



A Coordinated School Health Program Effect on Cardiorespiratory Fitness of South Texas Preschool Children: A Cluster Randomized Trial

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ABSTRACT -

BACKGROUND: The purpose of this study was to assess the effects of the Bienestar/NEEMA Coordinated School Health Program (BN CSHP) on cardiorespiratory fitness (CRF) of preschool children.

METHODS: A cluster randomized trial was conducted of preschools in South Texas. Of 48 eligible schools, 28 were randomly assigned (14 intervention, 14 control). Family demographics and household health characteristics were collected from parents and CRF from children. Generalized linear mixed model (GLMM) was used to analyze the data.

RESULTS: Family demographics, household health characteristics, and children's weight, obesity prevalence, and sedentary activity of the control group were similar to the intervention group at baseline. After adjusting for covariates, the number of laps ran by children in the control group increased by 23% (CI: -5% to 60%) per each data collection period compared with 53% (CI: 7% to 119%) in the intervention group.

IMPLICATIONS FOR SCHOOL HEALTH POLICY, PRACTICE, AND EQUITY: State mandates, parent engagement, and funding are key for designing effective health and Physical Education (PE) programs.

CONCLUSION: Children in the BN CSHP, compared to those in the control group, had a significantly higher increase in their CRF. This finding is important because of the health benefits of CRF in children. ClinicalTrials.gov Identifier: NCT05501392.

Keywords: coordinated school health program; cardiorespiratory fitness; obesity; preschool children.

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INTRODUCTION

 $C \ hildren \ worldwide \ have \ shown \ a \ downward \ trend \ in \ their \ cardiorespiratory \ fitness \ (CRF),^1 \ and \ an \ upward \ trend \ in \ obesity \ prevalence.^{2,3} \ These$

findings were before COVID-19. With COVID-19, this negative connection worsened.⁴ During the pandemic children worldwide showed a further decrease in physical activity⁵⁻⁹ and a further increase in obesity prevalence.¹⁰⁻¹³ The causal relationship between

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*This work was supported by the Office of the Assistant Secretary of Health (OASH), an operating agency of the United States Department of Health and Human Services under Grant Award No. CPIMP171151. Additional funding was provided by the Quest Diagnostics Foundation. This research is solely the responsibility of the authors and does not necessarily represent the official views of OASH or the Quest Diagnostics Foundation. decrease CRF and increase childhood obesity,¹⁴⁻¹⁶ calls for the assessment of school-health programs impact on children's CRF.

Youth today, are confronted with a wide variety of risk factors detrimental to their long-term development and health.¹⁷ A 5-year longitudinal study following adolescents into young adulthood found the proportion of adolescents becoming and remaining obese was 12.7% with only 1.6% shifting from obese to nonobese.¹⁸ It is recognized that both hereditary and environment are causes of childhood obesity. Nonetheless because the obesogenic environment is a driving force of the epidemic, neighborhoods, schools, and home should be the primary setting for the intervention.¹⁹

Medical and public health agencies have advocated for enhanced school-based physical activity programming to address the obesity epidemic.²⁰⁻²² Schools are the ideal environment to implement health and physical education (PE) programs because it is at schools where children spend up to 1100 hours a year, consume up to 2 meals a day, and engage in up to 1 hour of daily physical activity. Schools are also ideal to intervene because they reach the largest segments of youth and provide an infrastructure and support for intervention.^{23,24} Unfortunately, due to limited time, resources, funding, and competing pressures for academic achievement, it is that health and PE instruction remain a marginalized course in many school districts.²⁵

Multicomponent interventions that address environmental and individual influences, such as those modeled after the Ecological Theory, might have greater impact on children's health outcomes.²⁶ The Ecological Model emphasizes the critical role that parents, school parent liaisons, teachers, child nutrition staff, and school nurses play in scaffolding school health literacy programs aimed at improving students' health outcomes. Thus, the present intervention was based on the Ecological Model.

The South Texas Early Prevention Study-Prekindergarten (STEPS-PreK4) was а cluster randomized trial (CRT) of preschool children 4 years of age to test the effect of the Bienestar/NEEMA Coordinated School Health Program (BN CSHP) on childhood obesity prevalence. The purpose of focusing on this age group is because preschool children have lower prevalence of obesity compared to the older age groups²⁷ and because once obesity develops it is challenging to treat.²⁸ This report presents findings of the BN CSHP effects on children's CRF as measured by the number of laps ran in the Progressive Anaerobic Capacity Endurance Run (PACER) fitness test.

METHODS

Study Design and Participants

The STEPS-PreK4 was a CRT where preschools, embedded within elementary schools, were the unit of randomization, intervention, and analysis. The study was designed for 2 years of intervention (preschool to kindergarten) with 4 data collection periods, Period 1 (start of pre-k, fall 2018), period 2 (end of pre-k, spring 2019), period 3 (start of kindergarten, fall 2019), and period 4 (end of kindergarten, spring 2020). Due to the COVID-19 pandemic the study was stopped prematurely, therefore, only results from the first 3 periods are presented. The study was conducted in 2 school districts located along the Texas-Mexico border in the county of Hidalgo. These school districts with similar demographics were selected because of the high poverty and health risk-factor levels.²⁹ The preschools have 2 grade levels with children 3 and 4 years of age. This study only targeted children 4 years of age. Demographics of the 2 school districts were similar, 99% Hispanic, 92% economically disadvantaged, and 42% identified as English as a second language. This study followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline.

Intervention

The BN CHSP is a Texas Education Agency (TEA)approved CSHP. CSHP were designed to control and prevent childhood obesity, youth-onset type 2 diabetes, and cardiovascular disease by providing instruction in health, nutrition, physical education, and chronic disease knowledge across several environments. The Ecological Model guided the BN CSHP design. This theory postulates that health behaviors are molded by individual, interpersonal, and environmental interactions. Thus, the BN CSHP encompasses curricula from preschool to eighth grade and is designed to target the 4 environments that influence children's health behaviors: (1) Healthy Minds Healthy Lifestyles (Health), (2) Moving For Life (Physical Education), (3) Eat to Live (Child Nutrition/School Food Service), and (4) MyFamily/MiFamilia (Home). Table 1 presents the preschool health education components of both treatment arms.

Program components that focus on parental engagement are critical to improve and sustain the health behaviors of children. The *MyFamily/MiFamilia* book includes a series of workshops and newsletters that offer nutrition, health messages, and recommendations that encourage families to adopt an active and healthier lifestyle at home. It consists of 9 health, physical activity, and nutrition messages that equip busy families with attitudes, skills, and knowledge about healthy eating, moving more, and preventing chronic disease to improve the health of the entire family unit.

Component	BN CSHP Intervention	Control
Health	Materials: Teacher's book and student workbook, music cd Number of sessions: 30 lessons and a pre/post health knowledge exam	An instructor's guide and a student workbook 28 lessons and a pre/post health knowledge exam
	Frequency: Once per week; 40 minutes per session	Once per week; 30 minutes per session
Physical Education	Materials: Teacher's guide PE curriculum, music cd	Activity cards, music cd, minimal equipment for organized play
	Number of sessions: 100 structured lessons	90 structured activities
	Frequency: 4 days a week, 45 minutes per session aimed at reaching moderate-to-vigorous heart rates 50% of the class.	2 days a week, 45 minutes a session
Child Nutrition and Food Service Program	Materials: Instructor's book and a food service staff workbook	None
, i i i i i i i i i i i i i i i i i i i	Number of sessions: 11 lessons, pre/post health knowledge exam, and cafeteria learning labs	None
	Frequency: Once per week, 30 minutes per session	None
MyFamily/MiFamilia Workshops	Materials: MyFamily/MiFamilia workshop instruction book.	None
	Number of sessions: 9 workshops a school year	None
	Frequency: Once every month	None
Parent Bienestar Healthy Bytes Newsletters	Materials: Newsletters	None
	Number of sessions: 9 issues a school year	
	Frequency: Once every month	
Communications	Materials: Printed media such as posters, flyers, bulletin boards, cafeteria line messages, handouts	Printed media such as posters, flyers

Instrumentation

Household characteristics. Family demographic and household health characteristic questionnaires were sent to parents/guardians through 4 modes: online, face-to-face, school parent liaisons, and children. English and Spanish questionnaires collected information on age, sex, race/ethnicity, educational attainment, household income, poverty level, persons living per household, student's physical activity outside of school, hours spent TV viewing, playing with electronic devices, and sleeping, and family (first and second degree) history of hypertension and diabetes.

PACER Fitness Test (Shuttle Run). The PACER fitness test is a multistage shuttle run designed to measure CRF.³⁰ The objective of the PACER is to run as long as possible while keeping a specified pace. Children run back and forth across a 20-m course at a tempo that gets faster each minute paced by an audio signal. For this study, the PACER test was adapted for preschool children by adjusting the course to a 15-m distance and using a 20-m cadence. The test begins at a slow pace and each minute the pace increases. Beeps on the soundtrack indicate when a student should reach one end of the course where they stop and wait for the next beep. Children continue running until the pace can no longer be sustained for 2 laps, even if not continuous. As soon as children stop running, their number of laps are recorded. The week before the actual test, children were trained and had 2 practice runs. They were quick to learn and eager to do the actual run.

Anthropometric. Weight (wt.) was measured with a Tanita scale (Tanita Corp of America, Inc., Arlington

Heights, IL). Children were asked to remove excess clothing (sweatshirts, jackets) and shoes before they stepped onto the scale. Wt. was recorded to the nearest 0.1 kg. Height (ht.) was measured with a Detecto stadiometer (Detecto Corp., Webb City, MO). Ht. was recorded to the nearest 0.1 cm.

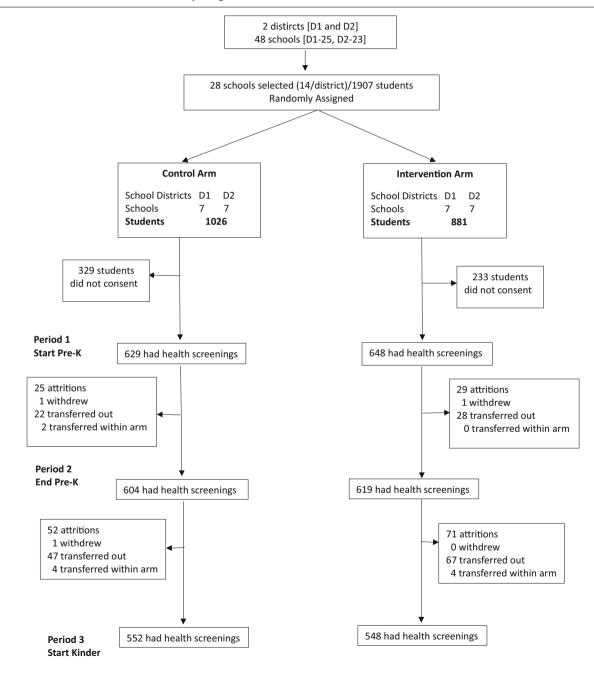
Sample Size Calculation

The sample size for the primary endpoint, obesity prevalence, assumed a 5% obesity rate decrease in the intervention compared to the control group, a SD of 1.4, an intra-cluster correlation coefficient of 0.01, a 70% response rate, and an attrition rate of 16% (source: LJ ISD, PSJA ISD). A total of 28 preschools (clusters) with a mean cluster size of 49 children per school was estimated to detect the effect size with 80% power at a significant level of $\alpha = .05$. The calculated sample size was enough for a difference of at least 4.5 laps between treatments (secondary outcome) and the statistical power was 82% for alpha .05 with a sample size of 40 children per cluster.

Statistical Analyses

Summary statistics by treatment groups are presented as means (SD) and frequencies (percentages) to describe the distribution and characteristics of general variables. Contrasts between groups were compared within clusters and adjusted by random factors. The primary aim of this report was to assess the longitudinal effect of the BN CSHP on the CRF of children in the intervention as compared to those in the control group. The CRF was measured by the number of laps in the PACER fitness (shuttle run) test. The counts of laps were positively skewed and assumed to follow a Poisson probability distribution. The fixed predictors of the average number of laps were time (continuous variable consisting of data collection periods), treatment effect (discrete factor with control group as the reference level), and their interaction. The random effects were the nested school district, elementary school, and school classroom to account for random intercepts. We detected a significant over dispersion in the laps count distribution. Therefore, a GLMM with a negative binomial regression was used to adjust the effect of the intervention and to obtain 95% confidence intervals (CI). All statistical analyses were performed with R package Ime4, version 1.1-27.1.27.³¹ The models were adjusted for covariates listed in the Methods section. As suggested by Brown³² all continuous variables were transformed to a unitscale and used the Bound Optimization BY Quadratic Approximation³³ optimizer in the lme4 package to ensure convergence in R version 4.1.0 (R Core Team, 2013).

Figure 1. Recruitment and Attrition as Study Progressed



RESULTS

Enrollment

Two school districts accepted to participate in the study. See Figure 1 for the Consort Diagram. Of the 48 eligible schools, 28 were randomly selected, 14 from each district (7 from each district were randomly assigned to control and 7 to intervention). Of 1907 children enrolled in 28 schools, 1277 parents/guardians consented to participate: 629 in the control and 648 in the intervention arms (period 1, start pre-k, baseline). At period 2 (end pre-k) 54 children were lost primarily due to transferring to other schools, leaving 1223 children (604 in the control and 619 the treatment groups). At period 3 (start kindergarten) another 123 children were lost for the same reason leaving 1100 children in the study (552 in the control and 548 in the treatment groups). The baseline characteristics of children included in the primary outcome analysis (n = 1277) was compared with those of children

lost to follow-up (n = 177), and there were no differences.

Household Characteristics

Of the 1277 children consented, 924 (72%) parents/guardians responded to the demographic and household health characteristics surveys. The surveys completed were mostly by female caretakers (mother, aunt, grandmother), 95.3% and 94.0% in the control and intervention groups, respectively (Table 2). Respondents who had an education level higher than high school (attended college, graduated from college, or had graduate education) were 52.3% in the control and 43.5% in the intervention groups. Near 95% of both treatment groups classified themselves as Hispanic or Latino. More than half of the respondents lived in poverty (53.3% in the control and 61.3% in the intervention groups). Near half of the respondents had a family history of hypertension (49.3% in the control and 53% in the intervention groups) and

	Treatment Group		
	Control	Intervention	p-Value
Characteristics of caretakers			
Response rate n, % fully completed	372 (59.1)	411 (63.1)	0.469
Person answered survey, n (%*)			
Mother	425 (94.4)	428 (92.2)	0.231
Father	21 (4.7)	27 (5.8)	0.459
Other	4 (0.9)	9 (2.0)	0.548
Age of person answered survey, mean (SD)	32.2 (6.21)	31.8 (6.90)	0.618
Female relative education level, n (%*)			
<high school<="" td=""><td>58 (13.3)</td><td>69 (15.1)</td><td>0.574</td></high>	58 (13.3)	69 (15.1)	0.574
Highschool	151 (34.5)	188 (41.3)	0.237
Some college or higher	229 (52.3)	198 (43.5)	0.168
Annual household income, n (%*)			
Under \$20,000	191 (44.0)	227 (51.9)	0.215
\$20,000 to \$34,999	73 (16.8)	60 (13.7)	0.229
\$35,000 to \$49,999	46 (10.6)	42 (9.6)	0.634
\$50,000 to \$74,999	53 (12,2)	45 (10.3)	0.498
\$75,000 to \$99,999	35 (8.1)	34 (7.8)	0.810
\$100,000 or more	36 (8.3)	29 (6.6)	0.400
Persons per household, mean (sd)	4.8 (1.35)	5.2 (1.57)	0.004*
Living in poverty*, n (%*)	220 (53.3)	263 (61.3)	0.269
Family medical history (first and second degree families), n (%*)			
Hypertension	214 (49.3)	241 (53.0)	0.341
Diabetes	243 (55.0)	216 (47.7)	0.064
Characteristic of students			
Male, n (%)	319 (50.7)	326 (50.3)	0.593
Age in years, mean (SD)	4.681 (0.300)	4.664 (0.298)	0.345
BMI, mean (SD)	16.721 (2.487)	16.661 (2.193)	0.649
BMI classification, n (%*)	. ,		
Underweight	16 (2.8)	10 (1.8)	0.254
Normal	351 (61.3)	355 (62.9)	0.593
Overweight	102 (17.8)	98 (17.4)	0.871
Obese	104 (18.2)	101 (17.9)	0.915
Physical activity in min/week, mean (SD)	218.45 (418.11)	198.37 (323.42)	0.615
Time watching TV 3+ hours/week, n (%*)	114 (25.7)	100 (21.8)	0.740

*% of answers provided.

of diabetes (55% in the control and 47.7% in the intervention groups). The only significant difference was the intervention group had on average 0.3 more people living per household than the control group.

Children Characteristics

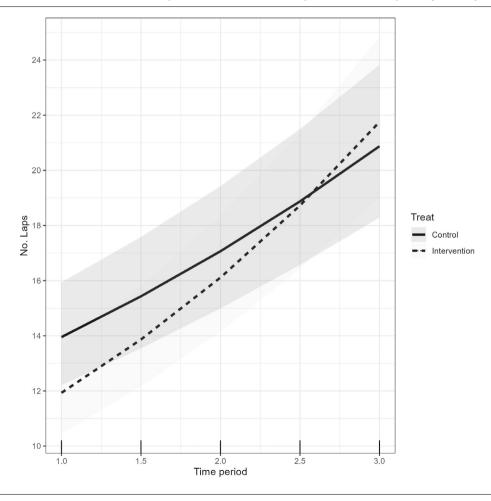
Children's mean (SD) age at baseline was 4.7 (0.3)years for both treatment groups (Table 2). The mean (SD) weight was 19.0 (4.2) kg and 18.7 (3.7) kg; BMI was 16.7 (2.5) and 16.7 (2.2) kg/m²; and obesity prevalence was 18.2% and 17.9% in control and intervention groups, respectively. At period 1 the mean (SD) number of laps ran by children in the PACER fitness test was 14.9 (8.0) and 11.8 (7.6) for control and intervention groups, respectively. This discrepancy cannot be attributed to any measurement bias nor other systematic cause. The mean (SD) hours children rest/sleep at night was 14.2 (1.07) and 14.2 (0.93); minutes/week that children were physically active was 218.5 (418) and 198.4 (323); and the percent of children who spent 1 hour or less playing with electronic devices was 49.2% and 58.1%, for control and intervention groups, respectively. Lastly, the percent of children who watched TV for 1 hour or less was 49.1%, in both treatment groups.

Intervention Effect

The unadjusted mean number of laps the children ran increased overtime for both the control and intervention groups (Figure 2). The increase, however, occurred at different rates: for the control group the average number of laps increased by 22% (CI: 19% to 26%) and for the intervention group it increased by 35% (CI: 26% to 45%) per data collection period. Using the prediction equations to compare the estimated rates of increase between groups shows that the intervention group ran, on average, 10.4% (CI: 6% to 15%) more laps per period than the control group.

After adjusting for covariates, children in both treatment arms still showed an increase in number of laps ran over time (Figure 3). The percentage increase, however, was higher in the intervention group. The number of laps ran by children in the control group

Figure 2. Predicted Rate of Rise of the Mean of Laps Ran in the PACER Test by Treatment Group Unadjusted by Covariates



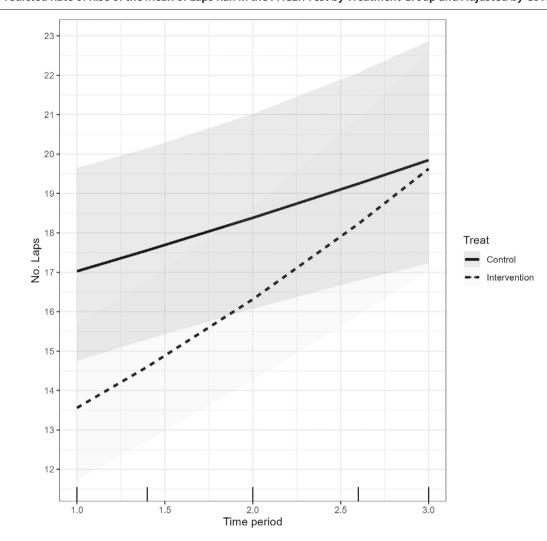


Figure 3. Predicted Rate of Rise of the Mean of Laps Ran in the PACER Test by Treatment Group and Adjusted by Covariates

increased by 23% (CI: −5% to 60%) per each data collection period compared with 53% (CI: 7% to 119%) in the intervention group. It is essential to note the association between CRF and some covariates (not shown). For each increase in a BMI unit, the average number of laps decreased by 2.8% (CI: 2.0% to 3.6%). Children who watch ≥5 hours of TV a day showed an 8% (CI: 0.1% to 15.2%) decrease in the number of laps compared with children who watched TV for ≤1 hour. Lastly, increasing the amount of exercise a child does outside of school by 30 minutes per day was associated with a 1.6% (CI: 0.4% to 2.7%) increase in the number of laps the child ran in the PACER fitness test.

DISCUSSION

The BN CSHP is a multi-pronged curriculum that includes structured instruction for the health class, physical education, child nutrition/school food service, and home environments. In all 4 components, exercise and physical activity are instructed and promoted. The major finding of this study was that children in the BN CSHP, compared to those in the control group, had a significantly higher increase in CRF. This finding is important because of the health benefits of CRF in children.^{15,34}

To our knowledge this is the only CRT to study the effects of a CSHP on CRF of preschool Latino children. This is important because CRF is associated with cardiometabolic factors among Latino children.³⁵ Low levels of CRF are also a risk factor for disease later in life.^{14,36} Unfortunately, there are not too many CRT of school-based studies that have used a physical measure such as CRF. A CRT conducted in Australia used an internet-based intervention and the PACER fitness test to measure CRF.³⁷ This study included 22 elementary schools and 1188 students from third and fourth grades. At 12- and 24-months assessments, the intervention schools had a significantly higher increase in CRF than the control schools. Another CRT study from Switzerland used a multi-prong health program and the PACER fitness test to measure CRF.³⁸ This study included 40 preschools and 727 preschool children. At the end of the preschool year, children in the intervention preschools had a higher increase in the CRF than children in the control schools. Both interventions included parent component.

Not all school-based health programs, evaluated in CRT design, have shown positive effects on children's CRF. A meta-analysis searched for CRT of school-based health intervention to determine their effect on students' fitness.³⁹ The criteria used to measure fitness was accelerometer-assessed moderate-tovigorous physical activity (MVPA). The investigators identified 17 trials that fit their criteria. They found that when studies were restricted to CRT, using an objective measure of fitness, the results showed no effect of the interventions. A common characteristic of the trials reviewed in this study was the lack of a component to engage parents. Studies have shown the importance of involving parents in their child's education to promote and sustain positive health behaviors.⁴⁰ A vital component of the BN CSHP is the MyFamily/MiFamilia workshops and newsletters. This component is implemented by school district parent liaisons and teaches families about healthier lifestyles and encourages them to walk at least 150 minutes a week and record this activity in a diary. The family component is equally important as is the Health Education and PE components. Parents are responsible for all the decisions that take place outside of the school environment. If parents and community become educated on the same subject their kids are exposed to at school, the odds of a positive behavior change in the home are likely to increase.

Although other studies have shown a positive impact of school-based health programs on physical activity, these have not been evaluated in CRT or used objective measures to assess CRF.^{41,42} CRT are the preferred method when groups or clusters of individuals rather than individuals are randomized.⁴³ The second concern with studies that have shown positive results is the use of self-reported measures. These have limited validity and challenging to compare results across studies.⁴⁴

IMPLICATIONS FOR SCHOOL HEALTH POLICY, PRACTICE, AND EQUITY

The implication for school health policy is that states mandate and provide means for schools to implement multi-prong school health programs coordinated across several environments. An example is Texas Senate Bill 19. It states that school districts are required by law to implement in grades K-8th a CSHP approved by the TEA. The bill mandates that instructional material be made available for health class, PE, child nutrition services, and home environments.

The implication for school health practices is involving parents in their child's health education. The literature reviewed in the present study showed that health interventions without a parent component had no effect and those that did showed an effect on children's fitness. The MyFamily/MiFamilia parent component involves in-school workshops and newsletters sent home with children. Children were encouraged to practice with their parents the health advice shown in the newsletters.

The implication for economic equity is the financial support of health and PE instruction. When school districts are faced with financial shortfalls one of the first departments administrators look to cut is health and PE. Health and PE are not only associated with favorable health outcomes, they are also associated with improved academic performance.⁴⁵ Schools are the ideal environment for health interventions because of the time children spend in school, the opportunity to participate in daily health and PE classes, and the availability of healthier meal options.

Strengths and Limitations

The strengths of this study were the research design and the objective measurement of physical activity. The strengths of the intervention were supported by cultural appropriateness and parent engagement. Although a CRT is more complex to design and analyze, and require more participants to obtain statistical power, it offers the ability to assess interventions that cannot be randomized at the individual level.⁴³ A study demonstrated that when physical activity was assessed by self-report and accelerometry in the same population, there was a tendency to overreport with the former.⁴⁶ The explanations given for this discrepancy are difficulty recalling, social desirability, structure of questions, and cultural differences. Thus, objectively assessing physical activity is best to overcome these limitations.

The BN CSHP is a bilingual (English and Spanish) curriculum that reaches parents with culturally appropriate messaging. Because of the need to increase fitness levels outside of the school, it is essential to involve parents and get them excited by providing educational material they understand and easily apply. Another strength of the BN CSHP is sustainability. Extensive resources are used to implement community-based programs but when funding ends, these programs are discontinued. The BN CSHP has been sustained because of state law and state recognition. Texas Senate bill 19 states that Texas school districts are required by law to implement in grades K-8 a CSHP approved by the Texas Education Agency (TEA).⁴⁷ The BN is a CSHP and it is approved by the TEA.

The study had some limitations. The study was designed for 2 school years of intervention (pre-k to kindergarten) and 4 data collection periods. The study, however, had to be stopped prematurely because of the global COVID-19 pandemic. Thus, this study only presented results of 3 data collection periods. It is unknown if the CRF results would have been sustained over the 4 data collection periods, and if recidivism would have occurred because of the pandemic putting a hold on outdoor activities. To circumvent the next pandemic, Quest Diagnostic Foundation provided funding to convert the BN CSHP instructional material to educational technology or EdTech platform. The new 3-D animated videos and gamification technology provide students with a livelier learning experience they and their parents can access online anywhere and with any instrument. The second limitation was that this study was designed to control and prevent childhood obesity after 2 years of intervention, but the programmed endpoint was not achieved as stated above. Nonetheless, to modify a biological marker the intervention must first modify a behavior, in this case CRF. The third limitation is the unknown validity and reliability of the PACER fitness test in preschool children. In the United States, the PACER fitness test is usually performed in third grade children and older. Other countries, however, have studied the PACER fitness test in children as young as 3 years of age. These investigators have shown the PACER fitness test to be valid compared with questionnaires⁴⁸ and ActiGraph Accelerometers⁴⁹; reliable using test-retest^{48,50}; and provided reference standards for children this young.^{51,52} Lastly, despite this health curriculum being designed specifically for South Texas Latino children, it might not be relevant to other US children.

Conclusion

The BN CSHP is a multi-prong school health intervention with a strong parent component that was assessed in a CRT to determine its effect on preschool children's obesity rates. In this study, CRF results were presented. It targeted mostly high-risk children living along the Texas-Mexico Border. Children in the intervention showed a significant increase in their CRF compared to children in the control schools. Further studies are needed to determine the impact of individual program components, the new EdTech platform, and translating it to other US children populations.

Human Subjects Approval Statement

The South Texas Early Prevention Study (STEPS) PreK4 IRB protocol with ref. no. IRB-18-0415 has been approved by the University of Texas-Rio Grande Valley office of Research and Compliance.

Conflict of Interest

The authors involved in this research study declared no conflict of interest.

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