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Healthy Families Study: Design of a Childhood Obesity Prevention Trial for Hispanic Families

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Abstract

Background—The childhood obesity epidemic disproportionately affects Hispanics. This paper reports on the design of the ongoing Healthy Families Study, a randomized controlled trial testing the efficacy of a community-based, behavioral family intervention to prevent excessive weight gain in Hispanic children using a community-based participatory research approach.

Methods—The study will enroll 272 Hispanic families with children ages 5–7 residing in greater Nashville, Tennessee, United States. Families are randomized to the active weight gain prevention intervention or an alternative intervention focused on oral health. Lay community health promoters implement the interventions primarily in Spanish in a community center. The active intervention was adapted from the *We Can!* parent program to be culturally-targeted for Hispanic families and for younger children. This 12-month intervention promotes healthy eating behaviors, increased physical activity, and decreased sedentary behavior, with an emphasis on parental modeling and experiential learning for children. Families attend eight bi-monthly group sessions during four months then receive information and/or support by phone or mail each month for eight months. The primary outcome is change in children's body mass index. Secondary outcomes are changes in children's waist circumference, dietary behaviors, preferences for fruits and vegetables, physical activity, and screen time.

Results—Enrollment and data collection are in progress.

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Conclusion—This study will contribute valuable evidence on efficacy of a childhood obesity prevention intervention targeting Hispanic families with implications for reducing disparities.

Keywords

Overweight; Obesity prevention; Cluster-randomized controlled trial; Children; Hispanics; We Can

1. Introduction

Childhood obesity is considered a critical public health threat in the United States (U.S.) due to rapidly increasing prevalence among children and adults over the past three decades [1]. Excess energy intake combined with insufficient physical activity are major contributing factors to the current childhood obesity epidemic. The rise in obesity parallels changes in the physical design of communities that reduce active transportation and recreation, changes in dietary practices, decreases in physical activity, and increases in sedentary behavior [2, 3]. Childhood obesity poses both intermediate and long-term health risks, leading to debilitating and life-threatening conditions, as well as considerable economic costs [4–6]. While this trend in the U.S. cuts across socioeconomic levels, low-income children and children from certain racial/ethnic groups, including Hispanics are disproportionately affected [7–10].

A landmark Institute of Medicine report on preventing childhood obesity identified the evaluation of obesity prevention interventions as a research priority with emphasis on dietary behaviors, increasing physical activity levels, and reducing sedentary behavior [11]. Additionally, recommendations focus on the development of interventions that use culturally-targeted approaches to meet the needs of ethnically diverse populations [12] as well as the use of community engagement and participatory research as a strategy for addressing health disparities in obesity [13]. Given that Hispanic communities carry a relatively heavy burden in the growing epidemic of obesity and related chronic conditions, innovative obesity prevention programs that are culturally appropriate and scalable are needed to target this population. The use of lay Community Health Promoters (CHPs, or *promotoras/promotores de salud*, also called lay health advisors or peer educators) has been demonstrated as an effective strategy for delivering culturally-appropriate health promotion interventions in Hispanic communities [14–16]. Interventions targeting Hispanics should also be designed to accommodate and address low levels of health literacy [17], since adult health literacy among U.S. ethnic groups is lowest for Hispanics and persons for whom Spanish is their first language [18].

Studies have tested culturally-targeted obesity prevention or treatment interventions involving Hispanic adults in community settings [19–21], Hispanic children in school settings [22–25], and Hispanic pre-school aged children in childcare and community settings [26–28]. However, few controlled trials have investigated family-based weight gain prevention interventions for elementary school-aged Hispanic children in community settings in the U.S. [29]. Recent reviews show that family-based interventions with at least one parent involved can be effective for preventing excessive weight gain in children [30–33]. Parents play a key role for younger children since they model behaviors, control access to food, control opportunities for physical activity, and determine feeding practices [34, 35]. Parents also transmit cultural practices to their children that may or may not be healthy [36]. For example, Hispanic children may learn from their parents preferences and patterns of eating and physical activity that are more common in Hispanic cultures, such as playing soccer, long screen time, traditional ethnic dishes, and eating large portion sizes [8, 37, 38].

The Healthy Families Study uses a community-based participatory research (CBPR) approach to address the need for more research that tests the efficacy of culturally-targeted, family-based childhood obesity prevention interventions for Hispanic families with school-aged children in community settings. This paper describes the active intervention condition and the research design of the ongoing randomized controlled trial (RCT).

2. Materials and Methods

The project is a collaborative academic-community partnership between Meharry Medical College, Vanderbilt University School of Medicine, Tennessee State University (TSU), the Nashville Latino Health Coalition, and a grassroots community-based organization called Progreso Community Center in Nashville, Tennessee, U.S. NLHC is comprised of 18 non-profit, public health, healthcare, and academic organizations (including Meharry, Vanderbilt, and TSU), with PCC as the lead organization. The mission of NLHC is to improve the health of the Nashville Latino community by empowering grassroots community members to work collectively with organizations to promote health and prevent disease. NLHC has employed participatory approaches since its foundation in 2005, including CBPR projects with member academic institutions that include community-based organizations and community members throughout the research process from identification of research questions to intervention development to data collection to dissemination of findings [39, 40]. These partners jointly conducted the 2007 Hispanic Health in Nashville Survey to assess health needs and guide planning of collaborative initiatives through NLHC. Among the survey findings, diabetes was the 3rd ranked health concern for Hispanic adults in the community [41]. Based on this finding and the rapidly increasing obesity rates among Hispanic adults and children, NLHC selected obesity prevention as one of its target areas, which led to the CBPR project reported here.

2.1. Development of Active Intervention

During 2008–2009, the academic partners and community partners conducted formative and pilot research to develop a culturally-targeted childhood obesity prevention intervention for Hispanic families. A detailed description of the formative research findings and intervention development process will be published elsewhere, but a brief summary is presented here. The team started with the “*We Can!*” (Ways to Enhance Children’s Activity & Nutrition) parent program curriculum as the base of the intervention content. *We Can!* is a general population obesity prevention program for 8 to 13 year olds developed by the National Heart, Lung and Blood Institute that is publicly available [42]. The parent curriculum consists of an instructor manual for four or six group educational sessions with parents, as well as a parent booklet and several handouts that are available in English and Spanish.

Following recommended strategies for creating culturally-appropriate health promotion programs,[43–46] the team reviewed literature regarding common values and beliefs in Hispanic cultures [47–51] and the impact of acculturation [47, 52, 53] and collected qualitative data from the target population (findings not reported here) to identify which aspects of the *We Can!* parent curriculum to modify. A key adaptation was for the intervention to be delivered by trained lay bilingual CHPs from the local Hispanic community. The team substantially modified the *We Can!* handouts to lower the health literacy level using “plain language” principles [54] and to include examples that reflect common Hispanic dietary and activity cultural preferences. Most of the content from the *We Can!* instructor manual was adapted into visually-appealing PowerPoint slides for the CHPs to use during educational discussions with parents, which highlight key concepts at a low health literacy level, illustrate ideas with visual images and images of Hispanic parents and children, and provide prompts for interactive discussions based on methods of popular

education and people-centered learning [55–57] We also added sampling of healthy snacks during the break in the educational session.

We pilot tested a four-session version with 21 Hispanic families to assess feasibility and acceptability, then the team collected additional qualitative data from the target population and incorporated input from the community partners in an iterative process. Based on this information and guidance from social cognitive theory (SCT) [58] and behavioral choice theory (BCT) [59] the team identified various aspects of the intervention format and materials that needed further modification and specific content and strategies that needed to be augmented to enhance comprehension and behavior change. While much of the information drawn from the *We Can!* curriculum was retained, the changes and additions were so extensive that the team renamed the new 12-month intervention *Familias Saludables Activas* (Active Healthy Families). The format of the group sessions was changed to eight 90-minute sessions to spread out the educational material over four months and to incorporate a 25-minute family physical activity segment, a joint healthy snack time for parents and children together, and active play centers for the children to engage in during the segments in which parents split into a separate room for educational discussions. We made extensive revisions to the handouts and PowerPoint presentations and added new content from other sources. We added bi-monthly newsletters with content from other sources for mailing to families as well as bi-monthly follow-up phone calls from the CHP during the eight months after concluding the group sessions. The final active intervention format and content are described below in section 2.5.

In addition to the cultural modifications, the team chose to target the final intervention for 5 to 7 year olds based on trends of increasing overweight and obesity prevalence among younger children [60,61] and because this developmental stage represents opportune timing for preventive intervention. Research has identified three critical developmental stages in which physiologic alterations can increase the subsequent risk of obesity: (1) the prenatal period, (2) the period between the ages 5 and 7 (the period of “adiposity rebound,” when body mass index begins to increase), and (3) adolescence [62,63]. Physical activity levels tend to decrease after children start school, in part due to reductions in physical education and recess time in schools [35]. Furthermore, research has demonstrated that parents play a crucial role in childhood weight outcomes. Parents can instill healthy eating and physical activity habits in their children by making healthy foods available, providing opportunities for physical activity, reducing screen time, and modeling these behaviors for their children [64–67]. However, the influence of parents decreases with age; as children grow older, they focus less on family and more on school, friends, and media, and they make more of their own choices about eating and physical activity [35]. At the time of transition to elementary school (ages 5 to 7), parents still play an influential role [35]. Thus, the age range of 5 to 7 years was chosen for the Healthy Families intervention to allow time for lifestyle changes to be made in families before children reach adolescence.

2.2. General Design

The study uses a two-group cluster RCT design (see Figure 1). After the baseline assessment, enrolled families are randomized to one of two study arms: the active intervention arm focused on weight gain prevention or the alternative (attention control) intervention arm focused on oral health, both lasting 12 months. The primary outcome for the children is change in body mass index ($BMI=kg/m^2$), and secondary outcomes are children’s waist circumference, behaviors related to healthy eating, increased preferences for fruits and vegetables, increased physical activity and reduced screen time.

2.3. Recruitment and Screening

Recruitment started in May 2010. The lead community partner, Progreso Community Center (PCC), recruits the participants from the community through: (1) distributing flyers at elementary schools to Hispanic students in kindergarten through second grade; (2) distributing flyers at health fairs, community events, and public places; (3) flyers and presentations at PCC, churches, and other local organizations; (4) announcements in Spanish language media (e.g., radio, newspaper); and (5) word of mouth. Interested families call PCC or speak in person with a PCC research staff member to inquire about the study. If interested, the staff member confirms that at least one parent is of Hispanic origin and at least one child is of age 5 to 7 years, then makes a study appointment.

At the first study visit, an interviewer screens the family for eligibility (Table 1). To be eligible, at least one parent has to self-identify as being of Hispanic origin, the child has to be 5 to 7 years old, and either (a) the child has a sex- and age-specific BMI $\geq 25^{\text{th}}$ percentile (according to Centers for Disease Control and Prevention (CDC) growth reference), or (b) at least one parent has a BMI $\geq 25 \text{ kg/m}^2$. Children are excluded if they have a BMI $> 35 \text{ kg/m}^2$, have medical conditions or take medications that affect growth, or have conditions or other circumstances that could interfere with participation in the measurements or the interventions. Families are also excluded if the parent does not give or is unable to give consent or the child does not assent, they do not complete baseline assessments, or they plan to move from the geographic area within the next 12 months. One parent or guardian enrolls per family, and more than one eligible child may be enrolled per family.

At the time of enrollment, a parent or guardian gives written informed consent, and then the children give verbal assent. Baseline assessments are collected upon enrollment at the same study visit or soon after enrollment (before randomization). The Institutional Review Boards of the participating universities approved the study protocol.

2.4. Randomization

Randomization is stratified into 9 clusters of recruitment, with 30 families enrolled in each (32 in the last one to reach 272). A biostatistician who does not have direct contact with study participants generated the random allocation sequences using a computerized random number generator. The allocations are concealed from research staff until after baseline assessments are completed for each cluster. At that point, the list of ID numbers and allocations for the respective cluster are provided to the study coordinator, who then provides the lists of participants to the lead CHP for each intervention. Since it is not possible to mask participants or interventionists (CHPs) to group assignment, and to reduce information bias, intervention staff do not collect measurements on participants after randomization, and the interviewers are masked to group assignment. There is no crossover of intervention staff between study arms.

2.5. Active Intervention

The Healthy Families active intervention (*Familias Saludables Activas*, or Active Healthy Families) is a culturally-targeted, family-based intervention implemented by trained lay CHPs in a community setting over a 12 month period. The behavioral goals of the intervention are to: (1) improve healthy eating behaviors [a) increased consumption of fruits, vegetables, and water, b) decreased consumption of sugar-sweetened beverages and other added sugars, c) decreased total dietary fat and fat content of milk]; (2) increase physical activity, and (3) decrease sedentary behavior. During the first four months, parents and children attend eight bi-weekly group sessions lasting 90 minutes each. The format and content of the eight group sessions are summarized in Table 2. Sessions are held at Progreso Community Center and led by the trained bilingual CHPs. A makeup session is also offered

at the end of the four months for those who missed one or more sessions. For the next eight months, the families receive bi-monthly phone call follow-ups from the CHPs to discuss their progress on setting and accomplishing goals, to provide motivation and social support, and to answer questions. In the alternating months, families receive bi-monthly newsletters that reinforce the intervention messages and give practical strategies for implementing changes at home. A description of the eight mail and phone contacts is presented in Table 3.

The intervention incorporates key concepts of social cognitive theory and behavioral choice theory, as well as drawing on some insights from food preference theory. Social cognitive theory, also known as social learning theory, posits that personal factors, environmental factors, and human behavior constantly influence each other in a reciprocal way [58]. The outside social environment represents a source of observational learning where people can observe others modeling certain behaviors, gain the skills needed to perform the behavior, form expectations of the beneficial outcomes of the behavior, become motivated to implement the behavior, and receive interpersonal support to reward and reinforce the behavior [68]. In the *Activas* intervention, the group sessions provide this environment of social learning where parents and children can observe others engaging in physical activity and healthy eating, gain knowledge and hands-on experience in how to perform these behaviors (e.g., group physical activity segment and healthy snacks), feel motivated by the CHPs and other participants to try new behaviors outside of class, and receive positive feedback from the CHPs and other participants during group discussions to continue engaging in physical activity and healthy eating. Furthermore, the intervention focus on parents as the agents for change in the social environment of the family, and they are reminded throughout the sessions that their children learn healthy (or unhealthy) behaviors by observing them do them every day.

The key personal factor in social cognitive theory is self-efficacy, or confidence in one's ability to perform the new behavior in spite of obstacles, and strategies to increase self-efficacy include taking small steps with specific, incremental goals, and using monitoring and reinforcement [58, 69]. The CHPs emphasize making incremental changes throughout the *Activas* intervention group sessions and follow-up phone calls. For example, at the conclusion of each class participants review a list of sample small steps for nutrition and physical activity changes, and in each class and phone call they set specific goals for nutrition and physical activity, monitor progress, discuss how to overcome challenges, and reinforce successes.

Behavioral choice theory, also known as behavioral economics, attempts to explain how people make choices from a set of alternatives about how to spend their time and set priorities [59]. Behavior is seen as a series of choices that people make in which they choose between one alternative that is highly reinforcing or pleasurable and another alternative that is less reinforcing or has a negative association [70, 71]. Thus, behavior change for obesity prevention essentially involves convincing people to stop doing what they usually do, such as drink soda, eat junk food, or play hours of video games, and start doing what they do not like to do, such as drink water, eating vegetables, or exercise. In order achieve change, strategies may include making the new healthy behavior seem more appealing, positively reinforcing increases in the new healthy behavior or decreases in the undesired behavior, and modifying the environment to remove the unhealthy options from the range of available choices while maintaining a sense of choice and control [59,70].

The *Activas* intervention incorporates all three of these strategies. The group sessions engage parents and children in physical activity and eating healthy snacks in a fun way that creates a positive association for these behaviors and they are reinforce through encouragement from the CHPs and other participants. Parents are encouraged to spend time

together as a family being active, such as walking, biking, dancing, playing sports, or going to the park, which is positively reinforcing for young children because they enjoy spending time with and getting positive attention from their parents. When children bring in their weekly logs to group sessions, the CHPs praise them for increasing physical activity and consumption of fruits, vegetables, and water for decreasing soda consumption and sedentary screen time. Parents are encouraged in group sessions and mailed newsletters to praise children when they choose healthy options at home by framing these options as delicious or fun, rather than making them feel obligated to do them. Finally, parents are encouraged in the group sessions to modify the home environment to make healthy options the easy choice for children to make, such as having fruits and vegetables rather than junk food readily available on the counter for children to snack on, or removing the television from children's bedroom and replacing it with active games.

In addition, the intervention includes some strategies suggested by Food Preference Theory, which posits that our genetic predispositions (e.g., preferences for sweet and salt) and tendency for food neophobia (i.e., rejection of unknown foods) can be modified by learning processes, especially during early childhood [72]. Strategies for modifying food preferences among children include repeated exposure to unfamiliar food to reduce food neophobia, children seeing adults and peers eating the healthy foods (modeling), presenting the healthy foods in a positive social context, and rewarding children when they eat the healthy foods. These strategies are all used in the *Activas* intervention group sessions during the healthy snack segments to expose children to new healthy snacks in a positive, fun context while observing their peers and adults eating the snacks. In addition, the CHPs explain to the parents during several group discussions that research has demonstrated that children need to be exposed to new foods at least eight times before acquiring a taste for it, so parents need to repeatedly offer the new healthy foods (in particular vegetables and fruits) and ask children to taste them even if they reject them [73, 74].

2.6. Alternative Intervention

The families randomized to the control arm receive an alternative intervention called *Familias Saludables Sonrientes*, or Smiling Healthy Families, focused on oral health that does not overlap with the content areas of the weight gain prevention intervention. Oral health was chosen as the focus of the alternative intervention because dental is the most common unmet health need in children [75], and Hispanic children in the U.S. are more likely to have poor oral health [76, 77] and to lack a usual source of dental care when compared to non-Hispanic white children [78]. In addition, oral health ranked 4th among community health concerns in the 2007 Hispanic Health in Nashville Survey [41], and NLHC selected oral health as one of its target areas.

Detailed information on the format and content of the *Familias Saludables Sonrientes* intervention is being published elsewhere (manuscript currently under review). The oral health intervention is structured in a parallel fashion to the obesity prevention intervention, as a family-based intervention implemented by trained lay CHPs in a community setting over a 12 month period. During the first four months, parents and children attend four monthly group sessions lasting 90 minutes, which are held at Progreso Community Center and led by the trained bilingual CHPs. Parents are also given a coupon for a free dental hygiene exam and cleaning for the enrolled children at a local university-based dental hygiene clinic and given the opportunity to sign up for appointments if they are interested. These optional dental hygiene visits are provided outside of the study. For the next eight months, the families receive bi-monthly phone call follow-up from the CHPs to reinforce information, answer questions, and give motivation and social support. In the alternating months, they receive bi-monthly newsletters that reinforce the intervention messages and provide practical tips for caring for their children's oral health at home.

Social cognitive theory and behavioral choice theory also guided the development of the alternative intervention, with a focus on teaching and modeling skills, encouraging practice, and increasing perceived competence. The content of the group sessions was identified with expert consultation from TSU dental hygiene faculty, based on standard recommendations for preventive oral health education for children. In addition to drawing on publicly available materials from various sources, three of the newsletters were adapted from an existing intervention developed in a previous study by one of our team members, which served as the alternative intervention in an RCT of a dental clinic-based intervention for childhood obesity prevention [79].

2.7. Training of Intervention Staff

The CHPs receive initial and ongoing training on the implementation of each intervention, the overall intervention objectives, content and format, and specific instructions for each intervention session. Training is also provided regarding the use of popular education methods and people-centered learning methods for facilitating discussions, engaging participants, and empowering them to make lifestyle changes [55–57]. Refresher training is provided before each intervention session. After each group session, the CHPs debrief with one of the investigators to review any issues or questions that came up during the session. In addition, CHPs are trained to implement the mailings and phone call follow-ups after completion of the group sessions, including use of a phone call script and log.

2.8. Assessments

Study participants respond to the baseline questionnaire before being randomized to a study arm. Research staff begin scheduling follow-up assessments at four months post-randomization (time 2, after completion of the group session phase of the intervention) and at 12 months post-randomization (time 3, at the end of the intervention). Trained interviewers take anthropometric measures and administer the questionnaires to participants. The interviewers are blinded to group assignment. Table 4 summarizes the measures that are taken at each data collection.

2.9. Anthropometric Measures

Staff take anthropometric measurements on both the parent and the participating child(ren) at the community center in a private room with the parent present, according to the protocol and quality control measures used in the National Health and Nutrition Examination Survey III [80]. Participants wear lightweight clothing and remove shoes. Height is measured using a stadiometer (Seca 216 Wall Mounted Stadiometer) to the nearest 0.1 cm, and weight is measured using a digital scale (Tanita BF-350) to the nearest 0.1 kg. Waist circumference and hip circumference are measured as indicators of central adiposity using a non-elastic metric girth tape (Seca 201 Girth Measuring Tape) to the nearest 0.1 cm. The measurements are performed with the person standing erect with feet together and weight evenly distributed on both feet. The waist is measured just above the uppermost lateral border of the ilium in the horizontal plane. For the hip, the measuring tape is placed around the buttocks at the maximum extension, and it is held snug but not tight.

Two measurements are taken at each assessment for height, weight, waist circumference and hip circumference, which are then averaged for analysis. BMI is commonly used as a proxy measure of adiposity, as the two are highly correlated [81, 82]. BMI is calculated based on the standard formula ($BMI = \text{weight (kg)} / \text{height (m}^2\text{)}$). For children, we also calculate BMI z-scores and age- and sex-specific BMI percentiles based on the CDC 2000 growth reference [83]. Weight categories are assigned based on CDC standards for adults (underweight: $BMI < 18.5$; normal weight: $18.5 \leq BMI < 25$; overweight: $25 \leq BMI < 30$; obese: $BMI \geq 30$) and for children (underweight: $BMI \text{ percentile} < 5^{\text{th}}$; normal weight: $5^{\text{th}} \leq BMI \text{ percentile} < 85^{\text{th}}$;

overweight: 85th BMI percentile<95th; obese: BMI percentile 95th). Waist circumference is adjusted by calculating the waist-to-height ratio and waist-to-hip ratio.

2.10. Dietary Intake

The Block Kids Food Frequency Questionnaire (FFQ, 2004 Hispanic version) is used to assess dietary intake of the children in the past seven days (NutritionQuest, Berkeley, CA). This instrument has demonstrated validity and reliability and is commonly used in childhood obesity research [83, 87]. The FFQ is comprised of 61 food items and asks about foods consumed by children over the past 7 days, including foods eaten at home, at school, from snack machines, or from fast food or other restaurants. The Hispanic version of the instrument (English and Spanish) includes additional food items that are common in Hispanic diets. Response categories for frequency of food intakes range from never last week to every day last week. The amount of food consumed in a day generated from the FFQ reflects the usual standard food portions consumed in one day. For example, juice or milk response categories range from half a glass or half a carton to 3 glasses or 3 cartons in one day. The parent reports on the frequency and portions consumed of each item by the child, in addition to the child's report of the foods and beverages she/he consumed for breakfast and/or lunch at school (at which times the parent was not present). In addition, the Healthy Families questionnaire includes two items that ask the parent to report the frequency and amount of water the child drank in the past seven days.

2.11. Food Preferences

We measure the children's preferences for fruits and vegetables using the Preschooler Food Preference Assessment Tool, available from Baylor College of Medicine, Houston, TX. This instrument was validated on a sample of African American and Hispanic pre-school children [36]. The assessment tool is administered directly to the child in the format of an interactive computer game that lasts around 15 minutes, in the child's language of choice (English or Spanish). A bird character presents the child a series of 30 images of fruits, vegetables, and juices, and asks the child to click on one of three faces to indicate if s/he thinks each one is yummy, okay, or yucky.

2.12. Physical Activity

The children's physical activity is measured objectively using GT3X Actigraph accelerometers (Actigraph, LLC, Pensacola, FL, US). Accelerometers are portable, wearable electronic devices that are well-validated for measuring the amount and patterns of physical activity in free living [88, 89]. The monitor is a small (3.8 cm × 3.7 cm × 1.8 cm), lightweight (27 grams) triaxial accelerometer that measures physical activity as time-varying accelerations denoting locomotion. This device has been validated in numerous studies [90–92] and provides accurate measurements of physical activity including vector magnitude, activity counts, and steps taken. Manufacturer provided software (ActiLife-6) [93] can also calculate energy expenditure and activity intensity levels using metabolic equivalents (MET) [94]. Participating parents are shown how a child should wear the device on a provided belt with minimal discomfort at the waist above the dominant side hip. Children are asked to wear the device for seven consecutive days except during sleep, bathing, or showering activities. Parents are asked to encourage and help their children to participate in their routine activities while completing the study.

Wearing and nonwearing time is assessed using a validated algorithm [95]. Days with at least ten hours of device wear are considered valid. Only individuals with at least three valid days are included in the final analysis. Each 1-minute wearing period is classified into sedentary, low, moderate, and vigorous activity intensity category using age-specific cutoff points [96, 97]. Time spend in each intensity category is expressed as percentage of total

wearing time. Total energy spent for physical activity (MET) is calculated using a validated equation [98].

In addition, the parents are administered two items asking how many days per week the child has physical education classes at school and whether the child played on sports teams in the past year. Parental physical activity is assessed using the Block Physical Activity Screener for adults administered in either English or Spanish (NutritionQuest, Berkeley, CA).

2.13. Screen Time

Screen time refers to the time children spend in front of television, computer, or video game screens, which is considered sedentary behavior. Two items adapted from the CDC Youth Risk Behavior Survey ask parents to report how many hours per day the child spent watching television, playing video games, or using a computer for activities other than schoolwork. One item refers to weekdays in the past week (Monday through Friday), and another item refers to the past weekend (Saturday and Sunday). Two additional items ask parents to report if the child has a television in his or her bedroom and if the family owns a video game system.

2.14. Psychosocial, Demographic, Oral Health Measures

Several psychosocial measures are collected from the parents as possible mediating or moderating variables of the targeted outcome variables, including parenting strategies, acculturation, and social desirability. Parenting strategies related to dietary and physical activity-related behaviors are measured using the Parenting Strategies for Eating and Activity Scale (PEAS), which is available in English and Spanish [99]. Acculturation is measured based on length of residence in the U.S. (child and parent), language spoken most often (child), English proficiency (parent), and for the parent using the General Acculturation Index, which is available in English and Spanish [100]. In addition, parents respond to a social desirability assessment, using the Marlowe-Crown Social Desirability Short Form M-C 2(10) [101, 102]. Our team created the Spanish version of the M-C 2(10) using parallel back-translation and comprehension assessment for cross-cultural research [103].

In the baseline assessment, the parent responds to a series of demographic items including age, educational attainment, monthly family income, employment status, occupation, household size, marital status, and country of birth (child and parent). Measures collected about the child to assess the alternative intervention focus on oral health include frequency of brushing teeth, use of fluoride toothpaste, and age of child's toothbrush.

2.15. Sample size

The sample size justification is based on the required subject enrollment to ensure adequate power to evaluate the primary objective, which is to assess the efficacy of the active intervention in preventing excessive weight gain in children. Since the study design is a cluster-randomized trial, where a cluster is defined as a family, responses from children within a family tend to be correlated. Ignoring this correlation can lead to an elevated Type II error rate in the design stage and an elevated Type I error rate in the analysis phase [104]. Hence, to take into account the within-cluster correlation, the sample size obtained for a non-cluster randomized trial is multiplied by a variance inflation factor, which is a function of the mean cluster size and the intraclass correlation coefficient (ICC).

In order to obtain at least 80% power to detect a clinically relevant difference of 0.75 BMI units between the active intervention and the alternative intervention groups at the 0.05

significance level, an estimate of mean cluster size of 1.3 children per family is used as obtained from our pilot study mentioned above. We assume a moderate ICC of 0.10 because underestimating the ICC can lead to a substantially underpowered study. An estimate of the baseline mean BMI of 16.34 and common variance of 4.73 were obtained by pooling the mean and variability estimates for 5–7 year old Hispanic children in Rosner, et. al [105]. Based on these estimates, we anticipate a need for an effective sample size of 136 families per study arm at baseline, taking into account an expected attrition rate of 30%.

2.16. Planned Data Analyses

Descriptive Analyses—Descriptive statistics such as frequencies and relative frequencies will be computed for all categorical variables. Numeric variables will be summarized using simple descriptive statistics such as the mean, standard deviation, range, etc. A variety of graphical techniques will also be used to display the data.

Primary Analyses—The primary outcome of change in mean BMI between the active intervention and alternative intervention group over time will be assessed using a mixed-effects model approach. The mixed methodology enables us to model and take into account the expected within-family correlation between study outcomes and also to utilize all the observations obtained from a single child regardless of whether outcomes at all time points are obtained. In order to analyze secondary outcomes such as waist circumference (waist-to-height and waist-to-hip ratios), behaviors related to healthy eating, preferences for fruits and vegetables, physical activity and screen time, generalized linear mixed effects models will be fit to the outcomes as a function of group with a random effect for family. The link function and error distribution will be chosen depending on the outcome to be analyzed.

Secondary analyses—To describe the observed variability in the data and test for differences between the active and alternative intervention groups in regards to change in the primary and secondary outcomes, a mixed-effects model will be fit as a function of group with a random effect for family and other relevant predictors such as parental and child demographic characteristics and intervention exposure (i.e., class attendance, phone and mail contact). Once the model is fit, specific linear contrasts based on the estimated model parameters will be constructed and used to test hypotheses of interest. We will examine possible mediating effects of the secondary behavioral outcome variables, parents' physical activity, parenting strategies, and acculturation on the intervention effect.

All analyses will be based on the intention-to-treat approach and no method of imputation will be used for missing data. All statistical tests will be two-sided and tested at a 0.05 nominal significance level. Standard diagnostic plots will be used to assess model fit when appropriate and transformations of variables may be considered in order to meet statistical assumptions. There will be no formal interim statistical analyses.

3. Discussion

This paper reports on the design of the ongoing Healthy Families Study RCT. The Healthy Families active intervention, which is based largely on the content of the *We Can!* parent program curriculum, is a one-year community-based, culturally-targeted, behavioral family intervention aimed at prevention of excessive weight gain in Hispanic children 5 to 7 years old. The alternative intervention focuses on promoting good oral health practices for children. The primary outcome is change in BMI of the children. Secondary outcomes are children's waist circumference, behaviors related to healthy eating, increased preferences for fruits and vegetables, increased physical activity, and reduced screen time.

The prevalence of obesity is greater among both Hispanic children and adults in the U.S. According to the most recent U.S. data (2009–2010) from the National Health and Nutrition Examination Survey (NHANES), prevalence of overweight and obesity (combined) was 26.7% for all children ages 2–5 and 32.6% for all children ages 6–11, compared to 33.1% and 39.7% for Hispanic children of the same ages, respectively [106]. In the national 2010 Pediatric Nutrition Surveillance System (PNSS) comprised of low-income children receiving public health benefits in the U.S., 30.5% of 2–4 year-olds were overweight or obese (combined), compared with 35% combined among Hispanic 2–4 year-old children [107]. For adults, the NHANES prevalence of overweight and obesity is 66.7% overall, and 78.8% for Hispanics [7]. As overweight and obesity have become more prevalent in children and at younger ages [106], the need for early intervention has become increasingly urgent, particularly culturally-targeted interventions for disproportionately affected groups.

Culturally-targeted interventions have demonstrated potential to reduce ethnic disparities in obesity and obesity-related diseases. The Healthy Families Study adds to the research focused on developing and testing obesity prevention interventions that target Hispanic children, which so far have had mixed results. Some school-based interventions targeting or including a high proportion of Hispanic children have been successful in significantly slowing BMI increase in overweight children [25, 108, 109], while others did not result in significant BMI differences but did impact improvements in obesogenic behaviors [23,24]. An intervention targeting pre-school aged, low-income Hispanic children in childcare settings did not result in significant changes in BMI, physical activity, or dietary intake [28]. However, another intervention for pre-school aged children and parents conducted in a community setting resulted in a significant BMI change [27]. Family-based interventions play a potentially important role, given the value of targeting parents as agents of change [110–112]. The Healthy Families Study will provide RCT efficacy data on a community-based obesity prevention intervention that is culturally-targeted for Hispanic families with young school-aged children. The CBPR approach used by our team has facilitated the cultural adaptation of the intervention content and strategies. A recent review of studies that developed and tested childhood obesity interventions concluded that the incorporation of community-engagement principles was positively associated with achievement of intervention target outcomes [16].

The study has several strengths. First, the intervention focuses heavily on parental modeling, since parents transmit cultural practices and serve as agents of change in the family, especially for younger children. Second, the intervention is delivered by lay health promoters in a community center setting that is conveniently located. If the intervention is demonstrated to be efficacious, it could be translated into practice in similar settings. Third, the study includes healthy children independent of weight status, so it should be generally comparable to other similar prevention and intervention studies in children of this age range. The active intervention promotes healthy eating behaviors, increased physical activity, and decreased sedentary behavior, which are generally recommended for all children and adults. Fourth, it has a cluster-randomized controlled design with a relatively large sample size and a reasonable period of follow up (12 months) to be able to assess mid-term effects of the intervention. Finally, we use objective measures for the assessment of the primary outcome and some of the secondary outcomes.

The Healthy Families Study also has some limitations. First, the Hawthorne effect is possible in community-based behavioral trials, meaning that families in both study arms may manifest some changes in behavior as a motivational response to being observed in the trial and the attention [113]. Second, there is a possibility of cross-contamination of participants in the two intervention arms, since both interventions are delivered in the same community center. To reduce the possibility of interaction across the two study arms, the

active and alternative intervention sessions are held on different days. Nevertheless, it is possible that some participants may know each other before enrolling in the study and could discuss their experiences in the interventions. Finally, while the Healthy Families active intervention goes beyond individual behavior to address culture and the family environment, the trial does not intervene on factors outside of the family that also impact children's behaviors and weight gain, such as access to healthy foods and opportunities for physical activity in the community and at school. Many of these contextual factors are outside of the control of parents and may limit their ability to apply the recommendations and strategies acquired during the intervention. A multi-level approach with multiple intervention strategies in the family, school and community would be needed to address these possible contextual barriers to behavior change. Future research should assess the impact of combining multiple intervention strategies that have been shown to be effective at each level.

In conclusion, we have described the basic rationale and design of the ongoing Healthy Families Study cluster RCT and its evolution from the earlier pilot study. The Healthy Families Study intervention aims to prevent excessive weight gain in Hispanic children ages 5 to 7. This trial will contribute valuable evidence on the efficacy of family-based childhood obesity prevention interventions targeted for Hispanic families with younger school-aged children in community settings. Effective early interventions are critical in addressing the alarming obesity trend among youth in the U.S., in particular Hispanic youth, and to reducing racial/ethnic disparities in obesity and obesity-related outcomes among Hispanic children and adults.

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Figure 1.
Study Design and Flow Chart

Table 1**Inclusion and exclusion criteria****Inclusion criteria:**

- 5–7 year-old girl or boy with at least one adult parent of Hispanic origin (self-identified)
- child with $\geq 25^{\text{th}}$ percentile of age- and sex-specific BMI (according to CDC growth charts) or one parent/caregiver with BMI ≥ 25 kg/m²

Exclusion criteria for children (no exclusions for parent):BMI ≥ 35 kg/m²

Self-reported medical conditions affecting growth:

- Diagnosis of a genetic or metabolic disease/syndrome associated with obesity (e.g., Cushing syndrome), growth hormone deficiency, hypothyroidism, insulin-secreting pancreatic tumor, Laurence–Moon–Biedl (Bardet–Biedl) syndrome, polycystic ovary (Stein–Leventhal) syndrome, Prader–Willi syndrome, pseudo-hypoparathyroidism type I, Turner syndrome)
- Type 1 diabetes, or type 2 diabetes requiring medication
- Chronic gastrointestinal disease (e.g., Crohn’s disease)
- Chronic kidney (renal) disease (e.g., nephrotic syndrome)
- Structural heart disease/congenital heart disease/failure (uncorrected) or transplant
- Anorexia nervosa, bulimia nervosa, or binge eating disorder (present or past)
- AIDS and/or HIV infection

Taking medications affecting growth

- Steroids taken by mouth or by injection for more than 2 weeks in the past year
- Insulin injections or oral anti-diabetic drugs
- Thyroid hormones
- Growth hormone injections

Conditions limiting participation in the interventions or measurements:

- Unable to participate in routine physical education classes at school
- Conditions requiring oxygen supplementation for exertion
- Developmental or physical disability preventing participation in interventions
- Medical inability to follow prescribed diet/exercise regimen

Other for family:

- No consent, inability to understand informed consent or no child assent
- Incomplete or missed baseline assessments
- Plan to move from geographic area within the next 12 months

Table 2

Overview of active intervention (*Familias Saludables Activas*, FSA) group sessions

Activity/Time *	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	Session 7	Session 8
Topic	Welcome to FSA	What is a healthy weight?	Energy Balance	Portion Distortion	Food Pyramid and Fun PA's	Go-Slow-Whoa, Sedentary time	Substitution: Reducing Fat/Sugar	Maintenance of positive changes
Objectives	1 Get to know each other	1 Understand what BMI is & what is healthy weight for adults & children.	1 Understand the balance of Energy In & Energy Out	1 Limit portion sizes	1 Limit portion sizes	1 Limit added fats and sugar	1 Limit added fats and sugar	1 Increase FV Consumption
	2 Understand purpose, goals and format of FSA classes	2 Identify healthy snacks	2 Consume more vegetables	2 Consume more fruits	2 Consume more FV	2 Increase water Intake	2 Increase water Intake	2 Increase water Consumption
	3 Increase water intake	3 Increase PA	3 Increase PA	3 Increase PA	3 Increase PA	3 Decrease sedentary behavior	3 Increase physical activity	3 Decrease added fats/sugars
	4 Start making goals for small changes in nutrition/PA							4 Increase PA
								5 Decrease sedentary activity
								6 Reinforce maintenance
Welcome (5 min)	P+C: Attendance, Motivational welcome, Review goals of FSA	P+C: Attendance, Motivational welcome, Review goals of FSA	P+C: Attendance, Motivational welcome, Review goals of FSA	P+C: Attendance, Motivational welcome, Review goals of FSA	P+C: Attendance, Motivational welcome, Review goals of FSA	P+C: Attendance, Motivational welcome, Review goals of FSA	P+C: Attendance, Motivational welcome, Review goals of FSA	P+C: Attendance, Motivational welcome, Review goals of FSA
Move it/Muévelo (25 min)	P, C: Ice Breakers (15 min) P+C: PA in group ** (15 min)	P+C: PA in group	P+C: PA in group	P+C: PA in group	P+C: PA in group	P+C: PA in group	P+C: PA in group	P+C: PA in group
Break (5 min)	Break	Break	Break	Break	Break	Break	Break	Break
Healthy Eating/ Alimentación Saludable (20 min)	P: Intro to FSA, Discuss healthy snacks & benefits of drinking water, Review nutrition tips on Small Steps handout (25 min) C: Active play 7	P: Discuss BMI (give BMI data for P & C) & what is a healthy weight, Review handout on Quick & Healthy Snacks C: Active play	P: Discuss energy balance, concepts of Energy In and Energy Out C: Active play, make vegetable boats	P+C: Play "Portion Distortion game in family teams, Discuss importance of serving small to medium portions while not limiting FV	P: Discuss MyPyramid, recommendations for each food group, balancing food groups on plate (half FV) C: Active play	P: Discuss how to use nutrition facts Label and Go, Slow, Whoa to make healthy choices C: Active play	P+C: Fat and sugar substitution activity P: Discuss Substituting ingredients in typical dishes C: Active play	P: Review key material from previous sessions, Discuss plans for maintaining new healthy eating strategies C: Active play
Snacks/Bocadillos (10 min)	P+C: Sample healthy snacks: raw broccoli, carrots, cherry tomato, light ranch dressing, water	P+C: Sample healthy snacks: watermelon, hot chili powder, water	P+C: Sample healthy snacks: vegetable boats (tomato, low fat chicken salad, celery, lettuce)	P+C: Sample healthy snacks: apple slices, orange slices, grapes, hot chili powder, water	P+C: Sample healthy snacks: low fat/low sugar granola bars, light yogurt, water	P+C: Sample healthy snacks: Apple yogurt salad (nonfat yogurt, parmesan cheese), water	P+C: Sample healthy snacks: Baked tortilla chips, salsa & spinach dip, water	P+C: Sample healthy snacks: raw broccoli, carrots, cherry tomato, light ranch dressing, water
Be Active /Seamos Activos (10 min)	P: Review PA tips on Small Steps handout (5 min) C: Active play	P: Discuss PA recommendations for adults/children, ways to incorporate PA into routine C: Active play	P: Review handout on Energy Balance: Energy Out, discuss varying intensity of PA C: Active play	P: Do "Energy Balance: Put it into Practice" activity, discuss balancing energy in & out C: Active play	P: Discuss range of possible physical activities, encourage fun PA together as family C: Active play	P: Discuss importance of and strategies for reducing screen time C: Active play	P: Discuss challenges/strategies for making changes in family to eat healthy & be more active C: Active play	P: Discuss handout & plans for maintaining new PA Strategies C: Active play
Small Steps /Pasos Pequeños (10 min)	P: Choose nutrition goal & PA goal for next 2 weeks, record on Weekly Goal Card (5 min) C: Active play	P: Assess progress on goals, choose/record nutrition goal & PA goal for next 2 Weeks C: Active play	P: Assess progress on goals, choose/record nutrition goal & PA goal for next 2 Weeks C: Active play	P: Assess progress on goals, choose/record nutrition goal & PA goal for next 2 Weeks C: Active play	P: Assess progress on goals, choose/record nutrition goal & PA goal for next 2 weeks C: Active play	P: Assess progress on goals, choose/record nutrition goal & PA goal for next 2 weeks C: Active play	P: Assess progress on goals, choose/record nutrition goal & PA goal for next 2 weeks C: Active play	P: Assess progress on goals, Discuss continuing to make & assess realistic goals C: Active play
Conclusion (5 min)	P+C: Summary, Review goals of FSA, handouts & incentives	P+C: Summary, Review goals of FSA, handouts & incentives	P+C: Summary, Review goals of FSA, handouts & incentives	P+C: Summary, Review goals of FSA, handouts & incentives	P+C: Summary, Review goals of FSA, handouts & incentives	P+C: Summary, Review goals of FSA, handouts & incentives	P+C: Summary, Review goals of FSA, handouts & incentives	P+C: Summary, Review goals of FSA, handouts & incentives
Handouts	Small Steps/Pasos Pequeños Weekly Goal Cards/Folders w/ weekly logs for tracking FVWS & PAST	BMI growth charts for children BMI table for adults Quick & Healthy Snacks Weekly logs for FVWS & PAST	Energy Balance: Energy Out Weekly logs for FVWS & PAST	Energy Balance: Put it into practice Weekly logs for FVWS & PAST	MyPyramid Weekly logs for FVWS & PAST	Using Nutrition Facts Label Go-Slow-Whoa Reducing Screen Time Weekly logs for FVWS & PAST	Go-Slow-Whoa (review) Weekly logs for FVWS & PAST	Maintain Physical Activity Certificates of Participation Weekly logs for FVWS & PAST
Incentives / Gifts	\$5 gift card, FSA T- shirt (P+C), healthy Latino recipe book	\$5 gift card, FSA Water bottles (P +C)	\$5 gift card, Jump rope(C) Apple slicer (P)	\$5 gift card, Baton or paddle ball (C), Measuring cup (P)	\$5 gift card, Light-up Yo-Yo (C)	\$5 gift card, Paint set (C)	\$5 gift card, Poster & markers (C)	\$5 gift card, Coloring book & crayons (C)

Abbreviations: FSA=*Familias Saludables Activas*; P=Parents (only); C=Children (only); P+C=Parents and children together; PA=Physical activity; FV=Fruits and vegetables; BMI=Body mass index; FVWS=Fruit, vegetable, water & soda; PAST=Physical activity & screen time

^{*} Some times are different in Session 1, where noted.

^{**} PA in Group: One CHP leads the parents and children (together) in a physical activity session using purchased exercise DVDs that are age-appropriate for children ages 5–7, including Denise Austin’s Fit Kids, Fit Kidz, Toucanz Trail Obstacle Adventure, and Zumba Family.

[†] Active play: One CHP assists the children with rotating through a series of active play centers, including Wii and Xbox Kinect game systems, active non-electronic games and toys, and coloring/craft activities related to healthy food and physical activity.

Table 3Active intervention (*Familias Saludables Activas*) mail and phone intervention content

Month	Mail or Phone	Description
5	Mailed Newsletter	Practical Goals for Maintaining Healthy Nutrition and Physical Activity: Presents 5-2-1-0 concepts (5 FV daily, less than 2 hours screen time daily, 1 hour of PA daily, 0 sweetened beverages), in Spanish. Adapted from Maine Center for Public Health Keep ME Healthy Project
6	Phone Call	CHP calls parents and follows script to: <ul style="list-style-type: none"> review the information in the newsletter and ask how they are putting it into practice answer any questions they have about the newsletter or the class sessions ask what their most recent nutrition and PA goals were and how they are progressing on achieving them; give suggestions for overcoming challenges motivate them to continue working on goals and to set new goals once they are achieved, using the Small Steps handout for ideas of possible goals
7	Mailed Newsletter	Activity Pyramid for Children: Illustrates activities that children and families can do everyday and activities that should be limited (i.e., screen time); back side is a tracking sheet to help children achieve 60 minutes of PA daily; in Spanish. Purchased from Park Nicollet HealthSource, item 2711-362, jdcpublishing.com.
8	Phone Call	CHP calls parents and follows script (same as month 6)
9	Mailed Newsletter	Nuts About Nutrition Activities for Kids: 8-page coloring and activity booklet focused on vegetables, milk, protein, grains, healthy snacks, and making healthy choices; in English. Purchased from Learning ZoneExpress, Item 6507, ISBN 1-5715-174-2, learningzoneexpress.com.
10	Phone Call	CHP calls parents and follows script (same as month 6)
11	Mailed Newsletter	Run for It! Exercise Game: Active board game that asks players to various quick PA tasks when landing on each space; in English and Spanish. From Children's Health Fund, childrenhealthfund.org.
12	Phone Call	CHP calls parents and follows script (same as month 6)

Abbreviations: PA=Physical activity; FV=Fruits and vegetables

Table 4**Healthy Families Study Measures**

	Baseline	4 months	12 months	Child or Parent
Anthropometric Measures				
Height	X	X	X	C, P
Weight	X	X	X	C, P
Waist circumference	X	X	X	C, P
Hip circumference	X	X	X	C, P
Dietary Intake				
Food frequency questionnaire – last seven days	X	X	X	C
Fruit and vegetable preferences	X	X	X	C
Physical Activity and Screen Time				
Accelerometers – three days of physical activity	X	X	X	C
PE class and sports participation	X	X	X	C
Self-reported physical activity – last 12 months	X	X	X	P
Self-reported screen time – last seven days	X	X	X	C
TV in bedroom and video game system in home	X	X	X	C
Oral Health				
Frequency of brushing teeth	X	X	X	C
Use of fluoride toothpaste	X	X	X	C
Age of toothbrush	X	X	X	C
Psychosocial				
Parenting strategies for diet and physical activity	X	X	X	P
Length of residence in U.S.	X			C, P
Language spoken most often	X			C
English proficiency	X			P
Acculturation index	X			P
Social desirability	X			P
Demographic				
Age	X			P
Educational attainment	X			P
Family income	X			P
Employment status	X			P
Occupation	X			P
Household size	X			P
Marital status	X			P
Country of birth	X			C, P

Note: C=Child, P=Parent