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Our Choice/*Nuestra Opción:*The Imperial County, California, Childhood Obesity Research Demonstration Study (CA-CORD)

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Abstract

Background: Despite recent declines among young children, obesity remains a public health burden in the United States, including among Latino/Hispanic children. The determining factors are many and are too complex to fully address with interventions that focus on single factors, such as parenting behaviors or school policies. In this article, we describe a multisector, multilevel intervention to prevent and control childhood obesity in predominantly Mexican-origin communities in Southern California, one of three sites of the CDC-funded Childhood Obesity Research Demonstration (CA-CORD) study.

Methods: CA-CORD is a partnership between a university-affiliated research institute, a federally qualified health center, and a county public health department. We used formative research, advisory committee members' recommendations, and previous research to inform the development of the CA-CORD project. Our theory-informed multisector, multilevel intervention targets improvements in four health behaviors: fruit, vegetable, and water consumption; physical activity; and quality sleep. Intervention partners include 1200 families, a federally qualified health center (including three clinics), 26 early care and education centers, two elementary school districts (and 20 elementary schools), three community recreation centers, and three restaurants. Intervention components in these sectors target changes in behaviors, policies, systems, and the social and physical environment. Evaluation activities include assessment of the primary outcome, BMI z-score, at baseline, 12-, and 18-months post-baseline, and sector evaluations at baseline, 12, and 24 months.

Conclusions: Identifying feasible and effective strategies to prevent and control childhood obesity has the potential to effect real changes in children's current and future health status.

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Introduction

hildhood obesity remains high in the United States at 18% among 6- to 11-year-old children, despite recent declines among 2- to 5-year-olds (currently 8%). Among 6- to 11-year-olds, rates are highest among Hispanic children, with 27% of boys and 23% of girls in the obese range. 1 More concerning are rates of overweight and obesity among Hispanic children 2–5 years of age (boys, 49%; girls, 43%). Children living in rural communities and on the US-Mexico border are at even greater risk. For example, Imperial County, California, has higher overweight and obese rates among fifth, seventh, and ninth graders than overall in California (47% vs. 38%).² These rates are concerning given the consequences of childhood obesity, including adult obesity, associated comorbidities (e.g., diabetes⁴), compromises in quality of life, ^{5,6} and early mortality.⁷ The "Our Choice...is to be healthy/Nuestra Opción...es ser saludables" (OCNO) project is designed to prevent and control obesity in a vulnerable young population living in a rural, border community.

Preventing and Controlling Childhood Obesity

Successful approaches need to target multiple sectors and levels of influence simultaneously, 8-11 as indicated by the whole-child approach, 12 "Total Worker Health," 13 the Social Ecological Framework (SEF), 14,15 and several reviews and commentaries. 16-21 According to SEF, including its application to US Latinos, 22,23 levels of influence range from most to least proximal to the individual (see Fig. 1). Factors within these levels exert influence over an individual's health behaviors and outcomes; these become the targets of our interventions. The influence exerted at various levels is not always most proximal to the individual (e.g., restaurant policies on cigarette smoking). Within the

many social and structural environments in which children's behaviors are shaped and enacted, specific sectors can be identified.²⁵ Of interest to OCNO are the sectors of home, healthcare, early care and education (ECE), school, community recreation, and restaurants.

Present Study

This article describes the "Our Choice" project, herein referred to as the Imperial County, California, Childhood Obesity Research Demonstration study (CA-CORD). It is one of three CORD studies funded by the CDC in 2011 to test multisector, multilevel approaches to prevent and control childhood obesity.²⁶ CA-CORD is translating evidence-based approaches for modifying behaviors, policies, systems, and environments to promote fruit, vegetable, and water consumption, physical activity (PA), and quality sleep. The ultimate goal is to assist Children's Health Insurance Program-eligible children between 2 and 12 years of age to attain a healthy weight. In addition to sector-specific intervention and evaluation activities, CA-CORD is working with the University of Houston Evaluation Center to conduct a cross-site evaluation on a set of shared measures.

Methods

Study Design

CA-CORD is a 2×2 factorial study (see Table 1) designed to assess BMI z-score change in 1200 children, ages 2–11 years, assigned to a Health Care (HC) plus Public Health (PH) intervention, a HC intervention only, a PH intervention only, or a control condition. The HC intervention involves the implementation of an obesity care model within a federally qualified health center (FQHC) and includes a family wellness program (FWP) delivered

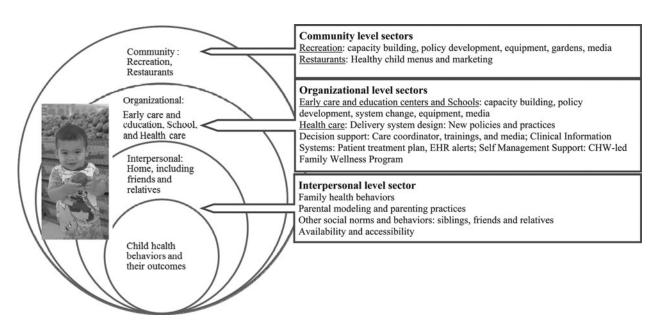


Figure 1. CA-CORD intervention model. CA-CORD, the Imperial County, California, Childhood Obesity Research Demonstration study.

Table I. CA-CORD C	Quasi-Experimental ¹ Study Design	
	Health Care	Intervention ²
Public Health Intervention ³	Health Care + Public Health n = 300 children (cities of El Centro and Brawley)	Public Health only n = 300 children (cities of El Centro and Brawley)
	Health Care only n = 300 children (city of Calexico)	Evaluation only n = 300 children (city of Calexico)

¹Condition assignment was based on city of residence and whether the child was a patient of CDSDP, the federally qualified health center delivering the Health Care intervention.

by community health workers (CHWs). The PH intervention involves working with ECE centers, schools, community recreation organizations, and restaurants to promote four health behaviors: fruit, vegetable, and water consumption; PA; and quality sleep.

Setting

Imperial County, California, is located on the US-Mexico border, and in 2010 had an estimated 174,528 residents, 77% of whom were of Mexican origin, including 32% who were foreign born.²⁷ Three quarters of all residents reported speaking a language other than English at home. The median household income was \$39,402, compared to \$61,632 in the state; and income disparities are reflected further in the differential poverty rates (county = 23% vs. state = 14%). Despite these data, the county has numerous strengths upon which CA-CORD was built, including pre-existing strong partnerships.

Partnerships

CA-CORD is a partnership between San Diego State University and the Institute for Behavioral and Community Health (IBACH), Clínicas de Salud Del Pueblo, Inc. (CDSDP), and the Imperial County Public Health Department (ICPHD). IBACH is an academically affiliated research institute.²⁸ Since 1987, IBACH's research has focused on the top contributors to early mortality, including diet, PA, and tobacco use, with a focus on the Latino community. For CA-CORD, IBACH leads on cohort recruitment and retention and on the school and restaurant interventions. CDSDP has had a 7-year partnership with IBACH and is a private, nonprofit, FQHC with the mission of providing direct access to comprehensive, quality, primary, and preventive healthcare for underserved residents. In 2013, CDSDP served 52,511 patients, including 37% who were under 18 years of age.^{29,30} For CA-CORD, CDSDP leads the HC intervention. ICPHD monitors local health problems, needs and resources, policy development, and leadership that foster local involvement and equitable distribution of resources. ICPHD was instrumental in

forming the Childhood Obesity Prevention Alliance (COPA), a key strategy of the 2008 Imperial County Children and Families First Commission Prop 10 funded program. For CA-CORD, ICPHD leads the Community Advisory Committee (CAC) and works with IBACH on the ECE and recreation interventions. The partners developed the media intervention collaboratively.

Development of the CA-CORD

Intervention Approach

The CA-CORD intervention is based on the study team's previous research, ^{29,31–36} several systematic reviews, ^{8–10,21,37–41} CA-CORD CAC input, and formative research. CA-CORD CAC members were identified during the grant-writing phase by responding to a request for participation in a community-wide approach to prevent and control child-hood obesity. Once the grant was funded, these individuals and COPA members were invited to an informational meeting. Their participation was formalized by completing a commitment form and a baseline survey. Over the first year of funding, the committee met 10 times to plan CA-CORD, and they established three working groups (healthcare, ECE, and school), ensuring that members represented a variety of agencies that serve Imperial County residents.

Focus groups of parents, healthcare providers, CHWs (promotores), ECE providers, and Special Supplemental Nutrition Program for Women, Infants, and Children providers revealed the importance of a multilevel, multisector approach to preventing and controlling overweight/obesity. It was also not uncommon for individuals from the various sectors to place responsibility on other sector members. In-depth interviews with school, restaurant, and community recreation representatives stressed the importance of feasibility and sustainability in selecting intervention activities. See Table 2 for key findings.

The CA-CORD Intervention

The CA-CORD intervention is multisector and multilevel. As depicted in Figure 1 and reflected in Table 3, it

²Health Care intervention involves clinic system changes and a family wellness program.

³Public Health intervention involves changes in early care and education centers, schools, community recreation, and restaurants.

CA-CORD, the Imperial County, California, Childhood Obesity Research Demonstration study.

Sector and method	Selected findings
Families (parents)	
Four Spanish-language focus groups $(n=36)$ and four English-language focus groups $(n=32)$ through CDSDP and ICPHD	Cost is a barrier to physical activity. Parents can be better role models. Doctors and other healthcare providers are the most credible source of weight and health information. Schools and early care and education centers can do more to promote healthy lifestyle
Healthcare	
One English-language focus group with healthcare providers $(n=4)$ through CDSDP	Parents lack education and fail to acknowledge child's weight issues. Healthcare providers need more training on how to discuss child weight issues with parents.
One bilingual focus group with CHWs/promotores $(n=14)$ through CDSDP	Parents lack education and resources to lead a healthy lifestyle. Community does not support a healthy lifestyle. Support for change needs to come from multiple sources and in multiple forms, such as policy and system changes.
One English-language focus group with WIC Providers $(n = $	Parents lack education and resources to lead a healthy lifestyle. Cultural beliefs make behavior change difficult and make it difficult to discuss weight issues with parents. Messages and other interventions need to be consistent across people and settings.
Early care and education	
Three English-language focus groups with early care and education providers $(n=6)$ through ICPHD	Obesity is the result of multiple factors, including unhealthy behaviors. The problems are many: Media influences parents; schools offer too much sugar; and restaurants try to sell foods. Important to be a role model and do what you want children to do
School	
Thirteen English-language interviews with elementary school principals through IBACH	Drinking water is accessible and students can bring water bottles, but some drinking fountains not in good working order. Most school fundraisers involve selling unhealthy foods during nonschool hours.
Two English-language interviews with food service directors through IBACH	Nutrition staff tend to be the "enforcers" making everyone accountable to follow feder guidelines. "I have become the 'no' person." Mixed message for school to allow unhealthy foods to be sold outside of school hou
Community	
Five English- and two Spanish-language interviews with restaurant owners/managers through IBACH	No child menus available in independent restaurants, thus a potential target for chang
Seven English- and seven Spanish-language interviews with restaurant employees through IBACH	Young children do make decisions on their own in restaurants. Marketing materials need to reach children.
Twenty-one English- and five Spanish-language interviews with restaurant customers through IBACH	More likely to order a fruit and vegetable side dish versus a low-fat item. Like the idea of adult menu options, but in smaller portion sizes
Three English-language interviews with community recreation organizations through IBACH	Biggest barriers for offering physical activity programs for children are finances, equipment, and skilled staff. Biggest barriers for offering healthy eating opportunities for children are lack of or limited kitchen facilities, finances, and appropriate equipment.

involves working with families, an FQHC, ECE centers, schools, community recreation organizations, and restaurants to create socially and physically supportive environments for the four targeted health behaviors of fruit, vegetable, and water consumption, PA, and quality sleep (e.g., sufficient duration of sleep). Three hallmarks of the CA-CORD intervention are that it: (1) is contextually and

behaviorally focused; (2) targets multiple levels and systems simultaneously; and (3) is informed by theory.

CA-CORD seeks to modify behaviors within the contexts in which they occur. This contextualized approach to behavior change is further supported by changes to the social and structural environments, a strategy for sustained behavior change supported by several theoretical models. ^{14,15}

		Media	• 10 copies of each CA-CORD poster each month at the three clinic sites (12 versions)	CA-CORD monthly newsletters (12 editions) Family wellness videos for workshops	CA-CORD poster (waves I and 2: 10 copies each of 8 posters distributed monthly BMI cards (similar to immunization cards)	continued on page 42
Se		Environment	• EHR changes in assessment and treatment of childhood overweight and obesity	None	Physical activity equipment: average of \$600 per center for equipment, including boom box and mp3 player with SPARK music (waves I and 2: one per center) Cooking toolkit: Average of \$250 for equipment, including water containers (waves I and 2: one per center)	100
ed Change Strategio	egies	System	Hired full-time patient care coordinator Hired full-time CHW coordinator Hired 6 full-time CHWs New system for assessment and treatment of childhood overweight and obesity, including chronic care clinic days Integration of a groupbased family wellness program into the Programs Department delivered by CHWs	Whole-family approach	• BMI assessment 2-to 5-year-olds (wave 1, years 1 and 2; wave 2, year 2)	
is of the Intervention and Selected Change Strategies	Change strategies	Policy	 Assessment of childhood overweight and obesity Treatment of childhood overweight and obesity Body weights and measures Staff meetings 	 Annual PA booster event Home environment recommendations 	NAP SACC ⁶⁹ (wave I: beginning of year I and end of year 2; wave 2: beginning and end of school year) Action planning and technical assistance (waves I and 2: quarterly meetings/year) Technical assistance (as requested)	
CA-CORD Conceptual Foundations of the Into		Capacity building (planned no. of trainings and time)	 Provider trainings (5 trainings, 4.5 hours) Staff trainings (5 trainings, 4 hours) CHW trainings (15 trainings, 114 hours) 	 Group-based parent and child wellness workshops (9 workshops, 14 hours) Group-based family physical activity workshops (8 workshops, 6 hours) Quarterly motivational interviewing calls (4 calls) 	 SPARK trainings (wave I, years I and 2: one 6-hour training plus I2-hour summer institute for agency champions in year I only: wave 2: one 6-hour training) SPARK curriculum (waves I and 2: 3 years full access to website for trainees plus average of 2 hard copies per center, depending on size of center) Provider trainings (wave I, years I and 2: four quarterly I.5-hour trainings—one series in English and one in Spanish; wave 2: four quarterly I.5-hour trainings. BMI measurement (wave I: one 2-hour training to four agencies representing centers) Toolkit (waves I and 2: 3 kits) Provider compensation for SPARK and provider training per center) 	
CA-CORD C		Conceptual foundations	Obesity care model ^{41,47}	Social cognitive theory ⁵⁰ Family systems ⁵¹ Health behavior change ^{52,53}	Social cognitive theory ⁵⁰ Organizational change theory ⁵⁴	
Table 3.		Intervention sectors	Healthcare: I Federally qualified health center 3 of 12 clinics involved		Early care and education centers: Wave 1: 13 center based Wave 2: 13 private/family	

Table 3.	CA-CORD	Table 3. CA-CORD Conceptual Foundations of the Inte	of the Intervention and Selected Change Strategies continued	ed Change Strategie	es continued	
			Change strategies	gies		
Intervention sectors	n Conceptual foundations	Capacity building (planned no. of trainings and time)	Policy	System	Environment	Media
School: 2 of 3 school districts 13 of 20 elementary schools	Social cognitive theory ⁵⁰ Organizational change theory ⁵⁴	 SPARK PE trainings (year I: two 6-hour trainings each for grades K-2 and 3-6; I2-hour summer institute for champions) SPARK champion and star training (year I: one 30-minute training) SPARK curriculum (year I: 3 years full access to website for trainees plus at least 2 hard copies per school; one K-2 and one 3-6, plus at least one afterschool curriculum per district) BMI training (year I: one training and one certification for district nurse and health aides; year 2: recertification for district nurse and health aides) Sleep curriculum (years I and 2: available upon request) Tip sheets distributed with poster (years I and 2: monthly during the school year) 	 School wellness committee (years 1 and 2: meeting attendance) Principal/ administrator/ champion/ liaison meetings (years 1 and 2: at least twice per year per school) School staff meetings (years 1 and 2: at least twice per year per school) Technical assistance (year 2: as requested) 	MMI assessment in K and fifth grade (years I and 2), second grade (years I and 2: one district), third grade (years I and 2: second district)	SPARK equipment (year I: \$1000 per district) One Shorr height board and one Seca scale (year I: one per district) Drinking water equipment (i.e., jets or containers) (year I) Water bottles with project logo (year I: all K-6 students)	CA-CORD poster (years I and 2: 10 copies of each of 10 posters per month from among I2 produced) Water poster and other water promotions (as requested) BMI parent letter template tailored to child's data
Community recreation: three organizations	Organizational change theory ⁵⁴	 SPARK trainings (two 6-hour trainings) SPARK curriculum (3 years full access to website for each trainee plus 5 hard copies per agency) Toolkit (3 kits) Community garden (four 2-hour trainings) 	 Goal setting, action planning, and technical assistance (quarterly for 2 years) Additional technical assistance as needed 	None identified	Water containers (one jug per organization) Community garden supplies (\$1000 per organization) PA equipment (\$1500 per organization for equipment, including player, speaker, and an mp3 player with SPARK music)	• CA-CORD posters (12 versions)
Restaurants: three organizations	Organizational change theory ⁵⁴	 Wait-staff training (one 45-minute training) Kitchen staff training (one 45-minute training) 	Adoption of healthy child menu items Adoption of new child menu	 Two new healthy main dish child menu offerings Three new healthy side dish child menu offerings Three new healthy child drink offerings 	Healthier foods and beverages available to children	 New menu posters (one per organization) Table tents (varied per organization) Child menus (varied per organization)
CA-CORD +	he Imperial County	CALCORD the Imperial County California Childhood Obesity Research Demonstration study. CHWs community health workers: PE physical education: PA physical activity. NAP SACO	tion study. CHWs community b	o colth workers: DE physical	Hication: DA physical act	COAD GAIN :vaivi

CA-CORD, the Imperial County, California, Childhood Obesity Research Demonstration study; CHWs, community health workers; PE, physical education; PA, physical activity; NAP SACC, the Nutrition and Physical Activity Self-Assessment for Child Care assessment tool; EHR, electronic health record.

The focus on increasing the frequency with which the four healthy behaviors occur is supported by previous research.^{29,31,33,34,42} Nevertheless, demonstrated through the concept of behavioral substitution, 43 the intervention also targets decreases in the consumption of high-fat, high-sugar snacks and beverages, as well as sedentary behaviors. For example, the family intervention promotes substituting television (TV) watching by engaging family participation in active play. An additional expected benefit of decreasing TV watching is improved sleep quality.⁴⁴ Based on previous research, behavioral substitution is an effective strategy for improving the diets of Mexican-origin children through a family-based intervention.³³ It was also successful in a tailored nutrition communication intervention with Mexicanorigin adult women. 45,46 Finally, evidence-based and theoryinformed change strategies are prioritized over those with insufficient evidence; where necessary, however, new strategies and associated materials were developed in response to our formative research findings. Described next are the HC and PH interventions.

Healthcare Intervention

The HC intervention is based on the obesity care model^{41,47} and several systematic reviews.^{10,48} Within the three largest of the 12 CDSDP clinics, new policies were adopted to promote the assessment and treatment of childhood obesity, including authorization to modify the electronic health records (EHRs) to accommodate practice changes. Using these policies and accompanying trainings developed by the study team, pediatric providers and staff were oriented to the new system, new EHR alerts, and a treatment plan for children in the overweight or obese range. To facilitate the adoption of system changes, a full-time patient care coordinator was hired to work across the three clinics to facilitate model implementation.

In addition to changes in healthcare delivery, an adapted FWP^{29,32–34,36} was integrated into CDSDP's Programs Department and is being administered by a full-time CHW coordinator and implemented by six full-time CHWs. A key feature of the FWP is its delivery by CHWs within a healthcare system and the documentation of CHW support in the child's EHRs. CHWs have been shown to be able to deliver an intervention with fidelity and achieve behavior change, ^{29,45,49} but their involvement as a team member to prevent and control childhood obesity is an innovation of CA-CORD. A second key feature of the FWP is that it simultaneously targets improvements in several health behaviors and parenting practices associated with these health behaviors, an evidence-based strategy. 34,36,37 This provides the opportunity for parents and their children to select a focus (e.g., reduce sugary beverage consumption) or behavioral strategy (e.g., do not have sugary drinks in the home) from several presented consistent with the Our

CHWs received 114 hours of training, were evaluated by direct observation preceding engaging study families, and were supervised by the CHW coordinator. The FWP is

based on social cognitive theory (SCT),⁵⁰ family systems theory,⁵¹ and health behavior change research.^{52,53} The program includes separate wellness workshops for parents and children, which are followed by PA workshops for families. Groups of families participate in these workshops together over the course of 12 weeks. The 1.5-hour wellness workshops provide opportunities for understanding and practicing the behavioral goals in age-appropriate ways. Parents were provided opportunities to discuss potential solutions to challenges encountered in adopting new behaviors when attempting to achieve goals and were empowered to try new behaviors and generalize behavior change to other settings. The 45-minute PA workshops provide family members opportunities to engage in fun PAs together and learn how to encourage others to be active. From the CHWs, families also receive 12 monthly newsletters, quarterly motivational interviewing phone calls, and an invitation to an annual PA community event.

Public Health Intervention

Early care and education centers and schools. The ECE and school interventions use similar change strategies, with the ultimate goal of providing opportunities for children to engage in healthy eating, PA, and sleep behaviors through policy, system, and environmental changes. The development of the interventions in both locations was informed by SCT50 and organizational change theory54 and recommendations from numerous professional organizations to affect changes in these sectors. 25,55 As an example, ECE providers and teachers were trained to use SPARK©⁵⁶ to promote PA throughout the day and as part of physical education (PE). ECE centers are encouraged to provide opportunities for active play throughout the day. Schools are mandated by the State of California to provide a minimum of 200 hours every 10 days for elementary schools.⁵⁷ This recognizes theory-informed recommendations to intervene in the environment to support healthier behaviors,⁵⁸ the importance of building organizational capacity to address identified needs,⁵⁹ and to respond to policy demands. 11,58,60 Despite their similarities, implementation of the ECE and school interventions are somewhat different (detailed further in Table 3).

Community: Recreation Organizations and Restaurants

The recreation intervention involves trainings and technical assistance to build capacity to promote the four behaviors, work toward policy changes in needed areas, and make environmental changes. The recreation intervention is notable for the development of gardens in two locations.

The restaurant intervention involves testing several strategies to promote healthy menu options for children in local independent restaurants. A systematic enumeration of all restaurants using three sources identified 132 restaurants in the PH intervention communities. Fifty percent (n=66) were randomly sampled and audits conducted to

describe the restaurant environment. The pilot restaurant intervention in three restaurants, informed by the work of others on how to market to children and parents, ^{61–63} has involved the implementation of healthy children menu options and their promotion through new menus, table tents, and wait-staff trainings.

Plans for sustaining the interventions in all sectors are ongoing,⁶⁴ with strategies including recognizing achievements of sector representatives and stakeholders, identifying organizational champions to facilitate the ongoing change process (*e.g.*, the superintendent, the assistant superintendent, an academic coach, an elementary school principal, and a teacher), making print resources available on the Web, and providing ongoing technical assistance through participation in COPA.

Evaluation Overview

The CA-CORD evaluation protocol includes process, impact, and outcome evaluation components that involve children, parents, and organizations. It complements and supports the University of Houston Evaluation Center activities through a set of shared consensus measures. To assess the primary aim of determining whether the HC plus PH intervention is more effective than the other three conditions at helping children to achieve a healthy weight, 1200 children and parents are being recruited to participate in data collection at baseline and again 12 and 18 months later. As depicted in Figure 2, in this quasi-experimental study, condition assignment is based on whether the child is a patient of CDSDP and if primary-school aged, a student in a participating school (or for non-school-age children, the family's residence is in an intervention city). For example, 3-year-old children who are patients of CDSDP and residents of El Centro are placed in the HC plus PH intervention condition, whereas resident children who are not CDSDP patients are assigned to the PH intervention condition.

Initial inclusion criteria for families was 1 child per household between 2 and 10 years of age, the child's BMI at or above the 75th percentile, and the child not currently taking medications that affect weight. The family had to have plans to remain in the area for the duration of the study, and the participating parent had to understand English or Spanish. Owing to recruitment challenges, inclusion criteria were expanded to include up to 2 children per household, children up to 11 years of age, those with a BMI at or above the 5th percentile, and those on stimulant medications for attention deficit hyperactivity disorder.

The outcome and impact evaluation protocols include measured and observed data collection from children and parents, interviews with parents reporting on themselves, their children, and their family, and interviews and observations with agency representatives from all sectors. To collect additional PA and sleep data, a subsample of cohort children and parents are also asked to wear a triaxial accelerometer (ActiGraph GT3X+; ActiGraph, Pensacola, FL) for 7 days. Cost data are also being collected from the

clinic and the school perspectives, including the extent to which the various organizations incurred costs associated with implementation. A cost-effectiveness analysis will combine these costs (excluding research costs) and the health outcomes achieved.

Process evaluation protocols are comprehensive, including measures of context, reach, dose delivered, dose received, and intervention fidelity. ^{67,68} Various methods are being used, including abstracting information from the EHR, CHWs using iPADs to log family contact, and interviews with parents and agency representatives.

Power Calculations

Several initial assumptions were made for the power calculations. The mean standardized BMI z-score in the control is assumed to be 0.8. The standard deviation of the mean standardized BMI z-score is assumed to be 0.2. The largest reduction (0.1) of the standardized BMI z-score is assumed to occur in the HC plus PH intervention condition versus the evaluation-only condition. The reduction from the HC intervention is assumed to be at 0.05 and that from the PH intervention at 0.025. The alpha level is set at 0.05. With N=1007, the study has 80% power to detect significant changes for different comparisons, except the PH intervention condition versus control condition. Inflated by 20% to account for attrition, the required sample size is 300 per condition or 1200 total, including a 20% attrition that is expected over the 18-month evaluation period. A second power calculation was performed when multiple children from the same household were included owing to recruitment challenges. The intraclass correlation on BMI between 2 children from the same household was found to be 0.246. Simulating the inflated sample size needed in order to maintain the previously estimated statistical power if 30% of the children were from the same household for example, then 1400 are needed to maintain the same statistical power of the previous study design.

Analysis of Primary Aim

Univariate statistics will be conducted on primary and secondary endpoints as well as baseline covariates to describe the sample characteristics. Cross-group comparisons will be conducted on all of the baseline covariates to identify potential sample differences and adjusted in the subsequent multivariate models. Propensity scores for belonging to each site on baseline covariates will be estimated using polychomotous logistic regression and used as an additional covariate in the subsequent multilevel modeling. Correlation matrices of repeated measures of different endpoints will be calculated to suggest the correct correlation structures in the subsequent multilevel modeling.

Mixed-effects models will be used for analyzing the primary endpoint—BMI z-score. The main independent variable will be the CONDITION and a TIME variable to represent the repeated measure time points. The main effects of CONDITION, TIME, and CONDITION×TIME will be tested. Other unbalanced covariates and the

estimated propensity score will be added to the mixed-effects model to control for their confounding effects. Whereas the primary endpoint is BMI z-score, path analytic partial least squares will explore the potential underlying mediation and moderation effects using demographics, cultural, behavioral, and environmental data. Finally, when evaluating multicomponent interventions, it is usually of interest to explore which component produced the largest effect on the outcome. The variance importance of projection in the partial least squares method will help determine which components contributed more influence on BMI z-score.

Discussion

CA-CORD is one of three field sites funded by the CDC to identify multisector, multilevel approaches to prevent and control childhood obesity. Sites in Massachusetts and Texas are implementing similar strategies, providing the Evaluation Center the opportunity to examine strategies across diverse communities and its members. There remains an urgent need to identify cost-effective strategies that target multiple sectors and levels of influence simultaneously. The CA-CORD study is working with families, an FQHC, ECE centers, schools, community recreation organizations, and restaurants to support healthier lifestyle behaviors.

Limitations

A number of limitations should be noted. This article describes the CA-CORD intervention as intended to be delivered. Differences, however, are emerging between what was planned and what is being delivered. For example, in the HC intervention, a registered dietitian was going to be hired per the obesity care model;^{41,47} but no qualified personnel applied. Intervention fidelity has been challenging given staff changes, time constraints, and competing demands. A second limitation is that only three cities are involved, and city is nested within study design; although the cities are comparable on some dimensions, such as being rural, they differ on others, such as proximity to the border. Analyses will attempt to control for sources of variance associated with city. Despite this concern, in our previous studies in these three communities, we found no differences in similar health outcomes and behaviors among children and their parents participating in a healthy eating randomized, controlled trial.³³ A third limitation is the inclusion of children below the 75th percentile. This study design element was modified during cohort recruitment to reach the goal of 1200 children. Such a wide variance in BMI percentile will make it more challenging to find a statistically significant effect.

Conclusions

These studies and studies, funded by the NIH, the Robert Wood Johnson Foundation's Active Living Research,

Healthy Eating Research, and SaludAmerica! programs, are among the leaders in identifying the best approaches for maintaining the health of children. This research has the potential to inform best practices across sectors.

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