Study Protocol for a Home-Based Obesity Prevention Program in Latino Preschool Children

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ABSTRACT

This article describes the study design for ANDALE Pittsburgh, a culturally appropriate, family-based intervention to promote a healthy weight in Latino preschool children. The study was organized into two major phases: phase I—conduct focus groups with 30 Latino parents of preschool children to inform the development of a culturally appropriate intervention; phase II—test the feasibility and effectiveness of the intervention with 50 families. Participants were recruited from an emerging Latino community through community gatherings, flyers, and word of mouth. Six *promotoras* (females >18 yr, active in community) received 25 h of training using the intervention curriculum finalized after phase I. Promotoras delivered the home-based intervention to families for ten 90-min weekly sessions that included education, practice, and action (i.e., goal setting). Behavior modification constructs and strategies (e.g., goal setting, problem solving, and social support), and building of self-efficacy through healthy recipe preparation and physical activity breaks, were also included. Outcomes (e.g., child body mass index) were assessed pre- and postintervention. Process evaluation assessed fidelity, dose, reach, recruitment, and contextual factors using multiple data sources and mixed methods. The ANDALE Pittsburgh study will expand the body of knowledge on interventions to promote a healthy weight in Latino preschool children living in an emerging Latino community. If successful, this approach will be evaluated in a future, larger-scale intervention and provide a potential model to help to address and prevent obesity in this population.

INTRODUCTION

Latinos comprise approximately 16% of the total U.S. population and are the largest growing minority group in the United States (22). Approximately 16.7% of Latino preschool children are considered obese compared with 3.5% non-Latino White, 11.3% non-Latino Black, and 3.4% non-Latino Asian children (41). Consequently, children from Latino families face greater risk of weight-related health problems such as diabetes, heart disease, and cancer compared with their non-Latino White counterparts (29). As the U.S. Latino population continues to increase, the public health need for effective, culturally appropriate obesity interventions for Latino children escalates.

Because families play an integral role in shaping children's health behaviors (9,32), early childhood obesity interventions targeting preschool children within the home environment are essential. To date, few effective child obesity prevention programs exist that target Latino preschool children (31,54). Family-based interventions tailored to Latinos may be particularly successful, given the emphasis on the family unit and the collectivist cultural orientation that puts the needs of the family above those of the individual (43). Furthermore, *promotoras* (i.e., peer health educators who are trusted individuals from the community and share common characteristics with the target population) (53) have been effective in increasing knowledge and promoting behavior changes in Latino populations (3). To our knowledge, only two previous promotora-mediated child obesity interventions targeted young Latino children and their parents (8,14). Although the interventions were effective in changing child physical activity and dietary behaviors, they were not effective in reducing child weight status. There have been two additional protocols published of randomized controlled trials that target Latino preschool children and their parents and included promotoras, and the results are forthcoming. In contrast to this study, one targeted only overweight or obese children (60), and the other supplemented brief motivational counseling in a pediatric primary care clinic with monthly home visits by a promotora (24).

Even less is known about the determinants of obesity and successful intervention approaches for Latinos living in emerging Latino communities (ELC). Approximately 20% of all Latinos live in ELC, areas with low (<5%) yet growing concentrations of Latinos (15). Because of insufficient linguistically and

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2379-2868/0214/0085–0091
Translational Journal of the ACSM

culturally appropriate services, they are likely at risk for poorer health outcomes. However, little is known or published on these populations (15,18). Promotoras could be especially effective in this group and improve intervention reach and retention given the ability to enhance cultural receptivity and foster trust among participants (36). As such, the purpose of this article was to describe the study design for ANDALE Pittsburgh (*Actividad, Nutrición, y Diversion, Apoyando a los Latinos en Pittsburgh*; Physical Activity, Nutrition, and Fun, Supporting Latinos in Pittsburgh), a culturally appropriate, home-based intervention to promote a healthy weight in Latino preschool children living in an ELC.

METHODS/DESIGN

Study Design

The ANDALE Pittsburgh study used a mixed methods sequential research design. Specifically, the research design was organized into two major phases: phase 1—(a) conduct focus groups with Latino parents of preschool children and (b) develop the intervention plan; phase 2—(a) test the feasibility of the intervention (i.e., protocols and implementation) and (b) evaluate the effectiveness of the intervention in changing primary and secondary outcome measures. The study was approved by the Institutional Review Board at the University of Pittsburgh.

Study Setting and Participants

Participants included Latino families with 2–5-yr-old children living in an ELC in Allegheny County, Pennsylvania. According to the U.S. Census data, the Latino population in Allegheny County experienced a 71% increase between 2000 and 2010 (55), estimating the population at 24,000. The majority of Latinos in the region come from Mexico (36%) and Puerto Rico (20%) (55). On average, the population tends to be young (median age of 26.6 yr) with low education (35% of those 25 yr and older have a high school diploma equivalent or less). The population is scattered throughout the region with no concentration in a single neighborhood or area (20,34) and faces barriers to health care, legal, and social services (18,20). For this study, eligibility criteria included the following: (a) parent self-identify as Hispanic/Latino, (b) have at least one child between 2 and 5 yr old, and (c) can speak English or Spanish. Study staff screened interested participants for eligibility on the phone or in person.

Recruitment Methods

Participants

During phase 1 of the study, 31 Latino parents of children ages 2–5 yr were recruited to participate in five focus group discussions that occurred between fall of 2014 and spring of 2015. Purposive sampling procedures were used to recruit participants representative of the Latino population in Allegheny County. Bilingual study staff recruited participants using various strategies, including approaching families at events (e.g., Three Kings Day celebration), and places where Latinos congregate (e.g., Latino grocery stores and churches), using flyers, Facebook, and word of mouth. Further, a bilingual health clinic and two community resource centers serving Latinos referred participants to the study team after receiving their approval.

During phase 2 of the study, 51 Latino parent/child dyads were recruited to participate in the 10-wk ANDALE Pittsburgh intervention. Similar recruitment strategies were used as to those in phase 1, with the addition of promotoras recruiting eligible families from their own social networks (i.e., personal and organizational contacts). Recruited families were representative of the Latino population in Allegheny County. Specifically, families were primarily from Mexico (65%), with low acculturation (86%), and 47% reported high school or less as highest education in the household. On average, children were 3.9 ± 1.3 yr old (40.8% female) and parents were 33.5 ± 6.1 yr old (100% female), 98% were married, and 71% were stay-at-home caregivers.

Promotoras

Consulting published literature on promotora roles, recruitment, and selection (27,39), the following characteristics were identified as required for promotoras in this study, including the following: Latina females >18 yr, Spanish speaking, strong ties/active in Latino community, resourceful, role models, and possessing leadership qualities. Other desirable qualities included being proactive, outgoing, empathetic, organized, and a problem solver. Promotoras were identified and recruited through several Latino-serving community-based organizations, preexisting community contacts, and word of mouth. Interested women were invited to submit their resume to the study team, and 12 candidates were interviewed by the project coordinator using an interview guide developed by the research team. Of the 12 interviewed women, 10 were invited to attend subsequent promotora trainings; one woman declined to continue the training after attending the first session.

Promotora Training

Nine promotoras completed 25 h of training for 5 d delivered by the project coordinator using a train the trainer model and the intervention curriculum finalized after phase 1. Session topics included promotora core roles and skills-based (e.g., record keeping and planning), health (e.g., obesity, physical activity, and nutrition), and research implementation knowledge (39). At the training, promotoras were oriented to the structure of and materials for home visits and engaged in role-play, recipe preparation/tasting, and physical activity breaks. During intervention implementation, three promotoras were not able to continue assisting with the study (two due to pregnancy complications and one due to the time commitment), resulting in six promotoras implementing the intervention with families. Table 1 includes an overview of the 5-d training module for promotoras.

Theoretical Framework

This study was guided by a socioecological framework (11) and the social cognitive theory (SCT) (5). A socioecological perspective emphasizes the interconnectedness of systems; the relationships between child physical activity, diet, and weight status are nested within the parent, home, and cultural environment. Furthermore, family has been identified as the foremost ecological level in which to prevent Latino child obesity (47). SCT provided a framework to explain why individuals develop and maintain health behaviors, and how these learned behaviors are influenced by the individual's environment and self-efficacy. The literature suggests that Latino parents can also influence their child's risk for obesity through parenting strategies, provision of instrumental support, family behaviors, and modeling of health behaviors (4).

Adopting this theoretical framework, this study aimed to assist Latino parents in creating supportive home environments to promote a healthy weight status in their children. Specifically, the intervention focused on building parental self-efficacy in planning and preparing healthy meals through skills-based learning (i.e., preparing and sampling healthy recipes, planning a healthy meal using the MyPlate model, and strategies to shop on a budget), as well as engaging parents in physical activity breaks with their children. The emphasis on increasing parental self-efficacy was further used through behavior modification strategies such as developing problem solving and goal setting skills weekly as well as

TABLE 1.
Overview of Five 5-h Promotora Training Modules.

Session	Main Topic	Content
1	Introduction to the study	• Study objectives • Introduction to a research study • Promotora's roles and responsibilities • Common challenges for promotoras working with families and strategies to overcome them
	Health topics	• Introduction to child obesity and statistics on Latinos living in the United States • Introduction to overweight/obesity: causes and effects • Physical activity and healthy eating
	Communication	• Different perspectives and feelings • Communication barriers
2	Ethics	• Ethical principles • Confidentiality, respect, and privacy
	Research study	• Behavior change strategies • Characteristics of participants and their neighborhoods • Recruitment strategies • Keeping track of information (filling out forms, planning home visits, and organizing information)
	Communication	• Listening skills • Observation skills
3	Intervention: review, practice, and identify key content	• Session 1: living healthy as a family • Session 2: physical activity and health • Session 3: healthy eating everyday • Session 4: skillful supermarket shopper
4	Intervention: review, practice, and identify key content	• Session 5: modification in food preparation • Session 6: movement and family health • Session 7: reducing sedentary time • Recipe preparation/practice
5	Intervention: review, practice, and identify key content	• Session 8: feeding practice and beverage guidelines • Session 9: portion control • Session 10: the community and your health needs

building social support networks. The goal of skills-based learning and behavior modification strategies to increase parental self-efficacy was to develop self-regulatory skills in creating a healthy home environment. Self-regulation, an important construct in SCT, is the goal of behavior modification strategies to develop an individual's skills to manage their own goal-directed behavior.

Intervention Development

The specific intervention components were drawn from (a) the research team's previous studies with preschool children (25,45, 46,56) and *promotores* (19,35), (b) published Latino child obesity prevention interventions (6,10,14,52,57,59), and (c) formative research conducted in phase 1 of the study. Guidance and suggestions to improve the intervention protocol were received through feedback from (a) the Community Research Advisory Board through the Center for Health Equity at the University of Pittsburgh; (b) the Latino Engagement Group for Salud, a coalition of community members, researchers, and health and social service providers; and (c) a research advisory board consisting of five faculty experts on family-based interventions and Latino health research from the University of South Carolina. The intervention was delivered in two waves; each wave included 25 parent/child dyads. After wave 1 was completed, feedback was received from the promotoras on the content and ease of delivery for the intervention protocol. Final adaptations from this feedback were made to the intervention protocol before being delivered in wave 2. Key adaptations for wave 2 included decreasing educational content and increasing skills-based learning activities.

Intervention Description

The intervention focused on improving dietary intake, decreasing sedentary behavior, and increasing physical activity using the 5-2-1-0 message (5 or more servings of fruits and vegetables, 2 h or less of recreational screen time, 1 h or more of physical activity, and 0 sugary drinks and more water) (1). Promotoras delivered the home-based, face-to-face intervention to families for ten 90-min weekly sessions that included education, practice, and action (i.e., goal setting and problem solving). Intervention topics included a healthy lifestyle (i.e., diet and physical activity), reducing sedentary time, healthy eating for the entire family, and community nutrition and physical activity resources. Behavior modification constructs and strategies (e.g., goal setting, problem solving, and social support), and building of self-efficacy through healthy

recipe preparation and physical activity breaks, were also included. A key feature of the intervention protocol was the use of promotora-guided but parent-derived goal setting activities. Each session allocated time for promotoras to discuss the barriers parents faced in implementing the components of the intervention for the past week and problem solve through those barriers with the families. Goal setting was derived from either implementing a brainstormed solution to a barrier they faced, or an area of the intervention in which they lacked self-efficacy. In this way, the intervention could be personalized to each families' specific abilities, barriers, and environments. The format and content of the ten 90-min home-based sessions are summarized in the supplemental content (see Table, Supplemental Digital Content 1, Overview of the ANDALE Pittsburgh intervention, http://links.lww.com/TJACSM/A17).

Process Evaluation

Process evaluation planning followed a six-step process adapted from Linnan and Steckler (33). Using a logic model guide, we developed a comprehensive set of questions to assess fidelity, dose, reach, recruitment, and contextual factors using multiple data sources and quantitative and qualitative methods. Table 2 outlines the process evaluation plan, including process evaluation questions, methods, and reporting. Process data were collected by the project coordinator and a trained research assistant.

Outcome Evaluation

A trained research assistant visited participating families' homes along with the promotora to get informed consent and to deliver the accelerometer for the child to wear 7–10 d before session 1. Detailed verbal and written instructions on how and when children wear the accelerometers were provided to parents. The research assistant completed the survey and anthropometric measures during the first and last home visits (sessions 1 and 10). At session 10, the research assistant also distributed the accelerometer for the child to wear during the following 7 d and picked them up upon completion of the study.

Child measures

Anthropometry and weight status

Anthropometric measurements were collected with the participants wearing light clothing without shoes, using standardized methods and equipment (2). Height and weight were measured using Seca 213 mobile stadiometer and Seca model 869 scales (Seca North America, Chino, CA). Body mass index (BMI) was calculated using the standard equation (body weight [kg]/height [m]^2). The primary outcome measures included child BMI *z*-scores and percentiles based on CDC growth charts and change in this outcome from baseline to follow-up. Secondary outcome measures included child waist circumference measured in triplicate at the level of the umbilicus to the nearest 0.1 cm.

Physical activity

Physical activity was measured by ActiGraph GT3X (Pensacola, FL) accelerometers during a 7-d period. Children wore the monitors on an elastic belt on their right hip. Parents were instructed to remove the monitor only during sleep or water-related activities (e.g., bathing and swimming). Data were collected and stored in 15-s intervals to capture the sporadic activity patterns that are typical of young children. Data were reduced using activity intensity cut points developed for preschool-aged children (44). Minutes per hour of sedentary, moderate-to-vigorous physical activity, and total physical activity were calculated.

Screen time behavior

Parents reported how many minutes per day their child spent watching TV, playing or working on the Internet/computer, and playing video games.

Dietary behavior

Child dietary intake was assessed via English or Spanish versions of the validated Block Food Screener for Kids 2007 (NutritionQuest, Berkeley, CA) (26). Parents completed the screener to assess children's dietary intake from the past week. A version of this screener has been used previously with Latino children (16). The screener included questions related to the consumption of approximately 42 food items as well as portion size (a little, some, and a lot). It took parents approximately 15–20 min to complete. Data were processed using standardized algorithms to yield estimates of the child's intake of fruit/fruit juice (cups per day), vegetables (without potatoes; cups per day), legumes (cups per day), whole grains (ounces per day), saturated fat (grams per day), added sugar and syrup (teaspoons per day), and sugar-sweetened beverages (calories per day; teaspoons per day).

Environmental measures

Parent anthropometry and weight status

Parent height and weight were measured using a similar protocol described for children, and BMI was calculated. Waist and hip circumferences were also measured using standard protocols (2), and waist-to-hip ratios were calculated.

Parent health behaviors

Parent physical activity was measured via self-report using three items adapted from a validated survey (38) and translated into Spanish. Specifically, parents reported the number of hours in a usual week that they spent in mild exercise (light physical activity), moderate exercise (moderate physical activity), and strenuous exercise (vigorous physical activity). Response options included the following: (a) none, (b) less than 0.5 h·wk^{-1}, (c) 0.5–2 h·wk^{-1}, (d) 2.5 to 4 h·wk^{-1}, (e) 4.5 to 6 h·wk^{-1}, and (f) 6+ h·wk^{-1}. To estimate time spent sedentary, parents also reported, on an average day, how many hours they spent watching TV, DVDs, or videos. Parents also reported in the last week how often they consumed breakfast, fruit, vegetables, sugar-sweetened beverages, and fast food (7).

Home social and physical environment

To assess the social and physical home environment related to diet and physical activity, parents completed a survey adapted from several sources and translated into Spanish. Specifically, physical activity items included physical activity resources and media availability (17), parent physical activity self-efficacy (49), modeling behaviors (21), and support for child physical activity (50). Diet items included meal and feeding behaviors (12,13) and support for child healthy eating (48). Parenting strategies related to children's diet and physical activity were also assessed (30).

Sociodemographics

Demographic variables were assessed via parent report at baseline and included information on parent and child age and gender, parent marital status, education, income, employment status, country of birth, and acculturation (37).

Sample Size and Power

The target of four to five focus groups (which would comprise approximately 30–35 participants) was selected based on focus group design recommendations to reach saturation for a single

TABLE 2.
Summary of Process Evaluation Methods.

Element	Question	Data Sources	Tools/Procedures	Timing of Data Collection	Data Analysis/Synthesis
Fidelity	To what extent was the curriculum implemented as planned?	• Promotoras	• Self-reported checklist and observation with checklist	• Promotoras reported once; at least two observations of promotoras during home visit	• Calculate score based on percent intended characteristics included
Dose delivered	To what extent were all lessons implemented?	• Promotoras • Participants	• Self-reported checklist	• Promotoras reported once; participants reported once	• Calculate score based on percent intended lessons included
Dose received	1. Did the parents enjoy the curriculum and activities? 2. Were the promotoras satisfied with the curriculum?	• Participants • Promotoras	• Satisfaction scales	• End of 10-wk period after curriculum was implemented	• Response frequencies summarized
Reach	Was the intervention delivered to at least 80% of the families?	• Promotoras	• Weekly attendance records	• Following each home visit	• Examine no. families who attended 80% of the sessions/total no. families
Recruitment	1. What procedures were followed to recruit families? 2. What procedures were effective/ineffective?	• Promotoras • Project coordinator	• Document all recruitment procedures	• Daily	• Narrative description of procedures
Context	What were the barriers and facilitators to implementing the curriculum?	• Promotoras • Project coordinator	• Group debriefing session with promotoras • Project coordinator log	• End of 10-wk period after curriculum is implemented	• Themes identified through qualitative analysis

category of participants (28). Sample size and power calculations for the intervention were based on repeated-measures ANOVA with pre- to postintervention change in BMI *z*-score as the primary outcome. We used GPower 3 software for all calculations (23). On the basis of data from a previous child obesity intervention with 2- to 4-yr-old Latino children (mean decrease in BMI *z*-score of 0.20, SE = 0.80) (52), we expected that, on average, children participating in the intervention will slightly decrease their BMI *z*-score. We anticipated an effect size of 0.15 to 0.20, with correlations between 0.60 and 0.80. With 50 parent–child dyads, we had 65% to 90% power using a two-sided *t*-test and a 5% significance level.

Statistical Analysis

Descriptive analyses will be conducted to assess the feasibility of participant recruitment and retention and the intervention procedure, and primarily based on qualitative process data collected from the project coordinator, promotoras, and participants, as well as promotora feedback after training. Descriptive analyses will also be conducted to quantify the level of intervention implementation (i.e., fidelity, dose, reach, and contextual factors) in a manner similar to previous work conducted by the investigative team (51). Briefly, results will be summarized (e.g., mean scores and overall percent scores), and an overall mean score will be calculated to reflect overall fidelity with which the curriculum was implemented.

Descriptive statistics for baseline sociodemographic characteristics will be summarized as either means and SD or percentages and sample size. Changes from pre- to postintervention will be tested for statistical significance using paired *t*-tests or nonparametric Wilcoxon signed-rank tests for categorical or nonnormally distributed data. To investigate the relationship between changes in the primary (e.g., child BMI *z*-score and percentile) and secondary (e.g., child diet and physical activity behaviors, parent BMI, parent self-efficacy, and home environment) outcomes, ANCOVA will be performed adjusting for baseline levels of the outcomes and covariates (e.g., gender and age). All data analyses will be performed using Stata version 14 (College Station, TX).

DISCUSSION

Despite the disproportionate levels of obesity experienced by Latino preschool children, evidence to prevent excessive weight gain and to promote healthy behaviors in this population is lacking. The efficacy of culturally tailored, home-based childhood obesity interventions to promote a healthy weight is inconclusive. At the time this investigation was initiated, to our knowledge only one study has exclusively used promotoras to deliver a child obesity intervention for Latino preschool-aged children, and this study only included overweight or obese children (60). Promotoras enhanced the cultural receptivity of the intervention and improved reach and retention of the study population (43). Furthermore, promotoras served as role models and provided social support to the families, empowering them to identify their own needs and implement their own solutions (58). Second, family-based interventions tailored to the Latino community may be particularly successful given the cultural emphasis on family cohesion (i.e., *familismo*) and respect (i.e., *respeto*) (42). The proposed research capitalized on traditional Latino cultural values by using promotoras to deliver the intervention in the home with parents, children, siblings, and other family members encouraged to participate. A focus on the entire family unit supports the feasibility, acceptability, and ultimately the success of the intervention.

A recent review of the literature exploring home environmental influences on childhood obesity in the Latino population concluded that parental influences (e.g., parent feeding practices and modeling), screen time, and physical activity/sedentary behavior were among those key factors that may contribute to the disproportionate burden of obesity experienced by Latino children (40). The described study, ANDALE Pittsburgh, targets those key factors through a culturally tailored, home-based child obesity prevention intervention. Further, the study is innovative because it includes Latino families with preschool-aged children living in an ELC, characterized by social isolation, limited infrastructure capacity, and limited resources (15,18). ANDALE Pittsburgh will expand the body of knowledge on interventions to promote a healthy weight in Latino preschool children. If successful, this approach will be evaluated in a future, larger-scale intervention and provide a potential model to help to address and prevent obesity in Latino families with preschool children, a highly significant and growing public health problem.

This work was supported by a grant from the National Heart, Lung, and Blood Institute at the National Institutes of Health (NIH/NHLBI 5R21HL119395-03). The authors thank the numerous individuals, both academic and community based, who provided valuable feedback on the intervention protocol.

There are no conflicts of interest to declare. The results of the present study do not constitute endorsement by the American College of Sports Medicine.

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