided intellectual content. TT
22
23 431 accepts direct responsibility for the manuscript. He was involved in the design of the project
24
25 432 and the interpretation of the data. He drafted and revised the manuscript.
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31 433 **Data sharing statement**
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33 434 No additional data available.
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437 **Figure 1** Flowchart for the study of families referral to the FBIP