Effect of a Behavioral Intervention for Underserved Preschool-Age Children on Change in Body Mass Index
A Randomized Clinical Trial

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IMPORTANCE Prevention of obesity during childhood is critical for children in underserved populations, for whom obesity prevalence and risk of chronic disease are highest.

OBJECTIVE To test the effect of a multicomponent behavioral intervention on child body mass index (BMI, calculated as weight in kilograms divided by height in meters squared) growth trajectories over 36 months among preschool-age children at risk for obesity.

DESIGN, SETTING, AND PARTICIPANTS A randomized clinical trial assigned 610 parent-child pairs from underserved communities in Nashville, Tennessee, to a 36-month intervention targeting health behaviors or a school-readiness control. Eligible children were between ages 3 and 5 years and at risk for obesity but not yet obese. Enrollment occurred from August 2012 to May 2014; 36-month follow-up occurred from October 2015 to June 2017.

INTERVENTIONS The intervention (n = 304 pairs) was a 36-month family-based, community-centered program, consisting of 12 weekly skills-building sessions, followed by monthly coaching telephone calls for 9 months, and a 24-month sustainability phase providing cues to action. The control (n = 306 pairs) consisted of 6 school-readiness sessions delivered over the 36-month study, conducted by the Nashville Public Library.

MAIN OUTCOMES AND MEASURES The primary outcome was child BMI trajectory over 36 months. Seven prespecified secondary outcomes included parent-reported child dietary intake and community center use. The Benjamini-Hochberg procedure corrected for multiple comparisons.

RESULTS Participants were predominantly Latino (91.4%). At baseline, the mean (SD) child age was 4.3 (0.9) years; 51.9% were female. Household income was below $25 000 for 56.7% of families. Retention was 90.2%. At 36 months, the mean (SD) child BMI was 17.8 (2.2) in the intervention group and 17.8 (2.1) in the control group. No significant difference existed in the primary outcome of BMI trajectory over 36 months (*P* = .39). The intervention group children had a lower mean caloric intake (1227 kcal/d) compared with control group children (1323 kcal/d) (adjusted difference, −99.4 kcal [95% CI, −160.7 to −38.0]; corrected *P* = .003). Intervention group parents used community centers with their children more than control group parents (56.8% in intervention; 44.4% in control) (risk ratio, 1.29 [95% CI, 1.08 to 1.53]; corrected *P* = .006).

CONCLUSIONS AND RELEVANCE A 36-month multicomponent behavioral intervention did not change BMI trajectory among underserved preschool-age children in Nashville, Tennessee, compared with a control program. Whether there would be effectiveness for other types of behavioral interventions or implementation in other cities would require further research.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT01316653

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Obesity often begins in childhood, with the highest rates among minority populations.[1,2] Numerous randomized clinical trials (RCTs) address childhood obesity treatment by targeting child health behaviors such as diet, physical activity, sleep, and media use.[3] These behavioral interventions have met with variable efficacy and often yield small, if any, effect sizes on child weight outcomes.[4,5] In addition, whereas several interventions have been successful at producing short-term reductions in child body mass index (BMI), few trials have been of sufficient length to assess sustainability.[6]

Obesity is a complex problem, affected by the dynamic interaction of biology, behavior, and children's social and physical environments.[7,8] Given the challenges associated with effective obesity treatment, recent focus has been on childhood obesity prevention.[5,9] The developmental origins of disease hypothesis suggests that early life influences can alter a person's life-long health trajectory, linking early obesogenic exposures and rapid weight trajectory to common chronic adult conditions including coronary artery disease and type 2 diabetes.[10,11] These problems are especially salient for families from traditionally underserved minorities,[12] who are confronted with significant barriers such as poverty.

The Growing Right Onto Wellness (GROW) RCT tested a theoretically grounded, 36-month behavior change intervention focused on childhood obesity prevention among preschool-aged children from underserved communities. It was hypothesized that the intervention would attenuate child BMI growth trajectories compared with the control group over 36 months.

Key Points

Question What is the effect of a 36-month multicomponent behavioral intervention for obesity prevention on body mass index (BMI) trajectories in underserved preschool-age children at risk for obesity but not yet obese?

Findings In this randomized clinical trial that included 610 parent-child pairs from underserved communities, the mean BMI in both the intervention and control groups was 17.8 at 36 months, with no significant difference in BMI trajectories.

Meaning The behavioral intervention was not effective in this low-income minority population.

Methods

This study was conducted within the Childhood Obesity Prevention and Treatment Research consortium, a National Heart, Lung, and Blood Institute/National Institute of Child Health and Human Development–sponsored collaborative effort to develop and evaluate novel approaches to prevent or treat childhood obesity. The study was supported by an independent coordinating center at the University of North Carolina at Chapel Hill.

The Vanderbilt University Medical Center institutional review board and a National Heart, Lung, and Blood Institute–appointed data and safety monitoring board approved the study protocol and conducted routine evaluations of participant safety and protocol adherence throughout the trial. Written informed consent was obtained by bilingual data collectors in participants' language of choice using an enhanced, low-literacy approach.[13]

The intervention focused on changing behavior and featured several key strategies hypothesized to maximize health behavior change, including (1) considering the health behaviors of both parent and child, (2) using the built environment of existing community centers, (3) implementing a tiered-intensity intervention to maximize sustainability of participation, and (4) using an adaptive intervention.[7] The study's design and methodology have been previously reported.[14] The protocol and statistical analysis plan are available in Supplement 1.

Setting and Participants

Parent-child pairs were recruited from 54 physicians' offices and community settings and enrolled from August 2012 to May 2014 in Nashville, Tennessee. The final 36-month follow-up was conducted between October 2015 and June 2017. Recruitment efforts included posters, mailed brochures, radio commercials, community events, in-person recruitment, and word of mouth. Child eligibility criteria included age 3 to 5 years, English or Spanish speaking, and high normal weight to overweight but not yet obese (BMI ≥50th and <95th percentile based on US Centers for Disease Control and Prevention standardized growth curves).[15] Caregiver eligibility included commitment to participate in the 36-month study, English or Spanish speaking, and consistent telephone access.

Participants also had to qualify for at least 1 service for underserved populations (eg, Medicaid; Special Supplemental Nutrition Program for Women, Infants, and Children). Participants were excluded if a medical condition precluded routine physical activity or if participants lived or worked outside an 8-km radius of participating community centers. Because obesity disproportionately affects children from underserved minorities,[12] race and ethnicity information was collected. Race and ethnicity for both parent and child were assessed by parent report, using fixed categories with an open-ended option.

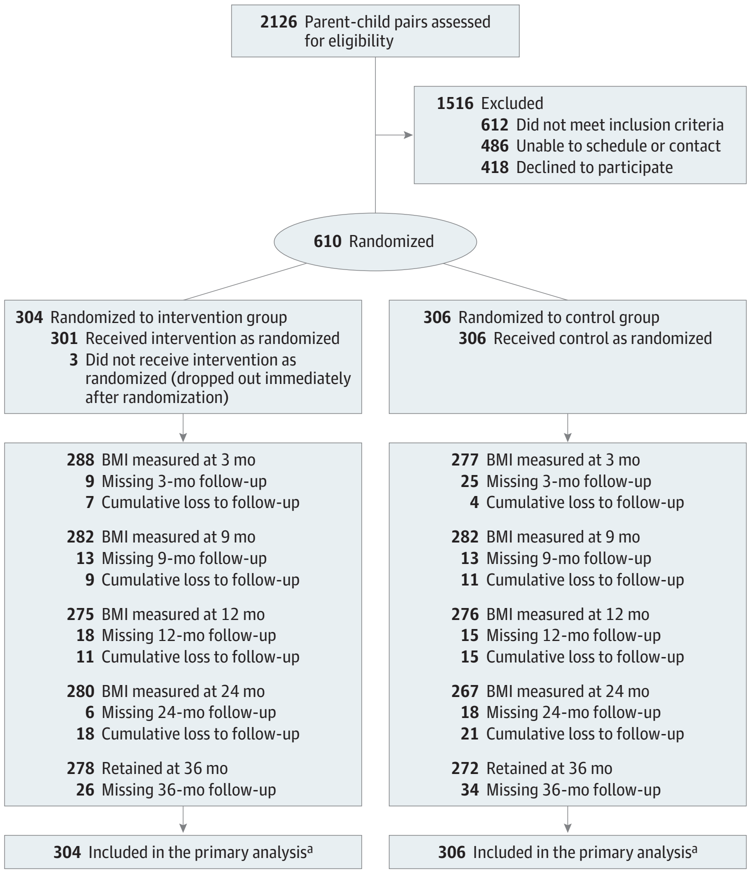
Randomization

Participants were randomized using a computer-generated schedule that was stratified by community center and parent language preference (English or Spanish). Randomly permuted block sizes varied from 2 to 6. Assignment was implemented through an electronic interface that concealed group assignment until each individual was enrolled. Only study staff not involved in data collection implemented randomization, and group assignment could not be changed.

Intervention Description

Informed by effective adult obesity treatment behavioral trials[16,17] and innovative concepts proposed by the National Institutes of Health,[18] the intervention (GROW Healthier) was a tiered-intensity program of decreasing intensity: (1) a 12-week intensive phase with weekly 90-minute skills-building sessions via either in-person groups or telephone calls; (2) a 9-month maintenance phase with monthly coaching telephone calls; and (3) a 24-month sustainability phase

Figure 1. CONSORT Flow Diagram of the Parent-Child Pairs



Of the 610 parent-child pairs randomized, 304 were randomized to the intervention group and 306 were randomized to the control group. At each time point, the number retained represents the number of children for whom BMI was collected. Missing body mass index (BMI) falls into 2 categories: BMI measure missing but BMI was collected at a later time point vs permanently lost to follow-up with no further BMI measures collected. The cumulative number of parent-child pairs permanently lost to follow-up is indicated at each time point above, and was 26 for the intervention group and 34 for the control group at year 3 follow-up.

[a] Because the primary analysis used an intention-to-treat approach, all participants were analyzed in the group to which they were randomized, regardless of missing data.

providing frequent cues to action (eg, texts, personalized letters, monthly calls) to use parks and recreation programming for healthy family behaviors. The intervention was based on social cognitive theory and the socioecological model, focusing on behavior change techniques including goal setting, self-monitoring, and problem solving in the context of participants' home and community environments.[19,20]

Intervention content included skills building for parents and children regarding nutritional choices, physical activity habits, use of the family and built environment, engaged parenting, healthy sleep, and reduced media time.[21] Each week (intensive phase) or month (maintenance phase), participants created a self-defined goal about family health behaviors targeted in the intervention (diet, physical activity, sleep, media use, engaged parenting). The intervention included an adaptive component, an additional coaching telephone call[14] that provided BMI results and additional guided goal setting and problem solving; this occurred when a child's BMI category increased or remained obese at a data collection time point.

The control condition (GROW Smarter) was a school-readiness program developed and delivered by the Nashville Public Library. The curriculum consisted of six 30-minute group-based activities delivered concurrently with data col-lection sessions. Participants in the intervention and control groups received the school-readiness program. Therefore, the only difference between conditions was the obesity prevention intervention.

Blinding

Data collectors were blinded to individual participant study condition and aggregated study results by group. All study staff, including the primary investigator and statisticians, were blinded to postbaseline data aggregated by group until all study data had been collected and cleaned.

Outcomes

The prespecified primary outcome was child BMI trajectory across 36 months modeled using linear and quadratic terms. BMI was calculated as weight in kilograms divided by height in meters squared. The protocol identified 7 prespecified secondary outcomes: (1) child mean daily energy intake (kcal); mean percentage of energy intake from (2) fat, (3) carbohydrates, and (4) protein; mean daily minutes spent in (5) rest and sedentary behavior and (6) moderate and vigorous physical activity (MVPA); and (7) community center use with child (never or at least once). Prevalence of child obesity (BMI ≥95th percentile) was the only post-hoc outcome analyzed. Parent anthropometrics and child waist circumference/triceps skinfold were also collected but not included as secondary outcomes in this analysis.

Data were collected at baseline and 3, 9, 12, 24, and 36 months by trained, blinded, bilingual data collectors in participant homes or local community centers. Data collected included parent and child height (without shoes, to nearest 0.1 cm) and weight (to nearest 0.1 kg) using wall-mounted stadiometers and research-grade scales. Annually, children were asked to wear a GT3X+ accelerometer (ActiGraph) on their waist for 24 hours daily for 7 consecutive days to assess physical activity. Previously validated cut points determined time spent in sedentary behaviors and light, moderate, and vigorous activities.[22] Data obtained annually from 24-hour diet recall on 2 weekdays and 1 weekend day assessed parent-reported child dietary intake (using NDS-R software).

Survey data were collected in the participant's chosen language via guided administration and included demographic, behavioral, and psychosocial domains. Parent-reported community center use with the child was assessed through the survey item: "How often do you go to your community recreation center with your children to be active together?" (6-point scale from "never" to "every day"), and the responses were dichotomized into "never" or "at least once" for analysis. Food insecurity was assessed using the 6-item short form of the US Household Food Security Survey Module.[23]

Participants were encouraged to complete all data collection elements within 45 days of anthropometric data collection. Process measures included fidelity of implementation and dose received. Fidelity was assessed using standardized tools[14] for both in-person and telephone call sessions. Dose received was measured by attendance at in-person sessions or participation in telephone calls throughout the study.

Adverse Event Reporting

Adverse events were identified throughout the study period by encouraging participants to contact the study team if an event occurred and by asking participants about adverse events using a structured questionnaire at all data collection time points.

Sample Size

A power analysis was conducted with a 2-tailed $\alpha = .05$ and 90% power to detect a standardized effect size of 0.4. Results suggested that a final sample of 480 pairs was required. Therefore, 600 pairs were planned, with an anticipated 80% retention rate. The effect size of 0.4 was selected based on data from a previous behavioral intervention conducted in Nashville among Latino participants (trial protocol in Supplement 1).[24]

Statistical Methods

Baseline characteristics were expressed as mean (SD) or median (quartile 1, quartile 3), depending on their distribution, or number (%) for categorical variables. This trial used an intention-to-treat approach to test the difference in the BMI growth trajectory between children in the intervention and control groups. The analysis fit a 2-level (time nested within child) mixed-effects regression model, using a maximum likelihood procedure to handle missing data and an unstructured variance-covariance matrix.[25] Data were assumed to be missing at random. Because clinical literature about childhood obesity indicates that the shape of the BMI trajectory across ages 3 to 8 years is curvilinear, a quadratic model was selected a priori, defining trajectory using both linear and quadratic terms.[15,26] Time varied individually and was measured as a continuous variable defined as years since baseline. Two child-level variables, age at baseline (mean-centered) and intervention condition, were covariates for the intercept, linear, and quadratic BMI growth trajectory terms. Child sex was a covariate for the intercept only. Success was evaluated by a likelihood ratio test to determine whether the linear and quadratic intervention effects were jointly equal to zero ($df = 2$; .05 level). The coordinating center independently replicated the primary outcome analysis and confirmed the findings.

Analysis of secondary and post-hoc outcomes used ordinary least squares regression for continuous outcomes and Poisson regression with robust standard errors for binary outcomes. Models were prespecified and accounted for covariates thought to be associated with each outcome, such as baseline outcome value, child age, and sex. The Benjamini-Hochberg procedure was used to control the false-discovery rate for multiple comparisons based on the number of time points analyzed for each outcome. The *P* values before and after correction are presented. Residual diagnostics were performed to ensure distributional assumptions were met.

Prior literature informed selection of a series of post-hoc moderator analyses based on the child BMI growth trajectory mixed-effects model to determine whether the intervention's effect on growth trajectory varied across different baseline values of child age; child sex; parent BMI; parent race/ethnicity; child energy intake; percentage of energy intake from fat, carbohydrates, and protein; percentage of wear time in sedentary behavior and MVPA; baseline child BMI percentile; child birth weight; food security status; and community center.[27,28]

Statistical analyses were conducted using Stata version 14.2 (StataCorp). Statistical significance was defined using a 2-sided test with $\alpha = .05$.

Results

Of the 2126 participants assessed for eligibility, 610 parent-child pairs were randomized, with 304 assigned to the intervention group and 306 to the control group. The 36-month retention rate was 91.4% for the intervention and 88.9% for the control (**Figure 1**). At baseline, the child mean (SD) age was 4.3 (0.9) years, 51.9% were female, 91.4% were Hispanic/Latino, 65.7% were between the 50th and 85th Centers for Disease Control and Prevention BMI percentiles, and 34.3% were between the 85th and 95th percentiles. Most study children were born in the United States (96.4%), whereas most adults were born outside the United States, including Mexico (63.6%), El Salvador (9.4%), Honduras (6.6%), and Guatemala (6.1%). The Special Supplemental Nutrition Program for Women, Infants, and Children and/or Supplemental Nutrition Assistance Program was used by 87.5% of families, and 42.6% of families reported food insecurity. **Table 1** shows baseline data by study group.

Table 1. Characteristics of the Participants at Baseline[a]

Characteristic	Intervention (n = 304)[b]	Control (n = 306)[b]
Child Characteristics		
Female, No. (%)	154 (50.7)	162 (52.9)
Age at anthropometry collection, y	4.3 (0.9)	4.3 (0.9)
Anthropometry		
BMI	16.7 (0.8)	16.6 (0.8)
BMI category percentiles, No. (%)[c]	n = 302	n = 301
50-84.9	193 (63.9)	203 (67.4)
85-94.9	109 (36.1)	98 (32.6)
BMI *z* score	0.83 (0.48)	0.82 (0.46)
Waist circumference, cm	53.0 (3.4) (n = 303)	53.1 (3.0) (n = 305)
Triceps skinfold, mm	9.5 (2.7) (n = 300)	9.7 (2.3) (n = 304)
Mean daily physical activity, min[d]	n = 302	n = 302
Total wear time, median (Q1, Q3)	1077 (954, 1122)	1070 (959, 1121)
Rest/sedentary behavior	638.1 (120.2)	634.3 (119.9)
Light physical activity	288.4 (59.4)	290.1 (56.6)
Moderate/vigorous activity	84.1 (30.3)	86.0 (31.4)
Diet	n = 304	n = 305
Mean daily total energy intake, kcal	1184 (334)	1202 (429)
Mean daily percentage of energy from fat, %	28.5 (5.2)	28.2 (5.3)
Mean daily percentage of energy from carbohydrates, %	55.4 (6.1)	56.1 (6.6)
Mean daily percentage of energy from protein, %	16.1 (3.2)	15.7 (3.3)
Race/ethnicity, No. (%)	n = 303	n = 304
Hispanic, Mexican origin	187 (61.7)	202 (66.5)
Hispanic, Non-Mexican origin	92 (30.4)	74 (24.3)
Non-Hispanic black	19 (6.3)	17 (5.6)
Non-Hispanic white	2 (0.7)	4 (1.3)
Non-Hispanic other	3 (1.0)	7 (2.3)
Adult Characteristics		
Female, No. (%)	300 (98.7)	300 (98.0)
Age at anthropometry collection, y	32.5 (6.2)	31.6 (5.8)
Anthropometry		
BMI	29.8 (6.2)	29.4 (5.3)
Waist circumference, cm[e]	97.7 (13.4) (n = 285)	96.7 (11.9) (n = 283)
Triceps skinfold, mm	31.5 (9.2)	31.3 (8.7)
Race/ethnicity, No. (%)		
Hispanic, Mexican origin	183 (60.2)	204 (66.7)
Hispanic, Non-Mexican origin	95 (31.3)	74 (24.1)
Non-Hispanic black	19 (6.3)	20 (6.5)
Non-Hispanic white	4 (1.3)	5 (1.6)
Non-Hispanic other	3 (1.0)	3 (1.0)
Time in the United States, median (Q1, Q3), y	10.0 (8.0, 14.0) (n = 303)	10.0 (7.0, 13.0) (n = 306)
Brief acculturation scale for Hispanics, median (Q1, Q3)[f]	4.0 (4.0, 7.0) (n = 274)	4.0 (4.0, 6.0) (n = 272)
Employment status, No. (%)	n = 303	n = 306
Working full time	51 (16.8)	57 (18.6)
Working part time	52 (17.2)	67 (21.9)
Not working for pay	200 (66.0)	182 (59.5)
Marital status, No. (%)	n = 303	n = 305
Married or living as married	260 (85.8)	244 (80.0)
Single	43 (14.2)	61 (20.0)
Relation to child, No. (%)	n = 303	n = 306
Mother	293 (96.7)	296 (96.7)
Father	3 (1.0)	6 (2.0)
Other	7 (2.3)	4 (1.3)

(continued)

Table 1. Characteristics of the Participants at Baseline[a] (continued)

Characteristic	Intervention (n = 304)[b]	Control (n = 306)[b]
Use of WIC and/or SNAP, No. (%)	257 (85.1) (n = 302)	273 (89.8) (n = 304)
Household income, No. (%), $		
≤14 999	85 (28.0)	89 (29.1)
15 000-24 999	90 (29.6)	82 (26.8)
25 000-34 999	39 (12.8)	37 (12.1)
35 000-49 999	7 (2.3)	9 (2.9)
≥50 000	2 (0.7)	2 (0.7)
Don't know or no answer	81 (26.6)	87 (28.4)
Education, No. (%)		
<High school diploma	182 (59.9)	192 (62.7)
≥High school graduate	122 (40.1)	114 (37.3)
CES-Depression (high = 16 or higher), No. (%)[g]	71 (23.4) (n = 303)	59 (19.3) (n = 306)
Food insecurity level, No. (%)[h]	n = 302	n = 304
Food secure [0-1]	165 (54.6)	183 (60.2)
Food insecure without hunger [2-4]	86 (28.5)	87 (28.6)
Food insecure with hunger [5-6]	51 (16.9)	34 (11.2)
Community center use with child, No. (%)[i]	n = 303	n = 305
Never	216 (71.3)	211 (69.2)
At least once	87 (28.7)	94 (30.8)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CES-Depression, Center for Epidemiological Studies–Depression; SNAP, Supplemental Nutrition Assistance Program; WIC, Special Supplemental Nutrition Program for Women, Infants, and Children.

[a] Data are expressed as mean (SD) unless No. (%) or median (Q1, Q3) are indicated. Data that were not normally distributed are expressed as median (Q1, Q3). All randomized patients are included.

[b] Some variables had a small amount of missing data due to not meeting the minimum criteria for inclusion (eg, insufficient wear time or not enough diet recalls), refusing to answer the question, or another unique issue.

[c] By design, all children were to be between the 50th and 95th percentiles based on population-standardized growth curves developed by the US Centers for Disease Control and Prevention. However, 2 participants were below the 50th percentile, and 5 participants were at or above the 95th. These participants are not included in either BMI category but are included in the intention-to-treat analyses for all variables for which they provided data.

[d] Physical activity measured with triaxial accelerometers. Individual wear time was averaged across valid wear days to produce a mean daily wear time and time in each physical activity category for each child.

[e] Adult waist circumference: Summary is based on a total of 568 nonpregnant adults. Forty-two adults were not measured due to pregnancy.

[f] A total of 556 Hispanic participants were eligible for assessment (intervention = 278, control = 278). The survey consists of 4 questions, and scores range from 4 to 20, with higher scores indicating greater acculturation.

[g] The CES-Depression survey consists of 20 questions, and scores range from 0 to 60, with higher scores indicating greater depressive symptoms. Scores of 16 or greater can aid in identifying individuals at risk for clinical depression.[29]

[h] Standard 6-question short-form survey for classifying households into food security status levels. The scale ranges from 0 to 6, with higher scores indicating greater food insecurity. Survey instructions were used to code raw scores into categories: 0-1, food secure; 2-4, food insecure without hunger; and 5-6, food insecure with hunger.[23]

[i] Dichotomized from original 6-point scale: never, once per month or less, more than once per month, once per week, more than once per week, and every day.

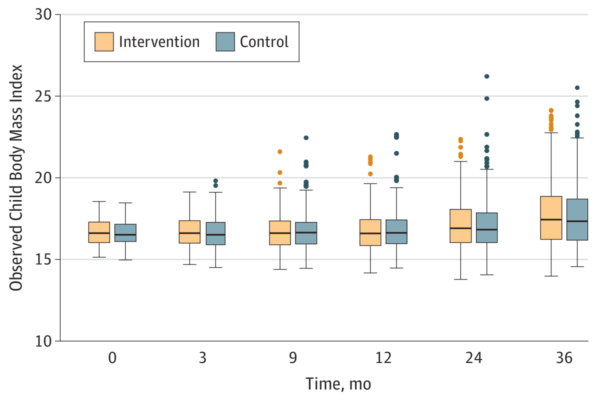
Primary Outcome

The mean (SD) child BMI at 36 months was 17.8 (2.2) in the intervention group and 17.8 (2.1) in the control group. Adjusted models showed no significant BMI difference (B = 0.05 [95% CI, −0.29 to 0.38]; P = .79) at 36 months (eTable 1 in Supplement 2). Box plots of child BMI at each time point for the intervention and control groups are presented in **Figure 2**. No meaningful intervention effect was detected on the prespecified primary outcome of child BMI trajectory over 3 years (joint likelihood ratio test, P = .39). Neither the linear intervention effect (BMI difference per year) (B = −0.082 [95% CI, −0.246 to 0.082]; P = .33) nor the quadratic effect (BMI difference per year squared) (B = 0.032 [95% CI, −0.014 to 0.078]; P = .18) was statistically significant (**Figure 3**). Model-estimated child BMI trajectories by sex and age are presented in eFigure 1 in Supplement 2.

Secondary Outcomes

Analyses of secondary outcomes are shown in **Table 2**. At 36 months, the mean (SD) child daily energy intake was 1227 (363) kcal for children in the intervention group and 1323 (397) kcal for children in the control group. The intervention resulted in a statistically significant reduction in mean child daily energy intake compared with the control group, which persisted across the 3 yearly time points. At 36 months, regression models indicated that parents in the intervention group reported their children consumed 99.4 kcal fewer than the control group (95% CI, 38.0-160.7; P = .002; corrected P = .003) and a slightly greater percentage of energy intake from protein at 24 and 36 months. No statistically significant intervention effects were detected for percentage of energy from fat or carbohydrates or mean daily time in sedentary behavior or MVPA. At 36 months, 56.8% of parents in the intervention group reported use of a community center with their child compared with 44.4% in the control group. Adjusted models indicated that participants in the intervention group were more likely to use a community center with their child vs those in the control group at all yearly time points (36-month adjusted risk ratio, 1.29 [95% CI, 1.08-1.53]; *P* = .004; corrected *P* = .006).

Figure 2. Child BMI by Group at Each Follow-up Time Point



Total No.						
Intervention	298	279	280	274	278	276
Control	302	271	280	275	266	272

Box plots are shown where the middle line represents the median observed child body mass index (calculated as weight in kilograms divided by height in meters squared), boxes represent the interquartile range, whiskers extend to the most extreme observed values with 1.5*IQR of the nearer quartile, and dots represent observed values outside that range.

Post-Hoc Outcomes

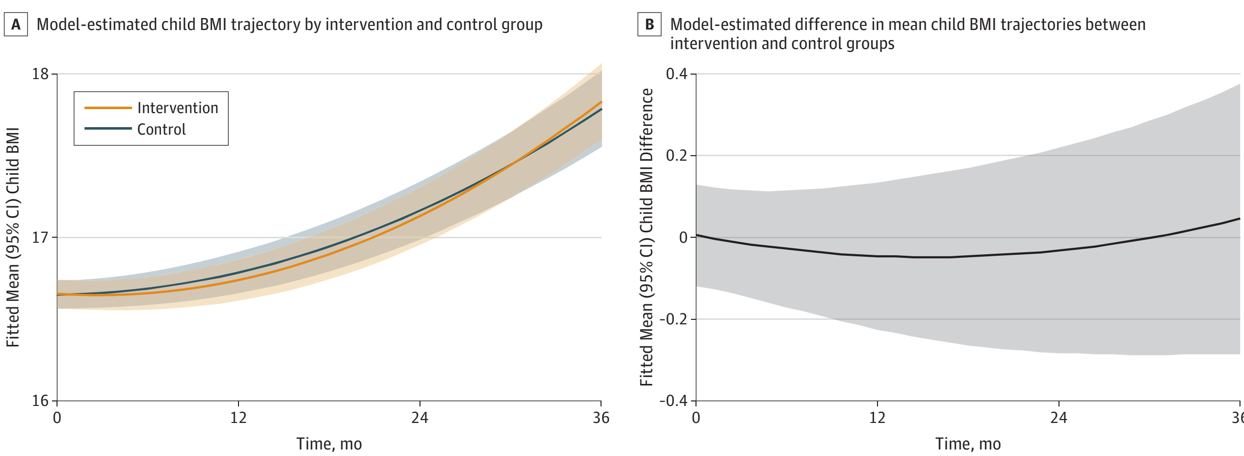
At study end, when children were ages 6 to 8 years, 25.4% of children in the intervention group and 23.5% of children in the control group were overweight, and 35.5% of children in the intervention group and 34.2% of children in the control group were obese. Children eligible for the adaptive intervention increased over time: n = 39 at 3-month; n = 45 at 9-month; n = 46 at 12-month; and n = 102 at 24-month follow-up. In post-hoc analysis, children in the intervention group had a significantly lower risk of developing obesity at 3-month follow-up compared with the control group before correcting for multiple comparisons (adjusted risk ratio, 0.51 [95% CI, 0.29-0.92]; *P* = .02; corrected *P* = .10). The intervention effect on reducing the estimated risk of obesity at 3 months increased as child baseline BMI increased above the mean (eFigure 2 in Supplement 2). The lower risk of obesity was not sustained at other time points (**Table 3**).

Post-hoc exploratory moderator analyses indicated statistically significant intervention effects on the linear and quadratic growth of BMI of children who were food insecure with hunger at baseline (eFigure 3 in Supplement 2). Significant quadratic intervention effects were also found for males and baseline child energy intake. No other statistically significant moderator effects were found (eTable 2 in Supplement 2).

Adherence to Study Protocol

The mean dose received among intervention participants was 92% for the intensive phase, 87% for the maintenance phase, and 85% for the sustainability phase. School-readiness dose receipt in both conditions was 83% throughout the study period. No crossover occurred between conditions. Fidelity to the intervention curriculum was 99% over the 3 years.

Figure 3. Intervention Effect on Child Body Mass Index (BMI)



A, Model-estimated child BMI trajectory for the intervention (n = 304) and control (n = 306) groups. Shaded regions represent 95% CIs around each trajectory. Model-based estimates indicate the BMI linear intervention effect (BMI difference/year) was −0.082 (95% CI, −0.246 to 0.082; *P* = .33) and the BMI quadratic intervention effect (BMI difference/year squared) was 0.032 (95% CI, −0.014 to 0.078; *P* = .18). The joint likelihood ratio test failed to reject the null hypothesis that the linear and quadratic terms were jointly different from zero (*P* = .39).

B, Model-estimated difference in the mean child BMI trajectories between intervention and control groups, where a value of zero indicates no difference. Shaded region represents 95% CIs around this difference. BMI was calculated as weight in kilograms divided by height in meters squared.

Table 2. Intervention Effect on Secondary Outcomes[a]

Prespecified Secondary Outcomes	Intervention (n = 304) No. With Data (%)	Intervention (n = 304) Mean (SD)	Control (n = 306) No.With Data (%)	Control (n = 306) Mean (SD)	Adjusted Difference (95% CI)[b]	*P* Value	Corrected *P* Value[c]
Dietary Intake							
Mean daily energy intake, kcal							
12 mo	227 (74.7)	1157 (306)	225 (73.5)	1261 (351)	−88.5 (−142.1 to −34.9)	.001	.003
24 mo	229 (75.3)	1212 (380)	209 (68.3)	1296 (372)	−82.8 (−144.6 to −21.1)	.009	.009
36 mo	227 (74.7)	1227 (363)	219 (71.6)	1323 (397)	−99.4 (−160.7 to −38.0)	.002	.003
Mean energy from fat, %							
12 mo	227 (74.7)	28.2 (5.0)	225 (73.5)	28.5 (4.7)	−0.3 (−1.2 to 0.5)	.45	.45
24 mo	229 (75.3)	27.8 (5.5)	209 (68.3)	28.4 (4.8)	−0.6 (−1.6 to 0.3)	.20	.45
36 mo	227 (74.7)	28.6 (5.1)	219 (71.6)	28.9 (5.2)	−0.4 (−1.4 to 0.5)	.36	.45
Mean energy from carbohydrates, %							
12 mo	227 (74.7)	55.1 (5.9)	225 (73.5)	55.2 (5.8)	0.1 (−0.9 to 1.2)	.83	.83
24 mo	229 (75.3)	54.9 (6.3)	209 (68.3)	55.5 (5.6)	−0.4 (−1.5 to 0.7)	.45	.80
36 mo	227 (74.7)	54.2 (6.0)	219 (71.6)	54.7 (5.8)	−0.3 (−1.4 to 0.7)	.53	.80
Mean energy from protein, %							
12 mo	227 (74.7)	16.7 (3.1)	225 (73.5)	16.3 (3.2)	0.2 (−0.3 to 0.8)	.46	.46
24 mo	229 (75.3)	17.3 (3.3)	209 (68.3)	16.1 (3.1)	1.0 (0.4 to 1.5)	.001	.003
36 mo	227 (74.7)	17.2 (3.3)	219 (71.6)	16.4 (3.0)	0.7 (0.2 to 1.3)	.01	.02
Physical Activity[d]							
Mean daily rest/sedentary time, min							
12 mo	230 (75.7)	619.9 (130.0)	232 (75.8)	618.5 (131.9)	−2.2 (−12.8 to 8.4)	.68	.77
24 mo	252 (82.9)	635.5 (121.7)	222 (72.5)	646.8 (124.6)	−1.5 (−11.7 to 8.6)	.77	.77
36 mo	248 (81.6)	663.6 (117.5)	234 (76.5)	660.0 (120.5)	3.6 (−6.5 to 13.6)	.49	.77
Mean daily moderate/vigorous physical activity time, min							
12 mo	230 (75.7)	85.2 (32.2)	232 (75.8)	83.5 (31.9)	1.7 (−2.7 to 6.1)	.45	.68
24 mo	252 (82.9)	80.9 (31.0)	222 (72.5)	83.3 (33.1)	−0.2 (−4.7 to 4.4)	.95	.95
36 mo	248 (81.6)	76.2 (31.8)	234 (76.5)	78.6 (29.3)	−1.7 (−6.0 to 2.5)	.43	.68
Community Center Use	**No. With Data (%)**	**No. Attending (%)**	**No. With Data (%)**	**No. Attending (%)**	**Adjusted Risk Ratio (95% CI)**[e]		
Center use with child (never vs at least once)[e]							
12 mo	259 (85.2)	147 (56.8)	258 (84.3)	101 (39.1)	1.47 (1.22-1.76)[f]	<.001	<.001
24 mo	263 (86.5)	145 (55.1)	243 (79.4)	110 (45.3)	1.21 (1.02-1.44)[f]	.03	.03
36 mo	259 (85.2)	147 (56.8)	248 (81.0)	110 (44.4)	1.29 (1.08-1.53)[f]	.004	.006

[a] Residual diagnostics were performed on each of the secondary outcome models to ensure distributional assumptions were met.

[b] Dietary intake and physical activity adjusted differences are model estimates adjusting for baseline value of the outcome variable, age at baseline, and sex. Physical activity models also adjusted for mean daily wear time.

[c] *P* values corrected for 3 comparisons using the Benjamini-Hochberg procedure.

[d] Physical activity data are from vector magnitude output from triaxial accelerometers.

[e] Dichotomized from original 6-point scale: never, once per month or less, more than once per month, once per week, more than once per week, and every day.

[f] Community center use adjusted risk ratios (95% CIs) are model estimates from Poisson regression models with robust standard errors and adjusting for baseline center use.

Adverse Events

One parent fractured an ankle while roller-skating during an event at a local community center. No additional intervention-related adverse events occurred.

Discussion

This 36-month community-based, family-centered, behavioral intervention did not change BMI trajectory in underserved preschool children who were not yet obese. The primary outcome of child BMI trajectory was selected in lieu of other standardized outcomes (eg, BMI *z* score) to capture potential differences in child growth curve shapes known to be predictive of later cardiovascular risk.[11,30] Throughout the 36-month trial, the intervention and control groups demonstrated nearly identical growth trajectories and rates of obesity. The prevalence of obesity observed in both the intervention and control groups was similar to the regional prevalence of obesity for Latino children (37.7%), indicating

Table 3. Prevalence of Child Obesity at Each Time Point

Post Hoc Outcome: Child Obesity[a]	Intervention (n = 304)		Control (n = 306)		Adjusted Risk Ratio (95% CI)[b]	*P* Value for Difference	Corrected *P* Value for Difference[c]
	No. With Data (%)	No. With Obesity (%)	No. With Data (%)	No. With Obesity (%)			
3 mo	279 (91.8)	16 (5.7)	271 (88.6)	25 (9.2)	0.51 (0.29-0.92)	.02	.10
9 mo	280 (92.1)	22 (7.9)	280 (91.5)	30 (10.7)	0.70 (0.42-1.15)	.16	.27
12 mo	274 (90.1)	30 (10.9)	275 (89.9)	39 (14.2)	0.73 (0.48-1.10)	.13	.27
24 mo	278 (91.4)	63 (22.7)	266 (86.9)	61 (22.9)	0.92 (0.70-1.21)	.57	.71
36 mo	276 (90.8)	98 (35.5)	272 (88.9)	93 (34.2)	0.99 (0.80-1.22)	.90	.90

[a] Obesity defined as 95th percentile or above based on population-standardized growth curves developed by the US Centers for Disease Control and Prevention.

[b] Risk ratios are from Poisson regression models with robust standard errors and adjusting for child baseline body mass index, age, and sex.

[c] *P* values corrected for 5 multiple comparisons using the Benjamini-Hochberg procedure.

that the behavioral intervention did not alter the usual pattern of obesity in this low-income minority population.[31] The study was adequately powered to detect differences in child BMI trajectory and achieved 90% retention with little differential attrition. In addition, the precision of the effect estimates (ie, confidence intervals for the difference in mean child BMI trajectories) is sufficient to conclude that no meaningful difference existed in the primary outcome between the intervention and control groups.

Of the more than 350 RCTs conducted to prevent or treat childhood obesity, few have demonstrated successful BMI change and most have studied higher-resourced populations, had small effect sizes not always of clinical significance, and/or lacked long-term follow-up. RCTs conducted with high quality and an independent coordinating center have consistently failed to produce meaningful, sustained results in childhood obesity prevention.[32,33] This pattern of unsuccessful childhood obesity prevention interventions is consistent with the findings of this study, which, to our knowledge, is the largest and longest obesity prevention RCT of its kind to date. This study was consistent with recent recommendations from the US Preventive Services Task Force to achieve 26 hours of contact time in year 1 but then it decreased in subsequent years.[34] The US Preventive Services Task Force examined the dose required for obesity treatment for children 6 years and older. There are no guidelines yet for what is needed to achieve effective obesity prevention. Prevention of childhood obesity in low-income, underserved populations could require an increased intensity of behavioral interventions over longer periods of time.

While there was no effect on the primary outcome, the multicomponent intervention demonstrated effects on the secondary outcomes of diet and use of the community center for physical activity. Children in the intervention condition consumed almost 100 fewer kcal per day and had a higher percentage of energy from protein compared with children in the control condition. While the intervention did not change the already high levels of child MVPA, children in the intervention used their local community centers for family physical activity more frequently than the control group, although the control group participants increased their use as well. Previous research has hypothesized that health behavior changes of this magnitude would result in modest improvements in BMI.[35] However, previous population-based modeling studies have indicated that populations from different socioeconomic strata as well as racial and ethnic subgroups have different thresholds for achieving healthy weight, with Latino and African American populations requiring more than 100-kcal differences.[35]

There are several potential explanations for why a close to 100-kcal reduction and increased use of the built environment would not result in child BMI change. First, measurement bias due to the reliance on parent-report measures may have led to these results, suggesting the need for confirmation in controlled settings.[36,37] However, the multipass protocol required for 24-hour diet recalls and the absence of direct nutrition education during the more passive 24-month sustainability phase might make a systematic measurement bias less likely. Second, while some individual behavior change can result from interventions such as these, achieving a sufficient amount of individual-level behavior changes in the family and community environment may not be feasible for these extremely low-income minority populations.

A notable characteristic of this trial was the exclusive enrollment of parent-child pairs from significant poverty. Parental depression was reported by 21.4% of these families, and 42.6% reported food insecurity at baseline. Previous literature suggests that biologically embedded obesity phenotypes can be produced by toxic stress, altering homeostatic regulation of pathways that influence resting metabolic rate, satiety set points, and epigenetics even before obesity manifests.[38] Research has also found that diversity of microbiome species and exposure to endocrine disruptors early in life affect changes in metabolic function, in some cases, regardless of calories consumed.[39,40] These influences could potentially alter an individual's energy balance so that even a statistically significant reduction in daily energy intake might not be clinically meaningful. Further evaluation may be warranted and underscores the importance of measuring biological-level mediators in long-term, high-intensity behavioral obesity interventions.

Post-hoc analyses indicated several findings that should be interpreted with caution, generating hypotheses for future research. First, the intervention reduced obesity prevalence after the 3-month intensive phase, but this reduction was not sustained. The effect was most pronounced in children with higher baseline BMI. This finding is consistent with previous literature on childhood obesity treatment in which short-term BMI improvements are achieved for those with higher baseline BMI, but long-term BMI improvements are not realized. Second, post-hoc moderator analyses indicated that the intervention may have been more effective for certain population subgroups, suggesting that tailored interventions may be needed. The moderator analyses indicated that intervention group children who experienced food insecurity with hunger at baseline had a different BMI growth trajectory over 3 years. This finding emphasizes the importance of addressing systemic factors that affect health behaviors to achieve child obesity prevention.

Limitations

This study had several limitations. First, because the study was conducted among low-income minority populations, the findings should not be generalized to other populations. Second, data on biological measures of cardiovascular or diabetes risk were not collected. Third, energy and nutrient intake were assessed by parent report of child diet and subject to social desirability bias that may differ as a result of intervention participation.[37] Fourth, this trial focused on the preschool period, which may not be the optimal age for obesity prevention. Future research should clarify the optimal timing of obesity prevention interventions.

Conclusions

A 36-month multicomponent behavioral intervention did not change BMI trajectory among underserved preschool-age children in Nashville, Tennessee, compared with a control program. Whether there would be effectiveness for other types of behavioral interventions or implementation in other cities would require further research.

ARTICLE INFORMATION

Accepted for Publication: June 11, 2018.

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Statistical analysis: Barkin, Heerman, Sommer, Martin, Truesdale, Stevens.
Obtained funding: Barkin, Buchowski.
Administrative, technical, or material support: Barkin, Heerman, Sommer, Po'e, Burgess, Escarfuller, Pratt, Stevens.
Supervision: Barkin, Sommer, Buchowski, Burgess.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Mr Escarfuller and Dr Stevens reported receiving grants from the National Institutes of Health (NIH). No other disclosures were reported.

Funding/Support: This research was supported by NIH grants (U01 HL103620, U01 HL103561, and NIH DK056350) with additional support from the remaining members of the COPTR Consortium (U01 HD068890, U01 HL103622, and U01 HL103629) from the National Heart, Lung, and Blood Institute (NHLBI) and the Eunice Kennedy Shriver National Institute of Child Health and Development (NICHD) and funding from the Office of Behavioral and Social Sciences Research. The REDCap Database is supported by National Center for Advancing Translational Sciences/NIH grant UL1 TR000445. Dr Heerman's time was supported by a K23 grant from the NHLBI (K23 HL127104). Also, part of Dr Barkin's time was supported by a P30 grant from the National Institute of Diabetes and Digestive and Kidney Diseases (2P30DK092986-07).

Role of the Funder/Sponsor: The NHLBI and NICHD played an advisory role in all phases of the study, including the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication. The sponsor did not have the right to veto submission of this manuscript.

Additional Contributions: We express our gratitude for our community partners, Metro Parks and Recreation in Nashville, Tennessee, and the Nashville Library Foundation, as well as our appreciation to all our GROW families and staff.

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