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ORIGINAL INVESTIGATIONS

Child Health Promotion in Underserved Communities

The FAMILIA Trial

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ABSTRACT

BACKGROUND Preschool-based interventions offer promise to instill healthy behaviors in children, which can be a strategy to reduce the burden of cardiovascular disease later. However, their efficacy in underserved communities is not well established.

OBJECTIVES The purpose of this study was to assess the impact of a preschool-based health promotion educational intervention in an underserved community.

METHODS This cluster-randomized controlled study involved 15 Head Start preschools in Harlem, New York. Schools and their children were randomized 3:2 to receive either a 4-month (50 h) educational intervention to instill healthy behaviors in relation to diet, physical activity, body/heart awareness, and emotion management; or their standard curriculum (control). The primary outcome was the change from baseline in the overall knowledge, attitudes, and habits (KAH) score of the children at 5 months. As secondary outcomes, we evaluated the changes in KAH subcomponents and emotion comprehension. Linear mixed-effects models were used to test for intervention effects.

RESULTS The authors enrolled 562 preschool children age 3 to 5 years, 51% female, 54% Hispanic/Latino, and 37% African-American. Compared with the control group, the mean relative change from baseline in the overall KAH score was ~2.2 fold higher in the intervention group (average absolute difference of 2.86 points; 95% confidence interval: 0.58 to 5.14; $p = 0.014$). The maximal effect was observed in children who received >75% of the curriculum. Physical activity and body/heart awareness components, and knowledge and attitudes domains, were the main drivers of the effect (p values <0.05). Changes in emotion comprehension trended toward favoring intervened children.

CONCLUSIONS This multidimensional school-based educational intervention may be an effective strategy for establishing healthy behaviors among preschoolers from a diverse and socioeconomically disadvantaged community. Early primordial prevention strategies may contribute to reducing the global burden of cardiovascular disease. (Family-Based Approach in a Minority Community Integrating Systems-Biology for Promotion of Health [FAMILIA]; NCT02343341) (J Am Coll Cardiol 2019;73:2011–21) © 2019 by the American College of Cardiology Foundation. Published by Elsevier. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

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ABBREVIATIONS AND ACRONYMS

BMI = body mass index

CV = cardiovascular

KAH = knowledge, attitudes, and habits

SES = socioeconomic status

TEC = Test of Emotion Comprehension

Cardiovascular (CV) disease is the leading cause of mortality and morbidity worldwide (1,2). There are alarming trends in the presence of modifiable risk factors and behaviors in children (3), threatening to further negatively impact future rates of mortality and morbidity (4). Data from several large epidemiological studies have documented the excess burden of major CV risk factors (at all stages of life) among African Americans and Hispanics compared with whites (5). Addressing such a disparate population burden of CV risk and disease remains a major clinical and public health challenge (6,7). In this regard, early-life intervention programs focused on healthy lifestyles and CV health that target high-burden communities through schools and families can be effective in reducing CV disease disparities in adulthood (8).

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Over the last few years, we have successfully tested a child health promotion educational program for preschoolers—*the SI! Program*—through cluster randomized trials involving approximately 3,500 children in Colombia and Spain (9,10). The SI! Program is a multidimensional school-based intervention designed to instill healthy lifestyle behaviors early in life that may be carried to adulthood. To date, this type of educational intervention has not been tested in an underserved urban multiethnic community. Therefore, and as a part of a long-term vision regarding global health, we designed the FAMILIA (Family-Based Approach in a Minority Community Integrating Systems-Biology for Promotion of Health) cluster-randomized trial (11). The FAMILIA study aimed to promote healthy behaviors in a minority community using a family-centered approach in the preschool setting that incorporated elements of the SI! Program. As part of the study, children attending Harlem public preschools and their parents/caregivers were recruited. Through their schools, they were randomized to parallel intervention studies and asked to donate genetic materials in an effort to understand the complex relationships between behavior and genomics (12). This paper reports the effects of the health promotion educational intervention on lifestyle-related behaviors among the children participating in the FAMILIA study.

METHODS

STUDY DESIGN, SETTING, AND PARTICIPANTS. The design and rationale of the FAMILIA study has been previously published (11). Briefly, the study is a parallel-group cluster-randomized controlled trial targeting children ages 3 to 5 years old by the end of the enrollment year, and their parents/caregivers from 15 public preschools in Harlem, New York City. Participating schools are part of The Head Start program (U.S. Department of Health and Human Services) that provides comprehensive services to low-income children and their families. During the course of the study, schools participating in FAMILIA agreed not to take part in any other major structured health intervention program aside from the usual curriculum. The trial used a hierarchical design, where the schools were units of randomization, intervention, and analysis; while the second and third level of analysis consisted of the child classroom and the individual children, respectively.

Schools and children were recruited between October 2015 and April 2017, and they were randomized in a 3:2 ratio (3 intervention/2 control). Children were evaluated at baseline (prior to the intervention) and at 5 months (post-intervention). Informed written consent for participation was required from the parents or legal guardians on behalf of their children. The Icahn School of Medicine at Mount Sinai Institutional Review Board approved the study (HS#:14-01054), which was conducted in accordance with institutional and federal guidelines involving human subjects research. The study is registered in ClinicalTrials.gov (NCT02343341).

INTERVENTION. There were 2 levels of intervention (a minimum of 37 h for children and 12 h for parents/caregivers) with a combined total of ~50 h of educational activities. The intervened preschool children received an intensive 37-h educational program over a period of 4 months, as previously described (11). Briefly, the intervention—based on the SI! Program—was designed in partnership with Sesame Street and academic partners in Colombia (Fundacion Cardioinfantil) and Spain (Centro Nacional de Investigaciones Cardiovasculares). It is a multicomponent (promoting healthy diet, increasing physical activity, understanding the human body, and managing emotions) school-based educational intervention. These

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components translate into curricular units that align with the child's age-appropriate development phase and are delivered by the preschool teacher. Teachers were required to provide reports on adherence to the program curriculum and the number of modules delivered to the children. The program curriculum was pilot tested in representative sample from 2 schools and revised as needed in the year prior to initiation of the randomized trial.

Moreover, the intervention included strategies to instill and develop child healthy behaviors that involved the parents (and other family members) of the participating children. Such strategies included invitations to informational and educational meetings, called FAMILIA days, and a minimum of 11 family health activities (12 h) that the teacher regularly provided to parents during the duration of the child educational intervention.

Because the intervention program involved minimal risk, the control arm schools and participants also received the educational program after the initial 4-month randomized trial period, irrespective of the program impact. This was carried out to ensure similar engagement of the control group and to abide by our responsibility as health care providers.

PRIMARY OUTCOME: CHANGE IN KNOWLEDGE, ATTITUDES, AND HABITS SCORE. The primary outcome was the change from baseline in the overall composite knowledge, attitudes, and habits (KAH) score of the child at 5 months (10,13). For assessing KAH, we used a questionnaire first developed in the Colombian Initiative for Healthy Heart Study (9,14), and subsequently used in the SI! Program for Cardiovascular Health Promotion in Early Childhood in Spain (10,13,15). The questionnaire assesses the domains of knowledge (K), attitude (A), and habits (H) in relation to the intervention components: diet (D), physical activity (PA), and understanding of the human body and heart work (BH). We culturally adapted the questionnaire in terms of language format and style. We introduced a slight modification in the section related to dietary habits by eliminating 1 item that was not suitable in the study context and by considering the child as regularly having breakfast unless otherwise specified, given that Head Start program preschools provide breakfast for all children. The details describing the data collection for the study were previously described (11). Briefly, the KAH questionnaire was administered by a trained team of early child education professionals with classroom teaching experience, under the direct supervision of the school staff. The questions in the KAH include prompts and staging to induce a response from the child to assess concepts that the children would have already been exposed to. There are also interactive materials utilized, like circles and a heart, to help the child visually represent what is being asked of him or her. As an example, in relation to physical activity, the questions were based on differentiating between healthy and unhealthy aspects in different domains. For Knowledge, physical activity questions were asked to identify movement, healthy physical activity, or sedentary activity. For Attitudes, questions were asked to identify preferences such as how often do they like to run, jump, and play versus watching television. For Habits, questions were asked for the child to remember what they do at home. Do they run, jump, and play? Do they watch TV?

Children that were unable to comprehend or coherently answer the questions, as in it was observed that there was no understanding of concepts or unable to sustain the interview process, were not included in the study as their responses were considered invalid. All children with at least 80% of the questionnaire completed were included in the analysis. The details of the scoring system were previously described (10,13). Briefly, an overall score (overall KAH, range 0 to 80 points), was derived from the sum of each domain-specific KAH ("K" range 0 to 30 points; "A" range 0 to 30 points, "H" range 0 to 20 points).

SECONDARY OUTCOMES: CHANGE IN TEST OF EMOTION COMPREHENSION SCORE AND BODY MASS INDEX. We used, with permission of the authors, the Test of Emotion Comprehension (TEC) questionnaire and scoring previously described to assess the emotional intervention component (16). The questionnaire assesses 9 domains of child emotional understanding: the recognition of emotions on the basis of facial expression; external causes of emotions; desire-based emotions; belief-based emotions; reminder influence on emotions; emotion regulation; possibility of hiding an emotional state; having mixed emotions; and moral emotion experiences. A general level of emotion understanding was determined by assigning a maximum of 1 point for each component answered correctly, as previously described (16). This produced a maximum of 9 points (success on each component) and a minimum of 0 points (failure on each component).

Body weight and height were measured following previously detailed protocols (11,17). All examinations were performed on small groups of children under the supervision of school staff. Body mass index (BMI) was calculated using the standard formula of weight (kg) divided by the square of height (m^2), and standardized to z-scores according to Centers for Disease

Control references (18) by using the user-written *zanthro* command (19). Nutritional status of the children was assessed following BMI z-score categorization according to international cutoffs: eutrophic (≤+1 SD), overweight (between >+1 SD and +2 SD), and obese (>+2 SD). BMI was not calculated for those children showing a negative height difference >−2 cm between follow-up and baseline, as this suggested a technical error in the measurement. Only standardized values and nutritional categorization are presented.

STATISTICAL ANALYSIS. All study data were first collected on paper, and then entered into a REDCap (Research Electronic Data Capture) database hosted at the Icahn School of Medicine at Mount Sinai, New York (20). To evaluate changes after the intervention, we conducted analyses in those children who had data for the primary outcome (overall score and subcomponents) at baseline and at follow-up coinciding with the end of intervention. Continuous variables are reported as mean ± SD, and discrete variables are reported as frequencies and percentages, unless otherwise specified.

Multilevel linear mixed-effects models that account for the hierarchical cluster randomized design were used to test for the adjusted intervention effect. Fixed effects were the corresponding baseline score (as a continuous variable) and treatment group. Schools and classrooms within each school were handled as random effects. No correction for multiple comparisons was used. The same linear mixed models were applied for the analysis of the change in domains (K, A, and H) and components (D, PA, and BH) of the KAH score, and the change in TEC score and BMI z-score. Interaction models were also fitted to identify possible baseline score-, age-, sex-, race/ethnicity-, and socioeconomic-by-treatment effects for the main outcome variable.

To assess a potential dose-response effect of the intervention, differences in KAH scores between children receiving <50% of the program modules (low adherence) versus those receiving 50% to 75% (intermediate adherence) or >75% (high adherence) of the modules were explored by the use of similar linear mixed-effects models. Data about adherence to the intervention was based on number of modules delivered to the children by the teacher and was collected at the classroom level. Fixed effects were the corresponding baseline score and the categorized adherence to the intervention, while schools were handled as random effect. Post-estimation test of linear hypothesis across categories of adherence to the intervention was performed by using coefficients of orthogonal polynomials.

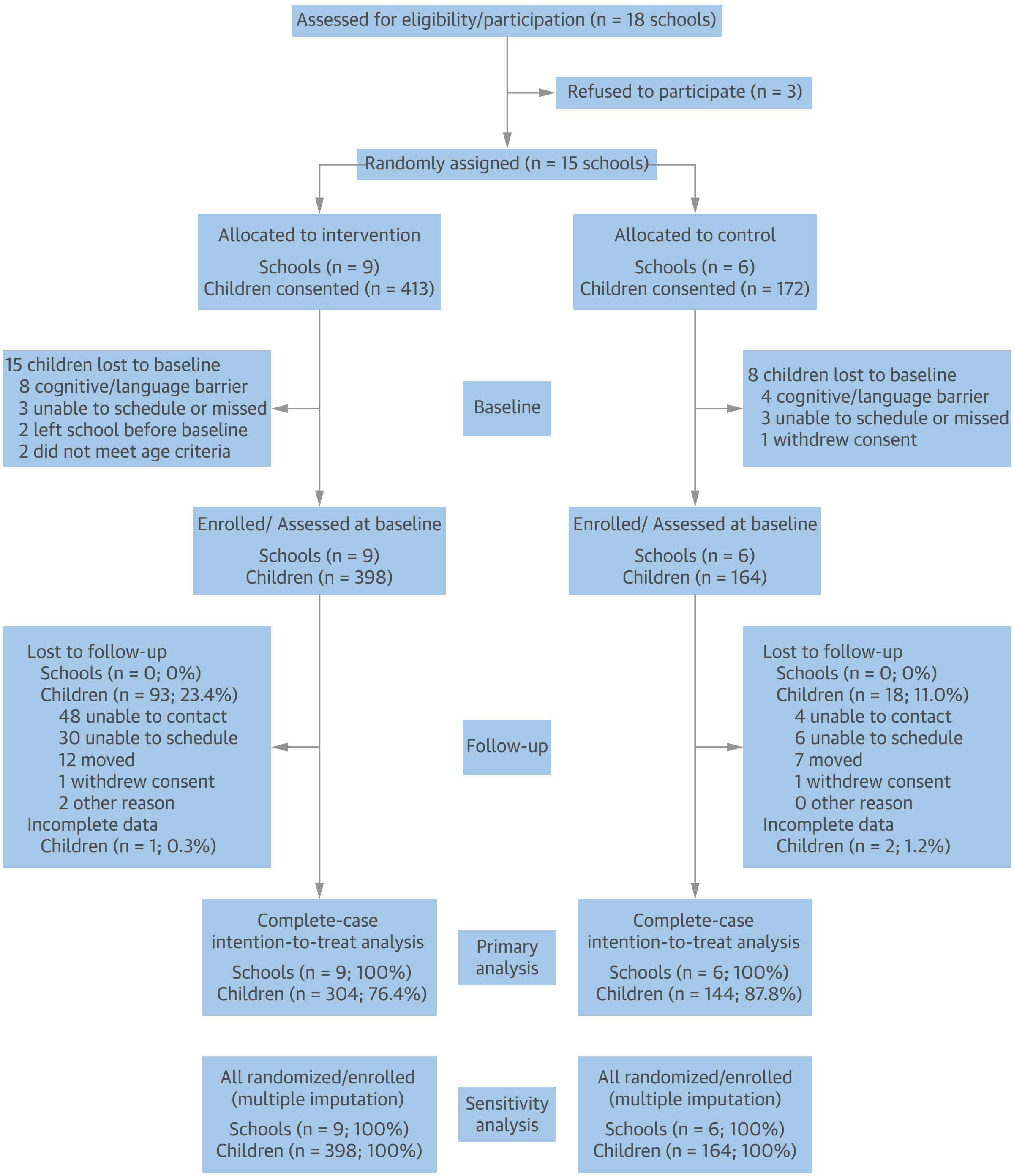
Every attempt was made to follow all enrolled participants irrespective of allocation or treatment withdrawal. All participants were included in the analysis in the groups to which they were randomized. A complete-case intention-to-treat analysis was performed as the main analysis. Under the assumption of missing at random, multiple imputation using multivariate normal distribution (Markov Chain Monte Carlo procedures) was performed to include all randomized enrolled participants as a sensitivity analysis. As an additional sensitivity analysis, reference-based multiple imputation using the control distribution was performed. Details on multiple imputation procedures carried out can be found in Online Appendix Methods. All analyses were performed using STATA version 15 (StataCorp, College Station, Texas).

RESULTS

PARTICIPANT FLOW DIAGRAM AND BASELINE CHARACTERISTICS. The FAMILIA study flow diagram is presented in **Figure 1**. The study enrolled 15 schools of which 9 were randomized to the intervention and 6 to the control condition, totaling 398 and 164 children assessed at baseline, respectively. After a median follow-up of 5.4 months, ~20% of children were lost to follow-up or had incomplete data; therefore, 448 children (304 in the intervention group and 144 in the control group) were included in the main analysis (complete-case intention-to-treat analysis) of the primary outcome of the study. No school withdrew from the trial during the study period, and no adverse events were reported. **Table 1** contains a summary of the collected baseline information at the school and children levels. Overall and component-specific baseline KAH scores are also presented. In summary, no significant differences were found between control and intervention groups at baseline, with the exception of a higher proportion of Hispanic/Latino compared with non-Hispanic black children in the intervention group as compared with the control group. No significant differences were observed in baseline demographic or outcome-related variables (KAH score and anthropometric measures) for those children lost to follow-up or with incomplete data compared with the remaining participants included in the analysis either in the intervention or control groups (Online Table 1).

PRIMARY OUTCOME: CHANGE IN OVERALL KAH SCORE AND ITS DOMAINS AND COMPONENTS. Baseline overall KAH scores were 47.3 ± 8.1 and 47.5 ± 8.5 in the control and intervention groups, respectively. **Table 2** presents the changes and differential

FIGURE 1 The FAMILIA Study Flow Chart



Recruitment of schools and children, and completeness of baseline and follow-up measures, according to the guidelines in the CONSORT 2010 statement for the reporting of cluster randomized trials (37). FAMILIA = Family-Based Approach in a Minority Community Integrating Systems-Biology for Promotion of Health.

TABLE 1 Baseline Characteristics of Enrolled Schools and Children in the FAMILIA Study

	Overall	Control	Intervention
Schools			
n	15	6	9
Children/school	37.5 ± 26.1	27.3 ± 18.6	44.2 ± 29.1
Classrooms	66	26	40
Children/classroom	8.5 ± 3.8	6.3 ± 3.4	10.0 ± 3.3
Children			
n	562	164	398
Age, yrs	4.1 ± 0.6	4.0 ± 0.6	4.1 ± 0.6
Female	287 (51.1)	79 (48.2)	208 (52.3)
Race/ethnicity			
Non-Hispanic black	210 (37.4)	82 (50.0)	128 (32.2)
Hispanic/Latino	303 (53.9)	69 (42.1)	234 (58.8)
Other/multiracial	49 (8.7)	13 (7.9)	36 (9.1)
KAH overall score (range 0–80)	47.5 ± 8.4	47.2 ± 7.9	47.7 ± 8.6
KAH-D score (range 0–30)	16.7 ± 4.2	16.4 ± 3.7	16.8 ± 4.3
KAH-PA score (range 0–30)	15.6 ± 4.2	15.2 ± 4.1	15.7 ± 4.2
KAH-BH score (range 0–20)	15.2 ± 4.9	15.5 ± 4.7	15.1 ± 5.0
TEC score (range 0–9)	3.5 ± 1.7	3.7 ± 1.7	3.5 ± 1.7
Nutritional status			
Eutrophic	283 (55.0)	72 (51.1)	211 (56.4)
Overweight	136 (26.4)	44 (31.2)	92 (24.6)
Obese	96 (18.6)	25 (17.7)	71 (19.0)

Values are n, mean ± SD, or n (%). Children's race/ethnicity was self-identified by their parents/caregivers.

BH = understanding of the human body and heart work; D = diet; FAMILIA = Family-Based Approach in a Minority Community Integrating Systems-Biology for Promotion of Health; KAH = knowledge, attitudes, habits; PA = physical activity; TEC = Test of Emotion Comprehension.

changes (intervention vs. control) in overall and component/domain-specific KAH scores for children by treatment group. The mean % relative change from baseline in the overall KAH score was 5.5% and 11.8% in the control and intervention groups, respectively. The average absolute difference in overall KAH was 2.86 points (95% confidence interval [CI]: 0.58 to 5.14 points; p = 0.014) between groups. Overall results were similar when including all randomized enrolled participants (n = 562) after multiple imputation: average absolute difference in overall KAH score of 3.07 points (95% CI: 0.88 to 5.27 points; p = 0.006) between groups. As expected, a slightly smaller effect size was observed when considering missing outcome data in the intervention group to have a distribution identical to the control group (reference-based multiple imputation): average absolute difference in overall KAH score of 2.64 points (95% CI: 0.50 to 4.78 points; p = 0.016) between groups.

By domain-specific KAH scores, the largest changes between intervention and control groups were found in knowledge (difference of 1.62 points; 95% CI: 0.41 to 2.82 points; p = 0.009) and attitudes (mean difference of 1.66 points; 95% CI: 0.26 to 3.05 points; p = 0.020) toward a healthy lifestyle. By component-specific KAH scores, the largest changes between intervention and control groups were found in physical activity (mean difference of 1.10 points; 95% CI: 0.13 to 2.06 points; p = 0.026) and understanding of how the human body and heart work (mean difference of 1.16 points; 95% CI: 0.15 to 2.17 points; p = 0.025). Changes in subdomains of the main components are presented in Online Table 2.

DOSE-RESPONSE EFFECT OF THE INTERVENTION. In the intervention group, 32% of the children (n = 96) received >75% of the educational program modules (high-adherence group) while 39% (n = 120) received between 50% and 75% of the modules (intermediate-adherence group) and 29% (n = 88) received <50% of modules (low-adherence group). Online Table 3 contains a summary of baseline characteristics by adherence group. **Figure 2** presents the change from baseline in the overall KAH score (primary endpoint of the study) for children by adherence group. An overall significant dose-response effect was observed with the largest benefit achieved in the high adherence group (p value for linear trend = 0.029). Compared with the low-adherence group, the high-adherence group showed a significantly larger change from baseline in the overall KAH score (mean difference of 3.10 points; 95% CI: 0.32 to 5.89 points).

DETERMINANTS OF THE INTERVENTION EFFECT. A breakdown of the mean differences (intervention vs. control) in overall KAH score according to several variables of interest is shown in **Figure 3**. This stratified analysis revealed an interaction of the intervention with baseline overall KAH score, with children starting from a lower baseline score benefiting more from the intervention (p for interaction = 0.01). We observed a trend suggesting the largest benefits among 4-year-old, male, and Hispanic/Latino children. Similarly, a greater effect was shown among children from families with relatively higher self-reported annual household income (≥$25,000) and education level (high school or higher). Interactions for age-, sex-, race/ethnicity-, and socioeconomic-by-treatment effects for the main outcome variable did not reach statistical significance.

SECONDARY OUTCOMES: CHANGE IN TEC SCORE AND BMI Z-SCORE. The changes and differential changes (intervention vs. control) in TEC score and BMI z-score for children by treatment group are presented in Online Table 4. Both the intervention and control groups increased their TEC scores at follow-up. A trend toward a higher change in TEC score in intervened children was observed, but it did not reach statistical significance. In regards to BMI, both

TABLE 2 Change in KAH Overall Score Toward a Healthy Lifestyle, and its Domains and Components, in the FAMILIA Study

		Within Group Differences		Between Group Difference	
	Score Range	Control	Intervention	Difference (95% CI)	p Value
KAH overall	0–80	2.62 (1.00 to 4.24)	5.61 (4.36 to 6.86)	2.86 (0.58 to 5.14)	**0.014**
Overall domains					
Knowledge	0–30	1.10 (0.26 to 1.95)	3.16 (2.59 to 3.73)	1.62 (0.41 to 2.82)	**0.009**
Attitudes	0–30	0.47 (−0.83 to 1.78)	2.29 (1.39 to 3.18)	1.66 (0.26 to 3.05)	**0.020**
Habits	0–20	1.04 (0.53 to 1.55)	0.16 (−0.21 to 0.54)	−0.33 (−0.80 to 0.14)	0.170
Overall components					
Diet	0–30	1.87 (1.01 to 2.73)	2.54 (1.92 to 3.16)	0.75 (−0.34 to 1.85)	0.178
Physical activity	0–30	0.20 (−0.69 to 1.08)	0.91 (0.28 to 1.54)	1.10 (0.13 to 2.06)	**0.026**
Body and heart	0–20	0.56 (−0.36 to 1.47)	2.16 (1.51 to 2.82)	1.16 (0.15 to 2.17)	**0.025**

Data are presented as mean differences (95% confidence intervals) as derived from linear mixed-effects models. Fixed effects were the corresponding baseline score and treatment group, while schools and classrooms within each school were handled as random effects. **Bold** p values are statistically significant.

Abbreviations as in Table 1.

the intervention and control groups showed a slight decrease in BMI z-score over the course of the follow-up period with no significant differences between groups. Finally, no significant differences by adherence were detected in the change of TEC score (Online Figure 1) or BMI z-score (Online Figure 2) in intervened children.

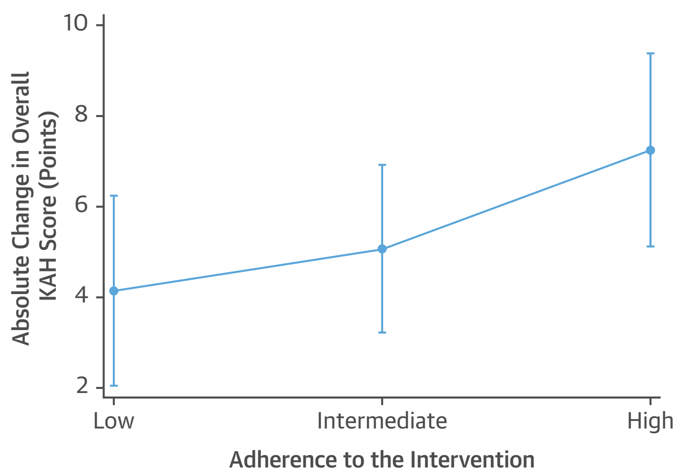
DISCUSSION

The FAMILIA cluster randomized trial demonstrated that a 4-month multidimensional health promotion educational program for preschoolers improved lifestyle-related knowledge and attitudes in an urban, socioeconomically disadvantaged, multiethnic community (**Central Illustration**). The largest improvement was observed in those children with a lower overall KAH score at baseline, and a dose-response effect of the intervention was observed with the greatest benefit seen in those children receiving >75% of the health promotion curriculum. The FAMILIA study included Head Start preschools from Harlem in NYC, which consists of a diverse, predominantly African American and Hispanic population (21). The prevalence of childhood risk factors and unhealthy lifestyle behaviors in Harlem are among the highest in the NYC metropolitan area (22,23). This trial addresses a global health priority challenge and provides support for the use of school-based early-life intervention programs for healthy lifestyles that target high-burden communities as potential effective means in reducing CV disease disparities (5,6).

OVERALL EFFECT SIZE OF THE INTERVENTION. In the preschool setting, many school-based intervention studies have been conducted; however, few have been tested in randomized trials (24). Most studies focused mainly on preventing weight gained by addressing only 1 component of lifestyle, such as diet or physical activity, with overall small intervention effect sizes. Similar issues and overall modest effect sizes have been reported in meta-analyses conducted in older children (25,26).

In this study, and as expected from their standard educational program and normal development, both the intervention and control groups increased their KAH scores at follow-up. However, the change was

FIGURE 2 Dose-Response Effect of the Intervention



Differential changes in the response effect according to adherence to intervention as derived from adjusted predictions (margins of response) after linear mixed-effects models. Data are presented as mean estimates and 95% confidence intervals (CIs) of the absolute change from baseline in overall knowledge, attitudes, and habits (KAH) score. Fixed effects were the corresponding baseline score and the categorized adherence to the intervention: completion of <50% of the program modules (low-adherence group), 50% to 75% (intermediate-adherence group), or >75% (high-adherence group) of modules. Schools were handled as random effect.

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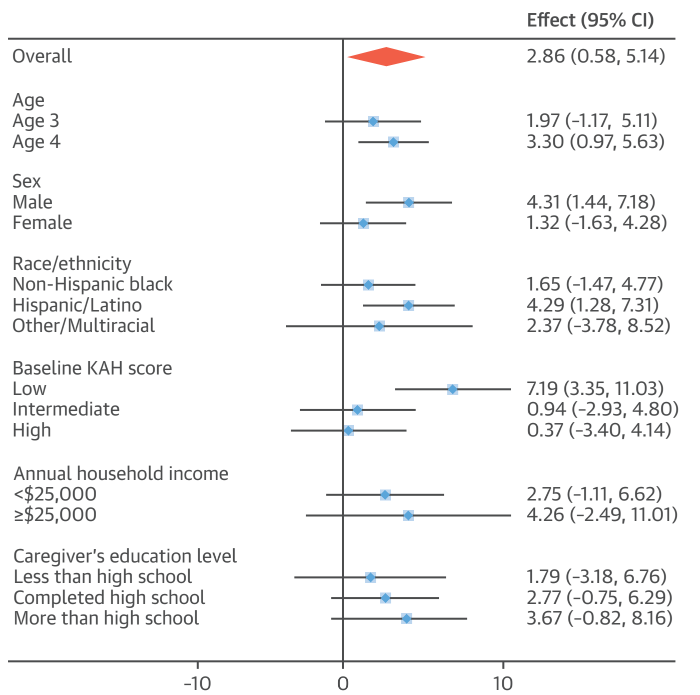
FIGURE 3 Forest Plot of the Primary Outcome in Selected Subgroups



Mean differences (95% confidence intervals [CIs]) in the overall knowledge, attitudes, and habits (KAH) score changes between children in the intervention and control groups, after stratified linear mixed-effects models by selected variables. Fixed effects were the corresponding baseline score (as a continuous variable) and treatment group. Schools and classrooms within each school were handled as random effects. For age subgroup analysis, children age 5 years by the end of enrollment year (n = 14; mean age 5.1 ± 0.1 years) were included in the 4-year category to minimize model convergence failures. For baseline KAH subgroup analysis, the score was categorized in tertiles (low, intermediate, high), and continuous baseline score was not included in the model. Highest annual household income and education level as self-reported by parents/caregivers; data available for 238 and 298 children, respectively.

consistently higher in intervened children for overall KAH and for most of its individual domains and components. The fact that Head Start preschools provide comprehensive services to children and their families may have diminished the ability of the educational intervention to produce a larger impact on overall KAH, and may explain the larger effect size observed in the trial previously conducted in Spain (10,13). Another important factor is socioeconomic status (SES). Other studies have shown that children from higher SES are generally more positively affected by lifestyle interventions, highlighting the need to address obstacles in low-SES settings (27). The mechanisms that predispose underserved children to higher rates of unhealthy outcomes are not well understood (28), but are likely multifactorial with major contributions from a child's access to healthy food, daily activity level, and the health literacy of their parents (29). Further studies, including children from different SES, are needed to study the impact of SES on the success of health promotion interventions along with strategies to address it.

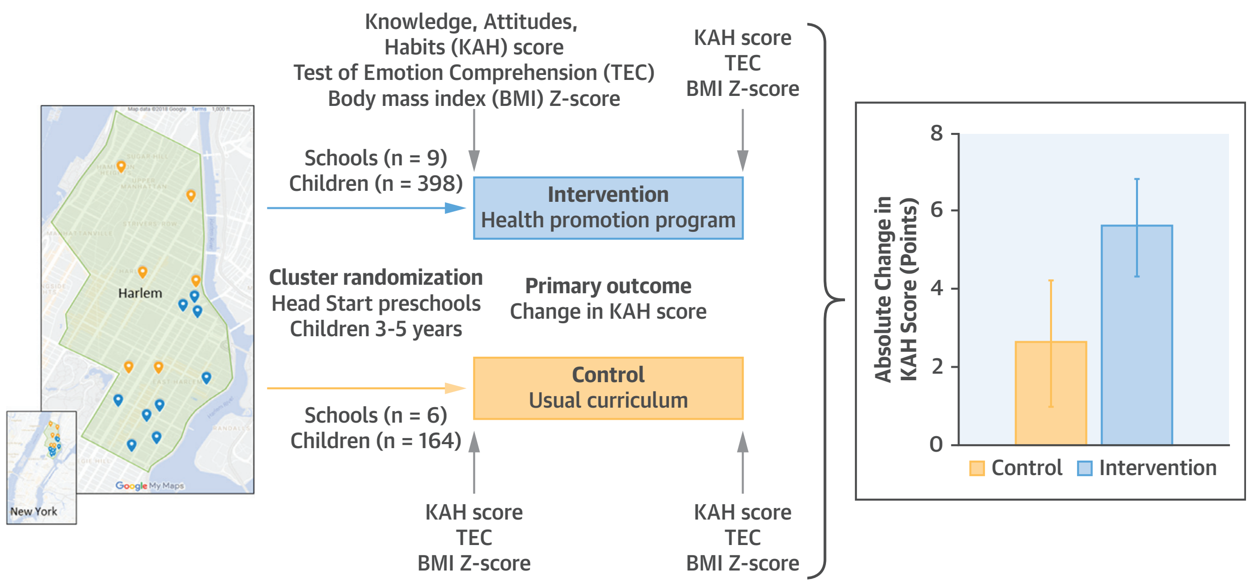
EFFECT BY DOMAINS AND COMPONENTS OF THE INTERVENTION. The results by the intervention domains (K, A, H) are consistent with previous observations in a middle- to high-income urban area of Spain (10,13) and in a low- to middle-income urban area of Colombia (9,14), in which the largest effect was observed for the knowledge and attitudes domains. This is in accordance with the transtheoretical model of sequential behavior change: knowledge to attitudes to habits (30).

Among the intervention components, the largest effect in FAMILIA was observed for physical activity and understanding of the human body and heart, whereas a lesser effect was achieved for the diet component. This finding might be explained because preschools belonging to the Head Start program participating in FAMILIA provide free of charge healthy meals and snacks for children (31). This might constitute ≥90% of their diet (32), reducing the magnitude and variability of response in this component.

DOSE-RESPONSE EFFECT OF THE INTERVENTION AND SUBGROUP ANALYSIS. We observed a dose-response effect with largest benefits shown in those intervened children receiving >75% of the educational program, as delivered by preschool teachers. This confirms the efficacy of the intervention if it was successfully implemented and gives hope that if the intervention is integrated into the standard curriculum, it could have a stronger impact. Also, we could speculate that there might be teacher-related factors affecting the implementation and the efficacy of school-based health promotion programs, which warrants future research. Teachers are one of the cornerstones in children's behavior development as they educate and shape their views and habits, given that children under the age of 5 years spend approximately two-thirds of their time in school (33).

A breakdown of the effect of the intervention suggested larger effects in some specific subgroups. However, the purpose of these subgroup analyses was exploratory, and most of the interactions analyzed did not reach statistical significance, with the exception of baseline KAH score. A larger effect was observed in those children with lower baseline score, as similarly found previously in Spain (13).

CENTRAL ILLUSTRATION Health Promotion Among Preschoolers in Underserved Communities



Fernandez-Jimenez, R. et al. J Am Coll Cardiol. 2019;73(16):2011-21.

Study design and main results of the FAMILIA trial for health promotion among preschoolers. **Bar graphs** represent mean differences and 95% confidence intervals in the overall knowledge, attitudes, and habits (KAH) score changes from baseline in control and intervention groups, as derived from linear mixed-effects models. BMI = body mass index; TEC = test of emotional comprehension.

IMPACT OF THE INTERVENTION ON SECONDARY OUTCOMES: EMOTION MANAGEMENT AND BMI. As an innovative component of the intervention, we introduced the concept of emotion management, which intends to provide very young children with tools to develop protective behaviors against substance abuse and psychological disorders upon reaching adolescence. The lack of a statistically significant improvement in emotional component at this point was expected, and it is in line with previous observations (13). These concepts are difficult to comprehend, and it will therefore take time for this component of the intervention to yield results.

The FAMLIA study did not demonstrate differences in BMI change between groups. With very few exceptions, prevention interventions of <2 years duration on preschoolers have not been successful in improving adiposity markers (24). In fact, 2 recent behavioral intervention trials with long-term follow-up showed conflicting results in regard to reduction in BMI of children (34,35). Our study was not powered to detect differences in BMI, which was unlikely after anticipated follow-up time of 5 months. Nevertheless, we will perform a long-term follow-up at an average of 24 months (11) to evaluate the sustainability and identify any delayed effect of the intervention.

STUDY STRENGTHS AND LIMITATIONS. The inclusion of emotional management as an important behavioral component is an innovative aspect of our intervention, with potential benefits in the transition from childhood to adolescence and young adulthood. Modeled on our previous initiatives, the FAMILIA study chose markers of behavior change (KAH) rather detailed measures of diet or physical activity by comprehensive questionnaires. This assessment is simpler and suitable for direct interaction with preschoolers, thus avoiding reporting (parental) bias. Moreover, acquiring knowledge about key components of a healthy lifestyle at this age is an important goal in itself, as may constitute the basis of sustainable changes in behavior (30). Nevertheless, the improvement in KAH does not necessarily translate into a reduction in CV risk factors or other harder endpoints (36). The long-term sustainability of the intervention effects are to be studied.

Despite implementing intensive retention strategies over the course of the study, ~20% of children were lost to follow-up mainly because preschoolers aged out and moved to other schools and/or residencies. The primary analysis was supplemented by sensitivity analyses conducted using multiple imputation procedures, which explored different assumptions for the distribution of the missing data. Similar results were obtained across these sensitivity analyses. Therefore, we might reasonably assume that the missing data did not significantly affect the validity of our findings.

One of the main strengths of the FAMILIA study is the cluster-randomized controlled design that allows isolation of the effects of the health promotion intervention. For the first time, we successfully adapted our preschool health promotion educational intervention, successfully tested before in Colombia and Spain, in an underserved urban multiethnic community. This constitutes a promising approach to reduce health disparities.

CONCLUSIONS

The FAMILIA trial demonstrates that a multidimensional school-based educational intervention seem to be an effective strategy for instilling healthy behaviors among preschoolers from an urban, underserved, multiethnic community. Physical activity and body/heart awareness components, and knowledge and attitudes domains, were the main drivers of the effect. In contrast, no significant differences between intervened and control children were observed in the change of the diet component and the habits domain. The maximal effect was observed in those children with poor baseline behaviors who received >75% of the health promotion curriculum. A wider adoption of the proposed intervention may have a meaningful impact on health promotion.

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PERSPECTIVES

COMPETENCY IN SYSTEMS-BASED PRACTICE: The preschool years offer a unique opportunity to instill healthy lifestyle behaviors. The FAMILIA trial demonstrates that a multidimensional, multicomponent, school-based health promotion intervention may be an effective strategy for encouraging healthy behaviors among preschoolers from a minority community.

TRANSLATIONAL OUTLOOK: Further research is needed to address factors such as socioeconomic status and teacher characteristics, which may affect the implementation and efficacy of school-based health promotion program.

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KEY WORDS attitude, diet, emotions, exercise, health promotion, vulnerable populations

APPENDIX For an expanded Methods section as well as supplemental tables and figures, please see the online version of this paper.