describes the NET-Works 3-year randomized trial primary and secondary outcome results. The researchers hypothesized that the 3-year NET-Works intervention would significantly reduce child BMI increases at 24 and 36 months compared with a usual care comparison group. Preplanned subgroup analyses based on previous research included intervention effect moderation by baseline child overweight status, sex, and Hispanic ethnicity.

METHODS

The Consort Diagram (Figure 1) shows participant recruitment, screening, measurement, and retention data. Participants were recruited in partnership with 12 Minneapolis–St Paul, Minnesota, primary care clinics that serve diverse populations. A child was eligible for the study if the child

1. Was aged between 2 and 4 years,
2. Had no medical problems that would preclude study participation,
3. Did not use any medications that would affect the child's growth,
4. Had body mass index (BMI) greater than or equal to the 50th percentile according to Centers for Disease Control and Prevention age and sex reference standards,
5. Had a family income of less than $65 000 per year,
6. Had a parent who agreed to participate in the study and did not plan to move out of the state in the next 3 years,
7. Had a parent who was willing and able to complete the evaluation measures and participate in intervention activities, and
8. Had a parent who spoke English or Spanish.

A BMI of greater than or equal to 50th percentile was an eligibility criterion because the trial was an obesity-prevention intervention and low-income, racial/ethnic minority children with BMI of 50th to 85th percentile were considered at risk for excess weight gain. Among those screened, 37% of children with Spanish-speaking parents and 15% of children with English-speaking parents were randomized. Among both English- and Spanish-speaking parents, the primary reason for not proceeding from telephone screening to enrollment and randomization was lack of interest in participating in the study.

Study Design, Measurement Protocol, and Randomization

The study was a 2-arm, randomized controlled trial with the child as the unit of randomization and evaluation.[14] Children whose families completed the minimum baseline measures were randomized to the intervention or to a usual-care comparison group for a 3-year period. These minimum measures included (1) measured child weight and height, (2) 2 parent-reported child 24-hour dietary intake recalls, (3) 4 days of valid child accelerometry data (6 hrs/d minimum), and (4) parent-reported household demographic questions. The study coordinator assigned children to condition according to age-by-gender stratified block randomization schedules. Over an 18-month period, 534 children were randomized (July 2012–January 2014). All investigators and data collection staff remained blinded to random assignments until all follow-up data were collected.

NET-Works Intervention Program

Intervention settings and strategies were chosen on the basis of social ecological theory,[14] previous research,[15,16] and potential for dissemination and sustainability of the intervention.[17,18] The intervention program consisted of home visiting, community-based parenting classes, and telephone check-in calls. Referrals to community resources for healthy foods and physical activity opportunities were embedded in the home visiting and parenting class components. Intervention component curricula were developed and pilot tested by the researchers and designed to be synergistic. The home visit setting enabled behavior and home environment change strategies to be tailored for individual families, and the parenting class setting provided group support for behavior changes. Target behaviors and behavior change strategies were similar across the home visiting and parenting class components. Planned intervention dose was the same across all 3 intervention years.

Trained professionals with a minimum of a bachelor's degree and several years of experience working with families and children conducted the home visiting and parenting class components. Home visits were about 1 hour in duration and were planned for monthly intervals with telephone check-in calls between home visits. Motivational interviewing and behavior change models were used as the intervention foundation.[19] Parenting classes were held weekly for 12 weeks in the communities where the families resided. Efforts were made to accommodate family schedules. The study provided or reimbursed transportation. Referrals to community resources were designed to support parent and family use of food and physical activity resources in their neighborhood and were implemented through the home visits, parenting classes, and check-in calls.

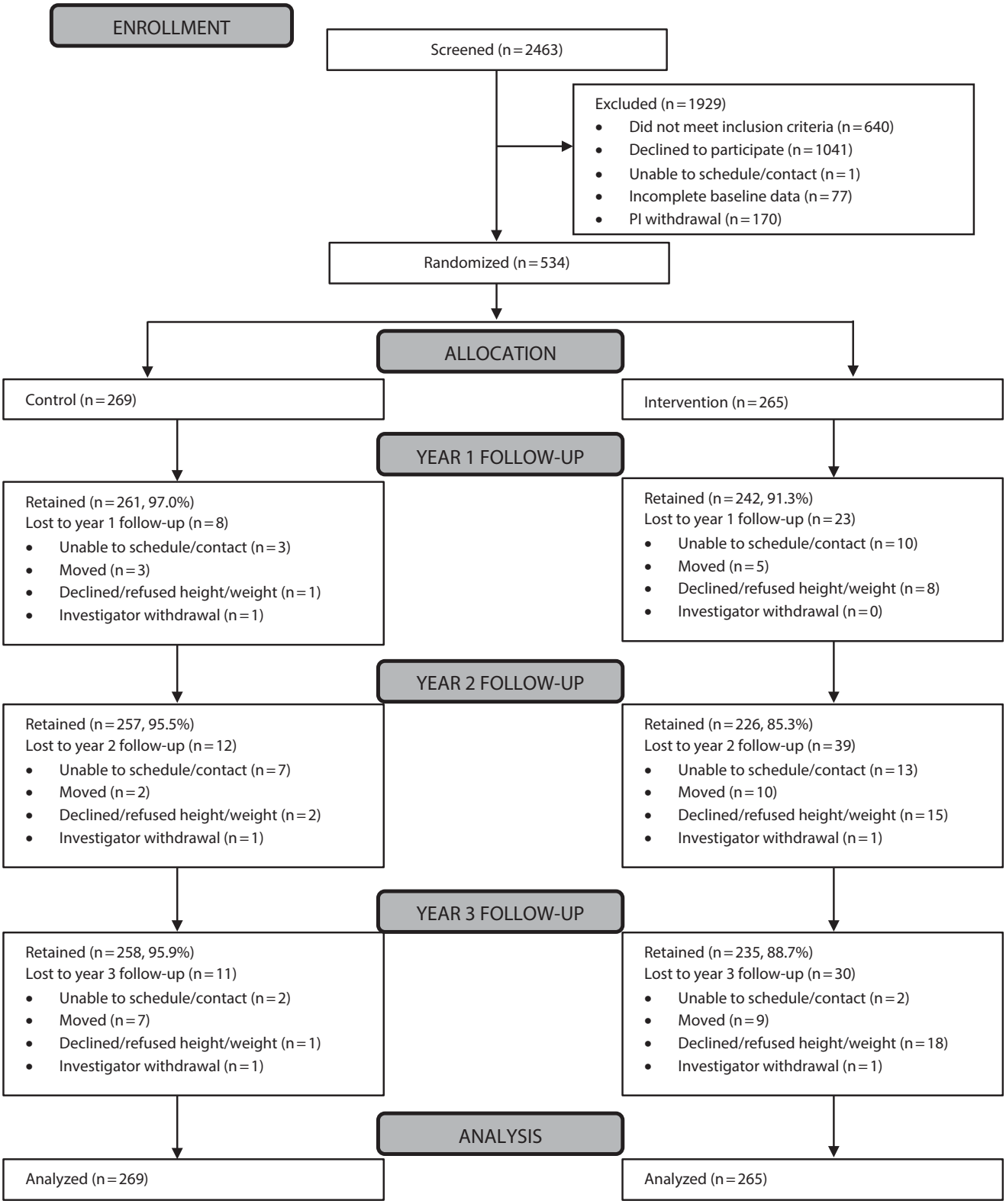
Usual Care Comparison Condition

A primary care provider intervention component was included for both intervention and usual care groups. Providers were trained to discuss child BMI with the parent at the annual well-child visit, by using a study-provided pamphlet with the child's BMI percentile and messages about healthful eating and physical activity for the child. In addition, parents randomized to the comparison condition received quarterly postcards that focused on child development and school readiness.

NET-Works Treatment Fidelity and Process Evaluation

Treatment fidelity measures were collected throughout the study for each intervention component (home visiting, parenting classes, and check-in calls) and included measures of implementation, dose delivered and received, and qualitative measures of intervention engagement.[20,21] Home visitors collected treatment fidelity data following each home- or phone-based interaction with parents. Parenting class educators completed treatment fidelity measures after each class session. Process evaluation staff not involved in the intervention activities described previously or the data collection activities described in the following paragraphs conducted phone surveys with study participants in both conditions every 6 months.

All anthropometric and survey measurements were collected at baseline, 12, 24, and



Note. Numbers retained at each follow-up include children who had measured body weight and height at that measurement time point. The 24- and 36-month primary outcome analyses were conducted using multiply imputed data sets that included measured data from all randomized children (control group n = 269 and intervention group n = 265) and imputed values for missing body weight and height (analyzed n = 534).

FIGURE 1—CONSORT Diagram for the NET-Works Trial: Minneapolis–St Paul, MN, 2012–2017

36 months in the participant's home by 2 trained and certified data collection staff who were not involved in intervention activities and were blinded to random assignment. Surveys were verbally administered in English or Spanish.

Body Mass Index

Weight and height were measured for both the child and the parent, with the participant in light clothing without shoes according to a standardized protocol.[22] Weight was measured to the nearest 0.1 kilogram by using research precision-grade, calibrated, digital scales and height was measured to the nearest 0.1 centimeter by using a free-standing stadiometer (Seca Corp, Hanover, MD). Measures were conducted in duplicate and averaged. The BMI was calculated as weight in kilograms divided by the square of height in meters. The BMI age- and sex-specific percentile was calculated for children.[23] We used BMI as the primary outcome because BMI-percentile or BMI-z is a less-accurate indicator of body fat for children in the upper extremes of the distribution.[24,25]

Dietary Intake

Child dietary intake was measured with 3 parent-reported 24-hour dietary recalls conducted on 2 weekdays and 1 weekend day with Nutrition Dietary Software for Research (Nutrition Coordinating Center, Minneapolis, MN) software and protocol.[26] Recalls were averaged to compute nutrient intake variables for the child. We examined total energy and diet quality (Healthy Eating Index 2010), dietary fat and saturated fat, added sugars, and servings of fruits and vegetables and sugar-sweetened beverages.

Physical Activity

Accelerometry data were collected on the child and parent by using the GT3X+ and GT3X monitors, respectively (Actigraph, Pensacola, FL). The minimum valid wear time criterion was 4 days (3 weekdays and 1 weekend day) of at least 6 hours of wear time (33% nonzero epochs per hour) between 5:00 AM and 11:59 PM. We converted accelerometry counts to sedentary, light, moderate, and vigorous minutes of physical activity according to accepted cutpoints for preschool-aged children and adults and standardized to a 12-hour day.[27,28] We calculated percentage of accelerometer wear time spent in moderate-to-vigorous physical activity.

TABLE 1—Baseline Characteristics of Participants by Treatment Group in the NET-Works Trial: Minneapolis–St Paul, MN, 2012–2017

	Usual Care (n = 269), % or Mean ±SD	NET-Works (n = 265), % or Mean ±SD	All (n = 534), % or Mean ±SD
Female	50.9	50.9	50.9
Age at randomization, y	3.4 ±0.7	3.4 ±0.7	3.4 ±0.7
2	27.5	28.3	27.9
3	47.6	50.9	49.3
4	24.9	20.8	22.9
Race/ethnicity			
Non-Hispanic White	16.0	9.1	12.6
Non-Hispanic Black	18.6	18.1	18.4
Hispanic, any race	55.0	61.9	58.4
Multiracial	7.8	9.1	8.4
Other	2.6	1.9	2.3
BMI	17.4 ±1.3	17.8 ±2.2	17.6 ±1.8
BMI percentile	82.5 ±13.3	81.0 ±15.2	81.7 ±14.3
Normal: 50% to < 85%	48.3	55.1	51.7
Overweight: 85% to < 95%	31.2	20.0	25.7
Obese: ≥ 95%	20.5	24.9	22.7
Weight, kg	16.8 ±2.5	17.3 ±3.5	17.0 ±3.1
Height, cm	98.1 ±6.5	98.4 ±6.5	98.2 ±6.5
Parent female	91.5	92.1	91.7
Parent age, y	30.8 ±6.1	32.1 ±6.6	31.4 ±6.4
Parent race/ethnicity			
Non-Hispanic White	20.1	15.5	17.8
Non-Hispanic Black	19.0	19.6	19.3
Hispanic, any race	52.4	56.6	54.5
Multiracial	3.7	4.5	4.1
Other	4.8	3.8	4.3
Primary language			
Spanish	50.6	57.0	53.8
English	40.2	36.2	38.2
Other	9.3	6.8	8.1
Parent BMI	30.0 ±7.4	30.3 ±6.6	30.1 ±7.0
Normal: 18 to < 25 kg/m^2	28.6	19.5	24.1
Overweight: 25 to < 30 kg/m^2	29.0	32.2	30.6
Obese: ≥ 30 kg/m^2	42.5	48.3	45.4
Parent weight, kg	76.7 ±20.4	76.7 ±18.9	76.7 ±19.6
Parent height, cm	159.9 ±8.8	158.9 ±8.1	159.4 ±8.5
Highest parental education			
< high school	29.0	37.7	33.3
High school	22.3	21.9	22.1
Some college	16.0	12.5	14.2
Technical degree	12.3	10.6	11.4
Bachelor's degree	12.6	10.6	11.6
Advanced degree	7.8	6.8	7.3

Continued

TABLE 1—*Continued*

	Usual Care (n = 269), % or Mean ±SD	NET-Works (n = 265), % or Mean ±SD	All (n = 534), % or Mean ±SD
Parent employment status			
Full time	23.8	35.9	29.8
Part time	31.2	24.2	27.7
Not working for pay	45.0	40.0	42.5
Annual household income			
≤ $14 999	38.7	36.6	37.6
$15 000–$24 999	24.9	25.7	25.3
$25 000–$34 999	15.6	20.4	18.0
$35 000–$44 999	11.2	8.7	9.9
$45 000–$64 999	9.7	8.7	9.2
Parent marital status			
Living as married	68.0	69.4	68.7
Not living as married	32.0	30.6	31.3
Household configuration			
Dual parent	70.6	73.1	71.9
Single parent	19.7	17.4	18.6
Other	9.7	9.5	9.6
Children living in household			
1	25.7	24.9	25.3
2	39.8	34.7	37.3
3	22.3	26.4	24.3
4 or more	12.3	14.0	13.1
Nonparent child care in own home, h/wk			
0	64.3	67.6	65.9
1–10	22.3	19.6	21.0
11–20	4.5	2.3	3.4
21–30	4.1	5.7	4.9
31–40	2.6	3.0	2.8
≥ 41	2.2	1.9	2.1
Nonparent child care in other's home, h/wk			
0	59.1	62.6	60.9
1–10	21.6	19.6	20.6
11–20	9.7	8.3	9.0
21–30	3.0	5.7	4.3
31–40	4.8	1.5	3.2
≥ 41	1.9	2.3	2.1
Nonparent child care in child care center, h/wk			
0	76.2	77.0	76.6
1–10	8.6	6.0	7.3
11–20	4.8	5.3	5.1
21–30	2.6	1.9	2.3
31–40	5.6	5.7	5.6
≥ 41	2.2	4.2	3.2
WIC participation	69.1	64.9	67.0
SNAP participation	42.5	43.4	43.0
Federal program income	11.2	10.9	11.1
Food security			
Secure	65.7	59.4	62.6
Insecure	28.3	34.1	31.2
Insecure with hunger	6.0	6.5	6.3

Note. BMI = body mass index; cm = centimeter; kg = kilogram; m = meter; SNAP = Supplemental Nutrition Assistance Program; WIC = Special Supplemental Nutrition Program for Women, Infants, and Children.

Screen Time

We computed child television viewing and computer use by using the parent-reported average hours per day the child spent watching television (2 questions) and using a computer (1 question).[9] We computed total weekly average media hours by adding the estimated average daily hours of television viewing and computer use.

Demographic Variables

Parents reported demographic information including child age, sex, race and ethnicity, parent employment status, household income, marital status, educational attainment, number of children and adults living in the household, childcare hours per week, and food assistance program (Special Supplemental Nutrition Program for Women, Infants, and Children and Supplemental Nutrition Assistance Program) participation.

Statistical Analyses

We used 2 general linear mixed models to evaluate treatment group differences in the primary outcome, change in child BMI at 24 and 36 months relative to baseline.[29,30] One model predicted BMI at 24 months, the other at 36 months. Fixed effects were treatment group and the prespecified covariates sex, baseline age group (2, 3, or 4 years), and baseline BMI. A random intercept and unspecified within-cluster covariance matrix accounted for dependence among intervention children whose parents received the home visiting component of the intervention from a common home visitor (NET-Works n = 265; 7 clusters), with each comparison child designated as a separate cluster (usual care n = 269 children; 269 clusters).[31] We used these same specifications to evaluate treatment group differences in all secondary outcomes, adapting the link function for binary (logit) and Poisson-distributed (log) variables.

We applied a generalized Holm procedure to the *P* values for the 24- and 36-month treatment group effects to ensure a family-wise type I error rate of 0.05 for the primary and secondary outcomes.[32] It was performed by setting critical α to 0.025 for the larger of the 24- and 36-month effects; if significant, we tested the smaller at $P < .05$.

TABLE 2—Primary and Secondary Outcomes Results at 12, 24, and 36 Months in the NETWorks Trial: Minneapolis–St Paul, Minnesota, 2012–2017

	Usual Care, No. (%) or Mean ±SD[a]	NET-Works, No. (%) or Mean ±SD[a]	Treatment Group Effect (95% CI)[b]
Anthropometry			
Sample size			
Baseline	269	265	
12 mo	261 (97.0)	242 (91.3)	
24 mo	257 (95.5)	226 (85.2)	
36 mo	258 (95.9)	235 (88.7)	
Body mass index, kg/m^2			
Baseline	17.4 ±1.3	17.8 ±2.2	
12 mo	17.4 ±1.7	17.5 ±2.6	
24 mo	17.7 ±2.2	17.9 ±2.9	−0.12 (−0.44, 0.19)
36 mo	18.3 ±2.7	18.4 ±3.3	−0.19 (−0.64, 0.26)
BMI-*z*			
Baseline	1.1 ±0.7	1.2 ±1.0	
12 mo	1.2 ±0.8	1.2 ±1.0	
24 mo	1.2 ±0.8	1.2 ±0.9	−0.05 (−0.17, 0.07)
36 mo	1.2 ±0.8	1.2 ±0.9	−0.07 (−0.23, 0.08)
BMI percentile			
Baseline	82.5 ±13.3	81.0 ±15.2	
12 mo	82.2 ±16.6	79.5 ±18.9	
24 mo	82.1 ±17.5	81.1 ±18.1	0.30 (−2.62, 3.22)
36 mo	81.9 ±18.1	81.1 ±18.8	−0.33 (−3.93, 3.26)
BMI percentile relative to 95th percentile			
Baseline	95.6 ±6.9	97.5 ±12.1	
12 mo	96.3 ±9.6	97.3 ±14.3	
24 mo	96.5 ±12.2	97.5 ±15.8	−0.90 (−2.44, 0.63)
36 mo	96.3 ±14.1	97.2 ±17.2	−1.17 (−3.30, 0.96)
BMI ≥ 95th percentile			
Baseline	55 (20.5)	66 (24.9)	
12 mo	63 (24.1)	60 (24.8)	
24 mo	73 (28.4)	64 (28.3)	0.87[c] (0.53, 1.42)
36 mo	82 (31.8)	68 (28.9)	0.68[c] (0.41, 1.14)
Weight, kg			
Baseline	16.8 ±2.5	17.3 ±3.5	
12 mo	19.6 ±3.4	20.0 ±4.6	
24 mo	22.5 ±4.3	23.0 ±5.7	−0.15 (−0.56, 0.27)
36 mo	26.0 ±5.6	26.5 ±6.8	−0.29 (−0.91, 0.33)
Waist circumference, cm			
Baseline	52.4 ±4.1	53.3 ±6.0	
12 mo	55.0 ±5.3	55.4 ±7.1	
24 mo	57.3 ±6.5	57.5 ±7.4	−0.06 (−1.10, 0.99)
36 mo	60.6 ±8.0	60.9 ±8.7	−0.58 (−1.91, 0.76)

Continued

The a priori power analyses estimated the minimum detectable treatment group effect on BMI at 24 or 36 months relative to baseline assuming n = 500 (n = 250 in each group); 15 intervention children per cluster (ICC); NET-Works ICC = 0.01–0.03; usual care ICC = 0; $SD_{BMI} = 2.35$; baseline follow-up autocorrelation within clusters (NET-Works r = 0.30–0.50; usual care r = 0) and children (r = 0.40–0.60)[33]; and retention (75%–85%). We powered the trial to detect between-group differences of Cohen's d = 0.28 ($\alpha = 0.025$) to 0.31 ($\alpha = 0.05$) for median values of these assumptions, corresponding to BMI differences of 0.65 to 0.72 kilograms divided by the square of height in meters (kg/m^2). The observed ICC among children with a common home visitor was 0.003 at 24 months and 0.00 at 36 months. The independent Research Coordinating Unit statistician replicated primary outcome analyses.

Planned secondary analyses assessed whether treatment effects at 24 and 36 months were modified by baseline BMI, sex, or baseline age. Enrollment among families of Hispanic ethnicity was higher than anticipated, making a moderation analysis by ethnicity feasible.

Ad hoc linear mixed models within the intervention group estimated associations between intervention participation accumulated from baseline to 24 or 36 months and change in BMI at 24 or 36 months, with adjustment for age and sex. We estimated these associations among intervention families and separately by Hispanic ethnicity status and baseline child overweight status.

We multiply imputed missing values for the primary and all secondary outcomes from all covariates in the primary analytic models (treatment group, age, sex, baseline BMI, baseline value, home visitor) and auxiliary variables (observed outcome values, race/ethnicity, primary parent education, highest household education, annual household income). We performed all primary, secondary, and ad hoc inferential analyses, including estimates of the treatment effect and 95% confidence intervals (CIs), on the 20 imputed data sets.

RESULTS

Cohort demographics are shown in Table 1 by treatment group. Fifty-eight percent of the children were Hispanic and 62.9% had annual household incomes of less than $25 000 per year. We defined postbaseline retention as having a measured body weight and height for the child. Overall cohort

TABLE 2—*Continued*

	Usual Care, No. (%) or Mean ±SD[a]	NET-Works, No. (%) or Mean ±SD[a]	Treatment Group Effect (95% CI)[b]
Triceps skinfold, cm			
Baseline	11.2 ±2.7	11.6 ±3.9	
12 mo	11.1 ±3.4	11.4 ±4.0	
24 mo	11.9 ±4.6	11.9 ±4.7	−0.25 (−1.52, 1.02)
36 mo	13.1 ±5.3	13.1 ±5.6	−0.35 (−1.62, 0.92)
Primary adult BMI, kg/m^2			
Baseline	29.9 ±7.4	30.3 ±6.7	
12 mo	30.2 ±7.6	30.9 ±6.6	
24 mo	30.4 ±7.6	31.3 ±6.9	0.42 (−0.51, 1.35)
36 mo	30.7 ±7.5	31.1 ±6.7	−0.20 (−1.10, 0.71)
Dietary intake			
Sample size			
Baseline	269	265	
12 mo	257 (95.5)	227 (85.7)	
24 mo	243 (90.3)	217 (81.9)	
36 mo	246 (91.4)	230 (86.8)	
Energy, kcal/d			
Baseline	1052 ±323	1040 ±3329	
12 mo	1158 ±345	1045 ±316	
24 mo	1283 ±374	1171 ±358	−90.3 (−164.3, −16.4)
36 mo	1434 ±379	1316 ±381	−100.8 (−164.3, −37.3)
Fat, % kcal			
Baseline	28.9 ±6.0	28.7 ±5.9	
12 mo	29.7 ±5.4	28.7 ±6.0	
24 mo	30.0 ±5.5	28.9 ±5.4	−0.75 (−2.05, 0.55)
36 mo	30.0 ±5.3	29.4 ±5.4	−0.50 (−1.67, 0.66)
Saturated fat, % kcal			
Baseline	10.8 ±2.9	10.6 ±3.0	
12 mo	10.5 ±2.6	10.3 ±2.5	
24 mo	10.6 ±2.4	10.3 ±2.3	−0.26 (−0.74, 0.21)
36 mo	10.6 ±2.5	10.3 ±2.4	−0.16 (−0.67, 0.35)
Healthy Eating Index			
Baseline	62.8 ±12.2	64.7 ±10.9	
12 mo	63.3 ±12.3	65.0 ±12.3	
24 mo	63.9 ±11.3	65.3 ±11.1	0.67 (−1.29, 2.64)
36 mo	64.6 ±11.4	66.5 ±11.2	0.89 (−1.40, 3.20)
Added sugars, g/d			
Baseline	31.3 ±20.9	30.7 ±19.8	
12 mo	34.3 ±19.2	31.3 ±18.5	
24 mo	37.7 ±19.8	33.9 ±20.7	−3.31 (−7.33, 0.70)
36 mo	43.2 ±22.5	37.1 ±21.2	−5.70 (−10.38, −1.01)
Sugar-sweetened beverages, servings/d			
Baseline	0.5 ±0.6	0.4 ±0.6	
12 mo	0.4 ±0.5	0.4 ±0.5	
24 mo	0.4 ±0.5	0.4 ±0.6	1.02[d] (0.72, 1.44)
36 mo	0.5 ±0.5	0.4 ±0.5	0.84[d] (0.63, 1.12)

Continued

retention was high: 94.2%, 90.4%, and 92.3% at 12, 24, and 36 months, respectively (Figure 1). More participants were retained in the comparison group than in the intervention group (12 months: 97.0% vs 91.3%; 24 months: 95.5% vs 85.3%; 36 months: 95.9% vs 88.7%, respectively; all $P < .05$). Two children died, before 12 and 24 months, of causes not attributable to study participation, and were withdrawn from subsequent measurements.

NET-Works Treatment Fidelity

Families received an average of 35.4 contacts over 3 years (15.5, 10.9, and 8.6, in years 1, 2, and 3, respectively). Families received an average of 18.3 home visits (of 36 intended; 50% of the intended dose), 9.3 parenting classes (25% of the intended dose), and 7.4 check-in calls (58% of the intended dose).

Primary and Secondary Outcomes

There were no significant between-group differences in the primary outcome of the child's adjusted BMI at 24 and 36 months (Table 2). The differences in BMI *z* scores and adjusted odds of being in the 95th percentile or higher of BMI for age and sex at 24 or 36 months also did not significantly differ by treatment group. According to parent reports, NET-Works children consumed fewer kilocalories (kcal) per day at 24 (–90 kcal; 95% CI = –164, –16) and 36 months (–101 kcal; 95% CI = –164, –37) compared with children in the usual care comparison group. Intake of added sugars at 36 months was significantly lower among intervention children (–5.7 g/d; 95% CI = –10.4, –1.0). Changes in specific foods and beverages targeted by the intervention (e.g., fruit and vegetables, sugar-sweetened beverages) did not significantly differ by treatment group at 24 or 36 months.

There were no significant between-groups differences in adjusted moderate-to-vigorous physical activity at either 24 or 36 months. We observed no significant differences in change in sedentary, light, moderate, or vigorous physical activity. Parent-reported television and computer use was significantly lower among children in the NET-Works group compared with children in the usual care group at 24 months (rate ratio [RR] = 0.84; 95% CI = 0.76, 0.94), and television

TABLE 2—*Continued*

	Usual Care, No. (%) or Mean ±SD[a]	NET-Works, No. (%) or Mean ±SD[a]	Treatment Group Effect (95% CI)[b]
Fruits and vegetables, servings/d			
Baseline	1.8 ±1.3	1.8 ±1.2	
12 mo	1.9 ±1.3	1.9 ±1.2	
24 mo	1.9 ±1.3	2.0 ±1.3	1.04[d] (0.93, 1.16)
36 mo	2.1 ±1.3	2.3 ±1.2	1.05[d] (0.97, 1.14)
Fruit and 100% fruit juice, servings/d			
Baseline	1.7 ±1.2	1.8 ±1.1	
12 mo	1.7 ±1.1	1.7 ±1.1	
24 mo	1.8 ±1.2	1.8 ±1.1	0.96[d] (0.86, 1.06)
36 mo	2.0 ±1.3	1.9 ±1.1	0.98[d] (0.88, 1.08)
Fruit, servings/d			
Baseline	1.1 ±1.0	1.2 ±0.9	
12 mo	1.1 ±0.9	1.2 ±0.9	
24 mo	1.2 ±0.9	1.2 ±0.9	1.05[d] (0.91, 1.22)
36 mo	1.3 ±1.0	1.4 ±0.9	1.03[d] (0.93, 1.14)
100% fruit juice, servings/d			
Baseline	0.6 ±0.7	0.6 ±0.7	
12 mo	0.6 ±0.7	0.5 ±0.6	
24 mo	0.7 ±0.7	0.5 ±0.7	0.81[d] (0.67, 0.99)
36 mo	0.7 ±0.8	0.6 ±0.7	0.89[d] (0.71, 1.11)
Vegetables, servings/d			
Baseline	0.6 ±0.6	0.7 ±0.6	
12 mo	0.8 ±0.7	0.8 ±0.7	
24 mo	0.8 ±0.6	0.8 ±0.8	1.03[d] (0.90, 1.18)
36 mo	0.8 ±0.6	0.9 ±0.6	1.09[d] (0.98, 1.21)
Physical activity			
Sample size			
Baseline	269	265	
12 mo	236 (87.7)	214 (80.7)	
24 mo	228 (84.7)	203 (76.6)	
36 mo	217 (80.7)	192 (72.5)	
Moderate or vigorous, std min/d			
Baseline	79.0 ±24.0	78.0 ±24.1	
12 mo	80.8 ±25.0	81.2 ±25.9	
24 mo	81.8 ±26.3	83.3 ±25.4	2.51 (–3.38, 8.41)
36 mo	78.9 ±25.5	76.8 ±23.1	–2.34 (–8.72, 4.03)
Moderate or vigorous, % of weartime			
Baseline	11.0 ±3.3	10.8 ±3.3	
12 mo	11.2 ±3.5	11.3 ±3.6	
24 mo	11.4 ±3.7	11.6 ±3.5	0.35 (–0.47, 1.17)
36 mo	11.0 ±3.5	10.7 ±3.2	–0.33 (–1.21, 0.56)
Vigorous, std min/d			
Baseline	22.1 ±10.0	21.1 ±10.1	
12 mo	24.3 ±10.9	23.7 ±10.9	
24 mo	25.6 ±12.0	25.8 ±11.4	1.07 (–1.28, 3.42)
36 mo	25.3 ±12.2	24.3 ±11.4	–0.74 (–3.63, 2.15)

Continued

viewing alone was significantly lower among the NET-Works group compared with the usual care group at 24 (RR = 0.84; 95% CI = 0.75, 0.93) and 36 months (RR = 0.88; 95% CI = 0.78, 0.99). The NET-Works group television viewing hours decreased by 16% and 12% at 24 and 36 months, respectively, relative to the comparison group.

Moderator Analysis Results

Planned moderator analyses showed that the adjusted increase in BMI of children who were overweight or obese at baseline (≥ 85th percentile) was significantly less among those in the NET-Works intervention compared with those in the usual care group at 24 (–0.44 kg/m^2; 95% CI = –0.87, –0.01) and 36 months (–0.71 kg/m^2; 95% CI = –1.30, –0.12; Figure 2a). There were no treatment group differences at 24 or 36 months among children with baseline BMI less than 85th percentile. Among Hispanic children, the intervention was effective in reducing BMI increases at 36 months compared with the children in the comparison group (–0.59 kg/m^2; 95% CI = –1.14, –0.04; Figure 2b). We did not observe a significant intervention effect for BMI at 36 months among non-Hispanic children. There were no significant differences in treatment response by child sex or baseline age.

Primary Outcomes and Intervention Participation

There were no differences in baseline BMI among children in the NET-Works group as a function of Hispanic ethnicity ($P < .99$) nor was there an interaction between overweight status and Hispanic ethnicity ($P < .75$).

Hispanic parents participated in more intervention sessions (mean = 39.5; 47% of planned contacts) compared with non-Hispanic parents (mean = 27.8; 33%; $P < .02$). This difference resulted from Hispanic parents participating in more home visits (mean = 20.4; 57%) than non-Hispanic parents (mean = 15.0; 42%; $P < .02$). We observed no differences in participation overall or by intervention component among parents of overweight and nonoverweight children. Children whose parents participated in more intervention sessions did not gain less weight

TABLE 2—*Continued*

	Usual Care, No. (%) or Mean ±SD[a]	NET-Works, No. (%) or Mean ±SD[a]	Treatment Group Effect (95% CI)[b]
Moderate, std min/d			
Baseline	56.9 ±15.2	57.0 ±15.6	
12 mo	56.5 ±15.5	57.4 ±16.3	
24 mo	56.3 ±15.8	57.6 ±15.8	1.45 (–2.08, 4.98)
36 mo	53.6 ±15.0	52.5 ±13.9	–1.55 (–5.22, 2.12)
Light, std min/d			
Baseline	211.1 ±30.9	215.2 ±32.2	
12 mo	209.4 ±30.7	214.1 ±31.8	
24 mo	213.4 ±33.4	216.6 ±30.8	1.45 (–6.23, 9.13)
36 mo	212.3 ±34.1	211.0 ±30.1	–4.24 (–14.15, 5.67)
Sedentary behavior, std min/d			
Baseline	430.0 ±45.5	426.8 ±46.7	
12 mo	429.9 ±46.6	424.7 ±48.9	
24 mo	424.8 ±51.0	420.1 ±45.8	–3.26 (–16.56, 10.03)
36 mo	428.8 ±51.4	432.3 ±43.4	7.47 (–6.63, 21.56)
Media use			
Sample size			
Baseline	269	265	
12 mo	258 (95.9)	226 (85.2)	
24 mo	240 (89.2)	205 (77.4)	
36 mo	242 (90.0)	217 (81.9)	
Television and computer time, hrs/d			
Baseline	2.8 ±1.7	2.8 ±1.7	
12 mo	2.9 ±1.7	2.6 ±1.5	
24 mo	2.9 ±1.8	2.5 ±1.4	0.84[d] (0.76, 0.94)
36 mo	2.7 ±1.6	2.4 ±1.5	0.89[d] (0.74, 1.07)
Television viewing, hrs/d			
Baseline	2.3 ±1.3	2.2 ±1.2	
12 mo	2.1 ±1.1	2.0 ±1.1	
24 mo	2.1 ±1.2	1.7 ±1.0	0.84[d] (0.75, 0.93)
36 mo	1.9 ±1.1	1.7 ±1.0	0.88[d] (0.78, 0.99)
Nonacademic computer use, hrs/d			
Baseline	0.5 ±0.9	0.6 ±1.0	
12 mo	0.8 ±1.0	0.6 ±0.9	
24 mo	0.9 ±1.0	0.8 ±0.9	0.86[d] (0.72, 1.03)
36 mo	0.7 ±0.9	0.7 ±0.9	0.94[d] (0.63, 1.39)

Note. BMI = body mass index; CI = confidence interval; cm = centimeter; g = gram; kcal = kilocalories; kg = kilogram; m = meter; std = standard.

[a]Unadjusted means and standard deviations.

[b]Model-estimated difference (NET-Works minus usual care) in outcomes at 24 and 36 mo, adjusted for gender, baseline age, and baseline value with imputed data sets.

[c]Model-estimated odds ratio (NET-Works vs usual care) at 24 and 36 mo, adjusted for sex, baseline age, and baseline value with imputed data sets.

[d]Model-estimated rate ratio (NET-Works vs usual care) at 24 and 36 mo, adjusted for sex, baseline age, and baseline value with imputed data sets.

than children whose parents participated less frequently. Intervention participation was not significantly associated with change in BMI at 24 or 36 months among children in the intervention group as a whole, nor were the associations significant within Hispanic ethnicity and overweight status subgroups.

Safety Monitoring

There were no serious adverse events that were probably or definitely attributable to study participation. Two children died of causes not attributable to study participation and were withdrawn from subsequent measurements.

DISCUSSION

This 3-year, community-based, multicomponent, parent-targeted obesity-prevention intervention designed explicitly for racially and ethnically diverse, low-income families did not have significant effects on child BMI or objectively measured physical activity at 24 or 36 months. Parent-reported child energy intake was significantly lower at both 24 and 36 months in the intervention group compared with the comparison group. Planned moderator analyses showed that the intervention was effective in reducing BMI increases among children who were overweight and obese at baseline. Additional moderator analyses showed that the intervention was effective in reducing BMI increases among children of Hispanic ethnicity.

The multicomponent, high-intensity, accessible intervention was designed to provide a consistent level of support to parents over a 3-year period. Intervention participation was highest during the initial 12 months, the period in which child BMI seemed to be stable compared with gains during the later years of the intervention. It was initially hypothesized that a longer, more intense dose would result in larger reductions in child BMI by the end of 3 years. However, given the competing priorities in these low-income families' lives and changes in life circumstances over a lengthy period, it seems necessary to revisit the optimal dose and type of intervention contact.

In the present study, we observed that intervention families moved in and out of various intervention program components across time. Families may have participated in home visiting for several months, then taken a break for several months because of family circumstances, then later rejoined the home-visiting program. The continuity in contact between the families and their home

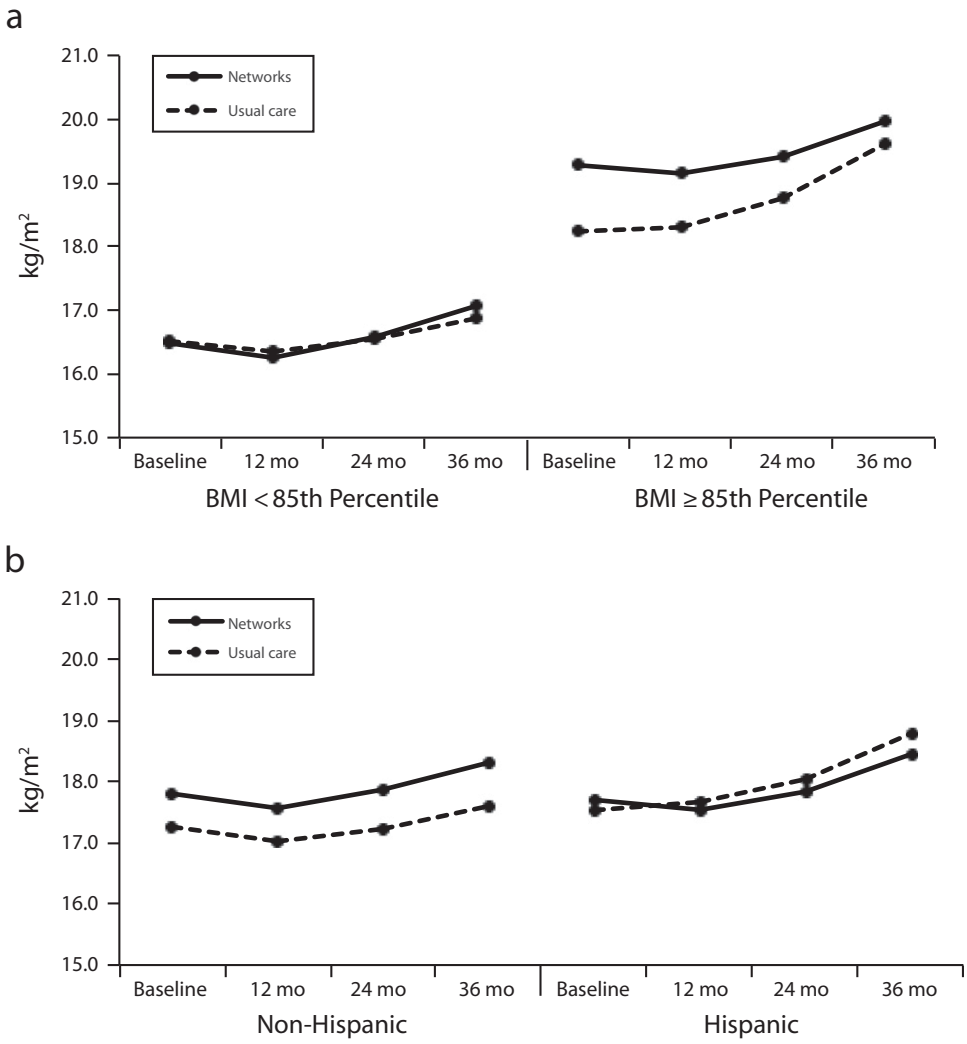


FIGURE 2—Secondary Analysis of Body Mass Index by Treatment Group and Time by (a) Baseline Body Mass Index and (b) Hispanic Ethnicity: NET-Works Trial, Minneapolis–St Paul, MN, 2012–2017

visitors enabled families to receive the intervention contact and dose that was feasible for them across 3 years. Flexible amounts of intervention contact and channels of delivery may optimize results for families at different time points in their lives. Research that evaluates the effectiveness of varied combinations of intervention components and dose could be a useful approach to better understand how best to create family-optimized interventions.[34,35]

A related issue is whether prevention interventions in young children are most effective when focused on children who are already overweight or obese.[4–6] In the present study, about half of the children aged 2 to 4 years were already 85th percentile or higher for age and sex and about 1 quarter were already obese (≥ 95th percentile). Among these children, the intervention was effective in reducing the rate of BMI gain over the 3 years, compared with usual care group children. These results suggest that family-based pediatric obesity interventions may need to focus on children who are already overweight or obese.

The intervention was more effective among Hispanic children compared with non-Hispanic children. In the present study, Spanish-speaking parents constituted about 25% to 28% of the available parents who were initially invited to participate. However, 55% of the sample randomized was of Hispanic ethnicity. These results suggest that Hispanic parents may be attracted to family-based, child-focused health promotion programs that target healthful eating, physical activity, and overall well-child development and that include a delivery format such as home visiting with supportive telephone calls.

Although participation rates were higher among Hispanic parents compared with non-Hispanic parents, participation was not significantly associated with smaller BMI gain among children over the 3 years of the intervention. The reasons for the greater effectiveness among Hispanic children warrant additional research that captures potential variables that might help explain the program's effectiveness on child BMI change.

Possible variables include parent motivation and family support for healthful home environment and parenting changes, and interpersonal processes between the parent and the home visitor. Some of these potential mechanisms are currently being examined with NET-Works home-visiting process evaluation data.

Strengths and Limitations

The present study had many unique strengths, including its low-income, diverse race/ethnicity sample; multilevel intervention delivered with high fidelity and dose over a lengthy time period; state-of-the-science evaluation measures; independent coordinating center; and excellent cohort retention over the 3-year study period.

A limitation of the study was the modest intervention participation relative to the planned dose and differential retention by study arm. If intervention children with higher or more rapidly increasing BMI were less likely to be retained, these results may optimistically estimate the treatment effect. The sample generalizability is tempered by the requirement that participants complete a lengthy set of measurements before enrollment in the study. The self-report measures of dietary intake and television viewing are susceptible to intervention-induced social desirability bias, although they represent the current gold standard methods in the field.

Conclusions

A 3-year, multicomponent, multilevel, parent-targeted behavioral intervention was successful in decreasing child energy intake and television-viewing time, but not in reducing BMI increases or increasing physical activity among preschool-aged children. We observed significant intervention effects on reducing BMI increases at 3 years in children who were overweight or obese at baseline and among Hispanic children. Family-level behavioral interventions may be most effective in children who are already overweight and when delivered through channels that are attractive to parents and at a dose that is tailored to optimize participation. AJPH

CONTRIBUTORS

S. A. French conceptualized and designed the study, wrote the article, consulted on data analysis, and led overall study administration. N. E. Sherwood conceptualized and designed the study, wrote the article, consulted on data analysis, and led overall study administration. S. Veblen-Mortenson contributed to conceptualization and study design, article editing, and study administration. A. L. Crain contributed to study design and was responsible for data analysis and article writing. M. M. JaKa contributed to intervention and measurement design, data interpretation, and article editing. N. R. Mitchell contributed to data analysis and article editing. A. M. Hotop contributed to measurement and data collection and article editing. J. M. Berge contributed to intervention development and implementation, data interpretation, and article editing. A. S. Kunin Batson contributed to measurement conceptualization, data collection implementation, and article editing. K. Truesdale and J. Stevens contributed to measurement development, data collection and analysis activities, and article editing. C. Pratt and L. Esposito contributed to intervention and measurement development and interpretation and article editing.

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HUMAN PARTICIPANT PROTECTION

The study was approved by the University of Minnesota institutional review board. All parents consented to participate.

REFERENCES

1. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of childhood and adult obesity in the United States, 2011–2012. *JAMA*. 2014;311(8):806–814.

2. Institute of Medicine, Committee on the Prevention of Obesity in Children and Youth. *Preventing Childhood Obesity: Health in the Balance*. Washington, DC: Institute of Medicine, National Academies; 2005.

3. Stevens J, Pratt C, Boyington J, et al. Multilevel interventions targeting obesity: research recommendations for vulnerable populations. *Am J Prev Med*. 2017;52(1):115–124.

4. Sherwood NE, JaKa MM, Crain AL, Martinson BC, Hayes MG, Anderson JD. Pediatric primary care–based obesity prevention for parents of preschool children: a pilot study. *Child Obes*. 2015;11(6):674–682.

5. Quattrin T, Roemmich JN, Paluch R, et al. Efficacy of family-based weight control program for preschool children in primary care. *Pediatrics*. 2012;130(4):660–666.

6. Taveras EM, Gortmaker SL, Hohman KH, et al. Randomized controlled trial to improve primary care to prevent and manage childhood obesity: the High Five for Kids study. *Arch Pediatr Adolesc Med*. 2011;165(8):714–722.

7. Gortmaker SL, Peterson K, Wiecha J, et al. Reducing obesity via a school-based interdisciplinary intervention among youth: Planet Health. *Arch Pediatr Adolesc Med*. 1999;153(4):409–418.

8. Caballero B, Clay T, Davis SM, et al. Pathways: a school-based, randomized controlled trial for the prevention of obesity in American Indian schoolchildren. *Am J Clin Nutr*. 2003;78(5):1030–1038.

9. Robinson TN, Matheson DM, Kraemer HC, et al. A randomized controlled trial of culturally tailored dance and reducing screen time to prevent weight gain in low-income African American girls: Stanford GEMS. *Arch Pediatr Adolesc Med*. 2010;164(11):995–1004.

10. Story M, Hannan P, Fulkerson J, et al. Bright start: description and main outcomes from a group-randomized obesity prevention trial in American Indian children. *Obesity (Silver Spring)*. 2012;20(11):2241–2249.

11. Dzewaltowski DA, Rosenkranz RR, Geller KS, et al. HOP'N after school project: an obesity prevention randomized controlled trial. *Int J Behav Nutr Phys Act*. 2010;7(1):90.

12. Fitzgibbon ML, Stolley MR, Schiffer L, Van Horn L, Kaufer Christoffel K, Dyer A. Two-year follow-up results for Hip-Hop to Health Jr: a randomized controlled trial for overweight prevention in preschool minority children. *J Pediatr*. 2005;146(5):618–625.

13. Pratt CA, Boyington J, Esposito L, et al. Childhood obesity prevention and treatment research (COPTR): interventions addressing multiple influences in childhood and adolescent obesity. *Contemp Clin Trials*. 2013;36(2):406–413.

14. Sherwood NE, French SA, Veblen-Mortenson S, et al. NET-Works: linking families, communities and primary care to prevent obesity in preschool-age children. *Contemp Clin Trials*. 2013;36(2):544–554.

15. Olds DL, Kitzman H, Cole R, et al. Effects of nurse home-visiting on maternal life course and child development: age 6 follow-up results of a randomized trial. *Pediatrics*. 2004;114(6):1550–1559.

16. Reynolds AJ, Temple JA, Ou SR, Arteaga IA, White BAB. School-based early childhood education and age-28 well-being: effects by timing, dosage and subgroups. *Science*. 2011;333(6040):360–364.

17. Baker AJ, Piotrkowski CS, Brooks-Gunn J. The Home Instruction Program for Preschool Youngsters (HIPPY). *Future Child*. 1999;9(1):116–133, 192–194.

18. Wagner MM, Clayton SL. The Parents as Teachers program: results from two demonstrations. *Future Child*. 1999;9(1):91–115, 179–189.

19. Miller WR, Rollnick S. *Motivational Interviewing: Preparing People for Change*. 2nd ed. New York, NY: Guilford Press; 2002.

20. Bellg AJ, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol*. 2004;23(5):443–451.

21. Borrelli B, Sepinwall D, Ernst D, et al. A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. *J Consult Clin Psychol*. 2005;73(5):852–860.

22. Lohman TG, Roche AF, Martorell R, eds. *Anthropometric Standardization Reference Manual, Abridged Edition*. Champaign, IL: Human Kinetics Books; 1988.

23. Centers for Disease Control and Prevention, National Center for Health Statistics. CDC Growth Charts: United States. 2000. Available at: https://www.cdc.gov/nchs/data/series/sr_11/sr11_246.pdf. Accessed October 15, 2018.

24. Daniels SR. The use of BMI in the clinical setting. *Pediatrics*. 2009.124(suppl 1):S35–S41.

25. Freedman DS, Butte NF, Taveras EM, et al. BMI z-scores are a poor indicator of adiposity among 2- to 19-year-olds with very high BMIs, NHANES 1999–2000 to 2013–2014. *Obesity (Silver Spring)*. 2017;25(4):739–746.

26. Johnson RK, Driscoll P, Goran MI. Comparison of multiple-pass 24-hour recall estimates of energy intake with total energy expenditure determined by the doubly labeled water method in young children. *J Am Diet Assoc*. 1996;96(11):1140–1144.

27. Trost SG, Pate RR, Freedson PS, Sallis JF, Taylor WC. Using objective physical activity measures with youth: how many days of monitoring are needed? *Med Sci Sports Exerc*. 2000;32(2):426–431.

28. Pate RR, Almeida MJ, McIver KL, Pfeiffer KA, Dowda M. Validation and calibration of an accelerometer in preschool children. *Obesity (Silver Spring)*. 2006; 14(11):2000–2006.

29. Hox J. *Multilevel Analysis: Techniques and Applications*. Mahwah, NJ: Lawrence Erlbaum Associates; 2002.

30. Raudenbush S, Bryk A. *Hierarchial Linear Models: Applications and Data Analysis Methods*. 2nd ed. Thousand Oaks, CA: Sage Publications; 2002.

31. Esserman D, Zhao Y, Tang Y, Cai J. Sample size estimation in educational intervention trials with subgroup heterogeneity in only one arm. *Stat Med*. 2013; 32(12):2140–2154.

32. Keselman HJ, Miller CW, Holland B. Many tests of significance: new methods for controlling type I errors. *Psychol Methods*. 2011;16(4):420–431.

33. Teerenstra S, Eldridge S, Graff M, de Hoop E, Borm GF. A simple sample size formula for analysis of covariance in cluster randomized trials. *Stat Med*. 2012;31(20): 2169–2178.

34. Kugler KC, Balantekin KN, Birch LL, Savage JS. Application of the multiphase optimization strategy to a pilot study: an empirical example targeting obesity among children of low-income mothers. *BMC Public Health*. 2016;16(1):1181.

35. Collins LM, Kugler KC, Gwadz MV. Optimization of multicomponent behavioral and biobehavioral interventions for the prevention and treatment of HIV/AIDS. *AIDS Behav*. 2016;20(suppl 1):S197–S214.