# Sustainability of and Adherence to Preschool Health Promotion Among Children 9 to 13 Years Old



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#### ABSTRACT

**BACKGROUND** Long-term evaluations of child health promotion programs are required to assess their sustainability and the need for reintervention.

**OBJECTIVES** This study sought to explore the long-term impact of a preschool health promotion intervention delivered in an urban low-income area of Colombia (phase 1) and to assess the effect of a new community-based intervention (phase 2).

METHODS In phase 1, a cross-sectional analysis of knowledge, attitudes, and habits (KAH) toward a healthy lifestyle and ideal cardiovascular health (ICH) scores of 1,216 children 9 to 13 years old was performed. Of the total, 596 had previously received a preschool health promotion intervention at 3 to 5 years old, whereas the remaining 620 were not previously intervened (intervention-naive group). In phase 2, all children were cluster randomized 1:1 to receive either a 4-month educational intervention (the SI! Program) to instill healthy behaviors in community centers (24 clusters, 616 children) or to control (24 clusters, 600 children). Previously intervened and intervention-naive children were not mixed in the same cluster. The primary outcomes were the change from baseline in KAH and ICH scores. Intervention effects were tested for with linear mixed-effects models.

**RESULTS** In phase 1,  $\sim$  85% of children had nonideal cardiovascular health, and those who previously received a preschool intervention showed a negligible residual effect compared with intervention-naive children. In phase 2, the between-group (control vs. intervention) differences in the change of the overall KAH and ICH scores were 0.92 points (95% confidence interval [CI]: -0.28 to 2.13; p=0.133) and -0.20 points (95% CI: -0.43 to 0.03; p=0.089), respectively. No booster effect was detected. However, a dose-response effect was observed, with maximal benefit in children attending >75% of the scheduled intervention; the difference in the change of KAH between the high- and low-adherence groups was 3.72 points (95% CI: 1.71 to 5.73; p<0.001).

**CONCLUSIONS** Although overall significant differences between the intervention and control groups were not observed, high adherence rates to health promotion interventions may improve effectiveness and outcomes in children. Reintervention strategies may be required at multiple stages to induce sustained health promotion effects (Salud Integral Colombia [SI! Colombia II]; NCTO3119792) (J Am Coll Cardiol 2020;75:1565-78) © 2020 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).



Listen to this manuscript's audio summary by Editor-in-Chief Dr. Valentin Fuster on JACC.org. From the <sup>a</sup>Centro Nacional de Investigaciones Cardiovasculares (CNIC), Madrid, Spain; <sup>b</sup>The Zena and Michael A. Wiener Cardiovascular Institute, Icahn School of Medicine at Mount Sinai, New York, New York; <sup>c</sup>Centro de Investigación Biomedica En Red en enfermedades CardioVasculares, Madrid, Spain; <sup>d</sup>Fundación CardioInfantil-Instituto de Cardiologia, Bogotá, Colombia; <sup>e</sup>Universidad del Rosario, Bogotá, Colombia; <sup>f</sup>Universidad de los Andes, Bogotá, Colombia; and the <sup>g</sup>Foundation for Science, Health and Education (Fundación SHE), Barcelona, Spain. \*Drs. Fernández-Jiménez and Briceño contributed equally to this work. This study was funded by the Santo Domingo Foundation. Dr. Fuster is the recipient of funding from the American Heart Association under grant no. 145FRN20490315. Dr. Fernández-Jiménez is the recipient of funding from the Carlos III Institute of Health-Fondo de Investigacion Sanitaria (PI19/01704) and has received funding from the European Union Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement no. 707642. The CNIC is supported by the Instituto de Salud Carlos III (ISCIII), the Ministerio de Ciencia e Innovación and the Pro CNIC Foundation, and is a Severo Ochoa Center of Excellence (SEV-2015-0505). All authors have reported that they have no relationships relevant to the contents of this paper to disclose. Julia Steinberger, MD, MS served as Guest Associate Editor for this paper.

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#### ABBREVIATIONS AND ACRONYMS

BMI = body mass index

CI = confidence interval

CV = cardiovascular

ICH = ideal cardiovascular health

KAH = knowledge, attitudes, and habits

SES = socioeconomic status

he prevalence of cardiovascular (CV) disease is rising disproportionately among low and low/middle-income populations, and the alarming increase in unhealthy behaviors and risk factors among children threatens to have a further negative impact (1). Health promotion programs starting in early childhood have the potential to reduce the global burden of CV disease (2). Some interventions aimed at instilling healthy behaviors in preschool children

have been shown to be effective over the short-term (3). However, long-term assessments are needed to determine whether the effects of interventions are sustained; without this information, it is impossible to firmly establish the value of health promotion reintervention strategies at different stages in children.

In 2009, a preschool-based health promotion program was initiated in an urban low-income area in Bogotá, Colombia (4). In this study, ~1,200 children from 14 preschools were randomized to receive their usual preschool curriculum (control) or an intervention called the SI! Program (Salud Integral-Comprehensive Health), which involved teaching preschool children key messages on the importance of healthy eating and living an active lifestyle. After 5 months, children in the intervention group showed larger increases in knowledge, attitudes, and habits (KAH) toward a healthy lifestyle than the control group (4). After the end of the 5-month intervention, the initial control group received a similar intervention, showing comparable short-term results.

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The main objectives of the present study were to assess the sustained effect of the preschool-based health promotion educational intervention successfully delivered 7 years previously and to evaluate the impact of a new community-centered SI! Programbased health promotion intervention targeting children 9 to 13 years of age on KAH toward a healthy lifestyle and ideal cardiovascular health (ICH) scores.

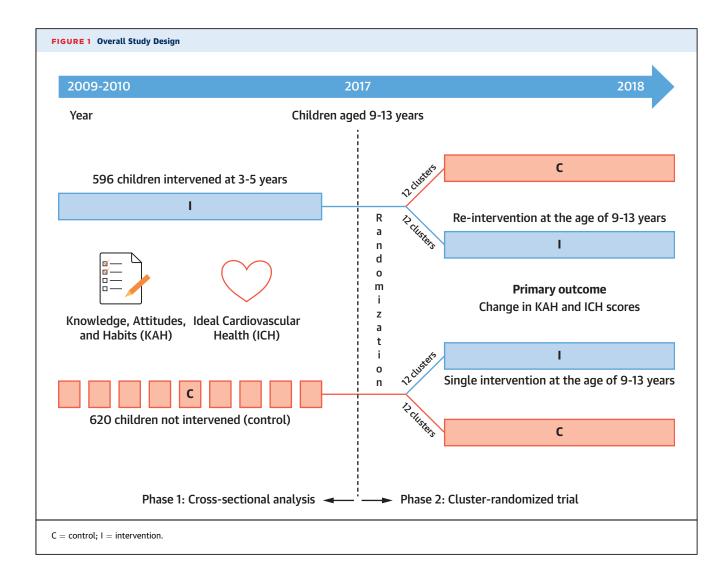
#### **METHODS**

**STUDY DESIGN, SETTING, PARTICIPANTS, AND RANDOMIZATION PROCESS.** Paralleling the 2 main objectives, this study was designed and conducted in 2 consecutive phases (**Figure 1**). In the first phase, we performed a cross-sectional assessment of 1,216 children 9 to 13 years of age from an urban low-income community in Bogotá, Colombia. Of the participating children, 596 had previously received a health

promotion educational intervention (the SI! Program) at preschool (3 to 5 years old) during 2009 to 2010 ( $\sim$ 50% of cohort retention after a 7-year follow-up); the remaining 620 children had not received a previous intervention (intervention-naive group). Children intervened at 3 to 5 years were recruited by a nonprobability sampling method using multiple contact strategies, including location of schools through secretary of education databases, phone calls, e-mails, and school visits. Recruitment strategies included both passive measures (sending circulars to parents, distributing flyers, and putting up posters) and active measures (direct contact with children, noneconomic incentives, and phone calls to parents). Similar strategies were used to recruit intervention-naive children from the schools currently attended by their previously intervened counterparts.

In the second study phase, we conducted a community-based cluster randomized trial. After the initial assessment, all children were assigned to similar-sized clusters (~25 children per cluster, n = 48 clusters in total) according to community center location and time preference (morning/afternoon). Previously intervened (n = 596) and intervention-naive (n = 620) children were not mixed in the same cluster. Thus, a block of 24 clusters consisted of children previously intervened in preschool, and another block of 24 clusters consisted of intervention-naive children. Clusters in each block were randomized 1:1 to control (no intervention) or to receive a 4-month community center-based educational intervention (the SI! Program) aimed at instilling healthy behaviors related to diet, physical activity, body/heart awareness, and emotion management. Thus, the control and intervention groups each consisted of 12 clusters of children previously intervened in preschool and 12 clusters of intervention-naive children. Before being enrolled in the study, all children assented to participate in the study, and their parents/guardians gave informed written consent. The study was conducted according to the Declaration of Helsinki and coordinated by the Fundación Cardioinfantil-Instituto de Cardiología (Bogotá, Colombia) and the Icahn School of Medicine at Mount Sinai (New York, New York). The corresponding local Institutional Review Boards approved the study protocol (CEIC-2836-2016, HS# 16-00820). The study is registered at ClinicalTrials.gov (NCT03119792).

**INTERVENTION.** The intervention description is detailed in the Supplemental Methods and adheres to the Template for Intervention Description and



Replication guidelines (5). The Template for Intervention Description and Replication checklist is presented in Supplemental Table 1. The SI! Program intervention was designed by a multidisciplinary team of experts to improve CV health and KAH toward a healthy lifestyle in children 9 to 13 years of age. The intervention focuses on body and heart awareness, healthy nutrition, promotion of physical activity, and emotion management (Supplemental Table 2). The intervention was delivered in 6 community centers located in the urban districts of Usaquén and Suba (Bogotá, Colombia). The rationale for a community center-based approach was due to the fact that most children were scattered around many different schools in the city, making the school setting logistically unfeasible for implementing the intervention, and was supported in prior communitybased lifestyle interventions targeting children of

similar age (6). Children assigned to the intervention group attended community centers for 4 h on alternate Saturdays over a period of 16 weeks. Children assigned to control clusters attended community centers on alternate Saturdays to receive 8 educational sessions on topics unrelated to promoting a healthy lifestyle including study skills and techniques, executive functions, and time management. Parents and caregivers did not receive any kind of structured intervention.

# DATA COLLECTION. Timeline and general considerations. Participants were evaluated at baseline and at the end of the intervention with the same battery of questionnaires and measurements. Every effort was made to follow up all participants, including those moving to another municipality. Questionnaires were guided and supervised, and measurements were performed in strict accordance

with a standardized protocol by a trained team of pediatricians and pediatric nurses. Information related to socioeconomic status (SES) was collected from adults/caregivers at the time of enrollment. All study data were collected first on paper by research staff from the Fundación Cardioinfantil-Instituto de Cardiología and then managed using REDCap electronic data capture tools hosted at the Icahn School of Medicine at Mount Sinai.

KAH toward a healthy lifestyle. We used a previously developed and validated 29-item questionnaire to assess KAH related to human body and heart awareness (10 items), physical activity (5 items), nutrition (8 items), and emotion management (6 items) in Colombian children 9 to 13 years of age. Details about the development and validation of the KAH questionnaire are presented in the Supplemental Methods and Results (Supplemental Figure 1, Supplemental Tables 3 to 6).

Health metrics. Body weight and height were measured with the participant wearing light clothes and no shoes. Body mass index (BMI) was calculated as body weight divided by height squared (kg/m<sup>2</sup>). Blood pressure values were the mean of up to 3 recordings made with an appropriately sized cuff at 5-min intervals following standard recommended procedures. Blood glucose and total cholesterol were measured in capillary blood sampled with a lancet using the Accutrend Plus (Roche Diagnostics, Indianapolis, Indiana) and Accu-Check Inform II systems (Roche Diagnostics), respectively. Smoking habits were assessed with a self-reported questionnaire that collected information on current and past smoking status and the number of cigarettes smoked per day. Physical activity was assessed with the Quantification de L'Activite Physique en Altitude chez les Enfants questionnaire (7) and was quantified according to both leisure time and transportation-based domains. Dietary intake was assessed with a validated food frequency questionnaire about selected food and drinks in the past month (fruit and vegetables, added sugars, and whole grains/fiber) (8).

SCORE DEFINITIONS. Score of KAH toward a healthy lifestyle. Survey responses were scored on a scale from 0 points (undesirable) to 2 points (desirable). The overall KAH score was derived from the weighted sum of each of the 12 component's subdomains, all ranged from 0 to 8 points (Supplemental Table 5), which comprised the 3 domains (knowledge, attitudes, and habits) for each of the 4 components (human body and heart awareness, physical activity, nutrition, and emotion management). Thus, each overall KAH domain (knowledge, attitudes, and habits) was scored from 0 to 32 points, each overall intervention component (human body and heart awareness, physical activity, nutrition, and emotion management) was scored from 0 to 24 points, and the overall KAH score ranged from 0 to 96 points. The analysis included all children with at least 90% of the questionnaire completed.

ICH score. As clinically relevant measures, the American Heart Association metrics for assessing ICH in children were followed as precisely as possible (9). The calculation of each American Heart Association metric is detailed in the Supplemental Methods. The 7 CV health factors and health behaviors (BMI, blood pressure, total cholesterol, blood glucose, smoking, physical activity, and dietary intake) were classified into 3 levels (poor = 0points, intermediate = 1 point, ideal = 2 points; total score: 0 to 14 points) (10). Participants were further categorized into 3 CV health groups as previously described (11). Thus, a value of 1 was assigned for each metric if the criterion for ICH was met. If the criterion was not met, the assigned value was 0. The range of scores was thus 0 to 7, with a higher score indicating a better CV health profile. A low ideal CV health score was defined as ≤3 ideal metrics, an intermediate score as 4 or 5 ideal metrics, and an ICH score as 6 or 7 ideal metrics (11).

HYPOTHESIS AND ENDPOINTS. The 2 main hypotheses mirrored the main study objectives. First, we tested the hypothesis that children previously intervened at preschool age would show a minimal or nonresidual effect after 7 years of follow-up compared with intervention-naive children. The primary endpoint was the difference in KAH and ICH between previously intervened intervention-naive children, as evaluated by the continuous scale scores. Second, we tested the hypothesis that a community-based health promotion intervention would demonstrate a beneficial effect in promoting CV health. The primary endpoint was the between-group difference (control vs. intervention) in the change from baseline in KAH toward a healthy lifestyle and/or in ICH scores, as evaluated by the continuous scale scores.

Secondary outcomes included the evaluation of differences and changes in subdomains and subcomponents of the KAH and ICH scores and an analysis of the effect of receiving an educational intervention only at the age of 9 to 13 years versus those receiving this as a reintervention 7 years after participating in the preschool SI! Program (booster effect).

**STATISTICAL ANALYSIS.** The sample size calculation and methods used for univariate analysis are detailed in the Supplemental Methods. For the first objective, we analyzed data obtained at baseline assessment. Mixed-effects linear regression models that account for the child and family levels were used to evaluate the adjusted effect of a previous preschool health promotion educational intervention (previously intervened vs. intervention-naive children) on KAH and ICH continuous scores. Models were adjusted for child age, sex, categorized BMI, and family SES. A similar strategy using mixed-effects ordered logistic regression models was used to assess differences in ICH score categories and health components. Multiple comparison adjustment was performed with the Bonferroni method for secondary outcomes, and differences were considered statistically significant at a 2-sided p value < 0.05.

For the second objective, we analyzed data obtained at baseline and post-intervention assessments. Linear mixed-effects models that account for the hierarchical cluster randomized design were used to test for the adjusted intervention effect (change from baseline in KAH or ICH scores). Fixed effects were the corresponding treatment group, whereas clusters and families were handled as random effects. The same linear mixed models were used to analyze changes in KAH score domains and components. Mixed-effects logistic regression models were used to assess between-group differences in the proportion of participants exhibiting a healthy change in any of the health factors or behaviors included in the ICH score. Interaction models were also fitted to identify possible by-treatment effects of baseline score, age, sex, and SES on the main outcome variables. A similar strategy was used to assess a potential booster effect of reintervention (in children exposed to the SI! Program in preschool and in the present intervention at 9 to 13 years old).

To assess a potential dose-response effect of the intervention, similar linear mixed-effects models were used to explore differences in overall KAH and ICH scores between children receiving <50% of the program modules (low adherence), 50% to 75% of the modules (intermediate adherence), and >75% of the modules (high adherence). Data on intervention adherence were based on the number of modules received by the children and were collected from individual attendance records. Fixed effects were the corresponding categorized adherence to the intervention, whereas clusters and families were handled as random effects. A post-estimation test of the linear hypothesis across intervention adherence categories

TABLE 1 Knowledge, Attitudes, and Habits (KAH) Scores and Differences Between Intervention-Naive and Previously Intervened Children

		Baseline Score $\pm$ SD		Between-Group Difference	
	Score Range	Intervention Naive	Previously Intervened	Difference (95% CI)	p Value
KAH overall	0-96	$69.7\pm9.2$	$70.8\pm8.7$	0.89 (-0.20 to 1.98)	0.110
Overall domains					
Knowledge	0-32	$20.6\pm5.2$	$21.5\pm5.0$	0.56 (-0.06 to 1.18)	0.078
Attitudes	0-32	$\textbf{27.4}\pm\textbf{4.4}$	$27.6\pm4.3$	0.17 (-0.36 to 0.70)	0.534
Habits	0-32	$21.7\pm3.6$	$21.6\pm3.6$	0.16 (-0.28 to 0.60)	0.469
Overall components					
Diet	0-24	$14.5\pm3.7$	$14.6\pm3.7$	0.21 (-0.24 to 0.66)	0.365
Physical activity	0-24	$\textbf{16.4} \pm \textbf{4.2}$	$16.6\pm4.1$	0.14 (-0.37 to 0.65)	0.590
Body and heart	0-24	$20.7 \pm 2.3$	$21.0\pm2.2$	0.13 (-0.14 to 0.40)	0.345
Emotions	0-24	$18.1 \pm 4.2$	$18.6\pm4.1$	0.40 (-0.10 to 0.90)	0.118

Values are mean  $\pm$  SD unless otherwise indicated. Differences are presented as mean (95% confidence interval [CI]) derived from mixed-effects linear regression models. Fixed effects were age, sex, and categorized body mass index of the child, family socioeconomic status, and group (with intervention-naive children as the reference group). Families were handled as a random effect. The p values are nonadjusted values for multiple comparisons.

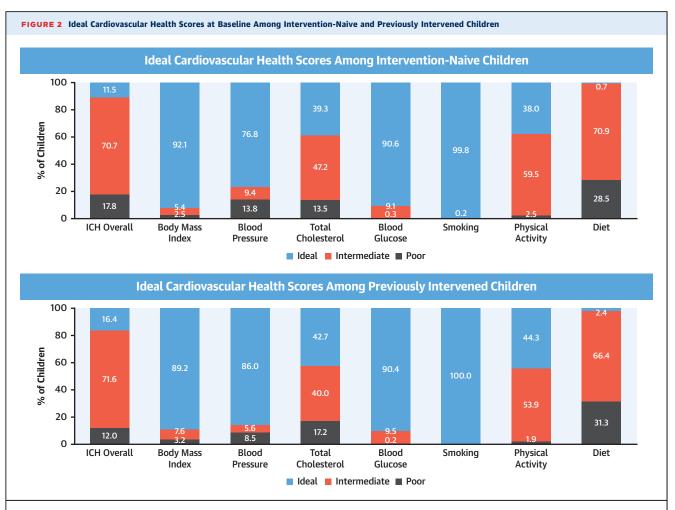
was performed using coefficients of orthogonal polynomials.

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. We performed a multiple imputation sensitivity analysis using multivariate normal distribution to include all randomized enrolled participants. The multiple imputation procedures are detailed in the Supplemental Methods.

All analyses were performed with Stata version 15.0 or superior (StataCorp, College Station, Texas).

#### **RESULTS**

**COMPARISON OF INTERVENTION-NAIVE AND PREVIOUSLY INTERVENED 9- TO 13-YEAR-OLD CHILDREN.** The intervention-naive group was composed of 620 children (51% girls) with a mean age of 11.0  $\pm$  1.2 years from families with a low (67%) or intermediate (32%) SES. The previously intervened group comprised 596 children (44% girls) with a mean age of 11.7  $\pm$  0.7 years from families with a low (58%) or intermediate (42%) SES. Baseline mean overall KAH score was 69.7  $\pm$  9.2 points for intervention-naive children and 70.8  $\pm$  8.7 points for previously intervened children, with no significant differences

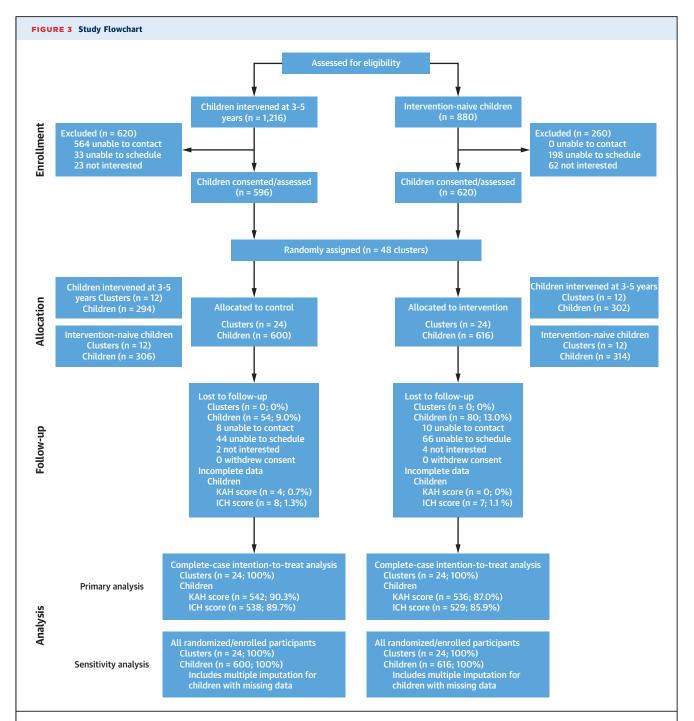


Bars represent the percentage of children with poor, intermediate, and ideal cardiovascular health in each study group overall and for each of the behavioral and clinical variables in the ideal cardiovascular health score.

between groups (adjusted absolute difference: 0.89 points; 95% CI: -0.20 to 1.98; p = 0.110). Similarly, no differences were found in the domain- and component-specific KAH scores by group (**Table 1**).

Most children in both groups had overall poor or intermediate CV health according to the categorized ICH score (Figure 2). Baseline mean  $\pm$  SD overall ICH scores were 10.8  $\pm$  1.4 and 10.9  $\pm$  1.4 points for intervention-naive and previously intervened children, respectively, with no significant differences among groups (adjusted absolute difference: 0.12 points; 95% CI: -0.04 to 0.27; p = 0.147). Multivariate analysis revealed no significant between-group differences for any of the health factors or health behaviors explored (differences were small and remained statistically nonsignificant after multiple comparison adjustment; data not shown).

TRIAL FLOW DIAGRAM AND BASELINE CHARACTERISTICS OF RANDOMIZED GROUPS. The trial enrolled 1,216 participants in 48 clusters, which were randomized 1:1 to the intervention and control condition (616 and 600 children, respectively) (Figure 3). After a median follow-up of ~8 months (first quartile: 7 months; second quartile: 9 months), 134 children (11.0%) were lost to follow-up, and 4 children (0.3%) and 15 children (1.2%) had incomplete data for calculating the change in the KAH and ICH scores, respectively. Therefore, the main analysis (complete-case intention-to-treat analysis) included 1,078 children for the change in KAH scores (536 in the intervention group and 542 in the control group) and 1,067 children for the change in ICH scores (529 in the intervention group and 538 in the control group). No cluster withdrew from the trial during the study



The chart summarizes recruitment of children, cluster randomization, and completeness of baseline and follow-up measures in the trial. In the "follow-up" section, lost to follow-up individuals with incomplete information for baseline knowledge, attitudes, and habits (KAH) (1 child in the intervention group) or ideal cardiovascular health (ICH) (2 children in the control group, 4 children in the intervention group) scores were only included in the "lost to follow-up" count.

period, and no adverse events were reported. Baseline information at the cluster and individual levels for the total study population and randomization groups is summarized in Table 2.

CHANGES IN KAH TOWARD HEALTHY LIFESTYLE SCORES. Baseline mean overall KAH scores were 70.4  $\pm$  8.8 and 70.0  $\pm$  9.2 in the control and intervention groups, respectively. Changes and

TABLE 2 Baseline Characteristics of Children by Randomization Group					
	Overall (N = 1,216)	Control (n = 600)	Intervention $(n = 616)$		
Clusters					
No. of clusters	48	24	24		
No. of children	1,216	600	616		
No. of children/cluster	$25.3\pm5.2$	$25.0\pm6.5$	$25.7\pm3.7$		
No. of children previously intervened	596 (49.0)	294 (49.0)	302 (49.0)		
Children					
Age, yrs	$11.4\pm1.0$	$11.3\pm1.0$	$11.4\pm1.0$		
Female	577 (47.5)	284 (47.3)	293 (47.6)		
Socioeconomic status					
Low	759 (62.6)	360 (60.3)	399 (64.8)		
Intermediate	449 (37.0)	234 (39.2)	215 (34.9)		
High	5 (0.4)	3 (0.5)	2 (0.3)		
Knowledge, attitudes, and habits (KAH)					
KAH overall, points (range 0-96)	$70.2 \pm 9.0$	$70.4\pm8.8$	$70.0\pm9.2$		
Overall domains					
Knowledge, points (range 0-32)	$21.1\pm5.1$	$20.9\pm5.2$	$21.2\pm5.1$		
Attitudes, points (range 0-32)	$27.5\pm4.3$	$27.8\pm4.2$	$27.3\pm4.5$		
Habits, points (range 0-32)	$21.6\pm3.6$	$21.8\pm3.6$	$21.5\pm3.6$		
Overall components					
Diet, points (range 0-24)	$14.6\pm3.7$	$14.5\pm3.7$	$14.6\pm3.7$		
Physical activity, points (range 0-24)	$16.5\pm4.2$	$16.6\pm4.0$	$16.4\pm4.2$		
Body and heart, points (range 0-24)	$20.9\pm2.3$	$20.9\pm2.3$	$20.9 \pm 2.2$		
Emotions, points (range 0-24)	$18.3\pm4.2$	$18.5\pm4.0$	$18.2\pm4.3$		

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differential changes (intervention vs. control) in overall and domain/component-specific KAH scores by treatment group are presented in Table 3. KAH scores of children at the final follow-up (post-intervention assessment) are shown in Supplemental Table 7. The mean change from baseline in the overall KAH score was 0.43 points (95% CI: -0.42 to 1.28; p = 0.319) and 1.36 points (95% CI: 0.50 to 2.21; p = 0.002) in the control and intervention groups, respectively. The mean between-group difference in overall KAH was 0.92 points (95% CI: -0.28 to 2.13; p = 0.133). A multiple imputation analysis including all randomized enrolled participants (N = 1,216) produced similar results, with a mean between-group difference in overall KAH score of 0.88 points (95% CI: -0.29 to 2.06; p = 0.140). No significant interactions were detected for by-treatment effects of age, sex, baseline KAH score, SES, or reintervention.

**CHANGE IN ICH SCORES.** Baseline mean overall ICH scores were  $10.8 \pm 1.4$  in the control group and  $10.8 \pm 1.4$  in the intervention group, meeting  $4.5 \pm 1.0$  of the 7 ideal metrics. None of the participants met 0 ICH score metrics, and just 2 participants (1 in each group) met all 7 metrics. Overall and component ICH scores

of children at the final follow-up (post-intervention assessment) are shown in Supplemental Table 8. The mean change from baseline in the overall ICH score was 0.17 points (95% CI: 0.00 to 0.33; p = 0.046) in the control group and -0.03 points (95% CI: -0.20 to 0.13; p = 0.682) in the intervention group. The mean between-group difference in overall ICH was -0.20 points (95% CI: -0.43 to 0.03; p = 0.089). A multiple imputation analysis including all randomized enrolled participants (N = 1,216) produced similar results, with a mean absolute between-group difference in overall ICH score of -0.17 points (95% CI: -0.40 to 0.07; p = 0.159). No significant interactions were detected for by-treatment effects of age, sex, baseline ICH score, SES, or reintervention. There were no significant differences by treatment group in the percentage of participants showing an unhealthy change (Table 4) or a healthy change (Supplemental Table 9) in specific ICH score metrics.

#### DOSE-RESPONSE EFFECT OF THE INTERVENTION.

Among children followed-up in the intervention group, 293 (55%) received >75% of the educational program modules (high-adherence group), 92 children (17%) received 50% to 75% of the modules (intermediate-adherence group), and 151 children (28%) received <50% of modules (low-adherence group). Changes from baseline in overall KAH score by adherence group are shown in Figure 4A. A significant overall dose-response effect was observed, with the largest benefit achieved in the high-adherence group (p value for linear trend: <0.001). Compared with the low-adherence group, the high-adherence group showed a significantly bigger change from baseline in the overall KAH score (mean difference of 3.72 points; 95% CI: 1.71 to 5.73; p < 0.001). For every day of participation in the intervention, the change from baseline in the overall KAH score increased by 0.64 points (95% CI: 0.34 to 0.94; p < 0.001). A doseresponse effect, albeit less pronounced, was observed for the ICH score (p value for linear trend across categorized adherence = 0.187) (Figure 4B). Compared with the low-adherence group, the highadherence group showed a trend toward a larger change from baseline in the overall ICH score (mean difference of 0.21 points; 95% CI: -0.10 to 0.51; p = 0.187). For every day of participation in the intervention, the change from baseline in the overall ICH score increased by 0.03 points (95% CI: -0.02 to 0.08; p = 0.195). Similar results were observed when dose-response effect analyses were adjusted for child age, sex and BMI, and family SES.

#### DISCUSSION

Unhealthy behaviors (smoking, physical inactivity, unhealthy diet) and factors (obesity, hypertension, elevated total cholesterol, elevated blood glucose) during childhood are associated with poor outcomes in adulthood (11,12), and child health promotion is considered a global priority. However, this challenge is far from being met. In the present study, we observed a low prevalence of overall ICH among children 9 to 13 years of age residing in a socioeconomically disadvantaged urban area in Bogotá. A successfully delivered preschool-based health promotion program had a negligible residual effect 7 years later. The implementation of a new communitybased intervention did not improve overall KAH toward a healthy lifestyle or CV health relative to the control group. However, a dose-response relationship was observed, with maximal benefit in children who attended >75% of the scheduled intervention (Central Illustration). These findings suggest that earlier reintervention health promotion strategies may be required to achieve sustained effects in children and that adherence to the intervention is critical to achieving such a potential positive impact.

LONG-TERM EFFECTS OF SCHOOL-BASED HEALTH **PROMOTION INTERVENTIONS.** Research on the sustained effects of child health promotion interventions is limited because few studies have included longterm follow-up (13). Published data indicate adequate assessment of sustainability outcomes requires a follow-up of at least 1 to 2 years (14). Our preschool educational program maintained a beneficial trend toward a healthy lifestyle up to 36 months; however, the absence of a long-term control group in the preschool intervention (due to crossover) makes it difficult to interpret these results (15). In the present study, we were able to re-examine ~50% of the children from the preschool intervention after 7 years and compare them with a group of interventionnaive children recruited from the same schools as those attended by their previously intervened counterparts. General characteristics (age, sex, nutritional status, KAH scores) of previously intervened children included versus not included in the present work did not differ at the beginning of the original study in the year 2009 to 2010 (data not shown). Despite the potential for some degree of selection bias, the positive effects of the original preschool intervention were not sustained in the 9to 13-year age group. In agreement with these results, 3 recent large cluster randomized controlled trials that included a multicomponent long-duration

TABLE 2 Continued			
	Overall (N = 1,216)	Control (n = 600)	Intervention (n = 616)
Ideal cardiovascular health (ICH)			
ICH overall, points (range 0-14)	$10.8\pm1.4$	$10.8\pm1.4$	$10.8\pm1.4$
Categorized ICH overall score			
Poor cardiovascular health	179 (14.9)	88 (14.9)	91 (15.0)
Intermediate cardiovascular health	854 (71.2)	422 (71.3)	432 (71.1)
Ideal cardiovascular health	167 (13.9)	82 (13.9)	85 (14.0)
Number of ideal ICH metrics			
0	0 (0.0)	0 (0.0)	0 (0.0)
1	3 (0.3)	2 (0.3)	1 (0.2)
2	33 (2.8)	8 (1.4)	25 (4.1)
3	143 (11.9)	78 (13.2)	65 (10.7)
4	420 (35.0)	205 (34.6)	215 (35.4)
5	434 (36.2)	217 (36.7)	217 (35.7)
6	165 (13.8)	81 (13.7)	84 (13.8)
7	2 (0.2)	1 (0.2)	1 (0.2)
Health metrics			
Body mass index			
Poor, >95th percentile	34 (2.8)	17 (2.9)	17 (2.8)
Intermediate, 85th-95th percentile	78 (6.5)	31 (5.2)	47 (7.7)
Ideal, <85th percentile	1,088 (90.7)	544 (91.9)	544 (89.5)
Blood pressure			
Poor, >95th percentile	134 (11.2)	63 (10.6)	71 (11.7)
Intermediate, 90-95th percentile	90 (7.5)	52 (8.8)	38 (6.3)
Ideal, <90th percentile	976 (81.3)	477 (80.6)	499 (82.1)
Total cholesterol			
Poor, ≥200 mg/dl	184 (15.3)	87 (14.7)	97 (16.0)
Intermediate, 170-199 mg/dl	524 (43.7)	259 (43.8)	265 (43.6)
Ideal, <170 mg/dl	492 (41.0)	246 (41.6)	246 (40.5)
Glucose			
Poor, ≥126 mg/dl	3 (0.3)	2 (0.3)	1 (0.2)
Intermediate, 100-125 mg/dl	111 (9.3)	57 (9.6)	54 (8.9)
Ideal, <100 mg/dl	1,086 (90.5)	533 (90.0)	553 (91.0)
Current smoking			
Poor, tried before	1 (0.1)	1 (0.2)	0 (0.0)
Ideal, never tried	1,199 (99.9)	591 (99.8)	608 (100.0)
Physical activity			
Poor, none	26 (2.2)	14 (2.4)	12 (2.0)
Intermediate, 1-59 min/day	681 (56.8)	329 (55.6)	352 (57.9)
Ideal, ≥60 min/day	493 (41.1)	249 (42.1)	244 (40.1)
Diet score			
Poor, O components	359 (29.9)	193 (32.6)	166 (27.3)
Intermediate, 1-2 components	823 (68.6)	389 (65.7)	434 (71.4)
Ideal, 3 components	18 (1.5)	10 (1.7)	8 (1.3)

Values are mean  $\pm$  SD or n (%). KAH and ICH baseline information available for 1,212 (597 in the control group, 615 in the intervention group) and 1,200 (592 in the control group, 608 in the intervention group) children, respectively.

intervention and long-term follow-up failed to prevent obesity or promote healthy habits among children (16-18). These findings suggest that intervention sustainability might require ongoing implementation (19).

**PROMOTION.** The school seems the ideal setting for the implementation of strategies to promote long-

0.176

0.446

0.327

0.678

Diet

Physical activity

Body and heart

TABLE 3 Changes in Overall Knowledge, Attitudes, and Habits (KAH) Score Toward a Healthy Lifestyle and its Domains and Components Within-Group Difference Between-Group Difference Control Difference (95% CI) p Value Score Range Intervention KAH overall 0-96 0.43 (-0.42 to 1.28) 1.36 (0.50 to 2.21) 0.92 (-0.28 to 2.13) 0.133 Overall domains Knowledge 0.98 (0.48 to 1.48) 1.14 (0.63 to 1.65) 0.16 (-0.55 to 0.88) 0-32 0.658 Attitudes 0-32 -0.20 (-0.61 to 0.21) 0.105 0.28 (-0.13 to 0.69) 0.48 (-0.10 to 1.06) Habits 0 - 32-0.31 (-0.74 to 0.13) -0.02 (-0.45 to 0.42) 0.29 (-0.32 to 0.91) 0.354 Overall components

0.31 (-0.08 to 0.71)

0.19 (-0.05 to 0.42)

0.29 (-0.12 to 0.71)

0.59 (0.10 to 1.08)

-0.07 (-0.46 to 0.32)

0.32 (-0.16 to 0.81)

0.02 (-0.21 to 0.25)

0.17 (-0.24 to 0.58)

Data are presented as mean difference (95% confidence interval [CI]) derived from linear mixed-effects models. Fixed effects were the corresponding treatment group, whereas cluster and family were handled as random effects.

lasting healthy habits in children because they spend most of their day there. This setting also facilitates the intervention to target different elements of children's immediate environment, including family, teachers, and the school environment itself. However, the fact that children often move from one school to another at some stage during their education imposes additional logistic and methodological challenges to reintervening and tracking the health of individuals as they grow. Thus, the ideal duration, dosage, and timing needed to achieve sustained positive effects on child health remain unclear (20-22). In the present study, most of the children were currently scattered around many different schools, making the school setting logistically unfeasible for implementing the intervention. Therefore, we decided to implement the new intervention in the community setting after demonstrating a negligible residual beneficial effect in previously intervened children at preschool age. Although our reintervention strategy was overall unsuccessful, several factors beyond intervention adherence may have decreased the ability to generate larger intervention effects in the trial. First, there was a long period (~7 years) with children not receiving any health promotion intervention; earlier reintervention strategies may be required to achieve sustained effects. Second, the children included in our study had a relatively better baseline health profile (as measured by the ICH metrics) than reported in other studies (12,20), making it more challenging to demonstrate a significant change. Thus, our study might have been underpowered to detect a difference in these clinically relevant health scores. Third, the new intervention was delivered exclusively at community centers and did not include multilevel strategies known to increase the success of health

0-24

0-24

0-24

0-24

promotion initiatives in children (23). Most community-based interventions that produced some positive results in child health promotion include strategies for enhancing the built environment or neighborhood such as policies promoting support from the school environment and family, mass media campaigns promoting physical activity and a healthy diet at school and in the local community, targeting risk groups through interventions at primary health care centers, and government regulation to promote healthy food access or reduce barriers to physical activity (9,24). Fourth, the relatively short duration of the intervention might preclude larger intervention effects. Although interventions of similar duration have been shown to be effective in the preschool setting (4,15,22,25), this might be insufficient in older children who are starting to develop autonomy in making conscious choices and become less dependent on external factors (20,21). Overall, our study does not invalidate the use of reintervention strategies and provides insights to improve future health promotion programs in children.

0.38 (-0.17 to 0.94)

0.27 (-0.42 to 0.96)

0.16 (-0.16 to 0.49)

0.12 (-0.46 to 0.71)

### THE IMPORTANCE OF INTERVENTION ADHERENCE.

As reported for other lifestyle programs, we observed a dose-response relationship for the intervention effects (25-27), suggesting that intervention adherence is critical in achieving a potential beneficial impact. Thus, approximately 50% of the children did not show high adherence to the intervention, and this may have also decreased the effect size for the intervention group as a whole. Some of the identified barriers to adherence were family-related issues such as parental illness or events (first communion, marriage, and so on) that interfered with Saturday scheduling, migration within the city to locations far from the community centers or to other cities, and

change of family contact telephone numbers. Other barriers were related to personal factors (attendance at sports activities, illness, and so on) and school-related issues (vacation period during the intervention, schoolwork, and so on). To optimize adherence, the present study included several retention strategies targeting children and their families including nonfinancial incentives, reminders, and community involvement (Supplemental Table 10). Factors that may affect fidelity to the intervention warrant further research.

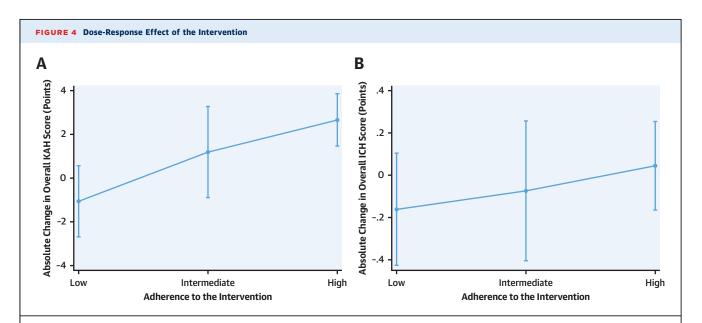
STUDY STRENGTHS AND LIMITATIONS. One of the main strengths of the study is that we were able to follow up a relatively high proportion of children from an underserved urban community who had received a preschool-based health promotion intervention 7 years before. The new trial used a cluster randomized controlled design and validated tools to measure both KAH toward a healthy lifestyle and CV health. A stronger intervention effect may have been precluded by the absence of actions to affect environmental and policy aspects, which can serve as barriers to behavior change (23). Nevertheless, it is fair to acknowledge that achieving such actions might be challenging, particularly in developing countries and vulnerable populations where the socioeconomic and institutional conditions might

TABLE 4 Prevalence of Unhealthy Changes in Ideal Cardiovascular Health (ICH) Metrics

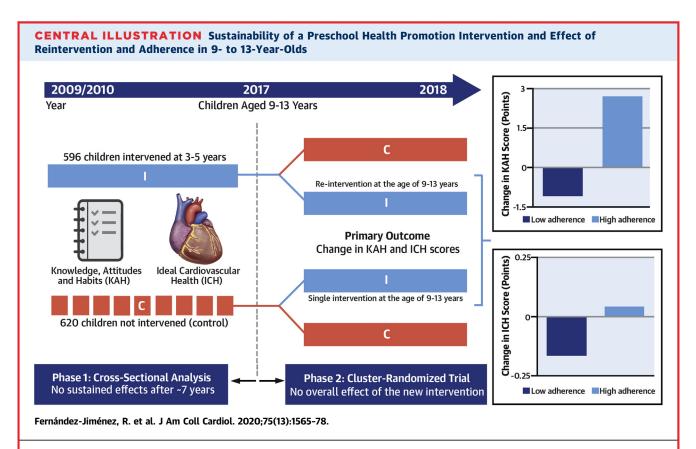
	Within-Gro	up Difference	Between-Group Difference	
	Control	Intervention	Odds Ratio (95% CI)	p Value
Categorized ICH overall	99 (18.4)	102 (19.3)	1.06 (0.75-1.49)	0.754
Health metrics				
Body mass index	21 (3.9)	16 (3.0)	0.76 (0.42-1.38)	0.374
Blood pressure	64 (11.9)	60 (11.3)	0.93 (0.63-1.39)	0.737
Total cholesterol	48 (8.9)	48 (9.1)	1.00 (0.66-1.51)	0.987
Glucose	121 (22.5)	114 (21.6)	0.96 (0.60-1.55)	0.867
Current smoking	1 (0.2)	1 (0.2)	0.98 (0.09-10.21)	0.990
Physical activity	118 (21.9)	137 (25.9)	1.28 (0.91-1.79)	0.152
Diet score	115 (21.4)	127 (24.0)	1.14 (0.82-1.59)	0.439

Values are n (%), unless otherwise indicated. Data are presented as counts (prevalences) of children exhibiting an unhealthy change for all component metrics of the ICH score (from ideal to intermediate or poor status). Between-group differences reflect odds ratio (95% confidence interval [CI]) derived from mixed-effects logistic regression models (with the control group as reference). Fixed effects were the corresponding treatment group, whereas cluster and family were handled as random effects. An odds ratio >1 indicates that the probability of an unhealthy change was higher in the intervention group than in the control group. An odds ratio lower than 1 indicates that the probability of an unhealthy change was higher in the control group than in the intervention group.

impose additional structural and administrative barriers to effective health promotion interventions. The fact that dietary intake and physical activity relied on self-reported data might pose the analysis susceptible to recall and misclassification bias. Despite the implementation of intensive retention strategies over the course of the study, ~12% of



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 of the absolute change from baseline in **(A)** overall knowledge, attitudes, and habits (KAH) score and **(B)** overall ideal cardiovascular health (ICH) score. Fixed effects were categories of intervention adherence according to the number of completed program modules: <50% (low-adherence group), 50% to 75% (intermediate-adherence group), or >75% (high-adherence group). Clusters and families were handled as random effects.



This study was designed and conducted in 2 consecutive phases. In phase 1, we performed a cross-sectional analysis of 1,216 children 9 to 13 years of age from an urban low-income community in Bogotá, Colombia. Of the total cohort, 596 children had originally received a health promotion educational intervention at ages 3 to 5 years in the preschool setting during 2009 to 2010 (~50% cohort retention after a 7-year follow-up). The remaining 620 children had not been previously intervened (intervention naive). The effects of a preschool health promotion intervention in children were not sustained. In phase 2, we conducted a community-based cluster randomized trial in which the children were assigned to different clusters and were randomized 1:1 to a control group or to receive a 4-month educational intervention in community centers aimed at instilling healthy behaviors. A dose-response effect was observed after implementing a new health promotion intervention at community centers in children 9 to 13 years of age; however, the intervention did not improve overall lifestyle and health scores. C = control; I = intervention. Intervention adherence is categorized according to the number of completed program modules: <50% (low adherence group) vs. >75% (high adherence group).

> children were lost to follow-up. The primary analysis was supplemented by sensitivity analyses using multiple imputation procedures. The similarity of the findings obtained suggests that missing data did not have a significant impact on our results.

#### CONCLUSIONS

The effects of a preschool health promotion intervention in children residing in an urban low-income area of Colombia were not sustained, suggesting that reintervention strategies at different stages may be needed. The reintervention strategy in a community setting did not improve overall KAH scores toward a healthy lifestyle or ICH scores in children 9 to 13 years of age. However, it is promising to note that a dose-response effect was observed indicating that intervention adherence is critical to achieving a beneficial impact. Further research is needed to attain effective strategies for health promotion in

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## **PERSPECTIVES**

COMPETENCY IN SYSTEMS-BASED PRACTICE: Effective child health promotion is an unmet global health priority. An initially successful preschool-based health promotion program had a negligible residual effect 7 years later, and repeated community-based intervention exhibited a dose-response relationship without improving overall lifestyle and health scores.

**TRANSLATIONAL OUTLOOK:** Repeated health promotion interventions in children at multiple stages may be necessary to achieve sustained effects, and further studies should seek strategies that enhance adherence and positively impact long-term health behavior.

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**KEY WORDS** child, health promotion, healthy lifestyle, preschool, prevention

**APPENDIX** For supplemental methods, results, figures, tables, and references, please see the online version of this paper.