Stage 1 Treatment of Pediatric Overweight and Obesity: A Pilot and Feasibility Randomized Controlled Trial

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Abstract

Background: Staged clinical treatment of pediatric obesity is recommended, but untested. Understanding the lowest intensity stage's effectiveness is necessary for future research.

Methods: This was a randomized controlled trial of children ages 4 to <9 years. Participants were recruited after routine evaluations at a primary care pediatric clinic revealed a BMI $\geq$ 85th percentile. The intervention was patterned after the "Prevention plus, Stage 1" treatment recommended by an expert committee. Groups were compared for changes, over a 3-month time period, in BMI z-score and parental reports of behavioral issues related to childhood obesity using intent-to-treat (ITT) analysis.

Results: Seventy-two (30% of eligible) children were enrolled and 64 were remeasured at 3-month follow-up. ITT analysis revealed that both groups improved mean BMI z-score [adjusted change -0.07 , control, and -0.04 , intervention; 95% confidence interval (CI) of difference = -0.14 – 0.20]. Over half of the children in each group improved their BMI z-score (adjusted proportion decreasing = 55% in control vs. 72% in intervention; 95% CI of difference = -0.07 – 0.42). The intervention group improved comparatively to the control group on numerous behavioral indicators.

Conclusions: Implementation of the lowest intensity stage of current recommendations is feasible and possibly of benefit toward lifestyle changes. Results of this study can be used by future clinical researchers designing protocols to test the full multi-staged approach for the treatment of pediatric overweight and obesity in primary care clinical settings.

Introduction

Approximately one third of US youth are overweight or obese (BMI, $\geq$ 85th percentile of CDC 2000 reference growth charts).¹ Childhood obesity clearly tracks into adulthood.² Once established in adulthood, obesity is difficult to treat³ and is associated with numerous morbidities and enormous cost, with estimates approaching \$1 trillion per year.⁴ Therefore, for the health of the US population, it is necessary to prevent and treat overweight and obesity effectively in childhood.

Reviews suggest that treatment of childhood obesity can be efficacious.^{5,6} However, the majority of quality studies

showing large treatment benefits were conducted in highly controlled tertiary care medical settings with subjects who were, on average, severely obese. The interventions that showed the greatest benefit involved a large number of contact hours (*e.g.*, many with ≥ 35 contact hours).^{7–12} Because of recruitment methods and treatment intensity, these studies have little applicability to primary care treatment of pediatric obesity. Primary care clinicians are in a unique position to identify and treat pediatric obesity as a result of frequent parent-child visits, especially in early childhood. Recently, a published survey of pediatric clinicians found that most were confident in their ability to counsel and effectively change unhealthy behaviors,¹³ and

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a few research studies conducted within primary care clinics report success in either body weight or behavioral outcomes.^{14,15}

With the goal of guiding the medical community, the CDC, the American Medical Association, and the Health Resources and Services Administration began a collaboration in 2005 to update clinical treatment recommendations for childhood obesity. Seeking feasibility for the greatest number of overweight and obese children, the collaboration proposed a staged approach beginning with primary-care-based counseling, close follow-up, and then a systematic intensification of efforts, if needed.^{16,17} The recommendations were endorsed by 16 medical organizations (*e.g.*, the American Academy of Pediatrics and American Academy of Family Physicians), and a recent survey in the Midwest suggests that most physicians are aware of the recommendations and report adherence.¹⁸ The committee writing the recommendations recognized that this staged approach “has not been evaluated.”^{16,17} To our knowledge, this statement remains true.

For this study, children 4–8 years of age who presented for a routine pediatric clinic visit and had a BMI $\geq$ 85th percentile were recruited and then randomized to either a low-intensity behavioral treatment program (intervention group) or a control group. The aim in this pilot study was to address key questions related to pediatric obesity research in primary care settings while simultaneously evaluating, over a 3-month follow-up period, the lowest intensity component of the recommended staged approach for childhood obesity treatment. These questions included the following: (1) What is the feasibility of recruitment and retention from a primary care clinic?; (2) what is the effectiveness of low-intensity treatment, compared with usual care, as related to body weight and behavioral outcomes?, and, to provide information toward future studies of a multi-staged approach; and (3) what proportion of overweight or obese children will increase BMI *z*-scores and thus possibly require more intensive treatment?

Methods

This study was approved by the University of Minnesota's Institutional Review Board (Minneapolis, MN) and registered with Clinicaltrials.gov (NCT01625910). Participants were children observed for routine clinical visits at a large, semiurban pediatric primary care clinic in Minneapolis. Patients 4.0 to <9.0 years of age with a BMI $\geq$ 85th percentile were eligible. Patients were excluded if they had any chronic or current health condition that might affect weight stability (*e.g.*, autism, acute gastrointestinal illness, and weight-altering medications). In addition, the parent needed to be conversationally fluent in English to participate in follow-up phone calls without the use of an interpreter. A research assistant (RA) received Health Insurance Portability and Accountability Act certification and approximately 2 hours of training in parental-based motivational interviewing.¹⁹

Recruitment and Randomization

Study enrollment occurred over a 9-month period (September 2011 through May 2012). The RA previewed the upcoming day's clinic schedule and was present at the clinic during hours with a high likelihood of potentially eligible children. If routine clinical evaluation resulted in a BMI percentile $\geq$ 85th percentile, the RA approached the child's clinician to request permission to discuss the study protocol with the parent and child. Parent-child dyads who agreed provided written parental consent and, if the child was at least 8 years of age, child assent. Before randomization, a parent filled out the survey “Brief Motivational Interviewing for Body Mass Index, BMI²”²⁰ and child height and weight were remeasured by the RA. The children were then randomly assigned to either the intervention or control group.

Group Assignments

The intervention group received management patterned after the “Prevention plus, Stage 1” treatment recommended by the expert panel and approved by the committee.^{16,17} Given the age of the children, the counseling was primarily directed toward the parents.^{21–23} On the day of enrollment, after randomization, the RA reviewed the BMI² survey²⁰ and discussed evidence-based recommendations for childhood obesity treatment with the parent (*e.g.*, eating breakfast daily, eating $\geq$ 5 servings of fruits and vegetables per day, watching $\leq$ 2 hours of screen time per day, minimizing or eliminating sugar-sweetened beverages, encouraging family meals at home, and being physically active $\geq$ 1 hour per day).^{16,24,25} The RA used motivational interviewing (MI) techniques as an entry way to discuss these lifestyle recommendations (*e.g.*, open-ended questions, reflective listening, discrepancy questions, and eliciting change talk).^{19,26,27} MI employs nonjudgmental questions and reflective listening to assess readiness to change and help resolve ambivalence about behavior changes in a nonconfrontational, nonjudgmental manner.^{19,26,27} On a few occasions, the RA consulted with an MI behavioral medicine provider regarding strategies to use with families.

The expert committee recommendations^{16,17} discuss both individually tailoring follow-up and having monthly assessments. For this study, monthly follow-up was chosen, allowing the parent to choose the format, either through a telephone conversation or in person. All parents chose telephone conversations. For these monthly phone conversations, the RA discontinued contact attempts if unsuccessful after approximately three calls and then sent a letter. The monthly phone calls were completed by 78% of the parents, whereas 16% completed one call and 6% did not complete either monthly call. Given that these phone calls lasted approximately 15–30 minutes, this treatment would fall under the category of “very low intensity” as defined by Whitlock and colleagues (as less than 10 hours per year).⁵

On the day of enrollment, after randomization to the control/usual care group, the RA provided age- and ability-

appropriate informational handouts on school readiness and/or performance.

Outcome Measures

At baseline and the 3-month follow-up visit, the child's height and weight were measured and parents filled out the BMI² survey.²⁰ The measurements at follow-up were done by a trained RA, blinded to group assignment. Height and weight were measured with the child in light indoor clothing, with shoes and socks removed. RAs measured height (cm), in triplicate, using a Shorr height board (Irwin Shorr, Olney, MD), and reported the mean of the three readings. Weight was measured using a Tanita scale (model TBF-300A; Tanita, Arlington Heights, IL). Age- and sex/gender-specific BMI z-scores were calculated using the US CDC 2000 growth charts.²⁸ The BMI² survey asks questions such as, "On a typical weekday, how many hours is your child involved in sports or active play?", and, "How concerned are you about your child's weight" (0 = not at all concerned, 10 = very concerned).²⁰ "Screen time" equaled the sum of reported time spent watching TV and playing computer games. For questions on the survey asking about weekday and weekend hours separately (e.g., screen time and physical activity questions), the average daily number of hours was calculated by the following formula: [(weekday hours $\times$ 5) + (weekend hours $\times$ 2)]/7.

Statistical Analysis

Baseline data were summarized overall and by group assignment status (intervention or control) using means for continuous variables and prevalences for categorical variables. To allow for natural growth, the calculated BMI values were converted to z-scores using the US CDC 2000 growth charts²⁸ implemented by applying the published LMS age- and sex/gender-specific parameters. *A priori*, it was decided to adjust the BMI z-score change for covariates that had known and/or theoretical impact on weight changes (i.e., child age, parental education and income level, duration of time in the study, baseline BMI z-scores, race/ethnicity, and sex/gender). Because of random assignment of a reasonably large number of children, an unadjusted analysis of change in outcomes between intervention and control groups is presented as well as the covariate-adjusted analysis of differences in changes during the approximate 3 months. An intent-to-treat (ITT) analysis required that, for those who did not have the follow-up measurement, data were filled in using the experience of those in the control group with follow-up measurements. Estimates of differences between groups were based on analysis of covariance regression; to indicate precision, 95% confidence intervals (CIs) were provided. Cross-tabulation was made of assignment group and those who increased or decreased BMI z-score between baseline and follow-up. This was also examined separately for those originally overweight (≥ 85 th but < 95 th percentile) and those obese (≥ 95 th percentile). This feasibility study was not powered to detect small differential changes in outcomes. A

comparison was made between those who declined to participate in the study versus those who participated.

Results

As shown in the CONSORT diagram (Fig. 1), the RA assessed 322 potentially eligible subjects. Fifty-two of these were excluded and 27 were missed because of the physician not inviting participation or other miscellaneous issues. Among the 243 who were approached, 70% ($n = 171$) refused and 30% ($n = 72$) agreed to participate in the study. Compared with those who declined participation, children who participated were slightly older (mean, 5.9 vs. 5.6 years; $p = 0.11$), slightly heavier (mean BMI percentile, 94.5 vs. 93.5; $p = 0.12$), and slightly more likely to be male (50 vs. 44%; $p = 0.43$).

Random allocation resulted in 35 participants in the intervention group and 37 in the control group. However, 1 participant in the control group was not included in the final analyses because of an interim injury and prolonged cast treatment. Seven participants were lost to follow-up (3 in the intervention group and 4 in the control group). Two intervention participants did not receive the allocated treatment (i.e., were unable to be reached for either monthly phone call). Consistent with the ITT method, these later 2 and the 7 lost to follow-up were all analyzed according to their respective initial group assignments.

As seen in Table 1, the groups were generally similar. Compared to the control group, the intervention group was slightly older (6.23 vs. 5.70 years). Participants came from racially and socioeconomically diverse backgrounds. Nearly half of the families reported annual incomes of less than \$40,000 per year, whereas approximately 20% reported incomes over \$150,000 per year. Approximately 30% of the consenting parents had less than a college education, whereas a similar proportion had completed a graduate degree. Regarding child behaviors, parents reported approximately 2.5 hours of screen time per day. Parents in the intervention group reported slightly more hours of screen time and physical activity and slightly more servings of fruit, vegetables, and sugar-sweetened beverages at baseline. In addition, parents in the intervention group reported slightly less confidence that their children would achieve healthy weight, change eating, or change screen time.

Table 2 compares group changes (unadjusted and adjusted) between baseline and follow-up measurements. Children in both groups, on average, had small decreases in BMI z-scores. At follow-up unadjusted changes in BMI z-scores were approximately 0.08 lower in the control group and 0.02 lower in the intervention group. Approximately 56% of those in the control group and 71% of those in the intervention group had lower BMI z-scores at follow-up than at baseline. Differences between groups were not statistically significant, and adjustment for child age, parental education and income level, duration of time in the study, baseline BMI z-scores, race/ethnicity, and sex/gender had

Figure 1. Study enrollment and randomization.

little effect on these estimates of change. Obesity severity had no effect on BMI z-score change (data not shown).

Compared with baseline, unadjusted parental report of child screen time per day was essentially unchanged in the control group and decreased by approximately 26 minutes per day (0.44 hours) in the intervention group. Similarly, parental report of changes in other obesity-related behaviors was slightly, but nonsignificantly, more favorable in the intervention group, compared to the control group. Again, unadjusted and adjusted estimates were generally similar.

Discussion

This project was designed to evaluate a number of factors related to the study of primary care clinic-based treatment of overweight and obesity in preschool and early

school-aged children. The study aimed specifically to gain knowledge concerning selected issues necessary before testing a full, multi-staged approach, where children are followed through systematic intensification of efforts. For example, what proportion of eligible parent-child dyads would agree to participate, and what would be the retention rate and cost? Although only a pilot study, not powered to detect statistically significant differences, behavioral and body weight outcomes were compared between usual care and a low-intensity intervention similar to that recommended by an expert committee and endorsed by major medical organizations.^{16,17}

Enrollment, Retention, and Cost

Our success in enrollment (30% of those eligible) was comparable to other studies evaluating recruitment from a

Table 1. Characteristics of Study Participants, Overall and by Group

	Overall	Control group	Intervention group
N	71	36	35
Mean age (SD)	5.96 (1.56)	5.70 (1.51)	6.23 (1.58)
Median BMI percentile	96th	95th	96th
Mean BMI percentile (SD)	95th (0.04)	94th (0.05)	96th (0.03)
Mean BMI z-score (SD)	1.90 (0.69)	1.89 (0.82)	1.90 (0.55)
Sex/gender = female, n (%)	36 (51)	17 (47)	19 (54)
Overweight (not obese), n (%)	27 (38)	17 (47)	10 (29)
Obese, n (%)	44 (62)	19 (53)	25 (71)
Child race, n (%)			
White	32 (45)	15 (42)	17 (49)
Black	19 (27)	9 (25)	10 (29)
Hispanic	8 (11)	4 (11)	4 (11)
Asian	9 (13)	6 (17)	3 (9)
Other	3 (4)	2 (6)	1 (3)
Parent completing questionnaire			
Mother, n (%) / father, n (%)	61 (86) / 10 (14)	30 (83) / 6 (17)	31 (89) / 4 (11)
Parental BMI, mean (SD)	29.32 (7.32)	29.51 (7.60)	29.14 (7.14)
Household income < \$40,000, n (%)	34 (48)	16 (44)	18 (51)
Education < college, n (%)	23 (32)	9 (25)	14 (40)
Child insurance, n (%)			
Private	46 (65)	24	22
Medicaid (government)	23 (32)	11	12
None	2 (3)	1	1
Behaviors			
Daily hours of screen time	2.66 (1.25)	2.39 (1.23)	2.94 (1.24)
Daily cans of sugared beverages	2.09 (1.40)	1.92 (1.18)	2.26 (1.60)
Daily hours of physical activity	2.39 (1.20)	2.08 (1.08)	2.71 (1.25)
Daily servings of fruits	1.82 (1.13)	1.56 (0.91)	2.09 (1.27)
Daily servings of vegetables	2.49 (1.36)	2.31 (1.43)	2.69 (1.28)
Confidence ^a child will achieve healthy weight	7.32 (2.31)	7.56 (1.95)	7.09 (2.64)
Confidence family will change eating	7.92 (2.00)	8.31 (1.74)	7.51 (2.19)
Confidence family will change physical activity	7.51 (2.31)	8.00 (2.00)	7.00 (2.52)
Confidence family will change screen time	7.49 (2.68)	7.54 (2.61)	7.43 (2.78)
Perceived child behavioral grade = A ^b , n (%)			
Snack foods	14 (20)	7 (19)	7 (20)
Sweetened beverages	38 (54)	19 (53)	19 (54)

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Table 1. Characteristics of Study Participants, Overall and by Group *continued*

	Overall	Control group	Intervention group
Eating out	30 (42)	15 (42)	15 (43)
Fruits	41 (58)	24 (67)	17 (49)
Vegetables	22 (31)	14 (39)	8 (23)
TV/screen time	18 (25)	12 (33)	6 (17)
Video/computer games	39 (55)	22 (61)	17 (49)
Physical activity/exercise	20 (28)	12 (33)	8 (23)

^aConfidence scales are from 1 ("not sure") to 10 ("very sure").

^bA child behavioral grade of "A" signifies that the parent perceives the child as behaving "great/healthy" in the respective categories.

SD, standard deviation; TV, television.

primary care clinic. McCallum and colleagues, in Australia, enrolled 40% of those eligible.²⁹ Recent studies recruiting from clinics in the United States reported recruitment rates of approximately 20%³⁰ and 15%.¹⁵ In this study participants were provided with a \$20 gift card as an incentive to return for follow-up and we were able to re-measure 90% at the 3-month follow-up visit. A Cochrane review of 54 lifestyle intervention studies found that about half reported completion rates over 80%.⁶ In addition to the \$20 per participant, the main cost of the study was RA time. Each control participant required approximately

90 minutes of RA time. Intervention participants required an additional 90 minutes of RA time for the initial in-person counseling and the two follow-up phone calls.

Behavioral outcomes

Parent-reported child behaviors all improved slightly more in the intervention group than in the control group. This includes intervention group parents reporting lower amounts of screen time and fewer cans of sugar-sweetened beverages at study follow-up. Whereas these changes suggest a beneficial effect of the intervention, the

Table 2. Group Changes (SE) and 95% CI in BMI z-Scores and Behavioral Variables: Control versus Intervention Group, Unadjusted and Adjusted^a

Variable	Unadjusted				Adjusted ^a			
	Control changes	Intervention changes	Net difference ^b	95% CI	Control changes	Intervention changes	Net difference ^b	95% CI
BMI z-scores								
Mean	-0.08 (0.05)	-0.02 (0.05)	0.06	-0.10-0.21	-0.07 (0.06)	-0.04 (0.06)	0.03	-0.14-0.20
Proportion decreasing	56% (8%)	71% (8%)	15%	-0.07-0.39	55% (8%)	72% (0.9%)	17%	-0.07-0.42
Behavioral outcomes, daily								
Hours of screen time	0.10 (0.22)	-0.44 (0.22)	-0.05	-1.15-0.08	0.05 (0.22)	-0.40 (0.22)	-0.45	-1.08-0.20
Cans of sugared beverages	0.03 (0.20)	-0.14 (0.20)	-0.17	-0.74-0.40	0.01 (0.20)	-0.12 (0.21)	-0.13	-0.73-0.47
Hours of physical activity	0.10 (0.13)	0.15 (0.13)	0.05	-0.33-0.42	0.04 (0.14)	0.21 (0.14)	0.17	-0.24-0.56
Servings of fruits	0.31 (0.87)	0.35 (0.19)	0.04	-0.22-0.85	0.01 (0.19)	0.36 (0.20)	0.35	-0.22-0.93
Servings of vegetables	-0.06 (0.16)	0.31 (0.17)	0.37	-0.10-0.84	-0.06 (0.18)	0.31 (0.18)	0.37	-0.15-0.89

^aAdjusted for child age, parental education and income level, duration of time in the study, baseline BMI z-scores, race/ethnicity, and sex/gender.

^bIntervention/control.

SE, standard error; CI, confidence interval.

magnitudes of these changes were small. Further, changes associated with the intervention may have been affected by social desirability bias in reporting, because the parents had discussions about these behaviors on a monthly basis with the RA as part of the intervention. As suggested by others, reports of behavior are likely subject to bias, and assessment is better accomplished with objective measures, when possible (*e.g.*, accelerometers).³¹

Body Weight

Both groups reduced mean BMI z-scores. A decrease in BMI z-scores over 3 months was observed in approximately 55% of those in the control group and approximately 70% of those in the intervention group. The improvement in BMI noted in both groups could have been the result of natural variation, regression toward the mean, and/or the parent-child dyads who agreed to participate might have had extra motivation to lose weight. There was no assessment of motivation in those who were eligible, but declined participation. Of note, this study was conducted within a clinic staffed by highly experienced, academic pediatricians, many of whom teach residents and medical students on topics such as pediatric obesity. It is possible that the children in the control group may have received better-than-average usual care. In addition, the control group may have been similar to what is occurring nationally as the most recent National Health and Nutrition Examination Survey suggests that the previously rising trend of childhood obesity may be plateauing.¹ Future researchers attempting to test a multi-staged approach with increasing intensification of efforts for those who do not improve must be aware that a substantial proportion of individuals who are overweight and/or obese will show improvement over a short time period.

Strengths and Limitations

Although this study was designed as a pilot study and conducted on a limited budget, it had several strengths. The 71 subjects that were followed represent a medium-sized cohort among studies selected in reviews of the pediatric obesity intervention literature.^{5,6,31} Participant families were a diverse group socioeconomically and by race/ethnicity. Though many other studies have recruited from media advertisements and/or children in tertiary care medical facilities, and sought only children who were obese,^{5,31} this study recruited directly from primary care clinic patients and, as per the recommendations,¹⁶ sought both overweight and obese youth. Among the 71 participants, 27 (38%) were overweight, but not obese. Children who are overweight, but not obese, are at high risk for future obesity.³² The study used a randomized, controlled design, and follow-up measurements were conducted by an RA who was blinded to group assignment.

This study had limitations. Because of cost issues and other logistics, recruitment and intervention were both conducted by the main RA. To avoid bias, the initial measurements were gathered before randomization. The

fact that the RA was not the child's clinician could decrease the generalizability of the intervention effects, although the recommendations for the low-intensity stage mimicked in this study state that the intervention can be conducted by ancillary staff with appropriate training. The study's RA received approximately 2 hours of training in MI before the study and a few brief troubleshooting discussions with a psychologist trained in MI. Current research by Resnicow and colleagues is evaluating whether more in-depth training in MI results in greater weight loss.²⁰ The 3-month follow-up may have been an insufficient duration to adequately test physical or behavioral outcomes.

Conclusions

This pilot study of the recommended Stage 1 treatment of pediatric overweight and obesity was designed as a starting point to provide information for testing of a multi-staged approach. These results indicate that implementation of this low-intensity intervention is feasible and, possibly, of some benefit toward lifestyle change. Future investigators may utilize these findings to find practical, effective approaches for pediatric overweight and obesity treatment that can be incorporated into clinical practice.

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Author Disclosure Statement

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