Two Family Interventions to Reduce BMI in Low-Income Urban Youth: A Randomized Trial

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abstract

BACKGROUND: Our primary aim was to evaluate the effects of 2 family-based obesity management interventions compared with a control group on BMI in low-income adolescents with overweight or obesity.

METHODS: In this randomized clinical trial, 360 urban-residing youth and a parent were randomly assigned to 1 of 2 behaviorally distinct family interventions or an education-only control group. Eligible children were entering the sixth grade with a BMI ≥85th percentile. Interventions were 3 years in length; data were collected annually for 3 years. Effects of the interventions on BMI slope (primary outcome) over 3 years and a set of secondary outcomes were assessed.

RESULTS: Participants were primarily African American (77%), had a family income of <25 000 per year, and obese at enrollment (68%). BMI increased over time in all study groups, with group increases ranging from 0.95 to 1.08. In an intent-to-treat analysis, no significant differences were found in adjusted BMI slopes between either of the family-based interventions and the control group (P = .35). No differences were found between the experimental and control groups on secondary outcomes of diet, physical activity, sleep, perceived stress, or cardiometabolic factors. No evidence of effect modification of the study arms by sex, race and/or ethnicity, household income, baseline levels of child and parent obesity, or exposure to a school fitness program were found.

CONCLUSIONS: In this low-income, adolescent population, neither of the family-based interventions improved BMI or health-related secondary outcomes. Future interventions should more fully address poverty and other social issues contributing to childhood obesity.

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Drs Moore and Borawski conceptualized and designed the study, supervised the conduction of the study and the analysis of results, and wrote the initial draft of the manuscript; Drs Love and Stevens and Mr Thomas designed the analysis plan and conducted, interpreted, and wrote the analysis of the study results; Ms Casey, Ms McAleer, and Drs Uli and Plow designed the data collection instruments for the study, coordinated and supervised data collection, and reviewed and revised the manuscript; Dr Truesdale, Ms Jones, and Mr Long designed and (Continued)

WHAT'S KNOWN ON THIS SUBJECT: Adolescent obesity continues to be a concerning issue in the United States. The need for effective interventions to reduce overweight and obesity is critical in low-income, minority families who suffer greater levels of obesity but are generally less responsive to intervention.

WHAT THIS STUDY ADDS: In a 3-year randomized trial, family-based interventions did not improve BMI or secondary health-related outcomes in a low-income, adolescent population. Future interventions should more fully address poverty and other social issues contributing to childhood obesity.

Adolescent obesity continues to be a concerning issue in the United States.[1] With 1 in 3 children today being overweight or obese[2] and significant disparities by race, ethnicity, and socioeconomic status,[3,4] it is critical to identify effective methods for weight management in these children to reduce their risk for future health issues, such as hypertension, diabetes, lipid abnormalities, and early mortality.[5] Currently, direct medical costs of obesity in the United States are $149 billion.[6]

Despite the epidemic of childhood obesity, effective and sustainable interventions to help children lose or maintain their weight as they grow remain elusive.[7–9] Evidence demonstrates that behavioral interventions to reduce overweight and obesity are less effective among prepubertal, young adolescents; boys; low-income families; single-parent households; and African American or Hispanic adolescents; many of whom have the highest rates of obesity.[10–15] In particular, low-income, urban-dwelling families have been shown to engage in less physical activity; often live in areas with less access to affordable, healthy food options; and frequently live in highly stressful environments.[16,17] In addition, adolescents with parents with overweight or obesity are more difficult to treat,[18] likely because of social norms and the family environment. Peer relationships, family eating and activity patterns, and community culture also have been shown to influence adolescents' weight status and response to weight-management interventions.[19–21]

This article reports the primary and secondary outcome results of the Ideas Moving Parents and Adolescents to Change Together (IMPACT) trial.[22] The IMPACT trial assessed the effects of 2 distinct family-based behavioral obesity management interventions compared with an education-only control group on BMI in middle school, low-income, urban adolescents with overweight and obesity. The effects of the interventions on a set of secondary outcomes also were evaluated: (1) healthy weight behaviors (diet, physical activity, sedentary activity, sleep, and perceived stress) and (2) cardiometabolic risk factors. IMPACT was 1 of 4 intervention trials of the Childhood Obesity Prevention and Treatment Research Consortium (COPTR), funded by the National Institutes of Health.[23] Each of 4 sites tested distinct 3-year interventions in low-income populations and was supported by a coordinating center (University of North Carolina at Chapel Hill). The study was monitored by a data and safety monitoring board appointed by the National Heart, Lung, and Blood Institute and received University Hospitals of Cleveland Human Subjects Institutional Review Board approval.

METHODS

Study Design, Population, and Recruitment

In this 3-group randomized controlled trial, 360 middle school, low-income, minority adolescents were recruited as part of an existing BMI and blood pressure (BP) screening program in the Cleveland Metropolitan School District and 5 charter schools. With parent permission, the schools provided the results of the BMI screening and parent contact information to the research team, who then consecutively contacted parents of all eligible adolescents (BMI ≥85th percentile and entering the sixth grade) for participation in the study. One parent or guardian per child also was enrolled. Children were excluded if they were taking medications that alter appetite or weight, had stage 2 hypertension or stage 1 hypertension with end organ damage,[24] had type 1 or 2 diabetes, had sickle cell disease (conditions that are primarily treated with medication rather than lifestyle interventions), or had a known medical condition that itself causes obesity (eg, Prader-Willi syndrome). Participants were recruited between May 2012 and January 2014 and followed for 3 years. Figure 1 shows the Consolidated Standards of Reporting Trials diagram of participant screening, random assignment, and retention.

Randomization Procedures

Participants were randomly assigned to 1 of 3 intervention study arms within 37 days of the baseline visit. A computerized minimization program[25,26] was used to help ensure that groups assigned to each study arm were similar in terms of BMI (overweight or obese), sex (male or female), and school location in Cleveland (east or west side).

Intervention Descriptions

Interventions

The effects of 2 theoretically different family-based interventions, Healthy Change and System Change, were assessed against a control group. The Healthy Change intervention consisted of behavior change strategies commonly used in cognitive behavioral and motivational interviewing interventions, such as problem-solving, goal setting, self-monitoring, and relapse-prevention skills. The System Change intervention was based on process improvement techniques and emphasized restructuring family daily routines (systems) to establish new healthy living habits. Participants were taught to use a series of small, family self-designed experiments to design new routines. Families also charted their daily routines associated with home, school, and work and used a storyboard to track their family change processes. Descriptions of and distinctions between the 2 experimental
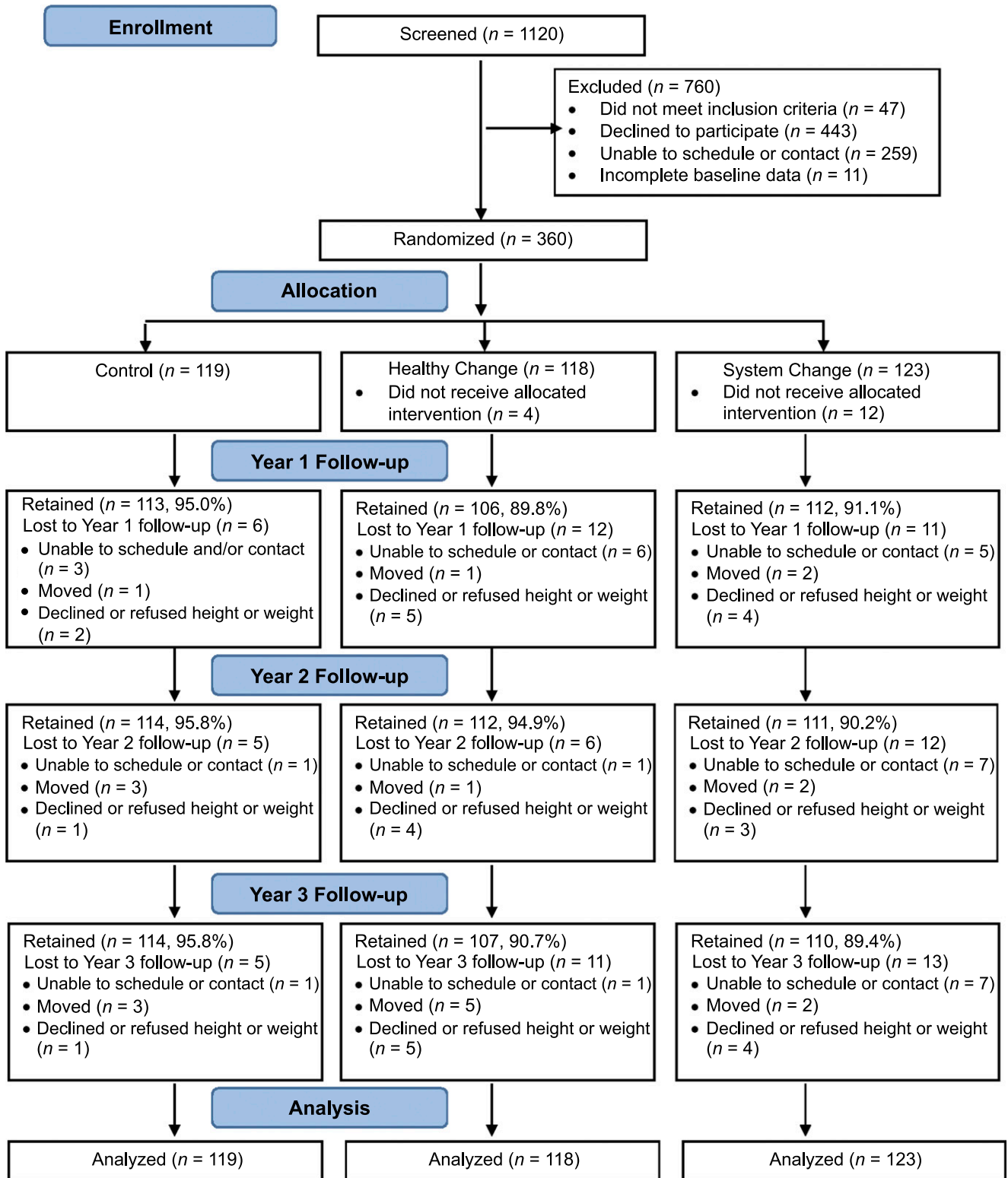
Enrollment

Screened (*n* = 1120)

Excluded (*n* = 760)
- Did not meet inclusion criteria (*n* = 47)
- Declined to participate (*n* = 443)
- Unable to schedule or contact (*n* = 259)
- Incomplete baseline data (*n* = 11)

Randomized (*n* = 360)

Allocation

Control (*n* = 119)

Healthy Change (*n* = 118)
- Did not receive allocated intervention (*n* = 4)

System Change (*n* = 123)
- Did not receive allocated intervention (*n* = 12)

Year 1 Follow-up

Retained (*n* = 113, 95.0%)
Lost to Year 1 follow-up (*n* = 6)
- Unable to schedule and/or contact (*n* = 3)
- Moved (*n* = 1)
- Declined or refused height or weight (*n* = 2)

Retained (*n* = 106, 89.8%)
Lost to Year 1 follow-up (*n* = 12)
- Unable to schedule or contact (*n* = 6)
- Moved (*n* = 1)
- Declined or refused height or weight (*n* = 5)

Retained (*n* = 112, 91.1%)
Lost to Year 1 follow-up (*n* = 11)
- Unable to schedule or contact (*n* = 5)
- Moved (*n* = 2)
- Declined or refused height or weight (*n* = 4)

Year 2 Follow-up

Retained (*n* = 114, 95.8%)
Lost to Year 2 follow-up (*n* = 5)
- Unable to schedule or contact (*n* = 1)
- Moved (*n* = 3)
- Declined or refused height or weight (*n* = 1)

Retained (*n* = 112, 94.9%)
Lost to Year 2 follow-up (*n* = 6)
- Unable to schedule or contact (*n* = 1)
- Moved (*n* = 1)
- Declined or refused height or weight (*n* = 4)

Retained (*n* = 111, 90.2%)
Lost to Year 2 follow-up (*n* = 12)
- Unable to schedule or contact (*n* = 7)
- Moved (*n* = 2)
- Declined or refused height or weight (*n* = 3)

Year 3 Follow-up

Retained (*n* = 114, 95.8%)
Lost to Year 3 follow-up (*n* = 5)
- Unable to schedule or contact (*n* = 1)
- Moved (*n* = 3)
- Declined or refused height or weight (*n* = 1)

Retained (*n* = 107, 90.7%)
Lost to Year 3 follow-up (*n* = 11)
- Unable to schedule or contact (*n* = 1)
- Moved (*n* = 5)
- Declined or refused height or weight (*n* = 5)

Retained (*n* = 110, 89.4%)
Lost to Year 3 follow-up (*n* = 13)
- Unable to schedule or contact (*n* = 7)
- Moved (*n* = 2)
- Declined or refused height or weight (*n* = 4)

Analysis

Analyzed (*n* = 119)

Analyzed (*n* = 118)

Analyzed (*n* = 123)

FIGURE 1
Consolidated Standards of Reporting Trials diagram.

interventions are described in detail elsewhere.[22,27]

In the 3-year interventions, both experimental interventions focused on the same healthy living behaviors (diet, physical activity, sedentary activity, sleep, and stress management). The intervention modes of delivery were the same across the 2 interventions, consisting of small group sessions of 12 to 15 families who met in 25 face-to-face sessions in Year 1, alternating monthly face-to-face group and individualized telephone sessions in Year 2, and 4 face-to-face and 8 telephone sessions in Year 3. Each intervention session was delivered by 2 trained interventionists (1 man and 1 woman), at least 1 of whom was of minority race and/or ethnicity. The interventionists were generally school teachers or recreation center personnel who were independently contracted for this role and were trained by using a structured protocol. All intervention materials and curricula for both parent and child were developed at the fifth-grade reading level. All didactic sessions (group and telephone coaching) were audiotaped, and 10% were randomly selected for review of fidelity of content delivery.

Interventions were tailored for adolescent participants in both intervention arms by using a responsive intervention design[28,29] in which a set of tailoring variables and decision rules for their application were specified a priori. In this responsive intervention protocol, adolescents received up to 60 minutes of personal coaching each month of the study in addition to the usual standard intervention if they met any of the following 4 criteria: identified as a binge eater, morbidly obese at baseline (>99.5 BMI percentile), low parent and/or family involvement (adolescent attending >50% of sessions alone without a parent), or excessive weight gain during the study (>2 lb per month in

a 3-month period resulting in an increase in BMI).

Control Group

A control group of brief education and social interaction only comprised the third study arm. Parent and child participants in this arm received 1 hour of private coaching from a registered dietitian on healthy eating and physical activity in Year 1 as well as a social telephone call and social event in all study years to enhance study retention.

Data Collection and Measurements

Participant outcome assessment data were collected at baseline and annually for 3 years by trained and certified personnel at the Clinical Research Units at 2 Cleveland hospital systems and, in some cases, in the children's schools. Written informed consent and assent were obtained from the parent and child, respectively, before any data collection. Interview-based data were obtained in private interviews by using audio-assisted survey software in English and Spanish. All measurements were collected by masked, certified staff who were not involved in the intervention. Descriptions of all data collection methods and measures are described in detail elsewhere[22] and in the Supplemental Information.

Primary Outcomes

BMI was the primary outcome and was calculated as weight in kilograms divided by the square of the height in meters. Height was measured to the nearest 0.1 cm by using a wall-mounted Harpenden Stadiometer. Weight was measured to the nearest 0.1 kg. Measures were collected in duplicate and averaged.

Secondary Outcomes

Secondary outcomes measured in the adolescent participants included waist circumference, tricep skinfold thickness, dietary intake (three 24-hour dietary recalls using the

Nutrition Data System for Research[30,31] software to calculate daily intake of calories, percentage of calories from fat, number of fruits and vegetables, and sodium), physical activity (using ActiGraph GT3X+ monitors), sleep, fitness, BP, and a set of cardiometabolic variables: fasting blood glucose, insulin resistance (homeostatic model assessment for insulin resistance), hemoglobin A1c, C-reactive protein, total cholesterol, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol, and triglycerides.

Exposure to an Existing School-Based Fitness Program

The We Run This City (WRTC) Youth Marathon program[32] is an existing school-based fitness program offered by the local YMCA in >30 Cleveland schools each year (one-third of study participants' schools). Thus, an opportunity presented itself to assess the effect of this school fitness program on BMI in addition to the effects of the IMPACT interventions. In WRTC, students join teams led by school personnel and train for ~14 weeks. Study-supported navigators (masked to study-arm assignment) encouraged IMPACT participants attending WRTC schools to enroll and stay active in the program. Participants were documented as being exposed to the WRTC program if they enrolled in the program and attended at least 1 training session (yes or no).

Demographic Characteristics

Self-reports by parents provided information on parent education, marital status, household income, number of people living in the household, employment status, food-program participation, and access to a vehicle. Standardized surveys were used to measure depressive symptoms and food security. Census-tract poverty level, unemployment, and crime rates were assessed along with the number of supermarkets and small grocery stores within one-half

mile of the participant's home. Throughout the study, residential and school changes were documented (see the Supplemental Information for details).

Statistical Analyses

Our primary hypothesis was that over a 3-year period, both System Change and Healthy Change would have greater impact on BMI slope than the education-alone control after adjusting for BMI at baseline and a random effect to account for clustering by school (at study enrollment). A BMI slope (trajectory over 3 years) was created for each participant. An F test with 2 degrees of freedom was used to test for between-group differences by using an α of .05. An a priori power analysis indicated that a minimum of 288 subjects (96 per arm) would provide 94% power to detect an effect size as small as 5% (considered a clinically significant effect).[33] The primary outcome analysis was replicated by the coordinating center.

Secondary outcomes were analyzed by using the same approach used for the primary outcomes. All secondary outcomes were analyzed in the continuous form as slopes. Additional planned analyses using BMI slope as the outcome examined effect modification of study arms by sex, race and/or ethnicity, household income, baseline level of child and parent obesity, and exposure to the WRTC school fitness program.

Missing Data and Imputation Process

Our intent-to-treat analysis included all index children. Interpolation and imputation were used in the calculation of slopes for BMI and the secondary outcome variables. Imputation was conducted for participants missing all BMI follow-up data by using 13 prespecified imputation variables and 1000 imputations. For the BMI measures available at multiple assessment

TABLE 1 Baseline Characteristics by Study Group

	Total (n = 360)	Control (n = 119)	Healthy Change (n = 118)	System Change (n = 123)
Child female sex, No. (%)	208 (57.8)	69 (58.0)	66 (55.9)	73 (59.3)
Child's age, y, mean (SD)	11.6 (0.6)	11.6 (0.6)	11.6 (0.6)	11.5 (0.6)
Child's race and/or ethnicity, No. (%)				
Non-Hispanic white	14 (3.9)	5 (4.2)	4 (3.4)	5 (4.1)
Non-Hispanic African American	276 (76.7)	93 (78.2)	91 (77.1)	92 (74.8)
Hispanic	59 (16.4)	18 (15.1)	17 (14.4)	24 (19.5)
Multiracial	8 (2.2)	2 (1.7)	5 (4.2)	1 (0.8)
Other	3 (0.8)	1 (0.8)	1 (0.8)	1 (0.8)
Child's pubertal status (yes), No. (%)	210 (61.4)	66 (59.5)	66 (57.9)	78 (66.7)
Child's wt, kg, mean (SD)	64.4 (14.3)	63.8 (15.0)	64.6 (12.9)	65.0 (14.8)
Child's height, cm, mean (SD)	153.7 (7.6)	153.6 (7.4)	153.8 (8.1)	153.7 (7.4)
Child's BMI, mean (SD)	27.1 (4.9)	26.8 (4.7)	27.3 (4.8)	27.4 (5.1)
Child's BMI percentile, mean (SD)	95.7 (3.7)	95.5 (4.0)	95.8 (3.6)	95.8 (3.6)
Child's BMI category, No. (%)				
Overweight	117 (32.5)	38 (31.9)	37 (31.4)	42 (34.1)
Obese	243 (67.5)	81 (68.1)	81 (68.6)	81 (65.9)
Waist-to-height ratio, mean (SD)	0.6 (0.1)	0.6 (0.1)	0.6 (0.1)	0.6 (0.1)
Body fat, %, mean (SD)	38.5 (5.8)	38.0 (5.5)	38.8 (5.9)	38.6 (5.9)
Child's systolic BP, mm Hg, mean (SD)	108.1 (8.3)	108.3 (8.6)	108.1 (7.7)	108.1 (8.6)
Child's diastolic BP, mm Hg, mean (SD)	63.9 (6.9)	63.6 (7.2)	64.2 (6.3)	63.8 (7.1)
Child's BP category, No. (%)				
Normal	326 (90.6)	108 (90.8)	109 (92.4)	109 (88.6)
Prehypertensive	20 (5.6)	5 (4.2)	6 (5.1)	9 (7.3)
Hypertensive	14 (3.8)	6 (5.0)	3 (2.5)	5 (4.1)
Child depressive symptoms, mean (SD)	16.0 (10.6)	15.1 (10.3)	16.5 (10.8)	16.5 (10.7)
Parent's BMI, mean (SD)	35.7 (8.8)	36.3 (9.0)	35.6 (9.1)	35.2 (8.3)
Parent's BMI category, No. (%)				
Underweight (<18.5)	3 (0.9)	2 (1.8)	1 (0.9)	0 (0.0)
Normal wt (18.5–24.9)	31 (9.0)	8 (7.1)	12 (10.5)	11 (9.4)
Overweight (25.0–29.9)	60 (17.5)	17 (15.2)	20 (17.5)	23 (19.7)
Obese (>30)	249 (72.6)	85 (75.9)	81 (71.1)	83 (70.9)
People living in household, mean (SD)				
Total	4.5 (1.5)	4.5 (1.6)	4.3 (1.3)	4.5 (1.6)
Adults	1.6 (0.7)	1.6 (0.7)	1.5 (0.6)	1.6 (0.7)
Children	2.8 (1.4)	2.9 (1.5)	2.8 (1.2)	2.9 (1.5)
Parent's education level, No. (%)				
No high school diploma	65 (18.0)	23 (19.3)	17 (14.4)	25 (20.3)
High school diploma	101 (28.1)	31 (26.1)	38 (32.2)	32 (26.0)
Some college, technical training, or associate's degree	162 (45.0)	53 (44.5)	54 (45.8)	55 (44.7)
Bachelor's degree or more	32 (8.9)	12 (10.1)	9 (7.6)	11 (8.9)
Parent marital status (single), No. (%)	239 (66.8)	84 (70.6)	81 (69.2)	74 (60.7)
Parent employment status, No. (%)				
Working full-time	136 (37.8)	48 (40.3)	44 (37.3)	44 (35.8)
Working part-time	64 (17.8)	22 (18.5)	18 (15.3)	24 (19.5)
Not working for pay	160 (44.4)	49 (41.2)	56 (47.5)	55 (44.7)
Annual household income, $, No. (%)				
≤14 999	105 (29.2)	34 (28.6)	33 (28.0)	38 (30.9)
15 000–24 999	71 (19.7)	22 (18.5)	26 (22.0)	23 (18.7)
25 000–34 999	47 (13.1)	16 (13.4)	13 (11.0)	18 (14.6)
35 000–49 999	36 (10.0)	12 (10.1)	15 (12.7)	9 (7.3)
50 000–74 999	25 (6.9)	10 (8.4)	8 (6.8)	7 (5.7)
≥75 000	10 (2.8)	4 (3.3)	3 (2.5)	3 (2.4)
Prefer not to answer	20 (5.6)	5 (4.2)	6 (5.1)	9 (7.3)
Do not know	46 (12.8)	16 (13.4)	14 (11.9)	16 (13.0)
Food assistance via WIC, No. (%)	58 (16.1)	20 (16.8)	18 (15.3)	20 (16.3)
Food assistance via SNAP, No. (%)	254 (70.6)	81 (68.1)	88 (74.6)	85 (69.1)
Child's food security, No. (%)				
Secure	238 (68.0)	80 (69.6)	82 (71.3)	76 (63.3)

points, we interpolated slopes. For all secondary outcomes, 100 runs were used for the computation of slopes.

RESULTS

Sample Characteristics

Table 1 provides a description of the study sample's baseline characteristics. There were no differences across study groups. Participants were primarily African Americans living in single-parent households with low household incomes. A high percentage of the parents and children were obese at baseline. One-quarter of the families reported no access to a car, and nearly 36% lacked a grocery store within one-half mile of their home. The neighborhood crime rates were 3 times that of the larger county rate. The children experienced a high rate of residential and school changes during the 3-year study (Table 2). Approximately 35% of the study participants were enrolled in a school that offered the WRTC school-based fitness program, of whom, on average, 50% were enrolled in the program.

Study Retention and Intervention Participation

Participant retention for measurement of BMI was 91.9%, 93.3%, and 91.9% in years 1, 2 and 3, respectively. Of the 360 enrolled participants, 14 had BMI available only at baseline and had a BMI slope imputed. Intervention participation was measured as the number of intervention contacts and the number of hours of intervention exposure over 3 years. Intervention participation rates were not statistically different between the 2 intervention arms. Rates of intervention participation averaged 58% with a mean intervention exposure time of 22 hours (range = 0–56). Forty-three percent (n = 103) of the adolescents in the intervention arms of the study qualified to receive the extra coaching sessions, in which

tailored information was provided for the following components: binge eating (51%), excess weight gain (49%), morbid obesity (16%), and lack of parent and/or guardian involvement (2%). These participants received an average of 1.4 hours (SD = 1.1; range = 0.25–5.25) of additional intervention exposure. Fidelity assessments of the intervention content delivery indicated a 99% compliance with the intervention protocols.

TABLE 1 Continued

	Total (n = 360)	Control (n = 119)	Healthy Change (n = 118)	System Change (n = 123)
Insecure, no hunger	102 (29.1)	33 (28.7)	28 (24.3)	41 (34.2)
Insecure, with hunger	10 (2.9)	2 (1.7)	5 (4.3)	3 (2.5)
Access to a car (no), No. (%)	89 (24.7)	24 (20.2)	33 (28.0)	32 (26.0)
Neighborhood factors[a]				
In poverty, %, mean (SD)	37.4 (15.9)	35.8 (15.6)	37.8 (16.8)	38.5 (15.3)
Unemployed, %, mean (SD)	22.7 (10.2)	22.5 (10.2)	23.0 (10.4)	22.5 (10.0)
Violent crime rate (per 100 000),[b] mean (SD)	1873.9 (964.4)	1835.1 (938.4)	1916.6 (905.8)	1869.2 (1044.6)
Participants without a full service or small grocery within one-half mile of home, No. (%)	114 (35.5)	40 (38.8)	36 (34.3)	38 (33.6)

SNAP, Supplemental Nutrition Assistance Program; WIC, Women, Infants, and Children program.
[a] Neighborhood indicators are reported at the census-tract level.
[b] For comparison, the violent crime rate (per 100 000) for the county is 560.5 per 100 000.

Primary and Secondary Outcomes

Results showed that over the 3-year study, there were no significant differences in BMI among the 3 study groups. As shown in Table 3, no differences were found in the adjusted BMI slopes between either the Healthy Change and the control groups or the System Change and the control groups. BMI increased over time with unadjusted annual estimates of 0.95 in the education-only control group and 0.82 and 1.08

TABLE 2 Residential and School Changes Reported by Participants

	Subjects, %			
	Total (n = 360)	Control (n = 119)	Healthy Change (n = 118)	System Change (n = 123)
Year 1				
Changed schools	32.1	30.5	31.6	34.2
Changed residence	24.6	28.0	18.8	26.9
Year 2				
Changed schools	29.2	28.8	27.2	31.6
Changed residence	25.7	25.0	25.0	27.1
Year 3				
Changed schools[a]	52.3	50.0	55.8	51.3
Changed residence	25.2	27.0	23.4	25.2
Total (years 1–3)[b]				
Did not change schools or residence outside of HS transition	34.7	34.2	37.5	32.5
Changed residence but not schools	19.7	23.9	17.0	17.9
Changed schools but not residence	16.5	14.5	17.9	17.1
Changed schools and residences at least once	29.2	27.4	27.7	32.5

HS, high school.
[a] A significant portion of students transitioned from kindergarten through eighth grade to high school by the time of the third-year assessment. All other changes in schools were within kindergarten–through–eighth-grade schools.
[b] Any participant who experienced 1 move or school change in each. Overall school change was limited to those who experienced school change in the first 2 years.

TABLE 3 Annualized Changes in Key Outcome Variables and Adjusted Differences in Annualized Change Between the Healthy Change or System Change Group and the Education-Only Controls

Variable	Unadjusted Annualized Change,[a] Mean (SD)			HC or SC Versus Education-Only, P	Adjusted Difference in Annualized Change (95% CI)	
	Education Only	HC	SC	F test	HC Versus Education-Only	SC Versus Education-Only
Primary outcome: BMI	0.952 (1.318)	0.821 (1.363)	1.083 (1.129)	0.35	−0.132 (−0.390 to 0.126)	0.137 (−0.071 to 0.346)
Secondary outcomes						
Anthropometric						
BMI percentile	−1.101 (3.206)	−1.363 (3.836)	−0.260 (1.555)	0.11	−0.309 (−1.034 to 0.416)	0.785 (0.497 to 1.072)
Waist-to-height ratio	−0.001 (0.020)	−0.003 (0.023)	0.002 (0.017)	0.34	−0.003 (−0.007 to 0.002)	0.002 (−0.001 to 0.005)
Waist circumference	2.200 (3.288)	1.814 (3.584)	2.339 (2.839)	0.58	−0.368 (−1.045 to 0.309)	0.134 (−0.393 to 0.661)
Body fat (Stevens equation), %	−0.044 (2.170)	−0.246 (2.376)	0.299 (1.889)	0.39	−0.217 (−0.672 to 0.238)	0.335 (−0.019 to 0.689)
BP, mm Hg						
Systolic	0.886 (2.787)	1.245 (3.319)	1.130 (3.075)	0.51	0.301 (−0.326 to 0.928)	0.184 (−0.387 to 0.755)
Diastolic	−0.162 (2.378)	−0.136 (2.796)	−0.074 (2.726)	0.65	0.069 (−0.459 to 0.598)	−0.038 (−0.544 to 0.469)
Systolic percentile	−2.028 (8.095)	−1.450 (9.206)	−1.053 (8.801)	0.60	0.325 (−1.415 to 2.065)	0.607 (−1.027 to 2.241)
Diastolic percentile	−2.132 (6.645)	−2.335 (8.228)	−2.044 (8.063)	0.72	−0.087 (−1.642 to 1.468)	−0.347 (−1.844 to 1.150)
Diet						
Calories per d	24.03 (250.44)	12.49 (226.65)	6.99 (211.04)	0.34	−26.584 (−70.613 to 17.445)	−11.781 (−51.486 to 27.925)
Calories from fat, %	−0.018 (2.601)	0.139 (2.905)	0.050 (2.589)	0.55	0.039 (−0.526 to 0.603)	0.138 (−0.349 to 0.625)
No. fruit servings per d	−0.055 (0.360)	−0.061 (0.239)	−0.050 (0.234)	0.38	−0.010 (−0.056 to 0.037)	−0.028 (−0.072 to 0.016)
No. vegetable servings per d	−0.008 (0.253)	0.013 (0.276)	0.008 (0.263)	0.14	0.020 (−0.034 to 0.073)	0.016 (−0.033 to 0.066)
Sodium intake per d, mg	39.15 (446.28)	−0.42 (425.7 9)	26.46 (409.34)	0.32	−30.046 (−112.759 to 52.667)	32.241 (−44.774 to 109.257)
Physical activity						
Moderate or vigorous, min per d	−3.523 (8.493)	−3.370 (10.123)	−4.619 (7.486)	0.346	0.050 (−1.964 to 2.065)	−0.788 (−2.249 to 0.673)
Bed rest or sedentary, min per d	11.022 (16.961)	10.501 (16.365)	13.052 (14.561)	0.62	−0.066 (−3.322 to 3.191)	−1.099 (−3.941 to 1.743)
Wear time in moderate-to-vigorous activity, %	−0.481 (1.149)	−0.426 (1.319)	−0.609 (0.986)	0.167	0.054 (−0.209 to 0.316)	−0.087 (−0.280 to 0.105)
Wear time in bed rest or sedentary activities, %	1.638 (2.231)	1.610 (2.228)	1.900 (2.059)	0.53	−0.033 (−0.476 to 0.411)	0.232 (−0.169 to 0.634)
Sleep						
Adolescent sleep, wake	−0.273 (2.089)	−0.239 (2.350)	−0.361 (2.618)	0.10	−0.019 (−0.465 to 0.427)	0.284 (−0.204 to 0.772)
Daytime sleepiness	−1.184 (7.749)	−1.061 (8.937)	−1.552 (9.755)	0.33	0.158 (−1.539 to 1.855)	1.029 (−0.791 to 2.848)
Sleep on weekends, min	−13.101 (65.529)	−9.032 (51.553)	−4.474 (48.285)	0.72	0.695 (−9.047 to 10.438)	−0.638 (−9.643 to 8.367)
Sleep on weekdays, min	−21.034 (35.040)	−19.867 (39.697)	−14.146 (31.819)	0.62	0.231 (−7.271 to 7.733)	2.949 (−2.985 to 8.883)
Stress						
Child's perceived stress	−0.044 (2.489)	0.311 (2.584)	−0.040 (2.744)	0.53	0.075 (−0.420 to 0.570)	0.588 (0.076 to 1.100)
Fitness						
Resting pulse rate	−1.392 (3.713)	−1.139 (3.312)	−1.279 (3.280)	0.33	0.047 (−0.579 to 0.672)	0.099 (−0.510 to 0.708)
Shuttle-run laps	1.744 (3.498)	1.126 (2.639)	0.906 (2.155)	0.10	−0.573 (−1.085 to 0.060)	−0.742 (−1.155 to −0.329)
Cardiometabolic factors						
Fasting glucose, mg/dL	−0.490 (2.864)	−0.146 (2.864)	−0.520 (3.805)	0.90	0.116 (−0.383 to 0.615)	0.155 (0.497 to 0.807)
Hemoglobin A1c, %	−0.017 (0.093)	−0.040 (0.210)	−0.021 (0.304)	0.45	−0.027 (−0.075 to 0.021)	0.018 (−0.052 to 0.088)
HDL cholesterol, mg/dL	−0.385 (2.906)	−0.3 (3.433)	−0.6 (2.526)	0.58	0.183 (−0.364 to 0.730)	−0.237 (−0.698 to 0.224)
High-sensitivity C-reactive protein, mg/L	−0.0185 (0.123)	−0.013 (0.163)	−0.002 (0.141)	0.73	0.003 (−0.032 to 0.038)	0.017 (−0.009 to 0.043)
Insulin, μU/mL	0.228 (4.568)	0.772 (4.761)	0.406 (6.875)	0.44	0.065 (−0.898 to 1.028)	0.510 (0.868 to 1.888)
HOMA-IR	0.004 (1.009)	0.032 (1.003)	0.037 (1.281)	0.55	−0.000 (−0.229 to 0.228)	0.063 (−0.210 to 0.336)
LDL cholesterol (derived), mg/dL	−2.357 (6.645)	−1.449 (7.915)	−1.970 (7.295)	0.439	1.384 (−0.053 to 2.821)	0.486 (−0.666 to 1.638)
Total cholesterol, mg/dL	−2.94 (7.201)	−2.409 (9.500)	−3.651 (8.280)	0.73	0.985 (−0.612 to 2.582)	−0.342 (−1.678 to 0.994)

Variable	Unadjusted Annualized Change,[a] Mean (SD)			HC or SC Versus Education-Only, P	Adjusted Difference in Annualized Change (95% CI)	
	Education Only	HC	SC	F test	HC Versus Education-Only	SC Versus Education-Only
Triglycerides, mg/dL	−1.516 (13.910)	−3.280 (17.847)	−5.054 (17.573)	0.56	−2.585 (−5.832 to −0.662)	−2.538 (−5.672 to 0.596)
Alanine aminotransferase, U/L	−0.775 (3.603)	−1.875 (5.115)	−0.811 (3.055)	0.46	−0.601 (−1.741 to 0.539)	0.049 (−0.553 to 0.651)

HC, Healthy Change group; HOMA-IR, homeostatic model assessment for insulin resistance; SC, System Change group.

[a] Analyses controlled for baseline BMI and school clustering at randomization. With the exception of the cardiometabolic factors involving blood samples, the sample described here, before imputation for most variables, includes 346 subjects, including 117 education-only, 112 Healthy Change, and 117 System Change subjects. Total enrollment was 360. At least 344 subjects are included in each row for the anthropometric and BP variables. At least 316 subjects are included for the cardiometabolic variables.

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in the Healthy Change and the System Change groups, respectively. The primary outcome was null, and the adjusted differences in annual BMI change (slope) were small (<0.2). Also shown in Table 3, no differences were found between the experimental groups and control group in any of the other anthropometric variables studied or secondary outcomes: diet, physical activity, sleep, perceived stress, or cardiometabolic factors. Using BMI slope as the outcome, we found no evidence of effect modification of the study arms by sex, race and/or ethnicity, household income, and baseline levels of child and parent obesity. Analysis of the effects of exposure to the school fitness program also yielded null direct and indirect effects on BMI slope.

DISCUSSION

Neither of the long-term family interventions tested in this randomized trial improved BMI or weight- and health-related secondary outcomes, nor was there any effect of exposure to the school fitness program. Although the study findings are disappointing, we believe them to be robust because of the considerable strengths of this randomized controlled trial. These strengths include the use of theory-based interventions, a lengthy follow-up period, and excellent study retention. The study was also strengthened by investigator participation in the larger COPTR and an independent coordinating center that facilitated strong quality control of data collection, management, and analyses. Limitations of the study include a moderate level of intervention participation and generalizability restricted to a low-resource, minority, urban population.

Several factors may have contributed to these null findings. Families in the study led challenging lives, which may have interfered with their ability to act on the healthy living information and behavior change techniques taught in the interventions. As shown in Table 1, many lived in high-poverty, sometimes violent, and economically depressed neighborhoods. As examples, during the study, 1 child participant was shot during a drive-by shooting, and several participants were friends of a youth killed in a high-profile police shooting. The disrupted lives of the participants were further indicated by the frequent residence changes of the families; nearly half of the study families changed residences at least once during the 3-year study, and 10% moved 3 or more times. We also found that >30% of children reported being food insecure, and most lived in neighborhoods with limited healthy food options.

It is possible that the lack of effect of the interventions tested was due to the high adolescent baseline BMIs (mean: 95.5 percentile), suggesting that the weight-management behaviors taught in the interventions required a considerable lifestyle behavior change. Also, 76% of the parents were obese, possibly contributing to the lack of effect of our interventions, and nearly one-quarter of parents of children with obesity (>95th percentile) did not believe their child's weight was a concern at baseline. Although the interventions used in this study were codesigned with families before the trial[34] and an intervention-tailoring protocol was included in the interventions, it is possible that more precise tailoring to specific family factors and environmental contexts is needed. Lastly, although the interventions were over a considerable period of time (3 years) and at a dose consistent with recommendations,[35] the timing and dose of childhood obesity interventions have yet to be determined.

Future research should include analyses of stratified subgroups, such as socioeconomic status, sex, age, or race and/or ethnicity. This would provide greater insight into how different groups may respond differently to the same intervention and help tailor future interventions to maximize their benefits. More attention to perceptions of obesity and motivation to make lifestyle changes could be useful before the introduction of other intervention components.

Lessons learned in this study that are relevant to practitioners include the following: (1) education alone is not sufficient to change lifestyle behaviors related to weight management in children; and (2) interventions for low-income, urban-dwelling, minority families likely need to be tailored specifically to the family's personal and environmental characteristics, and referral of families to weight-management programs that provide this personalized, tailored approach is important for sustained lifestyle change.

The null findings from this study are consistent with those of other major trials addressing childhood obesity in low-resourced, minority populations,[14,36,37] including those of the other recently completed COPTR studies.[38,39] This suggests that new approaches are needed to discover effective childhood obesity prevention and treatment interventions for this population. In addition to greater understanding of assisting behavior change that is tailored to specific populations, more research is needed that addresses underlying issues such as poverty and other social determinants of health-promoting behaviors. This may entail more policy-related and whole-community research. Additionally, the effect of biological influences was not taken into account in this study, such as microbiome, metabolic, and genetic influences on body weight.[40,41]

CONCLUSIONS

In this randomized controlled trial, we found no effect of 2 interventions to improve BMI in low-income, urban youth. Family, school, peers, community, and policy provide environmental contexts that shape children's energy intake and expenditure and therefore together influence the development of obesity and its comorbidities. Viewing childhood obesity from this socioecological perspective will assist in developing interventions that are likely to be more powerful in reducing obesity in low-income, urban youth.

ABBREVIATIONS

BP: blood pressure
COPTR: Childhood Obesity Prevention and Treatment Research Consortium
HDL: high-density lipoprotein
IMPACT: Ideas Moving Parents and Adolescents to Change Together
LDL: low-density lipoprotein
WRTC: We Run This City

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