A Parent Treatment Program for Preschoolers With Obesity: A Randomized Controlled Trial

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BACKGROUND AND OBJECTIVES: Early obesity treatment seems to be the most effective, but few treatments exist. In this study, we examine the effectiveness of a parent-only treatment program with and without booster sessions (Booster or No Booster) focusing on parenting practices and standard treatment (ST).

METHODS: Families of children 4 to 6 years of age with obesity were recruited from 68 child care centers in Stockholm County and randomly assigned to a parent-only program (10 weeks) with or without boosters (9 months) or to ST. Treatment effects on primary outcomes (BMI z score) and secondary outcomes (BMI and waist circumference) during a 12-month period were examined with linear mixed models. The influence of sociodemographic factors was examined by 3-way interactions. The clinically significant change in BMI z score (−0.5) was assessed with risk ratios.

RESULTS: A total of 174 children (mean age: 5.3 years [SD = 0.8]; BMI z score: 3.0 [SD = 0.6], 56% girls) and their parents (60% foreign background; 39% university degree) were included in the analysis (Booster, n = 44; No Booster, n = 43; ST, n = 87). After 12 months, children in the parent-only treatment had a greater reduction in their BMI z score (0.30; 95% confidence interval [CI]: −0.45 to −0.15) compared with ST (0.07; 95% CI: −0.19 to 0.05). Comparing all 3 groups, improvements in weight status were only seen for the Booster group (−0.54; 95% CI: −0.77 to −0.30). The Booster group was 4.8 times (95% CI: 2.4 to 9.6) more likely to reach a clinically significant reduction of ≥0.5 of the BMI z score compared with ST.

CONCLUSION A parent-only treatment with boosters outperformed standard care for obesity in preschoolers.

WHAT’S KNOWN ON THIS SUBJECT: Although obesity among preschoolers is common and on the rise, few existing treatment programs, including standard care, have been properly evaluated. Early treatment should be directed to parents and be of high intensity to be effective.

WHAT THIS STUDY ADDS: We show that parent-only obesity treatment, including parenting skills training with follow-up booster sessions (but not without), outperformed standard treatment regarding improvements in child weight status. Thus, for successful obesity treatment in preschoolers, only parents need to be involved.

The prevalence of obesity in preschoolers is still on the rise.\(^1\) Although treatment outcomes seem particularly promising when started early,\(^2\text{-}^5\) the effectiveness of interventions as early as preschool age (up to 6 years of age) is not well known.\(^6\) The Cochrane Institute included 7 randomized controlled trials (RCTs) to evaluate treatment of preschoolers with obesity.\(^7\) However, different outcome measures, sample size, and attrition make conclusions for effective interventions difficult. Given the significant role of parents in young children's lives, we created a treatment program grounded in evidence-based parenting practices\(^8\text{-}^12\) to test if a focus on parenting would be especially suitable for this age group, as suggested by others.\(^6,13,14\) To improve clinical relevance, the program was developed and conducted in close collaboration with the health care system.\(^15\)

In this article, we report results of the More and Less (ML) study, in which 2 obesity treatment approaches were examined: parent-only group treatment with follow-up booster sessions (Booster) or without follow-up booster sessions (No Booster) focusing on evidence-based parenting practices, and standard treatment (ST) focusing on lifestyle changes (parent and child). In addition, we examined the influence of sociodemographic factors on treatment results and the clinical significance of the results. We hypothesized that the parent-only treatment would be more effective than ST in reducing child BMI z score (primary outcome) with additional effects from booster sessions.

**METHODS**

**Trial Design**

The ML study is a parallel open-label RCT evaluating the effects of 2 treatment approaches for obesity in 4- to 6-year-old children for 12 months (parent-only [Booster and No Booster]) and ST. The study was approved by the ethics committee in Stockholm, Sweden on November 16th, 2011 (dnr: 2011/1329-31/4), and the trial protocol is available in Supplemental Information. The following amendments were made to the original study protocol: To minimize differences between the 3 groups, we decided to randomize to the booster follow-up from the start instead of after the parent program (approval No. 2012/1104-32; August 11, 2012). For practical reasons, we developed the parent-only program on the basis of Keeping Foster and Kin Parents Supported and Trained (KEEP) instead of the parent program the Parent Management Training –Oregon Model (PMTO) because the KEEP team had more flexibility to offer supervision (approval No. 2012/2005-32; November 23, 2012). Additionally, we expanded the age span to include 6-year-old children to be able to offer the program to more families. Finally, we added a 6-month follow-up post baseline to better evaluate the treatment program (approval No. 2013/486-32; March 12, 2013). The trial design was extensively described previously.\(^15\)

**Participants**

Families were primarily recruited through child health care centers (primary care) between March 2012 and March 2016 but were also recruited from outpatient pediatric clinics and from school health care offices in Stockholm County, Sweden. Some families were self-referred; these families heard about the study from health care professionals, through advertisements in a local newspaper, or on bulletin boards in public areas. Parents were informed about the study if they were eligible for participation (see below). When parents consented, a nurse sent a notice of interest to the research group together with the child's growth chart. Researchers provided written and oral information about the study before the family agreed to participate. Written informed consent was obtained from parents on behalf of their children.

Families were eligible for participation if the child was 4 to 6 years old, was diagnosed with obesity according to international recommendations,\(^16,17\) and had no other chronic diseases or developmental problems likely to influence child weight and height. In addition, parents had to be able to communicate in Swedish well enough to complete questionnaires and participate in treatment conducted in Swedish.\(^15\) Eligible families were randomly assigned (1:1:2) to Booster, No Booster, and ST by using an electronic randomization program with permuted blocks. The randomization sequence was maintained by the study statistician to ensure concealment. On the basis of power calculations, 75 children were needed in each treatment (parent-only and ST adjusted for dropout) to detect a difference of 0.3 BMI z score (0.5 SD) with 85% power at 12 months' follow-up. Data were collected from March 2012 to October 2017.

**Treatment Approaches and Settings**

**Parent-Only Treatment**

The ML program was developed in collaboration with the KEEP program developers,\(^8\text{-}^12\) with conceptual and cultural adaptations designed to fit the Swedish population of parents of preschoolers with obesity. The key concept of KEEP is to support parents in positive parenting practices (eg, encouragement and limit-setting strategies) to improve parent-child communication.\(^8,10,12\) Content regarding healthy food habits and physical activity was also included. In addition, inspired by the PMTO, techniques to regulate emotional control were added.\(^18,19\) Initially, the ML program consisted of 12 weekly 90-minute sessions with parents only. On the basis of program evaluation forms and interviews with
participants, the program was condensed to 10 sessions; however, the content was maintained (Supplemental Table 3).

Program group leaders were 5 registered dieticians. Before the program, they received training by the KEEP developers, who also provided weekly supervision on videotaped sessions for program certification and fidelity.

Each session introduced 1 parenting practice. Role plays and home practice assignments were used to facilitate better comprehension of the presented material. The meetings were held in health care facilities. Both parents were invited to participate, and child care was provided. If parents missed a session, material was sent home and key parts were reviewed over the phone by 1 of the group leaders.

Families and the group leaders were blinded to Booster or No Booster group allocation until after the parent program. The booster sessions consisted of 30-minute phone calls (maximum 7) every 4 to 6 weeks for 9 months. During the booster sessions, a group leader encouraged the parents to maintain healthy habits and provided support for challenges by reminding them about the strategies covered during the program.

ST

ST was offered in 14 outpatient pediatric clinics and was based on the action plan for childhood obesity in Stockholm County.20 Parents and children attended treatment together. The treatment focused on healthy food choices and active lifestyle habits. The families were offered ≥4 individual visits of ~30 minutes over 12 months; the first and the last visits were with a pediatrician, and the remaining visits were with a pediatric nurse. Some children were referred to dieticians and/or physiotherapists. The treatment setup varied between clinics; thus, each clinic filled out a protocol at every visit documenting what treatment the family had attended and on how many occasions.

Measures and Outcomes

At baseline, parents completed sociodemographic questionnaires (see Table 1). Child weight, height, and waist circumference (WC) were measured at baseline and at 3, 6, and 12 months post baseline by child health care professionals. Calibrated instruments were used. All measures were repeated 3 times, and mean values were derived. Child weight was measured to the nearest 0.1 kg with the child wearing underwear, and child height was measured to the nearest 0.1 cm by using a fixed stadiometer and the child’s WC to the nearest 0.1 cm in between the lower rib and the iliac crest by using nonextensible tape.

The primary outcome of the study was child BMI z score derived from age- and sex-specific reference data.16 The secondary outcomes were child BMI and WC and the clinical significance of the results (ie, a reduction in BMI z score using the cutoffs ≥0.25 and ≥0.5 after 3, 6, and 12 months). A reduction of ≥0.25 in BMI z score has been associated with improvements of the components included in the metabolic syndrome in both prepubertal and pubertal children, and a reduction of ≥0.5 doubled the effect.21–23

Statistical Analysis

Intention-to-treat analysis using linear mixed models were used to examine the difference in treatment effects on primary (BMI z score) and secondary outcomes (BMI, WC) at 3, 6, and 12 months follow-up. The main models included the following variables: time (months), treatment group (defined as parent-only and ST [primary aim] and Booster, No Booster, and ST [secondary aim]), and interaction (group by time). Random intercept and a random slope for time were used. Missing values on baseline covariates and on follow-up values were imputed simultaneously by using multiple imputation with chained equations (m [number of imputations] = 40).24 Three-way interactions with BMI z score as a dependent variable were used to evaluate if the treatment effect was moderated by any of the baseline covariates (ie, child age, sex, first born or not, living with both parents or not, parental BMI, foreign background, income, and education level). Differences between those that did and did not attend baseline and any follow-up measurements were analyzed by using independent sample t tests and χ² tests. Risk ratios (RRs) were calculated to compare the clinical significance of treatment effect (ie, reduction of BMI z score ≥0.25 and ≥0.5). In sensitivity analyses, we generated mixed models as described above on our primary outcome but considered time as a factor, thus not assuming a linear trend. We additionally investigated the possible effect of missing not at random (MNAR) using δ adjustment,25 adding a BMI z score value to all imputations for Booster but not the other 2 groups. A value of P < .05 was considered statistically significant. Stata 13.1 (Stata Corp, College Station, TX) was used for our primary analyses, and SPSS Statistics 23 was used for descriptive analyses (IBM SPSS Statistics, IBM Corporation).

RESULTS

In total, 68 child health care centers referred children to the study, and 336 children were screened for eligibility; 177 children were enrolled in the study (Fig 1). Three children were excluded post randomization as a result of receiving a diagnosis that affected the child’s physical development. Thus, 174 children qualified for the intention-to-treat analysis. See Table 1 for participants’ characteristics.
In total, 21% of the children were lost to follow-up (ie, no follow-up assessment): 30% in the parent-only (36% Booster, 25% No Booster) and 11% in the ST (P = .003) groups. Many dropped out before baseline assessments (Booster 21%, No Booster 11%, ST 9%). The most common reasons cited for dropout were parents’ work schedules or family situation. The only difference between those who remained in the study and those lost to follow-up with baseline measures (n = 8) was a higher BMI for fathers (P < .001) that remained in the study. No adverse events were reported.

For No Booster, the mean number of attended group sessions was 6.5 (SD = 3.1). The mean number of attended group sessions for the Booster group was 7.9 (SD = 3.1); with the addition of booster phone calls, the number of visits were 9.2 (SD = 3.6) at 6 months and 12.3 (SD = 4.7) at 12 months. For ST, the mean number of attended visits was 2.5 (SD = 1.5; range: 1–11) at 3 months, 3.8 (SD = 2.2; range: 1–13) at 6 months, and 5.5 (SD = 2.9, range: 1–15) at 12 months. After 12 months, between 1 and 4 failed visits were reported for 38% of ST families, and between 1 and 7 visits were cancelled by 70% of the families. Attendance differed only significantly

<table>
<thead>
<tr>
<th>Variable</th>
<th>n²</th>
<th>Mean (SD), N = 174</th>
<th>Booster (n = 44)</th>
<th>No Booster (n = 43)</th>
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<td>Live with both parents, n (%)</td>
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| **Inclusion measures were used for children who never attended the baseline assessments: 9 Booster, 5 No Booster, and 8 ST. Parents were classified as normal weight, overweight, or obese according to the World Health Organization’s cutoff criteria for BMI. Foreign origin was defined as parent and both grandparents born in other country than Sweden or parent born in Sweden and grandparents born abroad. The mean monthly income level in 2015 was 33 600 SEK (men) and 26 400 SEK (women). SEK, Swedish kronor; —, not applicable.**
<p>| <strong>TABLE 1 Sample Characteristics of Children and Parents in the ML Study</strong> |</p>
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after 6 and 12 months between Booster and No Booster (data not shown). There was no significant difference between attended visits between No Booster and ST at 12 months ($P = .08$).

**Effects of Treatment**

The children in the parent-only treatment had a greater reduction in their BMI $z$ score at all time points compared with ST ($-0.30$; 95% confidence interval [CI]: $-0.45$ to $-0.15$) after 12 months, compared with no significant decrease for ST (Fig 2, Supplemental Table 4). No significant changes were seen in BMI or WC except for significant increases at all time points for ST. See Supplemental Table 5 for the coefficients for the group by time interaction effect.

**Effects of Sociodemographics**

The only sociodemographic factor that moderated the effect of treatment was father’s foreign background (0.05 [95% CI: $-0.01$ to $-0.08$]; $P = .006$), but only for No Booster (Fig 3). Although the effect of the No Booster treatment was on par with the Booster treatment of children with Swedish fathers, it was inefficient for children with fathers with a foreign background. For results for other covariates, see Supplemental Table 8.

**Clinical Significance**

The probability of reaching a 0.25 decrease in BMI $z$ score was higher for the parent groups compared with ST, with the largest difference seen after 12 months: Booster, 3.3 (95% CI: 2.0 to 5.6); No Booster, 2.3 (95% CI: 1.3 to 3.9). Regarding the 0.5 decrease, the Booster group was 4.8 (2.4 to 9.6) times more likely to reach this level compared with ST after 12 months (Table 2).

The sensitivity analysis using the same models as above with time as a factor and not assuming a linear trend did not alter the results (Supplemental Fig 4). Applying $d$ adjustment, the “tipping point” (the point at which Booster was no longer statistically significantly better than ST) occurred when adding a BMI $z$ score of 0.7 to the imputed values for the Booster group (Supplemental Table 9).

**DISCUSSION**

We found that an intensive parent-only treatment focused on evidence-based parenting practices was superior to ST in treating obesity in preschoolers, with strongest effects for the Booster group. After 12 months, the Booster group was nearly 5 times more likely to reach a clinically significant decrease in BMI $z$ score of 0.5 as compared with ST.
The clinical relevance of treatment is important given the relevance for metabolic and cardiovascular health.21–23 Such information is seldom reported in intervention studies, yet critical when interpreting results.26,27 Of note, the US Preventive Services Task Force recommends a BMI $z$ score reduction of 0.15 to 0.25 to be clinically significant for many metabolic markers.27 We also included the higher cutoff of 0.5 because it has been shown to double the effect on the metabolic markers.23 In addition, our results on mean change in BMI $z$ score are within and greater than the range reported on RCTs targeting preschool obesity in the latest Cochrane review7 in which the mean decrease in BMI $z$ score ranged from 0.20 to 0.49 after 6 to 12 months. Our results are also of similar magnitude as those from parent-only treatment studies for children 5 to 11 years of age included in another Cochrane review.28 In this review, the largest treatment effects were obtained for 2 Australian programs similar to ML.29,30 However, none of the studies were specifically designed for preschoolers.29–35 We have found only 1 other study treating preschool obesity that also included parenting skills training.6 The results from that study are comparable to ours, supporting the focus on parenting skills as a potential mechanism for treatment success.

High intensity and longer duration have become 2 key determinants of effective interventions.27,36–39 Specifically, a minimum of 26 contact hours was found necessary by the US Preventive Services Task Force in studies with children $\geq$6 years of age.27 We also found increased contact and length to be deciding factors because the Booster group outperformed the other groups. However, in the ML study, the highest number of visits corresponded to 21 hours, suggesting that treatments in this young age group can be less intensive but still need follow-up visits. The difference in weight status between Booster and No Booster at 3 months is unexpected. However, we suggest that length of follow-up rather than intensity was more important. We examined the influence of several sociodemographic factors on treatment results, but none could explain the difference. We cannot rule out that the difference may be due to selection bias of variables not considered in this article. For example, we have yet to examine if the parent groups responded differently to the intervention of parent skills practice training. In addition, in future studies, we will examine the role of parent feeding practices, eating behaviors, and psychosocial health as possible underlying mechanisms for observed differences in weight status.

Parental education is the sociodemographic factor commonly associated with obesity in children.40

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**FIGURE 2**

Mean difference change over time in primary (BMI $z$ score) and secondary (BMI and WC) outcomes comparing obesity treatments over 12 months. A, Change in BMI $z$ score. Shown are a parent-only treatment and ST. B, Change in BMI. Shown are a parent-only treatment and ST. C, Change in WC (centimeters). Shown are a parent-only treatment and ST. D, Change in BMI $z$ score. Shown are a parent-only treatment and ST. E, Change in BMI. Shown are a parent-only treatment (Booster and No Booster) and ST. F, Change in WC (centimeters). Shown are a parent-only treatment (Booster and No Booster) and ST. *$P < .05$, **$P < .01$ (group difference, with ST as a reference).
background was the only factor that played a role in treatment effect. However, this effect was only seen in the No Booster group, suggesting that parents of foreign background may need prolonged support in treatment.

Studies are often criticized for failing to appeal to those most in need and thus lacking generalizability. What sets the ML study apart from previous interventions is the large study population with sociodemographic variation in parental education and foreign background. A limitation in our study was the rate of children lost to follow-up among the families in the parent-only treatment (30%). A similar finding was seen in an Australian study in which 35% of patients were lost to follow-up in the intervention group. In the ML study, many families were lost before starting treatment, indicating that a structured parent-only program may not be suitable for all families, whereas ST offers more flexibility, as shown by the many cancelled visits in the ST. The multiple-imputation model assuming MNAR could be questioned. However, the sensitivity analyses revealed that missing values would need to be >0.7 BMI z score to make our results nonsignificant, which is unlikely. In addition, we did not examine the impact of session content being reviewed over the phone; however, this is an area of interest for future studies, including the ML program. Another limitation is lack of blinding of assessors who conducted measurements in the parent groups and who analyzed the outcomes. The ML program was tested in Sweden and may not be generalizable to other populations; however, the program is currently being implemented in Spain and Romania within the European Union–funded Science and Technology in Childhood Obesity Policy project.

**CONCLUSIONS**

In this RCT conducted in a diverse population, we report the results from a parent-only treatment program with and without boosters compared with ST. The parent-only program with boosters was superior in improving the children’s weight status at all time points. In addition, children in the parent-only group were most likely to achieve clinically significant reductions in BMI z score. Such clinical reductions are connected to improvements in metabolic health but rarely evaluated. This study bolsters evidence from previous research in which intensive and parent-only obesity treatments for young children are favored.

### TABLE 2 The Clinical Significance of Treatment Results Expressed as RRs for Decrease in BMI z Score Using the Cutoffs 0.25 and 0.5

<table>
<thead>
<tr>
<th>Group</th>
<th>Decrease in BMI z Score ≥0.25, RR (95% CI)</th>
<th>Decrease in BMI z Score ≥0.5, RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-mo follow-up</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Booster</td>
<td>1.4 (1.2 to 1.5)**</td>
<td>1.5 (1.2 to 1.8)**</td>
</tr>
<tr>
<td>No Booster</td>
<td>1.2 (1.1 to 1.4)*</td>
<td>1.1 (0.9 to 1.4)</td>
</tr>
<tr>
<td>6-mo follow-up</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Booster</td>
<td>1.8 (1.4 to 2.4)**</td>
<td>2.2 (1.6 to 3.1)**</td>
</tr>
<tr>
<td>No Booster</td>
<td>1.5 (1.1 to 2.0)*</td>
<td>1.3 (0.8 to 2.0)</td>
</tr>
<tr>
<td>12-mo follow-up</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Booster</td>
<td>3.3 (2.0 to 5.6)**</td>
<td>4.8 (2.4 to 9.6)**</td>
</tr>
<tr>
<td>No Booster</td>
<td>2.3 (1.3 to 3.9)*</td>
<td>1.6 (0.6 to 4.0)</td>
</tr>
</tbody>
</table>

*ST was used as a reference in all calculations.

* P < .01; ** P < .001.
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