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SPECIAL FOCUS ISSUE: POPULATION HEALTH PROMOTION

ORIGINAL INVESTIGATIONS

The SI! Program for Cardiovascular Health Promotion in Early Childhood

A Cluster-Randomized Trial

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ABSTRACT

BACKGROUND The preschool years offer a unique window of opportunity to instill healthy life-style behaviors and promote cardiovascular health.

OBJECTIVES This study sought to evaluate the effect of a 3-year multidimensional school-based intervention to improve life-style-related behaviors.

METHODS We performed a cluster-randomized controlled intervention trial involving 24 public schools in Madrid, Spain, that were assigned to either the SI! Program intervention or the usual curriculum and followed for 3 years. The SI! Program aimed to instill and develop healthy behaviors in relation to diet, physical activity, and understanding how the human body and heart work. The primary outcome was change in the overall knowledge, attitudes, and habits (KAH) score (range 0 to 80). The intervention's effect on adiposity markers was also evaluated.

RESULTS A total of 2,062 children from 3 to 5 years of age were randomized. After 3 years of follow-up, the overall KAH score was 4.9% higher in children in the intervention group compared with the control group (21.7 vs. 16.4; $p < 0.001$). A peak effect was observed at the second year (improvement 7.1% higher than in the control group; $p < 0.001$). Physical activity was the main driver of the change in KAH at all evaluation times. Children in the intervention group for 2 years and 1 year showed greater improvement than control subjects (5.9%; $p < 0.001$ and 2.9%; $p = 0.002$, respectively). After 3 years, the intervention group showed a higher probability than the control group of reducing the triceps skinfold z-score by at least 0.1 (hazard ratio: 1.40, 95% confidence interval: 1.04 to 1.89; $p = 0.027$).

CONCLUSIONS The SI! Program is an effective strategy for instilling healthy habits among preschoolers, translating into a beneficial effect on adiposity, with maximal effect when started at the earliest age and maintained over 3 years. Wider adoption may have a meaningful effect on cardiovascular health promotion. (Evaluation of the Program SI! for Preschool Education: A School-Based Randomized Controlled Trial [Preschool_PSI!]; NCT01579708)
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ABBREVIATIONS AND ACRONYMS

A = attitude domain

BH = body and heart component

D = diet component

H = habit domain

K = knowledge domain

KAH = knowledge-attitudes-habits score

PA = physical activity component

The adoption of unhealthy life-style behaviors, such as poor diet, lack of physical activity, tobacco, and alcohol use, begins in early childhood, introducing the first stage of development of cardiovascular disease (CVD) risks (1,2). Research has demonstrated that unhealthy diets begin to influence CVD markers early in life and that conditions such as dyslipidemia, high blood pressure, impaired glucose tolerance, as well as obesity and metabolic syndrome may set in as early as 3 years of age, increasing the risk of development of atherosclerosis in adolescence and early adulthood (3,4). Underlying the onset of unhealthy habits during childhood is a complex behavioral framework (5,6) that determines our persistent choices and life-style patterns as adults (7). Thus, early childhood is a unique opportunity to implement preventive strategies tackling life-style (8,9). For very young children, school may be the most appropriate choice for a behavioral intervention, as it constitutes the most reliable means of effective transfer of knowledge and appropriate educational strategies (10,11). In the best-case scenario, the school-based intervention will also encompass the children's families to create a supportive environment and enhance its effect (6).

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Most published scientific data on school-based interventions relates to the prevention of childhood obesity and is focused on 2 traditional components related to energy balance: diet and/or physical activity; few studies have included other behavioral components related to cardiovascular health, such as prosocial behaviors (12,13). Incorporating the promotion of positive social interactions through improved management of emotions has been proposed as a way of preventing the initiation of addictions, such as smoking or alcohol consumption (2,14,15). Preventive strategies addressing the social context of children could increase the efficiency of the intervention, acting as a complementary and cohesive factor against the development of unhealthy behaviors.

The SI! Program intervention for preschoolers pursues a global vision of cardiovascular health promotion and obesity prevention by instilling appropriate life-style behaviors early in life that may be carried to adulthood. Designed as a long-term (3-year), multilevel (school, teachers, families, and children), multicomponent (healthy diet, increased physical activity, understanding the human body, and managing emotions), school-based intervention, the efficacy of the intervention was evaluated through a cluster-randomized controlled trial in the city of Madrid, Spain, during the years 2011 to 2014. This paper reports the effects of the intervention on life-style-related behaviors and adiposity markers among preschoolers.

METHODS

STUDY DESIGN, SETTING, AND PARTICIPANTS. The evaluation of the intervention was designed as a cluster-randomized, parallel-group controlled trial. The detailed study protocol was described previously (16). In brief, the study used a hierarchical design, where the schools were units of randomization, intervention, and analysis. The second level of analysis consisted of 3- to 5-year-old children (17). Participating schools were selected from among all public schools in the city of Madrid, Spain, on the basis of size (>50 children/class) and availability of cafeteria service. Schools were randomized 1:1 to either intervention with the SI! Program or the usual curriculum. A stratified randomization according to data on the percentage of students from an immigrant background and students receiving free or subsidized meals or school materials (information provided by the Madrid Regional Office for Education) was performed to account for discrepancies in socioeconomic status (16,17). Schools were evaluated at baseline (before the intervention started) and annually for a total of the 3 years of preschool (4 visits total) (**Central Illustration**). Informed written consent for participation was required from the parents or legal guardians on behalf of their children, as well as from the teachers. The information collected was treated according to Spanish Law 15/1999 for the Protection of Personal Data. A data encryption system was used to guarantee the confidentiality of the information provided. The Madrid Regional Committee for Clinical Research approved the study.

INTERVENTION. A complete description of the intervention was published previously (16,17). Briefly, the SI! Program aims to promote cardiovascular health among children using their proximal environment (school, teachers, and families) as an integrated

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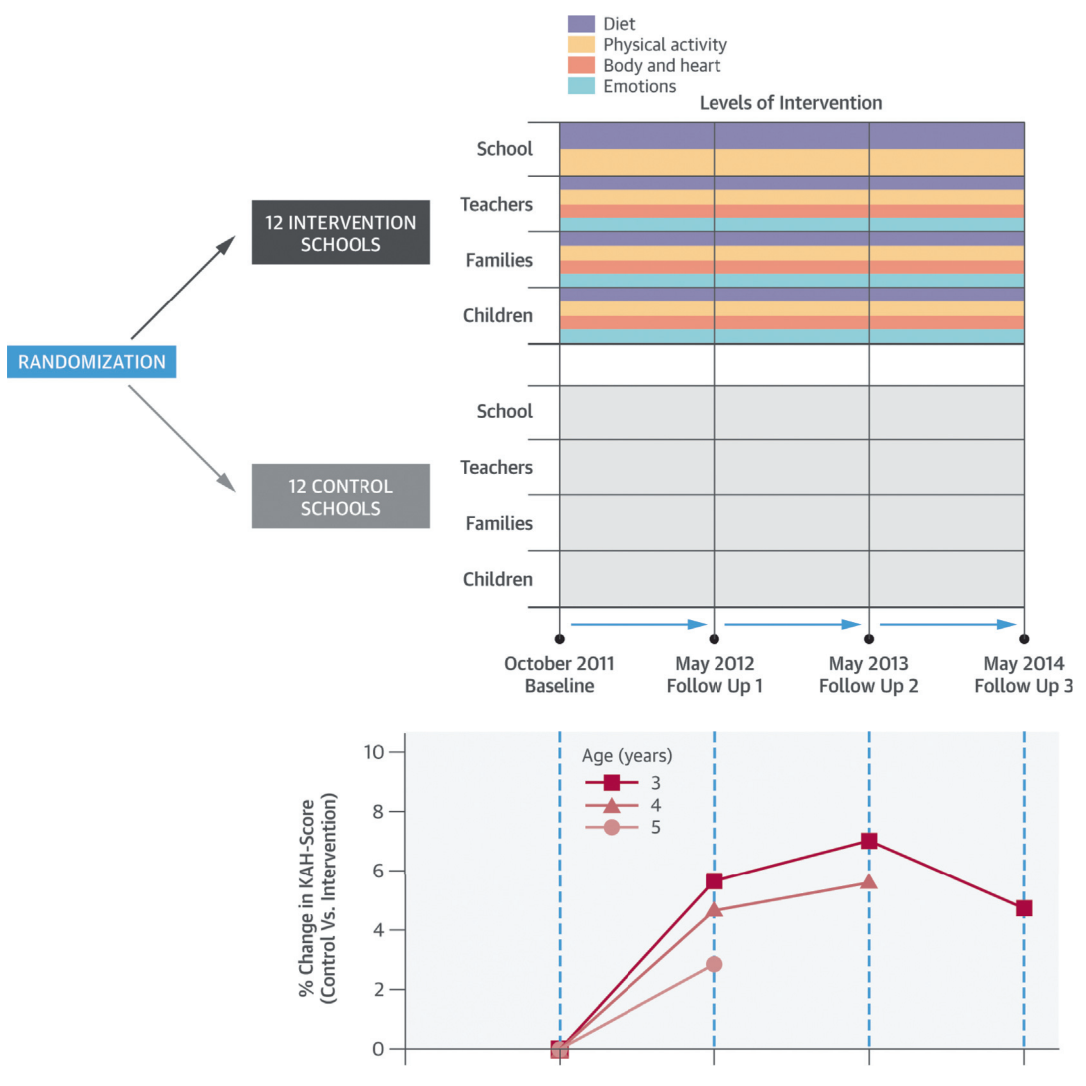
CENTRAL ILLUSTRATION Health Promotion in Early Childhood: The SI! Program for Preschoolers



Peñalvo, J.L. et al. J Am Coll Cardiol. 2015; 66(14):1525–34.

Design and main results of the effect evaluation study of the SI! Program for preschoolers. KAH = knowledge-attitudes-habits score.

system for intervention. For this study, the intervention was designed to be applied simultaneously at all preschool levels. Children were therefore exposed for 3 years, 2 years, or 1 year, depending on their starting grade. Children 3 years of age (1st preschool grade at baseline) were exposed to the intervention for 3 years (the entire duration of preschool), children 4 years of age (2nd preschool grade at baseline) were exposed for 2 years, and children 5 years of age (3rd preschool grade at baseline) were exposed for 1 year (Table 1). The intervention aimed to instill and develop healthy behaviors in relation to healthy diet, promotion of physical activity, and understanding how the human body and heart work. The intervention also introduced the topic of management of emotions as a cohesive component that would enhance the uptake of healthy behaviors. The intervention was embedded in the school curriculum and delivered by preschool teachers. In each school, a teacher volunteered as the intervention coordinator and received regional, government-certified training in the SI! Program contents and strategies (an expert-led 30-h course). Throughout the intervention, a customer relationship management tool was used to monitor

TABLE 1 Annual Changes From Baseline on KAH Scores by Intervention Component

		1-Year Visit			2-Year Visit			3-Year Visit		
	Score Range	Diff (95% CI)	% Diff	p Value	Diff (95% CI)	% Diff	p Value	Diff (95% CI)	% Diff	p Value
Age 3		**(n = 365) (C)/441 (I)**			**(n = 331) (C)/355 (I)**			**(n = 315) (C)/340 (I)**		
KAH overall	80	4.36 (1.87 to 6.86)	5.45	**0.001**	5.71 (3.74 to 7.68)	7.14	**<0.001**	3.92 (1.86 to 5.97)	4.90	**<0.001**
KAH-D	30	1.51 (0.10 to 2.92)	5.03	**0.035**	1.65 (0.33 to 2.97)	5.50	**0.014**	0.94 (0.19 to 1.70)	3.13	**0.014**
KAH-PA	30	1.41 (0.47 to 2.35)	4.70	**0.003**	3.72 (2.52 to 4.94)	12.40	**<0.001**	2.59 (1.41 to 3.77)	8.63	**<0.001**
KA-BH	20	0.83 (−0.22 to 1.88)	4.15	0.122	0.35 (−0.34 to 1.05)	1.75	0.320	0.33 (−0.36 to 1.02)	1.65	0.349
K	30	2.41 (1.54 to 3.29)	8.03	**<0.001**	3.12 (1.72 to 4.53)	10.40	**<0.001**	1.15 (0.34 to 1.97)	3.83	**0.005**
A	30	2.03 (0.83 to 3.22)	6.77	**0.001**	2.19 (1.23 to 3.14)	7.30	**<0.001**	1.39 (0.22 to 2.55)	4.63	**0.020**
H	20	0.52 (0.00 to 1.03)	2.60	**0.050**	1.31 (0.77 to 1.84)	6.55	**<0.001**	1.26 (0.63 to 1.89)	6.30	**<0.001**
Diet										
K	10	0.50 (−0.33 to 1.33)	5.00	0.240	0.52 (−0.39 to 1.43)	5.20	0.261	0.11 (−0.40 to 0.63)	1.10	0.663
A	10	0.69 (0.17 to 1.22)	6.90	**0.010**	0.69 (−0.05 to 1.43)	6.90	0.068	0.38 (−0.26 to 1.03)	3.80	0.247
H	10	0.18 (−0.32 to 0.69)	1.80	0.477	0.65 (0.04 to 1.26)	6.50	**0.037**	0.81 (0.18 to 1.45)	8.10	**0.011**
Physical activity										
K	10	0.60 (0.22 to 0.99)	6.00	**0.002**	1.50 (0.95 to 2.05)	15.00	**<0.001**	0.79 (0.31 to 1.27)	7.90	**0.001**
A	10	0.61 (−0.12 to 1.34)	6.10	0.099	1.50 (0.84 to 2.16)	15.00	**<0.001**	1.27 (0.67 to 1.88)	12.70	**<0.001**
H	10	0.35 (−0.01 to 0.71)	3.50	0.058	0.67 (0.10 to 1.24)	6.70	**0.022**	0.46 (−0.14 to 1.06)	4.60	0.132
Body and heart										
K	10	1.35 (0.76 to 1.94)	13.50	**<0.001**	1.10 (0.41 to 1.79)	11.00	**0.002**	0.30 (−0.49 to 1.08)	3.00	0.458
A	10	0.75 (−0.13 to 1.64)	7.50	0.095	0.02 (−0.70 to 0.75)	0.20	0.951	−0.31 (−0.96 to 0.33)	−3.10	0.342
Age 4		**(n = 283) (C)/348 (I)**			**(n = 263) (C)/287 (I)**					
KAH overall	80	3.49 (1.26 to 5.72)	4.36	**0.002**	4.69 (2.82 to 6.56)	5.86	**<0.001**			
KAH-D	30	0.83 (−0.10 to 1.77)	2.77	0.082	1.54 (0.76 to 2.32)	5.13	**<0.001**			
KAH-PA	30	2.10 (0.91 to 3.28)	7.00	**0.001**	2.69 (1.33 to 4.94)	8.97	**<0.001**			
KA-BH	20	0.61 (−0.24 to 1.45)	3.05	0.158	0.35 (−0.10 to 0.81)	1.75	0.131			
K	30	2.77 (1.77 to 3.78)	9.23	**<0.001**	2.36 (1.47 to 3.25)	7.86	**<0.001**			
A	30	1.89 (0.72 to 3.06)	6.30	**0.002**	1.67 (0.73 to 2.61)	5.56	**<0.001**			
H	20	0.33 (−0.31 to 0.96)	1.65	0.314	1.05 (0.29 to 1.80)	5.25	**0.006**			
Diet										
K	10	0.68 (−0.10 to 1.46)	6.80	0.089	0.94 (0.37 to 1.51)	9.40	**0.001**			
A	10	0.48 (−0.30 to 1.26)	4.80	0.230	0.61 (0.05 to 1.17)	6.10	**0.032**			
H	10	0.10 (−0.55 to 0.75)	1.00	0.759	0.48 (−0.01 to 0.96)	4.80	0.052			
Physical activity										
K	10	0.77 (0.15 to 1.40)	7.70	**0.015**	0.91 (0.32 to 1.50)	9.10	**0.002**			
A	10	0.71 (−0.15 to 1.57)	7.10	0.107	1.03 (0.28 to 1.78)	10.30	**0.007**			
H	10	0.24 (−0.14 to 0.63)	2.40	0.214	0.58 (−0.23 to 1.39)	5.80	0.162			
Body and heart										
K	10	1.35 (0.82 to 1.89)	13.50	**<0.001**	0.45 (0.05 to 0.85)	4.50	**0.029**			
A	10	0.72 (−0.33 to 1.78)	7.20	0.180	0.08 (−0.70 to 0.86)	0.80	0.842			

Continued on the next page

performance and track all intervention-related activities. All preschool teachers had access to an online repository of the intervention resources. Teachers also interacted via the intervention website on a blog where activities were shared between participating schools and in an open forum where they discussed any aspect of the intervention. Over the academic year, teachers delivered the intervention through classroom materials for a minimum of 20 h for the diet (D), physical activity (PA), and human body (HB) components and a minimum of 10 h for the emotion (E) management component. Additionally, the intervention included activities for the family over the weekends, as well as strategies involving the whole school environment, such as an annual health fair. Control schools followed their usual curriculum and were unaware of the specific details of the intervention. They were also asked to report back to the investigators whenever an internal or external initiative aside from the normal curriculum was being proposed to the school board.

PRIMARY OUTCOME: CHANGE IN KAH SCORES. We used the questionnaires and scoring system first developed in the Colombian Initiative for Healthy Heart Study (16,18,19). The questionnaires assessed the domains of knowledge (K), attitude (A), and habits (H) in relation to the intervention components: diet (D), physical activity (PA), and body heart (BH).

TABLE 1 Continued

	Score Range	1-Year Visit			2-Year Visit			3-Year Visit		
		Diff (95% CI)	% Diff	p Value	Diff (95% CI)	% Diff	p Value	Diff (95% CI)	% Diff	p Value
Age 5		(n = 254) (C)/323 (I)								
KAH overall	80	2.34 (0.89 to 3.79)	2.93	**0.002**						
KAH-D	30	0.14 (−1.02 to 1.29)	0.47	0.814						
KAH-PA	30	2.52 (1.50 to 3.55)	8.40	**<0.001**						
KA-BH	20	0.46 (−0.14 to 1.06)	2.30	0.134						
K	30	2.10 (1.31 to 2.89)	7.00	**<0.001**						
A	30	1.42 (0.61 to 2.23)	4.73	**<0.001**						
H	20	0.43 (−0.18 to 1.04)	2.15	0.164						
Diet										
K	10	0.34 (−0.12 to 0.80)	3.40	0.144						
A	10	0.40 (−0.03 to 0.82)	4.00	0.069						
H	10	−0.27 (−0.82 to 0.28)	−2.70	0.344						
Physical activity										
K	10	1.02 (0.47 to 1.57)	10.20	**<0.001**						
A	10	0.87 (0.17 to 1.57)	8.70	**0.015**						
H	10	0.74 (0.28 to 1.21)	7.40	**0.002**						
Body and heart										
K	10	0.75 (0.25 to 1.24)	7.50	**0.003**						
A	10	0.11 (−0.47 to 0.69)	1.10	0.713						

Bold values indicate statistical significance.

A = attitude domain; BH = body and heart component; C = control group; CI = confidence interval; D = diet component; Diff = difference; H = habit domain; I = intervention group; K = knowledge domain; KAH = knowledge-attitudes-habits score; PA = physical activity component.

An overall score, representing the intervention as a whole (overall KAH), was derived from the sum of each component-specific KAH (**Table 1**) and was defined as the primary outcome of the intervention. The overall KAH score range was 0 to 80. Trained pediatric psychologists under the direct supervision of the school staff administered the KAH questionnaires. The details of data collection for the study were described previously (16,17).

SECONDARY OUTCOME: CHANGE IN ADIPOSITY MARKERS. Body weight, height, waist circumference, and skinfold thickness (triceps and subscapular) were measured following previously detailed protocols (20). Body mass index (BMI) was calculated using the standard formula of weight (kg) divided by the square of height (m^2). BMI, waist circumference, and skinfold thickness were standardized to z-scores according to Centers for Disease Control (CDC) (21) and World Health Organization (22) references. Only standardized values are presented. All examinations were performed on small groups of children under the supervision of school staff.

STATISTICAL ANALYSIS. On the basis of previous effect sizes (23,24), we calculated that 20 schools (50 students/class) would be sufficient to detect differential effects with power >80% and a 0.05 chance of type I error. In anticipation of possible losses during the study, a total of 24 schools were randomized, 12 in each group (16). To evaluate changes after the intervention, we conducted analyses in those children who had data for the primary outcome (overall score) at baseline and after 1 (5 years of age), 2 (4 years of age), and 3 (3 years of age) years. Mixed-linear models that account for the cluster-randomized design were used to test for intervention effect. Fixed effects in each model were the corresponding baseline score, school year, and treatment group. Schools were handled as random effects. No correction for multiple comparisons was used. The same mixed-linear models were applied for the subcomponents of the primary outcome in children (D, PA, and BH). Interaction models were also fitted to identify possible age- or sex-by-treatment effects for the main outcome variable, as well as to study the influence of parental variables in the overall results. To evaluate the secondary outcome, the same mixed-linear models were used. Furthermore, we tested the changes from baseline adiposity markers over time between groups using log-rank tests and multivariate Cox models, adjusted for cluster. All analyses were performed using STATA version 12 (StataCorp, College Station, Texas).

RESULTS

OVERALL. A total of 24 schools were enrolled at baseline, including a total of 2,062 children from 3 to

5 years of age. During follow-up, 20% of children 3 years of age (3-year intervention), 13% of children 4 years of age (2-year intervention), and 3.2% of children 5 years of age (1-year intervention) were lost to follow-up. This was due to 1 intervention school discontinuing the study because the school's principal was replaced after the first year. No significant differences were found in baseline demographic or outcome-related variables (KAH score and anthropometric measures) for those children lost to follow-up compared to the rest of participants (intervention or control groups). Prospective changes measured at all follow-up visits always favored the children in the intervention group. No sex differences were observed. **Table 1** presents the differential change from baseline between children in the intervention and control groups in KAH scores. Direct scores are also provided for reference (Online Table 1). As expected from their standard educational program and normal development, both the intervention and control groups increased their KAH scores during the intervention, but children in the intervention group scored consistently higher at all follow-up times.

CHILDREN 3 YEARS OF AGE, 3-YEAR INTERVENTION. The 3-year intervention group showed higher overall KAH scores than the control group at every visit. Children in the intervention group scored 5.5%, 7.1%, and 4.9% higher ($p < 0.001$) at follow-up visits 1, 2, and 3, respectively (**Table 1**). The largest differential improvement was observed for the PA component (8.6%; $p < 0.001$). In these children, the largest effects were observed at the 2-year visit (overall KAH 7.1%; $p < 0.001$), again largely due to the change in the PA component (12.4%; $p < 0.001$). The D component in this group also improved (3.13%; $p = 0.014$), and the largest effect was again seen at the 2-year visit (5.5%; $p = 0.014$). Changes over time in the 3 domains (K, A, and H) are presented in **Table 1**. As expected for the knowledge domain, the largest changes compared with the control subjects were observed after 1 year of intervention. In accordance with the hypothesized sequential development (K to A to H) (25) of the 3 domains, the incremental change in the K and A domains tended to decrease over the follow-up time, whereas the incremental change in the H domain increased with time from 2.6% to 6.3% over the 3 years (**Table 1**).

CHILDREN 4 YEARS OF AGE, 2-YEAR INTERVENTION. The 2-year intervention group (4 years of age at baseline) showed 4.3% (visit 1) and 5.9% (visit 2) higher overall KAH scores ($p = 0.002$ and $p < 0.001$, respectively). In line with the results obtained in the 3-year intervention group, the greatest improvement at the end of the 2-year intervention was observed for the PA component (8.9%; $p < 0.001$), followed by the D component (5.13%; $p < 0.001$). Again, greater improvements were observed for the K and A domains after the first year. In fact, improvement in the H domain was only significant (5.2%; $p = 0.006$) after 2 years.

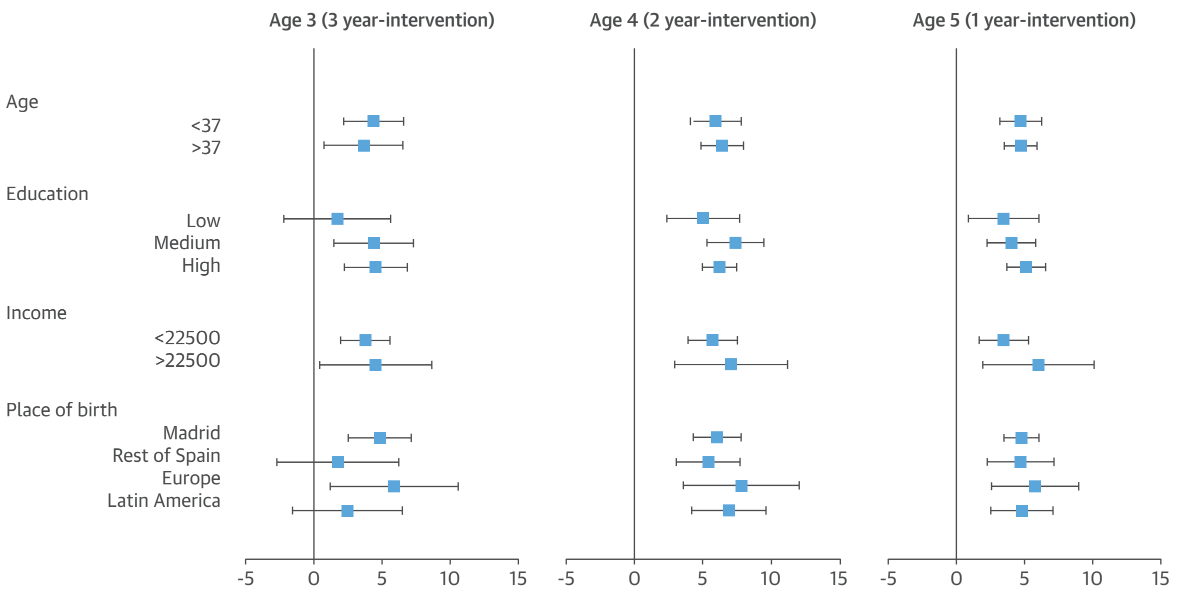
CHILDREN 5 YEARS OF AGE, 1-YEAR INTERVENTION. In the 1-year intervention group, the overall KAH and the KAH for the PA component increased significantly more (2.9%; $p = 0.002$, and 8.4%; $p < 0.001$, respectively) for the children in the intervention group compared with their control counterparts. In this group, no improvement in the D component was found.

In contrast to the overall positive effect of the intervention, there were no differences in the changes observed for the BH component ($p > 0.05$) between the intervention and control groups for any of the age groups during the visits.

SOCIOECONOMIC DETERMINANTS. Parental socioeconomic and demographic variables determining (p for interaction <0.05) the effect of the intervention in children are presented in **Figure 1**. The differential change of the overall KAH score was influenced by parental education, with a greater effect observed among children from families with at least a high school education (p for interaction <0.001) and higher (above the minimum annual wage) income (p for interaction <0.001). Despite the presence of interaction, no relevant distinction could be observed for parental age, but a greater effect was observed in children whose parents were of European origin ($p < 0.001$).

ADIPOSITY. According to the length of the intervention, the largest mean change difference was observed in the 3-year intervention group (3 years of age) for the skinfold measurements, but the results were only significant using World Health Organization standards (mean change difference for subscapular skinfold z-score −0.22, 95% confidence interval [CI]: −0.43 to −0.01; $p = 0.039$). No significant mean change differences were observed in either the 2-year (4 years of age) or the 1-year (5 years of age) intervention groups. As no clear effect was observed for the stratified sample, a pooled analysis was performed for the entire sample using CDC standards, showing differences favorable to the children in the intervention group, albeit not statistically significant (**Figure 2**). Only for waist circumference in the 3-year visit was the mean value for the control group (−0.2; SD 0.53) lower than for the intervention group (−0.1; SD 0.52), but this was not significant ($p = 0.179$). Furthermore, a subgroup analysis was

FIGURE 1 Effect of the SI! Program According to Parental Socioeconomic Variables



Differences (mean, 95% confidence interval) of children's overall KAH according to parental socioeconomic characteristics at baseline. Age is dichotomized on the basis of the median age of the sample. Parental education level is defined as low (none or primary school), medium (completed high school), or high (university studies). Income status cutoff defined according to the Spanish average annual wage (40). KAH = knowledge-attitudes-habits score.

also performed to investigate potentially different effects on overweight and obese children. Taking the different durations of the intervention into account and using CDC criteria for BMI, the prevalence of obese children at the end of the intervention was 1.3% (95% CI: 0.6% to 2.2%) in the control group and 1.1% (95% CI: 0.4% to 1.8%) in the intervention group (Online Figure 1). Total overweight (including obesity) was 7.4% (95% CI: 5.6% to 9.2%) in the control group and 7% (95% CI: 5.5% to 8.8%) in the intervention group. Although no significant differences were found for BMI or the other measures taking a subsample with a baseline z-score >1 and a baseline z-score >2, results were favorable to the intervention group at all time points (Figure 1). In addition, Cox proportional hazards models adjusted by cluster were used to model the probability of a 0.1 z-score reduction of the anthropometric variables for the entire sample. At the end of the intervention, a higher probability of reducing the waist circumference z-score (hazard ratio: 1.29, 95% CI: 1.03 to 1.63; p = 0.028) or the triceps skinfold z-score (hazard ratio: 1.40, 95% CI: 1.04 to 1.89; p = 0.027) by at least 0.1 was observed for children in the schools that participated in the intervention, compared with children in the control groups. No effect was found for BMI or subscapular skinfold.

DISCUSSION

This trial demonstrated that the SI! Program, a long-term (3-year) and multidimensional intervention for preschoolers, improved lifestyle-related behaviors and measures of adiposity. This improvement was already initiated during the first year of intervention, with an overall 5% differential increase (17). As hypothesized, the effect continued to increase as the intervention contents built up, with results peaking in the second year of the program and maintained thereafter.

Children in the intervention group improved their scores for overall KAH and for most of its individual components compared with the control group. The largest effect was observed for the PA component, followed by D, whereas a lesser effect was achieved for the human body and heart component. The lesser effect on the HB component may be due to the already ample coverage of basic health topics, especially those related to self-perception and autonomy, within the compulsory school curriculum. It also may be difficult to bring about palpable differences in knowledge regarding these complex components at such an early age. We are currently exploring alternative learning approaches in this area to better complement the existing school curriculum.

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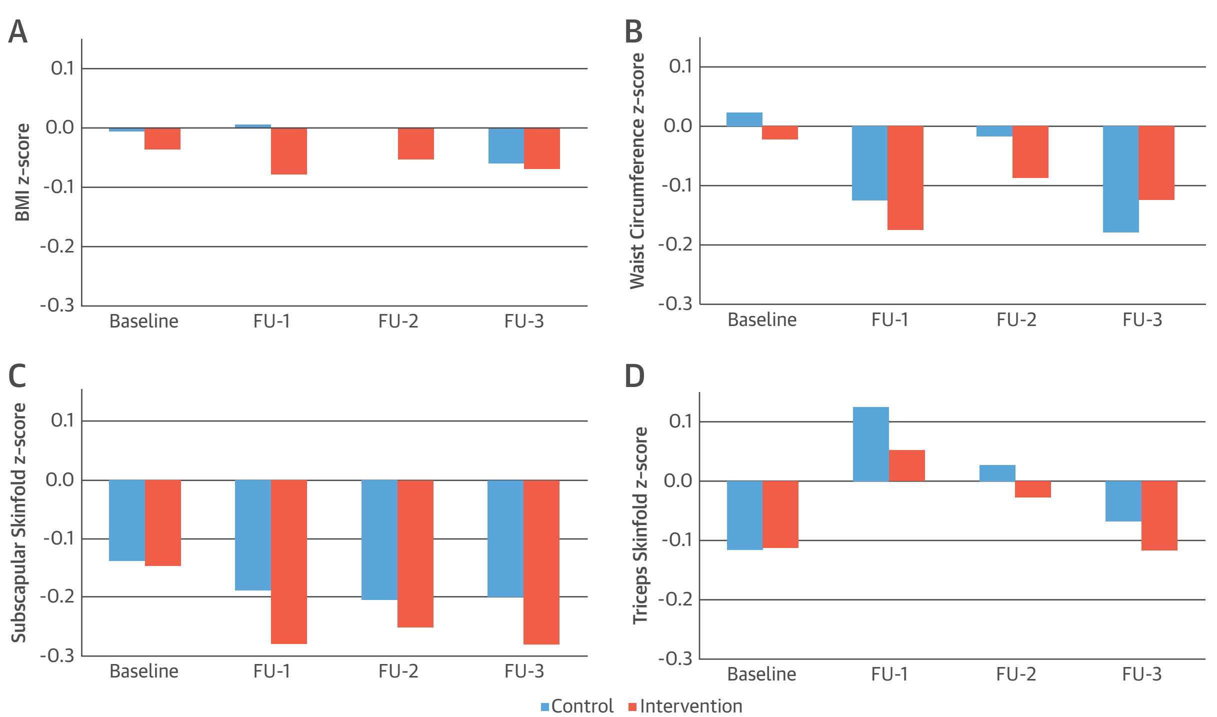
FIGURE 2 Effect of the SI! Program on Children's Anthropometry



Changes in anthropometric variables at each follow-up. **(A)** BMI z-score, **(B)** waist circumference z-score, **(C)** subscapular skinfold thickness z-score, and **(D)** triceps skinfold thickness z-score. BMI = body mass index; FU-1 = follow-up 1, 1-year visit; FU-2 = follow-up 2, 2-year visit; FU-3 = follow-up 3, 3-year visit.

The positive effect of the D and PA components of the intervention could have contributed to the improvements in skinfold and waist circumference without having an effect on BMI. These positive results constitute another validation of the efficacy of the SI! Program. With very few exceptions (26), interventions of <2 years duration on preschoolers have not been successful in improving adiposity markers (27–30). In some trials, positive results were observed after subgroup analyses, as with the 2-year intervention in Head Start schools, where a significant reduction of BMI was observed for non-Hispanic blacks but not for Hispanic children (31). In the Ballabeina study (32), an intervention similar to the SI! Program that also entails a multidimensional (physical activity, nutrition, media use, sleep, and adaptation of the built environment), 1-year intervention on immigrant children 5 years of age, changes in percent body fat were observed. These results are well in line with ours and emphasize the importance of addressing socioeconomic variables in these trials, as different cultural or economic backgrounds may lead to different effect sizes. Interventions targeting older children have also not been completely successful in their effect on clinical outcomes. The CATCH (Child and Adolescent Trial for Cardiovascular Health) study, a 3-year multidimensional intervention on children 8 years of age, had no significant effects on blood pressure, body size, or cholesterol measures (33). The 1-year Pathways study in 8-year-old American Indian children had no effect on body composition (23). Finally, in the Healthy study, a 3-year, comprehensive, multicomponent intervention in children 11 years of age did not result in greater decreases in the combined prevalence of overweight and obesity compared with control schools (34). However, the intervention did result in significantly greater reductions in various indexes of adiposity. This partial effect confirms the need for early and long-term multidimensional intervention on the basis of sustainable capacity-building strategies to ensure successful health education. Health promotion concepts, including personal responsibility for our own health status, should be instilled from early in life.

Several studies have attempted to evaluate the effects of various interventions on health behaviors and outcomes in children. There is a consensus that the most effective school-based interventions are those that include the family and that center on realistic intermediate objectives such as changes in knowledge, attitude, dietary patterns, or levels of physical activity as early control measures that promote cardiovascular health (7).

The results presented in this report are well in line with those obtained previously by the Colombian Initiative (18,19) and help reaffirm our hypotheses. After the intervention, Colombian preschoolers were followed up for 36 months, and a sustained effect toward healthier behaviors in children was observed (19), supporting the effort for nationwide expansion of the intervention. Similarly, children involved in the SI! Program for preschoolers in Madrid, Spain, are also being followed up throughout elementary school to evaluate maintenance of the effects over time. Additionally, a formal cluster-randomized trial has begun to evaluate the effect of the SI! Program in older children (6 to 12 years of age). Furthermore, the theoretical framework of the SI! Program is also being tailored to projects worldwide, such as the FAMILIA (Family-Based Approach in a Minority Community Integrating Systems-BioLogy for PromotIon of HeAlth) Study in Harlem, New York, involving preschool children and caregivers, where the SI! Program is supplemented with individual parental or peer-based intervention strategies and behavior-related genomic data. Within this comprehensive framework, the results reported here demonstrate the efficacy of the SI! Program intervention for preschoolers and serve as a proof-of-concept to support full development of the project strategy.

STUDY STRENGTHS AND LIMITATIONS. Our results could have been affected by the discontinuation of 1 of the schools participating in the intervention, even though this was random and unrelated to the intervention. Also, despite finding strong statistical associations, the lack of adjustment for multiple comparisons could have affected the results. Our main strength is the cluster-randomized controlled design that allows isolation of the effects of the SI! Program intervention. The trial was also preceded by qualitative studies of materials and strategies, as well as pilot testing of the evaluation tools. The results reported in this paper address the main outcome of the evaluation of the SI! Program for preschoolers, which is a comprehensive protocol addressing various hypotheses; additional analyses are currently ongoing to further explain the determinants of the SI! Program's effect. Modeled on our previous Colombian initiative (18,19), this study chose markers of behavior change (KAH) rather than harder endpoints, such as detailed measures of diet or physical activity by comprehensive questionnaires. This assessment is simpler and therefore suitable for direct interaction with preschoolers, thus avoiding reporting (parental) bias. Although we acknowledge the limitations of self-reported measurements of diet and physical activity, other studies have effectively used these tools in similar trials (23,33,35–37). At this age, acquiring knowledge about key components of a healthy life-style is an important goal in itself, as this constitutes the basis of behavior change (38,39). Although the generalizability of our findings may be limited to preschoolers of Spanish urban areas and middle-income families, this study proves that effective primordial strategies can be successful at a very young age.

CONCLUSIONS

The SI! Program is an effective strategy for instilling healthy habits among preschoolers, which translates into a beneficial effect on adiposity with a maximal effect obtained when started at the earliest age and maintained over a 3-year timeframe. Wider adoption of such a program may have a meaningful effect on cardiovascular health promotion.

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PERSPECTIVES

COMPETENCY IN PATIENT CARE AND PROCEDURAL SKILLS: A multilevel, multicomponent, school-based program can positively affect knowledge, attitudes, and behavior regarding healthy life-style in preschool children.

TRANSLATIONAL OUTLOOK: The SI! Program needs to be tested widely to confirm its efficacy. The program is being developed further for continued application through childhood and adolescence.

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APPENDIX For a supplemental table and figure, please see the online version of this article.